REPORT DOCUMENTATION PAGE

1. TITLE AND SUBTITLE
Clinical Investigation Program RCS MED-300(RI)
Department of Clinical Investigation
Walter Reed Army Medical Center

4. FUNDING NUMBERS

5. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Department of Clinical Investigation
Walter Reed Army Medical Center
Washington, DC 20307-5001

8. SPONSORING ORGANIZATION REPORT NUMBER
RCS MED-300(RI)

11. SUPPLEMENTARY NOTES
The findings in this report are not to be considered as an official Department of the Army position unless so designated by other authorized documents.

12b. DISTRIBUTION CODE
Approved for public release: Distribution unlimited.

13. ABSTRACT (Maximum 200 words)
This report identifies approved clinical research activities conducted at Walter Reed Army Medical Center through protocols approved by the Clinical Investigation Committee, the Human Use Committee/Institutional Review Board, and/or the Animal Use Committee, as appropriate. This report includes a Detail Summary Sheet outlining the progress of each protocol during Fiscal Year 93. Also included is a list of all known presentations and publications related to approved studies, as well as those not related to approved clinical investigation protocols. All research was conducted under the provisions of AR 40-38 (Clinical Investigation Program), AR 40-7 (Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances), AR 70-25 (Use of Volunteers as Subjects of Research), HSC Reg 40-23 (Management of Clinical Investigations, Protocols, and Reports), and AR 70-18 (The Use of Animals in DOD Programs).

14. SUBJECT TERMS
APR - Annual Progress Report, PI - principal investigator, protocol, study objective, technical approach, prior and current progress, conclusions, status, funding, publications

19. SECURITY CLASSIFICATION OF REPORT UNCLASSIFIED
19. SECURITY CLASSIFICATION OF THIS PAGE UNCLASSIFIED
19. SECURITY CLASSIFICATION OF ABSTRACT UNCLASSIFIED

20. LIMITATION OF ABSTRACT UNCLASSIFIED
The Annual Progress Report (APR) documents the continuing review during FY-93 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. The completed report consists of a detail summary sheet (DSS), a copy of the approved consent form, and a 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 approved detail summary sheets of 551 protocols are included in this document.

The FY-93 APR process at WRAMC was administered by the Editorial Office, Research Administration Service, Department of Clinical Investigation, in coordination with the Research Review Service.
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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

C. ORGANIZATION SCHEME

[Diagram of organizational structure]
D. DCI STAFF [Positions as of 30 September 1993; suffix (G) reflects grant-funded employees]

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<td>Hem/Onc(G)</td>
</tr>
</tbody>
</table>
Because of severe budget restraints, the Department of Clinical Investigation was not permitted to replace civilian employees when positions were vacated. This resulted in a decrease of 4 WRAMC-funded civilian employees, from 51 to 47. Grant-funded civilian employees remained at 16. DCI had a net gain of 1 officer and 3 enlisted personnel, from 4 to 5 and 7 to 10, respectively. The total of 78 assigned personnel remains at last year’s record high. In August 1993, the Research Operations Service welcomed a new Chief, LTC Daryl J. Kelly, MS. CPT Beverly D. Patton, SP, joined the staff in January 1993 as Chief, Nutrition Care, Kyle Metabolic Unit. More than $113,000 in extramural funding was obtained from the National Institutes of Health to support research being conducted in the Research Section, Army Audiology and Speech Center. Most of these monies were used to fund two Ph.D.-level researcher positions. The Clinical Studies Service was
established as part of a reorganization of the Department's TDA to prepare for the pending downsizing.

E. DCI FINANCIAL SUPPORT

<table>
<thead>
<tr>
<th></th>
<th>FY-89</th>
<th>FY-90</th>
<th>FY-91</th>
<th>FY-92</th>
<th>FY-93</th>
</tr>
</thead>
<tbody>
<tr>
<td>Civilian Personnel</td>
<td>$1,000,402</td>
<td>$1,500,001</td>
<td>$1,922,896</td>
<td>$2,365,661</td>
<td>$2,410,306</td>
</tr>
<tr>
<td>Consumable Supplies</td>
<td>$707,272</td>
<td>$708,572</td>
<td>$650,531</td>
<td>$834,703</td>
<td>$818,131</td>
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<tr>
<td>Civilian Contracts</td>
<td>$88,898</td>
<td>$107,000</td>
<td>$204,385</td>
<td>$123,186</td>
<td>$141,816</td>
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<tr>
<td>TDY</td>
<td>$35,186</td>
<td>$36,102</td>
<td>$31,399</td>
<td>$54,733</td>
<td>$59,764</td>
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<tr>
<td>Travel</td>
<td></td>
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<tr>
<td>(non-federal sources)</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>$22,211</td>
<td>$14,802</td>
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<tr>
<td>Capital Expense</td>
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</tr>
<tr>
<td>Equipment Program</td>
<td>$57,860</td>
<td>$30,932</td>
<td>$77,164</td>
<td>$270,374</td>
<td>$270,462</td>
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<tr>
<td>MEDCASE</td>
<td>$557,178</td>
<td>$572,892</td>
<td>$1,000,076</td>
<td>$1,438,216</td>
<td>$670,110</td>
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<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Grants</td>
<td>$298,467</td>
<td>$528,140</td>
<td>$500,252</td>
<td>$913,851</td>
<td>$1,118,690</td>
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<tr>
<td>Military</td>
<td>$429,718</td>
<td>$392,137</td>
<td>$397,960</td>
<td>$402,488</td>
<td>$451,683</td>
</tr>
<tr>
<td>T O T A L</td>
<td>$3,174,981</td>
<td>$3,875,776</td>
<td>$4,784,664</td>
<td>$6,425,123</td>
<td>$5,955,764</td>
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</table>

