

Inquiring Minds



News and notes from the Department of Clinical Investigation
Walter Reed Army Medical Center
Washington, D.C.

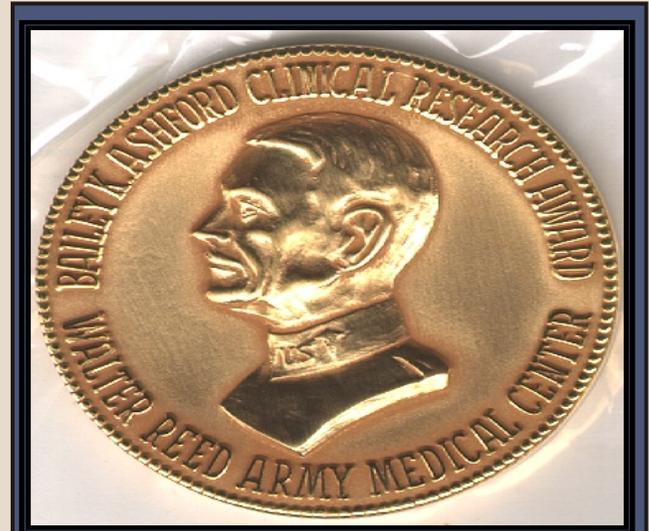
April 2002

Congratulations to the Bailey K. Ashford Research Award Nominees!

The Department of Clinical Investigation is proud to announce the nominees for the 28th Annual Bailey K. Ashford Clinical and Laboratory Research Award. DCI received a record number 44 nominations this year. The nominees are:

Clinical: LT David Allen (Nephrology), CPT Hiroshi Andrews (Internal Medicine), CPT David Bell (Internal Medicine), CPT Scott Brietzke (Otolaryngology), CPT Christopher Cote (Otolaryngology), MAJ Darrin Cox (General Surgery), MAJ Mark Cummings (Gastroenterology), CPT Peter Dunaway (Gastroenterology), CPT Michael Ellis (Internal Medicine), MAJ Jay Erickson (Neurology), CPT Christopher Glanton (Nephrology), CPT Geoffrey Grammer (Psychiatry), CPT Bruce Greenberg (Internal Medicine), MAJ Melanie Guerrero (Pulmonary & Critical Care), CPT(P) William Kelly (Pulmonary & Critical Care), CPT Mary Klote (Internal Medicine), MAJ Roy Langlely (Endocrinology), MAJ Jack Lewi (Endocrinology), CPT Vineeth Mohan, USAF (Endocrinology), CPT Malcolm Napier (Nephrology), MAJ Edmond Paquette (Urology), MAJ Benjamin Starnes (Vascular Surgery), CPT Stephen Thomas (Infectious Disease), CPT John Tis (Orthopaedics), & MAJ Fernando Trespalcacios (Nephrology).

Laboratory: MAJ Karla AuYeung (Pediatric Gastroenterology), MAJ Andrew Bauer (Pediatric Endocrinology), CPT Ronald



BKA Symposium: 2 May

Ceruti (Rheumatology), CPT Bryan Fisk (Internal Medicine), CPT(P) Joseph Flynn (Hematology/Oncology), MAJ Mark Fukuda (Infectious Disease), MAJ Lloyd Ketchum (Hematology/Oncology), CPT(P) William Lefkowitz (Neonatal/Perinatal), CPT Jeffrey Musser (Anesthesiology), MAJ Joseph Orchowski

(Continued on page 6)

New & Improved DCI Human Research Protocol Template

The Department of Clinical Investigation is continually working to improve the efficiency and effectiveness of the review of research protocols submitted for approval.

In recent months, DCI has updated and improved the template used to develop human research protocols. The template includes "Timesavers" and other pointers on how to make the review process go expeditiously for you.

Walter Reed researchers are now requested to use the new template, Human.doc, which can be found at <http://www.wramc.amedd.army.mil/departments/dci/templates/frame.htm>.

Please discard the floppy disk you may have received at the DCI Research Course -- the protocol template on the disk is now outdated.

DCI would also like to remind investigators that other templates are also regularly updated and are located on the DCI website. Thank you for your cooperation.

Inside This Issue

| | |
|--|---|
| FAQs Regarding IRB Exempt Research Projects..... | 2 |
| IRB Calendar..... | 2 |
| Correlation Coefficient and Regression..... | 3 |
| USUHS Reschedules Research Day..... | 4 |
| DCI Lectures & Talks Now Available..... | 4 |
| WRAMC Researchers Making Waves..... | 5 |
| Clinical Research Meetings & Conferences..... | 6 |
| Recent WRAMC Publications..... | 7 |
| DCI Information Resource Support..... | 8 |
| Recently Approved WRAMC Protocols..... | 9 |

FAQs Regarding IRB Exempt Research Projects

Who decides if my research is exempt from IRB review?

Although there are types of research that are considered exempt from IRB review, this decision is made at an institutional level. WRAMC staff cannot decide on their own whether research is exempt or not. At WRAMC, DCI has a mechanism in place to establish the status of research and must be consulted prior to the starting any research endeavor.

What type of research is considered exempt for IRB review?

Certain types of research do not fall within the purview of the Institutional Review Board (IRB) and may qualify for exempt status. The types of research activities that may qualify for exempt review are described in 45 CFR 46.101(b) and (c), 32 CFR 219.101(b), and AR 40-38, Appendix B. In order to qualify for exempt status the project must involve no more than minimal risk to the research subjects. Request for exemption from HUC/IRB review may be made for the following categories:

- Health Care Delivery & Epidemiology
- Educational Tests
- Educational Methods
- Public Behavior (Surveys, interviews or observation of public behavior)
- Existing Records or Specimens

Are retrospective chart reviews exempt from IRB review?

