

# WAKE FOREST UNIVERSITY

SCHOOL of MEDICINE  
THE BOWMAN GRAY CAMPUS

OFFICE OF RESEARCH  
<http://www.wfubmc.edu/or>

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ANGELA HORTON 62382

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## OFFICE OF CLINICAL TRIALS RESEARCH

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VICKIE HARDY, OPERATIONS MANAGER, FRIEDBERG CAMPUS  
61573

# PURSUIT

RESEARCH INFORMATION BULLETIN Vol. 17, No. 1 January 2003

## IMPORTANT ISSUES RELATED TO HUMAN RESEARCH

Wake Forest University Health Sciences is committed to the ethical principles and regulatory requirements for the conduct of human research. The ethical principles of respect for persons, beneficence and justice described in the Belmont Report and the regulatory requirements established in the Federal Regulations for the Protection of Human Subjects (45CFR46) establish the standards for the conduct of human research. To ensure continued commitment to these standards, researchers are reminded of the following requirements:

- Any research study that involves intervention or interaction with human subjects, obtaining or using information about human subjects, or obtaining or analyzing tissue, blood, or any other biological material from human subjects, must be reviewed and approved by the IRB.
- Informed consent must be obtained from all research subjects. Unless a specific waiver is granted by the IRB, signed informed consent containing all required elements must be obtained from each research subject or their legally authorized representative before their participation in the research study begins.
- Researchers obtaining even a single blood sample from a normal healthy volunteer for in-vitro analysis as part of a research study must obtain informed consent.
- Each research subject must be given a copy of the informed consent. Simply offering subjects a copy of the consent form is not sufficient.
- The most current IRB approved consent form must be used.
- Any changes in research activity, including changes to the informed consent or protocol must be reported to and approved by the IRB before they are implemented unless immediate change is required to ensure the safety of research subjects.
- Researchers must maintain complete and accurate research records.
- Researchers must provide a complete and accurate summary of research to the IRB for continuing review.

Any questions regarding the requirements for informed consent or the appropriate conduct of human research should be directed to the IRB Office at 716-4542.

\*See Insert for more IRB information.

**CONCERN LINES**

ANIMAL CARE & USE -  
716-5899

RESEARCH CONDUCT -  
716-0338

COMPLIANCE -  
1-877-880-7888

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**REGULATORY COMMITTEE  
DEADLINES**

ANIMAL CARE AND USE COMMITTEE -  
FEBRUARY 7 AND MARCH 7, 2003

INSTITUTIONAL REVIEW BOARD -  
NOON - FRIDAYS

\*\*\*\*\*

**INTRAMURAL RESEARCH  
SUPPORT COMMITTEE  
DEADLINES**

\*REGULAR AND INTERIM -  
APRIL 16, 2003

\* Clinical studies or other  
research involving humans  
are encouraged

**CORE FACILITIES UPDATE**

Below is a list of the Core Facilities listed on the Office of Research Website. If there is a core that your department is responsible for, please take a few minutes to review the information on the website ([http://www.wfubmc.edu/or/res\\_cores.html](http://www.wfubmc.edu/or/res_cores.html)). If any of the information is incorrect, or outdated, or, if your department has a core facility that is not listed on the website, please contact Amy Comer - 64549 or [acomer@wfubmc.edu](mailto:acomer@wfubmc.edu).