F. RESEARCH ACTIVITY

1. Accomplished in FY-93

With the mission to empower WRAMC researchers from planning to publication, the Department of Clinical Investigation (DCI) supported a record total of 717 active protocols this year (Table I). Twenty-three percent (166) of these studies were newly approved during the fiscal year, leaving 556 ongoing for at least one year that are summarized in this report. Medical Corps officers at WRAMC were principal investigators of 79% of the investigations. Medical Corps activities accounted for 96% of the investigations, and less than 1% were conducted at Army Community Hospitals in the Walter Reed Health Service Region (Table II). Human studies accounted for 92% of the investigations, with 32% involving research therapies including investigational drugs or devices and cooperative oncology group studies (Table III). Animal studies accounted for 6%, and laboratory studies
accounted for 2%. Publication and presentation productivity by WRAMC staff included 214 published abstracts, 334 published articles, and 312 conference presentations (Table IV). There were 31 Clinical Investigation Recognition Seminars (now in its seventh year) presented by WRAMC researchers, providing local dissemination of WRAMC research presented at regional and national conferences.

TABLE I. WRAMC Protocol Activity

<table>
<thead>
<tr>
<th>PROTOCOLS</th>
<th>FY-88</th>
<th>FY-89</th>
<th>FY-90</th>
<th>FY-91</th>
<th>FY-92</th>
<th>FY-93</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONGOING at the beginning of FY</td>
<td>456</td>
<td>474</td>
<td>520</td>
<td>552</td>
<td>535</td>
<td>551</td>
</tr>
<tr>
<td>NEWLY APPROVED (+)</td>
<td>145</td>
<td>197</td>
<td>172</td>
<td>153</td>
<td>150</td>
<td>156</td>
</tr>
<tr>
<td>TOTAL ACTIVE During FY</td>
<td>601</td>
<td>671</td>
<td>692</td>
<td>705</td>
<td>715</td>
<td>717</td>
</tr>
<tr>
<td>COMPLETED (-)</td>
<td>114</td>
<td>118</td>
<td>128</td>
<td>164</td>
<td>153</td>
<td>148</td>
</tr>
<tr>
<td>TERMINATED (-)</td>
<td>13</td>
<td>33</td>
<td>12</td>
<td>6</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>ONGOING at the end of FY</td>
<td>474</td>
<td>520</td>
<td>552</td>
<td>535</td>
<td>551</td>
<td>556</td>
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</table>

TABLE II. WRAMC FY-93 Active Investigations by AMEDD Officer Corps

<table>
<thead>
<tr>
<th>CORPS</th>
<th>GRAD TX PROG</th>
<th>OFFICERS IN TX</th>
<th>ACTIVE STUDIES</th>
</tr>
</thead>
<tbody>
<tr>
<td># (%)</td>
<td># (%)</td>
<td># (%)</td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>51 (77)</td>
<td>420 (88)</td>
<td>685 (96)</td>
</tr>
<tr>
<td>Medical Service</td>
<td>9 (14)</td>
<td>30 (6)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Dental</td>
<td>3 (5)</td>
<td>14 (3)</td>
<td>3 (&lt;1)</td>
</tr>
<tr>
<td>Medical Specialist</td>
<td>2 (3)</td>
<td>9 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Nursing</td>
<td>1 (1)</td>
<td>7 (1)</td>
<td>12 (2)</td>
</tr>
<tr>
<td>Veterinary</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (&lt;1)</td>
</tr>
<tr>
<td></td>
<td>66 (100)</td>
<td>480 (100)</td>
<td>712 (100)</td>
</tr>
<tr>
<td>Army Community Hospitals</td>
<td></td>
<td></td>
<td>6</td>
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</table>
### TABLE III. WRAMC FY-93 Active Investigations by Subject

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>ACTIVE STUDIES</th>
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<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>Human</td>
<td>662</td>
</tr>
<tr>
<td>Invest New Drug</td>
<td>50</td>
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<tr>
<td>Invest Device</td>
<td>4</td>
</tr>
<tr>
<td>Cooperative Oncology Group</td>
<td>176</td>
</tr>
<tr>
<td>Descriptive - Expedited</td>
<td>182</td>
</tr>
<tr>
<td>Greater Risk</td>
<td>250</td>
</tr>
<tr>
<td></td>
<td>662</td>
</tr>
<tr>
<td>Animal</td>
<td>45</td>
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<tr>
<td>Laboratory</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>718</td>
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</table>