Retrospective chart reviews fall under the category of "Existing Records and Specimens." Retrospective chart reviews, without identifiers, are exempt from review and approval by the Human Use Committee (HUC). However, retrospective chart reviews must be granted exempt status prior to beginning work. Case reports (< 10 cases) without identifiers do not fall under the purview of this exempt review mechanism and are not considered research.

I believe that my research qualifies for exempt status. Is there an application that I need to fill out for this type of research?

Yes. Projects that qualify for exempt review do not require preparation of a full human use protocol application packet.

However, a HUC/IRB Exemption Certification Application must be completed and submitted to the DCI Exempt Protocol Coordinator. Refer to the DCI website for an exempt protocol review application ("ExemptReview.doc") & instructions ("ExemptReview-ins.doc"). Please be sure to complete Table 1 and include it with the application.

What is the exempt review process once my application has been submitted?

Once the application has been completed and submitted to the Exempt Review coordinator, it is then distributed to at least two members of the HUC or one member of the HUC and the Chief, DCI. These members independently determine whether the proposed project is exempt from IRB review. If the reviewers agree that the proposed research is exempt from HUC review, a letter granting exempt status is prepared by the Chief RRS and provided to the PI. The project is assigned a unique work unit number for tracking purposes only. The action is reported to the HUC at the next meeting for informational purposes only. If the proposed research requires HUC review, a memo from the Chief of RRS is provided to the PI denying the request for exempt status. The PI will need to prepare a full protocol application packet for review by the CIC and/or HUC committee.

Do I have to submit an Annual Progress Report (APR) for my exempt protocol?

Currently, there is no continuing review for the exempt project, such as an annual progress report or audit.

Can I receive funding for an exempt protocol?

Funding from DCI for exempt protocols is limited to travel (\$1000 for a TDY trip to present the results of the research); this funding is included in the limit of 2 funded protocols per fiscal year. No other support, such as consumable supplies or computer support, is available for exempt protocols.

Who is the POC for exempt protocols at DCI?

Ms. Vicki Miskovsky at 202-782-7833 or Vicki.Miskovsky@na.amedd.army.mil.

IRB Calendar

The following Institutional Review Board (IRB) meetings will be held in the months of April, May & June 2002:

CLINICAL INVESTIGATION COMMITTEE (CIC):

| | | |
|----------|--------|---------|
| 02 April | 07 May | 04 June |
| 16 April | 21 May | 18 June |

HUMAN USE COMMITTEE (HUC):

| | | |
|----------|--------|---------|
| 09 April | 14 May | 11 June |
| 23 April | 28 May | 25 June |

LABORATORY SUBCOMMITTEE:

18 April

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC):

13 June

All meetings will begin at 1300, except HUC meetings which will start at 1200. All meetings will be held in the fourth floor conference room, Building 6, WRAMC.

Research Alert List

In order to provide better service to Walter Reed researchers, the DCI is establishing a Researcher Alert List.

The Researcher Alert List will consist of important periodic updates on policy changes, procedures, regulations, etc. that directly impact Walter Reed medical researchers.

For example, DCI has been receiving a record number of new protocols in the past two months, and has made a number of changes to assure these protocols are reviewed in a timely manner. We will be announcing these changes on the Researcher Alert List shortly.

If you are a Principal Investigator, Associate Investigator, research nurse, or want to be kept informed of key research developments, it is important that you be included on this list.

Don't be left in the dark. To be added to this List, email alfreda.dempsey@na.amedd.army.mil and type "Alert List" in the Subject box.

Correlation coefficient and regression: Concepts to consider

By Gregory Fant, Ph.D., M.S.P.H., Biostatistician

In the text "Intuitive Biostatistics," Motulsky (1995, p. 302) provides a nonmathematical explanation of when to use a correlation coefficient and when to use a regression. Many investigators are unaware of the differences between the two statistical techniques. This piece will briefly summarize and expand upon the discussion provided by Motulsky (1995).

A correlation coefficient should be used when the statistical goal is to quantify whether a linear association is present between two variables. The measurements for the variables are merely recorded, and the variables do not have a causal relationship to each other. The conceptual variables in a research project may be measured as either continuous- or ordinal-level data.

Technically, the value of the correlation coefficient is important to the researcher. The correlation coefficient may take a value between 1.0 and 0.0, where a value of 1.0 indicates a linear relationship and a value of 0.0 indicates no linear relationship. A negative sign in front of the correlation coefficient indicates that the line formed from the data for the two variables is "falling" from left to right in relation to the horizontal axis. (This axis is, also, known as the x-axis.) This situation is consistent with an inverse linear change between the two variables. A positive sign in front of the correlation coefficient indicates that the line formed from the data for the two variables is "rising" from left to right in relation to the horizontal axis; this situation,

on the other hand, indicates that there is a direct linear change between the two variables.

Several correlation coefficients exist, and selecting the one to use depends, in part, on the level of measurement utilized to record the conceptual variables. If the measurements for each variable are at the interval or ratio level (or, continuous-level data) and parametric conditions are assumed, then a Pearson correlation coefficient should be used. On the other hand, if the measurements for each variable are at least at the ordinal level and nonparametric conditions are assumed, then a Spearman correlation coefficient should be used. If one variable is recorded as continuous level data while another variable is recorded as ordinal level data, then the Spearman correlation may be used (Pett 1997, p. 274).

