

# Inquiring Minds

News and notes from the Department of Clinical Investigation, WRAMC  
April, 2000

## The 26th Annual Bailey K. Ashford Research Award

The Department of Clinical Investigation, Walter Reed Army Medical Center, is proud to announce the 26th 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.

A selection committee determines the award finalists, who are then 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 15 May 2000 at 1300 hours at the Joel Auditorium, Building 2, WRAMC.

(Continued on Page 2)

## WRAMC Establishes an Institutional Biosafety Committee (IBC)

WRAMC has recently established a new institutional review board to review protocols that involve recombinant DNA therapy. The WRAMC Institutional Biosafety Committee (IBC) is a committee mandated by the National Institutes of Health Office of Biotechnology Activities (NIH/OBA, formally known as the Office of Recombinant DNA Activities) and tasked with "evaluating recombinant DNA research to identify potential risks to public health and the environment".

The WRAMC IBC is, by NIH regulation, composed of both WRAMC affiliated and non-affiliated members. The committee chair is LTC Kent E. Kester, MC, an infectious disease specialist currently assigned to the Department of Immunology at the Walter Reed Army Institute of Research. Other committee members include Alternate Chair, LTC Craig D.

Shriver, General Surgery Service; LTC Naomi Aronson, Infectious Disease Service; LTC Ricke Weickum, Oncology Pharmacy Service; LTC Bryan L. Martin, Department of Allergy & Immunology; LTC (P) Judd W. Moul, Center for Prostate Disease Research; LTC Thomas Burklow, Department of Pediatrics; MAJ Catherine Dinauer, Department of Clinical Investigation; MAJ Rajat Bannerji, Hematology-Oncology Service; Dr. Diarmuid E. Nicholson, Department of Clinical Investigation; Dr. Shyh-Ching Lo, Armed Forces Institute of Pathology; Dr. Kuan-Teh Jeang, National Institutes of Health; Dr. Jerome H. Kim, Henry M. Jackson Foundation; and Dr. Michelle R. Frazier-Jessen, Food & Drug Administration.

The IBC held its first meeting on 17 February 2000. A one-hour block of training, detailing the

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## IRB Calendar

The following Institutional Review Board (IRB) meetings will be held in the months of March, April, and May, 2000:

### CLINICAL INVESTIGATION COMMITTEE (CIC):

4 April  
11 April  
2 May  
9 May

### HUMAN USE COMMITTEE (HUC):

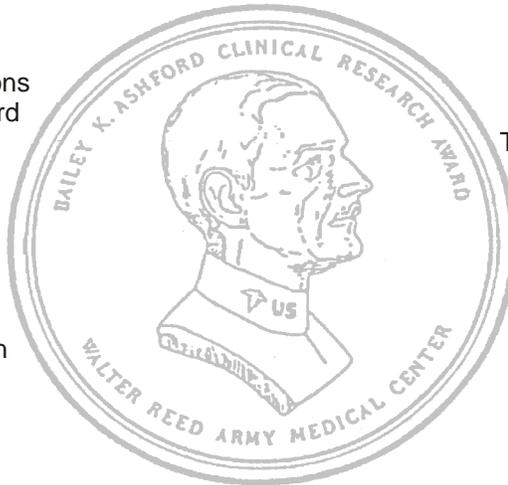
21 March  
28 March  
18 April  
25 April  
16 May  
23 May

All meetings will begin at 1300 and will be held in the fourth floor conference room, Building 6, WRAMC.

## Bailey K. Ashford Symposium set for 15 May (continued)

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, will be presented at the joint NNMC and WRAMC graduation ceremony to be held on 23 June, 2000.



The POC for this year's awards is MAJ Andrea Stahl, (202-782-7823/6391/6389). Please do not hesitate to call if you are interested in knowing more about this award or the upcoming symposium.

## The Triservice Bloodbank Fellowship Program: A Unique Training Opportunity at WRAMC

Company grade, Medical Service Corps officers desiring to become bloodbank program officers may apply for the Triservice Bloodbank Fellowship which is conducted at WRAMC. Successful completion of this program allows graduates to sit for the specialist in bloodbanking national certification examination. Most applicants to this program already hold a Bachelor's degree and are certified medical technologists. Each Service has its own methods for selecting the candidates who will enter the program.

