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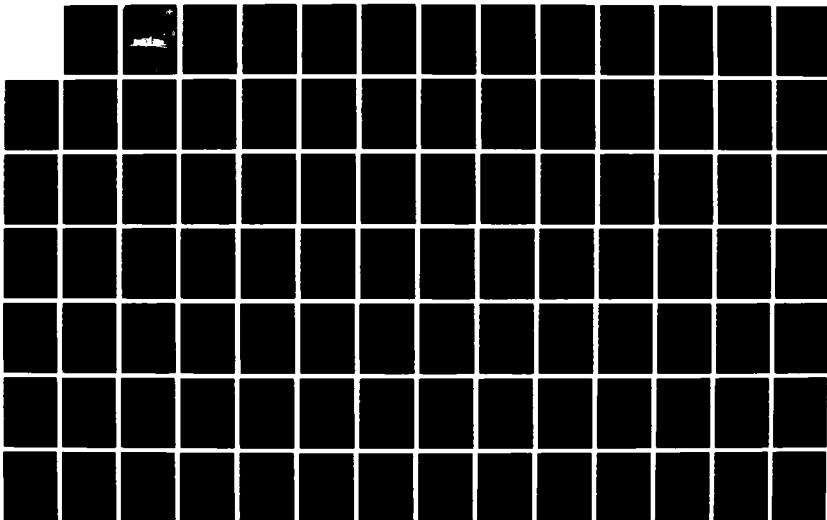
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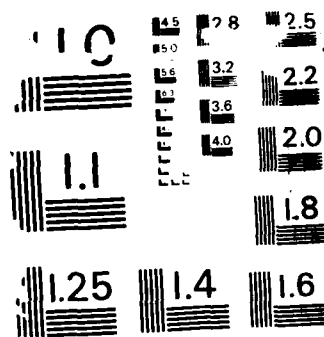
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FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1987 along with other known 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 40-23, 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 especially grateful to BRIGADIER GENERAL Thomas M. Geer, MC, Commanding General of Fitzsimons Army Medical Center, his professional and administrative staff, and to the Commanding Officers and staff of other supporting activities for the cooperation and assistance provided this Department of Clinical Investigation in our efforts to accomplish our mission. Finally, I would like to recognize the outstanding work, dedication, and wholehearted corroboration of my entire staff. I would especially like to thank my Research Protocol Specialist, Ms. Marcia Bilak and Ms. Chris Montoya, Secretary, without whose assistance and support this report would not have been possible.

John K. Podgore

JOHN K. PODGORE
Colonel, MC
Chief, Department of Clinical
Investigation

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UNIT SUMMARY

UNIT SUMMARY

Clinical Investigation Program, FAMC

Clinical Investigation efforts by FAMC personnel in FY 87 culminated in the publication of 65 articles and 54 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1987, there were 234 research protocols on the DCI register. Of these, 152 projects were ongoing, 26 projects completed, 56 projects terminated, and for this FY there were 43 new registrations.

Objectives:

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

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

Technical Approach:

This support is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 40-18, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters.

Manpower: current authorized strength is outlined.
Authorized

<u>Description</u>	Grade	MOS	Br	Auth	Req	Act	Name	Rank
C, Dept Clin Inv	Ø6	6ØP9B	MC	1	1	1	PODGORE	COL
C, Micro Svc	Ø5	68AØØ	MSC	1	1	1	Andron	LTC
C, Psychophys & Biostat Svc	Ø5	68TØØ	MSC	Ø	1	1	Sherman	MAJ
C, Biochem Svc	Ø4	68AØØ	MSC	1	1	1	White	MAJ
C, Immunol Svc	Ø4	68EØØ	MSC	1	1	1	Stewart	MAJ
C, Cell Phys Svc	Ø3	68JØØ	MSC	1	1	1	Ferris	CPT
C, Animal Res Svc	Ø4	64C9B	VC	1	1	1	Trahan	MAJ
NCOIC-Med Lab	E7	92B4R		1	1	1	Engle	SFC
Sr Med Lab Sp	E6	92B3R		1	1	1	Fernandez	SSG
Operating Rm Sp	E4	91D2R		1	1	1	Berger	SP4
Bio Sci Asst	E6	Ø1H3R		1	1	1	Chadwick	SSG
Bio Sci Asst				1	1	Ø		
Bio Sci Asst	E5	Ø1H3R		1	1	1	Sanders	SGT
Vet Sp	E5	91T3R		1	2	1	Barrett	SSG
Vet Sp	E4	91T2R		Ø	Ø	1	Lamb	SGT
Bio Sci Asst	E4	Ø1H1R					Schmidt	SP4
Bio Sci Asst				1	1	Ø		
Supv Res Chem	13	132Ø	GS	1	1	1	O'Barr	
Microbiologist	11	Ø4Ø3	GS	3	3	3	Lima Paine Hoyt	

<u>Description</u>	Grade	MOS	Br	Auth	Req	Act	Name	Rank
Microbiologist	09	0403	GS	3	6	3	Morse Tessier Muehlbauer	
Med Technologist	11	0644	GS	0	1	1	Rush	
Med Technologist	09	0644	GS	0	6	6	Harrison Ramirez Chadwick (Term) Schaff (Term) Pinney (Term) Sachanandani (Term)	
Med Technician	09	0645	GS	1	1	1	Nelson	
Research Chem	09	1320	GS	3	4	3	Noble Stewart Cisneros	
Bio Lab Tech (Animal)	09	0404	GS	1	1	1	Mercill	
Animal Caretaker (Foreman)	04	5048	WS	1	1	1	Jones	
Research Prot Sp	09	0301	GS	1	1	1	Bilak	
Animal Caretaker	05	7706	WG	1	3	2	Chase Hitchcock	
Secretary	06	0318	GS	1	1	1	Montoya	

Animal Resources Service - FY 87

Renovation of the service's physical plant has been completed. Because of the extended down-time experienced during the process, medical and surgical equipment is requiring extensive servicing and calibration before being returned to a fully operational status. An ethylene oxide gas sterilizer has been received and is currently awaiting final installation.

MAJ Albert H. McCullen was reassigned in October, 1986. He was replaced by MAJ Creighton J. Trahan in January, 1987. SGT Diane Lamb was certified as a Laboratory Animal Technologist by the American Association of Laboratory Animal Science.

The Animal Housing Facility, Bldg 610, had a new epoxy aggregate seamless floor poured in February, 1987, and an oil base epoxy paint applied to all interior walls in March, 1987. Project animals were housed, during this interim, at the Animal Facility, Denver General Hospital, an institution fully accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). Washable, sanitizable, acoustical ceiling tile has been received, and is awaiting installation in all dropped ceiling areas of Bldg 610.

AAALAC conducted an on-site visit of the services and facilities on 9 June 1987. Final results are pending.

Biochemistry Service - FY 87

During the past year, the biochemistry laboratory has used its resources to support protocols of interest to the medical staff at FAMC and to provide patient care. Patient care support has consisted primarily of the determination of glycosylated hemoglobin (HbA_{1c}) in whole blood. This intricate and sensitive assay is widely used by clinicians to evaluate the effectiveness of insulin therapy in diabetic patients.

Requests for protocol support came from many different departments and reflected a continuing high interest in basic medical research. These requests often required the establishment of new and sophisticated procedures. Areas of interest included: the effect of theophylline on calcium and vitamin D metabolism; the evaluation of carbohydrate metabolism in thyrotoxicosis; alterations in angiotensin-converting enzyme (ACE) activity; effect of gonadal steroids on arachidonic acid metabolites; food allergy in migraine headaches; energy sources for methemoglobin reduction in the red blood cell; conjugated estrogens in reducing blood loss during and after cardiac surgery; estradiol and progesterone receptors in human melanomas. Since many protocol-support assays involved the use of radioactivity, approval to purchase a multi-well gamma counter has been obtained. It is anticipated that this new instrumentation will greatly expedite the counting of radioactive samples.

Cell Physiology Service - FY 87

The Cell Physiology Service has three basal cell and keratinocyte protocols which are directed to study the cell biology and parameters of growth of basal cells and/or keratinocytes and the mechanisms of aberration which produce basal cell carcinomas (BCC).

Methodologies developed by members of the Cell Physiology Service and the physician investigators here at FAMC have augmented the study of this most prevalent skin cancer. These methodologies include but are not limited to:

(1) Pioneering new methods and subsequently being the first laboratory to successfully heterotransplant basal cell carcinomas into athymic (nude) mice. This permitted the study of these human tumors in an animal model.

(2) Adaptation of autoradiographic methods to determine that the tumors were growing within the animal and where this growth was localized.

(3) Collaborating with J.C. Huff and R.A.F. Clark and using the athymic mouse BCC model allowed us to also implement immunostaining techniques to determine the extent and location of matrix proteins of which cell growth is dependent.

(4) The Cell Physiology Service, in collaboration with outside researchers has developed a methodology to heterotransplant keratinocytes into athymic mice. This technique has resulted in the elucidation of proteins formed in the basement membrane zone during tissue organization.

Of the eight presentations and/or papers arising from this area of research, the importance of some of the work was highlighted in the February 1986 issue of the Journal of Investigative Dermatology. Our published article, "The Proliferating Cells of Human Basal Cell Carcinoma are Located on the Periphery of Tumor Nodules", used the athymic mouse BCC model and the autoradiographic technique. Additionally, the editorial comment from that issue explained the importance of the work. The comment addressed the fact that we now had an animal model which could be used in determining the growth parameter. A recently accepted article using the keratinocyte heterotransplantation technique will soon appear in the Journal of Investigative Dermatology. The techniques developed from these protocol will be used to methodologically spawn a protocol investigating the biology of lupus erythematosus. This protocol will be conducted in collaboration with the University of Colorado Health Sciences Center.

A joint Cell Physiology/OB-GYN Service protocol is continuing and attempts to determine if there are differences in steroid production related to induced luteal phase defects (in monkeys). Results of this study may lead to more germane treatment of this type of infertility.

An endocrinology protocol, of possible major importance, which the Cell Physiology Service is supporting deals with using radiolabeled TSH as a diagnostic imaging tool in recurrent thyroid cancer. If successful, the technique could well be applied to other radiolabeled hormones with receptors located in cancerous tissue and/or radiolabeled monoclonal antibodies to tumor specific antigens.

The renovation project did curtail research this past year, however, the CPS laboratory facilities are now much more conducive for research. A scanning electron microscope which will be used for any required departmental research has been added to the electron microscopy facility.

Immunology Service - FY 87

The Immunology Service has experienced several personnel changes over the past year. A new service chief, Major Robert Stewart, arrived in January after completing his doctoral research on the immune response to respiratory viruses at the University of California at Davis. Two other new technologists, Doris Sachanandani and Carmen Ramirez, were also brought on board to assist in the natural history and AZT protocol evaluations of lymphocyte subsets. To date over 400 individuals, both clinical and controls, have been evaluated and acquired by the database manager for these studies. Flow cytometric procedures currently include one and two color immunofluorescence and DNA content analysis. The Immunology Service hosted an HSC-wide weeklong

workshop on Flow Cytometric Quality Control and Quality Assurance which was attended by staff from all eight Army Medical Centers. There are four currently active research protocols, two more undergoing literature review and feasibility studies, and an additional three suggested for evaluation. Two new major pieces of equipment are being procured by the MEDCASE system including a third flow cytometer and an automated nephelometry system. The Easy 88 Flow Cytometry Data Evaluation System was upgraded and will soon be replaced by a new 80386-CPU based Easy 2 system which will increase efficiency and instrument reliability.

Microbiology Service - FY 87

The excellent performance of the Clinical Investigation Mycobacteriology laboratory on inspection by the College of American Pathologists (CAP) was an important part of the successful overall FAMC CAP laboratory accreditation. Significant progress was made in development of computerized database management of data from both natural history and Retrovir (AZT) studies of HIV infection. The study of Retrovir treatment of early AIDS has begun. It involves some funding from USAMRDC, some collaboration with Denver General Hospital, and the use of drug donated by Burroughs Wellcome. Fluorescent immunoassay kits for IgG and IgM antibodies to Toxoplasma and Cytomegalovirus (CMV) were brought on line and are useful in monitoring AIDS patients. With the help of MAJ Michael Hastriter, Fort Leonard Wood, a protocol involving epidemiology of Lyme disease was developed and field specimens were collected. The building 601 renovation project was completed with large increases in functional laboratory space.

Psychophysiology Service - FY 87

This Service is new to Clinical Investigation and began operations in June of 1987. Its missions are to (1) provide a modern Psychophysiology/Pain Evaluation Laboratory for clinical and research evaluations as well as psychophysiological treatments, (2) coordinate, provide opportunities for, and encourage the research related efforts of Orthopedic staff and residents, and (3) provide support to all MEDCEN staff and students in design and analysis of studies. To date, all major equipment items required for a state of the art Psychophysiology/Pain Evaluation Laboratory have been procured and grant funded staff for the laboratory have been hired. A clinical research training program for Orthopedic Surgery Residents has been designed and initiated. Appropriate statistical software and computer support for data analysis and design has been procured. Resources have been made available to advise investigators on optimal design and analysis options for their studies and the format for submission of research studies has been clarified to simplify protocol preparation.

Funding

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

		<u>FY 86</u>	<u>FY 87</u>
<u>OMA</u>	Civilian Personnel	631,180.55	653,076.36
	Contracts	41,275.90	39,964.93
	Supplies	239,869.74	297,881.20
	Ceep Equipment	26,876.09	17,215.14
	Travel	9,769.12	9.076.18
<u>OPA</u>	MEDCASE	237,000.00	241,152.77
<u>GRANTS</u>	VA (Psychophysiology Service)		

PUBLICATIONS

PUBLICATIONS

DEPARTMENT OF MEDICINE

Allergy Service

Bantz EW, Dolen WK, Nelson HS: A Double-Blind Evaluation of Skin Test Suppression Produced by Two Doses of Terfenadine. J. All. Clin. Imm., 80:99-103, 1987. (C)

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Endocrinology Service

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Asp AA, Hasbargen J, Blue P, and Kidd GS: Ectopic Thyroid Tissue on Thallium/Technetium Parathyroid Scan. Arch. Intern. Med. 147:595-596, 1987. (C)

Blue PW, Asp AA, Kidd GS: False Positive Parathyroid Thallium Per-technetate Subtraction Scintigraphy of the Mediastinum (in press Clin. Nucl. Med.).

Bornemann M, Hill SC, Kidd GS: Lactic Acidosis in Phenochromocytoma. Ann. Int. Med. (Letter) 107:259-260, 1987.

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Leidy JW, McDermott MT, Robbins RJ: Effect of Hypothyroidism and Hyperthyroidism on Hypothalamic Growth Hormone Releasing Factor in the Rat. Endocrinology, 120 (Suppl 1):110, 1987. (C)

McDermott MT, Kidd GS: The Role of Calcitonin in the Development and Treatment of Osteoporosis (in press Endocrine Reviews). (C)

McDermott MT, Burman KD, Hofeldt FD, Kidd GS: Lithium Associated Thyrotoxicosis. Toxicology Abstracts 10(5):14(2896), 1987.

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McDermott MT, Kidd GS: Chronic Hyperthyroidism and Glucose Tolerance. Diabetes 36(Suppl 1):169A, 1987. (C)

Schneider BK, Pickett CK, Zwillich CS, Weil JV, McDermott MT, et al: Influence of Testosterone on Breathing During Sleep. J. Applied Physiol. 61(2):618-23, 1986.

Sjoberg RJ, Kidd GS, Swanson EW, O'Barr TP, Corby DG, and Hofeldt FD: Effects of Hypothyroidism and Short-term Aging on Whole Blood Thromboxane and Arterial Prostacyclin Synthesis. (in press J. Lab. Clin. Med.). (C)

Hematology/Oncology

Ow CL, LeMar HJ, Weaver MJ: Literature Review Does Not Support Screening Proctosigmoidoscopy to Reduce Mortality From Colorectal Cancer. Clinical Research 35:744A, 1987 (abstract).

Iyengar VG, Peterson VM, Rundus C, and Robinson WA: Postburn Serum Inhibits In Vitro Production of Colony-Stimulating Factor by Mononuclear Peripheral Blood Cells. Int J Cell Cloning 4:472-482, 1986.

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(C) Direct result of approved registered protocol.

Nephrology Service

Asp A, Hasbargen J, Blue P, Kidd G: Ectopic Thyroid Tissue on Thallium/Technetium Parathyroid Scan. Vol 147, pp 595-596, 1987. (C)

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Rheumatology Service

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DEPARTMENT OF NURSING

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Staggers N: A Computer Manual for Nurses. Fitz His, p 36, FAMC pub., 1987.

(C) Direct result of approved registered protocol.

DEPARTMENT OF RADIOLOGY

Nuclear Medicine Service

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DEPARTMENT OF SURGERY

General Surgery Service

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(C) Direct result of approved registered protocol.

Clark JR: Cost-Effective Treatment of Esophageal Varices. Book entitled, Cost-Effective Surgery by Eiseman, Benjamin, WB Saunders publisher (in press).

McPhail JF, Tolls RM: Esophageal Cancer. Book entitled, Cost Effective Surgery by Eiseman, Benjamin, WB Saunders publisher (in press).

Otolaryngology Service

Barrs DM, Olsson JE: The Audiologic Evaluation of Cerebellopontine Angle Tumor Suspects: A Review of Tumor and Non-Tumor Suspects. Otolaryngology-Head and Neck Surgery 96:523-532, 1987.

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Speech-Language Rehabilitation Section

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Hashbrouck, JM: Performance of Adults with Auditory Figure-Ground Disorders Under Conditions of Unilateral and Bilateral Ear Occlusion. J Learning Disabilities 20:114-117, 1987.

Plastic Surgery Service

Kenevan, RJ: Medical Mobile Training Team, 1983-1985 - El Salvador. Military Medicine.

(C) Direct result of approved research protocol.

Urology Service

Horne DW: Primary Signet - Ring Cell Carcinoma of the Bladder: Report of a Case, Description of Unique Diversion, and a Review of the Literature. Urology (accepted for publication 15 August 1986 to appear in the September 1987 Urology Journal).

Horne DW: The Fitzsimons Experience with Nonseminomatous Germ Cell tumors 1976 - 1986. Proceedings of the Kimbrough Urologic Seminar, November 1986.

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MEDDAC

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Civilian Hospital

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Brinton LA, Schairer C, Haenszel W, Stolley P, Lehman HF, Levine R., and Savitz DA: Cigarette Smoking and Invasive Cervical Cancer. JAMA, Vol 255, No. 23, pp 3265-3269. (C)

(C) Direct result of approved registered protocol.

PRESENTATIONS

PRESENTATIONS

DEPARTMENT OF MEDICINE

Allergy Service

Bantz EW, Dolen WK, Nelson HS: Double-Blind Evaluation of Two Doses of Terfenadine. Presented: American College of Allergists, Las Vegas, Nevada, January 1987. (C)

Dolen WK: Fiberoptic Rhinolaryngoscopy in an Allergy Training Program. Presented: American College of Allergists, Las Vegas, Nevada, January 1987.

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

Goodman DL, McDonnell JT, Nelson HS, Vaughan TR, Weber RW: Chronic Urticaria Exacerbated by Antioxidant Food Preservatives, Butylated Hydroxyanisole (BHA) and Butylated Hydroxytoluene (BHT). Presented: American College of Allergists, Las Vegas, Nevada, January 1987.

Nelson HS, Weber RW, Dolen WK, Vaughan TR: Status Asthmaticus. Presented: American Academy of Allergy & Immunology, Washington, DC, February 1987.

Selner, JC, Wiener MB, Kolpke JW, Dolen WK, Staudenmayer H, Glover G: Rhinoscopy: Cross Sectional Area Measurements of Nasal Patency Comparison with Nasal Symptoms. Presented: American Academy of Allergy & Immunology, Washington, DC, February 1987.

Silvers WS, Weber RW, Ledoux RA, Tipton WR, Nelson HS: Aerobiology of the Colorado Rockies: Pollen Pattern Comparison of Denver and Vail. Presented: American College of Allergists, Las Vegas, Nevada, January 1987.

Silvers, WS, Weber RW, Dolen WK, Ledoux RA, Tipton WR, Nelson HS: Aerobiology of the Colorado Rockies: Comparative Pollen Counts of Aspen, Vail, and Aurora. Presented: Aspen Allergy Conference, July 1987.

Song SI, Lavins BJ, Zedalis D, Kossoy AF, Bantz EW, Vaughan TR, Weber RW, Nelson HS: The Efficacy of Astemizole in the Treatment of Seasonal Allergic Rhinitis. Presented: American College of Allergists, Las Vegas, Nevada, January 1987. (C)

Weber RW: Cross-Reactivity Among Chenopod-Amaranth Weeds: Skin Test Correlation. Presented: American College of Allergists, Las Vegas, Nevada, January 1987.

(C) Direct result of approved registered protocol.

Weber, RW: Local Anesthesia Allergy. Presented: American College of Allergists, Las Vegas, Nevada, January 1987.

Cardiology Service

Atchley SH: Exercise Factors Affecting Sensitivity and Predictive Accuracy of Thallium-201 Stress Testing. Presented: Third Annual Army Regional - American College of Physicians Meeting, San Francisco, CA, October 1986.

Endocrinology Service

Asp AA, Georgitis WJ, Waldron ET, and Kidd GS: Fine Needle Aspiration of the Thyroid in a Military Medical Center. Presented: Conference on Military Medicine, Bethesda, MD., October 1986.

Bornemann M, and Georgitis WJ: TRH Testing of Pituitary-Thyroid Axis in Early Hypothyroidism. Presented: Present Concepts in Internal Medicine Army Regional Meeting, American College of Physicians, San Francisco, CA., October 1986.

Leidy JW, McDermott MT, Robbins RJ: Effect of Hypothyroidism and Hyperthyroidism on Hypothalamic Growth Hormone Releasing Factor in the Rat. Presented: 69th Annual Meeting of the Endocrine Society, Indianapolis, IN., June 1987. (C)

McDermott MT, Swanson E, Jones LE, and Kidd GS: Chronic Hyperthyroidism and Glucose Tolerance. Presented: 3rd Annual Army ACP Meeting, San Francisco, CA., October 1986. (C)

McDermott MT, Hofeldt FD, and Kidd GS: Calcitonin Deficiency Does Not Affect the Rate of Radial Bone Loss. Presented: 3rd Annual Army ACP Meeting, San Francisco, CA., October 1986.

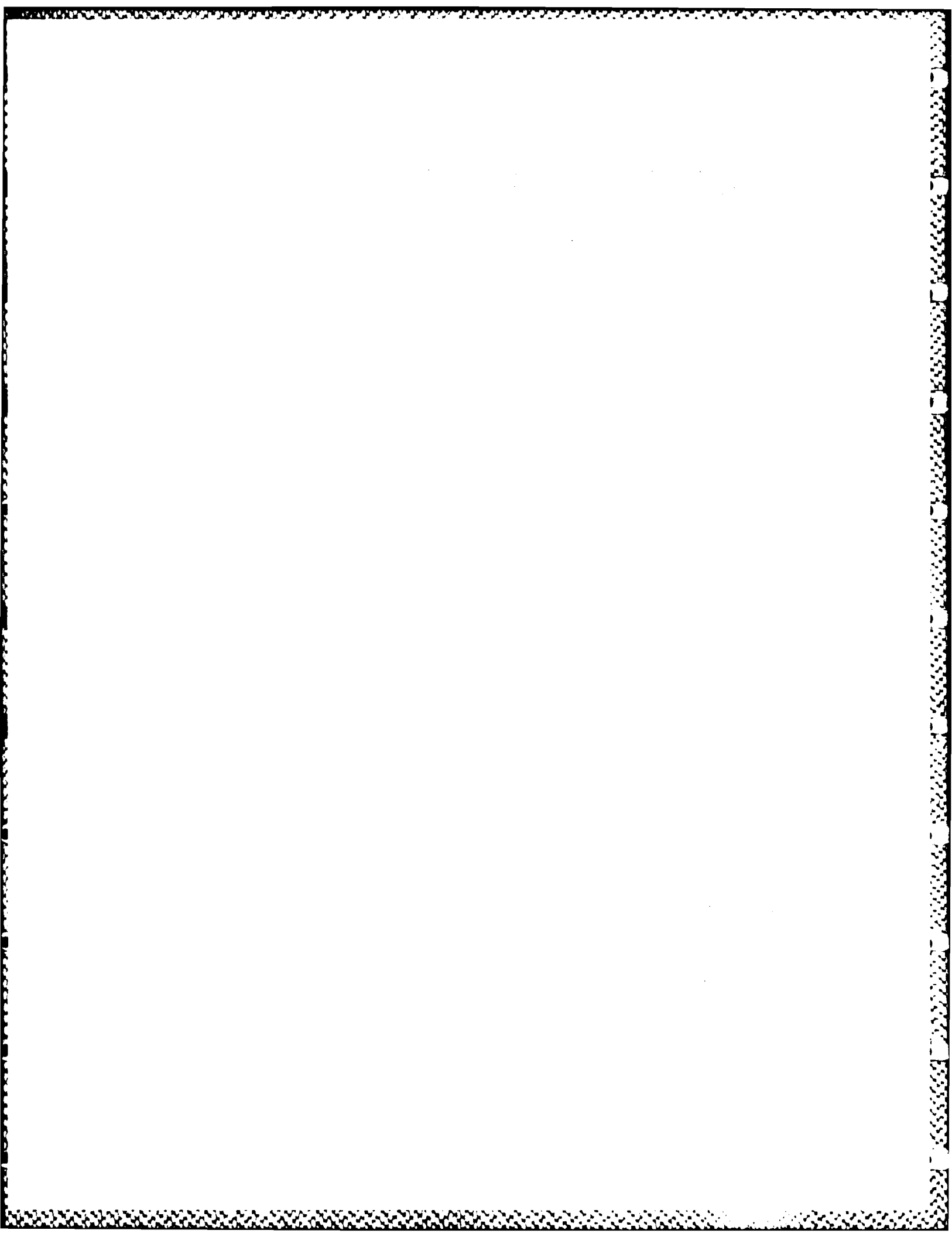
General Medicine Service

Weaver MJ: Critical Reading for the Practicing Internist: Therapy. Presented: Third Army Regional Meeting, San Francisco, CA., October 1986

Infectious Disease Service

Haburchak BR, Harrison SM, Andron LA, Grape R, Hannon RW, Clayton WL: Neuropsychiatric Evaluation of HIV Seropositive US Army Soldiers. Presented: III International Conference on AIDS, Washington, DC, June 1987.

(C) DIRECT result of approved registered protocol.