A "p-value" is less important when reporting the results of a correlation test. Since the possibility exists that a "significant" p-value may be found for a weak correlation between two variables, an investigator should examine and interpret the value of the Pearson correlation coefficient (or another correlation test, as appropriate). Salkind (2000) provides an interpretation of the correlation coefficient based on the range of the correlation coefficient. In the table below, a Pearson correlation coefficient used to quantify the association between two variables that lies between 0.2 and 0.4 is a "weak relationship," no matter what the p-value indicates.

| Interpretation of a correlation coefficient | |
|---|--------------------------|
| Size of the Correlation Coefficient | General Interpretation |
| 0.8 to 1.0 | Very strong relationship |
| 0.6 to 0.8 | Strong relationship |
| 0.4 to 0.6 | Moderate relationship |
| 0.2 to 0.4 | Weak relationship |
| 0.0 to 0.2 | Weak or no relationship |

Source: *Statistics for people who (think they) hate statistics* by Neil Salkind. Thousand Oaks: SAGE Publications, 2000, p. 96.

By contrast, a regression should be used when the statistical goal is to predict a variable from another variable. That is, a regression should be used when the goal is to predict the value of a dependent variable, y, from an independent variable, x. If the independent variable is manipulated, wrote Motulsky (1995), a linear regression should be used. Generally, a linear regression should be used when the data for each variable (x, y) is measured as continuous data and when parametric conditions are assumed. If the dependent variable is dichotomous; if the independent variables are measured as either continuous- or categorical-level data; and if nonparametric conditions are assumed, then a bivariate logistic regression should be employed.

The key difference between the two statistical techniques lies in the statistical goal. In application, the statistical goal is the result of adequate articulation of a testable study

question in the research protocol. Here is a "rule of thumb:" The correlation test seeks to quantify an association between two variables while the regression seeks to predict a value of a dependent variable from the values of independent variables. For a more detailed discussion, please read any statistical text or the suggested readings (see below). The WRAMC DCI biostatisticians can, also, explain the difference between these statistical techniques. Please call to schedule an appointment to discuss the possible application of either technique in the development of a study protocol.

Citations and Suggested Readings:

"Intuitive Biostatistics" by Harvey Motulsky (New York: Oxford University Press, 1995).

"Statistics for people who (think they) hate statistics" by Neil Salkind. (Thousand Oaks: SAGE Publications, 2000).

"Nonparametric Statistics for Health Care Research" by Marjorie Pett (Thousand Oaks: SAGE Publications, 1997).

USUHS Reschedules Annual Research Day for 15-16 May

The Uniformed Services University of the Health Sciences (USUHS) has rescheduled the ninth annual Faculty Senate Research Day & Graduate Student Colloquium for 15 and 16 May 2002. This year's theme is "The Postgenomic Era: Implications for Research, Education, and Public Health."

Research Day is held to promote basic science and clinical research collaboration among investigators at USUHS, WRAMC, the National Naval Medical Center, the Naval Medical Research Center, WRAIR, the Armed Forces Radiobiology Research Institute, the Henry M. Jackson Foundation for the Advancement of Military Medicine and other affiliated institutions.

The event seeks to promote research career enhancement and to educate the researcher in such topics as animal use, grants administration, new methodologies, ethics, patent issues, and radiation & lab safety. Research Day also aims to encourage student awareness and involvement in research activities.

The two day event will include invited lectures addressing this year's theme, workshops, and oral & poster presentations by USUHS graduate students and other affiliated institutions. The deadline to submit abstracts for presentations is 22 April and is available online.

For more information including the tentative schedule, submission of abstracts, registration, etc., see <http://www.usuhs.mil/resday/rd2002.html>.



Statistical Analysis Using SPSS: Levels 1, 2, & 3

The DCI, Research Review Service, will be offering a three-part series of workshops to help the clinical investigator learn SPSS statistical analysis software & concepts.

These courses are for military and civilian clinician researchers (and aspiring researchers) at WRAMC and designed to give 'hands-on' experience in utilizing statistical analysis software. The content of each session is as follows:

Level I: An Overview of Data Coding and Data File Creation

Level II: Statistical Methods for Comparing Differences between Two Groups

Level III: Nonparametric Statistics in Health Care Research

The course will be limited to 12 participants and is free of charge to WRAMC personnel. Each participant will attend all three courses with Level I a prerequisite for Levels II and III.

The course will meet on 3 consecutive Thursday afternoons in July (11, 18, 25 July) from 1330-1530. The courses are held in the DCI Computer Room (Bldg 6, Room 4075).

For further information or to register, please see the DCI website or contact Ms. Robin Howard at (202)782-7878 or via e-mail at Robin.Howard@na.amedd.army.mil.

DCI Lectures & Talks Now Available!

DCI has currently made available on its website a series of PowerPoint lectures and talks. These presentations are from various DCI educational offerings including the Research Course. Current titles and presenters include:

- Biostatistics & Clinical Epidemiology (Dr. Gregory Fant)
- Critical Appraisal Reading (LTC Raul Marin)
- Gifts, Grants & Loans (LTC Raul Marin)
- Human Subject Protection (Dr. Dale Vander Hamm)
- Doing "Informed Consent" (LTC Christina Yuan)
- Overview of DCI (LTC Raul Marin)
- Protocol Processing from "A to Z" (Corinne Maydonovitch)
- Research Publication Issues (LTC Charles Bolan)
- Tissue Banking Issues and Concerns (Eric Marks, M.D)
- Experimental (Study) Design (LTC Raul Marin)
- The Science of Medicine (LTC Raul Marin)
- Research in Clinical Medicine (Part I, II, & III; LTC Raul Marin & Dr. Gregory Fant)

- Study Design, Statistical Bias (Part I & II; Dr. Gregory Fant & Robin Howard)
- Scientific Misconduct (Jay B. Winchester)

Presentations will be regularly added. To view these lectures & talks or for an updated list, please see the DCI website. Click on "Education: Courses, Lectures & Other."

DCI will gladly present these lectures upon request at individual department and service grand rounds, didactics, etc. POC is LTC Raul Marin at (202)782-7840.