- Analytical Ultracentrifugation Facility
- Biomolecular Computing and Graphics Facility
- Cesium Irradiator Laboratory
- Circular Dichroism Spectroscopy Center
- Clinical Research Services
- Comparative Pathology Laboratory
- Fluorescence Lifetime Spectroscopy Facility
- Hypertension Core Laboratory
- Laser Light Scattering Laboratory
- Lipid Analytic Laboratory
- Lipid Surface Tension/Monolayer Facility
- Lipoprotein Analytic Laboratory
- Medical Imaging Laboratory
- Microarray Core Facility
- Micromed
- Molecular Genetics Computer Facility
- Neuropathology Research Laboratory
- Piedmont Triad Community Research Center Recombinant DNA Core Facility
- Positron Emission Tomography Center
- Rapid Reaction Kinetics and Spectroscopy Facility
- Recruitment Core
- Reproductive Endocrinology Laboratory

**Center for Investigative Neuroscience**

- Calcium Imaging Core Facility
- Cryostat Core Facility
- DNA Sequencing and Gene Analysis Facility
- Film Imaging Core
- Histology Core Facility
- Imaging and Light Microscopy Core Facility
- Molecular Biology Core Facility
- Electron Microscopy Core Facility

**Comprehensive Cancer Center of Wake Forest University Shared Resources**

- Analytical Chemistry-Mass Spectrometry Core Laboratory
- Analytical Chemistry-NMR (High Resolution Magnetic Resonance) Core Laboratory
- Analytical Imaging Core Laboratory
- DNA Synthesis Core Laboratory
- Electron Microscopy Core Facility (see Micromed)
- Experimental Therapeutics Core Laboratory
- Tumor Tissue Core Facility
- Molecular Graphics Core Facility
- Tissue Culture and Virus Vector Core Laboratory

**Public Health Sciences**

- Center for Community Research
- Health Services Research Center
- Medical Outcomes and Social Sciences (MOSS) Core
- Section on Biostatistics

## DEAR DR. OR

Dear Dr. OR:

My NIH grant ended August 31, 2002. In December, the Controller's Office notified me that there was an unspent balance left in the grant account. Since it is now January, and I still have work to do on my project, is it still possible to request a no-cost extension?

Signed,  
Underspent

Dear Underspent:

For grants covered under expanded authorities, the Institution can provide a 12 month no-cost extension and notify NIH that this has been done. However, NIH should be notified 10 days prior to the end date of the grant. Extensions cannot be granted just because there is money left in the account; there must be strong justification that there is still work to be done on the project. PIs should pay close attention to their monthly statements in the months before a grant is scheduled to end, and determine if a no-cost extension is needed. If so, they should contact the Office of Research to prepare the notification to NIH. Extensions requested after the grant has ended are not looked upon favorably by NIH. In your circumstance, you as PI would have to work with your Program Officer and the Grants Management Specialist at NIH to obtain approval prior to institutional action.

Questions for Dr. OR should be submitted in writing to Amy Comer, Office of Research, or by e-mail: [acomer@wfubmc.edu](mailto:acomer@wfubmc.edu)

## ATTENTION RESEARCH ADMINISTRATORS

North Carolina Society of  
Research Administrators  
(NCSRA)  
Annual Conference  
"Our First Line of Training"  
March 3 - 5, 2003  
Chapel Hill Sheraton  
Chapel Hill, NC

NCSRA is a resource for educators, leaders, managers, and administrators of every North Carolina organization involved in education, research and development. The annual meeting provides an accessible and comprehensive learning environment. For details about the conference including the agenda and registration materials contact Angela Horton, 62382.

## NEW ASSOCIATE DIRECTOR NAMED FOR TECHNOLOGY ASSET MANAGEMENT

Michael Batalia, Ph.D. has been appointed associate director of the Office of Technology Asset Management, effective January 6, 2003. Dr. Batalia comes to Wake Forest University Health Sciences from the Office of Technology Transfer at North Carolina State University, where he served as the interim associate vice chancellor and director of the office. Previously, Michael served as associate director, managing inventions and technology from the life sciences and physical sciences. Prior to his appointment at N.C. State, Batalia was a postdoctoral fellow at Lineberger Comprehensive Cancer Center at the University of North Carolina at Chapel Hill where his research focused on molecular immunology and structural biology. Dr. Batalia has a B.A. in chemistry from the University of Chicago and a Ph.D. in biochemistry from the University of Texas at Austin. "He has worked with many start-up companies and businesses licensing intellectual property into the commercial sector," said Spencer Lemons, director of Technology Asset Management. "We are extremely pleased to have someone of Michael's talent and experience joining our team." One function of this office at Wake Forest is to assist in developing startup companies.

