

# 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

## Congratulations to the 2008 Faculty Research Day Awardees!

### New Investigator in Basic Sciences

**Christos Constantinidis, Ph.D.**  
Assistant Professor  
Department of Neurobiology and Anatomy  
"Organization of Cognitive Functions in the Primate Brain"

### New Investigator in Basic Sciences

**Jason Grayson, Ph.D.**  
Assistant Professor  
Department of Microbiology and Immunology  
"Regulating CD8+T Cell Responses"

### New Investigator in Clinical Sciences

**Yongmei Liu, M.D., Ph.D.**  
Assistant Professor  
Division of Public Health Sciences  
Department of Epidemiology & Prevention  
"An Integrated Approach in Unraveling the Role of Inflammation in CVD"

### Mid-Career Investigator in Clinical Sciences

**Mark Wolfson, Ph.D.**  
Associate Professor  
Division of Public Health Sciences  
Department of Social Sciences and Health Policy  
"Community Trials and Tribulations: Alcohol, Tobacco and Beyond"

### Established Investigator in Basic Sciences

**Linda J. Porrino, Ph.D.**  
Professor  
Department of Physiology and Pharmacology

"What Can Animal Models Tell Us About Addiction?"

### Established Investigator in Clinical Sciences

**Barry I. Freedman, M.D.**  
Professor  
Department of Internal Medicine  
Section on Nephrology

"Hypertension-Association Kidney Disease-Perhaps No More"



Left to Right: Mark Wolfson, Yongmei Liu, Jason Grayson, Linda Porrino, Barry Freedman, Christos Constantinidis

## In The Spotlight

**A. William Blackstock, M.D.**, Professor of Radiation Oncology, was appointed Chair of the Department of Radiation Oncology. A WFUHS faculty member since 1996, he has been PI or co-PI in 10 large research studies of lung and gastrointestinal cancer. He was also named one of America's leading African-American physicians by *Black Enterprise* magazine.



**K. Bridget Brosnihan, Ph.D.**, Professor in the Hypertension and Vascular Research Center, recently received the Page-Bradley Lifetime Achievement Award from the American Heart Association's Council for High Blood Pressure Research. The award goes to an individual with over 20 years of achievements in hypertension-related research, teaching, and service.



**Shay Soker, Ph.D.**, Associate Professor of Regenerative Medicine, was elected President of North Carolina Tissue Engineering and Regenerative Medicine (NCTERM). NCTERM promotes research and development of tissue engineering and regenerative medicine in the state. Dr. Soker will organize and chair the 2009 NCTERM annual meeting, to be held at the Piedmont Triad Research Park.



## Animal Research Resources Available

**Vince Mendenhall, D.V.M., Ph.D.**, is the new Director of Preclinical Surgical services section. Services available through the section include surgery, pathology, imaging, and a clinical chemistry and endocrinology assay services laboratory. Dr. Mendenhall is based in the Piedmont Triad Research Park, facilitating work with multiple WFUHS and other PTRP researchers. Contact the Animal Resources Program (3-7394) for details about services and fees.

The **Transgenic Mouse Core Facility** at WFUHS (Director: Dr. Lijing Yu) provides access to state-of-the-art technologies for generation of genetically engineered mouse models. Mice are housed in a custom-designed space in the PTRP with all the essential equipment and expertise for their creation and care. The Core has already successfully generated 18 transgenic, 4 conventional knockout, and 3 conditional knockout mouse lines. It is committed to working closely with investigators to meet their research needs. Go to the Core's web site: [www1.wfubmc.edu/tgmc/core](http://www1.wfubmc.edu/tgmc/core) for more details, links to educational materials about transgenic animals, forms, and contact information.

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### CONCERN LINES

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

### ANIMAL CARE AND USE COMMITTEE DEADLINES

January 2, 2009, February 6, 2009, March 6, 2009, April 3, 2009, May 1, 2009, June 5, 2009

### INSTITUTIONAL REVIEW BOARD DEADLINES NOON ON FRIDAYS

### INTRAMURAL RESEARCH SUPPORT COMMITTEE DEADLINES

FEBRUARY 27, 2009 (F)  
MARCH 6, 2009 (C)  
APRIL 15, 2009 (R) (I)

### 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](mailto:ACOMER@WFUBMC.EDU)) TO  
BE ADDED TO THE EMAIL LIST.

January 8, February 12,  
March 12, April 9, May  
14, September 10, October  
8, November 12, December  
10

