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CLINICAL INVESTIGATION PROGRAM

30 SEPTEMBER 1993

DEPARTMENT OF CLINICAL INVESTIGATION
Fitzsimons Army Medical Center
Aurora, Colorado 80045-5001

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13. ABSTRACT *(Maximum 200 words)*
Subject report identifies these individual who are conducting investigative protocols at Fitzsimons Army Medical. 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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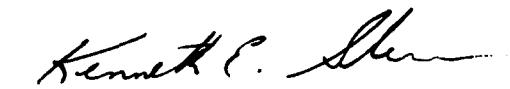
FOREWORD

This report highlights the research activities conducted by Fitzsimons Army Medical Center investigators during Fiscal Year 1993 as well as presentations and publications by FAMC professional staff.

The research protocols described in 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 Commanders, BG Thomas E. Bowen, and COL Thomas A. Verdon, Jr., 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 efforts. I should like to particularly recognize the outstanding work and dedication and wholehearted corroboration of all of the Services' within Clinical Investigation Department, the Assistant Chief, LTC Michael Lieberman, the Chief, Microbiology Service, LTC Richard Harris, the Research Protocol Specialist, Ms. Marcia Bilak, and Ms. Chris Montoya, Secretary, without whose assistance and support this year's progress and its report would not have been possible.



KENNETH E. SHERMAN
MAJ, MC
Chief, Department of
Clinical Investigation

UNIT SUMMARY

Clinical Investigation efforts by FAMC personnel in FY 93 culminated in the publication of 132 articles and 153 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1993 there were 308 research protocols on the DCI register. Over the course of the year there were 466 active protocols.

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. Investigators are encouraged to seek extramural funding based on preliminary data obtained from in-house studies.

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	Req	Auth	Act	Name	Rank
C, Dept Clin Inv	04	60G8N	MC	1	1	1	Sherman, K.	MAJ
NCOIC, DCI	E7	92B4R		1	1	1	Stinnett	SFC
Research Prot Sp	09	0301	GS	1	1	1	Bilak	
Secretary	06	0318	GS	1	1	1	Montoya	
Nurse Specialist	11	0610	GS				Palestro	
C, Animal Res Svc	04	64C9B	VC	1	1	1	Corcoran	MAJ
NCOIC, ARS, DCI	E5	91T2R		1	1	1	Barrett	SFC
Animal Care Sp	E4	91T2R		1	1	2	Bowers	SSG
							Zobrist	SGT
OR Nurse	10		GS				Wehba	
OR NCO, ARS	E5	91D2R		1	1	1	Shiver	SGT
Animal Care Foreman	04	5048	WS	1	1	1	Jones	
Animal Caretaker	06	5408	WG	1	3	3	Chase	
	05						Giese	
							Hitchcock	
C, Biochem Svc	03	68C9C	MS	1	1	1	Schofield	CPT
NCOIC, Biochem	E6	92B3R		1	1	1	Zahn	SSG
Med Technologist	09		GS	1	1	1	Vacant	
Research Chem	11	1320	GS	1	2	2	Noble	
							Sherva	
C, Biomet & Resch	05	68T00	MS	1	1	1	Sherman, R.	LTC
Statistical Asst.	05	1531	GS	0			Caminer	
Has several requirements w/o auth.								
C, Cell Phys Svc	13	1320	GM	1	1	1	Jackson, R.	
Bio Sci NCO	E6	01H2R		1	1	2	Johnson	SSG
							Cruz-Saez	SSG
Bio Sci Asst	E4	01H1R		2	2	2	Schaphorst	SGT
							Nystrom, S.	SPC

Description	Grade	MOS	Br	Auth	Req	Act	Name	Rank
C, Immunology Svc	05	68T00	MS	1	1	1	Lieberman	LTC
Microbiologist	11	0403	GS	3	3	3	Lima	
							Hoyt	
Microbiologist	09	0403	GS	1	1	1	Meuhlbauer	
Med Technologist	09	0644	GS	7	7	2	Ramirez	
							Sachanandani	
							Pinney	
C, Micro Svc	05	68A00	MS	1	1	1	Harris	LTC
NCOIC, Micro/Immuno	E5	01H2R		1	1	1	Brady	SSG
Bio Sci NCO	E4	01H1R		1	1	1	Sipple	SGT
Microbiologist	11	0403	GS	1	1	1	Paine	
Microbiologist	09	0403	GS				Andreatta	
Med Technician	07	0645	GS	2	2	1	Nelson	
C, Molecular Bio	13	1320	GS	1	1	1	Gutierrez	
Research Chem	11	1320	GS	1	1	1	O'Brien	

Funding

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

		FY 91	FY 92	FY 93
OMA	Civilian Personnel	1,129,389.	1,067,960.	1,128,000.
	Contracts/Supplies	44,019.	319,322.	306,000.
	Ceep Equipment	77,859.	55,183.	61,000.
	Travel	28,928.	9,624.	8,000.
	Military Personnel	813,626.	1,007,988.	1,109,000.
	Rentals	10,178.	400.	NA
OPA	MEDCASE	262,529.	220,366.	132,000.
Civilian Consultants		300.	1,850.	1,500.
Publication Costs		8,678.	12,026.	8,000.

Personnel

	Required	Authorized	Assigned
Officers	6	5	6
Enlisted	13	12	11
Civilian	29	22	22
VA Grant	2	2	2
Grant Emp.	5	5	5

GRANTS for FY 93

(1) Prospective collection and banking of lymphocytes and clinical data on HIV infected individuals taking antiretroviral agents.

FY 93 $190,000.
FY 92 $150,000.

TOTAL: $340,000.

(2) Work of breathing as a predictor of failure to wean from mechanical ventilation in patients with severe chronic obstructive pulmonary disease. FY 93 $1250.00

TOTAL: $20,981.

(3) Analysis of wounds by evaporative water loss in man. FY 93 $7000.00

TOTAL: $36,438.

(4) Etiology and progression of acute muscle tension related low back pain occurring during sustained activity inlcuding combat training exercise. $25,000.

(5) Use of body surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers. $25,000.

Veterans Administration (VA) - VA Funds (Sherman) $36,000

Henry M. Jackson Foundation for th Advancement of Military Medicine: Activity for FY 1993: $1,986.89 -- Balance $11,830.00

FACT

	1991	1992	1993
Personnel	27,711.60	80,976.30	83,900.52
Equipment/ Supplies	20,835.02	12,678.72	13,166.37
Trips	1,644.00	7,522.00	16,835.29

HUGH MAHON LECTURESHIP AWARD COMPETITION - 1993

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.

This year the Hugh Mahon Lectureship Award Competition was divided into the categories of literature reviews/case reports (8) and Residents (16) and Fellows' (4) studies for a total of 28 submissions. In 1992 there were 38 submissions: in 1991, 34 submissions; in 1990, 36, in 1989, the largest with 41, in 1988, 23 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, COL Verdon, Commander, Fitzsimons Army Medical Center, Joel Levine, MD, Associate Dean of Clinical Affairs, University of Colorado Health Science Center, and Harold Vogel, MD, Chief of Neurosurgery, Denver General Hospital. Manuscripts were scored on originality and medical significance, experimental design, presentation and interpretation of data, and literary quality.

The first and second prize winners were chosen from among the finalists in the Residents' and Fellows' categories based on the presentation and question-and-answer period during the Hugh Mahon Lectureship Conference.

The finalists for 1993 are as follows: <u>Residents' Papers</u>

1st Place: Articular Cartilage Degeneration in Chronic Anterior Cruciate Ligament Deficiency: Correlation of Synovial Fluid and Serum Markers with Arthroscopic and Radiographic Findings in Injured and Contralateral Control Knees.
Paul Spezia, MAJ, MC, Orth Surg.

2nd Place: The Prevalence of Hypothyroidism in Gout.
Alan Erickson, CPT, MC, Int Med.

<u>Fellows' Papers</u>

1st Place: The Effect of Low-Dose Methotrexate on Bone Metabolism and Histomorphometry in Rats.
Kimberly May, CPT, MC, Rheum.

2nd Place: Effects on the Thyroid of Prolonged Use of Iodine Containing Water Purification Tablets.
Gregory Hughes, MAJ, MC, Endo.

Case Report

Disseminated Intravascular Coagulation in Systemic Onset Juvenile Rheumatoid Arthritis (Still's Disease).
Vance Bray, MAJ, MC, Rheum.

Animal Resources Service - FY 93

The Animal Resources Service continued efforts to upgrade and improve the care provided to the laboratory animals assigned and to the support provided the medical center staff. This service provides regular training for various surgical skills (soft and hard tissue, gross and micro-surgery) and perioperative requirements (intubation training). Research efforts have continued with significant support to the orthopedic residency program, ophthalmology, otolaryngology, dermatology, and rheumatology.

Service personnel at year-end included 1 Laboratory Animal Veterinarian, 3 Animal Care Specialists, 1 Surgical Nurse, 1 Animal Facility Manager, and 2 Animal Care Providers. The service also received valuable support from 2 Red Cross volunteers. One Hahnemann University graduate student participated in a 4 month clerkship. During the year Mr. Milt Hitchcock, Animal Care Provider, retired after 40 years government service. MAJ Ron Banks PCS'ed to the Clinical Investigations Regulatory Office at Ft Sam Houston. He was replaced by MAJ Kevin Corcoran. MAJ Corcoran is a diplomate of the American College of Laboratory Animal Medicine.

A site visit by the American Association for Accreditation of Laboratory Animal Care was conducted in July resulting in continued Full Accreditation of the animal care and use program.

MAJ Banks attended the 43rd AALAS Annual Meeting in Anaheim, CA in November. MAJ Banks, Mr. Jones, and Ms. Giese attended the Annual Clinical Investigation Postgraduate Short Course in San Antonio. SFC Barrett, SSG Bowers, Ms. Giese, and Mr. Jones attended the AALAS Mile High Branch Annual Meeting in Denver in May. The Service presented five posters at the meeting and one received the Best Poster Award. MAJ Banks and MAJ Corcoran attended the AVMA Annual Meeting in Minneapolis in July. MAJ Banks (1993 academy president) presided over the Academy of Surgical Research Annual Meeting in Breckenridge in September.

Publications and presentations made by Service personnel are listed elsewhere in this report.

Biochemistry Service - FY 93

During FY 93, the Biochemistry Service has continued to adapt and implement changes in response to HSC and FAMC driven reductions in both personnel and funding resources, while continuing to support varied research requirements and improve facility capabilities.

The largest operational changes resulted from the Voluntary Early Retirement and Voluntary Separation Incentive Programs offered by FAMC. The impact on the Biochemistry Service was the management directed transfer of the medical technologist position to the Microbiology Service, Department of Pathology and the transfer of Ms. Elise Sherva, GS-11 Chemist, from an overhire position to the Directorate of Engineering and Housing where she assumed responsibilities in the hazardous materials program. On the positive side, we welcomed the arrival of a new Service NCOIC, SSG David Zahn, from the Basic Laboratory Science course. SSG Zahn immediately made contributions in performing clinical testing and becoming trained in amino acid analysis methods on the gas chromatograph/mass spectrometer, as well as assuming administrative duties.

Following on the loss of the medical technologist position, responsibility for clinical hemoglobin A_{1c} testing, along with the DIAMAT ™ instrument system, was transferred to the Special Chemistry Section, DPALS. Prior to this transfer DCI had implemented automated HPLC-based testing and completed quality control and correlation studies with the previously used manual column methods.

During this year the Biochemistry Service, in cooperation with the Department of Pediatrics, established a pediatric lead poisoning screening protocol for infants seen in the Twelve Month Well Baby Clinic. This effort, in anticipation of DoD mandated screening, was directed toward assessing the predictive value of the proposed risk questionnaire and subsequently incorporated in the FAMC Childhood Lead Poisoning Prevention Program. Also in the area of blood lead testing, CPT Schofield was an invited lecturer for the Colorado Association for Continuing Medical Laboratory Education (CACMLE) course in pediatric lead poisoning and laboratory methods of analysis.

Several research protocols came to completion during the year including analytical support of a clinical trial of melarsen oxime in the treatment of Rhodesian sleeping sickness, a second animal study of methotrexate induced osteoporosis, and a study of plasma lead levels and their relationship to attention deficit hyperactivity disorder and developmental delay (study conducted at MAMC). Ongoing support of several Endocrinology protocols and collaborative studies with the University of Colorado Health

Sciences Center Perinatal Research Group employs multiple radioimmunoassay and enzyme immunoassay methods and continue to provide a significant portion of total workload. Additional continuing projects include the studies of red blood cell metabolism and adenosine deaminase activity conducted by Dr. Nicholas Bethlenfalvay, Department of Primary Care, and the measurement of angiotensin converting enzyme activity in bronchial alveolar lavage and macrophage samplings from AIDS patients.

Personnel notes and accomplishments during the past year include CPO recognition of Ms. Sherva for exceptional performance with a substantial cash award and successful completion of Expert Field Medical Badge testing by CPT Schofield and SSG Zahn. SSG Zahn also passed the Clinical Pathologists Board of Registry Examination for MLT certification. We also hosted LT Mike Woll, a medical student research intern, during his summer military rotation.

Cell Physiology Service - FY 93

The diagnostic value of using monoclonal antibodies in identifying particular skin tumors or disorders is continuing under protocol 134-91. By altering culture conditions to mimic various pathologic environments, preconfluent, cultured keratinocytes are utilized to simulate acantholytic round cell carcinoma and will be compared with post-confluent keratinocytes (normal state) for binding antigens, vimentin and cytokeratin. Immunology Service is collaborating on this project by evaluating antibody binding using Fluorescence Assisted Cell Sorting (FACS). Data collection is in progress.

CPS successfully identified antibody titers for bullous pemphigoid and pemphigus vulgaris using indirect immunofluorescence staining in serum samples sent from the Mayo Clinic's Immunofluorescence Reference Laboratory. This work completes Dr. David-Bajar's protocol 92-131. Mayo Clinic sent a certificate identifying FAMC as an active participant in quality control for indirect immunofluorescence testing.

Utilizing electron microscopy and immunogold labeling, ultra-structural evaluation of the basement membrane zone (BMZ) of skin is on-going (protocol 91-125). Certain autoimmune diseases involve antigen components found both on the epidermal and dermal sides of the BMZ. Even with direct and indirect immunofluorescence staining, clinical differentiation of certain blistering diseases is sometimes difficult. This study may help to validate procedures which may have potential use in diagnosing autoimmune type diseases, specifically a split-skin technique. Separation of the epidermis from the dermis of a collected skin specimen (split) , when combined with immuno-fluorescence staining may improve current clinical methods for identifying certain blistering skin disorders.

Dr. Kim May successfully cultured bone osteoblasts (OB) . She used the bone cells in an in vitro study to examine the effects of various doses of methotrexate (MTX) on bone physiology. MTX, a widely used drug for treatment of rheumatoid arthritis, was previously demonstrated by Dr. May to cause osteopenia in rats. The study is completed and demonstrated that diminished OB function occurs with very low mean MTX concentrations, in a dose-responsive fashion. Dr. May will present this data before American College of Rheumatology and has submitted a manuscript for publication.

Data collection is ongoing for Dr. Kopke's study investigating the effects of smoking, alcohol ingestion and radiation treatment on Langerhans cells (LC's) in human oral mucosa. A much greater incidence of oral cavity cancers among smokers and chronic alcoholics has been reported in the medical literature. It is believed that these substances may alter the number and/or immune status of LC's, dendritic cells with antitumor immunity, in oral mucosa. Immunohistochemical staining suggests that these substances may change LC populations from T-cell activators, tumor destroyers, to T-cell suppressor cells which promote tumor growth.

CPS's collaboration with the Neonatology departments of FAMC and UC Health Sciences Center in developing human and ovine placental trophoblast cultures to facilitate in vitro study of fetal metabolism continues. Methodology for culturing normal human and ovine trophoblasts has already been established through a series of studies on cultured choriocarcinoma cell lines. These methodologies are now being applied to cultured sheep and human trophoblasts.

Nude mice received human skin grafts which were pretreated with different extracellular matrix attachment factors. The aim of this study was to determine whether these biological attachment factors could improve skin graft acceptance rates compared to skin grafted without inclusion of these attachment molecules. A total of 125 mice were grafted with human skin (one control and four different treatment groups of 25 each) obtained from plastic surgery. Grafts were evaluated for viability, maintenance of graft area,, clinical appearance and acceptance rate. Preliminary analysis of data suggests that certain attachment factors may improve at least take rate (%) and maintenance of graft viability (graft area).

Clinical Biometrics and Research Design Service - FY 93

All Orthopedic and General Surgery residents now rotate through the Service as part of their regular training programs. During the rotation, they and a variety of other physicians learn clinical research design, clinical statistics, computer work and data processing as well as plan, write and initiate a research project. Formal courses have been presented in both research design and in techniques for self-regulation as part of pain management to physicians, psychologists, occupational therapists, and others.

While research design support is still performed entirely within the Service, some of the support for statistical analysis is being performed through a grown set of BPAs.

During this fiscal year, the two major MRDC supported programs initiated three years ago were continued and broadened. The stress fracture treatment program has shown that stress reactions can be identified early enough to prevent progression to stress fractures and that stress fractures can frequently be treated successfully with the aid of electrical stimulation. We have show that shock absorbing inserts in boots and sneakers do not prevent lower limb pain among basic trainees.

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. Studies within the service have demonstrated that a large proportion of tension headaches occur only after an increase in shoulder muscle tension. Similar studies have demonstrated that cramping phantom pain only occurs after an increase in muscle tension in the residual limb. This fiscal year has also seen an increase in use of the new computer controlled CADCAM and digitizing systems.
The Service is now supported by HSC, MRDC, NIH, the VA, instrument manufacturers, and non-profit organizations.

Immunology Service - FY 93

The Immunology Service has continued to maintain its premiere position in a flow cytometry among military medical centers, with a high volume of work in lymphocyte immunophenotyping in HIV patients, leukemia and lymphoma typing, DNA and cell cycle analysis in breast cancers, and expanding work in the enumeration of lymphocyte subpopulations in immunodeficient and autoimmune patients. In addition, the past year has seen a large increase in work related to the functional analysis of immunocompetent cells, such as mitogen and antigen stimulated lymphocyte transformation assays, as well as flow cytometric studies of activation and "memory cell" markers on lymphocytes cultured from specific patients. Also, various immunochemical procedures such as electrophoresis and immunoblotting of antigens and antibodies ("Western blots") in specimens from autoimmune patients, enzyme-linked immunosorbent assays (ELISAs), radial immunodiffusion assays for immunoglobulin synthesized by cells cultured in vitro, immunochemical analysis of serum proteins by rate nephelometry, and peptide synthesis and sequence determinations have been performed. Finally, work continued on the research award winning protocols of Dr. Bethlenfalvay concerned with purine and pyrimidine metabolism in erythrocytes in adenosine deaminase deficiency (which is a cause of severe combined immunodeficiency-SCID).

Microbiology Service - FY 93

An HIV natural history study in collaboration with FAMC Infectious Disease service and the Department of Diagnostic Retrovirology at WRAIR is providing information on the development of AZT resistance at the molecular level in HIV-infected patients.

A study with the Allergy service is comparing the efficacy of various extraction procedures for pollen allergens used in skin testing.

This service is supporting a protocol examining Hepatitis C infections in military families. The Microbiology and Molecular Biology Service are jointly investigating genetic variation of Hepatitis C strains in HIV patients.

A model of fungal sinusitis is currently being developed in collaboration with the Otolaryngology service.

The Microbiology service and the Inpatient Pediatric Service have initiated a protocol examining therapy of Group B Streptococcal sepsis in neonatal rats. A collaborative study with the Pediatric service evaluating a rapid Group A Streptococcus antigen assay is presently being completed.

A multi-center HIV natural history study of antiretroviral resistance is providing information on the development of AZT resistance at the molecular level in HIV patients who are clinical treatment failures. The microbiology service is working with the Department of Diagnostic Retrovirology at WRAIR to analyze trends in the progression of HIV patients on long-term antiretroviral therapy.

Implementation of radiometric instrumentation in the mycobacteriology laboratory has permitted development of a study on synergy between antimycobacterial agents used for treatment of M. avium isolates from AIDS patients.

Methods for molecular epidemiology studies of clinical bacterial isolates re being evaluated. Plasmid analysis of

Molecular Genetics Service - FY 93

The assigned staff of the Molecular Biology Service are Dr. Anthony G. Gutierrez , Chef, GS13, Ph. D. in Molecular Genetics, and Ms. Judith O'Brien, Research Associate, GS11, Medical Technologist/Chemist. In addition to the assigned staff the service operated this year with four summer intems, 1LT Michael Wahl, a second year medical student at LSU on an Army Scholarship, Ms. Allegra Cummings and Ms. Vicki Simon third year premed students of Barnard College of Columbia University, N.Y. C., and Ms. Irene E. Carlson , second year Molecular Bio/Biochem major from the University of Colorado at Boulder. The service also benefitted from the Red Cross Volunteer work of Mr. Scott Verrill, a sales manager of MicroBio Products, Inc. Mr. Verrill is working part time in the lab under the auspices of the Red Cross Voluteeer program at FAMC to perform lab work in retum for on-the-job training. The Service has also taken on the long term intradepartment training of Cindy Andreatta, GS9, from microbiology. All non-service personnel were trained in handling and manipulation of BNA/RNA, Gel electrophoresis, PCR, and automated DNA synthesis and sequencing. Physician training includes Cpt. Kimberly Mays, M.D. an Air Force Medical Fellow in the FAMC Endocrine Program, Maj. Greg Hughes, M.D. and Cpt. L. Lewey, M.D., also of the endocrine program, and Cpt. Clive Daniels, M.D., an Air Force Medical Fellow in the Pediatrics Program.

In June the Molecular Biology Service acquired a Chiron Quantiplex Branched DNA System and Ms. O'Brien was trained on that system at the Chiron facility in Emeryville, California. The Chiron system makes possible the quantitation of hepatitis B, hepatitis C, and HIV virions in a volume of sample, using a chemiluminescent detection method. Chiron has asked this laboratory to be one of three evaluation sites for new lots of reagents, testing to begin in January 1994.

The results of Dr. Sherman's comparison of endpoint dilution RT-PCR for quantitating hepatitis C versus the Chiron chemiluminescent method were published in October (K. E. Sherman, et al, Quantitative Evaluation of Hepatitic C Virus RNA in Patients with Concurrent Human Immunodeficiency Virus Infections, Joumal of Clinical Microbiology, Vol. 3 1, No. 1 0, Oct. 1993.

Dr. Gutierrez attended Applied Biosystems DNA Automated Sequencer training May 1-3 in Foster City, California. We have subsequently established procedures for sequencing the E2/NSI hypervariable region of HCV and the reverse transcriptase gene of HIV. These sequence data are currently under analysis for subsequent publication.

In May the Department of Dermatology fellows were given a lab tour and format presentation on the training available in this service. In October another presentation was made for the Department of Allergy and Immunology.

The current projects ongoing in the molecular biology service are as follows:

-Sequence Analysis of the Reverse transcriptase gene of HIV in AZT treated patients- Gutierrez, O'Brien , Verrill.
-Sequence Analysis of E2/NS1 hypervariable region of Hepatitis C virus - Sherman, Gutierrez , Andreatta, O'Brien
-Quantitation of HCV virions in co-infected HIV/HCV patients- Sherman, O'Brien
-PCR detection of Papilloma Virus in paraffin embedded tissue samples from HPV infected patients- Daniels, Gutierrez, O'Brien
-PCR detection of measle virus from cultured cells and development of a PCR detection technique for patient samples- Lewey, Sherman, O'Brien
-Development of PCR detection asssay in Prairie Dogs as a model system for study of HBV- Sherman, O'Brien
-Molecular cloning and expression of a putative Helicase gene in HCV- Sherman, Andreatta, Gutierrez

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DEPARTMENT OF PRIMARY CARE & COMMUNITY MEDICINE

DEPARTMENT OF RADIOLOGY

DEPARTMENT OF NURSING

COLORADO DEPARTMENT OF HEALTH

FY 93

PUBLICATIONS

C = Protocol Related

DEPARTMENT OF MEDICINE

Allergy Service

Dyer PD: ACE inhibitor induced late onset angioedema. J Allergy Clin Immunol, in print, 1993. C

Glassheim JW, Spaulding HS: Epidemiologic study of patients taking L-tryptsophan-containing products. Immunology & Allergy Practice, 7 V(2):48-54, 1993. C

Silvers WS, Ledoux RA, Dolen WK, Morrison MR, Nelson HS, Weber RW: Aerobiology of the Colorado Rockies: Pollen count comparisons between Vail and Denver, Colorado. Ann of Allergy, 69:421-426, 1992.

Weber RW: Role of long-acting beta$_2$ agonists in asthma. Ann of Allergy, 69:381-384, 1992. C

Weber RW: Food additives and allergy. Ann of Allergy 70:183-192, 1993. C

Dermatology Service

David-Bajar KM: Subacute cutaneous lupus erythematosus. J Invest Dermatol, 100:2S-8S, 1993. C

Fitzpatrick JE: The cutaneous histopathology of chemotherapeutic reactions. J Cutan Pathol, 20:1-14, 1993.

Middleton MH, Bennion S, Norris DA: Induction of ICAM-1 expression in human keratinocytes by ultraviolet radiation (UVR) both in vitro and in vivo correlates with level of response to TNF-A. J Invest Dermatol, 100:570, 1993. C

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Khusro QE, Smith M, Uzer M, Mark D, Silverman W, Sherman S, Hawes R, Lehman GA. Biliary and colonic balloon pain provocation tests. Gastrointest Endosc. 1993;39:321.

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Khusro QE, Lehman G, Smith M, Seibert A, Hawes R, Sherman S. Celiac ganglionectomy for refractory upper abdominal pain. DDW/ASGE Boston, Mass May 18-19, 1993.

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Smith MA, McNally, PR, Kadakia SC, Maydonovitch CL, Wong RKH. Esophageal mucosal zinc levels significantly decrease following healing of Esophagitis. Dig Dis Week, Boston Mass May 15-21, 1993.

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DEPARTMENT OF CLINICAL INVESTIGATION

Banks RE: Medical advances made possible through research. William Smith School, Aurora, CO, March 1993.

Barrett V, Banks R, Chase C, Giese P: Small ruminant post operative recovery and restraint device. AALAS, Nashville, TN, May 1993.

Bowers T, Banks R, Coviello G, Zobrist P: Brown fat in the prairie dog. AALAS, Nashville, TN, May 1993.

Corcoran K et al: Experimental transmission of hepatitis E virus to swine. Platform presentation: 1993 International Symposium on Viral Hepatitis and Liver Disease, May 1993.

Corcoran K et al: Activity of WR182393 against Plasmodium cynomolgi bastianellii in rhesus monkeys. Poster Presentation, American Society of Tropical Medicine and Hygiene Annual Meeting, November 1992.

Corcoran K et al: Severe scrub typhus in Northern Thailand. Platform Presentation, Virology Association of Thailand Annual Meeting, October 1992.

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Giese P, Chase C, Banks R, Barrett V: Improved husbandry and housing for ferrets. AAALAS, Nashville, TN, May 1993.

Sherman K: Evaluation of liver enzyme abnormalities. Presbyterian/St. Lukes Medical Grand Rounds, Denver, CO, April 1993.

Sherman K, et al: Serologic and genomic markers of viral hepatitis in patients with HIV infection. Gastroenterology, 102(4):A887, 1992.

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Sherman KE, Pinto PC: Cyclosporin treatment of Type 1 autoimmune chronic active hepatitis. Hepatology (supp) October, 1992.

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Sherman R: How to use a biostatistician: Avoiding pitfalls and mutual misunderstanding during design and analysis of clinical research. U.S. Army Nursing Research Conference, Colorado Springs, CO, March 1993.

Sherman R: Development of mechanism based treatments for phantom limb pain. Annual Meeting of the International Association for the Study of Pain, Paris, France, August 1993.

Zobrist P, Banks R, Coviello G, Barrett V: Ringtail-like lesions in three North American opossums. AAALAS, Nashville, TN, May 1993.

