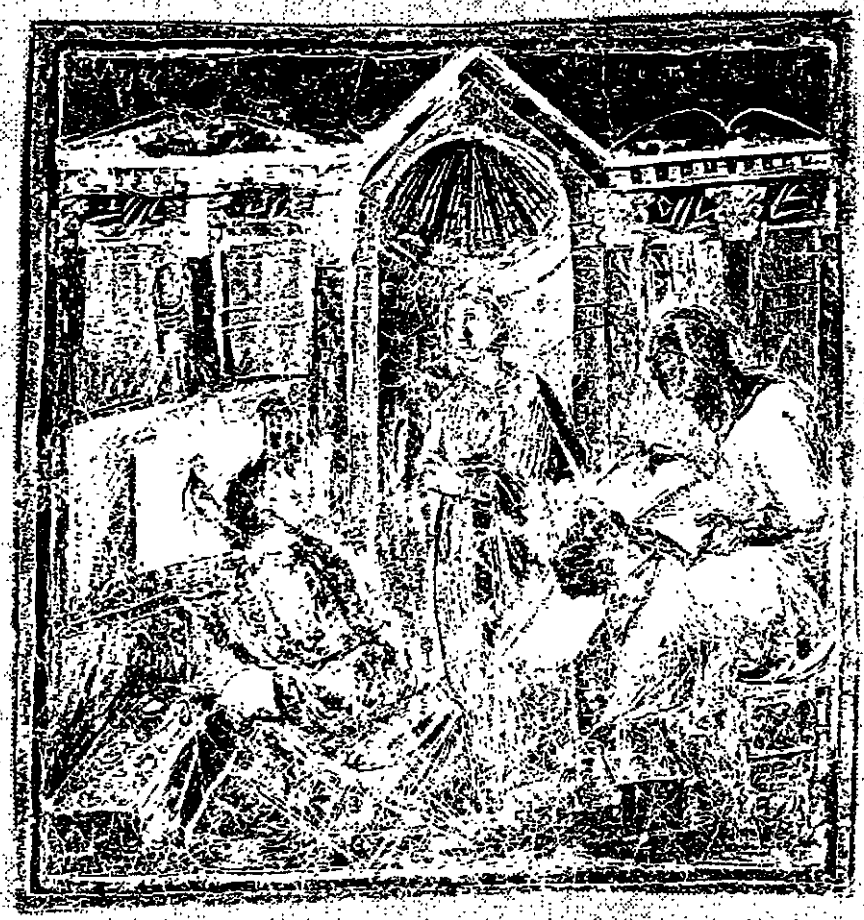
CLINICAL INVESTIGATION PROGRAM REPORT



DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FT GORDON, GA 30905

FY 93

REPORT DOCUMENTATION PAGE

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Clinical Investigation Program Report RCS MED-300 (R1)

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Colonel, Medical Corps
Chief, Department of Clinical Investigation

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Department of Clinical Investigation
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Fort Gordon, Georgia 30905-5650

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13. ABSTRACT (Maximum 200 words)

Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1993, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.

14. SUBJECT TERMS

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CLINICAL INVESTIGATION

PROGRAM REPORT

1 October 1993

CONTROL SYMBOL: RCS MED-300 (R1)

Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

FOREWORD

The illustration gracing this year's cover has suffered significant ravages in its survival. It depicts the author, Pedanios Dioskurides, as the scholar on the right recording his observations into his codex. Featured in the center is the allegorical figure of Epinoia (Rationality) holding the mandrake plant which is being faithfully drawn by the artist on the left. The far better known drawing depicting the author with Heuresis in accepting the mandrake plant, was featured on our FY 84 cover. The role of "discovery" and its practical implications are relatively obvious. Dioskurides certainly used his time as a surgeon travelling with the Roman army to good advantage. He gathered the information for his *Materia Medica* by using his military travels well. This document has survived into the modern age by taking his discoveries and combining them with reasoning to formulate a rational basis for therapeutics.

As noted before, military physicians in training should take heed to use their experiences and opportunities for discovery to advantage in advancing knowledge. To this exhortation might be added the implications of the current illustration. Rationality and reasoning are the virtues of the mature scholar who takes the fruits of earlier discovery, reflects on them, records them accurately, and then develops a practice of healing. This higher level of integration of thought is more than theoretical knowledge *(theoria)*; it represents a *praxis* involving the whole person.

The style and positioning of the figures suggests some similarities to religious iconography of the general period. The original of this painting probably dated to the fourth century, a time prior to most surviving religious examples. Typically, the icon of Christ would be flanked by the *Theotokos* (his mother, Mary) and the Forerunner (John the Baptizer) or by Moses and Elias, representing the Law and the Prophets in the Transfiguration. Interestingly in this image, only Epinoia is shown in full face and the artist and scholar are shown in profile. This latter depiction tended to represent a non-person. Perhaps this meant to portray the essential anonymity of the persons who do the labor of reasoning in following up on discovery. In any event, that is the practical result of most scholars throughout the ages. A few achieve recognition and even fame. Certainly Dioskurides did with the lasting success of his *Materia Medica*. Of course, most true scholars recognize the vagaries of fame and tend to ignore it as best they can. To do so well requires a visit from *Sophia* (Wisdom).

The progression from *Heuresis* to *Epinoia* to *Sophia* is a difficult one which requires a life dedicated to the truth and a willingness to struggle to find it at all costs. Our experience in the Clinical Investigation Program can help the young physician meet the first lady and perhaps later arrange an introduction to *Epinoia.* We can go no further. Unfortunately, all too many do not show the initial interest. We at EAMC have been fortunate to see a growing number of residents and staff

take a serious interest in scholarly endeavors with a steady growth in protocol based reasearch.

The most serious threat to Clinical Investigation at EAMC has been the continued hold on completing the design and construction of the new research building. It was put on hold a year ago pending the outcome of the GME future. It remains in that state as of this publication.

We in CI lost our most venerable member, Mrs. Rosina Martinez, to early retirement this year. She had been with the program from its founding in 1977. She knew where everything was and what needed to be done. The past six months have been difficult for me without her. I would like to dedicate this Annual Report to her. The only unfitting aspect is that this is the first time the report was not ready for the reproduction process by the end of October. We are not even the first MEDCEN to publish it this year. Our best regards to Rosie in her retirement.

Kent M. Plowman
COL, MC
C, Dept. Clin. Invest.

UNIT SUMMARY - FISCAL YEAR 1993

A. Objective.

The Department of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

Name	Rank	MOS	Title
Plowman, Kent M.	COL	61F00	Chief
Tobias, Steven	MAJ	64A00	Veterinarian
Craft, David	MAJ	68A9B	Immunologist/Microbiologist
Williams, Linda E.	SSG	92B30	NCOIC, Med Lab NCO
Rodriguez-Morales, Janet	SSG	92B30R	Med Lab Sp
Quilici, Kristine	SGT	92B20	Med Lab Sp
Collins, Demetrius	PFC	91T10	Veterinarian Technician
Horner, Jack A.	GM13	01301	Asst C, Res Histologist
McPherson, James C. III, PhD	GS13	01320	Biochemist
Runner, Royce R., MT, ASCP	GS11	00644	Medical Technologist
Best, Norma	GS9	00644	Medical Technologists
Chuang, Augustine H., Ph	GS9	00644	Medical Technologist (MRDC Grant)
Ferguson, Phyllis	GS5	00303	Protocol Coordinator
Searles, Rosa	GS6	00404	Biological Lab Technician
Reisenger, Rebecca	GS4	00312	Clerk-Steno

Officer: 4 authorized; 5 required; 3 assigned
Enlisted: 5 authorized; 9 required; 4 assigned
Civilian: 7 authorized; 13 required; 8 assigned

One third-party FACT physician assistant employee in Pulmonary Service.

D. Funding.

Type	Fiscal Year 92	Fiscal Year 93
Civilian personnel to include benefits	310,959.00	305,873.97
Consumable supplies	118,789.00	197,964.03
Civilian contracts to include consultants	2,400.00	6,829.00
TDY	2,000.00	4,856.40
Publications	2,243.00	619.40
CEEP	2,499.00	86,590.31
MEDCASE	316.215.00	218,820.71
Military	497,794.00	496,870.00
Total	1,252,899.00	1,318,424.82

Grant Funding:

MRDC - "Non-ionic Surfactants in the Treatment of Third Degree Burns in rats."
FY 93: $17,624.00

E. Progress.

Protocol Disposition FY 93

	Completed	Terminated	Ongoing to FY 94
FY 78	3		1
FY 84	1		
FY 85			1
FY 87	1		2
FY 88		1	2
FY 89	2	2	2
FY 90	3	4	5
FY 91	29	1	38
FY 92	11	6	60
FY 93	9	10	124
	59	24	235

Number of resident and fellowship programs: 1-Fellowship and 7-Residents
Number of programs using Clinical Investigation: 13
Number of residents and fellows on approved protocols: 36
Number of approved protocols held by this group: 37

Other training programs that use Clinical Investigation: Graduate Students, Transitional Interns, Psychology Interns, Nurse Anesthetist: 1 Transitional Intern Program - 6 Interns and 1 Psychology Intern Program - 4 Interns.

Number of approved protocols held by this group: 11

Number of hospital staff members on approved protocols: 14
Number of approved protocols held by this group: 93

Drug evaluation/comparison studies: 20
Treatment evaluation/comparison studies: 41

RESEARCH AWARDS

Recipients of

The Eleventh Annual DDEAMC Resident Research Award

was

Captain Brad Waddell, MC

for his paper

"The Effect of Octreotide on Wound Healing in Rats"

The paper was based on Protocol 92-26 and was presented at the Eisenhower Army Medical Center Annual Resident Research Presentation Day, May 1993.

Recipient of

The Seventh Annual Dental Activity Resident Research Award
was

Major Gregory W. Austin, CPDS, Periodontics Resident

for his paper

"Effect of nicotine on fibroblast integrin expression and distribution in vitro," based on Protocol 91-73.

INSTITUTIONAL REVIEW COMMITTEE

Clinical Investigation and Human Use Members

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Chief, Department of Medicine
Chief, Department of Surgery
Chief, Pharmacy Service
Research Director, Dental Activity
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Chief, Medical Records Administration Section

Animal Care and Use Members

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Chief, Department of Medicine
Chief, Department of Surgery
Veterinarian, Department of Clinical Investigation
Signal Center Representative, Ft Gordon, Georgia

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DEPARTMENT OF NURSING

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USA MEDDAC, FT RUCKER, AL

USA MEDDAC, FT Jackson, SC

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Code:

O - Ongoing
C - Completed
T - Terminated
W - Withdrawn
P - Published
PR - Presented

PUBLICATIONS FY 93

DEPARTMENT OF CLINICAL INVESTIGATION

Pashley DH, Ciucchi B, Hidehiko S, and Horner, JA: Permeability of Dentin to Adhesive Agents. Quintessence International 1993;24:618-631

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Farnsworth WJ, Chuang AH, Runner Rr, et al: The "glass effect" on red blood cells can be prevented by pluronic F-68. FASEBS, New Orleans, LA, 28 Mar - 1 Apr 93.

Aracuri M, LaVelle W, Tabor M, Fridrich K: Hyperbaric Oxygen Therapy Combined with Transcutaneous and Transmucosal Titanium Implants in Post-Radiotherapy Patients. Fifth International Congress on Preprosthetic Surgery: Vienna, Austria, 1993.

Paustain PW: Poloxamer 188 as a Treatment for Third-Degree Burns. Academic Emergency Medicine; 22:927,1993. Presented at the Annual Meeting of the society for Academic Emergency Medicine, May 17-20, 1993 in San Francisco, CA.

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DENTAL ACTIVITY

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Stone R, Dirksen TR, McPherson J Jr, Brennan W, McPherson J III: Blood coagulation following intravenous administration of pluronic polyols. Int Assn Dent Res, Chicago, IL, 10-14 Mar 93.

FAMILY PRACTICE

Carroll D: The family physician in disaster assistance. Unif Svc Acad Fam Phys, Corpus Christi, TX, 21-25 Mar 1993.

Blount BW: Time management. Unif Svc Acad Fam Phys, Corpus Christi, TX, 21-25 Mar 1993.

Dekoning B: EAMC's response to gateway to care. Unif Svc Acad Fam Phys, Corpus Christi, TX, 21-25 Mar 1993.

Wright G: The use of the computer-prescribing system as an instructional aid. Unif Svc Acad Fam Phys, Corpus Christi, TX, 21-25 Mar 1993.

Leibert B: Postpartum blues. Unif Svc Acad Fam Phys, Corpus Christi, TX, 21-25 Mar 1993.

Phelps K: Central diabetes insipidus presenting as acute renal failure. Unif Svc Acad Fam Phys, Corpus Christi, TX, 21-25 Mar 1993.

Moody R: Physician interface with a computer system. Unif Svc Acad Fam Phys, Corpus Christi, TX, 21-25 Mar 1993.

Robins G: The effect of terbutaline tocolysis on fetal weight and gestational duration. Unif Svc Acad Fam Phys, Corpus Christi, TX, 21-25 Mar 1993.

Beck RA: Retreat of Hemophilus Influenza Type B: Analysis of an immunization Program and Implications for OTO-HNS, Sep 1992.

Beck RA: Tumefactive fibroinflammatory lesion of pterygomaxillary space. Ann Mtg Am Acad OTO-HNS, Sep 1992.

Beck RA: Creation of a knowledge base in facial plastic and reconstructive surgery. Am Acad Facial Plastic Reconstructive Surg, Sep 1992.

Beck RA: Current Concepts in Otology Neurol. St. Thomas, VI, 10 Feb 93.

Blount BW, Hart G, Ehreth JL: A description of the content of army family practice. J Am Board Fam Pract 1993; 6:143-152.

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Blount BW: Time Management. Unif Svc Acad Fam Phys, Corpus Christi, Tx, 21-25 Mar 1993.

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DEPARTMENT OF MEDICINE

O'Connell MA, Sklarew PR, Goodman DL: Vocal cord dysfunction (VCD) in the outpatient setting. Am Coll Allergy Immunol Ann Mtg, Chicago, IL, 14-18 Nov 1992.

O'Connell MA: Effects of Beta adrenergic antagonists (BAA) on intracellular cyclic nucleotide generation in guinea pig airway smooth muscle. Am Acad Allergy Immunol 50th Anniversary Mtg, Chicago, IL, 12-16 Mar 1993.

Sen JK, Keaton MR: Acute myelogenous, minimally differentiated (Mo) leukemia subsequent to chemotherapy for chronic lymphocytic leukemia. Am Soc Clin Pathol Check Sample Hematology No. H 92-10 (H-247), Chicago: ASCP Press 1993.

O'Connell MA: Effects of Beta adrenergic antagonists (BAA) on intracellular cyclic nucleotide generation in guinea pig airway smooth muscle. Am Acad Allergy Immunol 50th Anniversary Mtg, Chicago, IL, 12-16 Mar 93.

Whitlock, WL: " Improved Metered-dose Inhaler Technique", 59th Annual International Scientific Assembly, American College of Chest Physicians, Orlando, FL 24-28 Oct 1993.

Whitlock WL: American College of Physicians, (Annual US Army Sponsored Meeting), "Diaphragmatic Myoclonus." Nov 1993.

PHARMACY SERVICE

Bookstaver DA: Evaluation of niacin compliance. Southeast Regional Clin Pharmacy Cholesterol Council, 26 Oct 1992.

Baldwin J, RANLETT RD, BREWER PD: Localized fibrous pleural lesion of the lung (Paper from Podium). Presented 11th Ann Resid Research Day Seminar, DDEAMC, Fort Gordon (GA), 21 May 1993.

Baldwin J, RANLETT RD, BREWER PD: Localized fibrous pleural lesion of the lung (Poster). Presented 11th Ann Res Research Day Seminar, DDEAMC, Fort Gordon (GA), 21 May 1993.

LEWIS, DM: Clinical pathology conference. Presented at Oral Pathology, Oral Diagnosis, and Oral Medicine Short Course, US Army Dental Activity, Walter Reed Army Medical Center, Washington (DC), 26-30 April 1993.

LYLE JD: Decentralized laboratory testing. Invited workshop for presentation at 18th Ann Mtg Soc Armed Forces Med Lab Sci, Reno (NV), 1993.

SEN JK, STINCER LB, BREWER PD: B-cell chronic lymphocytic leukemia with immunologic features of hairy cell leukemia (CD5 negative, CD11C positive) (Poster). Presented 7th Annual Postgraduate Pathology Symposium, Med Coll of Georgia, Augusta (GA), 24-25 April 1993.

SHIKLE JF: Wegener's granulomatosis (Case Report). Presented Quarterly Meeting Augusta Regional Society of Pathologists, Fort Gordon (GA), 28 October 1993.

SHIKLE JF: Lepromatous leprosy (Case Report). Presented Quarterly Meeting Augusta Regional Society of Pathologists, Fort Gordon (GA), 28 October 1993.

Steflik DE, Sisk AL, Parr GR, Hanes PJ, Lake FT, BREWER PD, McKinney RV, Koth DL: Dental implant-bone interface: TEM and HVEM observations. (Paper from Podium). Presented 21st Ann Mtg Amer Assoc Dent Res, Boston (MA), 14 March 1993.

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Steflik DE, Parr GR, Sisk AL, Hanes PJ, Lake FT, Berkery DJ, BREWER PD, Gardner LK: Ultrastructural and histomorphometric observations of a comparative experimental dental implant investigation (Paper from Podium). Accepted for presentation 25th Int Biomaterials Symposium, and 19th Ann Mtg Soc for Biomaterials, Birmingham (AL), 29 Apr 1993.

WHITE JC: The HPLC method for hemoglobin A1C. Invited lecture to Department of Pathology staff, Augusta Regional Medical Center, Augusta (GA), 14 July 1993.

WHITE JC: Blood lead testing. Invited seminar to Department of Pathology & Area Laboratory Services staff, Madigan Army Medical Center, Fort Lewis (WA), 24-26 August 1993.

WHITE JC: Blood lead testing. Invited seminar to Preventive Medicine staff, Office of The Surgeon General, Alexandria (VA), 13 September 1993.

WHITE JC: Blood lead testing. Invited seminar to Department of Pathology & Area Laboratory Services staff, Walter Reed Army Medical Center, Washington (DC), 14-16 September 1993.

WOZNIAK A, MANSELL KB, BREWER PD, GOODHUE WW: The contaminated blood culture rate at a tertiary care teaching medical center (Poster). Presented 7th Annual Postgraduate Pathology Symposium, Med Coll of Georgia, Augusta (GA),

24-25 April 1993.

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DEPARTMENT OF PSYCHIATRY & NEUROLOGY

Sahebarao PM, Mukherjee S, Correnti EE, Hemant S, Kelkar, Chandramohan GW, Costa RM, and Sheffer R.: Plasma Membrane Phospholipid and Cholesterol Distribution of Skin Fibroblasts from Drug-Naive Patients at the Onset of Psychosis submitted at the Society of Biological Psychiatry Annual Meeting - 1993.

Sheffer R, Correnti E, Mukherjee S, Costa: "Neurological Signs at the Onset of Psychosis APA Annual Meeting, San Francisco, CA, 24 May 1993

Sheeley, Warden, Staudenmeier, Salazar: Traumatic Brain injury and Alcohol in a military population, APA Annual Meeting, San Francisco, CA, 24 May 1993

Mukherjee S, Scheffer R, Correnti E, Mahadek et al: Fibroblasts Studies in the First Break Psychosis Study APA Annual Meeting San Francisco, CA, 25 May 1993.

Mahadek, Mukherjee S, Scheffer R, Correnti E, et al: Abnormal Growth of Skin Fibroblasts from Drug Naive Psychotic Patients, Biological Psych Annual Meeting 20 May 1993.

Ryder GC: Fourteenth Annual Operational Aeromedical Problems Course, Aeromedical Psychiatry and Alcoholism, 24 Mar 93.

Williford J: American Society of Psychosomatic Obstetrics and Gynecology, Charleston, SC, March 1993.

Williford J: Georgia Psychiatric Physicians Association Annual Meeting, Atlanta, GA, February 1993.

Schenk, D: American Psychiatric Association Annual Meeting, San Francisco, CA, May 1993.

Perrotta, C: Menninger Military Psychiatry Conference, Topeka, KS, February 1993.

DEPARTMENT OF SURGERY

General Surgery Service

Beck R. Current concepts in otology neurology. St Thomas, Virgin Islands, 10 Feb 1993.

Workman CR, Modesto VL, Lepage PA, Calton WC, Martindale RG: Laparoscopic Gastrostomy Using Four-Point Fixation, Scientific Exhibit, American College of Surgeons annual Meeting, New Orleans, LA, 12-15 Oct 1992.

Mulligan CR, Calton WC, Craft D, Best N, Martindale Rg: The Influence of "Immune Modulating" Formulas on Endotoxin Stimulated Bacterial Translocation in Mice, Gary P. Wratten Symposium, Brekenridge, CO, 29 Mar - 1 Apr 1993.

Cresci G, Calton WC, Martindale RG: The Influence of Immune Stimulating Formulas on Bacterial Translocation in the Mouse Model, American society for Parenteral and Enteral Nutrition, San Diego, CA, February 1993.

Chapman DC, Martindale Rg, Calton WC: Effect of Corticosteroids and vitamin A On Initial Stages of Wound Healing, Gary P. Wratten Symposium, Breckenridge, CO, 19 Mar - 1 Apr 1993.