## ClinicalTrials.gov to Include Basic Results Data

Effective late September 2008, basic results data for certain clinical trials are required to be submitted by the sponsor or designated principal investigator to ClinicalTrials.gov for public posting. The study record features a new tab entitled either “No study results posted” (in gray) or “Study Results” (in blue), depending on the availability of results. If no results are posted for a study, selecting the “grayed out” tab displays the following statement, “No Study Results Posted for this Study,” and explanatory information about why results may not be available (e.g., trial not yet completed, mandatory submission requirements do not apply). If results have been posted, clicking on the “Study Results” tab will display those basic results data. A mock-up of the basic results display template is presented at: [http://www.nlm.nih.gov/pubs/techbull/so08/so08\\_clinicaltrials.html](http://www.nlm.nih.gov/pubs/techbull/so08/so08_clinicaltrials.html). See the ClinicalTrials.gov “Basic Results” Data Element Definitions (Draft) document to learn about all information that may be posted on the Study Results page at: [http://prsinfo.clinicaltrials.gov/results\\_definitions.html](http://prsinfo.clinicaltrials.gov/results_definitions.html).

## Congratulations to the 2008 Medical Student Research Day Winners!

### First Place

**Elizabeth Routh, Class of 2011**

“Evaluation of Biomarkers for MEK Inhibitor Treatment in Pancreatic Cancer”

### Second Place

**Marlina E. Lovett, Class of 2011**

“Cosmos Are Not a Girl’s Best Friend: Effects of Social Drinking on Brain Matter Density”

### Third Place

**Jennifer Fuchs, Class of 2011**

“The Role of Health Fairs in Winston-Salem”

### Women’s Health Center of Excellence Award

**Nikki Parson, Class of 2011**

“African American Mothers Providing Breast Milk for VLBW Infants: Barriers and Supports”

### Translational Science Institute T1 Award

**Margaret Greven, Class of 2011**

“Bioengineering an Endothelialized Neo-Cornea”

### Translational Science Institute T2 Award

**Katherine Trumbull, Class of 2011**

“Prevalence of Community-Acquired Methicillin-Resistant Staphylococcus Aureus (CA-MRSA) Nasal Colonization among Children in India”



Left to Right: Marlina Lovett, Elizabeth Routh, Margaret Greven, Nikki Parson, Jennifer Fuchs, Katie Trumbull

## InfoEd News



### Frequently Observed InfoEd Proposal Errors

**1. Budget, Budget Items tab, Personnel folders, Personnel Role on Project.** NIH does not accept/recognize the Co-PD/PI designation; therefore, do not use this role on the project in the budget section.

- Multiple PI – if the proposal has multiple PI's, select PD/PI for both of the PI's in the budget section and identify the contact PI on the personnel tab.
- Other key personnel should be listed as 'Faculty' or 'Other' from the pick list. If other is selected, then 'Co-Investigator' can be typed into the text box.

**2. Budget, Budget Items Tab/Personnel Tab To Be Named/To Be Determined Personnel.** TBN/TBD should be entered in the Last Name field. If listed in the First Name field, the NIH eRA Commons system considers this an error.

**3. Budget, Budget Periods and Setups Tab, Performance Periods.** To update the begin and end dates of the project to a new date range, access the shift button in the budget periods and setups tab of the budget page.

**4. Setup Questions/Budget Tab Budgeting Model.** The budgeting model selected on the Setup Questions tab will apply to the entire proposal. Please give careful consideration to which model is most appropriate for the proposal when selecting. Be warned that you will encounter issues if you change budgeting models while you are working on the proposal budget.

**5. Copying proposals.** When creating a new proposal, it is highly discouraged that you copy a previously created proposal into your new proposal record. It has been observed that doing so can actually take more time to update and correct date and budget issues than creating a new proposal from the beginning would.

**6. All Uploaded Documents.** Uploaded documents cannot contain any header or footer information, as the NIH eRA Commons system inserts headers and footers into the submitted application. Please note that the system does not accept upload of Word 2007 documents at this time. Please convert the Word document to a .pdf or to a .doc prior to uploading.

**7. SF424 R&R Tab.** The Federal Identifier for Resubmission or Renewal Applications must be in the NIH Institute and 6-digit grant number format. Example - GM123456.

**8. Resources Tab.** When utilizing the document upload format for proposal resources, please be sure to separate out the equipment section into its own document for uploading to the equipment section.

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

**InfoEd 102** will provide 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 first, before registering for InfoEd 102.

**InfoEd Refresher** is geared towards experienced InfoEd users. Would you like to have an opportunity for Q&A on developing proposals in InfoEd? Are there specific areas of InfoEd that you would like to examine? This Refresher Course is designed to give you an opportunity to review the entire InfoEd system and resolve any problems that you may have experienced.

