

# PURSUIT

## Office of Research

ADMINISTRATION 64548

ANIMAL CARE AND USE  
COMMITTEE (ACUC) 63532

CONFLICT OF INTEREST  
COMMITTEE 62382

GRANTS ADMINISTRATION  
62382

INDUSTRY RELATIONS 69359

INSTITUTIONAL REVIEW BOARD  
(IRB) 64542

INTRAMURAL RESEARCH  
SUPPORT COMMITTEE (IRSC)  
60780

MONITORING AND OVERSIGHT  
64548

RESEARCH SUPPORT CORE  
RSCORE@WFUBMC.EDU

ANIMAL RESOURCES PROGRAM

BOWMAN GRAY CAMPUS  
37394

FRIEDBERG CAMPUS 61620

DOWNTOWN CAMPUS 31171

ENVIRONMENTAL HEALTH AND  
SAFETY 69375

## Announcing the 13th Annual Faculty Research Day!

Please join your colleagues for the 13th Annual Wake Forest University Health Sciences Basic and Clinical Research Awards on Thursday, October 1, 2009 from 12:00 PM - 2:00 PM in the Nutrition Research Center Conference Rooms. Sally Shumaker, Ph.D., Senior Associate Dean for Research, will provide opening remarks and give individual introductions of recipients. Following lectures by recipients, awards will be presented by John McConnell, M.D., Chief Executive Officer, and William Applegate, M.D., M.P.H., M.A.C.P., President and Dean.

## Congratulations to the 2009 Faculty Research Day Awardees!

### New Investigator in Basic Sciences

Cristina Furdui,  
Ph.D.  
Assistant  
Professor

Department of  
Internal Medicine  
Section on  
Molecular  
Medicine

### New Investigator in Clinical Sciences

Matthew Edwards,  
M.D.  
Associate Professor

Division of Surgical  
Sciences  
Department of  
Vascular and  
Endovascular  
Surgery

### Mid-Career Investigator in Basic Sciences

Sara R. Jones,  
Ph.D.  
(Co-Recipient)  
Associate  
Professor

Department of  
Physiology &  
Pharmacology

### Mid-Career Investigator in Basic Sciences

Carl Langefeld,  
Ph.D.  
(Co-Recipient)  
Associate Professor

Division of Public  
Health Sciences  
Department of  
Biostatistical  
Sciences

### Mid-Career Investigator in Clinical Sciences

Joseph Grzywacz,  
Ph.D.  
Associate  
Professor

Department of  
Family &  
Community  
Medicine

### Established Investigator in Basic Sciences

Thomas DuBose,  
M.D., M.A.C.P.  
(Co-Recipient)  
Professor and Chair

Tinsley R. Harrison  
Professor of Internal  
Medicine  
Professor of  
Physiology and  
Pharmacology

### Established Investigator in Basic Sciences

Douglas Lyles,  
Ph.D.  
(Co-Recipient)  
Professor and  
Chair

Department of  
Biochemistry

### Established Investigator in Clinical Sciences

Deborah Meyers,  
Ph.D.  
Professor of  
Pediatrics and  
Public Health  
Sciences

Co-Director, Center  
for Human  
Genomics

Lunch will be provided during the Awards Ceremony. As a courtesy to Awardees, please stay for the entire program.

## In The Spotlight



Ronny Bell, Ph.D., Director of the Maya Angelou Center for Health Equity and Professor of Public Health Sciences, has been appointed as a founding member of the North Carolina Indian Health Board. Dr. Bell's research is focused on improving the health of minority communities; in addition, he is a member of the Lumbee Indian tribe of eastern North Carolina. The Board seeks to become an authoritative source on Indian health issues in the state, and to serve as an advocate for improved health in those communities.



Barry I. Freedman, M.D., John H. Felts III Distinguished Professor and chief of the Section on Nephrology, was named a Health Care Hero "Innovator" by *The Business Journal*. The award recognizes Dr. Freedman's pioneering research in nephrology, such as his involvement in the recent finding of a specific gene linked to kidney failure in African Americans. The gene, MYH9, may contribute to nearly half of all cases of end-stage renal disease in these individuals. Dr. Freedman has helped spearhead the collection at WFUHS of one of the world's largest collections of DNA samples in patients (many of whom are African Americans) with kidney disease and diabetes.



James E. Johnson, Ph.D., Associate Professor of Neurobiology and Anatomy, has been named director of the new Center for Applied Learning as of July 1. The Center will use advanced instructional technologies to increase clinical capacities and skills of health care providers. It is envisioned as a regional, national and international educational service provider. Among its resources are high-fidelity patient simulation laboratories, a surgery academy, an anatomical training center, a program in medical ultrasound, and standardized patient assessment exam rooms.



## New Route Form Now Available

A revised version of the Proposal Review and Certification Form (Route Form) is now available on the Office of Research's Web site at: <http://www1.wfubmc.edu/NR/rdonlyres/E8045E73-A99F-46F5-A86BA78E45E021B1/93593routesheetfinal.doc> and Industry Relation's Web page at: <http://infinet.wfubmc.edu/depts/ord/industryrelations/Forms/routesheetfinal.doc>. The use of this form for all

grant and contract submissions regardless of the sponsor type became mandatory on **June 1, 2009**. Applications using the old version of this form will be returned. The new revision date on the form is 5/18/09. Thank you for your cooperation during this transition. Please share this information with your department. If you have any questions, please do not hesitate to contact us.