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Duh OY, Engleharta A, Grant JP, Wolfe B, Gadacz T, Martindale RG, Way LW: Prospective Evaluation of Safety and Efficacy of Laparoscopic Gastrostomy, Society of American Gastrointestinal Endoscopic Surgeons, Phoenix, Arizona, Apr 1993.

Chapman DC, Martindale RG: Influence of Vitamin A On Steriod Induced Defects in Wound Healing, A dose Response, Gary P. Wratten Symposium, Breckenridge, CO, Apr 1993.

Harkins MP, Modesto VL, Lepagae PA, St.Jean MR: Utilization of the "Crochet Hook Technique" in the Management of Branch Varicostits of the Lower Extremity. Scientific Exhibit, American College of Surgeons Anual Meeting, New Orleans, LA, 12 - 15 Oct 1992.

Waddell BE: The Effects of Octreotide on Wound Healing in Rats. The 79th Annual Clinical Congress American College of Surgeons Meeting, San Francisco, CA, 10 - 15 Oct 1993.

Jurkovich GH, Alverdy JC, Martindale RAG, Kudsk KA: Discouraging Post-operative Sepsis. Contemporary Surgery, 43:41-68, 1993.

Orthopaedic Service

Barja RH: External fixation during Operation Desert Storm: The Howmedica Ultra-x. Inter External Fixation Conf, Granada, Spain, 1-4 Oct 1992.

Barja RH: Pathologic metacarpal fracture secondary to amyloidoma. AAOS, San Francisco, CA, 18 Feb 1993.

Cresci, AB: Arthroscopic Evaluation and the Treatment of Osteochondral Lesions of the First Metatarsophalangeal Joint:, Federal Service Podiatry Conference, Hampton, Virginia, 27 Apr 93.

Erpelding, JM: Proximal Humerus Fractures: Indications and Technique for Arthroplasty, Jan 1993, 2nd SE Fracture Symposium, Charlotte, North Carolina.

Barja, RH: Hand Pathology IQ, American Academy of Orthopaedic Surgeons, Annual Convention San Francisco, California, February 1993.

Barja, RH: Use of External Fixator During Operation Desert Storm, The Persian Gulf War, The annual Meeting of the Virginia Orthopaedic Society,

Williamsburg, Virginia, April 30-May 2, 1993.

Barja, RH: Wound Healing, Upper Extremity and hand Therapy Course, Eisenhower Army Medical Center, Fort Gordon, Georgia, March 1-12, 1993.

Barja, RH: Hand Tumors, Benign and Malignant, Upper Extremity and Hand Therapy Course, Eisenhower Army Medical Center, Fort Gordon, Georgia, March 1-12, 1993.

Barja, RH: Biomechanics of the Shoulder, biomechanics Course for Orthopaedic Residents, Eisenhower Army Medical Center, Fort Gordon, Georgia, May 14-15, 1993.

Taylor DC: A Comparison of Passive Stretching and Muscular Contraction on the Viscoelastic Characteristics of Skeletal Muscle, 39th Annual Meeting of the Orthopaedic research Society, San
Farncisco, California February 16, 1993.

Taylor DC: Comparison of Stretching With Contraction on Biomechanical Characteristics of Muscle, 60th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, California, February 23, 1993.

Taylor DC: Groin Pain in Athelets, 3d Congress of the Knee and Sports Medicine Section of the Western Pacific Orthopaedic Association, Sydney, Australia, September 11, 1993.

Geissele, AE: Thoracoplasty for the Treatment of Rib Prominence in Thoracic Scoliosis: Results and Technique. A Controlled Study, 28th Annual Meeting, Scoliosis Research Society, Dublin, Ireland, September 21, 1993.

Taylor DC: A Comparison of Passive Stretching and Muscular Contraction on the Viscoelastic Characteristics of Skeletal Muscle, 39th Annual Meeting of the Orthopaedic Research Society, San Francisco, CA, February 1993.

Taylor DC: Comparison of Stretching With Contractions on Biomechanical Characteristics of Muscle., 60th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, CA, February 23, 1993.

Taylor DC: Arthroscopic Stabilization for Acute, Traumatic Anterior Shoulder Instability, Philippine Orthopaedic Society for Sports Medicine Symposium, Manila, Philippines, August 18, 1993.

Taylor DC: Groin Injuries in Athletes, Philippine Orthopaedic Society for Sports Medicine Symposium, Cebu City, Philippines, August 19, 1993.

Taylor DC: Arthroscopic Stabilization for Acute, Traumatic Anterior Shoulder Instability, Philippine Orthopaedic Society for Sports Medicine Symposium, Cebu City, Philippines, August 19, 1993.

Taylor DC: Syndesmosis Sprains of the Ankle, American Orthopaedic Society for Sports Medicine - Western Pacific Orthopaedic Association Traveling Fellowship Conference, Jaharta, Indonesia, August 21, 1993.

Taylor DC: Basic Science in Muscle Stretching and Injury, American Orthopaedic Society for Sports Medicine - Western Pacific Orthopaedic Association Traveling Fellowship Conference, Jaharta, Indonesia, August 23, 1993.

Taylor DC: Groin Injuries in Athletes, American Orthopaedic Society for Sports Medicine - Western Pacific Orthopaedic Association Traveling Fellowship Conference, Jaharta, Indonesia, August 23, 1993.

Taylor DC: Arthroscopic Shoulder Stabilization, American Orthopaedic Society

for Sports Medicine - Western Pacific Orthopaedic Association Traveling Fellowship Conference, Jaharta, Indonesia, August 23, 1993.

Taylor DC: Basic Science Studies in Muscle Stretching and Injury, American Orthopaedic Society for Sports Medicine - Western Pacific Orthopaedic Association Traveling Fellows Symposium, Brisbane, Australia, August 28, 1993.

Taylor DC: Arthroscopic Shoulder Stabilization, American Orthopaedic Society for Sports Medicine - Western Pacific Orthopaedic Association Traveling Fellows Meeting, Adelaide, Australia, August 30, 1993.

Taylor DC: Groin Injuries in Athletes, American Orthopaedic Society for Sports Medicine - Western Pacific Orthopaedic Association Traveling Fellows Meeting, Adelaide, Australia, August 30, 1993.

Taylor DC: Basic Science Studies in Muscle Stretching and Injury, American Orthopaedic Society for Sports Medicine - Western Pacific Orthopaedic Association Traveling Fellows Austin Meeting, Melbourne, Australia, September 1, 1993.

Taylor DC: Syndesmosis Sprains of the Ankle, Sports Medicine and Surgery Update, Wellington, New Zealand, September 3, 1993.

Taylor DC: Groin Injuries in Athletes, sports Medicine and Surgery Update, Wellington, New Zealand, September 3, 1993.

Taylor DC: Arthroscopic Shoulder Stabilization, Sports Medicine and Surgery Update, Wellington, New Zealand, September 3, 1993.

Taylor, DC: Basic Science Studies in Muscle Stretching and Injury, Orthopaedic and Sports Medicine Meeting, Queenstown, New Zealand, September 5, 1993.

Taylor DC: Syndesmosis Sprains of the Ankle, American Orthopaedic Society for Sports Medicine - Western Pacific Orthopaedic Association Sports Medicine Fellows Meeting, Sydney, Australia, September 1993.

Taylor DC: Groin Injuries in Athletes, 3d Congress of the Knee and Sports Medicine Section of Western Pacific Orthopaedic Association, Sydney, Australia, September 11, 1993.

Erpelding JM: "Proximal Humerus Fractures: Indications and Technique for Arthroplasty" at Second Annual Southeast Region Orthopaedic Trauma Association Symposium, January 1993, Charlotte, NC.

Erpelding JM: "Orthopaedic Emergencies in the Rural Trauma Setting", at Rural Emergencies Symposium, July 1993, Glasgow, MT.

Erpelding JM: "Cold Weather Injuries: Recognition and Management", Rural Emergencies Symposium, July 1993, Glasgow, MT.

ABSTRACTS

CLINICAL INVESTIGATION

Farnsworth WJ, Chuang AH, Runner RR, McPherson JC, McPherson JC: "The Glass Effect on Red-Blood Cells Can Be Prevented By Pluronic F-68(R)." FASEB Journal, 1993;4(7) 682.

Runner RR, Stone RL, McPherson JC, McPherson JC: "Polaxamer - 188 Administration Alters Some Events in the Blood-Clotting Cascade." FASEB Journal, 1993;4(7) 682.

Tobias SW, Stone Rl, Runner RR, McPherson JC, McPherson JC: "The Erythrocyte Sedimentation-Rate of Blood in Normal Rats Injected with Pluronic F-127(R)." FASEB Journal, 1993;4(7) 681.

Horner JA, Paustian PW, Chuang AH, Runner Rr, McPherson JC, McPherson JC: "Poloxamer 407 Increases Rouleau Formation Invivo But not Invitro." FASEB Journal, 1993, 4(7) 681.

Chuang AH, Farnsworth WJ, McPherson JC, McPherson JC: "Temperature-Dependent Fluoride Induced Hemolysis is antagonized by Polaxamer - 188." FASEB Journal, 1993 4(7) 681.

Paustian PW, Chuang AH, Runner RR, McPherson JC, McPherson JC: "Comparison of Poloxamer - 188 and Poloxamer - 407 on Early Burn Wound Contraction." FASEB Journal, 1993;3(7) 139.

Paustain PW, Chuang AH, McPherson JC III, McPherson JC Jr.: Palaxamer 188 as a Treatment for Third-Degree Burns from Annual Emergency Medicine.

Nang RM, Sutherland DE, Miller P, Haburchak DR: Reported Reduction in Sexual Activity After Discovery of HIV Seropositivity in U.S. Soldiers

Paustain PW, McPherson JC III, Haase RR, Runner RR, Plowman KM, Ward DF, Nguyen THE, and McPherson JC Jr.: Intravenous Pluronic F-127 in Early Burn Wound Treatments in Rats.

Farnsworth WJ, Chuang AH, Runner RR, McPherson JC III and McPherson JC Jr.: Rheological Changes in Rat Blood Cells Following Successive Washings in Saline, An Albumin, or a Pluronic F-68 Solution.

Shahan MH, Chuang AH, Brennan WA, Dirkesen TR, VanDyke TE, and McPherson JC: The Effect of Chlorhexidine Irrigation on Tensile Wound Strength

Paustian DP, Akujama DP, Chuang AH, McPherson JC III, and McPherson JC Jr.: Wound Repair and Regeneration 1993; 1:118

DENTAL ACTIVITY

Liewehr FR, Kulild JC, Primack PD: Obturation of A C-Shaped Canal Using An Improved Method of Warm Lateral Condensation.

Arcuri M, Tabor M: Hyperhavic Oxygen Therapy Combined with Transcutaneous and Transmucosal Titanium Implants in Post-Radiotherapy Patients (Abstract).

Guy SC, McQuade MJ, Scheidt MJ, McPherson JC III, Rossmann JA, and VanDyke TE:

In-Vitro Attachment of Human Gingival Fibroblasts to Endosseous Implant Materials.

Shahan MH, Chuang AH, Brennan WA, Dirkesen TR, VanDyke TE, and McPherson JC: The Effect of Chlorhexidine Irrigation on Tensile Wound Strength

Paustian DP, Akujama DP, Chuang AH, McPherson JC III, and McPherson JC Jr.: Wound Repair and Regeneration.

DEPARTMENT OF MEDICINE

Whitlock WL, Hilburn RB, Thompson J, Doers JT: "Metered-Dose Inhaler Utilization in a Military Outpatient Setting." 1993;4(147) 98.

DEPARTMENT OF PATHOLOGY

Paustain PW, McPherson JC III, Haase RR, Runner RR, Plowman KM, Ward DF, Nguyen THE, and McPherson JC Jr: Intravenous Pluronic F-127 in Early Burn Wound Treatments in Rats.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Mahadik SP, Wakade CG, Scheffer R, Correnti E, Borison RL, Mukherjee S: "Abnormal Growth of Skin Fibroblasts from Drug-Naive Psychotic-Patients." Biological Psychiatry, 1993;33:69.

DEPARTMENT OF SURGERY

Charney PC, Martindale RG: Early Post-op Enteral Nutrition: Feasibility and Recommendations. RD, 1993, 13:1-8.

Charney PC, Martindale RG: Nutritional Therapy in Patients with Enterocutaneous Fistulas. Submitted to Nutrition in Clinical Practice.

Martindale RA, Calton WC: Clinical Significance of Microbial Translocation, Submitted to Nutrition in Clinical Practice, Aug 1993.

TOTAL PUBLICATIONS: 69

PRESENTATIONS: 124

ABSTRACTS: 23

DETAIL

SUMMARY

SHEETS

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 28 Oct 93 **Status:** Ongoing	**Protocol #:** 87-16
Title: The utility of the 60-kilodalton oncofetal tumor marker in the monitoring of treatment of cancer patients	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Donald E. Sutherland, PhD, MAJ, MS	**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation, Surgery	
Key Words:	**Associate Investigators:**
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 92, Jan 93, & Oct 93 Continue

Study Objective: To determine if the 60-kilodalton tumor marker is effective in monitoring the tumor status of patients with various types of cancer by determination of its activity post-surgery.

Technical Approach: Patients undergoing surgery for colon, breast, and lung cancer, and melanoma will have plasma drawn prior to surgery and 48 and 72 hours after surgery. The 60-kilodalton oncofetal tumor marker will be determined in all specimens and compared with results obtained in healthy volunteers. If possible, cancer patients will have plasma drawn and assays run on followup examinations, three to six months after surgery.

Total number of subjects enrolled to date: 124
Total number of subjects enrolled for reporting period: 51

Progress: The collection of specimens have been received and are in the process of being analyzed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	28 Oct 93	**Protocol #:** 87-40	**Status** Ongoing
Title:	Pathology applications of x-ray spectrometric microanalysis		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Jack A. Horner, BS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation/Pathology		**Associate Investigators:** Phyllis Brewer	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To utilize specimens obtained during routine surgical and autopsy pathology examinations to gain expertise in applications of x-ray spectrometric microanalysis.

Technical Approach: Tissue specimens without known abnormalities of elemental composition are selected from the daily laboratory workload. These are examined for establishment of baseline spectrometric spectra following the use of various fixatives. These spectra can then be compared against specimens with known or suspected elemental abnormalities.

Progress: Sixteen additional samples were added to the data base. The use of these techniques for blood/lead determinations will be investigated in the near future. Suitable reference standards are being planned and prepared.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 28 Oct 93	**Protocol #:** 89-38 **Status:** *Ongoing*
Title: Non-ionic surfactants in the treatment of third degree burns in rats	
Start Date: Jul 89	**Est. Compl. Date:**
Principal Investigator(s): James C. McPherson III, PhD	**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation	
Key Words: Surfactant Burn treatment	**Associate Investigators:** James C. McPherson, Jr., MD Kent M. Plowman, MD, COL, MC Paul W. Paustian, MD Royce R. Runner, MT (ASCP) R. R. Haase, MAJ, MC
Accumulative *MEDCASE* Cost:	**Periodic Review Results:** Oct 93 Continue

Study Objective: To study potential protective effects on non-ionic surfactants in the treatment of third degree burns.

Technical Approach: Effect of single and multiple doses of non-ionic surfactants given IV thirty minutes following a full thickness burn will be studied to evaluate burn wound healing.

Progress: Pluronic polyols are non-ionic surfactants developed in the 1950's. They are block co-polymers of the ABA type where A is made up of ethylene oxide polymers and B is propylene oxide polymers. They differ only in their molecular weights. This protocol evaluates their effect on third degree scald burns in a rat model. Pluronic polyols were administered 30 minutes following a third degree scald burn to the chest of 300-320 gm male rats. Histological evaluation documented this burn. The pluronic polyol was administered IV at a concentration of 12 mm/l with a dose of 8 ml/kg B.W. Animals were followed for four weeks (complete healing). Pluronic polyol F-127 showed a significant protection of the burn area as evidenced by a significant reduction in the size of the burn as measured by contraction of the burn area at 48 hours tissue edema measurements in the burn wound showed significantly reduced edema formation in the burn area. This was confirmed by histological evaluation. The blood flow (in the microcirculation) was improved in the burn area as evidenced by thermographic evaluation of the animals and later confirmed in elevated isolated skin flaps where a significant increase in blood flow was measured by Doppler Blood Flow Techniques. Histological evaluation of the burn area revealed a lack of acute inflammation and extravasation of red blood cells into the wound. Pluronic polyols provide a membrane stabilization

effect which when combined with their membrane deforming effect on red blood cells promotes burn wound healing. Similar effects have been noted by our group in the healing of surgical wounds. The deformability of red blood cell membranes increases under the effect of pluronic polyols allows them to transverse partially closed capillaries and venules, allowing oxygen delivery to damaged tissue lysis products to be removed.

Pluronic polyols of different molecular weights have different degrees of effect on these processes. Pluronc polyol dose response curves show a burn

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 28 Oct 93 **Protocol #:** 91-18 **Status:** Ongoing	
Title: Effects of different methods of hair removal on the measurement of skin blood flow in the rat using a Doppler laser blood perfusion monitor and the effect of elevated body core temperature on skin blood flow	
Start Date: Dec 90	**Est. Compl. Date:**
Principal Investigator(s): James C. McPherson III, PhD	**Facility:** Eisenhower Army Medical Center
Department/Service: Clinical Investigation	
Key Words: Blood flow	**Associate Investigators:** A. Henry Chuang, PhD Royce R. Runner, ASCP Paul W. Paustian, MD James C. McPherson, Jr, MD
Accumulative MEDCASE Cost:	**Periodic Review Results:** Oct 93 Continue

Study Objective: To determine the best method for hair removal from a rat in order to accurately measure blood flow and to determine if skin blood flow is altered by increasing the body core temperature.

Technical Approach: Hair will be removed by clipping (current method), surgical clipping, wet shaving or chemical removal. Skin blood flow will be measured using a Doppler laser flow technique. Increased body core temperature effect on skin blood flow will be measured.

Progress: Hair removal by clipping leaves exposed hair follicle shafts and stubble which reflect the laser light to the sensor and give an artificial blood flow reading when they move during normal respiration of the animal. Surgical clippers, designed for use on humans, are not effective on rodents. Wet shaving gives an acceptable skin for blood flow mesurements but often results in abrasions of the skin which either interfere with blood flow measurements or increase blood flow locally. Two chemical agents were evaluated to remove hair. Surgex, a thick paste, was effective in hair removal but was difficult to use due to its consistency. When diluted 75%:25% (wt/wt) with Surgilube, the consistency became more cream-like and gave satisfactory results. Surgi-prep has a cream-like consistency from the tube and was easy to apply. It likewise gave satisfactory hair removal which resulted in consistent blood flow measurements with the Doppler Laser blood perfusion monitor. A medical depilatory removes rodent hair in a manner in which it does not abrade the skin and thus results in reproduceable blood flow

measurements. The measurement of body core temperature change on skin blood flow has not been completed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	28 Oct 93 **Protocol#** 91-19	**Status**	Ongoing
Title:	Development of a heat stroke model in the rat and treatment with pluronic polyols		
Start Date:	Jan 91	**Est. Compl. Date:**	Jan 93
Principal Investigator(s): James C. McPherson III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** A. Henry Chuang, PhD Paul W. Paustian, MD James C. McPherson Jr, MD	
Key Words: Heat stroke, Pluronic polyols			
Accumulative *MEDCASE* Cost:		**Periodic Review Results:** Oct 93 Continue	

Study Objective: To evaluate a new model for the production of heatstroke in the rat that will be more consistent in pathophysical parameters, will require less time to develop and will control the biological variation in the model. It will also study the effect of treatment of two pluronic polyols versus saline as the resuscitative fluid in heatstroke victims (in this case rats).

Technical Approach: Fur will be removed from the rat and the rat allowed to swim in a heated water bath. Pluronic polyol solutions or saline will be administered as resuscitative fluids. The pluronic polyols have been shown by investigators in this laboratory to have membrane protective properties and have been proposed for use as resuscitative agents.

Progress: The rat models of heat stroke that have previously been described do not take into consideration that there is some biological variation in animals in their response to any imposed condition or treatment. The proposed animal model overcomes these objections. Heat stroke is a syndrome occurring in response to an elevated environmental temperature combined with physical exertion. This is the first animal model to combine both factors simultaneously. Pluronic polyols have been shown to protect the red blood cell membrane from mechanical stress. We have demonstrated other effects on red blood cell membranes; i.e., deformability. They have been demonstrated to have a membrane protective effect on the capiallary cell membrane. These membrane protective effects may make them useful in treating heat stroke. Supplies necessary to support this protocol have been procured and the protocol is ready to begin.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	**28 Oct 93**	**Protocol** **91-24**	**Status** **Ongoing**
Title:	Derivation and characterization of human periodontal ligament fibroblasts		
Start Date: Jan 91		**Est. Compl. Date:**	
Principal Investigator(s): James C. McPherson III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Royce R. Runner Thomas E. Van Dyke, DDS	
Key Words: Periodontal ligament Tissue culture			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To establish human periodontal ligament fibroblasts in tissue culture, characterize the cells and investigate differences between human periodontal ligament fibroblasts and human gingival fibroblasts.

