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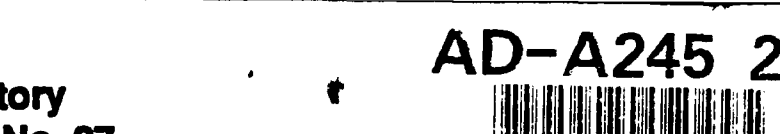

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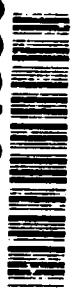

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Subject report identifies these individuals who are conducting investigative protocols at Fitzsimons Army Medical Center. An abstract of each protocol giving abbreviated technical approach, objectives, and progress is presented. Publications and Presentations by Fitzsimons Army Medical professional staff.

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FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1991 along with other known presentations and publications by FAMC professional staff.

The research protocols describe din this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 40-023, as amended, Management of Clinical Investigation protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations. In conducting the research described in this report, the investigator(s) adhered to AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs and the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is grateful to the Center's Commander, BG Thomas E. Bowen and all of the professional and administrative staff for departments and directorates who have furthered the mission of Clinical Investigation Department at Fitzsimons through their cooperation and extra effort as reflected in this report. I should like to particularly recognize the outstanding work and dedication and wholehearted corroboration of all of the Services' within Clinical Investigation Department, the Deputy Chief, LTC Leo A. Andron, the Research Protocol Specialist, Ms. Marcia Bilak, and Ms. Chris Montoya, Secretary, without whose assistance and support beyond the call of duty this year's progress and its report would not have been possible.

/s/ Harrison LTC MC

SHANNON M. HARRISON
LTC, MC
Chief, Department of
Clinical Investigation

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TABLE OF CONTENTS

REPORT NO. 27

	Page
Report Documentation Page	(1)
Reports Control Symbol Med-300	(2)
Foreword	(3)
Table of Contents	a-z
Unit Summary/HMLAC Report/Service Report/Training Support	i-xi
Publications FY 91	1-19
Presentations FY 91	20-34
Detail Summary Sheets	35-431
Investigator's Index	432-438
Key Word Index	439-445
Distribution	446

DEPARTMENT OF MEDICINE

No.	Status		
80/120	O	Evaluation of Carbohydrate Metabolism in Thyrotoxicosis: Investigations into the Frequency, Type and Mechanisms of Carbohydrate Tolerance	37
81/117	O	The Role of Calcitonin in Osteoporosis **(PR)(P)**	39
81/118	O	Hypothalamic Pituitary Gonadal Function in Hypothyroidism	41
83/107	T	Use of Isotretinoin in Prevention of Basal Cell Carcinoma **(PR)(P)**	42
83/113A	C	Growth of Human Keratinocyte **(P)**	44
83/122	O	The Role of Food Allergy in the Pathogenesis of Migraine Headaches **(PR)(P)**	46
83/126	O	The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism	48
84/100	C	The Effect of Abnormal Thyroid States on the Metabolism of Theophylline and Methylprednisolone **(PR)**	50
84/119	O	Treatment of Graves' Ophthalmopathy with Cyclosporin	51
85/100	O	SWOG #7804 - Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs. Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III	52

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
85/139	O	SWOG 8393 - National Intergroup Protocol for Intermediate Thickness Melanoma 1.0-4.0 mm. Evaluation of Optimal Surgical Martins (2 vs 4cm) Around the Melanoma and Evaluation of Elective Regional Lymph Node Dissection	53
85/165A	T	An Evaluation of Cross Allergenicity Among Pollen Extracts of Members of the Chenopodiaceae and Amaranthaceae Pollens and Mold Spores of the Same or Related Botanical Families (PR)(P).....	54
85/167	O	The Effect of Age on Thyroid Function Studies: The Perchlorate Discharge Test	56
86/107A	C	In-Vitro Drug Sensitivity Utilizing the Guinea Pig Airway Smooth Muscle Model (PR)(P)	57
86/109	O	The Effect of INH and Combination INH-Rifampin Therapy on Calcium and Vitamin D Metabolism	59
86/114	O	Natural History of HTLV-III Infection and Disease in a United States Military Community (PR)	60
86/120	O	SWOG #8516 - A Phase II Comparison of CHOP versus m-BACOD versus ProMaCE-CytaBOM versus MACOP-B in Patients with Intermediate or High Grade Non-Hodgkins' Lymphoma	61
87/103	O	Identification of Those at Risk for Osteoporotic Hip Fractures, by an Noninvasive Measurement (P)(PR)	62
87/104	O	SWOG 8600 - A Randomized Investigation of High-Dose Versus Standard Dose Cytosine Arabinoside with Daunorubicin in Patients with Acute Non-Lymphocytic Leukemia, Phase III	64
87/111	C	A Prospective Double Blind Study of Retrovir in Early HIV Infection (PR)(P)	65
87/112	O	SWOG 8598 - (RTOG-85-01) Prospective Trial for Localize Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation Therapy and Chemotherapy, Phase III Intergroup	66
87/114	O	Patient Evaluation of Physicians' Humanistic Qualities (P)(PR).....	67
87/116	O	Effect of Iodine Containing Water Purification Tablets on Thyroid Function in Man (PR)	69
88/104	C	Descriptive Study of Pastoral Care Interventions Designed to Assist HIV+/AIDS Patients in Achieving Their Maximum Quality of Life (P)(PR).	70
88/109	O	Methotrexate in the Treatment of Steroid Dependent Asthmatics (PR).....	73

Ongoing (O), Completed (C), Terminated, (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
88/110A	C	Biological Investigation of Cutaneous Lupus Employing Athymic Mice as Skin Heterotransplant Recipients	75
88/113	T	Methotrexate vs D-Penicillamine in Rheumatoid Arthritis: A Randomized Comparative Study	76
88/115	O	The Impact of an Ambulatory Care Rotation on Interns' Psychosocial Attitudes	77
88/116A	C	Mouse Anti-Chenopod/Amaranth Pollen Monoclonal Antibody Production (PR)	78
88/117	T	A Comparison of Amitriptyline vs. Trazodone vs. Placebo as Adjuvant to Opiate Analgesics in the Management of Pain in Cancer Patients	79
88/120	O	Ventilatory Effects of Transtracheal Oxygenation	80
88/121	O	Bone Density in Thyroid Extract Treated Patients (PR)	81
88/124	O	Corticosteroids in the Treatment of Stable Chronic Obstructive Pulmonary Disease	83
89/100	C	The Application of Orem's Self-Care Model in Type II Diabetes: An Outcome Study of Diabetic Self-Care Classes and Self-Care Contracting Comparing Self-Care Knowledge, Health Care	84
89/102	O	Factors Determining Peak Bone Mass and Subsequent Bone Loss	85
89/103	O	Transient Hypoxia During Sedated Endoscopic Procedures	86
89/104	O	Efficacy of Corticosteroids in the Acute Treatment of Asthma: Is Duration of Symptoms Important?	87
89/105	O	Role of Blood Pressure Control in Progression of Diabetic Nephropathy and Other Microangiopathies	88
89/106	T	Immunologic Criteria for the Cessation of Immunotherapy	89
89/108	O	Efficacy of Pentoxifylline in Treating Diabetic Impotence	90
89/109	O	The Effect of Percutaneous Endoscopic Gastrostomy Tube Place on Gastric Emptying	91
89/110	C	Cyclic Oxygen Therapy at Rest and During Exercise	92
89/111	O	Multicenter Clinical Evaluation of Penicillin Skin Testing Materials	93

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
89/114	C	Response of Arthritis and Microscopic Colitis to Sulfasalazine in Rheumatoid Arthritis Patients	94
89/115	O	The Effect of Congestive Heart Failure (CHF) on the Erythrocyte Sedimentation Rate (ESR)	95
89/117	C	Evaluation of Thermography in the Delineation of Late Phase Skin Tests (PR)(P)	96
89/119	C	Development of a Cardiopulmonary Resuscitation (CPR) Information Sheet and Assessment of Patient and Staff Exposure	97
90/100	O	Platelet Thromboxane, Aggregation and Whole Blood Prostacyclin Synthesis in Human Thyroid Disease	98
90/102	O	Effect of Prolonged Administration of Iodine Containing Water Purification Tables in Man	99
90/103	O	The Limulus Amoebocyte Lysate Assay for the Diagnosis of Spontaneous Bacterial Peritonitis in Ascitic Fluid	100
90/105	O	Incidence and Prevalence of Hematuria in Patients on Long-Term Anticoagulation	101
90/107	T	A Double-Blind, Placebo-Controlled Randomized Trial of the Clinical and Hemodynamic Effects of Vasopressin in Patients with Cirrhosis and Acute Variceal Hemorrhage --- A Multi-Center Study	102
90/108	O	Comparison of Impedance Plethysmography, Venogram and Doppler Ultrasound in Diagnosing Deep Vein Thrombosis	103
90/109	O	Altitude Effects on Oxygen Kinetics During Exercise in Acclimatized Fit Troops	104
90/110	O	Effects of Altered Calcium on Blood Pressure	105
90/111A	T	Prevention of Pseudomonas Colonization by Saccharomyces boulardii or Lactobacillus acidophilus in Antibiotic Treated Mice	106
90/112	O	Laboratory Screening to Detect Biochemical Evidence of Hemochromatosis Among Patients with Non-Insulin Dependent Diabetes Mellitus	107
90/113	O	Effect of Cold Remedies on Metabolic Control of Noninsulin Dependent Diabetes Mellitus	108
90/114	O	Assessment of Patient Utilities for Health Outcomes: Influence on Aspirin Prophylaxis to Prevent Myocardial Infarction	109

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/115	O	Relationship of Blood Flow in Hemodialysis Access to Recirculation with Variable Blood Pump Flow	110
90/116	O	Smoking Cessation Enhancement by Estimated Lung Age and Measured Expiratory Carbon Monoxide Levels	111
90/117	O	The Effect of Prolonged Thyroxine Suppression Therapy on Thyroid Nodule Size, Cytology and Serum Thyroglobulin in Patients with Solitary Palpable Thyroid Lesions	112
90/118	T	Effect of Gymnema Sylvestre on Blood Glucose and Serum Insulin Levels	113
90/119	C	Epidemiological and Retrospective Analysis of Patients Consuming L-Tryptophan Containing Products	114
90/120	C	Dose Hepatitis-B Vaccine Promote Eosinophilia, Increase Serum IgE Levels or Sensitize Recipients?	115
90/121	O	Temporal Course of Altitude Acclimatization	116
90/122	O	Evaluation of Viral Hepatitis in Patients Infected with the Human Immunodeficiency Virus (HIV)	117
90/123	O	Urinary Indices in Acute Renal Failure	119
90/124	O	The Effectiveness of Octreotide (Sandostatin*) to Prevent Pancreatitis Caused by Endoscopic Pancreacto-Biliary Procedures: A Double-blind, Randomized Study	120
90/125	O	SWOG 8697 Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF Versus Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation or Maintenance Therapy with CMF(P) TH or CMFH---Intergroup	121
90/126	O	SWOG 8710 Trail of Cystectomy Alone Versus Neoadjuvant M-VAC + Cystectomy in Patients with Locally Advanced Bladder Cancer, Phase III	122
90/127	O	SWOG 8737 A Phase III Study, AZQ 24 Hour Infusion Versus BCNU for Adult High Grade Gliomas (Intergroup 0093)	123
90/128	O	SWOG 8750 Pilot Study to Examine Cytogenic Abnormalities in Patients with Acute Leukemia, Ancillary	124
90/129	O	SWOG 8814 A Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors	125

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/130	O	SWOG 8899 A Prospective, Randomized Trial of Low-Dose Leucovorin + 5=FU, High-Dose Leucovorin + 5-FU, Levamisole + 5-FU, or Low-Dose Leucovorin + 5-FU + Levamisole Following Curative Resection in Selected Patients with Dukes' B or C Colon Cancer	126
90/131	O	VA Cooperative Study No. 316: Efficacy of Passive Immunization in the Prevention of Infection Due to Klebsiella Penumonjae and Psudomonas Aeruginosa	127
90/132	O	Prevention and Treatment of Steroid Induced Osteoporosis	128
90/133	O	The Effect of Terfenadine on Urination	129
90/134	O	Fibrinolytic and Thrombotic Activity in Unstable Coronary Disease	130
90/135	O	Comparison of Liver Biopsy Versus Noninvasive Testing Using Hepatic Ultrasound, Radionuclide Scanning, Erythrocyte Folate Levels and Methotrexate Levels for the Determination of Methotrexate-Induced Hepatotoxicity	131
90/136	O	SWOG 8921 A Phase II Trial of Cyclophosphamide/IL-2, DTIC/IL-2 and DTIC/Cisplatin/Tamoxifen in Stage IV Melanoma	132
90/137	C	SWOG 8312 Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III	133
90/138	O	SWOG 8520 Cis-Diamminedichloroplatinum (II), Methotrexate and Bleomycin in the Treatment of Advanced Epidermoid Carcinoma of the Penis, Phase II	134
90/139	O	SWOG 8621 Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast Cancer, Phase III	135
90/140	O	SWOG 8692 Therapy in Premenopausal Women with Advanced ER Positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs the LH-RH Analog, Zoladex Phase III Intergroup	136
90/141	O	SWOG 8711 A Study of Reproductive Function in Patients with Testicular Cancer	137
90/142	O	SWOG 8736 Treatment of Localized Non-Hodgkin's Lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy Plus Radiation Therapy	138

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/143	O	SWOG 8793 Randomized Phase III Evaluation of Hormonal Therapy VS Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy	139
90/144	O	SWOG 8794 Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy	140
90/145	C	SWOG 8806 A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Advanced Bladder Cancer	141
90/146	O	SWOG 8809 A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas	142
90/147	O	SWOG 8819 Central Lymphoma Repository Tissue Procurement Protocol	143
90/148	O	SWOG 8836 A Study of chest Irradiation Plus Concurrent Daily Low-Dose Cisplatin Followed by High Dose Consolidation for Locally Advanced Non-Small Cell Lung Cancer	144
90/149	C	SWOG 8896 Intergroup Phase III Protocol for Surgical Adjuvant Therapy of Rectal Carcinoma: A Controlled Evaluation of (A), Protracted Infusion of 5-Fluorouracil as a Radiation Enhancer and (B), 5-Fluorouracil Plus Methyl-CCNU Chemotherapy	145
90/150	O	SWOG 8905 Phase II/III Study of Fluorouracil (F-FU) and Its Modulation in Advanced Colorectal Cancer	146
90/151	O	Extrinsic Positive End-Expiratory Pressure (PEEP) Effects on Functional Residual Capacity in Normal Subjects and in Ventilated Patients Experiencing Air trapping (AUTO-PEEP)	147
90/152	O	Residual Renal Function in Dialysis Patients	148
90/153	O	Relationship of Calcium and Glucose Metabolism on Blood Pressure	149
90/154	O	SWOG 8326 Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III	150

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/155	O	SWOG 8810 Six Courses of 5-Fluorouracil and Cisplatinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck, Phase II Pilot Study	151
90/156	O	SWOG 8812 Treatment of Limited Small Cell Lung Cancer with Concurrent Chemotherapy, Radiotherapy, with or without GM-CSF and Subsequent Randomization to Maintenance Interferon or No Maintenance	152
90/157	O	SWOG 8828 A Phase II Trial of Carboplatin (CBDCA) in Relapsed or Refractory Acute Myeloid Leukemia	153
90/158	O	SWOG 8851 A Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Coladex and Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer.	154
90/159	O	SWOG 8892 A Study of Radiotherapy with or without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III	155
90/160	O	SWOG 8897 Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients and a Natural History Followup Study in Low-Risk, Node Negative Patients	156
90/161	O	SWOG 8910 Evaluation of Low Dose Continuous 5-Fluorouracil (F-FU) and Weekly Cisplatinum (CDDP) in Advanced Adenocarcinoma of the Stomach, Phase II Pilot	157
90/162	O	SWOG 8915 A Phase II Study of 6-Thioguanine Administered as 120 Hour Continuous Infusion for Refractory or Recurrent Small Cell Carcinoma	158
90/163	O	SWOG 8916 Evaluation of Merbarone in Pancreatic Adenocarcinoma, Phase II	159
90/164	O	SWOG 8952 Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study Comparing ABVD vs MOPP/ABV Hybrid	160
90/165	O	SWOG 8997 A Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin Plus Etoposide with Either Bleomycin or Ifosfamide	161

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/166A	O	Evaluation of Allergenic Cross-Reactivity Amongst Cockroach Species	162
90/167A	C	Animal Model of Physiologic PEEP (Positive End-Expiratory Pressure)	164
90/168A	O	A Histologic and Immunopathologic Study of the Skin and Internal Organs of MRL+/+Mice	165
90/169	O	The Effect of Steroid Therapy on Recovery After Tonsillectomy	167
90/170	C	SWOG 8744 A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Refractory Multiple Myeloma	168
90/171	O	SWOG 8789 A Randomized Study of Etoposide Plus Cisplatin and Etoposide Plus Carboplatin (CBDCA) in the Management of Good Risk Patients with Advanced Germ Cell Tumors	169
90/172	O	SWOG 8792 A Phase III Study of Alfa-nl (Wellferon) as Adjuvant Treatment for Resectable Renal Cell Carcinoma	170
90/173	O	SWOG 8842 Dihydroxyazacytidine in Malignant Mesothelioma, Phase II	171
90/174	O	SWOG 8900 A Phase II Pilot of VAD and VAD-Verapamil for Refractory Multiple Myeloma	172
90/175	O	SWOG 8931 Phase III Comparison of Cyclo-phosphamide, Doxorubicin and 5-Fluorouracil (CAF) and a 16-Week Multi-drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node-Positive Breast Cancer	173
90/176	O	SWOG 8994 Evaluation of Quality of Life in Patients with Stage C Adenocarcinoma of the Prostate Enrolled on SWOG 8794	174
90/177	O	National Co-operative rHu Erythropoietin Study in Patients with Chronic Renal Failure: A Phase IV Multi-Center Study	175
90/178	T	The Efficacy and Safety of Orally Administered SQ 32,756 in the Treatment of Acute, Localized Non-Trigemental Zoster in Immunocompetent Patients	176
90/179	O	A Randomized Prospective Study of Clindamycin or Pyrimethamine Therapy for Prevention of Toxoplasmic Encephalitis in HIV-Infected Individuals with Serologic Evidence of Latent Toxoplasma gondii Infection (CPCRA 001)	177

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
91/100	O	SWOG 8515 Evaluation of Menogaril (NSC-269148) in Non-Hodgkin's Lymphoma, Phase II	178
91/101	O	SWOG 8721 A Phase II Trial of Trimetrexate in the Treatment of Esophageal Cancer	179
91/102	O	SWOG 8894 A Comparison of Bilateral Orchiectomy with or without Flutamide for the Treatment of Patients with Histologically Confirmed Stage D_2 Prostate Cancer	180
91/103	O	SWOG 8906 Evaluation of Merbarone in Hepatoma, Phase II	181
91/104	O	SWOG 8925 Evaluation of Cisplatin + VP-16 Followed by Mitotane at Progression if no Prior Mitotane OR Cisplatin + VP-16 ONly if Prior Treatment with Mitotane in Advanced and Metastatic Adrenal Cortical Carcinoma	182
91/105	C	Endocrine Responses to Critical Illness as Predicators of Outcome	183
91/106	O	A Randomized, Controlled Trial of Interferon Alpha and Thymosine Alpha-1 in Patients with Hepatitis C Antibody Positive Chronic Active Hepatitis	184
91/107	O	Does Omeprazole (Losec*) Improve Respiratory Function in Asthma Patients with Gastroesophageal Reflux? A Double-Blind, Crossover Study	185
91/108	O	A Comparison of the Efficacy of Superpotent Topical Steroids Versus Intralesional Steroids in the Treatment of Discoid Lupus Erythematosus	186
91/109	O	SWOG 9037 Prediction of Recurrence and Survival in Node-Negative Breast Cancer Patients Using a Panel of Prognostic Factors. A Companion Protocol to SWOG 8897	187
91/110	O	SWOG 8795 Randomized Prospective Comparison of Bacillus Calmette-Guerrin and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder with DNA Flow Cytometric Analysis, Phase III	188
91/111	O	SWOG 8834 A Phase II Evaluation of Fazarabine in Central Nervous System Tumors	189
91/112	O	SWOG 8957 Feasibility Trial of Post-Operative Radiotherapy + Cisplatin Followed by Three Courses of 5-FU + Cisplatin in Patients with Resected Head and Neck Cancer	190
91/113	O	The Effect of Recombinant Growth Hormone on Pulmonary Function in Patients with Chronic Obstructive Pulmonary Disease	191
91/114	O	Detection of Renal Artery Stenosis by Noninvasive Testing	192

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
91/115	O	Prediction of Maximum Exercise Ventilation by Identification of Optimal Reciprocal Spirometric Timed Volumes	193
91/116	O	SWOG 9038 Extended Administration of Oral Etoposide and Cyclophosphamide for the Treatment of Advanced Non-Small Cell Lung Cancer	194
91/117	C	Influences of Neostigmine on Ultrafiltration and Solute Clearances in Peritoneal Dialysis	195
91/118	O	SWOG 9013 A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery versus Surgery Alone for Patients with Local Regional Disease, Phase III	196
91/119	O	SWOG 9039 Evaluation of Quality of Life in Patients with Stage D-2 Cancer of the Prostate Enrolled in SWOG 8894	197
91/120	O	What is the Prevalence of Gastroesophageal Reflux in Patients with Sleep Apnea - A Prospective Evaluation	198
91/121A	O	The Effect of Low-Dose Methotrexate on Calcium, Vitamin D and Bone Metabolism in Female Sprague-Dawley Rats	199
91/122	O	A Multicenter, Double-Blind Study to Evaluate the Safety and Therapeutic Efficacy of Omeprazole 20mg A.M. or 10mg A.M. as Compared to Placebo During 12 Months Maintenance Treatment of Patients with Duodenal Ulcer Healing Following 4 Weeks of Omeprazole 20mg A.M.	200
91/123	O	Relative Efficacy of Three Oxygen Delivery Systems in the Nocturnal Home Setting	201
91/124	O	A Controlled, Randomized, Open Pilot Study to Investigate the Effects of Intra-arterial Atrial Natriuretic, Peptide or Gallopamil in the Treatment of Acute Renal Failure	202
91/125	O	An Ultrastructural Study of the Dermal-Epidermal Junction Following Skin Splitting with Various Methods	203
91/126	O	Efficacy of Oral Cromolyn Sodium in Documented Adverse Food Reactions, A Double-Blind Placebo-Controlled Trial with Food Challenges	205
91/127	O	Effectiveness of Simethicone to Improve Visibility During Colonoscopy when Given with a Peroral FLEET Diphosphate Laxative: A Double-Blind Randomized Placebo Controlled Study	206

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
91/128	C	A Randomized, Open-Label, Comparative Trial of Dideoxyinosine (ddI) and Dideoxycytidine (ddC) in HIV Infected Patients Who Are Intolerant of or Have Failed Zidovudine (ZDV) Therapy	207
91/129	O	SWOG 9046 Evaluation of 10-EdAM in Patients with Squamous Cell Carcinoma of the Head and Neck, Phase II	208
91/130	O	MGI 136-07-P90-03: A Double-Blind, Randomized, Placebo Controlled Study of Diethyldithiocarbamate (DDTC) Used as a Protective Agent Against Cisplatin-Induced Toxicities in Patients with Small Cell or Non-Small Cell Carcinoma	209
91/131	O	Survey of Aerobic Bacteria in Chenopod and Amaranth Pollens and Their Effects on Pollen Extracts Used for Desensitization in Allergic Disease	210
91/132	O	Amldipine Cardiovascular Community Trial	211
91/133	O	SWOG 9111 (EST 1690) Post-Operative Adjuvant Interferon Alpha 2 in Resected High-Risk Primary and Regionally Metastatic Melanoma, Intergroup	212
91/134	O	The Use of Cultured Skin Cells and Monoclonal Antibodies to Evaluate the Development and Function of Various Proteins in Keratinocytes and Other Epidermal and Dermal Cells	213
91/135A	O	Induction of Clinical Lesions in XID/Beige/ Nude Mice Using Various Factors	214
91/136	O	I. A Clinical Radiographic Comparison of Parenteral Gold Versus Parenteral Methotrexate in the Treatment of Early Rheumatoid Arthritis. II. The Effect of Low-Dose Methotrexate on Bone Metabolism and Bone Density	215
91/137	O	Effect of Specific Immunotherapy on Peripheral Lymphocyte Intracellular Adhesion Molecules	216
91/138A	O	Effects of Beta-blockers on Intracellular Cyclic Nucleotide Generation in Guinea Pig (Cavia porcellus) Airway Smooth Muscle	217
91/139	O	SWOG 9045 Evaluation of Quality of Life in Patients with Advanced Colorectal Cancer Enrolled on SWOG 8905	218
91/140	O	SWOG 9040 Intergroup Rectal Adjuvant Protocol, A Phase III Study	219
91/141	O	SWOG 9009 Pilot Study for Analysis of Lymphocyte Subsets and Natural Killer Activity after Treatment with Levamisole	220

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
91/142	O	A Multicenter, Double-Blind, Double-Dummy, Placebo-Controlled, Group-Comparative Study of the Safety and Effectiveness of Four Doses-Levels of Tipredane as Compared to Beclomethasone Dipropionate in the Treatment of Adults with Moderate Asthma. Fisons Study No. 1900-2209	221
91/143	O	A Multi-Center Randomized Comparative Trial Evaluating Safety and Efficacy of Monopolar Versus Bipolar Polypectomy Snares	222
91/144	O	Effect of Glucose on Residual Renal Function in Peritoneal Dialysis	223
91/145	O	The Effect of PTH vs Phosphate on Osteoblast Function; and the Effect of Age on Stimulated Osteoblast Function	224
91/146	O	Work of Breathing as a Predicator of Failure to Wean From Mechanical Ventilation in Patients with Severe Chronic Obstructive Pulmonary Disease	225
91/147	O	SWOG 8730 Evaluation of Amonafide in Esophageal Cancer	226
91/148	O	SWOG 8911 Evaluation of Piroxantrone in Refractory Carcinoma of the Breast, Phase II	227
91/149	O	SWOG 8936 Evaluation of Piroxantrone in Gastric Cancer	228
91/150	O	SWOG 9007 Cytogenetic Studies in Leukemia Patients, Ancillary	229
91/151	O	SWOG 9108 A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate Plus Chlorambucil in Previously Untreated B-Cell Chronic Lymphocytic Leukemia	230
		DEPARTMENT OF SURGERY	
78/20X	T	1-Repair of Femoral Artery by Microvascular Technique in Rabbits and Rats	232
78/20X	T	2-Repair of Femoral Artery by Microvascular Technique in Rabbits and the Rat	233
78/20X	T	3-Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat	234
78/201	T	Clinical Study for Intraocular Lenses, General Leonard Wood Army Community Hospital	235
78/201	T	Clinical Study for Intraocular Lenses, Fitzsimons Army Medical Center **(PR)**	236

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
78/201A	T	Clinical Study for Intraocular Lenses, Munson Army Community Hospital	237
78/201C	T	Clinical Study for Intraocular Lenses, Ft. Riley, Ks	238
78/201D	T	Clinical Study for Intraocular Lenses, Ft. Sill, Ok	239
78/201E	T	Clinical Study for Intraocular Lenses, Ft.Carson, Co	240
84/20X	T	001 - Microvascular Arterial and Venous Anastomosis in Laboratory Rats	241
86/200A	T	Treatment of Urinary Tract Trauma in the Porcine Animal Model	242
87/202	C	Improving Cancer Management Through the Tumor Conference	243
87/203	O	Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Disorders Marked by Altered Patterns of Peripheral Blood Flow (PR)	244
87/204	O	Mechanism Based Treatment of Phantom Limb Pain (P)(PR)	245
87/205	C	Etiology of Low Back Pain Due to Muscle Tension (P)(PR)	248
87/206	O	Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain (P)(PR)	250
87/207	O	Determination of Mechanisms of Phantom Limb Pain: Phase 2 (P)(PR)	252
88/20X	T	003-Evaluation of the Goat as a Model for Bone Grafting	254
88/20X	T	004-Development of an Animal Model for the Study of Anterior Cruciate Ligament Repairs	255
88/200	C	Alcon Surgical Intraocular Lenses Study	256
88/201A	T	Use of Goats for Training in Advanced Trauma Life Support	257
88/202	O	A Comparison of Clinical Features of Ulnar Nerve Compression at the Elbow Before and After Medial Epicondylectomy	258
88/203	O	Evaluation of Current Nasal Surgical Techniques Used to Improve Nasal Obstruction (Subjective and Objective), Utilizing Anterior Rhinometric Techniques	259
88/209	C	A Comparison of Percutaneous Repair vs Open Repair of Achilles' Tendon Ruptures (PR)(SP)	261
88/213	O	Investigational Plan for the Clinical Study of Silicone Intraocular Lenses Sponsored by Allergan Medical Optics	263

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
88/214	C	Clinical Investigation of Intraocular Lenses in Minors Sponsored by COBURN Optical IND, Inc/Storz Ophthalmics Inc.	264
88/215	O	Plot Study For: Continuous Environmental Recording Activity, Headache, and Muscle Contraction Level Among Subjects with Tension, Migraine or No Headache **(PR)**	265
89/20X	T	001-Microsurgical Training in Free Flap Transfer, and Vessel and Nerve Repair Utilizing the Rat	266
89/202	T	The Effect of Harvesting the Central One-Third of the Patellar Tendon and Reapproximating the Medial and Lateral Edges of Patella femoral Joint Mechanics in Cadavers	267
89/203	O	Rates of Occurrence of Simultaneous and Independent Low Back Pain and Headache Among Patients with and without Chronic Pain	268
89/205A	C	Correlation of the Vocal Fold Vibratory Pattern to the Post Operative Surgical Wound in the Porcine Model	269
89/207	O	Etiology and Progression of Acute Muscle Tension Related Low Back Pain Occurring During Sustained Activity Including Combat Training Exercises	270
89/210	O	Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers	272
89/211	O	Randomization Study of Transurethral Resection of the Prostate vs Balloon Dilatation of the Prostate for Symptomatic Benign Prostatic Hyperplasia in Men	274
90/20X	T	001-Evaluation of the Goat as a Model for ACL Reconstruction Fixation Studies	275
90/200A	O	Comparison of ACL Graft Fixation Techniques in a Goat Model	276
90/201A	C	Use of Retrograde Cardioplegia in the Pig Model	277
90/202	O	Non-Surgical Treatment of Morton's Neuroma with Injection of Vitamin B-12/Lidocaine/Solumedral Combination **(PR)**	278
90/203	O	Synovial and Serum Keratin Sulfate Levels and Their Correlation with Arthoscopically Determined Articular Damaged Chronically Deficient Cruciate Ligament Knees	279
90/204	O	A Clinical Comparison of a Hydroxylapatite Coated versus Porous Coated Total Hip Implant for Use in Arthritic Human Hips	280

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/206	O	Pilot Trial of Potentiating Normal Healing of Stress Fractures Using Pulsing Electromagnetic Fields	281
90/207A	O	Patellar Tendon Healing and Strength Following Patellar Tendon Autograft Harvest in Goats	282
90/208A	O	Development of an Implanted, Hydroxyapatite Coated, Titanium Limb Prosthetic Through Tests in Tissue Culture, Then in Goats, and Finally in Humans	283
90/209	O	Reliability of Psychophysiological Measures Used to Evaluate Pain	284
90/210	O	Effectiveness of Treatments for Reflex Sympathetic Dystrophy	285
90/211A	O	Effects of Coumadin and Methotrexate on Bone Ingrowth and Fixation in Hydroxyl Apatite Coated Porous Implants in a Goat	286
90/212A	O	The Evaluation of Bone Ingrowth in Hydroxyl Apatite and in Non-Hydroxylapatite Porous Implants in a Goat	287
90/213	O	Eaton Trapezial Implant Long-Term Follow-Up	288
91/20X	T	001-Evolution of a Gelatin Film Barrier Following Parotidectomy for the Prevention of Frey's Syndrome	289
91/200	O	Clinical Evaluation of a Hydrogel Intracorneal Implant (Kerato-Gel) for the Correction of Aphakia	290
91/201	O	Utilization of Prostheses Among Relatively Healthy Traumatic Amputees	291
91/202A	O	Ciprofloxacin and Primary Fracture Healing: A Biomechanical and Histological Evaluation in the New Zealand White Rabbit	292
91/203A	O	Repair of Femoral Artery by Microvascular Technique in Rabbits and Rats	293
91/204A	O	Evaluation of a Gelatin Film Barrier Following Parotidectomy for the Prevention of Frey's Syndrome in the Goat	294
91/205	O	Holter Monitoring to Evaluate Possible Arrhythmias Following Epinephrine and Cocaine Use During Nasal Surgery	295
91/206A	O	Use of Goats for Training Advanced Trauma Life Support	296

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

DEPARTMENT OF CLINICAL INVESTIGATION

77/300	O	Immunologic Disorders in Children and Adults. I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies (PR))	297
82/302	O	The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory (P)(PR)	299
86/300	C	Early Identification of Borrelia burgdorferii Antibody in Human Sera	301
88/30X	T	Veterinarian & Veterinary Support Personnel Training in Emergency Care Procedures for Lab Animals	302
89/301	O	Biology of Cutaneous Lupus: I Skin Lesion Examination (P)(PR)	303
89/302	O	Biology of Cutaneous Lupus: II Characterization of Autoantigens and Autoantibodies in Lupus	305
89/303	O	Biology of Cutaneous Lupus: III The Study of the Effects of Ultraviolet Light on the Skin of Lupus Erythematosus Patients	306
89/304	C	Evaluation of the Protofluor-Z as a Screening Tool for Lead Intoxification in Children (P)(PR)	307
90/300	C	Videx (2',3'dideoxyinosine, ddI) Treatment IND Protocol No. 454-999-001. (Bristol-Myers Co.)	308
90/301	C	Videx (2',3' dideoxyinosine, ddI) Open Label Study Protocol No. 454-999-001. (Bristol-Myers Co.)	309
91/300	O	Collaborative Study of Anti-Retroviral Resistance in Multiple HIV Infected Populations	310
91/301A	O	Evaluation of Biological Attachment Factors for Skin Graft Acceptance in Athymic Nude (beige/nude/XID) Mice	311
91/302A	O	Training for Department of Clinical Investigation and Veterinary Services Personnel in Medical, Surgical, and Emergency Care Treatment, and Laboratory, Pathology and Radiologic Procedures for Various Laboratory Animal Species	312

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

DEPARTMENT OF OB-GYN

80/351	O	GOG #26 - Section A: Master Protocol for Phase II Drug Studies in the Treatment of Advanced Recurrent Pelvic Malignancies	313
80/352	O	GOG #26 - Section C: A Phase II Trial of Cis-Platinum	314
80/359	O	GOG #26 - Section S: A Phase II Trial of VM26.	315
80/378	O	GOG #72 - Ovarian Tumors of Low Malignant Potential A Study of the Natural History and a Phase II Trial of Melphalan and Secondary treatment with Cisplatin in Patients with Progressive Disease	316
80/380	O	GOG #73 - A Clinical Pathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy	317
87/353	O	GOG 90 - Evaluation of Cisplatin, Etopuside, and Bleomycin Induction Followed by Vincristine, Dactinomycin and Cyclophosphamide Consolidation in Advanced Ovarian Germ Cell Tumors (O)	318
87/354	O	GOG 95 - Randomized Clinical Trial for the Treatment of Women with Selected Stage IAi & IAii & IBii Ovarian Cancer (Phase III)	319
87/358	O	GOG 93 Evaluation of Intraperitoneal Chromic Phosphate After Negative Second-Look Laparotomy in Ovarian Carcinoma	320
87/359	O	GOG 99 Adjunctive Radiation Therapy in Intermediate Risk Endometrial Carcinoma	321
88/350	O	GOG 92 Radiation Therapy vs No Further Therapy in Selected Patients with Stage IB Invasive Carcinoma of the Cervix	322
88/351	O	GOG 94 A Phase II Study of the Treatment of Stage III and IV Disease of Advanced Endometrial Carcinoma and All Stages of Papillary Serious Carcinoma and Clear Cell Carcinoma of the Endometrium with Total Abdominal Radiation Therapy	323
88/355	O	GOG 104 Intraperitoneal (SWOG 8501) Intraperitoneal Cis-Platinum and Cyclophosphamide IV vs Intravenous Cis-Platinum and Cyclophosphamide IV in Patients with Optimal Stage III Ovarian Cancer	324

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
88/358	O	GOG 100 Monoclonal Antibody Against Free Beta HCG to Predict Development of PGTD in Patients with Hydaditoform Mole	325
88/359	O	GOG 102A - Master Protocol for Intraperitoneal Drug Studies in Residual Ovarian Malignancies After Second-Look Surgery	326
88/360	O	GOG 87C A Phase II Trial of Hydroxyurea, DTIC and VP16 in Patients With Advanced Uterine Sarcomas	327
89/351	O	GOG 87D A Phase II Trial of VP-16 in Patients with Advanced or Recurrent Uterine Sarcoma	328
89/352	O	GOG 101 A Phase II Evaluation of Preoperative Chemoradiation for Patients with Advanced Vulvar Cancer	329
89/354	O	GOG 107 A Randomized Study of Doxorubicin vs Doxorubicin Plus Cisplatin in Recurrent Endometrial Adenocarcinoma Previously Diagnosed as Primary Stage III or IV (Phase III)	330
89/355	C	GOG 102E Intraperitoneal Administration of Cisplatin (NSC#119875) and Etoposide (VP-16) (NSC#141540) in Patients with Residual Ovarian Carcinoma (Phase II)	331
89/356	O	GOG 102F Intraperitoneal Administration of Alpha Recombinant Interferon (aIFN) in Residual Ovarian Carcinoma (Phase II)	332
90/350	O	GOG 108 Ifosfamide and the Uroprotector Mesna, With or Without Cisplatin, in Patients With Advanced or Recurrent Mixed Mesodermal Tumors of the Uterus	333
90/351	O	GOG 109 A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy VS Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection	334
90/352	O	GOG 26EE: A Phase II Trial of Didemnin B in Patients with Advanced Pelvic Malignancies	335
90/353	O	GOG 26GG: A Phase II Trial of Fazarabine (NSC#281272) in Patients with Advanced/Recurrent Pelvic Malignancies	336
90/354	O	GOG 26HH: A Phase II Trial of 5-Fluorouracil and Leucovorin in Advanced Metastatic or Recurrent Pelvic Malignancies	337
90/355	O	GOG 102G: Intraperitoneal Administration of Cisplatin (NSC#119875) and Thiotepa in Residual Ovarian Carcinoma	338

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/356	O	GOG 111: A Randomized Phase III Study of Cisplatin and Cyclophosphamide Versus Cisplatin and Taxol in Patients with Suboptimal Stage III and Stage IV Epithelial Ovarian Carcinoma	339
91/350	O	GOG 26II A Phase II Trial of 5-FU and High Dose Leucovorin in Patients with Advanced/ Recurrent Pelvic Malignancies	340
91/351	O	GOG 26JJ A Phase II Trial of Taxol (NSC#125973) in Patients with Advanced Carcinoma of the Cervix	341
91/352	O	GOG 102H A Phase II Study of the Intraperitoneal Administration of Recombinant Interleukin-2 in Residual Ovarian Carcinoma ..	342
91/353	O	GOG 109 A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy vs Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection	343
91/354	O	GOG 110 A Randomized Study of Cisplatin vs Cisplatin Plus Dibromodulcitol (NSC#104800) vs Cisplatin Plus Ifosfamide and Mesna in Advanced Carcinoma of the Cervix	344
91/355	O	GOG 112 A Randomized Comparison of Chemoprophylaxis Using Methotrexate vs Routine Surveillance in Management of High Risk Molar Pregnancy	345
91/356	O	GOG 26KK A Phase II Trial of Merbarone (NSC 336628) in Patients with Advanced and Recurrent Endometrial, Cervical and Epithelial Ovarian Carcinoma	346
91/357	O	GOG 26LL A Phase II Trial of Prolonged Oral Etoposide (VP-16) in Patients with Advanced Pelvic Malignancies	347
91/358	O	GOG 113 An Evaluation of Hydroxyurea, 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stage II-B, III and IV-A Carcinoma of the Cervix and Negative Para-aortic Nodes	348
91/359	O	GOG 87F A Phase II Trial of Doxorubicin and Ifosfamide with Mesna in the Treatment of Recurrent or Advanced Uterine Leiomyosarcomas	349

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

DEPARTMENT OF PEDIATRICS

78/40X	T	-001 - Use of Laboratory Animals (Cats) to Teach Medical Skills	350
82/403	O	POG 7799 - Rare Tumor Protocol for Childhood Solid Tumor Malignancies, Ancillary	351
82/414	O	POG 8158 - NWTS Long Term Follow-Up Study: A Non-Therapeutic Study	352
82/420	O	POG 8451 - Intergroup Rhabdomyosarcoma Study III	353
86/408	C	POG #8600 - Laboratory Classification in Acute Lymphoid Leukemia of Childhood (ALinC 14C) Phase III	354
86/410	C	POG 8602 ALinC #14: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (AlinC#14) - A Pediatric Oncology Group Phase III Study	355
87/401	O	POG 8625/8626 - Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA1 Hodgkin's Disease in Pediatric Patients, A Pediatric Oncology Group Phase III Study	356
87/404	O	POG 8653/54 - A Study of Childhood Soft Tissue Sarcomas (STS) Other Than Rhabdomyosarcoma and Its Variants, A Pediatric Oncology Group Phase III Study	357
88/400	O	POG 8704 T-Cell #3 Protocol: A Pediatric Oncology Group Phase III Study	358
88/402	C	POG 8759 Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma or Unresectable Primary Osteosarcoma vs Previously Treated Recurrent Osteosarcoma	359
88/404	T	Ceftriaxone vs Amoxicillin/Clavulanate for Initial Empirical Therapy of Occult Bacteremia.	360
88/405A	C	Macromolecular Absorption in the Post-Asphyxiated Small Intestines of the Adult Rat	361
88/408A	O	Effect of Human/Animal Interaction on Stress Levels During Outpatient Pediatric Oncology Visits	362
89/400	C	POG 8710 Protocol for Second Induction and Maintenance in Childhood Acute Lymphoblastic Leukemia (SIMAL #5)	363
89/401A	O	An Observational Study on the Response of Children to the Presence of a Stuffed Animal VS a Live Animal During a Neuromuscular Exam **(PR)**	364

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
89/403A	T	Effect of Inflammation in Chronic Pneumonia in Rats Due to Pseudomonas Aeruginosa ---Medication by Bacterial Exoproducts	365
89/404	O	POG 8725 Randomized Study of Intensive Chemotherapy (MOPP/ABVD) + or - Low Dose Total Radiation Therapy in the Treatment of Stages IIB, IIIA-2, IIIB, IV Hodgkin's Disease in Pediatric Patients	366
89/405	T	Clonidine Treatment of Constitutional Delay of Growth and Puberty--A Prospective Double Blind Study	367
89/407	T	Baby Development Follow-up Network Project	368
89/408	C	Comparison of Cotinine Hair and Saliva Analysis in the Determination of Passive and Active Cigarette Smoking Exposure in Adolescents	369
90/401	T	Experience with Multiple Doses of Survanta in Premature Infants	370
90/402A	O	Training for Pediatricians in Emergency Procedures	371
90/403A	C	Studies of the Hemodynamic Consequences of Partial Cardiopulmonary Bypass in the Lamb	372
90/405	O	Followup of the NICU Graduate in Military Medical Facilities	373
90/406	O	POG 8788 Intergroup Ghabdomyosarcoma Study IV: A Pilot Study for Clinical Group III Disease	374
90/407	O	POG 8821 AML#3: Intensive Multiagent Therapy vs Autologous Bone Marrow Transplant Early in 1st CR for Children with Acute Myelocytic Leukemia	375
90/408	O	POG 8823/24 Recombinant Alpha Interferon in Childhood Chronic Myelogenous Leukemia	376
90/409	O	POG 8827 Treatment of Children with Hodgkin's Disease in Relapse - Phase II	377
90/410	O	POG 8829 A Protocol for a Case-Control Study of Hodgkin's Disease in Childhood: A Non-therapeutic Study	378
90/411	C	POG 8832 Pre-XRT Cisplatin and Ara-C for Children with Incompletely Resected Supratentorial Malignant Brain Tumors	379
90/412	O	POG 8850 Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone	380

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/413	O	POG 8889 Intergroup Rhabdomyosarcoma Study-IV Pilot Study for Clinical Group IV Disease	381
90/414	O	POG 8828 Late Effects of Treatment of Hodgkin's Disease: A Pediatric Oncology Group Non-Therapeutic Study	382
90/415	O	POG 8650 National Wilms' Tumor Study - 4 (NWTS-4), A Pediatric Hematology-Oncology Phase III Study	383
91/400	O	Normative Electrocardiographic Data in Healthy Newborns and Infants Living at Intermediate High Altitude	384
91/401A	O	Pediatric Intubation Training Using the Ferret Model	385
91/402	C	Personality and Infant Development	386
91/403	O	Evaluation of Test of Cure Using a DNA-Probe Test for Neisseria Gonorrhea	387
91/404	O	POG 8615 A Phase III Study of Large Cell Lymphomas in Children and Adolescents - A Comparison of Two Treatment Regimens - ACOP+ versus APO	388
91/405	O	Can Spirometry Significantly Impact the Healthy Adolescent in Influencing Smoke Cessation	389
91/406	O	POG 9000 POG Acute Lymphocytic Leukemia in Childhood #15 Classification: A Non-therapeutic Study	390
91/407	O	POG 9005 Dose Intensification of Methotrexate and 6-Mercaptopurine for Acute Lymphocytic Leukemia in Childhood: A Phase III Study	391
91/408	O	POG 9006 Up-Front Intensive 6-MP/Methotrexate versus Up-Front Alternating Chemotherapy for Children Acute Lymphocytic Leukemia: A Phase III Study	392
91/409	O	POG 9046 Molecular Genetic Analysis of Wilms' Tumor	393
91/410	O	Studies of the Neurologic Examination of Young Infants	394
91/411	O	POG 8945 An Intergroup Protocol for the Treatment of Childhood Hepatoblastoma and Hepatocellular Carcinoma	395
		DEPARTMENT OF PATHOLOGY	
91/450	C	Pathology Reference Ranges for Alpha Feto-Protein, Luteinizing Hormone and Follicle Stimulating Hormone	396

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

Page

DEPARTMENT OF RADIOLOGY

80/602 O I.V. Administration of 131-I-6-B Indomethyl-norcholesterol (NP-59) for Adrenal Evaluation and Imaging 398
88/601 T Body Fat Determination by Dual Photon Absorptiometry 399
88/602 T The Comparative Renal Clearances of Disofenin and Mebrofenin 400
89/602 C The Utility of the Bard "Biopty" Gun in the Breast: Correlation with Surgical Excisional Specimens 401

DEPARTMENT OF PRIMARY CARE & COMMUNITY MEDICINE

80/650A C The Ontogenesis of Hemoglobin in the American Opossum (Didelphis Virginia) (P) 402
91/650A O Study of Hemoglobin and Red Cell Metabolism in Didelphis marsupialis 405
91/651A O A Prevention of dATP Synthesis in Red Blood Cells of Didelphia virginiana Through Administration of ADGEN 406

DEPARTMENT OF NURSING

86/700A T Introduction to Suturing Techniques Using Outbred Adult Rats 407
90/700 C A Pilot Study: A Comparison of Subarachnoid Block Anesthesia with Tetracaine and Epidural Anesthesia with Lidocaine and the Effects on the Umbilical Artery Acid-Base Results and Five Minute Apgar Scores of Neonates Following Uncomplicated Cesarean Section 408
90/701 C Assessment of Post Myocardial Infarction Patients Learning Needs During Hospitalization and Post-Discharge 409
90/702 O The Impact of Practice at Fitzsimons Army Medical Center Upon Registered Nurses Professional Role Conception 410
91/700 C The Effects of Patient Positioning and Supplemental Oxygen on Post Operative Oxygen Saturation 411
91/701A O Suturing Techniques for FAMC Personnel 412
91/702 O Pilot Study for Psychometric Properties of Selected Tools for Pain Assessment and Management in Children 413

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

Page

PHYSICAL MEDICINE

90/750 T Onset-to-Onset Difference Between the Median Motor Nerve and the Anterior Interosseous Nerve Using a Common Stimulation at the Antebubital Fossae 414

ENVIRONMENTAL HYGIENE ACTIVITY-WEST

91/800A O Survey of Tick Vectors and Wild Rodents for the Presence of borrelia burgdorferi in the Deer Tick, Ixodes pacificus, and in the Black-legged Tick, ixodes scapularis 415

91/801A O Studies of the Metabolic Adaptation in Response to Chronic Severe Hypoxia in the Pregnant Sheep 416

MEDDAC

83/902A T Use of Goats for Training in Emergency Medical Procedures 417

88/900 T IOLAB Investigational Plan for the Clinical Study of Intraocular Lenses 418

88/901 T COBURN IOL at GLWACH, Ft. Leonard Wood, MO ... 419

89/900 O Evaluation of a Phase I Coxiella burnetii Vaccine (IND 610) for Immunization Against Q Fever 420

89/901 O Continued Evaluation of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, TC-83 Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel IND 142 421

89/902 O Evaluation of New Lots of Tularemia Vaccine, Protocol B: Comparative Assessment of Francisella tularensis Vaccine, Live, NDBR 101, IND 157 ... 422

89/903 O Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated. Protocol B: Continued Assessment of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 As a Booster in At-Risk Personnel, IND 914 423

89/904 O Use of the Sixteen Personality Factor Questionnaire to Predict Susceptibility to Occupational Stress Among US Army Recruiters 424

90/900 O Iron Deficiency Anemia in 11-14 Month Old Infants at 6,000 Feet, (1830m) Elevation. A Study to Evaluate the Response to a Therapeutic Trial of Iron 425

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/950A	T	Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care. Resuscitation of the Newborn Utilizing Young Cats	426
91/900	T	Trial to Evaluate the Effect of Digitalis on Mortality in Heart Failure	427
91/901	C	User Review of the Prototype Self-Contained Toxic Environment Protective Outfit (STEPO)	428
91/902	O	Administration of Equine Heptavalent Antitoxin for Therapy of Suspected Botulism Intoxication IND 3703	429
91/950A	O	Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care: Resuscitation of the Newborn Utilizing the Ferret Model	430

EMERGENCY USE PROTOCOLS

EU-89-2	C	POG 8743	431

Ongoing (O), Completed (C), Terminated (T), Published (P), or Submitted for Publication (SP), Presentations (PR).

