

WAKE FOREST UNIVERSITY

SCHOOL of MEDICINE
THE BOWMAN GRAY CAMPUS

OFFICE OF RESEARCH

<http://www.wfubmc.edu/or>

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PURSUIT

RESEARCH INFORMATION BULLETIN Vol. 19, No. 5, Sept./Oct. 2005

FACULTY RESEARCH AWARDS RECIPIENTS

The 9th Annual Wake Forest University Health Sciences Basic and Clinical Research Awards Day was held on Tuesday, September 27th. Following lectures by recipients, awards were presented by Richard H. Dean, M.D., President and Chief Executive Officer. The awardees are as follows:

New Investigator in Basic Sciences

Emilio Salinas, Ph.D., Assistant Professor
Department of Neurobiology and Anatomy

New Investigator in Clinical Sciences

Paul J. Laurienti, Ph.D., M.D., Assistant Professor
Department of Diagnostic Radiology

Mid-Career Investigator in Basic Sciences

Leslie B. Poole, Ph.D., Associate Professor
Department of Biochemistry

Mid-Career Investigator in Clinical Sciences

Dalane W. Kitzman, M.D., Professor
Department of Internal Medicine

Established Investigator in Basic Sciences

Donald W. Bowden, Ph.D., Professor
Department of Biochemistry

Established Investigator in Clinical Sciences

Gregory L. Burke, M.D., M.Sc., Professor and Chair
Department of Public Health Sciences

INCREASES IN NIH RANKINGS FOR NINE DEPARTMENTS

A total of 9 WFUHS departments moved up in the NIH grant rankings this past fiscal year relative to their counterparts in other U.S. medical schools. "In a climate of shrinking NIH dollars, this is a real testament to the quality of our research," said Sally Shumaker, Ph.D., Associate Dean for Research. Some high points: Family Medicine moved up 178% in one year, a remarkable accomplishment. And Internal Medicine gained 3 places in the rankings, despite an additional 5 departments being added to its category this year. Individual rankings of the 9 departments for FY04 are listed below. Our congratulations to all!

Neurobiology and Anatomy - 30th
Anesthesiology - 18th
Family Medicine - 11th
Internal Medicine - 40th
Pediatrics - 46th

Psychiatry - 67th
Public Health Sciences - 1st
Radiological Sciences - 19th
Surgical Sciences - 22nd

CONCERN LINES

ANIMAL CARE & USE -

716-5899

RESEARCH CONDUCT -

716-0338

COMPLIANCE -

1-877-880-7888

REGULATORY COMMITTEE**DEADLINES**

ANIMAL CARE AND USE

COMMITTEE - NOVEMBER 4 AND

DECEMBER 2, 2005

INSTITUTIONAL REVIEW BOARD -

NOON - FRIDAYS

INTRAMURAL RESEARCH**SUPPORT COMMITTEE****DEADLINES**

*REGULAR AND INTERIM -

NOVEMBER 11, 2005

* CLINICAL STUDIES OR OTHER

RESEARCH INVOLVING HUMANS

ARE ENCOURAGED

**RESEARCH
ADMINISTRATORS
SESSIONS****NOVEMBER 10, 2005 - EFFORT**

REPORTING

DECEMBER 8, 2005 - HOLIDAY

BRUNCH - OR UPDATES

ALL SESSIONS ARE HELD AT 10:00 AM
IN COMMONS CONFERENCE ROOMS
2&3. PLEASE EMAIL AMY COMER
(ACOMER@WFUBMC.EDU) TO BE
ADDED TO THE EMAIL LIST.

RESEARCH SUPPORT CORE UPDATE

In the May/June 2005 issue of Pursuit, we reported on some new programs offered by the Research Support Core. One of these, the "mini-study sections" for internal review of grant critiques by seasoned WFUSM investigators, has now begun. So far, 3 Principal Investigators have requested this review. All found it extremely helpful and were highly complimentary of their colleagues' input. If you are resubmitting a proposal, remember that this program is available on a first-come, first-serve basis. We recommend contacting us as early in your planning process as possible.