DEPARTMENT OF PEDIATRICS

Carter BS, McNabb F: Does fetal hyperinsulinemia truly reflect fetal hyperglycemia? Presented at the Western Society for Pediatric Research annual meeting in Carmel, CA, February 1993.

Carter BS: Ethical Concerns for Physicians Deployed to Operation Desert Storm. Presented at the 15th Joint Services Conference on Professional Ethics, National Defense University, Washington, D.C., January 1993.

DEPARTMENT OF SURGERY

Ophthalmology Service

Bradshaw DJ, Bray VJ, Enzenauer RW, Enzenauer RJ, Truwit CL, Damiana TR: Poster presentation, 19th Annual Meeting of the American Association of Pediatric Ophthalmology and Strabismus, Palm Springs, CA, April, 1993.

Heier JS, Waterhouse WJ, Dragoo R, Enzenauer RW: Annual Meeting of the Association for Research in Vision and Ophthalmology, Sarasota, FL, May, 1993.

Waterhouse WJ, Heier JS, Dragoo R, Enzenauer RW: Screening for ocular toxicity in the asymptomatic tamoxifen patients. IXth Symposium of the International Society on Metabolic Eye Disease, Jerusalem, Israel, September, 1993.

Orthopedic Service

Armstrong D, Cook SD, Enis J, Lisecki EJ: Experimental and clinical results with hydroxylapatite-coated total hip replacement. American Academy of Orthopaedic Surgeons, San Francisco, CA, February 1993. C

Callahan B, Wolff J, Lisecki EJ, Cook S, Banks R: Effects of methotrexate on bony ingrowth in hydroxyapatite coated and uncoated porous implants in a goat model. Academy of Surgical Research, 9th Annual Scientific Session, Breckenridge, CO, September 1993. C

Callahan B, Georgopolulos G, Eilert R: Hemivertebra excision for congenital scoliosis. Barnard Conference, Denver, CO, March 1993.

Callahan B, Georgopolulos G, Eilert R: Hemivertebra excision for congenital scoliosis. 11th Annual Ortho Residents Contest, Memphis, TN, August 1993.

Callahan B, Lisecki E, Wolff J, Banks R, Cook S, Dalton J: Attachment of hydroxyapatite-coated and uncoated porous implants is influenced by coumadin. Western Orthopedic Association, Rocky Mountain Chapter, Snowmass, CO, July 1993. C

Callahan B, Pals S, Eilert R: Latex allergy: A threat to you and your patient. 11th Annual Ortho Residents Contest, Memphis, TN, August 1993.

Castello P, Place H, Simonds G, Shannon S, Simons T: Quantification of lumbar root decompression produced by hemilaminotomy and foraminotomy versus diskectomy using somatosensory evoked potentials: A pilot study. Academy of Surgical Research, Breckenridge, CO, September 1993. C

Castello P, Place H, Simonds G, Shannon S, Simons T: Quantification of lumbar root decompression produced by hemilaminotomy and foraminotomy versus diskectomy using somatosensory evoked potentials: A pilot study. Barnard Conference, Denver, CO, March 1993. C

Castello P, Enzenauer R, Jones DEC: Multifocal avascular necrosis (AVN) in scleroderma (SSc). 1993 Regional Meeting, American College of Rheumatology, Denver, CO, March 1993.

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Castello P, Place H, Simonds G, Shannon S, Simons T: Quantification of lumbar root decompression produced by hemilaminotomy and foraminotomy versus diskectomy using somatosensory evoked potentials. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993. C

Chang L, Davis R: Surgical Drain Tube Breakage and Retention. Barnard Conference, Denver, CO, March 1993.

Chang L, Davis R: Surgical Drain Tube Breakage and Retention. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993.

Chang L, Davis R: Surgical Drain Tube Breakage and Retention. Academy of Surgical Research, Breckenridge, CO, September 1993.

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Clyde M, Deffer P, Wilkins RM, Friermood T, Rifkin R: The use of autologous bone marrow and allograft bone powder in the treatment of nonunions: A preliminary report. Barnard Conference, Denver, CO, March 1993.

Cope E, Lisecki E, Gomez M: The effect of proximal femoral cerclage wiring on prosthesis stability: A cadaveric study. Barnard Conference, Denver, CO, March 1993. C

Cope E, Lisecki E, Gomez M: The effect of proximal femoral cerclage wiring on prosthesis stability: A cadaveric study. Academy of Surgical Research, Breckenridge, CO, September 1993. C

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Deffer P, Johns JC, Weaver SH, Bavaro S, Jones DEC: Eaton Trapezial Implant: Radiographic and clinical results. Barnard Conference, Denver, CO, March 1993. C

Deffer P, Johns JC, Weaver SH, Bavaro S, Jones DEC: Eaton Trapezial Implant: Radiographic and clinical results. American Society for Surgery of the Hand, 11th Annual Residents and Fellows Hand Surgery Conference, Kansas City, MO, September 1993. C

Deffer P, Johns JC, Weaver SH, Bavaro S, Jones DEC: Eaton Trapezial Implant: Radiographic and clinical results. Society of Military Orthopedic Surgeons, Bethesda, MD, December 1993. C

Farber G, Place H, Mazur R, Jones DEC, Famiano T: Accuracy of pedicle screw placement in lumbar fusions by plain radiograph and computed tomography. Barnard Conference, Denver, CO, March 1993.

Farber G, Place H, Mazur R, Jones DEC, Famiano T: Accuracy of pedicle screw placement in lumbar fusions by plain radiograph and computed tomography. Scoliosis Research Society, Dublin, Ireland, September 1993.

Farber G, Place H, Mazur R, Jones DEC, Famiano T: Accuracy of pedicle screw placement in lumbar fusions by plain radiograph and computed tomography. North American Spine Society, San Diego, CA, October 1993.

Farber G, Place H, Mazur R, Jones DEC, Famiano T: Accuracy of pedicle screw placement in lumbar fusions by plain radiograph and computed tomography. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993.

Farber G, Place H, Mazur R, Jones DEC, Famiano T: Accuracy of pedicle screw placement in lumbar fusions by plain radiograph and computed tomography. Society of Military Orthopedic Surgeons, Bethesda, MD, December 1993.

Friedel S, Lisecki E: Comparison of three postoperative autologous blood transfusion techniques in 300 total hip and knee replacement patients. Academy of Surgical Research, Breckenridge, CO, September 1993. C

Friedel S, Jones DEC: Efficacy of percutaneous release of the trigger finger: An anatomic study. Barnard Conference, Denver, CO, March 1993. C

Garramone J, Callahan B, Banks R, Lisecki E: Nicotine administration in goats: Methodological considerations. Academy of Surgical Research, Breckenridge, CO, September 1993. C

Jones DEC, Friedel S: Efficacy of percutaneous trigger finger release: An anatomic study. Academy of Surgical Research, Breckenridge, CO, September 1993. C

Jones DEC, Reister J, Rak K, Borosky B: Carpal ligamentous injuries associated with fractures of the distal radius. Colorado Orthopaedic Trauma Symposium, 5th Annual Meeting, Englewood, CO, June 1993.

Jones DEC, Reister J, Rak K, Borosky B: Carpal ligamentous injuries associated with fractures of the distal radius. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993.

Jones DEC, Friedel S: Efficacy of percutaneous trigger finger release: An anatomic study. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993. C

Lisecki E, Cook S, Enis J, Armstrong D: Two-year followup with hydroxyapatite-coated and uncoated porous LSF total hip systems. Academy of Surgical Research, Breckenridge, CO, September 1993. C

Lisecki E, Cook S, Enis J, Armstrong D: Two-year followup with hydroxyapatite-coated and uncoated porous LSF total hip systems. Southern Orthopaedic Association, Vienna, Austria, August 1993. C

Lisecki E: Randomized, prospective clinical evaluation of hydroxyapatite-coated and uncoated porous total hip replacements by a single surgeon. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993. C

Lisecki E, Wolff J, Callahan B, Banks R, Cook S, Dalton J: Attachment of hydroxyapatite-coated and uncoated porous implants is influenced by methotrexate. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993. C

Lisecki EJ: Randomized, prospective clinical evaluation of hydroxyapatite-coated and uncoated porous total hip replacements by a single surgeon. Society of Military Orthopedic Surgeons, Bethesda, MD, December 1993. C

McBride J, Grant M, Sherman R: Comparison of three sizes of interference screws for graft fixation of the central one third of the patellar tendon in anterior cruciate ligament reconstruction. Academy of Surgical Research, Breckenridge, CO, September 1993. C

McBride J, Clyde M, Banks R, Taylor D, Ryan J: Healing of segmental bone defects in goat tibia. Academy of Surgical Research, Breckenridge, CO, September 1993. C

McBride J, Grant M, Sherman R: Comparison of three sizes of interference screws for graft fixation of the central one third of the patellar tendon in anterior cruciate ligament reconstruction. Barnard Conference, Denver, CO, March 1993.

Pals S, Gillogly S, Bizousky D, Banks R, Schaefer R: Biomechanical evaluation of the goat patellar tendon after harvest of its middle third. Academy of Surgical Research, Breckenridge, CO, September 1993. C

Parfenchuck T, Janssen M, Reister J: Cervical discogenic pain: A correlation of magnetic resonance imaging and discography/CT-discograms. Society of Military Orthopedic Surgeons, Bethesda, MD, December 1993.

Parfenchuck T, Janssen M, Reister J: Cervical discogenic pain: A correlation of magnetic resonance imaging and discography/CT-discograms. Barnard Conference, Denver, CO, March 1993.

Parfenchuck T, Janssen M, Reister J: Cervical discogenic pain: A correlation of magnetic resonance imaging and discography/CT-discograms. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993.

Place H, Donaldson D, Brown C, Stringer E: Stabilization of thoracic spine fractures resulting in complete paraplegia: A long-term retrospective analysis. North American Spine Society, 8th Annual Meeting, San Diego, CA, October 1993.

Place H, Donaldson D, Brown C, Stringer E: Stabilization of thoracic spine fractures resulting in complete paraplegia: A long-term retrospective analysis. Scoliosis Research Society, Dublin, Ireland, September 1993.

Place H, Donaldson D, Brown C, Stringer E: Stabilization of thoracic spine fractures resulting in complete paraplegia: A long-term retrospective analysis. Rocky Mountain Chapter, Western Orthopedic Association, Snowmass, CO, July 1993.

Place H, Donaldson D, Brown C, Stringer E: Stabilization of thoracic spine fractures resulting in complete paraplegia: A long-term retrospective analysis. Society of Military Orthopedic Surgeons, Bethesda, MD, December 1993.

Spezia P, Gillogly SD, Johnstone B, Bullard K, Caterson B: Articular cartilage degeneration in chronic anterior cruciate ligament deficiency: Analysis of synovial fluid markers in injured versus control knees. Smith & Nephew Richards 11th Annual Orthopaedic Resident's Conference, Memphis, TN, August 1993.

Spezia P, Gillogly SD, Johnstone B, Bullard K, Caterson B: Articular cartilage degeneration in chronic anterior cruciate ligament deficiency: Analysis of synovial fluid markers in injured versus control knees. Barnard Conference, Denver, CO, March 1993.

Spezia P, Gillogly SD, Johnstone B, Bullard K, Caterson B: Articular cartilage degeneration in chronic anterior cruciate ligament deficiency: Analysis of synovial fluid markers in injured versus control knees. Academy of Surgical Research, Breckenridge, CO, September 1993.

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Spezia P, Gillogly SD, Johnstone B, Bullard K, Caterson B: Articular cartilage degeneration in chronic anterior cruciate ligament deficiency: Analysis of synovial fluid markers in injured versus control knees. Society of Military Orthopedic Surgeons, Bethesda, MD, December 1993.

Urology Service

Donatucci CF. The Combined Intracavernous Injection and Stimulation Test: Diagnostic Accuracy, In: Clinical Digest Series: Urology/Nephrology Digest. Edited by H.H. van Osdol, Northbrook, Illinois. 1:5, 1993.

Donatucci CF. The Effect of Terfenadine on Voiding Function: A Randomized Double-Blind, Placebo Controlled Cross-Over Study. American Urological Association 88th Annual Meeting Abstracts, Journal of Urology, 149: 434A, 1993. C

Donatucci CF: Topical Anesthesia Well Tolerated for Urethrotomy. Urology Times, 20(9):17,1992.

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

(1) Date: 30 Sep 93 (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: 1993

(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: MAY 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. 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. FY92-FY93 - results are very promising. Data analysis indicates that 3-4 more patients need to be studied.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: 243
e. Note any adverse drug reactions reported to the FDA or 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: Data collection is complete. Longitudinal bone mass changes have been calculated as the slope of the lines depicting adjusted bone mass values over time. Consistent with our original hypotheses bone loss was fastest in the cancer group which also had the highest synthyroid doses of T4 levels. Bone loss was next fastest in the goiter group and slowest in the controls. These differences were all statistically significant at the spine, hip and forearm. Analysis of ancillary demographic data is in progress and a manuscript is in preparation.

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.

Perloff JJ, McDermott MT, Damiano MA, Kidd GS: The effects of thyroid hormone suppression and calcitonin deficiency on bone mass. 74th meeting of the Endocrine Society, San Antonio, TX, June 1992.

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

(1) Date: 30 Sep 93 (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, COL, 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 93 (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:

(7) Principal Investigator:
Gregory Hughes, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/ Endocrine

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

(11) Key Words:
prostaglandin synthetic
hypothyroidism

(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 funding problems, we are asking the University of Colorado to measure ADH levels, and as soon as they agree, the study will begin.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 84/119 (3) Status: Ongoing

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

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

(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. FY92-93 - 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 93 (2) Protocol #: 85/139 (3) Status: Completed

(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: Study is closed.

Publications and Presentations: None

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

(1) Date: 3 Mar 93 (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: 1992

(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

(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 FY 93. An addendum is neeed to add a control group.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 86/114 (3) Status: Ongoing

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

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

(7) Principal Investigator: Keith Konkol, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators Richard Harris, LTC, MS

(11) Key Words: HIV virus Jefferey Casserly, PA-C, CW3(RET)

(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: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 25
d. Total Number of Subjects Enrolled to Date: 670
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 staged by DA directives and any who request staging.

(17) Progress:

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 87/114 (3) Status: Completed

(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 questionnaire for a patient to rate the humanistic qualities of their own physician, and (c) to determine whether feedback, based on their own patients' 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 questionnaire developed, and measure whether there is any change on a repeat questionnaire, post-feedback.

(17) Progress: Data analysis completed and published.

CONTINUATION SHEET, FY 93, 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 93 (2) Protocol #: 87/116 (3) Status: Completed

(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 93 (2) Protocol #: 88/115 (3) Status: Ongoing

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

(5) Start Date: 1989 (6) Est Compl Date: 1998

(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: Two years of questionnaires have been administered to interns who are now junior and senior residents. Protocol was amended in May 92 to extend the study up to 6 years, administering the same questionnaire to these residents to determine the long-term changes in attitude through training and into their first years of practice or subspecialty training.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 88/121 (3) Status: Ongoing

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

(5) Start Date: 1988 (6) Est Compl Date: 1995

(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:30 controls
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 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: No progress FY 93.

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 93 (2) Protocol #: 88/124 (3) Status: Terminated

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

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

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

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators: David L. Goodman, 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:_____ 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 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. Protocol was administratively terminated FY 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: (8) Facility: FAMC
Michael T. McDermott, LTC, MC
Gerald S. Kidd, COL, MC
Peter W. Blue, COL, MC
Harry N. Tyler, Jr., DAC

(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 93 (2) Protocol #: 89/103 (3) Status: Terminated

(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

(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: 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 93 (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: No current fellow assigned to protocol. Will assign a new first year this fall.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: 32
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" **To day e no serious adverse events by FAMC patients thought to be secondary to study involvement.**

((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 42 Fitzsimons Army Medical Center patients have been enrolled in the protocol without complications. Apparently city-wide approximately 700 patients have agreed to participate, and several hundred are actively involved.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 89/108 (3) Status: Ongoing

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

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

(7) Principal Investigator:

John A. Merenich, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:

Nancy Pfander, MAJ, MC
William Georgitis, LTC, MC
Gerald S. Kidd, COL, 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: 39
d. Total Number of Subjects Enrolled to Date: 60
e. Note any adverse drug reactions reported to the FDA or 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: Data collection phase complete. All volunteers have finished medication as of 1 Oct 92. We are now in data synthesis phase.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 89/109 (3) Status: Terminated

(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: Stephen Freeman, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Int. Med. (10) Associate Investigators: Jeffery Dunkelberg, MAJ, MC

(11) Key Words: gastric emptying gastrostomy tube

Scott E. Hallgren, MAJ, MC
Peter Blue, LTC, MC

(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: PI is no longer here, 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 93 (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:

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

(9) Dept/Svc: Endocrinology (10) Associate Investigators: Gerald S. Kidd, COL, MC; Jan Perloff, 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:____22_____
e. Note any adverse drug reactions reported to the FDA or 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. Nee about 8 more patients 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 93 (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:

(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: 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 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: Eight volunteers have completed the entire study. All data has been collected except for the urinary iodide measurements which have beedn sent out to a lab for assay. Complete statistical analysis is pending, but preliminary analysis shows that during prolonged administration of water purification tablets thyroid hormone levels remain persistenlty decreased, TSH is persistently increased, the radioiodine uptake is promptly and persistently suppressed and thyroid gland size progressively increases.

CONTINUATION SHEET FY 93 ANNUAL PROGRESS REPORT Protocol No. 90/102

Presentations:

Georgitis WJ, Lemar HJ, McDermott MT: Goitrogenic effect of tetraglycine hydroperiodide water purification tablets. Presented: Am. College of Physicians (Army Regional Meeting) San Francisco, Ca, November 1992.

Hughes G, Lemar H, Georgitis W, McDermott M, Asp A, Merenich J, Kidd GS: Suppression of thyroid radioiodine uptake by tetraglycine hydropeniodide water purification tablets. Presented: Am. College of Physicians (Army Regional Meeting), San Francisco, Ca, November 1992.

Publications: None

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

(1) Date: 30 Sep 93 (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: Spencer Root, MD

(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 progress has been made in the last year due to insufficient time to gather patient samples of ascitic fluid. Dr. Root from G.I. Service will be added as co-investigator to improve accession of ascitic fluid samples.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/105 (3) Status: Completed

(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 240 Coumadin patients were followed for one year, resulting in approximately 3000 patient-months. The Coumadin group enrollment is now closed.

Presentations: Abstract presented at Army Regional ACP meeting, San Francisco, Oct 91. Abstract published in J Am Society Neph, vol 2, pg 305, 1991. Manuscript submitted to Annals of Internal Medicine.

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/108 (3) Status: Completed

(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: 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 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. Study completed.

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 93 (2) Protocol #: 90/109 (3) Satus: Completed

(4) Title: Altitude Effects on Oxygen Kinetics During Exercise in Acclimatized Fit Troops

(5) Start Date: 1990 (6) Est Compl Date: 1993

(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.

Publications: Meyer JI, Perry ME, Browning RJ, Brunson R, Annan WM, LaFraocios GT, Ferris CF: Effects of intermediate altitude on oxygen kinetics in acclimatized fit subjects. Am Rev Resp Dis 143:A174 (suppl), 1991.

Perry ME, Browning, Jackson R, Meyer JI: The effects of intermediate altitude of the Army physical fitness test. Military Medicine.

Presentations: Altitude effects on PT testing in acclimatized troops. Presented: Carl Tempel Symposium, San Francisco, CA October 1991.

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/110 (3) Status: Terminated

(4) Title: Effects of Altered Calcium on Blood Pressure

(5) Start Date: 1990 (6) Est Compl Date: 1992

(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

(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: Insufficient data for anlaysis at this time. No progress on research.

Publications and Presentations: None.

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

(1) Date: 3 Mar 93 (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: 1993

(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: 240
d. Total Number of Subjects Enrolled to Date: 800
e. Note any adverse drug reactions reported to the FDA or 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: Finishing data collection, expect paper to be written in April/May 1993.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: Peter Laird, 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: 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: The decision analysis has been restructured and is being reanalyzed.

Publications and Presentations: One presentation.

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

(1) Date: 30 Sep 93 (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: Arnold Asp, LTC, 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: Began recruiting patients Summer, 1992. Eight patients enrolled to date. No complication or problems.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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.

(17) Progress: Statistical evaluation and refinement of data in preparation for final publication is underway. Collaborative work with Chiron Corp. has led to the validation of quantitative techniques for hepatitis C in the HIV infected population.

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.

Sherman KE, O'Brien J, Gutierrez A, Morse P, Freeman S, Andron L, Harrison, S. Serologic and Genomic Markers of Viral Hepatitis in Patients with HIV Infection. (Abstract) **Gastroenterology**, (in press).

Sherman KE, O'Brien J, Gutierrez A, Harrison, Urdea M, Neuwald P and Wilber J: Quantitative evaluatin fo the hepatitis C virus RNA in patients with concurrent HIV infection (submitted J. Clin. Micro, 1993).

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

(1) Date: 30 Sep 93 (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: 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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient enrolled; doing well s/p radical cystectomy.

Publications and Presentations:

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

(1) Date: 30 Sep 93 (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: 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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient enrolled, randomized to Tamoxifen alone. Doing well.

Publications and Presentations:

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/130 (3) Status: Completed

(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: 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 SWOG.

(16) Technical Approach: To determine the most effective treatment.

(17) Progress: Two patients enrolled, one completed chemotherapy; in remission. The other patient is just completing chemotherapy.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: 22
e. Note any adverse drug reactions reported to the FDA or 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. Five patients have withdrawn for personal reasons.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/133 (3) Status: Ongoing

(4) Title: The Effect of Terfenadine on Urination

(5) Start Date: 1990 (6) Est Compl Date: 1994

(7) Principal Investigator: Shashi Kumar, 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

(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 determine if various antihistamines alter the urinary flow in normal, healthy men or in men with prostatic hypertrophy.

(16) Technical Approach: This is a multi-phase study using various commonly prescribed antihistamines. This is a randomized double blind, placebo-controlled, cross-over design. Thirty subjects will be randomized to receive either chlorpheniramine 8 mg BID or identical appearing placebo BID for 1 week each, with a washout period of 1 week between the two treatment periods.

(17) Progress: In Jan 93 the Addendum 3 was added to the original design of the study. The title was changed from "The Effect of Terfenadine on Urination" to the title as above to reflect the design of the study.

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 93 (2) Protocol #: 90/134 (3) Status: Terminated

(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:

(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: 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: Study is terminated.

Publications and Presentations:

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

(1) Date: 30 Sep 93 (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: 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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient had been in complete remission for a year, now relapsed.

Publications and Presentations:

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

(1) Date: 30 Sep 93 (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 93 (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 93 (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 93 (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 93 (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: 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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Patient continues to do well two years after surgery.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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 93 (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 93 (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 93 (2) Protocol #: 90/151 (3) Status: Terminated

(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:

(7) Principal Investigator: Ronald Jackson, Ph.D., DAC (8) Facility: FAMC

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

(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 measure 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: The project was delayed initially with problems in delivery of equipment and critical parts for the study. A critical software had to be written to interface this equipment with a data acquisition/controller unit. The principal investigator submitted a notification to terminate this project due to time constraints and loss of personnel.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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
E. Fortenbery, MAJ, 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: 2
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: 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: No progress FY 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/153 (3) Status: Terminated

(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: John Merenich, MAJ, MC

(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: 3
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 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: There have been problems with determination of intracellular ca# and patient enrollment.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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 93 (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 93 (2) Protocol #: 90/156 (3) Status: Completed

(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: 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 particpate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient in remission and doing well. The other patient has brain metastasis and is in hospice care.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/157 (3) Status: Completed

(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: 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 93 (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: 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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Patient has finished chemo and radiation and receives monthly injections to produce a chemical oophorectomy. 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 93 (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 93 (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: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(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 93 (2) Protocol #: 90/161 (3) Status: Completed

(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: 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 93 (2) Protocol #: 90/162 (3) Status: Completed

(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: 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 93 (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: 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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Patient has complete response to 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 93 (2) Protocol #: 90/165 (3) Status: Completed

(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: 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 93 (2) Protocol #: 90/172 (3) Status: Completed

(4) Title: SWOG 8792 A Phase III Study of Alfa-n1 (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: 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 93 (2) Protocol #: 90/173 (3) Status: Completed

(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: 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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: 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 93 (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: 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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient enrolled, on chemotherapy, doing well. 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 93 (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 93 (2) Protocol #: 90/177 (3) Status: Terminated

(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: 1
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: 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: 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 93 (2) Protocol #: 91/100 (3) Status: Completed

(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, M (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: Study is closed.

Publications and Presentations:

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

(1) Date: 30 Sep 93 (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 93 (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.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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 93 (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: Spencer Root, MD; 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: 33
e. Note any adverse drug reactions reported to the FDA or 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: To date 33 patients with chronic active hepatitis attributable to viral hepatitis C have been enrolled at FAMC. There have been no serious adverse events associated with drug therapy. One patient was dropped due to evidence of non-compliance which is much lower than the reported drop-out rate for patients on interferon therapy. Walter Reed Army Medical Center was added as a second site in the Spring of 1992, and they have enrolled 4 patietns 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 93 (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: Peter McNally, LTC, 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

(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: 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: 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: To date 35 patients enrolled. Preliminary data: 25% of asthma patients with GERD show objective improvement in PFT's when GERD treated with Omeprazole.

Presentations: Preliminary data presented: Dig. Dis. Week, April 1992; Follow-up presented Am. Coll Gastro, October 1992.

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

(1) Date: 30 Sep 93 (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 93 (2) Protocol #: 91/110 (3) Status: Completed

(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:_____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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: 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 93 (2) Protocol #: 91/112 (3) Status: Completed

(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:_____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 SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Both patients finished chemo and in remission.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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

(11) Key Words: growth hormone; COPD

(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: 2
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" 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.

(17) Progress: Fifteen patients were recruited. Six have dropped out for various reasons; inconvenience, intermittment illness and being "tired of taking shots" were the most common reasons. No one dropped out due to side effects. Six have completed one year, have had their final studies and are now off treatment. Three are from 3-7 months into the study and are doing well. Data collected thus far has not been analyzed as we remain blinded as to their treatment until the study's end.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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:

(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: No progress this FY. 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 93 (2) Protocol #: 91/115 (3) Status: Completed

(4) Title: Prediction of Maximum Exercise Ventilation by Identification of Optimal Reciprocal Spirometric Timed Volumes

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

(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 George Giacoppe, 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: 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.

(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.

Presentations: Poster Presentation: ALA/ATS 1991 International Conference, Anaheim, Ca, May 1991.

ALA/ATS 1992 International Conference, Miami, Fl, 1992.

Turner J, Perry ME, Browning RJ: Publication: ARRS:1432, no 4, April 1991 (A169).

Giacoppe, Turner, Perry: Prediction of maximal exercise ventilation by comprehensive spirometric analysis.

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

(1) Date: 30 Sep 93 (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 93 (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 93 (2) Protocol #: 91/120 (3) Status: Terminated

(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
Peter McNally, LTC, 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: No progress this FY. Protocol is terminated due to equipment problems.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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 12/24 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, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Gastroenterology (10) Associate Investigators: John Meier, MAJ, MC Robert Sudduth, MAJ, MC Nancy Stocker, Pharm.D.