Technical Approach: Fibroblast-like cells will be removed from freshly extracted teeth containing the periodontal ligament and grown in tissue culture using techniques specifically developed to isolate and grow the periodontal ligament fibroblasts.

Progress: The periodontal ligament is a highly specialized connective tissue which functions to attach the tooth the tooth to the alveolus. Evidence implicates cells from the periodontal ligaments as having the capacity to regenerate the periodontium. Periodontal ligament cells removed from freshly extracted teeth have been successfully grown in tissue culture, but the cells are viable for only 2-3 passages. This is in contrast to gingival fibroblast which can be maintained long term in tissue culture, but the cells are viable for only 2-3 passages. This is in contrast to gingival fibroblast which can be maintained long term in tissue culture and are customarily used in tissue culture experiments between the 6th and 10th passages. These, although in close proximity to each other in situ each cell type apparently exhibits unique requirements allowing for cell growth, proliferative rates and macro mollecular synthesis. Delineation of these requirements will allow long-term tissue culture of the periodontal ligament cells which may result in regeneration of the periodontal ligament during periodontal compromised conditions.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 91-37		**Status** Ongoing
Title:	The effect of pluronic polyols on experimental edema produced by various means: Arachidonic acid, carrageenin, histamine and thermal injury. A study in rats and mice.		
Start Date:	Jan 91	**Est. Compl. Date:**	Jan 93
Principal Investigator(s): James C. McPherson III, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** Royce R. Runner, ASCP A. Henry Chaung, PhD Paul W. Paustian, MD James C. McPherson Jr, MD	
Key Words: Edema Pluronic polyols			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93 Continue	

Study Objective: *Previous investigations* in this laboratory supported decreased skin edema in third degree burns. In this study we will investigate both pre- and post-injury IV administration of pluronic polyols on ear, skin and paw edema.

Technical Approach: Ear edema will be produced by topical application of the edema causing agents. Paw edema will be produced by injection of the edema causing agents into the foot pad or by thermal injury. Intradermal and topical applications of these agents will be used on the skin. Both pre- and post-injury IV administration of pluronic polyols will be utilized. Edema formation will be measured over time using a fluid displacement method for the paw and a micrometer caliper for the ear.

Progress: Pluronic polyol F-68 has been shown to blunt or delay the onset of the edema response, depending upon the time of administration in relation to the time of edema producing agent administration. Previous methods of edema measurement using the paw model used a wetting agent to measure the edema formation. This method was less accurate due to the wetting, drying (if possible) of the paw and the cooling effect of the evaporation of the wetting agent on the paw. We are now using a non-wetting agent to measure paw edema. This has increased our accuracy and reproducibility and reduced the variability between samples. In addition, we have just purchased an automated instrument and data logging system for edema measurements. A new resident has expressed interest in supporting this protocol and coupled with an improved methodology should result in significant progress.

HSHF-PAT
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DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 91-74	**Status** Ongoing
Title:	The effect of etidronate in the treatment of acute/chronic osteomyelitis in the rat tibial model		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): David W. Craft, MAJ, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation/Pathology		**Associate Investigators:** Donald E. Sutherland, PhD, MAJ, MS Tu H. Nguyen, MD, LTC, MC Norma Best T.B. Buxton, PhD Jack Horner	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 91 continue	

Objective: To investigate the effect of etidronate in the treatment of staphylococcal acute/chronic osteomyelitis in an experimental model.

Technical Approach: Animal model studies are complete. Analysis of bone by radiography and tensile strength is pending.

Progress: A pilot experiment has been initiated to analyze radiographs through objective analysis. Radiographs are being scanned by densitometry in order to assess bone damage parameters defined in the protocol. Procurement of new software for the densitometer has been suggested by the commercial vendor. Critical analysis continues with current capabilities. The instron unit for measuring tensile is now available. Pending radiography and histology, this analysis can be performed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-15		**Status** Ongoing
Title:	Cell membranes and the gastric mucosa from sodium fluoride in the rat		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): A. Henry Chuang, PhD		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation		**Associate Investigators:** James C. McPherson III, PhD Royce R. Runner James C. McPherson, Jr., MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93 Continue	

Objective: To investigate the effects of fluoride ion on red blood cells and the gastric mucosa in the rat. Also to evaluate the effects of pluronic polyols when the red blood cells and the rats are treated with sodium fluoride.

Technical Approach: Fresh heparinized rat red blood cells will be incubated in buffered isotonic sodium chloride and sodium fluoride solutions with or without the presence of pluronic polyol, F-68. At various time intervals the percent of hemolysis of red blood cells will be determined. Sodium fluoride solutions will be administered orally to the rats. The stomach and small intestine from the rats treated orally or IV with pluronic polyol, F-127 will be compared with those without F-127.

Progress: Since our last progress report on the effects of Pluronic F-68 and F-127 on the protection of the gastric membrane from NaF, we had extended our study with another reagent, Omeprazole, using Alcian Blue dye to measure mucus in the stomach. The results indicated some protective effect of Omeprezole on the stomach mucosa under the toxic level of NaF.

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DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-53	**Status** Ongoing	
Title: A study of p53 in the plasma of patients in stages II - VI of human immunodeficiency virus (HIV-1) infection			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Donald E. Sutherland, PhD, MAJ, MS		**Facility:** Eisenhower Army Medical Center	
Department/Service: Clinical Investigation, Medicine		**Associate Investigators:** Daniel B Craig, COL, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine if p53 appears and/or increases in the plasma of HIV-seropositive patients in stages II through VI of the disease.

Technical Approach: Plasma specimens will be drawn from HIV-positive patients in Stages II-VI of the disease and tested for mutant p53 protein by a specific ELISA technique. Patients who progress to a higher level may be asked for additional samples.

Subjects enrolled to date: 19

Progress: Nineteen subjects have been enrolled. We are now waiting on the arrival of the p53 kits to begin assaying them.

HSHF-PAT
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DETAIL SUMMARY SHEET

Date: 29 Oct 93 **Protocol** 91-9 **Status** *Ongoing*	
Title: Wear and Cutting Efficiency of Sonic Files	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Leander Lanier Sr, MAJ, DC	**Facility:** Eisenhower Army Medical Center
Department/Service: Dental Activity/Endodontics	**Associate Investigators:** James C. Kulild, COL, DC Patrice D. Primack, LTC, DC Jack A. Horner
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:**

Study Objective: To evaluate the wear of Shaper-sonic files after use *in vitro* in a simulated root canal in bovine bone and relate this wear to its cutting efficiency.

Technical Approach: Simulated root canals will be prepared from a single bovine femur. Forty-five specimens will be prepared 3x2x2 cm using a band saw. Three pilot holes, simulating artificial root canals, will be drilled along the 3 cm side of each block through the cortical plate completely through the 2 cm side. Three 0.6 mm diameter holes will be drilled in the first group of 15 blocks; 0.7 mm holes in the second group of 15 blocks; and 0.8 mm holes in the last group of 15 blocks. Lubricant will be used throughout the drilling procedure to prevent burning of the bone. The specimens will be maintained in a solution of 0.2% sodium azide to prevent bacterial growth.

Progress: Resident graduated, completed groups A & C but not B. He PCS'd to Ft Benning, GA. He is to return on leave to complete project but as of 28 Sep he has not done so.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 91-62	**Status** Ongoing	
Title: Parotid gland biopsy and transbronchial lung biopsy in the diagnosis of sarcoidosis: A comparison study			
Start Date: Jul 91		**Est. Compl. Date:**	
Principal Investigator(s): R. Terry Ellis, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dentistry, Pulmonary		**Associate Investigators:** Michael W. Tabor, COL, DC David M. Lewis, COL, DC Warren L. Whitlock, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To relate the involvement of the lungs and parotid gland in sarcoidosis.

Technical Approach: Patients with strong suspicion of sarcoidosis undergo open biopsy of parotid and transbronchial lung biopsy under intravenous sedation. OMS Staff or residents perform intravenous sedation and parotid gland biopsy, then transbronchial lung biopsy is performed by Pulmonary Staff physicians. Tissues are then evaluated by COL David Lewis, Staff Oral Pathologist.

Manpower: Existing clinic staff is utilized.

Number of subjects enrolled to date: 7

No adverse reactions.

Progress:

HSHF-PAT
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DETAIL SUMMARY SHEET

Date: 29 Oct 93 **Protocol** 91-72	**Status** Complete
Title: Evaluation of heat generated when exposed titanium implant fixture threads are removed using rotary instruments	
Start Date: Aug 91	**Est. Compl. Date:** Jun 93
Principal Investigator(s): Elise F. Adrian, LTC, DC	**Facility:** Eisenhower Army Medical Center
Department/Service: Dental Activity	**Associate Investigators:** William A. Brennan, COL, DC Michael A. Billman, LTC, DC Benjamin S. Hanson, LTC, DC Jack A. Horner
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:**

Study Objective: To determine if the technique of recontouring fixture threads raises the temperature of the fixture surface above the critical bone temperature of 47°C.

Technical Approach: A model system will be used to monitor temperature changes along a titanium implant during mechanical removal of exposed fixture threads.

Progress: Project is complete and submitted for publication.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 91-73	**StatusComplete**	
Title: Effect of nicotine on fibroblast integrin expression and distribution *in vitro*			
Start Date: Sep 91		**Est. Compl. Date:** Jun 93	
Principal Investigator(s): Gregory W. Austin, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity/Clinical Investigation		**Associate Investigators:** Benjamin S. Hanson, LTC, DC Michael A. Billman, LTC, DC William A. Brennan, COL, DC Donald E. Sutherland, MAJ, MS Thomas E. Van Dyke, DDS, PhD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the effect of various concentrations of nicotine on human fibroblast integrin expression and distribution *in vitro*.

Technical Approach: The expression of Beta-1 integrin by human gingival fibroblasts incubated in different concentrations of nicotine, 0.025, 0.05, 0.1, 0.2, and 0.4 uM, is being studied utilizing a monoclonal labelled antibody utilizing flow cytometry, cytoflow, and ELISA methods.

Progress: Project is complete and submitted for publication.

HSHF-PAT
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DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 91-75		**Status** Completed
Title:	Parenteral application of F-68 and F-127 surfactants to belly wounds in rats after an initial healing period of 48 and 96 hours		
Start Date:	Oct 91	**Est. Compl. Date:**	May 92
Principal Investigator(s): Ronnie K. Jones, LTC, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity/Clinical Investigation		**Associate Investigators:** Michael A. Billman, LTC, DC William A. Brennan, COL, DC Benjamin S. Hanson, LTC, DC James C. McPherson III, PhD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93 Completed	

Study Objective: To assess the effects of parenteral application of F-68 and F-127, non-ionic surfactants, on flank wounds in rats after healing of 24 or 48 hours.

Technical Approach:

Progress: Project has been completed and article is being submitted.

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DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 91-76	**Status** Completed	
Title: The effects of parenterally administered pluronic F-68 and F-127 on skin grafts in the rat			
Start Date: Jul 91		**Est. Compl. Date:** Jun 93	
Principal Investigator(s): Dennis P. Akiyama, LTC, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity/Clinical Investigation		**Associate Investigators:** William A. Brennan, COL, DC Michael A. Billman, LTC, DC Benjamin S. Hanson, LTC, DC A. Henry Chaung, PhD James C. McPherson III, PhD James C. McPherson, Jr, MD	
Key Words: Rats, Skin flaps, Wound healing Pluronic polyols, Vascularization,			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Sep 92 Continue	

Study Objective: To investigate the effects of parenterally administered pluronic polyols F-68 and F-127 on the healing ability of full thickness skin flaps in the rat.

Technical Approach: Histology, measurement of vascularity of flaps by injection of vital dyes.

Progress: Project is complete. Submitted for publication

HSHF-PAT
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DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 91-77	**Status** Completed	
Title: Comparison of effect of citric acid conditioning *versus* tetracycline on human gingival fibroblast attachment *in vitro*			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Eric P. Jankowski, LTC, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity/Clinical Investigation		**Associate Investigators:** William A. Brennan, COL, DC Benjamin S. Hanson, LTC, DC Michael Billman, LTC, DC James McPherson III, PhD Royce R. Runner, ASCP	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To examine and compare the effect on attachment rate and strength of attachment of human gingival fibroblasts (HGF) to dentin chips when the dentin has been conditioned using either citric acid or tetracycline.

Technical Approach:

Progress: Project is complete. Article being submitted for publication.

HSHF-PAT
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DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	91-78 **Status:**	Complete
Title:	*in vitro* effect of 30% hydrogen peroxide and sodium perborate on endodontic sealers in roots obturated with gutta-percha		
Start Date:		**Est. Compl. Date:**	May 93
Principal Investigator(s): Gary R. Karren, LTC,DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity/Clinical Investigation		**Associate Investigators:** James C. Kulild, COL, DC Patrice D. Primack, LTC, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the effect of 30% HP and SP on two root canal sealers used with gutta-percha to obturate root canals.

Technical Approach:

Progress:

HSHF-PAT
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DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 91-80		**Status** Complete
Title:	A comparison of the effects of bisphosphonate, gallium nitrate, and calcium hydroxide on osteoclast-like cells *in vitro* and *in vivo*		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Frederick R. Liewehr, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity/Clinical Investigation		**Associate Investigators:** James C. Kulild, COL, DC David K. Turgeon, MAJ, MS Donald E. Sutherland, MAJ, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate the ability of bisphosphonate and gallium nitrate impregnated dentin slabs to resist dentinoclastic activity *in vivo* in chick embryos and *in vitro* in tissue culture, and to introduce a simple and inexpensive experimental model which can be used for further dental *in vivo* studies of osteoclastic activity.

Technical Approach:

Progress:

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DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	92-31 **Status**	Ongoing
Title:	A clinical study of the relationship between computed tomography and bone sounding		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Eric Adrian, LTC, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Benjamin Hanson, LTC, DC Willaim A. Brennan, COL, DC Michael A. Billman, LTC, DC Michael W. Tabor, COL, DC Thomas Raltson, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: The anatomic surface topology of planned implant sites as recorded by CAT Scan and the bone mapping technique will be compared for accuracy, time and cost.

Technical Approach: Through the use of a location guide stent the bone is measured using the bone map technique and the CAT Scan.

Number of subjects enrolled to date: 20

Progress: Twelve patients have been mapped and eight have been scanned.

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DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-44		**Status** Terminated
Title:	Influence of the posterior horizontal plate angle on pantographic recording of immediate side shift		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Marcus F. McDonald, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Michael F. Gardner, COL, DC Max Gaston, LTC, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective:

Technical Approach:

Pprogress: Study did not produce usable data, study changed to literature review for possible publication.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-45	**Status**	Completed
Title:	The effect of loading on the porcelain labial margin of a ceramo-metal restoration		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Karen W. Tillman, LTC, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Michael F. Gardner, COL, DC Max L. Gaston, LTC, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective:

Progress:

Technical Approach: Data is being analysed and article is being written for possible publication. Abstract of article will be forwarded to Clinical Investigation when Article is completed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-46		**Status** Completed
Title:	A comparison of inpression techniques for the ceraOne abutment		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): James K. Schmitt, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Michael F. Gardner, COL, DC Eric Adrian, LTC, DC	
Key Words: autopolymerizing acrylic resin, transfer coping, vinyl polysiloxane			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective:

Technical Approach:

Progress: Nobelpharma has recently introduced a single tooth implant system, the CeraOne abutment. Two impression techniques are recommended for use with the implant The first involves taking an impression with a custom tray, then securing the impression coping to the tray autopolymerizing acrylic resin. The alternate technique recommends that the impression coping by shortened to a length not interfering with a stock tray. Teh tray is then loaded with the impression material and put in plce. The coping is entirely embedded in the impression. The purpose of this study was to compare the two techniques. Results showed that the use of autopolymerizing acrylic introduced significant distortion into the system.

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DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-56	**Status** Ongoing	
Title: A Clinical Evaluation of Autogenous Iliac Bone Grafts in Periodontal Osseous Defects			
Start Date: Jun 92		**Est. Compl. Date:** Jun 94	
Principal Investigator(s): Benjamin S. Hanson, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** William Brennan, COL, DC	
Key Words: Periodontitis, Iliac graft			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate the feasibility of the use of autogenous frozen marrow as a treatment modality in periodontal osseous defects.

Technical Approach: Twenty patients with hopeless teeth will be asked to participate in this study. Bone will be harvested from the ilium and stored in MEM at -6 C. Seven days after the cores have been taken they will be placed in periodontal defects.

Number of subjects enrolled to date: 4

Progress: In the four patients we have treated thus far we have had excellent results.

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DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-57		**Status** Ongoing
Title:	Evaluation of the benefits of screening tests done prior to periodontal therapy		
Start Date: Jun 92		**Est. Compl. Date:**	Jun 93
Principal Investigator(s): Benjamin S. Hanson, LTC, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** William Brennan, COL, DC	
Key Words: Screening tests			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate the value of adjunctive screening lab tests before periodontal therapy.

Technical Approach: One hundred patients over the age of 40 will be selected at random and referred for biochemical and hematologic profiles. The tests will include CBC, UA, SMAC-17, PT, PTT, and platelet count.

Number of subjects enrolled to date: 40

Progress: No conclusions at this time. Data collection is complete. Article is being written.

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SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol#** 92-58	**Status**	Ongoing
Title:	A comparison of the clinical success of the 5mm Nobelpharma implant fixture to the standard 3.75mm fixture		
Start Date:		**Est. Compl. Date:**	Jun 93
Principal Investigator(s): Eric Adrian, LTC, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To study the clinical success of the 5mm fixture at 1, 2 and 3 year intervals.

Technical Approach: Clinical and radiological parameters will be used to compare the new fixture to the 3.75mm fixture.

Number of subjects enrolled to date: 15

Progress: To date two fixtures have been placed with no complications.

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SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-74	**Status** Ongoing	
Title: Wear and Cutting Efficiency of the Rispi-sonic File			
Start Date: July 1992		**Est. Compl. Date:** April 1994	
Principal Investigator(s): Gordon W. Woollard, MAJ, DC		**Facility:** Tingay Dental Clinic	
Department/Service: Dental Activity		**Associate Investigators:** COL P. Primack Dr. R. Anderson Dr. F. Rueggeberg Dr. J. McPherson Mr. J. Horner	
Key Words: sonic; rispisonic; file; efficiency			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the cutting efficiency of Rispi-sonic files used in a MM 1500 endosonic system.

Technical Approach:

Progress: We have set up our research design to include the evaluation of 25 respisonic files, each of which will instruct 10 standard canals placed in methyl methacrylate resin. Each fill will be instrumented for a total of 15 minutes (90 seconds/canal). Scanning Electron Microscopy will be used to follow the file wear patterns and changes in flute design as the file wears.

An apparatus has been designed to eleminiate all the variables encountered when a researcher files canals by hand, as is frequently seen in projects of this type.

Ninteen files have been instrumented on the apparatus and we find no correlation of time of use with efficiency or cut of the files. The last six files will be instrumented at this time, with the changes being noted by SEM. Hopefully, reason will be found as to why the files show such varied cutting efficiencies.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-75		**Status** Ongoing
Title:	The Effects of Intracanal Medicaments, Cements (sealer), and Fillers on Fibroblast Growth and Attachment to a Tooth Which has Received Root Canal Therapy		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Lawrence G. Breault, MAJ, DC		**Facility:** Tingay Dental Clinic	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate the effects that the placemnt of intracanal medicaments, fillers, and cements in endodontically treated teeth may have on periodontal regenerative procedures.

Technical Approach: Various medications were placed in roots and then cultured with fibroblasts. MTTs assay was done to determine all viability. Presnetly gathering data.

Progress: Local approval late FY 92, no progress to report.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	92-76	**Status** Ongoing
Title:	Endogenous Prostaglandin Induced by IL-1B and TNFa Regulates IL-6 Production by Human Gingival Fibroblasts		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Charlene A. Czuszak, MAJ, DC		**Facility:** Tingay Dental Clinic	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To elucidate a mechanism by which the interaction of cytokines, such as Il-1B and TNFa, may promote IL-6 production.

Technical Approach: Fibroblast were grown with IL-1B or TNFa and the cultures were assayed for PG2 and IL-6. Curtures were done with and without indomethacin. Data collection is complete

Progress: Local approval late FY 92, no progress to report.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-77		**Status** Ongoing
Title:	The Effect of Transforming Growth Factor Beta (TGF-B) in Conjunction with Polyols on Wound Healing Rats		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): George E. Tolson IV, MAJ, DC		**Facility:** Animal Support Facility, Clinical Investigation	
Department/Service: Dental Activity		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To examine the effects of parenterally administered Transforming Growth Factor Beta in combination with topically applied pluronic polyols F-68 and F-127 on the tensile strength and healing of incisional wounds in the rat.

Technical Approach: Various concentration of F-68 and F-127 are applied to a standard wound in a rat. The tensile strength of the incision is then determined with the Instrom unit at the time of sacrifice.