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### CONCERN LINES

WFUBMC Compliance Hotline Confidential and Anonymous  
1-877-880-7888 or [www.tnvinc.com/reportline/international](http://www.tnvinc.com/reportline/international)  
24 hours a day 7 days a week

### ANIMAL CARE AND USE COMMITTEE DEADLINES

2009  
AUGUST 7, SEPTEMBER 4,  
OCTOBER 2, NOVEMBER 6 &  
DECEMBER 4

2010  
JANUARY 1, FEBRUARY 5,  
MARCH 5, APRIL 2, MAY 7 &  
JUNE 4

### INSTITUTIONAL REVIEW BOARD DEADLINES NOON ON FRIDAYS

### INTRAMURAL RESEARCH SUPPORT COMMITTEE DEADLINES

2009  
AUGUST 14 & DECEMBER 11

2010  
February 19, March 5 &  
April 16

### CONFLICT OF INTEREST REVIEW COMMITTEE DEADLINES

MANAGEMENT PLANS  
2ND MONDAY OF EACH MONTH

CIRC MEETINGS  
4TH WEDNESDAY OF EACH MONTH

### RESEARCH ADMINISTRATORS SESSIONS

ALL SESSIONS ARE HELD THE 2ND THURSDAY OF THE MONTH AT 10:00 AM IN COMMONS CONFERENCE ROOMS 2&3

PLEASE E-MAIL AMY COMER (ACOMER@WFUBMC.EDU) TO BE ADDED TO THE EMAIL LIST

September 3, October 8,  
November 12 &  
December 10

## The Freedom of Information Act (FOIA)

The Freedom of Information Act (FOIA) provides individuals with a right to access records in the possession of the federal government (e.g., funded grants). The government may withhold information pursuant to exemptions and exclusions in the act. There are certain reasons and occasions that records can be withheld. However, those reasons must fall within one of the exemption categories listed below. If the reason(s) for withholding the information cannot be supported by one of these exemptions, then the information cannot be withheld and will be required to be released to the requester.

### Exemptions for withholding Information

- National Defense and Foreign Policy
- Internal personnel rules and practices
- Records exempted by other statutes or laws
- Trade secrets and confidential commercial or financial information
- Internal memoranda
- Clearly unwarranted invasion of personal privacy
- Law enforcement
- Records on financial institutions

In the majority of cases, the requests for information will come directly from an agent of the federal government, i.e., NIH. The request will include a date by which you must reply if you object to disclosure of any part of the document/records being requested. You must state the reasons and how they apply within the exemptions for withholding information. Typically, if you do not hear back from the requester it means that your request to withhold information has been honored. **Important: If you do not reply in the time-frame provided by the requester, the information will be provided as requested.**

### UPCOMING MAJOR NIH GRANT DEADLINES

**All due at OR five working days before the deadline**

All F Series Fellowships  
August 8

New Training Grants  
September 25

New Program Project/Center Proposals  
September 25

New R01s  
October 5

New Ks  
October 12

New R21s & R03s  
October 16

Resubmissions R01 A1's  
November 5

K A1's  
November 12

R03 A1's & R21 A1's  
November 16

SBIR/STTR  
December 5

NRSA Fellowships  
December 8

Conference Grants  
December 12

AIDS and AIDS-Related (all mechanisms)  
January 7, 2010

## InfoEd News



The proposals submitted through InfoEd to NIH in FY09 totaled 347. The total number of proposals submitted through the system has more than doubled over the previous FY. This increase is due to the Institutional mandate that NIH electronic applications be prepared and submitted through the InfoEd system. The Office of Research continues to add still more functionality to the InfoEd system. In the very near future, the InfoEd system will become capable of processing any application that can be

submitted electronically to any federal sponsor via Grants.gov. Therefore, if you can find your opportunity number in Grants.gov you can prepare the application for submission through InfoEd. Please remember the need to create your proposals utilizing object codes. Use of object codes will become mandatory for upcoming deadlines and if you have not already, it is advisable to sign-up for an upcoming training session to assist in familiarization of this very important step.

## InfoEd Workshops

**InfoEd 101** is an introductory session for individuals with no or little experience with the system.

**InfoEd 102** provides more advanced training for individuals who have completed InfoEd 101 or have submitted a grant electronically. This session will focus more specifically on budgetary issues and attendees may be asked to bring examples or work on materials prior to the class. We recommend that an individual take InfoEd 101 before registering for InfoEd 102.

**InfoEd 101**  
9/2 - 9 - 11 am

**InfoEd 102**  
9/22 - 1- 3 pm

Please visit the Educational Outreach section of the Office of Research Web site for registration. Registration is required, as space is limited. All sessions are held in Classroom B of Carpenter Library. If fewer than 5 participants are registered, the session may be cancelled. You will be notified of any cancellations.

## Electronic Submissions of Individual National Research Service Awards

Effective with the **August 8, 2009** submission date, all grant applications for the Individual National Research Service Award (NRSA) Fellowships (F-series) will require electronic submission through Grants.gov to eRA Commons. Paper applications **will not** be accepted for submissions on or after the August 8 transition. For the August 8 deadline, applicants should use the Adobe Form set, which can be downloaded within the appropriate FOA. For a complete listing of Fellowship FOAs, see the F-Kiosk: [http://grants1.nih.gov/training/F\\_files\\_nrsa.htm](http://grants1.nih.gov/training/F_files_nrsa.htm). Several new business processes are being implemented at NIH concurrent with the transition to electronic submission:

**1. Reference Letters:** The electronic submission of reference letters is separate from the electronic submission of applications.