We are pleased to announce the roll-out of another new service in the Research Support Core - **manuscript editing**. Karen Klein, the editor in the Core, is now offering editorial assistance with manuscripts as well as grants. Karen has over 20 years of experience in biomedical editing, and her expertise is available free of charge to all WFUSM faculty. She can advise on journal selection, addressing critiques from reviewers, and other aspects of the peer-review publishing process, in addition to editing the text. Again, this assistance is on a first-come, first-serve basis, and editing of grants will take priority because of submission deadlines.

Another important service begun by the Core is our **mentoring program**, led by Dr. Charles McCall, Deputy Associate Dean for Research. This program provides guidance and mentorship to junior faculty in all aspects of professional development. Locating this program in the Research Support Core (as part of the Office of Research) facilitates mentees' access to institutional resources, including the manuscript editing and grant support services of the Core.

To access these or other services offered by the Core, send an email inquiry to rscore@wfubmc.edu. You can also go to the web site and download the "Request for Assistance" forms available for either grants or manuscripts at <http://www1.wfubmc.edu/OR/Research+Support+Core/>.

PROHIBITED ABBREVIATIONS

The JCAHO National Patient Safety Goals have established a series of abbreviations that are easily misinterpreted and compromise patient safety. To promote the safety of research subjects, the IRB will not accept the use of prohibited abbreviations in research consent documents. Hospital policy prohibits the use of these abbreviations in clinical consent forms and other clinical documents. The use of these prohibited abbreviations is equally inappropriate in the research setting.

PROHIBITED

QD

QOD

U

IU

MS or MSO₄MgSO₄

i g

AS, AD, AU

OS, OD, OU

X3d, etc.

Trailing zero (X.0 mg)

No leading zero (.X mg)

ACCEPTED

daily

every other day

units

international units

morphine sulfate

magnesium sulfate

microgram or mcg

left ear, right ear, both ears

left eye, right eye, both eyes

doses or days

Never write a zero by itself
after a decimal point (X mg)Use a zero before a decimal
point (0.X mg)

TOPICS IN CLINICAL TRIALS RESEARCH

Sponsored by the WFUHS General Clinical Research Center and the Office of Research.

- These ½-day lecture series will be of interest to those new to clinical research and anyone who would benefit from a formal review of the principles of clinical trials, GCP (Good Clinical Practice) guidelines, clinical research design and operational issues, and human subject protection and regulatory considerations.
 - The principles and practices discussed in these workshops also apply to non-interventional clinical studies, and are relevant to both federal and industry sponsored research.
 - Human subject protection training certification may be obtained by attending both Workshop I and Workshop II.
 - Registration for each workshop is \$30/person. Early registration is encouraged, as enrollment is limited.
- To register, go to <http://www.gcrc.wfubmc.edu/CTWRegistration.doc>. Please submit your completed registration forms to Sarah Hutchens at sarhutch@wfubmc.edu or via interoffice mail to the GCRC.

Workshop I (morning of Monday, December 12, 2005; Ardmore Conference Rooms 1&2)

Good Clinical Practices
Processing of IRB Documents
Adverse Events and Serious Adverse Events...What's the Difference?
Running Smoothly-Management and Conduct of Clinical Trials
Recruitment of Study Participants

Workshop II (morning of Friday, December 16, 2005; Ardmore Conference Rooms 1&2)

Overview of Randomized, Controlled Clinical Trials
The Informed Consent Process
The FDA Audit
Do's and Don'ts of Clinical Research

Statistical Considerations in the Design and Analysis of Clinical Trials

REMINDER

When preparing budgets for collaborative proposals with the Reynolda Campus (WFU), please allow adequate time for budget preparation and/or review from the Reynolda Campus. As soon as you know you will be preparing a budget including Reynolda Campus faculty, please contact Lori Messer (messerlj@wfu.edu) in the Research and Sponsored Programs Office at the Reynolda Campus. Lori can assist you in preparing the budget and completing the budget pages for WFU's portion of the application. Working with Lori **before** routing the budget to the WFUHS Controller's Office will help facilitate the budget review process. Remember, the Controller's Office **must** receive the budget **8 days before** the sponsor's deadline.

