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ANNUAL PROGRESS REPORT

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FY-89



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DEPARTMENT OF CLINICAL INVESTIGATION
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D. C. 20307 - 5001

CLINICAL INVESTIGATION PROGRAM

RCS MED-300 (RI)

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			PI - PRINCIPAL INVESTIGATOR		
			AUC - ANIMAL USE COMMITTEE		
			IRB - INSTITUTIONAL REVIEW BOARD		
19. ABSTRACT (Continue on reverse if necessary and identify by block number) This annual report identifies approved clinical research activities conducted at WRAMC (during FY89) which were approved and reviewed annually by the Human Use Committee/ Institutional Review Board or the Animal Use Committee as appropriate. A Detail Summary for each protocol, a list of publications and presentations are enclosed.					
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FORWARD

This Annual Progress Report (APR) documents the continuing review during FY-89 of research approved by the Clinical Investigation Committee (CIC), the Animal Use Committee (AUC), and the Human Use Committee/Institutional Review Board (HUC/IRB) of Walter Reed Army Medical Center (WRAMC). The review of each research protocol is initiated by the Department of Clinical Investigation (DCI) on the anniversary month of its approval. At that time, a request is sent to the principal investigator for submission of a progress report. This report consists of a detail summary sheet (DSS), an updated consent form, if needed, and a completed questionnaire regarding the continuing review of human subject participation or animal use. Members of the HUC/IRB or AUC review the progress reports throughout the year, and one of the following recommendations is made: (1) approval, (2) request additional information, or (3) request termination of the protocol. The members' recommendations are presented monthly to the HUC/IRB or AUC for final approval.

The FY-89 APR process at WRAMC was administered by the Chief, Army Medical Specialist Corps Clinical Investigation and Research Service, Department of Clinical Investigation, in coordination with the Research Review Service. Due to the ongoing nature of the APR process, an overlap of fiscal years is inevitable in presenting the data. A total of 474 protocols are included in this document.

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I. UNIT SUMMARY

A. OBJECTIVE

To implement and manage the clinical investigation program at Walter Reed Army Medical Center (WRAMC) by promoting, supporting, coordinating, planning, conducting and publishing ethical, scientific inquiry into clinical health problems of beneficiaries of the military health care system, to include studies in humans and animals.

B. TECHNICAL APPROACH

The clinical investigation program at WRAMC is conducted in accordance with the following:

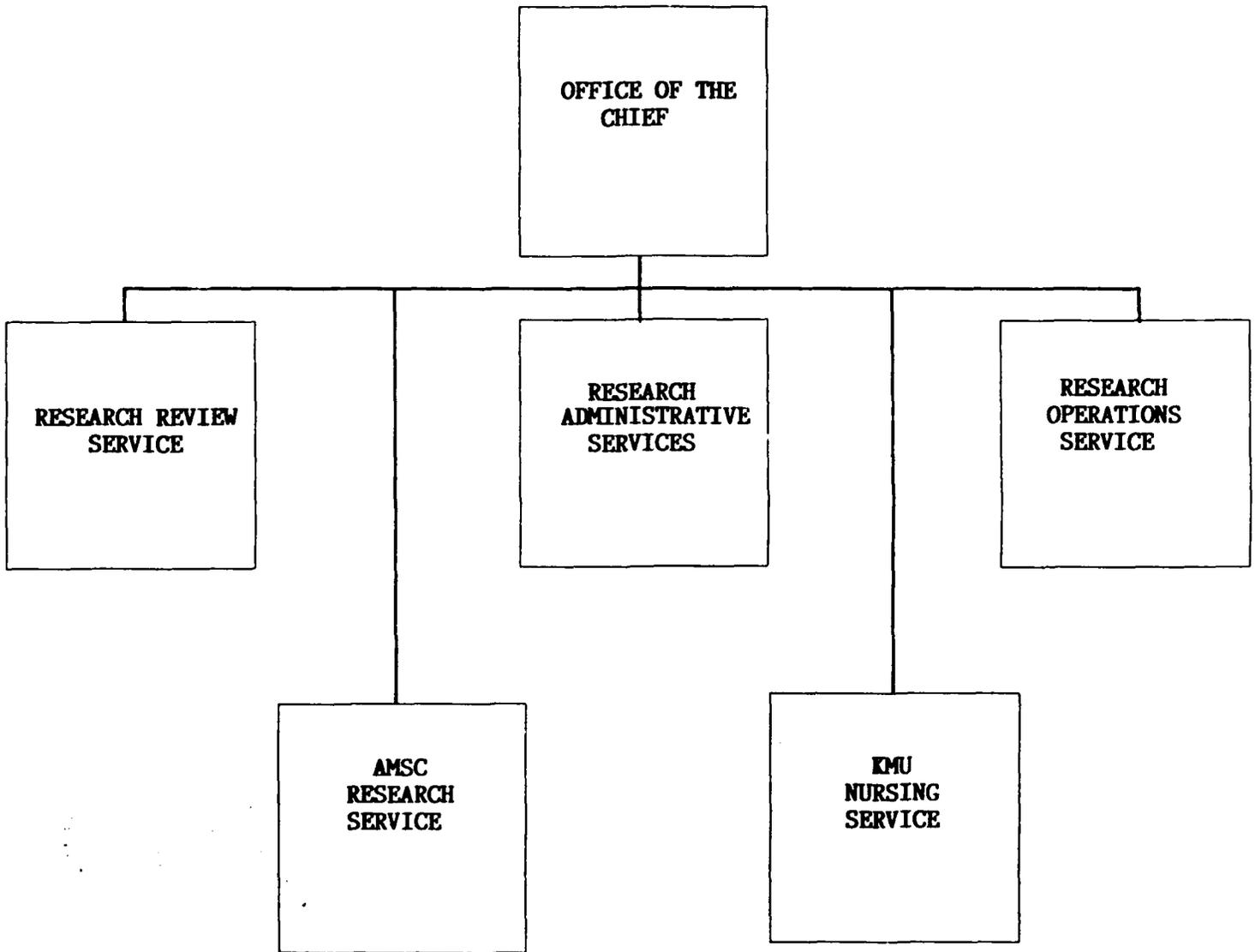
- AR 40-7 Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances
- AR 40-38 Clinical Investigation Program
- AR 70-18 The Use of Animals in DOD Programs
- TB MED 525 Control of Hazards to Health from Ionizing Radiation Used by the Army Medical Department
- HSC 40-23 Management of Clinical Investigation Protocols and Reports
- WRAMC 70-1 Clinical Investigation Program, WRAMC Research Activities
- 45 CFR 46 Protection of Human Subjects
- 21 CFR A,D,& F Food and Drug Administration

STATEMENT "A" per Jan Kinsey
 Dept. of Clinical Investigation/HS HL-CI
 Walter Reed Army Medical Center
 Washington, DC 20307-5001
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C. ORGANIZATION SCHEME