(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: 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: 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: Twelve patients have been enrolled to date. Eight entered the maintenance phase, two have elected not to participate in the 2nd year of maintenance and one had recurrent PUD in the 2nd year. No signifiant AEs.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/123 (3) Status: Terminated

(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, COL, 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: 2
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 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: Non-availability of monitors and problems recruiting subjects. 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 93 (2) Protocol #: 91/124 (3) Status: Terminated

(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:

(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:
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. No additional 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 93 (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: 1994

(7) Principal Investigator: Kathleen David-Bahar, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Dermatology (10) Associate Investigators: Scott Bennion, LTC, MC SSG Tom Johnson Don Mercill Ron Jackson

(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: For much of the last year we did not have an electromicroscopy technician. A new technician, SSG Johnson is now working on this project and has successfully processed intact neonatal skin. He is learning the split-skin techniques, and will begin working on the immunogold staining as soon as reagents are received.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: Bryan Martin, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Allergy (10) Associate Investigators: Anthony Henry, LTC, MC T. Ray Vaughan, 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: 2
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 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: Ten patients screened, 3 entered protocol, 2 completed protocol, no adverse reactions. Having problems finding appropriate subjects. All investigtors except Dr. Martin have 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 93 (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 Study

(5) Start Date: 1991 (6) Est Compl Date: 1993

(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: 25
d. Total Number of Subjects Enrolled to Date: 75
e. Note any adverse drug reactions reported to the FDA or 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 well with 75 patients enrolled and now our goal is 100. Should be done by Summer of 1993.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/129 (3) Status: Completed

(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: 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 93 (2) Protocol #: 91/132 (3) Status: Completed

(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: 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 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: Three patient enrolled 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 93 (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 93 (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: Continue to evaluate staining methods to determine the optimal staining procedures for the cultured human keratinocytes (HKs) with vimentin and cytokeratin. In addition we are also planning to alter the calcium concentrations of the cultures to alter the HK differentiation. We feel that the differentiation of the HKs may play an important part in the expression of both cytokeratin and vimentin.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/135A (3) Status: Terminated

(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:____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 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: The 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 93 (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: Sterling West, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Rheumatology

(10) Associate Investigators: Kimberly May, CPT, MC

Michael McDermott, LTC, MC
Paul Miller, MD, UCHSC
Daniel Battafarano, MAJ, MC

(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: 31
d. Total Number of Subjects Enrolled to Date: 31
e. Note any adverse drug reactions reported to the FDA or 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: Patient accrual continues.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/137 (3) Status: Terminated

(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:

(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: 31
e. Note any adverse drug reactions reported to the FDA or 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: Thus far 31 patients entered into the study. No conclusions can be formed from the data yet. Study terminated due to lack of personnel.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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 93 (2) Protocol #: 91/140 (3) Status: Completed

(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: 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 93 (2) Protocol #: 91/141 (3) Status: Completed

(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:_____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 the SWOG group protocols.

(16) Technical Approach: See protocol.

(17) Progress: 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 93 (2) Protocol #: 91/142 (3) Status: Completed

(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:

(7) Principal Investigator: Richard Weber, COL, MC (8) Facility: FAMC

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

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: 4
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: 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: Study completed, data being analyzed by Fisons. Total patients enrolled 9, 6 completed the study. Adverse effects, 4 patients complained of mild cough induced by study cannister #1 associated with bad taste from aerosol. Symptoms self-limited and all resolved with end of study.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (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, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:
Robert Sudduth, MAJ, MC
Spencer Root, MAJ, MC
Milton Smith, LTC, MC
Dirk Davis, CPT, MC
Steve Lawrence, MAJ, 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: 250
e. Note any adverse drug reactions reported to the FDA or 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 BLEND 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: Study is ongoing. Interim data analysis showed better results with the Bisnare, but have not reached statistical significance yet. Request one additional year for enrollment.

Publications and Presentations: Two presentations.

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/144 (3) Status: Completed

(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: 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 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: Study completed.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/145 (3) Status: Terminated

(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:

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

(9) Dept/Svc: Endocrine (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 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: Protocol administratively terminated.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (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: 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 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: Three subjects studied, one completed. Due to down-sizing of the Army, budget cuts, elimination of the new Pulmonary Fellowship, and lack of eligible subjects, the study cannot be completed as planned. Study will continue while PI is at FAMC and perhaps in the next two years sufficient subjects may be studied to provide evaluable data or some type of useful information.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/147 (3) Status: Completed

(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: 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 93 (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 93 (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 93 (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: 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 determine the most effective treatment of cancer.

(16) Technical Approach: Per NCI-approved protocol.

(17) Progress: Patient failed induction therapy, patient has died.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (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.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/100 (3) Status: Completed

(4) Title: The Efficacy and Safety of Misoprostol in the Prevention of NSAID-induced GI Complications

(5) Start Date: 1992 (6) Est Compl Date: July 1993

(7) Principal Investigator: Sterling West, COL, MC (8) Facility: FAMC

(9) Dept of MED/Rheumatology (10) Associate Investigators

(11) Key Words:
misoprostol
investigational new drug

Ruth Hugler, Rn

(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: 3
d. Total Number of Subjects Enrolled to Date: 29
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 investigate the efficacy and safety of misoprostol for a new indication, the prevention of gastrointestinal ulcer complications in patients with rheumatoid arthritis who are taking non-steroidal anti-inflammatory drugs for their arthritis.

(16) Technical Approach: Enroll 30 rheumatoid arthritis patients over the age of 60 on NSAIDS. Subjects will receive active drug, misoprostol, or placebo for six months in addition to their standard medication for rheumatoid arthritis. The study is double-blinded, and evaluation criteria is the comparison of the rate of GI events between the two groups.

(17) Progress: We have enrolled 29 patients into the study. Of this number, 5 patients terminated early; 4 patients has SAE's; and 24 patients completed 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 93 (2) Protocol #: 92/101 (3) Status: Ongoing

(4) Title: SWOG 8913 Evaluation of Mebarone in Malignant Melanoma, Phase II

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

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

(9) Dept of 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: 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 participate in the SWOG protocol in the study of 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 93 (2) Protocol #: 92/102 (3) Status: Ongoing

(4) Title: SWOG 8956 A Phase II Study of Cisplatin and 5-FU Infusion for Treatment of Advanced and/or Recurrent Metastic Carcinoma of the Urinary Bladder

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

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

(9) Dept of 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: 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 participate in the SWOG protocol in the study of 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 93 (2) Protocol #: 92/103 (3) Status: Completed

(4) Title: SWOG 9016 Study of External Brain Irradiation and Cisplatin/BCNU Followed by BCNU for the Treatment of Primary Malignant Brain Tumors, Phase II

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

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

(9) Dept of 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:_____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 protocol in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: Two patients enrolled, one patient taken off study for progression; patient has died, the other patient is doing well off chemotherapy.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/104 (3) Status: Terminated

(4) Title: C91-180 Phase III Randomized Controlled Trial Comparing the Efficacy of Combination Therapy with 5-Fluorouracil and Leucovorin Against the Efficacy of Combination Therapy with 5-Fluorouracil and Intron A in the Treatment of Metastatic Colorectal Cancer

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

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

(9) Dept of 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: ___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 participate in the SWOG protocol in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: Terminated, not chosen as a site.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/105 (3) Status: Ongoing

(4) Title: Bi-Bx Removal of "Hard to Reach' Colon Polyps: A Pilot Evaluation of a New Polypectomy Technique

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro

(10) Associate Investigators

(11) Key Words:
colon polyps
polypectomy

Dr. Suddeth
Ms. DeAngalis

(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: 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: To determine the utility of a new biopsy technique.

(16) Technical Approach: Prospective evaluation with followup for technical success and complications.

(17) Progress: Ten patients enrolled to date, no complications or untoward side effects. Plan to continue patient enrollment.

Publications: Am J Gastro 87:1329, 1992
Presentations: Will be presented in FY 93

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/107 (3) Status: Ongoing

(4) Title: Treatment of Graves' Disease with Cholestyramine

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Arnold Asp, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators
Michael McDermott, LTC, MC
Gregory B. Hughes, MAJ, MC

(11) Key Words:
hyperthyroidism
cholestyramine

(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: 2
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 evaluate the efficacy of adding cholestyramine to conventional antithyroid drug therapy in rapidly achieving a euthyroid state in patients with active hyperthyroid graves disease.

(16) Technical Approach: Parallel two-group repeated measures design in hwich half the patients receive traditional therapy with methimazole and ateolpl, while the other half receive methimazole and atenolol plus cholestryramine for a period of four weeks.

(17) Progress: Two patients enrolled at FAMC. Seven patients enrolled at WRAMC.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/109 (3) Status: Ongoing

(4) Title: Characterization of a Human Thyroid Cancer Cell Line

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:

Bill Georgitis, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators

Tony Gutierrez
Donald Mercill

(11) Key Words:
cell line thyroid
thyroid cancer

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Identify and characterize an immortal thyroid cancer cell line in terms of degree of differentiation and thryoid cell/molecular biology.

(16) Technical Approach: The cells will be studied using a variety of techniques including immunohisto chemistry, molecular biology and radioisotope methods.

(17) Progress: Positive immunohistochemical staining for thyroglobulin has been found. Attempts to reverse transcribe thryoglobulin cDNA from throglobulin message are under way.

Presentations:

1. Society of Uniformed Endocrinologists meeting, (poster) June 1992.

2. American Thyroid Association (poster) September 1992.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/111 (3) Status: Ongoing

(4) Title: The Effect of Exogenous Thyrotropin Releasing Hormone on Plasma Atrial Natriuretic Peptide

(5) Start Date: 1992 (6) Est Compl Date: 1994

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

(9) Dept of MED/Endocrine (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: DEC 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if TRH administration has any effect on serum levels of anpand, if so, whether this is a direct effect or due to the pressor response to TRH.

(16) Technical Approach: Various doses of TRH are given to normal volunteers on differenct days. After TRH administration blood is drawn for ANP levels and blood pressure and pulse are monitored continually.

(17) Progress: 6 subjects have been tested with one dose and no ANA response occured despite an increase in blood pressure. We are currenlty rechecking the samples and determining the performance characteristics of the assay kit. No progress FY 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/113 (3) Status: Ongoing

(4) Title: Cyclosporine Treatment of Idiopathic Chronic Active Hepatitis

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

(7) Principal Investigator: Kenneth Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 6
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: Multicenter trial to evaluate potential for cyclosporin as a therapeutic agent in steroid resistant autoimmune hepatitis.

(16) Technical Approach: Open label therapeutic trial of cyclosporin in patients with idiopathic chronic active hepatitis that is resistant to steroids and/or in patients who cannot tolerate standard immunosuppression methods.

(17) Progress: To date 6 patients with chronic active hepatitis have been enrolled with 4 of these at FAMC. All patients seemed to demonstrate a response. Among patients who completed at least 16 weeks of therapy, 3/4 were classified as responders as defined by normalization or near normalization of ALT. One hypertensive patient continued severe hypertension on this therapy. Creatinine rose in one patient but this was concurrent with amphotericin B use for Sporothrix infection that was present prior to initiation of therapy.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/114 (3) Status: Ongoing

(4) Title: Household Transmission of Hepatitis C Virus in Military Populations

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

(7) Principal Investigator: Kenneth Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 52
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: Multicenter trial to determine prospective incidence of hepatitis C in family members of index cases.

(16) Technical Approach: Demographic/risk questionnaire with serial serum collection and testing for hepatitis C nucleic acid and antibodies.

(17) Progress: To date 14 patients with chronic active hepatitis attributable to viral hepatitis C have been enrolled at FAMC. Additionally, 38 family members of the index cases have agreed to participate. There have been no adverse events associated with this protocol.

Publications and Presentations: American Association for Liver Disease National Meeting, November, 1992.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/116 (3) Status: Ongoing

(4) Title: Early Detection of Second Primary Lung Cancers by Sputum Cytology Immunostaining

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Jerry Pluss, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Pul. Dis. (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: 9
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: Study usefulness of immunostaining cytology compared to regular sputum cytology, cxr and examination in the detection of recurrent lung cancer. This very high risk population is being used instead of cigarette smokers to obtain data on a smaller group of patients in a shorter time frame.

(16) Technical Approach: Yearly examination of high risk population that develops lung cancer. Using history, physical examination, cxr, induced sputums, non-induced sputums and bronchoscopy to evaluate cytologic methods (routine techniques, immuno staining techniques and other tumor markers).

(17) Progress: Nine patients have been enrolled to date. Estimate patient accrual will continue into 1994.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/117 (3) Status: Terminated

(4) Title: A Comparison of the Efficacy, Safety and Tolerance of Ceftibuten (SCH 39720) 300 mg Given BID and Augmentin 500 mg Given TID in the Treatment of Community Acquired Pneumonia
Schering-Plough Research Protcol C91-248-00, IND # 30,303

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Daniel Ouellette, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Pul. Dis.

(10) Associate Investigators
Dr. David Kristo
Dr. J.F. Turner

(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: AUG 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". GI disturbances

(15) Study Objective: To compare the efficacy, safety, and tolerance of high dose ceftibuten (Sch 39720) 300mg BID with that of augmentin 500mg TID in the treatment of pneumonia.

(16) Technical Approach: Patients presenting to the pulmonary clinic with pneumonia are randomized to ceftibuten or augmentin after meeting study entrance criteria and signing a informed consent.

(17) Progress: Four patients enrolled 4/92, last one 8/28/92. 3 - terminated early because entrance criteria not met (i.e., sensitivities, bacteriology results). 1- dropped due to treatment failure. Study terminated by sponsor due to loss of study coordinator.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/118 (3) Status: Terminated

(4) Title: A Comparison of the Efficacy, Safety, and Tolerance of Ceftibuten (SCH 39720) 400mg (1 x400 mg capsule) in the Fed and Fasted State and Augmentin Amoxicillin/Clavulanate 1.5 gm (1 x 500 mg tablet TID) in the Fed State in the Treatment of Acute Exacerbations of Chronic Bronchitis Schering-Plough Research Protocol (C90-038-00, IND #30,303

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Daniel Ouellette, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Pul. Dis. (10) Associate Investigators

(11) Key Words: Dr. David Kristo
Dr. J.F. Turner

(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: Approved
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 22
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". **Pt. hospitalized with renal failure. Patient died as a result of intraabdominal sepsis (result of perforated gall bladder) ; GI Disturbances, nausea, etc.**

(15) Study Objective: To compare the efficacy, safety and primarily the GI tolerance of once-daily ceftibuten in both the fed and fasted state with that of augmentin given TID in the fed state in the treatment of acute exacerbations of chronic bronchitis in adults.

(16) Technical Approach: Patients presenting to the pulmonary clinic with acute exacerbation of chronic bronchitis are randomized to ceftibute or augmentin.

(17) Progress: Since 2/92, 22 patients have been enrolled, 14 patients completed, 1 patients dropped due to treatment failure; 3 pts terminated early due to entrance criteria not met and one adverse event. Study terminated by sponsor due to loss of study coordinator.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/120 (3) Status: Ongoing

(4) Title: Prevalence of Gluten Sensitive Enteropathy in Patients with Insulin Dependent Diabetes Mellitus

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

Dr. Davis
Dr. Merenich
Kenneth Sherman, MAJ, MC

(11) Key Words:
celiae disease
diabetes

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Prospective evaluation of the prevelance of GSE among type I IDDM patients.

(16) Technical Approach: Evaluation of the prevelance of GSE among type I IDDM patients.

(17) Progress: Demographics have been collected on 200 patients and lab draws done on 100 patients, within 1 week there will be 100 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 93 (2) Protocol #: 92/122 (3) Status: Ongoing

(4) Title: SWOG 9061 A Phase III Study of Conventional Adjuvant Chemotherapy versus High Dose Chemotherapy and Autologous Bone Marrow Transplantation as Adjuvant Intensification Therapy Following Conventional Adjuvant Chemotherapy in Patients with Stage II and III Breast Cancer at High Risk of Recurrence

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

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

(9) Dept of 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: 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 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 protocol in the study of 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 93 (2) Protocol #: 92/123 (3) Status: Ongoing

(4) Title: A Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter Study to Evaluate the Effect of Quinapril in Reducing Ischemic Events During a 3-Year Follow-up in Patients Post Intervention: QUIET (Quinapril Ischemic Event Trial). (IND) Parke-Davis Protocol 906-370

(5) Start Date: 1992 (6) Est Compl Date: 1996

(7) Principal Investigator: Richard Davis, COL, MC (8) Facility: FAMC

(9) Dept of MED/Cardiology (10) Associate Investigators Robert Cameron, LTC, MC Peter Bigham, MAJ, MC

(11) Key Words: investigational new drug ischemia quinapril

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

(14) a. Date, Latest IRC Review: MAR/Sep b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date: 11
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". **Unstable Angina; Viral Infection**

(15) Study Objective: To test the effectiveness of an investigational new drug, quinapril, to prevent ischemic events post angioplasty or atherectomy.

(16) Technical Approach: Multi-center international trial---double-blind, randomized, placebo-controlled. Approximately 75 patients will be enrolled at FAMC and followed for a three-year period.

(17) Progress: It appears from data gathered at other institutions where subjects have been enrolled for some time that the placebo group requires recatheterization, while treadmills are negative on the active drug group. Enrollment closed 3 Feb 93, patients will be followed for two years.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/124 (3) Status: Terminated

(4) Title: Frequency of Lovastatin and Pravastatin Induced ANA Antibodies and Antibody Identity

(5) Start Date: 1992 (6) Est Compl Date: 1995

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

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators

Sterling West, COL, MC
Jan Perloff, MAJ, MC

(11) Key Words:
lovastatin
pravastatin
antinuclear antibodies

(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: 100
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 the incidence of ANA positivity in patients taking Hmb Coa reductase inhibitors.

(16) Technical Approach: Cross-sectional - Patients taking lovastatin will have ANA determined and if positive they will be characterized as to the antibody type. Prospective: Patients started on pravastatin will have ANA determined before and periodically after being started on pravastatin.

(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 93 (2) Protocol #: 92/125 (3) Status: Ongoing

(4) Title: The Relationship Between High Resolution Electrocardiography and Ventricular Ectopy in Hypertensive Patients with Left Ventricular Hypertrophy: A Pilot Study

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Richard Shea, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators

Mark Dorogy, MD
Aryo Oopick, MD
William Highfill, MD
David Boike, MD

(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: MAR b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 38
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 relationship between echocardiographically determined LV mass, ectopy by Holter monitor, and abnormalities of the SAEIIG on hypertensive patients with LVH.

(16) Technical Approach: Prospective study of hypertensive patients. We obtain echo, Holter, and SAEIIG data and analyze in context of LV Mass vs percent of ectopy vs abnormal SAEIIG criteria.

(17) Progress: Enrollment continues at slower than predicted rate. Initial data suggests no relationship between LV mass and SAEIIG data, but more patients are needed. Negative results are still significant. Study design appears good. Results comparable to data available in literature.

Publications and Presentations: Interim results presented 05 Nov 92 at Army ACP meeting, Cardiology Section, by M. Dorogy.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/126 (3) Status: Completed

(4) Title: Study of the Effect of Oral Extended-Release Nitroglycerin Capsules in Patients with Angina Pectoris: KV NTG versus Placebo

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: William Highfill, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Cardiology (10) Associate Investigators

(11) Key Words:
nitroglycerin
anginapectoris

(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: 0
d. Total Number of Subjects Enrolled to Date: 1
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: Confirm results of previous trial of once a day long-acting oral NTG and establish that there is no clinically significant rebound effect from long-acting oral NTG.

(16) Technical Approach: Double-blind, two way crossover study using treadmill stress testing in ambulatory patients with chronic stable angina pectoris.

(17) Progress: Slow - about 10 patients have been screened. Only one patient was completely satisfactory, and has completed the study protocol and is back on his prior meds. He experienced no adverse effects. No additional patients have been screened. Recruitment has been terminated (in conjunction with VA). No adverse reactions occured in any patient.

Publications and Presentations: Preparation of publication (in conjunction with VA) is ongoing.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/127 (3) Status: Ongoing

(4) Title: A Phase III, Randomized Comparative Trial of ZDV versus ZDV plus ddI versus ZDV plus ddC in HIV-Infected Patients (NUCOMBO)

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

(7) Principal Investigator: Keith Konkol, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Inf. Dis. (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: 1
d. Total Number of Subjects Enrolled to Date: 6
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 see if combining ddI or ddC with ZDV is more effective than ZDV alone in controlling HIV.

(16) Technical Approach: See protocol.

(17) Progress: Too early to compile any data on 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 93 (2) Protocol #: 92/129 (3) Status: Ongoing

(4) Title: Randomized Comparison of Radiation Versus Radiation Plus Continuous 5-Fluorouracil Infusion for Palliation of Bone Metastases: Phase II Study

(5) Start Date: 1992 (6) Est Compl Date: 1993

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

(9) Dept of 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: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
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 determine whether better palliation of bone metastases and improved local control of tumor results from radiation plus continuous 5-Fu infusion compared to radiation alone.

(16) Technical Approach: Enroll at total of 42 patients, with 21 patients in each treatment group.

(17) Progress: Five patients enrolled to date, four of which were randomized to radiation alone. One patient has died. No patients currently on treatment. No conclusions about the treatment can be made.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/130 (3) Status: Ongoing

(4) Title: Antigen-Specific Immunoglobulin and Lymphocyte Responses in Systemic Lupus Erythematosus Patients Following Immunization with Three Clinically Relevant Vaccines

(5) Start Date: 1992 (6) Est Compl Date: Feb 93

(7) Principal Investigator:
Nicholas Battafarano, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Allergy

(10) Associate Investigators
Michael Lieberman, LTC, MC
Raymond Enzenauer, MAJ, MC
Daniel F. Battafarano, MAJ, MC
Lawrence Larson, MAJ, MC
David Goodman, COL, MC

(11) Key Words:
lupus
systemic lupus erythematosus
immunizations

(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: 51
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: Determine immunization responses in systemic lupus, erythematosus patients to develop practical immunization prescriptions for these patients.

(16) Technical Approach: Pre-immunization: Clinical evaluation immunoglobulin levels, lymphocyte responses; Immunize with pneumococcal, H. Influenza and test toxoid immunizations; Post-immunization: Clinical evaluation immunoglobulin levels, lymphocytes responses.

(17) Progress: Excellent - Patients have agreed to participate, 6 enrolled in test validation group, local injection inflammation has occurred as expected in a few patients. No difference in either group and all easily treated with tylenol, aspirin or NSAIDS. Symptoms sore, red area at site of injection.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/131 (3) Status: Completed

(4) Title: Determination of Indirect Immunofluorescence Results in Bullous Pemphigoid and Pemphigus

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

(7) Principal Investigator: (8) Facility: FAMC
Kathleen David-Bajar, MAJ, MC

(9) Dept of MED/Dermatology (10) Associate Investigators
Scott Bennion, COL, MC
Ronald Jackson, DCI

(11) Key Words:
skin splitting for immunofluorescence
basement membrane zone of skin

(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 determine the ultrastructural level of splitting of neonatal and adult skin using NaCl and EDTA.

(16) Technical Approach: Neonatal foreskins, and adult skin removed during surgery, which would normally be discarded will be split with standard methods, and the level of splitting willbe examined using structural landmarks, and standardized antibodies.

(17) Progress: Immunogold methods are not yet worked out. The electron microscopy technician has been separated from the Army. A new EM technician is not available.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/132 (3) Status: Ongoing

(4) Title: Aspects of Alveolar Macrophage Function During HIV Infection

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Daniel Ouellette, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Pulmonary Disease

(10) Associate Investigators

Mark Ptaskiewicz, CPT, MC

(11) Key Words:
HIV, macrophage, immunology

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Investigate the role of intracellular adhesion molecules in the development of HIV infection.

(16) Technical Approach: Measure levels of ICAM-1 in BAL fluid in HIV infected patients and in controls bronchoscoped for other reasons.

(17) Progress: Assay refinement almost completed. Will begin to enroll study patients in 4-6 weeks.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/133 (3) Status: Terminated

(4) Title: Patterns of Respiratory Diastole

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

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

(8) Facility: FAMC

(9) Dept of MED/Pul.Dis.

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To ascertain the airflow in COPD patients at end expiration.

(16) Technical Approach: Patients will breath through mask fitted with penumotach while resting in reclining chair.

(17) Progress: No 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 93 (2) Protocol #: 92/134 (3) Status: Terminated

(4) Title: Deadspace Interactions in Emphysema

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Michael Perry, COL, MC (8) Facility: FAMC

(9) Dept of MED/Pul.Dis. (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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate atypical relationship of physiologic and anatomic deadspace in emphysema.

(16) Technical Approach: Mechanical deadspace added and physiologic deadspace monitored with arterial blood gases.

(17) Progress: No 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 93 (2) Protocol #: 92/135 (3) Status: Terminated

(4) Title: Determination of Microbial Organisms in Russian Thistle Pollen and Their Effects on Protein Extraction from the Pollen

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Lawrence Larsen, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Allergy (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: NA
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: Determine best extraction method for Russian thistle pollen by examining bacterial content of pollen and effects of antibacterial method.

(16) Technical Approach: Extract aliquote of pollen at various temperatures, for various timer, with different buffers and antibacterial agents and protease inhibitors. Extracts examined for total protein and analyzed on PAGE and compared.

(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 93 (2) Protocol #: 92/138 (3) Status: Ongoing

(4) Title: A Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study of the Use of Weekly Azithromycin as Prohylaxis Against the Development of Mycobacterium Avioum Complex (MAC) Disease in HIV-Infected People

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Keith Konkol, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Inf.Dis. (10) Associate Investigators

(11) Key Words:
HIV
MAC
azithromycin

(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: 14
d. Total Number of Subjects Enrolled to Date: 14
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 the safety and efficacy of oral azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromised HIV infected patients with a CD4 cell count of <100/mm.

(16) Technical Approach: See protocol.

(17) Progress: Of 14 patients screened eight were randomized to Rx/placebo; three chose not to continue; one was MAC+ - failed screen; two waiting for screen cultures to qualify.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/139 (3) Status: Terminated

(4) Title: Phase I Study of Alferon N Injection in Persons with Asymptomatic Human Immunodeficiency Virus (HIV) Infection

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

(7) Principal Investigator: W.R. Byrne, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Inf.Dis. (10) Associate Investigators Robert Gates, 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: 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the safety and tolerance of subcutaneous injections of natural interferon-alpha (IFN) in asymptomatic HIV-positive persons and to record its effect on the HIV virus in these individuals.

(16) Technical Approach: See protocol

(17) Progress: Terminate study for administrative reasons.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/140 (3) Status: Terminated

(4) Title: The Detection of Antibodies to Helicobacter Pylori in Samples Obtained with the OraSure Oral Specimen Collection Device

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

(7) Principal Investigator: Bryan Larsen, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words:
helicobacter pylori
salivary antibodies
orasure salivary collection device

Jerry Sims, M.D.

(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: 18
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 if salivary antibodies collected with the orasure collection device is a reliable way to determine the presence or absence of helicobacter pylori.

(16) Technical Approach: 5cc of blood is obtained via venipuncture, spun with the serum frozen. Saliva obtained using the orasure salivary collection device and stored for testing of antibodies. Biopsies obtained from the stomach for analysis.

(17) Progress: Terminated

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/141 (3) Status: Ongoing

(4) Title: The Relationship of Gout and Hyperuricemia to Hypothyroidism

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Alan Erickson, M.D.

(8) Facility: FAMC

(9) Dept of MED/INT.MED.

(10) Associate Investigators

Raymond Enzenauer, MD
John Merenich

(11) Key Words:
gout
hypothyroidism

(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: 72
d. Total Number of Subjects Enrolled to Date: 75
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 survey the relationship of gout and hypothyroidism.

(16) Technical Approach: Retrospective and prospective review.

(17) Progress: The retrospective and prospective portions of the study are completed. The research is being compiled for publication. In the process of starting the metabolic portion of the research. to date 73 subjects enrolled, 72 this report period.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/142 (3) Status: Ongoing

(4) Title: Clarithromycin in Combination with Omeprazole or Omeprazole as a Single Agent for the Treatment of Patients with Duodenal Ulcers

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

MAJ Steven Hammond
MAJ Scott Lewey
LTC Milton Smith

(11) Key Words:
duodenal ulcer

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if omeprazole plus clarithromycin is more effective in preventing ulcer recurrence than omeprazole plus placebo.

(16) Technical Approach: Double blind randomized multi-center trial with endoscopic followup for recurrence.

(17) Progress: No patients enrolled to date; still awaiting FDA approval; anticipate start 1 Sep 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/143 (3) Status: Ongoing

(4) Title: SWOG 9035 - Randomized Trial of Adjuvant Immunotherapy with an Allogeneic Melanoma Vaccine for Patients with Intermediate Thickness, Node Negative Malignant Melanoma (T3NOMO) Phase III

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

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

(9) Dept of 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 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 protocol in study of malignancies.