## Women's Health Educational and Research Opportunities for Clinicians and Scientists

*For upcoming conferences and lectures, visit  
our calendar website at  
[www.wfubmc.edu/women](http://www.wfubmc.edu/women)*

### WOMEN'S HEALTH SEMINAR SERIES

#### **Attenuation of Human Breast Cancer Cell Growth by Angiotensin-(1-7), Feb 4, 2003**

Presented by Ann Tallant, PhD, Associate Professor, Hypertension and Vascular Disease Center/General Surgery. The seminar will take place at noon in the Sticht Center Auditorium. Dr. Tallant is a past recipient of a Women's Health pilot grant.

### RESEARCH WORKSHOPS: GRANTS AND MANUSCRIPTS

**Manuscripts Part II: How to Get Your Paper Published** focuses on navigating the peer-review process at biomedical journals. This is the final installment in the Women's Center's first series of workshops. Stay tuned for more details on upcoming workshops.

**To Register:** Call 713-4701 or [whcoe@wfubmc.edu](mailto:whcoe@wfubmc.edu)

**Date:** Monday, February 17, 8:30-10:30 AM

**Location:** Nutrition Center, Commons Conference Room 1

**Cost:** \$35.00

### WOMEN'S HEALTH PROMOTION SUMMIT

**February 17 through February 18, 2003**

In conjunction with the 14th Annual Art and Science of Health Promotion Conference, the Women's Health Promotion Summit is designed to bring women's health issues to the forefront of health promotion. There are two main educational goals for the Summit. First, the key health issues faced by women will be reviewed. Second, the ways in which health promotion concepts can be applied to meet these needs will be explored.

**Location:** Omni Shoreham Hotel, Washington, DC

**Cost:** \$395.00

**Visit** <http://www.healthpromotionconference.org> for more information.

### ANNOUNCING THE WOMEN'S HEALTH RESEARCH SUPPORT CORE

The Women's Health Center is pleased to announce a new resource for preparing grant proposals – the Research Support Core. Its purpose is to assist researchers, especially junior faculty, in the submission of proposals related to women's health research. The Core offers assistance with planning, study design, budget preparation, and editing – all free of charge.

The Core cannot:

- Write grant applications
- Assist with proposals that do not concern women's health or gender differences in disease prevalence or treatment

Researchers are assisted on a first-come, first-serve basis. One of the first set of Core users has already been funded! Beat the next deadline rush – if you think the Core could help you, contact the Director, Janeen Manuel ([jmanuel@wfubmc.edu](mailto:jmanuel@wfubmc.edu)) or the Assistant Director, Karen Klein ([kklein@wfubmc.edu](mailto:kklein@wfubmc.edu)) for a request form and assessment of needs.

### THE 5TH HEART DISEASE IN WOMEN: WHERE ARE WE NOW? WHERE ARE WE GOING?

**Saturday, March 29, 2003**

Directed by Rita F. Redberg, MD, MSc, FACC; Nanette Kass Wenger, MD, FACC

In cosponsorship with the University of California, San Francisco, Department of Medicine, Division of Cardiology; the American Society of Echocardiography; and the American Society of Nuclear Cardiology

**Location:** Chicago Hilton and Towers, Chicago, IL

**Visit** [http://www.acc.org/education/programs/brochures/redberg\\_mar03.htm](http://www.acc.org/education/programs/brochures/redberg_mar03.htm) for more information.