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DEPARTMENT OF PATHOLOGY

Reddy, B.V.V: Fine Needle Aspiration Biopsy (FNA bx) Experience at Fitzsimons Army Medical Center. Presented: Pediatric Oncology Group's (POG) Uniformed Services Oncology Consortium Meeting, Clearwater, FL, April 3, 1987. (C)

DEPARTMENT OF PEDIATRICS

Newborn Medicine Service

Carter BS: Prospectively Predicting Asphyxial Severity. Presented: 7th Annual Conference on Military Perinatal Research, Aspen, CO., July 1987. (C)

Frank CG: Prophylactic Intravenous Immunoglobulin (IVIG) in High Risk Neonates. Presented: 16th Aspen Conference on Perinatal Research, Aspen, CO., July 1987.

Pediatric Oncology

Mosijczuk A: Front-Loading Chemotherapy for Children with Increased Risk Medulloblastoma-Pilot Study to be used in POG. Presented: Semi-Annual Meeting of POG, St. Louis, MO, October 1986. (C)

Mosijczuk A: Increased Risk Medulloblastoma Proposed Pilot Study. Presented: Semi-Annual Meeting of POG, Clearwater, Florida, March 1987.

Mosijczuk A: Status of the ACTH Antiemetic Study. Presented: USOG Meeting, Clearwater Beach, Florida, March 1987. (C)

DEPARTMENT OF RADIOLOGY

Dydek GJ, Blue PW, McKinstry ER, Ghaed N: Pharmacy Service Support of a Nuclear Medicine Service. Presented: Colorado Society of Hospital Pharmacists - Second Annual Meeting, Denver, CO, November 1986.

Dydek GJ, Edwards MS, Blue PW, McKinstry ER: Pharmacy Support of a Hematology/Oncology and Nuclear Medicine Service. Ralph D. Arnold Pharmaceutical Services Management Conference, Washington, DC, May 1987.

(C) Direct result of approved registered protocol.

DEPARTMENT OF SURGERY

General Surgery Service

Conarro PA, Clark JR: Antireflux Surgery in Children After Repair of Tracheoesophageal Fistula. Presented: Gary Wratten Surgical Symposium, El Paso, TX, April 1987.

Herrold JW, Clark JR: Non-Toxic Megacolon in the Critically Ill Patient. Presented: Gary Wratten Symposium, El Paso, TX, April 1987.

Hovenga TL, Clark JR: Fine Needle Aspiration of Breast Masses. Presented: Gary Wratten Surgical Symposium, El Paso, TX, April 1987. (C)

Orthopedic Service

Colpini A: "Principles of Traction" Presented: Spring Orthopedic Day sponsored by Lakewood Orthopedic Clinic, St. Anthony Hospital Systems and FAMC. Lakewood, CO., May 1987.

Place HM: "Wrist and Forearm Trauma" Presented: Spring Orthopedic Day sponsored by Lakewood Orthopedic Clinic, St. Anthony Hospital Systems and FAMC. Lakewood, CO., May 1987.

Pruitt A: Intramedullary Fixation of Tibia Fractures: An Analysis of Fracture Healing. Presented: Med Central States Orthopedic Society Meeting. Colorado Springs, CO., April 1987.

Pruitt A: Orthopedic Complications of Burned Feet in Children. Annual Summer Meeting, Rocky Mountain Chapter of Western Orthopedic Association. Estes Park, CO., August 1987.

Otolaryngology Section (Speech Rehab)

Abkarian GG, Krappes T, King P: Enhancing Interaction in a Difficult to Test Child. Presented: American Speech-Language-Hearing Association Annual Convention, Detroit, MI, November 1986.

Hasbrouck JM, Mehlmann MB, Randle B, Nelson R: Fluency Diagnostics and Therapy. Presented: Metro Speech/Language Symposium, Colorado State Department of Education, Denver, CO, February 1987.

Otolaryngology Service

Barrs DM: Cochlear Implant. Presented: Anchorage Otolaryngologists and Audiologists, Anchorage, Alaska, June 1987.

(C) Direct result of approved registered protocol.

Barrs DM: Chronic Otitis Media. Presented: Madigan Army Medical Center, Tacoma, Washington, May 1987.

Lanier DM: Melanoma of the Head and Neck. Presented: University of Colorado Health Sciences Center and Colorado Maxillofacial Society, January 1987.

Urology Service

Castillo I, Wilson TM, Horne DW, Raife MJ: Testicular Involvement by Burkitts Lymphoma. Presented: Kimbrough Urologic Seminar, November 1986.

Horne DW: The Fitzsimons Experience with Nonseminomatous Germ Cell Tumors, 1976-1986. Presented: Kimbrough Urologic Seminar, November 1986.

Raife MJ: Spindle Cell Proliferation Mimicing Sarcoma of the Bladder. Presented: Kimbrough Urologic Serminar, November 1986.

Roy CR, Wilson TM, Horne DW, Raife MJ: Varicocele as Presenting Sign of Abdominal Mass - Case Report Burkitts Lymphoma of the Right Kidney. Presented: Kimbrough Urologic Seminar, November 1986.

(C) Direct result of approved registered protocol.

DETAIL SUMMARY SHEETS

DEPARTMENT OF MEDICINE

FAMC A.P.R (RCS MED300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 87 (2) Protocol WU#: 74/110 (3) Status: Ongoing

(4) Title: Reactive Hypoglycemia: An Analysis of Glucose-Insulin-Glucagon Interrelationships and Counter Hormonal Regulatory Factors

(5) Start Date: FY 71 (6) Est Compl Date: Indefinite

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

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

(11) Key Words: Insulin Coma Glucagon Blood Glucose Insulin Antagonists Fred D. Hofeldt, MD T.P. O'Barr, Ph.D. Annelie Shackelford, MT

(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: 399
e. Note any adverse drug reactions report to 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 the hypoglycemic study is to continue to investigate in our clinic population the glucose-insulin-glucagon and prolactin interrelationships and the response of counter-regulatory hormones to hypoglycemic stress. This project is a continuation of the previous project initiated in 1969 at the University of California Medical Center, Moffatt Hospital, San Francisco, CA.

(16) Technical Approach: The clinical research protocol involves evaluation of control subjects and hypoglycemic patients to assess the interrelationships of beta cell and alpha cell responsiveness to oral and intravenous glucose administration. Based upon findings in controls and patients with disease states, a classification system has been proposed. The data have allowed for an understanding of the basic pathophysiology of reactive hypoglycemia disorders. The clinical studies are being conducted in the Department of Medicine, Endocrine Clinic, with the assistance of an assigned GS-5 Medical Technician to perform blood sampling and to assist during the testing. During the glucose tolerance test, the patient has an indwelling catheter for frequent sampling of blood glucose, and is continually monitored by a cardiac monitor system and blood sampling. After

(16) Technical Approach - continued:

glucose administration, blood insulins, glucagons, growth hormones, prolactins and cortisol are sampled and values are determined by a sensitive radioimmunoassay. Blood glucoses are assessed by the Ames Reflectance Meter immediately after sampling. The procedure is designed to provide a minimum of patient inconvenience in the performance of these well standardized procedures. Many normal individuals experience a low blood sugar state sometime after glucose administration, the significance of a low blood glucose state is observed by recording appropriate adrenergic symptoms at the nadir of the glucose and determining if there is a counter hormonal responsiveness to defend the stress of a low blood glucose state. This approach allows strict definition of bona fide reactive hypoglycemia, and clearly distinguishes it from the benign low blood glucose states.

(17) Progress: This protocol represents a long standing clinical investigation effort which has resulted in multiple presentations and publications. During the current year, however, no patients were admitted to the study. The data from a multitude of previous patients studied has been entered into a computer data base and is being analyzed by two former physicians from Fitzsimons, Dr. Fred Hofeldt and Dr. Michael Bornemann. The PI and the associate investigators would like to keep this protocol active and request continuation for another year.

Presentations:

(1) Hofeldt, F.D.: Reactive Hypoglycemia: Update 1980. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO 16 January 1980.

(2) Sanders, L.R.: Reactive Hypoglycemia: Presented: Grand Rounds, University of Colorado Health Sciences Center, Denver, CO 13 March 1979.

(3) Sanders, L.R.: Reactive Hypoglycemia. Presented: Medical Grand Rounds, Denver General Hospital, Denver, CO 15 May 1979.

(4) Sanders, L.R.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Health Science Center, Denver, CO 11 April 1979.

(5) Hofeldt, F.D.: Hypoglycemia. Grand Rounds, Delgado Amphitheater, Tulane Medical School Charity Hospital, New Orleans, LA 28 April 1982.

(6) Hofeldt, F.D., and Scarlett, J.A.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO March 1982.

Publications:

- (1) Abrams, R., Hofeldt, F.D., Adler, R., O'Barr, T.P., and Morse, P.: Late Reactive Hypoglycemia in Hypothyroidism.
- (2) Hofeldt, F.D.: Transitional Low Blood Glucose States. Rocky Mountain Medical Journal 76:30, 1979.
- (3) McCowen, K.D., Adler, R.A., O'Barr, T.P., and Hofeldt, F.D.: Clinical Implications of Flat Oral Glucose Tolerance Test. Military Medicine 144:177, 1979.
- (4). Charles, M.A., Hofeldt, F.D., Dodson, L.E., Shackelford, A., Waldeck, N., Bunker, D., Coggins, J.T., and Eichner, H.: Comparison of Glucose Tolerance Tests and Mixed Meals in Patients with Idiopathic Reactive Hypoglycemia: Absence of Hypoglycemia after Mixed Meals. Diabetes 30:465, 1981.
- (5) Sanders, L.R., Hofeldt, F.D., Kirk, M., and Levin, J.: Refined Carbohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072, 1982.
- (6) Crapo, P.A., Scarlett, J.A., Kolterman, O., Sanders, L., Hofeldt, F.D., and Olefsky, J.: The Effects of Oral Fructose, Sucrose and Glucose in Subjects with Reactive Hypoglycemia. Diabetes Care 5:512, 1982.
- (7) Sanders, L.R., Hofeldt, F.D., Kirk, M.C., and Levin, J.: Refined Carbohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072-1075, 1982.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 79/105 (3) Status: Ongoing

(4) Title: Breathing Pattern Effects on Steady-State DLCO
Measurement

(5) Start Date: November 1979 (6) Est Compl Date: Indefinite

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

(9) Dept/Svc: Medicine/Pulmonary (10) Associate Investigators:
Neal B. Kindig, Ph.D.

(11) Key Words:
steady state DLCO
breathing pattern

(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 experimentally confirm theoretically determined corrections for breathing pattern during steady-state diffusion studies.

(16) Technical Approach: Breathing patterns with variations in inspiratory and expiratory breath-holds will be performed while the subject undergoes standard steady state diffusion measurement. If our approach is correct, mathematical corrections for breathing pattern will result in a constant value for diffusion capacity.

(17) Progress: Two subjects have participated in 5 studies of breathing pattern effects. Variation from predicted was noted during patterns with short apneustic indexes.

Presentations:

(1) Kindig, N.B.: DLCO Correction using PaCO Back Pressure Predicted from Venous Blood. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO 1981.

Presentations - continued

(2) Perry, M.E.: Simplified Room Air (A-a) $\dot{V}_2$ Calculation. Presented: Carl E. Temple Pulmonary Symposium, Denver, CO 1981.

Publications:

(1) Perry, M.E., Browning, R.J., Kindig, N.B.: The Abbreviated Alveolar Air Equation Revisited. Chest 80:763-764, 1981.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/118 (3) Status: Terminated

(4) Title: 5-Azacytidine in the Treatment of Acute Non-Lymphocytic
Leukemia

(5) Start Date: 1980

(6) Est Compl Date:

(7) Principal Investigator:
Elder Granger
MAJ, MC

(8) Facility: FAMC

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

(10) Associate Investigators:

(11) Key Words:

5-azacytidine

(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: 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". None

(15) Study Objective: To determine the efficacy of 5-azacytidine in patients with acute non-lymphocytic leukemia who have relapsed after conventional chemotherapy.

(16) Technical Approach: Patients who have proved to be refractory to standard forms of acute leukemia are given 5-azacytidine in an attempt to induce remission.

(17) Progress: Better therapy is now available for these patients.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 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:

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

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators:
T.P. O'Barr, Ph.D., DAC
Fred D. Hofeldt, COL, (Ret)
Robert J. Sjoberg, CPT, MC

(11) Key Words:
carbohydrate
Hyperthyroidism

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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: A new co-principal investigator has been assigned to this project, John A. Merenich, CPT, MC who is beginning his second year of Endocrinology fellowship. He has begun as of this date actively recruiting patients to try to finish up this study. Because the study is so complex and so time consuming, during the past year there was inadequate time available for the PI to continue this study. However, with the new co-principal investigator, it is hoped that we will be able to complete this study during the next physical year.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/121 (3) Status: Ongoing

(4) Title: An Evaluation of Pituitary and Thyroid Hormonal Response
to a 4-hour Continuous and a Bolus Intravenous Infusion
of TRH as a Useful Test of Thyroidal Functional Reserve

(5) Start Date: 1981 (6) Est Compl Date: 1987

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

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

(11) Key Words: thyroid function tests
pituitary
thyroid hormones
Thyrotropin
Michael Bornemann, COL, 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: 48
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e". None

(15) Study Objective: The objective of this study is to determine if the
diagnosis of mild or subclinical hypothyroidism can be more clearly es-
tablished by some integrated parameter reflecting both the pituitary and
thyroidal reserve responses to intravenous thyrotropin releasing hormone.

(16) Technical Approach: Three groups of subjects will be evaluated in this
protocol. Group 1 will consist of normal control patients; Group 2 will
consist of patients with mild hypothyroidism diagnosed by an elevated TSH
level but normal thyroid hormone levels; Group 3 will consist of patients
with the thyroid clinic with high-normal TSH values and normal thyroid
function tests, but who are clinical suspects of having mild
hypothyroidism. The patients will undergo two TRH infusion tests in a ran-
dom manner consisting of conventional bolus administration of 500 ug of TRH
solution and the constant infusion of TRH over a 4-hour period of 500 ug of
TRH diluted in normal saline and diffused at a rate of 2 ug/minute over the
4 hours using a Harvard infusion pump. The TSH values in the various
groups of patients will be determined and statistically analyzed for dif-
ferences between the groups.

(17) Progress: Thirty three patients and 15 controls have been studied to date. Further controls would be helpful, but in view of the advent of the new assays for TSH, we are preparing a manuscript based on the group studied to date.

Presentations:

(1) Bornemann, M.: Pitfalls in Mild Subclinical Hypothyroidism: Comparison of the TRH Bolus and Infusion. Submitted for Hugh Mahon Lectureship Award, FAMC, May 1983.

(2) Bornemann, M., Kidd, G.S., and Hofeldt, F.D.: Comparison of Thyrotropin Releasing Hormone Bolus and Infusion Testing in Patients with Suspected Subclinical Hypothyroidism. (Abst.) Clin. Res. 32:1, 1984.

(3) Bornemann, M., Kidd, G.S., and Hofeldt, F.D.: Comparison of Thyrotropin Releasing Hormone Bolus and Infusion Testing in Patients with Suspected Subclinical Hypothyroidism. Presented: Western Section, Western Meeting, Carmel, CA, February 1984.

(4) Bornemann, M. and Georgitis, W.: TRH Testing of Pituitary-Thyroid Axis in Early Hypothyroidism. Presented: Present Concepts in Internal Medicine, Army Regional Meeting ACP, 69-1, San Francisco, Ca, October 1986.

Publications: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 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, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

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

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

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ 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 abnormalities 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: One patient enrolled and studied. Her serum is frozen and awaiting assay.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 81/119 (3) Status: Ongoing

(4) Title: The Effect of Thyrotropin Releasing Hormone on Gonadotropin Releasing Hormone Stimulated Gonadotropin Secretion

(5) Start Date: 1981 (6) Est Compl Date: 1987

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

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

(11) Key Words:
hypothyroidism
gonadal dysgenesis

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

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: In order to gain a better insight into the mechanism of gonadal dysfunction in hypothyroidism, the objective of this protocol is to study the effect of a thyrotropin releasing hormone (TRH) infusion on basal and gonadotropin releasing hormone (GnRH) stimulated gonadotropins in normal subjects.

(16) Technical Approach: Ten normal males will be studied with either a normal saline infusion or a TRH infusion. During these infusions, GnRH will be given as a bolus with measurement of appropriate hormone to determine interaction between releasing hormones.

(17) Progress: Sixteen subjects have been studied and the data analysis is complete. The TRH infusion produced a statistically significant augmentation of the FSH response (both peak and total integrated response) to GnRH, while the LH response was unaffected.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 82/101 (3) Status: Terminated

(4) Title: Steroid and Immunosuppressive Drug Therapy in Idiopathic Crescentic Glomerulonephritis

(5) Start Date: 1982

(6) Est Compl Date: Terminated

(7) Principal Investigator:
James A. Hasbargen, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology

(10) Associate Investigators:

James E. Alow, MD

Howard A. Austin, MD

National Institutes of Health
Bethesda, Maryland

(11) Key Words:
immunosuppressive Agents
immunotherapy

(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 compare the efficacy of intravenous methylprednisolone vs. intravenous cyclophosphamide in the treatment of idiopathic crescentic glomerulonephritis. Comparison will be made of the number of favorable outcomes of renal function and renal pathology as well as drug related toxicities manifested by each treatment group at the time of the 6 study month.

(16) Technical Approach: Patients with idiopathic crescentic glomerulonephritis are randomized into one of two study groups to receive either monthly intravenous pulse methylprednisolone for six months or monthly intravenous pulse cyclophosphamide for 6 months. All patients are treated with oral prednisolone in addition. Effects of therapy are monitored with frequent histories and physical examinations as well as hematologic, urinalysis and renal function monitoring. At the end of 6 months a second renal biopsy is accomplished to determine the effect of the above mentioned therapy. Criteria for withdrawal from the study, retreatment of patients who exacerbate their course of glomerulonephritis, and analysis of the study are as indicated in the study protocol.

(17) Progress: Recommend discontinuation, secondary lack of 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 87 (2) Protocol WU#: 82/104 (3) Status: Ongoing

(4) Title: The Effect of Tamoxifen on Gynecomastia

(5) Start Date: 1982

(6) Est Compl Date: 1987

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

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:

Fred D. Hofeldt, MD

(11) Key Words:
tamoxifen
gynecomastia

Gerald S. Kidd, 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: 3

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 objective of this protocol is to evaluate, in a double-blind placebo controlled prospective trial, the effect of Tamoxifen on males with gynecomastia and to characterize any co-existent hormonal changes.

(16) Technical Approach: A randomized, double-blind placebo controlled study of the effects of Tamoxifen therapy on idiopathic gynecomastia will be performed. Breast size will be assessed by photographs, palpation and measurement of tissue.

(17) Progress: Seven subjects have completed the study. Three have dropped out: one simply did not return for final evaluation, one had a PCS move, one (lung cancer patient) had to have the code broken because of severe pain. One subject is currently under study. Patients with stage 1-3 gynecomastia had marked size and pain reduction. Patients with stage 4 & 5 had mainly pain reduction although some had variable decreases in size.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 82/114 (3) Status: Ongoing

(4) Title: Growth of Basal Cell Carcinoma Cells in Defined Medium
and Study of their Growth and Immunological
Characteristics

(5) Start Date: 1982 (6) Est Compl Date: 1988

(7) Principal Investigator: Charles F. Ferris, CPT, MS (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:
Ronald W. Grimwood, MD
(11) Key Words: basal cell, carcinoma J. Clark Huff, MD
Richard A.F. Clark, MC

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

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

(15) Study Objective: Growth and study of basal cell carcinoma cells
in culture.

(16) Technical Approach: The approach to culturing of basal cells has,
and will be the use of the media formulated by Dr. Ham's lab at the
University of Colorado in Boulder termed MCDB 153. We have been
successful to date in culturing normal cell carcinomas. This has
included an attempt utilizing fibronectin coated plates. We next will
be attempting growth utilizing basal cell tumors that we have success-
fully grown in nude mice. There is experimental evidence with other
tumors grown in nude mice to suggest that there is a greater success rate
of in vitro culture once the tumors have been grown in the animal model.

(17) Progress: Improved tissue culturing techniques.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 83/101 (3) Status: Terminated

(4) Title: Genetics of Exfoliatin B Production from Clinical Isolates of *Staphylococcus aureus*

(5) Start Date: 1983 (6) Est Compl Date: 1987

(7) Principal Investigator: Steven M. Opal, MAJ, MC (8) Facility: FAMC

Dept/Svc: MED/Inf. Dis. (9) (10) Associate Investigators: Pari L. Morse, GS-9

(11) Key Words:
exfoliatin B
staphylococcal plasmids

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

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

(15)
Study Objective: The objective of this study is to isolate plasmid DNA responsible for the production of exfoliatin B production in *Staphylococcus aureus* strains. The restriction endonuclease digestion pattern of this isolate will be compared with that of other exfoliatin B producers as well as reference strains from the CDC.

(16) Technical Approach: Staphylococcal plasmid DNA was isolated by cleared lysis technique and by cesium chloride ultracentrifugation density gradients. The isolated plasmid DNA was then run on agarose gel electrophoresis for molecular weight sizing. The endonuclease digestion pattern will then be obtained by digesting this plasmid with restriction endonuclease enzymes.

(18) Progress: None since the last review due to the loss of the principal investigator.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 83/106 (3) Status: Completed

(4) Title: Efficacy of Weekly Pulse Methotrexate in the Treatment of Rheumatoid Arthritis: A Double-Blind Crossover Study

(5) Start Date: 1983 (6) Est Compl Date: 1987

(7) Principal Investigator: Peter A. Andersen, MD
Sterling G. West, MD (8) Facility: FAMC
Walter Reed Army Medical
Brooke Army Medical Center

Dept/Svc: MED/Rheumatology (10) Associate Investigators: Robert G. Claypool, MD
Richard C. Welton, MD
Charles S. Via, MD

(11) Key Words:
methotrexate
rheumatoid arthritis

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

a. Date, Latest IRC Review: b. Review Results: Completed
c. Number of Subjects Enrolled During Reporting Period: 0
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". None

Study Objective: Evaluate effectiveness of weekly pulse MTX to control activity of RA in patients who have failed therapy with gold shots and D-Penicillamine; evaluate the potential of weekly pulse MTX to halt or decrease the progress of destructive changes of articular cartilage and bone and to evaluate the potential for toxicity of weekly pulse MTX.

(16) Technical Approach: Part I - 27 week double blind crossover study of MTX vs. placebo comparing joint counts, functional tests, laboratory parameters and subjective scores. Part II - Blinded comparison of pretreatment and 6month sequential roentgenographs of involved joints. Part III - Evaluation of biochemical liver function studies and comparison with sequential changes on liver biopsy.

(17) Progress: Data for Part II analyzed and manuscript completed and submitted for publication.

Presentations:

Nordstrom, D.M., West, S.G., Andersen, P.A., and Sharp, J.T.: A Controlled Prospective roentgenographic Study of Pulse Methotrexate. Presented: ARA Meeting, New Orleans, LA, June 1986.

Publications:

Andersen, P.A., et al: Weekly Pulse Methotrexate in Rheumatoid Arthritis. Ann Int Med 103:489-496, October 1985

Nordstrom, D.M., West, S.G., Andersen, P.A., and Sharp, J.T.: A Controlled Prospective Roentgenographic Study of Pulse Methotrexate. (Abstract) Arthritis and Rheumatism 29: (4 Supp):S58, 1986.

Nordstrom DM, West SG, Anderson PA, Sharp JT. A Controlled Prospective Roentographic Study of Pulse Methotrexate Therapy in Rheumatoid Arthritis. (Submitted for publicaition to Ann. Int. Med.)

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 83/107 (3) Status: Ongoing

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

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

(7) Principal Investigator: J. Ramsey Mellette, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology (10) Associate Investigators: John Adnot, LTC, MC

(11) Key Words:
retinoids
basal cell, carcinoma

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 15
d. Total Number of Subjects Enrolled to Date: 98
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Dry skin, chapped lips, myalgias.

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

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

(17) Progress: Ninety-eight patients were randomized prior to the choosing date of 06-28-87. Two patients have moved out of state and have been transferred to the programs in their respective locations. One patient is temporarily in Germany and is being followed by Linda Serwatka, M.D. Four patients are no longer in the program for the following reasons: (a) Two deceased, (b) One terminal cancer and (c) One randomized in error. Fourteen patients off medication permanently following adverse reactions consisting of back pain, macular degeneration, elevated triglycerides, relocated to Europe, wanted to stop medication, afraid of long term side effects, miscellaneous medical problems, mild cutaneous side effects, refused to continue medication, headaches, out of state and unable to follow on regular basis, and Stevens-Johnson Syndrome. Ten patients are on permanent dose of modification for the following reasons: mild cutaneous side effects, mild elevation triglycerides, mild anthalgias, moderate cutaneous side effects and gastric intestinal side effects.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 83/113 (3) Status: Ongoing

(4) Title: Growth of Human Keratinocytes

(5) Start Date: 1983 (6) Est Compl Date: 1986

(7) Principal Investigator: Charles F. Ferris, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:
Ronald E. Grimwood, MD
J. Clark Huff, MD
Phillip T. O'Barr, Ph.D., DAC

(11) Key Words:
keratin

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

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

(15) Study Objective: Growth and study of human kertainocytes in culture.

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

(17) Progress: Improved growth of cultures.

Publications:

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

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

Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 83/115 (3) Status: Terminated

(4) Title: The Effect of Oral Ketotifen on the Development of Sub-sensitivity to beta Agonists

(5) Start Date: 1984 (6) Est Compl Date: 1987

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

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

(11) Key Words: ketotifen W. Dolen, MAJ, MC
D. Goodman, CDR, MC
M. Muggelberg, MAJ, 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: 0
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 determine whether the drug ketotifen can prevent the development of subsensitivity to inhaled beta agonists in humans.

(16) Technical Approach: The bronchodilator response to inhaled terbutaline will be measured before and after chronic terbutaline administration during two periods of time, one when the patients are receiving in addition oral ketotifen, the second when they are receiving a placebo.

(17) Progress: Drug company supplying medication has suspended support for the protocol. It is reported that the collaborating facility, Wilford Hall Air Force Medical Center, has also suspended 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 87 (2) Protocol WU#: 83/117 (3) Status: Completed

(4) Title: The Role of Altered Arachidonic Acid Metabolism in the Atherogenesis and Bleeding Tendency of Hypothyroidism, and the Response of this System to Thyroid Hormone Replacement

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

(7) Principal Investigator: (8) Facility: FAMC
Gerald S. Kidd, LTC, MC
Robert J. Sjoberg, CPT, MC
T.P. O'Barr, Ph.D., DAC
Ellen Swanson, DAC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Donald G. Corby, COL, MC
(11) Key Words: Fred D. Hofeldt, COL, MC (Ret)
arachidonic acid metabolism
hypothyroidism

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor 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 effects of hypothyroidism or rat platelet thromboxane A₂ (TxA₂) and aortic ring prostacycline by measuring thromboxane B₂ (TxB₂) and 6-ketoprostaglandin Fl_α (6K-PGF_{1α}), respectively, in hypothyroid Sprague-Dawley rats. Second, to determine the effects of treatment on the same parameters with low and high dose levothyroxine.