D. DCI STAFF (positions as of 30 September 1989)

DESCRIPTION	GRADE	MOS	BRANCH NAME	ACTIVITY
<u>OFFICE OF THE CHIEF</u>				
Chief	06	61C	MC Wray, HL	DCI
Secretary	07	0318	GS Brock, ME	DCI
<u>RESEARCH REVIEW SERVICE</u>				
Chief	05	60F	MC Derderian, S	DCI
Biostatistician	13	1530	GS Vacant	DCI
Statistician	12	1530	GS Howard, R	DCI
Computer Programmer	11		GS vacant	DCI
Research Coordinator	09	1087	GS Hawkins, EJ	DCI
Editorial Asst	05	1087	GS Green, I	DCI
Computer Room Supv	E4	01H10	SP Gomez, R	DCI
<u>RESEARCH ADMINISTRATIVE SERVICES</u>				
Chief	12	0501	GS Burton, M	DCI
Tech Writer/Editor	09	1086	GS vacant	DCI
Supply Technician	06	2005	GS Thomas, D	DCI
Clerk Typist	05	0303	GS Smith, A	DCI
Med Records Tech	05	0675	GS Morgan, D	DCI
Nurse Specialist	12		GS Abt, MB	Urology
<u>Grant Personnel</u>				
Nurse Specialist	12	0610	GS Myers, D	Dermatology
Clinical Nurse	11	0610	GS Bailey, C	Hem/Onc
Secretary	05		GS Hopkins, S	Hem/Onc

DESCRIPTION	GRADE	MOS	BRANCH	NAME	ACTIVITY
Operations Asst	06		GS	Glover, C	OB-GYN
Bio Lab Tech	06		GS	Dawson, E	Thoracic Surgery
Clerk Med Typ	05	0318	GS	Sandfer, P	Pediatrics
Gen Health Sci	12	0601	GS	Summers, W	AA&SC
Clinical Nurse	11	0610	GS	vacant	Surgical Research

ARMY MEDICAL SPECIALIST CORPS CLINICAL INVESTIGATION AND RESEARCH SERVICE

Chief	05	65B9A	SP	Sweeney, JK	DCI
Secretary	06	0318	GS	Countee, K	DCI

RESEARCH OPERATIONS SERVICE

Chief	05	68F	MS	Lippert, L	DCI
Med Lab NCO	E7	92B40	NC	Sheldon, G	DCI
Bio Lab Tech	11	0404	GS	Kapur, J	DCI

General Support Lab

Chief	03	68C00	MS	Schaudies, RP	DCI
Chemist	11	1320	GS	Abdel Rahim, M	Biochemistry, DCI
Bio Lab NCO	E6	92B30	NC	Walker, M	DCI
Bio Sci Asst	E4	01H10	AMEDD	Caliboso, W	Surg Research, DCI
Med Lab Spec	E4	92B20	NC	Curry, BJ	Cell Biology, DCI

Animal Support Lab Research

Bio Lab Tech	10	0404	GS	Bailey, L	Animal Research, DCI
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DESCRIPTION	GRADE	MOS	BRANCH NAME	ACTIVITY
<u>INFECTIOUS DISEASE RESEARCH LABORATORY</u>				
Microbiologist	12	0403	GS Dcbek, A	DCI
Microbiologist	12	0403	GS Soprey, R	DCI
<u>TRANSPLANT IMMUNOLOGY LABORATORY</u>				
Chief	04	60M9B	MC vacant	DCI
Med Lab NCO	E6	92B30	NC Toro, L	DCI
<u>KYLE METABOLIC RESEARCH LABORATORY</u>				
C, Nutrition Care	03	65C00	SP Coffey, L	DCI
Supv Res Chem	14	1320	GS Carr, F	DCI
Physiologist	12	0413	GS Lukes, Y	DCI
Chemist	12	1320	GS Nicholson, D	DCI
Chemist	11	1320	GS Lahiri, S	DCI
Bio Lab Tech	09	0404	GS Butler, V	DCI
Med Tech	11	0644	GS Barnes, S	DCI
Med Tech	05	0645	GS Martin, J	DCI
Editorial Asst	C7	1087	GS Coleman, E	DCI
Secretary	05	0318	GS Simms, S	DCI
Med Lab NCO	E6	92B30	NC Ansley, R	DCI
Chemist	12	1320	GS Tseng, Y	DCI
Resch Asst	11	0610	GS Solomon, B	DCI

DESCRIPTION	GRADE	MOS	BRANCH	NAME	ACTIVITY
Med Tech	11	0644	GS	Anderson, J	DCI
Med Lab Spec	E4	92B10	NC	Kaseem, L	DCI

LAB SUPPORT UNIT

Research Chemist	12	0644	GS	Salata, K	Allergy/Immun
Chemist	11	1320	GS	Maydonovich, C	GI
Med Tech	11	0644	GS	Armstrong, J	Rheumatology
Med Tech	11	0644	GS	Burgess, D	Pediatrics
Bio Sci NCC	E5	1H20	NC	Andrada, F	Pulmonary
Med Lab Spec	E5	1H20	NC	Cortez, F	Pulmonary
Med Tech	11	0644	GS	Berger, T	Allergy/Immun

KYLE METABOLIC UNIT NURSING SERVICE

Supv Clin Nurse	11	00610	GS	Horton, E	KMU,DCI
Clinical Nurse	11	00610	GS	Bethea, J	KMU,DCI
Clinical Nurse	11	00610	GS	Crull, M	KMU,DCI
Clinical Nurse	10	00610	GS	Flowers, A	KMU,DCI
Clinical Nurse	11	00610	GS	Parchment, V	KMU,DCI
Clinical Nurse	11	00610	GS	Mathis, P	KMU,DCI
Nurse Asst	05	00620	GS	Keeve, M	KMU,DCI
Clinical Nurse	11	00610	GS	Stockton, J	KMU,DCI
Clinical Nurse	10	00610	GS	Brodie-Coley, Y	KMU,DCI
Clinical Nurse	9/11	00610	GS	vacant	KMU,DCI
Clinical Nurse	9/11	00610	GS	vacant	KMU,DCI
Clinical Nurse	9/11	00610	GS	vacant	KMU,DCI

E. DCI FINANCIAL SUPPORT

	<u>FY-86</u>	<u>FY-87</u>	<u>FY-88</u>	<u>FY-89</u>
CIVILIAN PERSONNEL	\$ 935,096	\$ 947,549	\$1,000,206	\$1,000,402
CONSUMABLE SUPPLIES	528,300	652,020	708,411	707,272
CIVILIAN CONTRACTS	123,779	121,579	115,000	88,898
TDY	34,645	23,182	28,401	35,186
CAPITAL EXPENSE EQUIP. PRG	52,633	38,734	32,000	57,860
MEDCASE	429,970	945,657	694,078	557,178
OTHER				
Grants	617,355	532,560	254,102	298,467
MILITARY	335,592	831,253*	432,504	429,718
TOTAL	\$3,057,307	\$4,092,534	\$3,264,702	\$3,174,981