UPCOMING GRANTS WORKSHOPS

WHAT - "THE NITTY GRITTY OF NIH GRANTS"

WHEN - WEDNESDAY, NOVEMBER 30, 2005

TIME - 9:00 - 12:00 NOON

WHERE - ARDMORE CONFERENCE ROOMS 1 AND 2

TO REGISTER - SEND AN EMAIL TO RSCORE@WFUBMC.EDU KAREN KLEIN FROM THE RESEARCH SUPPORT CORE WILL PRESENT PRACTICAL TIPS ON WHAT IT TAKES TO WRITE A SUCCESSFUL PROPOSAL. THE WORKSHOP IS OPEN TO ALL IN THE WFUHS COMMUNITY.

WHAT - "BUDGETS 201"

WHEN - JANUARY 17, 2006

TIME - 1:00PM - 5:00PM

WHERE - COMMONS CONFERENCE ROOMS 1 - 3

TO REGISTER - ANGELA HORTON, AHORTON@WFUBMC.EDU

THE SECOND IN A SERIES OF BUDGET WORKSHOPS WILL INCLUDE A DISCUSSION OF TECHNIQUES, GUIDELINES AND TIPS RELATED TO BUDGET PREPARATION AND MANAGEMENT OF FEDERAL, INDUSTRY AND OTHER TYPES OF APPLICATIONS. SOME TOPICS TO BE DISCUSSED INCLUDE: FACILITIES AND ADMINISTRATION (F&A), CONSORTIUMS, COST SHARING AND COMPLEX BUDGETS ASSOCIATED WITH PROGRAM PROJECTS. ATTENDEES SHOULD HAVE ATTENDED BUDGET 101 OR HAVE EXPERIENCE IN WORKING WITH SPONSORED RESEARCH BUDGETS.

DEAR DR. OR

Dear Dr. OR:

I have a contract to route to Industry Relations. The route form says "Allow THREE working days from agency deadline for Institutional Approval". Does this 3 day rule apply to industry contracts too?

Signed,

Curious about Contracts

Dear Curious:

No. The "3-day rule" is applicable to all non-industry submissions to allow for review and approval of the grant. When Industry Relations is negotiating the terms of a study contract, it needs sufficient time to complete that process in light of the specific needs of the study, as well as all institutional policies, and federal, state and local regulations. The length of this process can vary depending on the issues that need to be negotiated.

Dear Dr. OR:

A reporter from a national media outlet read a recent journal article of mine, and contacted me to do a story. I jumped at the chance to make our research known to such a wide audience, and the article appeared yesterday. But when my department chair asked if I'd followed the WFUHS policies about contact with the media, I didn't even know what they were. What should I have done?

Signed,

Famous But Flummoxed

Dear Famous,

Your excitement at being able to share your work with the world illustrates why we have policies – namely, that it's not something most of our faculty have much experience with. Our Public Relations/Marketing (PR/M) department is there to help WFUHS always put its best foot forward in the media. Reporters are always on tight deadlines, and may make you feel that you must answer their questions in the next 5 minutes. That's why it's wise to involve PR/M staff right away. They are most aware of the media's deadlines and policies, and know how to handle potentially sensitive topics. If you alert PR/M staff to an upcoming national-level publication or presentation, they will write a news release about it and become the initial contact for any subsequent inquiries. PR/M even offers media training classes for WFUHS faculty, and will work closely with you to polish your skills in these situations. The WFUSM Faculty Handbook contains the details of our media relations policies. So the next time you hear from a reporter, before you return that call or email, call PR/M first at 6-4857.

Dear Dr. OR:

I'm a new technician in a lab that does animal research. I would like to get more training to enhance my job performance and have the potential for growth in my position. Where can I obtain this type of training?