Progress: Data is being collected.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-2	**Status** Ongoing	
Title: Sealing Ability of Bases and Cements Following Exposure to 30% Hydrogen Peroxide and Sodium Perborate			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Jeffery D. Luzader, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Patrice D. Primack, LTC, DC Robert J. Loushine, LTC, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective:

Technical Approach:

Progress:

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	93-3	**Status** Ongoing
Title:	Stereomicroscopic Evaluation of Apical Retropreparation Shapes Utilizing an Ultra-sonic versus a Micro-head Handpiece		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Thomas F. Armstrong, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Patrice D. Primack, LTC, DC Robert J. Loushine, LTC, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective:

Technical Approach:

Progress

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-11	**Status** Ongoing	
Title: The Effect of Bone Marrow Storage on Interleukin-6 Production Using the HLA: (FCR)BR			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Frederick C. Bisch, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** Benjamin S. Hanson, LTC, DC William A. Brennan, COL, DC Michael A. Billman, LTC, MC Val L. Kudryck, LTC, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: Determine the effects of storage temperature and time on IL-6 production.

Technical approach: Culture osteoblasts and then store for various time frames from 1 day to 14 days at temperatures ranging from 4° C to 70° C and assay for IL-6 production.

Progress: Presently gathering data.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-12	**Status** Ongoing
Title:	The Effects of Transforming Growth Factor Beta and Platelet Derived Growth Factor on Human Gingival Fibroblasts and Human Periodontal Fibroblasts Grown in Serum and Serum Free Media		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Thomas J. Butts, MAJ, DC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Dental Activity		**Associate Investigators:** William A. Brennan, COL, DC Benjamin S. Hanson, LTC, DC Michael A. Billman, LTC, DC Val L. Kudryk, LTC, DC Donald E. Sutherland, MAJ, MS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: Determine if the use of TGF-B & PDGF might enhance second healing.

Technical Approach: Fibroblast are gorwn in vitro and then cultured with TGFB or PDGF.

Progress: Cells are then surveyed for viability and growth. Presently gathering data.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	93-39	**Status** Ongoing
Title:	The Efficacy of Procera Laser Welded Hybrid Restorations		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Eric D. Adrian, LTC, DC		**Facility:** Tingay Dental Clinic	
Department/Service:		**Associate Investigators:** COL John Agar, DC COL Michael Billman, DC COL Michael Gardner, DC COL James Hughbanks, DC LTC Ben Hanson, DC LTC Max Gaston, DC LTC Elise Adrian, DC LTC Stephen Cameron, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To compare the clinical performance of Procera laser welded hybrid restorations to the current lost wax cast framework technique in the restoration of human mandibular edentulous patients.

Technical Approach: The study includes a randomly assigned control group consisting of implant supported restorations made with a cast nobel alloy framework. All patients will be treated with a minimum of five Branemark system implants per patient and a hybrid cantilevered prostheses.

Number of subjects enrolled for the reporting period:

Progress: Final approval is suspended pending resolution of funding issues.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-48	**Status** Ongoing
Title:	An Average Mandibular Anterior Implant Angle		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Walter J. Morris, MAJ, DC		**Facility:** Tingay Dental Clinic	
Department/Service:		**Associate Investigators:** COL Michael F. Gardner, DC COL Max Gaston, DC LTC Eric Adrian, DC LTC Eladio DeLeon, DC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To evaluate existing radiographs to see if a significant mandibular anterior implant trajectory angle or range of angles can be used to guide the placing of mandibular anterior implants.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Data is still being gathered.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	93-49	**Status** Ongoing
Title:	A Comparison of Luting Cements for the CeraOne Abutment System		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): James E. Parker, MAJ, DC		**Facility:** Tingay Dental Clinic	
Department/Service:		**Associate Investigators:** COL Max Gaston, DC LTC Eric Adrian, DC Michael F. Gardner, DDS	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To evaluate the effectiveness of different luting cements on the retention of a ceramic crown and titanium implent abutment using the Instrom to measure retention forces.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: Data is still being collected.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-14	**Status** *Completed*	
Title:	Safety and efficacy of clarithromycin and erythromycin ethylsuccinate suspensions in the treatment of children with community-acquired pneumonia		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): George W. Wright, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** Bruce M. LeClair, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To compare the efficacy and safety of clarithromycin and erythromycin ethylsuccinate suspensions in the treatment of children with community-acquired pneumonia who are suitable candidates for oral macrolide therapy.

Technical Approach: Randomized, investigator blind, multicenter trial.

Subjects enrolled to date: 3

Progress: Three patients enrolled. Study completed 30 April 1993 with no serious side effects.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 92-16	**Status** Terminated
Title:	Comparison of family Apgar scores of outpatients with principal diagnoses and medication use		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): H. James Huffnagle, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** Roger Bruce, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To compare the family apgar scores of outpatients with their respective principal (1-3) diagnoses and number of current medications.

Technical Approach:

Progress: Inconclusive data.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	92-24	**Status** Terminated
Title:	The positive and negative predictive value of a routine fifty gram glucose screening test at the initial prenatal visit		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Karen S. Phelps, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** Kim DeStefano, CPT, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine usefulness of 1° glucola in all antepartum patients at first prenatal visit.

Technical Approach:

Number of subjects enrolled to date: 0

Progress: Cancelled after pilot study review.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 92-41	**Status** Terminated
Title:	The effectiveness of interventions to increase compliance with breast cancer screening guidelines of the US task force for clinical preventive services		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Dale Carroll, COL, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service:		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To develop a multi-component educational program aimed at both providers and patients within the primary care environment which will successfully increase compliance with current breast cancer screening recommendations and to identify and educate young soldiers at high risk for breast cancer regarding the importance of routine breast self-examination, clinical breast examinations, and mammography.

Technical Approach:

Subjects enrolled to date: 0

Progress: This study was not started pending funding approval from MRDC and the principal investigator has left the service.

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-54		**Status** Terminated
Title:	Determination of the prevalence of genital chlamydia infection in males using enzyme immunoassay of urinary sediment		
Start Date: May 92		**Est. Compl. Date:**	
Principal Investigator(s): Thomas P. Garigan, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** Eugenia Walsh, CPT, MC David P. Goldman, CPT, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To establish protocols for study of the epidemiology of urogenital chlamydia infections.

Technical Approach: Epidemiologic

Number of subjects enrolled to date: 97

Progress: None were positive of those tested. Study was terminated.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	93-14	**Status** Ongoing
Title:	Smoking Cessation in Active Duty Army Trainees: The Effects of Direct Health Care Provider Advice and Follow-up		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): John Littell, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** Charles Stargel, CPT, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: Trainees will be identified and surveyed at the time of both in and outprocessing (variable time frame usually 2-4 months) to determine the effectiveness of direct Health Care Provider (HCP) advice/counselling. The intervention and followup visits are to be arranged in conjunction with the trainee's command and excused by sick slip to insure compliance. Study design: Prospective quasi-experimental study, to ascertain behavior modification secondary to direct HCP advice alone and subsequently more extensive HCP counselling in a second group, as compared to a similar group without either of these interventions (total groups - 3). Investigator believed that composition of trainees is comparable among the three TMC's.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: Smoking cessation classes have been held, but changes in processing of troops and personnel have limited enrollment. Followup data is being sought with supplemental personnel.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-23	**Status** Completed
Title:	The Effect of Self-Care Booklet on the Self-Efficacy of Parents		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Michelle D. Bannon, PA, DAC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:**	
Key Words: Self-care booklet Self-efficacy			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To assess the effect of a self-care booklet on the self-efficacy of parents enrolled in the Family Practice Clinic at Fort Gordon, Georgia. The hypothesis was that parents receiving a self-care boolet with instructions and a motivational statement regarding its use would demonstrate a greater rise in self-efficacy than those participants receiving a booklet only.

Technical Approach:

Number of subjects enrolled for reporting period: A total of 60 participants were enrolled in the study. 49 completed follow-up surveys, 22 from the B/I group and 27 from the B/O group.

Progress: No significant difference in the level of self-efficacy was noted between the groups on the initial survey. On the follow-up survey, an increase in self-efficacy was noted for both groups with a significant increase noted in the control group. This was confirmed by a paired T-test ($p=.002$). Two variables, rank of the active duty sponsor and eductional levels of respondent were found to be significant. Those respondents with an enlisted sponsor, or those respondents with a high school (or less) education were more likely to significantly increase their self-efficacy score after the intervention. We concluded that a self-care booklet alone can be an effective tool in increasing the self-efficacy of parents, particularly in those groups previously mentioned.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-25	**Status** Ongoing
Title:	HELLP Syndrome: The Incidence - A Prospective Study		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Kenneth Trzepkowski, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice/OB-GYN		**Associate Investigators:** Wayne Blount, LTC, MC Keven Kelly, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the incidence of HELLP and determining clinical characteristics associated with the development of the syndrome.

Technical Approach: Measure serum marers prospectively on volunteer pregnant patients.

Number of subjects enrolled to date: 199

Progress: Approximately 75 patients have completed this study so far with the remaining in different stages of completion. There was a goal of 200 patients, but due to drop out of some of the patients (i.e., moving away from the area, etc.), this number will need to be increased to about 225.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-32		**Status** Ongoing
Title:	Infant Feeding Practices in the Military Community: The Incidence and Duration of Breast Feeding in the Military Community and the Factors Affecting this Decision		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): B. Wayne Blount, MD, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** Cindy Lee, MC John Kugler, MD Dana Anderson, MD Evelyn L. Lewis, MD Kathy Holder, MD William Blanke, MD	
Key Words:			
Accumulative *MEDCASE* Cost:		**Periodic Review Results:**	

Study Objectives: To determine the incidence and duration of infant feeding methods of women in the military community. To determine the incidence and duration of breast feeding in active duty women as a subset of employed mothers. To identify the factors affecting women's infant feeding decisions, specifically those affecting active duty women.

Technical Approach: Questionnaire will be completed by post-partum patients. Telephone or mail contact of subjects at six months for followup data.

Number of subjects enrolled to date: 25 active duty and 50 dependent women.

Progress: Continuing to enroll subjects. Anticipate completion by end of calendar year 1993.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-41		**Status** Terminated
Title:	Comparison of Oral, Tympanic Skin Thermometry in an Emergency Department		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Bruce N. Gibbon, MD, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Emergency Dept/Family Practice		**Associate Investigators:** Lisabeth J. Mortimore, SGT	
Key Words:		Medical Monitor: Mark Remz, M.D., MAJ, MC	
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objectives: To assess the correlation between the two thermometry methods and will evaluate if liquid crystal skin thermometry can accurately correlate with these two methods for spot temperature measurements.

Technical Approach:

Number of subjects enrolled to date:

Progress: The study has been completed and presentation was given on the Transitional Residents Research Day. The primary investigator has been transferred to Korea and the paper is in preparation.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol** 93-62	**Status** Ongoing
Title:	A Survey of Resident Perceptions of Effective Teaching Behaviors in Different Residencies		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): *J. Gregory Jolissaint, CPT, MC*		**Facility:** Eisenhower Army Medical Center	
Department/Service: Family Practice		**Associate Investigators:** David P. Goldman, CPT, MC B. Wayne Blount, LTC, MC Robert Webb, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objectives: This study is designed to inform faculty members of different residency programs of teaching behaviors their house officers deemed most helpful to their learning process in residency (as well as those felt to be least helpful). By "arming" faculty members with this information during faculty orientation and/or faculty development sessions, there should be a resultant improvement in training for physicians at DDEAMC and ultimately higher quality patient care delivered by graduates of DDEAMC residencies.

Technical Approach:

Number of subjects enrolled to date:

Progress:

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 28 Oct 93	**Protocol** 89-46	**Status** Completed	
Title: Effects of non-Ionic surfactants in sunburns using a rat model			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Michael S. Riel, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Clinical Investigation		**Associate Investigators:** James C. McPherson, III, PhD MAJ, MC James C. McPherson, Jr., MD Paul W. Paustian, MC Royce R. Runner, ASCP	
Key Words: sunburn Pluronic polyols			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93 Completed	

Study Objective: To evaluate possible protective effects of non-ionic surfactants in ultraviolet induced first degree skin burns using am albino rat model.

Technical Approach: Male, Aprague-Dawley rats weighing greater than 320 gm will be used. A 3x6cm area will be exposed to UV light at 3x the minimal erythermal dose. This study is based on earlier work which showed that the non-ionic surfactant F-127 injected shortly ater a full thickness burn of the skin could reduce the amount of damage to the underlying tissue and speed healing. The mechanism of this protective effect is not yet known. This study is an attempt to isolate the steps in the process by examining first degree burns to see if these same protective effects would also work with skin which is merely injured.

Progress: Completed pilot project. Results presented at ACP Associates of Georgia, DDEAMC, on Resident Research Day, and received Admiral Eske Award at AMOPS for outstanding research.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 90-16	**Status** *Ongoing*	
Title: Study of Vespa fire ant venom in the diagnosis of fire ant reactivity			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Angelina J. LePage, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Allergy		**Associate Investigators:** Chester Stafford, MD, MCG Richard T. Hatch, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To compare skin test reactivity of Vespa fire ant venom to that of two commercially available IFA whole body extract preparations.

Number of subjects enrolled to date: 35 adults
Number enrolled for reporting period:

Progress: The study in adults has been completed and results published. There were 35 adults enrolled. According to Dr. stafford, the study hopes to include children but at this time there are none enrolled and no progress to report.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	27 Oct 93 **Protocol**	91-14	**Status** Ongoing
Title:	Comparison of intravenous H-2 antagonists and their influence on gastric emptying on insulin dependent diabetics		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Michael P. Goldfinger, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine		**Associate Investigators:** Eugene H. Ryan, CPT, MC, Staff Internist, Fort Rucker, Alabama Stephen G. Oswald, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Jan 93 Continue	

Study Objective: To study the effect of a single standard IV dose of famotidine, cimetidine and ranitidine on GE in adult diabetics.

Technical Approach: Each patient will be studied in the fasting state on four different days spaced at least 72 hours apart. Prior to each gastric emptying study the subjects will receive an IV bolus injection of either one of cimetidine, ranitidine, famotidine, or placebo.

Number of subjects enrolled for the reporting period: 4

Progress: This study was amended to include females as subjects. The study and the consent were revised to include an HCG test for pregnancy within 24 hours preceding the test and to warn of the potential dangers to the fetus of any undetected pregnancy. The hope is to broaden the potential patient base sufficiently to complete the study.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-1	**Status**	Completed
Title:	Serologic survey of active duty dependent and retired military population for evidence of *helicobacter pylori (Campylobacter pylori)* infection at a US Army Medical Treatment Facility		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): David R. Haburchak, COL, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine		**Associate Investigators:** David W. Craft, PhD, MAJ, MS Donald E. Sutherland, PhD, MAJ, MS Norma Best, MT	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Jan 93 Continue	

Study Objective: What is the prevalence of *H. pylori* associated infection in a military population including gastroenterology pateints? What is the efficacy of triple therapy in a nonselected population of seropositive patients?

Technical Approach: A simplified nonblinded treatment protocol will be instituted based on the knowledge of the role of *Helicobacter* in association with gastritis and peptic ulcer disease in the literature, its reponsiveness to therapy and the ethics of withholding potentially curative therapy. This study will simultae clinical practical use of this modality of treatment/management for its practicality and ease.

Subjects enrolled to date: 22

Progress: 50% of 22 patients had evidence of H. pylori based on serology. All patients who received drug combination completed therapy with follow-up improvement in pain in most patients. Since the project was begun, the medical literature now supports use of triple antibiotics after endoscopy in patients who relapse after initial course of H2 blockers or have a complication of peptic ulcer. Non-ulcer dyspepcia is not been demonstrated to be caused by H. pylori. The frequency of h. pylori in the DDEAMC population is compatible with publicized results in larger studies.

Action: Study closed as new literature precludes benefit to patients.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-10		**Status** Ongoing
Title:	A comparison of the efficacy, safety, and tolerance of ceftibuten (SCH 39720) 300 mg given BID and augmentin 500 mg given TID in the treatment of community acquired pneumonia		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, MAJ, MC Jesse J. Doers, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

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

Technical Approach: Treatment will follow outline in Schering-Plough protocol.

Subjects enrolled to date: 5

Progress: Over 30 patients have been screened with 12 patients enrolled. The protocol will continue in 1994. Major problems have been isolation of the causative organism on cultures. The laboratory has started doing double culture plates to incruease the diagnostic yield.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-9		**Status** Ongoing
Title:	A comparison of the efficacy, safety, and tolerance of ceftibuten (SCH 39720) 400 mg (I x 400 mg capsule) in the fed and fasted state and augmentin amoxicillin/clavulanate 1.5 gm (I x 500 mg tablet TIC) in the fed state in the treatment of acute exacerbations of chronic bronchitis		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Wayne T. Honeycutt, MAJ, MC Jesse J. Doers, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To compare the efficacy, safety, and primarily, the GI tolerance of once-daily Cedax ceftibuten (SCH 39720) in both the fed and fasted state with that of Augmentin amoxicillin/clavulanate given TID int he fed state in the treatment of acute exacerbations of chronic bronchitis in adults.

Technical Approach: Treatment will follow outline in Schering-Plough protocol.

Subjects enrolled to date: 6

Progress: Over 70 patients have been screened and 24 patients have been enrolled. The protocol will end in 1993. There have been positive results in most patients without complications. We hope to finish enrollment before the end of the protocol.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-18		**Status** Terminated
Title:	Prediction of endogenous erythropoietin levels from the hematocrit and serum creatinine		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Bobby W. Jones, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Hematol-Oncol, Nephrology/Family Practice		**Associate Investigators:** Patrick W. Cobb, MAJ, MC John W. Nolan, MAJ, MC Amy W. Sprague, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine if the clinician can use values obtained from routine laboratory studies solely and appropriately in medical decision making with reference to exogenous erythropoietin therapy.

Technical Approach:

Subjects enrolled to date:

Progress: Test kits to assay erythropoietin are not available. Project terminated.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 92-30	**Status** Ongoing	
Title: Techniques of use of metered dose inhalers			
Start Date: Apr 92		**Est. Compl. Date:** June 93	
Principal Investigator(s): Richard B. Hilburn, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary Disease		**Associate Investigators:** Warren L. Whitlock, MAJ, MC Jesse T. Doers, MAJ, MC Ray Scarlett, CRT	
Key Words: MDI, Metered dose inhalers			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To evaluate the techniques of use of MDI by the EAMC patient population. To determine which of three teaching modalities is the most effective in improving technique. To detect any implication of impact of improved technique upon emergency room visits and hospitalizations for the study population.

Subjects enrolled to date: 43

Progress: 101 subjects have been enrolled to date. Phase I and II have been completed and Phase III is in progress. Phase I data was presented at the American Thoracic Society annual meeting in May 1993 and Phase II data will be presented at the American College of Chest Physicians' annual meeting in October 1993. A manuscript has been written and submitted to the journal Chest for publication of Phase I and II data.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-47	**Status** Ongoing	
Title:	A double-blind, placebo controlled, parallel group, multicenter study of the use of weekly azithromycin as prophylaxis against the development of *Mycobacterium avium complex* disease in HIV infected people		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Daniel B. Craig, COL, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Infectious Disease		**Associate Investigators:** Craig E. Smith, MAJ, MC David R. Haburchak, COL, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To evaluate the safety and efficacy of azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromised HIV infected patients with a CD4 count<100/ul.

Technical Approach: Treatment will follow outline per Pfizer protocol.

Subjects enrolled to date: 9

Progress: Nine patients screened. One patient did not meet entry qualifications, one patient dropped from study before receiving drug, one patient died while on study not related to drugs. Six patients continue on study.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 27 Oct 93	**Protocol** 92-60	**Status** Ongoing	
Title: A double-blind randomized parallel study of the antiemetic effectiveness of IV Dolasetron mesylate VS IV Zofran in patients receiving cisplatin chemotherapy (MCPR0031)			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Karen J. Bowen, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, MAJ, MC Robert Krywicki, MAJ, MC Stephen G. Oswald, LTC, MC Charles T. Thornsvard, COL, MC Lyle M. Glascock, PharmD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the relative effectiveness of a single 2.4 mg/kg intravenous (IV) dose of dolasetron mesylate versus a single 32 mg dose of IV Zofran for complete prevention of emesis due to ($\geq$ 70 mg/m^2) of cisplatin chemotherapy. To evaluate the safety and tolerance of dolasetron myesylate versus ondansetron when given for this indication. To compare patient satisfaction with the two antiemetic agents.

Technical Approach: This is a double-blind, randomized, parallel study in which patients with a history of histologically confirmed malignant disease will receive either IV dolasetron mesylate (2.4 mg/kg) or IV ondansetron (32 mg/kg). The cisplatin dose will be $\geq$ 70 mg/m^2 and infused over no more than 3 hours as the first component of a chemotherapy regimen.

Number of subjects enrolled to date: 12

Progress: The study objective and technical approach was amended in Nov 92 to include a single dose of Zofran as the comparative drug. There have been 12 patients enrolled and completed the study. There has been one serious adverse event - a Type I hypersensitivity reaction manifested by severe bronchospasm. The patient was treated with IV Benadryl, 50 mg, after Albuterol nebulizer therapy. The reaction subsequently subsided.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	27 Oct 93 **Protocol**	92-61	**Status** Ongoing
Title:	A five arm double-blind randomized dose-response study of the antiemetic effectiveness of IV Dolasetron mesylate in patients receiving cisplatin chemotherapy (MCPR0032)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Karen J. Bowen, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Stephen G. Oswald, LTC, MC Don Shaffer, MAJ, MC Robert Krywicki, MAJ, MC Charles T. Thornsvard, COL, MC Lyle M. Glascock, PharmD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To establish efficacy by showing that there is a trend toward decreased emesis following cisplatin ($\geq$ 70 mg/m^2) with increasing doses of dolasetron mysylate. To evaluate the dose-response relationship across 0.6,1.2,1.8, 2.4, and 3.0 mg/kg single intravenous (IV) doses of dolasetron mysylate in preventing emesis due to cisplatin ($\geq$ 70 mg/m^2) chemotherapy. To evaluate the safety and tolerance of dolasetron mesylate when given for this indication. To characterize the population pharmacokinetic and pharmacodynamic models of dolasetron mysylate and/or its metabolite(s) and their interindividual variabilities in patients receiving cisplatin. To compare the degree of patient satisfaction among the antiemetic dose levels.