### TABLE IV. WRAMC Publications and Presentations

<table>
<thead>
<tr>
<th>FY</th>
<th>FY-88</th>
<th>FY-89</th>
<th>FY-90</th>
<th>FY-91</th>
<th>FY-92</th>
<th>FY-93</th>
</tr>
</thead>
<tbody>
<tr>
<td>Published Articles</td>
<td>104</td>
<td>157</td>
<td>276</td>
<td>285</td>
<td>369</td>
<td>334</td>
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<tr>
<td>Abstracts</td>
<td>106</td>
<td>73</td>
<td>67</td>
<td>75</td>
<td>97</td>
<td>214</td>
</tr>
<tr>
<td>Presentations</td>
<td>93</td>
<td>61</td>
<td>106</td>
<td>110</td>
<td>232</td>
<td>312</td>
</tr>
</tbody>
</table>

* Published Articles related to approved clinical investigations: FY-89 = 22; FY-90 = 62; FY-91 = 71; FY-92 = 114; FY-93 = 138

+ Abstracts related to approved clinical investigations: FY-92 = 91; FY-93 = 56
The Clinical Investigation Program maintained a high level of activity during 1993 with a record number of active protocols (718 compared to 715 last year) despite a hiring freeze for civilian personnel and a decrease in financial support for equipment. The number of AMEDD officers in training at WRAMC decreased to 480 from the record high of 491 the previous year, with a decrease in physicians from 434 to 420.

The DCI Strategic Planning process resulted in the reorganization of the Department's TDA, the award of funding for the renovation of the laboratory animal facility to meet American Association for Accreditation of Laboratory Animal Care (AAALAC) standards, and the designation of Building 7 as the future site of research laboratory space in the WRAMC Master Plan.

In March, the Department moved from its long-occupied space on the sixth floor (Wards 62-63 area) of Building 2 to office space on the second floor (C sector) of Building 1. Ultimately, these offices are planned for the new BRAC Building, on which construction began late this year.

Under the auspices of the WRAMC Professional Education and Training Committee, the first WRAMC Research Course was completed in early FY-93. Attending the 15-hour course were 122 investigators, both in training and staff. Course evaluations were extremely favorable, and a second course has been developed for early FY-94.

The prestigious Bailey K. Ashford Clinical Research Award is bestowed annually on a member of the year's graduating class whose research accomplishments excelled during training. Fifteen graduating trainees, representing 10 training programs, were nominated for the 1993 award. A selection committee named four semi-finalists and five finalists. The finalists presented their results at a symposium sponsored by the Department of Clinical Investigation. The 1993 finalists were: MAJ Benje H. Boedeker, MC, Resident, Anesthesia-Operative Service, Department of Surgery, "Ultra-Long Duration Local Anesthesia Produced by Injection of Lecithin-Coated Tetracaine Microcrystals"; CPT Thomas B. Francis, MC, Fellow, Endocrine-Metabolic Service, Department of Medicine, "New Methods in YAC (Yeast Artificial Chromosome) Cloning"; MAJ Sharon G. Jackson, MC, Fellow, Endocrine-Metabolic Service, Department of Medicine, "Endothelin and the Thyroid"; MAJ David A. Nickels, MC, Fellow, Pediatric Endocrinology and Metabolism Service, Department of Pediatrics, "Effect of Somotostatin on Glomerular PGE₂ Production in the Diabetic Rat"; and MAJ James M. Roach, MC, Fellow, Pulmonary and Critical Care Medicine Service, Department of Medicine, "Validation of a New Bronchoprovocation Technique." Recipient of the 1993 Bailey K. Ashford Clinical Research Award, MAJ David A. Nickels, was announced at graduation in June.

The Research Review Service continued to be busy with an ever-increasing number of protocols being submitted. After 8 years as Assistant Chief of the Department and Chief of the Research Review Service, LTC Sarkis S. Derderian, MC, left for a new assignment as the Medical Director of the Sleep-Related Breathing Disorders Center, Pulmonary and Critical Care Medicine Service, Department of Medicine. His replacement,
MAJ George C. Tsokos, MC, had been assigned to the Uniformed Services University of the Health Sciences and, since 1992, as the Director of Rheumatology Research, Rheumatology Service, WRAMC. The Service streamlined, in collaboration with the Clinical Investigation Regulatory Office, the procedure for requesting and reporting the one-time use of an investigational new drug. Additionally, a Multiple Project Assurance was issued to WRAMC by the Department of Health and Human Services effective May 1993. The Biostatistics Section increased significantly the functions and capabilities of data analysis by upgrading STATISTIX to 4.0 and SPSS/PC to 6.0 Windows and by procuring BMDP and S+ software for non-standard statistical analyses and SOLO Power program for sample size estimation. During the year, the Computer Operations Section successfully completed a relocation of the computer room and an upgrade of the network operating system and began to develop a new database for improved financial management of protocols. The new network operating system greatly expanded the capabilities and performance of the DCINET, to include initiating the development of a centralized database for all departmental operations. In conjunction with the Directorate of Information Management, the Section developed a plan for a major network expansion to take place in 1994.