Reference letters are submitted directly through the eRA Commons and do not use Grants.gov. Therefore, fellowship applicants must follow the Reference Letter Instructions in the [SF424 \(R&R\) Individual Fellowship Application Guide](#) for specific directions (Part 1, Section 5.4). Letters of reference are an important component of the application for fellowship support. Applicants must arrange to have **at least three (but no more than five)** letters of reference submitted on their behalf to the eRA Commons Web site at: <https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp>.

**2. Resubmissions:** Applicants may submit a resubmission application, but must include an Introduction addressing the previous peer review critique (Summary Statement).

See new NIH policy on resubmission (amended) applications ([NOT-OD-09-003](#), [NOT-OD-09-016](#)). Please note that when resubmitting an application electronically via Grants.gov, applicants must also resubmit their letters of reference through the eRA Commons as described above.

**3. Review Criteria:** Reviewers will provide an overall impact/priority score, and will consider each of the five criteria below in determining scientific and technical merit and will give a separate score for each:

- Fellowship Applicant
- Sponsor(s), Collaborator(s), and Consultant(s)
- Research Training Plan
- Training Potential
- Institutional Environment and Commitment to Training.

## Preparation of Subcontracts on Non-Industry Grants and Contracts

If WFUHS is the applicant organization and colleagues at another location will perform some of the work proposed in a grant application, the following information is needed at the time the application is received in the Office of Research for review:

- The completed Institutional Proposal Review and Certification Form: <http://www1.wfubmc.edu/NR/ronlyres/E8045E73-A99F-46F5-A86B-A78E45E021B1/93593/routesheetfinal.doc>
- A letter from the institutional official of the subcontracting institution that includes the DUNS # and Congressional District and indicates their willingness to enter into a subcontract arrangement with WFUHS or a signed PHS 398 face page;
- The itemized budget for the subcontracting institution, including their F&A costs;
- The biographical sketch for the key personnel of the subcontracting institution;
- PHS 398 checklist for the subcontracting institution.

If WFUHS is the subcontracting institution and another organization is the lead applicant, the following information is needed to be routed through the Office of Research prior to submission:

- The completed Institutional Proposal Review and Certification Form: <http://www1.wfubmc.edu/NR/ronlyres/E8045E73-A99F-46F5-A86B-A78E45E021B1/93593/routesheetfinal.doc> with the sponsor listed as "subcontract from University of...";
- A Scope of Work for the project to be performed at WFUHS;
- Biographical sketches for the key personnel at WFUHS;
- An itemized budget for the WFUHS portion, including full F&A costs;
- PHS 398 checklist;
- A completed Letter of Intent, available on the Office of Research Web site at: <http://www1.wfubmc.edu/NR/ronlyres/B218ECD3-24C1-4C02-AAFB-EC9DCCB3F8CC/94573/LOI76091.doc> or a completed PHS 398 face page.

## Collaborating with the Reynolda Campus

Proposals involving the Reynolda Campus and Health Sciences faculty with paid effort must be routed through the appropriate office, Office of Research (WFUHS) and the Office of Research and Sponsored Programs (WFU). We have encountered proposals that were not routed through the appropriate office and contained errors. These errors required revisions and caused delays in proposal processing. With required electronic submission upon us, time is of the essence more than ever. Several new procedures have been put into place in both offices and we ask the research community to assist us so that there are no delays in processing proposals. **The following procedures are effective immediately:**

- When the Reynolda Campus (as the primary institution) requests a budget from a WFUHS department, the appropriate Grants Administrator in the Office of Research will be notified. This will alert OR that a subcontract with the Reynolda Campus is forthcoming. Once the subcontract is reviewed in OR, an e-mail approving the budget and amounts will be sent to the Reynolda Campus. We request that subcontracts with Reynolda be routed 8 days prior to the deadline so that we can review and communicate with the Office of Research and Sponsored Programs at WFU in time for the sponsor's deadline to be met.

- When a department at WFUHS (as the primary institution) requests a budget from the Reynolda Campus, please copy the appropriate Grants Administrator in the Office of Research. This will alert OR that a proposal that includes a subcontract to the Reynolda Campus is forthcoming. Once the proposal is received, we will verify the budget amounts with the Reynolda Campus before the proposal can be submitted. We request that proposals including subcontracts with the Reynolda Campus be routed in a timely fashion so that the appropriate approvals can be obtained before submission.

By informing each campus in advance and obtaining correct information, we will be able to process proposals in a timely manner and set up accounts properly when awarded. For questions related to the Reynolda Campus, please contact Lori Messer, Director, Office of Research and Sponsored Programs via e-mail at [Research@wfu.edu](mailto:Research@wfu.edu). For questions related to Health Sciences proposals, please contact Theresa Sears, Associate Director, Grants Administration at [grantsadmin@wfubmc.edu](mailto:grantsadmin@wfubmc.edu). Thank you in advance for your assistance.

## Dear Dr. OR



Dear Dr. OR:

I overheard some investigators talking about NIH reducing the page limits for R01s and other funding mechanisms. Is this true? Do you know when this will take effect and what the new limitations will be?

Signed,  
Worried about Reducing

Dear Worried:

Shortening the application for R01's and other mechanisms is part of NIH's mission to enhance peer review. According to notice NOT-OD-09-023, the shorter applications will begin with the January 2010 deadlines. The requirement of a shorter application will be noted in the individual FOA's. The Office of Research will send notices out as more information becomes available.

Dear Dr. OR:

I would like to apply for a grant from an agency that says they will consider only one application per institution. Do I need to submit anything ahead of time to qualify as the WFUHS applicant?

