

TABLE OF CONTENTS

Page 1

- Bailey K. Ashford Symposium**
- IRB Calendar**
- WRAMC Research Course**

Page 2

- Research Administration**

Service News

- Welcome to new DCI employees**
- BMAR reminder**
- DCI on the WWW**
- Editorial information**

Page 3

- CIRO Update**
- Recent Publications from WRAMC**

Page 4

- Short Research Course information**
- The DCI Molecular Biology Course**

Page 5

- Recently-approved WRAMC protocols**

Inquiring Minds

News and notes from the Department of Clinical Investigation, WRAMC
March/April, 1999

Bailey K. Ashford Award Symposium set for 12 May; applications wanted!

The Department of Clinical Investigation, Walter Reed Army Medical Center, is proud to announce the 25th Annual Bailey K. Ashford Clinical and Laboratory Research Award and Symposium. This prestigious award and symposium recognize the outstanding research performed by graduating residents and fellows at WRAMC.

The Bailey K. Ashford Clinical and Laboratory Research Award was established through the efforts of Colonel Marcel E. Conrad, the first Chief of Clinical Investigation at Walter Reed Army Medical Center. The award is dedicated to Colonel Bailey K. Ashford for his outstanding work in solving the problem of hookworm induced anemia in Puerto Rico during the early 1900s.

All graduating physicians and dentists who are full-time trainees in a WRAMC or WRAMC integrated training program are eligible to be nominated for this award. Any attending staff member assigned to WRAMC or to an integrated GME program may make a nomination.

A selection committee determines the award finalists, who are invited to present their major research findings at the Bailey K. Ashford Clinical and Laboratory Research Symposium. This year the symposium will be held on 12 May 1999 at the Vorder Bruegge Auditorium, Bldg. 1, WRAMC.

Based on the scientific presentations and follow-up interviews, two award winners--one for clinical research and one for laboratory research--are chosen. These awards, along with a monetary prize, are presented at the joint NNMC and WRAMC graduation ceremony held on 18 June 1999.

Nomination packets are due by 19 March 1999. The POC for this year's awards are CPT Andrea Stahl (202-782-7823/6391/6389) and Mr. William Woodcock (202-782-7829). Please do not hesitate to call if you are interested in knowing more about this award, or would like a nomination packet.

IRB Calendar

The following Institutional Review Board (IRB) meetings will be held in the months of March, April, and May, 1999:

CLINICAL INVESTIGATION COMMITTEE (CIC):

2 March
9 March
6 April
13 April
4 May
11 May

HUMAN USE COMMITTEE (HUC):

16 March
23 March
20 April
27 April
18 May
25 May

All meetings will begin at 1300 and will be held in the Fourth Floor Conference Room, Building 6, WRAMC.

WRAMC Research Course held on 4 and 5 March

DCI presented the first WRAMC Research Course of 1999 on 4 and 5 March at the Town Center Hotel in Silver Spring, MD. This course is sponsored by WRAMC in conjunction with the US Army Medical Command (MEDCOM), and is required of all current and prospective Principal Investigators who perform or who plan to perform research at WRAMC.

The course was attended by nearly eighty individuals, both military and civilian. Air Force and Navy personnel attended as well as Army personnel. Employees of the Henry M. Jackson Foundation and the TRUE Foundation were present, as well as visiting Army personnel from Ft. Belvoir, VA, Carlisle, PA, and from the DCI of Brooke Army Medical Center in San Antonio, TX.

(Continued on Page 4)

From the Research Admin Service:

The Research Administration Service (RAS), DCI requests that for all orders of reprints on publications, that the requestor submits, along with their request, a copy of the notification of publication clearance. This clearance memo should have been received by the PI prior to publication of the article.

Additionally, there are recent changes with regard to the Army Travel Entitlement program which went into effect on 1 January of which all potential travelers should be aware. First, there were some changes in per diem rates, which are available on the Internet at www.dtic.mil/perdiem/. Also, travelers should know that effective 1 January, the maximum lodging per diem included in CONUS does not include an amount for lodging taxes. Taxes are to be considered a separate lodging expense and are limited to the taxes on reimbursable lodging costs. However, for OCONUS, the maximum amount allowed for lodging DOES include an amount for lodging taxes. Also, a reminder, an original, itemized receipt for lodging is required when claiming lodging expense reimbursement. A credit card receipt is not acceptable.

There are still more changes with respect to travel entitlements. The MIE (Meals and Incidental Expense) tiers have increased. The new rates are \$30, \$34, \$38, \$42, and \$46. Also, the DTOD (Defense Table of Distance) will now be used for all distance calculations, replacing all existing distance calculation material used by DoD.