Department of Clinical Investigation

Walter Reed Army Medical Center

WRAMC Researchers Making Waves: No increased rate of carotid artery stenosis with head & neck carcinoma patients

This is a new section in the newsletter in which DCI randomly picks a WRAMC department/service and profiles a recent article of interest by that department/service. This article profiles the Department of Surgery, Otolaryngology-Head & Neck Service.

According to a recently published study, there is no increased rate of occult atherosclerotic carotid artery disease (ASCAD) in patients with squamous cell carcinoma of the head neck region (HNSCCA).

A team from the WRAMC, Department of Surgery, led by CPT Christopher Cote, M.D., completed this study to determine whether patients with HNSCCA have an increased risk of occult ASCAD compared with the general population. Carotid artery stenosis, which can lead to stroke, has risk factors common to head and neck cancer. It is imperative to identify patients with carotid stenosis as the risk of a stroke can be reduced with surgery.

Stroke and head & neck cancer are both devastating diseases in society. Stroke is the third leading cause of death, while cancer is the second leading cause in the United States. Cancer of the head & neck region accounts for about 4% of all new cases.

This study was performed to identify the prevalence of ASCAD in the population of patients with a diagnosis of HNSCCA using color flow duplex imaging. This is a noninvasive test that employs ultrasound imaging allowing one to view the flow of the blood vessels in color while simultaneously providing a sound waveform analysis. This allows for detection and measurement of arterial stenosis

and flow restricting or flow disturbing abnormalities.

Forty-nine patients with a diagnosis of HNSCCA completed a demographic and risk factor questionnaire followed by a duplex screening examination. The most common risk factor identified was tobacco smoking in 41 of 49 patients (84%). Alcohol use was also widely prevalent (74%). However, none of the patients in the study showed clinically significant carotid artery stenosis. Dr. Cote noted, "it was somewhat surprising to see that none of our patients had significant carotid stenosis since many of them had some of the same risk factors for stroke, particularly smoking."

Dr Cote concluded that even though patients with HNSCCA usually have risk factor(s) associated with ASCAD, the rate of ASCAD was not different from that found in the general population. Thus, this subpopulation of patients with head and neck cancer do not necessarily benefit from routine screening for carotid disease. "Of course, any patient that has other conditions that may indicate carotid disease should be tested, such as those with a history of stroke or a bruit in the neck (noise heard with a stethoscope). Larger studies are needed to identify further patient characteristics that increase stroke risk," CPT Cote added.

Cote CR, Goff J, Barry P, Casler J. **The prevalence of occult carotid artery stenosis in patients with head and neck squamous cell carcinoma.** *Laryngoscope.* 2001 Dec;111(12):2214-7.

DCI would like to welcome the following new personnel:

Roscoe Brunson (Grants Manager)
SPC Dawn Hoch (Admin. Assistant)
Mary-Frances Kornak (Biometrics)
Melanie Oringer (Protocol Coordinator)
Patrician Shirriel (Admin. Coordinator)

New Laboratory Subcommittee

The Laboratory Subcommittee has recently been established to review and approve tissue banking sub-studies, cadaver protocols, and animal research. The Subcommittee will meet on a monthly basis. The first meeting will be April 18 at 1300 in Building 6.

For more information, contact Edward Bartlett, PhD, IRB Administrator at edward.bartlett@na.amedd.army.mil.

DCI is SHARPP..

Striving to

Help

All

Researchers from

Planning to

Publication

Clinical Research Meetings & Conferences

Below is a list of meetings and conferences focusing on various aspects of clinical research. For more information, please see the specific website:

April 5-7, 2002: The State of Bioethics: Form Seminal Works to Contemporary Explorations. This conference is hosted by the Kennedy Institute of Ethics, Georgetown University, which is a teaching and research center offering ethical perspectives on major policy issues. This conference will focus on the role that seminal works have played and continue to play in the field of bioethics.

<http://www.georgetown.edu/research/kie/>

April 8-9 2002: The Community IRB Member: Neighbor & Partner. This conference held in Gaithersburg, Maryland is for IRB members and will: 1) focus on finding and educating organizations with potential to provide new community members 2) highlight success stories of community members and IRB administrators 3) explore unmet needs and issues among community members 4) explore the concept of "community".

<http://www.orau.gov/communityirb>

April 24-26, 2002. Accountability in Clinical Research: Balancing Risk & Benefit. Sponsored by the National Patient Safety Foundation, this conference will examine the funding, management, conduct and accountability of research involving human subjects from the operational, regulatory and ethical perspectives. This conference, held in Indianapolis, Indiana, is intended for investigators, IRB members, and clinical research administrators.

<http://www.npsf.org/html/accountability.html>

6-8 May 2002. 14th Annual Tri-Service Clinical Investigation Short Course. This annual conference is held in San Antonio, Texas and is sponsored by the U.S. Army Clinical Investigation Regulatory Office and the Henry M. Jackson Foundation for the Advancement of Military Medicine. This course serves as a venue for educating researchers and administrators responsible for overseeing and ensuring the ethical treatment of human research subjects enrolled in clinical research studies sponsored by the U.S. Army, Navy, and Air Force.

Personnel from all three Armed Services will be present. For more information, please contact CIRO at (210)221-2511 or DSN: 471-2511.

June 17-21, 2002. Ethics of Research with Humans: Past, Present, & Future. Sponsored by the University of Washington School of Medicine, Department of Medical History & Ethics, this course reviews the origins and development of the ethics and regulation of human research, examines the current federal regulations and their applications, and explores the emerging issues in research with humans that ethics and regulation must take into account.