* Includes Benefits

F. RESEARCH ACTIVITY

1. Accomplished in FY-89

With a mission to empower WRAMC researchers from planning to publication, the Department of Clinical Investigation (DCI) supported a record total of 671 active studies this year (Table I). A record 197 of these studies were newly approved. The 474 other studies were ongoing for at least one year and are summarized in this report. Ninety-six percent (96%) of the investigations were conducted by Medical Corps officers at WRAMC, and about 1% were conducted at Army Community Hospitals in the Walter Reed Health Service Region (Table II). Human studies accounted for 93% of the investigations, with 36% involving research therapies including investigational drugs or devices and cooperative oncology group studies (Table III). Animal studies accounted for 5%, and laboratory studies accounted for 2%. Clinical investigation productivity by WRAMC researchers included 73 published abstracts, 22 published articles, and 61 conference presentations (Table IV). Thirty-three (33) Clinical Investigation Recognition Seminars (now in its third year) were presented by WRAMC researchers and provided local dissemination of WRAMC research presented at regional and national conferences.

The DCI was involved in many transitions during this year, both in personnel and in its initiatives to improve by striving to help all researchers from planning to publication (DCI is SHARPP). The Chief, Transplant Immunology Laboratory, the Senior Statistician, and the Supervisor, Laboratory Animal Facility left the department, and only one of these vacancies was filled in FY-89. The Surgical Research Service was established within the Department of Surgery with COL Samuel A. Cucinell as Chief.

TABLE I. WRAMC Protocol Activity

<u>PROTOCOLS</u>	<u>FY-85</u>	<u>FY-86</u>	<u>FY-87</u>	<u>FY-88</u>	<u>FY-89</u>
ONGOING at the beginning of FY	395	383	408	456	474
NEWLY APPROVED (+)	142	159	170	145	197
TOTAL ACTIVE During FY	537	542	578	601	671
COMPLETED (-)	127	123	78	114	118
TERMINATED (-)	27	11	44	13	32
ONGOING at the end of FY	383	408	456	474	521

TABLE II. WRAMC FY-89 Active Investigations by AMEDD Officer Corps

<u>CORPS</u>	<u>GRAD TX PROG</u>	<u>OFFICERS IN TX</u>	<u>ACTIVE STUDIES</u>
	# (%)	# (%)	# (%)
Medical	51 (81)	408 (90)	635 (96)
Nursing	0 (0)	0 (0)	9 (1)
Medical Service	7 (11)	24 (5)	12 (2)
Specialist	2 (3)	13 (3)	3 (<1)
Dental	3 (5)	6 (2)	1 (<1)
Veterinary	0 (0)	0 (0)	2 (<1)
	<u>63 (100)</u>	<u>451 (100)</u>	<u>662 (100)</u>
Army Community Hospitals			9

TABLE III. WRAMC FY-89 Active Investigations by Subject

<u>SUBJECT</u>	<u>ACTIVE STUDIES</u>	
	#	(%)
Human	622	(93)
Invest New Drug	42	(6)
Invest Device	8	(1)
Cooperative Oncology Group	194	(29)
Descriptive - Expedited	127	(19)
Greater Risk	251	(38)
Animal	37	(5)
Laboratory	12	(2)
	<u>671</u>	<u>(100)</u>

TABLE IV. WRAMC Clinical Investigation Publications and Presentations

	<u>FY-85</u>	<u>FY-86</u>	<u>FY-87</u>	<u>FY-88</u>	<u>FY-89*</u>
Published Articles	72	79	55	104	22
Abstracts	74	119	86	106	73
Presentations	64	75	55	93	61

* The decrease in fiscal year figures is a result of a restructured method of data collection which narrowed the accounting criteria but still allowed for overlap in fiscal years resultant from the ongoing APR process.

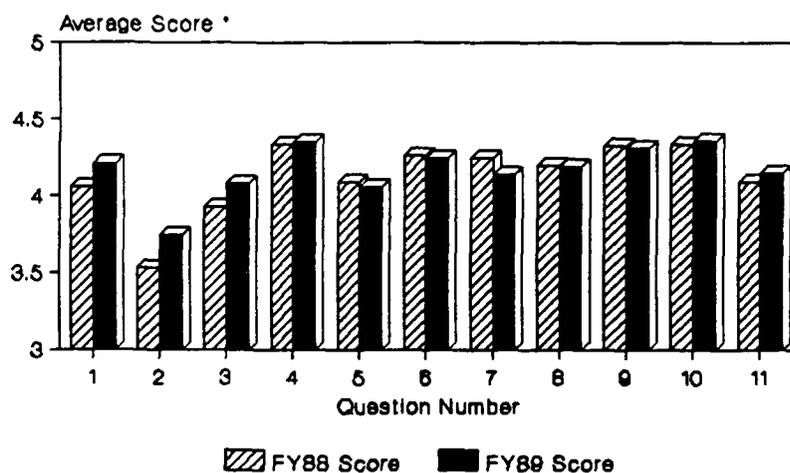
DCI Quality Improvement Questionnaire

The DCI Quality Improvement Questionnaire was completed by 252 of 474 investigators submitting annual progress reports from FY89 (compared to 310 of 456 investigators for FY88). The following eleven questions were presented:

1. DCI is doing all they can to support my research efforts.
2. DCI is providing adequate clerical support.
3. DCI is providing adequate statistical consultation.
4. DCI is making available adequate computer support.
5. DCI is providing adequate technical support.
6. DCI is providing adequate equipment and other logistical support.
7. DCI is providing adequate research space.
8. DCI is providing adequate financial support.
9. DCI conducts an adequate preliminary review of research applications.
10. DCI conducts an adequate annual review of research protocols.
11. Overall, DCI lives up to its slogan of being SHARPP
(Striving to Help All Researchers from Planning to Publication).