At WRAMC, this program leads to the Masters of Science degree, as a Specialist in Applied Biology. In addition to classroom study, completion of a clinical research project is also required. In total, the program takes approximately eighteen months to complete. Coursework is taken at WRAMC, NIH, and WRAIR; ultimately, program participants travel to Bowling Green University for their thesis defense. This program is the only one of its kind in the military, and one of a few such programs nationwide. Being unique to the military, the WRAMC program is a triservice environment, including Army, Navy, and Air Force participants.

Participants in this program have their research protocol applications processed, approved, and funded through DCI. Recently, DCI had the opportunity to ask some recent graduates of the bloodbank fellowship program for their thoughts on the program and to share their experiences.

"Refreezing Peripheral Blood Progenitor Cells: Is Progenitor Cell Recovery Acceptable for Patient Infusion?" Was the thesis title of CPT Barbara Bachman, MS. These cells are important for the treatment of various cancers, including some forms of leukemia as well as of solid tumors. CPT Bachman's research looked into ways that these cells could be refrozen and

preserved while maintaining their viability. While CPT Bachman's research yielded promising results, she commented that her time in the fellowship was "the most demanding one and a half years of training I've experienced." While her experience in the program was very positive, CPT Bachman cautions potential program applicants to be prepared to work hard.

CPT Melanie Sloan, MS, completed a thesis entitled, "Examination of the Effects of Filtration and Freezing on White Blood Cells in Fresh Frozen Plasma (FFP)". Transfused white cells have been responsible for producing certain diseases in immunocompromised patients who have received unirradiated "cellular" blood products. FFP is not considered to be such a product. CPT Sloan's work investigated the presence of white blood cells in FFP, and to determine the differences in FFP which had been filtered prior to freezing and storage, as opposed to unfiltered FFP. CPT Sloan's advice to those who may be considering entering into the fellowship program includes understanding all of the administrative requirements needed to conduct research at WRAMC prior to starting the project. CPT Sloan thanks the DCI staff for being very helpful in that regard.

DCI thanks CPT Bachman and CPT Sloan for their comments, and also thanks LTC Michael Stanton, MS, Chief of Blood Services, DPALS, and Mr. William Turcan, Blood Bank fellowship program coordinator, for their assistance in this article. For more information about the blood bank fellowship program, please call LTC Stanton or Mr. Turcan at (202) 782-6210.

# More Gene Therapy Experiments Are Suspended Hospital, Patient Groups Cite Safety Concerns

A recent article reprinted from the Washington Post concerning gene therapy

By Deborah Nelson  
Washington Post Staff Writer

A Harvard-affiliated medical center and two patient advocacy groups have temporarily halted gene therapy experiments because of concerns raised by the September death of a Tucson teenager undergoing treatment at the University of Pennsylvania.

Beth Israel Deaconess Medical Center in Boston decided last week to suspend its gene therapy program, while the Cystic Fibrosis Foundation and Muscular Dystrophy Association have placed a hold on three human gene experiments they are sponsoring.

Representatives of all three institutions cited general safety concerns about gene therapy that surfaced in the months following the death of Jesse Gelsinger at Penn, rather than any specific problems with their own experiments.

"The reason that we decided to temporarily hold our clinical trials is that we put patient safety first," Michael Rosenblatt, interim president of Beth Israel Deaconess, said yesterday. "We want to benefit from the national discourse."

Gelsinger's was the first death attributed to gene therapy, a 10-year-old science that has attempted--so far without success--to treat cancer, AIDS and inherited diseases by altering people's genetic makeup.

Since then, the Food and Drug Administration temporarily suspended Penn's gene therapy program after uncovering numerous safety lapses in the clinical trial that killed Gelsinger; the National Institutes of Health discovered that gene therapy researchers elsewhere had failed to promptly report more than 600 illnesses and deaths among gene therapy volunteers to the agency as required; and Sen. Bill Frist (R-Tenn.) initiated hearings last week on whether the federal government's oversight of gene therapy is adequate.