(16) Technical Approach: Rats made hypothyroid and controls were sacrificed at various intervals after collecting blood, counting platelets and aggregating platelets. TxB₂ was measured after aggregation by specific RIA segments of aorta were removed, sliced and incubated. Incubate solutions (at various times) were removed for the measurement of 6K-PGF_{1α} by RIA. Similar procedures were performed on hypothyroid L-thyroxine treated rats.

(17) Progress: Study is completed. There has been one abstract published and one presentation has occurred. The final manuscript has not yet been published.

Publications and Presentations:

Sjoberg, R.J., Kidd, G.S., O'Barr, T.P., Wetherill, S., Corby, D., and Hofeldt, F.D.: Thromboxane and Prostacycline Generation in Hypothyroidism. Presented: Eastern Section, AFCE, Philadelphia, PA, October, 1984.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 83/122 (3) Status: Ongoing

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

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

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

(9) Dept/Svc: MED/Allergy (10) Associate Investigators: Alan F. Kossoy, MAJ, MC

(11) Key Words:
migraine
food hypersensitivity
prostaglandins

(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: 91
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: In this study the value of skin testing to a battery of food allergens will be determined in directing therapy and defining a diet which will cause a decreased frequency of migraine headaches in affected patients.

(16) Technical Approach: Approximately 100 patients will be randomly referred from the Neurology Clinic who have at least 3 migraine headaches a month. Those patients will, on a regular diet, keep dietary records and be taken off any chronic medications over a 30-day period. They will then undergo skin testing to 83 common foods and be placed on an allergy elimination diet for 30 days. If there is a reduction in the frequency of headaches, they will undergo an open challenge and if that is positive, they will undergo double-blind challenges.

(17) Progress: Ninety-one patients studied thus far.

Presentations:

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

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

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

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

Publications: Manuscript in preparation.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 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: 1989

(7) Principal Investigator: (8) Facility: FAMC
Gerald S. Kidd, LTC, MC
Thomas P. O'Barr, Ph.D., DAB
Fred D. Hofeldt, COL, MC (Ret)
Robert J. Sjoberg, MAJ, MC

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

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

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

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled 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: No patients have been studied during the last fiscal year because of time constraints in relation to patient care and teaching activities and the performance of other research objectives. The investigators still feel that the hypothesis formulated within this protocol remains valid, and that the experimental methodology is good in terms of investigating that hypothesis. We would like to actively recruit patients within the next several months and so respectfully request that this protocol be continued.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/100 (3) Status: Ongoing

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

(5) Start Date: 1984 (6) Est Compl Date: 1987

(7) Principal Investigator: (8) Facility: FAMC
Michael T. McDermott, MAJ, MC
Ray Vaughan, CPT, MC

(9) Dept: MED/Endocrine (10) Associate Investigators:
Stanley J. Szeffler, MAJ, MC
Harold S. Nelson, COL, MC

(11) Key Words:
theophylline
methylprednisolone
hyperthyroidism
hypothyroidism

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To study the effects of hyperthyroidism and hypothyroidism on the metabolism of theophylline and methylprednisolone.

(16) Technical Approach: Consenting hyperthyroid and hypothyroid patients will have a 12-hr or intravenous infusion of theophylline or methylprednisolone, or both, (on separate days), and hourly blood levels measured. The study will be done while thyroid function is abnormal and will be repeated when thyroid function is normal.

(17) Progress: One hypothyroid and 2 hyperthyroid patients have been studied while thyroid function was abnormal and again while normal. Four others have been studied while hyperthyroid, but have not yet become euthyroid. Theophylline metabolism has thus far been increased in hyperthyroidism and normal in hypothyroidism. Methylprednisolone metabolism appears to be normal in hyperthyroidism and reduced in hypothyroidism.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/101 (3) Status: Terminated

(4) Title: Antibiotic Therapy of Acute Exacerbations of Chronic
Bronchitis: A Controlled Study using TMP/SMX

(5) Start Date: 1984 (6) Est Compl Date: 1986

(7) Principal Investigator: Richard Kucera, CPT, MC (8) Facility: FAMC

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

(11) Key Words:
trimethaprim/sulfamethoxazole
chronic bronchitis

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

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

(15) Study Objective: This double-blind study was undertaken in an attempt to clarify whether a specific therapeutically useful antibiotic plays a significant role in acute exacerbations of chronic bronchitis. The drug to be used is TMP/SMX. The patient population will include patients with documented moderate to severe bronchitis by clinical symptoms and pulmonary function tests who have acute exacerbations of their symptoms.

(16) Technical Approach: Patients admitted with worsening pulmonary symptoms, who have no documented allergy to TMP/SMX undergo a battery of tests as a baseline and a patient questionnaire and physical exam and CXR. These are repeated on day 4 & 7 to see if there has been any improvement. On day 1 the patient is placed blindly on either a placebo or the study drug, and kept on it for seven days.

(17) Progress: Insufficient patients available to continue study.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/108 (3) Status: Terminated

(4) Title: The Effect of Ultraviolet Light (UVB) on the Production of Prostacyclin (PGI₂) by Cultured Human Microvasculature Endothelial Cells

(5) Start Date: 1983 (6) Est Compl Date: 1986

(7) Principal Investigator: James Fitzpatrick, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology (10) Associate Investigators:
Thomas P.O'Barr, Ph.D., DAC
Ellen Swanson, DAC
Don Mercill, DAC
Charles Ferris, CPT, MS

(11) Key Words:
UVB
endothelial cells
prostacyclin

(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 UVB in physiologic doses will stimulate the release of prostacyclin from human endothelial cells.

(16) Technical Approach: Endothelial cells will be cultured from a dipose tissue and irradiated with various doses of UVB and PGI₂ will be assayed by a RIA.

(17) Progress: Protocol terminated because source of endothelial cells has been lost and endothelial cells in stock were lost during a power shortage.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/115 (3) Status: Ongoing

(4) Title: Heterotransplantation of Basal Cell Carcinomas to Nude Mice

(5) Start Date: 1984 (6) Est Compl Date: 1988

(7) Principal Investigator: Charles F. Ferris, CPT, MS (8) Facility: FAMC

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

(11) Key Words: carcinoma, basal cell
transplantation
mice, nude
R.E. Grimwood, MD
J. Clark Huff, 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:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To develop an in-vivo model of human basal cell carcinoma in the athymic mouse.

(16) Technical Approach: Basal cell carcinoma tissue obtained from excess tissue obtained from Moh's surgery is transplanted to a subcutaneous pocket created by a linear incision on the abdomen of the nude mouse. The mouse will have been splenectomized and transplantation is followed by weekly intraperitoneal injections of antilymphocyte serum. Tumor weight is taken before implantation and measurements of tumor size taken at weekly intervals. Autoradiography and immunofluorescent studies are performed at the time of tumor harvest as well as routine histology and tumor weight.

(17) Progress: No substantive progress this year. Renewed collaboration with Dr. Grimwood is anticipated.

Presentations:

(1) Grimwood RE, Johnson CA, Kramer LC, Mercill DB and Huff JC: Hetero-transplantation of Human Basal Cell Epitheliomas in Nude Mice. Presented: SID Meeting, Washington, DC, May 1984.

(2) Grimwood, RE, Ferris CF, Nielsen LE, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude mice Produce and Deposit Fibronectin in the Extracellular Matrix. Presented: SID Meeting, Washington, DC, May 1985.

Publications:

(1) Grimwood RE, Harbel J, Clark RAF: Fibronectin in Basal cell Epitheliomas: Sources and Significance. Journal of Investigative Derm 82:145-149, 1984.

(2) Grimwood RE, Johnson CA, Ferris CF, Mercill DB, Mellette JR, Huff, JC: Transplantation of Human Basal Cell Carcinomas in Athymic Mice. Cancer

(3) Ferris, CF, Grimwood, RE, Kramer LC, Mercill DB and Huff JC: The Proliferating Cells of a Human Basal Cell Carcinoma are the Peripheral Palisaded Cells. Abst. Clinical Research, Vol. 33, No. 2, 636A, April 1985.

(4) Grimwood RE, Ferris CF, Mercill DB and Huff JC: The Proliferating Cells of Human Basal Cell Carcinoma are Located on the Periphery of Tumor Nodules. J. Investigative Derm. Clin. Res., Vol. 33 No. 4, Page 825A.

(5) Grimwood RE, Ferris CF, Mercill DB, Huff JC: The Proliferating Cells of Human Cell Carcinoma are Located on the Periphery of Tumor Nodules. J. Invest. Dermatol., Vol 86, No. 2, Pg 191-194, February 1986.

(6) Grimwood RE, Ferris CF, Nielson LD, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude Mice Produce and Deposit Fibronectin in the Extracellular Matrix. J. Invest. Dermatol., 87:42-46, 1986.

(7) Grimwood RE, Siegle RJ, Ferris CF and Huff JC: The Biology of Basal Cell Carcinomas - A Revisit and Recent Developments. J. Dermatol. Surg. Oncol., 12:8, August 1986.

(8) Siegle R, Grimwood R: Athymic Mice - A Model for the Transplantation of Human Basal Cell Carcinoma. J. Dermatol. Surg. Oncol., 12:6, June 1986, pp. 646.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/119 (3) Status: Ongoing

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

(5) Start Date: 1984

(6) Est Compl Date: 1987

(7) Principal Investigator:
Michael T. McDermott, MAJ, 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: _____ 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". 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: Two patients have been studied at FAMC. Neither improved on cyclosporine or prednisone. No toxicity noted. Two from WRAMC with acute Graves' ophthalmopathy have shown a good response. The results of other patients studied at other centers are not yet available to me.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/100 (3) Status: Ongoing

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

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Continuing to accrue.

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/101 (3) Status: Ongoing

(4) Title: Combined Modality Treatment for Stages III and IV
Hodgkin's Disease - MOPP #6, Phase III
SWOG #7808

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/102 (3) Status: Ongoing

(4) Title: Combined Modality Therapy for Breast Carcinoma, Phase III
SWOG #7827

(5) Start Date: 1979 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/104 (3) Status: Completed

(4) Title: The Treatment of Chronic Stage CML with Pulse, Intermittent
Busulfan Therapy with or without Oral Vitamin-A, Phase III
SWOG #7984

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/109 (3) Status: Completed

(4) Title: Cis-Platinum in the Treatment of Refractory Epidermoid
Carcinoma of the Penis, Phase II
SWOG #8026

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/110 (3) Status: Completed

(4) Title: The Treatment of Resected Poor Prognosis Malignant
Melanoma: State I: Surgical Excision vs. Surgical Excision +
Vitamin A, Phase III
SWOG #8049

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/111 (3) Status: Terminated

(4) Title: (Intergroup Mesothelioma Study #1), Radiotherapy with and without Chemotherapy for Malignant Mesothelioma Localized to one Hemithorax, Phase III
SWOG #8094

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
chemotherapy

(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 SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/113 (3) Status: Terminated

(4) Title: Treatment of Advanced Seminoma (Stage cII(N₄) + cIII)
with Combined Chemotherapy and Radiation Therapy, Phase III
SWOG #8104

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
chemotherapy

(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 SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 85/114 (3) Status: Ongoing

(4) Title: Management of Disseminated Melanoma, Master Protocol,
Phase III
SWOG #8107

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Closed temporarily.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/115 (3) Status: Terminated

(4) Title: Treatment of Advanced Germ Cell Neoplasms of the Testis: A Comparison of Remission Induction with Vinblastine, Bleomycin & Cis-Platinum (VBP) vs. Vinblastine, Cis-Platinum & VP-16-213 (VPV); Surgical Removal of all Residual Tumor Following Remission Induction: Comparison of Maintenance Therapy with Cyclophosphamide, Actinomycin-D, Adriamycin & Vinblastine vs. Observation, Phase II

SWOG #8110

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
chemotherapy

(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 SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/120 (3) Status: Completed

(4) Title: Comparison of BCG Immunotherapy and Adriamycin for
Superficial Bladder Cancer, Phase III
SWOG #8216/38

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/121 (3) Status: Terminated

(4) Title: Evaluation of Combined or Sequential Chemo-Endocrine
Therapy in the Treatment of Advanced Adenocarcinoma of
the Prostate, Phase III
SWOG #8219

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
chemotherapy

(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 SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 85/122 (3) Status: Ongoing

(4) Title: Treatment of Advanced Bladder Cancer with Preoperative
Irradiation and Radical Cystectomy vs. Radical Cystectomy
Alone, Phase III
SWOG #8221

(5) Start Date: 1982 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results;
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/123 (3) Status: Completed

(4) Title: Correlation Between Progesterone Receptor and Response to
Tamoxifen in Patients with Newly Diagnosed Metastatic
Breast Disease, Phase II
SWOG #8228

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/124 (3) Status: Completed

(4) Title: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs. Sequential Half-Body Radiotherapy + Vincristine, Prednisone for Maintenance or Consolidations. Evaluation of Half-Body Radiotherapy + Vincristine-Prednisone for Patients who Fail to Achieve Remission Status with Chemotherapy Alone, Phase II

SWOG #8229/30

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/126 (3) Status: Completed

(4) Title: Evaluation of Continuous Infusion Vinblastine in Gastric
Carcinoma, Phase II
SWOG #8235

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/132 (3) Status: Ongoing

(4) Title: Evaluation of Adjuvant Therapy and Biological Parameters
in Node Negative Operable Female Breast Cancer,
Intergroup Study
SWOG #8294

(5) Start Date: 1982 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

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: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/133 (3) Status: Ongoing

(4) Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation
Versus Radiation Plus Chemotherapy (FOMi/CAP), Phase III
SWOG #8300

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/136 (3) Status: Ongoing

(4) Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER
Negative Stage II Carcinoma of the Breast, Phase III
SWOG #8313

(5) Start Date: 1974 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/139 (3) Status: Ongoing

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

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Continuing to accrue.

Publications and Presentations: None

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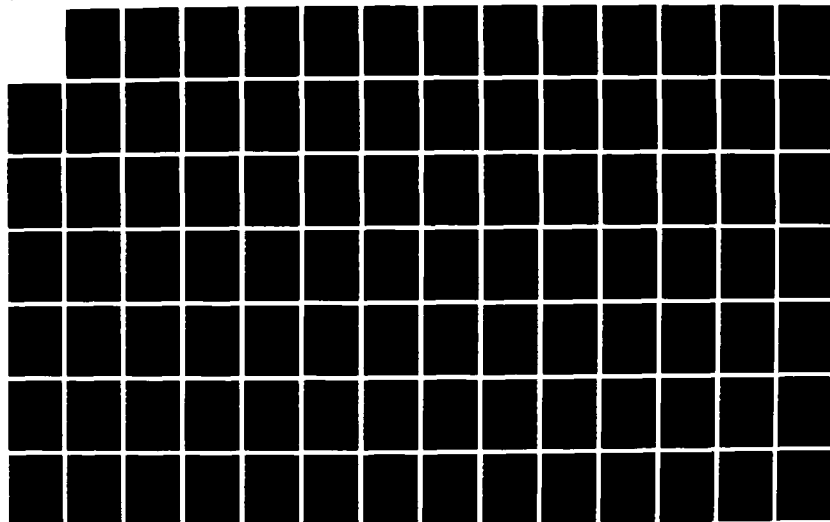
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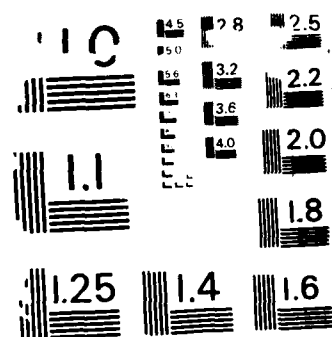
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FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/141 (3) Status: Ongoing

(4) Title: Evaluation of DTIC in Metastatic Carcinoid, Phase II
SWOG #8411

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/142 (3) Status: Ongoing

(4) Title: Evaluation of Tamoxifen in Unresectable and Refractory
Meningiomas, Phase II
SWOG #8415

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/143 (3) Status: Completed

(4) Title: Evaluation of Cisplatinum in Unresectable Diffuse
Malignant Mesothelioma, Phase II
SWOG #8418

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/145 (3) Status: Terminated

(4) Title: Radiation Therapy + 5-Fluorouracil vs Sandwich SMF
Chemotherapy + Radiation Therapy as Adjuvant Surgical
Treatment of Pancreatic Cancer, Phase III-Intergroup
NCI Intergroup #0031
SWOG #8492

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
chemotherapy

(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 SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 85/147 (3) Status: Ongoing

(4) Title: HLA and Gm Genes in Systemic Lupus Erythematosus
Antibody Expression

(5) Start Date: 1985 (6) Est Compl Date: 1988

(7) Principal Investigator: Christopher LeSueur, MD
Sterling West, MD (8) Facility: FAMC

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

(11) Key Words: lupus erythematosus, systemic
HLA antigens Moses Shanfield, 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: 14
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 see if patients with systemic lupus erythematosus
have increased prevalence of any HLA and Gm genes as it relates to their
autoantibody expression compared to a control group.

(16) Technical Approach: After patient education and consent form is
signed, the patient has eight tubes of heparinized blood drawn for HLA and
Gm typing. The patient's clinical symptoms, signs and other laboratory
parameters are collected according to protocol and correlated with the
patient's HLA and Gm typing.

(17) Progress: We have collected an additional 14 patients. The remainder
of patients will be collected over the next six months. Many need only Gm
typing due to previous HLA typing from another institution prior to coming
to FAMC.

Publications and Presentations: All data will be collected by 1 Jan 88 and
presented at the National ARA meeting in May 1988. Publications to follow.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/150 (3) Status: Terminated

(4) Title: Reactive Hyperemia as a Function of Control and Duration
of Disease in the Type I Diabetic

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

(7) Principal Investigator: Robert H. Slover, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
Mark S. Hayes, CPT, MC
Ronald J. Portman, MAJ, MC

(11) Key Words:
hyperemia
diabetes mellitus

(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: Transcutaneous oxygen monitoring of hyperemic
response could serve as a rapid screen of glucose control in a population
and of changing patterns of control longitudinally in an individual
patient. We plan to study 10 patients with duration of disease greater
than five years, 10 with duration 5-10 years, and 10 with duration greater
than ten years, as compared to a population of 60 controls. We shall
determine post ischemic hyperemia in each child. In diabetic subjects we
plan to obtain serum glycohemoglobin, creatinine, 24-hour urine for
creatinine clearance and glucose and to determine mean blood glucose. We
will analyze data obtained in the following areas: TCO₂, (transcutaneous
PO₂, ischemia, TCO₂ maximal response to post ischemic state and time to
return to baseline (duration of response).

(16) Technical Approach: Subjects are studied with a transcutaneous oxygen
monitor with the electrode (37⁰) placed on the left forearm allowing ten
minutes for equilibration. Blood pressure cuff is inflated to 40-50 mm mer-
cury above noted systolic pressure and left in place for four minutes. In
diabetic patients hemoglobin A1C, mean blood glucose, GFR, and 24-hour uri-
nary glucose are obtained.

(17) Progress: It has proven impossible to obtain the necessary patients
and time to allow completion of the project. There has been no progress
made on this study over the past two years.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/151 (3) Status: Completed

(4) Title: Adrenal Function in Malignancy

(5) Start Date: 1980

(6) Est Compl Date: 1986

(7) Principal Investigator:
Michael T. McDermott, MAJ, MC
Tony L. Walden, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Michael Witte, MAJ, MC
Elder Granger, CPT, MC
Gerald S. Kidd, LTC, MC

(11) Key Words:
bronchogenic carcinoma
impaired adrenal reserve

(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: 45 Ca pts/30 controls
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, premortem, those patients with known bronchogenic carcinoma and impaired adrenal reserve secondary to adrenal metastases.

(16) Technical Approach: A short ACTH stimulation test will be completed on patients with biopsy proven bronchogenic carcinoma. Patients being treated with steroid preparations will be excluded.

(17) Progress: The mean cortisol response to ACTH was similar in the 45 cancer patients and the 30 controls, but 2 cancer patients clearly had deficiency responses indicating subclinical adrenal insufficiency (decreased adrenal reserve).

Publications and Presentations: In preparation.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/153 (3) Status: Completed

(4) Title: Simultaneous Cis-Platinum + Radiation Therapy Compared
with Standard Radiation Therapy in the Treatment of
Unresectable Squamous or Undifferentiated Carcinoma
of the Head & Neck, Phase III
SWOG #8493

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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 is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See protocol

(17) Progress: Sufficient accrual, protocol closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/157 (3) Status: Ongoing

(4) Title: Phase III Study to Determine the Effect of Combining
Chemotherapy with Surgery and Radiotherapy for Resectable
Squamous Cell Carcinoma of the Head and Neck
SWOG #8590

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
chemotherapy

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

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/158 (3) Status: Ongoing

(4) Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole Plus 5-Fluorouracil as Surgical Adjuvant treatment for Resectable Adenocarcinoma of the Colon, Phase III-Intergroup
SWOG #8591

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 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: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/165 (3) Status: Ongoing

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

(5) Start Date: 1985

(6) Est Compl Date: 1988

(7) Principal Investigator:
R.W. Weber, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

(11) Key Words:
pollen
hypersensitivity
allergens

R. Ledoux
D. Zedalis, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

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

(16) Technical Approach: Anti-sera will be raised in rabbits and subjects to crossed immunoelectrophoresis and cross radioimmuno-electrophoresis to identify antigenic proteins and allergic proteins. Western blot technique will be used to separate constituents. Cross allergenicity will be assessed by ELISA inhibition with human allergenic sera.

(17) Progress: Antisera successfully raised to 6 extracts. Cross allergenicity studies progress.

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

Publications: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/166 (3) Status: Ongoing

(4) Title: Colon Inflammation in Reiter's Syndrome: Response to Sulfasalazine. Results in a Controlled Study

(5) Start Date: 1985 (6) Est Compl Date: 1989

(7) Principal Investigator: David Nordstrom, MD
Sterling West, MD
Peter Andersen, MD (8) Facility: FAMC

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

(11) Key Words:
Reiter's 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: 35
d. Total Number of Subjects Enrolled to Date: 55
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 see if patients with idiopathic Reiter's syndrome have colon inflammation and to see (in double-blinded fashion) if this responds to Sulfasalazine.

(16) Technical Approach: Colonoscopy with biopsy is performed on Reiter's patients and controls (patients with inflammatory arthritis that is not Reiter's).

(17) Progress: Patients and controls continue to be added to the protocol. Although numbers are still small, patients with Reiters seem to have a favorable response to Sulfasalazine, and their microscopic inflammation improves as well.

Publication: Nordstrom DM, West SG, Freeman S, Reddy V: HLA-B27 Positive Enterogenic Ractive Arthritis: Response of Arthritis and Microscopic Colitis to Sulfasalazine. Arthritis Rheum. 30:524, 1987.

Presentation: HLA-B27 Positive Enterogenic Reactive Arthritis: Response of Arthritis and Microscopic Colitis to Sulfasalazine. Presented: Nat. Am. Rheu. Ass., Washington, DC, July 1987.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 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:

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

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

(11) Key Words: thyroid diseases thyroid function tests thyroid gland
William J. Georgitis, MAJ, MC
Michael T. McDermott, MAJ, MC
Peter Blue, LTC, MC
Stephen M. Manier, MAJ, MC
Tony L. Walden, CPT, MC

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

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the ef-
fect 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: Two new patients were studied during FY 87 without complica-
tions or difficulties. The data so far analyzed appears to be negative in
terms of demonstrating an abnormal perchlorate discharge test in older
patients without known thyroid disease. However, during FY 88, we need to
study several more patients to finish up this protocol. Request continua-
tion of 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 87 (2) Protocol WU#: 85/170 (3) Status: Completed

(4) Title: A Comparison of Leuprolide with Flutamide and Leuprolide
in Previously Untreated Patients with Clinical Stage D2
Cancer of the Prostate, Phase III-Intergroup
SWOG #8494

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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 is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Sufficient accrual, study closed.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/173 (3) Status: Ongoing

(4) Title: The Effects of Gonadal Steroids on Arachidonic Acid
Metabolites and Angiotensin Converting Enzyme Activity
in Female Rats

(5) Start Date: Nov 85 (6) Est Compl Date: FY 87

(7) Principal Investigator: Tony L. Walden, CPT, MC
William J. Georgitis, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald S. Kidd, LTC, MC
Michael T. McDermott, MAJ,
Michael Bornemann, COL, MC
Arnold A. Asp, CPT, MC
Albert McCullen, MAJ, VC
T. Phillip O'Barr, DAC
Donald G. Corby, COL, MC
Ellen Swanson, DAC
Sharon Noble, DAC
Lawrence E. Jones, DAC

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

(14) a. Date, Latest IRC Review: 4 Aug 86 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 48 rats
d. Total Number of Subjects Enrolled to Date: 48 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: The investigation will examine the effects of sex
steroids on arachidonic acid metabolites and angiotensin converting enzyme
activity in female rats.

(16) Technical Approach: This study examines the effects of oophorectomy
and sex steroids on serum and lung ACE activity and prostaglandins in
female rats. The rats were divided into four groups - shams, castrates,
castrates treated with estradiol, and castrates treated with progesterone
delivered by Alzet osmotic minipumps.

(17) Progress: No alterations in prostaglandins were found. ACE results
are to be incorporated in a report with results found from a previous study
in male rats. Further investigation of prostaglandins may be done and
protocol should remain ongoing.

Presentations:

Georgitis W, Walden T, Noble S, McCullen A, Kidd GS: Oophorectomy and Sex Steroids Affect Angiotensin-Converting Enzyme Activity. Presented: Endocrine Society, Anaheim, CA, June 1986.

Walden TL, Georgitis WJ, Noble S, and Kidd GS: Oophorectomy and Sex Steroids Affect Angiotensin-Converting Enzyme Activity. Presented: Colorado Associate's Meeting, American College of Physicians Meeting, Denver, CO, April 1986.

Publications:

Georgitis W, Walden T, Noble S, McCullen A, and Kidd GS: Oophorectomy and Sex Steroids Affect Angiotensin-Converting Enzyme Activity. Endocrinology 118 (Suppl 1) 157 (Abs 506), 1986.

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

- (1) Date: 30 Sep 87 (2) Protocol WU#: 85/174 (3) Status: Ongoing
- (4) Title: Evaluation of Combination Chemotherapy Using High Dose
ARA-C in Adult Acute Leukemia and Chronic Granulocytic
Leukemia in Blastic Crisis, Phase III
SWOG 8326/27
- (5) Start Date: 1983 (6) Est Compl Date: Indefinite
- (7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC
- (9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC
- (11) Key Words:
drug therapy
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 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: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.
- (16) Technical Approach: See Protocol
- (17) Progress: Ongoing.
- Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/100 (3) Status: Ongoing

(4) Title: Assessment of Nonspecific Decrease in Skin Test Reactivity
During Immunotherapy

(5) Start Date: 1986 (6) Est Compl Date: 1988

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

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

(11) Key Words:
skin test
immunotherapy

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

(15) Study Objective: To determine whether there is a nonspecific decrease
in skin test reactivity to unrelated extracts during immunotherapy.