<http://depts.washington.edu/mhedep/conedu/rsethc/index-re.html>

National Human Subject Protections Education Workshop Program. The Office for Human Research Protections (OHRP) sponsor a series of workshop throughout the year on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects.

<http://ohrp.osophs.dhhs.gov/wrkshp.htm>

National Human Research Protections Advisory Committee (NHRPAC) Meetings: These meetings address a wide spectrum of issues regarding research involving human subjects and are scheduled to be held on a quarterly basis. For a meeting schedule with links to materials from past meetings see:

<http://ohrp.osophs.dhhs.gov/nhrpac/mtgs.htm>

PRIM&R Meetings: Public Responsibility in Medicine and Research (PRIM&R) hosts a series of workshops throughout the year focusing on the advancement of research programs and to the consistent application of ethical precepts in both medicine and research. These conferences address a broad range of issues in biomedical and behavioral research, clinical practice, ethics, and the law. Conferences for Cy2002:

<http://www.primr.org/conferences.html>

Congratulations to the BKA Research Award Nominees! (Cont from pg 1)

(Orthopaedics), CPT Aaron Pitney (Pediatrics), MAJ Scott Rehrig (General Surgery), MAJ James Rick (Pediatric Gastroenterology), MAJ Michael Rosner (Neurosurgery), LCDR William Scouten, USN (Pediatrics), LCDR Joanne Sutton, USN (Pediatrics), LTC Richard Trotta (Infectious Disease), CPT Clesson Turner (Pediatrics), MAJ Michael Weber (General Surgery).

The BKA is presented annually to the graduating trainee who has contributed the most significant research during his/her years of training at WRAMC. Finalists will be chosen by a selection committee, with each finalist presenting his/her research findings at the BKA Symposium on 2 May in Joel Auditorium at 1300 hours. DCI invites the WRAMC community to join us for these

presentations.

All finalists will be presented with an Army Commendation Medal, with the award winners (one from each category) presented with an engraved medallion and a \$750 prize at the graduation ceremony on 14 June.

A poster session will also be included as part of the symposium to feature some of the exceptional research achievements of our graduating residents and fellows in Rm 2H26 from 1000 to 1700 hours.

For questions about the award or symposium, please contact CPT Ken Capps at (202) 782-7823 or via E-mail at Ken.Capps@na.amedd.army.mil.

Recent WRAMC publications

Congratulations to the following WRAMC investigators on their recently published papers. This list was compiled from a recent MEDLINE search of the literature. Listed articles have been cleared through DCI and the WRAMC Public Affairs Office. If you have recently published, and we have not included your publication, please let us know so we may list your publication in the next issue of the newsletter.

Cote CR, Goff J, Barry P, Casler J. **The prevalence of occult carotid artery stenosis in patients with head and neck squamous cell carcinoma.** *Laryngoscope*. 2001 Dec;111(12):2214-7.

Lentz JJ, Leek MR. **Psychophysical estimates of cochlear phase response: masking by harmonic complexes.** *J Assoc Res Otolaryngol*. 2001 Dec;2(4):408-22.

Abbott KC, Hypolite I, Poropatich RK, Hshieh P, Cruess D, Hawkes CA, Agodoa LY, Keller RA. **Hospitalizations for fungal infections after renal transplantation in the United States.** *Transpl Infect Dis*. 2001 Dec;3(4):203-11.

Paquette EL, Peppas DS. **Lower pole ureteral obstruction secondary to fecal impaction in an 8-year-old girl.** *Tech Urol*. 2001 Dec;7(4):299-301.

Klemme WR, Cunningham BW, Polly LD DW Jr. **Microradiographic and histopathologic findings in a human cage explant after two-level corpectomy: a case report.** *Spine*. 2002 Jan 1;27(1):E15-7.

Kaplan KJ, Torske KR. **Pathologic quiz case: a 3-year-old boy with swelling of the right mandible.** *Arch Pathol Lab Med*. 2002 Jan;126(1):107-8.

Erickson JC, Carrasco H, Grimes JB, Jabbari B, Cannard KR. **Palatal tremor and myorhythmia in Hashimoto's encephalopathy.** *Neurology*. 2002 Feb 12;58(3):504-505.

Patrician PA. **Multiple imputation for missing data.** *Res Nurs Health*. 2002 Feb;25(1):76-84.

Svoboda SJ, McHale K, Belkoff SM, Cohen KS, Klemme WR. **The effects of tibial malrotation on the biomechanics of the tibiotalar joint.** *Foot Ankle Int*. 2002 Feb;23(2):102-6.

Marquart L, Mather MK. **Photo quiz. Piloileiomyomas.** *Cutis*. 2002 Feb;69(2):111, 127-8.

Patrician PA. **Multiple imputation for missing data.** *Res Nurs Health*. 2002 Feb;25(1):76-84.

Dhawan A, Hospodar PP. **Isolated posttraumatic posterior dislocation of the radial head in an adult.** *Am*

J Orthop. 2002 Feb;31(2):83-6.

Brown BA, Marx JL, Ward TP, Hollifield RD, Dick JS, Brozetti JJ, Howard RS, Thach AB. **Homocysteine: a risk factor for retinal venous occlusive disease.** *Ophthalmology*. 2002 Feb;109(2):287-90.

Abbott KC, Hypolite IO, Hshieh P, Cruess D, Taylor AJ, Agodoa LY. **Hospitalized congestive heart failure after renal transplantation in the United States.** *Ann Epidemiol*. 2002 Feb;12(2):115-22.

Svoboda SJ, McHale K, Belkoff SM, Cohen KS, Klemme WR. **The effects of tibial malrotation on the biomechanics of the tibiotalar joint.** *Foot Ankle Int*. 2002 Feb;23(2):102-6.