Technical Approach: This is a five arm, double-blind, randomized, dose response in which patients with a history of histologically confirmed malignant disease will receive a single dose of dolasetron mesylate. Patients of either sex and any race will be admitted to this study. They must be undergoing their first course of cisplatin-containing chemotherapy. The cisplatin dose will be $\geq$ 70 mg/m^2 and infused over no more than 3 hours as the first component of a chemotherapy regimen.

Number of subjects enrolled to date: 0

Progress: This study has not begun yet and is on hold while the other Dolasetron study (DDEAMC 91-61) is progressing. There may be some patients randomized this year and the pharmacokinetic samples would be deleted.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-67	**Status** *Terminate*	
Title:	Evaluation of the Use of ^{99m}Technetium Pertechnetate with Potassium Perchlorate Wash-out and ^{99m}Technetium MIBI in Parathyroid Imaging in Patients with Suspected Parathyroid Neoplasia or Hyperplasia		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Rama G. Eachempati, MD, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Infectious Disease		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective:

Technical Approach:

Progress: PI has left military service with no progress, terminate. No patients were enrolled.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	92-73	**Status** Terminate
Title:	Comparative Study of Liver Biopsies and Quantitative Hepatobiliary Scanning in Patients with Hepatitis C		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Anwar K. Malik, MD, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine if quantified hepatobiliary scan with 99Tc-IDA could be substituted for liver biopsy in patients with Hepatitis C.

Technical Approach:

Number of subjects enrolled to date: None

Progress: No progress to report.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 92-78	**Status**	Ongoing
Title:	A Multicenter, Open Label, Pilot Study of Azithromycin in the Outpatient Treatment of Lower Respiratory Tract Infection Due to Atypical Respiratory Pathogens		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, MD, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:**	
Key Words:			

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	93-6	**Status** Ongoing
Title:	Phase I, Trial of VP-16 + Immunex r-GM-CSF in Patients with Advanced Malignancies		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Don W. Shaffer, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Geoffrey R. Weiss, MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93 Continue	

Study Objective: To estimate the maximally tolerated dosage, and frequency and types of toxicities of etoposide when combined with r-GM-CSF in patients with advanced malignancy; to determine which schedule of administration of r-GM-CSF (prior to or during etoposide delivered; to determine a superior in terms of the greater amount of etoposide delivered; to determine a recommended dosage and schedule for etoposide +/- r-GM-CSF to be used in Phase II trials; to document any responses which may be observed during treatment with the combined regimen; and to evaluate the effects of rHuGM-CSF on the flood levels of etoposide administered orally.

Technical Approach:

Number of subjects enrolled for reporting period: 7

Progress: Since implementation of the protocol, we have enrolled 7 patients. Level 2 is nearing completion (3 more patients). Toxicities have been acceptable and if the additional three patients do well then Dr. Weiss (San Antonio) will go to level 3. One patient died of febrile neutropenia and sepsis on Arm A here at Eisenhower. There have been no other significant toxicities.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-24		**Status** Terminate
Title:	The Detection of Antibodies to *Helicobacter pylori* in Samples obtained with the Principal OraSure Oral Specimen Collection Device		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Timothy E. Mecredy, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Gastroenterology		**Associate Investigators:** *Francisco* I. Cuartas, COL, MC Howard M. Rosen, COL, MC Michael R. Fisher, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine if the OraSure device collects oral specimens which are suitable for use with enzyme immununoassay kits for the detection of *Helicobacter pylori* IgGs. To determine if OraSure samples result in sensitivities and specificities comparable to those obtained with serum when assayed with *H. pylori*-specific EIA kits.

Technical Approach:

Number of subjects enrolled for the reporting period:

Progress: This study was not started because of technician shortages.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-26	**Status** Ongoing	
Title:	A Comparative Trial of 256U87 and Acyclovir for the Treatment of First-Episode Genital Herpes Infection		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Mark G. Blaskis, MD, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Dermatology		**Associate Investigators:** Jerome C. Hill, MD, MAJ, MC William L. Heimer, MD, MAJ, MC Medical Monitor: David R. Haburchak, MD, COL, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine the efficacy of a new antiviral agent administered twice a day instead of five times a day as acyclovir is administered.

Technical Approach: Therapy will follow schema outlined in Burroughs-Wellcome protocol.

Number of subjects enrolled to date: Two

Progress: One patient has completed the trial with no adverse effects. The second patient decided to discontinue the trial after the second day.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	93-30	**Status** Ongoing
Title:	A Multicenter Investigator Blinded Study of the Efficacy and Safety of Azithromycin vs Amoxicillin/Clavulanate in the Treatment of Acute Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease (Chronic Bronchitis)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, MD, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		**Associate Investigators:** Jesse T. Doers, MD, MAJ, MC Wayne T. Honeycutt, MD, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To compare the safety and efficacy of orally administered azithromycin and amoxicillin/clavulanate in the treatment of acute exacerbatons of COPD (Chronic Bronchitis) Caused by susceptible bacterial pathogens.

Technical Approach: Therapy will follow schema outlined in Pfizer protocol.

Number of subjects enrolled to date: Three

Progress: Three patients have been enrolled with a total goal of 10 patients from our site.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-31		**Status** Ongoing
Title:	A Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Three Doses of CP-0127 and Placebo in Patients with Presumed Sepsis and the Systemic Inflammatory Response Syndrome (SIRS)		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, MD, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary, Infectious Disease		**Associate Investigators:** Wayne T. Honeycutt, MD, MAJ, MC Jesse T. Doers, MD, MAJ, MC Craig Smith, MD, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To investigate the efficacy and safety of a 72-hour infusion of three doses of CP-0127 or placebo in the treatment of patients with SIRS and presumed sepsis.

Technical Approach: Therapy will follow schema outlined in Cortech protocol.

Number of subjects enrolled to date: Four

Progress: Four patients have been enrolled with a plan for 10 patients. One patient died of causes not related to the protocol. Estimated mortality due to underlying disease is 45%. The blind will be broken when 50% of patients are enrolled from the multicenter sites nation-wide for initial review.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol**	93-34 **Status**	Completed
Title:	A Comparison of Arm and Calf Blood Pressure Values Obtained by the Dinamap Device		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Peter J. Ahn, MD, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To use the Dinamap device to measure the blood pressures from the arm and calf and to provide the comparative results.

Number of subjects enrolled during reporting period:

Progress: Clinical trials completd and information presented at the Transitional Intern Presentation Day. Written paper in progress with planned submission for journal acceptance within the calender year. The investigator has PCS'ed to Walter Reed AMC to start an Anesthesiology Residency.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93 **Protocol** 93-51		**Status** Ongoing
Title:	A study to Investigate the Efficancy and Safety of Oral Valacyclovir (1000 mg or 500 mg, twice daily) Compared with Placebo in the Treatment of Recurrent Genital Herpes in Immunocompetent Patients		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Marshall A. Guill, MD, COL, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Dermatology		**Associate Investigators:** Roger V. Bruce, LTC, MC Mark G. Blaskis, MAJ, MC Susan Montieth, MT (ASCP)	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: This is a company sponsored study to evaluate the efficacy and safety of valacyclovir to placebo in treating recurrent genital herpes in immunocompetent patients. By using the parent compound to acyclovir with less frequent dosing and giving to patients at home so as to start treatment within hours of symptom occurrence, it is hoped that greater efficacy may be found than has been true of earlier studies with acyclovir. It has three arms consisting of the two dose levels and placebo.

Technical Approach: Approve as a company sponsored more than minimal risk human use study and forward to HSC for further disposition and for permission to accept the drugs and placebos from Burroughs-Wellcome.

Number of subjects enrolled to date: None

Progress: No patients yet enrolled

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-64	**Status** Ongoing	
Title: A Randomized, Double-Blind, Multicenter Trial Comparing 10 Days of Oral Therapy with CP-99,219 (100 mg or 300 mg Daily) or Ofloxacin (800 mg Daily) for the Treatment of Acute Exacerbation of Chronic Bronchitis			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Warren L. Whitlock, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Pulmonary		***Associate Investigators:*** Wayne T. Honeycutt, MAJ, MC Jesse T. Doers, MAJ, MC Medical Monitor: David R. Haburchak, COL, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To Investigate the efficacy and safety of two doses of CP-99,219 and Ofloxacin in the treatment of patients with acute exacerbations of chronic bronchitis.

Technical Approach:

Number of subjects enrolled to date:

Progress:

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	12 Oct 93 **Protocol** 92-72	**Status**	Completed
Title:	Experiences of Couples Participating in a Counseling Program to Abate Spouse Abuse: A Descriptive Clinical Report		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Dorothy A. Anderson, MAJ, AN		**Facility:** Eisenhower Army Medical Center	
Department/Service: Nursing		**Associate Investigators:**	
Key Words: Spouse Abuse Abatement			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To provide an indepth description of couples' counseling process from the perspective of the couples in the program.

Technical Approach: Retrospective qualitative study.

Progress: This study has been completed. Defended on 9 Dec 92 for the completion of graduate course work.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol** 93-15	**Status** Ongoing	
Title: Satisfaction with Patient Controlled Analgesia			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Mary Hardy, MAJ, AN		**Facility:** Eisenhower Army Medical Center	
Department/Service: Nursing		**Associate Investigators:** Barbara Miller, CPT, AN Michael E. Streeter, CPT, AN	
Key Words: Analgesia patient controlled analgesia			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine patient satisfaction with postoperative pain control using the patient controlled analgesia (PCA) infuser, to identify the frequency of PCA use, and to identify problems associated with PCA use.

Technical Approach:

Number of subjects enrolled for reporting period: 40

Progress: Data have been collected on 40 inpatients receiving patient controlled analgesia and progressing as anticipated. Cursory analysis of data only completed to this point. It is expected to reach 100 subjects by Dec 93, and will stop at that time if greater than 50 is reached.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	25 Oct 93	**Protocol #:**	93-5	**Status:**	Closed
Title:	The Effect of Uncomplicated Labor and Delivery on Serum Levels of Creatine Kinase				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Thomas E. Page, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: OB-GYN		**Associate Investigators:** Joseph C. White, MAJ, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Study Objective: To determine the effects of uncomplicated labor and delivery on serum values of CK and its isoenzymes.

Technical Approach:

Number of subjects enrolled for reporting period: 30

Progress: Study closed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	25 Oct 93	**Protocol #:**	93-50	**Status:**	Ongoing
Title:	Application of Ophthalmoscopic Examination Fluorescein Angiography in Early Diagnosis of Candida Endophthalmitis in Rabbits				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): F. Ridgely Benton, Jr., LTC, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Pathology			**Associate Investigators:** John F. Fisher, MD, Staff Infectious Disease, Medical College of Georgia David Craft, MAJ, MS Steve Tobias, MAJ, VC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To assess the diagnostic efficacy of fluorescein labelled anti-Candida antibody to recognize infection by this organism at a clinically earlier stage than is now possible. It will look for early retinal lesions by using the tagged antibodies. This rabbit model has been used before and should be well suited for this type of study.

Technical Approach:

Number of animals used for reporting period: none

Progress: Study has not been implemented.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 92-23	**Status:** Completed	
Title: Determinants in the development of insight for substance dependence in rehabilitation facility inpatients			
Start Date: Feb 92		**Est. Compl. Date:** Jan 93	
Principal Investigator(s): James Spinelli, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Psychiatry & Neurology		**Associate Investigators:** Robert Ness, PhD Daniel Hendricks, PhD	
Key Words: Insight, Substance abuse, Substance dependence			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Jan 93 Completed	

Study Objective: To discern specific aspects of an Inpatient Rehabilitation Facility which are most closely associated with the development of patient insight into acceptance of the disease of substance dependence or abuse.

Technical Approach: Using a questionnaire, anonymously survey a number of substance abuse patients gauging their insight before and after enrolling in the RTF. Then, comparing that data with their feelings about specific aspects of the RTF, measure statistical significance to see if certain aspects of RTF are more closely associated with insight formation than others.

Subjects enrolled to date: 92

Progress: All data collection has been completed as well as calculations and tabulations with the assistance of Mr. Henry Davis and Dr. Bob Hess at MCG. LTC Spinelli is in the process of preparing both written and oral reports for future publications.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	92-43	**Status:**	Ongoing
Title:	The first break psychosis study				
Start Date:	Sep 92		**Est. Compl. Date:**	May 95	
Principal Investigator(s): Elaine Correnti, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry & Neurology			**Associate Investigators:** Richard Borison, MD Manuel Casanova, MD Laura Davidson, PhD Bruce Diamond, MD Sahebarao P. Mohadik, MD Sukdeb Mukherjee, MD Thomas Ralston, LTC, MC Russell Scheffer, CPT, MC Neal Trent, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To determine whether specific biological abnormalities previously found in chronic schizophrenic patients are present at the beginning of the illness and, if so, to examine their relations to clinical characteristics of the illness; and to examine whether selected clinical, historical, and biological measures are predictive of short-term clinical outcome in patients experiencing their first episode of psychosis.

Technical Approach: Patients will undergo comprehensive psychiatric, neuropsychological, and neurological examinations at baseline, and blood samples will be taken for determination of RBC activities of specific enzymes and measurement of tritiated imipramine binding in platelets. A skin biopsy will be performed to develop fibroblast cell lines in culture and examine whether fibroblasts from patients show the abnormalities of growth and morphology noted in studies of chronic schizophrenic patients.

Subjects enrolled to date: 15 as of 16 Sep 93

Progress: Two presentations at the American Psychiatric Association's Annual Meeting: (1) Neurological Signs at the Onset of Psychosis, (2) Fibroblast Studies in First Break Psychosis. Paper submitted to Biological Psychiatry: Plasma Membrane Phospholipid and Cholesterol Distribution of

Skin Fibroblasts from Drug-Naive Patients at the Onset of Psychosis. Presentation at the Society of Biological Psychiatry Annual Meeting.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	92-59	**Status:**	Completed
Title:	Monitoring of mood states in substance dependent subjects in inpatient rehabilitation facility				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Patrick W. Clapper, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry & Neurology			**Associate Investigators:** Daniel Hendricks, PhD		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To determine whether the variation of mood states for the rehab patient follows a predictable general trend and whether this study's findings replicate other studies generally (although other studies have not examined mood variation on a weekly basis). To determine what, if any, difference there is in the general trend of mood states in patients with ETOH dependence alone as compared to patients with mixed substance dependence.

Technical Approach: Administer assessment - POMS each week for six weeks of treatment.

Number of subjects enrolled to date:

Progress: Project completed. Cpt Clapper is writing up results presented at Grand Rounds of Psychiatry.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-13	**Status:**	Ongoing
Title:	Dexamethasone Augmentation in the Treatment of Major Depression				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Kerry Cleary, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry & Neurology			**Associate Investigators:** Russell Scheffer, CPT, MC Michael Sokol, MAJ, MC Joseph Sutcliffe, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: This is a double-blind, placebo controlled study to test the hypothesis of devreased latency of response to traditional antidepressant medication with a one time dose of Dexamethasone as adjunct on initiation of pharmacotherapy Double Blind Placebo Control.

Technical Approach:

Number of subjects enrolled for reporting period: 4 patients recruited; one disenrolled from study secondary to probably reaction to Prozac.

Progress: Recruitment of patients has been slow. Other possible candidates have been screened but have failed to meet inclusion criteria or have met an exclusion criteria (usually initiation of antidepressant medication has already taken place). Since changing the protocol to include outpatients, the number of patients screened has increased and we hope to continue with this trend. With the exception of the modification to include outpatients, there has been no indication to modify the initial protocol. Given the technical approach of our study, none of the raw data has yet been analyzed in order to insure the double blind and maintain investigator objectivity.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-18	**Status:**	Completed
Title:	Determination of Effects of Birth Order (First born vs Second Born) on Death Anxiety in a Military Outpatient and Non-Psychiatric Population				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Jeanette Oleskowicz, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Psychiatry & Neurology		***Associate Investigators:*** Neil Trent, MAJ, MS			
Key Words:					
***Accumulative* MEDCASE Cost:**		**Periodic Review Results:**			

Study Objective: As stated above.

Technical Approach: Self-completed questionnaires.

Number of subjects enrolled for reporting period:

Progress: Investigation completed. Questionnaires (birth order, state-trait and death anxiety) were randomly administered to 71 first born and 68 second born active duty soldiers of Charlie and Delta Companies at Fort Gordon. Full consent was obtained. A total of 33 questionnaires (17 first born and 16 second born) were not included in statistical analysis due in incomplete responses. Thus, 54 first born and 52 second born questionnaires were examined statistically to determine the effects of birth order on death anxiety. Results yielded no statistically significant findings that would indicate death anxiety was higher among first vs second borns. An incidental finding was that in this particular population, religious preference appeared to be an influencing factor. Those indicating they were of the Baptist denomination evidenced statistically significant higher death anxiety scores ($p < 0.05$) than those of the Catholic denomination.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-27	**Status:**	Completed
Title:	Evaluation of Smoking Rates After Cessation of Alcohol or Illicit Drug Use				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Timothy R. Jennings, MD, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Psychiatry/RTF		**Associate Investigators:**			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Study Objective: To document the change in smoking rate, if any, which occurs after the cessation of alcohol or illicit drug use.

Technical Approach: Self report questionnaire to be completed by inpatients on admission, 4th, and sixth week of treatment.

Number of subjects enrolled to date: 42

Progress: Data collection has been completed and statistical analysis of data is in progress.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-37	**Status:**	Ongoing
Title:	The Relationship of Menstrual Phase to Presentation of Acute Psychiatric Treatment				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Miguel Oquendo, MD, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Psychiatry			**Associate Investigators:** John F. Mackey, MD, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Objective: To evaluate the effect of menstrual cycle on the presentation of a patient for acute psychiatric evaluation.

Technical Approach: Subjects will be interviewed to include a review of systems, history of menstrual cycle. Epidemiologic data will then be evaluated to determine the characteristics of the patients considered.

Number of subjects enrolled for the reporting period: 60

Progress: In order to expand the study sample size, coordination with other MEDDACs in our area has been made with the purpose of enrolling these facilities in the data collection process. A total of 300 data collecting sheets were distributed among the Department of Psychiatry at Moncrief Army Hospital, Fort Jackson, Fort Benning; and Winn Army Hospital, Fort Stewart. A preliminary review of the data so far collected has been completed. All data is expected to be collected by January 1994. An abstract of this study has been submitted to the American Society of Psychosomatic Obstetrics and Gynecology for research awards and symposium as part of the Society 22nd Annual Meeting scheduled for 23-27 February 1994.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-47	**Status:**	Ongoing
Title:	A Double-Blind, Placebo Controlled Exploratory Study of Sertraline in Adolescent Outpatients with Nondelusional Major Depressive Disorder.				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Walter J. Duffy, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Psychiatry		**Associate Investigators:** Lawrence M. Correnti, MAJ(P), MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Objective: To compare the efficacy of sertraline HC1 (SER) in major depressive disorder without psychotic features with placebo in a double blind fashion using a population of thirty 12 to 18 year old adolescent outpatients.

Technical Approach: Various structured interviews and instruments will be used to insure that DSM-III-R criteria are met. A washout period will precede randomization.

Number of subjects enrolled for the reporting period:

Progress: No patients have been enrolled in the study yet as physicians are in the process of training themselves and associates in the use of the intake assessment instrument.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 90-1	**Status:** Ongoing	
Title: Technitium 99m antimony trisulfide colloid for investigation of lymphatic drainage			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Stephen G. Oswald, LTC, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Radiology/Nuclear Medicine		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Jan 93 Continue	

Study Objective: To provide a radiopharmaceutical whereby lymphatic drainage may be characterized.

Technical Approach: Intradermal injection of radiolabeled colloidal particles with serial gamma camera images to evaluate lymphatic drainage.

Number of subjects enrolled to date: 3

Progress: No additional patients enrolled. Radiopharmaceutical temporarily unavailable due to change in manufacturer. Protocol should remain open.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 90-36	**Status:** Ongoing
Title:	Treatment of internal contamination by plutonium and other transuranic elements with two investigational new drugs (Ca-DTPA and Zn-DTPA)	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert J. Kaminski, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Radiology/Nuclear Medicine		**Associate Investigators:** Stephen G. Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Study Objective: The principal objective of this protocol is to obtain approval from the IRC to use Ca-DTPA and Zn-DTPA for the treatment of patients at Eisenhower Army Medical Center who are internally contaminated with plutonium or other transuranic elements.