(16) Technical Approach: Patients placed on immunotherapy will receive pe-
riodic titrated skin tests to allergens in the treatment sets, as well as
allergens not in the treatment sets, as well as skin tests to histamine and
compound 48/80.

(17) Progress: In progress, active, 2 patients are actively enrolled, 4
are completed.

Publications and Presentations: None at present.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/102 (3) Status: Terminated

(4) Title: Evaluation of Aziridinylbenzoquinone (AZQ) (NSC-182986)
in Refractory and Relapsing Myeloma, Phase II
SWOG #8310

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
chemotherapy

(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 SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Protocol terminated.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/103 (3) Status: Ongoing

(4) Title: Evaluation of Low Dose Ara-C versus Supportive Therapy
Alone in the Treatment of Myelodysplastic Syndromes
(ECOG EST 4483)
SWOG #8592

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
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 in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/104 (3) Status: Ongoing

(4) Title: Comparison of Quantitative Immuno-electrophoresis (QIE),
Skin Prick Testing, RAST Inhibition, and ELISA Inhibition
(EI) Methods for Determination of Allergen Extract
Potency

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

(7) Principal Investigator: William K. Dolen MAJ, MC (8) Facility: FAMC

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

(11) Key Words: Robert L. Ledoux, DAC
immuno-electrophoresis
enzyme-linked immunosorbent assay

(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 examine the correlation between several methods by
which an allergen extract of unknown potency can be compared to a reference
extract.

(16) Technical Approach: Sera will be collected from persons allergic to
cat, artemesia, and used to assess the potency of allergic extracts by EAST
(ELISA) inhibition.

(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 87 (2) Protocol WU#: 86/105 (3) Status: Ongoing

(4) Title: Immune Response in Dialysis Patients Receiving
Desferrioxamine

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

(7) Principal Investigator: (8) Facility: FAMC
Robert W. Hull, MD
James A. Hasbargen, MAJ, MC

(9) Dept/Svc: MED/IntMed/Neph (10) Associate Investigators

(11) Key Words:
dialysis
desferrioxamine

(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: This study is designed to assess immunologic
parameters in a cohort of 12 dialysis patients before, during, and at the
completion of desferrioxamine therapy. Serial serum trace element deter-
minations will be made before and at the completion of therapy.
Study was amended by COL Shetler at the time of approval to include
controls.

(16) Technical Approach: We are measuring T lymphocytes subsets and mitogen
stimulation using Con A and PHA.

(17) Progress: No further enrollement. Have lengthened follow-up on en-
rolled patients.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/106 (3) Status: Terminated

(4) Title: Pharmacokinetics of Melphalan in Renal Insufficiency
and Failure

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

(7) Principal Investigator: (8) Facility: FAMC
Richard E. Whitlow, CPT, MC

(9) Dept/Svc: MED/Nephrology (10) Associate Investigators
James A. Hasbargen, MAJ, MC
Elwyn Chadwick, SSG, DCI

(11) Key Words:
kidney failure
melphalan

(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: This is strictly a prospective study which is not
blinded or controlled. Medications will be acquired through the National
Institute of Health, National Cancer Institute under a special investiga-
tion protocol and is titled melphalan, L-phenylalanine Mustard, L-PAM.
Prednisone will also be acquired through the Fitzsimons Pharmacy. The sub-
ject population to be observed are those patients, either sex, who require
melphalan for the treatment of their underlying disease and who do not have
an obstructive nephropathy, pregnant female, or patients less than 18 years
old.

(16) Technical Approach: A. Pharmacokinetics handling of Melphalan will be
approached by looking at Melphalan and its by products by high pressure
liquid chromatography preadministration and at 5, 10, 15, 20, 30, 45, 60,
90, 180, 240 minutes post administration.

(17) Progress: None, recommend termination of study due to lack of 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 87 (2) Protocol WU#: 86/107 (3) Status: Ongoing

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

(5) Start Date: 1986 (6) Est Compl Date: 1988

(7) Principal Investigator: T. Ray Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators
Richard W. Weber, COL, MC
Lawrence W. Larsen, CPT, MC

(11) Key Words:
drug hypersensitivity

(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: We have previously demonstrated in the guinea pig
tracheal model the development of subsensitivity to beta-adrenergic
agonists, it would be advantageous to have an animal model for subsen-
sitivity with antihistamine and anti-cholinergic drugs.

(16) Technical Approach: In-vivo blockade of histaminic receptors in al-
bino Dunken-Hartley guinea pigs with one or more of various currently
available antihistaminic agents will be achieved with the serial injec-
tions. Subsequently in in-vitro studies we will excise tracheal ring seg-
ments or peripheral lung strips. Dose response curves for histaminic
stimulation will also be done.

(17) Progress: Completed work with stability of methylcholine and atropine
methonitrate. Currently in planning stage to evaluate other antiasthmatic
drugs as per protocol.

Presentations: American College of Allergist National Meeting, 1986

Publications: Ann. All. 56:117-119, 1986.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/108 (3) Status: Ongoing

(4) Title: Investigation of Alterations in Angiotensin Converting Enzyme Activities Resulting from Different Prolactinemic States in the Male Sprague-Dawley Rat

(5) Start Date: 1986 (6) Est Compl Date: FY 87

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

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald S. Kidd, COL, MC
Tony L. Walden, CPT, MC
Arnold Asp, MAJ, MC
Ellen Swanson, DAC
Sharon Noble, DAC
Lawrence E. Jones, DAC
Charles F. Ferris, CPT, MS

(11) Key Words:
angiotensins

prolactinemic states

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

(14) a. Date, Latest IRC Review: 7 Jan 86 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 60 rats
d. Total Number of Subjects Enrolled to Date: 60 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". None

(15) Study Objective: This experiment is designed to investigate whether the activity of angiotensin converting enzyme in male Sprague-Dawley rats is altered by prolactin.

(16) Technical Approach: Four groups of rats were treated with vehicle, pergolide, metoclopramide, and metoclopramide plus testosterone delivered by Alzet osmotic minipumps for two weeks.

(17) Progress: A treatment effect was achieved but ACE and parameters of gonadal status were unaltered by the different states of prolactin achieved by the drugs. Further work may be done on frozen specimens in storage.

Presentations: None

Publications: Georgitis W., Asp., Swanson E., Noble S., and Kidd G: Angiotensin Converting Enzyme Activity in Different Prolactinemic States. (Abstract) Clinical Res. 35(1):119A, 1987.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/109 (3) Status: Ongoing

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

(5) Start Date: 1986 (6) Est Compl Date: Feb 1988

(7) Principal Investigator: John Merenich, CPT, MC
Gary Jackson, CPT, MC (8) Facility: FAMC

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

(11) Key Words: calcium
vitamin D rifampin
vitamin D deficiency
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 3
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: The purpose of this study is to see if INH therapy alters vitamin D and/or calcium metabolism in a significant manner. This may then lead to further evaluation to determine if patients would benefit from vit D or calcium supplementation while receiving INH therapy.

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

(17) Progress: Approximately six patients have been entered in the study as of this date. The previous principal investigators have departed Fitzsimons. Two new co-principal investigators have been assigned. They are CPT John Merenich and CPT Gary Jackson. The data has not been analyzed as the Vitamin D samples are in storage awaiting completion of the study. Request continuation of the protocol with the new principal investigators noted.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/110 (3) Status: Ongoing

(4) Title: The Use of Standardized Allergen Extracts in Prick Skin Testing

(5) Start Date: 1986

(6) Est Compl Date: 1988

(7) Principal Investigator:
William K. Dolen, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

(11) Key Words:
allergen extracts
skin test

Robert Ledoux, DAC

(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: 16 _____

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 determine the optimum concentration of standardized allergen extracts for routine use in prick skin testing.

(16) Technical Approach: Atopic and nonatopic patients will receive skin testing with standardized and nonstandardized extracts in order to determine whether the standardized extracts differ from the conventional ones in potency and incidence of false positive reactions.

(17) Progress: Work in progress, active. Eleven nonatopic patients have been tested, and 5 atopic subjects. Anticipate completion by July, 1988. New Fellows to be assigned to protocol.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/114 (3) Status: Ongoing

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

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

(7) Principal Investigator: Shannon M. Harrison, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Inf Dis

(10) Associate Investigators

Leo A. Andron, LTC, MC

(11) Key Words:
HIV virus

Roland N. Hannon, PA-C, CW3 (RET)

J. David Bales, LTC, MC

Robert H. Gates, MAJ, MC

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

(14) a. Date, Latest IRC Review: 9/86 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 125
d. Total Number of Subjects Enrolled to Date: 225
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 HTLV-III infection within the general military population in-
cluding 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: As noted an additional 125 patients have been added to the
Natural History Study in the previous year. However, there is about a 25%
attrition rate in terms of new patients added that dropped from follow-up
either through death, moving to another facility or being separated from
military beneficiary status. The data to date would suggest in fact that
the mean progression rate is 14% per year for 1 Walter Reed stage (this is
information of a sensitive nature for official use only).

Presentations: To Army ID & PM group, Washington, DC, September 1986.

Publications: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/115 (3) Status: Ongoing

(4) Title: A Prospective Evaluation of Neuropsychiatric Sequelae
of HTLV-III Disease

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:
William Clayton, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: of Medicine

(10) Associate Investigators

Shannon M. Harrison, LTC, MC

Richard G. Grape, SSG, USA

Leo A. Andron, LTC, MS

Rowland N. Hannon, PA-C CW3 RET

(11) Key Words:
human immunodeficiency virus
neuropsychological tests

(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: 15
d. Total Number of Subjects Enrolled to Date: 37
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 prevalence and progression of
neuropsychiatric disease in an HTLV-III positive military population.

(16) Technical Approach: Patients have been enrolled in the Neurop-
sychiatric Protocol from the umbrella Protocol dealing with Natural History
of HTLV-III Disease. This allocation has been random except for expecta-
tion of good follow up. There have been no significant changes in overall
protocol approach.

(17) Progress: Data continues to be accumulated in the serial WAISR deter-
minations and there was suggestively abnormal data. Specifically, that
many of the patients have very low percentile in WAISR scores, but that
they are relatively the same as a control group which was called up from
inpatient psychiatry and neurosurgery evaluations. There is a broad group
of abnormalities in the spinal fluid, to include small numbers of lym-
phocytes and some elevated protein. There seems to be no correlation be-
tween stage and CSF, IgG synthetic index, although all patients have had
antibody for HIV1.

Presentations:

Haburchak, D.R.: A Prospective Evaluation of Neuropsychiatric Sequelae of HTLV-III Disease. Presented: U.S. Army AIDS Conference, Arlington, VA, September 1986.

Haburchak D, Harrison S, Andron L, Grape R, Hannon R, Clayton W: Neuropsychologic Evaluation of HIV Seropositive U.S. Army Soldiers. Fitzsimons Army Medical Center.

Publications: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/116 (3) Status: Ongoing

(4) Title: Endocrine Function in the Acquired Immune Deficiency Syndrome

(5) Start Date: 1986

(6) Est Compl Date: July 1987

(7) Principal Investigator:
Michael T. McDermott, MAJ, MC
Arnold A. Asp, CPT, MC
John Merenich, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Gerald S. Kidd, LTC, MC
Michael Bornemann, COL, MC
William J. Georgitis, MAJ, MC
Shannon Harrison, MAJ, MC
David R. Haburchak, COL, MC

(11) Key Words:
acquired immunodeficiency
syndrome
adrenal glands
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: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 37 pt., 5 controls
d. Total Number of Subjects Enrolled to Date: 37 pt., 5 controls
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this study are to detect, define, and determine the incidence of abnormalities of the pituitary gland, adrenal gland, thyroid gland and gonads in patients with acquired immune deficiency syndrome and its variants.

(16) Technical Approach: Patients who are detected as being positive for HTLV III are staged and then endocrine function is studied with a combined pituitary test consisting of the intravenous injection of ACTH, TRH and GnRH with subsequent measurement over the next 3 hours for cortisol, aldosterone, TRH, T₄, T₃, FSH and LH.

(17) Progress: HTLV III positive patients are coming to FAMC with regularity and we anticipate reaching our goal of 50 patients within the next six weeks. The remainder of the time will be spent performing the tests on an age related 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 87 (2) Protocol WU#: 86/118 (3) Status: Ongoing

(4) Title: Maintenance vs. No Maintenance BCG Immunotherapy of
Superficial Bladder Cancer
SWOG #8507

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
chemotherapy

(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 SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/119 (3) Status: Ongoing

(4) Title: Randomized Comparison of Cisplatin + 5-Fluorouracil vs.
CBDCA + 5-Fluorouracil vs. Methotrexate in Advanced
Squamous Cell Carcinoma of the Head and Neck, Phase III
SWOG #8514

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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 in the study of
adult oncological malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Continues to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/120 (3) Status: Ongoing

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

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

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

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

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/121 (3) Status: Terminated

(4) Title: The Effect of Angiotensin-Converting Enzyme (ACE)
Inhibitors and Anti-Platelet Agents on Early Diabetic
Nephropathy

(5) Start Date: 1986 (6) Est Compl Date: June 1987

(7) Principal Investigator: Arnold Asp, CPT, MC
James Hasbargen, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald S. Kidd, LTC, MC
William Georgitis, MAJ, MC
Michael T. McDermott, MAJ, MC

(11) Key Words:
angiotensin converting enzyme
diabetic nephropathy

(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 determine whether ACE inhibitors or anti-platelet
drugs could reverse microalbuminuria and renal function.

(16) Technical Approach: Diabetic patients with microalbuminuria will be
administered Captopril, Dipyridazole or placebo in a randomized, double-
blind cross over fashion. The effect of ACE inhibitors or anti-platelet
agents on incipient diabetic nephropathy will be assessed.

(17) Progress: No patients enrolled, principal investigator leaving.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/122 (3) Status: Ongoing

(4) Title: Pulmonary Function Standards at FAMC: Correlation with
Anthropomorphic Measurement

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

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

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

(11) Key Words:
anthropometry
pulmonary gas exchange

(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: 51
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: To determine the spirometry, body plethysmography and
diffusion capacity normal standards for Fitzsimons Army Medical Center.

(16) Technical Approach: As pointed out in original protocol, non smoking
volunteers undergo spirometry, body plethysmography DLCO, at the PFT lab,
chest measurements/height/weight recorded and this data included for
regression analysis and assess any correlation.

(17) Progress: Data collection on 51 patients, insufficient data for
analysis.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/123 (3) Status: Ongoing

(4) Title: Phase II Evaluation of Methyl-Glyoxal Bis-Guanyldrazone
(MGBG) in Patients with Advanced Bladder Cancer
SWOG #8519

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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 in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/124 (3) Status: Ongoing

(4) Title: Treatment of Limited Small Cell Lung Cancer with Concurrent
Chemotherapy, Radiotherapy and Intensification with High
Dose Cyclophosphamide
SWOG #8573

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
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 in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/125 (3) Status: Ongoing

(4) Title: A Randomized Comparative Trial of Lobectomy versus Limited
Resection for Patients with Cancer of the Lung
LCSG #821

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

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

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled 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 LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/126 (3) Status: Ongoing

(4) Title: A Prospective Randomized Trial to Determine the Benefit
of Surgical Resection of Residual Disease Following
Response of Small Cell Lung Cancer to Combination
Chemotherapy
LCSG #832

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

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

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: 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: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/127 (3) Status: Ongoing

(4) Title: Phase II Pilot Program of Concurrent Chemotherapy and
Radiation Therapy Before Surgery in Patients with
Stage III Non-Small Cell Lung Cancer
LCSG #852

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

(7) Principal Investigator: Michael Stone, MAJ, 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: 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: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/128 (3) Status: Ongoing

(4) Title: A Clinical Trial in Patients with Stage II and III
Completely Resected Non-Small Cancer of the Lung
Comparing Chemotherapy vs. No Therapy Following
Surgery
LCSG #853

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

(7) Principal Investigator: Michael Stone, MAJ, 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: b. Review Results:
c. Number of Subjects Enrolled 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 LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/129 (3) Status: Ongoing

(4) Title: Evaluation of Ambulatory Recording Oximetry and
Holter Monitoring in Screening for Sleep Apnea

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

(7) Principal Investigator: Gary L. Jackson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pulmonary Dis. (10) Associate Investigators
Jean Foucauld, CPT, MC

(11) Key Words: oximetry
sleep apnea syndromes
Michael Perry, COL, 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: 20
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".

(15) Study Objective: To investigate a cost saving method to screen clinically suspected sleep apnea patients with a non-invasive recording pulse oximeter measuring oxyhemoglobin desaturation. No medications will be used. Patients will be seen and evaluated for SAS by the Pulmonary Disease Service.

(16) Technical Approach: Patients are selected on the basis of clinically suspected sleep apnea. Patients are then screened with overnight recording pulse oximetry and studied with holter monitoring simultaneously. Within 24 hours the patients are then studied with a formal sleep study to validate the findings in a positive predictive manner.

(17) Progress: To date 20 patients have been studied and there has been statistical evidence of correlation with those patients having sleep apnea by formal sleep study and those screened with recording pulse oximetry as outpatients.

Presentations: American College of Physicians USA Regional Meeting, San Francisco, CA., October 1987.

Abstract Submitted for American Thoracic Society, Las Vegas, Nevada, April, 1988.

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

(1) Date: 30 Sep 86 (2) Protocol WU#: 86/130 (3) Status: Terminated

(4) Title: Study of Small Bowel Transit Time in Hypothyroid Patients

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

(7) Principal Investigator: B.R. Larsen, CPT, MC (8) Facility: FAMC

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

F. M. Moses, MAJ, MC

(11) Key Words: M. T. McDermott, MAJ, MC

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for 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 hypothyroidism on small bowel motility by a standardized historical questionnaire and H2 breath analyzer testing. This project will differ from past studies as it will evaluate patients who have been on chronic replacement therapy instead of newly diagnosed hyperthyroid patients who were made hypothyroid with surgery or I-131 ablation therapy. In addition this protocol will compare the patients against themselves when they are euthyroid and hypothyroid, instead of against a normal population.

(16) Technical Approach: Terminated

(17) Progress: Principal investigators have departed FAMC. No further work is planned for this protocol.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/131 (3) Status: Terminated

(4) Title: Bowel Abnormalities in Adjuvant-Induced Arthritis in the Rat

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:

David Nordstrom MD
Sterling West, MD

(8) Facility: FAMC

(9) Dept/Svc: 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: b. Review Results:

c. Number of Subjects Enrolled 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 whether adjuvant-induced Reiter's syndrome in rats is associated with inflammatory bowel lesions similar to those seen in idiopathic Reiter's syndrome in humans.

(16) Technical Approach:

(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 87 (2) Protocol WU#: 86/132A (3) Status: Ongoing

(4) Title: The Effect of Theophylline on Calcium and Vitamin D
Metabolism in Male Sprague-Dawley Rats

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

(7) Principal Investigator: (8) Facility: FAMC
Edwin J. Fortenberry, CPT, MC
Michael T. McDermott, MAJ, MC

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

(11) Key Words:
theophylline
vitamin D
calcium

(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: 49 male rats
d. Total Number of Subjects Enrolled to Date: 49 male rats
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of the study are to determine the effect of chronic theophylline administration on calcium and Vitamin D metabolism and bone mineral content in rats.

(16) Technical Approach: Theophylline (n=25) or saline (n=24) are administered by continuous infusion with an Alzet osmotic pump for a period of 4 weeks. After 2 1/2 weeks, measurements are made of 24 hour calcium intake, urine calcium, and fecal calcium excretion and overall calcium balance is calculated. After 4 weeks, the rats are sacrificed and serum calcium PTH, 25 (OH) Vitamin D and 1,25 (OH)₂ vitamin D are measured. The rats are ashed for determination of total body calcium.

(17) Progress: Theophylline treated rats (n=25) had significantly greater urinary calcium excretion and significantly lower 25(OH) Vitamin D levels than did control rats (n=24). They also had slightly lower 1,25 (OH)₂ vitamin D levels and total body calcium per gram of body weight. PTH levels are pending.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/100 (3) Status: Completed

(4) Title: Fiberoptic Rhinoscopy as a Quantitative Method for
Assessing Nasal Patency

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
William K. Dolen, MAJ, MC
Matthew B. Wiener, PharmD
Jerald W. Koepke, MD
John C. Selner, MD

(8) Facility: FAMC
Denver
Denver
Denver

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

(10) Associate Investigators
FAMC Allergy-Immunology
Fellow
Donald Zedalis, MAJ, MC

(11) Key Words:

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

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

(15) Study Objective: To determine wheter fiberoptic rhinoscopy can be
developed as a quantitative technique for assessment of nasal airway
patency.

(16) Technical Approach: Fourteen patients received sequential examina-
tions of the nostril over a period of 30 minutes (FAMC). At the Denver
Center, 14 patients received repeated examinations over a 180 minute
period.

(17) Progress: Data are collected and analysis is underway, (FY 1987).
Publications and Presentations: None at present.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/101 (3) Status: Terminated

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

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

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

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators
Marcia L. Muggelberg, MAJ, MC
(11) Key Words: Richard W. Weber, COL, MC

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

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

(15) Study Objective: To determine whether the efficacy of corticos-
teroids in the treatment of acute asthma is related to the length of
time that symptoms had been present for that particular episode of
asthma.

(16) Technical Approach: See Protocol

(17) Progress: Revisions to the protocol was never submitted and as
such was cancelled at the 7 Apr 87 IRC meeting.

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/102 (3) Status: Ongoing

(4) Title: Anti-Histone Antibody Production in Procainamide Associated Drug-Induced Lupus Erythematosus: Association of Serologic Patterns and Lymphocyte Subsets

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

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

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

(11) Key Words:
procainamide
drug-induced lupus
histones

(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: 4
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: There are two study objectives: a) to survey the population of patients receiving procainamide to determine baseline data and b) to evaluate a subgroup of patients chosen randomly from patient populations determined by amount of drug administered, serologic status, and the presence of symptomatology.

(16) Technical Approach: Autoantibodies are one of the hallmarks of SLE yet mechanisms of their production and their pathogenetic import remain unclear. Drug-induced lupus makes feasible the investigation of potential early immunologic abnormalities which would lead to autoantibody production. Demographic, clinical and serologic data will be obtained on patients taking procainamide. Selected patients will, additionally, have T-cell and B-cell lymphocyte studies and be followed serially to discover correlates, if any, in studied parameters.

(17) Progress: Although only four patients have been enrolled in the study and baseline data obtained, approximately 110 individuals receiving procainamide have been identified. Efforts to contact these, obtain informed consent and finally enroll them in the study are ongoing.

Publications and Presentations: None

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

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

(4) Title: Identification of Those at Risk for Osteoporotic Hip Fractures, by a Noninvasive Measurement

(5) Start Date: Jan 87 (6) Est Compl Date: 1989

(7) Principal Investigator: Jan J. Perloff, CPT, MC
Michael McDermott, MAJ, MC
Kerry G. Perloff, CPT, MC
(8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology (10) Associate Investigators
Peter Blue, LTC, MC
Nasser Ghaed, COL, MC
Gerald S. Kidd, COL, MC
(11) Key Words:
osteoporosis
hip fractures

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 45
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: a) To compare the bone density at the spine and nonfractured hip, in patients with recent hip fractures, with those of control patients; b) To determine if other factors such as poor vision and medication intake, which may predispose to falling down, might be more important factors than bone density; c) To try to establish a level of bone density at the hip to which fractures are likely to occur.

(16) Technical Approach: Patients who are admitted to orthopedics with recent hip fractures are taken to Nuclear Medicine for measurement of bone density at the hip and spine. These are compared to a group of normal control patients. Hip fracture patients also have a thorough ophthalmology exam in addition to history and physical examination.

(17) Progress: Thirty controls and fifteen hip fracture patients have been studied. The data will not be analyzed until all of the anticipated subjects have been studied.

Publications and Presentations: None yet.

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

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

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

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Continuing to accrue.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/105 (3) Status: Ongoing

(4) Title: Pre-operative Cimetidine Therapy in Patients Undergoing Parathyroid Exploration: Efficacy and Mechanisms of Action

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

(7) Principal Investigator: (8) Facility: FAMC
John A. Merenich CPT, MC
Jeffrey R. Clark, COL, MC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators
Michael T. McDermott, MC
William J. Georgitis, MAJ, MC
Arnold A. Asp, MAJ, MC
Gerald S. Kidd, COL, MC

(11) Key Words:
hyperparathyroidism
postoperative hypocalcemia

(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: 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". One patient developed moderate elevations of liver function tests. She was completely asymptomatic, but her parathyroid surgery was postponed (until her tests returned to normal) and she was dropped from the study. She has subsequently undergone surgery without complications and LFT's remain normal.

(15) Study Objective: To determine whether or not pre-operative cimetidine therapy can reduce the incidence of post-operative hypocalcemia in patients undergoing parathyroid explorative surgery.

(16) Technical Approach: Patients are given placebo or cimetidine for 10 days prior to their surgery in a double-blind fashion. Calcium and its regulatory hormones are monitored before and after surgery to see if cimetidine favorably alters calcium homeostasis.

(17) Progress: Since the study's implementation, informed consent has been obtained from every patient undergoing parathyroid exploration at FAMC. Because the study is double-blinded, no comments concerning the efficacy of cimetidine 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 87 (2) Protocol WU#: 87/106 (3) Status: Ongoing

(4) Title: Effect of Concomitant Alcohol and Exercise on High Density Lipoprotein Subfractions and Lipolytic Enzymes in Sedentary, Healthy Men

(5) Start Date: 1987

(6) Est Compl Date: 1988

(7) Principal Investigator:
Kerry C. Prewitt, CPT, MC
John A. Merenich, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
William Georgitis, MAJ, MC
Robert Eckel, MD
Gerald S. Kidd, COL, MC

(11) Key Words:
alcohol
lipoproteins
apolipoproteins
lipase

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 11

d. Total Number of Subjects Enrolled to Date: 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". None

(15) Study Objective: To determine the effects of alcohol alone and in conjunction with exercise on lipid status (and the enzymes that control lipids) in healthy men.

(16) Technical Approach: Participants asked to completely abstain from alcohol or to drink alcohol at social levels while activity levels are manipulated. Lipids and lipoprotein activities are determined before and after these manipulations to assess their effect.

(17) Progress: The study is proceeding as planned. While the number of participants is not what we would have liked at this point we have had commitments from several people who are willing to participate after the Armed Forces PT test in October 1987.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/107 (3) Status: Ongoing

(4) Title: Weekly Low Dose CCNU for Extensive Adenocarcinoma of the
Colon and Rectum

(5) Start Date: 1987

(6) Est Compl Date: 1989

(7) Principal Investigator:
Michael Stone, MAJ, MC

(8) Facility: FAMC

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

(10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 2_____
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: To determine the efficacy and toxicity of low dose
oral CCNU in colon cancer.