Signed,

Eager Beaver

CONTINUED ON PAGE 5.....

DEAR DR. OR CONTINUED.....

Dear Eager:

A comprehensive training source is the American Association for Laboratory Animal Science (AALAS). Their "Learning Library" (at <http://www.aalaslearninglibrary.org/>) is designed to handle the training needs of researchers, technicians, animal facility managers and directors, members of the Institutional Animal Care and Use Committee, and other personnel involved with the care and use of laboratory animals. There are a variety of self-study modules available covering protocol writing, ethical principles, pain management, statistics, and more. Some of these are free, and some require a membership fee. In addition, AALAS offers three levels (ALAT, LAT, and LATG) of certification for laboratory technicians who work with animals. More information on this program can be found on the AALAS homepage (<http://www.aalas.org>) under the Education/Certification tab at the top of the page.

If you aren't sure which courses might be right for you, check with your lab manager or have your supervisor contact the Animal Resources Program for more information at 3-7391.

Dear Dr. OR:

How are paid leaves handled for personnel on federal grants? For example, a family medical leave?

Signed,

Planning FMLA

Dear Planning:

On federal grants, paid leave is discussed in the Office of Management and Budget (OMB) circular A21, section J 10:

Fringe benefits.

(1) Fringe benefits in the form of regular compensation paid to employees during periods of authorized absences from the job, such as for annual leave, sick leave, military leave, and the like, are allowable, provided such costs are distributed to all institutional activities in proportion to the relative amount of time or effort actually devoted by the employees.

If key personnel are going to be on extended leave such as family medical leave and their overall effort is going to be reduced on the sponsored project, then the sponsor will need to be informed. This is simply good project management, as the absence of any key personnel usually affects the overall objective of the grant. The sponsor should be aware of how this absence will affect the overall goals of the project. NIH sponsored agreements follow the NIH policy guidelines as stated below:

Change in Status, Including Absence, of Principal Investigator and Other Key Personnel: *The grantee is required to notify NIH if the PI or other key personnel named in the notice of grant award will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce his or her time devoted to the project by 25 or more percent from the level that was approved at the time of award (for example, a proposed change from 40 percent effort to 30 percent or less effort). NIH must approve any alternate arrangement, including any replacement PI or other key personnel proposed by the grantee.*

The request for approval of a substitute PI/key person should include a justification for the change, the curriculum vitae of the individual proposed, other sources of support, and any budget changes resulting from the proposed change. If the arrangements proposed by the grantee, including the qualifications of any proposed replacement, are not acceptable to NIH, the grant may be suspended and/or terminated. If the grantee wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the awarding office grants management officer, in writing, of its wish to terminate, and NIH will forward closeout instructions.

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



Wake Forest University Baptist
MEDICAL CENTER
Women's Health Center of Excellence

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

For upcoming conferences and lectures, visit our calendar website at
www.wfubmc.edu/women

10TH ANNUAL GRAYLYN CONFERENCE ON WOMEN'S COGNITIVE HEALTH - OCTOBER 26-28, 2005

The 2005 Graylyn Conference on Women's Cognitive Health is fast approaching. This year, the conference focus is *Women's Cognitive Health: Fostering a Dialogue That Leads to Cutting Edge Translational Research*. The conference will bring together leaders in the field from around the world to review current knowledge and to guide research efforts toward promising avenues of research.

The biennial Graylyn Conferences on Women's Health began in 1995. Past conferences have attracted the leading researchers in women's cognitive health for presentation of their most current work, and served as a catalyst for new collaborations and the development of further research.

The deadline for registration is **October 15, 2005**. For more information or to register visit: www1.wfubmc.edu/whcoe.