**InfoEd 101**  
1/8 - 1-3 pm  
2/19 - 9-11 am  
3/13 - 9-11 am

**InfoEd 102**  
1/27 - 9-11 am  
2/26 - 1-3 pm  
3/24 - 9-11 am

**InfoEd Refresher**  
1/14 - 9-11 am

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.

## Dear Dr. OR



Dear Dr. OR:

I am planning on submitting a pre-proposal to a funding agency and hoping for an invitation for a full proposal. The pre-proposal consists of an abstract only, and does not require institutional signature. Does the pre-proposal need to be routed through the Office of Research?

Signed,  
Curious

Dear Curious:

Pre-proposals that consist of only an abstract would not need to be routed through the Office of Research. However, if a pre-proposal requires a budget and/or institutional signature then you would need to route it through the OR for review and signature. If you are selected to submit a full proposal, it will need to be routed as usual.

Dear Dr. OR:

My PI is part of a grant application to NIH being submitted by UNC-CH. WFUHS will be a subcontract. UNC-CH has emailed us budget forms extracted from the SF424 for us to complete and email back to them.

When I tried to open these forms I got an error message, and I am not sure how to complete them. HELP!

Signed,  
Struggling to Complete

Dear Struggling:

Institutions that are not using a service provider (i.e. InfoEd) to submit their NIH applications are now transitioning from PureEdge to Adobe forms in order to complete the SF424 application. If an application includes a subcontract, then the prime institution must extract the subcontract budget pages and send to the subcontractor to complete and return. In order to complete the Adobe forms, you will need to download the grants.gov compatible version of Adobe to be able to complete the forms. Grants.gov currently recommends Adobe 8.1.3 or higher; compatible versions are listed at: [http://www.grants.gov/help/download\\_software.jsp#adobe811](http://www.grants.gov/help/download_software.jsp#adobe811).

Dear Dr. OR:

I will be talking with a company about a possible study I would like the company to support. Should I put a confidentiality agreement in place before I talk with them and if so, how do I get do this?

Signed,  
Keeping it Under Wraps

Dear Keeping:

If the proposal you will be sharing involves publically available information, then a confidentiality agreement is necessary. If the proposal contains proprietary or non-public information then a confidentiality agreement should be put in place. Note that if a confidentiality agreement is not put into place, the company is free to use the proposal or any other information you provide them without any obligation back to Wake Forest or you. Contact the Industry Relations contract administrator who works with your department to request a confidentiality agreement or help determine if one should be put in place prior to any discussions with companies.

## Controller's Corner

There is a new Effort Tool available within People Soft that will allow you to pull a query of Proposed, Awarded, Paid and Certified Efforts. This is currently being implemented on a go-forward basis. Therefore, as new grants are awarded or new years are renewed, we will be updating this information. You will probably not see much of an effect with the January variance report, but you should be able to see some changes when you run the variance report in July 2009. Instructions for the variance report are on page 14 of the [effort documentation](#) on the Controller's Office website.

As more departments are using InfoEd to submit proposals, it is a good idea to use object code budgeting. This will allow the Controller's Office to set up your budget in the intended manner with fewer questions.

eRFP is currently being implemented. If your department is in need of training, please contract Tonya Barga at 3-4283.

There are 2 new items on the [Grants Management section](#) of the Controller's Office website. One is a Termination Notice spreadsheet which will assist in calculating the stipend amount and days for the required termination forms for NRSA (F31-32) and training grants (T32). Also on the web site are instructions on how complete an [eRFP for subcontract invoice payments](#).

## WFU Translational Science Institute

### CTSA Grant Submitted: It's Official!

The WFU TSI CTSA application was submitted to the NIH on October 17<sup>th</sup> for the fall 2008 submission deadline. The document, a total of 823 pages, describes the TSI's mission, structure, and governance, and each of the 11 Programs. We anticipate that the application will be reviewed in the spring of 2009. We would like to thank everyone who contributed greatly to what we feel is a highly competitive proposal. Thanks to the TSI Program Leaders and members involved in the writing and budget work, the Research Support Core, internal and external reviewers, our external partners, letters of support writers, Office of Research administrators who advised and handled the institutional review, and leaders in other institutional offices who counseled and provided essential data for the application.