Signed,  
I'm the One

Dear I'm the One:

We describe our process for such applications on our Web site at "Limited Submissions Funding Programs" under the "Applications and Awards" tab. Briefly, you will need to inform OR in advance (by e-mail to [ktetraul@wfubmc.edu](mailto:ktetraul@wfubmc.edu)) of your intention to apply, providing the name of the agency, the award in question, and the link to their Web site for instructions. If the number of eligible and interested WFUHS applicants

exceeds the institutional limit, each potential applicant will be asked to submit a brief pre-proposal to OR by a specified deadline. We will then convene an internal review to select the proposal(s) recommended for submission. It is important that you notify OR first (not the sponsoring agency) of your interest well in advance, to avoid potential disqualifications. The Research Support Core can assist with the submission at the PI's request (e.g., to obtain an institutional official's signature, or assist with the overall application). Also on the "Limited Submissions" Web page is a calendar of upcoming deadlines for future limited-submission proposals, to assist with your long-term planning process. The calendar is updated regularly and includes links to each program announcement.

## WFU Translational Science Institute

### Medical Student Research Program

The WFUSM has a long-standing T35 grant to support summer research experiences for medical students. The 2009 Medical Student Research Program (MSRP), under the direction of Dr. Paul Laurienti, is currently underway. A total of 41 medical students are participating in weekly seminars and working with faculty mentors on designated research projects for a 10 week period this summer. Seminars include topics on team science, research ethics, use of animals and human subjects in research, presenting scientific results, and the importance of mentoring. Components of the program will be integrated with other summer research training programs (including high school students, undergraduate, and post-baccalaureate students) at WFUSM. An emphasis on team science and cross-campus collaborations is another key component including faculty with research expertise from the Schools of Business and Law, and the Department of Health & Exercise Science on the Reynolda Campus. Included is a trip to the WFU Primate Center at the Friedberg Campus.

Fellowships are awarded each year on a competitive basis. Applicants must submit a short research proposal including specific aims, background and literature review, and describe how the student will contribute to the research project. In return, awardees receive stipend support for the summer and access to a structured research experience to help build toward a career in clinical and translational science. Students began the program in early June and will conclude with a poster presentation session in October where they will present and be judged on their research findings.

We would like to congratulate the student awardees and thank all of the individuals, including faculty serving as mentors and conducting seminars, involved in making this a successful program.

### New Service: GCRC/CRU LabCorp Research Study Sample Processing

The General Clinical Research Center/Clinical Research Unit is pleased to announce that it has finalized two agreements through LabCorp for research sample processing.

The first agreement includes terms for information compliance (electronic and non-electronic) in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for information that is created, received, maintained or transmitted for a GCRC/CRU approved study.

The second agreement provides the GCRC/CRU with special pricing for laboratory research processing.

These two agreements allow us to provide multiple options for research laboratory studies to assist investigators in maximizing resources. To use these services and their negotiated price advantage, protocols must be submitted to the GCRC/CRU and approved. Laboratory-only submissions are welcome if other GCRC/CRU services are not required.

Research investigators may call Teresa Reagan, GCRC/CRU Center Coordinator at 6-9750 for information on how to take advantage of this new laboratory research processing service.

## Congratulations to the May 2009 IRSC Award Recipients!

Rodrigo A. España, Ph.D.  
Department of Physiology  
& Pharmacology

"Hypocretin/Orexin  
Regulation of Dopamine  
Neurotransmission"

W. Gregory Hundley, M.D.  
Department of Internal  
Medicine

"Pilot to Test Breast  
Cancer Patient Tolerance  
for Statin Therapy"

Hang Shi, Ph.D.  
Department of Internal  
Medicine

"The Role of Macrophage  
AMPK-Activated Protein  
Kinase (AMPK) in Regulat-  
ing Inflammation and  
Insulin Resistance"

Terrence R. Stanford,  
Ph.D.  
Department of  
Neurobiology & Anatomy

"Role of Dopamine in  
Associative Learning"

## SRA International and NCURA 2009 Annual Meetings

The Society of Research Administrators  
[2009 International Annual Meeting](#)

The SRA meeting will be held from  
October 17 - October 21, 2009 at the [Washington State  
Convention and Trade Center](#) in Seattle, WA.  
Registration and additional information is available at:  
<http://www.srainternational.org/sra03/index.cfm>

The National Council of University Research  
Administrators 51st Annual Meeting

The NCURA meeting will be held from  
October 21 - October 24, 2009 at the Washington  
Marriott Wardman Park Hotel in Washington, DC.  
Registration and additional information is  
available at: [http://www.ncura.edu  
contenteducational\\_programs/sites/51/](http://www.ncura.edu/contenteducational_programs/sites/51/)

## New Mandatory Financial Interest and COC Reporting Requirements at WFUHS

The annual online financial interest and conflict of commitment (COC) disclosure process began July 10, 2009. Previously, only faculty and key administrators were required to complete an online disclosure annually. To bring our policy and procedures in line with other major institutions and with recommendations by the American Association of Medical Colleges, WFUHS has expanded collection of disclosure information to include all exempt employees. The School encourages outside relationships that enhance its mission; however, financial and fiduciary conflicts of interest may naturally arise from these interactions. Conflicts must be addressed in accordance with federal regulation and school policy, whether the conflict is real or perceived. In addition, all time commitments to non-Medical School activities must be reported in accordance with school policy. Conflict of interest administrative staff will review disclosures made by exempt employees, and will seek information through the employee's supervisor if there are any questions. For more information, please contact Teresa Anderson at 713-2990.