This is not an investigational study, approval allows us to store the drugs in this facility.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-13	**Status:** Ongoing
Title:	Scintigraphy of tumors of neuroectodermal origin with 131-iodine-meta-iodobenzylguanibine sulfate (131-I-MIBG)	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Stephen G. Oswald, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Radiology/Nuclear Medicine		**Associate Investigators:** Robert J. Kaminski, LTC, MC James H. Corley, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Jan 93 Continue

Study Objective: To provide a mechanism whereby this agent is available for use in diagnostic studies in patients undergoing evaluation of pheochromocytoma or staging of neuroblastoma.

Technical Approach: Intravenous injection of a radiopharmaceutical (MIBG) with subsequent *gamma camera imaging.*

Number of subjects enrolled: 3

Progress: One additional patient enrolled during past year. No adverse side effects or reactions noted. Study ongoing.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-39	**Status:** Ongoing
Title:	Adrenal imaging with 131-iodine-6-beta-iodomethyl-norcholesterol (NP-59)	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Stephen G. Oswald, LTC, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Radiology/Nuclear Medicine		**Associate Investigators:** Robert J. Kaminski, LTC, MC Daryl S. Moyer, CPT, MS
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Study Objective: To provide a mechanism whereby NP-59 is available for correlative adrenal imaging for patients with biochemically established ACTH-independent Cushing's syndrome, primary aldosteronism, or androgen excess states as well as characterization of the functional status of euadrenal masses.

Technical Approach: Intravenous injection of a radiopharmaceutical (NP-59) with subsequent gamma camera imaging.

Progress: No patients enrolled. Study ongoing.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	25 Oct 93	**Protocol #:**	85-5	**Status:**	Ongoing
Title:	Advanced Trauma Life Support Course				
Start Date:	Jan 85		**Est. Compl. Date:**		
Principal Investigator(s): Paul Lepage, MAJ(P), MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Clinical Investigation			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Sep 93 Continue		

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

Technical Approach:

a. Design: The advanced trauma life support course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

b. Manpower: Requirements as follows: Course Director (1 MC)
Course Administrator (MS)
Instructors (6 MC)
Logistical support (2 EM)
Moulage patients (4 EM)

c. Funding: Administrative cost derived from Office of Medical Education.

Progress: Successful ATLS Course was given in 1992 with 32 physicians trained. A course is scheduled for early 1994.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	25 Oct 93	**Protocol #:**	88-5	**Status:**	Completed
Title:	Investigation of cryotreatment on the epiphysis of growing rabbit bones				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Roberto H. Barja, COL, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopedics			**Associate Investigators:**		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 93 Completed		

Study Objective: 1) To evaluate cryotherapy times on the epiphysis of 6 week old rabbits (right femur); 2) to examine both grossly and microscopically, the effects of cryotherapy on bone growth epiphyseal closure.

Technical Approach: A cryoprobe after surgical cut-down is applied to epiphyses in the distal right femur of 6 week old rabbits. Four weeks post-cryotreatment the rabbits are euthanized, then a surgical cut-down is performed to remove the right and left femur. The pathologist then determines the gross effect on growth plates and any deformities present on the right vs the left femur. Microscopic specimens of the cryotreated epiphyses are examined to evaluate remaining potential for growth, microvascular structures, and uniformity of cryological effects.

Progress: Ten rabbits underwent percutaneous epiphysiodesis by the cryoprobe. The growth plate was successfuly interrupted with promising results and data analysis is in progress.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 88-6	**Status:** Terminated
Title:	Distal thigh pain and stress transfer in uncemented total hip arthroplasties. A scintigraphic analysis	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Scott R. Duffin, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery/Orthopedics		**Associate Investigators:** Orthopedic Residents Joseph M Erpelding, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Study Objective: To determine if anterior thigh pain in uncemented total hip arthroplasties is caused by distal stress transfer through the femur prosthesis.

Technical Approach: Routine bone scans will be done at various time intervals following cemented and uncemented total hip arthroplasties. The bone scan is an accepted method of evaluating hip prostheses, having demonstrated both prospectively and retrospectively excellent sensitivity and good specificity in detecting and defining abnormalities such as loosening, fracture, and infection.

Number of subjects enrolled to date: 77
Number of subjects enrolled for reporting period: 0

Progress: Phase I completed: comparison of cemented vs uncemented PCA hips.
Phase II will compare above to uncemented cluster/E series hips.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 90-25	**Status:** Terminated	
Title:	A prospective randomized study of the prophylaxis of thromboembolism dihydroergotamine/heparin *versus* sodium warfarin in total joint patients		
Start Date: Jun 90		**Est. Compl. Date:**	
Principal Investigator(s): David A. Volgas, CPT, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Surgery/Orthopedics		**Associate Investigators:** Melissa McMillan, MAJ, MC Robert Scharstein, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To compare two regimens commonly used for thromboembolism prophylaxis in the total joint patient.

Number of subjects enrolled to date: 25
Number of subjects enrolled for reporting period: 0

Progress: Study terminated.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	25 Oct 93	**Protocol #:**	90-32	**Status:**	Ongoing
Title:	Training general surgery residents utilizing goat and pig models				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Paul A. LePage, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: *Surgery/Clinical Investigation*		**Associate Investigators:**			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** *Sep 93 Continue*			

Study Objective: To allow the practicing and refinement of surgical approaches and techniques on animal models prior to performing the same procedure in the human.

Progress: Two major Southeast regional courses were conducted to successfully train in new laparoscopic hernia and colorectal surgery to 38 students and weekly training to residents and staff. Also, nursing anesthesia students were trained on field Army anesthesia machines during these sessions. Operating room nurses were trained on laproscopic techniques and a multidisciplined laboratory training session for gynecologists and general surgeons in gastro/enterology laparascopy.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	91-59	**Status:**	Ongoing
Title:	Use of the rat model for teaching and practicing microvascular surgical technique				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Brian K. Barnard, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/Orthopedics			**Associate Investigators:** Orthopedic Residents		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Nov 93 continue		

Study Objective: To utilize the rat model for the practice and teaching of microvascular surgical techniques.

Technical Approach: Training procedures include end-to-end, end-to-side, and side-to-side anastomosis of the femoral artery and vein, as well as, interpositional vein grafting.

Progress: Six residents have undergone training.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	91-81	**Status:**	Ongoing
Title:	Evaluation of the current routine post op feeding regimens				
Start Date:			**Est. Compl. Date:**	Dec 93	
Principal Investigator(s): M. Brian Harkins, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** Robert G. Martindale, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Jan 93 Continue		

Study Objective: *To determine if patients* are able to tolerate a regular diet rather than clear liquids as their first P.O. intake following intraabdominal surgery.

Technical Approach: Randomized patients to alternate diets.

Number of subjects enrolled to date: approximately 125-150

Progress: Study ongoing, data collection continuing.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	91-82	**Status:**	Completed
Title:	The effect of non-ionic surfactants on GI mucosal integrity and bacterial translocation from the gut (mice)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert G. Martindale, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** James McPherson III, PhD David Turgeon, PhD, MAJ, MS		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 93 Completed		

Study Objective: To evaluate the potential protective effects of non-ionic surfactants on GI mucosa.

Technical Approach:

Progress: Dose responses have been completed, it appears surfactants have minimal effect, if any, on preventing translocation of bacteria. Had had problems establishing adequate dose of endotoxin to use.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 92-3	**Status:** Terminate	
Title: *Free dermal fat grafts in expanded tissue recipient pockets in the pig*			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Richard A. Beck, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Surgery/Otolaryngology-HNS		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93 Terminate	

Study Objective: To determine if free dermal fat grafts have improved survival and predictable rates of resorption after implantation in expanded tissue pockets in the pig model. Also, to determine the histologic characteristics of the capsule which forms around expanded/nonexpanded silicone prostheses, and the free dermal fat grafts at specified intervals following transplantation.

Technical Approach:

Progress: Investigator PCS'd, no progress, terminate.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	92-4	**Status:**	Ongoing
Title:	The effect of pentoxifyline vs allopurinol on sigmoid mucosal ischemia during abdominal aortic surgery				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): William C. Calton, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** Robert G. Martindale, MAJ, MC Manuel F. Ramirez, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Jan 93 Continue			

Study Objective: This study will make considerable use of a new noninvasive technique to measure the adequacy of tissue oxygenation called tonometry.

Technical Approach: Tonometry relies upon the fact that CO2 is freely permeable between the lumen, luminal fluid and superficial layer of the mucosa. By measuring CO2 in the luminal fluid and simultaneously measuring arterial blood gases, mucosal pH can be calculated using the Henderson-Hasselbalch equation. The validity and safety of this technique has now been substantiated in several studies.

Progress: Project on hold due to lack of technical assistance and equipment limitations. Protocol will continue when research nurse is available.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	92-12	**Status:**	Terminated
Title:	Implications of Urinary Phosphate Level After Thyroid or Parathyroid Surgery				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s):			**Facility:**		
William J. Kaiser, CPT, MC			Eisenhower Army Medical Center		
Department/Service:			**Associate Investigators:**		
Surgery/General Surgery			Robert G. Martindale, MAJ, MC Michael P. Byrne, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To prospectively follow serum Ca2+ and urinary PO4 in patients undergoing thyroid/parathyroid surgery; and to evaluate if it has any predictive effect.

Technical Approach:

Subjects enrolled for the reporting period: 16

Progress: Retrieval of data greater than two years old; paper to be presented to Army Surgical Symposium 1995.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	92-13	**Status:**	Ongoing
Title:	The effect of IV pentoxifylline on endotoxin mediated small bowel mucosal ischemia using the pig model				
Start Date:		**Est. Compl. Date:**	Dec 93		
Principal Investigator(s): William C. Calton, Jr., CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/General Surgery		**Associate Investigators:** Robert G. Martindale, MAJ, MC Michael P. Byrne, LTC, MC David Turgeon, PhD, MAJ, MS			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Study Objective: To determine if pentoxifylline can attenuate the splanchnic vasoconstriction seen with endotoxin.

Technical Approach:

Progress: The effect of Pentoxifylline is to be worked out in the rat model. Once this work has been completed, work on the pig model will be resumed with the expected date of Jan/Feb 94.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	92-21	**Status:**	Terminate
Title:	A comparison of rigidity of combat external fixators				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Scott R. Duffin, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/Orthopedics		**Associate Investigators:** Joseph Erpelding, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Study Objective: To determine which field external fixator has the most rigid combination of bars and connections; and, which system overall provides the greatest rigidity when applied in its most biomechanically sound configuration.

Technical Approach: The rigidity would be evaluated in an axial load, AP bending load, lateral bending load and torsional load.

Subjects enrolled to date: None

Progress: Study terminated.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	92-26	**Status:**	Ongoing
Title:	The effects of somatostatin analog (octreotide acetate) on wound healing in *the mouse model*				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert G. Martindale, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/General Surgery			**Associate Investigators:** Donald E. Sutherland, PhD, MAJ, MS William Calton, Jr, CPT, MC Sam Miller, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 93		

Study Objective: To determine if the somatostatin analog affects wound healing.

Technical Approach:

Progress: Techniques for PTFE implantation have been perfected. Study is near completion and researching additional information related to wound healing.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	92-27	**Status:**	Ongoing
Title:	Natural history of free gallstones within the peritoneum in a rabbit model and mouse model				
Start Date:			**Est. Compl. Date:**	Dec 93	
Principal Investigator(s): Ray Workman, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/General Surgery			**Associate Investigators:** Michael Byrne, LTC, MC Robert G. Martindale, MAJ, MC Thomas R. Gadacz, M.D.		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Oct 93		

Study Objective: To determine the physiologic response to free gallstones within the peritoneum in the rabbit and mouse models.

Technical Approach:

Progress: Initial surgery has been completed and waiting for specific times to gather data on acute inflammatory changes associated with spillage of gallstones using histologic, microbiologic, and immunologic procedures.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	6 Oct 92	**Protocol #:**	92-52	**Status:**	Ongoing
Title:	Laparoscopic appendectomy vs standard appendectomy				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Thomas Taylor, CPT, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery/General Surgery			**Associate Investigators:** Victor L. Modesto, MAJ, MC Paul A. LePage, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Aug 93 Continuue		

Study Objective: To compare hospital stay, amount of post-operative pain medications, amount of post-operative complications such as wound infection and abscess formation, and the percentage of false positives to that of open appendectomy. We also wish to become proficient in the art of laparoscopic appendectomy.

Technical Approach: Open appendectomy will be performed in the standard fashion utilizing a Rockey Davis incision. An extension of this incision may be utilized as deemed necessary by the senior surgeon performing the case. All open appendectomies will undergo irrigation of the pelvis in the reverse trendelenburg position.

Subjects enrolled to date: 17

Progress: We continue to gather subjects for our study. So far we have only 17. We need several more to better evaluate the difference. No problems encountered.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-1	**Status:** Terminated	
Title:	Early Detection of Hearing Loss Due to Ototoxic Agents by High Frequency Auditory Evaluation		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Vernon D. Larson, PhD, VA		**Facility:** Eisenhower Army Medical Center	
Department/Service: Audiology		**Associate Investigators:** Carl Loovis, LTC, MS Stephen A. Fausti, PhD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine whether the proposed experimental method of monitoring hearing detects drug related hearing loss earlier than the current clinical procedure.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress:None owing to personnel shortages

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-4	**Status:**	Ongoing
Title:	The Effect of Early Enteral Feeding on Patients Undergoing Abdominal Aortic Surgery				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): William C. Calton, Jr., CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		**Associate Investigators:** Robert G. Martindale, MAJ, MC Donald E. Sutherland, MAJ, MS			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Study Objective: To evaluate the effect of early enteral feeding on outcome, nutritional parameters and wound healing in patients undergoing abdominal aortic surgery.

Technical Approach:

Number of subjects enrolled for reporting period: 10

Progress: Still accumulating data on vascular patients (aortic cases). Principlal Investigator has departed but protocol will continue under supervision of C, Vascular Surgery.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-16	**Status:**	Completed
Title:	Stomate Valve Redesign Efficacy Study				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert G. Martindale, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** William C. Calton, CPT, MC Patricia Challenger, RN		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To compare the insertion performance of the slit dome Stomate and the flapper valve Stomate in an adult population, to compare potential complications associated with the flapper valve Stomate and the slit dome Stomate and to compare potential complications associated with the Stomate right angel extension tubing and Y-port connector utilized with the Stomate, and to compare the removal performance of the slit dome Stomate and flapper valve Stomate.

Technical Approach:

Number of subjects enrolled for reporting period: 16

Progress: Study has been completed. Sixteen patients were enrolled and 13 completed study. Findings revealed that new valve design decreases leaks and "stomate" breakdown.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-17	**Status:**	Terminated
Title:	Gastrostomy Tube Balloon Comparison Study				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert G. Martindale, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Surgery			**Associate Investigators:** William C. Calton, CPT, MC Patricia Challenger, RN		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To determine gastrostomy tube balloon life up to two months, to identify the incidence of mechanical complications associated with tube failure, and to compare the efficacy of balloons that are cured by two different methods.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: This study was terminated as it was never started.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-35	**Status:**	Ongoing
Title:	Effects of Somatostatin Analog (Octreotide Acetate) on Wound Healing in Bowel and Gastric Anastomosis in the Rat Model				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Samuel K. Miller, MD, CPT, MC		**Facility:** *Eisenhower Army Medical Center*			
Department/Service: Surgery		**Associate Investigators:** Robert G. Martindale, MD, MAJ, MC William Calton Jr, MD, CPT, MC Donald Sutherland, MAJ, MS			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Oct 93 Continue			

Objective: To determine the effects of somatostatin analog (Octreotide acetate) on bowel and gastric anastomosis.

Technical Approach:

Progress: Two sets of rats (35 in first; 40 in second) show trend but no significant progress as of yet.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

ate:	29 Oct 93	**Protocol #:**	93-36	**Status:**	Terminate
Title:	Efficacy of a New Blunt Tip Trocar				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Paul A. LePage, MD, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery		***Associate Investigators:*** Victor L. Modesto, MD, MAJ, MC Robert G. Martindale, MD, MAJ, MC Sidney R. Steinberg, MD, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Objective: To test the efficacy of a new trocar and cannula for open laparoscopy.

Number of subjects enrolled for reporting period: None.

Progress: Device approved by FDA and is now available on the market. Trocar no longer being evaluated. Terminate per investigator instructions.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:**	93-38	**Status:**	Ongoing
Title:	Biomechanical Analysis: Multiple Lag Screw vs Plate Fixation of the Distal Fibula				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Paul J. Cutting, MD, CPT, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Surgery/Orthopedics		**Associate Investigators:** Jeffrey M. Oettinger, MD, CPT, MC Francis K. Moll, MD, CPT, MC Joseph M. Erpelding, MD, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Objective: To analyze rotational strengths of multiple lag screw vs plate fixation.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: Specimens have been harvested and experimental fractures fixated. Awaiting completion of jig for Instron to measure torsional resistance to failure. Literature review complete.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-40	**Status:** Terminated
Title:	The Predictors of Long-Term Outcome in Elderly Patients with Colles' Fractures	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): David A. Volgas, MD, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery/Orthopedics		**Associate Investigators:** Brian Barnard, MD, MAJ, MC Ron Christopher
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Objective: To determine if the same risk factors which are associated with a poor outcome in young patients are applicable to older patients who may place less demand upon their wrists.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: Study terminated.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93 **Protocol #:** 93-42 **Status:** Ongoing	
Title: Mechanical Peritoneal Retraction Laparoscopic Surgery	
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Paul A. LePage, MD, MAJ, MC	**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery	**Associate Investigators:** Sidney R. Steinberg, MD, COL, MC David E. Rivera, MD, LTC, MC Manuel F. Ramirez, MD, LTC, MC General Surgery Service Kevin C. Kelley, MD, LTC, MC OB-GYN Service Medical Monitor: Richard C. Traugott, MD, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:**

Objective: To demonstrate whetgher the Laparolift System provides equivalent or better exposure than conventional pneumoperitoneum.

Technical Approach:

Number of subjects enrolled for reporting period: None

Progress: Progress is help waiting for MEDCASE approval for purchase of laprolift device

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-61	**Status:** Ongoing
Title:	The Effect of Vitamin A on the Steroid Induced Defect in Wound Healing: A Time Course Study in Mice	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Patricia S. Greatorex, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery		**Associate Investigators:** Robert G. Martindale, M.D., Ph.D. Peter M. Barcia, COL, MC Donald Sutherland, MAJ, MS Steven Tobias, MAJ, DVM
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Objective: To evaluate the potential beneficial effect of Vitamin A in reversing the detrimental effect steroids have on wound healing, examine in chronological sequence the inhibitory effect of corticosteroids on wound healing with and without the addition of Vitamin A, and create a time response curve that will demonstrate when steroids have their peak inhibitory effect and what role Vitamin A has in this time sequence.

Technical Approach:

Number of animals used for reporting period: None

Progress:Protocol was approved at the end of the fiscal year: will be started soon

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-63	**Status:** Ongoing
Title:	The Adverse Effects of Octreotide on Wound Healing in Rats Study in Mice	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Brad E. Waddell, CPT(P), MC		**Facility:** Eisenhower Army Medical Center
Department/Service: *Surgery*		**Associate Investigators:** Robert G. Martindale, M.D., Ph.D. Cheuk Y. Hong, CPT, MC Steven Tobias, MAJ, VC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Objective: To determine the nature and extent of octreotide's adverse effects on wound healing.

Technical Approach:

Number of animals used for reporting period: none

Progress:

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-65	**Status:** Ongoing
Title:	The Use of 1% Lidocaine With/Without Epinephrine in Breast Biopsy	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Samuel Miller, CPT, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Surgery		**Associate Investigators:** Darrem Chapman, CPT, MC Scott Needham, CPT, MC Paul A. Lepage, MAJ, VC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Objective: To determine complication rates in breast biopsies as influenced by the use of local anesthetic.

Technical Approach:

Number of subjects enrolled for reporting period:

Progress: Protocol was approved just prior to this reprting date

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-27	**Status:** Ongoing	
Title:	SWOG 8809 - A phase III study of alpha-interferon consolidation following chemotherapy with Promace-MOPP (Day 1-8) in patients with low grade malignant lymphomas		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** continue	

Study Objective: To compare the disease-free survival of patients with low grade malignant lymphoma who receive alpha interferon consolidation therapy after intensive induction with chemotherapy-radiation therapy, to those who receive induction therapy alone. To determine the complete response rate, response duration and survival of low grade lymphoma patients treated with ProMACE-MCPP (day 1-8). To compare the toxicities of induction and induction plus consolidation therapy in this patient population.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: One patient on therapy. No problems encountered during this period.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-29	**Status:** Ongoing
Title:	SWOG 8854 (ECOG 1189, NCCTG 898051) Prognostic value of cytometry measurements of breast cancer DNA from postmenopausal patients with involved nodes and receptor positive tumors: A comparison protocol to SWOG 8814	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Karen Bowen, MAJ, MC Robert D. Ranlett, LTC, MC Arthur Wozniak, LTC, MS Don Shaffer, MAJ, MC Charles T. Thornsvard, LTC, MC Stephen Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue

Study Objective: To determine if ploidy analysis of breast cancer by routine clinical flow cytometry (FCM) technique can predict response to therapy and survival of patients registered to SWOG 8814. To determine if ploidy analysis by image processing technique more accurately predicts patient response to therapy and survival than ploidy analysis by FCM.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled for reporting period: One patient enrolled.