The answers range from 'Strongly AGREE' (score = 5) to 'Strongly DISAGREE' (score = 1), with the option of 'Not Applicable':

Evaluation of Performance, FY88 - FY89 By Type of Service



* Scale from 1 to 5
Score of '5' represents *strong*
agreement with level of service

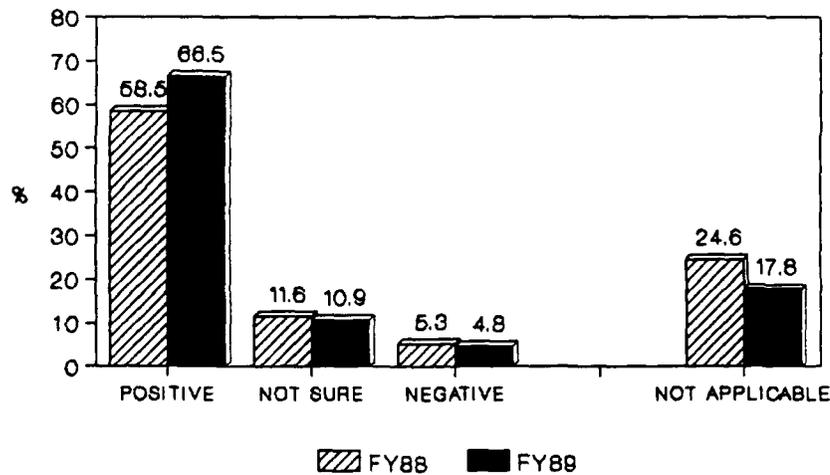
Ten of the eleven service areas had average scores greater than 4.00 in FY89. The overall average score for FY89 was 4.18, an increase from the 4.13 score for FY88 (not statistically significant, $P = .14$, by two sample t -test). The three greatest changes were all improvements: clerical support (2), DCI 'doing all they can' (1) and statistical consultation (3).

Summarizing a score of 4 or 5 as a 'Positive' response, and a score of 1 or 2 as a 'Negative' response, the 11:1 ratio of positive to negative replies in FY88 increased to a 14:1 ratio in FY89. Nine of the eleven areas queried showed an improvement in FY89.

In addition to the overall increase in positive responses and decline in negative responses between FY88 and FY89, there was a decline in the number of 'Not Sure' and 'Not Applicable' replies.

Overall Summary of Responses

FY88 - FY89



This survey of the effectiveness of services offered by the Department of Clinical Investigation directs our planning for FY90.

The Bailey K. Ashford Clinical Research Award finalists who presented their research at the third annual symposium were CPT Joseph J. Drabick, Fellow in Infectious Disease; CPT Patrick A. Cambier, Resident in Medicine; MAJ Dane K. Wukich, Resident in Orthopaedic Surgery; MAJ Garrison V. Morin, Resident in Otolaryngology/Head and Neck Surgery; and MAJ Raymond W. Phillips, Fellow in Gastroenterology. The recipient of the Bailey K. Ashford Clinical Research Medal awarded at the WRAMC Graduation Exercises was MAJ Garrison V. Morin for his research entitled "Wound Healing: Relationship of Wound Closing Tension to Tensile Strength and Scar Width."

The Research Review Service reviewed a record number of new protocols for approval. They implemented a quality improvement audit program which involved the initial auditing of twelve investigator study files for compliance with DA regulations and WRAMC Human Use Committee/Institutional Review Board guidelines. Results and recommendations of the audits were presented to the Human Use Committee. The Research Review Service, along with the Research Administrative Services, was successful in contracting to purchase a local area network linking all major clinical investigation activities to a minicomputer system with state-of-the-art graphics and enhanced statistical computing power.

The Research Administrative Services processed nearly 2900 purchase orders including over 11,000 line items for WRAMC investigators despite intense personnel turbulence during FY-89. New persons were recruited for two of the three clerical staff positions. The MEDCASE program grew to \$557,178 by the end of the fiscal year. A video imaging system was obtained for the Army Audiology

and Speech Center through the QRIP program. The Sleep Disorders Laboratory was relocated to the Pulmonary Disease Clinic.

The Research Operations Service initiated and completed a number of procedural upgrades to streamline and enhance the effectiveness of laboratory research support. Among those initiatives were to completely overhaul and expand the Laboratory Safety Manual, revise the Laboratory Animal Facility Standard Operating Procedures, develop mission statements for the General Support Laboratory and the Research Operations Service, and thoroughly document procedures for property accountability and equipment maintenance. The plans for accreditation of the animal facility were enhanced by identification of a consultant, LTC Bradford Goodwin, and by incorporating his recommendations into the animal facility design plan. LTC Lloyd E. Lippert, Chief, Research Operations, was selected as the Secretary of the Society of Armed Forces Medical Laboratory Scientists.

The Army Medical Specialist Corps (AMSC) Clinical Investigation and Research Service designed and directed the annual Mary Lipscomb Hamrick AMSC Research Course at the Xerox International Center for Training and Development in Leesburg, Virginia, from 31 July through 4 August. The course was attended by 48 officers, including 15 faculty. Fifteen of 44 submitted abstracts of AMSC research were selected for presentation. The instructional focus for the course included research methods, statistics, scientific writing, and research protocol review for clinical studies in Army hospitals.

The Kyle Metabolic Unit (KMU) Nursing Service reopened in June as a DCI service, reversing the persistent trend of diminishing patient bed capacity at WRAMC. Under the creative leadership of Ms. Ellen G. Horton, Head Nurse of the KMU Nursing Service, the patient census progressively increased despite problems with nurse staffing problems.

Two recently hired researchers in the Army Audiology and Speech Center were successful in obtaining substantial extramural research funding. Dr. Marjorie Leek, Hearing Scientist and Senior Researcher, obtained a 5 year, \$225,000 NIH grant, and Dr. David Fabry, Research Audiologist, was awarded a \$15,000 Nontenured Faculty Research Award by the 3M Corporation.

In recognition of the relevance and leadership role of the Kyle Metabolic Unit and of COL Leonard Wartofsky in basic research and clinical investigations related to the thyroid, the Office of the American Thyroid Association was moved to WRAMC with COL Wartofsky as its Secretary. The Kyle Metabolic Unit Laboratory began hosting Visiting Foreign Fellows with Dr. Wenyi Cai, M.D., Ph.D., from the Republic of China beginning a one year study period under the auspices of the Uniformed Services University of the Health Sciences. Individuals from Ethiopia and Hungary are to follow in this program.

Members of the Nursing Research Service of the Department of Nursing were deeply involved in three initiatives addressing nursing recruitment and retention. The first was development of an Army Nurse Corps survey, funded by the Office of the Surgeon General and supported by the Soldier Support Center, to determine satisfiers and dissatisfiers which may impact on active duty retention.

Second, a very similar survey of all registered nurses at WRAMC was conducted to ascertain how satisfied or dissatisfied they were with working conditions and to solicit recommended solutions. Third, LTC Jane Hudak served on the Health Professionals Special Pay Study task force and assisted in writing the "Report to Congress on Armed Forces Health Professions Special Pay--Military Nurse Corps."

The WRAMC Clinical Investigation Program encompassed all clinical departments and separate services, as well as the administrative directorates. The program supported 64 postgraduate training programs with research conducted by house staff and students, as well as assigned and affiliated staff. The medical training programs had substantial involvement in research, with 36 of the 51 programs having a total of 618 approved protocols. Fifty-nine of 408 Medical Corps interns, residents and fellows were principal investigators, with a total of 70 approved protocols. One hundred sixty-three of the assigned or affiliated Medical Corps staff were principal investigators, with a total 486 approved protocols. Assigned Medical Corps staff numbered 236. The 13 non-medical training programs with 53 trainees, including 10 Chaplain Corps trainees, were also involved in research with 6 programs having 12 approved protocols. WRAMC had a total of 265 principal investigators.