UNIT SUMMARY

Clinical Investigation efforts by FAMC personnel in FY 91 culminated in the publication of **215** articles and **157** presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1991, there were **271** research protocols on the DCI register. Of these, **181** projects were ongoing, **48** projects completed, **42** projects terminated, and for this FY there were **96** new registrations.

Objectives:

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e., active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medical education. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field.

Technical Approach:

This support is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use,

Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 40-18, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters.

Manpower: current authorized strength is outlined.

Description	Grade	MOS	Br	Auth	Req	Act	Name	Rank
C, Dept Clin Inv	05	GIG9B	MC	1	1	1	HARRISON	LTC
C, Micro Svc	05	68A00	MSC	1	1	1	Harris	LTC
C, Biomet & Resh	04	68T00	MSC	1	1	1	Sherman	MAJ
C, Biochem Svc	04	68C9C	MSC	1	1	1	Schofield	CPT
C, Immunol Svc	04	68A00	MSC	1	1	1	Lieberman	LTC
C, Cell Phys Svc	03	68J00	MSC	1	1			
C, Animal Res Svc	04	64C9B	VC	1	1	1	Banks	MAJ
NCOIC-Med Lab	E6	92B30M		1	1	1	Remmick	SSG
Operating Rm Sp	E5	91D2R		1	1	1	Haynes	SGT
Bio Sci Asst	E6	01H3R		1	1	1	Brady	SSG
NCO Biochem	E7	92B4RM		1	1	1	Dalton	SFC
Bio Sci Asst	E5	01H3R		1	1	1	Sanders	SGT
Vet Sp	E6	91T3R		1	2	1	Barrett	SSG
Vet Sp	E5	91T2R		1	1	1	Wendt	SGT
Bio Sci Asst	E4	01H1R		1	1	1	Cruz-Saez	SGT
Bio Sci Asst	E4	01H1R		1	1	1	Williams	SPC
Bio Sci Asst	E4	01H1R		1	1	1	Sipple	SPC
Bio Sci Asst	E4	01H1R		1	1	1	Schaphorst	SPC
	E6	01H1R		1	1	1	Stinnett	SSG
Supv Res Chem	13	1320	GS	1	1	1	Gutierrez	
Microbiologist	11	0403	GS	3	3	3	Lima	
							Paine	
							Hoyt	

Description	Grade	MOS	Br	Auth	Req	Act	Name	Rank
Psychology Tech.	07	0181	GS				Evans	
Statistical Asst.	05	1531	GS				Caminer	
Nurse	09	0610	GS				Ressman	
Nurse Specialist	11	0610	GS				Palestro	
Microbiologist	09	0403	GS	2	3	3	Morse	
							Andreatta	
							Muehlbauer	
Med Technologist	09		GS	1	1	1	Lollar	
Med Technologist	11	0644	GS	0	1	1	Rush	
Med Technologist	09	0644	GS	7	7	5	Ramirez	
							Pinney	
							Goodgion	
							Sachanandani	
							Granata	
							Schlichtemeier	
Med Technician	07	0645	GS	2	2	1	Nelson	
*Research Chem	11	1320	GS	2	3	3	Noble	
							O'Brien	
							Sherva	
Bio Lab Tech	09	0404	GS	1	1	1	Mercill	
Animal Manager	07	5048	WS	1	1	1	Jones	
Research Prot Sp	09	0301	GS	1	1	1	Bilak	
Animal Caretaker	05	5408	WG	1	3	3	Chase	
							Hitchcock	
							Giese	
Secretary	06	0318	GS	1	1	1	Montoya	

Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

		FY89	FY 90	FY 91
OMA	Civilian Personnel	1,260,000.	834,529.	1,129,389.
	Contracts/Supplies	218,800.	453,777.	44,019.
	Ceep Equipment	4,350.	64,424.	77,859.
	Travel	6,031.	9,978.	28,928.
	Military Personnel	1,260,000.	754,499.	813,626.
	Rentals			10,178.
OPA	MEDCASE	579,122.	740,811.	262,529.
Civilian Consultants	FY 90 - $828.00			300.
Publication Costs	FY 90 - $9,081.00			8,678.

Personnel

	Authorized	Required	Assigned
Officers	6	7	7
Enlisted	12	13	12
Civilian	23	29	26
VA Civilian	2	2	4

GRANTS for FY 91

USAMRDC

Prospective Double Blind Study of Zidovudine (AZT) in Early Stage HIV Infection. $86,544.

Pilot Trial of Potentially Healing Normal Healing of Stress fractures Uisng Pulsing Electromagnetic Fields. $11,470.

Etiology and Progression of Acute Mucle Tension Related Low Back Pain Occurring During Sustained Activity Including Combat Training Exercise. $75,760.

Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers. $85,130.

Efficacy of Passive Immunization in the Prevention of Infection Due To Klebsiella Pneumoniae and Pseudomonas Aeruginosa. $50,300.

Extrinsic Positive End-Expiratory Pressure (PEEP) Effects on Functional Residual Capacity in Normal Subjects and in Ventilated Patients Experiencing Air Trapping. $36,000.

USAMRDC Grants Total: $348,000

Veterans Administration (VA)

VA Funds (Sherman) $29,800

HUGH MAHON LECTURESHIP AWARD COMPETITION - 1991

This student research award was established in 1950 and honors the late Colonel Hugh W. Mahon, MC, USA, Retired, who was Chief, Department of Pathology, Fitzsimons Army Medical Center, for 12 years. The lectureship consists of the presentation of papers judged best from among those submitted by officers in training status at FAMC.

The Hugh Mahon Lectureship Award Competition is divided into the categories of retrospective or prospective clinical studies, basic laboratory investigations, and literature reviews/case reports. This year there were a total of 34 submissions; 6 manuscripts in the laboratory category, 17 in clinical studies, and 11 case reports/literature reviews. Last year's submission was 36 and 1989's the largest with 41. In 1988 there were 23 papers submitted and in 1987, 18.

Judging was done by the members of the FAMC clinical teaching staff and a panel of distinguished university and community professors. Manuscripts were scored on originality and medical significance, experimental design, presentation and interpretation of data, and literary quality.

A Grand Prize Winner was chosen from among the five finalists in all three categories based on the presentation and question-andanswer period during the Hugh Mahon Lectureship Conference. The finalists for 1991 are as follows:

Clinical Studies

Grand Prize and 1st Place: Triple Injection Wrist Arthrogram with Rapid Sequence 105 mm X-ray: Presentation of a New Technique. Ernest E. Cope, III, CPT, MC, Orthopedic Surgery.

2nd Place: Effect of Cold Remedies on Metabolic Control of Non-Insulin Dependent Diabetes Mellitus. Homer J. LeMar, MAJ, MC, Endocrinology.

Laboratory Investigations

1st Place: Effects of Intermediate Altitude on Exercise in Acclimatized Fit Men. James I. Meyer, CPT, MC, Pulmonary Disease.

2nd Place: Effect of Coumadin on Interface Mechanics of Hydroxyapatite-Coated Porous Co-Cr-Mo Alloy Implants in a Goat Model. Bert C. Callahan, CPT, MC, Orthopedic Surgery.

Case Remorts/Literature Reviews

One Prize Only: Woodtrimmer's Disease in a Tractor Driver. Michael A. O'Connell, CPT, MC, Allergy-Immunology.

Animal Resources Service - FY 91

The major task for this service during the early months of the fiscal year was the AAALAC re-accreditation inspection. In support of the re-accreditation, a dedicated animal transport vehicle was procured, through the local GSA fleet, and modified to carry animals. The suspended ceiling work in the hallways of bldg 610 was completed. All grass around building 610 was removed to a level of 3 inches and replaced with landscape fabric and rocks to discourage vermin habitation in close proximity to the vivarium. All interior doors and facing sin building 610 were re-pained. All of the above was performed by self-help.

To accommodate the changing research species requirements, the larger animal rooms were converted into corral type settings for livestock species and 2 corrals were constructed outside the vivarium. Research livestock are now housed out of doors during the day to encourage social behavior and facilitate cleaning, maintenance and repair of indoor facilities.

The work load of this service increased dramatically during this fiscal year, averaging over 200 procedures a month. This was in support of numerous services in the medical center in response to a need to accomplish staff research that would be halted during Operation Desert Storm. One of the services members was sent to ODS for a 6 month period. The increased workload justified an additional caretaker who was hired in September.

New operating room (Castle) surgical lights were installed in both research operating rooms. A hydraulic operating table was procured for OR 2. A hoist was fabricated and placed on the loading dock of bldg 610 to facilitate the movement of heavy loads on and off of delivery trucks. All SOP's of ARS were reviewed and updated.

The FAMC Lab Animal Handbook was published in June 1991. It consists of over 60 pages addressing all aspects of use of lab animals at FAMC. It was designed and prepared to assist the investigator from initiation of a research idea to incineration of the research animals. It is written in a "cookbook" format with the required information and warning for proper Army research. A copy of this document is attached for review.

United States Patent number 5,000,732 was awarded to MAJ Banks for development of a device and technique to deliver known quantities of antigen directly to the rabbit Gut Associated Lymphoid Tissue (GALT) bypassing the upper GI. The developed technique has proven pivotal for effective utilization of the rabbit lymphoid tissue in immunologic preparations and vaccine development.

Four manuscripts were accepted or published during this period. Ten oral presentations were given during this period either by or in association with service members. MAJ Banks attend and presented at

the National American Veterinary Medical Association (AVMA) meeting in Seattle, and Mr. Jones attended the National American Association of Laboratory Animal Science (AALAS) meeting in Milwaukee. MAJ Banks was elected to the board of directors of the Academy of Surgical Research. MAJ Banks and Mr. Jones were elected to the board of directors of the Mile High Branch of AALAS. Both MAJ Banks and Mr. Jones serve on the Advisory Committee of Pickens Technical School in Denver, Colorado.

Biochemistry Service - FY 91

The Biochemistry Service achieved several significant milestones this FY91. There were several personnel changes, Judy O'Brien was promoted to Chemist and Kathy Lollar was joined us our Medical Technologist. MAJ White departed for an assignment at Dwight D. Eisenhower Medical Center, Fort Gordon, GA. SSG Stinnett successfully completed AMEDD Advanced NCOES Course at Fort Sam Houston, TX. SPC Schaphorst completed the Primary Leadership Course, Fort Carson, CO. MAJ White and Elise Sherva completed Waste Management for Health Care Facility Personnel Course, US Army Environmental Hygiene Agency, Aberdeen Proving Grounds, MD.

We received several new pieces of equipment, gas chromatograph and automated sample preparation workstation. We also utilized the excess equipment program and gained an HPLC system with electrochemical detector from WBAMC. This was a noteworthy, as it enabled us to assay iodide.

Iodide eased into the spotlight as our forces mobilized to support Operation Desert Shield/Storm. Many ground forces removed from treated water sources had to rely on individually iodide-treated water. The desert conditions amplified the soldiers' need for water. The question - does long term consumption of iodide-treated water impair a soldier's combat fitness - nagged at us, as we struggled to develop an assay for serum iodide. We are now fine-tuning the methodology.

The cotinine and passive smoking study was completed. We presented two discussions. BIOTEX Laboratories, the manufacturer of the first cotinine assay we used, went out of business. SEREX, Inc. marketed another cotinine assay. This kit was unsatisfactory, and the vendor withdrew its product.

We reached several goals. Elise Sherva worked hard compiling drafts of the Department's Chemical Hygiene Plan and Hazard Communication Standard. Under her direction, the Department has an effective chemical management program. Sharon Noble and Tony Gutierrez were responsible for the Department's Radiation Safety Program, and its SOP. These programs are an integral to the safe laboratory operations of the Department.

Rapidly following her appointment, Kathy Lollar assumed her Quality Assurance responsibilities, and prepared for our first CAP

inspection. She has improved the quality of our Hb A_{1c} assay, with better assay performance and reduced turn-around time to the health care providers.

We have completed the preliminary work of the latex hypersensitivity protocol. The work will continue with the direction of a new Principal Investigator.

After an extensive self-help project, we laid down our saws and hammers in the Genetics Laboratory. Physical plant problems still exist. Central air conditioning is scheduled late fall installation. Tony Gutierrez visited with WRAIR laboratory, and returned with much information.

Dr. Bethlenfalvay presented an abstract at the Seventh International Symposium on Purine and Pyrimidine Metabolism in Man, held in Bourenmouth, England in July. Our laboratory has sustained much of his erythrocyte investigations in our HPLC laboratory.

This summer, we hosted a research intern from Barnard College. This was rewarding for our genetics laboratory, FAMC, and the student, Jeanne Rhee. We are planning to continue outreach program next summer.

Cell Physiology Service - FY 91

Cell Physiology Service (CPS) provides clinical research support for FAMC in a number of scientific areas. These include: histochemistry, immunocytochemistry, electron microscopy, tissue culture, and animal modeling in tumor growth and treatment.

Collaborative efforts by CPS during FY91 culminated in two presentations. In April the results of the polytetrafluoroethlene graft experiment were presented at the ARVO Meeting. The findings of the joint study of CPS and Pulmonary Disease Service were presented at the American Thoracic Society Meeting, May 1991. Final data was obtained by CPS for the Department of Pediatrics protocol which studied the effects of hypoxia on intestinal function.

The Dermatology Service collaborated with CPS in five new protocols. Dr. David-Bajar is studying the dermal-epidermal junction. The purpose is to further characterize a number of structural components of the basement membrane area of the dermal-epidermal junction in skin. Such characterization could be used as an adjunctive test in the diagnosis of different blistering diseases. Dr. David-Bajar is also investigating the MRL+/+ mouse as a model for lupus erythematosus. Dr. Bennion, CPS, and UCHSC are collaborating in determining the specificity of monoclonal antibodies for certain skin protein antigens which are implicated in skin tumors. This is an in vitro study in which CPS is culturing human keratinocytes and performing immunohistochemical staining for the demonstration of the antibodies. An in vivo study is in progress involving the bg/nu/xid

mouse. The objectives of the study are to: 1. Develop an animal model of subcutaneous lupus erythematosus (SCLE). 2. To induce clinical and histological lesions of SCLE in the bg/nu/xid. 3. To immunohistologically characterize the resulting lesions. This protocol involves the grafting of human skin to the bg/nu/xid and then inducing the lesions by subjecting the mouse to various factors including anti-Ro, UVB, mononuclear cells, and gamma interferon. Forty mice have been grafted and are starting treatment.

CPS is also investigating the use of biological attachment factors, commonly used in tissue culture, in improving the graft take rate in the athymic nude mouse.

The Otolaryngology Service is collaborating with CPS and UCHSC in studying the effects of smoking, alcohol ingestion, radiation therapy, and Beta carotene on Langerhans cells (LC) in human oral mucosa. LC play an important role in antitumor immunity. Depletion of these cells can increase the chances of the development of a neoplasia. The study will investigate whether vitamin derivatives can offset the depletion of the LC and induce tumor regression.

In addition, CPS developed several new cell lines. One is a fibroblast line from a patient with scleroderma. Another is a rare Thyroid Stimulating Hormone (TSH) sensitive papillary thyroid carcinoma. Studies are being designed to utilize both lines.

Clinical Biometrics and Research Design Service - FY 91

All orthopedic residents have been rotating through the Service as part of their regular training program for the last several years. This year they were joined by General Surgery residents who all have similar rotations through the Service during which they learn clinical research design, clinical statistics, computer work and data processing as well as plan, write and initiate a research project.

During this fiscal year, the two major MRDC supported programs initiated last year were continued and broadened. The lower limb pain etiology program centered at Fort Sill and FAMC has already resulted in virtual elimination of tibial stress fracture occurrence among basic trainees at Ft. Sill. The metatarsal stress fracture treatment program has produced early results which show that these fractures can be treated in a timely fashion. The ambulatory recording - low back pain program centered among soldiers at Ft. Carson participating in combat exercises and among people local to Fitzsimons AMC has produced early results demonstrating that low back pain frequently increases after low back muscle tension increases. The Service has initiated and is coordination an RSD clinic for the medical center.

Immunology Service - FY 91

The Immunology Service continues to maintain its premiere reputation in flow cytometry amongst the military medical centers.

Work expanded to include intracellular calcium analysis in the UV excitation wavelengths. A second argon laser will replace the unused krypton laser on the PICS V to provide dedicated support to this endocrinology research. The video densitometer has greatly enhanced our capabilities in gel and advanced image analysis. The HIV Natural History Protocol continues to constitute more than 60% of the Service's workload. The Allergy Therapy protocol continues with antigen analysis of the investigated pollens and may soon include binding studies. From Allergy Service Dr. Au's protocol has been submitted for publication. Advanced systems upgrade to the Department's graphic handling system will include optical character recognition hardware and software, a color image scanner, a color printer, and color video imaging software and firmware (Targa board). Protocol 80/650A produced two more publications (with presentation in England). Publications were in the Journal of Cellular PHysiology and Comp. Biochem. Physiol. At least two more publications are projected for FY 92.

Microbiology Service - FY 91

The Mycobacteriology Section continues to demonstrate excellent performance on CAP proficiency surveys and maintains its CAP accreditation. DNA probe technology instrumentation has been acquired giving the section the capability of providing four-hour identification of mycobacterial isolates. Radiometric instrumentation which will allow increased drug susceptibility testing as well as a more rapid detection of mycobacterial disease will be implemented soon. These additions will greatly improve the ability of physicians to treat infected patients.

A new, multi-center protocol pertaining to the delineation of retroviral resistance has been initiated. The use of newer culture and DNA/RNA technologies applied to the extensive library of lymphocytes presently maintained by the Microbiology Service will provide information as to the natural history of HIV infection as well as direction for the individual patient's physician for continuing a given retroviral agent or changing to another.

DEPARTMENT OF CLINICAL INVESTIGATION

ANIMAL RESOURCES SERVICE

Training Support Summary

Two Advanced Trauma Life Support (ATLS) exercises were conducted during the year, using eleven goats in the training of 44 staff physicians in the emergency management of casualties. 100-plus hours of training were provided, requiring 120 hours of support by Animal Resources Service personnel for planning, preparation, pre-op anesthesia induction, surgical preps, anesthesia monitoring, circulating, and cleanup.

Nine rats were utilized in support of microsurgery training in the re-anastomosis of small vessels, providing 30-plus hours of training to 9 staff surgeons and residents from Plastic Surgery Service. Support of this training by Animal Resources Service personnel totalled nearly 70 hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and resterilization.

Thirteen enlisted members of Emergency Medicine Service, in MOS 91A, 91B, or 91C, were trained in suturing techniques. Training consisted of an overview of operating room procedure, including aseptic technique, operating room rules of etiquette, instruction in the surgical hand scrub, and gowning and gloving, and hands-on experience in dry and wet labs. Training was conducted on two days and utilized thirteen rats. Forty-plus hours of training were received, requiring sixty-plus hours of support by Animal Resources Service personnel.

One exercise was conducted in "Resuscitation of Newborn" for the American College of Obstetricians and Gynecologists/Indian Health Service Postgraduate Course in Obstetrics, Gynecology and Neonatology. Over one hundred physicians, nurse practitioners, and midwives received 165 hours of training in methods of resuscitation and endotracheal intubation, using 20 ferrets and requiring nearly 100 hours of support by Animal Resources Service personnel.

Cost of Training

ATLS Exercises	$375/animal	x 11 animals	=	$ 4,125
Rat Microsurgery	117/animal	x 9 animals	=	1,053
Suture Labs (Rats)	15/animal	x 13 animals	=	195
				$12,013

There were no high school students trained during the year under the memorandum of agreement with Aurora Public Schools T.H. Pickens Technical Center.

PUBLICATIONS

C = Protocol Related

Allergy Service

Crosby BL, Ledoux RA, Vaughan TR, Weber RW, Goodman DL: Cross-allergenicity Amongst Chenopod-Amaranth Weeds: Assessment via ELISA Inhibition and Enzyme-linked Immunoblot Assays. J Allergy Clin Immunol 85:176, 1990.

Dyer PD, Vaughan TR, Weber RW: Retinal Vasculitis. Ann Allergy 64:499-502, 1990.

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Glassheim JW, Spaulding HS: Epidemiologic Study of Patients Taking L-Tryptophan Containing Products. Ann Allergy 66(1):93, 1991.

Goodman DL, O'Connell MA, Sklarew PR: Vocal Cord Dysfunction (VCD) Presenting as Anaphylaxis (Abstract). J Allergy Clin Immunol 87(1) Part 2:278, 1991.

Goodman DL, McDonnell JT, Nelson HS, Vaughan TR, Weber, RW: Chronic Urticaria Exacerbated by the Antioxidant Food Preservatives - Butylated Hydrox Yanisole (BHA) and Butylated Hydroxytoluene (BHT). J All Clin Immunol 86:570-575, 1990.

Green EW, Sklarew PR, Dolen WK, Goodman DL, Vaughan TR: A Comparison of Phenindamine, Terfinadine, and Placebo: Studies of Skin Test Suppression and Side Effect Scores. Ann Allergy 66:98, 1991.

Henry AR, Ledoux RA, Weber RW, Vaughan TR: The Effect of Physiologic Propranolol Concentrations on Isolated Guinea PIg Tracheal Ring Sections: Studies with Histamine, Albuterol, and Atropine Sulfate. J Allergy Clin Immunol 85:287, 1990.

Henry AR, Vaughan TR, Ledoux Ra, Weber RW: An In-vitro Animal Model for Beta-blocker Induced Bronchoconstriction. Ann Allergy 64:82, 1990.

Henry AR, O'Connell MA, Ledoux RA, Vaughan TR, Goodman DL: Bovine Thrombin as a Cause of Post-Operative Anaphylaxis: First Report of a Case (Abstract). J Allergy Clin Immunol 87(1) Part 2:275, 1991.

Joliat TL, Weber RW: Occupational Asthma and Rhinoconjunctivits from Inhalation of Bovine Serum Albumin (BSA) Powder (Abstract) Ann Allergy 66:75, 1991.

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Larsen LV, Copeland TA, Weber RW, Vaughan TR: Allergen Extraction Methods: Effects of Time, Temperature, Buffer, and Proteases Inhibitors (Abstract) J Allergy Clin Immunol 87:186, 1991.

O'Connell MA, Pluss JL, Vaughan TR: Woodtrimmer's Diseases in a Tractor Driver (Abstract). ann Allergy 66(1):78, 1991.

O'Connell MA, Henry AR, Vaughan TR: Comparison of Beta-adrenergic Antagonists on Guinea Pig Tracheal Smooth Muscle: Effects of Lipid Solubility, Beta-1-Selectivity, Intrinsic Sympathomimetic Activity, and Alpha-Adrenergic Antagonism (Abstract). J Allergy Clin Immunol 87(1) Part 2:307, 1991. **(C)**

Silvers WS, Ledoux RA, Tipton WR, Nelson HS, Dolen WK, Weber RW: Aerobiology of the Colorado Rockies: Pollen Count Comparison of Vail, Aspen and Denver, Colorado, Ann Allergy, 1991.

Sklarew PR, Vaughan TR, Goodman DL: Self-administration of Epinephrine: Analysis at a Large Teaching Hospital. Ann Allergy 66:93, 1991. **(C)**

Stafford WW, Weber RW, Vaughan TR: The Role of Food in Migraine Headache. Am J Asthma Allergy Pediat 3:143-152, 1990. **(C)**

Weber RW: Management of Adverse Reactions to Allergen Immunotherapy. Am J Asthma Allergy Pediat 3:135-140, 1990.

Weber RW: Adverse Reactions to Food Additives. Clin Adv Treatment Allergic Dis 1:1-39, 1990.

Weber RW: Editorial: Role of Anticholinergics in Asthma. Ann Allergy 65:348-350, 1990.

Weber RW, Vaughan TR: Food and Migraine Headache. Immunol Allergy Clin N Amer (in press) 1991. **(C)**

<u>Cardiology Service</u>

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<u>Dermatology Service</u>

Chesser RS, et al: Primary Cutaneous Adenoid Cystic Carcinoma Treated with MOHS Micrographic Surgery, Tolidose Blue Technique. J Derm Surg and Oncol, submitted for publication March 1991.

David-Bajar KM: Subacute Cutaneous Lupus Erythematosus - 1991. J Invest Derma, submitted for publication, October 1991.

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<u>Endocrinology Service</u>

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Rak KM, et al: MR Imaging of Symptomatic Vascular Malformations. Radiology, submitted for publication, January 1991.

Richards T, McBiles M, Collins PS: An Easy Method for Diagnosis of Lymphedema. Ann Vasc Surg 4(3):255-9, 1990.

Truwit CL: Pediatric Neuroimaging: A Casebook Approach. (Book) submitted for publication, October 1991.

Whorton W, Sondeen J, McBiles M, et al: Measurement of Glomerular Filtration Rate in ICU Patients Using 99mTc-DTPA and Insulin. Accepted for publication Kidney International 1991.

PRESENTATIONS

(C) = Protocol Related

DEPARTMENT OF MEDICINE

Allergy Service

Glassheim JW: Analysis of Meteorological Variable and Seasonal Aeroallergen Pollen Counts. Presented: Aspen Allergy Conference, Aspen, CO, July 1991.

Glassheim JW: Analysis of Meteorological Variable and Seasonal Aeroallergen Pollen Counts. Presented: Allergy-Immunology Symposium, FAMC, February 1991.

Glassheim JW: Epidemiologic Study of Patient Taking L-Tryptophan Containing Products. Presented: ACAI, San Francisco, Ca, November 1990. **(C)**

Glassheim JW, et al: Exercise-induced Anaphylaxis and Urticaria in an Adolescent Male Patient after Taking a Course of Augmentin®. Presented: FAMC Allerg-Immunology Symposium, February 1991.

Goodman DL, et al: Vocal Cord Dysfunction (VD) Presenting as Anaphylaxis. Presented: Am Acad Allergy & Immunology, San Francisco, Ca, March 1991.

Goodman DL: Office Spirometry. Presented: American College of Allergy & Immunology, San Francisco, CA, November 1990.

Goodman DL: Fiberoptic Rhinolaryngoscopy. Presented: American College of Allergy & Immunology, San Francisco, CA, November 1990.

Goodman DL: Asthma and Allergy Management in Pregnancy, Medical Grand Rounds. Presented: Brooke AMC, San Antonio, TX, September 1991.

Goodman DL: Chronic Asthma Management. Presented: Medical Conference, Brooke AMC, San Antonio, TX, September 1991.

Goodman DL: Summary Report of General Allergic Diseases Encountered in the Persian Gulf Theatre of Operations. Presented: Am Coll All/Immuno, New York, NY, November 1991.

Matheson EJ, et al: Variability in Pollen Concentrations Based on Sampling Sites and Conditions. Presented: Am Coll All/Immuno, New York, NY, November 1991.

O'Connell MA, et al: Potential Immunomodulation of Hypercatabolic Hypogammaglobulinemia with High-Dose Intravenous Immunoglobulin (IVIG). Presented: Am Coll Allergy and Immunology, New York, NY, November 1991.

O'Connell MA: Attenuation of Albuterol and Atropine Sulfate Induced Relaxation of Guinea Pig Tracheal Smooth Muscle by Pre-treatment with Beta Adrenergic Antagonists: A Comparative Study. Presented: Aspen Allergy Conference,f Aspen, CO, July 1991. (C)

O'Connell MA: Comparison of Beta Adrenergic Antagonists on Guinea Pig Tracheal Smooth Muscle: Effects of Lipid Solubility, Beta-1 Selectivity, Intrinsic Sympathomimetic Activity, and Alpha-adrenergic Antagonism (Abstract). Presented: AAAI, San Francisco, CA, March 1991. (C)

O'Connell MA: Woodtrimmer's Diseases in a Tractor Driver. Presented: ACAI, San Francisco, CA, November 1990.

Spaulding HS: Effects of Terfenadine on Urination in Normal Men. Presented: Aspen Allergy Conference, Aspen, CO, July 1991. (C)

Spaulding HS: The Mystery of L-Tryptophan. Presented: Denver Allergy Grounds, National Jewish Center, Denver, CO,.June 1991. (C)

Spaulding HS: Effects of Terfenadine on Urination in Normal Men. Presented: AAAI, San Francisco, CA, March 1991. (C)

Spaulding HS: Epidemiological Study of Eosinophilia-myalgia Syndrome. Presented: ACAI, San Francisco, Ca, November 1990. (C)

Vaughan TR: Anaphylaxis Workshop. Presented: ACAI, San Francisco, CA, November 1990.

Vaughan TR: Food and Migraine Seminar. Presented: AAAI, San Francisco, CA, March 1991. (C)

Weber RW: Drug Reactions/Urticaria-Angioedema. Presented: University of Michigan Medical Center, November 1990.

Weber RW: Oral Diagnosis #664: Allergy. Presented: University of Michigan Medical Center, December 1990.

Weber RW: Allergist's Approach to Asthma. Presented: University of Michigan Medical Center Medicine Noon Conference, October 1990.

Weber RW: Advances in Internal Medicine: Drug Allergy Vignette. Presented: University of Michigan Medical Center Noon Conference, April 1991.

Weber RW: Allergy for the Primary Care Physician: Indoor Allergens, Environmental Control Measures, Immunotherapy Panel, Unconventional Techniques in Allergy. Presented: University of Michigan Medical Center Medicine Noon Conference, April 1991.

Weber RW: Environmental Control Measures in Asthma. Presented: University of Wisconsin, October 1990.

Weber RW: Respiratory Disease Seminar. Presented: Naples, Fl, October 1990.

Weber RW: Aeroallergen Identification Workshop. Presented: ACAI, San Francisco, Ca, November 1990.

Weber RW: Urticaria Workshop. Presented: ACAI, San Francisco, Ca, November 1990.

Weber RW: Fatal Asthma. Presented: St. John Hospital, Detroit, Mi, December 1990.

Weber RW: Indoor Allergens and Environmental Control. Presented: National Jewish Center for Immunology and Respiratory Medicine Annual Conference, Keystone, CO, February 1991.

Weber RW: Respiratory Disease Seminar. Presented: Sarasota, FL, April 1991.

Weber RW: Aerobiology Poster Moderator. Presented: Pan American Aerobiology Association Annual Meeting, Ann Arbor, MI, June 1991.

Weber RW: Occupational Asthma and Rhinoconjunctivitis from Inhaled BSA Powder. Presented: Aspen Allergy Conference, Aspen, CO, July 1991.

Endocrinology Service

LeMar HJ, Georgitis WJ: The Effect of Cold Remedies on Metabolic Control on Non-insulin Diabetes Mellitus. Presented: Annual Society of Uniformed Endocrinologists Meeting, Washington, DC, June 1991. **(C)**

LeMar HJ, Georgitis WJ: The Effect of Cold Remedies on Metabolic Control on Non-insulin Diabetes Mellitus. Presented: Annual Army Regional ACP Meeting, San Francisco, CA, October 1991. **(C)**

Mendoza QP: Rare Manifestations of Light Chain Deposition Disease: New Insights on Pathogenesis. Presented: Colorado ACP Meeting, January 1991.

Merenich JA, Pfander NA, Georgitis WJ; Addition of Bedtime Ultralente (UL) Insulin to NIDDM Patients Suboptimally Controlled with Oral Agents (OA). Presented: Annual Army Regional ACP Meeting, San Francisco, Ca, October 1991.

Perloff JJ, McDermott MT: Mild Primary Hyperparathyroidism and the Effects of Estrogen Replacement on Bone Mass. Presented: Annual Society of Uniformed Endocrinologists Meeting, Washington, DC, June 1991. **(C)**

Perloff JJ, McDermott MT: Mild Primary Hyperparathyroidism and the Effects of Estrogen Replacement on Bone Mass. Presented: 12 Annual Scientific Meeting, American Society for Bone and Mineral Research, San Diego, CA, J Bone Min Res 6(suppl 1): 512S (169A), 1991. (C)

Perloff JJ, McDermott MT: Mild Primary Hyperparathyroidism and the Effects of Estrogen Replacement on Bone Mass. Presented: Annual Army Regional ACP Meeting, San Francisco, CA, October 1991. (C)

Yavorski R, Rak K, Merenich J, McDermott M, McNally P: Liver Density Estimates by Magnetic Resonance Scanning Assist in the Evaluation of Possible Hemochromatosis. Presented 1991.

Gastroenterology Service

Dunkelberg J, et al: Hepatic Inflammatory Pseudotumor (Hip): clinicopathologic Correlations in 30 Cases. Presented. American Gastroenterology Association, New Orleans, LA, May 1991.

Fisher MR, Stocker N, Freeman SR, Hallgren SE, McNally PR: The Effectiveness of Octreotide (Scandostatin) to Prevent Pancreatitis Caused by Endoscopic Pancreatobiliary Procedures. Presented: American College Physicians, San Francisco, CA, October 1991. (C)

Fisher MR, Stocker N, Freeman SR, Hallgren SE, McNally PR: The Effectiveness of Octreotide (Scandostatin) to Prevent Pancreatitis Caused by Endoscopic Pancreatobiliary Procedures. Presented: American College Gastroenterology, Boston, MA, November 1991. (C)

Murphy J, Peller P, McNally P, Shay S: Poor Clearance is the Predominant Abnormal Reflux Parameter in Patients with Progressive Systemic Sclerosis (PSS) with Esophagitis. Presented: Dig. Dis. Week, New Orleans, LA, May 1991.

Sherman KE, et al: Effect of Sample Preparation on Detection of Hepatitis B Genomic DNA by the Polymerase Chain Reaction. Presented: Army Regional ACP Meeting and American Association Liver Disease Meeting, San Francisco, CA, Chicago, IL, October, November 1991. (C)

Sherman KE, et al: Hepatitis C Antibody in the HIV Infected Patient. Presented: Army Regional ACP Meeting, San Francisco, Ca, October 1991. (C)

Sudduth RH, Bute BG, Schoelkopf L, Smith MT, Freeman SR, McNally PR: Small Bowel Obstruction in a Patient with PeutzJeghers Syndrome: The Role of Intra-Operative Endoscopy. Presented: Dig. Dis. Wee, New Orleans, LA, May 1991.

Yavorski R, Rak KP, Merenich JA, McDermott M, McNally PR: The Utility of Magnetic Resonance Scanning (MR) in the Evaluation of Patients with Genetic Hemochromatosis and Non-iron Overload States -- A Pilot Analysis. Presented: Am. Coll. Physicians, San Francisco, CA, October 1991.

Hematology/Oncology Service

Gates R: CPR Information Sheet. Presented: Annual Army Nurse Corps Nursing Research Conference, TAMC, Honolulu, September 1991. **(C)**

Lum GH, Cosgriff TM, Byrne R, Reddy V: Primary T-cell Lymphoma in a Patient Infected with Human Immunodeficiency Virus. Presented: Annual Associates Meeting of the Colorado Chapter, American College of Physicians, Denver, CO, April 1991. **(C)**

Sample S, Cosgriff TM, Reddy V: Systemic Castleman's Disease. Presented: Annual Associates Meeting of the Colorado Chapter, American College of Physicians, Denver, CO, April 1991.

Wang FS, Cosgriff TM, Bunner DL: Effects of Cytokines on the Protein C and Protein S Concentration in Supernates from Hep G2 Cell Culture. Presented: Annual Meeting of the American Society of Hematology, Boston, MA, December 1990.

Internal Medicine Service

Kristo D, Kolleff M: Prospective Study of the Diagnosis of Symptomatic Deep Vein Thrombosis in a Single Infection. Presented: American Thoracic Society, April 1991. **(C)**

Kristo D, Kolleff M: Prospective Study of the Diagnosis of Symptomatic Deep Vein Thrombosis in a Single Infection. Presented: ACP Meeting, April 1991. **(C)**

Sample SA: A Case of Multicentric Castleman's Disease and Kaposi's Sarcoma. Army American College of Physicians Meeting, LAMC, October 1991.

Weaver MJ, Gates RA, Gates RH: Written Information about Resuscitation: Preliminary Evaluation of Acceptability to Patients. Presented: Annual Meeting for the Society for General Internal Medicine, Seattle, WA, May 1991. **(C)**

Weaver MJ, Gates RA, Gates RH: Ethical Issues - Their Impact on Quality Care. Presented: American College of Health Care Executives, Colorado/Wyoming Regional Muster, Denver, CO, May 1991.

Nephrology Service

Culclasure T, et al: Prospectively Determined Incidence and Prevalence of Hematuria. Presented: ACP Meeting, New Orleans, LA, April 1991. (C)

Culclasure TF, Bray VJ, Hasbargen JA: Prospectively Determined Incidence and Prevalence of Hematuria. Presented: The American Society of Nephrology, Baltimore, MD, November 1991. (C)

Hasbargen J, Bergstrom R: Effects of Variable Blood Pump Speed (Q_B) on Recirculation. Presented: American Society of Nephrology, December 1990. (C)

Hasbargen JA, et al: The Effect of Intraperitoneal Neostigmine on Peritoneal Transport Characteristics in Continuous Ambulatory Peritoneal Dialysis Patients. Presented: National Kidney Foundation, Baltimore, MD, November 1991. (C)

Rheumatology Service

Baker MR, West SF: Pelvic Insufficiency Fractures in Rheumatoid Arthritis Patients: Presented: 54th National American College of Rheumatology Meeting, Seattle, WA, October 1990.

Enzenauer R: Retinal Vasculopathy Associated with Systemic Light Chain Disease: Presented: Central Regional American College of Rheumatology Meeting, San Antonio, TX March 1991.

Vogelgesang S, West SG: Long Term Toxicity and Efficacy of Methotrexate in Rheumatoid Arthritis Patients. Presented: 54th National American College of Rheumatology Meeting, Seattle, WA, October 1990.

West SG: Central Nervous System Lupus: A Ten Year Prospective Controlled Study. Presented: 54th National American College of Rheumatology Meeting, Seattle, WA, October 1990.

West SG: Methotrexate and Postoperative Joint Infections in Rheumatoid Arthritis Patients Undergoing Total Joint Arthroplasty. Presented: 54th National American College of Rheumatology Meeting, Seattle, WA, October 1990.

DEPARTMENT OF SURGERY

General Surgery Service

Dwyer KM, Hammond SL, and Gaines TE: Rare Complications Following Blunt Esophagectomy. Presented: Gary P. Wratten Surgical Symposium, San Francisco, CA 24-25 April 1991.

Freeman IHG, and Clark, JR: Surgical Management of Complications From Fiberoptic Endoscopy. Presented: Gary P. Wratten Surgical Symposium, San Francisco, CA 24-25 April 1991.

Ophthalmology Service

Cornell FM: The Role of Optometry in the Military. Presented: Association of University Professors of Ophthalmology, Naples, FL, January, 1991.

Cornell FM: Overview of Ophthalmology (1) peacetime health care (2) combat casualty care. Presented: WRAMC, June 1991.

Enzenauer RW, et al: Radial Keratotomy in the Soldier-Aviator. Presented: Aerospace Medical Association, Miami, Fl, May 1991.

Walton WT et al: Repair of the Tarsoligamentous Sling in New Zealand White Rabbits Using Polytetrafluoroethylene Graft Material. Presented: ARVO Meetin: 1991.

Orthopedic Service

Callahan, Lisecki, Banks: Effect of Coumadin on Fixation of Hydroxyapatite-coated Porous Coated-Chrome Implants in a Goat Model. Presented: Academy of Surgical Research (7th Annual Scientific Session) Scottsdale, AZ, September 1991. **(C)**

Callahan BC, et al: Effect of Coumadin on Interface Mechanics of Hydroxyapatite-Coated Porous Co-Cr-Mo Alloy Implants in a Goat Model. Presented: Barnard Competition, March 1991. **(C)**

Callahan BC, et al: Effect of Coumadin on Interface Mechanics of Hydroxyapatite-Coated Porous Co-Cr-Mo Alloy Implants in a Goat Model. Presented: Society of Military Orthopedic Services, El Paso, TX, November 1991. **(C)**

Callahan BC, et al: Effect of Coumadin on Interface Mechanics of Hydroxyapatite-Coated Porous Co-Cr-Mo Alloy Implants in a Goat Model. Presented: 9th Annual Orthopaedic Residents Conference, Memphis, TN, August 1991. **(C)**

Chang L: Aspiration of Dorsal Wrist Ganglions. Presented: Barnard Competition, March 1991.

Coe RA, et al: Occipitocervical Instability in Down Syndrome. Presented: Barnard Seminar, March 1991.

Cope EE, et al: Triple Injection Wrist Arthrogram with Rapid Sequence 105mm x-ray: Presentation of a New Technique. Presented: American Association for Hand Surgery, Vancouver, British Columbia, September 1991.

Cope EE, et al: Triple Injection Wrist Arthrogram with Rapid Sequence 105mm x-ray: Presentation of a New Technique. Presented: Am Acad Ortho Surg, Washington, DC, February 1991.

Deffer PA, et al: The Natural History of Thoracic Disc Herniation. Presented: North American Spine Society National Meeting, Keystone, CO, August 1991.

Deffer PA, et al: The Natural History of Thoracic Disc Herniation. Presented: Western Orthopedic Association, Tucson, AZ, October 1991.

Deffer PA, et al: The Natural History of Thoracic Disc Herniation. Presented: Barnard Seminar, March 1991.

Gillogly SD, Bizousky DT: Arthroscopic Evaluation and Debridement of the Scapulothoracic Articulation. Presented: Barnard Competition, March 1991.

Gillogly SD, et al: The Accuracy of Magnetic Resonance Imaging in Assessment of Patellar Tendon Autograft Anterior Cruciate Ligament. Presented: Mid-America Orthopaedic Association 9th Annual Meeting, Palm Springs, Ca, April 1991.

Gillogy SD, et al: The Accuracy of Resonance Imaging in Assessment of Patellar Tendon Autograft Anterior Cruciate Ligament Reconstruction. Presented: Am Acad Orth Surg Meet, Anaheim, CA, March 1991.

Hockenbury RT, et al: A Clinical Comparison of Percutaneous Versus Open Achilles Tendon Repairs. Presented: Barnard Competition, March 1991.

Lisecki EJ, et al: Attachment of HA Cutaneous Uncoated Porous Implants Is Influenced by Methotrexate and Coumadin. Presented: 38th Annual Meeting, Orthopedic Research Society, Washington, DC, February 1991. (C)

Lisecki EJ, et al: The Efficacy and Safety of Biocompatible Osteoconductive Polymer Fibers (BOP-F) as a Filler in Total Hip Revisional Arthroplasty. Presented: Orthopedic Research Society National Meeting, Washington, DC, February 1991.

Lisecki EJ, et al: Hip Lesions Mimicking Primary Osteoarthritis, A Radiographic and Histopathologic Study. Presented: American Academy of Orthopaedic Surgeon, Washington, DC, February 1991.

Pals SD, et al: Evaluation of the Goat Patellar Tendon After Harvest of its Middle Third. Presented: Barnard Competition, March 1991. (C)

Pals SD, et al: Evaluation of the Goat Patellar Tendon After Harvest of its Middle Third. Presented: 9th Annual Orthopedic Residents' Conference, Memphis, TN, August 1991. **(C)**

Pals SD, et al: Biomedical Evaluation of the Goat Patellar Tendon After Removal of Its Central One Third. Presented: 7th Annual Scientific Session of Academy Surgical Research, September 1991. **(C)**

Pals SD, et al: Evaluation of the Goat Patellar Tendon After Harvest of its Middle Third. Presented: Society of Military Orthopedic Services, El Paso, TX, November 1991. **(C)**

Schaefer RA, et al: Musculoaponeurotic Fibromatosis (Extra-abdominal Desmoid Tumors): A Rational Basis for Treatment. Presented: Musculoskeletal Tumor Society, Buffalo, NY, May 1991.

Schaefer RA, et al: Musculoaponeurotic Fibromatosis (Extra-abdominal Desmoid Tumors): A Rational Basis for Treatment. Presented: Barnard Competition, March 1991.

Schaefer RA, et al: Magnetic Resonance Imaging of the Knee Following Anterior Cruciate Ligament Reconstruction. Presented: Colorado Sport Medicine Symposium, May 1991.

Spezia P, Karstetter K: Morton's Neuroma: Non-Surgical Treatment with Local Injection of B-12/Solumedrol/Lidocaine Combination. Presented: AOA Residents' Conference, Kansas City, KS, April 1991. **(C)**

Spezia P, Karstetter K: Morton's Neuroma: Non-Surgical Treatment with Local Injection of B-12/Solumedrol/Lidocaine Combination. Presented: Society of Military Orthopedic Services, El Paso, TX, November 1991. **(C)**

Spezia P, et al: Femur Fractures in Alpine Skiers. Presented: Barnard Competition, March 1991.

Spezia P, et al: Femur Fractures in Alpine Skiers. Presented: Society of Military Orthopedic Services, El Paso, TX, November 1991.

Spezia P, et al: Femur Fractures in Alpine Skiers. Presented: American Academy of Orthopaedic Surgeons, Washington, DC, February 1991.

Wiedel JD, et al: Total Hip Arthroplasty in Conjunction with an Intertrochanteric Osteotomy for Correction of Excessive Anteversion and Valgus Deformity. Presented: Am Acad Orth Surg Meeting, Anaheim, CA, March 1991.

Wolff JD, et al: Effects of Methotrexate on Bony Ingrowth in Hydroxyapatite Porous Coated Implants in a Goat Model. Presented: Barnard Seminar, March 1991. (C)

Speech Language Rehabilitation Section

Beck WG, et al: A Further Examination of Speech Intelligibility Rating (SIR) Test. Presented: Am Speech-Lang Hearing Assoc 1991 Annual Convention, Atlanta, Ga, November 1991.

Lowry MF: do's and Don'ts for the Laryngectomee. Presented: American Cancer Society, October 1990.

Lowry MF: Laryngectomy. Presented: Adams County American Cancer Society, board of Directors, November 1990.

Lowry MF: Laryngectomy: Questions and Answers. Presented: Lost Chord Club, Colorado Springs, CO November 1990.

Lowry MF: Phoenix Task Force Results: Presented: SERTOMA Mid-Winter Conference, Colorado Springs, CO, March 1991.

Lowry MF: Phoenix Task Force Results: Presented: SERTOMA Mid-Winter Conference, Denver, CO, March 1991.

Lowry MF: Voice Clinic: Evaluation and Treatment of Professional Voices. Presented: Speech Therapy Associates, Las Vegas, NV, August 1991.

Otolaryngology Head and Neck Surgery Service

Kopke RD, Zieske LA: Pyogenic Prevertebral Abscess. Presented: Pacific Coast Oto-Ophthalmological Society Meeting, Monterey, CA, June 1991.

Lepore ML: Nasal Obstruction and Sinusitis. Presented: Family Practice Symposium, Estes Park, CO, June 1991.

Urology Service

Donatucci CF: Treatment Alternatives in Benign Prostatic Hyperplasia. Presented: Cygnus Research Corporation, Redwood City, Ca, October 1990.

Donatucci CF: Impotence and Infertility. Presented: School of Medicine, University of California, San Francisco, 3rd year Surgery Course, 1990-1991.

Donatucci CF: Current Concepts and Treatment in Male Impotence. Presented: 38th Annual Convention, The Licensed Vocational Nurses League of California, Foster City, CA, April 1991.

Donatucci CF, Lue TF: The Combined Intracavernous Injection and Stiumlation Test: Diagnostic Accuracy. Presented: 67th Annual Meeting, Western Section, American Urological Association, Vancouver, British Columbia, Canada, July 1991.

Donatucci CF, Donohue RE, Crawford ED, Kreder KJ, Yakely R, Whitesel J, Berger N: A Randomized, Community Based Study of Balloon Dilatation of the Prostate Versus Transurethral Resection: Presented: Rocky Mountain Urological Society, American Urological Association 86th Annual Meeting, June 1991.

Kreder KJ: A Randomized Comparison of Transurethral Resection of the Prostate and Transurethral Balloon Dilatation. Presented: Royal Society of Medicine, Vail, CO, February 1991.

Thrasher JB: Extravesical Versus Leadbetter-Politano Ureteroneocystostomy: A Comparison of Urological Complications in 320 Renal Transplants. Presented: American Urological Association, Western Section 66th Annual Meeting, Monterey, CA, October 1990.

Thrasher JB: The Effect of Terfenadine on Urination. Presented: American Academy of Allergy and Immunology, San Francisco, Ca, March 1991. **(C)**

Thrasher JB: Lidocaine as a Topical Anesthetic for Bladder Biopsies. Presented: Rocky Mountain Urological Society, Denver, CO, July 1991.