(16) Technical Approach: CCNU 60mg/wk p.o. x 6 wks. If no toxicity in-
crease to 70mg p.o Q wk x 6wks , then 80mg p.o Q wk. Continue theapy as
long as disease is stable and responsive.

(17) Progress: Continuing to accrue.
Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/108 (3) Status: Ongoing

(4) Title: Prostaglandin Synthesis Inhibition and Glucose Counter-Regulatory Hormone Secretion in Diabetes Mellitus

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

(7) Principal Investigator: Robert J. Sjoberg, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators
John Merenich, CPT, MC
Gerald S. Kidd, COL, MC
T.P. O'Barr, DAC
(11) Key Words:
prostaglandin synthesis
glucose counter regulation
diabetes mellitus
hypoglycemia

(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 and how well choline magnesium trisalicylate reverses the glucose counter-regulatory hormone defect and delayed hypoglycemia recovery associated with Type I diabetes mellitus.

(16) Technical Approach: To study 25 patients with Type I diabetes mellitus who are not excluded from the study (see exclusion criteria in protocol). The patients will be given an insulin infusion to cause slow onset hypoglycemia. Glucagon, epinephrine, glucose nadir, and the rate of glucose recovery will be determined with and without prior treatment with choline magnesium trisalicylate.

(17) Progress: No patients have been studied as yet. However, this protocol was just recently approved for institution at Fitzsimons Army Medical Center and one patient is planning to participate in the study in the near future.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/109 (3) Status: Ongoing

(4) Title: The Efficacy of Conjugated Estrogens in Reducing Blood Loss During and After Cardiac Surgery; Decreased Endothelial Prostacyclin Production as a Possible Mechanism

(5) Start Date: June 1987 (6) Est Compl Date: June 1988

(7) Principal Investigator: (8) Facility: FAMC
Robert W. Hull, CPT, MC
Stephen Fall, LTC, MC
James A. Hasbargen, MAJ, MC
T.P. O'Barr, DAC

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

(11) Key Words:
estrogen
bypass loagulopathy

(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: 9
d. Total Number of Subjects Enrolled to Date: 9
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: a. Efficacy of conjugated estrogens in reducing blood loss of bypass surgery and, b. Explore effects on prostacyclin production as a possible mechanism.

(16) Technical Approach: Patient receives I.V. conjugated estrogens 3 days prior to surgery. Venous PGF1 levels before and after infusion period. Vein sample also assayed for prostacyclin production. Blood loss of surgery and post-op period recorded for analyses between placebo and experimental groups.

(17) Progress: Enrolled 9 of 50 proposed patients. 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 87 (2) Protocol WU#: 87/110 (3) Status: Ongoing

(4) Title: The Role of Excess Prostaglandin Production in Causing
The Abnormal Hemodynamic Status of Adrenalectomized Rats

(5) Start Date: 1987 (6) Est Compl Date: 1988

(7) Principal Investigator: Robert J. Sjoberg, MAJ, MC (8) Facility: FAMC

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

John Merenich CPT, MC
Gerald S. Kidd, COL, MC
T.P. O'Barr, DAC

(11) Key Words:
prostaglandins
adrenal insufficiency

(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 clarify the role of altered renal and arterial
prostaglandin production in mediating the hemodynamic alterations as-
sociated with adrenal insufficiency.

(16) Technical Approach: The approach used involved investigations of a)
comparison of the physiologic response of adrenalectomized rats to pros-
taglandin synthesis inhibitors and to glucocorticoid replacement and b)
the ex vivo elaboration of prostaglandins by renal and arterial tissue
taken from adrenalectomized rats.

(17) Progress: During fiscal year ending 30 Sept 87, all of the
physiologic rat studies have been completed, and tissue incubations for
the elaboration of prostaglandins have likewise been completed without
difficulty. The prostaglandin and renin activity assays have yet to be
done, but preliminary data indicates that the dose of prostaglandin
synthesis inhibitor used in these studies adequately suppressed ex vivo
prostaglandin production. The physiologic studies demonstrated no ef-
fect of prostaglandin synthesis inhibitors on electrolyte or fluid
balance indicating that excess prostaglandin production is not involved
in mediating the abnormal hemodynamic status of adrenalectomized rats.
No definitive conclusions can, however, be made at the present time
without completion of the prostaglandin and renin activity assays.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/111 (3) Status: Ongoing

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

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

(7) Principal Investigator: Shannon Harrison, LTC, MC (8) Facility: FAMC

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

(11) Key Words:

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

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

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

(15) Study Objective: To look for efficacy and toxicity in terms of difference in natural history of Walter Reed Stage II through early V, HIV infected individuals given zidovudine at 200mg every 6 hours vs placebo.

(16) Technical Approach: See protocol.

(17) Progress: Protocol is still in a pending status.

Publications and Presentations: None

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

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

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

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

(7) Principal Investigator: (8) Facility: FAMC
Michael Stone, MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: 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 87 (2) Protocol WU#: 87/113 (3) Status: Ongoing

(4) Title: A Phase II Randomized Trial of Combination Therapy for Multiple Myeloma: Comparison of (1) VMCP/VBAP to VAD or VMCP/VBAPP for Induction, (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha -2b Interferon + Dexamethasone for Incomplete or Nonresponders

SWOG 8624

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

(7) Principal Investigator: Michael Stone, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: Protocol is still in a pending status.

Publications and Presentations: None

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

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

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

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

(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

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

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

(16) Technical Approach: The study consists of three phases: (a) open-ended interviews with patients to elicit specific behaviors that are important indicators of physicians' humanistic behaviors; (b) development of a questionnaire from the responses generated in Phase 1, and testing of the questionnaire to determine the mean, standard deviation, and range of scores of specific residents, as rated by their own patients; 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: Protocol is still in a pending status.

Publications and Presentations: None

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

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

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

(5) Start Date: Aug 87

(6) Est Compl Date:

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

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators

John R. Barrett, LTC, MC

(11) Key Words:

William J. Georgitis, LTC, MC

Robert J. Sjoberg, MAJ, MC

John A. Merenich, CPT, MC

Kenneth Simcic, CPT, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: 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: This is a new study just approved in August, 1987.

Publications and Presentations: None

DEPARTMENT OF SURGERY

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

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

(7) Principal Investigator: (8) Facility: FAMC
Floyd M. Cornell, COL, MC

(9) Dept/Svc: SUR/Ophthalmology (10) Associate Investigators

(11) Key Words:
intraocular lens

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 170
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". None

(15) Study Objective: To determine postoperative visual acuity of patients
receiving intraocular lens, and to compare those results with those of a
control group of patients who undergo cataract surgery but do not receive
an intraocular lens.

(16) Technical Approach: Post-operative examinations include: pachymetry,
keratometry and specular microscopy. Contraindications to surgery include:
patients with good visual potential in only one eye, proliferative diabetic
retinopathy, rubeosis irides, high axial myopia, and inadequately con-
trolled glaucoma, Fuch's endothelial dystrophy.

(17) Progress: Because of the FDA's continued monitoring of intraocular lens
implants, we continue to maintain this protocol and report all lens implants,
both primary and secondary, and any adverse reactions. This continues to be
the primary mode of rehabilitation of patients who have had cataract sur-
gery, and enjoys excellent results. We anticipate this to be monitored
continuously as newly designed lenses continue to be produced.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Luis Colon, MAJ, MC

(8) Facility: FAMC
General Leonard Wood Army
Community Hospital

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators
David A. Hanks, MAJ, MC

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period: 53

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: pachymetry, keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

Approved for 3M, Coburn.

(17) Progress: 39 posterior chamber, 14 anterior chambers.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Jeffrey L. Bezier, CPT, MC

(8) Facility: FAMC
Reynolds Army Hospital
Ophthalmology, Box 21
4700 Hartell Blvd.
Ft. Sill, OK 73503-6300

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 40
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 postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: pachymetry, keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

Implanting CILCO lenses now, but also authorized to implant Precision Cosmet, 3M, Alcon, and IOLAB.

(17) Progress: Cataract surgery with the intraocular lens implantation has been satisfactory with no major post operative complications 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 87 (2) Protocol WU#: 85/200 (3) Status: Ongoing

(4) Title: Differential Fixation of Centrifuged and Non-Centrifuged
Acrylic Bone Cement Specimens

(5) Start Date: 1985 (6) Est Compl Date: 1988

(7) Principal Investigator: Joseph N. Wilson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators
Joe K. Ozaki, COL, MC

(11) Key Words:
bone cements
acrylic resins

(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: We propose to study volumetric change in acrylic ce-
ment as it is used in surgery with and without centrifugation; strength of
bonding of acrylic cement to bone and to the prosthesis by "pull out"
strength testing comparing cements with and without centrifugation and the
variability of the shrinkage in the different type of acrylic cement avail-
able for orthopedic surgical use.

(16) Technical Approach: Acrylic bone cement will be mixed and changes re-
corded by direct and indirect (fluid displacement) methods. Model systems
of initial/cement/bone will be tested to determine bonding strength of in-
terface using a tensiometer.

(17) Progress: First stage of experiments are complete and have been
presented at national and international meetings, fixation experiments are
ongoing at this time.

Presentations:

Wilson, J.N.: Volume Changes During Polymerization. Presented: Barnard
Seminar, Denver, CO March 1985.

Wilson JN: Volume Changes During Polymerization. Presented: SOMOS' 1986,
Society of Military Orthopedic Surgeons, Colorado Sprngs, CO.

Wilson JN: Volume Changes During Polymerization. Presented: Interna-
tional Symposium on Orthopedics, Mexico, September 1987.

Publications: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/201 (3) Status: Terminated

(4) Title: Keratorefractive Surgical Techniques; Epikeratophakia, Keratophakia, and Keratomileusis; A Feasibility Study

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

(7) Principal Investigator: (8) Facility: FAMC
Floyd M. Cornell, COL, MC
Michael J. Trynosky, CPT, MC

(9) Dept/Svc: SUR/Ophthalmology (10) Associate Investigators
Margaret Lisecki, RS

(11) Key Words: John A. McCubbin, CPT, MC
cornea

(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 determine if the animal species in question, New Zealand Albino Rabbit will demonstrate specific ophthalmological anatomical considerations to enable further research in keratorefractive surgery, comparing the effects of epikeratophakia, keratophakia, and keratomileusis in the correction of refractive errors.

(16) Technical Approach: New Zealand Albino Rabbits, 40 weeks of age or older will be used in this study. Rabbits will be studied to determine their body weight, corneal keratometry measurements, corneal thickness, corneal diameter, corneal curvature with a placido disc, intraocular pressures, refractive errors, ophthalmodynamometry measurements will be taken to determine which intraocular pressures that will not occlude the central retinal artery, and slit lamp examinations to detect the presence or absence of external eye disease. Rabbit will be anesthetized and eyes covered with a plastic drape to help maintain proptosis. A teflon adapter specifically designed to conform to the size and curvature of the rabbit glove is then placed over the eye of the rabbit and then the pneumatic ring of the microkeratome is placed onto the grooved anterior surface of the teflon adapter to allow for adequate transfer of suction to the rabbit's glove. With the teflon adapter and pneumatic suction ring in place, the base plate is fixed onto the microkeratome and the instrument is placed into the groove of the pneumatic pressure ring. The microkeratome is then engaged and slid smoothly across the cornea resulting in a lamellar resection. The button is then placed onto the Delring base, stained, frozen and lathed to the appropriate dioptric power using the appropriate calculations for the

specific keratorefractive procedure. Following cryolathing, the button, now referred to as alenticule, is thawed and sutured onto the animals eye using 10-0 or 11-0 nonabsorbable nylon sutures. After all sutures have been placed an appropriate size therapeutic bandage contact lens will be applied followed by a 5-10mg subconjunctival gentamycin injection.

(17) Progress: This study has not been undertaken and is currently under redesign. Protocol will be withdrawn. We anticipate the submission of a redesigned protocol within the near future.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/202 (3) Status: Ongoing

(4) Title: NSABP Protocol C-02 - A Clinical Trial Evaluating the Postoperative Portal Vein Infusion of 5-Fluorouracil and Sodium Heparin in Patients with Resectable Adenocarcinoma of the Colon

(5) Start Date: 1985 (6) Est Compl Date: 1989-1990

(7) Principal Investigator: Bruce P. Cleland, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Gen. Surg. Svc. (10) Associate Investigators: Jerry E. Sims, MD
Jeffrey R. Clark, MC

(11) Key Words:
colonic neoplasms
heparin
fluorouracil

(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: 3
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: To determine the efficacy of perioperative portal vein infusion as an adjuvant therapy in patients with Duke's A, B, and C adenocarcinoma of the colon as compared to standard therapy which is surgery alone. The study is designed to determine whether there will be prolongation of the disease-free interval and increasing survivorship in patients undergoing curative resection of colonic adenocarcinomas and treated in this manner.

(16) Technical Approach: Patients will be assigned by random selection to one of the following groups: a) surgery alone; b) surgery plus additional continuous portal vein infusion with 5-FU 600 mg/M2 and 5000 units sodium heparin per day, given for a total of 7 consecutive days. Portal vein catheters will be inserted intraoperatively after the colonic anastomosis has been completed. All portal vein infusions will be started within 6 hours of the operative procedure.

(17) Progress: This is the second year of the protocol. Three more patients were enrolled from FAMC in this national cooperative study. No significant complications or liver toxicity has been noted. Follow-up has been good and no recurrent disease noted as yet.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/200 (3) Status: Ongoing

(4) Title: Treatment of Urinary Tract Trauma in the Porcine Animal Model

(5) Start Date: 1986

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Michael J. Raife, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Urology Svc

(10) Associate Investigators
Edward J. Pienkos, LTC, MC
Daniel W. Horne, LTC, MC
Clyde R. Roy, CPT, MC
Isabello C. Castillo, MAJ, MC
David L. Jones, CPT, MC
Deogracia Quinones, CPT, MC

(11) Key Words:
renal trauma
renovascular surgery
bladder substitution

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

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

(15) Study Objective: To provide an opportunity for urologists in training to develop expertise in the surgical techniques which are useful in the management of urinary tract trauma, to include renovascular surgery, renal autotransplantation, and repair of damage to ureters or bladder by various types of bowel segment augmentation or replacement.

(16) Technical Approach: Animals are subjected, under anesthesia, to simulated urinary tract trauma situations. Various surgical procedures are performed to allow resident training in management of these situations.

(17) Progress: Resident training in renovascular/autotransplantation surgery was excellent. We anticipate emphasis on bladder augmentation or replacement surgery this year.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/201 (3) Status: Ongoing

(4) Title: Vasovasostomy in the Porcine Animal Model

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

(7) Principal Investigator: Michael J. Raife, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Urology Svc (10) Associate Investigators
Edward J. Pienkos, LTC, MC
Daniel W. Horne, LTC, MC
Clyde R. Roy II, CPT, MC
Isabello C. Castillo, MAJ, MC
David L. Jones, CPT, MC
Deogracia Quinones, CPT, MC

(11) Key Words:
vasectomy
vasovasostomy
microsurgery

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

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

(15) Study Objective: To develop and maintain microvascular surgical skills for vasovasostomy.

(16) Technical Approach: The vasa are isolated, severed, and reanastomosed using the operating microscope.

(17) Progress: Satisfactory microsurgical training has been offered to the resident house staff, allowing for better microscopic vasovasostomy for the patients.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/202 (3) Status: Completed

(4) Title: A Comparison of Atracurium, Succinylcholine, and Vecuronium: The Priming Principle

(5) Start Date: 1986

(6) Est Compl Date: Nov 1986

(7) Principal Investigator:

(8) Facility: FAMC

Vickie L. Harazin, CPT, AN

Terry C. Wicks, CPT, AN

James R. Halliburton, 1LT, AN

Timothy A Newcomer, 1LT, AN

(9) Dept/Svc: SUR/Anesthesia Svc

(10) Associate Investigators

(11) Key Words:

atracurium

succinylcholine

vecuronium

(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: 66

d. Total Number of Subjects Enrolled to Date: 66

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". N/A

(15) Study Objective: To determine if there is a faster onset of intubation conditions for surgical patients who receive D-tubocurarine and succinylcholine combination than patients given either a divided vecuronium dose or a divided atracurium dose.

(16) Technical Approach: Monitoring of muscle relaxation with a peripheral nerve stimulation after administration of bolus dose of drug. Patient assigned to groups randomly based on SSN.

(17) Progress: Study complete. Manuscript ready for submission for publication.

Publications and Presentations: Manuscript submitted for publication.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/203 (3) Status: Terminated

(4) Title: A Prospective Randomized Comparison of Endoscopic
Gastrostomy and Open Gastrostomy

(5) Start Date: 1986

(6) Est Compl Date: Terminated at
FAMC; ongoing at U. of Colo.

(7) Principal Investigator:
Bruce P. Cleland, MAJ, MC

(8) Facility: FAMC
University of Colorado
Denver VA Hospital

(9) Dept/Svc: SUR/Gen Sur Svc

(10) Associate Investigators

(11) Key Words:
gastrostomy

Jeffrey R. Clark, COL, MC
Chris Shaw, MAJ, MC
Frank M. Moses, MAJ, 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:

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: To compare the safety and effectiveness of endoscopy-
placed gastrostomies with those placed operatively, patients needing
gastrostomies will be randomized to one of the two techniques. The time
required for placement, the morbidity of placement, length of hospital
stay, function of the gastrostomy, clinical outcome, mortality, and cost
will be assessed.

(16) Technical Approach: The surgically placed gastrostomies will be done
under general anesthesia in the operating room with an abdominal incision.
The endoscopically placed gastrostomies are done by giving patient local
anesthesia, I.V. sedation. The gastrostomy is then placed using the endo-
scope, percutaneous puncture of the stomach with a Saks-Vine gastrostomy
kit.

(17) Progress: It has become clear over the last year that all patients
referred to the Gastroenterology Service were given percutaneous gastro-
stomy and not randomized. Thus, the study has been terminated here at FAMC,
although more than fifty patients have been enrolled at the University of
Colorado.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/206 (3) Status: Terminated

(4) Title: Minimizing Postoperative Nausea and Vomiting in
Strabismus Surgery

(5) Start Date: 1986 (6) Est Compl Date: 1987

(7) Principal Investigator: Douglas A. Freeley, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Anes/Oph (10) Associate Investigators
Eric Cohn, CPT, MC
Michael Coatney, CPT, MC

(11) Key Words:
strabismus
anesthesia
adjustable suture

(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 determine which combination of anesthesia and
techniques and premedications will produce the least amount of nausea and
vomiting in patients undergoing strabismus surgery.

(16) Technical Approach: As described in protocol.

(17) Progress: Study terminated because neither regimen of medications was
giving adequate results and new combination has proven to be superior.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/207 (3) Status: Terminated

(4) Title: The Use of Bacillus Calmette-Guerrin for the Intravesical Treatment of Superficial Transitional Cell Carcinoma of the Bladder and Carcinoma in Situ of the Bladder: Its Efficacy and Safety

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Daniel W. Horne, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Urology

(10) Associate Investigators

Torrence Wilson, COL, MC

(11) Key Words:

Michael J. Raife, 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:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Protocol was never started.

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/208 (3) Status: Ongoing

(4) Title: Medical Readiness Support Program

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

(7) Principal Investigator: Stephen M. Fall, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Card Surg (10) Associate Investigators

(11) Key Words:

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

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

(15) Study Objective: The United States Air Force Medical Readiness Program requires that all dental officers be trained to participate as first or second assistants in the operating room during a general mobilization. The dental activity at Lowry Air Force Base is not associated with the USAF Hosptial through which this rquirement can be met. The Department of Surgery, Fitzsimons Army Medical Center, has been requested to provide an annual exercise to familiarize the dental officers with the skills necessary to assist in the operating room.

(16) Technical Approach: Training protocol.

(17) Progress: The protocol is being rewritten and progress will be reported next FY.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/209A (3) Status: Ongoing

(4) Title: Effects of Nonsteroidal Anti-inflammatory Agents on
Tendon Healing

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

(7) Principal Investigator: Joseph N. Wilson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators
James Johns, MAJ, MC

(11) Key Words:
tendon healing
non-steroidal anti-inflammatory
agent

(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 NSAID's effect heal rate of
strength in rat tendon model.

(16) Technical Approach: Suture tendon laceration followed by haling
with and without NSAID's.

(17) Progress: Rats and dose pumps are on order.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/201 (3) Status: Ongoing

(4) Title: Lipid Composition of Normal and Abnormal Foot Pads

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

(7) Principal Investigator: (8) Facility: FAMC
William G. Winter, MD VAMC, Denver, CO
David B. Hahn LTC, MC FAMC
Oscar K. Reiss, Ph.D. UCHSC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words:
foot pads
lipid analysis

(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: We propose a) to establish the biochemical composition of the human plantar foot pads, b) to investigate their metabolic activities compared to similar (adipose) tissues at other anatomical sites and c) to attempt to correlate the chemical composition and metabolic activities with their functional performance.

(16) Technical Approach: See Protocol.

(17) Progress: We have not been notified by the VA board regarding funding for this study, therefore, no progress has been made.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/202 (3) Status: Ongoing

(4) Title: Improving Cancer Management Through the Tumor Conference

(5) Start Date: (6) Est Compl Date: 1989-1990

(7) Principal Investigator: Jeffrey R. Clark, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Gen. Surg. Svc. (10) Associate Investigators
Daniel T. Tell, MAJ, MC
(11) Key Words: Bruce P. Cleland, MAJ, MC

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

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

(15) Study Objective: FAMC Tumor Board will be one of 22 in the state where in a randomized controlled fashion, multifaceted educational intervention (maintaining a randomly selected control group) will be introduced. The hypothesis is: Given emphasis on stimulating case presentations in a concert of patient management decision making, tumor boards can function as key elements in patient care and medical education.

(16) Technical Approach: The first 6 months will be baseline evaluation of tumor boards as they now exist. Then an interventional education package is randomly introduced to half the boards over one year and impact is seen. the other half receive no intervention. A crossover of intervention will occur after one year for one year's time. Then, six months of final analysis and recommendation made to NCI.

(17) Progress: Funding to start this protocol will begin 28 September 1987.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/203 (3) Status: Ongoing

(4) Title: Comparison of Thermography and Standard Techniques for
Detection, Diagnosis and Tracing of Disorders Marked by
Altered Patterns of Peripheral Blood Flow

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

(7) Principal Investigator: (8) Facility: FAMC
Joe Ozaki, COL, MC
Richard A. Sherman, MAJ, MS

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words:
thermography
pain
orthopedic disorders

(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 optimal utilization of thermog-
raphy in clinical evaluation of the vascular status of the affected area
for patients with orthopedic related pain disorders.

(16) Technical Approach: We will make thermographic recordings of groups
of ten subjects having one of the following conditions each time they
come to Orthopedic Clinic from the initial diagnostic appointment
through post-resolution follow-up: Frostbite, Charcot Joints, Carpel
Tunnel Syndrome, Fibrositis, Sympathetic Dystrophy and Peripheral
Neuropathy, Pre-amputation preparation, and Prediction of Bed Sore For-
mation. The clinical evaluations will not be related to the ther-
mographic evaluations until the subject has completed participation in
the study.

(17) Progress: Protocol is new at FAMC.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 72/302 (3) Status: Ongoing

(4) Title: Comparison of Metabolic and Functional Changes in Defects of Platelet Function

(5) Start Date: 1972

(6) Est Compl Date:

(7) Principal Investigator:
T.P. O'Barr, DAC

(8) Facility: FAMC

(9) Dept. of Clin Investigation

(10) Associate Investigators

(11) Key Words:
platelet function tests

(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 correlate biochemical and functional parameters of gain a better understanding of the pathophysiology of the disorders of platelet function.

(16) Technical Approach: Platelet Function Studies: When indicated clinically, platelet counts, bleeding times, platelet adhesion, and whole blood and PRP aggregation in response to ADP, collagen, epinephrine, or ristocetin will be performed in the Coagulation Section, Department of Pathology or the Biochemistry Service, Department of Clinical Investigation. Biochemical Studies: Assessment of the content and release of the content of the platelet's subcellular storage organelles (alpha and dense granules) and evaluation of the platelet membrane will include, but not be limited to the following: a) Electron microscopy and mepacrine staining of granules; b) Content of platelet factor 4 and B-thromboglobulin activity in the alpha granules; c) Production of platelet-derived growth factor; d) ³H-thymidine incorporation in 3T3 mouse fibroblasts by platelet conditioned medium; e) Measurement of secretory acid hydrolases (B-glucuronidase, B-galactosidase and membrane P-nitrophenyl phosphatase) activities; f) Platelet protein and phospholipid content; g) Release of arachidonate and other phospholipids by phospholipase C and diglyceride lipase; h) Measurement of ⁴⁵Ca⁺⁺; h) Other studies as they become available.

CONTINUATION SHEET, FY 87 ANNUAL PROGRESS REPORT Proto No.: 72/302

(17) Progress: No progress was made this reporting period due to the transfer of the principal investigator. Plan to keep this study ongoing for FY 88.

Presentations:

(1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDE): Reversal with Total Parenteral Alimentation (TPA). Presented: Western Society for Pediatric Research, Carmel, CA, February 1973.

(2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. Presented: III Congress International Society on Thrombosis and Hemostasis, Vienna, Austria, June 1973.

(3) Corby, D.G.: Mechanism of Platelet Dysfunction in Newborn Infants. Presented: Society for Pediatric Research, APS-SPR, Washington, D.C., May 1974.

(4) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. Presented: Vith International Congress on Thrombosis and Haemostasis, Philadelphia, Pennsylvania, June 1977.

(5) Corby, D.G., and O'Barr, T.P.: Decreased - Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Presented: VII Congress International Society of Thrombosis and Haemostasis, London, England, 1979.

Publications:

(1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). (Abst.) Clin. Res. 21:304, 1973.

(2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. (Abst. p. 107), III Congress, Int. Soc. Thromb. Hemos. (Vienna, Austria), June 1973.

(3) Corby, D.G., (Intr. by Wm. E. Hathaway): Mechanism of Platelet Dysfunction in Newborn Infants. J. Ped. Res., Vol. 8, No. 4, April 1974.

(4) Corby, D.G., Preston, K.A., O'Barr, T.P.: Adverse Effect of Gel Filtration of the Function of Human Platelets. Pro. Soc. Exp. Bio. & Med., 146:96-98, 1974.

(5) Corby, D.G., Putnam, C.W., Greene, H.L.: Impaired Platelet Function in Glucose-6-Phosphatase Deficiency. The J. Ped., 85:71-76, July 1974.