The decision by Beth Israel Deaconess came less than a week after The Washington Post reported that the hospital had failed to immediately notify the NIH about three deaths and one serious illness among the first seven volunteers in another gene therapy experiment involving terminally ill cancer patients. Both Rosenblatt and the researcher said they did not know they were supposed to notify the NIH, which makes such information public, in addition to the FDA, which does not.

Federal regulations require researchers to report all deaths and serious illnesses among gene therapy volunteers to the NIH regardless of whether they are caused by the gene therapy, the underlying illness or something else. In this case, the lead researcher decided that earlier health problems caused the three deaths shortly after treatment, but that the therapy likely caused high fever and severe heart problems in a surviving volunteer. The medical center suspended the experiment following the serious illness last summer and had planned to restart it this month with an improved protocol.

Now, however, Rosenblatt said, the experiment won't resume until he gets some sort of signal from the FDA and the NIH that they consider gene therapy safe and will continue to support it. In addition, he said, he has stopped the one other gene experiment at the medical center, involving hemophilia patients, even though there have not been any deaths and only one serious but unrelated illness eight months after treatment.

NIH and FDA officials are exploring whether they need to improve the way gene therapy experiments are approved and conducted, as well as whether they should change the way adverse events are reported to the public.

"What we will be looking for is a reaffirmation of the commitment [to gene therapy] from these agencies," Rosenblatt said.

Representatives of the Muscular Dystrophy Association and Cystic Fibrosis Foundation also said they are waiting to see what comes out of regulators' discussions and the Senate hearings before proceeding.

The Muscular Dystrophy Association stopped an experiment it is sponsoring at Ohio State University that used a genetically engineered virus manufactured at Penn. The study was the first, long-awaited gene experiment on people with muscular dystrophy.

The FDA action against Penn had already stopped one of the two gene experiments sponsored by Cystic Fibrosis Foundation that used the same type of altered virus that killed Gelsinger. Ronald Crystal of Cornell University Medical College suspended the other one at the request of the Cystic Fibrosis Foundation.

# Research design in medical research studies

By Gregory Fant, PhD, MPA, MSPH

After reviewing the medical literature on a specific topic of interest wherein a clinical research question is proposed, the next major consideration facing an investigator is to develop a strategy to answer the question. Research design (also known as study design) is the formal name given to this consideration. Trochim (1999) wrote that research design is the structure describing how basic design elements interact with one another to address the central research question. The central research question contains the empirical indicators for the conceptual dependent (or outcome) variable and independent variables or risk factors. The strengths and limitations of a medical research study are related, in part, to the strengths and weaknesses inherent with the research design selected and modified by the investigator to answer the clinical research question.

The five, basic elements of research design include observations (or measures), treatments (or programs), groups, group assignment, and time (Trochim 1999). The design element of observation (or measures) refer to one measurement (e.g., body weight), an instrument with multiple items (e.g., a 10-item self-esteem scale), a complex multi-section instrument (e.g., a survey), or a battery of tests and measures administered at a specific encounter. Treatments refers to a specific intervention such as the administration of a particular surgical technique or something complex such as a infant care instructions. Usually, a research design includes groups of subjects studied. In a research design, study subjects may be assigned to a particular group by random assignment (e.g., randomly assign patients to one of two treatment groups), cutoff assignment (e.g., Patients with a lab test above a threshold value are assigned to one group or another), or in a nonequivalent manner (subjects with the exposure assigned to the case group while subjects without the exposure group are assigned to the reference group). The time element in a research design refers to the linear dimension of time where later time periods follow an earlier time period. With these elements, a research design can be depicted as shown in Figure 1 where subjects are randomly assigned to groups.

Research designs fall into one of three categories--randomized experiment, quasi-experiment, and non-experiment. (Trochim 1999). A true, randomized experiment has random assignment of units or subjects to one group or more. If the assignment of subjects is not random, then the next condition that must be assessed is whether or not control groups or multiple measures are needed. A quasi-experiment has either a control group or multiple measures. A non-experiment does not have a control group or multiple measures.