Thrasher JB: The Effect of Terfenadine on Urination. Presented: Aspen Allergy Conference, Aspen, CO, July 1991. **(C)**

DEPARTMENT OF CLINICAL INVESTIGATION

Banks RE: The Institutional Animal Care System and the IACUC Veterinarian. Presented: National Clinical Investigation Meeting, US Army, San Antonio, TX May 1991.

Banks RE, Davis JA: A Modification of the RITARD Model in the Rabbit. Presented: American Veterinary Medical Association, San Antonio, TX July 1990.

Banks RE: Zoonosis Update: Rodent Diseases of Concern. Presented: FAMC Continuing Education Program, March 1991.

Banks RE, Jones LA: Quality Assurance in Animal Facilitated Research: Presented: Society of Quality Assurance; Rocky Mountain Chapter Meeting, Ft. Collins, CO, April 1991.

Banks RE: Legislative Update: Current Proposal and Recent Regulation Changes Affecting Animal Facilitated Research: Presented: US Army Clinical Investigation Symposium, San Antonio, TX, May 1991.

Banks RE: Rabbit Husbandry, Anesthesia, Diseases and Euthanasia: Presented: American Veterinary Medical Assn Annual Meeting, Seattle, WA, July 1991.

Banks RE: Rabbit Diseases: Pathology, Therapy and Prevention: Presented: American Veterinary Medical Assn Annual Meeting, Seattle, WA, July 1991.

Banks RE: Review of the Animal Rights Movement: Presented: Officer Personal Development, Aberdeen, Maryland, October 1991.

Banks RE: Review of the Animal Rights Movement: Presented: Briefing for the Assistant Secretary of Defense for Health Affairs, The Pentagon, October 1991.

Callahan BC, Wolff JD, Banks RE, Cook SD, Lisecki EJ: Effect of Coumadin on Fixation of Hydroxyapatite-Coated Porous Cobalt-Chrome Implants in a Goat Model: Presented: Academy of Surgical Research, Scottsdale, AZ, September 1991. (C)

Lisecki EJ, Cook SD, Dalton JE, Callahan BC, Wolff JD, Banks RE: Attachment of HA Coated & Uncoated Porous Implants in Influenced by Methotrexate and Coumadin: Presented: Accepted for presentation Orthopedic Research Society, Washington, DC, February 1992. (C)

Pals SD, Bizousky DT, Gillogly SD, Banks RE et al: Evaluation of the Goat Patellar Tendon After Harvest of its Middle Third: Presented: Barnard Symposium, National Jewish Hospital, March 1991. (C)

Pals SC, Bizousky DT, Gillogly SD, Banks RE: Evaluation of the Goat Patellar Tendon after Removal of its Central Third (Acute Post-op Review): Presented: Academy of Surgical Research, Scottsdale, AZ, September 1991. (C)

Pals SD, Bizousky Dt, Gillogly SD, Banks RE, Schaefer RA: Evaluation of the Goat Patellar Tendon after Harvest of its Middle Third (Chronic Post-op Review): Presented: Society of Military Orthopedic Services (Abstract Accepted), El Paso, TX, November 1991. (C)

Sherman RA, et al: Pain and the Problem Causing It Aren't Always in the Same Place. Presented: Assoc Applied Psychophysiology and Biofeedback 23rd Annual Meeting, Colorado Springs, CO, March 1991.

Sherman RA, et al: Ambulatory Recording of Patients in their Normal Environments. Presented: American Pain Society, New Orleans, LA, November 1991. (C)

Sherman RA, et al: Changes in Paraspinal Muscle Tension as Predictors of Changes in Low Back Pain. Presented: American Pain Society, New Orleans, LA, November 1991. (C)

Wolff JD, Callahan BC, Lisecki EJ, Cook SD, Banks RE: Effect of Methotrexate on Bony Ingrowth in Hydroxyapatite-Coated Porous Cobalt-Chrome-Molybdenum Implants in a Goat Model. Presented: Barnard Symposium, National Jewish Hospital, March 1991. **(C)**

DEPARTMENT OF OB-GYN

Anderson J: Intra-Amniotic Levothyroxine for Fetal Lung Maturation in a Pregnancy Complicated by Insulin Dependent Diabetes. Presented: ACOG Meeting, October 1991.

Poore SE: Low Grade Intraepithelial Lesion; CIN-1 or HPv Does it Make a Difference. Presented: April 1991.

DEPARTMENT OF PEDIATRICS

Kinesl1a JP, et al: Cerebral Blood Flow Following Premature Delivery in a Non-Human Primate Model of Hyaline Membrane Disease. Presented: Western Society for Pediatric Research, Carmel, Ca, February 1991. **(C)**

Kinsella JP, et al: The Effect of Extracorporeal Membrane Oxygenation on Coronary Perfusion and Regional Blood Flow Distribution. 7th Annual ECMO Symposium, Breckenridge, CO, February 1991. **(C)**

PHARMACY SERVICE

Grabenstein JD: Protecting Patients Against Hepatitis B: Choosing a Vaccine and Choosing Patients. Presented: Virginia Academy of Consultant Pharmacists, Wintergreen, VA, October 1990.

Grabenstein JD: Immunization Responsibilities of Pharmacists: Activities Throughout the Department. Presented: American Society of Hospital Pharmacists, 25th Midyear Clinical Meeting, Las Vegas, Nevada, December 1990.

Grabenstein JD: Community Pharmacists as Immunization Advocates: A Clinical Pharmacoepidemiologic Approach. Presented: American Pharmaceutical Association 138th Annual Meeting, New Orleans, LA, March 1991.

Grabenstein JD: Pharmacists' Roles in Immunization Advocacy: A Review. Presented: American Society of Hospital Pharmacists 48th Annual Meeting, San Diego, CA, June 1991.

DEPARTMENT OF PRIMARY CARE AND COMMUNITY MEDICINE

Bethlenfalvay NC, Lima JE, White JC: NAD and NAD Synthesis in ADA Deficient Red Cells of the Opossum, D. Virginiana. Presented: 7th International Symposium of Purine and Pyrimidine Metabolism in Man, Bournemouth, England, 1991. **(C)**

DEPARTMENT OF PSYCHIATRY

Kolb MM: Post Traumatic Stress Syndrome: Civilian Physicians, Denver, CO, 1991.

Kolb MM: Post Traumatic Stress Syndrome: Colorado Society of Osteopathic Medicine Annual Meeting, June 1991.

DEPARTMENT OF RADIOLOGY

Whorton W, Sondeen J, McBiles M, et al: Assessment of Glomerular Filtration Rate in ICU Patients with Renal Dysfunction Using 99mTc-DTPA, Insulin and Creatinine. Presented: Western Regional Meeting, Society of Nuclear Medicine, November 1990. (C)

Whorton W, Sondeen J, McBiles M, et al: Assessment of Glomerular Filtration Rate in ICU Patients with Renal Dysfunction Using 99mTc-DTPA, Insulin and Creatinine. Presented: American Society of Nephrology, 23rd Annual Meeting, December 1990. (C)

DETAIL SUMMARY SHEETS

DEPARTMENT OF MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 80/120 (3) Status: Ongoing

(4) Title: Evaluation of Carbohydrate Metabolism in Thyrotoxicosis: Investigations into the Frequency, Type and Mechanisms of Carbohydrate Tolerance

(5) Start Date: 1981 (6) Est Compl Date: 1991

(7) Principal Investigator:
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators:

Fred D. Hofeldt, COL,(Ret)
Robert J. Sjoberg, MAJ, MC

(11) Key Words:
carbohydrate
hyperthyroidism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____11_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance test. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach: Ten non-diabetic patients who are taking no medications, are less than age 45, are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Each

patient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Progress: No patients have been enrolled in this study during the past academic year. The research study is still entirely valid and worthwhile in purpose. The principal investigator has not had adequate time to pursue this project as it is very complex. However, it is still hoped that a new Endocrine Fellow will pick up this project and complete it within the next year to a year and a half. A tremendous amount of effort has already been expended on this study, and it is requested that the protocol be continued in hopes of mobilizing associate investigators to pursue the project.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 81/117 (3) Status: Ongoing

(4) Title: The Role of Calcitonin in Osteoporosis

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator:
Michael T. McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Gerald S. Kidd, COL, MC

(11) Key Words:
osteoporosis
bone density
calcitonin deficiency
thyroid hormone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if, longitudinally, thyroid cancer patients who have calcitonin deficiency and are on suppressive doses of thyroid hormone, loose radial bone more rapidly than goiter patients, who are also on suppressive doses of thyroid hormone but are not calcitonin deficient, and than normal controls. Also to compare these 3 groups, cross-sectionally, for bone density of the spine and hip.

(16) Technical Approach: 3 Groups: (a) thyroid cancer patients - calcitonin deficient and on thyroid hormone; (b) goiter patients - not calcitonin deficient but are on thyroid hormone, and (b) normal

controls. (SPA) single photon absorptiometry-distal and midradius serially for 5-6 yrs (in progress since 1981) (DPA) dual photon absorptiometry - spinal & hip- cross-sectionally.

(17) Progress: Thyroidectomized patients had lower bone density in the forearm in the first cross-sectional analysis but after 2 years did not lose bone at a greater rate than goiter or control patients. 6-8 year longitudinal data in the forearm and cross-sectional data in the spine and hips have been collected in most patients but the data have not yet been analyzed. (FY 90) Many of the initial subjects have had their followup single photon absorptiometry and their initial dual photon absorptiometry, but not all have been restudied as of yet. Subjects benefit from knowledge of their bone density value but have no other benefit. No progress in FY 91.

Publications:

McDermott MT, Kidd GS, Blue P, Ghaed V, Hofeldt FD: Reduced bone mineral content in totally thyroidectomized patients: Possible effect of calcitonin deficiency. J Clin Endocrinol Metab 56:936-9, 1983.

McDermott MT, Hofeldt F, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. J Bone Min Res (1(suppl. 1):352, 1986 (Abstract).

Presentations:

McDermott MT, Hofeldt FD, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. Presented: 8th Annual Scientific Meeting, American Society for Bone and Mineral Research, Anaheim, CA 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 81/118 (3) Status: Ongoing

(4) Title: Hypothalamic Pituitary Gonadal Function in Hypothyroidism

(5) Start Date: 1981 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Michael T. McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Gerald S. Kidd, LTC, MC

(11) Key Words:
hypothyroidism
gonadal dysgenesis
gonadotropins, pituitary

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalties resolve after treatment of the hypothyroid state.

(16) Technical Approach: A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progress: No progress in the past year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 83/107 (3) Status: Terminated

(4) Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma

(5) Start Date: 1984 (6) Est Compl Date: 1991

(7) Principal Investigator:
M. James Schleve LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology

(10) Associate Investigators:
John Adnot, LTC, MC
Richard Gentry, LTC, MC
Scott Bennion, LTC, MC

(11) Key Words:
retinoids
basal cell carcinoma

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 98
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the effectiveness of low dosage levels of Isotretinoin in reducing the incidence of basal cell carcinomas in high risk population; to examine possible side effects with long term administration of isotretinoin.

(16) Technical Approach: The study is a double-blind study with participants randomly assigned to the medication. Patients will take the med for three years and will be followed for a total of five years. Compliance side-effects and basal cells are very closely monitored.

(17) Progress: Total 98 patients were randomized. 84 remain on the study. Five patients are deceased: Four have transferred to other sites: Five other are off the study for misc. reasons. All patients have completed the three years on the medication and have been notified as to whether or not they were on isotretinoin or the placebo. All patients have opted to stay on the program until closure which will be 30 September 1991.

CONTINUATION SHEET, FY 91, ANNUAL PROGRESS REPORT Protocol #: 83/107

Publications:

Fitzpatrick JE, Mellette, JR: Geriatric Dermatology. In Geriatric Medicine: The Care of the Elderly Patient. First edition. W.B. Saunders Company.

Reed OM, Mellette JR, Fitzpatrick JE: Familiar Cervical Hypertrichosis with Underlying-Kypho-Scoliosis. Journal of the American Academy of Dermatology.

Presentations:

Flap Combinations for Large Facial Defects - American Academy of Dermatology Annual Meeting, San Antonio, Texas, December 1987.

Helpful Hints for Dermatological Surgery - Thirteenth Annual Tri-Services Dermatology Symposium, San Antonio, Texas.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 83/113A (3) Status: Completed

(4) Title: Growth of Human Keratinocytes

(5) Start Date: 1983 (6) Est Compl Date:

(7) Principal Investigator:
Ronald L. Jackson, CPT, MS

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:
Scott D. Bennion, LTC, MC
Jose A. CruzSaez, SPC
Rodney F. Williams, SPC

(11) Key Words:

keratin

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Growth and study of human kertinocytes in culture and subsequent studies using athymicmice as an in vivo culture system.

(16) Technical Approach: The technical approach has been to grow keratinocytes obtained from newborn foreskins using serum-free media. A more successful approach has been to culture the cells in complete MCDB 153 media. A new mechanism of freezing the cells has commenced. The final phase of the study will include identifying specific proteins expressed by these cells and the presence of protein hormone receptors on the cell surfaces.

(17) Progress: All the work under this protocol is now covered under new protocol 91/134.

Publications:

Grimwood RE, Clark RAF, Baskin JB, Nielson LD, Ferris CF: Fibronectin is Deposited by Keratiocytes in the Basement Membrane Zone during Tissue Organization. Accepted for publication in Journal of Investigative Dermatology.

Grimwood RE, Ferris CF, Baskin JB, Nielson LD, Clark RAF: Fibronectin is Depostied by Keratinocytes in the Basement Membrane Zone during Tissue Organization. J. Invest. Dermatol., Vol 86, #4, 479, 1986.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 83/122 (3) Status: Ongoing

(4) Title: The Role of Food Allergy in the Pathogenesis of Migraine Headaches

(5) Start Date: 1983 (6) Est Compl Date: 1990

(7) Principal Investigator:
Thurman R.Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators:
Teresa Copeland, CPT, MC
David L. Goodman, LTC, MC

(11) Key Words:
migraine
food hypersensitivity
mediators

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____12_____
d. Total Number of Subjects Enrolled to Date:____103__104 completed pro.
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To study the value of allergy food skin test in directing and defining a diet which will cause a decrease in the frequency of migraine headaches in affected patients. To determine if immunological mediators can be detected in positive responders.

(16) Technical Approach: Approximately 100 patients with dx of migraine headaches who suffered 3 or more HA/month will keep a 1 month food diary/st diary. They will then be skin tested to 83 common foods and undergo an additional 1 mo diet eliminating suspected food, and skin test positive foods. Positive regimens will be studied with open chall. and double blind food challenge with immunologic mediators precursors.

(17) Progress: 104 patients completed the protocol. 37% report a 50% reduction in migraine frequency; 17 patients with positive double-blind food challenge. Five patients studied with histamine, PGD2 determinations during DBPCFC's. No problems encountered. Results of immunol. studies show initial increase in histamine and PGD2 and late rise of PGD2 alone during active challenge. Source of late PGD2 is unclear. Request one year extension to study additional patients with addition of serotonin assay. This will allow cell source of PGD2 to be determined (basophil vs platelet).

Presentations:

(1) Vaughan, TR, Stafford, WW, Miller, BT, Weber, RW, Tipton, WR, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: American College of Allergists, Phoenix, AZ, January 1986.

(2) Vaughan, TR, Stafford, WW, Miller, BT, Tipton, WR, Weber, RW, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: Aspen Allergy Conference, Aspen, CO, July 1986.

(3) Vaughan TR, Stafford WW, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Presented: Southwest Allergy Forum, El Paso, TX, March 1987.

(4) Vaughan TR, Stafford WS, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Accepted for presentation American College of Allergists.

(5) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double-Blind, Long-term Followup Study. Presented: VI International Food Allergy Symposium, Boston, MA., November 1987.

(6) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double Blind, Long Term Followup Study. Presented: Harold S. Nelson Allergy Symposium, Aurora, CO., January 1988.

(7) Vaughan TR: Food and Migraine Headache. Presented: Keystone Allergy Conference, Keystone, CO., February 1988.

Publications:

1. Stafford WM, Weber RW, Vaughan TR. The Role of Food in Migraine Headache. Am J Asthma Allergy, 3:143-152, 1990.

2. Vaughan TR. Food and Migraine Headache: A Review. Current Views in Allergy (in press) 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 83/126 (3) Status: Ongoing

(4) Title: The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism

(5) Start Date: 1983 (6) Est Compl Date: 1991

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/ Endocrine (10) Associate Investigators:

(11) Key Words:
prostaglandin synthetic
hypothyroidism
water electrolyte balance, imbalance

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to determine in an indirect manner i.e., with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in

a relatively volume depleted state, that is before the water loading is performed. Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach: By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

(17) Progress: Because of competing priorities, no subjects have yet been studied. A new fellow will be assigned to complete the study, protocol is still worthwhile and should be continued.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 84/100 (3) Status: Completed

(4) Title: The Effect of Abnormal Thyroid States on the Metabolism of Theophylline and Methylprednisolone

(5) Start Date: 1984 (6) Est Compl Date: 1990

(7) Principal Investigator:
Michael T. McDermott, LTC, MC
Ray Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Stanley J. Szefler, MD
Harold S. Nelson, MD

(11) Key Words:
theophylline
methylprednisolone
hyperthyroidism
hypothyroidism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___0_____
d. Total Number of Subjects Enrolled to Date:_____7_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine whether hyperthyroidism and hypothyroidism result in alterations of theophylline and methylprednisolone metabolism.

(16) Technical Approach: Hypo- and hyperthyroid subjects are studied when thyroid function is abnormal and again when it is normal by studying the disappearance rate of theophylline and methylprednisolone from serum after bolus injections.

(17) Progress: No further patient enrollment. A manuscript is being prepared.

Presentations: Lavins B, Vaughan R, Szefler S, Weber R, Nelson H: Effect of thyroid disease on metabolism of theophylline and methylprednisolone. Meetings of the American College of Allergists, Boston, Mass, October 1987.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 84/119 (3) Status: Ongoing

(4) Title: Treatment of Graves' Ophthalmopathy with Cyclosporin

(5) Start Date: 1984 (6) Est Compl Date: 1992

(7) Principal Investigator:
Michael T. McDermott, LTC, MC
Leonard Wartofsky, COL, MC

(8) Facility: FAMC
WRAMC
MAMC
BAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Anthony Truxal, CPT, MC

(11) Key Words:
eye disease
cyclosporin
prednisone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Cyclosporinte - Acne (1 pt.) Prednisone - Acne, swelling (1 pt.) Arthralgia on withdrawal (1 pt.)

(15) Study Objective: To determine the effectiveness of cyclosporin in the treatment of Graves' eye disease.

(16) Technical Approach: Patients with Graves' eye disease will receive a 3-week course of cyclosporine or prednisone, then have a 3-week rest. Then, 3 weeks of prednisone or cyclosporine (crossover). They will be followed by complete eye examination and CT scan of the orbits before and after each drug period, and twice weekly with CBC, SMA-18, urinalysis and B-2 microglobulin (urine).

(17) Progress: No new patients enlisted from FAMC in the past year. Two patients added from other medical centers. Results in patients evaluated thus far as a group are kept at Walter Reed and have not yet been analyzed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 85/100 (3) Status: Ongoing

(4) Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs. Surgery Alone for Patients with Localy Advanced Gastric Adenocarcinoma, Phase III
SWOG #7804

(5) Start Date: 1978 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 85/139 (3) Status: Ongoing

(4) Title: National Intergroup Protocol for Intermediate Thickness Melanoma 1.0-4.0 mm. Evaluation of Optimal Surgical Margins (2 vs 4 cm) Around the Primary Melanoma and Evaluation of Elective Regional Lymph Node Dissection
SWOG #8393

(5) Start Date: 1983 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 85/165A (3) Status: Terminated

(4) Title: An Evaluation of Cross Allergenicity Among Pollen Extracts of Members of the Chenopodiaceae and Amaranthaceae

(5) Start Date: 1985 (6) Est Compl Date: 1990

(7) Principal Investigator: David Goodman, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators

R. Ledoux
Bernard L. Crosby, MAJ, MC

(11) Key Words:
pollen
hypersensitivity
allergens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate patterns of cross allergenicity among pollens of the weed families, Chenopodiaceae and Amaranthaceae.

(16) Technical Approach: Evaluation of cross reactivity using human antigen and ELISA in inhibition, rabbit antisera and CIE, CRIE. Allergen characterization using PAGE, IEF, and Western Blot.

(17) Progress: Protocol is being re-written to conform with current animal-use regulations.

Presentations:

Crosby BL, Ledoux RA, Vaughan TR, Weber RW, and Goodman DL: Cehnopod-Amaranth Crossreactivity: Evaluation of Cross-Reactivity Between Redroot Pigweed, Russian Thistle, Palmers Amaranth, and Lenscale by ELISA Inhibition and Enzyme-Linked Immunoblots: Presented: Harold S. Nelson Allergy Symposium, FAMC, February 1990 and American Academy of Allergy and Immunology, Baltimore, MD, March 1990.

Goodman DL, Crosby BL, Weber RW, Vaughan TR: Chenopod-Amaranth Cross-Reactivity: Comparison of Four Adjuvant Systems in the Production of Rabbit Anti-Russian Thistle IgG: Presented: Harold S. Nelson Allergy Symposium, FAMC, February 1990.

Goodman DL, Ledoux RA, Weber RW: Comparison of Adjuvant Systems in the Production of Pollen Antisera in Rabbits. Presented: American Academy of Allergy & Immunology Annual Meeting, Washington, DC, February 1987.

Muggleberg, ML, Ledoux RA, Weber RW: Cross-Allergenicity of Western Prairie Grasses Evaluation by ELISA Inhibition. Presented: American Academy of Allergy & Immunology, Anaheim, CA., March 1988.

Publications: Two publications expected to be completed this FY.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 85/167 (3) Status: Ongoing

(4) Title: The Effect of Age on Thyroid Function Studies: The Perchlorate Discharge Test

(5) Start Date: 1985 (6) Est Compl Date: 1991

(7) Principal Investigator:
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
William J. Georgitis, MAJ, MC
Michael T. McDermott, MAJ, MC
Peter Blue, LTC, MC
Stephen M. Manier, MAJ, MC
Tony L. Walden, CPT, MC

(11) Key Words:
thyroid diseases
thyroid function tests
thyroid gland

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the effect of age on the perchlorate discharge test in individuals with thyroid disease.

(16) Technical Approach: Patients over the age of 60 years without thyroid disease by history, physical examination and lab evaluation will be studied. A perchlorate test will be performed in Nuclear Medicine.

(17) Progress: No progress has been made due to inadequate time of principal investigator; however, the study is thought to still be valid and worthwhile. A new Endocrine Fellow will pick up this protocol and complete it. No progress in FY91.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 86/107A (3) Status: Completed

(4) Title: In-Vitro Drug Sensitivity Utilizing the Guinea Pig Airway Smooth Muscle Model

(5) Start Date: 1986 (6) Est Compl Date: 1991

(7) Principal Investigator:
T. Ray Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators
Anthony R. Henry, LTC, MC
Michael A. O'Connell

(11) Key Words:
drug sensitivity

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____47-60 Guinea PIgs_
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: We have previously demonstrated in the guinea pig tracheal model the development of subsensitivity to beta-adrenergic agonists. It would now be useful to have an animal model in which we can safely study the pharmacodynamic interactions involved in beta-adrenergic blocker induced bronchoconstriction. Specifically, it will be important to determine the direct effects of beta-adrenergic blockers on tracheal smooth muscle prior to histamine-induced tracheal constriction. Then, it will be important to determine the effects of beta-adrenergic agonists and anticholinergics on beta-adrenergic blocker induced tracheal constriction.

(16) Technical Approach: In-vitro blockade of beta-adrenergic receptors of the guinea pig trachea will be achieved after the guinea pig tracheas have been excised, divided into segments, and placed into tissue chambers under physiologic conditions. Subsequently, the effects of beta-adrenergic blockers will be studied before and after the induction of tracheal smooth muscle contraction by histamine. Finally, the effects of beta-adrenergic agonists and anticholinergics on the beta-adrenergic blocker induced tracheal smooth muscle constriction will be studied.

CONTINUATION SHEET, FY 91, ANNUAL PROGRESS REPORT Protocol #: 86/107

(17) Progress: (a) Propranolol (10-4M) causes no significant tracheal smooth muscle contraction. (b) Pretreatment with propranolol potentiates histamine-induced tracheal smooth muscle contraction. (c) Pretreatment with propranolol attentuates albuterol reversal of histamine-induced smooth muscle contraction. (d) We have established an in-vitro model with which we can safely study the pharmacodynamic interactions involved in beta-blocker potentiated bronchoconstriction. (e) Atropine methylnitrate causes no significant reversal of the histamine-induced tracheal smooth muscle contraction during the observation period (5-10 minutes). (f) Atropine sulfate causes reversal of the histamine-induced tracheal smooth muscle contraction. (g) Propranolol (10-6M) causes no significant tracheal smooth muscle contraction. (h) Pretreatment with propranolol (10-6M) appears to potentiate histamine-induced tracheal smooth muscle contraction. (i) Both g & h are important because of 10-6M propranolol reflects reported tissue concentrations of propranolol in the lung.

Presentations: American College of Allergist National Meeting, 1986; Hugh Mahon Lectureship Award Competition (1st place award in lab category and grand prize award) FAMC, 1989. Aspen Allergy Conference Regional Meeting, 1989. American College of Allergy & Immunology National Meeting, 1989. American Academy of Allergy & Immunology 1990. Harold S. Nelson Symposium, FAMC 1990. Aspen Allergy Conference, Aspen, CO 1990. 1st Place Lab Category HMLAC 1990.

Publications: Ann. All. 56:117, 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 86/109 (3) Status: Ongoing

(4) Title: The Effect of INH and Combination INH-Rifampin Therapy on Calcium and Vitamin D Metabolism

(5) Start Date: 1986 (6) Est Compl Date: 1991

(7) Principal Investigator: John Merenich, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald S. Kidd, LTC, MC
Michael E. Perry, COL, MC
Michael T. McDermott, MAJ, MC
Fred Negron, CPT, MC
Peter Blue, LTC,MC

(11) Key Words:
calcium
vitamin D rifampin
vitamin D deficiency

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The purpose of this study is to see if INH therapy alters vitamin D and/or calcium metabolism in a significant manner. This may then lead to further evaluation to determine if patients would benefit from vit D or calcium supplementation while receiving INH therapy.

(16) Technical Approach: Ten to 20 patients will be begun on INH therapy for their recent PPD conversion. Determinations of Vit D (25-OH, 1,25-OH), serum calcium, PTH, 24-hour urine calcium and SMA-18 are drawn at baseline, 2 weeks, 6 and 9 months. Bone densitometry is obtained before and after therapy.

(17) Progress: Seven patients have been entered in the study as of this date. No progress made concerning patients. The following events and progress has been made: 1) Protocol approved in November at Eisenhower AMC (Dr. Asp); 2) A plan has been set up with LTC Criswell, Preventive Medicine, for recruiting patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 86/114 (3) Status: Ongoing

(4) Title: Natural History of HTLV-1 Infection and Disease in a United States Military Community

(5) Start Date: 1986 (6) Est Compl Date: 1992

(7) Principal Investigator: Gates, Robert H. LTC, MC (8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators
Leo A. Andron, LTC, MS
Roland N. Hannon, PA-C, CW3(RET)
Jefferey Casserly, PA-C, CW3(RET)
Shannon M. Harrison, LTC, MC
William R. Byrne, LTC, MC

(11) Key Words:
HIV virus

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan 91 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 100
d. Total Number of Subjects Enrolled to Date: 550
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To develop an accurate, thorough understanding of the pattern of disease progression and clinical course in individuals with documented HIV infection within the general military population including active duty, dependents, and retirees. This will provide critical information for clinical and administrative management of patients.

(16) Technical Approach: Collect data on all patients who are required to be stagged by DA directives and any who request stagging.

(17) Progress: No changes except as noted for amendments in the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 86/120 (3) Status: Ongoing

(4) Title: A Phase II Comparison of CHOP versus m-BACOD versus ProMaCE-CytaBOM versus MACOP-B in Patients with Intermediate or High Grade Non-Hodgkin's Lymphoma
SWOG #8516

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/103 (3) Status: Ongoing

(4) Title: Identification of Those at Risk for Osteoporotic Fractures by a Non-Invasive Measurement

(5) Start Date: 1987 (6) Est Compl Date: June 1990

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators Gerald Kidd, COL, MC

(11) Key Words:
osteoporosis
hip fractures

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 25
d. Total Number of Subjects Enrolled to Date: 70
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate possible risk factors for osteoporosis by comparing hip fracture patients and matched controls for bone density, calcium intake, smoking, medications, mental status, visual acuity, vitamin D leves and exercise history.

(16) Technical Approach: Hip fracture patients, within 5 days of fracture, and normal matched controls will have measurement of bone density at 3 sites in the unaffected hip and in the spine by dual photon absorptiometry and in the non-dominat midradius by single photon

absorptiometry. All subjects will have a history and physical examination to include dietary and exercise history. Twenty subjects from each group will have visual acuity and 25-hydroxy vitamin D levels evaluated.

(17) Progress: Patients with hip fractures had significantly reduced bone density in the hip and lumbar spine and significantly lower calcium intakes. No further progress. The manuscript has been submitted for publication.

Presentations:

(1) McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. Presented: 10th Annual Scientific Meeting, American Society for Bone and Mineral Research, New Orleans, La, 1988.

Publications:

(1) Perloff JJ, McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. J Bone Min Res 3(Suppl. 1):587(73A), 1988, (Abstract).

(2) Perloff JJ, McDermott MT, Perloff KG, Blue PW, Enzenhauer R, Seik E, Chantelois A, Dolbow A, Kidd GS: Risk factors for osteoporotic hip fractures (Submitted for publication).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/104 (3) Status: Ongoing

(4) Title: A Randomized Investiation of HIgh-Dose Versus Standard Dose Cytosine Abarinoside with Daunorubicin in Patients with Acute Non-Lymphocytic Leukemia, Phase III
SWOG 8600

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/111 (3) Status: Completed

(4) Title: A Prospective Double Blind Study of Zidovudine in Early HIV Infection

(5) Start Date: 31 Oct 87 (6) Est Compl Date: 1 Oct 91

(7) Principal Investigator:
Shannon Harrison, LTC, MC

(8) Facility: FAMC
Denver Health & Hospitals

(9) Dept/Svc: DCI

(10) Associate Investigators

R.N. Hannon, PA-C
Leo Andron, LTC, MS
Robert H. Gates, LTC, MC

(11) Key Words:
ZDV
asymptomatic HIV

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report. (Fenced HSC/HIV monies & P6 MED R&D Grant renewed for FY 90 & 91

(14) a. Date, Latest IRC Review: Feb 91 b. Review Results: Completed
c. Number of Subjects Enrolled During Reporting Period: none
d. Total Number of Subjects Enrolled to Date: 66 & 150 DH&H
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". (1 RBC aplasia; 4 granulocytopenia; 6 thrombocytopenia; 1 severe nausea and vomiting; none off study).

(15) Study Objective: To look for efficacy and toxicity in terms of difference in natural history of DoD class 2 through early 5, HIV infected individuals given zidovudine at 200mg every 6 hours, 1/2 started 87, 88, 1/2 started 15 Aug 90.

(16) Technical Approach: 18 study endpoints/78 withdrawals: misentries, 1 for toxicity.

(17) Progress: Protocol was closed 1 February 1989. 110 patients still on study. 70 patients carried to 1 Oct 91.

Publications and Presentations: (a) 3 abstracts; International HIV Meeting, San Francisco, CA, Jun 90; (b) 2 presentations; WRAIR Retrovirology Seminar, Sep 88, Sep 89; (c) 1 presentation; US Army HIV symposium, Dallas, TX 28 Jan 90 - 2 Feb 90.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/112 (3) Status: Ongoing

(4) Title: (RTOG-85-01) Prospective Trial for Localized Cancer of The Esophasgus: Comparing Radiation as a Single Modality to the Combination of Radiation Therapy and Chemotherapy, Phase III Intergroup
SWOG-8598

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/114 (3) Status: Ongoing

(4) Title: Patient Evaluation of Physicians' Humanistic Qualities

(5) Start Date: (6) Est Compl Date: 1992

(7) Principal Investigator:
Michael J. Weaver, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Gen. Med Svc.

(10) Associate Investigators
Cathy L. Ow, CPT, MC
Debbie Walker, LTC, AN
Ernest Degenhardt, MAJ, AN

(11) Key Words:
humanistic qualities
medical residents

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) to determine what behaviors are considered by patients to be important markers of humanistic qualities in their physicians; b) to develop and test a questionnarie for a patient to rate the humanistic qualities of their own physician, and (c) to determine whether feedback, based on their own paients' ratings, can result in a change in physicians' humanistic behaviors.

(16) Technical Approach: The study consists of three phases: (a) open-ended interviews with patients to elicit important physicians' humanistic behaviors; (b) development and testing of a questionnaire from the responses generated in Phase a, and (c) we will give back feedback to physicians, based on their own patients'evaluation of their humanistic behaviors, using the questinnaire developed, and measure whether there is any change on a repeat questionnaire, post-feedback.

(17) Progress: Data analysis completed for 1st version of questionaire. Questionaire is being revised for 2nd version to be tested on larger number of interns and residents. Data collecti and analysis for 2nd phase. 3rd phase now being planned.

CONTINUATION SHEET, FY 91, ANNUAL PROGRESS REPORT Protocol #:87/114

Publications:

Weaver MJ, Ow CL, Walker DJ and Degenhardt EF: Evaluation of Residents Humanistic Qualities by Patients and Attending Physicians (Abstract Submitted)

Presentations:

Ow C, Weaver M, Walker D, Degenhardt E: Patient Evaluation of Physicians Humanistic Qualities. (Accepted for presentation at Army Regional LAP meeting, October 1989).

Weaver MJ, Ow CL, Walker DJ, Degenhardt EF: Evaluation of resident's humanistic qualities by patients and attending physicians. Presented at 5th Biennial Symposium for Teaching Internal Medicine, Boston, MA Nov. 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/116 (3) Status: Ongoing

(4) Title: Effect of Iodine Containing Water Purification Tablets on Thyroid Function in Man

(5) Start Date: Aug 87 (6) Est Compl Date:

(7) Principal Investigator:
Michael T. McDermott, LTC, MC
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators
John R. Barrett, LTC, MC
William J. Georgitis, LTC, MC
Robert J. Sjoberg, MAJ, MC
John A. Merenich, CPT, MC
Kenneth Simcic, CPT, MC

(11) Key Words:
iodine
water purification tablets
thyroid function tests

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this study are to investigate the effects of iodine containing water purification tablets on thyroid function and job performance in soldiers in a field environment.

(16) Technical Approach: See Protocol

(17) Progress: No progress has been since last FY. The manuscript has been submitted for publication and the reviewers have asked that we measure serum iodine levels. We have been working with Biochemistry Service, DCI, since then to try to develop an assay for serum iodine but have so far been unsuccessful. Alternately we may eventually send them to a commercial lab. We are still trying to get serum iodide measurements.

Presentations: Georgitis WJ, McDermott MT: Iodide water purification tablets alter thyroid function in man. Presented: 71st Meeting of the Endocrine Society, Seattle, WA. Endocrinology 124(Suppl):480 (1830A), 1989.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/104 (3) Status: Completed

(4) Title: A Descriptive Study of Pastoral Care Interventions Designed to Assist HIV+/AIDS Patients in Achieving Their Maximum Quality of Life

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator:
F. William Miles, LTC, USAR
(Chaplain)

(8) Facility: FAMC

(9) Dept/Svc: Minis. & Past. Care

(10) Associate Investigators
Shannon M. Harrison, LTC, MC
Robert L. Campbell (CH), COL
Jerry Webb, COL (CH)
Robert H. Gates, LTC, MC

(11) Key Words:
psycho-social-spiritual
cognitive, moral and
faith development

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:Tst 47/Intr 7
d. Total Number of Subjects Enrolled to Date: Tst 397/Intr 96
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: (a) To observe and document the continuity of pastoral care with a traumatically stressed patient population (FAMC and beyond). (b) To conduct a longitudinal descriptive study that shows process from the point of view of patient, family member, supervisor and pastoral care giver. (c) To encourage personal processing of issues that impact on a sense of well being, decision making, psycho-social-spiritual growth through the use of an intentional and prescribed series of pastoral interventions. To provide the patient personal gain from telling his/her own "story." (d) To look at life histories, values, moral/faith development, personality types as they inform the pastoral care giver for ministry.

(16) Technical Approach: We have developed a pastoral data base of information relative to providing pastoral care to HIV+/AIDS patients. This was accomplished through regular personality inventories and interviews every six months during the HIV staging process, as well as follow-up questionnaires and support visits/calls to determine continuity of pastoral care and individuals functioning at unit/home.

CONTINUATION SHEET, FY 91, ANNUAL PROGRESS REPORT Protocol # 88/104

(17) Progress: The protocol ended the data gathering phase in May 1990. We cut off new data gathering, except for followup testing and interviews, and prisoners and women, by 30 Mary 90. Coordination with HSC, FORSCOM, and Ft. Carson to obtain a control group, a random sample of soldiers by age, MOS, and rank, with whom to compare our patient group was not successful. An inadequate (not randomized, etc.) control group is used which consists mostly of soldiers and dependents from the FAMC area (or who came through the I.D.S. for other reasons), as well as spouses of patients. During the last two years, the following testing was completed in the HIV Pastoral Research Project (since began testing o/a 1 Oct 87). Totals for the current year are included to the right in [bold] parentheses.

a. Patients tested/interviewed - 397 **[47]** (Black=136, White=156, Others=36)
b. Second testings - 115 **[18]** (Prisoners=30)
c. Third testings - 45 **[9]** (Women=63, HIV+=25) (Total=86)
d. Fourth testings - 12 **[6]**
e. Fifth testings - 6 **[6]**
d. Values inventories - 302 **]26]** (includes 43 HIV-)
e. Second values Inv.- 6 **[2]**
e. D.I.T. - 290 **[16]** (includes 47 HIV-)
f. D.I.T. #2 - 79 **[22]** (given at 1 year)
g. MBTI - 335 **[27]**
h. TJTA - 493 **[66]** (253+, 63-)
i. MPD - 212 **[27]** (includes 33 HIV-)
j. MPD #2 - 18 **[5]**
k. Fowler Interviews - 96 **[0]**
l. 2nd Interviews - 51 **[7]**

Publications:

(1) For the General Convention of the Episcopal Church, Detroit, Michigan, July 1988, Short article describing the research projects being conducted in Infectious Disease Service/DMPC at FAMC.

(2) Haburchak DR, Harrison SM, Hannon RN, Miles FW: Resolving Patient Feelings of Guilt - A Need for Physician Chaplain Liaison. AIDS Patient Care, Oct 1989, p.42-3.

(3) Letter to the Editor of the Colorado Episcopalian, dated June 1989.

(4) Miles F.Wm: Churches Must Be Hospitable as AIDS Virus Spreads. Colorado Episcopalian, p. 10, October 1989.

(5) Miles F.Wm: What Happens When a Soldier is HIV+? Submitted to Command Magazine, in press, 1990.

Presentations:

(1) Psycho-social-spiritual Aspects of HIV+Patients: Presented: Ft. Leavenworth, Kansas, September 1987.

(2) AIDS for professionals, The Next Step. 2 presentations: "Guilt, Shame, and Grief" and "A Wellness/wholeness Approach for the HIV+ Patient." New York City, 15 April 1988.

(3) Episcopal Diocese of Colorado Workshop: AIDS, The Church's Response. w/Mr. Hannon and Dr. Harrison. Presented: Denver, Colorado, 6-7 February 1988.

(4) HIV/AIDS Briefing - Psycho-social-spiritual Aspects. Physical Therapy Students. Presented: University of Colorado Medical Center, Denver, CO, April 1988.

(5) HIV/AIDS Briefing/A Psycho-Social-Spiritual Model of Wellnes in the HIV+ Patient. Presented: MEDDAC, Ft. Hood, Texas, May 1988.

(6) Workshop on Ministry to the HIV+Soldier/AIDS Ministry. Presented four times; FORSCOM/TRADOC Chaplains' Conference, st. Luis, MO, December 1988

(7) HIV/AIDS Update-A Psycho-Social-SpiritualModel of Wellness in the HIV+ Patient. Presented: Chaplain Training Conference, Health Services Command, San Antonio, TX, May 1988.

(8) HIV/AIDS Briefing for Physical Therapists w/a Wellness model of Treatment. Presented: Physical Therapy Students, UCMC, February 1990.

(9) Wellness & Spiritual Aspects of Ministry to HIV+PWA for Medical Professionals. Presented: Patient Care Conference; Nursing Conference on AIDS, FAMC March 1990.

(10) The Challenge to the Church in the Age of AIDS. Presented: Wild Rose UCC, Evergreen, CO April 1990.

(11) Free Indeed: Christians Workshop: AIDS and Addictions Reaching the Addicted. Presented: Second Annual National Freed Indeed Conference, Denver, CO, August 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/109 (3) Status: Ongoing

(4) Title: Methotrexate in the Treatment of Steroid Dependent Asthmatics

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators

David L. Goodman, LTC, MC

(11) Key Words: asthma, steroid dependent methotrexate

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the effectiveness of weekly methotrexate in reducing the steroid requirements of steroid dependent asthmatics. The purpose is to demonstrate a statically significant reduction in the steroid dose over the placebo control, without involvement of the other parameters.

(16) Technical Approach: Double blind crossover design with methotrexate and placebo following pulmonary function tests, symptom scores with attempt to taper corticosteroids.

(17) Progress: Fourteen patients have completed the study, and nine have benefited judged by increase in PFTs and decrease in total steroid use.

Presentations:

Dyer PD, Vaughan TR, Weber RW: Methotrexate in the treatment of steroid dependent asthmatics. Presented: Harold S. Nelson Symposium, FAMC, Feb 89.

Dyer PD, Vaughan TR, Weber RW: Methotrexate in the treatment of steroid dependent asthmatics. Presented: Aspen Allergy Conference, Aspen, CO July 1989.

American College of Allergy & Immunology Annual Scientific Meeting, Orlando, FL, Nov, 89.

Publications:

(1) Dyer PD, Vaughan TR, Weber RW: Methotrexate in the Treatment of Steroid Requiring Asthma. J All Clin Immunol (April) 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/110A (3) Status: Completed

(4) Title: Biological Investigation of Cutaneous Lupus Employing Athymic Mice as Skin Heterotransplant Recipients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology Svc. (10) Associate Investigators Larry Urry, MAJ, MC Don Mercill, DAC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop an in vivo model demonstrating cutaneous lupus as manifestedin humans and to use such model to sequentially study the biological causes of the diseases.

(16) Technical Approach: See Protocol.

(17) Progress: We determined that nude mice are adequate recipients for human skin grafts and when injected with anti-RO sera, the anti-RO antibodies will be deposited within the human epidermal tissue. We found that only IgG1 was the only subclass deposited in the skin in significant amounts to be seen with immunofluorescent microscopy. Although the HSD nude mice were adequate to evaluate immunoglobulin deposition in SCLE, current efforts to induce clinical lesions of SCLE required a better quality of graft. This work is now being done under a new protocol 91/135A.

Publications: Bennion SD, Ferris C, Tsu-San L, Reimer CB, Lee LA: IgG Subclasses in the Serum and Skin in Subacute Cutaneous Lupus Erythematosus and Neonatal Lupus Erythematosus. J Invest Dermatol 95:643-646, 1990.

Bennion SD, et al: The Nude Mouse as an Animal Model in Dermatology. J Military Dermatology, 1990.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/113 (3) Status: Terminated

(4) Title: Methotrexate versus D-Penicillamine in Rheumatoid Arthritis: A Randomized Comparative Study

(5) Start Date: 1988 (6) Est Compl Date: 1991

(7) Principal Investigator: James D. Singleton, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology Svc (10) Associate Investigators Sterling G. West, LTC, MC

(11) Key Words:
methotrexate
D-penicillamine
rheumatoid arthritis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 28
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare clinical efficacy, toxicity and radiographic progression of joint disease in patients receiving methotrexate or D-penicillamine.

(16) Technical Approach: Patients with rheumatoid arthritis will be randomly assigned to receive either methotrexate or D-penicillamine. Clinical assessment will be performed every 3 months and radiographic assessment every year.

(7) Progress: A total of 28 pts have now been in enrolled in study. Very few patients have dropped out of the study; several have been continued on the protocol on the "other" medication. MTX patients have responded more quickly overall; D-PCM patients are responding but more slowly. No progress since FY 90 report.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/115 (3) Status: Ongoing

(4) Title: The Impact of an Ambulatory Care Rotation on Interns Psychosocial Attitudes

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 24
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We propose to test the hypotheses that this ambulatory care rotation will result in increased awareness of psychosocial problems and the increase in awareness will be correlate with an increase in knowledge of psychosocial content.

(16) Technical Approach: Each intern who does a one month ambulatory care rotation in the internal medicine clinic is given a cognitive knowledge test and a psychosocial attitudes questionnaire at the beginning of the rotation, and again at the end of the rotation.

(17) Progress: We have completed testing 8 more interns during the training 1990-91. We will continue testing the next 8 interns who are scheduled to have the ambulatory care rotation through June 1991. Data collection is completed. Analysis and write-up are in progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/116A (3) Status: Completed

(4) Title: Mouse Anti-Chenopod/Amaranth Pollen Monoclonal Antibody Production

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators

(11) Key Words: Lawrence V. Larsen, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop mouse monoclonal antibodies to chenopod-amaranth pollen antigens. The purpose is to use these antibodies to study the crossreactivity of chenopod-amaranth pollen antigens. The importance of the latter is the eventual improvement of allergen extracts for diagnostic and therapeutic utilizations.

(16) Technical Approach: Stage I: Characterization of allergen extracts by PAGE and Western Blot. Stage II: Monoclonal antibody production and characterization by injecting mice with allergen extract, screen for antibody with ELISA, and develop hybridomas.

(17) Progress: Original principal investigator, Dr. Larsen, has PCS'd. LACUC administratively terminated this out-of-date study.

Publications: None

Presentations:

(1) Larsen LV, Copeland T, Vaughan TR: Allergen Extraction Methods: Effect of Temperature and Time: Presented: Harold S. Nelson Symposium, FAMC, February 1990.

(2) Larsen LV, Copeland T, Vaughan TR: Characteristic of Chenopod-Amaranth Extract Enzyme Activity: Presented: Harold S. Nelson Symposium, FAMC, February 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/117 (3) Status: Terminated

(4) Title: A Comparison of Amitriptyline vs. Trazodone vs. Placebo as Adjuvants to Opiate Analgesics in the Management of Pain in Cancer Patients

(5) Start Date: 1988 (6) Est Compl Date: 1991

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hemo/Oncol Svc (10) Associate Investigators Rose A. Gates, MAJ, ANC

(11) Key Words: drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE ___ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____3___ _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NONE

(15) Study Objective: a. To compare the relative effectiveness of amitriptyline and trazodone as adjuvants to opiate analgesics for the management of pain of malignant diseases; b. Quantify the "opiate sparing" effect of these two agents when used in conjunction with morphine sulfate; c. Evaluate the cost-efficiency/effectiveness of trazodone and amitriptyline, as adjuvants to opiate analgesics in the treatment of pain associated with malignant disease.

(16) Technical Approach: See protocol.

(7) Progress: Three subjects at Fitzsimons. One of our patients receiving an antidepressant noted a difference in pain control when the study medication was withdrawn. Problems encountered was obtaining patients who meet the criteria and getting patients who are willing to complete the pain diary.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/120 (3) Status: Ongoing

(4) Title: Ventilatory Effects of Transtracheal Oxygenation

(5) Start Date: 1988 (6) Est Compl Date: July 1991

(7) Principal Investigator:
Michael Perry, COL, MC
Peter Blue, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Pulmonary Dis.

(10) Associate Investigators:
Douglas Dothager, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate the ventilatory effects of transtracheal oxygen therapy.

(16) Technical Approach: A group of 10 COPD patients will have their resp. parameters measured while receiving supplemental oxygen through a nasal cannula and then again while receiving transtracheal oxygen at a flow rate equivalent to that of the nasal cannula. The 2nd part of the study will examine the effects of transtracheal oxygen on radioactive xenon wash.

(17) Progress: Computer program modified as per ammendment. One new patient enrolled since modification.

Publications and Presentations: HMLAC, Oct 88, 89; Army ACP meeting; An. Thoracic Soc. May 89; Abstract: Review of Am. Respiratory, Apr 89. HMLAC 1991, An. Thoracic Soc. May 91, Abstract, Am Rev. Resp. Dis., April 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/121 (3) Status: Ongoing

(4) Title: Bone Densitometry in Thyroid Extract Treated Patients

(5) Start Date: 1988 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
William J. Georgitis, LTC,MC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:Approved
c. Number of Subjects Enrolled During Reporting Period:27 controls
d. Total Number of Subjects Enrolled to Date: 47
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether thyroid extract has greater adverse effects on bone density and calcium metabolism than synthetic l-thyroxine. The second is to assess the reversibility of any documented effect.

(16) Technical Approach: The effects of thyroid extract treatment on bone densitometry will be investigated. Subjects taking thyroid extract treatment matched with a thyroxine controlled group will have assessments of thyroid replacement therapy status, mineral metabolism and bone density. Thyroid extract subjects found to be subclinially hyperthyroid may enter a longitudinal assessment of bone density after crossing over to euthyroid thyroxine replacement.