Many individuals associated with the WRAMC Clinical Investigation Program were recognized by outside organizations for their research accomplishments. The awards are listed below:

1. CPT Patrick A. Cambier, MC, Internal Medicine Resident - Best Associate's Paper at the Army Regional Meeting of the American College of Physicians in October 1988 for his study, "Objective Benefit of Diltiazem in the Treatment of Raynaud's Phenomenon: A Controlled Double Crossover Study."

2. CPT Svetislava J. Vukelja, MC, Hematology/Oncology Fellow - Best Fellow's Research Award in Hematology/Oncology at the Army Regional Meeting of the American College of Physicians in October 1988 for her study, "Mean Platelet Volume in the Evaluation of Thrombocytopenia."
3. CPT M. Frank Lyons, MC, Fellow in Gastroenterology - William Beaumont Research Award at the Army Regional Meeting of the American College of Physicians in October 1988 for his study, "Fleet^R Hypertonic Phosphate Enemas Cause Hyperphosphatemia and Acidemia in Patients with Ulcerative Colitis After Routine Colonic Cleansing."
4. LCDR Michael S. Opsahl, MC, Reproductive Endocrinology Fellow - The Chairman's Award for the best paper on Endocrinology and Infertility from a teaching hospital at the 27th Annual Meeting of the Armed Forces District, American College of Obstetricians & Gynecologists in November 1988 for his study, "Lymphocyte Subsets in Fertile and Infertile Women."
5. MAJ Paul G. Perlik, MC, Chief, Hand Surgery, Founders' Award at the 30th Annual Meeting of the Society of Military Orthopaedic Surgeons in December 1988 for his paper, "The Use of Magnetic Resonance Imaging to Assess Vascularity of Scaphoid Nonunions."
6. LTC Thomas E. Wiswell, MC, Neonatal Service, Department of Pediatrics - Election to membership in the Society of Pediatric Research in December 1988.
7. MAJ Garrison V. Morin, MC, Resident, Otolaryngology/Head and Neck Surgery Service, Department of Surgery - the Military Regional Award for the Committee on Trauma presented by the American College of Surgeons in February 1989 for his paper, "Wound Healing: Relationship of Tensile Strength to Closing Tension in Rats."
8. LTC(P) Jane K. Sweeney, SP, Chief, Army Medical Specialist Corps Clinical Investigation and Research Service - the 1989 Dissertation Award by the section on Pediatrics, American Physical Therapy Association in February 1989 for her doctoral dissertation, "Physiological and Behavioral Effects of Neurological Assessment in Preterm and Full-Term Neonates."
9. CPT R. Paul Schaudies, MS, Chief, General Support Laboratory, Department of Clinical Investigation - Outstanding Young Research Scientist Award at the meeting of the Society of Armed Forces Medical Laboratory Scientists in March 1989 for his research accomplishments.
10. LTC Thomas E. Wiswell, MC, Neonatal Service, Department of Pediatrics - the Ogden Bruton Award for Research at the 25th Annual Uniformed Services Pediatric Seminar in March 1989 for his work, "The Effect of Different High Frequency Ventilator Strategies on the Propagation of Tracheobronchial Histopathologic Changes."
11. COL Joan T. Zajtchuk, MC, Chief, Otolaryngology/Head and Neck Surgery Service, Department of Surgery - Honorable Mention in the Candidate's Thesis Competition held by the American Laryngological, Rhinological and Otological Society, Inc. in April 1989 for her thesis, "Mucosal Leishmaniasis in Brazil."

12. CPT Patrick A. Cambier, MC, Internal Medicine Resident - National Finalist for Associate's Award at the meeting of the American College of Physicians in April 1989 for his paper, "Objective Benefit of Diltiazem in the Treatment of Raynaud's Phenomenon: A Controlled Double Crossover Study."

13. MAJ Raymond W. Phillips, MC, Fellow in Gastroenterology, Department of Medicine - the Glaxo Research Award presented at the 90th Annual Research Meeting of the American Gastroenterology Association in May 1989 for his work, "Beta-Carotene Normalizes Rectal Mucosal Ornithine Decarboxylase Activity in Patients with Colon Carcinoma."

14. LTC William Hopkinson, MC, Orthopaedics Service, Department of Surgery - the O'Donoghue Award in Sports Medicine at the meeting of the American Orthopaedic Society in June 1989 for his paper, "The Efficacy of a Prophylactic Knee Brace to Reduce Knee Injuries in Football: A Prospective, Randomized Study at West Point."

15. MAJ Melissa W. Sinnott, SP, Director, Education and Research, Occupational Therapy Section, Physical Medicine and Rehabilitation Service - Abstract of the Year Award for Occupational Therapy Research at the Mary Lipscomb Hamrick AMSC Research Course in August 1989 for her abstract, "Clinical Specialization in Occupational Therapy: A Pluralistic View of Practice."

16. MAJ Garrison V. Morin, MC, Resident, Otolaryngology/Head and Neck Surgery Service, Department of Surgery - 1st Place Research Paper Award presented by the Society of Military Otolaryngologists in September 1989 for his paper, "Wound Healing: Relationship of Tensile Strength to Closing Tension in Rats."

2. Planned for FY-90

The start-up of the DCI Editorial Office with one staff position will allow the department to begin to address the most critical and chronic need identified by ongoing survey of WRAMC researchers. The installation and subsequent development of applications of the recently purchased computer network will greatly enhance the department's ability to provide statistical and data analysis support, as well as graphics and administrative support. CPT R. Paul Schaudies, Chief, General Support Laboratory, is leaving the department to attend the AMEDD Officers Advanced Course. He has been a tremendous asset to the department during his four and one half year assignment. The establishment of a WRAMC Clinical Investigation Special Fund in the Henry M. Jackson Foundation will

provide a much needed new avenue to fund expansion of the clinical investigation program.

The planned relocation of the Kyle Metabolic Unit will relieve some of the space problems of the WRAMC intensive care and operating areas on the fourth floor of Building 2. Definitive plans to renovate Building 7 to accommodate an AAALAC-approved Laboratory Animal Facility as well as a major portion of DCI should be completed to include transition space for the DCI activities currently housed in Building 7.

3. Ongoing and Future Issues

The time required to obtain approval of research studies continues to be an important area of concern at WRAMC. DCI will continue to monitor the time required for each component of the review and approval process and will implement changes to reach the present goal of a mean approval time for all WRAMC studies of less than 50 days. Ongoing efforts to obtain extramural funding through the Medical Research and Development Command and the Jackson Foundation are the best prospects to increase research funding at WRAMC. Clinical investigation education will receive more emphasis, working to develop better programs in all areas from animal research, study design, and statistics, to ethics and conflict of interest.