Lastly, a change to the Joint Travel Regulations (JTR) for civilians: when official travel is within the CONUS, and requires at least four consecutive nights of TDY/PCS lodging, the cost of laundry, dry cleaning, and pressing of clothing is now a separate reimbursable expense, in addition to per diem. For travel OCONUS, these are not separate reimbursable expenses.

For questions regarding any of the above, please see Mr. Ed Garcia, Chief, RAS, DCI, in Room 4009, Building 6, or call him at (202) 782-7829.

**Welcome to the following
new DCI employees:
Deborah Kessler--Research Review
Service
William Woodcock--Research
Administration Service**

ATTEND BMAR!!!

In order to be fully compliant with JCAHO and WRAMC guidelines, all DCI personnel must be up to date in their BMAR training. DCI is among the leaders at WRAMC in BMAR compliance, but we need to keep up the great work! BMAR will be held on the following dates in March-May, 1999. BMAR is held from 0730-1200 in the Joel Auditorium, Building 2:

8 March
11 March
25 March
8 April
22 April
6 May
20 May

The following DCI personnel have birthdays in the months of March, April, and May:

Jeffrey Anderson
Jana Bednarek
Elmer Jenkins
Mary Jane Muchui
Maged Abdel-Rahim
Verna Parchment
Walter Van Summers
Marty Green
Aneeta Patel

Happy Birthday, but please don't forget to attend your BMAR training!!

DCI on the WWW
<http://www.wramc.amedd.army.mil/departments/dci>
DCI news and information
Tools for investigators
and much more!!!

Inquiring Minds is published six times a year by the Department of Clinical Investigation, WRAMC, as a service to DCI employees and the WRAMC research community.

Any submissions or questions about content should be directed to the editors:
Mr. William Woodcock, (202) 782-7829
CPT Andrea Stahl, (202) 782-7823

Inquiring Minds Mar/Apr 1999 2

CIRO Update

The following information comes from the Clinical Investigation Regulatory Office (CIRO), at Ft. Sam Houston in San Antonio, Texas:

--FY99 could be the most successful year ever for Cooperative Research and Development Agreements (CRDAs). A CRDA represents an agreement between the Government and a private organization to exchange technology and resources in order to promote research. These CRDAs must be approved by the local medical center, the collaborating partner, and CIRO for the transfer of technology to begin. Most importantly, the protocol must first be approved before work can begin. To date in this FY, CIRO has approved 33 CRDAs for Army medical centers, worth almost \$2 million. Twenty-one of these CRDAs have been in support of WRAMC research. There are also 13 additional CRDAs which are currently being processed through CIRO.

--The final coordination for DoD Directive 6000.8 (Funding and Administration of Clinical Investigation Programs) has begun. The new revision contains a clause that mandates the informed consent document specify whether or not the research subject volunteer will be compensated for participating in the research. Consent form boilerplates should indicate this change as of now.

--CIRO receives "Investigator Agreements" that indicate consent between an individual investigator and a private organization to collaborate on research projects. **These documents are ILLEGAL!!** Only the Chief, CIRO can legally obligate the government through use of a CRDA.

--All assurance statements should be reviewed to make sure that they do not expire soon. Assurance statement paperwork should be submitted to CIRO in a timely manner.

--CIRO now has a site on the WWW. Their address is <http://kmmn.army.mil/auth/hckb/ci.html>. At this site can be found Army Regulations, CFRs, DoD Directives, policy statements, official reports, newsletters, etc.--all geared towards research activities.

--Regarding oncology group studies, many oncology group protocols are now requiring the research site to get the drug directly from the manufacturer and are no longer providing the drug themselves. It is a violation of AR 40-38 to receive the drug **FREE OF CHARGE** if it is being received from the manufacturer. The drug may only be obtained free of charge when it is provided by the oncology group itself.

--Regarding the enrollment of nonbeneficiaries in clinical research, AR 40-38 prohibits the enrollment of nonbeneficiaries in clinical research that is funded with P-8 (medical) funds.

--CIRO is at your service to assist you at DSN 471-2511 or commercial (210) 221-2511.

Inquiring Minds Mar/Apr 1999 3

Recent WRAMC Publications

Congratulations to the following authors for these recently published papers. This list was compiled from a recent MEDLINE search of the literature. All listed articles have been cleared through DCI and the Public Affairs Office. If you've recently published, and we have not included your publication, please let us know and it will be listed in the next copy of the newsletter.

Aronson NE, Wortmann GW, Johnson SC, et al. Safety and efficacy of intravenous sodium stibogluconate in the treatment of leishmaniasis: recent U.S. military experience. *Clin Infect Dis* 1998; 27:1457-64.