O'Malley PG, Rupard EJ, Jones DL, Feuerstein I, Brazaitis M, Taylor AJ. **Does the diagnosis of coronary calcification with electron beam computed tomography motivate behavioral change in smokers?** *Mil Med*. 2002 Mar;167(3):211-4.

Abbott KC, Mann S, DeWitt D, Sales LY, Kennedy S, Poropatich RK. **Physician-to-physician consultation via electronic mail: the Walter Reed Army Medical Center Ask a Doc system.** *Mil Med*. 2002 Mar;167(3):200-4.

Kelly WF, Eliasson AH, Stocker DJ, Hnatiuk OW. **Do specialists differ on do-not-resuscitate decisions?** *Chest*. 2002 Mar;121(3):957-63.

Johnson VV, Gaertner EM, Crothers BA. **Fine-needle aspiration of renal angiosarcoma.** *Arch Pathol Lab Med*. 2002 Apr;126(4):478-80.

CITI Web Based Research Course Reminder

DCI would like to remind all current and potential Principle Investigators, Associate Investigators, and Research Coordinators that a new web based research course is now available. DCI has elected to use the Collaborative IRB Training Initiative (CITI) Human Subjects Research Education Module, which is operated and maintained by the University of Miami. For more information and to register for this course, see the DCI website.

DCI Information Resource Support

POCs: J. Gregory Rose, MS Computer Specialist (202) 782-7884, 0409 (Fax)
greg.rose@na.amedd.army.mil

Guy Durant, Contractor, Computer Specialist (202) 782-7889, 0409 (Fax)
Guy.durant@na.amedd.army.mil

Location & Hours: WRHCS Bldg. 6 (Borden Pavilion), Rm. 4075 (Lab & Offices)
HOURS OF OPERATION: Monday - Friday 0800-1700

Resources: Provides specific and general automation resources, information, and support to the DCI mission, staff, and protocol related research/researchers throughout WRHCS which helps to expedite the research process. **In general, services are accessible to all researchers who are working with DCI staff member to establish or have an established protocol project through DCI.** These resources include:

(1) a research-oriented resource network service (DCINET) under AMEDDNA accessible 24 hours daily through (a) client/server networking for all applications and resources used by staff and specific personnel; and (b) web/browser interface to register for courses; obtain departmental information and resources such as templates, news, schedules, and regulations at <http://www.wramc.amedd.army.mil/departments/dci> which is DCI's Home Page;

(2) a Computer Lab (Room 4075) for high availability of required automation; ie, hardware and software applications, with consultations on how to use and apply to protocol-related research; and

(3) a class-oriented teaching and workshop environment for statistical and other research specific applications.

SOFTWARE/HARDWARE SUPPORTED PRESENTLY:

The DCI Information Resource Center supports the most common software applications, as well as some specialized packages. All software/hardware support listed is only offered in the DCI computer lab. End-user workstations include Wintel Pentium and Macintosh PowerPC (6100 and 8100) computers. Peripherals include color scanners, color printers, a 3-foot wide DesignJet poster printer, Polaroid Palettes (slide production), Nikon 35mm slide scanner, and Zip, Jaz, LS120 disk drives. IBM compatible software applications include:

- Statistical/analytical programs such as SPSS 6.1,8.0,9.0,10.0; BMDP, Minitab, Statistics 4.0, Power Analysis, Log & Stat Exact, etc.
- Sigmaplot 2001 for scientific graphing
- CorelDraw 9.0 for poster preparations
- Adobe Pagemaker 6.5 and Illustrator, MS Publisher, & various photo-editing software
- Harvard Graphics 3.0 & 4.0
- Visual Dbase 5.0
- Microsoft Office 4.3, 95, 97, 2000 Professional Suites (MS Word, PowerPoint, Excel, Access)
- WordPerfect 6.1, 8.0, 2000
- AMEDDNA supplied applications

Macintosh applications include (not updated in couple years due to lack of demand):

- Statistical/Analytical programs such as Systat, StatView, and SAS-JMP
- MS Office Suite 98 and Previous Office (PowerPoint 4, Word 6, Excel 5)
- WordPerfect 3.5
- Photoshop 3.0, Pagemaker 5.0, and Persuasion 2.1
- Netscape Navigator

In order for DCI to continue the above services all researcher are asked to sign in and out of the automated ledger when utilizing our services in the computer lab. This allows DCI to evaluate software and hardware needs and increase our support efforts.



Recently Approved Protocols at WRAMC

Congratulations to the following principal investigators on their recently approved protocols. The following protocols have been approved since last issue.

Department of Allergy-Immunology

LTC Michael Nelson, MC 02-33005E: The role of skin testing and RAST in the evaluation of bee sting allergy

Department of Clinical Investigation

Marcos Rojkind, M.D. 01-92005: The Role of the Acute Phase Response in Alcoholic Liver Cirrhosis

Marcos Rojkind, M.D. 01-92006: Alcohol-Induced Liver Fibrosis: An In Vitro Model

Department of Medicine

Cardiology Service

LTC Anwar Malik, MC 01-12002: Remote Echocardiographic Consults - Diagnostic Concordance - Intra and Inter Consults

Endocrinology Service

LTC(P) Henry Burch, MC 02-13009E: Comparison of total hyperthyroid time in patients previously pretreated or not pretreated with antithyroid drugs before ablation with radioiodine for Graves' disease: A retrospective analysis

Gastroenterology Service

COL Kent Holtzmuller, MC 01-14005: Tele-Hepatitis Phase I: Validation of Desktop Video Teleconferencing for Evaluation of Patients with Hepatitis C

MAJ Mark Cummings, MC 02-14009E: The significance of belching in upright reflux disease

MAJ Mark Cummings, MC 02-14010E: The significance of postprandial reflux in upright reflux disease