Publications - continued

(6) Corby, D.G., and Zuck, T.F.: Newborn Platelet Dysfunction: A Storage Pool and Release Defect. *Throm. & Haemo.*, 36:200-207, 1976.

(7) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. *Throm. & Haemo.* (Stuttgart), 38:35, 1977 (Abstract).

(8) Corby, D.G., O'Barr, T.P.: Decrease in α -Adrenergic Binding Sites in Newborn Platelets: Cause of Abnormal Response to Epinephrine? *Blood*, 52:161, 1978.

(9) Corby, D.G.: Aspirin in Pregnancy: Maternal and Fetal Effects. *Pediatrics*, 62:930, 1978.

(10) Corby, D.G., O'Barr, T.P.: Decreased Alpha-Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine. *Dev. Pharmacol. & Ther.*, 2:215-225, 1981.

(11) Corby, D.G., O'Barr, T.P.: Neonatal Platelet Function: A Membrane-Related Phenomenon. *Haemostasis*, 10(4):177-232, 1981.

(12) Corby, D.G., O'Barr, T.P.: Newborn Platelet Function. Chapter in Book, "Acquired Bleeding Disorder in Childhood". Masson Publ, p 31-37, 1981.

(13) Corby, D.G., O'Barr, T.P., and Swanson, E.E.: Evidence for a Deficiency of Alpha-Granule Proteins in the Platelets of Newborn Infants. *Soc. Ped. Res.*, May 1983.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 77/300 (3) Status: Ongoing

(4) Title: Immunologic Disorders in Children and Adults.
I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies

(5) Start Date: 1977 (6) Est Compl Date: Open-Ended

(7) Principal Investigator: Robert S. Stewart, MAJ, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators
John K. Podgore, COL, 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: May 86 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 90
d. Total Number of Subjects Enrolled to Date: 1026
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 gammopathics evaluated by SPEP, IEP, and immunoglobulin quantitation by RID. Lymphocyte phenotyping by flow cytometry. Lymphocyte activated determined by quantitative mitogenesis.

(17) Progress: Ongoing.

Presentations:

(1) Brown, G.L., and Heggors, J.: Medical Mycology: Assessment of Bacteriologic and Serologic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

(2) Dolan, W., Hill, S., Hasbargen, J., Rickman, W., and Weber, R.: Acquired Hypogammaglobulinemia with Absence of Leu-12 Antigen Following Bilateral Nephrectomy and Renal Transplantation for Goodpasture's Syndrome. Presented: 14th Annual Allergy--Immunology Symposium, Aurora, CO, 21-23 January 1986.

CONTINUATION SHEET FY 87 Annual Progress Report Proto. No. 77/300

(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.

Publications:

Smolin, M.R., Hasbargen, J., and Rickman, W.J.: Profound Panhypogammaglobulinemia in a Renal Transplant Recipient. Ann. Int. Med. (in press) 1986.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 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: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Pari L. Morse
Clifford Butler

(9) Dept of Clin Investigation (10) Associate Investigators

(11) Key Words:
microbiology
microbiological technics

(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 recently introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within that 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: FY 84 - Two commercially available products were tested: Wellcogen B (for group B strep) and Directogen (for H. flu, S. Pneumo, and N. Men.). Wellcogen B was determined to be a valuable diagnostic tool while Directogen was not found to be effective. FY 85: Two commercially available test kits were utilized in combination for the rapid detection of group B streptococcus antigen from vaginal swabs: Culturette Brand Ten-Minute group A strep ID System (for the micronitrous acid extraction of the swabs) and Wellcogen B (for the antigen detection). Specificity and sensitivity for the testing procedure were 100% and 93%, respectively. FY 87: Two kits are being tested: FIAX Toxo-G and FIAX Toxo-M. Both are Fluorescent antibody tests for IgG and IgM to Toxoplasma gondii. Both show promise for the rapid detection of antibodies to Toxoplasms in AIDS patients. Plans are also underway to evaluate a fluorescent antibody test for CMV and ELISA test kits for IgG and IgM to Toxoplasma and CMV.

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 87 (2) Protocol WU#: 85/301 (3) Status: Terminated

(4) Title: Studies of the Antigen-Specific Recognition Receptor on Human T Lymphocytes

(5) Start Date: 1985

(6) Est Compl Date: June 1987

(7) Principal Investigator:
William J. Rickman, CPT, MS

(8) Facility: FAMC

(9) Dept of Clin Investigation

(10) Associate Investigators
Joseph Lima, DAC

(11) Key Words:
t cell antigen receptor

Ann Hoyt, DAC
Sheri Muehlbauer, DAC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: June 86 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period:

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: The purpose of this study is to evaluate the structural and functional aspects of the thymus-derived lymphocyte (T-cell) antigen receptor on normal lymphocytes resulting from tetanus toxoid immunization.

(16) Technical Approach: Lymphocytes from healthy subjects with a history of DTP immunization and tetanus booster are cultured in-vitro in the presence of tetanus toxoid antigen preparations. Lymphocyte cultures are sampled for DNA content, HLA-DR, T3, T4, T8 and interleukin-2 receptor expression by flow cytometric evaluation. Cell cultures are enriched for antigen responding cells and subjected to long-term tissue culture cloning procedures. Lymphocyte membranes from responding clones are harvested for electrophoretic blotting analysis to characterize receptor molecules involved in antigen recognition.

(17) Progress: Principal Investigator PCS'd. No progress since last review.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/300 (3) Status: Ongoing

(4) Title: Early Identification of Borrelia burgdorferi Antibody
in Human Sera

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

(7) Principal Investigator: Sandy L. Tessier, DAC (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators
Alan G. Barbour, MD, NIH
Hamilton, MT

(11) Key Words:
borrelia infections

(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 a sensitive and specific screening assay
to detect human IgM directed against B. burgdorferi. The procedure
proposed here will determine if the avidinbiotin system can detect IgM an-
tibody bound to B. burgdorferi on nitrocellulose paper (NCP).

(16) Technical Approach: The spirochetal antigen is prepared by first
separating on SDS-PAGE and then transferring the proteins to nitrocellulose
paper by the Western blot method. The nitrocellulose paper strips are in-
cubated with sera and then probed with the appropriate anti-immunoglobulin.

(17) Progress: Due to the problems encountered in obtaining patient serum
we made arrangements to receive serum from Ft. McCoy. Over 700 acute and
200 convalescent serums have been collected and are scheduled to be shipped
to us within the month. I am now in the process of growing up large quan-
tities of spirochete to use as the antigen for the Western blot and im-
munoassays.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/301 (3) Status: Ongoing

(4) Title: ELISA and Western Blot Detection of Pneumocystis carinii Antigen in Rat Lung and Human Tissue Culture Models

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

(7) Principal Investigator: Richard M. Conran, CPT, MC
Donald D. Paine, DAC (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators

(11) Key Words: enzyme-linked immunosorbent assay
pneumocystis carinii Leo A. Andron, MAJ, MS
Carmen Ramirez, DAC
Sandy Tessier, DAC

(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 identify Pneumocystis carinii (PC) antigens useful for distinguishing clinical from sub-clinical pneumonitis.

(16) Technical Approach: Steroid induced PC pneumonia is produced in rats. Blood and lung tissue are harvested from control and clinically ill animals to study PC specific antibodies and antigens. Antigens are analyzed by gel electrophoresis, transblotting and reaction with specific antibodies. Finding unique antigens in clinically ill animals will indicate the feasibility of applying this diagnostic approach to humans.

(17) Progress: Due to lack of CO₂ incubator space, the human tissue culture model could not initiated. Technical difficulties have also hampered progress in identification of pneumocystis-specific antigens by gel-electrophoresis and transblotting.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/300 (3) Status: Ongoing

(4) Title: Etiology of Low Back Pain Due to Muscle Tension

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Clin Invstgn

(10) Associate Investigators

(11) Key Words:
low back pain
environmental recording
surface EMG

Joe E. Ozaki, COL, MC
Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, Ph.D., Denver,
VAMC
Bertram Rothschild, Ph.D.,
Denver, VAMC
John Arena, Ph.D., Augusta, VAMC

(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 relationship between (a) the intensity and duration of work, (b) patterns of muscle tension, and (c) onset of low back pain. To determine whether patterns of muscle tension occurring during normal daily activities are different among people with (a) chronic low back pain, (b) intermittent pain, and (c) no pain. To determine relationships between patterns of muscle tension observed among relatively young active duty soldiers with intermittent low back pain and relatively older veterans with intermittent and chronic low back pain of muscle tension origin. To determine whether simple preventive measures can decrease intensity and frequency of episodes of pain by changing response patterns of low back muscle tension.

(16) Technical Approach: We will do two week long, continuous muscle tension, activity, and pain recordings of relatively young active duty soldiers with duties ranging from strenuous to sedentary who are either pain free, report intermittent low back pain due to muscle tension, or report almost continuous low back pain due to muscle tension. We will do similar recordings of relatively older veterans having similar activity patterns and similar back pain problems.

If we are able to identify abnormal patterns, we will provide people who clearly show these patterns with behaviorally oriented muscle control treatments or mild muscle relaxants in order to determine the effect of these interventions on muscle contractions patterns and pain.

(17) Progress: New study at FAMC.

Publications and Presentations: None at FAMC.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/301 (3) Status: Ongoing

(4) Title: Determination of Mechanisms of Phantom Limb Pain: Phase 2

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators

Joe E. Ozaki, COL, MC
Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, MD, Ph.D.,
Denver, VAMC

(11) Key Words:
phantom limb pain
mechanisms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled 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 use MRI, nerve recording, and other techniques
to monitor veteran and active duty amputees who report shocking, shoot-
ing, and stabbing descriptors of phantom limb pain while they are ex-
periencing 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 am-
putees four times. In the pilot, only two amputees from each group will
participate. Two of the recordings will be at one particular pain in-
tensity 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: New study, not started yet.

Publications and Presentations: None

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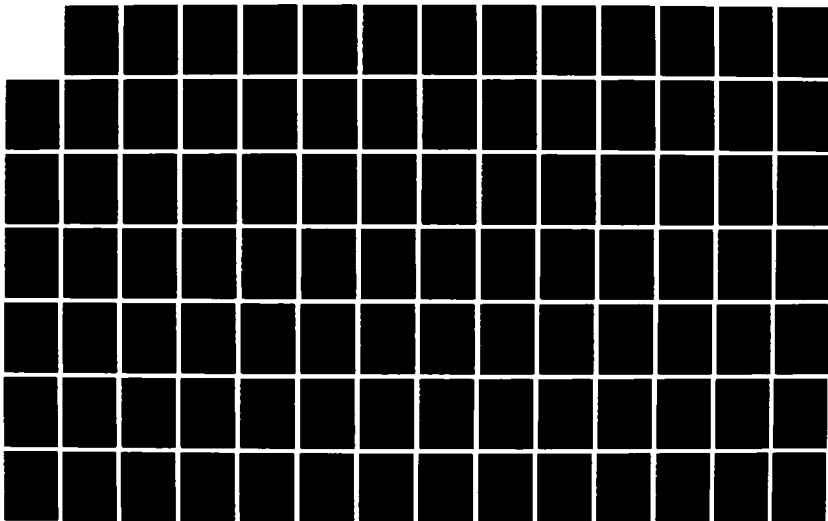
CLINICAL INVESTIGATION PROGRAM(U) FITZSIMONS ARMY
MEDICAL CENTER AURORA CO J K PODGORE 30 SEP 87 23

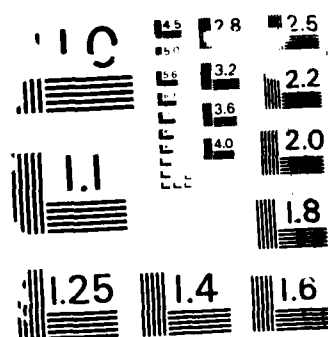
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IMAGING RESOLUTION TEST CHART
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FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/303 (3) Status: Ongoing

(4) Title: Mechanism Based Treatments of Phantom Limb Pain

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators

(11) Key Words:
phantom limb pain
treatments

Joseph K. Ozaki, COL, MC
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: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate the effectiveness of 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) trena-
tal 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: Project has not started yet.

Publications and Presentations: None from FAMC.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/304 (3) Status: Ongoing

(4) Title: Use of Heat Patterns in Evaluation of Spinal Cord
Injured Veterans

(5) Start Date: 1987

(6) Est Compl Date: 1989

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS
Jeffrey L. Ernst, Ph.D.,

(8) Facility: FAMC
Augusta, VAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators
Janusz Markowski, MD, Augusta,
VAMC

(11) Key Words:
spinal cord injury
thermography
phantom body pain

(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 confirm the results of two trials in which surface body heat patterns produced by spinal cord injured (SCI) veterans were compared with (a) completeness of injury and (b) reported location of sensations which appear to emanate from areas of the body no longer connected to the brain through the spinal cord (phantom sensations).

(16) Technical Approach: (a) Differences in trunk heat patterns produced by complete and incomplete SCI veterans will be evaluated through multiple recordings of twenty surgically complete SCI veterans and twenty veterans having similar but incomplete injuries who are matched on all other clinically important parameters; (b) relationships between heat patterns and location of phantom sensations will be evaluated by doing four thermographic recordings of each of 100 veterans diagnosed as having complete SCIs and then comparing the patterns with sensations maps filled out at each session.

(17) Progress: New study.

Publications and Presentations: None from FAMC.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/305 (3) Status: Ongoing

(4) Title: Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain

(5) Start Date: 1987

(6) Est Compl Date: 1989

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS
John G. Arena, Ph.D.

(8) Facility: FAMC
Augusta, VAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators
Joe Ozaki, COL, MC
Timothy Young, MD, Augusta, VAMC

(11) Key Words:
low back pain
thermography
surface EMG
MMPI

(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 test the effectiveness of paraspinal surface EMG, the MMPI, videothermography, physical examination, and standard diagnostic procedures for ascertaining objective data concerning the patient's actual low back pain intensity and underlying physical problems.

(16) Technical Approach: We will do paraspinal surface EMG and videothermographic recordings of at least 360 subjects with low back pain of six diagnostic categories and who hurt most while in one of six different positions (6 x 6 cell design with ten subjects in a group). Each subject will be recorded four times: Twice while their pain intensity is the same and twice while it varies up or down from the two similar recordings. Thus, each subject will be recorded at between two and three pain intensities. This provides data on change with time while pain is constant. All of these subjects will be given a modified version of the MMPI designed to differentiate between psychological factors and changes in responses due to presence or absence of low back pain. Each subject will also be given a complete orthopedic physical examination and any standard diagnostic procedures not already well documented will be done.

(17) Progress: New Study.

Publications and Presentations: None from FAMC.

DEPARTMENT OF CLINICAL INVESTIGATION

ANIMAL RESOURCES SERVICE

Training Support Summary

Training support was drastically curtailed during this report year due to total renovation of the Surgery Support Section of Animal Resources Service and the installation of a new epoxy-aggregate floor in the animal housing facility and epoxy painting of the animal housing facility throughout.

During the year, twenty 91A, B, C, and T personnel were trained in suturing techniques. Eleven were from Emergency Medicine Service, FAMC, two from Department of Pediatrics, and seven from Animal Disease Prevention and Control, FAMC. Training consisted of an overview of operating room procedure, including aseptic technique and operating room rules of etiquette, instruction in the surgical scrub, proper gowning and gloving technique, and hands-on experience in dry and wet labs. Training was conducted on 4 days, using 20 rats. 100 hours of training were provided, requiring 28 hours of training support by Animal Resources Service personnel.

Thirty-one microsurgery training sessions were conducted, providing 165 hours of training to 16 staff surgeons and residents. Eleven sessions were conducted for Orthopedic Service, 19 for Plastic Surgery Service, and one for Department of OB-Gyn. Sixty-plus hours of training support were required by Animal Resources Service personnel, and utilized 31 rats.

Two Advanced Trauma Life Support (ATLS) exercises were conducted during the year, using 8 goats in the training of 40 staff and Army Reserve physicians in the emergency management of casualties. 160-plus hours of training were received, requiring 84 hours of support by personnel of Animal Resources Service for planning, preparation, pre-op anesthesia induction, surgical preps, anesthesia monitoring, circulating and clean-up.

One kitten intubation exercise was conducted for The American College of Obstetricians and Gynecologists/Indian Health Service Postgraduate Course in Obstetrics, Gynecology and Neonatology. Ninety-seven physicians and nurses received 100-plus hours of training in resuscitative methods and endotracheal intubation, using 17 kittens and requiring 30-plus hours of support by Animal Resources Service personnel in planning, preparation, anesthesia monitoring and cleanup.

Two kitten intubation exercises were conducted for Department of Pediatrics. Forty physicians and nurses received 60-plus hours of training, using six kittens and requiring 20-plus hours of support by Animal Resources Service personnel in planning, preparation, anesthesia monitoring and cleanup.

Cost of Training

Suture Labs (Rats):	\$ 105/session x 4 sessions =	\$ 420
Microsurgery (Rats):	85/session x 31 sessions =	2,635
ATLS Exercises:	500/session x 2 sessions =	1,000
Intubation Exercises:	1,000/session x 3 sessions =	<u>3,000</u>
		\$ 7,055

DEPARTMENT OF OB-GYN

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 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

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

(7) Principal Investigator: George Phillips, COL, 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: 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
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: Master protocol that is still ongoing for many phase II
agents.

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 87 (2) Protocol WU#: 80/352 (3) Status: Ongoing

(4) Title: Section C: A Phase II Trial of CIS-Platinum

GOG 26

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: Open only for first line treatment of uterine neoplasms.

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 87 (2) Protocol WU#: 80/353 (3) Status: Ongoing

(4) Title: Section D: A Phase II Trial of VP 16

GOG 26

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: VP 16 appears to have minimal activity against ovarian and endometrial adenocarcinoma, squamous cell of the cervix at the dose and schedule tested.

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 87 (2) Protocol WU#: 80/354 (3) Status: Completed

(4) Title: Section L: A Phase II Trial of Tamoxifen

GOG 26

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: Tamoxifen has definite second-line activity for epithelial ovarian carcinoma and minimal toxicity.

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 87 (2) Protocol WU#: 80/355 (3) Status: Ongoing

(4) Title: Section N: A Phase II Trial of DHAD

GOG 26

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, 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: _____ b. Review Results: _____
c. Number of Subjects Enrolled 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: Minimal activity in ovarian cancer previously treated with
doxorubicin. Also minimal activity in previously treated carcinoma of the
cervix and non-squamous carcinoma of the cervix.

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 87 (2) Protocol WU#: 80/356 (3) Status: Ongoing

(4) Title: Section 0: A Phase II Trial of AZQ

GOG 26

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, 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: _____ b. Review Results: _____
c. Number of Subjects Enrolled 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: Open only for patients with ovarian carcinoma who are in-
eligible for the #26-N(DHAD) because of prior doxorubicin exceeding 400mg.

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 87 (2) Protocol WU#: 80/357 (3) Status: Ongoing

(4) Title: Section Q: A Phase II Trial of Aminothiadiazole

GOG 26

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: Minimal activity in previously treated ovarian carcinoma and
squamous cell of the cervix.

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 87 (2) Protocol WU#: 80/358 (3) Status: Ongoing

(4) Title: Section R: A Phase II Trial of Progestin

GOG 26

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

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

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: No patients entered yet.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/359 (3) Status: Ongoing

(4) Title: Section S: A Phase II Trial of VM26

GOG 26

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, 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: 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 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: Modest activity in previously treated epithelial ovarian carcinoma and squamous cell cervical carcinoma.

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 87 (2) Protocol WU#: 80/360 (3) Status: Terminated

(4) Title: Section T: A Phase II Trial of 4'-Deoxydoxorubicin

GOG 26

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, 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: _____ b. Review Results: _____
c. Number of Subjects Enrolled 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: Terminated

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/361 (3) Status: Terminated

(4) Title: A Randomized Study of Adriamycin as an Adjuvant After
Surgery and Radiation Therapy in Patients with High
Risk Endometrial Carcinoma, State I and Occult State II
GOG 34

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

(7) Principal Investigator: George Phillips, COL, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/362 (3) Status: Ongoing

(4) Title: A Clinical-Pathologic Study of Stages I and II Uterine
Sarcomas
GOG 40

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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

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 87 (2) Protocol WU#: 80/363 (3) Status: Terminated

(4) Title: Surgical Staging of Ovarian Cancer
GOG 41

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
GOG protocol

(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 cancer.

(16) Technical Approach: See protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/364 (3) Status: Terminated

(4) Title: Evaluation of Adjuvant Vincristine, Dactinomycin and
Cyclophosphamide Therapy in Malignant Germ Cell Tumors
of the Ovary After Resection of all Gross Tumor (Phase II)
GOG 44

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/365 (3) Status: Terminated

(4) Title: Evaluation of Vinblastine, Bleomycin and CIS-Platinum in
Stages III and IV and Malignant Germ Cell Tumors of the
Ovary (Phase II)

GOG 45

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/366 (3) Status: Terminated

(4) Title: A Study of Progestin Therapy and a Comparison of
Adriamycin Versus Adriamycin Plus Cyclophosphamide in
Patients With Advanced Endometrial Carcinoma After
Hormonal Failure (Phase III)

GOG 48

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/367 (3) Status: Terminated

(4) Title: A Surgical-Pathologic Study of Women With Invasive
Carcinoma of the Cervix, Stage I-B and Randomly Assigned
Radiation Therapy Versus No Further Therapy in Selected
Patients (Phase III)

GOG 49

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/368 (3) Status: Terminated

(4) Title: A Phase III Randomized Study of Cyclophosphamide Plus
Adriamycin Plus Platinol Versus Cyclophosphamide Plus
Platinol in Patients With Optimal Stage III Ovarian
Cancer

GOG 52

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(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 87 (2) Protocol WU#: 80/369 (3) Status: Ongoing

(4) Title: The Treatment of Women With Malignant Tumors of The
Ovarian Stroma with Combination VCR, Dactinomycin and
Cytosan (Phase III)

GOG 54

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: Treatment with Adriamycin has been deleted.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/370 (3) Status: Ongoing

(4) Title: Hormonal Contraception and Trophoblastic Sequelae After
Hydatidiform Mole (Phase III)
GOG 55

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: Multiple entries nationally.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/372 (3) Status: Terminated

(4) Title: A Phase III Randomized Study of Doxorubicin and
Cyclophosphamide Plus CIS-Platinum Plus BCG in Patients
with Advanced Suboptimal Ovarian Adenocarcinoma,
Stages III and IV

GOG 60

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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:
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: Terminated

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/374 (3) Status: Ongoing

(4) Title: A Clinical-Pathologic Study of Stages II-B, III and
IV-A, Carcinoma of the Cervix
GOG 63

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/375 (3) Status: Terminated

(4) Title: A Randomized Comparison of Rapid Versus Prolonged 24
Hour Infusion of CIS-Platinum in Therapy of Squamous Cell
Carcinoma of the Cervix, Phase III
GOG 64

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/376 (3) Status: Ongoing

(4) Title: Ultrastructural Staging and Therapeutic Consideration in
Small Cell Carcinoma of the Cervix (Phase II)
GOG 66

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

(7) Principal Investigator: George Phillips, COL, 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: 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
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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/377 (3) Status: Completed

(4) Title: Randomized Comparison of Single Agent Chemotherapy
Methotrexate and Methotrexate with Folinic Acid
Rescue, in Good Prognosis Metastatic Gestational
Trophoblastic Disease (Phase III)

GOG 70

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, 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: _____ b. Review Results: _____
c. Number of Subjects Enrolled 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: Completed

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/378 (3) Status: Ongoing

(4) Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin in Patients with Progressive Disease

GOG 72

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/379 (3) Status: Ongoing

(4) Title: Early Stage I Vulvar Cancer Treated with Ipsilateral
Superficial Inguinal Lymphadenectomy and Modified
Radical Hemivulvectomy (Phase III)

GOG 74

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(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: b. Review Results:
c. Number of Subjects Enrolled 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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/380 (3) Status: Ongoing

(4) Title: A Clinical Pathologic Study of Primary Malignant Melanoma
of the Vulva Treated by Modified Radical Hemivulvectomy
GOG 73

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: Acquiring acceptable number of patients nationally.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/381 (3) Status: Ongoing

(4) Title: Postoperative Pelvic Radiation in Stages I and II Mixed
Mesodermal Tumors of the Uterus (Phase III)
GOG 75

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/382 (3) Status: Terminated

(4) Title: Ovarian Cancer Study Group Protocol for all State I-C
and II-A, B and C, Selected Stages IA-2 and IB-2
GOG 7602

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(17) Progress: Terminated

Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/383 (3) Status: Completed

(4) Title: Chip Versus Carboplatin in Advanced/Recurrent Squamous
Cell Carcinoma of the Cervix
GOG 77

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(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: b. Review Results:
c. Number of Subjects Enrolled 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: Both regimens sufficiently active to justify phase III
study.

Publications and Presentations: Several submitted by GOG.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/384 (3) Status: Ongoing

(4) Title: Evaluation of Adjuvant Vinblastine, Bleomycin and Cis-platinum Therapy in Total Resected Choriocarcinoma, Endodermal Sinus Tumor, or Embryonal Carcinoma of the Ovary Pure and Mixed with Other Elements

GOG 78

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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.

6. Technical Approach: See protocol

(17) Progress: Ongoing

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/385 (3) Status: Terminated

(4) Title: Single Agent Weekly Methotrexate (NSC#740) Therapy in the
Treatment of Nonmetastatic Gestational Trophoblastic
Disease, Limited Access, Phase II

GOG 79

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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
cancer.

(16) Technical Approach: See protocol

(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 87 (2) Protocol WU#: 80/386 (3) Status: Terminated

(4) Title: Extended Field Radiation Therapy & Hydroxyurea (NSC032065)
Followed by a Randomized Comparison of Cisplatin
(NSC119875) or No Further Therapy in Patients with
Cervical Squamous Cell Carcinoma Metastatic to High
Common Iliac and/or Para-Aortic Lymph Nodes (Phase III)

GOG 59

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

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
GOG protocol

(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:
1. Number of Subjects Enrolled During Reporting Period:
2. Total Number of Subjects Enrolled to Date:
3. 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,
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: Terminated

(18) Publications and Presentations:

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/352 (3) Status: Ongoing

(4) Title: Characterization of Steroid Hormones Produced by Short-Term Incubation of Luteal Cells Obtained from Macaca fascicularis with Induced Luteal Phase Defects

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

(7) Principal Investigator: Edward Miller, CPT, MC
Charles F. Ferris, CPT, MS (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators
Donald G. Corby, COL, MC
Albert H. McCullen, MAJ, VC
Edward Lundblad, LTC, MC

(11) Key Words: corpus luteum

(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: The objective is to determine if differences exist between control and luteal phase defect induced cycles in the short-term production of steroids significant during the mid-luteal phase of the menstrual cycle of monkeys. If differences exists, possible new therapy for specific types of infertility may be recommended.