Call for Poster Presentations

This year's Graylyn conference, *Women's Cognitive Health: Fostering a Dialogue That Leads to Cutting Edge Translational Research*, will incorporate new issues in cognitive health, providing an overview on encoding, storage and retrieval, examining effects of diseases more prevalent in women and their treatments, exploring advances in the basic science of cognitive decline through animal models, and investigating advances in diagnostic criteria and new treatments. Submissions of poster proposals on recent and ongoing basic science, clinical, or epidemiological research on dementia, cognitive functioning or learning are invited. Two \$500 prizes will be awarded: (1) the best student poster presentation, and (2) the best junior faculty poster presentation. For poster information or to send abstracts, contact **Stacy Rega** at srega@wfubmc.edu or 716-9714. They can also be mailed to: Women's Health Center of Excellence for Research, Leadership, Education, Wake Forest University School of Medicine, PO Box 573050, Medical Center Boulevard, Winston-Salem, NC 27157.

RESEARCH SEMINAR SERIES – DR. KATHERINE HARTMANN TO SPEAK

Katherine E. Hartmann, MD, PhD will speak on Tuesday, Nov. 10 from noon until 1 pm in Rooms 2C & D in the Comprehensive Cancer Center. Her talk is titled "Right from the Start: Lessons from the Study of Early Pregnancy Loss". Dr. Hartmann is the Co-Director of the North Carolina Program for Women's Health Research, Assistant Professor in the Department of Obstetrics and Gynecology for the School of Medicine, and Assistant Professor in the Department of Epidemiology for the School of Public Health at the University of North Carolina at Chapel Hill.

Luncheon will be provided. No registration is required. For more information, contact Diana Cornelison at dcorneli@wfubmc.edu or 713-4222.

UPDATE FROM THE SECTION OF INDUSTRY RELATIONS:

INDUSTRY RELATIONS PROCESS REMINDERS

All Industry Studies Must Be Routed

When receiving funds from industry for the support of research, you must route documentation to Industry Relations. This allows Industry Relations to negotiate the appropriate type of agreement for the receipt of, and any obligations related to, those funds.

Do Not Start Work on a Project Until the Appropriate Agreement is Executed

Actual work should not begin on a project until the appropriate documents are submitted through Industry Relations' review process and both parties sign a mutually acceptable agreement. The signature must come from an authorized institutional representative and not the faculty member. If you are unsure of the status of your agreement, please contact Industry Relations to verify whether it is completed before starting your project.

Completed Industry Studies

When you have completed your industry-supported study, please let Industry Relations know so we can assist you with making sure that all funds have been received, help pursue any outstanding funds and close out our files appropriately.

Terminated Industry Studies

If you or the company decides to terminate your industry-supported study before it is completed, please let Industry Relations know. Many times if a study is terminated early, the company will request a refund of any amounts they believe were overpaid for the work completed. We can assist you in determining if the amount requested is correct and if not, help negotiate a more appropriate refund amount. This will also help us close out our files appropriately.

NIH ANNOUNCES LOCATIONS FOR 2006 NIH REGIONAL SEMINARS IN PROGRAM FUNDING AND GRANTS ADMINISTRATION

Two regional seminars covering topics related to NIH extramural program funding and grants administration have been planned for 2006. The regional seminars provide information about the entire funding process, from opportunity identification and application preparation through post-award administration.

March 30 - 31, 2006 - Boston, Massachusetts, co-hosted by Harvard University and Massachusetts General Hospital

May 31 - June 1, 2006 - Riverside, California, hosted by University of California, Riverside

Space for these seminars is limited. Programmatic and logistical information will be posted as it becomes available at: <http://grants.nih.gov/grants/seminars.htm>.

CONTROLLER'S CORNER - GRANTS MANAGEMENT

Effort reporting:

Effort reports for monthly paid employees are now past due for the period of January 1, 2005 - June 30, 2005. If you have not done so, please log in to PeopleSoft and complete your effort report. If you are a departmental administrator, we would appreciate your assistance with encouraging all those who are delinquent to submit ASAP. If you have questions about efforts or how to run the exception reports, please call Kimberley Hale at 3-4303.