(17) Progress: From eighty-five refill prescriptions for thyroid extract, seventy-one patients were sent letters. Twenty-eight potential subjects were counseled about the study and twenty have been studied. TRH tests and 24hr urine collections have been completed on the controls who are all awaiting bone densitometry measurements through the Nuclear Medicine Service.

Publications and Presentations:

1. Georgitis WJ, Abrams LF, Dolbow A, Bunker DM: Bone densitometry in patients taking thyroid extract. Presented: American Society for Boen and Mineral Research/International Conference on Calcium-regulating Hormones. 1st Joint Meeting. Abstract 219:S172, Montreal, Quebec, September 1989.

2. Abrams L, Georgitis W, Dolbow A, Bunker D, Kidd G: Is anyone taking thyroid extract consistently euthyroid? The Endocrine Society, 72nd Meeting, Atlanta, GA, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/124 (3) Status: Ongoing

(4) Title: Corticosteroids in the Treatment of Stable Chronic Obstructive Pulmonary Disease

(5) Start Date: (6) Est Compl Date: 1992

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators: David L. Goodman, LTC, MC

(11) Key Words:
COPD
obstructive lung disease
corticosteroids

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 7 - complete 7 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine if subjects with severe obstruction lung disease would benefit from extended therapy with corticosteroids.

(16) Technical Approach: Approximately 10 subjects who have COPD that is not responsive to maximal beta-agonist therapy will be enrolled (elevated FEC, <10%) they will then be randomized to receive either 32mg methylprednisolone per day or placebo for 4 weeks followed by a washout period of 4 weeks and finally crossover to receive the alternate drug. Spirometry and body plethysmography will be performed prior to beginning the study and at 2 week intervals throughout the study period.

(18) Progress: Seven subjects enrolled; Seven complete. Patient recruitment is somewhat difficult in that most "irreversible" COPD subjects have demonstrated a >10% response to B2 therapy. B2 therapy still remains a problem. No fellow currently involved in study. Although patients with appropriate entry criteria remain very difficult to recruit, we will try to find 3 additional patients to complete the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/100 (3) Status: Completed

(4) Title: The Application of Orem's Self-Care Model in Type II Diabetes: An Outcome Study of Diabetic Self-Care Classes and Self-Care Contracting Comparing Self-Care Knowledge, Health Care Beliefs, Weight Loss and Metabolic Control

(5) Start Date: Aug 88 (6) Est Compl Date: Aug 91

(7) Principal Investigator: Ann Marie Bianchi, MAJ, An (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators: Nancy Pfander, MAJ, AN

(11) Key Words:
noninsulin dependent diabetes
Orem's self-care model

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___6_____
d. Total Number of Subjects Enrolled to Date:_____30_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To examine whether Type II (NIDDM) clients who attend diabetic self-care classes and also contract for specific self-care activities will significantly gain in self-care knowledge and activities as measure by knowledge questionnaire, Locus of control tool, wt. control, and metabolic control (FBS, HgbA1c, chol, TG), relative to those who do not contract for self-care behaviors.

(16) Technical Approach: Subjects were randomly selected from type II diabetic clients referred for diabetic education. They were given a pretest questionnaire. The locus of control tool was also given to elicit information about subjects' health beliefs. Metabolic data (FBS, HgbA1c, chol. TG) was also obtained. The clients were then randomly assigned to the contract or noncontract group. The above data will be collected again at 3 mo., 6 mo., and at 12 months.

(17) Progress: This is a collaborative study in which MAJ Pfander collected the data, and MAJ bianchi is analyzing the data for presentation in a graduate education thesis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/102 (3) Status: Ongoing

(4) Title: Factors Determining Peak Bone Mass and Subsequent Bone Loss

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Michael T. McDermott, LTC, MC
Gerald S. Kidd, COL, MC
Peter W. Blue, COL, MC
Harry N. Tyler, Jr., DAC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators:

(11) Key Words:
bone density
peak bone mass

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine factors associated with the development of peak bone mass and subsequent bone loss.

(16) Technical Approach: Bone density of the radius (single photon absorptiometry) and of the hip and spine (dual photon absorptiometry) will be done in a large group of male and female volunteers, who will also, on another protocol, be having total body fat and lean mass measured by dual photo absorptiometry. Questionnaire concerning present and past calcium intake, exercise and other habits will also be administered.

(17) Progress: No progress this FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/103 (3) Status: Ongoing

(4) Title: Transient Hypoxia During Sedated Endoscopic Procedures

(5) Start Date: Dec 88 (6) Est Compl Date: 1992

(7) Principal Investigator: Stephen Freeman, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastroent

(10) Associate Investigators:
Steve Lawrence, LTC, MC
Scott Hallgren, MAJ, MC
Jeffrey Dunkelberg, MAJ, MC
John Van Deren, CPT, MC

(11) Key Words:
endoscopy
hypoxia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the incidence of transient hpoxia during sedated endoscopy and correlate this with changes in blood pressure, cardiac rhythm, overall clinical status of the patient and type and/or stage of endoscopy.

(16) Technical Approach: Room air arterial oxygen saturation, blood pressure and heart rate will be recorded prior to, during and after intravenous sedation and endoscopy.

(17) Progress: No progress has been made on this protocol in FY90. The protocol, however, should remain active. Adequate monitoring equipment to simultaneously monitor oxygenation, blood pressure, heart rate, and ECG has heretofore been lacking. Equipment which will allow such monitoring has finally been purchased as of 30 Sep 91. It is anticipated by the principal investigator that the protocol can be finally carried out to completion during FY92.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/104 (3) Status: Ongoing

(4) Title: Efficacy of Corticosteroids in the Acute Treatment of Asthma: Is Duration of Symptoms Important?

(5) Start Date: Sep 89 (6) Est Compl Date: Sep 91

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators: David L. Goodman, LTC, MC

(11) Key Words:
asthma
corticosteroids
emergency management

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if the beneficial effect of corticosteroids seen in the treatment of status asthmatics is dependent on the duration of asthmatic symptoms.

(16) Technical Approach: 120 subjects presenting to the E.R. or allergy clinic with acute episode of asthma will be studied. Subjects will receive either 125mg methylpredisolone or placebo within 30 minutes of arriving for tx. They will be divided into 2 sps - these with IRS of <24 hours duration and those with sxs for more than 24°. Spirometry and admission rate will be analyzed.

(17) Progress: Pharmacy and ER staff have been consulted and have agreed to participate in the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/105 (3) Status: Ongoing

(4) Title: Appropriate Blood Pressure Control in Diabetes Trial Protocol (ABCD Trial)

(5) Start Date: 1991 (6) Est Compl Date: 1998

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:

(11) Key Words:
nephropathy
diabetes

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: a) Define a level of blood pressure control in a prospective, randomized, non-blinded fashion needed to prevent or delay the progression of diabetic nephropathy and other microvascular complications of diabetes; b) determine if there is a specific advantage to either a CEI or a Ca++ channel blocker as a mode of treatment for hypertension in regard to the onset or progression of diabetic nephropathy.

(16) Technical Approach: See protocol.

(17) Progress: Approximately 10 Fitzsimons Army Medical Center patients have been enrolled in the protocol without complications. Apparently city-wide approximately 500 patients have agreed to participate, but only a relatively small number have actually begun.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/106 (3) Status: Terminated

(4) Title: Immunologic Criteria for the Cessation of Immunotherapy

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator:
James S. Brown, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc.

(10) Associate Investigators:
Richard Weber, COL, MC
Robert Stewart, MAJ, MS

(11) Key Words:
immunotherapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 26
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the presence of a marker for long term efficacy of immunotherapy.

(16) Technical Approach: A. Identifiable change in sub-populations of lymphocytes with immunotherapy; B. Identification of anti-idiotypic antibodies to allergens; C. Demonstration of effect of immunotherapy on late-phase skin tests.

(17) Progress: Cellular and serologic assays were inconsistent. Findings: An interesting tendency for allergen to adhere to lymphocytes in highly allergic subjects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/108 (3) Status: Ongoing

(4) Title: Efficacy of Pentoxifylline in Treating Diabetic Impotence

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator:

John A. Merenich, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Clyde Roy, MAJ, MC
Nancy Pfander, MAJ, MC
William Georgitis, LTC, MC
Gerald S. Kidd, COL, MC
Ernie Lin, LTC, MC

(11) Key Words:
diabetes
impotence
pentoxifylline

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if pentoxifylline is more effective than placebo in improving sexual function in non-insulin dependent diabetic men.

(16) Technical Approach: A single center, double-blind, placebo controlled study to examine the efficacy of pentoxifylline in improving sexual function in impotent NIDDM men. Diabetic men with impotence who meet the protocol entrance criteria will be randomly assigned placebo or pentoxifylline for 12 weeks. After completion of the treatment course subjects will be reevaluated, and groups will be compared to determine beneficial effects.

(17) Progress: Two subjects have completed the protocol. Eight more subjects contacted; counseled, but have not started medication.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/109 (3) Status: Ongoing

(4) Title: The Effect of Percutaneous Endoscopic Gastrostomy Tube Placement on Gastric Emptying

(5) Start Date: Jan 89 (6) Est Compl Date:

(7) Principal Investigator: Michael Fisher, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Int. Med.

(10) Associate Investigators:
Jeffery Dunkelberg, MAJ, MC
Stephen Freemen, LTC, MC
Scott E. Hallgren, MAJ, MC
Peter Blue, LTC, MC

(11) Key Words:
gastric emptying
gastrostomy tube

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To define the effect of PEG placement on gastric emptying.

(16) Technical Approach: Baseline gastric emptying studies will define subjects' status prior to PEG placement. Repeast gastric emptying studies at definite intervals post procedure will allow detection of any changes in gastric emptying. This will impact possibly on defining a standard approach to feeding these patients.

(17) Progress: To date only two patients have been enrolled who meet the inclusion criteria. However, both subjects expressed significant improvement in life by study participation, and one subject has actually gained weight while on protocol. Insertion of the PEG has allowed the two subjects who completed this protocol adequate means of maintaining nutritional status.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/110 (3) Status: Completed

(4) Title: Cyclic Oxygen Therapy at Rest and During Exercise

(5) Start Date: Jan 89 (6) Est Compl Date: Jun 89

(7) Principal Investigator:
Ray C. Johnson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Pul. Dis.

(10) Associate Investigators:
Michael E. Perry, COL, MC
Peter Blue, COL, MC

(11) Key Words:
cyclic oxygen therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if cyclic oxygenation can be used as an oxygen conservation measure. To determine physiologic correlates of efficacy.

(16) Technical Approach: A "baseline" continuous flow rate will be determined for each subject. The timing sequence and cycling flow will identify the corrected cycle flow for each subject at rest. The studies will be repeated while the subjects exercise to ascertain exercise baseline flows as a benchmark for comparison, to determine optimum timing sequences independant of resting conditions and to determine the effect of higher cycling flows.

(17) Progress: Preliminary findings indicate some people have good response to this therapy (two out of ten). The other subjects did not experience benefit. No subjects experienced adverse reactions.

Presentations: ACCP Conference Oct, 1990; 56th Annual Assembly, American College of Chest Physicians Toronto, Canada, Oct 22-26 1990.

Publications: Asynchronous Cyclic Oxygen Therapy at Intermiediate Altitude, Chest 98:22S 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/111 (3) Status: Ongoing

(4) Title: Multicenter Clinical Evaluation of Penicillin Skin Testing Materials

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: Richard Weber, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators: James Brown, COL, MC Robert Ledoux, DAC

(11) Key Words: penicillin minor determinants

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 21
d. Total Number of Subjects Enrolled to Date: 180
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the optimal test reagent in assessment for anaphylactic grade sensitivity to minor determinants of penicillin.

(16) Technial Approach: Prick and intradermal skin testing.

(17) Progress: 180 patients have been studied to date. Findings: Good positives for all minor determinant mixes used. Problems: No studies to determine sensitivity or specificity.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/114 (3) Status: Completed

(4) Title: Response of Arthritis and Microscopic Colitis to Sulfasalazine in Rheumatoid Arthritis Patients

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Sterling West, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology

(10) Associate Investigators:
Sterling G. West, MD
James Singleton, MD
Stephen Freeman, MD
Kenneth Sherman, MD, Ph.D.

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 10 patients entered
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the effect of sulfasalazineon both microscopic colitis and arthritis in RA.

(16) Technical Approach: See Protocol.

(17) Progress: Ten total control colonoscopies with biopsy have been completed per the protocol addendum. Ten patients completed the protocol. Data analysis is complete and a manuscript is being prepared.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/115 (3) Status: Ongoing

(4) Title: The Effect of Congestisve Heart Failure (CHF) on the Erythrocyte Sedimentation Rate (ESR)

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: Ben Mendoza, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Cardiology Svc

(10) Associate Investigators: Raymond Enzenauer, MAJ, MC Mitchell Kruger, CPT, MC

(11) Key Words: congestive heart failure erythrocyte sedimentation rate

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish the effect of acute uncomplicated CHF on the ESR and attempt to analyze specific variables affecting the ESR in the setting of CHF.

(16) Technical Approach: Fifty patients evaluated will be admitted for routine elective cardiac catheterization while fifty patients evaluated will be admitted for treatment of congestive heart failure. This study will analyze certain blood chemistries that are not routinely drawn for examination in patients with CHF or for routine cardiac catheterization.

(17) Progress: Control subjects have been entered into the study. Patient's with CHF have been difficult to obtain. Many were excluded because of acute MI, some witn CHF could not have appropariate labs drawn. Protocol is in the process of being revised.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/117 (3) Status: Completed

(4) Title: Evaluation of Thermography in the Delineation of Late Phase Skin Tests

(5) Start Date: Sep 89 (6) Est Compl Date: Mar 90

(7) Principal Investigator: James Brown, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Allergy Svc (10) Associate Investigators: Edward Green, COL, MC Richard Sherman, MAJ, MS Richard Weber, COL, MC

(11) Key Words: skin tests thermography

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: COMPLETED
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The accurate measurement of the area of involvement in the late phase reaction would enhance this parameter as a tool in studying the immunologic reaction of sensitizing substances.

(16) Technical Approach: Skin test materials will be applied to six allergic and six non-allergic volunteers. The sites will be photographed using the thermographic camera from the time of testing until the maximal immediate reaction has been reached (usually 15-20 minutes), and then photographed hourly for six hours. All studies will be recorded on a VCR. Visual estimations of reaction size will be made by circumscribing the area of involvement with a ballpoint pen and transferring the image to paper using transparent tape.

(17) Progress: Eight subjects studied. Resulted in one presentation, one abstract, and a manuscript is is preparation.

Publications: Brown J, et al: Evaluation of Thermography in Aclimation of Late Phase Skin Tests. J All Clin Immun, 85:209, 1990.

Presentations: Brown J: Evaluation of Thermography in Aclimation of Late Phase Skin Tests: Presented: 46th Annual Meeting of American Academy of Allergy and Immunology, Baltimore, MD, March 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/119 (3) Status: Completed

(4) Title: Development of a Cardiopulmonary Resuscitation (CPR) Information Sheet and Assessment of Patient and Staff Response

(5) Start Date: Oct 89 (6) Est Compl Date: Sep 91

(7) Principal Investigator: Rose Gates, MAJ, An (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators: Michael Weaver, COL, MC Robert Gates, MAJ, MC

(11) Key Words: cardiopulmonary resuscitation do-not-resuscitate order

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 11
d. Total Number of Subjects Enrolled to Date: 230
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: a) To assess the acceptability of an information sheet on CPT to both patients and professional staff; b) To determine the attitude of patients and professional staff regarding discussion of CPR and CPR options.

(16) Technical Approach: A CPR information sheet and questionnaire will distributed as per objective. Discussions will be held at the time of collection of the questionnaires.

(17) Progress: Data collected and analyzed. Mnauscript being prepared. A follow-up protocol may be forthcoming.

PRESENTATION: Annual Meeting Society of General Internal Medicine in Seattle, WA, May 1991.

PUBLICATIONS: Abstract, Clinical Research 1991, 39; pg 632A.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/100 (3) Status: Ongoing

(4) Title: Platelet Thromboxane and Aggregation and Whole Blood Prostacyclin Synthesis in Human Thyroid Disease

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Jan Perloff, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrinology (10) Associate Investigators: Gerald S. Kidd, COL, MC John A. Merenich, MAJ, MC Michael T. McDermott, LTC, MC Chris White, MAJ, MS Lynn Abrams, CPT, MC Sharon Noble, DAC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:____15_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the roles of thromboxane and prostacyclin in mediating the phenomenon associated with thyroid dysfunction.

(16) Technical Approach: See protocol.

(17) Progress: As of this date pre- and post- data have been completed on 15 patients. About 15 more patients are required to complete the study. No complications. Laboratory methods are analysis are progressing well. New investigators have been added to the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/102 (3) Status: Ongoing

(4) Title: Effect of Prolonged Administration of Iodine Containing Water Purification Tablets in Man

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrinology (10) Associate Investigators: William J. Georgitis, LTC, MC Homer LeMar, MAJ, MC

(11) Key Words: iodine goiter thyroid

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if prolonged iodine administration (3 mos) causes persistent hypothyroidism or if compensation occurs and if goiters occur.

(16) Technical Approach: Iodine containing water purification tablets (4 tabs/day, 8mg iodine/tab) will be given to 15 subjects for 3 months. Baseline studies will include thyroid hormone and TSH levels, a TRH test, a radioactive iodine uptake and thyroid ultrasound thereafter, thyroid hormone levels, tSH and TRH test will be repeated at 7, 28 and 90 days. The radioactive iodine uptake will be separated at 7 and 90 days and the thyroid ultrasound will be repeated at 90 days.

(17) Progress: None thus far. We received funds which we have used to acquire the equipemnt needed for ultrasound and thyroid volume calculations. This is now being standardized. Volunteer recruitment is expected to begin in one to two months.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/103 (3) Status: Ongoing

(4) Title: The Limulus Amoebocyte Lysate Assay for the Diagnosis of Spontaneous Bacterial Peritonitis in Ascitic Fluid

(5) Start Date: 1990 (6) Est Compl Date: June 1991

(7) Principal Investigator: Kenneth E. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gastro. (10) Associate Investigators: Stephen Freeman, LTC, MC

(11) Key Words:
limulus
SBP

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: Determine efficacy of the limulus amoebocyte lysate assay in the early diagnosis of Gram negative spontaneous bacterial peritonitis.

(16) Technical Approach: The limulus assay is run on peritoneal fluid obtained from patients with ascites, and then compared to standard cell count/culture definitions of SBP.

(17) Progress: No cases of gram negative SBP have been seen since the onset of this study at this hospital. The cases examined to date were all negative by the limulus assay, as would be expected. However, several cases resulted in a negative inhibition control, indicating reaction inhibition does occur.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/105 (3) Status: Ongoing

(4) Title: Incidence and Prevalence of Hematuria in Patients on Long-Term Anticoagulation

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: James A. Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology Svc (10) Associate Investigators: Talley F. Culclasure, CPT

(11) Key Words:
hematuria
anticoagulation

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:____DEC_b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____180_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To assess incidence and prevelance of hematuria in anticoagulated population.

(16) Technical Approach: UA performed montly on patients in coumadin clinic.

(17) Progress: Approximately 1200 pt/months followup.

Publications and Presentations: Abstract submitted to Army Regional ACP meeting.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/107 (3) Status: Terminated

(4) Title: A Double-Blind, Placebo-Controlled Randomized Trial of the Clinical and Hemodynamic Effects of Vasopressin in Patients with Cirrhosis and Acute Variceal Hemorrhage -- A Multi-center Study

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Michael Fisher, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Gastro. (10) Associate Investigators: Stephen Freeman, LTC, MC

(11) Key Words:
vasopressin
variceal hemorrhage

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Clinical: to evaluate the effect of vasopressin on the volume of variceal bleeding, early rebleeding, and death from bleeding compared to placebo. Hemodynamic: (1) to determine the relationship between the infusion rate of vasopressin, hepatic extraction of vasopressin, peripheral plasma concentration of vasopressin, and its clinical efficacy; (2) to determine whether hemodynamic tachyphylaxis occurs during prolonged infusion of vasopressin; (3) to determine whether abrupt discontinuation of vasopressin causes a rebound increase in portal pressure.

(16) Technical Approach: Multicenter, double-blind, placebo-controlled, randomized trial using a medical intensive care unit patient population.

(17) Progress: Study is terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/108 (3) Status: Ongoing

(4) Title: Comparison of Impedance Plethymography, Venogram and Doppler Ultrasound in Diagnosing Deep Venous Thrombosis

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: David Kristo, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Int. Med. (10) Associate Investigators: Marin Kollef, MAJ, MC James Luethke, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To compare IPG and doppler vs and with venogram at this facility.

(16) Technical Approach: A blinded comparison fo the three studies.

(17) Progress: 15 patients enrolled to date.

Publications: Abstract sent to American Thoracic Society October 1990.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/109 (3) Status: Ongoing

(4) Title: Altitude Effects on Oxygen Kinetics During Exercise in Acclimatized Fit Troops

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Michael E. Perry, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Svc (10) Associate Investigators: James Meyers, CPT, MC

(11) Key Words:
altitude
exercise
oxygen kinetics

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 29
d. Total Number of Subjects Enrolled to Date: 29
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate effects of altitude on exercise performance and oxygen kinetics in altitude-acclimatized troops.

(16) Technical Approach: Troops stationed at altitude for a least 1 year will undergo formal exercise testing both at altitude and at sea level.

(17) Progress: 29 subjects have completed studies at 5800 ft elevation (Ft. Carson) and -300 ft elevation (Death Valley, CA). Data indicates profound effects on ventilation parameters and also on oxygen kinetics. Data is still being analyzed for anaerobic threshold determinations as well as additional parameters of oxygen kinetics.

Publications and Presentations: Abstract submitted to American Thoracic Society pending acceptance.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/110 (3) Status: Ongoing

(4) Title: Effects of Altered Calcium on Blood Pressure

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: James A. Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology Svc (10) Associate Investigators: Philip S. Travis, MAJ, MC

(11) Key Words:
renal failure
dialysis
hypercalciemia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Establish the effect of high calcium dialysate with calcium supplementation vs low calcium dialysate without calcium supplementation on blood pressure.

(16) Technical Approach: Randomized prospective crossover study utilizing a low or high calcium dialysate bath in the correction of hypertension in patients with renal failure.

(17) Progress: Patient enrollment continues. Insufficient data for anlaysis at this time.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (USCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/111A (3) Status: Terminated

(4) Title: Prevention of Pseudomonas Colonization by Saccharomyces boulardii or Lactobacillus Acidophilus in Antibiotic Treated Mice

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Mark J. Jarek, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Svc (10) Associate Investigators: Marin Kollef, MAJ, MC Raymond Johnson, MAJ, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prove a benefit of prophylactic administration of either Saccharomyces boulardii or Lactobacillus acidophilus in the prevention of enteric Pseudomonas colonization in mice treated with antibiotics.

(16) Technical Approach: See protocol.

(17) Progress: This study has never been started due to difficulties in obtaining support for maintenance of the study animals. No plans to continue it in the near future exist.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/112 (3) Status: Ongoing

(4) Title: Laboratory Screening to Detect Biochemical Evidence of Hemochromatosis Among Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM)

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: John A. Merenich, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators: Michael T. McDermott, LTC, MC Donna Bunker, DAC Vishnu V. Reddy, LTC, MC Darci D. Ashley, DAC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 50
d. Total Number of Subjects Enrolled to Date: 400
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a systemic means for all NIDDM patients at FAMC to be screened and to make physicians aware of the need for this intervention.

(16) Technical Approach: See protocol.

(17) Progress: 400 patients screened to date, no complications. POC is Dr. McNally and Dr. McDermott.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/113 (3) Status: Ongoing

(4) Title: Effect of Cold Remedies on Metabolic Control of Noninsulin Dependent Diabetes Mellitus

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Homer Lemar, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators: W.J. Georgitis, LTC, MC Darci U. Ashley

(11) Key Words:
diabetes mellitus
sucrose
alcohol
antitussive

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 14
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: Determine if sugar and alcohol free cough formulas have clinically significantly fewer adverse metabolic effects inpatients with diabetes mellitus compared to standard (sugar and alcohol containing) cough formulas.

(16) Technical Approach: Prospective crossover study in which all subjects will take both preparations in series and effects on blood sugar and lipids will be compared. Two groups of patients will be studied (well controlled and poorly controlled) in this manner.

(17) Progress: Fourteen subjects have been enrolled and have completed the study. Six more subjects are planned to be enrolled in March 1991. This will complete the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/114 (3) Status: Ongoing

(4) Title: Assessment of Patient Utilities for Health Outcomes: Influence on Aspirin Prophylaxis to Prevent Myocardial Infarction

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Gen. Int. Med. (10) Associate Investigators: William Reed, MAJ, MC (Letterman AMC)

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 72
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine what patients' utilities are for various health outcome states: (1) MI; (2) mild CVA; (3) moderate - severe CVA. Determine whether patient utilities influence decision to take ASA to prevent MI.

(16) Technical Approach: Decision analysis tree constructed using probabilities from published trials of ASA as prophylaxis against MI. Determine patient utilities by standard reference gamble interview.

(17) Progress: 70 subjects interviewed.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/115 (3) Status: Ongoing

(4) Title: Relationship of Blood Flow in Hemodialysis Access to Recirculation with Variable Blood Pump Flow

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology (10) Associate Investigators: CPT Bergstrom

(11) Key Words:
recirculation
access
dialysis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: Relationship between blood pump flow rate and recirculation.

(16) Technical Approach: Measure recirculation at variable blood pump speeds.

(17) Progress: Twelve patients enrolled, no data yet.

Publications: Hasbargen J, Bergstrom, R: Effects of Variable Blood Pump Speed (QB) on Recirculation. J. Am. Soc. Nephrology, 1:360, 1990.

Presentations: 23rd Annual Meeting of Am. Soc. Nephrology, Washington, DC, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/116 (3) Status: Ongoing

(4) Title: Smoking Cessation Enhancement by Estimated Lung Age and Measured Expiratory Carbon Monoxide Levels

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Vance Bray, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Int. Med. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 42
d. Total Number of Subjects Enrolled to Date: 42
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Evaluate the effect of patient education based upon calculated lung age and measured carbon monoxide exhalation on smoking cessation.

(16) Technical Approach: Initial spirometry, carbon monoxide measurement and questionnaires will be repeated at 6, 12 and 18 months in groups participating in the current smoking cessation classes and groups of smokers not participating in the classes to evaluate the long-term success rate of patient education.

(17) Progress: Protocol progress has been impaired by temporary duty associated with operation desert shield/storm. Principal investigator has returned. No changes have been made in the protocol. The 6 month assessment was missed due to deployment but will begin at the 12 month interval in May, 1991.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/117 (3) Status: Ongoing

(4) Title: The Effect of Prolonged Thyroxine Suppression Therapy on Thyroid Nodule Size, Cytology and Serum Thyroglobulin in Patients with Solitary Palpable Thyroid Lesions

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: John Merenich, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators: Homer J. Lemar, MAJ, MC Gerald S. Kidd, COL, MC Michael McDermott, COL, MC William Georgitis, COL, MC Mark Larson, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if suppressive doses of levothyroxine (documented by an 'ultrasensitive" TSH assay) reduces the size (by ultrasound) of newly discovered, biopsy "non-malignant" thyroid nodules; if response to suppression therapy differs between patients with truly uninodular lesions VS those in whom ultrasound examination uncovers the presence of multiple nodules; if any FNA cytologic changes occur after a course of suppression therapy and the utility of serum thyroglobulin as a biochemical marker of changes in nodular size or cytology.

(16) Technical Approach: See protocol.

(17) Progress: No data yet, placebo to arrive by 1 September 90 and then the project can be started.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/118 (3) Status: Terminated

(4) Title: Effect of Gymnema Sylvestre on Blood Glucose and Serum Insulin Levels

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Lynn Abrams, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report .

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate the acute effects of gurmar on blood glucose/insulin levels acutely during a 7-day treatment period.

(16) Technical Approach: A baseline 5-hour oral glucose tolerance test with measurement of glucose, insulin and c-peptide will be performed. Three days later the acute effect of the ingestion of 2 tablets of gurmar on glucose, insulin and c-peptide will be studied over 5 hours. Following this a 7-day period of daily ingestion of gurmar will be followed by a repeat 5-hour oral glucose tolerance test.

(17) Progress: The 3-hour acute challenge studies showed no effect on basal or nadir blood sugar or insulin levels. Comparison of the 5-hour oral glucose tolerance test done before and after one week of chronic herbal medicine use also showed no significant effects. Area under the curves for blood sugar, insulin and c-peptide levels were also analyzed and showed no significant differences. To achieve a power of 80% at alpha equal to .05, 10 subjects would need to be studied to exclude missing a mean treatment effect on blood sugar of 40. Since we were looking for only a decline in blood sugar, the 5 subjects studies are probably sufficient to exclude missing a significant effect of this herbal medicine preparation on glycemia. No further investigation appears necessary.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/119 (3) Status: Completed

(4) Title: Epidemiological and Retrospective Analysis of Patients Consuming L-Tryptophan Containing Products

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Harry Spaulding, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators:

(11) Key Words:
L-tryptophan
eosinophilia-myalgia syndrome

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:__ MAY__b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____54_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To understand the side effects of L-tryptophan ingestion and its association with eosinophilia-myalgia syndrome.

(16) Technical Approach: A review of records, a questionnaire, and selected laboratory studies will be performed. Positive results will be relayed to the subject and a generic information letter will be sent to each subject explaining the results of the overall study.

(17) Progress: This was an entirely an epidemiological study. No patients were found to have sub-clinical disease with the exception of one person who was taking another product that may have given him some eosinophilia. All patients have received one generous report in the form of a generic letter discussing the pros and cons and causes of eosinophilia-myalgia syndrome.

Publications and Presentations: This study has resulted in two presentations at National Meetings and there is one manuscript i preparation now for publication.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/120 (3) Status: Completed

(4) Title: Dose Hepatitis-B Vaccine Promote Eosinophilia, Increase Serum IgE Levels or Sensitize Recipients?

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Harry Spaulding, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators:

(11) Key Words:
hepatitis-B vaccine
eosinophilia
IgE

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 24
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if the standard hepatitis vaccine, in this case, Hepatvax-B, lot 074R, promotes any sensitivity, eosinophilia, or changes in total IgE to human recipients.

(16) Technical Approach: Only patients who are receiving this first series of vaccinations and, therefore, antibody negative will be entered into the study. Prick skin testing will be performed to hepatitis vaccine, 1:10 and full strength. After 15 minutes histamine control will be added. If prick testing is negative, they will be tested intradermally to 1:100 dilution of the vaccine. Blood will be drawn for baseline determinations. Subjects will be re-evaluated after their first booster and then 6 months after the third booster was administered.

(17) Progress: Subjects are currently being enrolled. No data is yet available. Several were lost to followup due to PCS moves at various times during the study. No positive findings have been developed to date regarding sensitivity, however there may be some hidden factors after the serum is analyzed for IgE and IgG sub-class reactivity.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/121 (3) Status: Ongoing

(4) Title: Temporal Course of Altitude Acclimatization

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator:
Michael Perry, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Pul. Dis. Svc.

(10) Associate Investigators:
William Annan, COL, IN
Harry Dolton, Jr., LTC, FA
Gerald Kidd, COL, MC
John O'Connor, LTC, IN

(11) Key Words:
altitude effects
acclimatization

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:__ MAY__b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___20_____
d. Total Number of Subjects Enrolled to Date:_____20_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the time requirement for completion of altitude-acclimatization.

(16) Technical Approach: Subjects' anaerobic threshold will be determined using a 2-mile run and a two-part bicycle ergometer test at Ft. Sill. Arterial blood sample will be obtained. Using the same troops, the identical protocol will be carried out at Ft. Carson at 72 hrs, 1 mo, 6 mo, 9 mo, 12 mo, and 18 mo after arrival for duty with the 4th ID.

(17) Progress: Approximately 20 subjects at Ft. Sill have undergone testing according to protocol guidelines. The same subjects are now undergoing testing at Ft. Carson. Next testing period is May 91 then Nov 91.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/122 (3) Status: Ongoing

(4) Title: Evaluation of Viral Hepatitis in Patients Infected with the Human Immunodeficiency Virus (HIV)

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Kenneth Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastro. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the prevalence of serologic markers of viral hepatitis including hepatitis B, hepatitis C, and hepatitis D in a military population and to determine the effect of AZT therapy on the markers of HB infection.

(16) Technical Approach: Bank sera of 220 HIV subjects will be used. Sera banked prior to AZT therapy will be studied using qualitative hepatitis B DNA probe assay. Data will be correlated to helper: suppressor status and serum markers of hepatic injury. Hepatitis C assay by ELISA will be performed on serial serum samples and at 6 months to 1 yr intervals to determine the incidence of hepatitis C in this population. Hepatitis D antibody testing will be performed in all HBsAG positive samples as well as any that may be HBV DNA positive but antigen negative on testing.

CONTINUATION SHEET, FY 91, ANNUAL PROGRESS REPORT Proto.# 90/122

(17) Progress: Subset of patients with stored serum identified based on presence of serial blood samples; all serum tested for hepatitis C antibody by ELISA assay; positive samples confirmed with RIBA assay. A further subset of samples has been evaluated for hepatitis B genomic markers using Polymerase chain reaction technique.

Publications:

Sherman KE, Freeman S, Harrison S, Andron L: Prevalence of Antibody to Hepatitis C Virus in Patients Infected with the Human Immunodeficiency Virus. J. Inf. Dis, 163:414-415, 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/123 (3) Status: Ongoing

(4) Title: Urinary Indices in Acute Renal Failure

(5) Start Date: 1990 (6) Est Compl Date: 1993

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephro. (10) Associate Investigators:

(11) Key Words:
renal failure
serum creatinine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the use of several tests in diagnosing acute renal failure.

(16) Technical Approach: Prospective survey of serum creatinine in hospitalized patients for acute renal failure. Review of urinary diagnostic indices to include U/P creatinine, osmolality, FENA and FECL, FELI, NMR spectroscopy and transmission electron microscopy of urine as well as chart review.

(17) Progress: No progress at this time since VA has not funded the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/124 (3) Status: Ongoing

(4) Title: The Effectiveness of Octreotide (Sandostatin*) to Prevent Pancreatitis Caused by Endoscopic Pancreato-Biliary Procedures: A Double-Blind, Randomized Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Peter McNalley, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastroent. (10) Associate Investigators: Stephen Freeman, COL, MC Scott Hallgren, MAJ, MC Michael Fisher, CPT, MC

(11) Key Words: pancreatitis octreotide

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if administration of octreotide will decrease the risk of pancreatitis associated with endoscopic pancreato-biliary procedures and facilitate ampullary cannulation by decreasing S.O.and small bowel motility.

(16) Technical Approach: Patients undergoing endoscopic pancreato-biliary procedures will be randomized to either a treatment or placebo group, given 5-6 hours pre- and then immediately post procedure. After each procedure the investigators will perform an abdominal exam and interview directed toward the presence or absence of pain. Cholangiopancreatography will be done by standard method.

(17) Progress: Currently undergoing interim data anlaysis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/125 (3) Status: Ongoing

(4) Title: SWOG 8697 Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF Versus Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation or Maintenance Therapy with CMF(P)TH or CMFH---Intergroup

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment method.

(17) Progress: Open to patient accural. No patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/126 (3) Status: Ongoing

(4) Title: SWOG 8710 Trial of Cystectomy Alone Versus Neoadjuvant M-VAC + Cystectomy in Patients with Locally Advanced Bladder Cancer, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accural.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/127 (3) Status: Ongoing

(4) Title: SWOG 8737 A Phase III Study, AZQ 24 Hour Infusion Versus BCNU for Adult High Grade Gliomas (Intergroup 0093)

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accural.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/128 (3) Status: Ongoing

(4) Title: SWOG 8750 Pilot Study to Examine Cytogenic Abnormalities in Patients with Acute Leukemia, Ancillary

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accural.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/129 (3) Status: Ongoing

(4) Title: SWOG 8814 A Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accural.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/130 (3) Status: Ongoing

(4) Title: SWOG 8899 A Prospective, Randomized Trial of Low-Dose Leucovorin + 5-FU, High-Dose Leucovorin + 5-FU, Levamisole +5-FU, or Low-Dose Leucovorin +5-FU + Levamisole Following Curative Resection in Selected Patients with Dukes' B or C Colon Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/131 (3) Status: Ongoing

(4) Title: VA Cooperative Study No. 316: Efficacy of Passive Immunization in the Prevention of Infection Due to Klebsiella Penumoniae and Psudomonas Aeruginosa

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: William Byrne, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Inf.Dis.Svc (10) Associate Investigators: Marion Kollef, MAJ, MC Phillip Mallory, MAJ, MC Thomas Cosgriff, COL, MC Robert Gates, LTC, MC Shannon Harrison, LTC, MC

(11) Key Words: IVIG

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if prophylactic administration of hyperimmune IVIG will prevent the acquisition of infection with those Klebsiella and P. aeruginosa serotypes included in the vaccine and that it will delay the onset and/or decrease the severity of infection in those patients who do become infected with these strains.

(16) Technical Approach: See protocol.

(17) Progress: Five patients enrolled, four survive, one expired due to cancer.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/132 (3) Status: Ongoing

(4) Title: Prevention and Treatment of Steroid Induced Osteoporosis

(5) Start Date: 1990 (6) Est Compl Date: 1994

(7) Principal Investigator:
Michael McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
John Merenich, MAJ, MC
William Georgitis, LTC, MC
James Singleton, MAJ, MC
Sterling West, LTC, MC
James Brown, COL, MC

(11) Key Words:
osteoporosis
steroids

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Prevention and treatment of steroid induced osteoporosis.

(16) Technical Approach: Randomized controlled prospective single blind evaluation of the efficacy of a coherence therapy regimen in the prevention and treatment of steroid induced osteoporosis.

(17) Progress: Patients are being studied with more undergoing enrollment.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/133 (3) Status: Ongoing

(4) Title: The Effect of Terfenadine on Urination

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Madhukar Punja, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc

(10) Associate Investigators:
Harry Spaulding, COL, MC
Brant Thrasher, CPT, MC
Craig Donatucci, MAJ, MC

(11) Key Words:
antihistamine
urodynamics

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if terfenadine alters the urinary pattern in normal, healthy men or in men with prostate hypertrophy.

(16) Technical Approach: Randomized crossover study with at least a one-week washout. Subjects will be skin tested prior to the initiation of the drug, after 72 hours, and after one week of treatment. Following skin testing, the urinary flow rate will be measured with a Lifetech flowmeter. Total urine volume voided, micturation time, peak or maximum flow rate and corrected maximum flow rate will be measured.

(17) Progress: Seldane did not have any appreciable effects on urinary function. Phase I has been completed. Phase II will be beginning shortly at which time the subjects BPH (prostatic hypertrophy) will be studied on Seldane. This, hopefully, will take less than six months to complete this phase and then an entirely new protocol along these line will be requested.

Publications and Presentations: American Academy of Allergy & Immunology, San Francisco, Ca, Presented March 1991. Aspen Allergy Meeting, July 1991, Presented.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/134 (3) Status: Ongoing

(4) Title: Fibrinolytic and Thrombotic Activity in Unstable Coronary Disease

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator:
Mark Dorogy, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Cardiology

(10) Associate Investigators:
Christopher Kozlowski,CPT,MC
Thomas Cosgriff, COL, MC
bohdan Kudryk, Ph.D.

(11) Key Words:
fibrinopeptide anlaysis
coronary disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date: 28
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the relative contributions of thrombosis and fibrinolysis in the development of acute myocardial infarction and unstable angina.

(16) Technical Approach: Specific markers of thrombosis and fibrinolysis will be studied. These markers are the fibrinopeptide A, and two other fibrinopeptides known as B-beta-1-42 and B-beta-15-42.

(17) Progress: Twenty eight patients enrolled. Collection technique being refined after analysis of first 18 patients.

Publications and Presentations: Being presented at the Army ACP meeting October 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/135 (3) Status: Ongoing

(4) Title: Comparison of Liver Biopsy Versus Noninvasive Testing Using Hepatic Ultrasound, Radionuclide Scanning, Erythrocyte Folate Levels and Methotrexate Levels for the Determination of Methotrexate-Induced Hepatotoxicity

(5) Start Date: 1990 (6) Est Compl Date: 1997

(7) Principal Investigator: Stephen Freeman, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastro (10) Associate Investigators: Jeffrey Dunkelberg, MAJ, MC

(11) Key Words:
methotrexate
hepatotoxicity

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To correlate the findings at the time of liver biopsy with blood tests as well as images of the liver obtained by ultrasound and nuclear imaging of the effect of methotrexate on the liver.

(16) Technical Approach: See protocol.

(17) Progress: Subjects are being enrolled in the study. It will be several years to accumulate sufficient data. New associate investigators will join the study when the new Fellows arrive.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/136 (3) Status: Ongoing

(4) Title: SWOG 8921 A Phase II Trial of Cyclophosphamide/IL-2, DTIC/IL-2 and DTIC/Cisplatin/Tamoxifen in Stage IV Melanoma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accural.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/137 (3) Status: Completed

(4) Title: SWOG 8312 Megestrol Acetate and Aminoglutethimide/ Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Closed.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/138 (3) Status: Ongoing

(4) Title: SWOG 8520 Cis-Diamminedichloroplatinum (II), Methotrexate and Bleomycin in the Treatment of Advanced Epidermoid Carcinoma of the Penis, Phase II

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accural.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/139 (3) Status: Ongoing

(4) Title: SWOG 8621 Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast Cancer, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accural.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/140 (3) Status: Ongoing

(4) Title: SWOG 8692 Therapy in Premenopausal Women with Advanced ER Positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs the LH-RH Analog, Zoladex. Phase III Intergroup

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/141 (3) Status: Ongoing

(4) Title: SWOG 8711 A Study of Reproductive Function in Patients with Testicular Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/142 (3) Status: Ongoing

(4) Title: SWOG 8736 Treatment of Localized Non-Hodgkin's Lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy Plus Radiation Therapy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/143 (3) Status: Ongoing

(4) Title: SWOG 8793 Randomized Phase III Evaluation of Hormonal Therapy Vs Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient enrollment.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/144 (3) Status: Ongoing

(4) Title: SWOG 8794 Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/145 (3) Status: Completed

(4) Title: SWOG 8806 A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Advanced Bladder Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/146 (3) Status: Ongoing

(4) Title: SWOG 8809 A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/147 (3) Status: Ongoing

(4) Title: SWOG 8819 Central Lymphoma Repository Tissue Procurement Protocol

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/148 (3) Status: Ongoing

(4) Title: SWOG 8836 A Study of Chest Irradiation Plus Concurrent Daily Low-Dose Cisplatin Followed by HIgh Dose Consolidation for Locally Advanced Non-Small Cell Lung Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/149 (3) Status: Completed

(4) Title: SWOG 8896 Intergroup Phase III Protocol for Surgical Adjuvant Therapy of Rectal Carcinoma: A Controlled Evaluation of (A), Protracted Infusion of 5-Fluorouracil as a Radiation Enhancer and (B), 5-Fluorouracil Plus Methyl-CCNU Chemotherapy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Closed for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/150 (3) Status: Ongoing

(4) Title: SWOG 8905 Phase II/III Study of Fluorouracil (5-FU) and Its Modulation in Advanced Colorectal Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/151 (3) Status: Ongoing

(4) Title: Extrinsic Positive End-Expiratory Pressure (PEEP) Effects on Functional Residual Capacity in Normal Subjects and in Ventilated Patients Experiencing Air Trapping (AUTO-PEEP)

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: James Mayer, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pul.Dis.Svc. (10) Associate Investigators: Marin Kolef, MAJ, MC Phillip Mallory, MAJ, MC Robert Browning, BS, DAC Douglas Dothager, CPT, MC

(11) Key Words: lung volume

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine lung volume changes when air-pressure is added through a ventilator in patients with lung disease on ventilators.

(16) Technical Approach: Ventilated subjects will be placed in an "iron lung" which will be used to mearure lung volumes and changes in lung volumes. Computer hookup to subject will allow measurement of lung volume changes. Air pressure will be added to the ventilator a little at a time and any change in lung volumes will be measured. Blood pressure and heart rate will also be monitored.

(17) Progress: Funding for protocol was approved by U.S. Army Medical R&D Command in March 1991. Currently, an iron lung and computer hardware/software are being purchased. These items are necessary prior to patient enrollment in the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/152 (3) Status: Ongoing

(4) Title: Residual Renal Function in Dialysis Patients

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology

(10) Associate Investigators:
Barbara Hasbargen, RN, BSN
Peter Blue, COL, MC

(11) Key Words:
dialysis
renal function

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___3_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The principal objective of the study is to elucidate the relationship between modality of dialysis and residual renal function.

(16) Technical Approach: Fifteen patients who are on hemodialysis and 15 patients who are on CAPD and approximately 6 patients that will change from one modality to the other will be studied using blood samples and renal scans.

(17) Progress: Patients are currently being enrolled on this study which was approved in August 1990.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/153 (3) Status: Ongoing

(4) Title: Relationship of Calcium and Glucose Metabolism on Blood Pressure

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology (10) Associate Investigators: Joseph White, MAJ, MS

(11) Key Words:
hypertension
calcium
glucose

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To allow for a more rational approach to antihypertensive therapy.

(16) Technical Approach: Evaluate the subgroups of essential hypertensives with respect to calcium/PTH axis, vs glucose/insulin axis, vs Na/renin axis. Specifically to evaluate the relationships of Ca/PTH and the potential role of diminished insulin release and hyperglycemia in essential hypertensives.

(17) Progress: Patients are currently being enrolled in this study which was approved in August 1990.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/154 (3) Status: Ongoing

(4) Title: SWOG 8326 Evaluation of Combination Chemotherapy Using High Dose Ara-C inAdult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/155 (3) Status: Ongoing

(4) Title: SWOG 8810 Six Courses of 5-Gluorouracil and Cis-Platinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck, Phase II Pilot Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc:MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/156 (3) Status: Ongoing

(4) Title: SWOG 8812 Treatment of Limited Small Cell Lung Cancer with Concurrent Chemotherapy, Radiotherapy, with or without GM-CSF and Subsequent Randomization to Maintenance Interferon or No Maintenance

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To particpate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient randomized to GM-CSF developed severe orthostatic hypotension and thrombocytopenia. GM-CSF stopped.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/157 (3) Status: Ongoing

(4) Title: SWOG 8828 A Phase II Trial of Carboplatin (CBDCA) in Relapsed or Refractory Acute Myeloid Leukemia

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/158 (3) Status: Ongoing

(4) Title: SWOG 8851 A Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Zoladex and Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/159 (3) Status: Ongoing

(4) Title: SWOG 8892 A Study of Radiotherapy with or without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/160 (3) Status: Ongoing

(4) Title: SWOG 8897 Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients and a Natural History Follow-up Study in Low-Risk, Node Negative Patients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/161 (3) Status: Ongoing

(4) Title: SWOG 8910 Evaluation of Low Dose Continuous 5-Fluorouracil (5-FU) and Weekly Cisplatinum (CDDP) in Advanced Adenocarcinoma of the Stomach, Phase II Pilot

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/162 (3) Status: Ongoing

(4) Title: SWOG 8915 A Phase II Study of 6-Thioguanine Administered as 120 Hour Continuous Infusion for Refractory or Recurrent Small Cell Carcinoma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/163 (3) Status: Ongoing

(4) Title: SWOG 8916 Evaluation of Merbarone in Pancreatic Adenocarcinoma, Phase II

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/164 (3) Status: Ongoing

(4) Title: SWOG 8952 Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study Comparing ABVD vs MOPP/ABV Hybrid

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/165 (3) Status: Ongoing

(4) Title: SWOG 8997 A Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer withCisplatin Plus Etoposide with Either Bleomycin or Ifosfamide

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/166A (3) Status: Ongoing

(4) Title: Evaluation of Allergenic Cross-Reactivity Amongst Cockroach Species

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: David Goodman, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators: T. Ray Vaughan, MAJ, MC; Anthony Henry, LTC, MC; Robert Ledoux, BS, DAC; Richard W. Weber, COL, MC; Duane J. Harris, LCDR, MC, USN

(11) Key Words: cross-reactivity

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 9
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the incidence of clinical hypersensitivity to cockroach, common insects, and mites in an atopic disease population; to determine if there is significant cross-reactivity among the five common cockroach pests in North America; to determine cross-reactivity among cockroach, other common indoor insect pests and mite antigens.

(16) Technical Approach: Animal models will be used to develop antisera specific for cockroach and other insect species under investigation in this protocol. Prior to skin testing blood will be drawn for immunochemical analysis. Subjects will then be skin tested.

(17) Progress: a. Antisera production: Rabbit antisera production with each of the 5 cockroach species has been accomplished. Preliminary studies with ELISA demonstrate potentially significant cross-reactivity between American, Oriental, and Smokey-Brown cockroach species, and surprisingly weak German cockroach reactivity.

It is anticipated that an additional 5-10 rabbits will be required at some point during the next four months, in order to further evaluate German cockroach allergenicity and to evaluate our extraction technique for that species.

b. Immunoblot studies: Techniques for protein separation of each cockroach species have been refined, and presently we are producing mass quantities of SDS-PAGE gels and nitrocellulose immunoblots to be subsequently used in our serological studies.

c. Patients: Nine patients have been recruited, and have undergone blood testing and skin testing with no adverse sequelae. Skin test data is too preliminary to assess statistically, but grossly appears to corroborate the aforementioned ELISA results.