Observational Studies	Experimental Studies
Descriptive or case studies	Controlled trials Parallel or concurrent controls, either randomized or non-randomized Sequential controls, either self-controlled or crossover External controls (including historical)
Case-control studies (usually, retrospective) Causes and incidence of disease Identification of risk factors	Studies with no controls (ie, pilot studies)
Cross-sectional studies (usually, prevalence) Disease description Diagnosis and staging Disease processes, mechanisms	
Cohort studies (usually, prospective) Causes and incidence of disease Natural history, prognosis Identification of risk factors	
Historical cohort studies	

Table 1: Common research designs in medical research

The previous table classifies the study designs common to medical research studies into observational studies or experimental studies. Given the general categories of research designs outlined by Trochim (1999), Dawson-Saunders and Trapp (1990) provide a straightforward review of the research designs that are most frequently used in medical research. The quasi-experimental and non-experimental designs from Trochim (1999) are included under the observational studies by Dawson-Saunders and Trapp (1990). Not only do they describe each research design, Dawson-Saunders and Trapp (1990) also present the strengths and weaknesses associated with each design. Investigators should review the section on research design in Dawson-Saunders and Trapp (1990) early in the development of a research proposal.

A true understanding of a specific research design will highlight the necessity for addressing the elements of good research design early in the development of the research proposal. Selection of a research design for use in a study will affect the methods used to collect and statistically analyze data.

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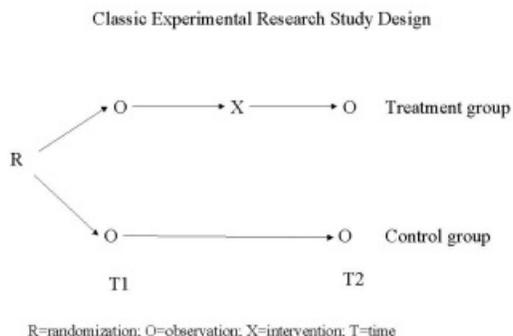


Figure 1: Classic experimental research design

# Father's Complaints Shut Down Research; U.S. Agencies Act On Privacy Concerns

A recent article reprinted from the Washington Post about privacy issues in research

By Jay Mathews  
Washington Post Staff Writer

Richard Curtin, a Defense Department budget analyst living in Falls Church, does not usually open his daughter Allison's mail, but in the fall of 1998 she was away at college and the envelope was large and thick.

He pulled out a 25-page questionnaire from a researcher at Virginia Commonwealth University who was studying twins, like Allison and her brother Kevin. Curtin read the questions. The more he saw, the less he liked. His daughter was being asked, among other things, if her father had ever suffered from depression or had abnormal genitalia. This seemed to him an invasion of his privacy.

Curtin complained to the Virginia Commonwealth researcher, who wrote back that there was nothing to worry about because the study was voluntary and names were kept confidential. Curtin also got nowhere when he wrote to VCU officials.

So he contacted federal regulators. As a result of his complaint and at least one other, most of VCU's medical research has been shut down. About 1,100 out of 1,500 VCU research projects have been halted while the Richmond university responds to demands from two federal agencies to improve its procedures for protecting research subjects' privacy and safety.

The Food and Drug Administration last month suspended 1,000 VCU studies involving human subjects, saying that a university review board had failed to adequately document its monitoring of the experiments. The FDA also required the school to hire an independent panel to review research policies and bring them into compliance with federal rules.

Yesterday, the federal Office for Protection from Research Risks ordered VCU to stop another 100 projects that are not FDA-regulated, citing similar problems. The agency told the university it had violated Curtin's rights by not seeking his consent before sending a questionnaire that asked for personal information about him, and it said that in another study VCU had broken rules on how blood samples should be taken.

VCU President Eugene P. Trani has told his faculty that he and research administrators "will work around the clock" to satisfy federal regulators and permit resumption of the 1,100 studies, which bring in more than \$10 million a year in federal funding.