TABLE V: Human Use Committee/Institutional Review Board Members

Thomas A. Klein, COL, MC	Chairman, HUC/IRB Chief, Department of Obstetrics and Gynecology, Rep, Deputy Commander
H. Linton Wray, COL, MC	Co-Chairman, HUC/IRB Chief, DCI
Robert Smallridge, COL, MC*	Rep, Director, WRAIR
Wayne Johnston, COL, JA	Center Judge Advocate
Sarkis Derderian, LTC, MC	Assistant Chief, DCI
Valerie Biskey, LTC, AN	Rep, Chief, Department of Nursing
Richard Patterson, LTC, SP	Chief, Education and Research, Nutrition Care Directorate
Frank Lombardo, MAJ, SP	Rep, Chief, Pharmacy Service
Robert Hill, MAJ, CH	Rep, Chief, Department of Ministry and Pastoral Care
Eric Marks, M.D.*	Rep, Department of Medicine, Uniformed Services University of the Health Sciences
Laurel Meaney, DAC	Patients' Rights Representative

*Non-affiliated member

TABLE VI: Clinical Investigation Committee Members

H. Linton Wray, COL, MC	Chairman Chief, DCI
Samuel Cucinell, COL, MC	Rep, Chief, Department of Surgery
Charles Yeager, COL, MC	Rep, Radiation Control Committee, Radiation Therapy
Wayne Johnston, COL, JA	Center Judge Advocate
Jane Sweeney, LTC(P), SP	C, AMSC Clinical Investigation and Research, DCI
Sarkis Derderian, LTC, MC	Co-Chairman Assistant Chief, DCI
Patricia Rikli, LTC, AN	Rep, Chief, Nursing Research Svc
Jack Moore, LTC, MC	Rep, Chief, Dept of Medicine
Robin Howard, DAC	Biostatistician, DCI

TABLE VII: Rotating Senior Investigators, CIC

INVESTIGATOR

Thomas Wiswell, LTC, MC	Dept of Pediatrics
Harlan Bridenbaugh, COL, MC	Dept of Psychiatry
Bahmann Jabbari, COL, MC	Neurology Service
Brian Walden, Ph.D., DAC	Audiology & Speech Center
Edward Squire, LTC, MC	Allergy-Immunology Service
Steven Shay, COL, MC	Gastroenterology Service

TABLE VIII: Animal Use Committee/Clinical Investigation Committee Members

Charles Raflo, COL, VC	Attending Veterinarian Director, Div Vet Med, WRAIR
Hernando Mena, LTC, MC	Asst. Chairman, Dept Neuropath (AFIP)
Lloyd Lippert, LTC, MS	C, Research Operations Svc, DCI

TABLE IX: HIV Research/Clinical Investigation Committee Members

Edmond, Tramont, COL, MC	Director, HIV Research Program
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EXPENSES FOR PROTOCOLS OF CURRENT AND PREVIOUS FISCAL YEARS,
BY DEPARTMENT AND SERVICE, LISTED IN ALPHABETICAL ORDER

DEPARTMENT/ SERVICE	PROTOCOL NUMBER*	PRIOR FY's (\$)	CURRENT FY (\$)	TOTAL (\$)
HIV RESEARCH				
	9269	7,001	384	7,385
	TOTAL	7,001	384	7,385
ALLERGY/IMMUNOLOGY SERVICE				
	3214	16,761	8,538	25,299
	3221	13,332	8,195	21,527
	3225	0	1,430	1,430
	3340	0	5,606	5,606
	TOTAL	30,093	23,769	53,862
DEPARTMENT OF CLINICAL INVESTIGATION				
	9027	22,744	10,502	33,246
	9261	76,008	23,904	99,912
	9262	98,554	8,926	107,480
	9263	0	864	864
	9267	0	577	577
	9271	8,008	542	8,550
	9272	0	29,024	29,024
	TOTAL	205,314	74,339	279,653
DEPARTMENT OF MEDICINE				
Endocrine-Metabolic Service				
	1300-88	0	2,400	2,400
	1301-88	0	3,653	3,653
	1302-88	0	14,231	14,231
	1305-88	0	10,400	10,400
	1307-88	0	596	596
	1323-80	83,629	22,576	106,205
	1330-81	0	15,400	15,400
	1338-82	4	5,998	6,002
	1339-82	3,024	9,800	12,824
	1349-84	837	17,634	18,471
	1351-84	538	0	538
	1353-84	6,800	0	6,800
	1354-84	7,924	9,868	17,792
	1356-84	3,854	498	4,352
	1359-85	40,273	4,163	44,436
	1361-85	79,217	0	79,217
	1363-85	6,559	6,841	13,400
	1367-86	167	7,014	7,181
	1369-86	1,634	2,719	4,353
	1371-86	555	6,958	7,513
	1372-86	38,173	2,561	40,734
	1373-86	5,432	1,662	7,094
	1376-86	17,766	157	17,923
	1377-86	0	1,081	1,081
	1382-86	0	50	50

* Protocol is not listed if total expense is zero.

EXPENSES FOR PROTOCOLS OF CURRENT AND PREVIOUS FISCAL YEARS,
BY DEPARTMENT AND SERVICE, LISTED IN ALPHABETICAL ORDER

DEPARTMENT/ SERVICE	PROTOCOL NUMBER*	PRIOR FY's (\$)	CURRENT FY (\$)	TOTAL (\$)
DEPARTMENT OF MEDICINE				
Endocrine-Metabolic Service (continued)				
	1383-86	1,056	260	1,316
	1384-86	0	4,234	4,234
	1385-87	36,195	20,213	56,408
	1386-87	0	3,979	3,979
	1387-87	13,021	11,833	24,854
	1390-87	0	2,650	2,650
	1392-87	0	371	371
	1393-87	77,234	26,610	103,844
	1394-87	11,696	9,174	20,870
	1395-87	13,877	44,478	58,355
	1398-87	0	101	101
	1399-87	0	24,061	24,061
	TOTAL	449,465	294,224	743,689
DEPARTMENT OF MEDICINE				
Gastroenterology Service				
	1400-88	0	2,658	2,658
	1401	0	226	226
	1432	185	1,678	1,863
	1435	75	239	314
	1448	6,055	153	6,208
	1450	12,016	734	12,750
	1453	0	49	49
	1462	1,121	1,800	2,921
	1466	95	218	313
	1470	944	623	1,567
	1471	1,028	521	1,549
	1483	1,653	676	2,329
	1487	1,143	15	1,158
	1488	650	118	768
	1489	118	312	430
	1490	1,623	95	1,718
	1491	0	42	42
	1492	0	1,040	1,040
	1494	0	355	355
	1495	0	2,038	2,038
	1496	0	503	503
	1497	0	1,250	1,250
	1499	0	1,768	1,768
	TOTAL	26,796	17,111	43,817
DEPARTMENT OF MEDICINE				
Hematology-Oncology Service				
	1602-81	5,626	549	6,175
	1616-82	1,716	428	2,144

* Protocol is not listed if total expense is zero.