(16) Technical Approach: See protocol

(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 93 (2) Protocol #: 92/144 (3) Status: Ongoing

(4) Title: Double-Dummy, Double-Blind, Randomized, Single-Center Study on the Effect of Hormone Replacement Therapy on Blood Pressure

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Fred Pfalsgrath, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators
William Georgitis, COL, MC
Rhonda Wagner, CPT, AN

(11) Key Words:
hormone replacement
b l o o d p r e s s u r e

(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: 18
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 estrogen replacement therapy effects on blood pressure in post menopausal women.

(16) Technical Approach: This is a 6-month study of 100 women assinged to either Premarin 0.625mg/day, placebo shoulder patch; or Estraderm 0.05mg patch, placebo pill/day. Blood, urine and blood pressure will be monitored.

(17) Progress: To date 18 patients enrolled. One patient dropped out secondary to rash induced by patch adhesive and spotting.

Publications and Presentations: None

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

(1) Date: 30 Sep 92 (2) Protocol #: 92/145A (3) Status: Completed

(4) Title: The Effects of Methotrexate on Mouse (Mus musculus) Osteoblasts and Osteoclasts in Culture

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Kimberly May, CPT, USAF

(8) Facility: FAMC

(9) Dept of MED/

(10) Associate Investigators

Don Mercill, CPS
Sterling West, COL, MC
Michael T. McDermott, LTC, MC

(11) Key Words:
methotrexte
osteopenia
osteoblasts

(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: 7 adult mice/63 newborns
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 methotrexate (MTX) on mouse osteoblasts (OB) and osteoclasts (OC) grown in culture.

(16) Technical Approach: Have completed initial part of study; successfully separated osteoblasts and osteoclasts.

(17) Progress: We have shown that chronic low-dose MTX causes severe osteopenia when administered to female rats. This osteopenia is characterized by decreased OB function without decreased numbers, and increased resorption felt to represent a physiologic remodelling response.

Presented: 57th Annual Scientifc Meeting, November 1993, San Antonio, TX.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/100 (3) Status: Terminated

(4) Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of Healing and Relapse Rates Following Oral GR122311X (Ranitidine Pluse Bismuth Citrate) Compared with GR88502X (Bismuth Citrate), Ranitidine and Placebo in Patients with Duodenal Ulcer. (IND/Glaxo H2B-302)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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:

(16) Technical Approach:

(17) Progress: Terminated by sponsor.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/101 (3) Status: Terminated

(4) Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of Healing and Relapse Rates Following Oral GR122311X (Ranitidine Pluse Bismuth Citrate) Compared with GR88502X (Bismuth Citrate), Ranitidine and Placebo in Patients with Benign Gastric Ulcer. (IND/Glaxo H2B-312)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC

(9) Dept of 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: ___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:

(16) Technical Approach:

(17) Progress: Terminated by sponsor.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/102 (3) Status: Terminated

(4) Title: The Effect of Quinapril on Endothelial Dysfunction in Angiographically Normal Coronary Arteries as Assessed by Serial Intracoronary Acetylcholine Challenge: A Sub-Study of the Quinapril Ischemic Event Trial (QUIET)

(5) Start Date: 1993 (6) Est Compl Date: 1993

(7) Principal Investigator: Robert Cameron, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Cardiology 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: N/A

(16) Technical Approach: N/A

(17) Progress: IRC approval was pending revision of consent form, RPC review, and hospital impact statement for overnight stay for followup angiogram. MAJ McBiles reported that at RPC review on 31 Mar 93 the investigators stated they wished to terminate the study due to failrue to interest patients in enrolling. The IRC requests notification in writing from the investigators to this effect.

Publications and Presentations: N/A

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/103 (3) Status: Ongoing

(4) Title: A Randomized, Comparative, Prospective Study of Daily Trimethoprim/Sulfamethoxazole (TMS) and Thrice Weekly TMS for Prophylaxis Against PCP in HIV-Infected Patients

(5) Start Date: Oct 92 (6) Est Compl Date: 1994

(7) Principal Investigator: Keith Konkol, MAJ, MC (8) Facility: FAMC

(9) Dept of Med/Infect Dis (10) Associate Investigators

(11) Key Words:
HIV, prophylaxis, PCP, trimethoprim, sulfamethoxazole

(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: Approved
c. Number of Subjects Enrolled During Reporting Period: None
d. Total Number of Subjects Enrolled to Date: None
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 evaluate the safety and efficacy of two dose regimens (daily or 3x a week) of Trimethoprim/Sulfamethoxazol (TMP/SMX) in the prevention of Pneumocystis carinii pneumonia (PCP) in high-risk HIV-infected patients.

(16) Technical Approach: There will be two drug regimens, TMP/SMX daily or 3x a week (Monday, Wednesday and Friday). Patients will be assigned therapy according to a prepared randomization schedule.

(17) Progress: 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 93 (2) Protocol #: 93/104 (3) Status: Ongoing

(4) Title: A Randomized, Prospective, Double-Blind Study Comparing Fluconazole with Placebo for Primary and Secondary Prophylaxis of Mucosal Candidiasis in HIV-Infected Women (CPCRA 010)

(5) Start Date: Oct 92 (6) Est Compl Date: 1995

(7) Principal Investigator: Keith Konkol, MAJ, MC (8) Facility: FAMC

(9) Dept of Med/Infect Dis (10) Associate Investigators

(11) Key Words: HIV, prophylaxis, Candidiasis

(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: Approved
c. Number of Subjects Enrolled During Reporting Period: None
d. Total Number of Subjects Enrolled to Date: None
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 evaluate the efficacy of Fluconazole vs. placebo for the prevention of Candida esophagitis and vaginal/oropharyngeal candidiasis in HIV-infected women.

(16) Technical Approach: Patients will be assigned one of the two drug regimens, Fluconazole or placebo weekly, according to a prepared randomization schedule.

(17) Progress: None

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/105 (3) Status: Ongoing

(4) Title: Amlodipine Study of the Angina Population

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Robert Cameron, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators
Brian Horvath, MAJ, MC
Mike McBiles, LTC, MC

(11) Key Words:
Amlodipine, angina, IND

(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 determine safety and efficacy of amlodipine as replacement therapy for other antianginal medications in patients with chronic angina.

(16) Technical Approach: Randomized, double-blind, placebo controlled, multi-center trial. Ten subjects per site. Phase I baseline 4 weeks; Phase II is 4 weeks of taper-off heart medication period, then assignment to study drug treatment for 4 weeks; Phase III is an optional 3 month treatment on open label.

(17) Progress: None. CIRO approved 2 Sep 93

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/106 (3) Status: Terminated

(4) Title: Helicobacter pylori Associated Gastric Atrophy: Effect of Antibiotic Therapy

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Frank Jahns, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 studying 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: PI PCS'd prior to initiating 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 93 (2) Protocol #: 93/107 (3) Status: Ongoing

(4) Title: SWOG 9030 Phase II Study of High Dose Ara-C/Mitoxantrone for the Treatment of Relapsed/Refractory Acute Lymphocytic Leukemia

(5) Start Date: 1993 (6) Est Compl Date:

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

(9) Dept of 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: 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 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 study protocols.

(16) Technical Approach: Per protocol.

(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 93 (2) Protocol #: 93/108A (3) Status: Completed

(4) Title: Prevention of Low-Dose Methotrexate Induced Osteoporosis in Female Sprague Dawley Rats (Rattus norvegicus) by Salmon Calcitonin, Pamidronate and Leucovorin Resuce

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Matthew Carpenter, CPT, USAF, MC

(9) Dept of MED/Rheumatology (10) Associate Investigators

(11) Key Words:
osteoporosis
methotrexate

(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:_____53 rats_____
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: Determine if diphosphonates, calcitonin, or leucovorin can ameliorate methotrexate-induced osteoporosis.

(16) Technical Approach: Per protocol.

(17) Progress: Completed.

Publications and Presentations: Manuscript and presentation in preparation.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/109 (3) Status: Ongoing

(4) Title: SWOG 9148 A Phase II Study of Cisplatin Preceded by a 12 Hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (Ara-C) for Patients with Untreated, Extensive Stage Small Cell and Non-Small Cell Lung Carcinoma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: ___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 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 protocol.

(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 93 (2) Protocol #: 93/110 (3) Status: Ongoing

(4) Title: SWOG 9215 Quality of Life on Breast Cancer Adjuvant Trial (SWOG 8931)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/111 (3) Status: Ongoing

(4) Title: An Open Protocol for the Use of Agrelin (Anagrelide) for Patients with Thrombocythemia

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Daniel Tell, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators

Patrick Judson, LTC, MC
David Faragher, MAJ, MC

(11) Key Words:
IND, anagrelide,
thrombocytopenia

(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: 1
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 if anagrelide is a safe and effective treatment to reduce the number of platelets in the blood. This is also a dose ranging study.

(16) Technical Approach: Open label study, 3-month supply of drug in 0.5 mg and 1.0 mg capsules.

(17) Progress: One patient was enrolled but was taken off study due to non-compliance.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/112 (3) Status: Ongoing

(4) Title: A Phase I-II Study of Daily Carboplatin and Simultaneous Accelerated Hyperfractionated Chest Irradiation Followed by Single Agent Carboplatin in Patients with Regionally Inoperable (Stages IIIa and IIIb) Non-Small Cell Lung Cancer

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Daniel Tell, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators

(11) Key Words:
carboplatin, radiation therapy,
lung cancer

(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: 0
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 improve response rates by combining radiation therapy (standard treatment) with carboplatin chemotherapy and to study the side effects of this treatment

(16) Technical Approach: Initial treatment is daily chest irradiation and intravenous carboplatin chemotherapy (except on weekends) for four weeks. Rest period of 3-4 weeks between three cycles of treatment.

(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 93 (2) Protocol #: 93/113 (3) Status: Ongoing

(4) Title: A Pilot Phase II Study of Induction Therapy with Daily Etoposide, Daily Cisplatin and Simultaneous Chest Irradiation Followed by Four Cycles of Consolidation Cisplatin/Etoposide Therapy in Limited Stage Small Cell Lung Cancer

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Daneil Tell, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators

(11) Key Words:
lung cancer, etoposide,
cisplatin, radiation therapy

(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: 0
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 a new combination of this standard treatment.

(16) Technical Approach: Per University of Colorado Cancer Center Clinical Trial Protocol.

(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 93 (2) Protocol #: 93/114 (3) Status: Ongoing

(4) Title: Parathyroid Hormone-Related Peptide in Connective Tissue Disease

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Gregory Hughes, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Endo

(10) Associate Investigators
LTC Arnold Asp
MAJ James Singleton
CPT Matthew Schofield

(11) Key Words:
connective tissue 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: 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 determine if PTH&P levels are elevated in connective tissue disease.

(16) Technical Approach: Open, repeated measures comparison of controls, rheumatoid arthritis and scleroderm patients.

(17) Progress: Eight subjects of projected 63 total obtained.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/115 (3) Status: Terminated

(4) Title:
TRC 9202: Taxol (NSC 125973) in Patients with Previously Treated Refractory Breast Cancer

(5) Start Date: 1993 (6) Est Compl Date:

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

(8) Facility: FAMC

(9) Dept of 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: ___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 studying 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: This protocol was submitted to the IRC for approval; however, the NCI obtained a sufficient number of participating physicians/institutions for this study. FAMC was not chosen as a site. This study has never been activated.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/116 (3) Status: Ongoing

(4) Title: SWOG 9008 Trial of Adjuvant Chemoradiation After Gastric Resection for Adenocarcinoma, Phase III

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/117 (3) Status: Ongoing

(4) Title: SWOG 9119 Primary Chemotherapy of Poor Prognosis Soft Tissue Sarcomas, Phase II

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/118 (3) Status: Ongoing

(4) Title: SWOG 9134 A Phase II Trial of Taxol and Granulocyte-Colony Stimulating Factor (G-CSF) in Patients with Advanced Soft-Tissue Sarcoma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/119 (3) Status: Ongoing

(4) Title: SWOG 9216 A Randomized Phase III Study of CODE Plus Thoracic Irradiation Versus Alternating CAV and EP for Extensive Stage Saml1 Cell Lung Cancer (NCIC CTG)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: ___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 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 protocols.

(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 93 (2) Protocol #: 93/120 (3) Status: Ongoing

(4) Title: A Comparative Trial of 256U87 and Acyclovir for the Treatment of First-Episode Genital Herpes Infection (IND)

(5) Start Date:1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Kathleen David-Bajar, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Derm.

(10) Associate Investigators
Scott D. Bennion, COL, MC
Richard Gentry, COL, MC
James Fitzpatrick, COL, MC

(11) Key Words:
primary herpes simplex
infections of the genitals

(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: 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".

(15) Study Objective: To compare the efficacy and safety of 256U87 with acyclovir in the treatment of first-episode genital herpes infection of immunocompetent patients.

(16) Technical Approach: Patients presenting to the clinic within 3 days (72 hours) of lesion onset with signs/symptoms consistent with first-episode genital herpes are entered after informed consent is obtained. Lesions will be swabbed and cultured for the presence of herpes simplex virus. supernatant fluid from the initial viral culture will be sent to BW Co. for determination of acyclovir sensitivity as part of a surveillance study of viral resistance. Patients will be equally randomized to one of two treatment groups: Group A: 256U87 1000mg orally 2x/day for 10 days; Group B: Acyclovir 200mg orally 5x/day for 10 days. Patients will be frequently evaluated with clinical and laboratory exams throughout a 14 day examination period or until all lesions have healed.

(17) Progress: Seven patients have been entered thus far, and no significant problems have been encountered. No data is yet available, as all codes are still unbroken.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/121 (3) Status: Ongoing

(4) Title: Outpatient Screening for Sleep Apnea

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Hai Bui, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/

(10) Associate Investigators
William Reed, 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: 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Develop an inexpensive, convenient method of screening for sleep apnea.

(16) Technical Approach: Record patients.

(17) Progress: Awaiting software sound recording translator.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/122 (3) Status: Ongoing

(4) Title: SWOG 9003 Fludarabine for Waldenstrom's Macroglobulinemia (WM): A Phase II Pilot Study for Untreated and Previously Treated Patients

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/123 (3) Status: Ongoing

(4) Title: SWOG 9031 A Double-Blind, Placebo-Controlled Trial of Daunomycin and Cytosine Arabinoside with or without rhG-CSF in Elderly Patients with Acute Myeloid Leukemia

(5) Start Date:1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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:____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 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 protocol.

(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 93 (2) Protocol #: 93/124 (3) Status: Ongoing

(4) Title: SWOG 9032 A Controlled Trial of Cyclosporine as a Chemotherapy-Resistance Modifier in Blast Phase Chronic Myelogenous Leukemia

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(16) Technical Approach: To determime 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 93 (2) Protocol #: 93/125 (3) Status: Ongoing

(4) Title: SWOG 9133 Randomized Trial of Subtotal Nodal Irradiation vs. Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease

(5) Start Date:1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/126 (3) Status: Terminated

(4) Title: The Effects of Altered Magnesium on Blood Pressure

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: John Hagan, CPT, MC (8) Facility: FAMC

(9) Dept of MED/Nephrology (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: 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 studying 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: Due to budgetary constraints and the discontinuation of chronic hemodialysis at Fitzsimons Army Medical Center, the patient population for the protocol has been reassigned to civilian units.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/127A (3) Status: Completed

(4) Title: The Dose-Response Curve for Methotrexate in Mouse (Mus musculus) Osteoblasts in Culture

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: KImberly May, CAPT, USAF, MC (8) Facility: FAMC

(9) Dept of MED/Rheumatology (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: Mar 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine effect of various doses of methotrexate on osteoblast function. Explore mechanisms of this effect.

(16) Technical Approach: Per protocol.

(17) Progress: Completed.

Publications and Presentations: Manuscript in preparation; to be presented at the National ACR meeting, November 1993.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/128 (3) Status: Ongoing

(4) Title: The Efficacy of a Standardized Acupuncture Regimen and Amitriptyline compared with Placebo as a Treatment for Pain Caused by Peripheral Neuropathy in HIV-Infected Patients (CPCRA 022)

(5) Start Date: Apr 93 (6) Est Compl Date: 1995

(7) Principal Investigator: Keith Konkol, MAJ, MC (8) Facility: FAMC

(9) Dept of Med/Infect Dis (10) Associate Investigators Rowland Hannon, PA-C Jeffrey Casserly, PA-C

(11) Key Words: HIV, acupuncture, amitriptyline, neuropathy

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

(14) a. Date, Latest IRC Review: Apr/Oct 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 evaluate the separate and combined efficacy of a standardized acupunture regimen and amitriptyline on the relief of pain due to HIV-related peripheral neuropathy and on the quality of life of HIV-infected patients.

(16) Technical Approach: Randomized, modified double-blind, 2x2 factorial, multicenter clinical trial. Patients will be treated for 14 weeks. There will be a 4-week post treatment followup to assess short term relief of pain. Patients will be randomized according to schedules prepared to ensure an approximate allocation ration of 1:1:1:1. Use of amitriptyline or placebo will be double-blind. Although the acupunturist cannot be blinded to acupuncture or alternate point treatment, the patient will be blinded (modified double-blind design).

(17) Progress: The protocol was amended 1 Jun 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/129 (3) Status: Ongoing

(4) Title: A Randomized, Comparative, Placebo-Controlled Trial of the Safety and Efficacy of Oral Ganciclovir for Prophylaxis of Cytomegalovirus (CMV) Retinal and Gastrointestinal Mucosal Disease in HIV-Infected Individuals with Severe Immunosuppression. CPCRA 023.

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Keith Konkol, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Inf. Dis.

(10) Associate Investigators

Robert H. Gates, LTC, MC
Jeffrey Casserly, PA-C

(11) Key Words:
cytomegalovirus (CMV)
ganciclovir

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and efficacy of oral ganciclovir for prophylaxis against CMV retinal and gastrointestinal mucosal disease in HIV-infected patients with severe immunosuppression.

(16) Technical Approach: See protocol.

(17) Progress: None 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 93 (2) Protocol #: 93/130 (3) Status: Ongoing

(4) Title: Calcitonin Response to Pentagastrin Stimulation Testing After Near-Total Thyroidectomy and Radioactive Iodine Ablation

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Michael Rensch, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators
Arnold A. Asp
Gerald S. Kidd
Gregory B. Hughes
Michael T. McDermott
John A. Merenich
William Georgitis

(11) Key Words:
radioactive iodine
medullary carcinoma of thyroid

(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: 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 establish a range of stimulated calcitonin valves following near-total thyroidectomy and determine the effect of radioactive iodine upon these values.

(16) Technical Approach: Open, repeated measures prospective study.
(17) Progress: Two patients enrolled; calcitonin batched and performed anually.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/131 (3) Status: Ongoing

(4) Title: A Retrospective Evaluation of the Use of the Bard Liver Biopsy Needle: Adequacy of Specimens and Complications

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Spencer Root, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

(11) Key Words:
baird liver biopsy needle

Kenneth E. Sherman, MAJ, MC

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We will attempt to quantitatively evaluate biopsy parameters and objectively determine comparative efficacy of the Bard Monopty needle to standard liver biopsy methods.

(16) Technical Approach: To anlayze the biopsy size, quality and types of complications associated with these 18g needles. There are no safety concerns associated with this study as it will be retrospective and involve only records review.

(17) Progress: Review charts, the study is ongoing.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/132 (3) Status: Ongoing

(4) Title: SWOG 9034 Phase III Study of Three Intensive Post-Remission Therapies in Adult Acute Non-Lymphocytic Leukemia: Comparison of Autologous Bone Marrow Transplantation, Intensive Chemotherapy and Allogeneic Bone Marrow Transplantation

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/133 (3) Status: Ongoing

(4) Title: SWOG 9104 Evaluation of Doxorubicin/Vinblastine Combined with Inhibitors (Trifluoperazine/Verapamil) of P-Glycoprotein in Patients with Advanced Renal Cell Carcinoma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/134 (3) Status: Ongoing

(4) Title: SWOG 9143 Evaluation of Cisplatin Preceded by a 12-hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (Ara-C) for Patients with Untreated Malignant Mesothelioma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 protocols.

(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 93 (2) Protocol #: 93/135A (3) Status: Ongoing

(4) Title: Gastroenterologic Service Training Using Laparoscopic Techniques in the Swine (Sus Scrofa)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Bryan Larsen, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words: Peter McNally, LTC, MC

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Per protocol.

(16) Technical Approach: Per protocol.

(17) Progress: Two workshops have been conducted to date. Excellent feedback from participants. This is a very important teaching tool.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/136 (3) Status: Ongoing

(4) Title: A Double-Blind, Randomized, Multi-Dose, Placebo-Controlled, Parallel Group Dose Ranging Study to Evaluate the Effects of MK-0591 in Induction of Symptomatic and Endoscopic Remission in Patients with Active Mild to Moderate Ulcerative Colitis. IND#41-060 (MK-0591; Protocol #024-00) AND Amendment #1 (MK-591; Prot No 024-01

(5) Start Date: 1993

(6) Est Compl Date:

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED, Gastro.

(10) Associate Investigators
MAJ Robert Suddeth
MAJ Dirk Davis
MAJ Stephen Lawrence
MAJ Spencer Root

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The study is to determine if MK-0591, an investigational drug, is safe and effective in the treatment of ulcerative colitis.

(16) Technical Approach: Per protocol.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/137 (3) Status: Ongoing

(4) Title: Aspirin in the Prevention of Neoplastic Polyps--A MultiCenter Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators
Sophia DeAngelis, RN
Spencer Root, MAJ, MC
Robert Suddeth, MAJ, MC
Dirk Davis, MAJ, MC
Stephen Lawrence, MAJ, MC

(11) Key Words:
neoplastic polyps

(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 investigate the efficacy of aspirin in preventing the recurrence of neoplastic polyps of the large bowel.

(16) Technical Approach: Conduct a randomized, double-blind, placebo-controlled clinical trial. Test the hypothesis that aspirin taken orally will reduce the occurrence of neoplastic polyps among those patients with a recent history of these tumors.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/138 (3) Status: Ongoing

(4) Title: A Screening Study for Myocardial Sarcoidosis Comparing Transesophageal Echocardiography, Transthoracic Echocardiography, Electrocardiography, Gallium-67 Scintigraphy and 99mTcSestamibi Scintigraphy

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Querubin Mendoza, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators
David Kristo, CPT, MC
Mike McBiles, LTC, MC
Robert Cameron, LTC, MC
Daniel Oulette, MAJ, MC

(11) Key Words:
sarcoid
electrocardiography
gallium, sestamibi

(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: 13
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: Assess most effective non-invasive test for detecting sarcoidosis in the heart.

(16) Technical Approach: Compare electrocardiography, transthoracic and transeophageal echocardiography, gallium-67 and 99mTc sestamibi scintigraphy.

(17) Progress: No notable difference among electrocardiography and echocardiography. Still await results of both scintigraphy.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/139 (3) Status: Ongoing

(4) Title: The Presence of HOuse Dust Mite Antigens in Colorado Homes Utilizing Evaporative Coolers: A Multicenter Study

(5) Start Date: 5/93 (6) Est Compl Date: 9/93

(7) Principal Investigator:
Amy Ellingson, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Allergy

(10) Associate Investigators
Robert LeDoux, BS
P.K. Vedanthan, MD
Richard W. Weber, MD

(11) Key Words:
dust mite
prevalence
humidity

(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 study the prevlaence of home dust mite antigen in Colorado homes utilizing evaporate coolers.

(16) Technical Approach: Collect samples of dust from 20 homes in Colorado which use swamp coolers during May and again in August. Analysis of dust extracts for specific HDM antigen (Der P1 & Der f1) using a monoclonal antibody in a sandwich ELISA.

(17) Progress: We have collected all the samples, extracted them and just completed the ELISAs. Currently the data is being analyzed. An abstract is being submitted to the American Academy of Allergy & Immunology for the national meeting in March 1994.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/140 (3) Status: Ongoing

(4) Title: A Study to Investigate the Efficacy and Safety of Oral valacyclovir (1000 mg or 500 mg, Twice Daily) Compared with Placebo in the Treatment of Recurrent Genital Herpes in Immunocompetent Patients

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Kathleen David-Bajar, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Derm.

(10) Associate Investigators
Scott D. Bennion, COL, MC
Richard Gentry, COL, MC
James Fitzpatrick, COL, MC

(11) Key Words:
recurrent herpes simplex
infections of the genitals

(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: 14
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 compare the efficacy and safety of two different doses of valacyclovir (1000mg twice daily, or 500mg twice daily) compared to placebo in immunocompetent patients with frequently recurring genital herpes simplex virus infections.

(16) Technical Approach: Immunocompetent patients with frequently recurring genital herpes simplex virus infections will be randomized according to a 3:3:2 randomization, such that for the total of 640 patients (from all centers), 240 will receive 100mg of valacyclovir twice daily, 240 will receive 500mg of valacyclovir twice daily, and 160 patients will receive placebo twice daily for 5 days. After being entered into the study, patients will self-initiate therapy at the first sign of symptom of an HSV infection recurrence, and continue the study medication for 5 days. Beginning within the first 24 hours of starting the study medication, and continuing until all lesions are healed, the patients will be examined frequently, with cultures taken from their lesions, and laboratory tests monitored.

(17) Progress: Fourteen patients have been entered thus far, and no significant problems have been encountered, No data is yet available, as all codes are still unbroken.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/141 (3) Status: Ongoing

(4) Title: A Controlled Trail of Implantable Cardiac Defibrillators Versus Medical Anti-Arrhythmic Drug Therapy

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Richard Davis, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators
Robert Cameron, LTC, MC

(11) Key Words:
cardiac defibrillator

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether ICD placement reduces total mortality when compared to conventional antiarrhythmic drug therapy. Secondary objectives include an economic assessment of the relative cost-effectiveness of the alternative treatment options and a quality-of-life evaluation.

(16) Technical Approach: 200 patients will be recruited for the pilot and a total of at least 1,000 patients recruited for the full-scale trial. The patients will be recruited at FAMC.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/142 (3) Status: Ongoing

(4) Title: Hypertension Optimal Treatment International Study

(5) Start Date: 1993 (6) Est Compl Date: 1996

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Nephrology

(10) Associate Investigators

Dr. Jane Yeun

(11) Key Words:
hypertension
diastolic blood pressure
o p t i m a l b l o o d p r e s s u r e

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine optimal diastolic blood pressure goal and if ASA is efficacious in hypertensive patients.

(16) Technical Approach: Patients randomized to 3 BP goals, 90, 85, 80 mm Hg diastolic. Patients also randomized to ASA vs placebo. Endpoints cardiovascular events and death.

(17) Progress: Protocol recently approved, in process of enrolling patients.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/143 (3) Status: Ongoing

(4) Title: Does Gastroesophageal Reflux Induce Myocardial Ischemia?

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Michael Kunkel, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/GI

(10) Associate Investigators
Steve Lawrence, MAJ, MC
Peter McNally, LTC, MC
Mike McBiles, LTC, MC

(11) Key Words:
gastroesophageal reflux
myocardial ischemia

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if esophageal acid infusion induces myocardial ischemia; (2) to determine the nature of cardiovascular responses (if any) to gastroesophageal reflux simultated by esophageal acid infusion; (3) to correlate patient symptoms with objective findings.

(16) Technical Approach: Patients will be assigned per study algorithm to recreate the conditions found in gastroesophageal reflux in order to see what affects it may have on the heart.

(17) Progress: Approved in Aug 93 by the IRC as a 10-subject pilot. No progress 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 93 (2) Protocol #: 93/144 (3) Status: Ongoing

(4) Title: A Comparison of Ranitidine 300 mg BID, Ranitidine 150 mg BID and Placebo in the Treatment of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Gastric Ulcers in Patients with Osteo- or Rheumatoid Arthritis. (IND GLAXO RAN-481)

(5) Start Date: Oct 93

(6) Est Compl Date: Sep 93

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/GI

(10) Associate Investigators
Sterling West, COL, MC
Milton Smith, MD
Robert Sudduth, MAJ, MC
Thomas Kepczk, MAJ, MC, et al

(11) Key Words:
Ranitidine, NSAID, ulcers, arthritis,IND

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Sep 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: Efficacy and safety.

(16) Technical Approach: As per title, randomized, double-blinded IND study, 10 patients to be enrolled over 15 months, drug administration for 12 weeks, four endoscopies and quality of life and ecomonic questionnaires.