(16) Technical Approach: Luteal cells are obtained 5-8 days post-ovulation by luteectomy. The luteectomy obtained cells are processed, then cultured for 3 hours. The supernatant will be assayed for pregnenolone, progesterone, 17OH progesterone and testosterone using RIA procedures. The differences in assay levels of the steroid production from the control and treated cells will be statistically measured using multiple mean tests.

(17) Progress: Culture and production of luteal cells from the control cycle has been completed. Problems have occurred during the treatment phase and will be evaluated.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/350 (3) Status: Terminated

(4) Title: A Phase II Trial of Hexamethylmelamine in Advanced or
Recurrent Endometrial Cancer
GOG 86

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: Minimal activity.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/351 (3) Status: Completed

(4) Title: Cytoreductive Surgery and PAC Chemotherapy vs. PAC
Chemotherapy
GOG 80

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

(7) Principal Investigator: George Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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: Data now 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 87 (2) Protocol WU#: 87/350 (3) Status: Terminated

(4) Title: A Phase III Trial Comparing Combination Chemotherapy with
Whole Abdominal Radiation Therapy for Stage III Optimal
Epithelial Ovarian Cancer with no Gross Residual Disease
GOG #82

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George L. Phillips, COL, 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: _____ b. Review Results: _____
1. Number of Subjects Enrolled During Reporting Period: _____
2. Total Number of Subjects Enrolled to Date: _____
3. Note any adverse drug reactions reported to the FDA or 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: Terminated

(18) Publications and Presentations: None

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

(1) Date: 30 Sep 87 2) Protocol WU#: 87/351 (3) Status: Ongoing

(4) Title: A Randomized Comparison of Hydroxyurea Versus 5-FU
Infusion and Bolus Cisplatin as an Adjunct to Radiation
Therapy in Patients with Stages II-B, III and IV-A
Carcinoma of the Cervix and Negative Para-Aortic Nodes

GOG 85

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

(7) Principal Investigator: George L. Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amend-1)

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/352 (3) Status: Ongoing

(4) Title: A Phase II Trial of Methotrexate in Patients with Advanced
or Recurrent Endometrial Carcinoma

GOG 86D

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George L. Phillips, COL, 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: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

Study Objective: The objective is to participate in the GOG group
study of malignancies.

Treatment Approach: See Protocol

Progress: Ongoing

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/353 (3) Status: Ongoing

(4) Title: Evaluation of Cisplatin, Etoposide, and Bleomycin
Induction Followed by Vincristine, Dactinomycin and
Cyclophosphamide Consolidation in Advanced Ovarian
Germ Cell Tumors

GOG 90

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

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(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: b. Review Results:
c. Number of Subjects Enrolled 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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 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: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(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: b. Review Results:
c. Number of Subjects Enrolled 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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/355 (3) Status: Ongoing

(4) Title: Evaluation of a Shortened Course of Vincristine, Dactinomycin and Cyclophosphamide as Adjuvant Therapy for Immature Teratoma of the Ovary, Stage I, Grade 2, Completely Resected

GOG 84

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

(7) Principal Investigator: George L. Phillips, COL, 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: b. Review Results:
c. Number of Subjects Enrolled 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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/356 (3) Status: Ongoing

(4) Title: A Phase III Randomized Study of Cyclophosphamide and Cisplatin in Patients with Suboptimal Stage III and State IV Epithelial Ovarian Carcinoma Comparing Intensive and Non-Intensive Schedules

10-1-87

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

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(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: b. Review Results:
Number of Subjects Enrolled During Reporting Period: 3
Total Number of Subjects Enrolled to Date:
List any adverse drug reactions reported to 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 study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

(18) Publications and Presentations: None

DEPARTMENT OF PEDIATRICS

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 82/403 (3) Status: Ongoing

(4) Title: Rare Tumor Protocol for Childhood Solid Tumor
Malignancies, Ancillary
POG 7799

Start Date: (6) Est Compl Date:

Principal Investigator: (8) Facility: FAMC
Askold D. Mosijczuk, COL, MC

Dept of Pediatrics (10) Associate Investigators
Thomas Carter, COL, MC
Key Words: Jeffrey Clark, COL, MC
POG protocol Randal Henderson, MAJ, MC
neoplasms Vishnu Reddy, LTC, MC
Michael Edwards, CPT, MC

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

a. Date, Latest IRC Review: b. Review Results:
Number of Subjects Enrolled During Reporting Period:
Total Number of Subjects Enrolled to Date:

Note any adverse drug reactions reported to the FDA or sponsor for
lying under an FDA-awarded IND. May be continued on a separate sheet,
designated as "(14)e".

c. Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

d. Technical Approach: See protocol

e. Progress: Two patients have been registered at FAMC, one pt. with su-
bconjunctival melanoma of the eye is continuing to do well, in complete remis-
sion. The other patient, a new born with metastatic undifferentiated sar-
coma of the face has died. The study remains open for new patient entry.

f. Lectures and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 82/404 (3) Status: Terminated

(4) Title: Evaluation of Systemic Therapy for Children with T-Cell
Acute Lymphatic Leukemia
POG 7837

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

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

(11) Key Words:

(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 malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WC#: 82/405 (3) Status: Terminated

(4) Title: Intergroup Rhabdomyosarcoma Study (IRS)-II
POG 7879

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:

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

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

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

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 82/406 (3) Status: Terminated

(4) Title: Evaluation of MOPP Adjuvant Chemotherapy in the Treatment
of Localized Medulloblastoma and Ependymoma, Phase III
POG 7909

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

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

(11) Key Words:

(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 malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Terminated

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCP 40 22 on rounded)

(1) Date: 30 Sep 87 (2) Protocol WU#: 82/407 (3) Status: Pending

(4) Title: National Wilms' Tumor Study-3 Phase III

POG 8000

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

Principal Investigator: (8) Facility: FAMC
Isidoro Mosijczuk, COL, MC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigator:

(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. Number of adverse drug reactions reported to the FDA:
f. Study conducted under an FDA-awarded IND. May be conducted under an
IND, and designated as "(14)e".

Study Objective: The objective is to perform a phase III trial of
the treatment of pediatric malignancies.

Study Approach: See Protocol

Study Design: Patients have been entered as per protocol
and patient entry.

Adverse and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 82/408 (3) Status: Terminated

(4) Title: Laboratory Subclassification and Evaluation of Treatment
Regimens in Acute Lymphoid Leukemia of Childhood
(ALinc #13)

POG 8035/36

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

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

(11) Key Words:

(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 malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 82/409 (3) Status: Terminated

(4) Title: Acute Nonlymphocytic Leukemia (ANLL) in Children,
Phase III
POG 8101

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, Col, MC

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

(11) Key Words:

(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 malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 82/410 (3) Status: Terminated

(4) Title: Comprehensive Care of the Child with Neuroblastoma:
A Stage and Age Oriented Study, Phase III
POG 8104/8105

(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: The objective is to participate in the POG group in the study of malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 82/411 (3) Status: Terminated

(4) Title: High-Dose Cyclophosphamide/High Dose Methotrexate with
Coordinated Triple Intrathecal Therapy for Stages III and
IV Nonlymphoblastic Lymphoma
POG 8106

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

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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 FAMC. 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 87 (2) Protocol WU#: 82/412 (3) Status: Terminated

(4) Title: Multi-Institutional Controlled Trial of Adjuvant
Chemotherapy in the Treatment of Osteosarcoma
POB 8107

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: One patient was entered at Fitzsimons who has sub-
sequently died of progressive disease. The study is closed 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 87 (2) Protocol WU#: 82/413 (3) Status: Terminated

(4) Title: Evaluation of DHAD in Children with Solid Tumors
Unresponsive to Standard Therapy, Phase II
POG 8139

(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: The objective is to participate in the POG group in the study of malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 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: 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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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 87 (2) Protocol WU#: 82/415 (3) Status: Terminated

(4) Title: Combination Chemotherapy for First Bone Marrow and/or Testicular Relapse of Childhood Acute Lymphoblastic Leukemia (ALL) During or Shortly Following Initial Continuation Therapy (SIMAL #3)

POG 8303

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: One patient was entered at FAMC and continues to be in complete remission status 10 months after completing two years of therapy on this protocol. Previous toxicity has been described in this patient. The study is no longer 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 87 (2) Protocol WU#: 82/416 (3) Status: Terminated

(4) Title: SIMAL #4 - Combination Chemotherapy for Remission Induction and Maintenance for: 1) Recurrent Childhood Lymphocytic Leukemia Occurring Six Months or Greater After Elective Cessation of Therapy; 2) Children with Occult Testicular Lymphocytic Leukemia After 3 Years of Continuous Complete Remission; 3) Children with Their First CNS Relapse (Whether on or off Maintenance Therapy at the Time of Relapse), Phase III

POG 8304

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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 FAMC. The study is closed 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 87 (2) Protocol WU#: 82/417 (3) Status: Terminated

(4) Title: Evaluation of Azirdinylbenzoquinone 9AZQ in Pediatric Patients with Recurrent Brain and Other Solid Tumors, Phase II

POG 8336

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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 FAMC. 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 87 (2) Protocol WU#: 82/418 (3) Status: Terminated

(4) Title: Evaluation of Response and Further Determination of
Toxicity of DBD in Children with Recurrent Solid
Tumors and Brain Tumors Resistant to Standard Therapy,
Phase II

POG 8370

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

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

(11) Key Words:

(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 malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 82/419 (3) Status: Terminated

(4) Title: Four-Drug Combination Chemotherapy for Children with
Stage D Neuroblastoma Older than 365 Days at Diagnosis,
Phase III
POG 8441

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

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

(11) Key Words:
drug therapy

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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) Technique / Approach: See Protocol

(17) Progress: One patient was entered at FAMC with Stage D metastatic
neuroblastoma. The patient had a mixed response with tolerable toxicity
and subsequently underwent an autologous bone marrow transplant. The
patient is still alive with progressive disease. The study is closed 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 87 (2) Protocol WU#: 82/420 (3) Status: Ongoing

(4) Title: Intergroup Thabdomyosarcoma 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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: One patient has been entered at FAMC. The patient is currently 23 months from the start of treatment and continuing to be in complete remission after having responded dramatically to treatment with chemotherapy and radiation therapy according to protocol as well as hemipelvectomy. Toxicity has been mild to moderate myelosuppression. The study remains open 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 87 (2) Protocol WU#: 83/401 (3) Status: Ongoing

(4) Title: Prevalence of Endometriosis Externa in Adolescent
Women Complaining of Severe Dysmenorrhea

(5) Start Date: 1983

(6) Est Compl Date:

(7) Principal Investigator:
Mark E. Blaedel, LTC, MC
Edward Lundblad, LTC, MC
David W. Wells, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:
endometriosis
dysmenorrhea

(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: 622

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: An epidemiologic survey of young women will document
the prevalence of symptomatic endometriosis externa in a middle class
primary care population of adolescent women complaining of dysmenorrhea.
This prevalent figure will tell the health care provider how alert he has
to be to this condition.

(16) Technical Approach: This retrospective stage of epidemiologic survey
is designed to isolate by questionnaire those young women who might have
endometriosis and subject them to laparoscopy.

(17) Progress: Number of patients enrolled during this reporting period:
Stage I, 622; Stage II, 85; Stage III, 10* - Stage III - six patients have
been shown to have laparoscopy proven endometriosis and four have been
shown to have laparoscopy proven primary dysmenorrhea. There have been no
significant progress since August 1985 at which time Principal Investigator
Wells to Fort Polk, LA. PI returned October 1986 but is again scheduled to
go to Fort Bragg, NC October 1987. Study has been hampered and no easy
way to analyze the large data base. These major problems have been al-
leviated by appointing a new Principal Investigator and acquisition of a
microcomputer. Data is being input.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 83/402 (3) Status: Ongoing

(4) Title: B₂ Microglobulin as a Measure of Renal Tubular Function
in the Neonate

(5) Start Date: 1983

(6) Est Compl Date: 1988

(7) Principal Investigator:
Beverly Anderson, CPT, MC

(8) Facility: FAMC
St. Louis Children's Hospital
Ronald Portman, MD, U. Texas at
Houston
Gerald B. Merenstein, MD, Univ. of
Colo. Health Sciences Center

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:
kidney tubles
natriuretic peptides

(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: 7

d. Total Number of Subjects Enrolled to Date: 64

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 the study is to examine renal handling
of low molecular weight proteins in the neonate at various gestational and
postpartum ages who manifest evidence of normal or abnormal intrauterine
environments as well as extrauterine insults. Recent data has shown that
these insults can cause previously undiagnosed renal damage.

(16) Technical Approach: We will study the effects of these insults on
the neonatal kidney from the standpoint of GFR as well as tubular function.
These will both be evaluated in light of the rapid and profound changes in
fluid and electrolytes in the first days of life. The protocol continues
to be low risk as blood sampling is minimal. The protocol will clearly
benefit the patient as renal damage from the aforementioned insults cannot
be diagnosed in any other fashion with current technology.

(17) Progress: The Atriopeptin arm of the protocol has recently been inac-
tive secondary to technical problems with the assay; however, the B₂
Microglobulin evaluations have continued. The protocol was accepted at the
UCHSC in February 1987 and enrollment of patients is now being conducted
through their CRC.

Presentations:

- (1) Portman, R.J.: B2 Microglobulin as a Marker of Renal Tubular Injury in the Neonate. Presented: COMPRA, Aspen, CO 1984.
- (2) Portman, R.J., Cole, J.: B2 Microglobulin as a Marker of Renal Tubular Injury in the Full Term Neonate with Meconium Stained Amniotic Fluid. Presented: National Student Forum for Research by Medical Students, New Orleans, LA, 1983. Winner of the best renal paper.
- (3) Portman, R.J.: B2 Microglobulin as a Measure of Tubular Damage From Meconium Staining of the Amniotic Fluid. Presented: The USPS 1984 - Finalist for the Ogden Bruton Award.
- (4) Portman, R.J.: B2 Microglobulin as a Marker of Renal Tubular Dysfunction. Presented: Society for Pediatric Research, San Francisco, CA, 1984.
- (5) Portman, R.J., Anderson, B.: Atriopeptin as the Cause of the Diuresis in the Newborn in the First days of Life. Presented: COMPRA, Aspen, CO 1986.

Publications:

Cole, JW, Portman, RJ, Perlman, J, et al: Urinary B2 Microglobulin in Full Term Newborns: Evidence for Proximal Tubular Dysfunction in Infants with Meconium Stained Amniotic Fluid. Pediatrics, 76:958-964, 1985.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/402 (3) Status: Completed

(4) Title: Hypertension in Adolescents

(5) Start Date: 1984

(6) Est Compl Date:

(7) Principal Investigator:
V. Lugo-Miro, CPT, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators
R. J. Portman, MAJ, MC

(11) Key Words:
hypertension
adolescence

(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: _____ 1426

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: Establish normal blood pressure values for height and weight rather than by age.

(16) Technical Approach: For all patients visiting our clinic we will record age, height, weight, race, sex, Tanner stage of sexual development. Then will proceed to measure first, fourth and fifth Korotkoff sounds for blood pressure on right arms of seated individuals. For those that consent, body fat determinations are also recorded.

(17) Progress: Study being prepared for publication.

Presentations:

(1) Lugo-Miro, V.I., Portman, R.J.: The Use of Height Age and Weight in the Diagnosis of Adolescent Hypertension. Presented: Society for Adolescent Medicine, Boston, MA, March 1986.

(2) Lugo-Miro, V.I., Portman, R.J.: The Use of Height Age and Weight in the Diagnosis of Adolescent Hypertension. Presented: Society for Pediatric Research, Washington, DC, May 1986.

Publications: In preparation.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/401 (3) Status: Ongoing

(4) Title: Evaluation of Adrenocorticotrophic Hormone (ACTH) in the Prevention of Cancer Chemotherapy Induced Nausea and Vomiting in Children

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

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words: drug therapy
adrenal cortex hormones
corticotropin
Michael Shull, CPT, MC
Kenneth Beougher, MAJ, MS
Michael Edwards, CPT, MS

(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: Evaluate the effectiveness of ACTH in decreasing nausea and vomiting in children undergoing cancer chemotherapy. To evaluate the toxicity of ACTH and thorazine in this setting.

(16) Technical Approach: This will be a multi-center, double blinded, randomized, crossover study with patients serving as their own control. Patients undergoing at least two courses of identical cancer chemotherapy will be randomized at the beginning of the study to receive either of 2 combinations of antiemetics; (a) ACTH with thorazine or (b) placebo with thorazine. Patients will then receive the other combination prior to their next course of chemotherapy. Extent of nausea, vomiting, side effects and patient preference will be measured and compared between the 2 combinations of antiemetics.

(17) Progress: In FY 87 no new patients have been entered on study. Currently, there have been four patients entered on study, one at FAMC, three at Brooke Army Medical Center. Toxicity has been mild and related to side effects of the thorazine, such as drowsiness and dry mouth. There have been no other toxicities noted. Both treatment arms have been well tolerated. A major problem with this study is the difficulty of recruiting eligible patients to receive the treatment arm with ACTH. Also, our further difficulty is that the ACTH is given IM which necessitates three IM

injections. Because of this the study has been discussed with other coordinators at the other institutions with the possibility of modifying the protocol to include IV ACTH; however, this would be a reasonable option since the half-life of IV ACTH is quite brief. At this point I plan to rediscuss this problem with the other coordinators of the study at the other Army Medical Centers at the upcoming October meeting in St. Louis and will be making recommendations following this meeting.

Presentations:

Mosijczuk, A.D.: Evaluation of Adrenocorticotrophic Hormone (ACTH in the Prevention of Cancer Chemotherapy Induced Nausea and Vomiting in Children. Presented: Uniformed Services Oncology Consortium Meeting, Orlando, Florida, April 1986.

Publications: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/402 (3) Status: Completed

(4) Title: Naloxone Therapy of Streptococcal Sepsis in a Suckling Rat Model

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
M. Gail Murphy, CPT, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

Gerald B. Merenstein, COL, MC

(11) Key Words:

James T. Berkenbaugh, MAJ, MC

naloxone
sepsis

(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: 400 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: Study the effect of Naloxone on survival in an animal model of Group B strep.

(16) Technical Approach: Survival of those infected animals treated with intraperitoneal Naloxone is compared to those not treated.

(17) Progress: With LD₂₅ Naloxone survival improved. When an LD₉₅ was given, no statistical difference in survival.

Presentations:

(1) Murphy, MG, Pierce, JR, Berkenbaugh, JT, Merenstein, GB: Naloxone Therapy of Streptococcal Sepsis in a Suckling Rat Model. Presented: COM-ASA, Aspen, Colorado, July 1985.

(2) Murphy, MG, et al: Naloxone Treatment of Sepsis in a Suckling Rat Model. Presented: Uniformed Services Pediatric Seminar, Denver, CO, March 1986.

(3) Murphy, MG, et al: Naloxone Treatment of Sepsis in a Suckling Rat Model. Presented: American Academy of Pediatrics, District VIII Section Perinatal Pediatrics, Las Vegas, NV, May 1986.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/405 (3) Status: Terminated

(4) Title: Blood and Marrow Neutrophils in Experimental Group B
Streptococcal Sepsis: The Effects of Indomethacin
and Naloxone

(5) Start Date: 1985

(6) Est Compl Date:

(7) Principal Investigator:
James T. Berkenbaugh, MAJ, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:
streptococcus
septicemia

Vishnu Reddy, LTC, MC
Paul Simon, CPT, MC
Stephen Nelson, MAJ, MC
Gerald B. Merenstein, COL, MC
Askold D. Mosijczuk, 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: _____
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 buffy coat smears reflect the status
of the marrow neutrophil storage pool. To study the effects of in-
domethacin and naloxone in blood and marrow neutrophil kinetics.

(16) Technical Approach: Experimental Group B Streptococcal Sepsis is in-
duced by SC inoculation of newborn rats at 3-4 days of age. Group of
animals are sacrificed at 2, 6, 20 and 24 hours. Blood is obtained from the
jugular vein for WBC, peripheral smear, buffy coat and differential. Bone
marrow is obtained from the tibia or femur, and neutrophil proliferative
and storage pools determined.

(17) Progress: Principal and Associate Investigators have departed FAMC.
Attempts to obtain adequate bone marrow specimens for evaluation and inter-
pretation were unsuccessful.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 85/406 (3) Status: Ongoing

(4) Title: Live Attenuated Oka/Merck Chickenpox Vaccine in Healthy Children in Day Care Centers

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

(7) Principal Investigator: John K. Podgore, COL, MC (8) Facility: FAMC

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

(11) Key Words: varicella vaccine Myron J. Levin, M.D.
U Co. HSC

(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: 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: In order to determine if the live varicella vaccine administered during the study induces sustained immunity comparable to naturally acquired varicella infection. Follow-up blood specimens for antibody determination are requested at approximately 12-16 months and 24-28 months post vaccination.

(16) Technical Approach: See Protocol

(17) Progress: Thirty-one children in the day care center were entered into the trial. Fifteen received vaccine with the first injection, while 16 received placebo, and then received vaccine six weeks later as per protocol. No vaccinees had any systemic symptoms. Thus the vaccine was well tolerated. Four patients had serologic evidence of past varicella prior to immunization. All the true susceptibles developed a good antibody response. Plans are to bleed these children at one year to determine persistence of immunity.

Publications and Presentations: None.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/401 (3) Status: Ongoing

(4) Title: Initial Induction Failures in Childhood Acute
Lymphoblastic Leukemia, A Group-Wide Pilot Study
POG 8461

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

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators

(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
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: No patients have been entered at FAMC. 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 87 (2) Protocol WU#: 86/403 (3) Status: Ongoing

(4) Title: Prophylactic Intravenous Immunoglobulin for Infections
in High Risk Neonates

(5) Start Date: March 86 (6) Est Compl Date: 1989

(7) Principal Investigator: C. Gilbert Frank, LTC, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators
Beverly A. Anderson, MAJ, MC

(11) Key Words:
high risk neonates
prophylactic IVIG

(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: 10
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 evaluate in a double blind manner the effective-
ness compared to an albumin placebo of IVIG preventing infectious disease
and/or reducing morbidity and mortality in the high risk neonate.

(16) Technical Approach: 2,000g, 34 wks gestation are eligible for the
study. Routine evaluations and therapy will be given as necessary to all
infants. IgG antibody titers will be drawn pre and post infusion as well
as at 1, 2, and 8 weeks. The incidence of infection as well as mortality
and morbidity will be evaluated.

(17) Progress: Patient entry and data collection have begun.

Publications and Presentations: Prophylactic Intravenous Immunoglobulin
(IVIG) in High Risk Neonates. Presented. 16th Aspen Conference on Perina-
tal Research (ACPR) Aspen, CO July, 1987.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/404 (3) Status: Ongoing

(4) Title: Intensive Chemotherapy (MOPP-ABVD) plus Low-Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, III₂A, IIIB, IV Hodgkins Disease in Pediatric Patients, A Groupwide Pilot Study
POG 8426

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

(7) Principal Investigator: Arkold D. Mosijczuk, COL, MC (8) Facility: FAMC

(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:
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: No patients have been entered at FAMC. 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 87 (2) Protocol WU#: 86/405 (3) Status: Terminated

(4) Title: Phase II Study of Carboplatin in the Therapy of Children
with Progressive or Recurrent Brain Tumor

POG 8464

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

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

(11) Key Words:

(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 malignancies.

(16) Technical Approach: See Protocol

(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 87 (2) Protocol WU#: 86/406 (3) Status: Ongoing

(4) Title: Infant Leukemia Protocol, A Group-Wide Pilot Study
POG 8493

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(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: _____

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: One pt. was treated according to this protocol at FAMC after transferring from Brooke Army Medical Center. The child did well until approximately nine months after diagnosis when she developed progressive leukemia and subsequently died 10 months from diagnosis. Toxicity was mild to moderate myelosuppression with no other unusual toxicities. 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 87 (2) Protocol WU#: 86/407 (3) Status: Ongoing

(4) Title: Treatment of Children with Newly Diagnosed Acute Non-Lymphoblastic Leukemia Using High-Dose Cytosine Arabinoside and Etoposide + Azacytidine for Intensification of Early Therapy, POG Pilot Study
POG 8498

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

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(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:
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: No patients have been entered at FAMC. 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 87 (2) Protocol WU#: 86/408 (3) Status: Ongoing

(4) Title: Laboratory Classification in Acute Lymphoid Leukemia of
Childhood (ALinC 14C) Phase III
POG 8600

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(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
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: Two new patients at FAMC have been entered on study as well
as a third patient who was entered on study at Walter Reed and transferred
here. Since this is a laboratory classification study, there is no
toxicity. The three patients include one with T-cell ALL and two with
null-cell CALLA pos. ALL. The study is ongoing and is 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 87 (2) Protocol WU#: 86/409 (3) Status: Ongoing

(4) Title: ALinC #14 Pharmacology: A Pediatric Oncology Group
Non-Therapeutic Study
POG 8601

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(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: _____
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 ongoing and is open to new patient entry. The
same three patients that were entered in POG 8600 were also entered on the
8601 study. This is a pharmacology study to measure methotrexate and folic
acid metabolites. All three patients remain on study.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/410 (3) Status: Ongoing

(4) Title: ALinC #14: Evaluation of Treatment Regimens in Acute
Lymphoid Leukemia of Childhood (ALinC#14) - A Pediatric
Oncology Group Phase III Study
POG 8602

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

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(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
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: Two patients, one entered at FAMC and another entered at
Walter Reed and transferred to FAMC are currently on this study. The
patient diagnosed at FAMC has subsequently been transferred to Travis Air
Force Base and continues on protocol with information being related peri-
odically to the principal investigator at FAMC. Significant toxicity in
that patient has included severe myelosuppression with septicemia secondary
to high-dose methotrexate and high-dose Ara-C chemotherapy as per protocol.
The other patient on this protocol who was received in transfer from Walter
Reed is doing well with only minimal hepatotoxicity and expected mild grade
I myelosuppression. That patient is receiving a less aggressive regimen on
this study. 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 87 (2) Protocol WU#: 86/411 (3) Status: Ongoing

(4) Title: Diagnosis and Therapy of Glomerular Hyperfiltration in Pediatric Patients with Type I Diabetes Mellitus

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

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

(9) Dept/Svc: Pediatrics (10) Associate Investigators
Ronald J. Portman, MAJ, MC
Kerry R. Johnson, CPT, MC
Charlotte Stahl, RD

(11) 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: 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: Principal Investigator did not fill in.

(16) Technical Approach: Principal Investigator did not fill in.