Presentations:

a. 1991 ACAI meeting: Skin-test correlation data.
b. 1992 AAAI meeting. Immunochemical correlates.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/167A (3) Status: Completed

(4) Title: Animal Model of Physiologic PEEP (Positive End-Expiratory Pressure)

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Marin Kollef, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pul.Dis.Svc. (10) Associate Investigators:

(11) Key Words:
positive end-expiratory pressure

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine that physiologic PEEP does exist and that its removal will cause a decrease in lung volume, worsening gass exchange, and decrease in end-expiratory pressures of the trachea.

(16) Technical Approach: A prospective animal model will be used to evaluate the above stated hypothesis.

(17) Progress: Animal studies completed. Currently writing a paper on results.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/168A (3) Status: Ongoing

(4) Title: A Histologic and Immunopathologic Study of the Skin and Internal Organs of MRL+/+Mice

(5) Start Date: (6) Est Compl Date: 1991

(7) Principal Investigator:
Kathleen David, MAJ, MC

(8) Facility: FAMC
VA Hospital , Denver

(9) Dept/Svc: MED/Dermatology

(10) Associate Investigators:
Cheryl Teuton, CPT
Lele Lee, MD
Thomas Santoro, MD
Pat Skavlen, DVM

(11) Key Words:
lupus erythematosus

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 14
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: We predict that the MRL-+/+ mice will have pathologic findings similar to those reported in MRL/lpr mice, but will develop these findings in a more delayed manner. Further, we predict that the lpr gene is not a prerequisite for autoimmune disease in the MRL mouse.

(16) Technical Approach: This autopsy study will involve 10 animals in each age group studied, 4,16,32,40,48 and 60 weeks or approximately 60-100 animals. Blood will be obtained, and various internal organs removed for pathologic studies. We will compare out findings with those reported for MRL/lpr mice and with findings reported in humans with lupus.

(17) Progress: A smaller number of MRL-+/+ mice than originally planned are being evaluated due to the unexpected permanent move of one of the co-investigators, Dr. Thomas Santoro, to the NIH. He owned the mice and moved the entire colony. However, the following mice were sacrificed prior to the move and are being studied: 2 mice at 46 weeks, 2 mice at 42 weeks, 4 mice at 34 weeks, 4 mice at 22 weeks, and 2 mice at 6 weeks of age. Lesional and non-lesional skin, as well as kidney, liver, spleen, heart, brain and lymph nodes were harvested from each mouse.

Another complication arose due to the move of Dr. Santoro. He was supplying the monoclonal antibodies to be used for typing the cells in the inflammatory cell infiltrates. Following his move, he was unable to supply these for the study. These reagents were requested through he DCI, with 3 received already, and the remainder to be received when funds are available.

The tissues have been processed for routine histology, and are currently being examined by Dr. Teuton, pathologist. Specific histopathologic results are still pending.

Publications and Presentations:

David KM, Davis DA, Santoro JT, Lee LA: Antibody deposition is not critical for the development of skin disease in the MRL -+/+ mouse. J Invest Dermatol 96:533, 1991.

David KM, Davis DA, Santoro TJ, Lee LA: Antibody deposition is not critical for the development of skin disease in the MRL-+/_ mouse. Presented: Annual meeting of the Society for Investigative Dermatology, Seattle, WA, 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/169 (3) Status: Ongoing

(4) Title: The Effect of Steroid Therapy on Recovery After Tonsillectomy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Glen Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Otolaryn. (10) Associate Investigators:

(11) Key Words:
steroids
tonsillectomy
anti-inflammatory

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP... b. Review Results: _____ c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate the effectiveness of steroids to reduce the incidence and severity of postoperative symptoms and complications in patients undergoing tonsillectomy.

(16) Technical Approach: Twenty adult subjects will be randomized to receive either steroid or placebo intravenously at the time of surgery. A total of three doses will be given every 6 hrs. Patients will be asked to answer questions pertaining to their postoperative course at 24 hrs, 2 weeks and 2 months.

(17) Progress: No progress, PI was "backfill" for Desert Storm.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/170 (3) Status: Completed

(4) Title: SWOG 8744 A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Refractory Multiple Myeloma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/171 (3) Status: Ongoing

(4) Title: SWOG 8789 A Randomized Study of Etoposide plus Cisplatin and Etoposide Plus Carboplatin (CBDCA) in the Management of Good Risk Patients with Advanced Germ Cell Tumors

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the SWOG group protocols.

(16) Technical Approach: To determine the most effective approach for cancer patients.

(17) Progress: Open for patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/172 (3) Status: Ongoing

(4) Title: SWOG 8792 A Phase III Study of Alfa-nl (Wellferon) as Adjuvant Treatment for Resectable Renal Cell Carcinoma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/173 (3) Status: Ongoing

(4) Title: SWOG 8842 Dihydroxyazacytidine in Malignant Mesothelioma, Phase II

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Patient progressed on treatment. Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/174 (3) Status: Ongoing

(4) Title: SWOG 8900 A Phase II Pilot of VAD and VAD/Verapamil for Refractory Multiple Myeloma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/175 (3) Status: Ongoing

(4) Title: SWOG 8931 Phase III Comparison of Cyclophoasphamide, Doxorubicin and 5-Fluorouracil (CAF) and a 16-Week Multi-drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node-Postiive Breaset Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc:MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/176 (3) Status: Ongoing

(4) Title: SWOG 8994 Evaluation of Quality of Life in Patients with Stage C Adenocarcinoma of the Prostate Enrolled on SWOG 8794

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/177 (3) Status: Ongoing

(4) Title: National Co-operative rHu Erythropoietin Study in Patients with Chronic Renal Failure: A Phase IV Multi-center Study

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology (10) Associate Investigators:

(11) Key Words:
renal failure
erythropoietin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 9
d. Total Number of Subjects Enrolled to Date: 9
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Expand the safety profile of erythropoietin in anemic patients with chronic failure. To understand the medical and social impact of erythropoietin therapy on the United States chronic renal failure population, including patients currently receiving erythropoietin and patients receiving therapy for the first time.

(16) Technical Approach: Active study of patients currently receiving or starting on erythropoietin.

(17) Progress: Data not yet analyzed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/178 (3) Status: Terminated

(4) Title: The Efficacy and Safety of Orally Administered SQ 32,756 in the Treatment of Acute, Localized Non-Trigemental Zoster in Immunocompetent Patients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: No work was started on this study, protocol terminated.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/179 (3) Status: Ongoing

(4) Title: A Randomized Prospective Study of Pyrimethamine Therapy for Prevention of Toxoplasmic Encephalitis in HIV-Infected Individuals with Serologic Evidence of Latent Toxoplasma gondii Infection (CPCRA 001).

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Robert Gates, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Inf.Dis.Svc. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___2_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate clindamycin and pyrimethamine as prophylactic agents against toxoplasmic encephalitis in individuals who are coinfected with HIV and latent t. gondii.

(16) Technical Approach: Multicenter, prospective, 2-arm, placebo-controlled pyrimethamine, placebo for pyrimethamine) randomized, modified double-blind study.

(17) Progress: None - both subjects doing well.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/100 (3) Status: Ongoing

(4) Title: SWOG 8515 - Evaluation of Menogaril (NSC-269148) in Non-Hodgkin's Lymphoma, Phase II.

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: OCT b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/101 (3) Status: Ongoing

(4) Title: SWOG 8721 - A Phase II Trial of Trimetrexate in the Treatment of Esophageal Cancer.

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: OCT b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/102 (3) Status: Ongoing

(4) Title: SWOG 8894 - A Comparison of Bilateral Orchiectomy with or without Flutamide for the Treatment of Patients with Histologically Confirmed State D_2 Prostate Cancer

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: OCT b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/103 (3) Status: Ongoing

(4) Title: SWOG 8906 - Evaluation of Merbarone in Hepatoma, Phase II

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: OCT b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patient enrolled at FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/104 (3) Status: Ongoing

(4) Title: SWOG 8925 - Evaluation of Cisplatin + VP-16 Followed by Mitotane at Progression if No Prior Mitotane OR Cisplatin + VP-16 Only if Prior Treatment with Mitotane in Advanced and Metastatic Adrenal Cortical Carcinoma

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/105 (3) Status: Completed

(4) Title: Endocrine Responses to Critical Illness as Predictors of Outcomes

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Mark Jarek, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:
hormone measurements
endocrine dysfunction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 50
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Hormone measurements in critically ill patients may identify patients with endocrine dysfunction prior to onset of clinical manifestations. Analysis of hormone levels may provide values or tends which are predictors of ultimate outcome. In patients with endocrine dysfunction, hormonal supplementation may improve outcome.

(16) Technical Approach: Assess endocrine function in critically ill patients using serial endocrine laboratory panels measured on and after admission to the MICU, SIU, and CCU. Endocrine function will be compared to APACHE II scores and to ultimate outcome.

(17) Progress: Fifty patients were enrolled and completed the study. The data is now being collected and analyzed and if findings suggest reliable predictors of outcome, the study will be submitted for publication and presentation at a later date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/106 (3) Status: Ongoing

(4) Title: A Randomized, Controlled Trial of Interferon Alpha and Thymosin Alpha-1 in Patients with Hepatitis C Antibody Positive Chronic Active Hepatitis

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator: Kenneth Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gastroenterology (10) Associate Investigators: Stephen Freeman, COL, MC; Zachary Goodman, MD, PhD; Kamal Ishak, MD, PhD

(11) Key Words: hepatitis; interferon alpha; thymosin alpha-1; IND

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Demonstrate efficacy of recombinant interferon alpha 2b among military personnel and those eligible for care under the auspices of DOD for treatment of chronic hepatitis C. Attempt to augment the response to interferon using Thymosin alpha-1 as in a immunomodulator.

(16) Technical Approach: Randomized, three-arm study: 1) treatment with interferon alpha + placebo; 2) interferon alpha + thymosin alpha-1; and 3) placebo (controls). Six-month study cycles with 40 adult chronic hepatitis C patients per arm.

(17) Progress: The start of this investigation new drug protocol was delayed 10 months after IRC approval by HSC approval (Feb 91) and FDA approval (Aug (1). The first patient was enrolled in Aug 91. To date three patients have been enrolled and four more should start within the next several weeks. Recruitment efforts have been made in DOD Region III Medical Treatment facilities and future contact with other potential referral sites is planned.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/107 (3) Status: Ongoing

(4) Title: Does Omeprazole (Losec*) Improve Respiratory Function in Asthma Patients with Gastroesophageal Reflux? A Double-Blind, Crossover Study

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: John Meier, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Gastroenterology (10) Associate Investigators: Harry Spaulding, COL, MC; Madhukar Punja, MAJ, MC; Michael Perry, COL, MC; Nancy Stocker, Phar. D.; Michael Fisher, MAJ, MC; Stephen Freeman, COL, MC; Peter McNally, MAJ, MC

(11) Key Words: GI reflux; omeprazole; asthma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 20 (10 randomized)
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to determine whether asthmatic patients with GER will experience improved respiratory function when GER is treated with omeprazole.

(16) Technical Approach: Patients will be randomized to drug or placebo and evaluated by a number of tests to include gastrointestinal investigation to evaluate for GER, intermittent pulmonary function testing, blood tests, esophageal manometry, Bernstein test, 24=hr. esophageal pH monitoring and EGD.

(17) Progress: Adequate. Ten patients randomized of the 20 enrolled. Two had moderate asthma exacerbations (not hospitalized). One patient died in the placebo group, but this did not appear related to therapy.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/108 (3) Status: Ongoing

(4) Title: A Comparison of the Efficacy of Superpotent Topical Steroids Versus Intralesional Steroids in the Treatment of Discoid Lupus Erythematosus

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
Scott Bennion, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Dermatology

(10) Associate Investigators:
Kathleen David, MAJ, MC
James Fitzpatrick, LTC, MC
Pamela Homas, CPT, MC
Brenda Kodama, CPT, MC
Charlotte Kutsch, MD

(11) Key Words:
discoid lupus erythematosus
superpotent topical steroids
intralesional steroids

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of the study is to compare the efficacy of ultra-potent topical steroids versus intradermal injection of steroids in the treatment of DLE lesions.

(16) Technical Approach: Evaluators will be blinded. Patients will be randomized to either entire body group (which will be randomized to either topical or intradermal treatment) or half- and half- treatment group (which will be randomized to right-side or left-side body treatment injections).

(17) Progress: No progress. Although the protocol was approved by the FAMC IRC in Nov 90, the drug sponsor, GLAXO, is withholding the drug until approved by the FDA.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/109 (3) Status: Ongoing

(4) Title: SWOG 9037 - Prediction of Recurrence and Survival in Node-Negative Breast Cancer Patients Using a Panel of Prognostic Factors. A companion protocol to 8897

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/110 (3) Status: Ongoing

(4) Title: SWOG 8795 - Randomized Prospective Comparison of Bacillus Calmette-Guerrin and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder, with DNA Flow Cytometric Analysis, Phase III

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/111 (3) Status: Ongoing

(4) Title: SWOG 8834 - A Phase II Evaluation of Fazarabine in Central Nervous System Tumors

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/112 (3) Status: Ongoing

(4) Title: SWOG 8957 - Feasibility Trial of Post-Operative Radiotherapy + Cisplatin Followed by Three Courses of 5-FU + Cisplatin in Patients with Resected Head and Neck Cancer

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/113 (3) Status: Ongoing

(4) Title: The Effect of Recombinant Growth Hormone on Pulmonary Function in Patients with Chronic Obstructive Pulmonary Disease

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator:
Homer LeMar, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrinology

(10) Associate Investigators:
Michael McDermott, LTC, MC
Michael McCormack, CPT, MC
Marin Kollef, MAJ, MC
William Georgitis, LTC, MC
John Merenich, MAJ, MC
Michael Perry, COL, MC
Edwin Fortenbery, MAJ, MC
Nancy Pfander, MAJ, AN
Donna Dolan, CPT, RD

(11) Key Words:
growth hormone
COPD
investigational new drug

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 9
d. Total Number of Subjects Enrolled to Date: 9
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" No adverse reactions

(15) Study Objective: To test the effect of recombinant growth hormone on breathing ability.

(16) Technical Approach: Randomized, prospective, double-blind, placebo-controlled design using recombinant human growth hormone or sterile saline placebo in patients with severe chronic obstructive pulmonary disease currently under follow-up in the Pulmonary Clinic at FAMC. Patients will be treated for one year. Pre- and post course measurements such as hand grip strength,pulmonary function, tests of endurance, bone density, lean body mass and laboratory tests, will be taken and compared.

(17) Progress: Nine patients recruited and six have now started treatment (growth hormone or placebo). Recruitment continues.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/114 (3) Status: Ongoing

(4) Title: Detection of Renal Artery Stenosis by Noninvasive Testing

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nephrology

(10) Associate Investigators:
James Luethke, MAJ, MC
Edwin Fortenbery, MAJ, MC
Allan Chantelois, MAJ, MC

(11) Key Words:
renal artery stenosis
captopril
enalaprilat
renogram

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the specificity and sensitivity of Captopril challenge, Captopril renogram, Enalaprilat renogram, and duplex ultrasonography in the diagnosis of RAS compared to the standard arteriography.

(16) Technical Approach: All patients studies will undergo captopril challenge, captopril renogram, enalaprilat renogram, duplex ultrasonography and renal arteriogram. Power analysis will be conducted to determine requirements for total number of patients after first 20 enrolled.

(17) Progress: Patient enrollment slower than anticipated. Data collection only to this point.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/115 (3) Status: Ongoing

(4) Title: Prediction of Maximum Exercise Ventilation by Identification of Optimal Reciprocal Spirometric Timed Volumes

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator: J. Turner, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Disease (10) Associate Investigators: Robert Browning, BS, DAC Michael Perry, COL, MC

(11) Key Words: l u n g v o l u m e

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To improve the prediction of maximum exercise ventilation during incremental exercise testing.

(16) Technical Approach: Twenty normal and forty COPD subjects will perform maximal inspiratory and expiratory vital capacity maneuver on a standard water-seal spirometer while a computer collects volume-time data. Computer iteration will yield theoretical optimal reciprocal spirometric times volumes. Patients will then perform standard incremental exercise studies, and the ventilation parameters observed at maximum exercise will be compared with the spirometrically derived predictions.

(17) Progress: Spirometry and exercise study data has been collected from 25 subjects; 9 normals and 16 abnormals (people with flow data consistent with OAD). The raw data from these studies is currently under review, with he study continuing.

Publications and Presentations:

Poster Presentation: ALA/ATS 1991 International Conference, Anaheim, Ca, May 1991.

Turner J, Perry ME, Browning RJ: Publication: ARRS:1432, no 4, April 1991 (A169).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/116 (3) Status: Ongoing

(4) Title: SWOG 9038 - Extended Administration of Oral Etoposide and Cyclophosphamide for the Treatment of Advanced Non-Small Cell Lung Cancer

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/117 (3) Status: Completed

(4) Title: Influences of Neostigmine on Ultrafiltration and Solute Clearances in Peritoneal Dialysis

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nephrology

(10) Associate Investigators:
Barbara Hasbargen, RN, DAC
Edwin Fortenbery, MAJ, MC

(11) Key Words:
peritoneal dialysis
neostigmine

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objectives: To assess difference in ultrafiltration and solute clearance with and without intraperitoneal neostigmine.

(16) Technical Approach: Eight patients with CAPD will be randomized to PET with 5.0mg of intraperitoneal neostigmine or PET without neostigmine. A small amount of radioactive tracer will be added to the peritoneal dialysate for nuclear scan. Patients will be crossed over and study repeated within two months.

(17) Progress: Completed.

Publications and Presentations:
Presented: National Kidney Foundation Annual Meeting, November 1991, and U.S. Army Meeting Region, ACP October 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/118 (3) Status: Ongoing

(4) Title: SWOG 9013 - A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery versus Surgery Alone for Patients with Local Regional Disease, Phase III

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative *MEDCASE:** (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/119 (3) Status: Ongoing

(4) Title: SWOG 9039 - Evaluation of Quality of Life in Patients with Stage D-2 Cancer of the Prostate Enrolled in SWOG 8894

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/120 (3) Status: Ongoing

(4) Title: What is the Prevalence of Gastroesophageal Reflux in Patients with Sleep Apnea - A Prospective Evaluation

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator:
Robert Sudduth, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:
Michael Perry, COL, MC
David Everett, E-6, RPSGT-CPFT
Shannon Harrison, LTC, MC
Peter McNally, MAJ, MC

(11) Key Words:
gastroesophageal reflux
sleep apnea

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prospectively determine the prevalence of GER in adults with the sleep apnea syndrome.

(16) Technical Approach: Polysomnography will be performed in the usual fashion with monitoring of the following variables: EEG, electrooculogram, nasal air-flow monitor, oxygen saturation and respiratory effort. Probe will be placed to monitor esophageal pH and intra-esophageal pressure. Esophageal pH data will be graphically analyzed and compared to polysomnographic events, specially examining for correlation between acid reflux and episodes of apnea.

(17) Progress: Protocol is ongoing, though there was a major delay due to equipment problems which are to be shortly resolved.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/121A (3) Status: Ongoing

(4) Title: The Effect of Low-Dose Methotrexate on Calcium, Vitamin D and bone Metabolism in Female Sprague-Dawley Rats.

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator:
Kimberly May, CPT, MC, USAF

(8) Facility: FAMC

(9) Dept/Svc: Rheumatology

(10) Associate Investigators:
Daniel Battafarano, MAJ, MC
Sterling West, LTC, MC
Michael McDermott, LTC, MC
Edward Fortenbery, MAJ, MC

(11) Key Words:
methotrexate
bone metabolism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____63_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objectives of the study are to determine the effect of low dose methotrexate administration on calcium and vitamin D metabolism, and bone mineral content in rats.

(16) Technical Approach: Per protocol approved by LACUC on 15 Jan 91.

(17) Progress: Due to technical problems, no recent progress. a) Dosing studies (18) were completed in May. b) Study began in July and would have been completed by 31 Oct 91. However, the thermostat in the rat hold area malfunctioned 28-29 Oct 91. All rats were heat stressed with 3 deaths. The PI, Dr. Banks, the AIs and the LACUC are currently deciding: 1) whether the study should continue as planned with short extension; 2) whether another study group (small) should be looked at; 3) whether the project should start over which would require 40 more rats.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/122 (3) Status: Ongoing

(4) Title: A Multicenter, Double-Blind Study to Evaluate the Safety and Therapeutic Efficacy of Omeprazole 20mg A.M. or 10mg A.M. as Compated to Placebo During 12 Months Maintenance Treatment of Patients with Duodenal Ulcer Healing Following 4 Weeks of Omeprazole 20mg A.M.

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Peter McNally, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gastroenterology (10) Associate Investigators: John Meier, MAJ, MC; Robert Sudduth, MAJ, MC; Nancy Stocker, Pharm.D.; Stephen Freeman, COL, MC

(11) Key Words: omeprazole; duodenal ulcer; investigational new drug

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this investigational new drug study is to determine if patients identified to have a duodenal ulcer that is healed with omeprazole can be prevented from experiencing an ulcer relapse when given on of two dosages or concentrations of this medicine when compared to a placebo.

(16) Technical Approach: After endoscopy verifies ulcer healing with omeprazole, patients will be randomized to receive either maintenance treatment with omeprazole (10 mg or 20 mg each morning) or placebo. Laboratory tests and EGD will be performed.

(17) Progress: Study will be extended to 2 years of maintenance treatment for subjects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/123 (3) Status: Ongoing

(4) Title: Relative Efficacy of Three Oxygen Delivery Systems in the Nocturnal Home Setting

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Scott Sample, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Disease (10) Associate Investigators: Michael Perry, CCL, MC

(11) Key Words: hypoxemic lung disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine which of three standard modes of oxygen delivery are the most efficacious in an ambulatory setting using nocturnal pulse oximetry as a measure of efficacy.

(16) Technical Approach: To compare the efficacy of transtracheal oxygen therapy, nasal cannula and reservoir pendant oxygen systems in an ambulatory setting using nocturnal pulse oximetry recorders in patients on home oxygen therapy.

(17) Progress: Seven patients have completed the study. Three or four patients are followed on a weekly basis. Total of 15 subjects will be enrolled. Study should be completed within one year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/124 (3) Status: Ongoing

(4) Title: A Controlled, Randomized, Open Pilot Study to Investigate the Effects of Intra-arterial (or Intravenous) Atrial Natriuretic Peptide in the Treatment of Acute Renal Failure

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology (10) Associate Investigators: James Luethke, MAJ, MC

(11) Key Words:
investigational new drug
Gallopamil
atrial natriuretic peptide

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This study should serve as a preliminary investigation as to whether two medications can reverse kidney failure and whether giving the medications directly into the arteries to the kidneys will be practical.

(16) Technical Approach: Prospective study of effectiveness of atrial natriuretic factor versus Gallopamil in the treatment of acute renal failure. The medications will be given via the renal artery. Study recently amended for intravenous use.

(17) Progress: Gallopamil discontinued secondary to principal investigator's request. Also protocol was amended to use the intravenous formulation, and in fact 3/4 subjects used the IV form.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/125 (3) Status: Ongoing

(4) Title: An Ultrastructural Study of the Dermal-Epidermal Junction Following Skin Splitting with Various Methods

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator: Kathleen David-Bahar, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Dermatology (10) Associate Investigators: Scott Bennion, LTC, MC Rodney Williams, SPC

(11) Key Words: skin splitting

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Feb b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate a reproducible site of separation, routine use of such "split skin" methods that will become the standard for the indirect immunofluorescence evaluation of bullous skin disorders.

(16) Technical Approach: Specimens of discarded human adult skin and neonatal foreskin will be subjected to dermal-epidermal separation using each of three methods: NaCl, EDTA, and dispase. Each specimen will then be processed for electron microscopy, after incubation in specific monoclonal antibodies to known anatomic components of the dermal-epidermal junction. Two investigators independently evaluate and be blinded to the source of the specimens in making their assessments.

(17) Progress:Successful splitting of the skin has been accomplished with both the NaCl and the EDTA methods. This splitting has been evaluated with routine hematoxylin and eosin staining on the light microscopy level, demonstrating the split is occurring in the area of the basement membrane zone. We have had numerous difficulties in the methodology of our immunogold technique for mapping the split with monoclonal antibodies. Extensive technical trials and alterations have been tried. We have not yet had success in immunogold staining with our monoclonal antibodies to the basement membrane zone components, however, we have demonstrated staining using immunofluorescence techniques.

With anti-laminin antibodies, the staining has appeared on the epidermal side of the split skin,a nd with anti-BG-3 antibodies, we have shown consistent staining on the dermal side of the split. Thus, we believe that the relevant antigens are preserved in our splitting techniques, and that technical problems are the likely reason for our lack of staining with immunogold techniques. We are pursuing the technical difficulties at this time.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/126 (3) Status: Ongoing

(4) Title: Efficacy of Oral Cromolyn Sodium in Documented Adverse Food Reactions, A Double-Blind Placebo-Controlled Trial with Food Challenges

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
Evan Matheson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Allergy

(10) Associate Investigators:
Anthony Henry, LTC, MC
T. Ray Vaughan, MAJ, MC
Bryan Martin, MAJ, MC

(11) Key Words:
food reactions
cromolyn sodium

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the efficacy of oral cromolyn sodium in patients with documented adverse food reactions.

(16) Technical Approach: Food skin testing and breathing tests will be done followed by food challenges, using placebo or real food, to document subject's reaction. Subjects will be randomized to placebo or drug. After 10 days the subjects will be re-challenged in a double-blind fashion. After a two-week washout, subjects will be crossed over and the challenges repeated after 10 days.

(17) Progress: Four patients screened, two qualified and entered into the study. No adverse reactions. The actual start date of this study was delayed until 9/91.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/127 (3) Status: Ongoing

(4) Title: Effectiveness of Simethicone to Improve Visibility During Colonoscopy When Given with a Peroral FLEET Diphosphate Laxative: A Double-Blind Randomized Placebo Controlled S t u d y

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Robert Sudduth, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gastroenterology (10) Associate Investigators: Nancy Stocker-Stolpman, PharmD Peter McNally, MAJ, MC

(11) Key Words: colonoscopy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Feb b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prospectively determine if the co-administration of simethicone with Fleet per oral bowel pre can improve preparation for colonoscopy.

(16) Technical Approach: The subject population (220) will be randomized to Fleet with simethicone or to Fleet with placebo. During colonoscopy the investigators will use a scoring system to evaluate the number of bubbles and visibility while examining five areas of the colon.

(17) Progress: Going fairly well with 40 patients studied - may need until Spring 92 to complete.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/128 (3) Status: Completed

(4) Title: A Randomized, Open-Label, Comparative Trial of Dideoxyinosine (ddI) and Dideoxycytidine (ddC) in HIV Infected Patients who are Intolerant of or have Failed Zidovudine (ZDV) Therapy

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator:
Robert H. Gates, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Infectious Disease

(10) Associate Investigators:
W. Russell Byrne, LTC, MC
P. Bakker, MSN
R. Wright, MAJ, MC
S.M. Harrison, LTC, MC

(11) Key Words:
HIV
ddI/ddC
investigational new drugs

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate and compare the efficacy and toxicity associated with ddI and ddC in patients with HIV infection who are intolerant of or have failed Zidovudine therapy.

(16) Technical Approach: A 2-year, prospective, 2-arm, randomized, multicenter, comparative study. Switchover is optional once a primary endpoint has been met after 12 wk on the original drug assignment. Switchover may occur at any time once a drug intolerance endpoint has been met.

(17) Progress: No additional patients will be enrolled on this study. FDA approval to market ddI and ddC as prescription drugs is due 1 Nov, which precludes the need for this protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/129 (3) Status: Ongoing

(4) Title: SWOG 9046 - Evaluation of 10-EdAM in Patients with Squamous Cell Carcinoma of the Head and Neck, Phase II

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/130 (3) Status: Ongoing

(4) Title: MGI 136-07-P90-03: A Double-blind, Randomized, Placebo Controlled Study of Diethylidithiocarbamate (DDTC) Used as a Protective Agent Against Cisplatin-Induced Toxicities in Patients with Small Cell or Non-Small Cell Carcinoma

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:
DDTC
cisplatin-induced toxicities
lung cancer
investigational new drug

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to determine whether DDTC significantly reduces cisplatin-induced side effects in patients treated with cisplatin for small cell or non-small cell lung cancer.

(16) Technical Approach: Multi-center, investigational new drug protocol sponsored by Molecular Genetics, Incorporated. By double-blind randomization patients will be treated with either cisplatin and VP-16 plus DDTC or Cisplatin and VP-16 plus a placebo. It is estimated that approximately five eligible subjects will be enrolled at FAMC. treatment.

(17) Progress: No progress, no eligible patients seen to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/131 (3) Status: Ongoing

(4) Title: Survey of Aerobic Bacteria in Chenopod and Amaranth Pollens and Their Effects on Pollen Extracts Used for Desensitization in Allergic Disease

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Lawrence Larson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Allergy (10) Associate Investigators: Terese Copeland, MAJ, MC

T. Ray Vaughan, MAJ, MC
Leo Andron, LTC, MS
Pari Morse, DAC

(11) Key Words:
pollen extracts
aerobic bacteria

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Determine the following parameters: 1) Extent of aerobic bacteria present in Chenopod-Amaranth pollen with determination of different species and relative amounts. 2) The effects of aerobic bacteria on the amounts and kinds of protein obtained during the extraction of pollen will be assessed.

(16) Technical Approach: A number of highly technical laboratory procedures will be performed according to the plan of the protocol.

(17) Progress: Laboratory procedures completed on bacterial survey. Preliminary data has been submitted for presentation and publication.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/132 (3) Status: Ongoing

(4) Title: Amlodipine Cardiovascular Community Trial

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology (10) Associate Investigators:

(11) Key Words:
hypertension
Amlodipine
investigational new drug

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the effectiveness of Amlopidine in the treatment of essential hypertension (diastolic blood pressure 95-110 off medications).

(16) Technical Approach: The study will include a 2-3 week placebo run-in phase followed by a 4-week efficacy phase and a 12-week maintenance phase. At that time, the study may be terminated or the patient may be extended on long-term followup dependent upon the patient's desires.

(17) Progress: No one is currently enrolled.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/133 (3) Status: Ongoing

(4) Title: SWOG 9111 - (EST 1690) Post-Operative Adjuvant Interferon Alpha 2 in Resected High-Risk Primary and Regionally Metastatic Melanoma, Intergroup

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____ _____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/134 (3) Status: Ongoing

(4) Title: The Use of Cultured Skin Cells and Monoclonal Antibodies to Evaluate the Development and Function of Various Proteins in Keratinocytes and Other Epidermal and Dermal Cells

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
Scott Bennion, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Dermatology

(10) Associate Investigators:
James Fitzpatrick, LTC, MC
Loren Golitz, MD, UCHSC
Ron Jackson, CPT, MS
Don Mercill, DAC

(11) Key Words:
keratinocytes
monoclonal antibodies

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Through the use of cultured human epidermal cells this study will determine the specificity of monoclonal antibodies for certain skin protein antigens implicated in skin tumors and whether the expression of these antigens changes with alterations in the celll culture environment such as density of cells and exposure to UV light.

(16) Technical Approach: This study involves a number of highly technical laboratory procedures as outlined in the protocol.

(17) Progress: Study recently started. Keratinocytes are currenlty growing.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/135A (3) Status: Ongoing

(4) Title: Induction of Clinical Lesions in XID/Beige/Nude Mice Using Various Factors

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Dermatology (10) Associate Investigators: Lela Lee, MD, UCHSC Ronald Jackson, PhD Donald Mercill, DAC

(11) Key Words: lupus erythematosus

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To develop a working animal model of subcutaneous lupus erythematosus; to induce clinical and histological lesions of SCLE in the beige/nude/XID mouse; to characterize the lesions produced histologically and immunologically.

(16) Technical Approach: Per protocol approved by LACUC 18 Jul 91.

(17) Progress: Forty Bg/nu/xid mice were grafted with human tissue on 9 Sep 91. They are now in the graft healing phase. On 1 Oct 91 three groups of three mice each were injected with human lymphocytes. Two groups received normal lymphocytes and one group received lymphocytes from a patient with lupus erythematosus. As per schedule, the remainder of the experiment will be completed within two weeks.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/136 (3) Status: Ongoing

(4) Title: I. A Clinical and Radiographic Comparison of Parenteral Gold Versus Parenteral Methotrexate in the Treatment of Early Rheumatoid Arthritis. II. The Effect of Low-Dose Methotrexate on Bone Metabolism and Bone Density

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator:
Daniel Battafarano, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Rheumatology

(10) Associate Investigators:
Kimberly May, CPT, MC
Sterling West, LTC, MC
Michael McDermott, LTC, MC
Paul Miller, MD, UCHSC

(11) Key Words:
arthritis
methotrexate
bone density

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Part I: a) to compare the clinical efficacy of parenteral gold and parenteral methotrexate in the treatment of rheumatoid arthritis; b) to compare radiographic progression of RA in these two treatment groups. Part II: to evaluate the effect of low-dose methotrexate on bone metabolism and bone density.

(16) Technical Approach: Patients will be randomly assigned to receive either intramuscular methotrexate or gold. Laboratory tests and bone densitometries will be performed periodically to monitor rheumatoid arthritis and drug therapy.

(17) Progress: None to date. No funding available for this study at this time. The study will be submitted for a 1992 Arthritis Foundation Research Award.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/137 (3) Status: Ongoing

(4) Title: Effect of Specific Immunotherapy on Peripheral Lymphocyte Intracellular Adhesion Molecules (ICAM 1)

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
Allan Au, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Allergy

(10) Associate Investigators:
T. Ray Vaughan, MAJ, MC
Richard Weber, COL, MC
Anthony Henry, LTC, MC
Matthew Cary, CPT, MC

(11) Key Words:
immunotherapy
lymphocytes
ICAM 1

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if there is up regulation or down regulation of cell surface ICAM molecules on circulating T lymphocytes when comparing patients on successful specific immunotherapy compared to age and sex matched controls.

(16) Technical Approach: This study will use the cytofluorometric technique to measure changes in the relative number of cell surface ICAM molecules comparing patients on successful immunotherapy to controls.

(17) Progress: To date 10 control and 10 subject samples have been analyzed, but no conclusion can be formed from the data yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/138A (3) Status: Ongoing

(4) Title: Effects of Beta-blockers on Intracellular Cyclic Nucleotide Generation in Guinea Pig (Cavia porcellus) Airway Smooth Muscle

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator: Michael O'Connell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Allergy (10) Associate Investigators: Anthony Henry, LTC, MC T. Ray Vaughan, MAJ, MC

(11) Key Words: beta-blockers

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____7_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Airway smooth muscle treated with beta-blocker will show significantly less generation of cyclic AMP than control (untreated) smooth muscle when constricted with histamine or relaxed with albuterol.

(16) Technical Approach: Per protocol approved by LACUC on 15 Aug 91.

(17) Progress: As of 30 Sep 91 a total of 28 experiments utilizing seven guinea pigs have been performed. Tracheal tissue from each experiment has been frozen and stored at -70° C awaiting arrival of the cyclic AMP assay kits from the manufacturer. Once these kits have arrived at FAMC, we can proceed with the cyclic AMP measurements and analyze the data.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/139 (3) Status: Ongoing

(4) Title: SWOG 9045 Evaluation of Quality of Life in Patients with Advanced Colorectal Cancer Enrolled on SWOG 8905

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the SWOG group protocols.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/140 (3) Status: Ongoing

(4) Title: SWOG 9040 Intergroup Rectal Adjuvant Protocol, A Phase III Study

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the SWOG group protocols.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/141 (3) Status: Ongoing

(4) Title: SWOG 9009 Pilot Study for Anlaysis of Lymphocyte Subsets and Natural Killer Activity after Treatment with Levamisole

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the SWOG group protocols.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/142 (3) Status: Ongoing

(4) Title: A Multi-Center, Double-Blind, Double-Dummy, Placebo-Controlled, Group-Comparative Study of the Safety and Effectiveness of Four Dose-Levels of Tipredane as Compared to Belcomethasone Dipropionate in the Treatment of Adults with Moderate Asthma. FISONS Study No. 1900-2209

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Anthony Henry, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Allergy (10) Associate Investigators: Richard Weber, COL, MC T. Ray Vaughan, MAJ, MC David Goodman, LTC, MC

(11) Key Words: tipredane investigational new drug

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Aug b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Based on efficacy, laboratory and adverse event data, the overall objective of this study will be to determine the optimum doses, in relation to safety and efficacy, of tipredane with which to conduct future clinical trials.

(16) Technical Approach: Study centers will enroll 30 subjects each for a total of 540 patients to complete this investigational new drug trial sponsored by Fisons.

(17) Progress: None. Study recently approved by the IRC and pending approval by HSC.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/143 (3) Status: Ongoing

(4) Title: A Multi-Center Randomized Comparative Trial Evaluating Safety and Efficacy of Monopolar Versus Bipolar Polypectomy Snares

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
Peter McNally, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:
Robert Sudduth, MAJ, MC
John Meier, MAJ, MC
Frank Jahns, MAJ, MC
Dirk Davis, CPT, MC
Stephen Freeman, COL, MC

(11) Key Words:
polypectomy
snares

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To compare the efficacy, generator settings, and complication rates in the use of the monopolar versus bipolar polypectomy snares for the removal of colonic polyps.

(16) Technical Approach: Large sessile and pedunculated polyps will be lassoed with either the wire snare or the Bi-Snare in a standard fashion. For the Bi-Snare, electrical current will be applied using current settings of CUT 7 wats & COAG 6 with BLENB 2 on FORCE 1B; 1.0 CUT & 1.5 COAG blended-cut on the SSEL2. For the monopolar, electrical current will be applied using standard settings of coagulation 3 and cut 0, at 1 to 2 second pulses.

(17) Progress: None. Study recently approved by the IRC.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/144 (3) Status: Ongoing

(4) Title: Effect of Glucose on Residual Renal Function in Peritoneal Dialysis

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Neph (10) Associate Investigators: Barbara Hasbargen, RN, DAC Edwin Fortenbery, MAJ, MC

(11) Key Words: peritoneal dialysis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To assess difference in residual renal function in patients with and without intraperitoneal glucose.

(16) Technical Approach: The studies will be done after the patients (6-8) utilize the standard peritoneal dialysate which contains 1.5-4.25% glucose, and the other study will be done utilizing peritoneal dialysate which is identical with the exception of glucose. The patients will be on the non-glucose containing dialysate for a period of 24 hrs prior to doing the nuclear medicine study. The order in which the residual renal function determinations are performed will be in a randomized fashion.

(17) Progress: Recently approved study. No patients enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/145 (3) Status: Ongoing

(4) Title: The Effect of Parathyroid Hormone versus Phosphate on Osteoblast Function; and the Effect of Age on Stimulated Osteoblast Function

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
Jan Perloff, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrine

(10) Associate Investigators:
Michael McDermott, LTC, MC

(11) Key Words:
osteoblast
parathyroid hormone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if Neutraphos is helpful in making bones stronger or if another synthetic hormone is necessary to stimulate the bones to be stronger. The study is also trying to determine if age has an effect on the ability to stimulate normal bone formation and strength.

(16) Technical Approach: Prospective study using subjects as their own controls using synthetic human PTH in a dose preset by the pilot trial subcutaneously q day for 3 days followed by a washout period of 2 weeks, then Neutrophos 500 mg po 4 times per day for 3 days.

(17) Progress: None. Study recently approved by IRC.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/146 (3) Status: Ongoing

(4) Title: Work of Breathing as a Predictor of Failure to Wean From Mechanical Ventilation in Patients with Severe Chronic Obstructive Pulmonary Disease

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Jack DePriest, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Med/MICU (10) Associate Investigators:

(11) Key Words:
COPD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prospectively determine whether measuring the work of breathing by metabolic cart in patients with severe COPD can be useful in predicting their ability to sustain spontaneous respirations. It will also validate or determine new cutoff values for the CROP score and f/Vt ratios.

(16) Technical Approach: Just prior to extubation the patient will have his work of breathing measured by the metabolic cart. The patient is then extubated as planned. The patient will then be followed to see if he tolerates extubation or develops respiratory failure, requiring reintubation.

(17) Progress: No progress. Recently approved study submitted for MRDC funding.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/147 (3) Status: Ongoing

(4) Title: SWOG 8730 Evaluation of Amonafide in Esophageal Cancer

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective treatment of cancer.

(16) Technical Approach: Per NCI-approved protocol.

(17) Progress: No patients enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/148 (3) Status: Ongoing

(4) Title: SWOG 8911 Evaluation of Piroxantrone in Refractory Carcinoma of the Breast, Phase II

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective cancer treatment.

(16) Technical Approach: Per NCI-approved protocol.

(17) Progress: No patients enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/149 (3) Status: Ongoing

(4) Title: SWOG 8936 Evaluation of Piroxantrone in Refractory Carcinoma of the Breast, Phase II.

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective cancer treatment.

(16) Technical Approach: Per NCI-approved protocol.

(17) Progress: No patients enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/150 (3) Status: Ongoing

(4) Title: SWOG 9007 Cytogenetic Studies in Leukemia Patients, Ancillary

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective treatment of cancer.

(16) Technical Approach: Per NCI-approved protocol.

(17) Progress: No patients enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/151 (3) Status: Ongoing

(4) Title: SWOG 9108 A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate Plus Chlorambucil in Previously Untreated B-Cell Chronic Lymphocytic Leukemia

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective treatment of cancer.

(16) Technical Approach: Per protocol.

(17) Progress: No patient enrolled to date.

Publications and Presentations: None.

DEPARTMENT OF SURGERY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 78/20X-001 (3) Status: Terminated

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbit and Rats

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator:
James C. Johns, Jr.
MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedic

(10) Associate Investigators

(11) Key Words:
microvascular education
and training

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To increase microsurgical technique for orthopedic staff and residents.

(16) Technical Approach: Perform all microvascular studies/techniques prior to human surgery.

(17) Progress: Continued training/education for resident/interns and students. Continued maintenance of staff skills. Microvascular techniques used for vein grafts, arterial and venous anastamoses, nerve repairs, and grafts. Protocol more than 5 years old, and protocol needs to be written to current regulation standards.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 78/20X-002 (3) Status: Terminated

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbits and the Rat

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas E. Carter, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Neurosurgery (10) Associate Investigators

(11) Key Words:
microvascular education
and training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To increase microsurgical technique for staff and residents.

(16) Technical Approach: Perform all microvascular studies/techniques prior to human surgery.

(17) Progress: Administratively terminated because the protocol is more than 5 years old and needs to be re-written to meet current regulations.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date 30 Sep 91 (2) Protocol #: 78/20X-003 (3) Status: Terminated

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Berry E. Morton, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Training protocol.

(16) Technical Approach: See protocol.

(17) Progress: This out-dated protocol needs to be re-written according to current regulations.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 78/201 (3) Status: Terminated

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Jeffrey Bloom, MAJ, MC

(8) Facility: FAMC
General Leonard Wood Army
Community Hospital

(9) Dept/Svc: Ophthalmology (10) Associate Investigators:

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: APRIL b. Review Results
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient. (See original protocol).

(16) Technical Approach: Extracapsular cataract extraction with posterior chamber IOL.

(17) Progress: No longer using investigational lenses.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 78/201 (3) Status: Terminated

(4) Title: Clinical Study of Intraolcular Lens

5) Start Date: 1978 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Floyd M. Cornell, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators
MAJ Robert Enzenauer
MAJ Ricardo J. Ramirez
CPT Thomas A. Gardner

(11) Key Words

cataract
aphakia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 450
d. Total Number of Subjects Enrolled to Date: 400/year
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NONE
3M, ALCON, IOLAB (PRECISION-COSMET), COBURN , CILCO, IOPEX, COPELAND, PHARMACIA INTERMEDICS, SURGIDEV, AMERICAN MEDICAL OPTICS

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: pachyometry, keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

(17) Progress: Core and adjunct lenses covered under this protocol are now FDA approved. Newer IDE lenses are covered under seperate protocols.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 78/201.A (3) Status: Terminated

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Robert Dragoo, COL, MC

(8) Facility: FAMC
Munson ACH
ATTN: HSXn-EENT
Ft. Leavenworth, KS
66027-5400

(9) Dept/Svc: Ophthalmology (10) Associate Investigators:

(11) Key Words:
cataract extraction
intra ocular lens implanting

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 80
d. Total Number of Subjects Enrolled to Date: 160
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Participation in IOL implantation to meet FDA requirements for safety and efficacy and to improve eyesight in patients having cataracts.

(16) Technical Approach: See Protocol

(17) Progress: Investigational lenses no longer required due to availability of large selection of fully approved lenses.

Publications and Presentatins: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol WU#: 78/201.C (3) Status: Terminated

(4) Title: Clinical Study of Intraolcular Lens

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Paul Kuck, MAJ, MC

(8) Facility: FAMC
Irwin Army Community Hospital
Ft. Riley, Kansas 66442

(9) Dept/Svc: SUR/Ophthalmology (10) Associate Investigators

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and compare those results with those who undergo cataract surgery without an implant. To determine the occurrence and time of postoperative ocular complications and and adverse reactions for intraocular lens implant; to identify subgroups within the implant group that are risk of a particular complication.

(16) Technical Approach: After completing his residency, didactic courses, laboratory practice and assistance with an experienced surgeon, a surgeon who can perform a successful cataract surgery is then allowed to perform intraocular lens surgery. Postroperative examination includes: refraction, pachymetry, keratometry and a complete anterior and posterior segment examination. Contraindications to surgery with intraocular implants include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, any history of anterior or posterior uveitis. History of glaucoma would preclude the use of an anterior chamber implant.

(17) Progress: No longer using investigational lenses.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 78/201.D (3) Status: Terminated

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Jeffrey L. Bezier, MAJ, MC

(8) Facility: FAMC
Reynolds Army Hospital
Ophthalmology, Box 21
4700 Hartell Blvd.
Ft. Sill, OK 73503-6300
AV 639-0295/0296

(9) Dept/Svc: Ophthalmology

(10) Associate Investigators:

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: APRIL b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_45-50_____
d. Total Number of Subjects Enrolled to Date:_____160_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None [CILCO]

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: visual acuity testing and keratometry. Contraindications to surgery include: proliferative diabetic retinopathy, rubeosis irides. Implanting CILCO lens now, but also authorized to implant Precision Cosmet, 3M, Alcon, and IOLAB.

(17) Progress: Investigational lenses which were being used are now FDA approved.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 78/201.E (3) Status: Terminated

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Charles E. Aronson, COL, MC

(8) Facility: FAMC
Evans Army Community Hospital
ATTN: EENT Clinic
Ft. Carson, CO 80913-5207
AV 691-7450

(9) Dept/Svc: Ophthalmology

(10) Associate Investigators:
Horace Gardner, M.D.

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Arp b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 200
d. Total Number of Subjects Enrolled to Date: 200
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None [COBURN]

(15) Study Objective: Participation in IOL implantation.

(16) Technical Approach: See protocol.

(17) Progress: Lens center well, none needed repositioned or removed. No evidence of prolonged inflammation other than normal healing process. No unusual complications. Protocol no longer needed since FDA apprval of lenses.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 84/20X-001 (3) Status: Terminated

(4) Title: Microvascular Arterial and Venous Anastomosis in Laboratory Rats

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Michael J. Raife
COL, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Urology

(10) Associate Investigators

(11) Key Words:
microsurgery

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep 90 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 30
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop and maintain microvascular skills.

(16) Technical Approach: Microsurgical exercises of increasing complexity will be performed under anesthesia.

(17) Progress: The protocol has been valuable in training residents in microsurgery, and in maintaining staff proficiency. No action this FY. Terminated administratively because the protocol is out-dated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol WU#: 86/200A (3) Status: Terminated

(4) Title: Treatment of Urinary Tract Trauma in the Porcine Animal Model

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael J. Raife, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Urology Svc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To provide an opportunity for urologists in training to develop expertise in the surgical techniques which are useful in the management of urinary tract trauma, to include renovascular surgery, renal autotransplantation, and use of various types of bowel segments for augmentation or substitution.

(16) Technical Approach: Animals are subjected, under anesthesia, to simulated urinary tract trauma. Various surgical procedures are performed to allow resident training in management of these situations.

(17) Progress: This was an important teaching protocol for urology. No action in FY 91, protocol needs to be updated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/202 (3) Status: Completed

(4) Title: Improving Cancer Management Through the Tumor Conference

(5) Start Date: (6) Est Compl Date: 1989-1991

(7) Principal Investigator: Jeffrey R. Clark, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Gen. Surg. Svc.

(10) Associate Investigators
Daniel T. Tell, MAJ, MC
Harris W. Hollis, Jr., LTC, MC

(11) Key Words:
cancer management

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 851
d. Total Number of Subjects Enrolled to Date: 851
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: FAMC Tumor Board will be one of 22 in the state where in a randomized controlled fashion, multifaceted educational intervention (maintaining a randomly selected control group) will be introduced. The hypothesis is: Given emphasis on stimulating case presentations in a concert of patient management decision making, tumor boards can function as key elements in patient care and medical education.

(16) Technical Approach: The first 6 months will be baseline evaluation of tumor boards as they now exist. Then an interventional education package is randomly introduced to half the boards over one year and impact is seen. the other half receive no intervention. A crossover of intervention will occur after one year for one year's time. Then, six months of final analysis and recommendation made to NCI.