### Team Science Training

One goal of the TSI is to foster interdisciplinary research teams to enhance collaboration across the institution and beyond to academic and community partners. To do this, TSI has partnered with the Center for Creative Leadership (CCL) to offer a Team Science Training program to help individuals develop successful working relationships. The most recent Team Science training session

focused on leadership and decision-making styles and the dynamics of interactive teams, included 28 participants from a variety of backgrounds including WFU and WFUHS faculty and administration, and TSI partner faculty from Virginia Tech. The TSI will offer a follow-up session, in collaboration with CCL, in spring 2009. To learn more, please contact Dr. Todd Thornburg, [tthornbu@wfubmc.edu](mailto:tthornbu@wfubmc.edu) or 716-5773.

### WFU Primate Center Announces Pilot Awards

The TSI and WFU Primate Center congratulate the following individuals on receiving pilot awards for primate-specific research initiatives. Individuals will receive approximately \$20,000 of funding for one year of support.

- **Jeff Carr, Tom Register** - Quantitative CT Phenotyping of Vervet Monkeys Consuming a Chow Diet
- **Anthony G. Comuzzie** - Gene-by-Diet Interaction in Obesity-Related Traits in Vervets
- **Timothy Howard** - Identification of Genetic and Epigenetic Contributors to the Metabolic Syndrome and Related Phenotypes in the Vervet Research Colony

- **Iris Leng** - Development of Quantitative Techniques for Longitudinal Assessment of Disease Risk
- **Nilamadhab Mishra** - Epigenetic Histone Modification Landscape Changes in Response to an American Diet in African Green Monkeys
- **Larry Rudel** - Measuring Diet-Sensitive Lipid and Lipoprotein Predictors of Coronary Heart Disease Risk in the Vervet Research Colony
- **Carol Shively** - Aging and Physical Function in Primates
- **William Strawn** - Development of a Nonhuman Model of Spontaneous Hypertension

### TSI Scholar Awarded AHA Grant

Chad Miller, M.D., a TSI-supported Translational Scholar, has received support from the American Heart Association for his proposal "Randomized Cost Comparison of Cardiac MRI Use in ED Patients". The 2-year study begins in January 2009. We are pleased that another K12 Scholar has leveraged TSI support successfully for an external grant award. Congratulations to Chad!

### Topics in Clinical Trials Research Workshops

The WFUHS General Clinical Research Center (GCRC) and the Office of Research are sponsoring the Topics in Clinical Trials Research Workshops. The workshops are scheduled on the following dates:

**Workshop I: January 20, 2009**

**Time: 8:30 am - 12:45 pm**

**Location: Ardmore Cafeteria Conference Rooms 1 & 2**

**Workshop II: February 3, 2009**

**Time: 8:30 am - 12:50 pm**

**Location: Ardmore Cafeteria Conference Rooms 1 & 2**

These workshops are designed to provide an overview of the research resources and regulatory requirements for conducting clinical research studies. The workshops will be of interest to those who are new to clinical research, as well as those who would benefit from a review of the principles of clinical trials, Good Clinical Practices guidelines, clinical research design and operational issues, and human subject protection and regulatory considerations. Human subject protection training certification may be obtained by attending both workshops.

Registration for each workshop is \$30.00 per person. Early registration is encouraged, as enrollment is limited. For more information or to register, please contact Sarah Hutchens at [sarhutch@wfubmc.edu](mailto:sarhutch@wfubmc.edu).

## New No-Cost Extension Request Form

A new form to request no-cost extensions on grants and contracts is available on the Office of Research web site at: <http://www1.wfubmc.edu/OR/Grants/Forms/Forms.htm>. This form should be used whenever requesting a no-cost extension to a **non-industry** sponsored grant or contract. This new process is effective immediately and applies to all no-cost extension requests (1st, 2nd, etc.) To request an extension, complete the form and send it to your grants administrator for review. Please contact your grants administrator with any questions.

## Industry Relations News

Effective January 1, 2009, Industry Relations will be implementing a complete routing package policy. This policy provides that all required routing documents be provided to Industry Relations before a contract is assigned to the appropriate contract administrator for review or negotiation. This policy also provides for all required forms to be complete and all signatures obtained (except if a co-investigator is traveling and unavailable to execute the route form).

This process has already been in place, but is now being implemented as a policy for all types of contracts under Industry Relations' purview. If a significant portion of the routing package is missing or incomplete, the package may be returned for completion and re-submission.

Required routing packages by types of agreements are as follows:

- a) Basic research, clinical trial, services: route form, Research Agreement Questionnaire, protocol (draft acceptable); budget (preliminary acceptable); and agreement (if available)
- b) Material transfer agreements: Material Transfer Agreement Questionnaire (incoming or outgoing depending on transfer); agreement (for incoming materials, if available)

- c) Subcontracts: route form, protocol (draft acceptable); budget (preliminary acceptable); if incoming subcontract also requires Research Agreement Questionnaire and agreement (if available)
- d) Fellowship, travel, educational, conference or non-CME grants: route form and budget (preliminary is acceptable).