(17) Progress: Study recently approved by IRC; CIRO approval pending.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/145 (3) Status: Ongoing

(4) Title: A Comparison of Ranitidine 150 mg BID and Placebo in the Treatment of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Duodenal Ulcers in Patients with Osteo- or Rheumatoid Arthritis. (IND GLAXO RAN-482)

(5) Start Date: Oct 93 (6) Est Compl Date: Sep 93

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/GI

(10) Associate Investigators
Sterling West, COL, MC
Milton Smith, MD
Robert Sudduth, MAJ, MC
Thomas Kepczk, MAJ, MC, et al

(11) Key Words:
Ranitidine, NSAID, ulcers, arthritis, IND

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Sep 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: Efficacy and safety.

(16) Technical Approach: As per title, randomized, double-blinded IND study, 10 patients to be enrolled over 15 months, drug administration for 12 weeks, four endoscopies and quality of life and ecomonic questionnaires.

(17) Progress: Study recently approved by IRC; CIRO approval pending.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/146 (3) Status: Ongoing

(4) Title: A Comparison of Ranitidine 300 mg BID, Ranitidine 150 mg BID and Placebo for Prophylaxis of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Gastric Ulcers in Patients with Osteo- or Rheumatoid Arthritis and NO History of Gastric or Duodenal Ulcer Duodenal Ulcer. (IND GLAXO RAN-498)

(5) Start Date: Oct 93 (6) Est Compl Date: Sep 93

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/GI

(10) Associate Investigators
Sterling West, COL, MC
Milton Smith, MD
Robert Sudduth, MAJ, MC
Thomas Kepczk, MAJ, MC, et al

(11) Key Words:
Ranitidine, NSAID, ulcers, arthritis,IND

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Sep 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: Efficacy and safety.

(16) Technical Approach: As per title, randomized, double-blinded IND study, 10 patients to be enrolled over 15 months, drug administration for 12 weeks, four endoscopies and quality of life and ecomonic questionnaires.

(17) Progress: Study recently approved by IRC; CIRO approval pending.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/147 (3) Status: Ongoing

(4) Title: A Comparison of Ranitidine 300 mg BID, Ranitidine 150 mg BID and Placebo for Prophylaxis of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Gastric Ulcers in Patients with Osteo- or Rheumatoid Arthritis and a History of Gastric or Duodenal Ulcer. (IND GLAXO RAN-499)

(5) Start Date: Oct 93 (6) Est Compl Date: Sep 93

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/GI

(10) Associate Investigators
Sterling West, COL, MC
Milton Smith, MD
Robert Sudduth, MAJ, MC
Thomas Kepczk, MAJ, MC, et al

(11) Key Words:
Ranitidine, NSAID, ulcers, arthritis,IND

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Sep 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: Efficacy and safety.

(16) Technical Approach: As per title, randomized, double-blinded IND study, 10 patients to be enrolled over 15 months, drug administration for 12 weeks, four endoscopies and quality of life and ecomonic questionnaires.

(17) Progress: Study recently approved by IRC; CIRO approval pending.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/148 (3) Status: Ongoing

(4) Title: Patient Utilities for Screening with Flexible Sigmoidoscopy

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: William Reed (8) Facility: FAMC

(9) Dept of MED/Int. Med. (10) Associate Investigators Michael J. Weaver

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine utility assessments for screening flexible sigmoidoscopy for several patient and physician groups. Our secondary objectives are to determine whether demographic factors influence utility assessment, to asses show published decision analyses on screening sigmoidoscopy will be affected, and to assess test-retest reliability of our methods over a three month period.

(16) Technical Approach: In addition to obtaining demographic information from subjects, we will use the techniques of the standard reference gamble and time tradeoff. Will assess the risk they are willing to take to avoid a lifelong protocol of regular screening flexible sigmoidoscopy. We hope to repeat the utility assessments approximately three months after the initial interview.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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, LTC, 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: 3
d. Total Number of Subjects Enrolled to Date: 99
e. Note any adverse drug reactions reported to the FDA or 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).

Sherman RA, Griffin VD, Evans CB, Grana AS: Temporal relationships between changes in phantom limb pain intensity and changes in surface electromyogram of the residual limb. Int. J. Psychophysiology, 13:71-77, 1992.

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 93 (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:

(7) Principal Investigator: Richard A. Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators

(11) Key Words: phantom limb pain mechanisms

Jeffrey Ginther, MAJ, MC
JD Griffin, RN

(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: 5
d. Total Number of Subjects Enrolled to Date: 45
e. Note any adverse drug reactions reported to 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: Twenty 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).

Sherman RA, Griffin VD, Evans CB, Grana AS: Temporal relationships between changes in phantom limb pain intensity and changes in surface electromyogram of the residual limb. Int. J. Psychophysiology, 13:71-77, 1992.

Sherman RA: Phantom limb pain: Mehcnaisms, incidence, and treatment. Critical Review in Physical and Rehabiliation Medicine, 41:(1,2)1-26, 1992.

CONTINUATION SHEET, FY 93, ANNUAL PROGRESS REPORT Protocol #:87/207

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 93 (2) Protocol #: 88/202 (3) Status: Terminated

(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:

(7) Principal Investigator: Dr. Deffer, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(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:
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. Project 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 93 (2) Protocol #: 88/213 (3) Status: Completed

(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
Monte S. Dirks, MAJ, MC
Eric A. Sieck, 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: Onoging
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: 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: Two patients have been enrolled to date at FAMC. FDA approved these lenses for general use. Protocol 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 93 (2) Protocol WU#: 88/215 (3) Status: Ongoing

(4) Title: Environmental/Temporal Relationships Between Headache and Muscle Tension

(5) Start Date: 1988 (6) Est Compl Date: 1994

(7) Principal Investigator: Richard A. Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators
Cecile Evans, BA COL, MC
Carson Henderson, MSW, Psy.D.
Crystal Sherman, MS
Ellynore Cucinell, COL, MC

(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: 6
d. Total Number of Subjects Enrolled to Date: 38
e. Note any adverse drug reactions reported to 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: Data from 5 males and 5 females (ages 22-67) having tension (5), migraine (3), or mixed (2) headaches participating in the study were analyzed. In each case, the wearable device recorded two channels of EMG from the left and right trapezius muscles, movement, and button presses indicating pain intensity. Subjects wore it all day in their normal environments for three to five days. In two subjects (one tension headache and one migraine), trapezius EMG increased before pain increased. In a third subject (tension headache), EMG was elevated during high pain. In a fourth subject (mixed headache), EMG was lower during pain free recordings than during headaches. In a fifth subject (tension headache), EMG decreased after pain increased. There was no relationship between EMG and pain intensity in the remaining subjects (two tension headaches, two migraine headaches, and one mixed). Thus,

there may be a small sub-set of people who do, in fact, have muscle tension components of their headaches. This is the first time evidence has actually been recorded to support this well accepted but theoretical relationship. All previous, in-laboratory, studies have failed to fine any support for the relationship.

Publications: Sherman RA, Evans CB, Henderson CY, Sherman CJ, Griffin V, and Arena JG: Continuous environmental recordings of relationships between trapezius EMG, movement, activity, and headache pain intensity. Biofeedback and Self-Regulation, in press, 1992.

Presentations: Sherman RA, Evans CB, Henderson CY, Sherman CJ, Griffin V, and Arena JG: Continuous environmental recordings of relationships between trapezius EMG, movement, activity, and headache pain intensity Presented Annual Meeting of the Association for Applied Psychophysiology, Colorado Springs, 1992.

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

(1) Date: 3 Mar 93 (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: 1993

(7) Principal Investigator: Richard A. Sherman, LTC, MS (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

(11) Latest IRC Review: MARCH Review Results: Ongoing
Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 95

(12) Study Objective: To determine the temporal relationships between the above pain problems among subjects with and without chronic pain.

(13) Technical Approach: Survey deers eligible people with and without pain while they are waiting for appointment at FAMC.

(14) Progress: No results yet due to lack of staff.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (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:

(7) Principal Investigator: Richard A. Sherman, LTC, 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: 33
d. Total Number of Subjects Enrolled to Date: 131
e. Note any adverse drug reactions reported to the FDA or 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: Temporal relationships between (a) headache and trapezius muscle contraction patterns and (b) low back pain and paraspinal muscle contraction patterns are being established. A sub-group of subjects show clear, consistent relationships.

CONTINUATION SHEET, FY 93, ANNUAL PROGRESS REPORT Protocol # 89/207

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. 156:245-248, 1991.

Sherman R, Sherman C: Physiological parameters that change when pain changes: Approaches to unraveling the "cause-or-reaction" quandary. Bulletin of the American Pain Society. 1(4):11-15, 1991.

Sherman R, Varnado S, Caminar S, Arena J: Changes in paraspinal muscle tension as predictors of changes in low back pain. Proceedings of the 1991 annual meeting of the American Pain Society p. 64, 1991. (Abstract)

Sherman R, Evans C, Henderson C, Griffin V, Sherman C, Arena J: Continuous environmental recordings of relationships between Trapezius EMG and headache pain intensity. Biofeedback and Self-Regulation, 17:338, 1992 (Abstract)

Sherman R, Griffin V, Evans C, Grana A: Temporal relationships between changes in phantom limb pain intensity and changes in surface electromyogram of the residual limb. Int. J. of Psychophysiology 13:71-77,1992.

Evans C, Sherman R: Does biofeedback for headache and mechanical low back pain change relationships between muscle tension and pain in the normal environment? Biofeedback and Self-Regulation, accepted for publication 1992. (Abstract)

Sherman R, Evans C, and Arena J: Environmental - temporal relationships between pain and muscle tension. Chapter in Biofeedback: Theory and Practice, edited by M Shtark and T Sokhadze, Nauka publishers, 1992. (Chapter)

Presentations: None

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

(1) Date: 30 Sep 93 (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 94

(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: 705
d. Total Number of Subjects Enrolled to Date: 1445
e. Note any adverse drug reactions reported to the FDA or 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. Shock absorbing boot inserts issued prior to initiation of training do not reduce the lower limb pain rate among basic trainees during training.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/200A (3) Status: Completed

(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:_____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 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: Study completed except for endoscopic screw data. Endoscopic screw data carried over to protocol #93/217A.

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 93 (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:

(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 93 (2) Protocol #: 90/203 (3) Status: Completed

(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.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: 1993

(7) Principal Investigator: Edward Lisecki, LTC, 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: 36
d. Total Number of Subjects Enrolled to Date: 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"

(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 scores on hydroxy apatite hips is consistently higher than the non HA coated hip. HA hip scores run about 8 points higher than non HA for same time period. No adverse reactions to the HA coating have been found.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/206 (3) Status: Ongoing

(4) Title: Pilot Trial of Potentiating Normal Healing of Stress Fractures Using Pulsing Electromagnetic Fields

(5) Start Date: 1990 (6) Est Compl Date: 1994

(7) Principal Investigator:
Richard Sherman, LTC, MS

(8) Facility:
Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:
Steven Pals, MAJ, MC
Kent Karstetter, MAJ, MC
David Teuscher, MAJ, MC
Howard May, LTC, 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: Oct b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 29
d. Total Number of Subjects Enrolled to Date: 57 e. Note any adverse drug reactions reported to the FDA or 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: Pulsing electromagnetic fields of two types are being utilized with soldiers having tibial and tarsal stress fractures during basic training at Ft. Sill. One type is generated by an ambulatory device which soldiers strap over their stress fractures and wear for twelve hours per day. The other type is generated by a fixed place device which soldiers come to for one hour per day. An additional third of the participants use the fixed place device but are not aware that the device is not actually generating any fields. The members of the health care evaluative team do not know which participants are in which group so this is a double blind study.

(17) Progress: This phase of the study has only entered 29 of its required 60 subjects. No data have been evaluated yet as most of the subjects are still participating.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/207A (3) Status: Completed

(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:
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:_____12 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 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: Study is complete. Results showed that closing the defect is not necessary and may lead to altered patellofemoral mechanics. All investigators have left FAMC.

Presentations:

Western Ortho. Association - August 1991
American Society for Surgical Research - September 1991
Society of Military Orthopedic Surgeons - November 1991
American Orthopedic Association Resident's Contest - March 1992
Society of Military Orthopedic Surgeons - December 1992
Barnard Competitions - March 1991
Barnard Competitions - March 1992

Publications: J. Investigative Surg. 1992

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/208A (3) Status: Terminated

(4) Title: Development of an Implanted, Hydroxyapatitie 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:
Philip Deffer, CPT, MC
Edward J. Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:

(11) Key Words:
percutaneous implant
prosthetic
amputees
goats

Ronald L. Jackson, DAC
William Hall, MD
Stephen Cook, PhD
Donald Mercill, DAC

(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 an HA-coated titanium artificial limb in terms of (1) occurrence of infection, (2) ability of skin to grow to the prosthesis, and (3) ability of goats to bear weight on prosthesis.

(16) Technical Approach: To develop a new type of artificial limb in which a rod is inserted into the bone at the end of the amputation site. The rod goes thru the skin. Rod is HA-coated to incourage skin to grow onto rod, thus reducing occurrence of infection.

(17) Progress: Tissue culture showed that goat and human skin did grow to an HA-coated titanium alloy. Implants placed into the neck of 4 goats also showed good results. This protocol is terminated, plan to submit a new pilot protocol for goats.

Publications & Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/209 (3) Status: Ongoing

(4) Title: Reliability of Psychophysiological Mesures Used to Evaluate Pain

(5) Start Date: (6) Est Compl Date: 1995

(7) Principal Investigator: Richard Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: John Arena, Ph.D. Carson Henderson, Psy.D. E. Cucinell, 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: 40
d. Total Number of Subjects Enrolled to Date: 51
e. Note any adverse drug reactions reported to the FDA or 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 first set of data are currently being analyzed.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (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, LTC, 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 CC Evans, BA 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: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 32
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: 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 has gradually been reinstituted as sufficient manpower to perform the medical portions of the program becomes available.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/211A (3) Status: Completed

(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:

(11) Key Words:
coumadin
methotrexate

(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:_____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 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: Study is completed.

Presentations:
Presented at Barnard Competition, March 1991.
Academy of Surgical Research, Breckenridge, CO March 1993
American Academy of Ortho Surg., Seattle, WA, March 1993
American Academy of Ortho Surg., San Francisco, CA, January 1993

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

(1) Date: 30 Sep 93 (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: Edward J. Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators:

(11) Key Words: bone ingrowth implants

Stephen Cook, PhD
Jerome Weidel, MD

(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:_____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 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: The principal and associate investigator are still evaluating solutions to the problem addressed in the 22 Oct committee meeting: the prostheses which have been prepared for the study do not correctly fit the goat.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 90/213 (3) Status: Completed

(4) Title: Eaton Trapezial Implant Long-Term Follow-up

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

(7) Principal Investigator: (8) Facility: FAMC
Phillip Deffer, CPT, MC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators:

(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. Unable to obtain sufficient funds for civilian part of the study. Will recall 19 FAMC patients for additional strength and motion testing and submit paper for presentation/publication. FY 93, the study is completed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/201 (3) Status: Ongoing

(4) Title: Utilization of Prostheses Among Relatively Healthy Traumatic Amputees

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Richard Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators: Melissa Daminano, MS Philip Deffer, CPT, MC Stephen Caminer, BS

(11) Key Words: prosthesis amputees

(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: 175
d. Total Number of Subjects Enrolled to Date: 175
e. Note any adverse drug reactions reported to the FDA or 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 those people who are in most need of effective prostheses can use them as required.

(16) Technical Approach: Two phase study to determine the existence of sub-groups of otherwise healthy, working age of amputees who may need different types of prostheses than are currently available. First phase is to reanalyze data from previous surveys. Second phase is to send surveys to all 343 of the soldiers discussed above who had traumatic amputations while on active duty or were otherwise unhurt. This is a pilot study to determine how the questionnaire needs to be revised and to determine how many veterans should receive the questionnaire.

(17) Progress: None. Surveys sent out, waiting to analyzed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/202A (3) Status: Terminated

(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

(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: Thirty rabbits will undergo surgery in which an oscillating saw is used to create simulated fractures. After surgery, rabbits are assigned to one of three groups (placebo, low dose ciprofloxacin, a high dose ciprofloxacin). Rabbits will undergo euthanasia at 180 days. Fractured bones will undergo histological testing and strength testing.

(17) Progress: Terminated due to technical problems.

(18) Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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:___1-2/week_____
e. Note any adverse drug reactions reported to the FDA or 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. Protocol is ongoing. Have trained 4 people in microsurgical repair of small vessels, nerves, and tendons.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (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:_____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: 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: Superfical parotidectomy on goat bilaterally, gel film placed unilaterally, evaluate sweating with starch/iodine test, sacrifice at intervals to evaluate histology (effect on facial nerve and rate of resorption).

(17) Progress: Frey's Syndrome was not produced in the subject animals. Initial pathology did show dissolutiun of the gel film. Final histology unable to be performed due to lack of technical help and spcimen damage by tissue handler when processing for mailing. Earlier samples salvaged and recut, photos pending.

Publications and Presentations: Presented as poster: American Academy Oto/HNS Washington, DC, Oct 92. Published abstract: Oto/Head & Neck Jornal, August 1992.

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

(1) Date: 30 Sep 93 (2) Protocol #:91/205 (3) Status: Completed

(4) Title: Arrhythmias Following Epinephrine and Cocaine Use During Nasal Surgery

(5) Start Date: 1991 (6) Est Compl Date: July 1993

(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: 5
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or 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: Results of the monitoring of 23 patients to date has shown no arrhythmias during cocaine and epinephrine use.

Publications: None.

Presentations: Interim results presented at Association for Military Plastic Surgeons, April 1992.

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

(1) Date: 30 Sep 93 (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:
advanced trauma life support

(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 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: Progress report for FY 93 was not received.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/200 (3) Status: Ongoing

(4) Title: Analysis of Wounds by Evaportive Water Loss in Man: A Pilot Methodology Study

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Sharon Hammond, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen.Surg.

(10) Associate Investigators

Sam Cucinell, COL, MC
Richard Gonzalez, Ph.D., USAR
Scott Bennion, LTC, MC
Todd Morton, 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: ___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: Develop statistical curve to compare evaporate water loss to wound.

(16) Technical Approach: TWEL device is utilized for this purpose.

(17) Progress: Due to the inability to procure the needed equipment for this protocol, we have been unable to begin work. We have received the equipment as of 23 August 1993 and are currently in the process of understanding the mechanics of the Evaprimeter. We anticipate entering our first patient within the next few weeks.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/201 (3) Status: Ongoing

(4) Title: Effect of Smoking, Alcohol Ingestion, Radiation Therapy and Beta-Carotene on Langerhans Cells in Human Oral Mucosa: A Pilot Study

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Richard Kopke, MAJ, MC (8) Facility: FAMC

(9) Dept of SURG/Otolaryngology (10) Associate Investigators
Donald Mercill, DAC
John Peterson, MAJ, MC
Gerald Trammel, COL, MC

(11) Key Words:
langerhans cells
beta carotene
radiation therapy

(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: 73
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: This study will provide further understanding of the theory of field cancerization by documenting Langerhans cells (LC) response to smoking, smoking and alcohol, irradiation and beta-carotene treatment.

(16) Technical Approach: The density (number) of epithelial LC's will be quantified histologically using 10 random readings from each of three microscopic sections. LC number willbe expressed as number per mm^2 of epighelial surface area of buccal oral mucosa for the following subject groups: 1) habitual smokers (Grp A) vs Grp C (Control); 2) habitual smokers and alcohol users (Grp B) vs Grp C; 3) XTR patients (Grp D) vs Grp C; 4) XRT patients plus beta-carotene (Grp E) vs Grp C; 5) Grp D vs Grp E; 6) Patients in Grp D and Grp E who continue to smoke and use alcohol will be subgrouped and compared to Groups A, B, and C as appropriate.

(17) Progress: Only 3 patients from non-control group have yet to be tested. 85% of the microscopic specimens have been evaluated. The study is nearly completed. Unfortunately, the B-carotene arm had to be dropped due to non-availability of B-carotene.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/202A (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat

(5) Start Date: 1991 (6) Est Compl Date: 1996

(7) Principal Investigator:
Royal K. Gerow, LTC, MC

(8) Facility: FAMC

(9) Dept of SURG/Plastic Surg.

(10) Associate Investigators
Robert Wilson, COL, MC

(11) Key Words:
microvascular surgery training
utilizing rat blood vessels and nerves

(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:_____20_____
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: Training protocol to attain and maintain proficiency in microvascular surgical repair of small nerves and blood vessels.

(16) Technical Approach: The femoral artery, vein and nerve of the rat is well suited for this type of study. Two animals will be used per week.

(17) Progress: The training is an integral and invaluable step in the education and technical experience of plastic surgery residents and staff in microvascular surgery with direct clinical application.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/204 (3) Status: Ongoing

(4) Title: Effect of Intravenous Erythromycin on Postoperative Ileus

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

(7) Principal Investigator: Joseph Kolb, CPT, MC (8) Facility: FAMC

(9) Dept of SURG/Gen. Surg. (10) Associate Investigators

(11) Key Words: Dr. Hollis

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if erythromycin helps resolve post operative ileus.

(16) Technical Approach: This is a randomized, double-blind study.

(17) Progress: Awaiting randomization of specimens. The project is, in essence, ready to begin.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #:92/206 (3) Status: Ongoing

(4) Title: Intraocular Liquid Silicone for Complicated Retinal Detachments. (IDE)

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: William Waterhouse, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Ophthalm/Surg. (10) Associate Investigators:

(11) Key Words: silicone oil Robert Dragoo, COL, Mc

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

(14) a. Date, Latest IRB Review: June/Jan b. Review Results: Ongoing
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: Clinical trial of intraocular liquid silicone for treatment of complicated retinal detachments.

(16) Technical Approach: See protocol.

(17) Progress: 6-month review high risk study. 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 93 (2) Protocol #: 92/207 (3) Status: Ongoing

(4) Title: Vivonex Ten Versus Immun-Aid in a SICU Population: Effects on Restoring Normal Protein Markers

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Henry Jefferson, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen.Surg.

(10) Associate Investigators

Dr. Mallory
Dr. Hammond
Joan Friend

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Compare two enteral formulas in respect to nutritional aspects.

(16) Technical Approach: Protocol will take place in SICU.

(17) Progress: Enrolling patients into protocol.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/208 (3) Status: Ongoing

(4) Title: Response of Serum Cytokines in Patients Undergoing Laparoscopic Cholecystectomy to Support the Use of Laparoscopic Techniques for Other Surgery

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
John Cho, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen. Surg.

(10) Associate Investigators
Dallas Homas, CPT, MC
Jeffrey Clark, COL, MC
Matthew Schofield, CPT, MS
Sharon Hammond, MAJ, MC

(11) Key Words:
cytokines
cholecystectomy

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate that the clinical benefits seen in minimally invasive laparoscopic gallbladder surgery versus open cholecystectomy result from a lack of cytokine release leading to attenuation of the acute phase response.

(16) Technical Approach: Measuring 11-6 the acute phase protein-C-reactive protein- and demonstrating a correlation between and a diminution of cytokine and APP release in laparoscopic versus open cholecystectomy should prove this point.

(17) Progress: Eleven patients enrolld out of 20. Blood being analyzed on six or seven more. Study is almost complete.

Publications and Presentations:

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/209 (3) Status: Ongoing

(4) Title: A Randomized Study of the Stryker OP Device vs Bone Autograft for the Treatment of Tibial Non-Unions

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator:
Edward Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept of SURG/Orthopedics

(10) Associate Investigators
Paul Castello, CPT, MC

(11) Key Words:
non union BMP
IDE

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:MAR/SEP_ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____2_____
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 increase the rate of healing of tibial non unions.

(16) Technical Approach: Non union debridement either use crest graft or OPI.

(17) Progress: Two additional patients enrolled for a total of three. 6-month review: No new patients enrolled. To qualify for study, tibial fractures must fail to unite for 9 months and patients must meet strict qualifying quidelines. The investigators have been in communication with other military hospitals who are cooperating with us to locate potential candidates.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/210A (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair in Rabbits and Rats

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

(7) Principal Investigator: Glen Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept of SURG/Otolaryn (10) Associate Investigators

(11) Key Words: Richard Kopke, LTC, MC

(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: 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: Training of Oto-HNS residents, staff in microsurgical techniques for nerve and vessel repair.

(16) Technical Approach: Transection and repair of femoral nerve, artery, vein of the rat/rabbit utilizing microsurgical techniques.

(17) Progress: Maintenance of microsurgical proficiency has been achieved. Over this period 3 residents received 20 hrs of training.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/211A (3) Status: Terminated

(4) Title: The Staffland Rabbit as a Model for Induced Bipolaris Sinusitis

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Richard Kopke, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURG/Otolaryngology

(10) Associate Investigators
L. Ziesbe, LTC, MC
R. Harris, LTC, MS

(11) Key Words:
fungal sinusitis
B. polaris species
stauffland rabbit

(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: 6
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 if the stauffland rabbit may serve as a model for experimental bipolaris fungal sinusitis.

(16) Technical Approach: Anesthetized animals will have their parinasal sinus ostia occluded surgically, and imourlated with different concentrations of fungal hyphae. The animals will be euthanized and observed for fungal infection.

(17) Progress: Three rabbits were innoculated with bipolaris. None of the 3 rabbits developed fungal infection by culture. We will submit a new protocol with technique changes.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/212 (3) Status: Ongoing

(4) Title: The Incidence and Association of Carpal Ligamentous Injuries with Distal Radius Fractures

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

(7) Principal Investigator: John Reiser, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Orthopedics

(10) Associate Investigators
LTC D.E. Casey Jones, MC
MAJ Kevin Rak, MC
MAJ Bernard Borosky, 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: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 31
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 the incidence of carpal ligament injury with distal radial and ulnar fractures. Additionally, we will determine the association between the incidence of carpal ligament injury and the classification on severity of distal forearm fractures.

(16) Technical Approach: Data from MRI and radiographic evaluations will be compiled as to severity and classification of the fractures. This data will be analyzed statistically for an association of ligaments injury with distal radial and ulnar fractures, and the incidence with which this association occurs. Carpal ligament injury will be analyzed for association with severity on classification of distal radial and ulnar fractures.

(17) Progress: Twenty-two patients have completed the study. project ongoing.

Publications and Presentations: Presented at the National Hand Surgery Symposium.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/213 (3) Status: Ongoing

(4) Title: Efficacy of Percutaneous Release of the Trigger Finger: An Anatomic Study

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

(7) Principal Investigator: D.E. Casey Jones, LTC, MC (8) Facility: FAMC

(9) Dept of SURG/Orthopedics (10) Associate Investigators

CPT Steven Friedel, MD

(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: 17
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 anatomically check the efficacy of the percutaneous release.

(16) Technical Approach: A percutaneous release will be followed by a standard open release (to determine if the percutaneous release has completely divided the A1 pulley).

(17) Progress: 17 releases have been performed using this protocol. We anticipate doing a power study of our data at 30 cases. Preliminary data will be presented at the Summer meeting of the Western Orthopaedic Association, July 1993, and the Academy of Surgical Research Annual Meeting, September 1993.

Publications: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/214 (3) Status: Ongoing

(4) Title: Centocor: HA-1A Efficacy in Septic Shock Trial (CHESS Trial) Centocor Protocol C0041T20 dated 29 May 92.

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Phillip Mallory, LTC, MC

(8) Facility: FAMC

(9) Dept of Surg/General

(10) Associate Investigators
Jack L. DePriest, MAJ, MC

(11) Key Words:
septic shock
HA-1A
monoclonal antibody
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: Jun 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if the HA-1A monoclonal antibody reduces 14-day mortality in patients with gram negative shock. It is a randomized, placebo-controlled double-blinded study.

(16) Technical Approach: Randomized, placebo-controlled, double-blinded, multi-institutional study.

(17) Progress: After the study was approved, the investigators were informed that the military is not allowed to perform placebo trials without the patient's own consent. Family and guardians are unable to give consent. This simply means that doing almost any meaningful critical care research is impossible, as will be evidenced when this study is complete. Any future involvement in collaborative studies will be a waste of time.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/215 (3) Status: Ongoing

(4) Title: Comparison of Three Pneumatic Compression Devices in 300 Total Hip and Knee Replacement Patients.