(17) Progress: The data which was collected over the last two years is being analyzed, and a report will be written by the National Tumor Conference. When the report is received by the C, Gen. Surg., FAMC, a copy will be sent to DCI.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/203 (3) Status: Ongoing

(4) Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Disorders Marked by Altered Patterns of Peripheral Blood Flow

(5) Start Date: (6) Est Compl Date: 6/92

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words: thermography/pain

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 59
d. Total Number of Subjects Enrolled to Date: 214
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the optimal utilizatin of thermography in clinical evaluation of the vascular status of the affected area for patients with orthopedic related pain disorders.

(16) Technical Approach: We will make thermographic recordings of groups of ten subjects having one of the following conditions each time they come to Orthopedic Clinic from the initial diagnostic appointment through post-resolution follow-up: Frostbite, Charcot Joints, Carpel Tunnel Syndrome, Fibrositis, Sympathetic Distrophy and Peripheral Neuropathy, Pre-amputation preparation, and Prediction of Bed Sore Formation. The clinical evaluations will not be related to the thermographic evaluations until the subject has completed participation in the study.

(17) Progress: This study is going smoothly but there are too few subjects in each group to determine the effectiveness of thermography for any of the groups begun to date. We have determined that videothermography is <u>not</u> a good way to track carpal tunnel syndrome, but is good for tracking reflex dystrophy. In July 1991 we are applying for funding for this study. If the study is funded, progress should be significantly quicker.

Presentations: Thermography and Carpal Tunnel Syndrome. Presented to the Barnard Series at the UCHSC, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/204 (3) Status: Ongoing

(4) Title: Mechanism Based Treatments of Phantom Limb Pain

(5) Start Date: 1987 (6) Est Compl Date: 1992

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators

(11) Key Words:

phantom limb pain
treatments

Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, MD, Denver, VAMC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 16
d. Total Number of Subjects Enrolled to Date: 83
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate the effectiveness of treatments for burning phantom limb pain.

(16) Technical Approach: We will treat four groups of ten amputees each with the same six interventions. The amputees will be grouped by the description of their phantom pain. We will work with those describing their phantom pain as (1) only burning, (2) only cramping, (3) mixed cramping and burning, and (4) shooting / stabbing / shocking. Before treatment begins, there will be a three week baseline in which each amputee will be interviewed and stump muscle tension and heat outflow patterns will be recorded. Each amputee will receive each treatment for one month unless side effects force withdrawal. Treatment months will alternate with three week "washout" periods to permit phantom pain to return to baseline. The treatments will be: (1) topical application of nitroglycerine for mainly venous-side vasodilatative effects, (2) trental to reduce blood viscosity so more blood can reach tissues in the stump having compromised vascular beds, (3) Nifedipine as a Calcium channel blocker for its known peripheral vasodilatative effects, (4) Cyclobenzaprine for its ability to reduce spasms of local origin without interfering with muscle function, (5) muscle tension recognition and relaxation training for its proven ability to reduce microspasms and

tension related to intensification of phantom pain, and (6) body surface temperature recognition and control training for its ability to help-people control vasodilation of peripheral vessels while under stress. Subjects will be recorded the same way they were during the baseline at each session to permit objective verification of physiological changes. They will come to the clinic every other week during treatments. At the end of the last treatment, there will be another three week baseline. Following the final baseline, the treatment which proved most effective, if any, will be continued for one year. Subjects will be recorded at monthly intervals. If no treatments are effective, subjects will still be followed for one year but will be recorded at six and twelve months.

(17) Progress: Virtually all patients have buring or cramping phantom pain were cured or helpd substantially to the point where no more medication is required. Patients with shocking pain were two exceptions, were either helped marginally or not at all. One of the exceptions found a local herbal medicine that stops the pain which we are investigation with the pharmacy's help. The other learned to avoid permitting the pain to begin by controlling limb temperature.

Publications:

Sherman R, Ernst J, Barja R, Bruno G: Phantom pain: A lesson in the necessity for carrying out careful clinical research in chronic pain problems. Rehabilitation Research and Development, 25(2): vii-x, 1988. (Editorial)

Sherman R, Barja R: Treatment of post-amputation and phantom limb pain. In (K. Foley and R. Payne, eds.) Current therapy of pain. B.C. Decker, Publisher, Ontario, 1988. (Chapter)

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 13(1):55, 1988. (Abstract)

Sherman R, Arena JG, Bruno GM, Smith JD: Precursor relationships between stress, physical activity, meterorological factors, and phantom limb pain: Results of six months of pain logs. Proceedings of the Joint meeting of the Canadian and American Pain Societies, Toronto Canada, November, 1988 (Abstract).

Sherman R: Phantom limb and stump pain. chapter in (R. Portenoy, ed) Neurologic Clinics of North America. W.B. Saunders Co., Publisher, 1989, (Chapter).

Sherman R, Sherman C, Grana A: Occurrence of acture muscle contractions in the residual limbs of amputees preceding acute episodes of phantom limb pain. Biofeedback and Self-Regulations, 1989 (Abstract).

Arena J, Sherman R, Bruno G: The relationship between humidity level, temperature, and phantom limb pain: Preliminary Analysis. Proceedings of the annual meeting of the Association for Applied Psychophysiology, 1989 (Abstract).

Presentations:

Sherman R: Mechanisms of phantom pain: new findings: Presented: Proceedings of the 21 Annual meeting of the Association for Applied Psychophysiology, Washington, D.C., 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/205 (3) Status: Completed

(4) Title: Etiology of Low Back Pain Due to Muscle Tension

(5) Start Date:1987 (6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators
David Hahn, LTC, MC
Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, Ph.D., Denver, VAMC
Bertram Rothschild, Ph.D., Denver, VAMC
John Arena, Ph.D., Augusta, VAMC

(11) Key Words:
low back pain
environmental recording
surface EMG

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the relationship between (a) the intensity and duration of work, (b) patterns of muscle tension, and (c) onset of low back pain. To determine whether patterns of muscle tension occurring durng normal daily activities are different among people with (a) chronic low back pain, (b) intermittent pain, and (c) no pain. To determine relationships between patterns of muscle tension observed among relatively young active duty soldiers with intermittent low back pain and relatively older veterans with intermittent and chronic low back pain of muscle tension origin. To determine whether simple preventive measures can decrease intensity and frequency of episodes of pain by changing response patterns of low back muscle tension.

(16) Technical Approach: We sill do two week long , continuous muscle tension, activity, and pain recordings of relatively young active duty soldiers with duties ranging from strenuous to sedentary who are either pain free, report intermittent low back pain due to muscle tension, or report almost continuous low back pain due to muscle tenison. We will do similar recordings of relatively older veterans having similar activity patterns and similar back pain problems. If we are able to

identify abnormal patterns, we will provide people who clearly show these patterns with behaviorally oriented muscle control treatments or mild muscle relaxants in order to determine the effect of these interventions on muscle contractions patterns and pain.

(17) Progress: No problems have been encountered. When they are pain free, subjects who frequently report low back pain have low back muscle patterns similar to subjects who virtually never report low back pain. When experiencing low back pain, these subjects have very different patterns than pain free subjects. EMG increases prior to onset of low back pain. This project has been incorporated into fAMC 89/207.

Publications:

Sherman R, Sherman C: Relationships between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Biofeedback and Self-Regulation, 1989.

Sherman R, Sherman C: Relationship between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Biofeedback & Self-Regulation (14(2):168, 1989.

Sherman R, Arena J, Searle J: Development of an ambulatory recorder for evaluation of muscle tension related to low back pain and fatigue in soldier's normal environments. Accepted, Military Medicine, 1990.

Presentations:

Sherman R, Arena JG, Searle J, Sherman CJ: Relationships between low back pain, stress, and continuous recordings of paraspinal surface EMG and movement in patients' normal environments. Presented: Joint meeting of the Canadian and American Pain Societies, Toronto, Canada, November, 1988.

Sherman R, Sherman C: Relationships between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Presented: Annual meeting of the Association for Applied Psychophysiology, San Diego, 1989.

Searle J, Arena J, Sherman R: A portable activity monitor for musculoskeletal pain disorders. Proceedings of the IEEE Engineering in Medicine Society's 11th Annual International Conference, 1989.

Sherman R: Ambulatory recording methodology. Proceedings of the 21st Annual Meeting of the Association for Applied Psychophysiology, Washington, DC, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/206 (3) Status: Ongoing

(4) Title: Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain

(5) Start Date: 1987 (6) Est Compl Date:

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS
John G. Arena, Ph.D.

(8) Facility: FAMC
Augusta, VAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators
Jeffrey Ginther, MAJ, MC
Timothy Young, MD, Augusta, VAMC

(11) Key Words:
low back pain
thermography

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 168
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To test the effectiveness of paraspinal surface EMG, the MMPI, videothermography, physical examination, and standard diagnostic procedures for ascertaining objective data concering the patient's actual low back pain intensity and underlying physical problems.

(16) Technical Approach: We completed process of performing paraspinal surface EMG and videothermographic recordings of at least 360 subjects with low back pain of six diagnostic categories and who hurt most while in one of six different positions (6 x 6 cell design with ten subjects in a group). Each subject is being recorded four times: Twice while their pain intensity is the same and twice while it varies up or down from the two similar recordings. Thus, each subject is recorded at between two and three pain intensities. This provides data on change with time while pain is constant. All of these subjects are given a modified version of the MMPI designed to differentiate between psychological factors and changes in responses due to presence or absence of low back pain. Each subject is also given a complete orthopedic physical examination and any standard diagnostic procedures not already well documented is done.

(17) Progress: Thermography is usually able to pick up low back disorders independently diagnosed as being related to nerve problems but

is not sensitive to pain due to muscle tension in the low back. Surface EMG is sensitive in the opposite way. When the two tests are used together, they are very efficient at quickly and noninvasively determining the physiological cause of the back pain. The recorder portion of this study has been completed. The MMPI portion is proceeding according to the approved addendum. This study is on hold until Dr. Gintner arrives at Ft. Carson in August 1991.

Publications:

Arena J, Sherman R. Bruno G & Young T: Electromyographic recordings of five types of low back pain subjects and non-pain controls in different positions. Pain, 37:57-65, 1989.

Arena J, Sherman R. Bruno G & Young T: Electromyographic recordings of five types of low back pain subjects and non-pain controls in six different positions. Pain, 1990.

Arena J, Sherman R, Bruno G: Professionals and low back pain patients expectations of differences in response patterns on the MMPI as a function of presence or absence of chronic pain. Biofeedback and Self-Regulation, 1989.

Arena J. Sherman R, Bruno G: Reliability of multiple surface electromyographic recordings of the paraspinal muscles among subjects with and without low back pain. Int. J. Psychophysiology, 1989.

Sherman R Arena J, Bruno: Electromyographic recordings of low back pain subjects in different positions during low and high pain levels. Biofeedback and Self-Regulation, 1989.

Arena J, Sherman R, Bruno G, Young T: Temporal stability of paraspinal electromyographic recordings in low back pain and non-pain subjects. Int. J. of Psychophysiology, 9:32-37, 1990.

Presentations:

Arena J, Sherman R, Bruno G, Young T: Reliability of paraspinal electromyographic recordings in low pack pain and non-pain subjects. Presented: Am. Psychological Assoc., 1988.

Sherman R, Arena J, Bruno G, Young T: Electromyographic recordings of low back pain subjects in different positions vs. results of standard diagnosis. Presented: Am. Psychological Assoc, 1988.

Sherman R, Arena J, Bruno G, Young T: A comparison of surface EMG and thermographic evaluations of five diagnostic categories of low back pain subjects. Presented: Proceedings of the American Pain Society's 1989 annual meeting, Phoenix, AZ October 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/207 (3) Status: Ongoing

(4) Title: Determination of Mechanisms of Phantom Limb Pain: Phase 2

(5) Start Date: 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators
Michael D. Getter, MAJ, MC
Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, MD, Ph.D., Denver, VAMC
Jeffrey Ginther, MAJ, MC

(11) Key Words:
phantom limb pain
mechanisms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 24
d. Total Number of Subjects Enrolled to Date: 24
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To use MRI, nerve recording, and other techniques to monitor veteran and active duty amputees who report shocking, shooting, and stabbing descriptors of phantom limb pain while they are experiencing various intensities of pain in order to ascertain the physiological changes which are related to changes in pain intensity.

(16) Technical Approach: We will carry out the pilot for a full proposal in which we would record groups of twenty active duty or veteran amputees four times. In the pilot, only two amputees from each group will participate. Two of the recordings will be at one particular pain intensity while the other two will be at two different intensities. This will permit factoring changes due to time from those due to changes in pain intensity. Each subject will be recorded at about weekly intervals but the exact timing will have to depend on when their pain intensity changes. The groups will consist of two amputees with (1) only stabbing phantom pain, (2) only shooting phantom pain, (3) only shocking phantom-pain, (4) a combination of all three (which is common), and (5) no phantom pain. The fifth group of amputees without phantom pain is necessary

to further evaluate changes which occur in the normal stump over time so we can differentiate them from abnormal changes. We know from our experience in Phase I of this study that twenty is the minimum number of amputees we can have in a group due to normal physiological variability and in variability in reporting pain intensity. However, two per group will give us an idea of whether the following techniques are likely to show any differences at all. We propose to use MRI to record overall stump anatomy, plethysmography to record swelling and internal stump pressure, and signals from the neuroma to record responses to mechanical and other stimuli. Because of its invasive nature, we will carry out only one nerve signal study from the stump. For subjects who report phantom pain, we will perform the test on a day when they report the maximum phantom pain they usually experience. We will compare the results of this recording with those from pain free amputees. Due to its cost, we will do MRI recordings of only one subject per pilot group. Two MRI's will be done for each pilot subject. One will be while the subject is as pain free as they get and the other will be while they are experiencing the most pain they generally expect.

(17) Progress: Four amputees experiencing numerous acute episodes of cramping phantom pain had the surface muscle tension in their residual limbs recorded. They pressed a button during episodes of phantom pain. Temporal relationships between initiation of episodes and spasms in the limb were established. Spasms preceed start of pain by more than reaction time so causes the phantom pain.

Publications:

Sherman R, Sherman C, Grana A: Occurrence of acute muscle contractions in the residual limbs of amputees preceeding acute episodes of phantom limb pain. Biofeedback & Self-Regulation 14(2):169, 1989.

Sherman R, Bruno G: Concurrent variation of burning phantom limb and stump pain with near surface blood flow in the stump. Orthopedics, 10:1395-1402, 1987.

Sherman R, Sherman C, Bruno G: Psychological factors influencing chronic phantom limb pain: An analysis of the literature. Pain, 28:285-295, 1987.

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 1988, (Abstract).

Presentations:

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Presented at the 19th Annual meeting of the Society for Applied Psychophysiology in Colorado Springs, CO, March 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/20x-003 (3) Status: Terminated

(4) Title: Evaluation of the Goat as a Model for Bone Grafting Studies

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: David B. Hahn, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators: Richard Sherman, MAJ, MS; Ross M. Wilkins, MD, Presbyterian Hospital

(11) Key Words: bone graft

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 3 animakls
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To utilize the goat as a model for testing a variety of bone graft materials, in different combinations, to determine which is best.

(16) Technical Approach: To create a defect of 3 cm, or approximately three times the diameter of the ulna. If this defect creates a nonunion, the rest of the protocol will be continued.

(17) Progress: No progress has been made. Per Dr. Schaefer, the goat is not a good model. The defects made in the goats healed consistently. Dr. Schaefer will look for another animal model to study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/20x-004 (3) Status: Terminated

(4) Title: Development of an Animal Model for the Study of Anterior Cruciate Ligament Repairs

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Steven D. Pals, CPT, MC

(9) Dept/Svc: Orthopedic Surgery (10) Associate Investigators:

(11) Key Words:
anterior cruciate ligament
reconstruction
graft
instron testing

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 3 animals
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test different methods of attaching grafts in ACL repairs.

(16) Technical Approach: In three groups of four animals each, we will attempt graft reconstruction of ACL using three different techniques.

(17) Progress: None. Study terminated because other investigators at FAMC have been successful in demonstrating that the goat is the model of choice fo these studies.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/200 (3) Status: Completed

(4) Title: ALCON Surgical Intraolcular Lens Study

(5) Start Date: (6) Est Compl Date: 1991

(7) Principal Investigator:
Floyd M. Cornell, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators
Jonathan Stock, MAJ, MC
Ricardo J. Ramirez, MAJ, MC
Robert W. Enzenauer, LTC, MC
Thomas A. Gardner, CPT, MC
Margaret B. Lisecki, CPT, MC
Joseph E. O'Boyle, CPT, MC
Robert W. Weller, CPT, MC
William Walton, CPT, MC
Roger K. George, CPT, MC

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____11_____
d. Total Number of Subjects Enrolled to Date:_____25_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Adjunctive study with FDA for intraocular lenses used following cataract extraction.

(16) Technical Approach: Intraocular lenses are implanted into the anterior segment of the eye following cataract extraction either as a primary procedure or as a secondary procedure.

(17) Progress: All lenses in place are doing well. No adverse reactions. Lenses are now FDA approved and protocol is no longer necessary.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/201A (3) Status: Terminated

(4) Title: Use of Goats for Training in Advanced Trauma Life Support

(5) Start Date: 1988 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Stephen M. Fall, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Cardiothoracic (10) Associate Investigators Dick R. Smith, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14, e".

(15) Study Objective: To conduct training courses in Advanced Trauma Life Support (ATLS).

(16) Technical Approach: See protocol

(17) Progress: Replaced by a more up to date protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/202 (3) Status: Ongoing

(4) Title: A Comparison of Clinical Features of Ulnar Nerve Compression at the Elbow Before and After Medial Epicondylectomy

(5) Start Date: 1989 (6) Est Compl Date: 1990

(7) Principal Investigator:
Dr. Deffer, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics

(10) Associate Investigators
James C. Johns, MAJ, MC
Douglas Hemmler, CPT, MC

(11) Key Words:
nerve compression
conduction velocity

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MARCH Review Results:
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 21
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Assess results of medial epicardylectomy in the treatment of cubital tunnel syndrome.

(16) Technical Approach: Comparison of pregoperative and postoperative and electrical parameters.

(17) Progress: Approximately 21 patients have undergone the procedure of medial epicohdylectomy. Clinical impression is that operation is working well. No adverse reactions recorded. Data continues to be collected.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/203 (3) Status: Ongoing

(4) Title: Evaluation of Current Nasal Surgical Techniques Used to Improve Nasal Obstruction (Subjective and Objective) Utilizing Anterior Rhinometric Techniques

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Michael L. Lepore, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Otolyn/Hd&NkSur. (10) Associate Investigators

(11) Key Words:
rhinomanometry
nasal obstruction
nasal surgery

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (a) to utilize anterior rhinometric principles in the pre-op assessment of patients prior to nasal surgery, (b) to utilize anterior rhinometric principles in the post-op evaluation of patients who have had either septoplasty surgery and/or total nasal septal reconstructive surgery (opened or closed), and (c) to determine, utilizing anterior rhinomanometric techniques, if the unobstructive nasal cavity after nasal surgery (opened or closed) is significantly altered at the expense of correcting the pre-op obstructive side, and is this subjectively noted by the patient to the point of causing secondary obstructive symptoms, of any degree on the unobstructive side which will be objectively measured.

CONTINUATION SHEET, FY 91, ANNUAL PROGRESS REPORT Protocol #: 88/203

(16) Technical Approach: Measurements of nasal airflow utilizing anterior rhinomanometry will be performed before surgery and after surgery at definite periods. Correlation will be made between the various surgical procedures and the measured test results to note if any significant alterations on the unobstructed side have resulted from the surgical procedures.

(17) Progress: This protocol has not been started due to multiple administrative problems and inability to set aside the appropriate research time because of lack of staff. It is hopeful, that when my operation is stable, I will be able to begin my endeavors. I would appreciate having the project open, so when I am able to begin, I will not have any particular delays.

I will be able to begin this project in April. I will be happy to give the committee an indepth response if they desire however, the same problem has continuously existed in Hem#17.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/209 (3) Status: Completed

(4) Title: A Comparison of Percutaneous Repair Versus Open Repair of Achilles Tendon Ruptures

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: R. Todd Hockenbury, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators James C. Johns, MAJ, MC Rick Wilkerson, MAJ, MC

(11) Key Words: achilles tendon ruptures percutaneous repair of achilles tendon ruptures

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 34
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (a) To compare the clinical results of percutaneous repair to open repair of achilles tendon rupture and to investigate the complications and long-term outcome of these techniques. (b) To compare the initial repair strengths of these techniques.

(16) Technical Approach: Patients are now being randomized into 2 separate groups and surgery is being performed. The cadaver study is completed.

(17) Progress: We have completed this retrospective review of patients who had undergone open vs. percutaneous Achilles tendon repair to compare long term clinical results, patient satisfaction,a nd leg strength. We evaluated thirteen patients who underwent percutaneous repair and twenty-one patients who underwent open repair. The patients' medical records were reviewed. The patients were contacted by mail or

by phone and asked questions regarding their current activity level, changes in lifestyle, and satisfaction with the surgery. Patients who were able to return to Fitzsimons were reexamined specifically for gastrosoleus strength, calf atrophy, foot sensation, gait, ankle

motion, and appearance of the repair site. We tested four patients who had undergone percutaneous repair and six patients who had undergone open repair. The percutaneous repair group had a better cosmetic appearance at the repair site. No long term clinical difference in peak plantar flexion torque was found. However, the rate of Achilles tendon rerupture was 23% in percutaneous repairs and 0% in open repairs. Also, the rate os sural nerve injury was 21% in percutaneous repairs in this study. Thus the percutaneous repair is not recommended for the high caliber athlete who cannot afford a chance of rerupture.

Publications:

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" (Submitted for publication, Journal of Foot and Ankle Surgery).

Presentations:

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: The Western Orthopaedic Society National Meeting. Honolulu, Hawaii, October 1988. Winner of the Vernon P. Thompson Award.

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: Foot and Ankle Society Section of The National Academy of Orthopedics Meeting. Las Vegas, Nevada, February 1989.

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: Rocky Mountain Chapter Meeting of the Western Orthopedic Society Barnard Lecture Competition. February 1988, and was selected as one of the five finalist papers.

"Barnard Competition, March 1991, Denver, CO."

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/213 (3) Status: Ongoing

(4) Title: Investigational Plan for the Clinical Study of Silicone Intraocular Lenses Sponsored by Allergan Medical Optics

(5) Start Date: 1988 (6) Est Compl Date:

(7) Principal Investigator:
Floyd M. Cornell, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: SURG/Ophthalmology

(10) Associate Investigators:
Robert W. Enzenauer, LTC, MC
Thomas A. Gardner, MAJ, MC
Jonathan Stock, MAJ, MC
William Walton, CPT, MC
Ricardo J. Ramirez, MAJ, MC

(11) Key Words:
silicone IOL

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to establish the safety and efficacy of the silicone intraocular lens according to FDA regulations.

(16) Technical Approach: The technical approach is the standard surgical method of cataract extraction and lens implantation to treat visually disabling cataracts.

(17) Progress: Although no patients have been enrolled to date at FAMC, subjects are being enrolled nationwide. The opportunity may arise in the future to enroll patients here at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/214 (3) Status: Completed

(4) Title: Clinical Investigation of Intraocular Lenses in Minors Sponsored by COBURN Optical IND, Inc/Storz Ophthalmics Inc.

(5) Start Date: 1988 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Floyd Cornell, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ophthalmology (10) Associate Investigators: Robert W. Enzenauer, LTC, MC

(11) Key Words:
minors
IOL
cataract extraction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to evaluate the safety and efficacy of intraocular lenses in children.

(16) Technical Approach: Patients are selected based on inability to utilize spectacles, contact lenses, or the use of epikeratoplasty. Only posterior chamber lenses are utilized. The lenses are placed in the capsular bag when available, into the ciliary sulcus when appropriate, or sutured into place when sulcus fixation is otherwise not achievable.

(17) Progress: There have been two patients enrolled because of traumatic cataracts, two patients enrolled because of irregular astigmatism and/or lack of iris support. All patients were enrolled because of cataract formation to one degree or another as a result of trauma. All patients are achieving their preoperative best corrected visual acuity and having no adverse reactions to the lens implant. Sufficient data accured to meet FDA requiremetns.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol WU#: 88/215 (3) Status: Ongoing

(4) Title: Continuous Environmental Recording of Activity, Headache, and Muscle Contraction Level AmongSubjects with Tension, Migraine or No Headache

(5) Start Date: 1988 (6) Est Compl Date: 1992

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators
Richard Calkins, COL, MC
David Hahn, LTC, MC
Crystal Sherman,

(11) Key Words:
headache
muscle tension
environmental recording

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine relationships between motion, muscle tension in the frontal and trapezius muscles, and onset and intensity of headaches among subjects recorded in their normal environments.

(16) Technical Approach: Subjects wear a small EMG and motion recorder during all working hours for one week. They keep an hourly log of types and activity and pain intensity while wearing the recorder.

(17) Progress: No relationship between either shoulder or forehead muscle tension and headache are obvious. The data on relationships between these factors and movement are still being evaluated.

Publications: None

Presentations: Presented at the Annual Meeting of the Association for Applied Psychophysiology in San Diego, CA 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/20x-001 (3) Status: Terminated

(4) Title: Microsurgical Training in Free Flap Transfer, and Vessel and Nerve Repair Utilizing the Rat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Glen Y. Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Surgery/Otolary. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This training protocol is to attain and maintain proficiency in microvascular surgical repair of small nerves and blood vessels. The femoral artery and nerve of the rat is well suited for this type of study.

(16) Technical Approach: See protocol.

(17) Progress: Protocol terminated.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/202 (3) Status: Terminated

(4) Title: The Effect of Harvesting the Central One-third of the Patellar Tendon and Reapproximating the Medial and Lateral Edges of Patellofemoral Joint Mechanics in Cadavers

(5) Start Date: 1989 (6) Est Compl Date: 1990

(7) Principal Investigator: Richard A. Schaefer, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators: Scott D. Gillogly, MAJ, MC Alexander Pruitt, MAJ, MC

(11) Key Words: arthroscopy anterior cruciate ligament

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine differences in patellofemoral joint contact area and pressure resulting from two standard treatments after harvesting the central third of the patellar tendon for ACL reconstruction (suturing versus not suturing the cut edges).

(16) Technical Approach: The radiographic and patellofemoral joint contact area and pressure changes in cadavers pre- and post harvesting the central one-third of the patellar tendon will be investigated.

(17) Progress: Study terminated. Recent study very similar to above presented at American Academy of Ortho Surgeons Meeting Feb 90.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/203 (3) Status: Ongoing

(4) Title: Rates of Occurrence of Simultaneous and Independent Low Back Pain and Headache Among Patients with and without Chronic Pain

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: Richard A. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators: John G. Arena, Ph.D. Jeffrey R. Ginther, MAJ, MC Melissa Damiano, M.S.

(11) Key Words: low back pain tension headache incidence

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 25
d. Total Number of Subjects Enrolled to Date: 44 69
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the temporal relationships between the above pain problems among subjects with and without chronic pain.

(16) Technical Approach: Survey deers eligible people with and without pain while they are waiting for appointment at FAMC.

(17) Progress: No results yet as surveys are still being distributed. Study has been slowed due to catch-up work left over from the hiring freeze.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/205A (3) Status: Completed

(4) Title: Correlation of the Vocal Fold Vibratory Pattern to the Post Operative Surgical Wound in the Porcine Model

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: Vincent D. Eusterman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Otolaryngology (10) Associate Investigators: Don B. Blakeslee, RET,COL

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To correlate the vocal fold vibratory pattern to the post operative surgical wound in the porcine model.

(16) Technical Approach: Per protocol approved by LACUC 22 May 1989.

(17) Progress: Animal studies are done, data has been tabulated, manuscript is now being written by Dr. Blakeslee.

Publications and Presentations: None as of this date.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/207 (3) Status: Ongoing

(4) Title: Etiology and Progression of Acute Muscle Tension Related Low Back Pain Occurring During Sustained Activity Including Combat Training Exercises

(5) Start Date: Oct 1989 (6) Est Compl Date: Sep 1992

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC & Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: SURG/Orthopedics

(10) Associate Investigators: David Hahn, LTC, MC; Jeffrey R. Ginther, MAJ, MC; John G. Arena, Ph.D. (VA, Augusta, GA)

(11) Key Words: low back pain; EMG

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 54
d. Total Number of Subjects Enrolled to Date: 62
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Determine the etiology and progression of acute muscle tension related low back pain occurring during sustained activity including combat training exercises.

(16) Technical Approach: Use ambulatory recorders to make second by second records of bilateral surface paraspinal EMG and back movement as well as hourly back pain and fatigue rating entries for 20 hours per day while subjects function in their normal environment.

(17) Progress: During the first seven months the project has been in progress the staff has been trained, the equipment has been tested, the test-retest reliability and confidence limits of the system have been established, and the first 62 subjects have completed participation. Of 34 participants seven had no histories or current reports of low back

pain and were normal upon examination; 23 were diagnosed as having intermittent back pain due to muscle tension, medical problems, 3 were diagnosed as having intermittent low back pain due to disk-nerve entrapment problems, and one had continuous pain due to arthritis. The most outstanding result was that the recordings look very different for subjects with different etiologies of low back pain. Visual inspection alone was sufficient to differentiate controls from people with back pain due to muscle spas. Although we had only 4 cases of people with back pain due to disk or arthritic problems, their recordings also looked very different from those of people with muscle spasms. Among people with muscle spasm related back pain, the muscle tension level was loosely related to activity. Muscle tension began increasing between somewhat less than one minute to forty-five minutes before pain increased. Decreases in tension were followed by decreases in pain about the same duration as later. The magnitude of muscle tension and pain changes tended to be similar. There was little relationship between change in type of activity and changes in pain. The patients with disk problems and the patients with arthritis showed a very distinct relationship between changes in types of activity and changes in pain. There was little or no relationship between changes in muscle tension and changes pain. Several subjects with disk problems did show increases in muscle tension following increases in pain, as one might expect of a reflex reaction or guarding following increased pain.

Publications:

Sherman R, Arena J, Searle J, and Ginther J: Development of an ambulatory recorder for evaluation of muscle tension related low back pain and fatigue in soldiers' normal environments. Military Medicine.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/210 (3) Status: Ongoing

(4) Title: Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers

(5) Start Date: Oct 89 (6) Est Compl Date: Sep 92

(7) Principal Investigator:
Richard Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedic Svc

(10) Associate Investigators:
Allyn Woerman, LTC, PT
Ft. Sill, OK
Kent Karstetter, CPT, MC
FAMC

(11) Key Words:
thermography
lower extremity pain
surface temperature

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 421
d. Total Number of Subjects Enrolled to Date: 432
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide immediate, on-site diagnosis of stress fractures in the lower extremities of active duty soldiers using a comparison of high technology videothermography and bone scan with filed viable contact thermography and surface temperature probes.

(16) Technical Approach: Phase I) Use videothermography and standard physical evaluations to establish baselines for trainees initially entering service at Ft. Sill, OK. Repeat thermograms will be performed on all trainees reporting to the troop medical clinic for treatment of pain in their knees, lower legs, and feet. Thermography will be performed on a matched group of trainees who come in to the clinic for other problems. This will permit differentiation of changes which occur among most trainees from pathological changes.
Phase II) Compare videothermograms, contact thermograms, bone scans and other recordings of 100 trainees and 100 relatively senior soldiers suspected of having stress fractures with similar evaluations of matched controls to establish the efficacy of low technology contact thermography for evaluation of stress fractures.

(17) Progress: Phase I: Over half of the trainees had asymetrical patterns during their pro-training baseline. The majority of those develped lower limb pain. Ways to predict which trainees will develop severe lower limb pain will based on baseline thermograms being developed. Phase II: Contact thermography has been shown to be useless for evaluating lower limb pain in our population because the device can not be pressed against hot areas of the limb.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/211 (3) Status: Ongoing

(4) Title: Randomization Study of Transurethral Resection of the Prostate vs Balloon Dilitation of the Prostate for Symptomatic Benign Prostatic Hyperplasia in Men

(5) Start Date: Sep 89 (6) Est Compl Date: Sep 90

(7) Principal Investigator:
Craig Donatucci, MAJ, MC
Karl Kreder, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Urology Svc

(10) Associate Investigators:
Michael Raife, COL, MC

(11) Key Words:
transurethral resection of prostate (TURP)
balloon dilitation of prostate (BDP)

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 39
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the effectiveness of balloon dilitation of the prostate (BDP) to TURP in moderately symptomatic men over 45 who suffer from benign prostatic hyperplasia (BPH).

(16) Technical Approach: This is a multi-center, two-arm, randomized study to examine the efficacy of BDP in improving symptoms of urinary outlet obstruction and urinary flow in men with symptomatic BPH, and compare and contrast the results with those of men undergoing TURP. Men with urinary outlet obstruction who need TURP and meet the protocol entrance criteria will be randomly assigned to TURP or BDP. After operation the patients will be followed for 1 year to determine improvement in symptoms, urinary flow parameters and post void residual urines. Groups will be compared to determine whether any beneficial effects from BDP have occurred.

(17) Progress: First patient underwent TUP 11/89 - to complete 1-yr. follow-up in 11/90.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/20x-001 (3) Status: Terminated

(4) Title: Evaluation of the Goat as a Model for ACL Reconstruction Fixation Studies

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
R. Todd Hockenbury, CPT, MC
Scott D. Gillogly, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Surgery/Ortho

(10) Associate Investigators:
Steven Pals, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The overall objective is to determine the suitability of the goat as a model for ACL reconstruction.

(16) Technical Approach: Three goats will be anesthetized and open ACL reconstruction will be performed on one of the hindlegs, using a different graft fixation technique on each goat. Following surgery the goats will be housed in Bldg 610 in large animal enclosures, which permit the animals full freedom of movement. No postoperative immobilization will be used. They will be euthanatized at one week postop and the knee will be harvested and subjected to biomechanical and histologic testing.

(17) Progress: Pilot study terminated.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/200A (3) Status: Ongoing

(4) Title: Comparison of ACL Graft Fixation Techniques in a Goat Model

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Scott D. Gillogly, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic Svc (10) Associate Investigators: Todd Hockenbury, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine which of three standard ACL graft fixation techniques provides the best graft fixation in reconstruction of the anterior cruciate ligament utilizing the central one-third of the patellar tendon.

(16) Technical Approach: See protocol.

(17) Progress: No recent progress due to Desert Storm assignment of PI.

Publications and Presentations: Accepted for presentation for FY 91.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/201A (3) Status: Completed

(4) Title: Use of Tetrograde Cardioplegia in the Pig Model

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator:
Thomas Gaines, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Cardiothor. Surg.

(10) Associate Investigators:
Stephen Fall, COL, MC
Carmelo Otero, MAJ, MC
James Claybrooks, CW03

(11) Key Words:
cardioplegia
antegrade/retrograde
pig model

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____1 animal_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To become familiar with the use of retrograde administration of cardioplegia.

(16) Technical Approach: To try it out on a pig.

(17) Progress: Successfully tried a pig. Retrograde cardioplegia is now used routinely to train cardiac surgical cases. No more use of an animal model is needed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/202 (3) Status: Ongoing

(4) Title: Non-Surgical Treatment of Morton's Neuroma with Injection of Vitamin B-12/Lidocaine/Solumedral Combination

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Paul Spezia, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The aim of the first phase is to determine whether the injection produces good enough results with a sufficient percent of the patients to be worth giving as a simple first try prior to offering surgery.

(16) Technical Approach: Our plan is to inject a combination of 0.5cc of lidocaine, 0.5cc solumedrol, and 0.5cc of vitamin B-12 into the interdigital neuroma of all patients in a series of two injections.

(17) Progress: The study injection works as a temporary measure at the 90-day followup. Long-term effects cannot yet be determined as the on-year followup data is pending. No progress this FY year.

Publications and Presentations: Presentation in 1989 at the Barnard Residents's competition.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/203 (3) Status: Ongoing

(4) Title: Synovial and Serum Keratan Sulfate Levels and Their Correlation with Arthoscopically Determined Articular Damaged Chronically Deficient Cruciate Ligament Knees

(5) Start Date: 1990 (6) Est Compl Date: 1993

(7) Principal Investigator: Paul Spezia, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic (10) Associate Investigators: Scott Gillogly

(11) Key Words:
keratan sulfate
arthroscopic cruciate deficient

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 18
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if there is a correlation between keratan sulfate and cruciate deficient knees as determined by arthroscopy and bone scan.

(16) Technical Approach: No significant data.

(17) Progress: Currently 36 samples harvested. No progress this FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/204 (3) Status: Ongoing

(4) Title: A Clinical Comparison of a Hydroxylapatite Coated Versus Porous Coated Total Hip Implant for Use in Arthritic Human Hips

(5) Start Date: 1990 (6) Est Compl Date: Sep 91

(7) Principal Investigator: Edward Lisecki, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators: James Wolfe, CPT, MC Frederick Coville, COL (RET)

(11) Key Words: hydroxyapatite

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 29
d. Total Number of Subjects Enrolled to Date: 29
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Compare results of two porous ingrowth hip components to improve amount of ingrowth, thereby, reduce the need for revisions.

(16) Technical Approach: Posterior approach to the hip routine implantation of a porous femoral/acet. component.

(17) Progress: Hip socres on hydroxy apatite hips is consistently higher than the non HA coated hip.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/206 (3) Status: Ongoing

(4) Title: Pilot Trial of Potentiating Normal Healing of Stress Fractures Using Pulsing Electomagnetic Fields

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator:
Kent Karstetter, CPT, MC

(8) Facility: FAMC
Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:
Allyn Woerman, LTC, MC
Richard Sherman, MAJ, MS

(11) Key Words:
stress fractures
pulsing magnetic fields

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate that a full study of pulsing magnetic fields is warranted for treatment of stress fractures.

(16) Technical Approach: Doulbe-blind, placebo controlled study. Electrical stimulators will be used in half of the subjects.

(17) Progress: No progress, funding arrived late Jan 91, study should start March 1991.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/207A (3) Status: Ongoing

(4) Title: Patellar Tendon Healing and Strength Following Patellar Tendon Autograft Harvest in Goats

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Steve Pals, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators: R. Todd Hockenbury, CPT, MC Richard Schaefer, CPT, MC Scott Gillogly, MAJ, MC

(11) Key Words: autograft patellar tendon

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine which method of handling the defect from harvesting the central third of the patellar tendon produces stronger, faster healing in the goat.

(16) Technical Approach: See protocol.

(17) Progress: Initial surgeries just done in early October 1990. No progress has been made since the Annual Continuing Review in April 1991. We expect to be doing more surgeries very soon.
Publications and Presentations: None

Publications and Presentations: J. Investigative Surg.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/208A (3) Status: Ongoing

(4) Title: Development of an Implanted, Hydroxyapatite Coated, Titanium Limb Prosthetic Through Tests in Tissue Culture, Then in Goats, and Finally in Humans

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators: Philip Deffer, CPT, MC; Ronald L. Jackson, CPT, MS; Edward J. Lisecki, MAJ, MC; William Hall, MD; Stephen Cook, PhD; Paul Glick MAJ, DC; Donald Mercill, DAC

(11) Key Words: percutaneous implant, prosthetic, amputees, goats

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test a percutaneous implant in a goat model to evaluate long term (a) infection through the skin - implant interface, (b) strength of the interface, and (c) ability of the goat to walk on the implanted prosthesis.

(16) Technical Approach: Tissue culture will be used to refine methods for evaluating tissue growth into the prosthesis. A goat model will be used to test which combination of coatings and materials give the best skin adhesion with the least infection and formation of fistulas. The optimal combination will be used to produce a percutaneously implanted prosthetic which will be implanted into several goats to test the above objective.

(17) Progress: No progress since the FY 90 Annual Progress Report.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/209 (3) Status: Ongoing

(4) Title: Reliability of Psychophysiological Mesures Used to Evaluate Pain

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: John Arena, Ph.D. Carson Henderson, Psy.D. Richard Calkins, COL, MC Kimford Meador, MD Jeffrey Ginther, MD

(11) Key Words: chronic pain psychophysiological responses comprehensive assessment

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: to evaluate the test/retest reliability of several commonly used psychophysiological measures when used with patients and controls.

(16) Technical Approach: Three groups of chronic low back pain subjects, two groups of tension headache and 75 age-matched controls will be assessed five times. The pain groups will be seen three times when at no or low pain levels and twice when at high pain levels. The assessments will consist of the standard six position measurment of surface EMG patterns, standard psychophysiological evaluations and cold presser test.

(17) Progress: Funding arrived 14 June 1991. The project will begin as soon as the equipment arrives.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/210 (3) Status: Ongoing

(4) Title: Effectiveness of Treatments for Reflex Sympathetic Dystrophy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: Douglas Hemler, MAJ, MC; Kent Karstetter, MAJ, MC; Muhammad Shaukat, LTC, MC; Mary Brinkman, MAJ, RPT; Darlene Mullon, MAJ, MC; Robert Ketchum, COL, MC

(11) Key Words: reflex sympathetic dystrophy; nerve block; corticosteroids; physical therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective of the standard treatments for reflex sympathetic dystrophy.

(16) Technical Approach: After standard workup and videothermography, subjects will be randomized to one of the three standard treatments--corticosteroids, multiple nerve blocks or vigorous physical therapy. Patients will be followed at 3-mo intervals for one year. If there is no improvement, the patient willbe randomized to one of the remaining treatments.

(17) Progress: This study was suspended during Desert Shield and will be reinstituted when PMER has sufficient time to perform the medical portions of the program.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/211A (3) Status: Ongoing

(4) Title: Effects of Coumadin and Methotrexate on Bone Ingrowth and Fixation in Hydroxyl Apatite Coated Porous Implants in a Goat

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: James Wolff, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: Edward Lisecki, MAJ, MC Stephen Cook, Ph.D.

(11) Key Words:
coumadin
methotrexate
bone ingrowth
hydroxyl apatite implants

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:___ _____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____27_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To quantify the biomechanical histological effects of coumadin and methotrexate on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: Thirty-six adult goats will be randomized to treatment groups 1-6. Of the coumadin and methotrexate animals, one will be given the medication beginning one month prior to surgery and the other will not receive the medication until the day of surgery. Five transcortical rods will be placed in the femur. Each rod is coated for half its length so each acts as its own comparison control. Specimens will be collected, radiographed and prepared for biomechanical and histological evaluation from 3 to 104 weeks postoperatively.

(17) Progress: MTX has a detrimental effect at a 15 mg dose but not at a 7.5 mg dose. We have encountered problems with fractured femurs. Study is ongoing.

Publications and Presentations: Presented at Barnard Competition, March 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/212A (3) Status: Ongoing

(4) Title: The Evaluation of Bone Ingrowth in Hydroxyl Apatite and in Non-Hydroxylapatite Porous Implants in a Goat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Richard Schaefer, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: Edward Lisecki, MAJ, MC Stephen Cook, PhD Jerome Weidel, MD

(11) Key Words: bone ingrowth implants

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To quantify the biomechanical and histological effects of hydroxyl apatite on bone growth into porous-coated implants.

(16) Technical Approach: The following parameters will be evaluated in a weight loaded goat hip: (a) the interface attachment sher strength and stiffness; (b) rate of development of interfaciary strength and stiffness; (c) the amount, rate and organization of bone ingrowth.

(17) Progress: No progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/213 (3) Status: Ongoing

(4) Title: Eaton Trapezial Implant Long-Term Follow-up

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Phillip Deffer, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho

(10) Associate Investigators:
James Johns, MAJ, MC
Frank Scott, MD

(11) Key Words:
eaton trapezialimplant

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 19
d. Total Number of Subjects Enrolled to Date: 19
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate through long-term followup that the Eaton trapezial implant provides a strong, stable, mobile and useful thumb without significant complications.

(16) Technical Approach: Retrospective analysis of postoperative records; subjective questionnaire; clinical exam; radiographic evaluation to look for evidence of implant failure, osseous changes or arthritic progression.

(17) Progress: 19 subjects enrolled to date. No results ready yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/20X (3) Status: Terminated

(4) Title:
Evaluation of A Geletin Film Barrier Following Parotidectomy for the Prevention of Frey's Syndrome

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Vincent Eusterman, MAJ, MC

(9) Dept/Svc: Otolaryngology (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: See protocol

(16) Technical Approach: See protocol

(17) Progress: Pilot study is terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/200 (3) Status: Ongoing

(4) Title: Clinical Evaluation of a Hydrogel Intracorneal Implant (Kerato-Gel) for the Correction of Aphakia

(5) Start Date: 1991 (6) Est Compl Date: 1996

(7) Principal Investigator: Floyd Cornell, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Ophthalmology (10) Associate Investigators: Robert Enzenauer, LTC, MC

(11) Key Words:
intracorneal implant
aphakia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Oct b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To improve vision and evaluate a new intracorneal implant.

(16) Technical Approach: Per Allergan Medical Optics protocol as approved by the FDA for use of this investigaional new device.

(17) Progress: As yet no patients at Fitzsimons AMC have been appropriate subjects for this specialized type of lens.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/202A (3) Status: Ongoing

(4) Title: Ciprofloxacin and Primary Fracture Healing: A Biomechanical and Histological Evaluation in the New Zealand White Rabbit

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator: Bert Callahan, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Surg/Orth (10) Associate Investigators: Edward Lisecki, MAJ, MC

(11) Key Words:
ciprofloxacin
fracture healing

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the effect of Ciprofloxacin on primary fracture healing in the rabbit.

(16) Technical Approach: Per protocol approved by LACUC on 19 Feb 91.

(17) Progress: Study is still ongoing. It is too early to form any conclusions.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/202A (3) Status: Ongoing

(4) Title: Ciprofloxacin and Primary Fracture Healing: A Biomechanical and Histological Evaluation in the New Zealand White Rabbit

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator: Bert Callahan, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Surg/Orth (10) Associate Investigators: Edward Lisecki, MAJ, MC

(11) Key Words:
ciprofloxacin
fracture healing

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the effect of Ciprofloxacin on primary fracture healing in the rabbit.

(16) Technical Approach: Per protocol approved by LACUC on 19 Feb 91.

(17) Progress: Study is still ongoing. It is too early to form any conclusions.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/203A (3) Status: Ongoing

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbits and Rats

(5) Start Date: 1991 (6) Est Compl Date: indefinite

(7) Principal Investigator: D.E. Casey Jones, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Surg/Orth (10) Associate Investigators:

(11) Key Words: microsurgery

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This is an ongoing and indefinite study used to maintain proficiency in the microsurgical repair of small vessels, nerves, and tendons. The femoral arteries of rabbits and rats (having a diameter of approximately .7 mm) are ideally suited for this type of study and have been used in past years to maintain proficiency for microvascular technique by the Hand Surgery Service of the Dept. of Surgery.

(16) Technical Approach: Per protocol approved by LACUC on 23 May 91.

(17) Progress: This protocol outlines a well-defined technique for education in, and ongoing skills maintenance for, microsurgical repair of small vessels and nerves. As such, it is an integral part of the hand surgery rotation for the orthopedic residency program at FAMC. Due to the interruption of normal schedules necessitated by support of Desert Storm, this protocol was not fully utilized FY91. Since Dr. Johns has departed, there has been no one qualified to teach microsurgical vessel repair to the orthopedic residents, further delaying the return to use of this protocol. With Dr. Jones' assumption of responsibility for the hand surgery service, this protocol will be reactivated in the upcoming months and made a regular part of the hand surgery rotation.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/204A (3) Status: Ongoing

(4) Title: Evaluation of a Gelatin Film Barrier Following Parotidectomy for the Prevention of Frey's Syndrome in the Goat (Capra hircus)

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Vincent Eusterman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Surg/ENT (10) Associate Investigators: Glen Yoshida, MAJ, MC

(11) Key Words:
Frey's syndrome

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Twofold: (1) to develop an animal model to produce post-parotidectomy Frey's Syndrome; (2) to objectively document the ability of a gelatin barrier (Gelfilm), to delay the production of Frey's Syndrome following superficial parotidectomy.

(16) Technical Approach: Per protocol approved by LACUC on 18 Jun 91.

(17) Progress: Currently all goats have undergone the surgical protocol. We are now testing for Frey's Syndrome using the starch-iodine protocol. On 28 Oct goat #4 will be euthanized in order to determine the gelfilm reaction at 2 months. To date one goat (surgery 23 Aug 91) is showing a positive starch iodine test.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #:91/205 (3) Status: Ongoing

(4) Title: Holter Monitoring to Evaluate Possible Arrythmias Following Epinephrine and Cocaine Use During Nasal Surgery

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: William Harpster, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Plastic Surgery (10) Associate Investigators: Jennifer Ladner, CPT, MC David Cheney, MAJ, MC Berry Morton, LTC, MC

(11) Key Words: arrhythmias

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the incidence of arrhythmias following nasal surgery using the standard regimen of 2% lidocaine with 1:100,000 epinephrine plus 5 ml 4% tpical cocaine hydrochloride solution.

(16) Technical Approach: Monitor all patients undergoing nasal surgery, using Holter monitor for 24 hrs before, during and following nasal surgery.

(17) Progress: None. Recently approved study.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/206A (3) Status: Ongoing

(4) Title: Use of Goats for Training in Advanced Trauma Life Support

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Phillip Mallory, II, LTC (8) Facility: FAMC

(9) Dept/Svc: Surgery/SICU (10) Associate Investigators: Dick Smith, COL, MC

(11) Key Words: a d v a n c e d t r a u m a l i f e s u p p o r t

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prcvide ealistic training opportunities for physicians in Advanced Trauma Life Support (ATLS) Course.

(16) Technical Approach: Per protocol approved by the LACUC on 12 Aug 91.