Prior to the policy change, submissions could indicate budgets were in negotiations and details be provided at a later date. With the new policy, we will now require both effort and budget information on the Route Form and a preliminary budget at a minimum. Preliminary budgets should already be determined prior to routing as part of the feasibility evaluation of a study/project, so this additional documentation should not cause delays in routing packages to our office.

We are also in the process of updating all of our Questionnaires. The new forms, as well as the new policy, and a listing of the required routing packages for each agreement type will be available on our web site.

Please do not hesitate to contact our office with questions.

## Financial Research Compliance Workshops 2009

### 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).

February 11, 2009  
February 19, 2009

9:00 a.m. – 11:00 a.m.  
5:00 p.m. – 7:00 p.m.

March 17, 2009

9:00 a.m. – 11:00 a.m.

### Standard Sessions for Staff

8:30 a.m. – 12:30 p.m.

January 14, 2009  
March 12, 2009

May 27, 2009  
July 23, 2009

September 9, 2009  
November 11, 2009

## Office of Research 2009 Workshop Schedule

### Study Coordinator 101

This is a hands-on workshop designed to cover IRB policies and procedures, federal regulations, Good Clinical Practices 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: January 7, 2009

Time: 1:30 - 5:00 p.m.

Location: Commons 2 & 3, G floor, Nutrition Bldg.

Presenters: Cheryl Byers & Debra McBride

#### Study Coordinator 101 - Part II

Date: January 14, 2009

Time: 1:30 - 5:00 p.m.

Location: Commons 2 & 3, G floor, Nutrition Bldg.

Presenters: Cheryl Byers & Debra McBride

### Interpreting Grant and Contract Award Documents

Awards come in all shapes and sizes. Whether it is a grant or contract, it is important to know the critical elements of the award so it will be administered appropriately. This workshop will include a discussion of award elements, such as terms and conditions, fiscal responsibility, restrictions and exclusions, responsible parties and deliverables. The workshop will include discussion of sample awards and review of language and terms. Special situations, such as transferring awards, will also be discussed.

Date: January 13, 2009

Time: 1:30-4:30 p.m.

Location: Commons 2& 3, G Floor, Nutrition Bldg.

Presenters: Paula Means & Janice Grace

Who should attend: Faculty, research administrators

### Revise and Resubmit:

#### How to Respond to Manuscript Reviews

Revising a manuscript to comply with reviewers' suggestions is an important step in getting published. But it is often difficult to know where to start, or how to move past your initial reactions to the comments. Bring your lunch and join us as this session will provide practical advice - and some insider tips - on how to assess the comments you receive and how to address them constructively so that your manuscript will be published sooner.

Date: February 10, 2009

Time: 12:00 - 1:00 p.m.

Location: Commons 3, G floor, Nutrition Building

Presenter: Karen Klein

Who should attend: Faculty, postdoctoral fellows & graduate students

### NIH: Start to Finish

This workshop is designed to give participants a "big picture" of the NIH grant/contract continuum. Participants will be provided with an understanding of the NIH research grants/contracts process and presenters will share information related to all aspects of the NIH cycle, from submission of the new proposal, to submission of the competitive renewal. The content will familiarize participants with NIH terminology and include topics related to proposal preparation, institutional review of proposals, electronic proposal submission, awards, supplements, and programmatic and fiscal accountability.

Date: February 24, 2009

Time: 9:00 a.m. - 12:00 p.m.

Location: Commons 1 & 2, G floor, Nutrition Building

Presenters: Paula Means, Theresa Sears & Amy Comer

Who should attend: Faculty, postdoctoral fellows, graduate students, and staff

### An Overview of the WFUHS Transgenic Mouse Core

Bring your lunch and join Dr. Liqing Yu, Director of the WFUHS Transgenic Mouse Core Facility, as he provides basic knowledge about the generation of genetically-engineered mouse lines. Services provided by the WFUHS Transgenic Mouse Core will also be discussed. A Q&A session will follow the presentation.

Date: March 18, 2009

Time: 12:00-1:00 p.m.

Location: Commons 2 & 3, G floor, Nutrition Building

Presenter: Liqing Yu, M.D., Ph.D.

Who should attend: Faculty & Administrators

All workshops organized by the Research Support Core are free; however, registration is required unless otherwise stated.