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Edward Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept of SURG/Orthopedics

(10) Associate Investigators
Mark Clyde, 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: Sep/Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 43
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 which three pneumatic compression devices is most effective in preventing DVT.

(16) Technical Approach: Patients will be randomly assinged to one of three pneumatic compression devices following total hip or total knee replacement. Patients will be monitored for clinical sings of DVT. Also, patients will undergo doppler ultrasound if DVT are suspected, or on their 10-14th day post-op.

(17) Progress: Study is now underway with 43 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 93 (2) Protocol #: 92/216 (3) Status: Ongoing

(4) Title: Comparison of Three Postoperative Autologous Blood Transfusion Techniques (Haemonetics Cell Saver, AUTOVAC LF System, and Stryker ConstaVac System) in 300 Total Hip and Knee Replacements

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Steven Friedel, CPT, MC (8) Facility: FAMC

(9) Dept of SURG/Ortho (10) Associate Investigators

(11) Key Words: Edward J. Lisecki, LTC,MC

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

(14) a. Date, Latest IRC Review: Sep/Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 55
d. Total Number of Subjects Enrolled to Date: 75
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 compare three methods of postoperative autologous blood transfusion. Methods will be compared for; amount of blood recovered/reinfused; amount of blood bank transfusions required; hemolysis of collected blood product, bacterial contamination of collected blood product; febrile reactions; fat embolism syndrome.

(16) Technical Approach: 300 patients will be randomly assigned to one of three methods of postop autologous blood transfusion following total hip or totoal knee replacement.

(17) Progress: Study ongoing.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/217 (3) Status: Terminated

(4) Title: Hybritech Treatment Protocol: Detection of Colorectal Carcinoma Using Hybri-CEAker in Patients with Primary, Recurrent, Metastatic or Occult Disease

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Bradley Bute, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURG/General Surgery

(10) Associate Investigators
Mike McBiles, MAJ, MC

(11) Key Words:
anti CEA monoclonal antibody for colorectal cancer

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP/MAR__ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____1_____
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". One adverse event reported at the 2 Mar 93 IRC review.

(15) Study Objective: To determine efficacy of anti-CEA monoclonal antibody in detecting (recurrent) colorectal carcinomas, as well as safety of IND.

(16) Technical Approach: Indium ^{111}- labelled monoclonal antibody studied with state of the art nuclear medicine gamma sanners and compared to operative or other diagnostic findings.

(17) Progress: Terminated by sponsor.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/218A (3) Status: Ongoing

(4) Title: Effect of Nicotine on Bone Ingrowth and Fixation in Hydroxyapatite Coated and Uncoated Porous Co-Cr-Mo Alloy Implants in a Goat Model

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

(7) Principal Investigator: Bert C. Callahan, MAJ, MC (8) Facility: FAMC

(9) Dept of SURG/Ortho (10) Associate Investigators

(11) Key Words: LTC Edward Lisecki, MC
Stephen D. Cook Ph.D.

(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:_____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: To quantify the biomechanical and histological effects of nicotine on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: Twenty goats will be randomly assigned to either a treatment group (receives nicotine) or a control group. Four rods which are hydroxyapatite coated for 1/2 of their length will be placed into each femur of each goat. Following euthanasia, the implants will be removed and tested to determine bony ingrowth and fixation strength.

(17) Progress: Study just begun. No results calculated yed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/200A (3) Status: Ongoing

(4) Title: Comparison of Healing Rates of Bones Plated Following Fractures, Among Yucatan Swine Having Open and Closed Epiphyses

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: D.E. Casey Jones, LTC, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (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:____12_____
d. Total Number of Subjects Enrolled to Date:_____19_____
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 the feasibility of a full study to compare the healing rates in plated long bone fractures before and after physical closure.

(16) Technical Approach: Six mature and six immature pigs will be used. In each pig, the right foreleg radius and ulna will be fractured under direct visualization. All pigs will undergo surgical internal fixation using plates and screws. Euthanasia time will be determined by radiographic examination for callus formation. Healing rates in mature vs immature pigs will be determined by histological examination.

(17) Progress: All animals operated on. All animals have undergone euthanasia. Still have to do histo and biomechanical analysis, as well as number crunching.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/201A (3) Status: Terminated

(4) Title: Strength and Healing Characteristics of PEA-10,2 Ligament Augmentation Devices After Implantation in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date:

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

(9) Dept of SURGERY/Ortho (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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the strength of the prototype PEA-10,2 Ligament Augmentation Device, after implantation in a goat model.

(16) Technical Approach: Per protocol.

(17) Progress: Protocol terminated. Company involved suspended study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/202A (3) Status: Ongoing

(4) Title: Vascular/General Surgery Staff and Resident Training Using Laparoscopic Techniques in the Swine (Sus scrofa)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Sharon L. Hammond, MAJ, MC (8) Facility: FAMC

(9) Dept of SUR/Gen.Surgery (10) Associate Investigators Dr. Beso Bule

(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 train staff and residents in the techniques of laparoscopic surgery.

(16) Technical Approach: Animal model.

(17) Progress: Most recent lab held 15, 16 September 1993.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/203A(3) Status: Ongoing

(4) Title: Urology Service Training Using Laparoscopic Techniques in the Swin (Sus scrofa)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Ronald Sutherland, MAJ, MC (8) Facility: FAMC

(9) Dept of SUR/Urology (10) Associate Investigators

(11) Key Words:
laparoscopy

(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:____4 swine_____
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 train staff and residents on laparoscopic techniques.

(16) Technical Approach: No change from protocol.

(17) Progress: Training from DCI has enabled us to continue utilizing laparoscopic techniques in the OR.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/204A (3) Status: Terminated

(4) Title: Healing of Segmental Bone Defects in Goat Tibia

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Jack McBride, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (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:_____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 determine the critical size defect (smallest osseous defect which results in nonunins 100% of the time) for a weight bearing long bone (tibia) in a goat model.

(16) Technical Approach: Per protocol.

(17) Progress: Defects healed in the first group fo goats studied. 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 93 (2) Protocol #: 93/205A (3) Status: Ongoing

(4) Title: Comparison of Three Sizes of Interference Screws for Graft Fixation of the Central One-Third of the Patellar Tendon in Anterior Cruciate Ligament Reconstruction

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Jack McBride, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (10) Associate Investigators Michael Grant, CPT, MC Richard Sherman, LTC, MS

(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:_____20_____
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 comapre three different sizes of interference screws for graft fixation of the central one-third of the patellar tendon in ACL reconstruction; to compare cannulated versus noncannulated screws for graft fixation of the central one-third of the patellar tendon in ACL reconstruction.

(16) Technical Approach: Three groups of six goats will be used; groups will be divided based on size of interference screws. A patellar graft will be harvested in bone-tendon-bone construct, placed into a bony tunnel in the tibia, and held in place by an interfernce screw, using an endoscopic interference technique. After the graft is fixed in place, pull-out strength will be established.

(17) Progress: Data collected, need 4-6 more legs and should be completed.

Publications and Presentations: J. Invest Surg 6(4):370, 1993.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/206A (3) Status: Ongoing

(4) Title: Feasibility of the Use of the Immature Pig (Sus scrofa) for Bronchoscopy Training

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Glen Y. Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY (10) Associate Investigators

(11) Key Words: Richard D. Kopke, LTC, 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:_____1_____
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: Training and maintenance of broncchoscopy utilizing the immature pig.

(16) Technical Approach: See protocol

(17) Progress: Pending the use of the 2nd pilot animal for its feasibility for use in training the technique of bronchoscopy. A final protocol will then be proposed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/207 (3) Status: Terminated

(4) Title: Perfluoron (perfluoro-n-octane) Study for Use in Vitreoretinal Surgery

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

(7) Principal Investigator: William Waterhouse, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ophthal. (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:

(16) Technical Approach:

(17) Progress: Study was not approved by FDA.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/208 (3) Status: Ongoing

(4) Title: ^{99m}Tc-HMPAO Labeled Leukocyte Scintigraphy in the Evaluation of Hemodialysis Access PTFE Grafts

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Daniel Clark, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Gen.Surg.

(10) Associate Investigators
Margaret L. Clark, CPT, MC
Sharon L. Hammond, MAJ, MC
Michael McBiles, LTC, MC
Morakinyo Toney, LTC, MC

(11) Key Words:
hemodialysis grafts
scintigraphy

(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: 2
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 the efficacy of 99mTC-HMPAO leukocyte scintigraphy in evaluating hemodialysis access grafts.

(16) Technical Approach: Per protocol.

(17) Progress: At present, two subjects have been studied with 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 93 (2) Protocol #: 93/209 (3) Status: Ongoing

(4) Title: The Determination of the Amount of Lumbar Root Decompression After Hemilaminotomy and Foraminotomy Versus After Discectomy Using Somatosensory-Evoked Potentials

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Paul Castello, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators
MAJ Howard Place
MAJ Gary Simonds
MAJ Steven R. Shannon

(11) Key Words:
lumbar root decompression
hemilaminestomy
foraminotomy

(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
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 quantify the lumbar nerve root decompression using SSEP after discectomy, after hemilaminectomy and foraminotomy, and after the combination of the two in consenting patients with herniated lumbar discs who meet the standard objective criteria for surgical treatment.

(16) Technical Approach: Patients will be randomly assigned into two groups. Group 1 will undergo hemilaminotomy and foraminotomy followed by partial excision of the disc. Group 2 will undergo the same procedure in reverse order. Each patient will undergo preoperative, continuous intraoperative, and postoperative SSEP monitoring.

(17) Progress: Study in progress. Results to date show that bony decompression of the neural root is of prime importance when performing nerve root decompression for lumbar herniated nucleus pulposus.

Publications and Presentations: Western Orthopedic Assoc. Snowmass, CO, July-August 1993.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/210A (3) Status: Ongoing

(4) Title: An Attempt at Differentiation of Malignant Glial Cell Tumors in Rattus Norvegicus: A Pilot Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Gary R. Simonds, MAJ, MC

(8) Facility: FAMC

(9) Dept of SUR/NeuroSurg.

(10) Associate Investigators
C, Neurosurgery, DGH
Staff Physician, FAMC
Harold B. Vogel, MD

(11) Key Words:
brain tumor

(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:_____45_____
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: Attempt at differentiation of malignant glial tumors in tissue culture by growing them in media which had originally supported the growth of hefal glia.

(16) Technical Approach: Ensure induction of tumors in newborn rats; growth of hefal glia in tissue and culture and collection of media; growth of rat brain tumors in tissue culture media obtained in the best; measurement of change by alternation in tumor kango type before and after testing.

(17) Progress: Tumors have been induced and media has been collected.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/211 (3) Status: Ongoing

(4) Title: Effect of Proximal Femoral Cerclage Cable in Femoral Hip Prosthesis Micromotion: A Cadaveric Study

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
David Kim, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators

LTC Edward Lisecki, MC
Robert Brown

(11) Key Words:
cerclage wire
hip prothesis
micromotion

(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: 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 assess if there is any decrease in micromotion of the bone-prosthesis interface after the application of a dall mile cerclage wire.

(16) Technical Approach: Ten proximal femoral cadaveric stems will be examined to insure there are no structural defects. Ten LSF prosthesis will be placed according to manufacturer recommendations. Micromotion will be tested using the instron device in axial and torsional load. Dall mile cerclage wire will be placed and testing will be repeated.

(17) Progress: Results to date show that cerclage wire does not decrease or increase the amount of motion in the constructs.

Publications and Presentations: Acad of Surg Research (breckenridge, CO, 30 Sept -2 Oct 93); Barnard Competition, Mar 93.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/212 (3) Status: Ongoing

(4) Title: Vacuum Therapy Versus Intracavernous Autoinjection of Vasoactive Drugs as the Treatment for Erectile Dysfunction in Diabetic and Anti-Coagulated Patients: A Study of Satisfaction and Safety

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: Jerome Limoge, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Urology (10) Associate Investigators

(11) Key Words:
impotenance
vacuum therapy
intracavernous
anticoagulation

CPT Kozlowski
MAJ Stack
CPT Olins

(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: 26
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: Safety and satisfaction of injection (intracavernous) and vacuum therapy.

(16) Technical Approach: Patients use ICI or vacuum therapy for 12 weeks each. Diaries are kept, questionnaires completed each 4 weeks.

(17) Progress: Twenty patients have been crossed over and are in the second arm.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/213 (3) Status: Ongoing

(4) Title: A Randomized, Double-Blind, Placebo-Controlled, Partial Crossover Study of Combination Topical Nitroglycerin and Yohimbine Therapy on Erectile Dysfunction in Diabetics

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: Christina Manthos, CPT, MC (8) Facility: FAMC

(9) Dept of SURGERY/Urology (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: Mar 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if there is improvement in diabetic patients with enteric dysfunction.

(16) Technical Approach:

(17) Progress: Enrolled and did initial evaluation of 20 patients with H.P. lab tests. All awaiting reception of placebo NTG patches. Because Yocon is a non-patented drug, I solicited several drug companies - only Palisade Pharmaceuticals requested more information, but no product information has been forthcoming. I probably be on clinical hold by the FDA and it will probably be indefinite, unless the Palasades Corporation will provide basic science information.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/214 (3) Status: Ongoing

(4) Title: Comparison of Cementless Hydroxyapatite-Coated vs Cementless Non-Hydroxyapatite-Coated vs Cemented Ortholoc Advantim Total Knee Systems

(5) Start Date: 1993 (6) Est Compl Date: 1996

(7) Principal Investigator:
Edward Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators

CPT Paul Castello

(11) Key Words:
total knee replacement
hydroxyapatite
cement

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the safety and efficacy of the cementless use of the ortholoc advantin total knee system, with and without HA coating.

(16) Technical Approach: 480 patients will be studied nationwide. 160 will be assigned to the cementless HA device. 160 will be assigned cementless non-HA-coated device, and 160 will be assigned to the cemented device. At FAMC, 40 patients will be assigned to the HA-coated/non HA coated devices.

(17) Progress: Waiting for FDA to assign and IDE #.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/215 (3) Status: Ongoing

(4) Title: Comparison of Femoral Hip Prosthesis Micromotion Between Eight Types of Prosthetic Devices: A Cadaveric Study

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Edward Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Orthr.

(10) Associate Investigators

CPT David Kim, MC

(11) Key Words:
hip prosthesis
micromotion

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare the amount of micromotion at the bone-prosthesis interface when using 8 different femoral prosthetic devices.

(16) Technical Approach: 40 proximal cadveric femoral stems will be randomly assigned to one of 8 groups of prosthesis types. Prosthesis will be placed according to manufacturer recommendations. Micromotion will be tested using Instron maxiam and torsional loads.

(17) Progress: No progress to date @ Sept 1993.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/216A (3) Status: Ongoing

(4) Title: Effect of Ketolorac on Bone Healing Following Simulted Fracture in the Stauffland White Rabbit (Oryctolagus Cuniculi)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Bert Callahan, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (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:_____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 evaluate the effect of ketolorac on fracture healing in the rabbit.

(16) Technical Approach: 30 rabbits will be assigned to 1 of 3 treatment groups, (high dose ketolorac, low dose ketolorac, or control). A simulated fracture will be made in the right leg of each rabbit. Rabbits will undergo euthanasia at 35 days postop. Femurs will be collected and will undergo mechanical testing.

(17) Progress: Study just begun. No results calculated.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/217A (3) Status: Ongoing

(4) Title: Evaluation of the Endoscopic Screw for Fixation of the Patellar Tendon in Anerior Cruciate Ligament Reconstruction in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Paul H. Castello CPT, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the amount of fixation provided by endoscopic screw in the central one-third of the patellar tendon. The results of this study will be compared to those of protocol 90/200A for the interference screw and the suture screw.

(16) Technical Approach: One group of 10 animals will be used. The animals will undergo euthanasia at 0 weeks or 6 weeks. All animals will undergo removal of their ACL on one hind leg. The ACL will be reconstructed using the middle 1/3 of the patellar tendon. Fixation will be achieved using an endoscopic interference screw. At euthanasia, the reconstructed ACLs will undergo biomechanical and histological testing

(17) Progress: Dr. Castello is temporarily down-town on a training rotation. Work will begin when he returns.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/218A (3) Status: Ongoing

(4) Title: Evaluation of the Repeat Harvest of the Central One-Third of the Patellar Tendon in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Jack McBride, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (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:_____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 perfect the technique of repeat harvest of central one-third patellar tendons.; to evaluate the strength of a repeat harvest of central one-third patellar tendons which were left open on initial harvest to those which were closed on initial harvest.

(16) Technical Approach: Per protocol.

(17) Progress: Pilot study successfully completed. Protocol for full study 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 93 (2) Protocol #: 93/219A (3) Status: Ongoing

(4) Title: The Effects of Pentoxifylline on Hyphema in a Rabbit Model (Orytolagus cuniculus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of SUR/ (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:

(16) Technical Approach:

(17) Progress: Did not receive any report for FY 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/220A (3) Status: Ongoing

(4) Title: Effect of Nosteroidal Antiinflammatory Drugs on Bone Ingrowth and Fixation in Hydroxyapatite Coated and Uncoated Porous Co-Cr-Mo Alloy Implants in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Bert C. Callahan, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (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 studying 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 nonsteroidal antiinflammatory drugs on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: 42 goats will be assigned to 1 of 3 treatment groups, according to time of euthanasia. All groups will have 14 animals. Within groups, 2 animals will receive 1 of 7 different NSAIDs. Four rods will be paced into the diaphyseal region of each femur. After euthanasia, rods will undergo biomechanical and histological evaluation.

(17) Progress: Committee suggested we write a pilot protocol to develop assays for the NSAIDs. Pilot protocol is 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 93 (2) Protocol #: 93/221A (3) Status: Ongoing

(4) Title: Effect of Nicotine on Soft Tissue Ingrowth and Fixation in a Hydroxyapatite Globe in a Goat Model (Capra hircus)

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Robert W. Enzenauer, LTC, MC

(8) Facility: FAMC

(9) Dept of SUR/Ophthalmology

(10) Associate Investigators
Margaret Lisecki, CPT, MC
Stuart Farris, MAJ, MC

(11) Key Words:
hydroxyapatite orbit implant
nicotine

(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: Assess effect of nicotine on fibrovascular ingrowth of hydroxyapatite orbital implants.

(16) Technical Approach:

(17) Progress: New study, just started 13 Sept 1993.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/222 (3) Status: Ongoing

(4) Title: Treatment of Degenerative Spondylolisthesis: A Prospective Comparison of Uninstrumented Posterior Spine Fusion with Decompression, Anterior-Posterior Instrumented Spine Fusion with Decompression, and Instrumented Posterior Spine Fusion with Decompression

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Howard Place, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators
MAJ John Dietz, MC
MAJ David Polly, MC

(11) Key Words:
degenerative spondylolisthesis
spine fusion
decompression

(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 compare 3 surgical methods used to treat degenerative spondylolisthesis in terms of complication rate, long-term relief.

(16) Technical Approach: 50 patients will be randomly assigned to one of three surgical treatments for degenerative spondylolisthesis. Preoperative and postoperative questionnaires will be used to determine which treatment, if any, provides the best long-term relief of symptoms and the least complications.

(17) Progress: Three patients are considering entry into 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 93 (2) Protocol #: 93/223 (3) Status: Ongoing

(4) Title: Biofeedback for Pain: A Multipractitioner Outcome Study

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Richard Sherman, LTC, MS

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators
Frank Andrasik, PhD, U. of FL
John G. Arena, PhD, VAMC, GA
Douglas E. DeGood PhD, U. VA
Alan G. Glaros, PhD, U. MO

(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: 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: The objective of this study is to determine the effectiveness of biofeedback techniques as they are actually practiced for control of chronic musculoskeletal low back pain and muscle related orofacial pain. This is intended to be an initial study to test the proposed design, data gathering techniques, and scientist-practitioner interactions as well as to provide sound data on the short term effectiveness of techniques at the borderline between clinical acceptance and research.

(16) Technical Approach: The effectiveness of the techniques as they are actually practiced at this time with the types of patents normally treated by biofeedback practitioners will be established by performing a multipractitioner outcome study. This is intended to assure the rapid and inexpensive acquisition of a large number of subjects while permitting the independent followup of patients required for credibility. Participating practitioners will sequentially enter appropriate subjects and the study team will mail two week pain logs to the patients before, just after, six months after, and one year after treatment.

(17) Progress: None. We have not heard on funding yet and the project can not be performed without outside funds.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/224 (3) Status: Ongoing

(4) Title: Control of Swelling After Hand and Foot Surgery for Fractures, Long Bone Fracture Stabilization, and Ankle Sprains Using Pulsed, High Frequency Electromagnetic Energy

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Casey Jones, LTC, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators
Kent Karstetter, MD
CPT Bendt Peterson, MC
LTC Jeffrey Ginther, MC
CPT Keith Wroblewski, MC
LTC Richard Sherman, Ph.D.

(11) Key Words:
swelling
hand & foot surgery
ankle sprains

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether pulsing electromagnetic fields after hand and foot surgery will significantly: (a) decrease the initial amount of swelling, (b) decrease the amount of time the area remains swollen, (c) decrease the intensity of pain and time in pain, (d) increase the rate of return of normal motion, (e) decrease the amount of therapy required for rate of healing of skin and fracture, (f) decrease the amount of therapy required for return of normal motion.

(16) Technical Approach: 400 patients will be randomly assigned to one of two groups. Group I will use the stimulator, but it will not be turned on (control). Group II will use the stimulator and it will be turned on. Swelling will be assessed.

(17) Progress: Study just approved and begun, funding has been approved. Study will start in October 1994.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/225A (3) Status: Ongoing

(4) Title: Comparison of Two Types of Synthetic Hydroxyapatite Coatings on a Titanium Rod in a Goat Model (Capra hircus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Edward J. Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare the biomechanical and histological effects of 2 types of synthetic hydroxyapatite coatings on titanium implants in a goat model.

(16) Technical Approach: 9 goats will be assigned to 1 of 3 groups, based upon time to euthanasia. Four rods will be placed into each femur of each goat. Rods will receive either 1 of 2 experimental coatings or not coating (control). At euthanasia, the rods will be removed and will undergo biomechanical and histological testing.

(17) Progress: Study just received committee approval.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/226A (3) Status: Ongoing

(4) Title: Comparison of Three Types of Synthetic Hydroxyapatite Coatings on a Titanium Rod in a Goat Model (Capra hircus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Edward J. Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (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 compare the biomechanical and histological effects of 3 types of synthetic hydroxyapatite coatings on titanium implants in a goat model.

(16) Technical Approach: 9 goats will be assigned to 1 of 3 groups, based upon time to euthanasia. Four rods will be placed into each femur of each goat. Rods will receive either 1 of 3 experimental coatings or not coating (control). At euthanasia, the rods will be removed and will undergo biomechanical and histological testing.

(17) Progress: Study just received committee approval.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/227 (3) Status: Ongoing

(4) Title: Comparison of Modulus Compatible Stability (MCS) Porous Coated Hip System Either with or without Hydroxylapatite (HA) Mineral Coating, Placed without Bone Cement; and the MCS Socket Portion, with or without HA Coating, Placed without Bone Cement along with a Cemented Femoral Stem to Stem to Hip Prostheses Placed with Bone Cement

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Edward Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators

(11) Key Words:
total hip replacement
press fit
cement

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and effectiveness of the MCS total hip system.

(16) Technical Approach: 50 patients will be enrolled from FAMC. 1200 patients will be enrolled nationwide. P.I. will decide whether patients require a cemented or uncemented prosthesis. If P.I. does not use cement, patients will be randomly assigned to receive either a porous coated prosthesis or a porous coated prosthesis with an HA coating.

(17) Progress: Just received committee approval. Will begin very soon.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/228A (3) Status: Ongoing

(4) Title: Infusion of Neurotrophins and Retinoic Acid into the Perilymph of Guinea Pigs Using a Mini Osmotic Pump

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Richard D. Kopke, LTC, MC

(8) Facility: FAMC

(9) Dept of Surgery/Otolaryngology

(10) Associate Investigators
Ronald Jackson, Ph.D.
Steven Ackley, Ph.D.
David Asher, Ph.D.
Matthew Schofield, CPT, MS

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if neurotrophins and retinoic acid can be infused into the perilymph of guinea pig inner ears via a mini osmotic pump system at a desired rate and concentration.

(16) Technical Approach: After animals are placed in general anesthesia, microsurgical techniques will be employed to approach the cochlea through the tympanic bulla. A microcannula will be passed into the scala tympani of the basal turn of the cochlea. After its placement the microcannula will be attached to a mini osmotic pump.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/229A (3) Status: Ongoing

(4) Title: Evaluation of the Repeat Harvest of the Central One-Third of the Patellar Tendon in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Jack McBride, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Orthopedics

(10) Associate Investigators
Bruce E. Piatt, MD
Wayne K. Gersoff, MD

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This study will evaluate (a) the ultimate strength of a repeat harvest of central one-third patellar tendons. (2) the strength of a repeat harvest of central one-third patellar tendons which were left open on initial harvest, compared to that of central one-third patellar tendons which were closed on initial harvest.

(16) Technical Approach: As per protocol, approved September 1993.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/230A (3) Status: Ongoing

(4) Title: A Pilot Study to Evaluate the Stauffland Rabbit as a Model for Induced Bipolaris Sinusitis

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Richard D, Kopke, LTC, MC

(8) Facility: FAMC
Tripler Army Medical Center

(9) Dept of SURGERY/Otolaryngology

(10) Associate Investigators
L. Zieske, MAJ, MC
Christopher K. Sinha, MAJ, MC
Richard Harris, LTC, MS

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if the sinuses of the Stauffland rabbit will develop a fungal sinusitis with a Bipolaris species; to determine if the immunosuppression of the rabbit is required for induction of fungal sinusitis.

(16) Technical Approach: As per protocol, approved September 1993.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/231A (3) Status: Ongoing

(4) Title: The Effects of Pentoxifylline on Laser Induced Traumatic Hyphema in a Rabbit Model (Oryctolagus cuniculus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Larry K. Andreo, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ophthalmology

(10) Associate Investigators
Monte S. Dirks, LTC, MC
Eric A. Sieck, 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: 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess the effect of Pentoxifylline on traumatic rabbit hyphema.

(16) Technical Approach: Per protocol approved September 1993.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: Michael Lieberman, LTC, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators Nicholas Battafarano, MAJ, MC Amy Ellingson, CPT, 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: 73
d. Total Number of Subjects Enrolled to Date: 1614
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: Data collection and analysis continues with four presentations in 1993.

Publications and Presentations: 4 new presentations for FY 93.

Presentations:

(1) Brown, G.L., and Heggers, J.: Medical Mycology: Assessment of Bac- teriologic 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.: Ac- quired 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 Panhypogam- maglobulinemia 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 93 (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: LTC Richard Harris (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators

(11) Key Words:
microbiology
microbiological techniques

Donald D. Paine, DAC

(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 Hepatitis 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 generation 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.

Evaluation of an ELISA kit (Whittaker), RheumELISA, for the detection of autoantibodies to Sm, RNP, SS-A/Ro, SS-B/La. Patients with a positive ANA screen were tested using this kit. It was found to be too sensitive for clinical use. Several kits are under consideration for evaluation inlcuding an ELISA for Helicobacter pylon.

Evaluation of new Group A streptococcus rapid test procedure is in progress in coordination with the Dept of Pediatircs.

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 93 (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: 1994

(7) Principal Investigator:
Scott Bennion, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn

(10) Associate Investigators:
Lela Lee, MD, UCHSC
Ann Hoyt
Michael Lieberman, LTC, MS
Kathleen David-Bajar, MD

(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: Techniques . Western Blotting are being improved, including comparison of different antigen extracts. Additional patients with subacute cutaenous lupus erythematosus and neonatal lupus erythematosus have been evaluated with Western Blotting.

Presentation: European Society for Dermatologic Research, Copenhagen, Denmark, June 1991. "Subacute cutaneous lupus erythematosus is distinguishable clinically, histologically, and by immunofluorescence".

Abstract: David KM, Bennion SD, DeSpain JD, Golitz LE, Lee LA: Subacute cutaneous lupus erythematosus is distinguishable clinically, histologically, and by immunofluorescence.