EXPENSES FOR PROTOCOLS OF CURRENT AND PREVIOUS FISCAL YEARS,
BY DEPARTMENT AND SERVICE, LISTED IN ALPHABETICAL ORDER

DEPARTMENT/ SERVICE	PROTOCOL NUMBER*	PRIOR FY's (\$)	CURRENT FY (\$)	TOTAL (\$)
DEPARTMENT OF MEDICINE				
Hematology-Oncology Service (continued)				
	1647-87	0	250	250
	1649-87	0	2,992	2,992
	1657-88	0	13,650	13,650
	TOTAL	7,342	17,869	25,211
DEPARTMENT OF MEDICINE				
Infectious Disease Service				
	1933	12,347	489	12,836
	1940	0	8,473	8,473
	1956	5,556	1,680	7,236
	9103	853	1,359	2,212
	TOTAL	18,756	12,001	30,757
DEPARTMENT OF MEDICINE				
Nephrology Service				
	1152	0	1,332	1,332
	1154	0	206	206
	1156	0	1,131	1,131
	TOTAL	0	2,669	2,669
DEPARTMENT OF MEDICINE				
Pulmonary Disease Service				
	1702	1,466	200	1,666
	1707	0	1,309	1,309
	1710	0	398	398
	1714	120	50	170
	1716	2,848	2,985	5,833
	1717	0	215	215
	1720	1,649	11,818	13,467
	1722	0	100,000	100,000
	1724	0	170	170
	1727	0	195	195
	1728	0	388	388
	1730	0	721	721
	1732	0	924	924
	TOTAL	6,083	119,373	125,456
DEPARTMENT OF MEDICINE				
Rheumatology Service				
	3220R	6,584	5,439	12,023
	3700	0	7,813	7,813
	3701	7,442	6,732	14,174
	TOTAL	14,026	19,984	34,010
NEUROLOGY SERVICE				
	9200	0	6,875	6,875
	TOTAL	0	6,875	6,875

* Protocol is not listed if total expense is zero.

EXPENSES FOR PROTOCOLS OF CURRENT AND PREVIOUS FISCAL YEARS,
BY DEPARTMENT AND SERVICE, LISTED IN ALPHABETICAL ORDER

DEPARTMENT/ SERVICE	PROTOCOL NUMBER*	PRIOR FY's (\$)	CURRENT FY (\$)	TOTAL (\$)
DEPARTMENT OF NURSING				
	7507	0	814	814
	TOTAL	0	814	814
DEPARTMENT OF OBSTETRICS AND GYNECOLOGY				
	4228	0	4,760	4,760
	4242	511	2,330	2,841
	4243	0	50	50
	4259	0	500	500
	TOTAL	511	7,640	8,151
DEPARTMENT OF PATHOLOGY AND AREA LABORATORIES				
	4802	0	1,720	1,720
	TOTAL	0	1,720	1,720
DEPARTMENT OF PEDIATRICS				
	6042	22,305	4,278	26,583
	6043	2,649	3,846	6,495
	6045	0	2,237	2,237
	6050	15,400	6,251	21,651
	6055	3,453	2,719	6,172
	6056	0	5,600	5,600
	6057	5,829	1,509	7,338
	6058	0	588	588
	6059	0	3,031	3,031
	6061	0	350	350
	6215	0	2,248	2,248
	TOTAL	49,636	32,657	82,293
DEPARTMENT OF PEDIATRICS				
Pediatric Oncology Group				
	6213	0	2,116	2,116
	TOTAL	0	2,116	2,116
DEPARTMENT OF PSYCHIATRY				
	7236	0	2,500	2,500
	TOTAL	0	2,500	2,500
DEPARTMENT OF SURGERY				
General Surgery Service				
	2027	0	772	772
	TOTAL	0	772	772
DEPARTMENT OF SURGERY				
Organ Transplant Service				
	2610	0	376	376
	2629	35,330	300	35,630
	2630	212	150	362
	2631	995	1,200	2,195
	TOTAL	36,537	2,026	38,563

* Protocol is not listed if total expense is zero.

EXPENSES FOR PROTOCOLS OF CURRENT AND PREVIOUS FISCAL YEARS,
 BY DEPARTMENT AND SERVICE, LISTED IN ALPHABETICAL ORDER

<u>DEPARTMENT/ SERVICE</u>	<u>PROTOCOL NUMBER*</u>	<u>PRIOR FY's (\$)</u>	<u>CURRENT FY (\$)</u>	<u>TOTAL (\$)</u>
DEPARTMENT OF SURGERY				
Orthopedics	Surgery Service			
	2410	0	7,995	7,995
	TOTAL	0	7,995	7,995
DEPARTMENT OF SURGERY				
	Otolaryngology-Head & Neck Service			
	2569	0	400	400
	2570	0	195	195
	2571	360	600	960
	2573	0	162	162
	2574	0	750	750
	2577	2,564	2,930	5,494
	2583	0	769	769
	2587	0	4,154	4,154
	TOTAL	2,924	9,960	12,884

* Protocol is not listed if total expense is zero.

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HIV RESEARCH		
1151	Link, Christine CPT MC. Evaluation of Renal Function, Protein Excretion and the Urinary Sediment in Patients with Antibody to the Human Immunodeficiency Virus (HIV) (3/87)	1
1948	Wright, Craig MAJ MC. A Double Blind Randomized Placebo-Controlled Trial of Fansidar Prophylaxis in Patients with HTLV-III Disease (WR Stage 5) (11/86)	2
1951	Rhoads, Joanne MAJ MC. Human Immune Response to HTLV-III Infection (12/86)	3
1952	Oster, Charles COL MC. The Clinical Presentation of HIV Infected Patients at Walter Reed Army Medical Center (1/87)	4
1953	Drabick, Joseph CPT MC. The Generation of Human Monoclonal Antibodies to the HIV (1/87)	5
1955	Hoover, David MAJ MC. T Helper Cell Depleted Mouse Model to Study Immunopathogenesis and Immunotherapy in AIDS (3/87)	6
1958	Hoover, David LTC MC. In Situ Hybridization for Detection of HIV in Langerhans Cells of HIV Infected Patients (7/87)	7
3342	Birx, Deborah MAJ MC. Delayed Type Hypersensitivity Skin Testing: Correlation of Intradermal Injection Vs. Epicutaneous Antigen Placement and CD4 Number in Normals and HIV Seropositive Subjects (8/88)	8
6218	Fischer, Gerald COL MC. Evaluation of Human Immunodeficiency Virus Related Proteins on the Surface of Lymphocytes from Children with Evidence of HIV Exposure or HIV Illnesses (5/88)	9
6220	Fischer, Gerald COL MC. Epidemiology of HIV In Pediatric and Perinatal Patients - A Natural History Study (7/88)	10
6222	Fischer, Gerald COL MC. Core Project: Evaluation of Diagnostic Assays for Human Immunodeficiency Virus (HIV) in Children with Evidence of HIV Exposure or HIV Illnesses (9/88)	11