## NIH News



### Non-Competing Grant Awards under the Current Continuing Resolution - NOT-OD-09-002

The Department of Health and Human Services (HHS) continues to operate on a continuing resolution (CR) [Public Law 110-329 Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009] that currently extends through March 6, 2009. The CR applies the terms of the FY 2008 appropriations for the period covered by the CR. Until the final FY 2009 appropriation is enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This is consistent with the practice during the CRs of FY 2006 - 2008. NIH will consider upward adjustments to these levels after the final appropriation is enacted, but expects institutions to monitor their expenditures carefully during this period. Additional details will appear at <http://grants1.nih.gov/grants/financial/index.htm>.

### Clarification on New NIH Policy on Resubmission (Amended) Applications - NOT-OD-09-016

The notice clarifies the recently announced change in the existing policy on resubmission (amended) applications go to: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html>. The policy takes effect beginning with applications submitted for awards in fiscal year 2010 (first standard receipt date for fiscal year 2010 is January 25, 2009). The complete set of official submission dates can be found at: [http://grants.nih.gov/grants/funding/submission\\_schedule.htm](http://grants.nih.gov/grants/funding/submission_schedule.htm). The last applications that will be permitted two amendments are those that were submitted for award in fiscal year 2009. Thus, some specific examples:

Last submission date for a new R01 application eligible for an A2: October 5, 2008

Last submission date for a new R21 application eligible for an A2: October 16, 2008

Last standard date for a new AIDS application eligible for an A2: January 7, 2009

Another clarification concerns the last date at which R01, R21, and R34 applications from Study Section members can be submitted and still be eligible to submit an A2 application. To be assigned to the last Council of fiscal year 2009, non-AIDS R01, R21 or R34 applications needed to be submitted no later than December 16, 2008. AIDS R01, R21 or R34 applications must be submitted no later than February 7, 2009 (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-026.html>). This policy applies to all types of applications submitted to NIH, including small business (SBIR and STTR), fellowships, and career awards.

### NIH Now Recognizes "Early Stage Investigators"

The NIH recently announced that New Investigators within 10 years of completing their terminal research degree, or within 10 years of completing their medical residency, will now be designated **Early Stage Investigators** (ESIs). For details: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-021.html>. ESIs will be identified on R01 applications beginning in February 2009, and the applicant's career stage will be considered at the time of review and award. The New and Early Stage Investigator web site at: [http://grants.nih.gov/grants/new\\_investigators/index.htm](http://grants.nih.gov/grants/new_investigators/index.htm) contains detailed information. The rationale behind this change is so that the NIH can better meet its goal of supporting New Investigators at success rates comparable to those for established investigators submitting new applications (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html>.) ESIs should comprise most of the New Investigators supported. Where possible, New Investigator applications will be clustered during review. Because most FY 2009 grant applications already have been submitted, ESIs will be identified using available information for FY 2009. Applications from New Investigators will be clustered during initial peer review to the extent possible. The NIH strongly encourages New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding. To implement this modified policy, **all New Investigators must update their eRA Commons profiles to ensure they receive appropriate consideration. (This is the PI's responsibility; the Office of Research does not have access to this profile.)** The data in your eRA Commons profile will be used to determine ESI eligibility. Once you enter the degree and/or residency completion dates in your profile, you will be notified by email to verify your eligibility for ESI or New Investigator status. The eRA Commons will be ready to accept the completion date of medical residency after January 17, 2009.

### Revised PHS 416-1 (Individual Fellowship Ruth L. Kirschstein National Research Service Award Application) Now Available - NOT-OD-09-004

The newly revised "Application for an Individual Fellowship Ruth L. Kirschstein National Research Service Award" (PHS 416-1, Rev. 9/08) forms and instructions are now available and will be accepted for submission/receipt dates beginning in December 2008.

# NIH News



All applications received for submission dates in December 2008 and thereafter must use only the new forms. NIH and AHRQ anticipate this to be the last paper-based submission for Individual Fellowship applications. Plans are still on target to transition Individual Fellowship applications to electronic submission beginning with the April 2009 cycle. For more information on NIH's transition plans, see the website for Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>. The newly revised forms and instructions are available at <http://grants.nih.gov/grants/funding/416/phs416.htm>.

### Clarification of NIH Policy on Late Submission of Grant Applications - NOT-OD-08-111

This notice points out a change in text in Notice OD-08-027 (<http://grants1.nih.gov/grants/guide/notice-files/not-od-08-027.html>). Previously the notice had the following text:

“Late applications have been accepted for reasons such as: death of an immediate family member of the Principal Investigator, sudden acute severe illness of the Principal Investigator or immediate family member, temporary or ad hoc service on a NIH extramural peer review group, service on a NIH Board of Scientific Counselors or Advisory Board/Council, or large scale natural disasters.”