The Research Administration Service provided support for the Department and all WRAMC investigators, managing intra- and extramural monies totalling over $5,950,000. Of this total, $670,110 was received by the Department in MEDCASE funds, which was a decrease of $768,106. Extramural funding continued to expand, up $204,839 from 1992, and includes support from the National Institutes of Health, the U.S. Army Medical Research and Development Command, and the Veterans Administration. During the past year, a large increase was seen in gifts, grants, and sponsored studies. To monitor, assist, and promote extramural funding to support research at WRAMC, a new vital office was created, the Extramural Funding Office. The Editorial Office continued to improve its services, providing comprehensive support to investigators/authors in composing research protocols and manuscripts. The compilation of the Annual Progress Report continues to closely monitor the progress of ongoing research projects, with all reports submitted within 30 days of the anniversary date of approval or the protocol is administratively reviewed and terminated. Additionally, the Editorial Office continues to update the "Clinical Investigator's Guide," explaining the research review process and research resources at WRAMC and providing checklists, formats, and guidelines. To assist principal investigators further, a program continues whereby the routine forms and instructions required to compile a protocol are available to researchers on a user-friendly floppy disk.

During 1993, the Research Operations Service initiated and successfully completed several major projects. In August 1993, LTC Daryl J. Kelly, MS, reported from the Walter Reed Army Institute of Research as the new Chief of this section. Through coordination with the Directorate of Engineering and Housing, the Research Operations Service submitted and was awarded a contract for the renovation of the research animal facility to be completed in August 1994 and for the construction of a new infectious disease laboratory to be completed in March 1994. The research animal use program successfully passed a congressionally mandated, DOD directed, IG
Inspection, which recommended completion of the planned animal facility renovations. By centralizing research efforts and realigning personnel, the Research Operations Service continued to increase laboratory research support to principal investigators throughout the medical center.

The DCI Flow Cytometry Laboratory provided support for 12 fellows and a number of staff from departments around the medical center, including the Allergy-Immunology Service, Rheumatology Service, Pediatric Hematology-Oncology Service, Department of Pathology and Area Laboratories, and Pediatric Endocrinology Service, with eight new protocols initiated. The DCI Immunogenetics Laboratory has aggressively expanded collaboration with researchers, supporting six protocols during this fiscal year. After establishing DNA-PCR and applying it to HLA typing, the laboratory is taking up several protocols dealing with Hepatitis B and C.

The Kyle Metabolic Unit Nursing Service supports 16 beds that are utilized for the evaluation and treatment of endocrine and metabolic disorders. CPT Beverly D. Patton was assigned as the metabolic dietitian.

The 7-year polyp prevention study (NIH grant), now in its third year, headed by LTC James Kikendall, MC, Gastroenterology Service, Department of Medicine, focused on enrolling additional subjects. This is a multi-center study of patients who have undergone colonoscopic removal of adenomas. Subjects are randomized to no intervention or to a low fat, high fiber, high fruit and vegetable diet and extensive counselling. Nutrition counselling for those in the dietary intervention group was ongoing during this past year.

As in years past, principal investigators conducting research under the Clinical Investigation Program at WRAMC continued to receive national recognition during FY-93 for their outstanding research. CPT Michael D. Eisenhauer, MC, Resident, Department of Medicine, received several recognitions this past year for this work entitled "Incidence of Cardiac Arrhythmias During Intravenous Pentamidine Therapy in HIV-Infected Patients." In November 1992, he won the Associates' Competition at the 9th Army Regional Meeting of the American College of Physicians, San Francisco, CA; in January 1993, he won the Associates' Competition, Metropolitan D.C. Chapter of the American College of Physicians, Washington, DC; and in April 1993, his poster received recognition as a finalist at the 74th Annual Session of the American College of Physicians National Meeting, Washington, DC.

MAJ Donald J. Lewis, MC, Urology Service, Department of Surgery, received two resident research awards. In February 1993, he received the Washington Urologic Society Residents Day Research Essay Award, and in April 1993, he received the Joseph Baugh Military Resident Research Award at the Uniformed Services Surgical Associates Annual Meeting, Bethesda, MD. Both of these awards were for his work on "Evaluation of the P53 Tumor Suppressor Gene in Human Testicular Cancer."

CPT Kimberly Peele, MC, Fellow, Neuro-Ophthalmology Service, Departments of Ophthalmology and Neurology, won the 1993 Residents' and
Fellows' Competition at the Annual Meeting of the North American Neuro-Ophthalmology Society for her research evaluating peripheral visual fields in pseudotumor cerebri. The title of her presentation was "The Role of Peripheral Visual Fields in Idiopathic Intracranial Hypertension."

MAJ David A. Nickels, MC, Fellow, Pediatric Endocrinology and Metabolism Service, Department of Pediatrics, was the recipient of the Ogden Bruton Award at the Annual Tri-Service Pediatric Seminar in February 1993. This award honors the best basic science research by an active duty pediatrician. Dr. Nickels' paper was entitled "Prevention of Diabetic Nephropathy: Potential New Mechanisms."

First Place honor went to MAJ Joachim J. Tenuta, MC, Orthopaedic Surgery Service, Department of Surgery, at the Residents' Night Competition, Washington Orthopaedic Society, for his work entitled "Arthroscopic Evaluation of Miniscal Repairs: Factors that Affect Healing." Dr. Tenuta presented his paper to the Society at their meeting held in Arlington, VA, in April 1993.


The Charles A. Hufnagel Award of the Uniformed Services University of the Health Sciences was awarded to CPT John S. Xenos, MC, Orthopaedic Surgery Service, Department of Surgery, for his study "The Tibiofibular Syndesmosis: Evaluation of the Ligamentous Structures and Methods of Fixation." Dr. Xenos presented his work at the Annual Reserve Components Surgical Day, Bethesda, MD, in April 1993.