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7139	Salazar, Andres COL MC. Intramuscular Poly-ICLC and Zidovudine in the Management of HIV Infection: An Open Pilot Trial (7/88)	13
8801	Rhoads, Joanne MAJ MC. Identification and Characterization of Human Immunodeficiency Virus in Human Semen (3/88)	14
8802	Oster, Charles COL MC. VA Cooperative Study No. 298, Treatment of AIDS and AIDS Related Complex; Part I: Treatment of Patients with ARC (AZT Vs. Placebo) (4/88)	15
8803	Burke, Donald COL MC. Core Protocol for HIV Developmental Diagnostics (Adults) (5/88)	16
8804	Oster, Charles COL MC. The Natural History of HIV Infection and Disease in United States Military Beneficiaries (5/88)	17
9269	Baker, James MAJ MC. Evaluation of human Immunodeficiency Virus (HIV)-Related Proteins on the Surface of Lymphocytes from Patients with Evidence of HIV Exposure or HIV Illnesses (6/87)	18
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3214	Birx, Deborah MAJ MC. In Vitro Lymphocyte Suppression by Calcium Channel Blocking Drugs (4/84)	19
3221	Engler, Renata MAJ MC. The Role of IgG Subclasses in Hymenoptera Hypersensitivity and Immunotherapy (8/84)	20
3224	Smith, Laurie. Assessment of Target Organ Reactivity in Anaphylaxis (1/85)	21
3225	Baker, James MAJ MC. Development of Human Hybridoma IgE Antibodies for Use in Clinical Applications (11/85)	22
3229	Squire, Edward LTC MC. Delayed-type Hypersensitivity Skin Testing: Correlation with Skin Biopsy and In Vitro Lymphocyte Testing in Normal Volunteers. (8/86)	23

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3335	Squire, Edward LTC MC. Do Aeroallergens Exacerbate Atopic Dermatitis (9/87)	25
3336	Yang, Edward MAJ MC. The Effect of Human Breast Milk Cell Supernatants on In Vitro Immunoglobulin Secretion (11/87)	26
3337	Squire, Edward LTC MC. What is the Dose Response to Ipratropium Bromide (IB) Among Steroid Dependent Asthmatics? (2/88)	27
3338	Herrera, Alma MAJ MC. Comparison of Skin Test Reactivity to Dilutions of Histamine Using the Volar Surface of the Arm Vs. the Back (3/88)	28
3339	Squire, Edward LTC MC. Comparison of House Dust Mite Educational Programs on Selected Outcome Variables (7/88)	29
3340	Salata, Kalman PhD. Analysis of Carbohydrate Epitopes on Food Allergen Proteins: A Pilot Study (8/88)	30
3341	Squire, Edward LTC MC. Occurrence of Laryngeal Dysfunction Among Patients Initially Diagnosed as Having Bronchial Asthma (8/88)	31
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9027	Dobek, Arthur PhD. Prevalence of Antibiotic Associated Colitis among Patients on Prolonged Antibiotic Therapy (3/81)	32
9255	Schuster, Brian LTC MC. Evaluation of DIGDOS, an HP-85 Program to Assist in Digoxin Dosing Decisions (10/83)	33
9261	Baker, James MAJ MC. Development of Human Hybridomas for Use in Histocompatibility Testing (8/85)	34
9262	Schaudies, Paul CPT MS. Internalization and Cellular Processing of 125-I-Epidermal Growth Factor (EGF) in Responsive and Unresponsive Cell Lines (10/85)	35

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9263	Derderian, Sarkis LTC MC. Neurohumoral Regulation of Ventilation in Patients with Elevated Adrenocorticotropic Hormone (ACTH) and Beta Endorphins (BE) (10/85)	36
9266	Baker, James MAJ MC. The Treatment of Graves' Disease with Anti-Idiotypic Therapy Using Intravenous Immunoglobulin (5/86)	37
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9271	Derderian, Sarkis LTC MC. The Ventilatory Response to Carbon Dioxide in Compensated Hepatic Cirrhosis (9/87)	41
9272	Lippert, Lloyd LTC MS. Relationship of Major Histocompatibility Complex Class II Genes to Inhibitor Antibody Formation in Hemophilia A (9/88)	42
9273	Burman, Kenneth COL MC. Identification and Characterization of Thyroid Autoantigens (9/88)	43
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1516-84	Weiss, Raymond MD. CALGB 8364: Immunological Diagnostic Studies in Adult ALL (10/83)	45
1522-84	Weiss, Raymond MD. CALGB 8461: Cytogenetic Studies in Acute Leukemia: A Companion to CALGB 8011, 8323, 8321, and 8411 (9/84)	46

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1527-85	Weiss, Raymond MD. CALGB 8591: A Phase III Study of Combining Chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck (2/85)	47
1528-85	Weiss, Raymond MD. CALGB 8541: Adjuvant CAF for Pathologic Stage II Node Positive Breast Cancer: A Comparison of Three Dose Regimens (3/85)	48
1536-85	Weiss, Raymond MD. CALGB 8582: A Comparison of Pentostatin and Alpha Interferon in Splenectomized Patients with Active Hairy Cell Leukemia (5/85)	49
1539-85	Weiss, Raymond MD. CALGB 8561: Retrospective Assessment of Psychosocial Sequelae in Long-term Survivors of Advanced Hodgkin's Disease (9/85)	50
1540-85	Weiss, Raymond MD. CALGB 8562: Retrospective Assessment of Psychosocial and Psychosexual Sequelae in Three Treatment Regimens for Advanced Hodgkin's Disease (9/85)	51
1543-86	Weiss, Raymond MD. CALGB 8513: A Phase III Trial of Intensive Treatment for Adult Acute Lymphocytic Leukemia: A Comparison of Combination Chemotherapy plus Alternating Mitoxantrone and Daunorubicin Vs. Combination Chemotherapy plus Daunorubicin (12/85)	52
1544-86	Weiss, Raymond MD. CALGB 8661: The Epidemiology of the Acute Leukemias in Adults with Special Reference to Cytogenetically Determined Subgroups (12/85)	53
1550-86	Weiss, Raymond MD. CALGB 8534: Combination Chemotherapy with Intensive ACE/PCE and Radiation Therapy to the Primary Tumor and Prophylactic Whole Brain Radiation Therapy with or without Warfarin in Limited Small Cell Carcinoma of the Lung (8/86)	54
1551-86	Weiss, Raymond MD. CALGB 8362: Pharmacokinetics of Ara-C in Patients with Acute Myelogenous Leukemia, A Companion to CALGB 8525 (9/86)	55

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