Hirota WK, Loughney TM, Lazas DJ, Maydonovitch CL, Rholl V, Wong RK. Specialized intestinal metaplasia, dysplasia, and cancer of the esophagus and esophagogastric junction: prevalence and clinical data. *Gastroenterology* 1999; 116:277-85.

Kelly WF, Crawley EA, Vick DJ, Hurwitz KM. Spontaneous partial expectoration of an endobronchial carcinoid. *Chest* 1999; 115:595-8.

Kenner JR, Aronson NE, Benson PM. The United States military and leishmaniasis. *Dermatol Clin* 1999; 17:77-92, viii.

Miner TJ, Shriver CD, Flicek PR, et al. Guidelines for the safe use of radioactive materials during localization and resection of the sentinel lymph node. *Ann Surg Oncol* 1999; 6:75-82

Moul JW. Pelvic muscle rehabilitation in males following prostatectomy. *Urol Nurs* 1998; 18:296-301.

Polhemus ME, Aronson NE. Persistent nephrolithiasis after discontinuation of indinavir therapy. *Clin Infect Dis* 1998; 27:1536-7.

Preston DM, Bauer JJ, Connelly RR, et al. Prostate-specific antigen to predict outcome of external beam radiation for prostate cancer: Walter Reed Army Medical Center experience, 1988-1995. *Urology* 1999; 53:131-8.

Roy MJ, Koslowe PA, Kroenke K, Magruder C. Signs, symptoms, and ill-defined conditions in Persian Gulf War veterans: findings from the Comprehensive Clinical Evaluation Program. *Psychosom Med* 1998; 60:663-8.

Statler JD, Ronsiville JA, Depper MH, Rao KC. Bilateral carotid artery dissection during the Army physical fitness test. *Mil Med* 1998; 163:857-60.

WRAMC Research Course (continued)

The Research Course began on 4 March with a talk by COL Maria Sjogren, MC, Chief, DCI, orienting attendees to DCI services and the personnel who perform those tasks. Next, Dr. Audrey Chang, Acting Chief, Research Review Service, DCI spoke on how a protocol is processed through DCI. Dr. David Cruess of USUHS described the basics of research study design. Following Dr. Cruess, MAJ Lisa Moores, MC, a 1997 recipient of the Bailey K. Ashford Award, gave an "investigator's perspective" on how to effectively develop a research protocol. Ms. Robin Howard of DCI then spoke about how to use statistical methods to your benefit in the protocol planning process.

Following Ms. Howard, MAJ Mike Tuttle, MC, Assistant Chief, DCI, discussed how the concept of "Research Review" does not end when a protocol is approved, but is indeed, an ongoing process. After MAJ Tuttle, COL Carl Alving of WRAIR gave a philosophical overview of scientific methodology and the nature of scientific discovery. Ms. Corinne Maydonovitch of DCI ended the day with a talk which offered attendees tips on how to maintain protocol compliance throughout the life of the protocol.

On 5 March, COL Louis Diehl, MC, began the day with a history of regulations in military medical research. He was followed by MAJ (Ret) Dale Vander Hamm, who discussed recent developments in the field of human subject protection regulations. COL James Kikendall, MC then spoke on how to write an informed consent document, and Mr. Scott Murdoch of the Center Judge Advocate, WRAMC ended the course with a talk on the nature of scientific misconduct, how to identify it, and how to avoid it.

DCI plans an offering of the long course in September. In addition, an abbreviated version of the course is scheduled for 14 April.

Short Research Course to be held 14 April

DCI, WRAMC also presents a short version of the DCI Research Course. The short version of the Research Course is intended for administrators, service chiefs, or supervisors who find themselves dealing with research-related issues, and for very experienced investigators who need to update themselves on the current research environment at WRAMC. The short course is NOT a substitute for the long course, but a compliment to it.

The next short course will be held on Wednesday, 14 April in Vorder Bruegge Auditorium in Building 1, WRAMC. The course will run from 0800 to 1230. There is no registration fee.

For more information or for registration information, call Mr. Derrick Hunter, Secretary to the Chief, DCI at (202) 782-6389.

The DCI Molecular Biology Course--what, who, when

DCI recently completed its 2nd Molecular Biology Course in February. The course was conducted over four consecutive Wednesday afternoons in the DCI research labs, located in Building T-2. This research course is designed to provide an introduction to the concepts and techniques associated with molecular biology. Major R. Michael Tuttle (Assistant Chief, DCI) is the primary instructor for the course.

Following a short block of instruction designed to provide an overview of the subject area, students move to the laboratory where DCI research operations staff guide them in performing the molecular techniques. Students learn and perform basic molecular biology techniques such as DNA/RNA isolation and analysis, as well as more advanced techniques like the Polymerase Chain Reaction (PCR) and High Performance Liquid Chromatography (HPLC).