Progress: None to date.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-30	**Status:** Ongoing
Title:	SWOG 8814 (ECOG-4188, NCCTG-883051) Phase III Comparison of adjuvant chemoendocrine therapy with CAF and concurrent or delayed tamoxifen to tamoxifen alone in postmenopausal patients with involved axillary nodes and positive receptors	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Robert D. Ranlett, LTC, MC Arthur Wozniak, LTC, MS Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Stephen Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue

Study Objective: To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen and/or progesterone receptors treated with standard adjuvant therapy with long-term tamoxifen, or with chemoendocrine therapy with CAF, followed by long-term tamoxifen, or with concurrent chemoendocrine therapy with tamoxifen and CAF. To compare the relative toxicity of the three therapies.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: Two patients enrolled.

Progress: None to date.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-31	**Status:** Ongoing
Title:	SWOG 8897 (EST-2188, CALGB-8897, INT0102) Phase III Comparison of adjuvant chemotherapy with or without endocrine therapy in high-risk, node negative breast cancer patients, and a natural history follow-up study in low-risk, node negative patients	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Karen Bowen, MAJ, MC Robert D. Ranlett, LTC, MS Arthur Wozniak, LTC, MS Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Stephen Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue

Study Objective: To compare disease-free survival (DFS) and overall survival (S) of high risk primary breast cancer patients with negative axillary lymph nodes treated with standard adjuvant chemotherapy with CMF for six cycles or with chemotherapy using CAF for six cycles. To assess the value of the addition of tamoxifen for five years compared to no tamoxifen in these patients. To compare the relative toxicity of the therapies. To assess the prognostic significance of DNA flow cytometry in patients with small, occult invasive breast cancer treated by local therapy only. To evaluate the DFS and S of low risk invasive breast cancer determined by receptor status, tumor size and S phase treated by local therapy only.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 6 patients enrolled.

Progress: One patient taken off study. No patient contact since June 1992. One patient has developed deep left thalomic lesion. Metastic disease plan: Neuro sterotactic Biopsy. No other problems encountered with the other patients.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-34	**Status:** Ongoing
Title:	SWOG 8931 (EST-3189, INT-0108) Phase III Comparison of Cyclophosphamide, Doxorubicin, and 5-Fluorouracil (CAF) and a 16-Week *Multi-Drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor* Negative, Node Positive Breast Cancer	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki,MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Karen Bowen, MAJ, MC Paulino O. Vasallo, COL, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC *Stephen Oswald, LTC, MC*
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue

Objective: To compare disease-free and overall survival in node positive receptor negative breast cancer patients receiving adjuvant CAF or a 16-week multi-drug chemotherapy regimen. To *compare toxicities of adjuvant CAF and a 16-week multi-drug regimen.*

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: Two patients enrolled.

Progress: Two patient on therapy. No problems encountered.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-35	**Status:** Ongoing
Title:	SWOG 8947 Central lymphoma serum repository protocol. (Companion study to SWOG 8516, 8736, 8809 or 8816)	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Rodney G. Day, LTC, MS Stephen Oswald, MAJ, MC Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Charles T. Thornsvard, COL, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue

Study Objective: To establish a central lymphoma serum repository that will serve as a resource to provide specimens for current and future scientific studies. To utilize the SWOG database to perform clinicopathologic correlations with the results of those studies.

Technical Approach: Blood sample will be drawn and shipped to the Serum Repository Laboratory for testing.

Number of subjects enrolled for reporting period: 2

Progress: Two patients on therapy. No problems encountered.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-36	**Status:** Terminated	
Title:	*SWOG 9037 Prediction of recurrence and survival in node negative breast cancer patients using a panel of prognostic factors*		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** *Eisenhower Army Medical Center*	
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Karen Bowen, MAJ, MC Robert D. Ranlett, LTC, MC Arthur Wozniak, LTC, MS Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue	

Study Objective: To measure histologic and nuclear grade, estrogen and progesterone receptors, HER-2 oncogene, cathepsin D, EGF receptor, PS2, hsp27, 70 and 90, in paraffin-embedded histopathological specimens from lymph node-negative breast cancer patients. To correlate the above factors with biological and clinical features including recurrence and survival in patients entered on SWOG 8897.

Technical Approach: Paraffin-embedded histopathological specimens will be submitted to a San Antonio laboratory for measurements.

Number of subjects enrolled for reporting period: 0

Progress: Study closed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	20 Oct 93	**Protocol #:**	91-41	**Status:**	Ongoing
Title:	SWOG 8736 Treatment of localized non-Hodgkin's lymphoma: Comparison of chemotherapy (CHOP) to chemotherapy plus radiation therapy				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Charles T. Thronsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue			

Study Objective: The primary study objective is to evaluate, in a cooperative group setting, the difference in survival, time to treatment failure and toxicity of two curative approaches to the treatment of patients with localized, intermediate or high grade, non-Hodgkin's lymphoma. The first treatment approach is chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) for eight cycles. The second uses CHOP for three cycles followed by involved field radiation therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: 1

Progress: One patient on therapy.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-42	**Status:** Completed
Title:	SWOG 9040 Intergroup rectal adjuvant protocol, A Phase III study	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology		***Associate Investigators:*** Paulino O. Vasallo, COL, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue

Study Objective: To determine the relative efficacy of 5-FU, 5-FU and leucovorin, 5-FU and levamisole, and 5-FU, leucovorin and levamisole when combined with pelvic radiation therapy in the treatment of Stages B-2 and C (TNM Stage II and III) rectal cancer. End points used will include local recurrence rates, probability of distant metastases, disease free survival rates, and overall survival. 5-FU with radiation therapy will comprise the control arm of the study. This will be a 4-armed study with the same radiation therapy program in all arms, but with varying drug regimens.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for the reporting period: 0

Progress: Study closed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	20 Oct 93	**Protocol #:**	91-50	**Status:**	Ongoing
Title:	SWOG 8851 Phase III comparison of combination chemotherapy (CAF) and chemohormonal therapy (CAF + Zoladex or CAF + Zoladex + Tamoxifen) in premenopausal women with axillary node-positive, receptor-positive breast cancer -- intergroup				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Robert D. Ranlett, LTC, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Stephen Oswald, LTC, MC Karen Bowen, MAJ, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue			

Study Objective: To compare the recurrence rates, disease-free intervals (DFI), and hormone-receptor-positive survival for premenopausal women with axillary lymph node-positive breast cancer given adjuvant therapy with chemotherapy (CAF) alone or chemotherapy (CAF) followed by Zoladex (Z) or chemotherapy (CAF) followed by Zoladex plus Tamoxifen (X + T). We will compare CAF with CAF + Z and CAF + Z with CAF + Z + T. To compare the relative toxicities of these 3 regimens. To assess the effect of CAF, CAF + Z, and CAF + Z + T on hormone levels (LH, FSH, and estradiol) in premenopausal women treated with these adjuvant therapies.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: Patient completed regiment. Taken off study. Patient is active duty and has since relocated to another area.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-53	**Status:** Ongoing
Title:	SWOG 8952 Treatment of advanced Hodgkin's disease - A randomized Phase III study comparing ABVD vs MOPP/ABV hybrid	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Jayanti K. Sen, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Continue

Study Objective: To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, disease-free survival, failure-free survival and both immediate and long-term toxicities. To compare the rate of drug delivery of the anti-neoplastic agents, especially the comparative dose rate of ABV in the two treatment groups. To examine the prognostic importance of time to response, performance status, age, presence of bulky disease, C-reactive protein, erythrocyte sedimentation rate, and prior radiotherapy on survival.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: One

Progress: No problems encountered.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 91-55	**Status:** Ongoing
Title:	SWOG 9013 A prospective randomized comparison of combined modality therapy for squamous carcinoma of the esophagus: Chemotherapy plus surgery alone for patients with local regional disease. Phase III intergroup	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Paulino O. Vasallo, COL, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Mar 93 Continue

Study Objective: To compare, using a prospective controlled randomized study design, the outcomes of therapy of surgery alone, versus pre- and post-operative chemotherapy and surgery for patients with local regional esophageal cancer. Outcome is defined as survival and relapse pattern. To assess the toxicities of a multimodality approach to esophageal carcinoma involving systemic chemotherapy and surgery. The toxicities of surgical resection, as initial therapy or following chemotherapy will be assessed as operative morbidity and mortality. To compare the local and distinct control rates with the two approaches and to define the pattern of failure. To compare the impact on overall and disease free survival of multimodality therapy with surgery alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: 1

Progress: One patient on therapy died February 1992

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 20 Oct 93	***Protocol #:*** 91-67	**Status:** Closed	
Title:	SWOG 9012 Evaluation of low dose alpha-interferon in patients with advanced renal cell carcinoma		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Stephen Oswald, LTC, MC Karen Bowen, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: The objectives of this Phase II study of low dose alpha-interferon in patients with advanced renal cell carcinoma, Stage II-IV, are to: 1) evaluate the likelihood of response in order to assess whether low dose alpha-interferon should be advanced to further studies and, 2) evaluate the qualitative and quantitative toxicities.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 0

Progress: Study Closed

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	20 Oct 93	Protocol #:	91-68	Status:	Ongoing

[redacted]

development of P-glycoprotein expression. To evaluate the relationship between the magnitude of cytoreduction and survival. To evaluate the significance of pretreatment serum lactic dehydrogenase (LDH) as a marker for aggressive myeloma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 0

Progress: None.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	91-69	**Status:**	Ongoing
Title:	SWOG 9111 (EST-1690) Post-operative adjuvant interferon alpha-2 in resected high risk primary and regionally metastatic melanoma, intergroup				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, MAJ, MC Stephen Oswald, LTC, MC Karen Bowen, MAJ, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue			

Study Objective: To establish the efficacy of 1 year at maximally tolerable dosages (IV and SC) interferon alpha-2 as an adjuvant to increase the disease free interval and overall survival in patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence. To evaluate the efficacy and tolerance of long-term interferon alpha-2 at 3 MU/d (Sc TIW) as an adjuvant to increase the disease-free survival and overall survival of patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence with melanoma, in comparison to 1 year of treatment of maximally tolerable dosages.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: 0

Progress: None.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	91-70	**Status:**	Ongoing
Title:	SWOG 9125 A Phase II trial of CVAD/Verapamil/Quinine for treatment of non-Hodgkin's lymphoma				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Continue		

Study Objective: To evaluate the effectiveness of the CVAD chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and dexamethasone) when administered in combination with chemosensitizers (verapamil and quinine) which are intended to block the emergence of multidrug resistance in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. The effectiveness of CVAD plus verapamil and quinine will be based on the estimate of the complete response rate and the time to treatment failure. To assess the toxicities and side effects associated with the CVAD regimen when combined with verapamil and quinine. A secondary objective is to further investigate the utility of the proliferative rate (determined by Ki-67 monoclonal antibody), the importance of cell-cell recognition molecules (using a panel of monoclonal antibodies specific for several cell recognition antigens), the role of host response (using markers of tumor infiltrating T-cells in B-cell lymphomas) and the value of detectable levels of P-glycoprotein as prognostic indicators of outcome (see companions study SWOG 8819). A secondary objective is to further utilize the central serum repository enabling clinicopathologic correlations with the results of studies on the material collected (see companion study SWOG 8947).

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled: 0
Progress: None.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-6	**Status:**	Ongoing
Title:	SWOG 9008 Trial of adjuvant chemoirradiation after gastric reaction for adenocarcinoma, Phase III				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Paulino O. Vasallo, LTC, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, MAJ, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue			

Study Objective: 1) A comparison of overall and disease free survival between patients being treated with surgical resection only and those being treated with surgery plus adjuvant therapy. 2) A comparison of incidence and patterns of disease failure between surgery and surgery plus adjuvant therapy treated patients. 3) An assessment of patient tolerance of upper abdominal chemoradiation after gastric resection.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-7	**Status:**	Ongoing
Title:	SWOG 9108 (CALGB-9011, NCIC-CTGCL.1) A Phase III comparison of fludarabine phosphate vs chlorambucil vs (fludarabine) phosphate plus chlorambucil in previously untreated B-cell chronic lymphocytic leukemia				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Jayanti K. Sen, COL, MC Don Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue			

Study Objective: 1) To compare in previously untreated CLL patients the response rates and progression free survival with the following three therapeutic regimens: i) fludarabine phosphate, ii) chlorambucil and iii) fludarabine phosphate + chlorambucil. 2) To determine whether the quality of life (need for transfusions, incidence of infections, and performance status) is superior using any of the three regimens. 3) To determine whether these two drugs (fludarabine phosphate and chlorambucil) are non-cross-resistant by a crossover design for patients failing to respond to the single agent to which they are initially randomized.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 1

Progress: No problems encountered.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-37	**Status:**	Ongoing
Title:	SWOG 9007 Cytogenic studies in leukemia patients, ancillary				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Charles T. Thornsvard, MAJ, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue			

Study Objective: To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment. To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients. To provide quality control for all Southwest Oncology Group cytogenetic data.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled to date: Two

Progress: No problems encountered.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-38	**Status:**	Ongoing
Title:	SWOG 9031 A Double-blind placebo controlled trial of daunomycin and cytosine arabinoside with or without rhG-CSF in elderly patients with acute myeloid leukemia, Phase III				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Charles T. Thornsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Continue		

Study Objective: To compare the complete response rates and durations of survival in patients aged 65 or older with acute myeloid leukemia (AML) when treated with standard doses of cytosine arabinoside (Ara-C) and daunorubicin (DNR), with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). To assess the frequency and severity of toxicities of the two treatment regimens. To compare the duration of neutropenia and thrombocytopenia; the total number of febrile days; the number of days of antibiotic therapy; the number and type of infection episodes; and the number of hospital days in patients treated with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). To correlate biological parameters including cell surface immunophenotype, ploidy and cytogenetics with clinical response.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Subjects enrolled to date: 0

Progress: None.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-39	**Status:**	Ongoing
Title:	SWOG 9139 Adjuvant therapy of primary osteogenic sarcoma, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Charles T. Thornsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Continue		

Study Objective: To estimate the time to treatment failure and survival rate of the three drug combination adriamycin, cisplatin, and ifosfamide as adjunctive treatment of osteosarcoma of the extremity. To evaluate histopathologic tumor necrosis following preoperative adriamycin, cisplatin, and ifosfamide. To assess the feasibility of determining histopathologic tumor necrosis in a cooperative e group setting. To assess the influence of clinical prognostic variables on disease outcome. To assess the toxicity of this regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-40	**Status:**	Terminated
Title:	SWOG 9151 Evaluation of topotecan in hepatoma				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Charles T. Thornsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To evaluate the response rate of topotecan. To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: Study closed - has met it's accural.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	11 Feb 93	**Protocol #:**	92-48	**Status:**	Completed
Title:	SWOG 9054 Ancillary bone mineral density study in premenopausal women on EST 5188 (Intergroup 0101)				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Charles T. Thornsvard, COL, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Don Shaffer, MAJ, MC Jayanti K. Sen, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC Charles T. Thornsvard, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Closed		

Study Objective: To determine whether tamoxifen (10 mg BID) protects against loss of bone mineral density in the lumbar spine and in the femur in premenopausal women with breast cancer following their being made postmenopausal by cytotoxic and ovarian function-suppressing hormonal therapy. To determine the effects Zoladex therapy has on bone mineral density in the lumbar spine and femur in premenopausal women with breast cancer following treatment with 6 cycles of cytotoxic chemotherapy. To determine the rates, pattern of rates and pattern of bone loss in the lumbar spine and femur occurring in premenopausal women treated with a standard course of 6 cycles of cytoxic chemotherapy. To investigate the serum marker of bone mineral metabolism, serum osteocalcin, in a population of women undergoing significant changes in their bone density.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: Study closed, has met it's accural.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-49	**Status:**	Ongoing
Title:	SWOG 9019 A Phase III, Randomized prospective comparison between chemotherapy plus radiotherapy and the same chemotherapy plus radiotherapy together with surgery for selected Stage IIIA (positive mediastinal nodes) and selected Stage IIIB (no malignant effusion) non-small cell lung cancer				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Robert D. Ranlett, LTC, MC Charles T. Thornsvard, COL, MC Stephen Oswald, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue			

Study Objective: To assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, overall, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa (Ne-positive) and selected IIIb non-small cell lung cancer. To evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: Two

Progress: One of the patients enrolled has completed therapy and no problems encountered. No problems experenced from the other patient enrolled.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-50	**Status:**	Ongoing
Title:	SWOG 9035 Randomized trial of adjuvant immunotherapy with an allogenic melanoma vaccine for patients with intermediate thickness node negative malignant melanoma (T 3NOMO)				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Don Shaffer, MAJ, MC, Paulino D. Vasallo, COL, MC Charles T. Thornsvard, COL MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue			

Study Objective: To compare disease-free survival and overall survival between patients with T3NOMO malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patients with T3NOMO malignant melanoma.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: None.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	14 Oct 93	**Protocol #:**	92-51	**Status:**	Terminated
Title:	SWOG 9116 Evaluation of piroxantrone in disseminated malignant melanoma, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Don W. Shaffer, MAJ, MC Paulino D. Vasallo, COL, MC Charles T. Thornsvard, COL, MC Stephen Oswald, LTC, MC Karen Bowen, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Continue		

Study Objective: To evaluate the response rate of disseminated malignant melanoma treated with piroxantrone. To assess the qualitative and quantitative toxicities of piroxantrone administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Subjects enrolled to date: 0

Progress: Study closed - has met its accural.

HSHF-PAT-
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	20 Oct 93	**Protocol #:**	92-62	**Status:**	Terminated
Title:	SWOG 9062 - Evaluation of 96 hour infusion 5-FU + cisplatin + alpha interferon in patients with recurrent/metastatic squamous cell carcinoma of head and neck, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Charles T. Thornsvard, COL, MC Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Jayanti K. Sen, COL, MC Stephen Oswald, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:**		

Study Objective: To evaluate the complete response rate i order to assess whether this regimen should be advanced to further studies. To evaluate the qualitative and quantitative toxicities associated with this regimen. To assess the feasibility of this regimen.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during reporting period: 0

Progress: Study closed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 20 Oct 93	**Protocol #:** 92-63	**Status:** Terminate	
Title: SWOG 9134 - A Phase II, trial of taxol and granulocyte-colony stimulating factor (G-CSF) in patients with advanced soft-tissue sarcoma			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Charles T. Thornsvard, MC Robert Krywicki, MAJ, MC Jayanti K. Sen, COL, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To evaluate the clinical rate of taxol administered with G-CSF in advanced soft tissue sarcomas. To define the qualitative and quantitative toxicities of taxol administered with G-CSF in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled during reporting period: 0

Progress: Study closed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	20 Oct 93	**Protocol #:**	92-64	**Status:**	Terminated
Title:	SWOG 9135 - A Phase II trial of taxol and granulocyte-colony stimulating factor (G-CSF) in patients with pancreatic adenocarcinoma				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ,MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology, Pathology			**Associate Investigators:** Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Jayanti K. Sen, COL, MC Charles T. Thornsvard, COL, MC Stephen Oswald, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Hold		

Study Objective: To evaluate the clinical response rate of taxol administered with G-CSF in pancreatic adenocarcinoma. To define the qualitative and quantitative toxicities of taxol administered with G-CSF in this patient population.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled to date: 0

Progress: Study closed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	20 Oct 93	**Protocol #:**	92-65	**Status:**	Terminated
Title:	SWOG 9147 - Evaluation of tamoxifen in desmoid tumors, Phase II				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology, Pathology		**Associate Investigators:** Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Jayanti K. Sen, COL, MC Stephen Oswald, LTC, MC Charles T. Thornsvard, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:**			

Study Objective: To assess the response rate of fibromatosis to treatment with tamoxifen. To assess the clonality in "informative" female patients (i.e., females heterozygous for the genetic locus) utilizing a molecular probe for an X-linked enzyme.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: 0

Progress: Study closed.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	8 Oct 93	**Protocol #:**	92-68	**Status:**	Ongoing
Title:	SWOG 8955 - Treatment of Stage D, Hormone Refractory Carcinoma of the Prostate with 5-Fluorouracil and Roferon-A, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Jayanti K. Sen, MD, COL, MC Karen Bowen, MAJ, MC Don Shaffer, MAJ, MC Stephen Oswald, LTC, MC Charles T. Thornsvard, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Continue		

Study Objective: To evaluate the likelihood of response of hormone refractory, metastatic carcinoma of the prostate treated with F-FU and Roferon-A in order to assess whether this regimen should be advanced to further studies. To assess the qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled to date: None

Progress: None to date.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	8 Oct 93	**Protocol #:**	92-69	**Status:**	Ongoing
Title:	SWOG 9059 - Phase III Comparison of Standard Radiotherapy *versus* Radiotherapy Plus Simultaneous Cisplatin, *versus* Split-Course Radiotherapy Plus Simultaneous Cisplatin and 5-Fluorouricil, in Patients with Unresectable Squamous Cell Carcinoma of the Head and Neck				
Start Date:		**Est. Compl. Date:**			
Principal Investigator(s): Robert F. Krywicki, MC		**Facility:** Eisenhower Army Medical Center			
Department/Service: Medicine/Oncology		**Associate Investigators:** Jayanti K. Sen, MD, COL, MC Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC Charles T. Thornsvard, COL, MC			
Key Words:					
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue			

Study Objective: To compare the effectiveness of standard radiation therapy alone to radiation therapy and simultaneous chemotherapy with cisplatin to split-course radiation therapy with cisplatin and 5-fluorouracil infusion in patients with unresectable Stage III and IV squamous cell carcinoma of the head and neck. Endpoints will include complete response rate, time to treatment failure, and overall survival. To compare the relative toxicities of these three treatment arms in this patient population. To compare patterns of relapse or treatment failure among these regimens. To further assess the role, timing, and success of surgery in patients achieving a response to non-operative therapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	8 Oct 93	**Protocol #:**	92-70	**Status:**	Ongoing
Title:	SWOG 9129, Phase III Randomized Study of All-Trans Retinoic Acid *versus* Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients with Previously Untreated Acute Promyelocytic Leukemia				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Jayanti K. Sen, MD, COL, MC Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC Charles T. Thornsvard, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Continue		

Study Objective: To compare the complete remission rate and disease-free survival of TRA to that achieved with conventional induction chemotherapy including Cytosine Arabinoside plus Daunorubicin in Patients with previously untreated APL. To compare the toxicities of TRA to those of Cytosine Arabinoside plus Daunorubicin as induction therapy in APL. To determine the value of maintenance therapy with TRA.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: One

Progress: One patient enrolled. Patient died due to advanced disease.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date:	8 Oct 93	**Protocol #:**	92-71	**Status:**	Ongoing
Title:	SWOG 9150 - Evaluation of Topotecan in Gastric Cancer, Phase II				
Start Date:			**Est. Compl. Date:**		
Principal Investigator(s): Robert F. Krywicki, MAJ, MC			**Facility:** Eisenhower Army Medical Center		
Department/Service: Medicine/Oncology			**Associate Investigators:** Jayanti K. Sen, MD, COL, MC Don Shaffer, MAJ, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC Charles T. Thoransvard, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:			**Periodic Review Results:** Feb 93 Hold		

Study Objective: To evaluate the response rate of gastric carcinoma treated with topotecan. To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled to date: None.