## **CONTROLLER'S CORNER** **GRANTS MANAGEMENT**

### **EFFORT REPORTING**

Effort reporting is a federal requirement. Principal Investigators are obligated to follow the federal requirements concerning effort reporting upon acceptance of a federal award. Federal effort reporting guidelines require that either the individual or someone having firsthand knowledge of the work performed, e.g. the Principal Investigator, must sign the effort reports. The Principal Investigator must be able to verify that persons paid on their contracts or grants actually performed the work and must be in a position to provide agreement to the effort certified.

As a general rule, exempt employees should understand how their salary charges are being distributed, and should verify for themselves that there is a close relationship between that and the actual proportion of their effort devoted to the functions and projects being charged. For Research Assistants and support staff, these allocation decisions are often made by faculty Principal Investigators, who are assumed to be most knowledgeable about the relationship between effort devoted and benefit received.

Prompt completion of effort certifications is needed in order to comply with OMB Circular requirements and for the maintenance of current information within the Controller's Office database.

\*\*bottomline: turn in your effort report!!\*\*

### **VIGILANCE:**

UPDATES FROM WFUSM  
ENVIRONMENTAL HEALTH AND SAFETY

### **LAST CALL FOR CHEMICAL INVENTORIES FROM PRINCIPAL INVESTIGATORS**

**February 28, 2003** is the last day that EH&S will accept chemical inventories from principal investigators for inclusion in the start up phase of the web based chemical inventory system. The chemical inventory submission format can be found on the EH&S website (<http://www.wfubmc.edu/ehs/>) under "Forms", then "Chemical Forms".

For over 2 years, EH&S has been developing an online chemical inventory system which will be maintainable at a laboratory level. EH&S personnel are entering the baseline inventory for each chemical in a laboratory received from a principal investigator. All inventories received by February 28<sup>th</sup> will be entered by EH&S.

After the 28<sup>th</sup>, all bets are off. Laboratories will need to enter their own initial inventory information.

The inventory system maintains chemical, biological, and radiological emergency information. Hence, the system has been dubbed CBREIIS (sea breeze) for (C)hemical, (B)iological, (R)adiological, (E)mergency (I)nformation and (I)nventory (S)ystem

### **SELECT AGENT TOXINS**

PIs using the following materials are reminded that all users of these materials must be pre-approved by the Chemical Safety Committee:

- **ABRIN**
- **DIACETOXYSCIRPENOL**
- **SAXITOXIN**
- **SHIGATOXIN**
- **T 2 TOXIN**
- **CONOTOXINS**
- **RICIN**
- **TETRODOTOXIN**
- **STAPHYLOCOCCAL ENTEROTOXIN**

The PI must submit a completed Chemical Safety Application and Standard Operating Procedures for the specific materials. After committee approval and any appropriate regulatory steps, the PI may purchase the material. Purchases of these materials will not be approved unless the PI has approval from the Chemical Safety Committee and the responsible Facility Official, David A. Brown.

WFUSM ENVIRONMENTAL HEALTH  
AND SAFETY

# INTRAMURAL FUNDING OPPORTUNITIES

## CENTER FOR INVESTIGATIVE NEUROSCIENCE

Request for Applications - Neuroscience Research Studies

The WFUHS Center for Investigative Neuroscience (CIN) announces a request for applications for research studies involving the neurosciences. **The purpose of this program is to foster opportunities for collaboration between clinical and basic scientists.** Priority will be given to applications which have basic science and clinical faculty as co-investigators. The maximum budget is \$20,000. The proposal must be neuroscience in nature, i.e., an interdisciplinary effort integrating basic and clinical neurosciences, which targets one of the major research areas of the CIN and the medical school, and has the potential for extramural grant support. **A letter of intent must be received no later than February 17, 2003** and should include the following:

Title

Faculty participants (designate one PI)

Specific aims

**The deadline for the completed grant application is March 19, 2003.** Awards will be announced by June 1, 2003, with funding to begin no later than July 1, 2003. For additional information about this program and to receive a copy of the application guidelines and a listing of major research areas, interested individuals should contact Mrs. Pam Pitts at 6-0083 or visit [www.wfubmc.edu/cin/](http://www.wfubmc.edu/cin/).