Publication: David-Bajar KM: Subacute cutaneous lupus erythematosus. J Invest Dermatol 100:2S-8S, 1993.

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

(1) Date: 30 Sep 93 (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: 1993

(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: Since last protocol summary no progress has been made. We continue to encounter the same problems as noted earlier. We have been unable to find a patient to determine UV dosage. We wish to extend the protocol an additional year during which we hope to find a suitable subject; if no subject can be found within the year, we will terminate the protocol. The data collected by such a protocol would be valuable since no previous studies in this area have been done.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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:
Harris, Richard W., LTC, MS

(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: Banking of lymphocytes and collectin of clinical data is successfully progressing with a total of 645 patients currently enrolled, 5700 separate data collection times and over 14,000 specimens banked for serum and/or lymphocytes.

Presentation: The Duration of Clinical Stabilization with AZT Therapy; D.L Mayers et al: International HIV Conference.

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/301A (3) Status: Completed

(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:_____125_____
e. Note any adverse drug reactions reported to the FDA or 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 effectiveness of biological attachment factors in improving graft acceptance rates and viability for skin grafted on nude mice.

(16) Technical Approach: Per protocol.

(17) Progress: All 125 animals were completed. Data analysis is not complete but it appears that the treatment groups are not significantly different from controls for percent take rates. Area of viable grafts is currently undergoing evaluation.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (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: Kevin D. Corcoran, 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: Training conducted as needed. 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 93 (2) Protocol #: 92/300 (3) Status: Ongoing

(4) Title: Studies on Mycobacterium avium. I. Determination of the Minimum Inhibitory Concentration (MIC) and the Minimum Bactericidal Concentration (MBC) of Various Anti-Mycobacterial Agents and Synergistic Effects with Combinations of Agents

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Michael Lieberman, LTC, MS

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators

LTC Richard Harris, MS
Donald Paine, DAC

(11) Key Words:

antibiotic synergy
mycobacterium avium

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (1) Determine values for the MICs and MBCs for each antibiotic with each of the study strains of M. avium; (2) calculate the MIC 90 and MBC 90 values for each antibiotic (the MIC or MBC for at least 90% of the strains, respectively); (3) calculate an index of synergy for various combinations of anti-mycobacterial agents by determining MIC and MBC values for each agent in the presence of fractional MIC or MBC concentrations of the other agents and in the absence of other agents.

(16) Technical Approach: Laboratory benchwork as described in technical detail in the protocol methodologies.

(17) Progress: MIC's or 7 antimycobacterial agents have been determined for 3 strains of M. avium and the synergistic potential of various combinations of two of these antibiotics determined.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/301 (3) Status: Ongoing

(4) Title: Molecular Epidemiological Studies on Bacterial Isolates from Patients on Intensive Care Units and Other Wards at FAMC

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Richard Harris, LTC, MS (8) Facility: FAMC

(9) Dept of DCI (10) Associate Investigators

Pari Morse, 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: 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine feasibility of epidemiological typing of bacterial isolates by plasmid analysis.

(16) Technical Approach: A minilysate procedure was used for rapid extraction of several groups of clinical isolates. Whole plasmid extracts and restriction enzyme digests were compared.

(17) Progress: The technique was found to be useful in strain comparison of several species of clinical isolates. Comparisons of clusters of infections are now being performed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/303A (3) Status: Terminated

(4) Title: The Determination of Hemoglobin (Hb) Coefficients of Sheep and Goat Whole Blood Utilizing the IL 482 Co-Oximeter

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

(7) Principal Investigator: Ronald Jackson, Ph.D.

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators

Jose A. Cruz-Saez

(11) Key Words:
hemoglobin
methemoglobin
oxyhemoglobin
carboxyhemoglobin

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To derive the coefficients for the different hemoglobin species in whole blood from goat and sheep. Concentrations could then be determined for each of these hemoglobin fractions sphectrophotometrically which in turn could be used to measure total hemoglobin, 0_2 saturation, etc.

(16) Technical Approach: Whole blood (60 mls) will be taken from either goats or sheep and chemically treated to isolate individual hemoglobin species within the blood. These solutions will then be analyzed for their respective spectral properties and coefficients derived for each Hb species.

(17) Progress: This study never got off the ground. Due to problems of procuring carbon monoxide gas, certain supplies and now a shift in research priorities, this 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 93 (2) Protocol #: 92/304A (3) Status: Ongoing

(4) Title: Evaluation of Serotonin (5-hydroxytryptamine), Bleeding Times, and Blood Platelets in Athymic Nude and Normal Mice

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Ronald Jackson, Ph.D.

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators

Scott Bennion COL, MC

(11) Key Words:
serotonin
athymic nude mice

(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: 49
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: This study will determine blood levels of serotonin, platelet counts, and bleeding times of three strains of athymic nude mice and compare the findings with the same parametes measured with other mouse species.

(16) Technical Approach: Mice from different strains, both heterozygous and homozygous for beige trait, were anesthetized and then bleeding times were determined after amputating a standard length of their tails. Matched groups of mice were injected with serotonin prior to tail nipping. Besides bleeding times, blood was collected to determine platelet counts and 5-hydroxytryptamine.

(17) Progress: Forty-nine animals have been studied. One strain of beige nudes was ordered, however, the 12 animals were a mixture of both pigmented and non-pigmented animals. An additional problem was noted. The group of control animals were housed in cages in groups of 3 animals per cage. Some animals' tails were amputated to varying degrees prior to the experiment due to infighting. This affected the bleeding times.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/306A (3) Status: Ongoing

(4) Title: Evaluation of the Blacktailed Prairie Dog Cynomys ludovicianus as a Model for Hepadnavirus Replication

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Kenneth E. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept of DCI (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 evaluate the black-tailed prairie dog for a potential model for replication of hepatitis B-like viruses.

(16) Technical Approach: (a) Development of laboratory colony of priarie dogs followed by infection with four hepadnavirus agents (b) Field collection and evaluation of wild prairie dogs.

(17) Progress: 65 prairie dogs collected and evaluated. Possible new parasite found. Several animals with biochemical hepatitis.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/300 (3) Status: Completed

(4) Title: Feasibility of Using Oral Fluids for the Detection of Hepatitis C Infection

(5) Start Date: Oct 92 (6) Est Compl Date: Oct 93

(7) Principal Investigator:
Kenneth Sherman, MAJ, MC

(8) Facility: FAMC

(9) Dept of Clin Invest

(10) Associate Investigators
Robin Creager, RN

(11) Key Words:
hepatitis C, oral fluids, OraSure

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Oct b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 50
d. Total Number of Subjects Enrolled to Date: 50
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 the feasibility of using oral fluid samples for screening for hepatitis C.

(16) Technical Approach: Single site, paired comparison study with specimen pairing blinded to the personel procesing and analyzing the specimens. Participation is limited to confirmed hepatitis C patients. Approximately 50 subjects will be enrolled.

(17) Progress: All samples collected and tested. Oral salivary antibodies have very high sensitivity/specificity for detection of HCV Ab. Data analysis is 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 93 (2) Protocol #: 93/301A (3) Status: Terminated

(4) Title: Antibody Production to Hepatitis C Peptides in Rabbits (Oryctolagus cuniculus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Kenneth E. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept of DCI (10) Associate Investigators Michael Lieberman, LTC, MS Tony Bowers, SGT

(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 produce antibodies to peptide sequences derived from the hepatitis C genome.

(16) Technical Approach: Per protocol.

(17) Progress: Significant levels of antibody were not detected in sera from rabbits immunized with any of the three peptides conjugated to diphtheria toxoid using a sensitive ELISA technique developed in-house. The ELISA did demonstrate high levels of antibody to diphtheria toxoid produced in these rabbits in response to vaccination, thus validating the immunization procedures and the ELISA. Since peptide-specific antibodies could not be produced, this protocol will be terminated.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/302 (3) Status: Completed

(4) Title: Conclusion of Clinical Trial of Melarsen Oxide: Dimercaprol in the Treatment of Rhodesian Sleeping Sickness (Mel B/Arsobal)

(5) Start Date: 1993

(6) Est Compl Date: 1994

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

(8) Facility: FAMC
AMEDD C&S
San Antonio, TX 78234-6100

(9) Dept of DCI

(10) Associate Investigators
Elise Sherva, DAC
Erin Palestro, DAC
Matthew Schofield, CPT, MC

(11) Key Words:
arsenic
rhodesian sleeping sickness

(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: Determine arsenic levels.

(16) Technical Approach: Analyze 150 urine specimens by Graphite furnace techniques in a Perkin-Elmer atomic absorption spectrophotometer.

(17) Progress: Lab studies completed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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 93 (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 93 (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 93 (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 93 (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 93 (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: 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, 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 93 (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 93 (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 93 (2) Protocol #: 88/355 (3) Status: Completed

(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: Closed. 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 93 (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 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 93 (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 93 (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 93 (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: (8) Facility: FAMC
Mark E. Potter, MAJ, MC

(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:_____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 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 patients with positive groin nodes will receive additional radiotherapy to the 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: One patient enrolled.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 89/354 (3) Status: Completed

(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: Closed for enrollement.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (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 93 (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: (8) Facility: FAMC
Mark Potter, MAJ, MC

(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 93 (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 93 (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 93 (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 93 (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 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 93 (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 93 (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:____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 the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: One 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 93 (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 93 (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 93 (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 93 (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 93 (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:_____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 the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: One patient entered.

Publications and Presentations:

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

(1) Date: 30 Sep 93 (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 93 (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:_____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 the GOG studies.

(16) Technical Approach: See protocol.

(17) Progress: 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 93 (2) Protocol #: 92/350 (3) Status: Ongoing

(4) Title: GOG 26MM: A Phase II Trial of Edatrexate (ETX) in Gynecologic Malignancies

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

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of 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 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 study.

(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 93 (2) Protocol #: 92/351 (3) Status: Ongoing

(4) Title: GOG 119: A Study of the Use of Provera and Tamoxifen Citrate (NSC #180973) for the Treatment of Advanced, Recurrent or Metastatic Endometrial Carcinoma

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

(7) Principal Investigator: (8) Facility: FAMC

Mark Potter, MAJ, MC

(9) Dept of 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 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 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 93 (2) Protocol #: 93/350A (3) Status: Completed

(4) Title: OB-GYN Staff and Student Trainign Using Laparoscopic Techniques in the Service

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of SUR/OB/GYN (10) Associate Investigators

(11) Key Words:
training
laparoscopy

Richard Allen

(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". 2 pigs 1 goat

(15) Study Objective: Train staff and residents in laparoscopic surgical techniques.

(16) Technical Approach: No change from protocol.

(17) Progress: Completed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/351 (3) Status: Ongoing

(4) Title: GOG 114 A Phase III Randomized Study of Intravenous Cisplatin and Cyclophosphamide Versus Intravenous Cisplatin and Taxol Versus High Dose Intravenous Carboplatin Followed by Intravenous Taxol and Intraperitoneal Cisplatin in Patients with Optimal Stage III Epithelial Ovarian Carcinoma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of 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: 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 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 studies.

(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 93 (2) Protocol #: 93/352 (3) Status: Ongoing

(4) Title: GOG 120 A Randomized Comparison of Hydroxyurea Versus 5-FU, Hydroxyurea Infusion and Bolus Cisplatin Versus Weekly Cisplatin as Adjunct to Radiation Therapy in Patients with Stages II-B, III, IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes, Phase III

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of 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: 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 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 studies.

(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 93 (2) Protocol #: 93/353 (3) Status: Ongoing

(4) Title: GOG 132 A Phase III Randomized Study of Cisplatin (NSC #119875) Versus Taxol (NSC #125973) Versus Taxol and Cisplatin in Patients with Suboptimal Stage III and IV Epithelial Ovarian Carcinoma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of 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: 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 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 studies.

(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 93 (2) Protocol #: 93/354 (3) Status: Ongoing

(4) Title: GOG 134 A Phase III Trial of Taxol at Three Dose Levels and G-CSF at Two Dose Levels in Platinum-Resistant Ovarian Carcinoma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of 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: 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 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 studies.

(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 93 (2) Protocol #: 93/355A (3) Status: Ongoing

(4) Title: Investigator Training Using Laproscopic Techniques in the Swine (Sus scrofa)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of SUR/ (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:

(16) Technical Approach:

(17) Progress: Did not receive any report for FY 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/356 (3) Status: Ongoing

(4) Title: Correlation Among Parity, Exercise, Age and Urinary Incontinence in the Female Military Member: A Pilot Study

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Gary Davis, LTC, MC

(8) Facility: FAMC

(9) Dept of OB/GYN

(10) Associate Investigators

(11) Key Words:
urinary incontinence

(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: 150
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 the rate of urinary incontinence in female military members.

(16) Technical Approach: Questionnaires are given to participants after the standard PT test.

(17) Progress: Greater than 150 surveys were returned during the last PT test. We will hand out approximately 200 during the October PT test.

Publications and Presentations: Will be presented at the 1994 Army ACO meeting.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/357 (3) Status: Ongoing

(4) Title: Quantitation of Urinary Incontinence During Exercise in the Female Military Member

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Gary Davis, LTC, MC

(8) Facility: FAMC

(9) Dept of OB/GYN

(10) Associate Investigators

(11) Key Words:
quantitation of incontinence

(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: 14
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: Quantify incontinence during simulated PT test in military females complaining of incontinence.

(16) Technical Approach: Pad weighing during exercise.

(17) Progress: 14 subjects have completed the study.

Publications and Presentations: Plan to present results at the 1994 ACO Army meeting.

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

(1) Date: 30 Sep 93 (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: (8) Facility: FAMC
George Maher, MAJ, MC

(9) Dept of 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:_____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 93 (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: George Maher, MAJ, MC (8) Facility: FAMC

(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 93 (2) Protocol #: 82/420 (3) Status: Completed

(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

(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: Study is closed to 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 93 (2) Protocol #: 87/401 (3) Status: Completed

(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

(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 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 93 (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:
George Maher, MAJ, MC

(8) Facility: FAMC

(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 93 (2) Protocol #: 88/400 (3) Status: Completed

(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

(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: 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 93 (2) Protocol #: 88/408A (3) Status: Completed

(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

(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. Study is completed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 89/404 (3) Status: Completed

(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: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept/Svc:PEDS/Hemo/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 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 93 (2) Protocol #: 90/402A (3) Status: Terminated

(4) Title: Training for Pediatricians in Emergency Procedures

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

(7) Principal Investigator: Brian Carter, 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: Departmental training program's future was uncertain. 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 93 (2) Protocol #: 90/406 (3) Status: Completed

(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: 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 93 (2) Protocol #: 90/407 (3) Status: Completed

(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: George Maher, MAJ, 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 93 (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: George Maher, MAJ, 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 93 (2) Protocol #: 90/409 (3) Status: Completed

(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: 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 93 (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: George Maher, MAJ, 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 93 (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: George Maher, MAJ, 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 93 (2) Protocol #: 90/413 (3) Status: Completed

(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: 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 93 (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 of 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 93 (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: 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 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 93 (2) Protocol #: 91/400 (3) Status: Terminated

(4) Title: Normative Electrocardiographic Data in Healthy Newborns and Infants Living at Intermediate High Altitude

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

(7) Principal Investigator: Herbert Whitley, LTC, MC (8) Facility: FAMC, Aspen and Leadville, CO

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:
newborns
altitude
EKG

Robert Wolfe, MD

(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: Project 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 93 (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:
Brian Carter, 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:_461 procedures on 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 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: Anticipate an animal lab under this protocol in the summer of 1994.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/403 (3) Status: Completed

(4) Title: Evaluation of Test of Cure Using a DNA-Probe Test for Neisseria Gonorrhea

(5) Start Date: 1990 (6) Est Compl Date: 1992

(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: 3
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or 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: Final results, 705 total screens, 23 positive, 20 enrolled. All tests of cure negative.

Presented: Poster presentation, National Meeting of Microbiologists. Accepted for poster presentation at National Society for Adolescent Medicine, February 1993.

Publications: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/404 (3) Status: Completed

(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: George Maher, MAJ, 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: 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 93 (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: George Maher, MAJ, 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 the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: One patient still in treatment, in remission; had previously been treated for brain tumor.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: George Maher, MAJ, 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 93 (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: George Maher, MAJ, 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 93 (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: George Maher, MAJ, 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 93 (2) Protocol #: 91/411 (3) Status: Completed

(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: George Maher, MAJ, 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 the POG protocols.

(16) Technical Approach: See Protocol

(17) Progress: Closed, no new patients.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/400 (3) Status: Ongoing

(4) Title: POG 9151 IRS-IV Stage 2 and 3 Disease

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

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of 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: ___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 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 93 (2) Protocol #: 92/401 (3) Status: Ongoing

(4) Title: POG 9153 Intergroup Rhabdomyosarcoma Study Laboratory Evaluation of Tumor Tissue

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 93 (2) Protocol #: 92/402 (3) Status: Ongoing

(4) Title: Restandardization of Bayley Scales of Infant Development

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

(7) Principal Investigator: Majorie Feinberg, OTR, DAC EFMP (8) Facility: FAMC

(9) Dept of 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: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 30
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 recruit and test 10 subjects per examiner using the updated Bayley scale of infant development as part of national restandardization effort.

(16) Technical Approach: Recruited subjects from well baby clinic. Scheduled appointments for teting. Tested subjects. Submitted test results to psychological corporation.

(17) Progress: On 21 Oct 93, MAJ Sherman expeditiously approved a minimal risk addendum to extend the study to include the restandardization of the Bayley Scales of Infant Neurodevelopmental Screen.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/403 (3) Status: Ongoing

(4) Title: POG 9150 IRS-IV Stage 1 Disease

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 93 (2) Protocol #: 92/404 (3) Status: Ongoing

(4) Title: POG 9152 IRS-IV Stage 4 and/or Clinical Group IV Disease

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 93 (2) Protocol #: 92/405 (3) Status: Ongoing

(4) Title: Hypertrophic Cardiomyopathy and Disproportionate Septal Hypertrophy in Newborns

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Brian Carter, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS/Newborn

(10) Associate Investigators

MAJ Steven Neish, MC

(11) Key Words:
newborn
cardiac hypertrophy

(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: 17
d. Total Number of Subjects Enrolled to Date: 17
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: Determine presence of hyperinsulinemia in macrosomic infants not born to diabetic women and assess any relationship of sach macrosomia and hyperinsulinemia with cardiac hypertrophy.

(16) Technical Approach: Cord blood analysis and newborn echocardiogram.

(17) Progress: 17 total enrolled, lab lost/discarded samples of cord blood on 6, echocardiogram not done on 2 others leaving 9 completed studies. Need to enroll and complete studies on at least 11 more subjects.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/406 (3) Status: Ongoing

(4) Title: POG 9031 Treatment of Children with High-Stage Medulloblastoma: Cisplatin/VP-16 Pre- vs Post-Irradiation: A Phase III Study

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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:___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 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 93 (2) Protocol #: 92/407 (3) Status: Ongoing

(4) Title: POG 9135 Pre-Radiation Chemotherapy for Children with Supratnetorial Malignant Gliomas and Poorly-Differentiated Embryonal Tumors. A Randomized Phase II Study

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 93 (2) Protocol #: 92/408 (3) Status: Ongoing

(4) Title: POG 9136 Phase I/II Dose Escalating Trial of Hyperfractionated Irradiation in the Treatment of Supratentorial Malignant Tumors of Childhood

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 93 (2) Protocol #: 92/410 (3) Status: Completed

(4) Title: POG 9061 The Treatment of Isolated Central Nervous System Leukemia - A Pediatric Oncology Group-Wide Pilot Study

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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 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: Closed, 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 93 (2) Protocol #: 92/411 (3) Status: Completed

(4) Title: POG 9110 SIMAL #6 Rotational Drug Therapy After First Marrow Relapse of All-Group-Wide Pilot

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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 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: Closed, 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 93 (2) Protocol #: 92/412 (3) Status: Ongoing

(4) Title: POG 9132 Hyperfractionated Irradiation for Posterior Fossa Ependymona. A Phase II/III Study

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 1
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 POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: One new patient, 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 93 (2) Protocol #: 92/414 (3) Status: Ongoing

(4) Title: POG 9259 Carboplatin in the Treatment of Newly-Diagnosed Metastatic Osteosarcoma or Unresectable Osteosarcoma: A POG Phase III Study

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 93 (2) Protocol #: 92/415 (3) Status: Completed

(4) Title: POG 9107 Infant Leukemia Protocol: A Pediatric Oncology Groupwide Pilot Study

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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: Closed, 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 93 (2) Protocol #: 92/416 (3) Status: Ongoing

(4) Title: Improved Group A Strep Growth in Selective Media As an Indicator of True Infection

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Frederic Bruhn, COL, MC (8) Facility: FAMC

(9) Dept of PEDS (10) Associate Investigators Robert Wittler, MAJ, MC

(11) Key Words: group A strep

(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 demonstrate increased recovery of Group A beta hemolytic streptococci (GABS) on selective media (Sheep blood agar supplemented with trimethoprim-sulfamethoxazole, i.e., SBA-SXT) compared to standard media (sheep blood agar, SBA), and to correlate increased recovery of GABS with "true" infection versus a carrier state.

(16) Technical Approach: Approximately 300 patients ages 5-15 will have throat culture and venopuncture as part of this multi-institutional study.

(17) Progress: No patients entered, awaiting lab materials from the Children's hospital. No progress FY 92 and FY 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/417 (3) Status: Terminated

(4) Title: Protocol for the Treatment of Newly Diagnosed Osteogenic Sarcoma in Children, Adolescents, and Adults Incorporating Intra-arterial Cisplatinum and Prolonged Systemic Infusion Adriamycin

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of PEDS\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: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
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: Determine tolerance of intra-arterial cisplatin in pediatric patients, evaluate response of the primary tumor to pre-op intra-arterial cisplatin.

(16) Technical Approach: Pre-op chemo with I.V. adriamycin and intra-arterial cisplatin followed by surgery followed by additional chemotherapy.

(17) Progress: One patient was treated on protocol, but later died. No further patients will be enrolled due to the recenlty discovered fact that the pump used in the study is not FDA approved for this purpose.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/418 (3) Status: Completed

(4) Title: POG 8617 Therapy for B-Cell Acute Lymphoblastic Leukemia and Advanced Diffuse Undifferentiated Lymphomas

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of PEDS/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: 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 POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: Closed, 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 93 (2) Protocol #: 92/419 (3) Status: Completed

(4) Title: POG 9225 Study for Advanced-Stage Hodgkin's Disease

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of PEDS/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: 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 POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: Closed, 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 93 (2) Protocol #: 92/420 (3) Status: Ongoing

(4) Title: POG 9233/34 A Phase III Randomized Trial of Standard vs Dose-Intensified Chemotherapy for Children 3 Years of Age with a CNS Malignancy Treated with or without Radiation Therapy

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of PEDS/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: 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 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 93 (2) Protocol #: 92/421 (3) Status: Ongoing

(4) Title: POG 9243 Treatment for Children with Intermediate-Risk Neuroblastoma: POG Stage B (All Ages) and Stages C, D, and DS (365 Days at Diagnosis)

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

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of PEDS/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: ___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 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 93 (2) Protocol #: 92/422 (3) Status: Ongoing

(4) Title: Family History of Growth and Pubertal Development in Children with Constitutional Delay

(5) Start Date: (6) Est Compl Date: 1993

(7) Principal Investigator: Robert Slover, LTC, MC

(8) Facility: FAMC

(9) Dept of PEDS/Adol

(10) Associate Investigators

John Hanks, CPT, MC

(11) Key Words:

constitutional delay
delayed puberty

(12) Accumulative MEDCASE:*

(13) Est Accum O[illegible]. 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:____230 questionnairs___
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: Compare pertinent information.

(16) Technical Approach: Use of identical questionnaires in families with children with and without constitutional delay.

(17) Progress: About 1200 questionnaires given out, about 700 returned. Project is progressing well. Have been unable to locate adequate number of families with constitutionally delayed children. Would like to continue data gathering. Will be leaving FAMC July 93 for WBAMC.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/423 (3) Status: Ongoing

(4) Title: Development of a Placental Trophoblast Cell Culture for the in Vitro Study of Placental Metabolism

(5) Start Date: (6) Est Compl Date: 1997

(7) Principal Investigator:
Brian Carter, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS/Newborn

(10) Associate Investigators
Ron Jackson, Ph.D
Beverly Anderson, MAJ, MC
Phil Vaughan, M.D., UCHSC
Fred Battaglia, M.D., UCHSC
Ann Anderson, MD

(11) Key Words:
tissue culture
placental trophoblast

(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 develop an in vitro placental trophoblast culture for human placental trophoblast to study basic normal and abnormal metabolism.

(16) Technical Approach: In vitro cell culture; tracer studies with stable or radioactive isotope labelled substrates.

(17) Progress: We have made great progress in use of the choriocarcinoma cells to establish techniques and methods for study, the human placental cells are growing well and ready for study at this time, and work with the sheep placenta will be undertaken this next academic year.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/400 (3) Status: Ongoing

(4) Title: The Effects of Antenatal Phenobarbital Administration in High Risk Pregnancies and the Prevention of Intraventricular Hemorrhage in Premature Babies

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: Una Espenkotter, CPT, MC (8) Facility: FAMC

(9) Dept of PEDS (10) Associate Investigators Rob Howard

(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: 105
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 identify the incidence of intraventricular hemorrhage in high risk neonates before and after the antenatal use of phenobarbital.

(16) Technical Approach: A retrospective chart review of high risk neonates and the effects of antenatal phenobarbital administration in preventing intraventricular hemorrhage.

(17) Progress: Charts from 1985-1991 have been reviewed. We are currently gathering data from 1992 and 1993, at which point, our chart review will be completed.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/401 (3) Status: Ongoing

(4) Title: POG 9226 Treatment of Stage I, IIa and IIIa, Hodgkin's Disease with ABVE and Low-Dose Irradiation

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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:____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 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 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 93 (2) Protocol #: 93/402 (3) Status: Ongoing

(4) Title: The False Negative Rate of the Denver II in the Fitzsimons Army Medical Center Pediatric Population 7-36 Months of Age

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator:
David Burgess, DAC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators
J. Householder
C. Spicer
L. Smith

(11) Key Words:
screening
child development
Denver II

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine false negative rate of Denver II; this will allow calculation of sensitivity and specificity of the Denver II as a screening test.

(16) Technical Approach: Will test all children with normal Denver II results over a 24-month period (N=400).

(17) Progress: Study suspended until 1/94 pending completion of training with the Revised Bayley Scales of Infant Development which will then be used as the "gold standard". Training with the new test to start 30 Sep 93 (test published Sept 93).

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/403 (3) Status: Ongoing

(4) Title: Lead Screening for 12 Month Old Children Seen in the Pediatric Well Child Clinics at the Fitzsimons Army Medical Center

(5) Start Date: 1993 (6) Est Compl Date: 1993

(7) Principal Investigator:
David Burgess, DAC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators
U. Espenkotter
C. Wrubel
R. Wittler
M. Schofield

(11) Key Words:
screening
blood lead levels

(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: 170
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: Determine prevalence rate of 12-month old children with increased blood lead levels at FAMC. Determine sensitivity, specificity and positive predictive value of lead screening questionnaire.

(16) Technical Approach: Compare screening questionnaire results to "gold standard" capillary blood lead level.

(17) Progress: Will complete on time.