General Medicine

CPT Dimitri Cassimatis, MC 02-10009E: Evaluation of Knowledge and Practices of Internal Medicine Residents or Chronic Hepatitis C

Hematology-Oncology Service

MAJ Lloyd Ketchum, MC 01-15010: CALGB 49801-Phase III Trial of Tamoxifen Alone Vs. Tamoxifen Plus Radiatin for Good Risk Duct Carcinoma In-Situ (DCIS) of the Female Breast

COL Joseph Drabick, MC 01-15011: CALGB 159902-Molecular Markers of Pleural Involvement in Resected Non-Small Cell Lung Cancerr

MAJ Edward Gorak, MC 01-15012: CALGB 509901-Phase II Study of Melanoma Vaccine (NSC #683472/675756, IND 6123) and Low-Dose, Subcutaneous Interkeukin-2 in Advanced Melanoma

COL Joseph Drabick, MC 02-15013: CALGB 79803-Phase III Chemo prevention Trial of Selenium Supplementation in Persons with Resected Stage 1 Non-Small Cell Lung Cancer

CPT Joseph Flynn, MC 02-15015: CALGB 99904-Adjuvant Androgren Deprivation Versus Mitoxantrone Plus Prednisone Plus Androgren Deprivation in Selected High Risk Prostate Cancer Patients Following Radical Prostatectomy, Phase III

Infectious Disease

LTC Clifton Hawkes, MC Work Unit # 02-19001E: Anthrax Exposure Clinic: Tolerability, Compliance and Follow-up of Antibiotic Prophylaxis Regimens

Nephrology Service

CPT Christopher Glanton, MC 02-11003: Does the Combination of Pirfenidone, Enalapril, and Lovastatin Reduce Proteinuria and Glomerular/Interstitial Histologic Score in Rats with PAN-Induced SGS and Existing Nephrotic Syndrome?

(Cont. on page 10)

Recently Approved Protocols at WRAMC (cont. from page 9)

Pulmonary & Critical Care Medicine Service

| | |
|--------------------------|--|
| Yvonne Taylor, DAC | 01-17004: A Comparison Between an Internet Communications Platform and Traditional Medical Care as a Health Care Management Model in Patients with Obstructive Sleep Apnea |
| MAJ Andrew Shorr, MC | 02-17008: Tc-99m Depreotide Scanning in Sarcoidosis |
| LTC Lisa K. Moores, MC | 02-17006E: Retrospective Validation of Clinical Prediction Scores for Diagnosing Pulmonary Embolism |
| MAJ Andrew Shorr, MC | 02-17015E: Acute Respiratory Distress Syndrome (ARDS) following renal transplantation: Incidence, risk factors, and outcomes |
| LTC Joseph M. Parker, MC | 02-17016E: Clinical Characteristics of patients with vocal cord dysfunction at Walter Reed Army Medical Center and Tripler Army Medical Center. |

Department of Neurology

| | |
|------------------------|---|
| LTC Robert Labutta, MC | 02-71004: Evaluation of the Analgesic Effects of Botulinum Toxin A in Post-Operative Pain and Recovery After Lumbar Spine Surgery |
| MAJ Marc Difazio, MC | 02-71005: Assessment of the Efficacy of Botulinum Toxin A for Treatment of Chronic Neck and Back Pain Secondary to Trauma or Acute Strain |
| MAJ John Choi, MC | 02-71004E: Feasibility Study of Wireless Teleradiology in Acute Brain and Cervical Spine Injury |

Department of Nursing

| | |
|----------------------------|---|
| CPT Anne Mitzak, AN | 02-75011: Intravenous Site Selection and Its' Role in Reducing Propofol Injection Pain |
| LTC Laura Brosch, AN | 02-75012: The Relationship of Job Stress to Job Satisfaction and the Intent of Army Nurse Corps Officers to Stay in Active Military Service |
| LTC Patricia Patrician, AN | 02-75013: Providers' Evaluation of Alternative Medications Use by Patients |
| Janice B. Agazio, DNSc | 02-75013E: Military Nurses' Perceptions of Autonomy in Fixed Facilities: Implications or Readiness |

Department of Obstetrics and Gynecology

| | |
|--------------------------|--|
| LTC Scott Rose, MC | 02-43006: GOG O174:-A Randomized Phase III Trial of Weekly Parenteral Methotrexate Versus "Pulsed" Dactinomycin as Primary Management for Low Risk Gestational Trophoblastic Neoplasia |
| MAJ Larry Maxwell, MC | 02-44006: The Chemoprotective Effects of Progestin on the Endometrial Lining |
| LTC Ernest G Lockrow, MC | 02-44019E: Laparoscopic appendectomy using the laparoscopic coagulating shears |

Department of Orthopaedics and Rehabilitation

| | |
|---------------------------|--|
| LTC William Doukas, MC | 02-24012: Global Advantage CTA Humeral Head Prosthesis for Treatment of Cuff Tear Arthropathy |
| CPT Kevin Kirk, MC | 02-24013: Initial Stability of Cementless Revision Femoral Stems after Extended Trochanteric Femoral Osteotomy: A Biomechanical Analysis of Distal Stem Design |
| CPT Kevin Kirk, MC | 02-24014: Bean-Shaped" Foot Treated by Cuneiform/Cuboid Osteotomy: Long Term Follow-up |
| CPT Philip J. Belmont, MC | 02-24018E: <i>In Vivo</i> Accuracy of Transpedicular Thoracic Screws in Patients with and without Coronal-Plane Spinal Deformities |

(Cont. on page 11)