2. Planned for FY-94

The Department of Clinical Investigation hopes to maintain the essence of the Clinical Investigation Program despite severe budget restrictions in FY-94. The Bailey K. Ashford Research Symposium, the WRAMC Research Course, and the Clinical Investigation Recognition Seminars will be continued. Areas of particular interest for the upcoming year include the following:

a. Close coordination and oversight of the renovation of the laboratory animal facility and the departmental space in the BRAC Building.

b. Continued emphasis on departmental reorganization to support increased extramural funding.

3. Ongoing and Future Issues

It is probable that WRAMC activities in patient care, training, and research will decrease substantively in the future. The major ongoing and
future issue is the same as last year, funding of the VRAMC Clinical Investigation Program in this new environment.

**TABLE V: Human Use Committee/Institutional Review Board Members**

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenneth Burman, COL MC</td>
<td>Co-Chairman, Chief, Endocrine-Metabolic Service, Representing Deputy Commander</td>
</tr>
<tr>
<td>Stephen Sihelnik, LTC MC</td>
<td>Co-Chairman, Assistant Chief, Urology Service, Representing Deputy Commander</td>
</tr>
<tr>
<td>Sarkis Derderian, LTC MC</td>
<td>Acting Co-Chairman, Assistant Chief, DCI</td>
</tr>
<tr>
<td>Dominic Solimando, MAJ MS</td>
<td>OIC, Hematology-Oncology Pharmacy, Representing Chief, Pharmacy Service</td>
</tr>
<tr>
<td>David DeDonato, LTC CH</td>
<td>Chief, Dept of Ministry and Pastoral Care</td>
</tr>
<tr>
<td>Jack Farrell, Ph.D.*</td>
<td>Chief, Psychology Section, U.S. Soldiers' &amp; Airmen's Home</td>
</tr>
<tr>
<td>Eric Marks, M.D.*</td>
<td>Associate Professor, Dept of Medicine, USUHS</td>
</tr>
<tr>
<td>Laurel Meaney, DAC</td>
<td>Patients' Rights Representative, WRAMC</td>
</tr>
<tr>
<td>Scott Murdoch, J.D.</td>
<td>Chief, Claims Office, Representing Center Judge Advocate</td>
</tr>
<tr>
<td>Cheryl Hostetler, DAC</td>
<td>Clinical Instructor, Dietetic Internship Education and Research, Nutrition Care Directorate, Representing Ch, Nutrition Care Dir</td>
</tr>
<tr>
<td>Jean Reeder, LTC AN</td>
<td>Chief, Nursing Research Service, Representing Chief, Dept of Nursing</td>
</tr>
<tr>
<td>Robert Smallridge, COL MC*</td>
<td>Chief, Dept of Clinical Physiology, Division of Medicine, WRAIR, Representing Director, WRAIR</td>
</tr>
<tr>
<td>Estelle Coleman-Fraser, DAC</td>
<td>Research Review Coordinator, Department of Clinical Investigation</td>
</tr>
<tr>
<td>*Non-affiliated</td>
<td></td>
</tr>
</tbody>
</table>

*Non-affiliated
### TABLE VI: Clinical Investigation Committee Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sarkis Derderian, LTC MC</td>
<td>Acting Chairman, Assistant Chief, DCI</td>
</tr>
<tr>
<td>Stephen Sihelnik, LTC MC</td>
<td>Acting Co-Chairman, Staff, Urology Service, Dept of Surgery</td>
</tr>
<tr>
<td>Ana Rodriguez, COL MC</td>
<td>Chief, Nuclear Medicine, Representing Radiation Control Comm</td>
</tr>
<tr>
<td>Audrey Chang, Ph.D.</td>
<td>Senior Biostatistician, DCI</td>
</tr>
<tr>
<td>Gary Klipple, COL MC</td>
<td>Chief, Nephrology Service, Representing Chief, Dept of Medicine</td>
</tr>
<tr>
<td>Scott Murdoch, J.D.</td>
<td>Chief, Claims Office, Representing Center Judge Advocate</td>
</tr>
<tr>
<td>Jean Reeder, LTC AN</td>
<td>Chief, Nursing Research Service</td>
</tr>
<tr>
<td>Douglas Hale, MAJ MC</td>
<td>Staff, General Surgery Service, Representing Chief, Dept of Surgery</td>
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</table>