Progress: None

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-7	**Status:** Ongoing
Title:	SWOG 9104 - Evaluation of Doxorubicin/Vinblastine Combined with Inhibitors (Trifluoperazine/Verapamil) of P-Glycoprotein in Patients with Advanced Renal Cell Carcinoma, Phase II	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Jayanti K. Sen, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue

Study Objective:

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled for reporting period: None

Progress:None to date.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-8	**Status:** Ongoing
Title:	SWOG 9133 - Randomized Trial of Subtotal Nodal Irradiation versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Jayanti K. Sen, COL, MC Stephen Oswald, LTC, MC Karen Bowen, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		***Periodic Review Results:*** Feb 93 Continue

Study Objective: To compare athe ability of two treatment regimens (radiation therapy alone or radiation plus chemotherapy), one of which will be chosen to treat the cancer. This study will also determine whether these treatments have any effect on the patients disease free survival, and whether the effects of tretment are different for different people based on age, gender, type of disease and number of disease sites.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: None

Progress: None at this time.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-9	**Status:** Ongoing
Title:	SWOG 9148 - A Phase II Study of Cisplatin Preceded by a 12-Hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (ARA-C) for Patients with Untreated Extensive Stage Small Cell and Non-Small Cell Lung Carcinoma	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Karen Bowen, MAJ, MC Don W. Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Jayanti Sen, COL, MC Stephen Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue

Study Objective: To determine if the chemotherapy agents cisplatin, cytosine arabinoside (ARA-C) and Hydroxyurea when used together may be more effective in lung cancer patients than when used alone.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled for reporting period: None

Progress: None at this time.

HSHF-PAT
SUBJECT: Annual Publications Report - November 1993

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-10	**Status:** Ongoing	
Title: SWOG 9215 - Quality of Life on Breast Cancer Adjuvant Trial			
Start Date:		***Est. Compl. Date:***	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, MAJ, MC Charles T. Thornsvard, COL,MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue	

Study Objective:

Technical Approach:

Number of subjects enrolled for reporting period:

Progress:

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-19	**Status:** Ongoing
Title: SWOG 9003 - Fludarabine for Waldenstrom's Macroglobulinemia (WM): A Phase II Pilot Study for Untreated and Previously Treated Patients		
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology	**Associate Investigators:** Don W. Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Jayanti K. Sen, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:** Feb 93 Continue	

Study Objective: The objective of this study is to find out how well patients respond and how well patients respond and how long their response lasts when treated with Fludarabine. Fludarabine is now being evaluated to determine its benefits and effectiveness on Waldenstrom's Macroglobulinemia. We want to learn more aobut this disease and how long it can be observed without chemotherapy.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: None

Progress: None at this time.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-20	**Status:** Ongoing
Title:	SWOG 9015 - A Randomized Trial of Pre- and PostOperative Chemotherapy Compared to Surgery Alone for Patients with *Operable Non-Small Cell Carcinoma of the Lung, Phase III*	
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F .Krywicki, MAJ, MC		**Facility:** Eisenhower Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Jayanti K. Sen, COL, MC Stephen Oswald, LTC, MC Karen Bowen, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:** Feb 93 Continue

Study Objective: To compare how well patients respond and how long the response lasts when treated with a combination of VP-16 and carboplatin before and after surgery or surgery alone, and to estimate the side effects of these drugs and how often they occur.

Technical Approach: Therapy will follow schema outlined in SWOG protocol

Number of subjects enrolled for reporting period: None.

Progress: None at this time.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-21	**Status:** Ongoing
Title: SWOG 9201 - Phase III, Trial to Preserve the Larynx: Induction Chemotherapy and Radiation Therapy versus Radiation Therapy		
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology	**Associate Investigators:** Don W. Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Jayanti K. Sen, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:** Feb 93 Continue	

Study Objective: To preserve the larynx by using non-surgical treatments. Three treatments will be compared: (1) chemotherapy followed by radiation, or (2) chemotherapy given at the same time, or (3) radiation alone.

Technical approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled for reporting period: None

Progress:None at this time.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-22	**Status:** Ongoing
Title: SWOG 9205 - Central Prostate Cancer Serum Repository Protocol		
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology	**Associate Investigators:** Don W. Shaffer, MAJ, MC Charles T. Thornsvard, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:** Feb 93 Continue	

Study Objective: To serve as a repository for serum of patients with prostate cancer entered onto Southwest Oncology Group approved studies. The purpose of this activity is to provide the opportunity for study of new or existing markers or other tests in a prospective or retrospective fashion in order to test their usefulness as diagnostic or management tools in prostate cancer at all stages.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled for reporting period: None

Progress: None at this time.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-28	**Status:** Ongoing
Title: SWOG 9158 - Evaluation of Trans Retinoic Acid and Alpha Interferon in Patients with Squamous Cell Carcinoma of the Lung (Stage IV)		
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology	**Associate Investigators:** Don W. Shaffer, MD, MAJ, MC Charles T. Thornsvard, COL, MC Jayanti K. Sen, MD, MAJ, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:**	

Study Objective:To assess the response rate to trans-Retinoic Acid and Alpha Interferon used in a daily schedule for patients with advanced, well differentiated squamous cell carcinoma of the lung. To further define the qualitative and quantitative toxicities of this regimen administered to this patient population in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-29	**Status:** Ongoing
Title: SWOG 9216 - A Randomized Phase III Study of CODE Plus Thoracic Irradiation *versus* Alternating CAV and EP for Extensive Stage Small Cell Lung Cancer		
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, MD, MAJ, MC Charles T. Thornsvard, COL, MC Jayanti K. Sen, MD, COL, MC Karen Bowen, MAJ, MC Stephen Oswald, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Study Objective: To determine whether the CODE regimen plus thoracic irradiation is superior to standard alternating CAV and EP in the treatment of extensive stage small cell lung cancer in terms of: overall survival, time to disease progression, response rate, response duration, and quality of life.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None at this time.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:**	93-43	**Status:** Ongoing
Title:	SWOG 9126 - A Controlled Trial of Cyclosporine as a Chemotherapy-Resistance Modifier in High Risk Acute Myeloid Leukemia, Phase III		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, M.D., MAJ, MC Charles T. Thornsvard, MAJ, MC Stephen G. Oswald, M.D., LTC, MC Jayanti K. Sen, M.D., COL, MC Karen Bowen, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To compare the complete remission rate and duration of survival in patients with high-risk acute myeloid leukemia (AML), when treated with either chemotherapy (ara-C/Daunomycin) alone, or chemotherapy plus the resistance modifier cyclosporine-A (CyA): To estimate the frequency of p-glycoprotein expression and the correlation with prognosis in patients with relapsed AML, primary refractory AML, and secondary AML; to compare the frequency and severity of toxicity of the two treatment regimens; and to investigate the relationship between response to treatment and the blood levels of cyclosporine-A and daunorubicin achieved.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-44	**Status:** Ongoing
Title: SWOG 9237 - Evaluation of Topotecan in Refractory and Relapsing Multiple Myeloma, Phase II		
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, M.D., MAJ, MC Charles T. Thornsvard, COL, MC Stephen G. Oswald, M.D., LTC, MC Jayanti K. Sen, M.D., COL, MC Karen Bowen, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Study Objective: To evaluate the response rate for refractory myeloma treated with topotecan; the qualitative and quantitative toxicities of topotecan administered in a Phase II study; and measure topoisomerase levels in multiple myeloma cells.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress:None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-45	**Status:** Ongoing
Title: SWOG 9240 - A Phase II Trial of CVAD for Treatment of Non-Hodgkin's Lymphoma		
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology	**Associate Investigators:** Don W. Shaffer, M.D., MAJ, MC Charles T. Thornsvard, COL, MC, MC Stephen G. Oswald, M.D., LTC, MC Karen Bowen, MAJ, MC Jayanti K. Sen, M.D., COL, MC	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:**	

Study Objective: To evaluate the effectiveness of the CVAD chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and dexamethasone) in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. The effectiveness of CVAD will be based on the estimate of the complete response rate and the time to treatment failure.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:**	93-46	**Status:** Ongoing
Title:	SWOG 9246 - A Phase II Evaluation of Taxol in Patients with Relapsed Non-Hodgkin's Lymphoma or Relapsed Hodgkin's Disease		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, M.D., MAJ, MC Charles T. Thornsvard, COL, MC Stephen G. Oswald, M.D., LTC, MC Jayanti K. Sen, M.D., COL, MC Karen Bowen, MAJ, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To assess the response rate of relapsed low grade non-Hodgkin's lymphoma, relapsed intermediate or high grade non-Hodgkin's lymphoma and relapsed Hodgkin's disease treated with taxol and to assess the qualitative and quantitative toxicities of taxol administered in a Phase II study.

Technical Approach: Therapy will follow schema outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-53	**Status:** Ongoing
Title: SWOG 9221 - Phase III Double-Blind Randomized Trial of 13-Cis Retinoic Acid (13-cRA) to Prevent Second Primary Tumors (SPTs) in Stage I Non-Small Cell Lung Cancer		
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, M.D., MAJ, MC Charles T. Thornsvard, COL, MC Stephen G. Oswald, M.D., LTC, MC Jayanti K. Sen, M.D., COL, MC Karen Bowen, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Study Objective: To compare daily oral administration of 13-Cis Retinoic Acid against placebo in preventing new primary lung tumors from patients having had surgical treatment of a Stage I non-small cell lung tumor.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-54	**Status:** Ongoing
Title: SWOG 9157 - Trial of All Trans-Retinoic Acid in Hepatoma, Phase II		
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, M.D., MAJ, MC Charles T. Thornsvard, COL, MC Stephen G. Oswald, M.D., LTC, MC Jayanti K. Sen, M.D., COL, MC Karen Bowen, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Study Objective: To compare thrice daily oral administration of all trans-retinoic acid or placebo on three week cycles for hepatoma, a malignancy for which no good treatment exists. Evidence of efficacy will lead to a wider clinical study.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress:None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-55	**Status:** Ongoing
Title: SWOG 9210 - A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD-P to VAD-P/Quinine for Induction; (2) Randomization of Prednisone Dose Intensity for Remission Maintenance		
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC	**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology	**Associate Investigators:** Don W. Shaffer, M.D., MAJ, MC Charles T. Thornsvard, COL, MC Stephen G. Oswald, M.D., LTC, MC Jayanti K. Sen, M.D., COL, MC Karen Bowen, MAJ, MC	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:**	

Study Objective: To compare the effectiveness of the VAD-P chemotherapy regimen when administered alone or in combination with the chemosensitizer quinine. It will evaluate the chemosensitizing potential of quinine to reverse drug resistance.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-56	**Status:** Ongoing	
Title: SWOG 9248 - A Phase II Trial of Paclitaxel (Taxol) in Patients with Metastatic Refractory Carcinoma of the Breast			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center	
Department/Service: Medicine/Oncology		**Associate Investigators:** Don W. Shaffer, M.D., MAJ, MC Charles T. Thornsvard, COL, MC Stephen G. Oswald, M.D., LTC, MC Jayanti K. Sen, M.D., COL, MC Karen Bowen, MAJ,MC, MD	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To evaluate the subjective improvement in patients with symptomatic refractory carcinoma of the female breast treated with paclitaxel. Information obtained from patients in studies like this one can, in the future, help a doctor and a patient make treatment decisions.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled to date: None

Progress: None to date.

DETAIL SUMMARY SHEET

Date: 29 Oct 93	**Protocol #:** 93-56	**Status:** Ongoing
Title: SWOG 9248 - A Phase II Trial of Paclitaxel (Taxol) in Patients with Metastatic Refractory Carcinoma of the Breast		
Start Date:		**Est. Compl. Date:**
Principal Investigator(s): Robert F. Krywicki, MAJ, MC		**Facility:** Eisenhower Army Medical Center
Department/Service: Medicine/Oncology		**Associate Investigators:** Charles T. Thornsvard, M.D., COL, MC Karen Bowen, M.D., MAJ, MC Stephen G. Oswald, M.D., LTC, MC Jayanti K. Sen, M.D., COL, MC Don Shaffer, MAJ, MC, MD
Key Words:		
Accumulative MEDCASE Cost:		**Periodic Review Results:**

Study Objective: To evaluate the subjective improvement in patients with symptomatic refractory carcinoma of the female breast treated with paclitaxel. Information obtained from patients in studies like this one can, in the future, help a doctor and a patient make treatment decisions.

Technical Approach: As outlined in SWOG protocol.

Number of subjects enrolled to date: Two

Progress: No problems encountered.

DETAIL SUMMARY SHEET

Date: 6 Oct 92	**Protocol #:** 78-14	**Status:** Ongoing	
Title: Intraocular Lens Study			
Start Date: Oct 81		**Est. Compl. Date:**	
Principal Investigator(s): Emil A. Stein, CPT, MC		**Facility:** USA MEDDAC, Ft Campbell, KY	
Department/Service: Surgery/Ophthalmology		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Extracapsular cataract extraction followed by the implantation of an intraocular lens implant.

Subjects enrolled to date: 333
Subjects enrolled for the reporting period: 96

Progress: Continued excellent surgical and visual results without significant complications.

DETAIL SUMMARY SHEET

Date: 6 Oct 92	**Protocol #:** 78-14A	**Status:** Closed	
Title: Pediatric Intraocular Lens Study			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Emil A. Stein, MAJ, MC		**Facility:** USA MEDDAC, Ft Campbell, KY	
Department/Service: Surgery/Ophthalmology		**Associate Investigators:**	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To provide pediatric patients with the latest development in ophthalmic surgery for the treatment of surgical aphakia.

Technical Approach Extracapsular cataract extraction followed by implantation of an intraocular lens implant.

Subjects enrolled to date: 2
Subjects enrolled for reporting period: 1

Progress: PI has left the service. Study closed

DETAIL SUMMARY SHEET

Date:	29 Oct 93	**Protocol #:** 92-33	**Status:** Terminated
Title:	Prolotherapy in the treatment of chronic low back pain - A double-blind study		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Michael D. Jacobson, MAJ, MC Mark A. Bonneville, MAJ, MC		**Facility:** USA MEDDAC, Ft Campbell, KY	
Department/Service: Family Practice		**Associate Investigators:** Walter E. Carnahan, CPT, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Objective: To demonstrate the effectiveness of using a proliferant solution for the treatment of chronic, mechanical low back pain.

Technical approach:

Progress: The principal and associate investigators have left the Army and no other information is available.

DETAIL SUMMARY SHEET

Date: 6 Oct 92	**Protocol #:** 92-55	**Status:** Ongoing	
Title: The effects of parental deployment on childhood behavior			
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Marvin C. Arnold, MAJ, MS		**Facility:** USA MEDDAC, Ft Campbell, KY	
Department/Service: Psychiatry		**Associate Investigators:** Stephen N. Xenakis, COL, MC	
Key Words:			
Accumulative MEDCASE Cost:		**Periodic Review Results:**	

Study Objective: To determine those elements that impact on family functioning during deployment of the soldier, particularly on the children. To determine what neuro-psychological, social, and behavioral dysfunction occurred in children of deployed parents before, during and after Operation Desert Storm.

Technical Approach: (1) Experimental design: The study utilizes a stratified multi-cell (five cells) design. The population consists of parents of children in the following categories: single parents, dual career couples, intact/traditional families, parents of disturbed children (seen at Child Psychiatry, Community Mental Health Activity and Social Work Services during deployment), parents of nondisturbed children (seen at regular Family Practice visits). Stratified probability sampling will be employed to select the research sample. Sample size estimation is 200 subjects per cell. Sample size determination was made by selecting a population size (n) that is sufficient for the standard error of estimate not to exceed 0.05.

(2) Manpower: Consists of the Principal Investigator, a 91G Behavioral Science Specialist,a nd five research assistants employed at Blanchfield Army Hospital.

(3) Funding: Obtained from the Department of Military Psychiatry, Walter Reed Army Institute of Research, Washington, DC. Funding required for FY 92 only.

(4) Number of subjects enrolled to date: 1,836

(5) Number of subjects enrolled for reporting period: 336

(6) Nature and extent of significant adverse reactions: No adverse reactions to date. All subjects required to read and sign the Volunteer Agreement Affidavit.

Progress: Data collection is continuing at Blanchfield Army Hospital until 30 Sep 92. As of this date some conclusions have been made regarding the research. No studies have been terminated or completed. There have been no presentations at scientific meetings nor submission of articles for publication related to this research. Two to three publications are in progress.

DETAIL SUMMARY SHEET

Date:	**Protocol #:**	93-33	**Status:** Ongoing
Title:	Vocal Cord Function and Voice Quality Evaluation of Active Duty U.S. Army Drill Instructors		
Start Date:		**Est. Compl. Date:**	
Principal Investigator(s): Jeffrey Paffrath, CPT, MC		**Facility:** USA MEDDAC, Ft Jackson, SC	
Department/Service:		**Associate Investigators:**	
Key Words:			
Accumulative *MEDCASE* Cost:		**Periodic Review Results:**	

Objective:To document the laryngeal pathology and record the acoustic effects of acute voice abuse in active duty US Army drill instructors during periods of intense training.

Technical Approach: Subjects will be chosen for videostroboscopy and acoustic analysis preceding and during the early phases of small unit training.

Number of subjects enrolled for the reporting period:

Progress: This protocol requested funding form the Medical Research and Development Command, Ft. Detrick, MD. CI has been informed that the study will be considered for early Feb 94 funding.

DETAIL SUMMARY SHEET

Date: 8 Jul 93	**Protocol #:** 93-52	**Status:** Ongoing
Title: Pregnancy Exercise Patterns and Post-partum Fitness		
Start Date:	**Est. Compl. Date:**	
Principal Investigator(s): Lori B. Newman, AN	**Facility:** USA MEDDAC, Ft Campbell, KY	
Department/Service:	**Associate Investigators:** Terence J. Caldwell, LTC, AN Bari C, Knobel, MAJ, AN Judith L. Chantelois, MAJ, MC Frank W. Montgomery, III, Asst Prof	
Key Words:		
Accumulative MEDCASE Cost:	**Periodic Review Results:**	

Objective: To describe pregnancy outcome measures in active duty women with various levels of self-directed or organized prenatal exercise.

Technical Approach: Compare the physical fitness test scores of active duty soldiers before and after experiencing pregnancy and childbirth.

Number of subjects enrolled for the reporting period:

Progress: Protocol not yet started. Waiting for funding from hospital's '94 budget.

DETAIL SUMMARY SHEET

Date:	**Protocol #:** 93-60 **Status:** Ongoing
Title:	Clinical Comparability of Two Once-Daily Forms of Diltiazem: Effect of Substitution on Blood-Pressure Control
Start Date:	**Est. Compl. Date:**
Principal Investigator(s): Myron Piziak, LTC, MS	**Facility:** USA MEDDAC, Ft Rucker, AL
Department/Service: Pharmacy Service	**Associate Investigators:** John D. Grabenstein, MAJ, MS Roger P. Potyk, LTC(P) MAJ, MS
Key Words:	
Accumulative MEDCASE Cost:	**Periodic Review Results:**

Objective: To access the comparability of clinical effects of Cardizem CD and Dilacor XR in the treatment of hypertension. directed or organized prenatal exercise.

Technical Approach: The Food and Drug Administration has already found evidence of the safety and efficacy of these two dosage forms for this indication. Investigators will examine available medical records and maintain confidentiality.

Number of subjects enrolled for the reporting period:

Progress: Implementation has just begun.

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