## FACULTY FOREIGN TRAVEL AWARDS

The Program will be held again this year, and up to six Faculty Foreign Travel Awards will be made. These awards are to encourage career development among faculty members in the junior and intermediate levels of seniority through participation in international scientific endeavors. Applications will be competitively evaluated by the Intramural Research Support Committee. Potential for career development, and unique scientific, academic, or clinical opportunities will be the chief considerations in their review. Awards are limited to one-half of allowable travel costs, to a maximum of \$1,500 from this award. Eligible applicants include assistant professors, associate professors or professors who do not have access to unrestricted research and development funds for travel. Preference will be shown to junior faculty. Complete information about the application process can be found at <http://www.wfubmc.edu/or>. The deadline is **February 27, 2003**.

## CROSS-CAMPUS COLLABORATIVE RESEARCH SUPPORT FUND

The Collaborative Research Support Fund (CRSF) has been established to stimulate creative pilot research projects between the School of Medicine and Reynolda Campus faculty. The goal of the CRSF is to assist faculty research pursuits and to generate extramural funding for both institutions. CRSF grant awards will be restricted to collaborative efforts between full-time faculty members, with preference given to projects that are not yet competitive for external funding. A maximum of \$15,000 over a 12-month period will be awarded for each collaborative project. Application information and instructions can be obtained at [http://www.wfubmc.edu/or/comm\\_irsc.html](http://www.wfubmc.edu/or/comm_irsc.html). The deadline for submission is **March 14, 2003**.

### GRANT AND CONTRACT PROPOSAL WATCH

|                     | This Fiscal Year<br>July - Dec. | Last Fiscal Year<br>July - Dec. | %<br>Change |
|---------------------|---------------------------------|---------------------------------|-------------|
| Proposals Submitted | 418                             | 417                             | 0.2%        |
| Dollars Requested   | \$253,238,079                   | \$200,509,054                   | 26.3%       |

## HEREDITARY DISEASE FOUNDATION

**POSITION:** Research Grants and Postdoctoral Fellowships

**DESCRIPTION:** The Foundation offers support for research projects that will contribute to identifying and understanding the basic defect of Huntington's disease. Areas of interest include trinucleotide expansions, animal models, gene therapy, neurobiology and development of the basal ganglia, cell survival and death, and intercellular signaling in striatal neurons. Research grants are for up to \$50,000. Postdoctoral fellowships are based on years of experience since Ph.D. was received. For complete information including application process see <http://www.hdfoundation.org/fundinga.htm>.

**DEADLINE:** February 15, 2003

## ALCOHOL BEVERAGE MEDICAL RESEARCH FOUNDATION

**POSITION:** Research Grants

**DESCRIPTION:** The Alcoholic Beverage Medical Research Foundation (ABMRF) accepts applications for grants to conduct research on important aspects of alcohol consumption and its effects, particularly in the following areas:

- Factors influencing transitions in drinking patterns and behavior,
- Effects of moderate use of alcohol on health and well-being,
- Mechanisms underlying the behavioral and biomedical effects of alcohol,
- Biobehavioral/interdisciplinary research on the etiology of alcohol misuse.

The ABMRF funds biomedical, biobehavioral and psychosocial research in these areas. Awards are for up to \$50,000 per year for up to two years. The Foundation is especially interested in providing funding for newly independent investigators, and investigators who are new to the field of alcohol research. For further information and application materials, please visit the ABMRF web site <http://www.abmrf.org>.