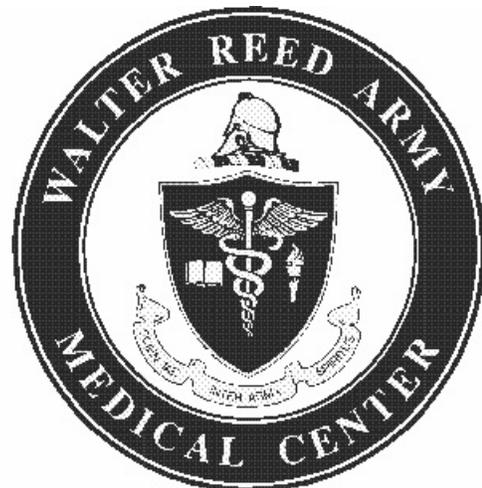
The federal actions "do not adversely reflect on the care of our research participants," William L. Dewey, vice president for research at VCU, said in an interview yesterday. "The participants in our research studies are our number one priority, and their safety has not been compromised."

Dewey said it could take as long as a year before the school has addressed all of the FDA's concerns and received permission to resume the FDA-regulated experiments. The other projects might be restarted in a couple of months, he said.

He said the researcher who was working on the twins project was following university rules that are among those now being reviewed. Dewey said he has not spoken to Curtin, whose identity had been kept confidential by federal regulators. But he said of the Falls Church father, "I can relate to his being concerned about this issue and I hope this will help us correct our procedures for everyone."

The disciplinary action against Virginia Commonwealth follows similar orders last year affecting Duke University, the Los Angeles Veterans Administration Hospital, the University of Illinois at Chicago and the University of Colorado Health Sciences Center. Health experts say the moves stem from growing concern among government officials and advocacy groups that federal protections for human research subjects are inadequate or poorly enforced.

Curtin said he is happy to see VCU take action, particularly against a review board "that was just not doing its job."



# Research design in medical research studies (continued)

The weaknesses inherent with a specific research design and what will be done to minimize them should be addressed during the development phase of a research project. Addressing design weaknesses during the collection of measurements in subjects of a group or, worse, during the statistical analysis of data is inefficient and counterproductive. The biostatistical techniques employed to analyze collected data should serve the research design and the research question that the design was meant to answer. Since the validity, generalizability, and possible conclusions of a clinical study are affected by any weaknesses in the study, Gordon (1978) was wise to remind seasoned and novice investigators to seek the assistance of competent help when selecting a research design.

Gordon, Michael. (1978). "Research Workbook: A guide for initial planning of clinical, social, and behavioral research projects." *Journal of Family Practice*, 7, p. 145-160.

Dawson-Saunders, Beth, and Trapp, Robert. (1990). *Basic and Clinical Biostatistics*. Norwalk, CT: Appleton & Lange.

Trochim, William. (1999). *Research Methods Knowledge Base, 2nd edition*. <http://trochim.human.cornell.edu/kb/design.htm> (accessed: Nov.24, 1999).

## 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.

Byrd JC, White CA, Link B, Lucas MS, Velasquez WS, Rosenberg J, Grillo-Lopez AJ. **Rituximab therapy in Waldenstrom's macroglobulinemia: preliminary evidence of clinical activity.** *Ann Oncol* 10(12):1525-27, 1999.

Clouse HR. **The impact of managed care in dentistry.** *General Dent* 47(2):210-16, 1999.

Dawson NA. **Response criteria in prostatic carcinoma.** *Semin Oncol* 26:174-84, 1999.

Grant KW, Seitz PF. **The recognition of isolated words and words in sentences: individual variability in the use of sentence context.** *J Acoust Soc Am* 107:1000-11, 2000.

Hocate PP, Jimenez CE. **Detection of distant medullary thyroid carcinoma metastases by Tc-99m arcitumomab scintigraphy.** *Clin Nucl Med* 25: 145-6, 2000.

Hwang I, Kulas PM, Starnes BW, Balingit AG, Shriver CD. **Incidental detection of carcinoid with Tc-99m-labeled carcinoembryonic antigen monoclonal antibody scintigraphy during evaluation of metastatic colon cancer.** *Clin Nucl Med* 24: 978-9, 1999.