If you are interested in attending the next DCI Molecular Biology Course, or if you have any questions about the course, please contact Mr. Derrick Hunter at (202) 782-6389. The next course is tentatively scheduled for sometime this summer.

DCI is SHARPP...

**Striving to
Help
All
Researchers from
Planning to
Publication**

Recently- approved protocols at WRAMC

Congratulations to the following primary investigators for their recently approved protocols. These protocols received final approval in January or February.

Department of Medicine

Endocrinology

The Effect of Retinoic Acid on Sodium-Iodide Symporter mRNA Expression in Thyrocytes Circulating in the Blood Stream--A Pilot Study
PI: MAJ Joseph C. Wood, MC

General Medicine

Disordered Sleep and Depression as Predictors of the Effectiveness of Low-Dose Nortriptyline in Chronic Headache Prophylaxis
PI: MAJ Glenn Tomkins, MC

Diagnostic Accuracy of Pleural Fluid Cholesterol and Lactate Dehydrogenase in Identifying Exudates vs. Transudates
PI: CPT Joseph T. Daniels, MC

Hematology-Oncology

CALGB 9863: Phase I Study of Irenotecan (CPT-11) in Patients with Abnormal Liver or Renal Function with Prior Pelvic Radiation Therapy
PI: MAJ John C. Byrd, MC

Infectious Disease

A Phase I/II Study of the Safety, Survival, and Trafficking of Autologous CD4-zeta Gene-Modified T Cells with and without Exogenous IL-2 in HIV Infected
PI: LTC Naomi Aronson, MC

Nephrology

The Impact of Therapeutic Plasma Exchange on the Medications Used in Transplantation
PI: CPT Kevin Stiles, MC

Na⁺, K⁺-ATPase Inhibitor in the Mechanism of Hypertension in Diabetes Mellitus
PI: Christina M. Yuan, LTC

Patterns of Protein Size-and Charge-Selectivity in Clinical Kidney Disease
PI: MAJ James D. Oliver, MD

Pulmonary & Critical Care Medicine

The Effect of Nocturnal BIPAP on Exercise Performance in Patients with Severe Chronic Obstructive Pulmonary Disease
PI: MAJ Lawrence Lepler, MC

Rheumatology

Rheumatoid Arthritis of the Robust Reaction Type
PI: CPT Thomas A. Rennie, MC

The Clinical Efficacy and Tolerability of Moderate Dose Oral Compared to Subcutaneous Methotrexate in Rheumatic Arthritis: A Prospective Crossover Trial
PI: CPT Christopher Parker, MC

Department of Nursing

E-Mail as a Communication Tool in Army Nursing Management
PI: MAJ Caterina Lasome, AN

Stress Inventory
PI: COL Janet Harris, AN

DPALS

The Prevention of Transfusion Transmitted Rickettsial Disease by Leukocyte Depletion (Filtration), Utilizing Ehrlichia *cafeensis* as Model
PI: CPT Robin M. Whitacre, MS

Plasma Lyophilization Utilizing Baxter PL2410 Plasma Bags
PI: LT Robert Davis, MS

Examination of the Effect of Pre-Storage Leukodepletion and Freezing on WBCs in Fresh Frozen Plasma
PI: CPT Melanie A. Sloan, MS

A Pilot Study of Refreezing Peripheral Blood Stem Cells: Is Stem Cell Recovery Acceptable for Patient Infusion?
PI: CPT Barbara J. Bachman, MS

Department of Psychiatry

Assessing Pre-Military Psychiatric Illness, Risk Factors Leading to Early Onset of Psychiatric Illness, and Inter-Rater Reliability of Psychiatric Diagnosis
PI: LTC Cameron E. Ritchie

Department of Surgery

Orthopedics

Braided Hamstring Grafts Versus Unbraided Grafts and Patellar tendon Grafts: A Biomechanical Study
PI: CPT John C. Tis, MC

Audiology

Spectral Shape Discrimination by Normal-Hearing and Hearing Impaired Listeners
PI: Jennifer Lentz, DAC, Ph.D.

Peripheral Vascular Surgery

Does Protease Gene Expression Vary by Location in the Lower Extremity in Patients with Primary Varicose Veins or Chronic Venous Insufficiency as Compared to Controls?
PI: LTC David L. Gillespie, MC

DENTAC

Absorption Rate for a New Bioabsorbable Membrane--A Pilot Study
PI: COL Daniel M. Theberge, MC

Other Facilities

An Analysis and Comparison of Pharmacy Service Provider Selection Among Military Beneficiaries for Maintenance Medication
PI: Major John Spain, MS

Compliance with National Asthma Management Guidelines at a Military Outpatient Treatment Facility: A Provider Practice Pattern Study
PI: Sajidah I. Husain, M.D.