### TABLE VII: Rotating Senior Investigators, Clinical Investigation Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Majorie Leek, Ph.D.</td>
<td>Army Audiology &amp; Speech Center</td>
</tr>
<tr>
<td>Bahman Jabbari, COL MC</td>
<td>Neurology Service</td>
</tr>
<tr>
<td>Terry Schultz, COL MC</td>
<td>Department of Psychiatry</td>
</tr>
<tr>
<td>Roy Wong, COL MC</td>
<td>Gastroenterology Service</td>
</tr>
<tr>
<td>Gary Carpenter, COL MC</td>
<td>Allergy-Immunology Service</td>
</tr>
<tr>
<td>Russell Moores, MAJ MC</td>
<td>Department of Pediatrics</td>
</tr>
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### TABLE VIII: Animal Use Committee Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>Sarkis Derderian, LTC MC</td>
<td>Acting Chairman</td>
</tr>
<tr>
<td></td>
<td>Assistant Chief, DCI</td>
</tr>
<tr>
<td>Judith Davis, MAJ VC</td>
<td>Attending Veterinarian</td>
</tr>
<tr>
<td></td>
<td>Chief, Animal Resource Department</td>
</tr>
<tr>
<td></td>
<td>Div of Veterinary Medicine, WRAIR</td>
</tr>
<tr>
<td>Matthew Payne, CPT MS</td>
<td>Acting Ch, Research Operations Service</td>
</tr>
<tr>
<td></td>
<td>Dept of Clinical Investigation, WRAMC</td>
</tr>
<tr>
<td>Hernando Mena, LTC MC*</td>
<td>Asst Chairman, Dept of Neuropathology</td>
</tr>
<tr>
<td></td>
<td>Armed Forces Institute of Pathology</td>
</tr>
<tr>
<td>Ted Hadfield, LtCol BSC*</td>
<td>Chief, Division of Microbiology</td>
</tr>
<tr>
<td></td>
<td>Armed Forces Institute of Pathology</td>
</tr>
</tbody>
</table>

*Non-affiliated

### TABLE IX: HIV Research/Clinical Investigation Committee Member

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Charles Oster, COL MC</td>
<td>Chief, Infectious Disease Service</td>
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EXPENSES FOR PROTOCOLS OF CURRENT AND PREVIOUS FISCAL YEARS
BY DEPARTMENT AND SERVICE, LISTED IN ALPHABETICAL ORDER

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| 9275 | 16,791 | 0 | 16,791 |
| 9284 | 1,900 | 3,892 | 5,792 |
| 9285 | 1,394 | 335 | 1,729 |
| TOTAL | 38,695 | 4,227 | 42,922 |

| HIV RESEARCH | | | |
| 6325 | 0 | 1,106 | 1,106 |
| 8802 | 996 | 0 | 996 |
| TOTAL | 996 | 1,106 | 2,102 |

* 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

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* 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

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* 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

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

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# ADDENDUM

EXPENSES FOR PROTOCOLS APPROVED DURING FY-93
(FIRST ANNUAL PROGRESS REPORT TO BE SUBMITTED IN FY-94)
AND EXPENSES FOR PROTOCOLS PREVIOUSLY CLOSED
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ADDENDUM

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(FIRST ANNUAL PROGRESS REPORT TO BE SUBMITTED IN FY-94)
AND EXPENSES FOR PROTOCOLS PREVIOUSLY CLOSED
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* Protocol is not listed if total expense is zero.
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AND EXPENSES FOR PROTOCOLS PREVIOUSLY CLOSED

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| General Surgery Service |                 |                |               |          |
| 2037                | 1,365           | 1,400          | 2,765         |          |
| TOTAL               | 1,365           | 1,400          | 2,765         |          |

| **DEPARTMENT OF SURGERY** |                 |                |               |          |
| Orthopaedic Surgery Service |                 |                |               |          |
| 2423                | 797             | 17,783         | 18,580        |          |
| 2428                | 0               | 88             | 88            |          |
| 2429                | 819             | 1,054          | 1,873         |          |
| 2437                | 0               | 7,811          | 7,811         |          |
| 2438                | 0               | 19,868         | 19,868        |          |
| 2440                | 0               | 1,106          | 1,106         |          |
| 2441                | 0               | 2,595          | 2,595         |          |
| 2442                | 0               | 837            | 837           |          |
| 2444                | 0               | 1,598          | 1,598         |          |
| 2445                | 0               | 9,593          | 9,593         |          |
| 2447                | 0               | 30,000         | 30,000        |          |
| 2450                | 0               | 42             | 42            |          |
| 2452                | 0               | 20             | 20            |          |
| 2454                | 0               | 1,912          | 1,912         |          |
| 2473                | 0               | 180            | 180           |          |
| TOTAL               | 1,616           | 94,487         | 96,103        |          |

| **DEPARTMENT OF SURGERY** |                 |                |               |          |
| Otolaryngology-Head & Neck Surgery Svc |                 |                |               |          |
| 2509                | 0               | 126            | 126           |          |
| 2526                | 0               | 485            | 485           |          |
| TOTAL               | 0               | 611            | 611           |          |

* Protocol is not listed if total expense is zero.
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BY DEPARTMENT AND SERVICE

PROTOCOL NUMBER: PRINCIPAL INVESTIGATOR, TITLE, AND APPROVAL DATE

ALLERGY-IMMUNOLOGY SERVICE

1400-88 Engler, Renata COL MC. A Pilot Study Evaluating Intestinal and Serum Immunoglobulin Levels in Patients with Acquired Hypogammaglobulinemia and Recurrent/Chronic Diarrhea of Undefined Etiology (2/88) 1

3221 Engler, Renata COL MC. The Role of IgG Subclasses in Hymenoptera Hypersensitivity and Immunotherapy (8/84) 2

3336 Engler, Renata COL MC. The Effect of Human Breast Milk Cell Supernatants on In Vitro Immunoglobulin Secretion (11/87) 3

3339 Squire, Edward LTC MC. Comparison of House Dust Mite Educational Programs on Selected Outcome Variables (7/88) 4

3340 Salata, Kalman PhD. Analysis of Carbohydrate Epitopes on Food Allergen Proteins: A Pilot Study (8/88) 5

3343 Salata, Kalman PhD. Standardized Vs. Nonstandardized Allergen Products Containing Dust Mite Antigens (10/88) 6

3344 Carpenter, Gary COL MC. The Effect of UVB (Ultraviolet-B) Light on Immediate, Late and Delayed Hypersensitivity (12/88) 7