Malik AK, Taylor AJ. **Can warfarin randomized trials be reproduced in 'real life'? Adherence to warfarin guidelines for intensity of anticoagulation in a university-based warfarin clinic.** *South Med J* 93: 58-61, 2000.

McClellan MD. **Patterns of orofacial movement velocity across variations in speech rate.** *J Speech Lang Hear Res* 43: 205-16, 2000.

Taylor AJ, O'Malley PG. **Detecting coronary calcification with electron beam computed tomography: its role in managing coronary artery disease.** *West J Med* 171: 338-40, 1999.

Vick DJ, Goodman ZD, Ishak KG. **Squamous cell carcinoma arising in a ciliated hepatic foregut cyst.** *Arch Pathol Lab Med* 123: 1115-7, 1999.

Welch Dinauer CA, Tuttle RM, Robie DK, McClellan DR, Francis GL. **Extensive surgery improves recurrence-free survival for children and young patients with class I papillary thyroid carcinoma.** *J Pediatr Surg* 34: 1799-804, 1999.

# Breast Cancer Researcher Admits Falsifying Data

An Article reprinted from the New York Times about research and medical errors

By DENISE GRADY

A South African researcher has admitted that he falsified data, and is retracting a widely publicized study claiming that bone-marrow transplantation and high-dose chemotherapy could prolong the lives of women with advanced breast cancer.

The admission of fraud came only after a team of American scientists visited the researcher's laboratory last week to examine his records, and found that they did not match what he had reported.

The researcher, Dr. Werner Bezwoda, of the University of Witwatersrand in Johannesburg, presented his findings last May in Atlanta at a major conference of the American Society of Clinical Oncology. Of five studies discussed at that meeting, his was the only one indicating that the arduous treatment helped women. The others showed no benefit. Dr. Bezwoda's results were widely reported, and taken as a ray of hope. Some researchers were eager to try his methods in this country.

But Dr. Bezwoda's findings differed so markedly from those of other researchers that other scientists were immediately skeptical. Even before the meeting ended, some were calling for an independent group to travel to Johannesburg to examine his data before scientists here tried to replicate his experiments.

A group of American cancer experts did so last week. Dr. Bezwoda let them see only part of his data, and they quickly found problems. They reported their findings to the university, which began its own inquiry.

Dr. Peter Cleaton-Jones, chairman of University of Witwatersrand Committee for Research on Human Subjects, said in a telephone interview that Dr. Bezwoda's study had compared two groups of patients, an experimental group given the high-dose treatment and a control group that was supposed to have been given a more conventional treatment. Dr. Bezwoda reported that the high-dose group had fared much better than the controls.

"But what he labeled as the control group was not accurate," Dr. Cleaton-Jones said. The control patients were given a completely different treatment from what was stated in Dr. Bezwoda's reports. Dr. Cleaton-Jones said that as far as he knew, no patients were harmed.

But, he said "the comparison he made was not valid." As a result, the study is worthless, researchers said.

Dr. John Durant, executive vice president of the oncology society, said, "It means you should just throw it out."

On Feb. 3, the University of Witwatersrand posted a news release on its Web site announcing the investigation of Dr. Bezwoda. It quoted a letter Dr. Bezwoda sent to colleagues on Jan. 30 admitting that he had "committed a serious breach of scientific honesty and integrity" and had misrepresented his results. Dr. Bezwoda has resigned from his university positions. A university spokeswoman, Martha Molete, said bluntly that Dr. Bezwoda had lied.

Asked how Dr. Bezwoda was allowed to present bogus work at the society's most important conference, Dr. Durant said the group had rigorous scientific standards, but essentially used an honor system, in which researchers submitted summaries of their work before the conference and assured the society that the research had been reviewed and approved by human research monitors at their own institutions.

"And we believe that's what everybody does, except this guy," Dr. Durant said. "He misled us, he misled the public, he misled the people who are being treated. I am very, very distressed, and very angry."