(17) Progress: Recently approved, 3 goats were used to train 12 students in September.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 77/300 (3) Status: Ongoing

(4) Title: Immunologic Disorders in Children and Adults. I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies

(5) Start Date: 1977 (6) Est Compl Date: Open-Ended

(7) Principal Investigator: Robert S. Stewart, MAJ, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators Shannon M. Harrison, LTC, MC

(11) Key Words: immunologic diseases

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 213
d. Total Number of Subjects Enrolled to Date: 1541
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Existing specialized immunochemical procedures will be consolidated into a registered protocol for use on a consultative basis by the FAMC hospital staff.

(16) Technical Approach: Serum gammapathics evaluated by SPEP, IEP, and rate nephelometry. Lymphocyte phenotyping, DNA analysis, and neutrophil activation potential by flow cytometry. Lymphocyte activation determined by quantitative mitogenesis.

(17) Progress: We continue to provide specialized immunological evaluations and testing with this protocol.

Presentations:

(1) Brown, G.L., and Heggers, J.: Medical Mycology: Assessment of Bacteriologic and Serologic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

(2) Dolan, W., Hill, S., Hasbargen, J., Rickman, W., and Weber, R.: Acquired Hypogammaglobulinemia with Absence of Leu-12 Antigen Following Bilateral Nephrectomy and Renal Transplantation for Goodpasture's Syndrome. Presented: 14th Annual Allergy--Immunology Symposium, Aurora, CO, 21-23 January 1986.

(3) Rickman, W.J., Lima, J.E., and Muehlbauer, S.L.: U.S. Army HTLV-III Testing Program Flow Cytometry Workshop. Presented: 11th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists, San Antonio, TX, 18-20 March 1986.

(4) Rickman, W.J.: Epidemiology, Pathogenesis and Military Implications of HTLV-III Infection. Presented: Health Service Command Annual Pharmacy Conference. Aurora, CO, 5-9 May 1986.

(5) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Lymphocyte Subsets in Human Immunodeficiency Virus Infection: A Prospective Study. Presented: 2nd Annual Symposium of the Rocky Mountain Flow Cytometry Users Group, Albuquerque, New Mexico, 10-11 September 1986.

(6) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Human Immunodeficiency Virus (HIV) Natural History Study: Abnormal Proliferation of Leu-7 Positive Suppressor T Cells in Asymptomatic Seropositive Patients. Presented: United States Army AIDS Conference, Arlington, VA, 16-18 September 1986.

(7) Stewart, RS, and Hoyt, AJ: Utilization of an Automated Windowless Geiger Chamber Apparatus In Lieu of Liquid Scisntillation for Lymphocyte Transformation Assays. Presented: 15th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists. Baltimore, MD, March 1990.

Publications:

Smolin, M.R., Hasbargen, J., and Rickman, W.J.: Profound Panhypogammaglobulinemia in a Renal Transplant Recipient. Ann. Int. Med.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 82/302 (3) Status: Ongoing

(4) Title: The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory

(5) Start Date: FY 84 (6) Est Compl Date: Ongoing

(7) Principal Investigator: Pari L. Morse (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators

(11) Key Words:
microbiology
microbiological techniques

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within the laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.

(16) Technical Approach: A separate protocol will be designed for each product evaluated.

(17) Progress: Evaluation of a ELISA kit (ortho) for the measurement of antibody to hepatitis C (formerly non-A, non-B). This kit appears useful for large scale screening but is not specific enough for confirmation of Heaptitis C. Evaluation of a western blot kit (CHIRON-RIBA) for the measurement of antibody to Hepatitis C in sera. This kit

Progress continued - appears to be more specific than the ELISA (ORTHO). We recently evaluated a second generatio Western Blot kit (CHIRON_RIBAII) and found it to be more sensitive in detecting antibodies to Hepatitis C in serum than the original RIBA method. Several kits are under consideration including Hepatitis D and a DNA probe for H. influenza.

Presentations:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur,J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrus Acid Extraction Technique. Presented: a) Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985; b) 5th Annual Conference on Military Pediatrics Research, Aspen, CO, July 1985;) 14th Aspen Conference on Pediatric Research, Aspen, CO, July 1985.

Publications:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococcus by Direct Swab Micronitrus Acid Extraction Technique. J. Clin. Microbiol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 86/300 (3) Status: Completed

(4) Title: Early Identification of Borrelia burgdorferi Antibody in Human Sera

(5) Start Date: 1986 (6) Est Compl Date: 1991

(7) Principal Investigator: Leo A. Andron, LTC, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators

(11) Key Words:
borrelia
lyme disease
spirochete

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___Oct____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop a sensitive and specific screening assay to detect human IgM directed against B. burgdorferi. The procedure proposed here will determine if the avidinbiotin system can detect IgM antibody bound to B. burgdorferi on nitrocellulose paper (NCP).

(16) Technical Approach: Preliminary studies confirmed that the probes currently available against IgG are more sensitive and much more specific than the anti IgM probes. A new IFA kit using the FIAX fluorometer system that detects IgG/IgM antibodies to B. burgdorferi was found to have the best sensitivity and specificity of currently available commercial kits.

(17) Progress: FAMC portion of this protocol is complete. Data and sera have been transferred to COL Hastrider of the Army Environmental Hygiene Agency for anlaysis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/30X (3) Status: Terminated

(4) Title: Veterinarian and Veterinary Support Personnel Training in Emergency Care Procedures for Laboratory Animals

(5) Start Date: Jul 88 (6) Est Compl Date: Ongoing

(7) Principal Investigator: Ron E. Banks, MAJ, VC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators: Terrie R. Clark

(11) Key Words:
laboratory animals
emergency procedures
veterinary personnel training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: N/A b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide veterinary resources personnel training in routine and emergency medical procedures in government owned animals.

(16) Technical Approach: See Protocol.

(17) Progress: No animals used under this protocol. Terminated this FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/301 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: I Skin Lesion Examination

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator:
Scott Bennion, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn

(10) Associate Investigators:

(11) Key Words:
lupus erythamatosus
immunofluorescence
icam

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:____FEB____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____20_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether systemic lupus erythematosus, discoid lupus erythematosus, and subacute lupus erythematosus can be differentiated by specific auto-antibody binding patterns in the skin using immunofluorescent staining techniques.

(16) Technical Approach: Direct immunofluoresence, immunoperoxidase staining, H&E histology.

(17) Progress: In addition to the original IF studies we have been performing on the specimens, we are studying the tissue for the presence of intracellular adhesion molecule. This molecule is thought by many to be important in the trafficking of inflammatory cells through the epidermis.

CONTINUATION SHEET, ANNUAL PROGRESS REPORT FY 91 Proto. No. 89/301

Publications: 2 papers in progress - 3 abstracts given.

Presentations: Western Regional Meeting of the American Federation of Clinical Research.
National Meeting of the Society of Investigative Dermatology.
National Meeting of the American College of Rheumatology.
Poster presentation at the annual meeting of the American Society of Dermatopathology.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/302 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: II Characterization of Autoantigens and Autoantibodies in Lupus

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators: Lela Lee, MD, UCHSC

(11) Key Words:
neonatal lupus erythematosus
autoantigens
autoantibodies
Ro

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The major objectives of this project are to characterize the autoantigens and autoantibodies involved in neonatal lupus erythematosus (NLE) and subacute cutaneous lupus erythematosus (SCLE) and to determine if certain characteristics of the autoantigens or autoantibodies can be related to the major clinical findings in these diseases.

(16) Technical Approach: Immunoblotting technique, cloning of Ro, rabbit immunization with Ro to attempt to produce animal model.

(17) Progress: It has been found that the La RNA-binding antigen is present in greater quantities in neonatal than in adult tissues. (These studies were done using antisera from patients who were from the Univ. of Colorado Medical Center.) There have been no direct benefits to the human subjects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/303 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: III The Study of the Effects of Ultraviolet Light on the Skin of Lupus Erythematosus Patients

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator:
Scott Bennion, LTC, MC
Lela Lee, MD

(8) Facility: FAMC
UCHSC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators:

(11) Key Words:
ultraviolet light
cutaneous lupus

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate and better correlate the cutaneous lupus subsets with their respective responses to ultraviolet light to be performed by phototesting patients with systemic lupus erythematosus (SLE), discoid lupus erythematouss (DLE) and subacute cutaneous lupus erythematosus (SCLE) then analyzing tissue and serologic specimens.

(16) Technical Approach: UV exposure followed by immunfluoresenct.

(17) Progress: No progress. Currently we are having difficulty in determining the appropriate dosage of UV light. We are utilitzing one patient who is at the UCHSC to adjust the area and time of UV light exposure. Until we feel comfortable with the UV dosage we are not going to begin a large study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/304 (3) Status: Completed

(4) Title: Evaluation of the Protofluor-Z as a Screening Tool for Lead Intoxication in Children

(5) Start Date: 30 Aug 89 (6) Est Compl Date: 30 Aug 91

(7) Principal Investigator: Joseph C. White, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators: COL Askold Mosijczuk David B. Burgess, MD

(11) Key Words: blood lead heated graphite atomiztaion

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1000
d. Total Number of Subjects Enrolled to Date: 1400
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to reduce the cost of blood lead screening by placing hematofluorometers in a clinic setting. Only samples that fail the screening criteria need be analyzed further for anemia or lead intoxication.

(16) Technical Approach: Blood lead assayed by the gold standard method: atomic absorption, then reuslts compared with hematofluorometers measuring ZPP.

(17) Progress: 1000 samples assayed by aa; 800 samples assayed by hematofluorometer; methods developed for both instruments; survey certification complete in March, 1990. CDH portion complete. Army participation open. Continue to refine the method. Changed to whole blood calibration. We continue to maintain our OSHA certification for blood lead. In Nov 1990 started doing clinical samples for Pathology. Writing a paper on method now. Completed collaborative superfund study Aug 90 on Peds in Idaho Springs area.

Publications: Abstract Mar, 1990, Society of Armed Forced Medical Laboratory Scientists. Baltimore, MD.

Presentations: "Aqueous vs. Whole Blood Calibration for Blood Lead by Electrothermal Zeeman Background Corrected Atomic Absorption", presented at the above cited meeting.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/300 (3) Status: Completed

(4) Title: Videx (2', 3'dideoxyinosine, ddI) Treatment IND Protocol No. 454-999-001 (Bristol-Myers Co)

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Robert H. Gates, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: DCI/MDI (10) Associate Investigators: Shannon M. Harrison, LTC, MC; William R. Byrne, LTC, MC; Rowland N. Hannon, PA-C/IDS

(11) Key Words: HIV therapy; anti-retroviral therapy; reverse transcriptase inhibitor

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Treatment with ddi in patients with severe ARC or AIDS who clinially deteriorate on Zidovudine therapy and cannot participate in NIAID phase II study.

(16) Technical Approach: Study design is an open label salvage treatment using 2', 3' dideoxyinosine (ddi), in patients with advanced HIV disease. These patients are followed in the Infectious Disease Clinic at Fitzsimons Army Medical Center, and treated according to protocol, and in coordination with the sponsor.

(17) Progress: Two patients remain on protocol at FAMC. Two patients withdrew by patient choice--no adverse drug effects. One patient transferred to the VA after losing beneficiary status. As of 9 Oct 91 VIDEX is available by prescription; therefore, this protocol is being phased out.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/301 (3) Status: Completed

(4) Title: Videx (2', 3'dideoxyinosine, ddI) Open Label Study
Protocol No. 454-999-002 (Bristol-Myers Co)

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator:
Robert H. Gates, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:
Shannon M. Harrison, LTC, MC
William R. Byrne, LTC, MC
Rowland N. Hannon, PA-C

(11) Key Words:
HIV therapy
anti-retroviral therapy
reverse transcriptase inhibitor

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___1_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" **Peripheral neuropathy, which developed in one subject, was reported to the sponsor.**

(15) Study Objective: Treatment with ddi in patients with severe ARC or AIDS who clinically deteriorate on Zidovudine therapy and cannot participate in NIAID phase II study.

(16) Technical Approach: Study design is an open label salvage treatment using 2', 3' dideoxyinosine (ddi), in patient with advanced HIV disease. These patients are followed in the Infectious Disease Clinic at Fitzsimons Army Medical Center, and treated according to protocol, and in coordination with the sponsor.

(17) Progress: To date, two patients have been treated with ddi on this protocol. One patient, as noted above, had the drug discontinued secondary to peripheral neuropathy. This peripheral neuropathy has improved greatly off drug. The other patient has noted improved energy, appetite, and sense of well-being. This patient remains clinically stable, without obvious adverse side effects. This protocol is being phased out because VIDEX is now approved as a prescription drug.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/300 (3) Status: Ongoing

(4) Title: Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents

(5) Start Date: 1991 (6) Est Compl Date: 1997

(7) Principal Investigator:
Shannon M. Harrison, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:
David Cohn, MD, DH&H
Chip Schooley, MD, UCHSC
Douglas Mayers, MD, WRAIR

(11) Key Words:
antiretroviral

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Aug b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a resource collection of lymphocytes and clinical information on HIV infected patients who are taking antiretroviral agents in known amounts and duration on other protocols.

(16) Technical Approach: Update of history and physical parameters every 12 weeks, collection of 2 x 10^7 lymphocytes after CD4 helper enumeration, beta-2 microglobulin and P24 antigen every 12 weeks, chem 18 every 12 weeks, skin testing every 12 weeks (desirable but not essential).

(17) Progress: None, recently approved study submitted for MRDC funding.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/301A (3) Status: Ongoing

(4) Title: Evaluation of Biological Attachment Factors for Skin Graft Acceptance in Athymic Nude (beige/nude/Xid) Mice

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Donald Mercill, DAC (8) Facility: FAMC

(9) Dept/Svc: CI/Cell Phys (10) Associate Investigators: Ronald Jackson, CPT, MS Scott Bennion, LTC, MC

(11) Key Words: skin graft

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to investigate whether biological attachment factors can be used beneficially in vivo, particularly in skin grafting techniques.

(16) Technical Approach: Per protocol approved by LACUC on 18 Jul 91.

(17) Progress: To date no work has been performed. When FY92 funds become available, mice will be purchased and work will proceed according to schedule.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/302A (3) Status:Ongoing

(4) Title: Training for Department of Clinical Investigation and Veterinary Services Personnel in Medical, Surgical, and Emergency Care and Treatment, and Laboratory, Pathology, and Radiologic Procedures for Various Laboratory Animal Species

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Ron Banks, MAJ, VC (8) Facility: FAMC

(9) Dept/Svc: CI/Animal Res (10) Associate Investigators: Marta Acha, CPT, VC

(11) Key Words: training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide training in routine and emergency medical, surgical, laboratory, pathology and radiology procedures for personnel of the Department of Clinical Investigation and Veterinary Services, using government-owned animals.

(16) Technical Approach: Per protocol approved by LACUC on 18 Jul 91.

(17) Progress: Continue to use as mechanism for personnel training.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 80/351 (3) Status: Ongoing

(4) Title: Section A: Master Protocol for Phase II Drug Studies in the Treatment of Advanced Recurrent Pelvic Malignancies
GOG 26 A

(5) Start Date: 4/14/86 (6) Est Compl Date: Unknown

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:__ MAY____ b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Ongoing, not a treatment protocol.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 80/352 (3) Status: Ongoing

(4) Title: Section C: A Phase II Trial of CIS-Platinum
GOG 26 C

(5) Start Date: 4/27/77 (6) Est Compl Date: Unknown

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients; one partial remission. No adverse reactions.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 80/359 (3) Status: Ongoing

(4) Title: Section S: A Phase II Trial of VM26
GOG 26

(5) Start Date: 7/9/84 (6) Est Compl Date: Unknown

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Four patients, three progressive disease, 1 stable. No adverse reactions.

Publications and Presentations: Multiple by GOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 80/378 (3) Status: Ongoing

(4) Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin in Patients with Progressive Disease
GOG 72

(5) Start Date: 12/20/83 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients, surgical-pathological study only, no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 80/380 (3) Status: Ongoing

(4) Title: A Clinical Pathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy
GOG 73

(5) Start Date: 11/1/83 (6) Est Compl Date: 1990

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: No patients entered.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/353 (3) Status: Ongoing

(4) Title: Evaluation of Cisplatin, Etopuside, and Bleomycin Induction Followed by Vincristine, Dactinomycin and Cyclophosphamide Consolidation in Advanced Ovarian Germ Cell Tumors

GOG 90

(5) Start Date: 9/18/86 (6) Est Compl Date: 1991

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:____ MAY__ b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/354 (3) Status: Ongoing

(4) Title: Randomized Clinical Trial for the Treatment of Women with Selected Stage IAi & IAii & IBii Ovarian Cancer (Phase III) GOG 95

(5) Start Date: 9/22/86 (6) Est Compl Date: 1994

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:___ MAY___ b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet. and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/358 (3) Status: Ongoing

(4) Title: Evaluation of Intraperitoneal Chromic Phosphate After Negative Second-Look Laparotomy in Ovarian Carcinoma

GOG 93

(5) Start Date: 6/1/87 (6) Est Compl Date: 1992

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/359 (3) Status: Ongoing

(4) Title: Adjunctive Radiation Therapy in Intermediate Risk Endometrial Carcinoma

GOG 99

(5) Start Date: 6/1/87 (6) Est Compl Date: 1991

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:___ MAY___ b. Review Results: Approved_
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/350 (3) Status: Ongoing

(4) Title: Radiation Therapy vs No Further Therapy in Selected Patients with Stage IB Invasive Carcinoma of the Cervix

GOG 92

(5) Start Date: 3/9/88 (6) Est Compl Date: 1992

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:___ MAY __ b. Review Results:_Approved_
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/351 (3) Status: Ongoing

4) Title: A Phase II Study of the Treatment of Stage III and IV Disease of Advanced Endometrial Carcinoma and All Stages of Papillary Serious Carcinoma and Clear Cell Carcinoma of the Endometrium with Total Abdominal Radiation Therapy
GOG 94

(5) Start Date: 12/22/86 (6) Est Compl Date: 1990

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:___ MAY___ b. Review Results:_Approved_
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/355 (3) Status: Ongoing

(4) Title: Intraperitoneal (SWOG8501) Intraperitoneal Cis-Platinum and Cyclophosphamide IV vs Intravenous Cis-Platinum and Cyclophosphamide IV in Patients with Optimal Stage III Ovarian Cancer
GOG 104

(5) Start Date: 6/15/88 (6) Est Compl Date: Unknown

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, one patient living with no evidence of disease. No adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/358 (3) Status: Ongoing

(4) Title: Monoclonal Antibody Against Free Beta HCG to Predict Development of PGTD in patients with Hydaditoform Mole

GOG #100

(5) Start Date: 1/88 (6) Est Compl Date: 1/92

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_ MAY____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or s ponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/359 (3) Status:Ongoing

(4) Title: GOG 102A - Master Protocol for Intraperitoneal Drug Studies in Residual Ovarian Malignancies after Second-Look Surgery

(5) Start Date: 1/4/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:__ MAY__b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group in the study of malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/360 (3) Status: Ongoing

(4) Title: A Phase II Trial of Hydroxurea, DTIC and VP-16 in Patients with Advanced Uterine Sarcomas

87C

(5) Start Date: 3/7/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:___ MAY__b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/351 (3) Status: Ongoing

(4) Title: A Phase II Trial of VP-16 in Patients with Advanced or Recurrent Uterine Sarcoma

GOG 87D

(5) Start Date: Aug 89 (6) Est Compl Date: 1994

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
VP-16
uterine sarcoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:____ MAY__b. Review Results:_Approved
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To identify active drugs against each of the two major types of sarcomas which have a high recurrence rate and against which combination chemotherapy has not been effective. VP-16 has been included because it has been shown to have elicited some response in a very small sample and the data suggest the need for study in previously untreated patients.

(16) Technical Approach: This is a non-randomized study which will involve treating an average sample size of 30 evaluable patients per drug. This method allows for rapid replacement of ineffective agents.

(17) Progress: No patients have been enrolled at FAMC to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/352 (3) Status: Ongoing

(4) Title: A Phase II Evaluation of Preoperative Chemoradiation for Patients with Advanced Vulvar Cancer
GOG 101

(5) Start Date: Aug 89 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
preoperative chemoradiation
vulvar cancer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:____ MAY___b. Review Results:_Approved
c. Number of Subjects Enrolled During Reporting Period:_____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if using preoperative chemoradiotherapy will obviate the need for pelvic exenteration in patients with advanced vulvar cancer; will its use allow less extensive surgical resection without compromising survival or cure.

(16) Technical Approach: All patients will be treated with split-course radiotherapy to the primary lesion as well as chemotherapy. Only p nts with positive groin nodes will receive additional radiotherapy to e groin and pelvic nodes. Four to eight weeks after radiotherapy is completed, all patients will have surgical resection of the primary tumor plus bilateral groin node dissection.

(17) Progress: No FAMC patients enrolled to date on this recently approved protocol.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/354 (3) Status: Ongoing

(4) Title: A Randomized Study of Doxorubicin vs Doxorubicin Plus Cisplatin in Recurrent Endometrial Adenocarcinoma Previously Diagnosed as Primary Stage III or IV (Phase III)
GOG 107

(5) Start Date: Aug 89 (6) Est Compl Date: 6/92

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
doxorubicin
cisplatin
endometrial adenocarcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:___ MAY____b. Review Results:Ongoing_
c. Number of Subjects Enrolled During Reporting Period:___0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether the addition of cisplatin to doxorubicin offers significant improvement in the frequency of objective response, in the duration of progression-free interval and the length of survival as compared with the administration of doxorubicin alone.

(16) Technical Approach: Patients will be randomized to one of the two regimens and will be treated until the maximum tolerated dose of doxorubicin is reached or until there is progression of disease.

(17) Progress: No FAMC patients enrolled.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/355 (3) Status: Completed

(4) Title: Intrperitoneal Administration of Cisplatin (NSC#119875) and Etoposide (VP-16) (NSC #141540) in Patients with Residual Ovarian Carcinoma (Phase II)
GOG 102E

(5) Start Date: 1989 (6) Est Compl Date: 2/91

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:
cisplatin
etoposide
carcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:___ MAY____b. Review Results:_Ongoing
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of these two drugs used in combination when there has been a partial response to Cisplatin as determined by second-look surgery.

(16) Technical Approach: 200 mgm/M2 of Etoposide and 100 mgm/M2 of Cisplatin every 4 weeks for six doses.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/356 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Alpha Recombinant Interferon (aIFN) in Residual Ovarian Carcinoma (Phase II)
GOG 102F

(5) Start Date: 1989 (6) Est Compl Date: 2/91

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:
Interferon
carcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:___ MAY____b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:___0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of this agent when it is administered directly into the area where the tumor is localized when there has been a partial response to Cisplatin.

(16) Technical Approach: 50x106 units of Interferon administered IP in 250ml NS after 1750 ml dialysate solution is given IP via the IP catheter. Therapy is given weekly for 12 weeks.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/350 (3) Status: Ongoing

(4) Title: Ifosfamide and the Uroprotector Mesna, with or without Cisplatin, in Patients with Advanced or Recurrent Mixed Mesodermal Tumors of the Uterus

GOG 108

(5) Start Date: 1990 (6) Est Compl Date: 10/93

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/351 (3) Status: Ongoing

(4) Title: A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy vs Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterctomy and Node Dissection

GOG 109

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in teh GOG protocol in the study of Cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/352 (3) Status: Ongoing

(4) Title: A Phase II Trial of Didemnin B in Patients with Advanced Pelvic Malignancies

GOG #26EE

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/353 (3) Status: Ongoing

(4) Title: A Phase II Trial of Fazarabine in Patients with Advanced/Recurrent Pelvic Malignancies
GOG 26GG

(5) Start Date: 1990 (6) Est Compl Date: Undetermined

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/354 (3) Status: Ongoing

(4) Title: A Phase II Trial of 5-Fluorouracil and Leucovorin in Advanced Metastatic or Recurrent Pelvic Malignancies

GOG #26HH

(5) Start Date: 1990 (6) Est Compl Date: Undetermined

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASF:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/355 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Cisplatin (NSC#119875) and Thiotepa in Residual Ovarian Carcinoma

GOG 102G

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/356 (3) Status: Ongoing

(4) Title: A Phase III Randomized Study of Cyclophosphamide (NSC#26271) and Cisplatin (NSC#19875) Versus Taxol (NSC#125973) and Cisplatin (NSC#119875) in patients with Suboptimal Stage III and Stage IV Epithelial Ovarian Carcinoma

GOG 111

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Onoging, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/350 (3) Status: Ongoing

(4) Title: GOG 26II - A Phase II Trial of 5-FU and High Dose Leucovorin in Patients with Advanced/Recurrent Pelvic Malignancies

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/351 (3) Status: Ongoing

(4) Title: GOG 26JJ - A Phase II Trial of Taxol (NSC#125973) in Patients with Advanced Carcinoma of the Cervix

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/352 (3) Status: Ongoing

(4) Title: GOG 102H - A Phase II Study of the Intraperitoneal Administration of Recombinant Interleukin-2 in Residual Ovarian Carcinoma

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/353 (3) Status: Ongoing

(4) Title: GOG 109 - A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy vs Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/354 (3) Status: Ongoing

(4) Title: GOG 110 - A Randomized Study of Cisplatin vs Cisplatin Plus Dibromodulcitor (NSC#104800) vs Cisplatin Plus Ifosfamide and Mesna in Advanced Carcinoma of the Cervix

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/355 (3) Status: Ongoing

(4) Title: GOG 112 - A Randomized Comparison of Chemoprophylaxis Using Methotrexate vs Routine Surveillance in Mangement of High Risk Molar Pregnancy

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/356 (3) Status: Ongoing

(4) Title: GOG 26KK - A Phase II Trial of Merbarone (NSC 336628) in Patients with Advanced and Recurrent Endometrial, Cervical and Epithelial Ovarian Carcinoma

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG studies.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/357 (3) Status: Ongoing

(4) Title: GOG 26LL - A Phase II Trial of Prolonged Oral Etoposide (VP-16) in Patients with Advanced Pelvvic Malignancies

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG studies.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/358 (3) Status: Ongoing

(4) Title: GOG 113 - An Evaluation of Hydroxyurea, 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stage II-B, III and IV-A Carcinoma of the Cervix and Negative Para-aortic Nodes

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG studies.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/359 (3) Status: Ongoing

(4) Title: GOG 87F - A Phase II Trial of Doxorubicin and Ifosfamide with Mesna in the Treatment of Recurrent or Advanced Uterine Leiomyosarcomas

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG studies.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 78/40X-001 (3) Status: Terminated

(4) Title: Use of Laboratory Animals (Cats) to Teach Medical Skills

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Beverly A. Anderson, MAJ, MC

(9) Dept of Pediatrics (10) Associate Investigators

John P. Kinsella, MAJ, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:____2_____
d. Total Number of Subjects Enrolled to Date:_____10_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Teaching protocol.

(16) Technical Approach: See protocol.

(17) Progress: Annual laboratory exercise which was successful in teaching intubation/chest tube placement skills to Pediatric House Officers. This was an excellent model for teaching skills. No action in FY 91. Replaced by Ferret-model protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 82/403 (3) Status: Ongoing

(4) Title: Rare Tumor Protocol for Childhood Solid Tumor Malignancies, Ancillary
POG 7799

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators
Thomas Carter, COL, MC
Jeffrey Clark, COL, MC
Randal Henderson, MAJ, MC

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___0_____
d. Total Number of Subjects Enrolled to Date:_____5_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 82/414 (3) Status: Ongoing

(4) Title: NWTS Long Term Follow-Up Study: A Non-therapeutic Study

POG 8158

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:____0_____
d. Total Number of Subjects Enrolled to Date:_____0_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons, the study remains open to new patient registrations.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 82/420 (3) Status: Ongoing

(4) Title: Intergroup Rhabdomyosarcoma Study III

POG 8451

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
Dr. Clark
Dr. Reddy
Dr. Henderson
Dr. Bodlien

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___0_____
d. Total Number of Subjects Enrolled to Date:_____4_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Four patients have been entered at FAMC. The first patient has relapsed with metatastic disease after having completed the prescribed two years of chemotherapy and has died. Another patient, who entered in 1987 achieved complete remission status of his undifferentiated sarcoma of the pelvis region, but has subsequently died of overwhelming sepsis as a result of severe myelosuppression from chemotherapy; another patient entered in October 1986 had pulmonary metastases of chest and died on 10 July 1990. The other patient who was entered in 1988 with nasopharyngeal rhabdomyosarcoma is currently in complete remission status having completed chemotherapy. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 86/408 (3) Status: Completed

(4) Title: Laboratory Classification in Acute Lymphoid Leukemia of Childhood (ALinC 14C) Phase III
POG 8600

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators
Dr. Reddy
Dr. Bodlien
Dr. Henderson

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____8_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Eight patients at FAMC are on this study. The study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 86/410 (3) Status: Completed

(4) Title: ALinC #14: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (ALinC#14) - A Pediatric Oncology Group Phase III Study
POG 8602

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators
Dr. Reddy
(11) Key Words: Dr. Bodlien
drug therapy Dr. Henderson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____8_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: The study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/401 (3) Status: Ongoing

(4) Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA Hodgkins Disease in Pediatric Patients, A Pediatric Oncology Group Phase III Study
POG 8625/26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold D. Mosijczuk, COL, MC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators
Dr. Reddy
Dr. Bodlien
Dr. Henderson

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___2_____
d. Total Number of Subjects Enrolled to Date:_____4_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No unusual toxicities have been encountered. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 87/404 (3) Status: Ongoing

(4) Title: A Study of Childhood Soft Tissue Sarcomas (STS) Other than Rhabdomyosarcoma and Its Variants, A Pediatric Oncology Group Phase III Study
POG 8653/54

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold D. Mosijczuk, COL, MC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators
Dr. Clark
Dr. Reddy
Dr. Bodlien

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/400 (3) Status: Ongoing

(4) Title: T Cell#3 Protocol - A Pediatric Oncology Group Phase III Study

POG 8704

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator:
Askold D. Mosijczuk, COL,MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators
B. Vishnu Reddy, LTC, MC
Randal Henderson, MAJ, MC
John M. Bodlien, CPT, MS

(11) Key Words:
T cell ALL

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:____1_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The one patient entered at FAMC (MP) is an eight-year-old girl who presented with an extremely high white count at diagnosis (852,000) and was found to have T-cell ALL. The patient responded well to initial leukophoresis and chemotherapy according to protocol. She relapsed 8 months from diagnosis and died. Toxicity has been the expected severe myelosuppression. The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/402 (3) Status: Completed

(4) Title: The Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma (MOS) or Unresectable Primary Osteosarcoma vs Previously Treated Recurrent Osteosarcoma
POG 8759

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator:
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators
B. Vishnu Reddy, LTC, MC
David Hahn, LTC, MC
John M. Bodlien, CPT, MS
Jeffrey R. Clark, COL, MC

(11) Key Words:
phase II agents in untreated or recurrent osteosarcoma

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/404 (3) Status: Terminated

(4) Title: Ceftriaxone vs Amoxicillin/Clavulanate for Initial Empirical Therapy of Occult Bacteremia in Children

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: Frederic W. Bruhn, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
bacteremia
Ceftriaxone
Clavulanate

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if one of the antibiotic regimens used for the emperic therapy of occult bacteremia will be more effective in preventing serious complications.

(16) Technical Approach: See protocol.

(17) Progress: Administratively terminated in accordance with FAMC Reg 40-18, 3-5.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/405A (3) Status: Completed

(4) Title: Macromolecular Absorption in the Post-Asphyxiated Small Intestine of the Adult Rat

(5) Start Date: 1988 (6) Est Compl Date: 1991

(7) Principal Investigator: Kevin J. Kelly, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
macromolecular absorption
asphyxial injury

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:____48_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This protocol will attempt to demonstrate the mechanism of movement of whole protein macromolecules through small intestinal absorptive cells which have been subjected to an asphyxial injury, as compared to controls.

(16) Technical Approach: No new experimental techniques have been introduced. The animals are still anesthetized and subjected to laparotomy, as previously approved. The intestinal sacs constructed post-removal are now subjected to a new experimental variable. They are being incubated in the same nutrient media as previously described with the addition of a metabolic inhibitor 2.4 dinitrophenol. This will attempt to determine active vs. passive transport.

(17) Progress: All laboratory studies are complete. Data is being analyzed and tentatively indicates a negative study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/408A (3) Status: Ongoing

(4) Title: The Effect of Human/Animal Interaction on Stress Levels During Outpatient Pediatric Oncology Visits

(5) Start Date: (6) Est Compl Date: 1993

(7) Principal Investigator: Mary Woolverton, MSW (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators Askold Mosijczuk, COL, MC

(11) Key Words:
animal interaction
stress reduction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a. Does the presence and interaction with animals during outpatient treatment visits have any measurable effect on the patient's stress level as measured by blood pressure and fingertip temperature; b. Does the presence and interaction with animals during outpatient treatment visits have any measurable effect on the patient's anxiety level (as measured by behavioral questionnaires) or discomfort as measured by the visual analog pain scale).

(16) Technical Approach: Blood pressure, temperature and questionnaire will be used to evaluate stress levels in study subject.

(17) Progress: A total of 12 patients have been entered into the study. Due to investigators' time constraints we have not been able to gather data as projected. Hope to begin enrollment in fall of 1991.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/400 (3) Status: Completed

(4) Title: Protocol for Second Induction and Maintenance in Childhood Acute Lymphoblastic Leukemia (SIMAL #5)

POG 8710

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Hemo/Oncol (10) Associate Investigators: Dr. Reddy Dr. Bodlien

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/401A (3) Status: Ongoing

(4) Title: An Observational Study on the Response of Children to the Presence of a Stuffed Animal VS a Live Animal During a Neuromuscular Exam

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator:
Mary Woolverton, MSW
Terri R. Clark, CPT, VC

(8) Facility: FAMC

(9) Dept/Svc:PEDS/EFMP

(10) Associate Investigators:
David Hahn, LTC, MC

(11) Key Words:
animal interaction
stress reduction

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: ____DEC____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: ___10_____
d. Total Number of Subjects Enrolled to Date: _____36_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: By introducing an interaction with an animal we may be able to decrease anxiety and lessen the apprehension associated with potentially uncomfortable hospital visits.

(16) Technical Approach: See protocol

(17) Progress: Children seen in neuromuscular clinic are introduced first to a large white stuffed rabbit and later a dog/or cat to see how it effects their stress level during their physical exam in the clinic. This is documented on films and by independent observation. A total of 26 patients have been observed. This study is being actively pursued with more patients enrolled each month as they qualify by age and mental capacity. Children who have been to the clinic and around the animals now ask for them as soon as they come in.

Publications and Presentations: 3 presentations.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/403A (3) Status: Terminated

(4) Title: Effect of Inflammation in Chronic Pneumonia in Rats Due to Pseudomonas Aeruginosa----Medication by Bacterial Exoproducts

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
LeRoy M. Graham, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: PEDS/Pulmonary

(10) Associate Investigators:
Michael L. Vasil, PhD
Norbert F. Voelkel, MD
Kurt R. Stenmark, MD

(11) Key Words:
pneumonia
pseudomonas aeruginosa
rats

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish an animal model for cystic fibrosis using rats.

(16) Technical Approach: See protocol

(17) Progress: Have just returned from Operation Desert Storm. Assuming position as Clinical Chief, Pediatric In-Patient Svc, cannot make time committment for this type of research program. Will submit protocol in more clinical area in the near future.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/404 (3) Status: Ongoing

(4) Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) + or - Low Dose Total Nodal Radiation Therapy in the Treatment ofStages IIB, IIIA-2, IIIB, IV Hodgkin's Disease in Pediatric Patients
POG 8725

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc:PEDS/Hemo/Oncol

(10) Associate Investigators:
Dr. Reddy
Dr. Clark
Dr. Henderson
Dr. Bodlien

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/405 (3) Status: Terminated

(4) Title: Clonidine Treatment of Constitutional Delay of Growth and Puberty--A Prospective Double Blind Study

(5) Start Date: Sep 89 (6) Est Compl Date: Mar 92

(7) Principal Investigator: Robert Slover, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Adol Med (10) Associate Investigators: Linda Brantner, CPT, MC Linda Ikle, PhD

(11) Key Words: growth delay clonidine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results: Ongoing c. Number of Subjects Enrolled During Reporting Period:_____ d. Total Number of Subjects Enrolled to Date:_____ e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether chronic oral clonidine therapy is effective when compared to placebo in accelerating linear growth in constitutionally delayed pre-pubertal pediatric and adolescent patients.

(16) Technical Approach: Double-blind crossover study of 20 subjects.

(17) Progress: This study was administratively terminated by the IRC due to no progress and no response to requests thru DCI from HSC for clarification of the study and revision of the consent form.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/407 (3) Status: Terminated

(4) Title: Baby Development Follow-up Network Project

(5) Start Date: (6) Est Compl Date: Dec 90

(7) Principal Investigator: (8) Facility: FAMC
Beverly A. Anderson, MAJ, MC

(9) Dept/Svc:PEDS/Newborn

(10) Associate Investigators:
Majorie Feinberg EFMP
C. Gilbert Frank, MD

(11) Key Words:
developmental evaluation
high risk infants

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Developmental evaluation of all infants with birth weight of 1,000 to 1,500 grams who are Colorado residents.

(16) Technical Approach: The examinations will be done at 36-40 weeks post-conceptual age and eight months corrected age by physical or occupational therapists with at least one year experience in the Newborn Nursery who have been given special training sessions for this project.

(17) Progress: The infants enrolled in the followup study have continued to receive both medical and developmental evaluations routinely and per protocol. The occupational/physical therapists have been allowed to utilize current testing materials in a controlled manner and the communication between health care givers and the families of this high risk population has been optimized. Ended community wide. Other facilities were unable to do follow-up which was necesary for data collection.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/408 (3) Status: Completed

(4) Title: Comparison of Cotinine Hair and Saliva Analysis in the Determination of Passive and Active Cigarette Smoking Exposure in Adolescents

(5) Start Date: Oct 89 (6) Est Compl Date: 6/91

(7) Principal Investigator: Elise Sherva, DAC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators: Joseph White, MAJ, MS Neil Goodman, CPT, MC

(11) Key Words:
cigarette smoke exposure
passive smoking

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 50
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if commercially available EIA techniques for detecting cotinine correlate with historical survey to determine if the values accurately reflect the smoking history.

(16) Technical Approach: Small amounts of hair and saliva will obtained for EIA assay of cotinine from an adolescent population. A self-administered questionnaire detailing history of passive and active smoking over the preceding 3 months will also be given.

(17) Progress: There were some technical problems. The manufacturer for the cotinine assay went out of business. We located another manufacturer, and the field testing was unsatisfactory.

Publications and Presentations: 2 presentations, Goodman UCHSC June 91, and White in May 1991. Manuscript is in preparation.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/401 (3) Status: Terminated

(4) Title: Experience with Multiple Doses of Survanta in Premature Infants

(5) Start Date: 1990 (6) Est Compl Date: Indefinite

(7) Principal Investigator: John Kinsella, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Neonatal/PEDS (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: ___FEB__ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Treatment IND; surfactant therapy for premature infants with hyaline membrane disease.

(16) Technical Approach: Surfactant is instilled through the endotracheal tube; up to four doses may be given as indicated by respiratory status.

(17) Progress: Study terminated; shortly after approval of this treatment IND another product (Exosure) received formal approval by FDA, this product is now on the FAMC formularly.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/402A (3) Status: Ongoing

(4) Title: Training for Pediatricians in Emergency Procedures

(5) Start Date: 1990 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Beverly Anderson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Neonatal/PEDS (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To train pediatricians in invasive emergency procedures.

(16) Technical Approach: Goat, swine, and rabbits are to be used for training in intubation, femoral venous and arterial cutdown procedures, thoracostomy tube placement, and percutaneous jugular venous catheter placement.

(17) Progress: No action in FY 91.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/403A (3) Status: Completed

(4) Title: Studies of the Hemodynamic Consequences of Partial Cardiopulmonary Bypass in the Lamb

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: John Kinsella, MAJ, MC (8) Facility: UC Perinatal Unit at FAMC

(9) Dept/Svc: Neonatal/PEDS (10) Associate Investigators: Adam A Rosenberg, MD

(11) Key Words: cardiopulmonary bypass

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____10_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To study the distribution of blood flow during partial cardiopulmonary bypass in lambs.

(16) Technical Approach: Blood flow will be measured using microspheres during control period and at two levels of cardiopulmonary bypass (50 and 100 ml/kg/min).

(17) Progress: We studied the distribution of blood flow to three compartments (heart, upper body, lower body). We found that ECMO did not change the overall distribution of blood flow; however, blood flow from the ECMO circuit was preferentially directed to the upper body. Coronary artery and abdominal organs' blood flow was predominantly derived from the left ventricle at both ECMO flow rates. Coronary arterial blood flow was not compromised at the ECMO flow rates studied.

Publications and Presentations:
Distribution of Systemic Blood Flow During Partial Cardiopulmonary Bypass in the Lamb: 7th Annual ECMO Symposium, Breckenridge, CO, Feb 91.

The Effect of Extracorporeal Membrane Oxygenation on Coronary Perfusion and Regional Blood Flow Distribution: Society for Pediatric Research, New Orleans, LA, May 91.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/405 (3) Status: Ongoing

(4) Title: Followup of the NICU Graduate in Military Medical Facilities

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Beverly Anderson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Newborn/PEDS (10) Associate Investigators: Brian S. Carter, MAJ, MC

(11) Key Words:
NICU graduate follow-up

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 204
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance of NICU graduates in military medical facilities.

(16) Technical Approach: Information retrieved through questionnaire sent to every military facility serving a pediatric population.

(17) Progress: Information from questionnaire is currently being assessed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/406 (3) Status: Ongoing

(4) Title: POG 8788 Intergroup Rhabdomyosarcoma Study IV: A Pilot Study for Clinical Group III Disease

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/407 (3) Status: Ongoing

(4) Title: POG 8821 AML#3: Intensive Multiagent Therapy vs Autologous Bone Marrow Transplant Early in 1st CR for Children with Acute Myelocytic Leukemia

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/408 (3) Status: Ongoing

(4) Title: POG 8823/24 Recombinant Alpha Interferon in Childhood Chronic Myelogenous Leukemia

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____1_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, one patient enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/409 (3) Status: Ongoing

(4) Title: POG 8827 Treatment of Children with Hodgkin's Disease in Relapse - Phase II

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/410 (3) Status: Ongoing

(4) Title: POG 8829 A Protocol for a Case-Control Study of Hodgkin's Disease in Childhood: A Non-Therapeutic Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/411 (3) Status: Completed

(4) Title: POG 8832 Pre-XRT Cisplatin and Ara-C for Children with Imcompletely Resected Supratentorial Malignant Brain Tumors

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/412 (3) Status: Ongoing

(4) Title: POG 8850 Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of of Patients with Newly Diagnosed Ewing's Sarcoma or Primative Neuroectodermal Tumor of Bone

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/413 (3) Status: Ongoing

(4) Title: POG 8889 Intergroup Rhabdomyosarcoma Study-IV Pilot Study for Clinical Group IV Disease

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/414 (3) Status: Ongoing

(4) Title: POG 8828 Late Effects of Treatment of Hodgkin's Disease: A Pediatric Oncology Group Non-Therapeutic Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:
quality of life
questionnaire

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual. Two patients enrolled and questionnaires completed. Next quality fo life questionnaire not due for 3 years.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/415 (3) Status: Ongoing

(4) Title: POG 8650 National Wilms' Tumor Study - 4 (NWTS-4), A Pediatric Hematology-Oncology Group Phase III Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:
wilm's tumor

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, two patient enrolled at FAMC, alive and doing well.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/400 (3) Status: Ongoing

(4) Title: Normative Electrocardiographic Data in Healthy Newborns and Infants Living at Intermediate High Altitude

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: James Schroeder, MAJ, MC (8) Facility: FAMC, Aspen and Leadville, CO

(9) Dept/Svc: Pediatrics (10) Associate Investigators: Herb Whitley, MAJ, MC; Michael Schaffer, MD; Robert Wolfe, MD

(11) Key Words: newborns, altitude, EKG

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: ___Nov__ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine normal values of heart rate, PR interval, QRS complex duration, QT interval, P wave axis, frontal plane QRS axis, T wave axis, and morphology of precordial QRS complexes and T waves in healthy infants carried in utero and born at altitude, up to the age of 12 months.

(16) Technical Approach: We will obtain EKGs from healthy infants at a variety of ages from birth to 12 months, in conjunction with routine newborn nursery evaluations and well-child clinic visits at three different altitude sites. Approximately 100 subjects will be studied.

(17) Progress: Due to administrative difficulties and logistics, the Aspen and Leadville portions of the study have not progressed to the point of beinning data collection; therefore, the entire project is on indefinite hold. No data collection has begun at Fitzsimons, pending developments at the outlying sites.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/401A (3) Status: Ongoing

(4) Title: Pediatric Intubation Training Using the Ferret Model

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Beverly Anderson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:
John Kinsella, MAJ, MC

(11) Key Words:
training

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a live, realistic animal model for teaching the life-saving skills of neonatal endotracheal intubation.

(16) Technical Approach: Per protocol approved by LACUC 6 Dec 90.

(17) Progress: No ferret models were used by the Newborn Medicine Service this reporting period.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/402 (3) Status: Completed

(4) Title: Personality and Infant Development

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: David Burgess, MD (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:
personality
infant development

Judy Morrow, Ph.D.

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_ DEC____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:___36_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine how infant behavior (attention span, persistence, socialability, etc.) during routine developmental assessments affects the results of those developmental assessments.

(16) Technical Approach: Multi-institutional study using a longitudinal repeated measure design. Each infant will be seen at approximately 6 1/2 months and then again at 7 1/2 months. The following assessment tools will be used: Fagan Test of Infant Intelligence, Denver-2, Infant Behavior Record, and Short Infant Temperament Questionnaire. A total of 50 well babies will be studied, approximately 40 from FAMC.

(17) Progress: Dr. Burgess facilitated collection of data by Dr. Morrow who is the originator of this study. Data collection is complete, and data analysis will be accomplished in the near future.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/403 (3) Status: Ongoing

(4) Title: Evaluation of Test of Cure Using a DNA-Probe Test for Neisseria Gonorrhea

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: John Hanks, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators: Clifford Butler, SM, DAC Christine Scott, CPT, MC

(11) Key Words: DNA probe gonorrhorea

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 17
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine that the Gen-Probe PACE 2 system is a sensitive and specific predictor of gonorrhea infection of the female cervix or male urethra in the young adult (age 13-28 yrs). Also to determine if the Gen-Probe PACE 2 system can be used to test for cure of gonorrhea following treatment, and if so, the best time to test after treatment is completed (e.g. 7,14,21, or 28 days following treatment).

(16) Technical Approach: Specimens from 30-50 patients with positive gonococcal cultures will be evaluated. This study is a test of a test. Patients will be treated in the usual manner and will be re-tested on their followup visits.

(17) Progress: Between Feb 91 and Oct 91, 650 total screening cultures, 20 (3.1%) positive GC cultures, 71 (85%) enrolled in study. Results: Test of cure obtained between 6-11 days after treatment. (Median = 7 days). All 17 have shown negative GC culture and negative DNA probe.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/404 (3) Status: Ongoing

(4) Title: POG 8615 - A Phase III Study of Large Cell Lymphomas in Children and Adolescents - A Comparison of Two Treatment Regimens - ACOP+ versus APO

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/405 (3) Status: Ongoing

(4) Title: Can Spirometry Significantly Impact the Healthy Adolescent in Influencing Cessation

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: J.H. Walker, CDR, MC, USN (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:
smoking cessation
spirometry

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the effectiveness in various approaches to adolescent smoking cessation.

(16) Technical Approach: The study involves comparing two different techniques of presentation to encourage adolescents to quit smoking. Spirometry will be used in the study group.

(17) Progress: No progress due to training commitments of the investigator. Study should begin in FY92.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/406 (3) Status: Ongoing

(4) Title: POG 9000 - POG Acute Lymphocytic Leukemia in Childhood #15
Classification: A Non-therapeutic Study

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/407 (3) Status: Ongoing

(4) Title: POG 9005 - Dose Intensification of Methotrexate and 6-Mercaptopurine for Acute Lymphocytic Leukemia in Childhood: A Phase III Study

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/408 (3) Status: Ongoing

(4) Title: POG 9006 - Up-Front Intensive 6-MP/Methotrexate versus Up-Front Alternating Chemotherapy for Childhood Acute Lymphocytic Leukemia: A Phase III Study

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/409 (3) Status: Ongoing

(4) Title: POG 9046 - Molecular Genetic Analysis of Wilms' Tumor

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/410 (3) Status: Ongoing

(4) Title: Studies of the Neurologic Examination of Young Infants

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Beverly Anderson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Ped/Newborn

(10) Associate Investigators: Patricia Ellison, MD, UCHSC Bonnie Camp, MD, UCHSC

(11) Key Words: Neoneuro

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to provide normative data and scoring for an assessment method (which we call the Neoneuro) which we have previously developed. This will help clinicians to appropriately evaluate and score infants of these ages.

(16) Technical Approach: In this collaborative study with UCHSC 500 neurological evaluations with as many subjects as possible will be performed by trained nurse practitioners. The scores for all infants (normal and abnormal) in thses new age groupings will then be reviewed for descriptive statistics for itmes, factors and total scores: frequencies, means, standard deviations, skews, and kurtoses.