3345 Salata, Kalman PhD. Cross Allergenicity of Pollen Allergens from American Linden and Europen Linden (6/89) 8

3346 Salata, Kalman PhD. Comparison of Three Methods of Assessing Induction of Mitogen and Allergen Specific Lymphocyte Proliferation (6/89) 9

3347 Salata, Kalman PhD. A Simple Prick Puncture End Point Titration Procedure to Evaluate the Safety of Switching from Nonstandardized to Standardized Allergen Extracts for Use in Immunotherapy (8/89) 10

3348 Engler, Renata COL MC. Immunotherapy Reactions (11/89) 11

3349 Salata, Kalman PhD. Mitogen-Inducible T Suppressor Cell Assay by Flow Cytometry (12/89) 12

* Reference is to page number(s) in Volume II.
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* Number in [ ] is the protocol number.
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HIV RESEARCH (continued)


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HIV RESEARCH (continued)


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HIV RESEARCH (continued)


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CITATION* TYPE**

HIV RESEARCH (continued)


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HIV RESEARCH (continued)


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DEPARTMENT OF MEDICINE                      
Cardiology Service (continued)


DEPARTMENT OF MEDICINE                      
Endocrine-Metabolic Service


* Number in [] is the protocol number.
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DEPARTMENT OF MEDICINE
Endocrine-Metabolic Service (continued)


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DEPARTMENT OF MEDICINE
Gastroenterology Service


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DEPARTMENT OF MEDICINE
Gastroenterology Service (continued)


* Number in [] is the protocol number.
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DEPARTMENT OF MEDICINE
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Nephrology Service (continued)


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Nephrology Service (continued)


DEPARTMENT OF MEDICINE
Pulmonary Disease Service


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** P = publication, Ab = abstract, Pr = presentation
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Pulmonary Disease Service (continued)


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DEPARTMENT OF MEDICINE
Rheumatology Service (continued)


* Number in [ ] is the protocol number.
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DEPARTMENT OF MEDICINE
Rheumatology Service (continued)


NEUROLOGY SERVICE

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DEPARTMENT OF NURSING


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Farley J: Clinical significance of the inflammatory pap smear. Residents' Day Forum, Walter Reed Army Medical Center, Washington, DC, May, 1993. [4304]

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Daugirda J: Survivability of viscerotropic Leishmania tropica from Desert Storm participants in human blood products maintained at blood bank conditions. Master's Thesis, Bowling Green State University, Bowling Green, Ohio, August, 1993. [4813]

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DEPARTMENT OF PEDIATRICS


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DEPARTMENT OF PEDIATRICS (continued)


DEPARTMENT OF PEDIATRICS
Pediatric Hematology-Oncology Service


* Number in [ ] is the protocol number.
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PHYSICAL MEDICINE AND REHABILITATION SERVICE


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Hall D, Benedek D, Chang A: Intra-daily mood variance in depression. 146th Annual Meeting of the American Psychiatric Association Abstracts 1993; NR 152. [7245]


Joslin S: An outcome study of schizophreniform disorder diagnosed at Walter Reed Army Medical Center: interim findings. Grand Rounds, Walter Reed Army Medical Center, Washington, DC, June, 1993. [7251]

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Anesthesia-Operative Service (continued)


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Army Audiology and Speech Center


McCLean M: Kinematic and reflex analysis of adult stutterers' speech. Invited presentation to the Department of Speech and Hearing Sciences, Indiana University, Bloomington, IN, 1992. [2510]

* Number in [] is the protocol number.
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### DEPARTMENT OF SURGERY

**Army Audiology and Speech Center (continued)**

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<td>McClean M</td>
<td>Physiologic analyses of stutterers' speech. Invited presentation to the Department of Audiology and Speech Sciences, Purdue University, West Lafayette, IN, 1992.</td>
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<td>McClean M</td>
<td>Analysis of lip muscle reflexes during speech preparation in stutterers.</td>
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<td>Surr R, Cord M</td>
<td>Comparison of linear class D and k-amp hearing aid fittings by experienced hearing aid users.</td>
<td>Ab</td>
<td>Audiology Today 1993;5:50. [2520]</td>
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## DEPARTMENT OF SURGERY

**Critical Care Medicine Service**

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<td>Stoltzfus D</td>
<td>Capnography directed ventilation during intrahospital transport of critically ill, mechanically ventilated patients.</td>
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<td>4th AMEDD Clinical Investigation Postgraduate Short Course, San Antonio, TX, 1992. [3008]</td>
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Department of Surgery  
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** P = publication, Ab = abstract, Pr = presentation
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DEPARTMENT OF SURGERY
Orthopaedic Surgery Service (continued)


Brown M: The effect of extracorporeal shockwaves on bone and soft tissue in rabbits. Annual Hufnagel Award Competition, Uniformed Services University of the Health Sciences, Bethesda, MD, April, 1993. [2435]


Popovic N, Brown M, Van Dam B, Sweet D: Preliminary data on the effects of extracorporeal shockwaves on bone and soft tissue in rabbits. Meeting of the International Osteostar Users, Erlangen, Germany, October, 1992. [2435]