### Controller's Corner



#### eRFP (Electronic Request for Payment)

eRFP has been fully implemented. Please remember that it should not be used for travel, computers or equipment. Also please take the time to search for the vendor name (if we have paid the person or vendor in the past, then they are set-up in the system), rather than choosing the "unknown vendor" option. Choosing "unknown vendor" will delay the processing of the request due to the additional steps needed to establish the vendor. Questions or training needs should be directed to Tonya Barga at 3-4283.

If you worked on any projects during this period that do not appear on your pre-filled report, you will need to add them. If you had any cost-shared effort, you will need to include those chartfields as well, although they may not appear on your preprinted report. It is extremely important that you certify your effort correctly. Since we certify effort after the fact, re-opening any certification should be very rare. Please ask your departmental resources for help, if you are not sure of your effort. Instructions can be accessed within the effort report or on the Controller's Office Web site under Grants Management. Business Managers/Administrators, please remember that variance reports are due within 45 days or August 31, 2009. If you have not sent your variance reports for the prior period please do so immediately. Variance reports can be sent to [postaward@wfubmc.edu](mailto:postaward@wfubmc.edu).

#### Effort Certifications

Efforts will be released for monthly paid faculty and staff in July 2009. Please remember to certify your January 1 - June 30, 2009 effort within the 30-day window.

## ACUC Protocols to go Paperless on August 1

The WFU IACUC is migrating to a paperless, enterprise-wide system (eIACUC) for the receiving, reviewing, and archiving of IACUC protocols. The software platform is the same one used by the Institutional Review Board, eIRB. Our rollout has been very successful, so as of **August 1**, eIACUC will be mandatory for all ACUC protocols. In addition to protocol submission, eIACUC will also house the protocol review process. Automated e-mails will notify users when action is needed, and links within the e-mail will direct users where to respond within eIACUC. We are holding frequent training sessions so that users will be prepared for this change. The hands-on sessions introduce users to the new IACUC protocol forms and help them understand how the online review process will work.

#### eIACUC Training Sessions

8/17 - 9-11 am	9/15 - 9-11 am
8/19 - 1-3 pm	9/16 - 1-3 pm
8/26 - 1-3 pm	9/23 - 9-11 am
8/28 - 9-11 am	9/25 - 1-3 pm

Questions about eIACUC or the training process? Please contact David Lyons ([dlyons@wfubmc.edu](mailto:dlyons@wfubmc.edu)) or MJ Busa ([mjbusa@wfubmc.edu](mailto:mjbusa@wfubmc.edu)). Training for Researchers and Staff will be conducted in Classroom B, Carpenter Library. Please visit the Educational Outreach section of the Office of Research Web site at: <http://www1.wfubmc.edu/OR/Educational+Outreach/Scheduled+Trainings.htm> for registration. If fewer than 3 participants are registered, the class may be cancelled. (Seating is limited.)

## Office of Research 2009 Workshop Schedule



### Nitty Gritty of NIH Grants

This workshop is geared toward less experienced grant writers, as well as people who want to learn more about the whole grant submission process. The goal is to make the grant-application experience less harried and more likely to succeed. Because of their importance and complexity, the focus will be on NIH-style applications. We will cover insider tips – “tricks of the trade” – that can make all the difference in today’s highly competitive grants environment. Discussion of the recent changes in the NIH review process is included.

**Date:** August 28, 2009

**Time:** 10:00 am - 12:00 pm

**Location:** Commons Conf Rooms 1 & 2, G-floor,  
Nutrition Building

**Presenter:** Karen Klein

**Who Should Attend:** Faculty, Postdoctoral Fellows &  
Graduate Students

### Study Coordinator 101

Study Coordinator 101 consists of a two-part hands-on workshop designed to cover IRB policies and procedures, federal regulations, Good Clinical Practice guidelines, and HIPAA rules and regulations. Participants will also be able to identify the essential documents of a regulatory binder, create source documents and a subject binder, develop a consent form, and other essential tools needed to be a successful research study coordinator.

#### Study Coordinator 101 - Part I

**Date:** September 30, 2009

**Time:** 1:30 - 5:00 pm

**Location:** Comprehensive Cancer Center Conference  
Rooms 1A & 1B

**Presenters:** Jeanie Baird & Debra McBride

#### Study Coordinator 101 - Part II

**Date:** October 7, 2009

**Time:** 1:30 - 5:00 pm

**Location:** Comprehensive Cancer Center Conference  
Rooms 1A & 1B

**Presenters:** Jeanie Baird & Debra McBride

### Pilot Project Skills Development Program: New!

**Purpose:** To enable junior faculty to develop, write applications for, conduct, and then successfully leverage their pilot results into larger, externally funded studies.

**Intended Audience:** Junior faculty with 20% or more effort devoted to research; new faculty; or faculty who are changing research directions and need to generate new pilot data.

**Date and Time:** September 30, 2009; 12:00-4:45 p.m.

**Location:** Sticht Center Auditorium

**Deadline for Applicants: July 31.** Attendance is limited to first 30 respondents. Applicants may be nominated by a department chair, section head, or self-nominated. Optional follow-up sessions are planned to further develop ideas from this initial session. To make this program goal-directed, one or more institutional RFA’s will be issued specifically for pilot project development. To apply to attend or to learn more, please contact Abby Haymore ([abhaymor@wfubmc.edu](mailto:abhaymor@wfubmc.edu)). This program is jointly planned and sponsored by the Pepper Center Older Americans Independence Center and the Sticht Center Program on Aging; the Maya Angelou Center for Health Equity; the WFU Primate Center; the WFU Translational Science Institute and the WFU Clinical Research Unit (GCRC); the Women’s Health Center of Excellence for Research, Leadership, Education; and the Office of Research.