Dr. Durant was not part of the investigating group, but he said members told him they had discovered that Dr. Bezwoda circumvented the board at his university that was supposed to monitor human studies. "He was conducting this trial sort of on his own," Dr. Durant said.

The National Breast Cancer Coalition, a patient's advocacy group, said in a statement that the disclosures confirmed there was no data to support the use of high-dose treatment and bone marrow transplantation in breast cancer.

The treatment is one of the most contentious subjects in breast cancer, with some saying it is the only hope for women with advanced disease, and others saying women should not be subjected to its harsh side effects because it has not been proved to lengthen survival.

But Dr. Durant said the final verdict was not yet in, because the studies showing no benefit were still going on, and might eventually show that some patients were helped. Many doctors, though, say that if no benefit has shown up by now, any that does is likely to be extremely small.

# Recently- approved protocols at WRAMC

Congratulations to the following principal investigators on their recently approved protocols.

## Department of Medicine

### Cardiology Service

00-1202 SWITCH: Statins at WRAMC: Interventions for the Treatment of Cholesterol- An Observational Study of the Formulary Switch to HMG- coA Reductase Inhibitors Mandated by the Department  
Taylor, Allen LTC MC 12/20/99

1224-99 Non- Invasive Coronary Artery Disease Reversal  
Vernalis, Marina COL MC 1/31/00

### Dermatology Service

1832-99 Protocol Number ST-99-001 - A Randomized, Placebo-Controlled, Multiple-Dose, Double-Blind Study of the Efficacy of Terbinafine HCL Solution Spray, 1% for Prophylactic Treatment of Tinea Pedis in Military Personnel  
Keller, Richard LTC MC 12/15/99

### Endocrine Service

00-1301 The Effect of Retinols, Tamoxifen, and Octreotide on Cellular Proliferation and Control of Throglobulin, TSH Receptor, and Sodium-Iodide Synperter mRNA Expression in Thyroid Cancer Tumor Cell Lines  
Wood, Joseph MAJ MC 12/8/99

### Gastroenterology Service

00-1402 Is Schatzki's Ring Protective Against Acid Reflux?  
Winters, George R. III MC 2/4/00

### Hematology-Oncology Service

00-1501 CALGB 89804: A Randomized Phase III Trial of Two Different Regimens of CPT-11 Plus 5-Flurouracil and Leucovorin, Two Different Regimens of Oxalplatin (OXAL) Plus 5-Flurouracil and Leucovorin, and One Regimen of Oxaliplatin and CPT-11 compared to 5-Flurouracil and Leucovorin as Initial Treatment of Patients with Advanced Adenocarcinoma of the Colon and Rectum  
Willis, Carl R. MAJ MC 1/7/00

00-1601 A Feasibility Study of Campath-1H and GM-CSF Combination in Patients with Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma  
Byrd, John C. MAJ MC 2/4/00

1524-99 CALGB 19802: Phase II Study in Adults with Untreated Lymphoblastic Leukemia Testing Increased Doses of Daunorubicin During Induction and Cytarabine During Consolidation  
Byrd, John C. MAJ MC 12/21/99

1627-99 A Phase II Multicenter Study of Decitabine in Patients with Accelerated Phase or Blast Crisis of Chronic Myelogenous Leukemia (CML)  
Byrd, John C. MAJ MC 12/22/99

1630-99 A Randomized, Multicenter, Open-Label Study of Single-dose Filgrastim-SD/01 Versus Daily Filgrastim Following ESHAP Chemotherapy for Non-Hodgkin's Lymphoma  
Byrd, John C. MAJ MC 12/9/99

### Infectious Disease Service

1911-99 Linezolid (PNU-10076) Given Intravenously or Orally for Compassionate Use in Patients with Significant, Resistant Bacterial Infections  
Wortmann, Glenn MAJ MC 12/10/99

### Nephrology Service

00-1101 The Effect of Enalapril and Mycophenolate Mofetil in PAN-Induced FSGS in the Rat  
DeNunzio, Troy M. CPT MC 12/10/99