(17) Progress: Evaluations have recently begun at both institutions.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/411 (3) Status: Ongoing

(4) Title: POG 8945 An Intergroup Protocol for the Treatment of Childhood Hepatoblastoma and Hepatocellular Carcinoma

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, one patient enrolled on study and has completed four courses of chemotherapy. Doing well.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/450 (3) Status: Completed

(4) Title: Pathology Reference Ranges for Alpha Feto-Protein, Luteinizing Hormone and Follicle Stimulating Hormone

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator: Harry Slife, CPT, MS (8) Facility: FAMC

(9) Dept/Svc: Pathology (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish reference ranges for newly obtained methodologies.

(16) Technical Approach: The new methodologies include alpha feto-protein, luteinizing hormone, and follicle stimulating hormone.

(17) Progress: Completed satisfactorily for lab certification.

Publications and Presentations: None

DEPARTMENT OF RADIOLOGY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 80/602 (3) Status: Ongoing

(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol (NP-59) for Adrenal Evaluation and Imaging

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Peter W. Blue, COL, MC

(8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med.

(10) Associate Investigators

(11) Key Words:
adosterone
adrenal glands

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 33
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

(16) Technical Approach: Each patient will be studied while taking Lugol's or SSKI to protect thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicurie dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progress: Two patients were treated with NP-59 during this period. Both were negative.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/601 (3) Status: Terminated

(4) Title: Body Fat Determination by Dual Photon Absorptiometry

(5) Start Date: 1988 (6) Est Compl Date:

(7) Principal Investigator:
Peter W. Blue, COL, MC

(8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med.

(10) Associate Investigators
Harry N. Tyler, Jr.

(11) Key Words:
absorpotiometry
body fat

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: approx.
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate body fat composition by absorptiometry and other current modalities.

(16) Technical Approach: Each patient will be studied by four methods and the methods compared.

(17) Progress: No progress. Abandoned due to lack of funding.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/602 (3) Status: Terminated

(4) Title: The Comparative Renal Clearances of Disofenin and Mebrofenin

(5) Start Date: (6) Est Compl Date: July 1991

(7) Principal Investigator: Jay Cook MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Radiology (10) Associate Investigators: Peter Blue, COL, MC

(11) Key Words:
renal clearance
disofenin
mebrofenin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The intent of the study is to objectively compare the renal serum clearance of each of the agents in the most optimally controlled environment possible, the individual patient. In this manner, the claims of the manufacturer can be established or refuted and the best agent determined.

(16) Technical Approach: The subjects will be categorized into normal (total serum bilirubin of less than 2.0), and four groups of abnormal (greater than 2.0, 5.0, 10.0 and 20.0). Each patient will then be given the minimal suggested dose (4 millicures to 10 millicuries) and renal and hepatic clearances will be calculated. Hepatobiliary scans will also be performed on the patients with each agent. The abnormal group with bilirubins greater than 20 will receive the mebrofenin first followed by the disofenin to asses for competitive binding interference.

(17) Progress: Some preliminary work using plasma levels on one patient was accomplished. However, no patients were enrolled or given the study drugs. MAJ Cook has PCS'd and there is no further interest in conducting this study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/602 (3) Status: Completed

(4) Title: The Utility of the Bard "Biopty" Gun in the Breast: Correlation with Surgical Excisional Specimens

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator: James Leuthke, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Radiology (10) Associate Investigators: Steve H. Parker, MAJ, MC Jeffrey Lovin, CPT, MC Wayne Yakes, MAJ, MC

(11) Key Words: Bard "biopty" gun breast biopsy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: ___DEC___ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____105_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To ascertain the accuracy of breast biopsies performed with the Bard "Biopty" biopsy gun utilizing stereotaxic mammagraphic and ultrasonographic guidance.

(16) Technical Approach: As outlined in objective.

(17) Progress: Results indicate that Bard "biopty" gun produces specimens as good as surgical biopsy.

Presentations: Abstract to be presented at the Radiological Society of North America 75th Annual Meeting, 26 Nov-1 Dec 89, Chicago, IL.

Publications: Parker SH, Lovin JD, Jobe WE, Luethke JM, Hopper KD, Yakes WF, Burke BJ. Radiology 1990; 176:741-747.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 80/650 (3) Status: Completed

(4) Title: A Study of Hemoglobin and of Red Cell Metabolism in the American Opossum (Didelphis virginiana)

(5) Start Date: 1980 (6) Est Compl Date: 1991

(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators: J.E. Lima

(11) Key Words:
opossums
marsupial
erythrocytes
purine metabolism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____NA____
d. Total Number of Subjects Enrolled to Date:_____NA__
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: An inquiry into the energy metabolism of opossum erythrocytes (glucose, purines and pyrimidines) and factors involved which maintain cell viability and function.

(16) Technical Approach: Radiolabelled purine and pyrimidinenucleosides, bases and glucose are provided to red cells in-vitro and synthetic/catabolic pathways are determined with the aid of HPLC/radiochromttography.

(17) Progress: We found NAD content in opossum red cells to be in direct proportion to ATP and in inverse proportion to cellular dATP concentration. No dNAD nor its synthesis was observed in whole cells or in lysates.

Collaborative Efforts:

1. Division of Clinical Pharmacology, Department of Medicine, Brown University, Providence, RI - Isoenzymes of adenosine deaminase (40.000 and 100.000 Dalton species) were isolated from red cells, plasma, spleen and liver of D. virginiana. Their activities in these tissues, and their kinetic constants (Km and Vmax) to adenosine and deoxyadenosine were determined. A paper is in preparation for publication.

2. Department of Biology, Federal University of Santa Catarina, Florianopolis, Brasil - Purine nucleotide patterns of red cells of D. marsupialis and of D. albiventris have been determined. D. marsupialis, from which D. virginiana has evolved, does not have detectable deoxy ATP in its erythrocytes suggesting interesting genetic and evolutionary possibilities. A paper is in preparation for publication.

3. Department of Pharmacology, University of Columbia-Missouri, Columbia, MO - Cation transport in red cells of D. virginiana containing ATP/dATP, or dATP alone is being investigated. Membrane Na, K, Mg and Ca ATPase(s) are also being investigated using ATP and dATP as substrates.

4. Department of Physiology, University of New England, Armidale, Australia - A study of red cell nucleotide patterns and cation ATPase(s) of small Australian marsupialia is intended to commence in the Spring of 1991.

Publications:

1. Petty C, Bethlenfalvay NC, and Bageant T: Spectrophotometric measurement of hemoglobin oxygen saturation in the opossum, Didelphis virginiana. Comp. biochem. Physiol. 50:273, 1975.

2. Bethlenfalvay NC, Block M, and Brown GB: Hemoglobins of the opossum (Didelphis Virginiana Kerr) I. Developmental changers from yolk sac to definitive erythropoiesis. Lab. Animal Sci. 26:106-165, 1976.

3. Bethlenfalvay NC, Brown GL, and Waterman M: I. Hemoglobins of the opossum (Didelphis marsupialis) II. Electrophoretic and chromatographic observations. Lab Animal Sci. 26:908-912, 1976.

4. John ME, Bethlenfalvay NC, and Waterman MR: Oxidation - reduction properties of the hemoglobin of the opossum Didelphis Virginiana. Comp. Biochem. Physio. 73B:585-591, 1982.

5. Bethlenfalvay NC, Waterman MR, Lima JE, and Waldrup T: Cystolic and membrane bround methmoglobin reductases in erythrocytes of the opossum Didelphis virginiana. Comp. biochem. Physiol. 738:594, 1982.

6. Bethlenfalvay NC, Waterman MR, Lima JE, and Waldrup T: Comparative aspects of methemoglobin foration and reduction in opossum Didelphis Virginiana and human erythrocytes. Comp. Biochem. Physiol. 75A:635-639, 1983.

7. Bethlenfalvay NC, Lima JE, and Waldrup T: Studies on the energy metabolism of opossum (Didelphis Virginiana) erythrocytes. I. Utilization of carbohydrates and purine nucleosides. J. Cellular Physiol. 120:69-74, 1984.

8. Bethlenfalvay NC, Lima J, Waldrup T, and Chadwick E: Studies of the energy metabolism of opossum Didelphis virginiana erythrocytes. II. Comparative aspects of 2-deoxy-D-glucose catabolism in opossum and human red cells in-vitro. Comp. biochem. Physiol. 89A:113, 1988.

9. Bethlenfalvay NC, Lima J, Stewart I, and Chadwick E: Studies on the energy metabolism of opossum Dedelphis virginiana erythrocytes. III. Metabolic depletion with 2-deoxyglucose markedly accelerates methmeglobin reduction in opossum, but not in human erythrocytes. Comp. Biochem. Physiol. 89A:119, 1988.

10. Bethlenfalvay NC, Lima JE, Chadwick E: Studies on the energy metabolism of opossum Didelphis virginiana erythrocytes -IV. Half-millimolar levels of deoxy adenosine triphophate in red cells are found associated with low adenosine deaminase activity. Life Sciences 44: 963-970, 1989.

11. Bethlenfalvay NC, White JC, Chadwick E, Lima JE: Studies on the Energy Metabolism of Opossum (Didelphis virginiana) Erythrocytes: V. Utilizatin of Hypoxanthine for the Synthesis of Adenine and Guanine Nucleotides in-vitro. J. Cell Physiol. 143:563-568, 1990.

12. Bethlenfalvay NC, White JC, Chadwick E, Lima JE: Studies on the Energy Metabolism of Opossum (Didelphis virginiana) Erythrocytes: VI. De-Novo Purine Nucleotide Biosynthesis is Limited to the Final steps of the Pathway In-vitro. Comp. Biochem. Physiol. 97B: 193-196, 1990.

Presentations: Bethlenfalvay NC, White JC, Lima JE: NAD and NAD synthesis in ADA deficient erythrocytes of the opossum D. virginiana. Presented: Joint 7th Internaltional and 3rd Eruopean Symposium on Purine and Pyrimidine Metabolism in Man. Borunemouth, England, 30 June - 5 July 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/650A (3) Status: Ongoing

(4) Title: Study of Hemoglobin and Red Cell Metabolism in Didelphis marsupials

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
N.C. Bethlenfalvay, MD

(8) Facility: FAMC

(9) Dept/Svc: Primary Care

(10) Associate Investigators:
J.E. Lima, DAC

(11) Key Words:
hemoglobin
red cell metabolism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: 1) To establish normal values for hematology, red cell metabolism, red cell survival, and immunology of the South American Opossum, thereby providing a comparison to data observed in the North American Opossum already studied under protocol 80/650. 2) To determine if levels of red cell nucleotides and ADA are dissimilar in South American opossum, the progenitor of the N.A. opossum.

(16) Technical Approach: Per protocol approved by LACUC on 19 Feb 91.

(17) Progress: Due to bureaucratic difficulties encountered within the governmental agencies of Brazil, the four animals promised by the government have not yet been released for shipment.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/651A (3) Status: Ongoing

(4) Title: A Prevention of dATP Synthesis in Red Blood Cells of Didelphia virginiana Through Administration of ADGEN

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
N.C. Bethlenfalvay, MD

(8) Facility: FAMC

(9) Dept/Svc: Primary Care

(10) Associate Investigators:
J.E. Lima, DAC

(11) Key Words:
red blood cells

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish similarity between the human and D. virginiana in the action of ADAGEN at preventing the accumulation of dATP in the newly formed RBC.

(16) Technical Approach: Per protocol approved by LACUC 19 Feb 91.

(17) Progress: Two animals have been entered in the study. Plasma adenosine deaminase levels have risen from 180 nmoles/ml/h to 20.000 nmoles/ml/h with weekly injections of 10 U/kg of ADAGEN. dATP in red cells declined 30% from baseline 6 weeks into the study. The response to ADAGEN by the two animals so far closely parallels that seen inpatients having SCID due to ADA deficiency receiving treatment with ADAGEN.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 86/700A (3) Status: Terminated

(4) Title: Introduction of Suturing Techniques Using Outbred Adult Rats

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: LTC Castellan (8) Facility: FAMC

(9) Dept/Svc: Nursing/Ambul (10) Associate Investigators:

(11) Key Words:
suture techniques training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_Ongong___
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on separate sheet, and designated as "(14)e"

(15) Study Objective: To instruct selected department of nursing personnel to properly suture traumatic lacerations, to establish and maintain a sterile field during the suturing procedure, to cleanse traumatic lacerations, to instruct the patient to manage the wound and facilitate healing, and to correctly remove suture when healing is complete.

(16) Technical Approach: Students are detailed to perform at least 1 successful suturing episode under direct supervision of an Emergency Medical Service staff physician to validate learning and clinical competence. Once certified, suturing activities become a part of the staff members' scopes of nursing practice. Skills are revalidated annually to ensure continued competence.

(17) Progress: Outdated protocol. Recently replaced by protocol 91/701A.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/700 (3) Status: Completed

(4) Title: A Pilot Study: A Comparison of Subarachnoid Block Anesthesia with Tetracaine and Epidural Anesthesia with Lidocaine and the Effects on the Umbilical Artery Acid-Base Results and Five Minute Apgar Scores of Neonates Following Uncomplicated Cesarean Section

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: William Gillis, CPT, AN (8) Facility: FAMC

(9) Dept/Svc: Anesthesia/Nursing (10) Associate Investigators: Arthur Brehn, CPT, An Arthur Bryson, CPT, An Jenifer Crawford, CPT, An John Wong, CPT, AN

(11) Key Words: subarachnoid block epidural anesthesia apgar scores

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___20_____
d. Total Number of Subjects Enrolled to Date:_____20_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: Via a process of random selection compare 2 groups of 10 patients, 1 group to receive subarachnoid block anesthetic the other an epidural anesthetic for cesarean section, and compare the 5 min. apgar scores and umbilical artery acid-base results from the infants of the two groups.

(16) Technical Approach: Refer to "6.c. Evaluations" of the protocol.

(17) Progress: The mean age of the parturients was 28 y/o for the spinal group and 26 y/o for the epidural group. There were no other statistical differences between groups with respect to height, weight, race, gravida/para status, preload, or block level. One subject was excluded from the study after her EKG monitor revealed multiple dysrhythmias which required pharmacologic intervention. The total number of subjects in the epidural group was n=11. The total number of subjects in the spinal group was n=9. All infants were of normal weight and gestational age.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/701 (3) Status: Completed

(4) Title: Assessment of Post Myocardial Infarction Patients Learning Needs During Hospitalization and Post-Discharge

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Greg Cannon, 1LT, AN (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_ MAY___b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the priority of learning needs of the cardiac patient.

(16) Technical Approach: Utilize questionnaire developed by Peggs S. Gerard, RN, MS.

(17) Progress: Performed study to satisfy requirements for graduation from coronary care nursing course.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/702 (3) Status: Ongoing

(4) Title: The Impact of Practice at Fitzsimons Army Medical Center Upon Registered Nurses Professional Role Conception

(5) Start Date: (6) Est Compl Date: 1992

(7) Principal Investigator: A.J. Frelin, COL, AN (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators:

(11) Key Words:
registered nurses
role conception

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: a) Compare the role conception of neophyte RNs upon their assignment to FAMC and one year after assignment. b) Compare the role conception of experienced RNs upon their assignment to FAMC and one year after assignment. c) Assess similarities and dissimilarities between the two groups. d) Evaluate especially items of role discrepancy among all groups with the intent of making decisions regarding possible system changes which could decrease role conflict and impact positively on retention.

(16) Technical Approach: Comparative study using questionnaires distributed over an 18-month period.

(17) Progress: First anniversary of data collection has occured. Thus, first 1 yr comparisons begun in June 1991. It is expected that the study will continue longitudinally past the projected completion date with a new principal investigator.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/700 (3) Status: Completed

(4) Title: The Effects of Patient Positioning and Supplemental Oxygen on Post Operative Oxygen Saturation

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator:
Mark Oswald, CPT, AN

(8) Facility: FAMC

(9) Dept/Svc: Nursing/Anesthesia

(10) Associate Investigators:
Daniel Geniton, MAJ, AN
John Blower, CPT, AN
Matthew Cowell, CPT, AN
Robert Moore, CPT AN

(11) Key Words:
oxygen saturation
position

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Feb b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of the study is to compare the effects of supine and supine with head elevated position with or without oxygen on the oxygen hemoglobin saturation of immediate post operative patients. Based on results of this study, an optimal position for patient transport immediately post-op may be determined.

(16) Technical Approach: Subjects will be randomized to one of four groups. Pulse oximetry will be utilized to determine oxygen saturation of subjects. Patients will receive either room air or supplemental oxygen and be placed in either supine or supine with head elevated.

(17) Progress: Completion of this six-month research is required as part of the graduation requirements for the Program in Anesthesia Nursing Course, Phase II.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/701A (3) Status: Ongoing

(4) Title: Suturing Techniques for FAMC Personnel

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Debra Walker, LTC, AN (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14) e"

(15) Study Objective: Training professional and paraprofessional nursing personnel at FAMC in basic suturing techniques.

(16) Technical Approach: Training will consist of a didactic classroom component and practical proficiency component. The lesson plan of the protocol approved by LACUC on 16 Apr 91 will be followed when conducting both components.

(17) Progress: No progress due to PCS of original investigator. New PI recently returned from Desert Storm assignment. Arrangements will be made for a course in FY 92.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/702 (3) Status: Ongoing

(4) Title: Pilot Study for Psychometric Properties of Selected Tools for Pain Assessment and Management in Children

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator:
Catherine Johnson, LTC, AN

(8) Facility: FAMC

(9) Dept/Svc: Nursing

(10) Associate Investigators:
Loretta Forlaw, LTC, AN
Sue Wood, MAJ, AN
Jeff Jones, MAJ, AN

(11) Key Words:
pain assessment

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: July b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Pilot study to examine the feasibility of a protocol for pain assessment and management with hospitalized children ages birth through 18 years and to estimate the psychometric properties of the related tools.

(16) Technical Approach: The descriptive correlational design will involve implementing the Policy for Pain Assessment and Management which outlines a protocol or systematic pain assessment and recommends nursing actions for pain relief in accordance with existing physicians' orders.

(17) Progress: Due to a staffing turnover and the JCAHO inspection, the study has been delayed until November.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/750 (3) Status: Terminated

(4) Title: Onset-to-Onset Difference Between the Median Motor Nerve and the Anterior Interosseous Nerve Using a Common Stimulation at the Antebubital Fossae

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Douglas Hemler, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Phy. Med. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To mathematically define the temporal relationship between the anterior interosseous nerve and the median nerve.

(16) Technical Approach: To study subjects with normal upper extremities to determine the normal interlatency difference between the median nerve and the anterior interosseous nerve and to establish an interlatency coefficient.

(17) Progress: Investigators ETS'd without providing a final report.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/800A (3) Status: Ongoing

(4) Title: Survey of Tick Vectors and Wild Rodents for the Presence of Borrelia burgdorferi in the Deer Tick, Ixodes pacificus, and in the Black-legged Tick, Ixodes scapularis

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Lester Hale, Ph.D. (8) Facility: FAMC

(9) Dept/Svc: USA Environ.Hyg. (10) Associate Investigators: Thomas Gargan, MAJ, MS

(11) Key Words:
ticks
Lyme disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to survey for the above cited tick vectors, and to determine by selected methods the presence of Borrelia burgdorferi in tick vectors and wild rodents on military installations within the USAEHA-W support area. The USAEHA-W has been tasked by the US Army Health Services Command to conduct surveillance of Lyme disease on Army installations within CONUS to determine the health threat posed to the military community.

(16) Technical Approach: Per protocol approved by LACUC on 18 June 1991.

(17) Progress: The causal agent was not found in rodents trapped at Fort Lewis, Washington, and Yakima Firing Center, Washington. Data from collections at Iowa Army Ammunition Plant, Middletown, Iowa, are still being analyzed. Numerous sites will be studied in the future.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/801A (3) Status: Ongoing

(4) Title: Studies of the Metabolic Adaptation in Response to Chronic Severe Hypoxia in the Pregnant Sheep

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator:
S. Gwynn Geddie, MAJ, MC

(8) Facility: UC Perinatal Research Facility located at FAMC

(9) Dept/Svc: Ped

(10) Associate Investigators:
Frederick Battaglia, MD

(11) Key Words:
hypoxia
metabolic adaptations

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To study the metabolic adaptations which occur under chronic hypoxia.

(16) Technical Approach: Per protocol approved by LACUC on 18 Jul 91.

(17) Progress: No progress. Funding not available until sometime in FY92.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 83/902A (3) Status: Terminated

(4) Title: Training Study, Emergency Medical Procedures

(5) Start Date: 1982 (6) Est Compl Date: Ongoing

(7) Principal Investigator:
Mark A. Larsen, COL, MC

(8) Facility: FAMC
Ft. Carson Vet. Activity &
Ft. Carson MEDDAC Emergency
Medical Service
A-691-7226/7111

(9) Dept of Emerg Med & Vet Svc

(10) Associate Investigators:
MAJ Irwin Rubin

(11) Key Words:
emergency medical services

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____78_____
d. Total Number of Subjects Enrolled to Date:__ __85_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This project is a refresher/teaching course in emergency medicine operative procedures. It is conducted on a monthly basis for EMS physicians and PAs'.

(16) Technical Approach: Under general anesthesia animals are subjected to common emergency medicine operative procedures including venous cutdown, peritoneal lavage, chest tube insertion, and thorocotomy with aortic cross clamp with cardiac laceration repair. At the end of the exercise, the animals are disposed of by lethal injection.

(17) Progress: Terminate study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/900 (3) Status: Terminated

(4) Title: IOLAB Investigational Plan for the Clinical Study of Intraocular Lenses

(5) Start Date: 8/87 (6) Est Compl Date: 1991

(7) Principal Investigator:
David Pernelli, MAJ, MC

(8) Facility: FAMC
Fort Leonard Wood, MO
65473-5700

(9) Dept/Svc: Ophthalmology Svc

(10) Associate Investigators

(11) Key Words:
IOL (posterior chamber)

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 21
d. Total Number of Subjects Enrolled to Date: 46
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient.

(16) Technical Approach: Extracapsular cataract extraction with PC IOL secondary intraocular lens (IOL) implants.

(17) Progress: No adverse effects noted to date. PI PCS'd.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 88/901 (3) Status: Terminated

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Luis Colon, MAJ, MC

(8) Facility: FAMC
General Leonard Wood Army Community Hospital

(9) Dept/Svc: SUR/Ophthalmology (10) Associate Investigators

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___42_____
d. Total Number of Subjects Enrolled to Date:_____62_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cateract patient. (See original protocol)

(16) Technical Approach: Extracapsular cataract extraction with posterior chamber IOL.

(17) Progress: No complications thus far. PI PCS'd.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/900 (3) Status: Ongoing

(4) Title: Evaluation of a Phase I Coxiella burnetii Vaccine (IND 610) for Immunization Against Q Fever

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator:
Mark Clyde, CPT, MC

(8) Facility: FAMC
US Army Health Clinics
Dugway Proving Grounds
Dugway, Utah 84022

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 21
d. Total Number of Subjects Enrolled to Date: 21
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/901 (3) Status: Ongoing

(4) Title: Continued Evaluation of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, TC-83 Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel IND 142

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Mark Clyde, CPT, MC (8) Facility: FAMC US Army Health Clinic, DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/902 (3) Status: Ongoing

(4) Title: Evaluation of New Lots of Tularemia Vaccine, Protocol B: Comparative Assessment of Francisella tularensis Vaccine, Live, NDBR 101, IND 157

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Mark Clyde, CPT, MC

(8) Facility: FAMC
Dugway Proving Grounds
US Army Health Clinic

(9) Dept/Svc:

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Reserach Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/903 (3) Status: Ongoing

(4) Title: Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated. Protocol B: Continued Assessment of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 as a Booster in At-Risk Personnel, IND 914

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Mark Clyde, CPT, MC (8) Facility: FAMC US Army Health Clinic DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: ___Jan___ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____20_____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached. No new enrollments for this reporting period.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 89/904 (3) Status: Ongoing

(4) Title: Use of the Sixteen Personality Factor Questionnaire to Predict Susceptibility to Occupational Stress Among US Army Recruiters

(5) Start Date: Aug 89 (6) Est Compl Date: Aug 90

(7) Principal Investigator:
John Kaicher, CPT, MC

(8) Facility: FAMC
US Army Health Clinic
Ft. Sheridan, IL

(9) Dept/Svc:

(10) Associate Investigators:
Peter Orris, MD, MPH and
Robert Moretti, PhD,
Northwestern University
Medical School
Walter Teachout, CPT, MS, FAMC

(11) Key Words:
occupational stress
Army recruiters
personality factors

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine a mechanism to identify those soldiers who are predisposed to disabling occupational stress problems, considerable psychopathological morbidity and its attendant costs.

(16) Technical Approach:To determine the validity of the 16PF to predict Army Recruiters predisposed to occupational stress related psychological and behavioral problems.

(17) Progress: Progress was delayed while I completed a medical internship at UCHSC. I have resumed work on the project. All data has been collected and evaluated and statistical analyses completed; I hope to have the first draft of these completed by mid-August 1991.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/900 (3) Status: Ongoing

(4) Title: Iron Deficiency Anemia in 11-14 Month Old Infants at 6,000 Feet (1830m) Elevation. A Study to Evaluate the Response to a Therapeutic Trial of Iron

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator:
Steve Lang, MAJ, MC

(8) Facility: FAMC
Ft. Carson, CO
Family Practice

(9) Dept/Svc: Ft. Carson

(10) Associate Investigators:
Joe Cravlro, CPT, MC
Ft. Carson, CO
Ray Yips, MD, MPH, CDC
Atlanta, GA

(11) Key Words:
anemia
infants
high altitude

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUG b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether one year old infants at higher altitudes are more likely than children at sea level to be iron deficient.

(16) Technical Approach: Hemoglobin response in healthy 11-14 month old infants living at altitude to 3-month oral iron treatment will be assessed using a HemoCue hemoglobin measuring instrument.

(17) Progress: None to date, principal investigator assigned to Desert Storm.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 90/950A (3) Status: Terminated

(4) Title: Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care. Resuscitation of the Newborn Utilizing Young Cats

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: To be announced. (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a live, realistic animal model for teaching the life-saving skill of neonatal endotracheal intubation to Indian Health Service (IHS) personnel newly assigned to remote Service Units where successful resuscitation of asphyxiated infants may depend on their ability to intubate.

(16) Technical Approach: Animal models will be used to teach the skills of neonatal endotrachealintubation and bag and mask ventilation.

(17) Progress: This was a recurring post graduate course, the yearly outline will determine the principal and associate investigator and the number of course attendees. Replaced by Ferret-model protocol. No action in FY91.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/900 (3) Status: Terminated

(4) Title: Trial to Evaluate the Effect of Digitalis on Mortality in Heart Failure

(5) Start Date: 1991 (6) Est Compl Date: 1996

(7) Principal Investigator: David Waddell, CPT, MC (8) Facility: Ft. Leonard Wood, MO

(9) Dept/Svc: Cardiology (10) Associate Investigators:

(11) Key Words:
digitalis
heart failure

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This is a randomized, multi-institutional study designed to critically evaluate the role of digitalis in the context of current regimens that include widespread use of ACE-inhibitors.

(16) Technical Approach: Per US National Heart, Lung and Blood Institute and the Dept of Veterans Affairs Cooperative Studies Program protocol, 7,000 patients with heart failure and an ejection fraction of <.45 will be randomized to receive either digoxin or placebo in the main trial. Heart failure patients with an ejection fraction >.45 will also be entered into an ancillary study. Patients will be enrolled over three years and followed for a minimum of two further years or until the end of the study.

(17) Progress: None. Principal investigator withdrew from participation due to dissatisfaction with the military medical care system.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/901 (3) Status: Completed

(4) Title: User Review of the Prototype Self-Contained Toxic Environment Protective Outfit (STEPO)

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator:
Charles Dunemn, DAC

(8) Facility: FAMC
Pine bluff Arsenal, AR
71601-9500

(9) Dept/Svc:

(10) Associate Investigators:
John Bennett, CPT, MC

(11) Key Words:
hazardous material
protective suit

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To assess functional aspects and human factors suitability of the STEPO for use in performing emergency response and routine operations involving toxic chemical agents.

(16) Technical Approach: Testing will be conducted the the Pine Bluff Arsenal inside Bldg. 61-460 which will be staged to simulate an M55 rocket ammunition bunker. No contact will be made with any hazardous material.

(17) Progress: Project was successfully completed 4 May 91. Complete report was appropriately submitted to U.S. Army Natick, Research, Development and Engineering Center.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/902 (3) Status: Ongoing

(4) Title: Administration of Equine Heptavalent Antitoxin for Therapy of Suspected Botulism Intoxication

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Maria Sjogren, LTC, MC (8) Facility: USAMRIID

(9) Dept/Svc: (10) Associate Investigators: Mark Clyde, CPT, MC, Dugway PG Shannon Harrison, LTC, MC, C, DCI, FAMC

(11) Key Words: antitoxin botulism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The principle objective is to provide the depeciated botulinum antitoxin to individuals who may be exposed to botulinal toxins by foodborne, parenteral, or aerosol routes. A secondary objective is the collection of information regarding reactogenicity and efficacy of the product in humans.

(16) Technical Approach: Per Medical Research Institute of Infectious Diseases protocol IND 3703.

(17) Progress: None. Protocol recently approved by OTSG.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: 91/950A (3) Status: Ongoing

(4) Title: Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care: Resuscitation of the Newborn Utilizing the Ferret Model

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
Thomas Harris, MD, FAAP, Director, Perinatal Center, St. Mary's Hospital, Grand Junction, CO

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:
training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a live, realistic animal model for teaching the life-saving skill of neonatal endotracheal intubation to Indian Health Service (IHS) personnel newly assigned to remote Service Units where successful resucitation of asphyxiated infants may depend on their ability to intubate.

(16) Technical Approach: Per protocol approved by the LACUC on 15 Aug 91.

(17) Progress: The first training course was held in Sep 91.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 91 (2) Protocol #: EU-89-2 (3) Status: Completed

(4) Title: POG 8743

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Ped Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____1_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Treatment study for stage IV neuroblastoma sponsored by NCI.

(16) Technical Approach: See protocol.

(17) Progress: Study closed October 1990.

Publications and Presentations: NA

INVESTIGATORS INDEX

NAME	PAGE
Abrams, L.F.	98,113
Acha, M.	312
Adnot, J.	42
Anderson, B.	350,368371,373,385,394
Andron, L.A.	60,65,210,301
Anman, W.	116
Arena, J.	248,250,268,270,284
Aronson, C.E.	240
Ashley, D.D.	107,108
Au, A.	216
Bakker, P.	207
Banks, R.E.	302,312
Barrett, J.R.	69
Battafarano, D.	199,215
Battagalia, F.	416
Bennett, J.	428
Bennion, S.	42,44,75,176,186,203,213, 214, 303,305,306,311
Bergstrom,	110
Bethlenfalvay, N.C.	402,405,406
Bezier, J.L.	239
Bianchi, A.M.	84
Blakeslee, D.B.	269
Bloom, J.	235
Blower, J.	45
Blue, P.	56,59,80,85,91,92,148,399,400
Bodlien, J.	353-359, 363
Brantner, L.	367
Bray, V.	111
Brehn, A.	408
Brinkman, M.	285
Brown, J.S.	89,93,96,128
Browning, R.	147,193
Bruhn, F.W.	360
Bryson, A.	408
Bunker, D.	107
Butler, C.	387
Burgess, D.B.	307,386
Byrne, W.R.	60,127,207,308,309
Calkins, R.	265,284
Callahan, B.	291,292
Camp, B.	394
Campbell, R.L.	70
Cannon, G.	407
Carter, B.	373
Carter, T.	233,351,353

Cary, M. ---------- 216
Casserly, J. ---------- 60
Castellon, ---------- 407
Chantelois, A. ---------- 192
Cheney, D. ---------- 295
Clark, J.R. ---------- 243,351
Clark, T. ---------- 302,364,366
Claybrook, J. ---------- 277
Clyde, M. ---------- 420,421,422,423,429
Cohn, D. ---------- 310
Colon, L. ---------- 419
Cook, J. ---------- 400
Cook, S. ---------- 283,286,287
Copeland, T. ---------- 46,210
Cornell, F.M. ---------- 236,256,263,264,290
Cosgriff, T. ---------- 52,53,61,64,66,79,121-126,127
130,132-146,150-161,168-174,
178-182,187-190,194,196,197,
208,209,212,218-220,226-230
Coville, F. ---------- 280
Cowell, M. ---------- 41
Cravero, J. ---------- 425
Crawford, J. ---------- 408
Crosby, B.L. ---------- 54
Cruz-Saez, J.A. ---------- 44
Culclosure, T.F. ---------- 101

Damiano, M. ---------- 268
David-Bahar, K. ---------- 165,186,203
Davis, D. ---------- 222
Leffer, P. ---------- 258,283,288
Dengenhardt, E. ---------- 67
Depriest, J. ---------- 225
Dolan, D. ---------- 191
Dolton, H. ---------- 116
Donatucci, C. ---------- 129,274
Dorogy, M. ---------- 130
Dothager, D. ---------- 80,147
Drago, R. ---------- 237
Dunemn, C. ---------- 428
Dunkelberg, J. ---------- 86,91,131

Ellison, P. ---------- 394
Enzenauer, R.J. ---------- 95,236
Enzenauer, R.W. ---------- 256,263,264,290
Eusterman, V.D. ---------- 269,289,294
Everett, D. ---------- 198

Fall, S. ---------- 257,277
Feinberg, M. ---------- 368
Fisher, M. ---------- 91,102,120,185
Fitzpatrick, J.E. ---------- 186,213

Forlaw, L. ---------- 413
Fortenberry, E.J. ---------- 191,192,195,199,223
Frank, C.G. ---------- 368
Freeman, S. ---------- 86,91,94,102,120,131,184,185,
200,222
Frelin, A.J. ---------- 410

Gaines, T. ---------- 277
Gardner, T.A. ---------- 236,240,256,263
Gargan, T. ---------- 415
Gates, R.H. ---------- 60,65,70,79,97,127,177,207,
308,309
Gates, R. ---------- 97
Geddie, S.G. ---------- 416
Geniton, D. ---------- 411
Gentry, R. ---------- 42
George, R.K. ---------- 256
Georgitis, W.J. ---------- 56,69,81,96,99,108,112,128,191
Getter, M.D. ---------- 252
Gillis, W. ---------- 408
Gillogly, S.D. ---------- 267,275,276,282
Ginter, J. ---------- 250,252,268,270,284
Glick, P. ---------- 283
Golitz, L, ---------- 213
Goodman, D.L. ---------- 46,54,73,83,87,162,184,221
Goodman, N. ---------- 369
Graham, L.M. ---------- 365
Green, E.W. ---------- 96

Hahn, D.B. ---------- 248,254,265,270,359,364
Hale, L. ---------- 415
Hall, W. ---------- 283
Hallgren, S.E. ---------- 86,91,120
Hanks, J. ---------- 387
Hannon, R.N. ---------- 60,65,308,309
Harpster, W. ---------- 295
Harris, D.J. ---------- 162
Harris, T. ---------- 430
Harrison, S.M. ---------- 60,65,70,127,198,207,297,308,
309,310,429
Hasbargen, B. ---------- 101,148,195,223
Hasbargen, J.A. ---------- 105,110,119,148,149,175,192,
202,211,223
Hemler, D. ---------- 258,285,414
Henderson, C. ---------- 284,366
Henderson, R. ---------- 351,353-356
Henry, A.R. ---------- 57,162,205,216,217,221
Hockenbury, R.T. ---------- 261,275,276,282
Hofeldt, F.D. ---------- 37
Hollis, H.W. ---------- 243
Homas, P. ---------- 186

Ikle, L.O. ---------- 367
Ishak, K. ---------- 184

Jackson, R.L. ---------- 44,213,214,283,311
Jahns, F. ---------- 222
Jarek, M.J. ---------- 106,183
Johns, J. ---------- 232,258,261,288
Johnson, C. ---------- 413
Johnson, R.C. ---------- 92,106
Jones, D.E. Casey ---------- 293
Jones, J. ---------- 413

Kaicher, J. ---------- 424
Karstetter, K. ---------- 272,281,285
Kelly, K.J. ---------- 361
Ketchum, R. ---------- 285
Kidd, G.S. ---------- 37,39,41,48,56,59,62,69,85,
90,98,112,116
Kinsella, J.P. ---------- 350,370,372,385
Kollef, M.H. ---------- 103,106,127,147,164,191
Kreder, K. ---------- 274
Kodama, B. ---------- 186
Kozlowski, C. ---------- 130
Kristo, D. ---------- 103
Kruger, M. ---------- 95
Kuck, P. ---------- 238
Kudryk, B. ---------- 130
Kutsch, C. ---------- 186

Ladner, J. ---------- 295
Lang, S. ---------- 425
Larsen, M.A. ---------- 112,417
Larsen, L.V. ---------- 78,210
Lawrence, S.P. ---------- 86
Ledoux, R.A. ---------- 54,93,162
Lee, L. ---------- 165,214,305,306
Lemar, H.J. ---------- 99,108,112,191
Lepore, M.L. ---------- 259
Leuthke, J. ---------- 401
Lima, J. ---------- 402,405,406
Lin, E. ---------- 90
Lisecki, M.B. ---------- 256,280,283,286,287,291,292
Lovin, J. ---------- 401
Luethke, J. ---------- 103,192,202

Maher, G. ---------- 382,383
Mallory, P.L. ---------- 127,147,296
Manier, S.M. ---------- 56
Martin, B. ---------- 205
Matheson, E. ---------- 205
May, K. ---------- 199,215
Mayer, D. ---------- 310

Mayer, J. ---------- 147
McCormack, M. ---------- 191
McDermott, M.T. ---------- 39,41,50,51,56,59,62,69,85,98,
99,107,112,128,191,199,215,224
McNalley, P.J. ---------- 120,185,198,200,206,222
Meador, K. ---------- 284
Meier, J. ---------- 185,200,222
Mendoza, B. ---------- 95
Mercill, D.B. ---------- 75,213,214,311
Merenich, J. ---------- 59,69,90,98,107,128,191
Meyers, J.I. ---------- 104
Miles, F.W. ---------- 70
Miller, P. ---------- 215
Moore, R. ---------- 411
Moretti, R. ---------- 424
Morrow, J. ---------- 386
Morse, P.L. ---------- 210,299
Morton, B.E. ---------- 234,295
Mosijczuk, A.D. ---------- 307,351-359,362,363,366,
374-381,388,390-393,395,
431
Mullon, D. ---------- 285
Negron, F. ---------- 59
Nelson, H.S. ---------- 50
Noble, S. ---------- 98

O'Boyle, ---------- 256
O'Connell, M.A. ---------- 57,217
O'Connor, J. ---------- 116
Orris, P. ---------- 424
Oswald, M. ---------- 411
Otero, C. ---------- 279
Ow, C.L. ---------- 67

Pals, S.D. ---------- 255,275,282
Parker, S. ---------- 401
Perloff, J. ---------- 98,224
Pernelli, D.P. ---------- 418
Perry, M.E. ---------- 59,80,92,104,116,185,191,
193,198,201
Pfander, N. ---------- 84,90,191
Potter, M.E. ---------- 313-349
Pruitt, A. ---------- 267
Punja, M. ---------- 129,185
Raife, M.J. ---------- 241,242,274
Ramirez, R.J. ---------- 236,256,263
Reddy, V. ---------- 107,353-359,363,366
Reed, W. ---------- 109
Rodinelli, R. ---------- 245,248,252
Rosenberg, A.A. ---------- 372
Rothschild, B. ---------- 248

Roy, C.R. - ---------- 90
Rubin, I. ---------- 417

Sample, S. ---------- 201
Santoro, T. ---------- 165
Schaefer, R.A. ---------- 267,282,287
Schaffer, M. ---------- 384
Schleve, M.M. ---------- 42
Schooley, C. ---------- 310
Schroder, J. ---------- 384
Scott, C. ---------- 387
Scott, F. ---------- 288
Shaukat, M. ---------- 285
Sherman, C. ---------- 265
Sherman, K. ---------- 94,100,117,184
Sherman, R.A. ---------- 96,244,245,248,250,252,254,265,
268,270,272,281,283,284,285
Sherman, S. ---------- 96
Sherva, E. ---------- 369
Simcic, K. ---------- 69
Singleton, J.D. ---------- 76,94,128
Sjoberg, R.J. ---------- 37,69,429
Skavlen, P. ---------- 165
Slife, H. ---------- 396
Slover, R. ---------- 367
Smith, D.R. ---------- 257,296
Spaulding, H.S. ---------- 114,115,129,185
Spezia, P. ---------- 278,279
Stenmark, K.R. ---------- 365
Stewart, R.S. ---------- 89,297
Stock, J. ---------- 256,263
Stocker, N. ---------- 285,200,206
Suddeth, R. ---------- 198,200,206,222
Szefler, S. J. ---------- 50

Teachout, W. ---------- 424
Tell, D.T. ---------- 243
Teuton, C. ---------- 165
Thrasher, J.B. ---------- 129
Travis, P.S. ---------- 105
Truxal, A.R. ---------- 51
Turner, J. ---------- 193
Tyler, H.N. ---------- 85,399

Urry, L. ---------- 75

VanDeren, J.M. ---------- 86
Vasil, M.L. ---------- 365
Voelmeck, W. ---------- 365
Vaughan, R. ---------- 46,50,57,73,83,87,162,205,210,
216,217,221

Waddell, D. ---------- 427
Walden, T. ---------- 56
Walker, D.J. ---------- 67,412
Walker, J.H. ---------- 389
Walton, W. ---------- 256,263
Wartofsky, L. ---------- 51
Weaver, M. J. ---------- 67,77,97,109
Webb, J. ---------- 70
Weber, R.W. ---------- 89,93,96,162,216m,221
Weidel, J. ---------- 287
Weller, R.W. ---------- 256
West, S.G. ---------- 76,94,128,199,215
White, J.C. ---------- 98,149,307,369
Whitley, H. ---------- 384
Wilkerson, R. ---------- 261
Wilkins, R.M. ---------- 254
Williams, R.F. ---------- 44,203
Woerman, A. ---------- 272,281
Wolfe, J. ---------- 280,286
Wolfe, R. ---------- 384
Wong, J. ---------- 408
Wood, S. ---------- 413
Woolverton, M. ---------- 362,364
Wright, R. ---------- 207

Yakes, W. ---------- 401
Yips, R. ---------- 425
Yoshida, G. ---------- 167,266,294
Young, T. ---------- 245,248,250,252

KEY WORD INDEX

KEY WORDS	Page
absorpotiometry	399
access	110
acclimatization	116
achilles tendon rupture	261
adosterone	398
adrenal glands	398
advanced trauma life support	296
aerobic bacteria	210
alcohol	108
allergens	54
altitude	104,384
effects	116
amlodipine	211
amputees	283
anemia	425
animal interaction	362,364
antegrade/retrograde	277
anterior cruciate ligament	255,267
anticoagulation	101
antihistamine	129
antiinflammatory	167
antiretroviral therapy	308,309,310
antitoxin	429
antitussive	108
aphakia	236,290
apgar scores	408
army recruiters	424
arrhythmias	295
arthritis	215
arthroscopic cruciate deficient	279
arthroscopy	267
asphyxial injury	361
asthma	73,87,185
asymptomatic HIV	65
atrial natriuretic pepetide	202
autoantibodies	305
autoantigens	305
autograft	282
bacteremia	360
baird biopty gun	401
balloon dilitation of prostate	274
basal cell CA	42
beta blockers	217
blood lead	307
body fat	399

bone density 39,85,215
graft 254
ingrowth 286,287
metabolism 199
borrelia 301
botulism 429
breast biopsy 401

calcium 149
calcitonin deficiency 39
cancer management 243
captopril 192
carbohydrate 37
cardioplegia 277
cardiopulmonary resuscitation 97
bypass 372
cataract 236
extraction 237,264
ceftriaxone 360
chronic pain 284
cigarette smoking exposure 369
ciprofloxacin 291,292
clavulanate 360
clonidine 367
colonscopy 206
comprehensive assessment 284
conduction velocity 258
congestive heart failure 95
congnitive, moral & faith development . 70
copd 83,191,225
coronary disease 130
corticosteroids 83,87,285
coumadin 286
cromolyn sodium 205
cross reactivity 162
cutaneous lupus 306
cyclic oxygen therapy 92
cyclosporin 51

ddi/ddc 207
d-penicillamine 76
development evaluations 368
diabetes 88
mellitus 108
dialysis 105,110,148
digitalis 427
discoid lupus erythematous 186
disofen 400
dna 387
do not resuscitate order 97
drug sensitivity 57

drug therapy 52,53,61,64,66,79,351-359
duodenal ulcer 200

eaton trapezial implant 288
ekg 384
emergency medical services 417
emergency procedures 302
    management 87
emg 270
enalaprilat 192
endocrine dysfunction 183
endoscopy 86
environmental recording 248,265
eosinophilia 114,115
    myalgia syndrome 114
epidural anesthesia 408
erythrocytes 402
erythrocytes sedimentation rate 95
erythropoietin 175
exercise 104
eye disease 51

fibrinopeptide analysis 130
food hypersensitivity 46
    reactions 205
fracture healing 292
frey's syndrome 294

gallopamil 202
gastric emptying 91
gastroesophageal reflux 198
gi reflux 185
glucose 149
goats 283
goiter 99
gonadal dysgenesis 41
gonadotropins 41
gonorrhea 387
graft 255
growth delay 367
    hormone 191

hazardous material 428
headaches 265
heart failure 427
heated graphite atomization 307
hematuria 101
hemoglobin 405
hepatitis 115,184
    b vaccine 115
hepatotoxicity 131

high altitude 425
high risk neonates 368
infants 425
hip fracture 62
hiv 207
hiv virus 60
therapy 308,309
hormone measurement 183
humanistic qualities 67
hydroxyapatite 280,286
hypercalciemia 105
hypersensitivity 54
hypertension 149,211
hyperthyroidism 37,50
hypothyroidism 48,50
hypoxemia lung disease 201
hypoxia 86,416

icam 216,303
immunofluorescence 303
immunologic diseases..... 297
immunotherapy 89,216
implants 287
incidence 268
infants development 386
interferon alpha 184
intracorneal implant 290
intralesional steroids 186
intraocular lens 235,238,239,240,256,419
implanting 237
ind 184
instron testing 255
investigational new drug 191-200,202,207,211,221
iodine 69,99
iol 264,418
ivig 127

keratin..... 44
sulfate 279
keratinocytes 213

laboratory animals 302
limulus 100
low back pain 248,250,268,270
lower extremity pain 272
l-tryptophan 114
lung volume 147,193
lupus erythematosus..... 165,214,303
lyme disease..... 301,415
lymphocytes 216

macromolecular absorption 361
marsupial 405
mebrofenin 400
mechanisms..... 252
mediators..... 46
medical residents..... 67
metabolic adaptations 416
methotrexate 73,76,131,199,215,286
methylprednisolone 50
microbiological techniques..... 299
microbiology..... 299
microsurgery..... 241,293
microvascular education & training 232,233
migraine 46
minor 264
minor determinants 93
monoclonal antibody 213
muscle tension..... 265

nasal obstruction..... 259
nasal surgery..... 259
neonatal lupus erythematosus 305
neoneuro 394
neostigmene 195
nephropathy 88
nerve block 285
    compression 258
newborns 384
nicu graduate followup 373
non-insulin dependent diabetes 84

obstructive lung disease 83
occupational stress 424
octreotide 120
omeprazole 185,200
opossum 405
orem's self-care model 84
osteoblast 224
osteoporosis..... 39,62,128
oxygen kinetics 104
    saturation 411

pain..... 244
    assessment 413
pancreatitis 120
parathyroid hormone 224
passive smoking 369
patellar tendon 282
peak bone mass 35
pelvic neoplasms..... 313-349

penicillin 93
percutaneous implant 283
  tendon ruptures..... 261
peritoneal dialysis 195,223
personality 386,424
phantom limb pain..... 252
   treatments 245
phychophysiological responses 284
physical therapy 285
pig model 277
pituitary 41
pneumonia 365
pollen 54
    extracts 210
polypectomy 222
position 411
positive end expiratory pressure 164
prednisone..... 51
prostaglandins synthetics 48
prosthetic 283
protective suit 428
pseudomonas aerugenosa 365
psycho-social-spiritual..... 70
purine metabolism..... 405
pulsing magnetic fields 281

quality of life 382
questionnaire 382

recirculation 110
reconstruction 255
red blood cell 406
red cell metabolism 405
reflex sympathetic dystrophy 285
registered nurses 410
renal clearance 400
    artery stenoses 192
    failure 105,119,175
    function 148
renogram 192
retinoids 142
reverse transcriptase inhibitor 308,309
rheumatoid arthritis 76
rhinomanometry 259
ro 305
role conception 410

sbp 100
serum creatinine 119
skin splitting 203
silicone iol 263

skin test 96,311
sleep apnea 198
smoking cessation 389
snares 222
spirochete..... 301
spirometry 389
steroid 73,128,167
    dependent 73
stress fractures 281
    reduction 362,364
subarachnoid block 408
sucrose 108
superpotent topical steroids 186
surface EMG..... 248
  temperature 272
suture techniques training..... 407

tension headache 268
theophylline 50
thermography..... 96,244,250,272
thymosin alpha 1 184
thyroid 99
thyroid function tests..... 56,69
   gland 56
   hormones..... 39
   disease 56
ticks 415
tipredone 221
tonsillectomy 167
training 312,385,430
transurethral resection of prostate ... 274

ultraviolet light 306
urodynamics 129

variceal hemorrhage 102
vasopressin 102
veterinary personnel training 302

water electrolyte balance..... 48
  imbalance..... 48
water purification tablets 69
wilms tumor 383

zdv 65

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