All workshops organized by the Office of Research’s Research Support Core are free; however, registration is required unless otherwise stated. You may register online at: <http://www1.wfubmc.edu/OR/Educational+Outreach/Scheduled+Trainings.htm>.

## NIH News



### NIH Opens xTrain to All Institutions Registered with the eRA Commons

Effective immediately, the National Institutes of Health (NIH) invites all institutions registered with the electronic Research Administration (eRA) Commons to use xTrain, a Commons module that provides institutional users with the ability to electronically prepare and submit appointment forms and other related documents. Currently, xTrain is available for use with Kirschstein-NRSA research training grants supported by NIH (i.e., activity codes T32, T34, T35, T90, TL1 and TU2). However, NIH continues to develop the capability to use xTrain for other training programs and will announce broader use in future editions of the NIH Guide.

xTrain accepts training grant appointments and reappointments, amended appointments and termination notices, and provides pre-filled payback agreements for eligible postdoctorates to sign. NIH staff also use xTrain to review and approve training grant appointments and terminations submitted electronically. Once a training grant appointment (or other action) has been initiated, xTrain allows institutional and NIH users to track its status. For ARRA funding, xTrain also accommodates separate appointments for ARRA supplements to training grants.

To begin using xTrain, no additional registration is required as long as institutions and PD/PIs are already Commons-registered. xTrain does require registration of trainees that are not already Commons-registered; however, that registration is part of the appointment process for trainees. PD/PIs may wish to delegate their xTrain authority to an assistant or department administrator. Additional information, resources (including quick reference sheets), and an updated Institution User Guide for xTrain can be found on the eRA Commons page at: [http://era.nih.gov/services\\_for\\_applicants/other/xTrain.cfm](http://era.nih.gov/services_for_applicants/other/xTrain.cfm).

### NIH Stem Cell Guidelines Released

The final NIH Guidelines for Human Stem Cell Research implementing the Executive Order (EO)13505 Removing Barriers to Responsible Scientific Research Involving Human Stem Cells and establishing policy and procedures under which the NIH will fund such research, have been released and are available at <http://stemcells.nih.gov/index.asp>. These guidelines became effective on July 7, 2009. Public comments on the draft Guidelines have also been released and are available at <http://stemcells.nih.gov/index.asp>.

The Guidelines will ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Policies and procedures consistent with the EO and these Guidelines, will govern the conduct of intramural NIH stem cell research. The Guidelines prescribe the assurances and supporting documentation that must accompany requests for NIH funding for research using human embryonic stem cells (hESCs), and describe research ineligible for NIH funding. NIH will provide more guidance concerning the implementation of the Guidelines and the status of pending applications in future Guide Notices. Ongoing NIH-supported research involving previously approved hESC lines may continue. No new uses of hESC may be initiated in ongoing funded studies unless reviewed and approved by the NIH.

### New Web Site on ARRA-Funded NIH Research

The National Institutes of Health is developing a Web page dedicated to distributing information about NIH research grants funded by the American Recovery and Reinvestment Act (ARRA). The page, which is located in the agency's Research Portfolio Online Reporting Tool site, contains solicitations for grant funding, as well as interactive maps illustrating research grants and opportunities by state. Information: <http://report.nih.gov/recovery/index.aspx>.

### Enhanced Notice of Award (NoA) E-mail Notification

When NIH issues NoAs, the official document is made available to grantee officials and corresponding Program Directors/Principal Investigators via eRA Commons, the official repository for this document. As part of the NoA process, NIH has continued the practice of notifying the grantee via e-mail when an award has been issued. Recently, the NIH has determined that the e-mail notification system can be improved to ensure that e-mail notifications are consistently and correctly sent. While implementing this improvement, NIH determined that certain NoA notifications were not initially sent to the grantee. For those in this category since July 1, 2009, NIH has regenerated these notifications and sent them to the grantee. Please note that the delayed sending of NoA e-mail notification does not affect the original content or their posting in the eRA Commons system. System improvements will be implemented in the next few months by the NIH. A partial system improvement is scheduled for late July, and the final improvement will be made in October 2009. An automated notification monitoring system will also begin in October to ensure that any NoA notification errors are addressed promptly. Meanwhile, NIH staff will perform daily, manual checks to identify any notification anomalies and regenerate NoA notifications as needed. If you have any questions, please contact your Grants Administrator in the Office of Research.

## Funding Opportunities



### Comparative Effectiveness Research Opportunities from DHHS

Comparative effectiveness research (CER) has been identified as a priority in the government's stimulus-related funding plans. Congress has now appropriated \$1.1 billion to "jump-start the nation's efforts to accelerate CER," in the words of the Institute of Medicine, which formed a committee to recommend funding priorities.

First, the Institute of Medicine (IOM) defined CER as "the generation and synthesis of evidence that compares the benefit and harm of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care". CER can take many forms – systematic literature reviews, use of large databases, prospective registries and cohort studies, and randomized controlled trials. Clearly, the vision of CER is a broad one.

After consulting multiple stakeholders, the IOM committee developed priorities for CER based on criteria that emerged from their fact-finding and deliberations. The resultant priority list includes 29 research areas. The top 5 are health delivery, disparities, disabilities, cardiovascular topics, and geriatrics. A brief version of the IOM report is available for free at: <http://www.iom.edu/CMS/3809/63608/71025/71107.aspx>. In the meantime, the NIH has issued its first RFA on comparative effectiveness research at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-10-008.html>. The link is also on our "ARRA Opportunities" page on the Office of Research Web site. We will be adding further RFAs of this nature to our page as they are issued.