Recently Approved Protocols at WRAMC (cont. from page 10)

| | |
|---|---|
| CPT Aman Dhawan, MC | 02-24019E: Thoracic Pedicle Screw Trajectory: Which method allows greatest margin of error |
| MAJ Joseph Orchowski, MC | 02-24020E: Reliability of Pedicle Probing in the Thoracic Spine |
| LTC Martha Lenhart, MC | 02-24021E: Use of Telemedicine in Optimizing Care for Phalangeal Fractures |
| MAJ Joseph Orchowski, MC | 02-24022E: Analysis for Salvage of Straight Forward Pedicle Screws with the Anatomic Trajectory in the Thoracic Spine |
| Department of Pediatrics | |
| MAJ Andrew Bauer, MC | 02-65005: The Potential Role of Gastric Inhibitory Polypeptide in Obesity and in Cortisol Secretion |
| Department of Radiology | |
| MAJ Jong-Ho Choi, MC | 02-47004: Multi-Center Trial of Detection of Colorectal Neoplasma by CT Virtual Colonoscopy in a Screening Population |
| Lorraine G. Shapeero, M.D., DAC | 02-47007E: Imaging Abnormalities of the Proximal Tibiofibular Joint: Diagnosis and Prevalence |
| Department of Surgery | |
| <i>Anesthesiology Service</i> | |
| LTC Steven Cohen, MC | 02-31003E: Intradiscal Electrothermoplasty: Risk Factors for Complications and Failures |
| <i>Army Audiology & Speech Center</i> | |
| Brian Walden, PhD DAC | 02-25004: Predicting Hearing Aid Microphone Preference in Everyday Listening |
| <i>Critical Care Medicine Service</i> | |
| MAJ Christian Popa, MC | 01-30001: Remote Management of the Critically Ill Patient Via Telecommunication |
| MAJ Anthony Ramage, MC | 02-30003: Oropharyngeal Decontamination for the Prevention of Ventilator Associated Pneumonia with Chlorhexidine Oral Rinse |
| <i>Neurosurgery Service</i> | |
| CDR Ross Moquin, MC | 02-22001: Pre and Post-Surgical Evaluation of Gait in Patient with L4/5 or L5/S1 Spondylolysis or Spondylolisthesis |
| <i>Ophthalmology Service</i> | |
| LTC Kraig Bower, MC | 01-2335-99c: Operational Assessment of Refractive Surgery for Rated Army Aviators: A Prospective Evaluation |
| <i>Otolaryngology-Head & Neck Service</i> | |
| LTC John Casler, MC | 00-2509: The Determination of a Suitable Animal Model for Teaching Endoscopic Surgery of the Paraanasal Sinuses Based on CT Imaging, Endoscopic Examination and Anatomical Skull Analysis |
| CPT Ian McLeod, MC | 02-32009: The Use of Intraoperative Rapid Parathyroid Hormone Assay in Predicting Postoperative Hypocalcemia Following Total/Near-Total Thyroidectomy |
| <i>Peripheral Vascular Surgery Service</i> | |
| MAJ Mary Parker, MC | 02-21002: Three-Dimensional Computed Tomography Versus Arteriography for Endovascular Aortic Graft Sizing |

(Cont. on page 12)

Attention DCI Employees! Don't Forget Your BMAR!

All DCI personnel must be up to date in their BMAR training. BMAR on-line is available at:

WWW.CMECOURSES.COM/DOD

Login is the first four(4) letters of last name and the password is the last five(5) numbers of your SSN. The BMAR course assignments will appear under the **My Course** tab. To take a course, simply click on the course link. To receive credit for a course you must complete all twenty-two(22) modules. As you complete each course, the course link will be removed from the **My Course** link and added to the **My Transcript** link. The online BMAR takes approximately 2½ - 3 hours to complete, with a test at the end to test your knowledge of the covered material.

DCI personnel are reminded to print off their evaluation sheets after they complete the training. These sheets certify that you have completed the course.

BMAR is still given didactically. The next didactic versions of BMAR will be given on 03 & 17 April, 08 & 22 May and 05 & 19 June. All BMAR sessions are from 0730-1245 in Joel Auditorium, Bldg 2..

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

Verna Parchment (01 April)
SPC Brian Reinhardt (06 April)
Maged Abdel-Rahim (13 April)
LTC Raul Marin (28 April)
Dan Rosen (1 May)
Roscoe Brunson (25 May)
Marty Green (30 May)
Audrey Chang (04 June)
Corrine Maydonovitch (10 June)
Michelle Porter (11 June)
Daisy Word (11 June)



Recently Approved Protocols at WRAMC (cont. from page 11)

LTC(P) Sean O'Donnell

02-21000E: Popliteal Entrapment - An anatomical review

CPT Matthew Wakefield, MC

02-21001E: Re-evaluation of carotid duplex for visual complaints: who really needs to be studied?

Urology Service

COL David McLeod, MC

01-2871-98c: Characterization of a Prostate Specific G-Protein Coupled Receptor (PSGR) in Prostate Cancer

COL Judd Moul, MC

02-2857-98f: A Deterministic Computer Model of Prostate Cancer Progression Following Radical Prostatectomy

Outside

LTC Dennis Driscoll, AN

02-85005: Nursing's Retention of Trauma Resuscitation Skills

Telemedicine Directorate

Mark Jacobs, MA, DoD

01-87001: The Comparison of Digital Camera Running Gait Analysis to the Telemedicine Consult System: A Pilot Study

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

Contact Information:

Walter Reed Army Medical Center
Department of Clinical Investigation
6900 Georgia Avenue, NW
Borden Pavilion (Bldg 6)
Washington, DC 20307-5001

Tel: (202) 782-6389

Fax: (202) 782-3881

E-mail: WRAMC.DCI@NA.AMEDD.ARMY.MIL

Any submissions or questions about content should be directed to CPT Ken Capps at (202) 782-7823.