**DEADLINE:** February 15, 2003

## NIAMS

**POSITION:** High Risk Rheumatic and Musculoskeletal and Skin Diseases Research - AR-03-009

**DESCRIPTION:** The purpose of this initiative is to broaden the base of inquiry in fundamental biomedical, biobehavioral, and biomedical technology research by encouraging applications for research projects that involve an especially high degree of innovation and novelty and, therefore, require a preliminary test of feasibility. The goal is to solicit research applications with the potential for developing ground-breaking technology or methodology that may lead to a significant expansion of biomedical research horizons, precipitate a paradigm shift in research, or lead to substantial improvements in human health. Research projects proposed under this RFA may involve substantial experimental risks such that their potential for highly significant outcomes may be difficult to judge by the standard criteria used in evaluating investigator initiated (R01) proposals. Preliminary data are not required. The work proposed may not overlap with the aims of currently supported projects or those in which the PI has participated during the past five years. This RFA will use the NIH exploratory/developmental research grant (R21), award mechanism. Applicants may request up to \$50,000 per year for up to two years.

**DEADLINES:** Letter of Intent - February 18, 2003  
Full Application - March 18, 2003

# Research Funding Opportunities

For all funding information contact Angela Horton, Office of Research, 62382, unless noted otherwise in the funding announcement

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For all funding information contact Angela Horton, Office of Research, 62382, unless noted otherwise in the funding announcement

## NIBIB

**POSITION:** Image-Guided Interventions

**DESCRIPTION:** The Institute invites applications for NIH Research Project Grant (R01) awards to support interdisciplinary basic research or Exploratory/Developmental Research (R21) awards that support novel investigations in image-guided interventions. The primary purpose of this RFA is to support research and development for image-guided interventions, including biopsies, surgery, and image-guided therapies. This initiative is intended to drive the development on new technology in areas related to image-guided interventions because of the need for minimally invasive, image-guided treatment of disease and injury. Applications are expected to describe how image-guided interventions will benefit from the proposed technology or research. Research areas for image-guided interventions include technologies for detecting, monitoring, locating, navigating and treating disease and injury. Research areas should emphasize the multidisciplinary nature of the research. The complete RFA is available at: <http://grants1.nih.gov/grants/guide/rfa-files/RFA-EB-03-008.html>

### KEY FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) INSTITUTES - (<http://www.nih.gov/icd/>)

**AHRQ** - Agency for Healthcare Research and Quality

**NCCAM** - National Center for Complementary and Alternative Medicine

**NCI** - National Cancer Institute

**NCNR** - National Center of Nursing Research

**NCRR** - National Center for Research Resources

**NEI** - National Eye Institute

**NHLBI** - National Heart, Lung and Blood Institute

**NHGRI** - National Human Genome Research Institute

**NIAAA** - National Institute on Alcohol Abuse and Alcoholism

**NIA** - National Institute on Aging

**NIAID** - National Institute of Allergy and Infectious Diseases

**NIAMS** - National Institute of Arthritis and Musculoskeletal and Skin Diseases

**NIBIB** - National Institute of Biomedical Imaging and Bioengineering

**NICHD** - National Institute of Child Health and Human Development

**NIDA** - National Institute on Drug Abuse

**NIDCD** - National Institute on Deafness and Other Communication Disorders

**NIDDK** - National Institute of Diabetes and Digestive and Kidney Diseases

**NIDCR** - National Institute of Dental and Craniofacial Research

**NIHES** - National Institute of Environmental Health Sciences

**NIGMS** - National Institute of General Medical Sciences

**NIMH** - National Institute of Mental Health

**NINDS** - National Institute of Neurological Disorders and Stroke

**NLM** - National Library of Medicine

**ORWH** - Office of Research on Women's Health

## CENTERS FOR DISEASE CONTROL (CDC)

The CDC Potential Extramural Projects (PEPs) were released on January 14, 2003. These provide an opportunity for funding for a variety of research projects. Full information is available at [www.cdc-cafunding.org](http://www.cdc-cafunding.org). The deadline for submission of a letter of intent is **February 19, 2003**.

### PURSUIT STAFF

SHEILA VRANA, PH.D.

DAVID LYONS, PH.D.

AMY COMER