### NC Biotechnology Center Grant News

The North Carolina Biotechnology Center (NCBC) has posted new guidelines on their Web site for Regional Development grants (**Deadline: August 12**). Changes to note: Institutional Development grant applications (due September 12) are limited to invited resubmissions. NCBC also announced an increase in the approved amounts for funded Biotechnology Event Sponsorship and Biotechnology Meeting Grant proposals. Deadlines for both are now quarterly. Check their Web site at [www.ncbiotech.org](http://www.ncbiotech.org) for updates and details.

### National Headache Foundation Grants

The National Headache Foundation is interested in research that will contribute to a better understanding of and treatment for, headache and pain. Grants may be used to support supplies, patient recruitment, and data analyses. No salaries, equipment purchases, or overhead costs are allowed. **Deadline: December 1, 2009**. For details, go to [www.headaches.org](http://www.headaches.org).

### Epilepsy Foundation Fall 2009 Research Grants & Fellowships

The Epilepsy Foundation's investment in research supports a series of grants and fellowships to help increase the number of qualified scientists conducting epilepsy research and supports research that will advance the understanding of epilepsy, lead to better treatment, prevention, and ultimately to a cure.

**Proposals are due August 31, 2009 (unless otherwise noted below) and awards are granted starting January 1, 2010 for the following programs:**

- **Predocctoral Training Fellowship**  
\$20,000 for one year
- **Postdoctoral Training Fellowship**  
\$45,000 for one year
- **Research & Training Fellowship for Clinicians**
- **Proposals due October 1, 2009**  
\$50,000 per year (maximum \$100,000 for 2 years)
- **Research Grants**  
\$50,000 per year (maximum \$100,000 for 2 years)
- **Partnership for Pediatric Epilepsy Research**  
up to \$100,000 for one to three years

For application submission instructions go to <http://www.epilepsyfoundation.org/research/grants.cfm>.

### Thrasher Research Fund Grants

The Thrasher Research Fund provides grant opportunities in understudied areas of pediatric research. Clinical and translational research is a special interest. Three-page Concept Papers are required as the initial step, and are accepted on a rolling basis. Full applications, if requested, are limited to 3 years; funded awards range from \$150,000-\$300,000. Salary support for the Principal Investigator cannot exceed 20% and indirect costs are limited to 7%. For more details, see <http://www.thrasherresearch.org>.

## Funding Opportunities



### Daland Fellowships in Clinical Investigation

Daland Fellowships are given by the American Philosophical Society for patient-oriented research in clinical medicine, including internal medicine, neurology, pediatrics, psychiatry, and surgery. Applicants should have held an MD or MD/PhD degree for less than 8 years. Preference is usually given to candidates with less than 2 years of postdoctoral training and research. Direct contact with patients is required. Fellowships are \$40,000 in the first year, with renewal for 1 year possible. Applicants are expected to spend most of their time in research, with only limited teaching or clinical service activities. **Deadline: September 1, 2009.** For more details, see [www.amphilsoc.org](http://www.amphilsoc.org).

### American Lung Association

#### TRAINING AWARDS

#### **Lung Health Dissertation Grant: \$21,000/yr.**

Pre-doctoral support for nurses or students with an academic career focused on the various disciplines of social science. Research areas of particular interest to the American Lung Association are: psychosocial, behavioral, health services, health policy, epidemiological, biostatistical and educational matters related to lung disease. Duration: up to two years.

#### **Senior Research Training Fellowship: \$32,500/yr.**

Post-doctoral support for MDs and/or PhDs receiving further academic training as scientific investigators. Research areas of particular interest to the American Lung Association are: adult pulmonary medicine, pediatric pulmonary medicine and lung biology. Duration: up to two years.

#### INDEPENDENT INVESTIGATOR AWARDS

#### **Biomedical Research Grant: \$40,000/yr.**

Provides seed monies for investigators researching the mechanisms of lung disease and general lung biology. Duration: up to two years.

#### **Clinical Patient Care Research Grant: \$40,000/yr.**

Provides seed monies for investigators working on traditional clinical studies examining methods of improving patient care and/or treatment for lung disease. Duration: up to two years.

#### **Social-Behavioral Research Grant: \$40,000/yr.**

Provides seed monies for investigators working on epidemiological and behavioral studies examining risk factors affecting lung health. This grant includes studies concerning the ethical, legal and economic aspects of health services and policies. Duration: up to two years.

#### ALLIANCE AWARDS

#### **American Lung Association / AAAAI Allergic Respiratory Diseases Award: \$50,000/yr.**

Supports research on allergic respiratory disease. Duration: up to two years.

#### **American Lung Association / The CHEST Foundation: \$40,000/yr.**

Supports clinical research on asthma. Duration: up to two years.

#### **American Lung Association Dalsemer Research Grant: \$40,000/yr.**

Supports research on interstitial lung disease. Duration: up to two years.

#### **American Lung Association / LUNGevity Foundation Lung Cancer Discovery Award: \$100,000/yr.**

Supports research on novel medical treatments or cures for lung cancer. Duration: up to two years.

#### **Application Process**

Application materials are available online at <https://proposalcentral.altum.com>. It is **STRONGLY RECOMMENDED** that applicants first read through the Program Descriptions (located as an icon directly adjacent to Award Title) to determine eligibility and the Program Instructions (located under the FAQ column) to ensure accurate preparation of an application. For applicants interested in the ALA/LUNGevity Lung Cancer Discovery Award, a letter of intent is required.