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DEPARTMENT OF SURGERY

Urology Service


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<tr>
<td>Moul J: The molecular biology of prostate cancer: what the clinician needs to know now. Controversies in the Diagnosis and Management of Prostate and Bladder Cancer Conference, Orlando, FL, October, 1992. [2860]</td>
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<tr>
<td>Moul J: The molecular biology of prostate cancer: what the clinician needs to know now. Visiting Professor, Department of Pathology Grand Rounds, Medical College of Virginia, Richmond, VA, November, 1992. [2860]</td>
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Moul J: Prognostic factors in low stage testicular nonseminoma. Invited Visiting Professor, University of Iowa, Iowa City, IA, September, 1993. [2862]

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DEPARTMENT OF MEDICINE
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DEPARTMENT OF MEDICINE
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Nagy E, Burch H, Burman K. Unidirectional shift of the dominant T cell epitope in the human thyrotropin receptor in Graves’ disease. Thyroid 1993;3(suppl 1):114. [1316-89]


Wong N, Carr F. Members of the thyroid/steroid receptor superfamily that regulate apolipoprotein Al gene expression. Transcription of the Keystone Symposium, Keystone, CO, January, 1993. [1393-87]


* Number in [ ] is the closed protocol number
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DEPARTMENT OF MEDICINE
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Holland J. Comparison of psychosocial adaptation and sexual function of survivors of advanced Hodgkin’s disease treated by MOPP, ABVD, or MOPP alternating with ABVD. Cancer 1992; 70:2508-16. [1540-85]


* Number in [ ] is the closed protocol number
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Argyros G. Water loss without heat flux in exercise induced asthma. 1st National Conference on Asthma Management, Crystal City, VA, October, 1992. [1728]


* Number in [ ] is the closed protocol number
** P = publication, Ab = abstract, Pr = presentation

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Moores L. The effect of acute and chronic diltiazem administration on pulmonary gas exchange and oxygen delivery in severe COPD. 9th Army Regional Meeting of the American College of Physicians, San Francisco, CA, November, 1992. [1740]


* Number in [ ] is the closed protocol number
** P = publication, Ab = abstract, Pr = presentation

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DEPARTMENT OF MEDICINE  
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Rajagopal K. Hormonal influences on respiration during sleep. 6th Annual Meeting of the Association of Professional Sleep Societies, Phoenix, AZ, 1992. [1716]  


DEPARTMENT OF PEDIATRICS  


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CITATION*

PHYSICAL MEDICINE AND REHABILITATION SERVICE


DEPARTMENT OF SURGERY
Army Audiology and Speech Center


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DEPARTMENT OF SURGERY
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DEPARTMENT OF SURGERY
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DEPARTMENT OF SURGERY
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Moul J. Cathepsin-D expression in prostate cancer. 51st Mid Atlantic American Urological Association Meeting, Palm Beach, FL, September, 1993. [2877]


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ALLERGY-IMMUNOLOGY SERVICE


HIV RESEARCH


* P = publication, Ab = abstract, Pr = presentation
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* P = publication, Ab = abstract, Pr = presentation

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* P = publication, Ab = abstract, Pr = presentation

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* P = publication, Ab = abstract, Pr = presentation

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* P = publication, Ab = abstract, Pr = presentation

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DEPARTMENT OF MEDICINE
Hematology-Oncology Service

Dawson N: Treatment of progressive metastatic prostate cancer.


458-77.

Weiss R: Idarubicin, a third anthracycline for acute leukemia.

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| 60-2. |  |
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| Weiss R: The anthracyclines: will we ever find a better doxorubicin? Sem Oncol 1992;19:670-86. | P  |
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Infectious Disease Service (continued)


Department of Medicine

General Medicine Service

Herbers J Jr, Lange P: Screening with prostate-specific angigen: should we or shouldn’t we? JAMA 1993;269(17):2212.


Department of Medicine

Nephrology Service


* P = publication, Ab = abstract, Pr = presentation

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* P - publication, Ab - abstract, Pr - presentation
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* P = publication, Ab = abstract, Pr = presentation

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DEPARTMENT OF PEDIATRICS


* P = publication, Ab = abstract, Pr = presentation
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* P = publication, Ab = abstract, Pr = presentation

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Berrey B: Ewing's sarcoma; state of orthopaedics in the military; orthopaedic infections; reconstruction/limb salvage/soft tissue; musculoskeletal oncology in the active duty population. 44th Annual Military Medical Surgical Clinical Congress, Willingen, Germany, May, 1993.


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<td>Fu F, Thompson W, Thaete F, Olson E</td>
<td>Combined anterior and posterior cruciate ligament kinematics by non-orthogonal magnetic resonance imaging</td>
<td>Pr</td>
<td>Combined Congress of the International Society of the Knee and the International Arthroscopy Association, Copenhagen, Denmark, June, 1993.</td>
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<td>McHale K, Clemence E: Efficiency in the pediatric orthopaedic clinic and the effect on the parents: a comparison of military and civilian medical centers. Mil Med, Sep 92.</td>
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<td>Smith A: Rheumatoid surgery of the hand and Dupuytren's disease. William Beaumont Army Medical Center, El Paso, TX, November, 1992.</td>
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