This has been changed to:

“Late applications have been accepted for reasons such as: death of an immediate family member of the Principal Investigator, sudden acute severe illness of the Principal Investigator or immediate family member, or large scale natural disasters. Recent service by the Principal Investigator **only** (this does **not** include other participants in the application) on an NIH extramural review group, NIH Board of Scientific Counselors or Advisory Board/Council that could reasonably be expected to require a time commitment that could have been used to prepare an application is also an allowable reason.” The change emphasizes that this consideration applies only to those with the PD/PI role who have **recent** service, not past service.

### The NIH Center for Scientific Review Updates the Descriptions of its Chartered Review Panels - NOT-OD-09-027

CSR has updated the descriptions or guidelines of its study sections that applicants often use to suggest which CSR study section(s) might best review their applications. These changes only apply to CSR's chartered study sections, not other study sections organized by CSR or the other NIH Institutes or Centers. For updated descriptions, see <http://cms.csr.nih.gov/PeerReviewMeetingsCSRIRGDescriptionNew/>. CSR revised these descriptions in response to requests from study section chairs and others who evaluated CSR's review groups. These changes were designed to make CSR's chartered study section descriptions more transparent and reflective of the types of applications actually reviewed. The updated descriptions were also designed to be more user-friendly, especially for new applicants. NIH encourages applicants to submit a cover letter with their application to suggest which study section(s) they think could best review their applications. CSR cannot guarantee it will follow these suggestions, but it does so when appropriate and possible. Having applications reviewed by study sections with the needed experts helps ensure the quality of NIH peer reviews and the identification of those projects most likely to advance science and health. More information on cover letters is available in the SF424 (R&R) Application Guide for NIH and Other PHS Agencies: <http://grants.nih.gov/grants/forms.htm>. The format for descriptions for chartered study sections is:

- A one-paragraph overview of the scientific areas reviewed by the study section.
- A bulleted list of the key specific topics.
- Links to the membership roster and the three most recent meeting rosters of the review panel.
- Links to related study sections that review similar areas of science.

Updated descriptions of recurring panels will be produced early in 2009. Study section chairs will revise these descriptions during biannual reviews of CSR Integrated Review Groups (IRGs).

### At a Glance: NIH Changes Coming in 2009

<b>May 2009 Review Meetings</b> (FY 2010 funding)	-9-Point Scoring System -Formatted Reviewer Critiques -Scoring of Individual Review Criteria -Enhanced Review Criteria -Cluster New Investigator Applications During Review
<b>Jan 2010 Receipt Dates</b> (FY2011 funding)	-Shorter applications for R01s and Other Mechanisms - Restructured Applications to Align with Review Criteria

## Funding Opportunities



### Healthy Kids, Healthy Communities

The Robert Wood Johnson Foundation (RWJF) (<http://www.rwjf.org>) sponsors this national program to implement healthy eating and active living initiatives. The program focuses on reaching children at highest risk for obesity because of race/ethnicity, background, income, or geographic location. RWJF will award about 60 grants to help local community partnerships across the US. Special consideration will be given to areas where risk for childhood obesity is greatest (includes North and South Carolina). The Program will accept only 1 application per community (defined as a city, county, district or region with partners who plan, advocate for, and implement changes in policies, environments, and systems). Grants of up to \$360,000 each will be awarded for up to 4 years. **Deadline: February 3, 2009.**

### NIH Issues New Program Announcements for K Awards

#### K02 Independent Scientist Award

<http://grants.nih.gov/grants/guide/pa-files/PA-09-038.html>

#### K01 Mentored Research Scientist Career Development Award

<http://grants.nih.gov/grants/guide/pa-files/PA-09-040.html>

#### K07 Academic Career Award

<http://grants.nih.gov/grants/guide/pa-files/PA-09-041.html>

#### K08 Mentored Clinical Scientist Research Career Development Award

<http://grants.nih.gov/grants/guide/pa-files/PA-09-042.html>

#### K22 NCMHD Disparities Research and Education Advancing Mission (DREAM) Career Transition Award

<http://grants.nih.gov/grants/guide/rfa-files/RFA-MD-09-001.html>

#### K23 Mentored Patient-Oriented Research Career Development Award

<http://grants.nih.gov/grants/guide/pa-files/PA-09-043.html>

#### K24 Midcareer Investigator Award in Patient-Oriented Research

<http://grants.nih.gov/grants/guide/pa-files/PA-09-037.html>

#### K24 Midcareer Investigator Award in Patient-Oriented Research

<http://grants.nih.gov/grants/guide/pa-files/PA-09-037.html>

#### K25 Mentored Quantitative Research Development Award

<http://grants.nih.gov/grants/guide/pa-files/PA-09-039.html>

#### K99/R00 Pathway to Independence Award

<http://grants.nih.gov/grants/guide/pa-files/PA-09-036.html>

Next deadline for all K's is **February 12, 2009.**

Not sure which K is right for you? Go to the NIH's "K Kiosk" (<http://grants.nih.gov/training/career-developmentawards.htm>) for eligibility and other details.