**A letter of intent is only required for the ALA/LUNGevity Lung Cancer Discovery Award.**

**Application Deadline Date: October 21, 2009**

## Reminder on Importance of Allowable Costs

The Office of the Inspector General (OIG) recently reported at <http://www.oig.hhs.gov/oas/reports/region4/40501014.pdf> that Duke University claimed approximately \$1.7 million in unallowable charges as direct costs to grants, contracts, and other agreements with HHS components during fiscal years 2003 and 2004. The OIG recommended that Duke (1) return that amount to the Federal Government and (2) revise its policies as needed to comply with the requirements of OMB Circular A-21 and ensure consistent treatment of administrative and clerical costs. This was a reduced amount from the original recommendation of \$2.4 million to be returned, based on the University's response to the audit. In general, the finding did not support the University's assertion that the charges in question were allowable. This report serves as a reminder on the importance of good cost-accounting principles and documentation that proper fiscal policies have been followed.

## WFUHS Institutional Data & Safety Monitoring Board

The WFUHS Institutional Data & Safety Monitoring Board (I-DSMB) is available to monitor government, foundation or industry-sponsored clinical research being conducted by WFUHS or WFUHS-affiliated investigators. The I-DSMB Web page: [WFUHS Institutional DSMB](#) provides useful information, such as when an independent monitoring board is needed to periodically review a clinical trial for study integrity, conduct, safety and efficacy outcomes. The Web page also provides links to DSMB report templates as well as other useful information. There is no charge for use of the I-DSMB for investigator-initiated trials receiving NIH, departmental, or other non-industry support. For questions about the level of safety monitoring needed for your study, contact Susan Margitić, I-DSMB Director at [smargiti@wfubmc.edu](mailto:smargiti@wfubmc.edu) or 716-5647.

## Financial Research Compliance Workshops

### Information Protection Workshop

Date: August 27, 2009

Time: 2 - 3:30 pm

Location: Comprehensive Cancer Center, Rooms 2A-2B

Jointly sponsored by WFUHS Information Services, WFUHS Privacy Office, WFUHS and WFUBMC Compliance Offices. Learn more about how to protect health information, how to store and protect research-related data, and how and when to contact institutional resources regarding information protection. For more information or to register, contact Mary Truell at 6-5262.

### Financial Research Compliance for Faculty

Provides a look into the financial administration and management of sponsored research grants. Focuses on the areas of financial compliance for which researchers are responsible and will provide a general awareness of the rules governing sponsored research grants. All classes are held in the Comprehensive Cancer Center, Room 2A.

To register, or for more information, please contact Laura Hemrick at [lhemrick@wfubmc.edu](mailto:lhemrick@wfubmc.edu).

August 18, 2009	9:00 am - 11:00 am	February 17, 2010	5:00 pm - 7:00 pm
September 15, 2009	9:00 am - 11:00 am	March 16, 2010	9:00 am - 11:00 am
October 29, 2009	2:00 pm - 4:00 pm	April 8, 2010	10:00 am - 12:00 pm
January 13, 2010	9:00 am - 11:00 am	May 20, 2010	2:00 pm - 4:00 pm

### Standard Sessions for Staff

8:30 am - 12:30 pm

September 9, 2009	November 11, 2009	January 28, 2010	March 10, 2010
May 13, 2010	July 14, 2010	September 23, 2010	November 17, 2010

**WOMEN'S  
HEALTH CENTER**  
*of EXCELLENCE*  
*Research, Leadership, Education*

**P**lans are already underway for the **5<sup>th</sup> Annual Women's Health Research Day** on April 20<sup>th</sup>, 2010 in Babcock Auditorium. This year's theme is Cardiovascular Health and Disease in Women. The keynote speaker will be Dr. Lori Mosca. Lori Mosca, MD, MPH, PhD, is Professor of Medicine and Director of Preventive Cardiology at New York-Presbyterian Hospital/Columbia University Medical Center. Dr. Mosca founded and is Director of the Columbia Center for Heart Disease Prevention in midtown Manhattan. She is author of *Heart to Heart: A Personal Plan for Creating a Heart-Healthy Family*, published by HCI Books. Dr. Mosca's area of clinical expertise is preventive cardiology with an emphasis on the management of lipid disorders. Her research focuses on novel methods for the early detection and prevention of cardiovascular disease. She is Principal Investigator of a National Institutes of Health (NIH) funded study to test the effectiveness of a family heart health screening and educational intervention. She currently holds an NIH Mid-Career Investigator Development Award in Applied Preventive Cardiology Research. Dr. Mosca is a mother of two boys, wife of a pediatric cardiac surgeon, is a competitive triathlete, and Hawaii Ironman finisher. Registration for this event is required. **Details on the day, including registration form and agenda, are located at: <http://www1.wfubmc.edu/whcoe/Research/>.**

**12th Annual Graylyn Conference  
on Women's Health**

October 14-16, 2009!

For details and registration, go to  
[http://www1.wfubmc.edu/whcoe/  
Graylyn+Cognition+Conferences/](http://www1.wfubmc.edu/whcoe/Graylyn+Cognition+Conferences/).

Visit the Research Program page on our Web site for details on events and current funding opportunities in women's health research: [http://  
www1.wfubmc.edu/whcoe/  
Research/index.htm](http://www1.wfubmc.edu/whcoe/Research/index.htm).

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