## Department of Obstetrics and Gynecology

4420-99 Hyperspectral Diagnostic Imaging of the Cervix  
Parker, Mary F. MAJ MC 2/7/00

## Department of Pediatrics

00-6503 Role of Thyroid Transcription Factor-1 in Differentiated Thyroid Cancer  
Fenton, Cydney MAJ MC 12/15/99

00-6504 Role of Focal Matrix Metalloproteinases in Different Thyroid Cancer  
Fenton, Cydney MAJ MC 12/28/99

## Department of Radiology

### Nuclear Medicine Service

00-4501 Feasibility, Accuracy, and Efficiency of an Internet Based Tele-Nuclear Consultation System for the Military. Phase I: Phantom Studies  
Hwang, Inku MAJ MC 12/8/99

## Department of Surgery

### Orthopedic Surgery Service

00-2402 A Comparison of Standard Intraoperative Fluoroscopy vs. Fluoroscopy Using the FluoroNav Stereostatic System  
Polly, David Jr. LTC MC 12/17/99

00-2403 The Relationship of Femoral Notching, Osteoporosis, and Supracondylar Fractures  
Shawen, Scott B. CPT MC 1/28/00

### Otolaryngology-Head & Neck Service

00-2501 Spectro-Temporal Properties of Auditory-Visual Integration for Understanding Spoken Language  
Grant, Ken W. Ph.D., DAC 12/30/99

00-2502 Efficacy of Endobronchial Adhesives in Experimental Lung Volume Reduction  
Mair, Eric A. LTC MC 1/6/00

2591-99 Complex Sound Analysis by Persons With Impaired Hearing (Application for NIH NRSA Post Doctoral Fellowship)  
Lentz, Jennifer J. Ph.D., DAC 12/29/99

## Gulf War Health Center

00-8901 Survey of Stressors and Their Impacts on Women in the Army and Army Reserves  
Engel, Charles C. LTC MC 1/20/00

# BMAR Calendar for March, April, and May, 2000

BMAR will be held on the following dates in March, April and May, 2000. BMAR is held from 0730-1200 in the Joel Auditorium, Building 2:

22 March  
5 April  
19 April  
3 May  
17 May

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

Jeffrey Anderson  
Jana Bednarek  
Elmer Jenkins  
Mary Jane Muchui  
Norman Gardner  
SPC Brian Reinhardt  
Maged Abdel-Rahim  
Verna Parchment  
Walter Van Summers  
Irene Green  
Dan Rosen  
Gregory Fant

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

### IBC (From Page 1)

responsibilities of biosafety committees was presented by Ms. Jacque Kovacic, Manager of Occupational Safety with the Henry M. Jackson Foundation. Ms. Kovacic discussed several significant issues. Importantly, she explained the broad functions of an IBC, which include reviewing and approving recombinant DNA proposals, defining appropriate containment levels for biological activities (i.e.: Biological Safety Levels 1-4), assessing proposed research facilities, reviewing the procedures, practices, training, and expertise of personnel involved in recombinant DNA research, and ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements outlined in the NIH guidelines.

In addition to discussing three proposed protocols, the committee made several important decisions on future operating procedures. Specifically, the committee decided that all principal investigators submitting a protocol for IBC approval must provide written responses to the questions listed in Appendix M of the May 1999 NIH Guidelines. NIH Guidelines are available on the web at <http://www.nih.gov/od/oba>. Additionally, DCI has created an Appendix M template for investigators to use when preparing this document for IBC review. The template is available at the DCI web site at <http://www.wramc.amedd.army.mil/departments/dci> under the *Protocol Template* heading in the folder marked *Gene Therapy Research*. Also available in this folder is the WRAMC SOP governing the operation of the IBC.

Protocols will be reviewed by the IBC following approval by the WRAMC Clinical Investigation Committee and the Human Use Committee. The IBC decided to meet quarterly but will consider meeting more frequently if warranted by the number of protocols to be reviewed.

Investigators who are planning to engage in research subject to IBC approval should consult with their DCI research protocol coordinators. As always, the DCI staff is available to answer any questions that might exist about this committee. Please call (202) 782-6389/6391 for further information.

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