Publications and Presentations: Screening for lead posioning at the FAMC. Presented: Howard Johnson Award, 1993.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/404 (3) Status: Ongoing

(4) Title: POG 9047 Neuroblastoma Biology Protocol

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 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 93 (2) Protocol #: 93/405 (3) Status: Ongoing

(4) Title: POG 9048 Treatment of Children with Localized Malignant Germ Cell Tumors-A Phase II Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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: Both patients on observation alone after surgery because of tumor state. Both are 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 93 (2) Protocol #: 93/406 (3) Status: Ongoing

(4) Title: POG 9049 High Risk Germ Cell Protocol

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 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 93 (2) Protocol #: 93/407 (3) Status: Ongoing

(4) Title: POG 9130 Treatment of Newly Diagnosed Low-Grade Astrocytoma. A Phase III POG/CCSG Intergroup Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 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 93 (2) Protocol #: 93/408 (3) Status: Ongoing

(4) Title: POG 9239 Cisplatin and Hyperfractionated vs Conventional Radiotherapy for Brain Stem Glioma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 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 93 (2) Protocol #: 93/409 (3) Status: Ongoing

(4) Title: POG 9227 Treatment of Recurrent or Refractory Hodgkin's Disease with Cyclosporine-A, Actinomycin-D, Vincristine. A Phase II Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 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 93 (2) Protocol #: 93/410 (3) Status: Completed

(4) Title: POG 9072 Ifosfamide, Carboplatin, Etoposide (ICE) Treatment of Recurrent/Resistant Malignant Solid Tumors of Childhood, Pilot Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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 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: Closed, 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 93 (2) Protocol #: 93/411 (3) Status: Ongoing

(4) Title: POG 9219 Treatment of Patients with Localized Non-Hodgkin's Lymphoma, Phase IV

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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 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 study of pediatric malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Study 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 93 (2) Protocol #: 93/412 (3) Status: Ongoing

(4) Title: POG 9244 OPEC/OJEC Chemoptherapy for Children Older Than 1-year of Age with INSS Stages 2B and 3 Neuroblastoma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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 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 study of pediatric malignancies.

(16) Technical Approach: See protocol.

(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 93 (2) Protocol #: 93/413 (3) Status: Ongoing

(4) Title: POG 9262 A Phase II Study of Taxol in Chidlren with Recurrent/Refractory/Soft-Tissue Sarcoma, Rhabdomyosarcoma, Osteosarcoma, Ewing's Sarcoma, Neuroblastoma, Germ Cell Tumors, Wilms' Tumor, Hepatoblastoma, and Hepatocellular Carcinoma

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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 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 study of pediatric malignancies.

(16) Technical Approach: See protocol.

(17) Progress: The study is remains 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 93 (2) Protocol #: 93/414 (3) Status: Ongoing

(4) Title: POG 8935 A Study of the Biological Behavior of Optic Pathway Tumors

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 study of pediatric malignancies.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered, remains 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 93 (2) Protocol #: 93/415 (3) Status: Completed

(4) Title: POG 9060 Intensive QOD Ifosfamide for the Treatment ofChildren with Recurrent or Progressive CNS Tumors. A Phase II Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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:____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 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: Closed, 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 93 (2) Protocol #: 93/416 (3) Status: Ongoing

(4) Title: POG 9170 Etoposide and Ifosfamid eplus G-CSF in Children with Sarcomas; including Soft Tissue Sarcoma, Ewing's Sarcoma, Rhabdomyosarcomas and Osteosarcoma. A Pediatric Oncology Group Pilot Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 study of pediatric malignancies.

(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 93 (2) Protocol #: 93/417 (3) Status: Ongoing

(4) Title: Identification of Family Strenghts and Needs Using the Q-Sort Process

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Marjorie Feinberg, DAC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

MAJ Pat Chandler

(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: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 15
d. Total Number of Subjects Enrolled to Date: 15
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 what families perceive as important supports during babies' hospitalization.

(16) Technical Approach: Parent interview and demonstration of Q-Sort Process to prioritize needs of family.

(17) Progress: 15 families whose babies meet the criteria for part II eligibility have been interviewed. A total of 40 families is our goal. Completion data is dependent on census in NICU which has been low in the past 2 months.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/418 (3) Status: Ongoing

(4) Title: POG 9264 Chemotherapy Regimen for Initial Induction Failures in Childhood Acute Lymphocytic Leukemia

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 study of pediatric malignancies.

(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 93 (2) Protocol #: 93/419 (3) Status: Ongoing

(4) Title: POG 9317 Chemotherapy for Children with Advanced Stage (III/IV) Diffuse Undifferentiated Burkitt's Lymphoma and B-Cell ALL

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of 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: 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 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 study of pediatric malignancies.

(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 93 (2) Protocol #: 93/420A (3) Status: Ongoing

(4) Title: Adjuvant Therapy with Interferon-gamma for Group B Streptococcal Sepsis in Neonatal Rats

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Robert R. Wittler, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDIATRICS

(10) Associate Investigators
Richard W. Harris, Ph.D.
Frederick W. Bruhn, COL, MC

(11) Key Words:
group b streptococcus
interferon-gamma
neonatal rats

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if interferon-gamma in conjunction with penicillin has a beneficial effect on the mortality resulting from group B streptococcal sepsis in a neonatal rat model.

(16) Technical Approach: Newborn rats will be infected with an group B streptococcus. Mortaility will be assessed in four treatment groups: (1) controls, no penicillin or IFN; (2) rats receiving IFN; (3) rats receiving penicillin; and (4) rats receiving penicillin and IFN.

(17) Progress: To begin October 1993.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/475 (3) Status: Ongoing

(4) Title: Clinical Comparability of Two Once-Daily Forms of Diltiazem: Effect of Substitution on Blood Pressure Control

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Lea Conyers, DAC

(8) Facility: FAMC

(9) Dept of Pharmacy

(10) Associate Investigators
MAJ John Grabenstein
LTC Roger Potyk
MAJ Lisa Johnson

(11) Key Words:
Diltiazem, hypertension, comparability

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess the comparability of clinical effects of Cardizem and Dilacor in the treatment of hypertension.

(16) Technical Approach: Multicenter retrospective analysis of patient records.

(17) Progress: None, recently approved.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/650A (3) Status: Ongoing

(4) Title: Study of Hemoglobin and Red Cell Metabolism in Didelphis marsupials

(5) Start Date: 1993 (6) Est Compl Date: Indifinite

(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:
didelphis marsupialis
erythrocytes purine nucleoside 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: To compare red cell purine nucleotide content, and purine nucleoside metabolism in these cells with those of Didelphis virigniana on record.

(16) Technical Approach: Purine nucleotides and activities of red cell adenosine deaminase, deoxyadenosine kinase, (d) AMP deaminase, S-AMP synthetase, HGPRT will be studied in intact cells and in cell lysates by HPLC.

(17) Progress: Two animals were received in April 1993. Preliminary work reveals that red cells do have a high activity deoxyadenosine kinase and S-AMP synthetase. Unlike red cell of D. virginiana, red cells of D. marsupialis have abundant adenosine deaminase activity. dATP content of cells is much lower than that in D. virigniana red cells.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/651A (3) Status: Completed

(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 R.E. Banks, MAJ, VC

(11) Key Words: D. virginiana. erythrocytes, purine nucleotides, adenosine deaminase enzyme replacement

(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: Changes in red cell (deoxy) nucleotides following adenosine deaminase enzyme replacement.

(16) Technical Approach: Per protocol.

(17) Progress: Unlike the situation observed in human red cells, only a 40% decline in deoxyribonucleotides was observed in opossum red cells after 2 months of enzyme replacement. This moderate decline was found to be due to the presence of a high affinity/high activity deoxyadenosine kinase.

Bethlenfalvay N, Lima J, Banks R (1993) The effect of enzyme replacemnet on red cell adenine deoxyribonucleotides in adenosine deaminase deficient erythrocytes of the opossum, Didelphis virginiana. Comp Biochem Physiol (in press).

Bethlenfalvay N, Lima J, Banks R (1993) 1'deoxyadenosine metabolism in human and opossum Didelphis virginiana erythrocytes in-vitro. Comp Biochem Physiol (in press).

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

(1) Date: 30 Sep 93 (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: Mike McBiles, LTC, 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: 1
d. Total Number of Subjects Enrolled to Date: 34
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 93 (2) Protocol #: 92/600 (3) Status: Terminated

(4) Title: CT (Computerized Tomography) Detected Coronary Artery Calcification in Adult Patients Under Age Sixty and Its Relationship to Significant Coronary Artery Stenosis. A Radiologic Pathologic Correlation Study

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Fred Caruso, CPT, MC (8) Facility: FAMC

(9) Dept of Radiology (10) Associate Investigators

(11) Key Words:
computerized tomography
coronary artery calcifications

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To enable radiologists to more confidently alert the clinician on the presence and significance of this incidental chest CT finding.

(16) Technical Approach: Prospective radiologic pathologic correlation.

(17) Progress: Protocol requires revision for IRC approval. None to date due to boards preparation. Study terminated, IRC stipulations were not met for approval.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/601 (3) Status: Terminated

(4) Title: Pontine Lesions on Screening MR (Magnetic Resonance) Imaging of the Brain: Correlation with Cardiovascular Risk Factors

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Thomas Damiano, MAJ, MC

(8) Facility: FAMC

(9) Dept of Radiology

(10) Associate Investigators
Charles Truwit, MAJ, MC

(11) Key Words:
pontine lesions
cardiovascular risk factors
magnetic resonance imaging

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This study is designed to determine the causes, and therefore the potential clinical significance of pontine lesions detected on screening MR imaging examinations of the brain.

(16) Technical Approach: Initially 100 patients will be taken from the population of patients referred to the FAMC Dept of Radiology for cranial MR imaging. A questionnaire will be administered. Power analysis will be performed to determine the number required for the study.

(17) Progress: Being outpaced by studies being performed by a multi-institutional of thousands, therefore, termination of 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 93 (2) Protocol #: 92/602 (3) Status: Terminated

(4) Title: Focal Cerebral Ischemia in Severe Acute Asthma and Its Association with Beta-Adrenergic Agonists

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Stephen Yoest, CPT, MC (8) Facility: FAMC

(9) Dept of Radiology (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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if children having acute asthma attacks have areas of decreased blood flow to the brain which my be detected by magnetic resonance imaging (MRI) of the brain.

(16) Technical Approach: Obtain MRI scan of brain after standard and routine asthma treatment has taken place in either the emergency room, pediatric ward of intensive care unit.

(17) Progress: No response to two written requests and one request by phone, 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 92 (2) Protocol #: 92/650 (3) Status: Ongoing

(4) Title: Patient Education Through Record Sharing

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Stuart Smith, M.D., DAC

(8) Facility: FAMC

(9) Dept of PCCM

(10) Associate Investigators

(11) Key Words:
patient education
record sharing

(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: 35
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 the role of patients in cost/quality.

(16) Technical Approach: Partial record sharing.

(17) Progress: To date 35 patients have participate and 30 have completed the initial steps. Ten have completed all steps and 20 mailings went out in Aug 93.

Publications and Presentations: Three papers are in the process of preparation. A poster presentation was accepted for the 15th Annual Conference on Patient Education sponsored by the American Academy of Family Physicians and the Society for Teachers of Family Medicine, Nove 18-21, 1993, at Scottsdale, AZ.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/600 (3) Status: Completed

(4) Title: Use of Strontium-89 for Intractable Bone Pain from Metastatic Breast and Prostate Cancer

(5) Start Date: Oct 92 (6) Est Compl Date: Oct 93

(7) Principal Investigator: Morakinyo A.O. Toney, LTC, MC (8) Facility: FAMC

(9) Dept of Rad/Nuc Med (10) Associate Investigators Mike McBiles, LTC, MC Albert Lambert, CPT, MC

(11) Key Words: IND, pain relief, cancer

(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:_Approved
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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Palliative relief of intractable bone pain in terminal patients with metastatic breast and prostate bone disease leading to an improvement in the quality of remaining life.

(16) Technical Approach: Injection of Strontium-89 Chloride at the minimum effective dose of 40 uCi/kg (1.48 MGq/kg) by IV push over 5 to 10 minutes via an established IV line by a nuclear medicine physician.

(17) Progress: The FDA recently approved strontium-89 for this indication; therefore, a protocol is no longer necessary. Two patients were treated, one did not have much pain relief with this treatment.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/601 (3) Status: Ongoing

(4) Title: Comparison of Three Quality Control Methods Used in the Preparation of Tc-99m Exametazine (Ceretec)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Grant Morgan, MAJ, MC (8) Facility: FAMC

(9) Dept of RADIOLOGY (10) Associate Investigators

(11) Key Words: Richard E. Stotler, LTC, MS

(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 assess two methods of quality control testing for practical use within the Nuclear Medicine Service and demonstrate the validity of these methods using a dose calibrator system common to all Nuclear Pharmacy Hot Labs.

(16) Technical Approach: Per protocol.

(17) Progress: New study.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/602 (3) Status: Ongoing

(4) Title: A Prospective Evaluation of Technetium^{99m} Sestamibi in the Detection of Breast Cancer

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Marc Cote, MAJ, MC

(8) Facility: FAMC

(9) Dept of RADIOLOGY/Nuc Med

(10) Associate Investigators
Mike McBiles, LTC, MC
Gloria Komppa, M.D.
Thomas Verdon, COL, MC
Sharon Hammond, MAJ, MC
Phillip Mallory, LTC,
Richard Stotler, LTC, MS
Cathy Parsells, MAJ, MC
Bruce Hamilton, LTC, MS

(11) Key Words:
Technetium 99m, sestamibi
breast, cancer

(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: 0
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 find an imaging modality that can help differentiate cancer from benign lumps or fibrocystic changes seen on mammography.

(16) Technical Approach: SPECT and planar nuclear imaging of women with breast lumps having biopsies will be imaged.

(17) Progress: None. Study recently approved by the IRC and reviewed by CIRO.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 91/701A (3) Status: Terminated

(4) Title: Suturing Techniques for FAMC Personnel

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: (8) Facility: FAMC
Deborah M. Castellan, LTC, AN
Debra J. Walker, LTC, An
Robert A. Leibold, CPT, MC

(9) Dept/Svc: Nursing (10) Associate Investigators:

(11) Key Words:
suturing
trianing
mobilization skills

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

(14) a. Date, Latest IRC Review: APR 92 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 44 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: Training professional and paraprofessional nursing personnel at FAMC in basic suturing techniques.

(16) Technical Approach: 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: Terminated.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: 1992

(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: 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: 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: The pilot study has been completed and the preliminary data analyzed. The data indicates that some modification to the Child Pain Scale needs to occur prior to the implementation of the tool in the funded 5 year study. Evaluation of this tool indicated most nurses thought it contained relevant content but it was too lengthy, complex, and cumbersome to use in its current form.

The Pain Experience History forms were felt by the nurses to be excellent but the information obtained may need to be transferred to forms at the bedside.

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The Poker Chip Tool was felt to be easy to use and easy to obtain valid information on the child's pain but there was concern about giving the tool to the child at the same time that the parent evaluated the child's pain using the tool. Perhaps the child would feel the nurse did not believe the child's assessment of their own pain. Orientation to the tools and program was felt to be appropriate in time and content but more support during their study for questions/problems may be needed.

The Pain Flow Sheet was assessed to be positive but amy also need some minor changes to make the form easier and faster to use.

Although the collection of data for the pilot study has been completed, the Child Pain Scale is being revised and we request that the study be continued to allow for retesting of this tool here. There is minimal risk associated with this tool as it measures a child's behavioral responses to pain and involves mostly observation.

New Addendum reviewed 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 93 (2) Protocol #: 92/701 (3) Status: Terminated

(4) Title: Post-Op Pain Control: Randomized Comparison of PCA, PCA Plus Continuous Infusion, and Regularly Scheduled Nurse Administered Intravenous Morphine Sulfate

(5) Start Date: (6) Est Compl Date: 1993

(7) Principal Investigator: (8) Facility: FAMC
Rose Gates, LTC, AN

(9) Dept of 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: 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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To comapre the efficacy of post-op pain control using PCA, PCA plus continuous infusion, and regularly scheduled nurse administered medications.

(16) Technical Approach: Use of PCA devices

(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 93 (2) Protocol #: 93/700 (3) Status: Ongoing

(4) Title: A Pilot Survey of Timing and Utilization of Preventive Examinations at Fitzsimons Army Medical Center

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Ernest Degenhardt, MAJ, AN

(8) Facility: FAMC

(9) Dept of NURSING

(10) Associate Investigators
James Hanley, COL, MC
Mary Miller, MAJ, AN
Paula Nelson-Marten, LTC, AN
Sandra Smith, MAJ, AN
Janet Wilson, CPT, AN
Kathryn Gaylord, CPT, AN

(11) Key Words:

preventive examinations

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this pilot study is the assessment of current utilization of preventive evaluations by active duty and retired beneficiaries of FAMC and members of the 5502d USAR as recommended by ACT, CTF, UsPSTF and ACS guidelines. A secondary purpose is to identify the usefulness of the Health Maintenance Survey in identifying the timing and utilization of preventive evaluations.

(16) Technical Approach: Per protocol.

(17) Progress: Data not evaluated as of this date.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/701 (3) Status: Ongoing

(4) Title: Advanced Practice Nursing Impact on Patients and Staff

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Wynona Stephens, LTC, AN

(8) Facility: FAMC

(9) Dept of NURSING

(10) Associate Investigators
LTC Mucha
Dr. Sherman
CPT Gaylord
CPT Boucher
LTC E. Smith
Mr. Pearce

(11) Key Words:
advanced practice nursing

(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: 300
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 the impact of the health-care delivery system of advanced practice nursing groups of the quality of patient care and staff work satisfaction.

(16) Technical Approach: (a) INdex of work satisifaction (stamps and piedmonte) administered every 6 months to all DOA personnel; (b) Structured interviews conducted every three months with key personnel; (c) Pertinent indicators monitored monthly, as med errors, falls, patient representative reports.

(17) Progress: Index of work satisfaction computeriezed and copied for 6 Oct 93 distribution; structured interviews conducted as scheduled; indicators monitored monthly.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/702 (3) Status: Ongoing

(4) Title: Hospitals as Teaching Sites: Converging Theory and Practice Through Clinical Application Programs Based Upon Adult Learning Concepts.

(5) Start Date: 1993 (6) Est Compl Date: Dec 1993

(7) Principal Investigator: (8) Facility: FAMC
Wynona Stephens, LTC, AN

(9) Dept of NURSING (10) Associate Investigators

(11) Key Words:
clinical applications

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the perceived effectiveness of clinical application programs such as preceptorships as a teaching strategy, particularly as a means of achieving principles of adult learning and to determine the influence of variable upon the clinical application experience particularly those inherent to program within hospitals functioning as teaching sites.

(16) Technical Approach: Computerizes survey to be administered to all 66Js in DON; survey findings to be related to theoretical framework and other areas of literature review.

(17) Progress: Proposal revised to include all 66Js, not just those arrived in last 12 months; survey revised-tailored more to military audience, with more andrological base; Vanderbilt committee suggested title change; All changes minor and does not change study intent and will be submitted to DCI after Vanderbilt University IRB approves.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/750 (3) Status: Ongoing

(4) Title: Inter-Examiner Reliability of the Trigger Point Examination in Myofascial Pain Syndrome

(5) Start Date: 1993 (6) Est Compl Date: 12/93

(7) Principal Investigator:
Steven Shannon, MAJ, MC

(8) Facility: FAMC

(9) Dept of Physical Medicine

(10) Associate Investigators
Dr. Robert Gerwin, MD
Dr. C.Z. Hong, MD
Dr. David Hubbard, MD

(11) Key Words:
trigger points
myofacial pain
inter-examiner reliability

(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: 25
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: To see if four experienced examiners can obtain similar physical examination data when examining for myofascial trigger point characteristics.

(16) Technical Approach: Four physicians will each sequentially examine a series of subjects, male and female, age 18 years and older in groups of 8-10 at a time randomized by a latin square design.

(17) Progress: Most of statistical anlaysis completed, but some aspects being looked at more closely.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (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: 1994

(7) Principal Investigator: Lester Hale, Ph.D. (8) Facility: FAMC

(9) Dept/Svc: USA Environ.Hyg. (10) Associate Investigators: Michael Quintana, CPT, MS Thomas P. Gargan II, MAJ

(11) Key Words: 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:____257_____
d. Total Number of Subjects Enrolled to Date:_____571_____
e. Note any adverse drug reactions reported to the FDA or 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: Nine installations will have been surveyed by 30 Sep 93. The presence of tick vectors have been determined on those installations surveyed. Borrelia burdorferi was found at Camp Riley, MN

Publications and Presentations: Nine Lyme disease risk assessments will have been written by the end of this reporting period.

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

(1) Date: 30 Sep 932 (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: Matthew Schofield, CPT, MS (8) Facility: UC Perinatal Research Facility located at FAMC

(9) Dept/Svc: DCI/Biochem. (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. The experimental design tests the hypothesis that a key factor in maintaining viability during severe chronic hypoxia is the ability of the fetus to metabolize lactate for production of non-essential amino acids, that are, in turn, metabolized by the placenta.

(16) Technical Approach: Chronic hypoxia in the fetal sheep is created (125-130 d. gestation) by means of a balloon occluder placed around the common internal iliac in a chronically catheterized pregnant ewe. Isotope labelled substrates are used to measure metabolism and transport of metabolites.

(17) Progress: Progress is currently pending MRDC funding, anticipated for 1 October 1993. No studies conducted 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 93 (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: Unknown

(6) Est Compl Date: Ongoing

(7) Principal Investigator: Gerald G. Mindrum, COL, MC

(8) Facility: FAMC
US Army Health Clinics
Dugway Proving Grounds
Dugway, Utah 84022

(9) Dept/Svc:

(10) Associate Investigators: Steven Boyea, 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: 1
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or 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 93 (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: Unknown

(6) Est Compl Date: Active at present time. IND protocol current.

(7) Principal Investigator: Gerald G. Mindrum, COL, MC

(8) Facility: FAMC US Army Health Clinic, DPG

(9) Dept/Svc:

(10) Associate Investigators: Steven Boya, 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: 8
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or 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 worker.

(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 93 (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: Unknown

(6) Est Compl Date: Ongoing

(7) Principal Investigator: Gerald G. Mindrum, COL, MC

(8) Facility: FAMC
Dugway Proving Grounds
US Army Health Clinic

(9) Dept/Svc:

(10) Associate Investigators: Steven Boyea, 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: 6
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or 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 93 (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: Unknown

(6) Est Compl Date: Active at present time. IND protocol current.

(7) Principal Investigator: Gerald G. Mindrum, COL, MC

(8) Facility: FAMC
US Army Health Clinic
DPG

(9) Dept/Svc:

(10) Associate Investigators: Steven Boyea, 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: 1
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: 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 93 (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:
Gerald G. Mindrum, COL, MC

(8) Facility: USAMRIID
CDC

(9) Dept/Svc:

(10) Associate Investigators:
Steven Boyea, CPT, MC, DPG
Shannon Harrison, COL, MC,
Ft. Sam Houston, TX

(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: 1
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: Protocol recently approved by OTSG. One patient enrolled.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/901 (3) Status: Ongoing

(4) Title: Army Pregnancy Study

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator:
Joseph Creedon, Jr., CPT, MC

(8) Facility: FAMC
Ft. Carson, CO
Evans Army Community Hospital

(9) Dept of Occupational Health

(10) Associate Investigators

(11) Key Words:
reproductive outcome
occupational factors

(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: The purpose of this current investigation is to attempt to quantify risk to the offspring of female soldiers in teh U.S. Army by CMF and MOS for the following outcomes: spontaneous abortions, ectopic pregnancies, intrauterine fetal demise, preterm birth, low birth weight infant, preterm and low birth weight infant, and congenital abnormalities.

(16) Technical Approach: Initially to be conducted as a pilot study at Evans ACH. Multi-center demographic questionnaire will be performed on study group comprised of female soldiers and the comparison group will consist of wives of soldiers.

(17) Progress: The pilot phase of this study is complete. Amendments to the protocol, questionnaire and consent form were reviewed and approved by the IRC at the 2 Mar 93 meeting. The protocol will be sent to associate investigators at other sites.

Publications and Presentations: None.

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/902 (3) Status: Terminated

(4) Title: Non-Thermal Pulsed Electromagnetic Energy (Diapulse) in the Functional Rehabilitation of Ankle Sprains

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

(7) Principal Investigator:
Gerard Pennington, MAJ, MC

(8) Facility: FAMC
Evans Army Community Hospital
Ft. Carson, CO

(9) Dept of Orthopedics

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Assess and measure objectively the effect of Diapulse on the decrease of rehabilitation and functional recovery time due to reduction of edema following ankle sprains.

(16) Technical Approach: Randomized, placebo-controlled trial of 50 subjects.

(17) Progress: Administratively terminated due to failure to comply with IRC stipulations for approval.

Publications and Presentations:

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

(1) Date: 30 Sep 93 (2) Protocol #: 92/904 (3) Status: Ongoing

(4) Title: The Effect of Placing Infants in Bed Awake at Night on Infant's Sleep Pattern.

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Helen Cook, MAJ, AN

(8) Facility:
Evans Army Community Hospital
Ft. Carson, CO 80913

(9) Dept of Nursing

(10) Associate Investigators
Ruth Crutchfield, PNP
Shirley Stewart, PNP
Carol Wetzig, PNP

(11) Key Words:
infants
sleep pattern

(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: 16
d. Total Number of Subjects Enrolled to Date: 36
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 the infant at an eraly age to sleep through the night will reduce family stress and possibley reduce child abuse.

(16) Technical Approach: Pilot project using 25 subjects for control and intervention groups.

(17) Progress: Started enrolling people once they had compiled a week of sleep data (baseline) on their child, which cut down on the number of drop outs. If person returns in one week to sign the consent form the majority will stay with the collection phase. The summer is a slower time period for well babies so we would like to request another year's collection time to get 25 members in each group (control and treatment).

Publications and Presentations: Presented, May 1993 for Nursing Research Symposium sponsored jointly by FAMC and EACH. Focus: Trials and joys of designing and collecting data for research.

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/900 (3) Status: Ongoing

(4) Title: Fort Riley Health Promotion Intervention Project

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Steven Finder, MAJ, MC

(8) Facility: FAMC
MEDDAC, Ft. Riley, Ks

(9) Dept of 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: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 563 families
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: Can a health prevention and promotion program reduce short-term direct hospital costs.

(16) Technical Approach: Three-arm multi-year study incorporating two study groups and a control group.

(17) Progress: Since Jan 93, the study has acquired a building, developed the intervention and study instruments and begun the intervention. Currently, the project is developing a hospital wide data base to track hopsital outpatient costs.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/901 (3) Status: Ongoing

(4) Title: Measurement of Isokinetic Forces of Elbow Flexors and Extensors - A Normative Study

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Mary Koch, MAJ, SP

(8) Facility: FAMC
General Leonard Wood Army Community Hospital

(9) Dept of PHYSICAL THERAPY

(10) Associate Investigators

(11) Key Words:
isokinetic exercise
elbow

(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: 13
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: Unchanged from original protocol Aug 93.

(16) Technical Approach: Unchanged from original protocol Aug 93.

(17) Progress: (only approved August 93), data collection is ongoing since 20 Aug 93.

Publications and Presentations: None

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

(1) Date: 30 Sep 93 (2) Protocol #: 93/902 (3) Status: Ongoing

(4) Title: Epidemiology of Prescribed Medication Use Among Active-duty Troops, Retired Soldiers and Their Families

(5) Start Date: 1993

(6) Est Compl Date: 1994

(7) Principal Investigator:
Lisa Johnson, MAJ, MS

(8) Facility:
Irwin Army Community Hospital
Ft. Riley, Ks
66442-5037

(9) Pharmacy Service

(10) Associate Investigators
MAJ John Grabenstein
LTC Roger Potyk

(11) Key Words:
epidemiology, medication

(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 studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To quantify use of prescribed medications among active-duty soldiers, retired soldiers, and their families at representative Army posts.

(16) Technical Approach: Descriptive report of the incidence and prevalence of use of prescription medications among various groups and subgroups during a 9-month interval.

(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 93 (2) Protocol #: 93/950A (3) Status: Ongoing

(4) Title: Study to Determine the Effectiveness of the Permethrin Insecticide, PCC-331, Placed in Bait Stations, to Control Flea Vectors of Plague on Tree Squirrels

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of USAEHA-W (10) Associate Investigators

(11) Key Words:
squirrel

Thomas P. Gargan II

(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:___50_____
d. Total Number of Subjects Enrolled to Date:_____50_____
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 if insecticide placed in bait stations will effectively eliminate fleas on tree squirrels with vector plague.

(16) Technical Approach: Capture 50 squirrels - remove fleas and count release captured squirrels, place bait stations with insecticide - impregnated collars in threes - recapture squirrels in 30 days and count fleas.

(17) Progress: 50 squirrels captured in June - released - bait stations put in place - squirrels damaged bait stations - no conclusions - repeat in fall 93.

Publications and Presentations: None

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