### Mary Kay Ash Cancer Research Grants Program

The Mary Kay Ash Charitable Foundation (<http://www.mkacf.org/>) sponsors research grants to cure cancers that affect women. They seek applications for innovative, translational research in breast, cervical, ovarian, or uterine cancer. The program will award at least 8 two-year grants of up to \$100,000 each (total direct and indirect costs). Only one application will be accepted from each U.S. medical school. If you are interested in applying, please contact Paula Means in the Office of Research well before the sponsor's deadline. **Deadline: February 13, 2009.**

### 21<sup>st</sup> Century Science Initiative Research Awards

The James S. McDonnell Foundation (<http://www.jsmf.org/>) has updated program descriptions and application guidelines for these Awards. They support investigator-initiated research in the study of complex systems and in brain cancer. Projects should be at an early or preliminary stage, be intended to break new ground, and be sufficiently cross-disciplinary to have a strong likelihood of influencing new ways of thinking about the problem. A maximum of \$450,000 can be requested for a period of 3-6 years; smaller requests are also considered. **Deadline: March 17, 2009.**

## Web-based Statistical Power Calculators

One of the most common questions fielded by biostatisticians is “How many subjects/animals/samples do I need?” To assist WFUHS investigators with this question, the Department of Biostatistical Sciences has developed web-based calculators (<http://power.phs.wfubmc.edu>) for estimation of power and/or sample size for some basic study designs. SAS is used behind the scenes as the computational engine. Existing designs include correlation, one-sample *t*-tests, two-sample *t*-tests, paired *t*-tests, one-sample frequencies, two-sample frequencies, and paired frequencies. Also available are a series of questions to aid investigators in the selection of a calculator. We plan to add additional calculators in the future. As always, we encourage investigators to consult with a statistician when there are questions about these calculations.

*W*OMEN'S  
HEALTH CENTER  
of EXCELLENCE  
*Research, Leadership, Education*

The Women's Health Center of Excellence is proud to announce our new **Women's Health Research Awards** designed to reward and encourage the continued pursuit of excellence in women's health research at WFUHS. Two awards will be given: New Investigator and Mid-Career Investigator. Applications are due by February 15, 2009. Contact Shannon Golden at 6-9714 or [sgolden@wfubmc.edu](mailto:sgolden@wfubmc.edu) for details.

### Research Strategy Workshop Series

This series of workshops has been developed for faculty and are designed to enhance research skills. Lunch is provided. Registration requested. Our next workshop is:

**Topic: Managing Research Conflict: Sabotage, Power Struggles, and Difficult People**  
**Date: February 19, 2009, 11:30 a.m. – 1:00 p.m.**  
**Location: Cancer Center, 2A & 2B**  
**Facilitators: Carol Shively, Ph.D.; David Roberts, Ph.D.**

Dealing with collaborators, colleagues, staff and students can be tricky when problems arise. When not adequately addressed, these problems can undermine the efforts of the researcher as well as impact the research itself. Learn strategies for identifying and addressing conflict in the research world.

**Cheryl Bushnell, M.D.**, Associate Professor in Neurology, became Associate Director of the WHCOE on October 1. Her research focuses on sex differences in stroke risk, stroke outcomes in women, the impact of hormone therapy and co-morbidities on these outcomes, and stroke in pregnancy, including preeclampsia. Dr. Bushnell has received many professional awards, including the Cornelius G. Dyke Award in Neurology, a Resident Scholarship from the American Neurological Association, the Pharmacia-Upjohn Research Award for Outstanding Research, and the American Medical Women's Association Janet M. Glasgow Memorial Achievement Citation. At WFUHS, she is actively involved in mentoring women faculty, residents, and fellows.

### Save the Date in 2009!

**March 20: 4<sup>th</sup> Annual Women's Health Research Day, Sticht Center.** This year's theme is “Hormones and Hormone Therapy Revisited.” Registration is \$25; students are free.

Visit our web site's Research Program page for details on events and current women's health funding opportunities: <http://www1.wfubmc.edu/whcoe/Research/index.htm>

### Pursuit Staff

Amy Comer  
Penny Gatsis  
Karen Klein  
Paula Means  
Anne Watterson