(17) Progress: We have continued to add patients to our study design. It has proven to be extremely intensive to take patients through the entire 6 weeks of the study. Currently we are exploring possibilities to add Herman Hospital in Houston, Texas, diabetes program to ours in order to expand our study population. Preliminary look at the data on the first patients collected shows early evidence to support the hypothesis 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 87 (2) Protocol WU#: 86/412 (3) Status: Ongoing

(4) Title: Adolescent Oral Contraceptive Study: A Comparison of a Triphasic Formulation (Triphasil) with a Fixed-Combination Pill (Ortho-Novum 1/35)

(5) Start Date: 1986

(6) Est Compl Date: 1988

(7) Principal Investigator:
Charles S. Horn, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: PED/Adol. Med.

(10) Associate Investigators
David W. Wells, COL, MC
CPT Schaffrinna

(11) Key Words:
oral contraceptives
comparison

(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: 60

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: Compare the clinical usefulness of a triphasic oral contraceptive with a standard, fixed-combination, low-dose pill in an adolescent patient population.

(16) Technical Approach: Patients that agree to enter the study will be randomized by the pharmacy into one of two groups: a) Triphasil and b) Ortho-novum 1/35. An induction questionnaire and physical will be obtained. Subsequent at 1,3 and 6 month intervals the patients will be contacted and further information obtained. If the patient decides to discontinue pill use a discontinuation form will be filled out.

(17) Progress: Compliance has been one of the greatest difficulties encountered with this study. At the time of departure of the principal investigator, 51 individuals had entered the study with 6 completions and 18 discontinuations. Currently that tally has changed to 60 total patients enrolled with 16 completions and 18 discontinuations. Those that have completed the study often only complete the induction questionnaire and the 6 month followup. It is hoped that this limited information will still be useful in the final assessment.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/413 (3) Status: Completed

(4) Title: Physician Survey on Adolescent Health

(5) Start Date: Sep 86 (6) Est Compl Date: Sep 87

(7) Principal Investigator: David O. Chastain, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Adol. Hlth. (10) Associate Investigators: Joe Sauders, COL, MC

(11) Key Words:

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

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

(15) Study Objective: To study the impact of recent changes in pediatric education on the involvement of pediatricians in the delivery of health care to adolescents.

(16) Technical Approach: See protocol.

(17) Progress: The study has been completed. We have analyzed the data and are in the process of writing a paper for submission to a pediatric journal.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/400 (3) Status: Ongoing

(4) Title: Pilot Protocol for Marrow Relapse on Continuation Therapy
in Childhood Acute Lymphoblastic Leukemia
POG 8594

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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
remain 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 87 (2) Protocol WU#: 87/401 (3) Status: Ongoing

(4) Title: Combined Therapy and Restaging in the Treatment of Stages
I, IIA, and IIIA Hodgkins Disease in Pediatric Patients,
A Pediatric Oncology Group Phase III Study
POG 8625/26

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

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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 FAMC. 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 87 (2) Protocol WU#: 87/402 (3) Status: Terminated

(4) Title: Medulloblastoma Favorable Prognosis: Randomized Study of
Reduced Dose Irradiation to Brain and Spinal Contents
vs Standard Dose Irradiation---A Phase III Study in
Conjunction with CCSG

POG 8631

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

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

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

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/403 (3) Status: Ongoing

(4) Title: Randomized Phase II Study of Carboplatin (CBCDA) vs.
CHIP in Treatment of Children with Progressive or
Recurrent Brain Tumor

POG 8638

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

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: One patient, a twelve-year-old girl with recurrent pon-
tine glioma was entered on this study in November of 1986. She is con-
tinuing to do well with stable disease. Toxicity has been limited to
moderate myelosuppression. The study is 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 87 (2) Protocol WU#: 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: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

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

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CLINICAL INVESTIGATION PROGRAM(U) FITZSIMONS ARMY
MEDICAL CENTER AURORA CO J K PODGORE 30 SEP 87 23

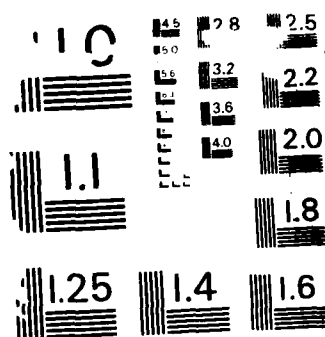
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FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/405 (3) Status: Ongoing

(4) Title: Front Loading Chemotherapy in Children with Increased Medulloblastoma

POG 8695

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

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(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:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or 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: One patient has been entered at Fitzsimons. The patient suffered severe grade IV myelosuppression secondary to the high-dose cyclophosphamide as per protocol but recovered; however, subsequently during radiation therapy, the patient developed severe bone marrow hyperplasia lasting for two months and is currently in the MICU on multiple antibiotics. It is not certain whether the initial chemotherapy prior to radiation as per protocol may have contributed to this severe prolonged myelosuppression seen during radiation therapy. Group wide 11 patients have been entered on protocol. Data is too preliminary to evaluate for rate of response. 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 87 (2) Protocol WU#: 87/406 (3) Status: Ongoing

(4) Title: Effects of Oral Contraceptive Agents on Coagulation
Parameters in the Adolescent Patient

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

(7) Principal Investigator: (8) Facility: FAMC
Patrice T. Gaspard, MAJ, MC
Vishnu Reddy, LTC, MC
Judy Barber, DAC
Patricia Rush, DAC

(9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators
Donald G. Corby, COL, MC

(11) Key Words:
oral contraceptive agents
thromboembolic disorders
clotting factors

(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: 18
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 assess if the newer oral contraceptive agents
used today have effects on the levels of clotting factors in adolescent
patients (specifically Factor VIII, PT, PTT, fibrinogen, Antithromb III,
and protein C).

(16) Technical Approach: Patients have the above studies measured at
baseline, then 3 months, 6 months and one year after being on oral con-
traceptives.

(17) Progress: Eighteen patients enrolled so far, just 3 months 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 87 (2) Protocol WU#: 87/407 (3) Status: Ongoing

(4) Title: Headaches Among Adolescents

(5) Start Date:

(6) Est Compl Date: 1988

(7) Principal Investigator:

Michael G. Schaffrinna, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: PED/Adolescent Med.

(10) Associate Investigators

Mark Blaedal, COL, MC

(11) Key Words:

headaches
adolescents

(12) Accumulative MEDCASE:*

*Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:*

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 210

d. Total Number of Subjects Enrolled to Date: 210

e. Note any adverse drug reactions reported to the FDA or 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 prevalence, type and sex distribution of headaches in adolescents.

(16) Technical Approach: Patients will be given the opportunity to fill out a headache questionnaire when they arrive at the adolescent medicine clinic. Questions were designed to evaluate any headache complaint according to type i.e., migrainous, muscle contraction (tension) or other. The data will then be evaluated to arrive at some demographic information.

(17) Progress: As recommended by the IRC a control trial of the questionnaire was started shortly after approval of the study. After 50 patients enrolled, the questionnaire and results were analyzed and questions clarified where necessary or deleted. Current questionnaire began in July and results thus far are good. Of note is the presence of light headedness/dizziness in patients with tension headache. This has to my knowledge not been reported before. I am awaiting higher numbers before this finding will be significant.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/408 (3) Status: Ongoing

(4) Title: Efficacy of Prophylactic Anti-Migraine Therapy in the Adolescent Therapy Patient - A Double Blinded Study

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

(7) Principal Investigator: Michael J. Schaffrinna, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators

MAJ Miller, MD
LTC Dorsett, MD

(11) Key Words:
migraine headaches
verapamil

(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".

*I am awaiting final approval from HSC prior to starting enrollement.

(15) Study Objective: Determine efficacy of prophylactic verapamil in a double blinded study in adolescent migraine sufferers. At the same time this study would establish a per kilogram dose for younger adolescents.

(16) Technical Approach: Patients will be evaluated at entry for the diagnosis of migraine headaches with a frequency per history of at least two events per month. Presence of organic disease will be evaluated via physical and laboratory evaluation. If no contraindications to verapamil exist then enrollment will occur. Over the next two months no medications will be given. The patient will see two different neurologists who will again evaluate them and fill out an interval history sheet. If both concur with the diagnosis, the patient will be randomly assigned by the pediatric pharmacy to receive either verapamil or placebo for two months. The patient will be seen every month for evaluation of therapy. At the end of two months, they will have a 7 day washout period. Then they will take the counterpart placebo or verapamil depending on which they were initially assigned. They will again take the drug for two months at which time the study will be completed.

(17) Progress: Awaiting HSC approval.

Publications and Presentations: None

DEPARTMENT OF PATHOLOGY

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/450 (3) Status: Terminated

(4) Title: Corticostoid Enhanced Plateletpheresis -- A Feasibility Study

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

(7) Principal Investigator: (8) Facility: FAMC
B. Vishu V. Reddy, LTC, MC

(9) Dept of Pathology (10) Associate Investigators

(11) Key Words: blood component removal
Willis Rieker, CPT, MC
Rick E. Martinez, DAC
Judy Barber, DAC
Patricia Rush, DAC

(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 obtain increased yield of platelets during "plateletpheresis".

(16) Technical Approach:

(17) Progress: Terminated because no progress has been made on this protocol for two years.

Publications and Presentations: None

DEPARTMENT OF RADIOLOGY

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/602 (3) Status: Ongoing

(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol
(NP-59) for Adrenal Evaluation and Imaging

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Peter W. Blue, LTC, MC (8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med. (10) Associate Investigators
Nasser Ghaed, COL, MC

(11) Key Words:
adosterol
adrenal glands

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

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for
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: No studies were performed this period.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 84/601 (3) Status: Ongoing

(4) Title: An Evaluation of Computed Tomography of the Chest in Changing the Stage or Treatment of Patients with Hodgkin's Disease

(5) Start Date: 1984 (6) Est Compl Date: 1988

(7) Principal Investigator: Kenneth D. Hopper, MAJ, MC
Louis F. Diehl, LTC, MC
Elder Granger, MAJ, MC
Marge Barnes, MAJ, MC
Jeffrey K. Giguere, MAJ, MC

(8) Facility: FAMC
WRAMC

(9) Dept of Radiology (10) Associate Investigators
May Lesar, MD

(11) Key Words: tomography
hodgkin's disease

John Buaman, MAJ, MC
Daniel Tell, MAJ, 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: 35
d. Total Number of Subjects Enrolled to date: 109
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 routine use of chest CT/C in the initial staging and evaluation of patients with newly diagnosed Hodgkin's Disease.

(16) Technical Approach: All patients newly diagnosed with Hodgkin's Disease both at FAMC and at WRAMC are requested to enter the study. If they agree, a chest CT will be obtained, even if there is a normal chest x-ray. The chest x-ray is evaluated using form A by one investigator (ML) without knowledge of the CT. The chest CT is evaluated by one investigator (KH) with the use of the chest x-ray. The results are entered on Form B. The two forms are compared and compared to the patients clinical data on Form C.

(17) Progress: a) continued accumulation of data; b) data on 109 cases presented and manuscript published; c) three associated projects using same data initiated: 1. The Role of Thoracic CT in the Evaluation of HD; 2. The Use of Serial CT in the Clinical Response of HD; 3. Pattern of Intrathoracic Spread of HD Assessed with CT (to be presented RSNA).

CONTINUATION SHEET, FY 87 ANNUAL PROGRESS REPORT Proto No.: 84/601

Presentations:

(1) Granger, E., Hopper, K. Diehl, L: An Evaluation of Computed Tomography of the Chest in Changing the Stage or Treatment of Patients with Hodgkin's Disease (40 cases). Presented: Current Concepts in Internal Medicine, October 1985.

(2) Hopper, K.: An Evaluation of Computed Tomography of the Chest in Changing the Stage or Treatment of Patients with Hodgkin's Disease (40 cases). Presented: Radiological Society of North America, December 1986.

(3) Giguere J, Diehl L, Hopper K. Granger E, Lesar M: Pattern of Intrathoracic Spread of Hodgkin Disease Assessed with CT. To be presented: Radiological Society of North America, December 1987.

Publications:

(1) Hopper K, Diehl L, Granger E, Barnes M, Lesar M, Baumann J, Ghaed N: Clinical Utility of Thoracic CT in the Initial Staging of Hodgkin Disease. Radiology 1987, 161P:216.

(2) Abstract on presentation #3 above to be published December 1987.

DEPARTMENT OF PRIMARY CARE & COMMUNITY MEDICINE

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 74/651 (3) Status: Ongoing

(4) Title: Establishment of and Training in Methods for Special
Studies of Abnormal Hemoglobins and Red Cell Metabolism

(5) Start Date: 1974 (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
Nicholas C. Bethlenfalvay, MD

(9) Dept of Primary Care (10) Associate Investigators
Joseph Lima, DAC
Ian Stewart, DAC
Elwyn Chadwick, SSG, USA

(11) Key Words:
hemoglobin, abnormal
hemoglobinometry
purine - pyrimidine metabolism
cellular energy 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
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To establish and conduct training in methods for special studies of abnormal hemoglobins.

(16) Technical Approach: To acquaint and to train existing personnel in the performance of various procedures as they pertain to biochemical study of hemoglobins and red cell enzymes involved in hemoglobin function.

(17) Progress: Work has been ongoing and now the capability exists for radiochemical study of de-novo synthesis, salvage, and catabolism and compartmentation of purine and pyrimidine compounds. Detailed study of metabolism of AZT in hemopoietic tissues of HIV infected persons is thus available.

Presentations: None

Publications:

(1) Boehme, W.M., Piira, T.A., Kurnick, J.E., and Bethlenfalvay, N.C.: Acquired Hemoglobin H in Refractory Sideroblastic Anemia. A Pre-leukemic Marker. Arch. Int. Med. 138:603-606, April 1978.

(2) Weatherall, D.J., Higgs, D.R., Bunch, C., Old, J.M., Hunt, D.M., Pressley, L., Clegg, J.B., Bethlenfalvay, N.C., Sjolin, S., Koler, R.D., Magenis, E., Francis, J.L., and Bebbington, D.: Hemoglobin H Disease and Mental Retardation, A New Syndrome or a Remarkable Co-incidence?. N. Eng. J. Med., 305:607-612, September 1981.

(3) Bethlenfalvay, N.C., Hadnagy, Cs., and Heimpel, H.: Unclassified Type of Congenital Dyserythropoietic Anaemia (CDA) with Prominent Peripheral Erythroblastosis. Brit. J. Haema. 60:541-550, 1985.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 80/650 (3) Status: Ongoing

(4) Title: The Ontogenesis of Hemoglobin in the American Opossum
(Didelphis Virginia)

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
Nicholas C. Bethlenfalvay, MD

(9) Dept of Primary Care (10) Associate Investigators
J.E. Lima, DAC
Ian Stewart, DAC
Elwyn Chadwick, SSG, USA

(11) Key Words:
opossums
erythrocytes
methemoglobin

(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: This is a continuation of a previous clinical investigation study that was completed in June 1975. The overall objective is to follow and define the kinetics of methemoglobin reduction of opossum hemoglobin, in specific, as part of the overall energy metabolism of the red cell of this species.

(16) Technical Approach: In-vivo and in-vitro reduction of nitrite induced methemoglobinemia will be followed hourly by quantitative, electrophoretic and spectroscopic means. Methemoglobin reductases will be quantitated and electrophoretically demonstrated, and compared to human reductases.

(17) Progress: 2-deoxy-D-glucose was found to be metabolized to a similar extent in opossum and human erythrocytes suggesting a limited metabolism of this substance. The source of energy for the rapid reduction of methemoglobin in opossum red cells in the absence of substrate was proven to be ribose, which becomes available during the rapid catabolism of adenine nucleotides. Two papers have been submitted on the above data, and are now in press, (Comp. Biochem. Physiol).

Publications:

- (1) Petty, C., Bethlenfalvay, N.C. and Bageant, T.: Spectrophotometric measurement of Hemoglobin Oxygen Saturation in the Opossu, Didelphis Virginiana. Comp. Biochem. Physiol. 50:273, 1975.
- (2) Bethlenfalvay, N.C., Block, M. and Brown, G.B.: Hemoglobins of the Opossum (Didelphis Virginiana Kerr) I. Developmental Changes from Yolk Sac to Definitive Erythropoiesis. Lab. Animal Sci. 26:106-165, 1976.
- (3) Bethlenfalvay, N.C., Brown, G.L., and Waterman, M.: I. Hemoglobins of the Opossum (Didelphis Marsupialis) II. Electrophoretic and Chromatographic Observations. Lab Animal Sci. 26:908-912, 1976.
- (4) John, M.E., Bethlenfalvay, N.C., and Waterman, M.R.: Oxidation - Reduction Properties of the Hemoglobin of the Opossum Didelphis Virginiana. Comp. Biochem. Physiol. 73B:585-591, 1982.
- (5) Bethlenfalvay, N.C., Waterman, M.R., Lima, J.E. and Waldrup, T.: Cytolic and Membranebound Methemoglobin Reductases in Erythrocytes of the Opossum Didelphis Virginiana. Comp. Biochem. Physiol. 73B:594, 1982.
- (6) Bethlenfalvay, N.C., Waterman, M.R., Lima, J.E., Waldrup, T.: Comparative Aspects of Methemoglobin Foration and Reduction in Opossum Didelphis Virginiana and Human Erythrocytes. Comp. Biochem. Physiol. 75A:635-639, 1983.
- (7) Bethlenfalvay, N.C., Lima, J.E., and Waldrup, T.: Studies on the Energy Metabolism of Opossum (Didelphis Virginiana) Erythrocytes. I. Utilization of Carbohydrates and Purine Nucleosides. J. Cellular Physiol. 120:69-74, 1984.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/650 (3) Status: Ongoing

(4) Title: Clonal Fidelity of Erythroid Lineage in
Dyserythropoiesis: An Inquiry Into Ultrastructure

(5) Start Date: July 1987 (6) Est Compl Date: July 1989

(7) Principal Investigator: N.C. Bethlenfalvay, DAC, MD
V.V. Reddy, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators

C.F. Ferris, CPT, MS

(11) Key Words: dyserythropoiesis
ultrastructure
x-ray microanalysis D.B. Mercill, DAC

(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 investigate the aspects of ultrastructural components of erythroid precursors to include elemental composition of these components for determination of their role on erythroid maturation, morphology, the process of erythroid denucleation, and functional differentiation in various dyserythropoietic states.

(16) Technical Approach: Burst forming erythroid colonies will be grown in semi-solid tissue-culture media. The erythroid bursts will be isolated, fixed, embedded and evaluated by electron microscopy and concurrent x-ray microanalysis of metallic cellular inclusions.

(17) Progress: None. First patients to be studied late this year.

Publications and Presentations: None

DEPARTMENT OF NURSING

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/700 (3) Status: Ongoing

(4) Title: Introduction to Suturing Techniques Using Outbred Adult Rats

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

(7) Principal Investigator: (8) Facility: FAMC
Rita W. Van Lith,, COL, AN

(9) Dept of Nursing (10) Associate Investigators

(11) Key Words:
Suture Techniques

(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 instruct DON personnel in the proper techniques of suturing traumatic lacerations, sterile technique, debridement of wounds, and wound cleaning.

(16) Technical Approach: Following instruction, demonstration and return demonstration on suturing skills in the FAMC Animal Laboratory, personnel are detailed to perform a minimum of 3 successful suturing episodes under direct supervision of a physician in the ER to validate learning. When credentialed, suturing activities become a part of the individual soldier's scope of practice, and skills are validated on an ongoing basis and at least annually.

(17) Progress: Due to renovation of the Animal Resources Service, the past fiscal year was not productive.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/751 (3) Status: Completed

(4) Title: Exercise During Pregnancy: The Beliefs, Behavior and Information Needs of Pregnant Women

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

(7) Principal Investigator: CPT Elise M. De Wit, AMSC (8) Facility: FAMC

(9) Dept/Svc: Physical Therapy (10) Associate Investigators

(11) 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: 600
d. Total Number of Subjects Enrolled to Date: 600
e. Note any adverse drug reactions reported to the FDA or sponsor 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 the exercise-related beliefs of pregnant women and to identify and compare the exercise information priorities of pregnant women and health care providers.

(16) Technical Approach: Survey Design

(17) Progress: Limited number of subjects expressed interest in research results, many expressed desire to help project.

Publications and Presentations: None

MEDDAC

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

(1) Date: 30 Sep 876 (2) Protocol WU#: 83/902 (3) Status: Ongoing

(4) Title: Training Study, Emergency Medical Procedures

(5) Start Date: 1982

(6) Est Compl Date:

(7) Principal Investigator:
Martin Artman, MAJ, MC

(8) Facility: FAMC
Ft. Carson Veterinary Activity
and Ft. Carson MEDDAC Emergency
Medical Service
AV 691-7226/7111

(9) Dept of Emerg Med & Vet Svc

(10) Associate Investigators

(11) Key Words:
emergency medical services

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
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 project is a refresher/teaching course in Emer-
gency Medicine operative procedures. It is conducted on a quarterly basis
fo EMS physicians and PA's.

(16) Technical Approach: Under general anesthesia animals are subjected to
common emergency medicine operative procedures including venous cutdown,
peritoneal lavage, chest tube insertion, and thorocotomy with aortic cross
clamp with cardiac laceration repair. At the end of the exercise, the
animals are disposed of by lethal injection.

(17) Progress: Held 6 times since Oct 86 with 2 animals each lab. Trained
4 students per exercise. Training exercise is for physicians and dentists.
MAJ Martin Artman will replace departing COL Walsh.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/900 (3) Status: Completed

(4) Title: Music: A Method for Anxiety Reduction in the Preoperative Patient

(5) Start Date: May 1986 (6) Est Compl Date: August 1987

(7) Principal Investigator: Larry D. Curtis, CPT, ANC (8) Facility: FAMC Fort Riley, Kansas

(9) Irwin Army Community Hospital (10) Associate Investigators

(11) Key Words:
music
premedication
anxiety

(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: 45
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: To investigate possible alternatives to medication as a method of reducing anxiety in preop patients, thus reducing risk of possible side effects of the preop medications. The author of this proposal has chosen to investigate music as that alternative.

(16) Technical Approach: This is covered in the application for clinical investigation project under 6. Plan.

(17) Progress: To date 45 subjects have consented to and participated in the project. The data collection is complete. The data has been analyzed and the study is complete.

Publications: Music: A Method for Anxiety Reduction in the Repoperative Patient. Master Degree Project: Bound summary of this study on file at State University of New York at Buffalo.

Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/901 (3) Status: Completed

(4) Title: Transmission of Bunyamwera Viruses to Humans by the Biting Midge Culicoides Varripennis

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

(7) Principal Investigator: Martin Anderson, CPT, MC (8) Facility: FAMC
Dugway Proving Grounds, Utah

(9) Dugway Proving Grounds, Utah (10) Associate Investigators
Louis Blake, CPT, MC

(11) Key Words:
ceratopohonidae viruses

(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: 71
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 expected to yield significant data if we are able to show that only those who seroconvert are in the study group, compared to preexisting titers in the control group.

(16) Technical Approach: Acute and convalescent titers to Lokern, Cache, Main Drain, Valley, Button Willow and CE viruses were assayed for neutralizing antibodies and were checked when antibody was present by HI, CF and MACELISA.

(17) Progress: We undertook a limited study of possible viral etiologies in 71 individuals. All sera were studied for neutralizing antibody to the five arthropodborne viruses known to circulate in this area by Dr. Charlie Callisher in the CDC's arbovirus research lab. No patient's titers increased appreciably. None of the sera with neutralizing antibody had HI or CF antibody and none were positive in the IgM antibody capture ELISA. We have not been able to establish any human illness associated with this or the other viruses studied.

Publications and Presentations: None

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 86/902 (3) Status: Completed

(4) Title: Defining Successful Breast-Feeding: The Mother's
Prospective

(5) Start Date: Oct 87

(6) Est Compl Date: Jan 87

(7) Principal Investigator:
Deborah R. Edwards, CPT, ANC

(8) Facility: FAMC
Munson Army Community Hospital
Fort Leavenworth, Kansas
Pediatric Well Baby Clinic

(9) Dept/Svc: Pediatrics

(10) Associate Investigators

(11) Key Words:
breast feeding

(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: 15
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 ascertain and categorize the criteria that
mothers use to define successful breast-feeding.

(16) Technical Approach: A qualitative study utilizing a semi-structured
interview schedule to interview breast-feeding mothers recruited from
the Pediatric Clinical at Ft. Leavenworth, KS.

(17) Progress: Interviews were conducted with 15 women who were breast-
feeding infants between 2 weeks and 8 months of age at the time of the
study. The mothers were asked to give their personal criteria for a
definition of successful breast-feeding. Responses from the interviews
were analyzed utilizing grounded theory methodology. Eight categories
of criteria were identified from the interviews: Conditional State of
the Mother, Conditional State of the Infant, Provision, Incorporation,
Confirmation, Appraisal, Closeness, and Time. The central integrating
theme was Well-Being. The Well-Being Model of Successful Breast-Feeding
was developed to illustrate the interaction of the categories. Subjects
primarily defined successful breast-feeding in terms of maternal satis-
faction, infant health and contentment, and the closeness of the mother-
infant relationship.

CONTINUATION SHEET, FY 87 ANNUAL PROGRESS REPORT

Proto. No.: 86/902

Publications and Presentations: Master's Thesis "Defining Successful Breast-Feeding The Mother's Perspective" University of Kansas, Kansas City, KS May 1987.

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

(1) Date: 30 Sep 87 (2) Protocol WU#: 87/900 (3) Status: Ongoing

(4) Title: Serological Assessment of Lyme Disease Among Soldiers
Training at Fort McCoy, Sparta, Wisconsin

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

(7) Principal Investigator: (8) Facility: FAMC

Michael W. Hastriter, MAJ, MC

Fort Leonard Wood, MO 65473-5700
Preventive Medicine Service
A-581-9471

(9) Dept/Svc: US Army MEDDAC

(10) Associate Investigators

Kim Mello, DAC, Fort McCoy,
Sparta, WI

(11) Key Words:

lyme disease
ixodes dammini

Paul H. Duray, MD, Yale Univ.
Leo A. Andron, LTC, MS, FAMC
Sandra L. Tessier, DAC, FAMC

(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: 713

d. Total Number of Subjects Enrolled to Date: 713

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To determine the number of cases of Lyme Disease contracted at Fort McCoy among a small population of soldiers at high risk which are those soldiers bitten by a tick.

(16) Technical Approach: Soldiers training at Fort McCoy who receive tick bites are initially bled and a second follow-up blood samples is obtained after 6 weeks. Serum samples will be tested for Lyme Disease antibodies by the ELISA technique.

(17) Progress: FY 87 - 495 initial serum samples have been obtained from Reserve and National Guard personnel training at Fort McCoy. 54 follow-up samples have been obtained with an additional 25 anticipated by mid-October. An additional 218 soldiers from Fort Leonard Wood were bled prior to training at Fort McCoy during 2-17 Aug 87. Anticipate 200 follow-up samples from Ft. Leonard Wood personnel scheduled 28 Sep 87. In summary, an estimated total of 179 follow-up sera and 713 initial samples will be forwarded to Clinical Investigations, FAMC by 1 Nov 87.

Publications and Presentations: None

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