Travel reimbursement:

To assist us in the timely reimbursing and processing of travel expenses, it is imperative that the travel expense voucher (TEV) be turned in within 10 days of returning from the trip. Not doing so causes many issues and delays reimbursements to the traveler. Some of these problems occur upon closeout of a sponsored project or after the employee leaves the university, which simply compounds the issues. Each department should have a dedicated person to ensure that these TEV's are completed in a timely manner. A reminder is sent from the Controller's Office about every other month. If you are not getting these reminders, please contact Carolyn Sheets (3-4214) and she will be happy to send them to you.

All trainee travel should be coded to 413001, not 415001.

Research participant payments:

We have been asked to issue checks for small amounts (under \$5.00) to people participating in studies. We can certainly issue these checks, but experience has shown that many people do not cash them. When this occurs, we are ultimately required to remit these uncashed checks to the state (escheats process). This is a very time-consuming requirement and we would appreciate your assistance in reducing how often it happens.

Two possible alternative ways to disburse these small payments:

1. Petty cash
2. Issuing gift cards for average mileage incurred, instead of calculating exact amounts for each participant's mileage reimbursement.

General reminders:

A contact person should be indicated on all correspondence with the Controller's Office. This person should be knowledgeable about the request being made, to ensure requests are processed as quickly as possible. Common correspondence includes: requests for payments (RFP), requests for cost transfers, grant proposals, and other requests that are simply sent to us.

Please staple all attachments for any RFP together. Often these items get separated, which can cause delays.

REGISTRATION OF CLINICAL TRIALS

Allegations of selective publication and biased reporting of clinical trials have led to the demand for full disclosure and transparency. In response to these concerns, the members of the International Committee of Medical Journal Editors (ICMJE) have stipulated that clinical trials will be considered for publication in their journals only if they are registered in a public-access database **before the enrollment of the first patient**. This covers trials that started recruiting patients on or after **July 1, 2005**. Such trials were to be registered before **September 13, 2005** to comply with the ICMJE policy.

Journals that participate in ICMJE include JAMA, The New England Journal of Medicine, Lancet and Annals of Internal Medicine among others.

Investigators are responsible for evaluating whether a trial needs to be registered and ensuring trials are registered when applicable. The following FAQs have been developed to provide assistance.

Which trials need to be registered?

- Phase 3 or 4 clinical trials with a prospectively assigned concurrent control or comparison group
- Phase 2 trials (designed to provide preliminary data for larger, clinically directive trials) or other unregistered trials will be considered on a case-by-case basis by the ICMJE journal editors

Who is responsible for registration?

- For investigator-initiated trials – Lead Principal Investigator
- For sponsor-initiated trials – the sponsor
- For federal government-sponsored trials (e.g. NIH) – the grantee (lead investigator)
- Trials associated with Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications with the U.S. FDA – the IND/IDE holder
- If the individual or sponsor who should register the trial is unwilling or unable to register the trial, a participating investigator should do so

Where can a trial be registered?

ClinicalTrials.gov, developed and maintained by the National Library of Medicine at NIH, is the only site in the U.S. that currently meets the ICMJE requirements. To begin registration, go to <http://prsinfo.clinicaltrials.gov/>. ClinicalTrials.gov will then create an account and send email instructions on how to log in and register the trial. There is no charge for registering or accessing the database.

Is registering trials the same as a registry of trial results?

No – the ICMJE policy refers to ongoing trials only.

More FAQs are available on the Office of Research web site, at the “Monitoring and Oversight” tab.

NEW SERVICE OFFERED BY TRANSGENIC MOUSE CORE

The Transgenic Mouse Core Facility now provides a mouse embryo rederivation service. Embryo rederivation at the zygote stage is the gold standard for removing infectious agents such as viruses from your valuable mouse research models. This new service also will be critical to achieving the institution's goal of making all of the mouse research housing facilities specific pathogen free. The fee for this service and additional details can be found on the Transgenic Mouse Core web page at <http://www.wfubmc.edu/pathology/tgmc/core/>. For specific questions, please call the Core Director, Dr. Liqing Yu (6-0920).

VIGILANCE:

UPDATES FROM WFUSM ENVIRONMENTAL HEALTH AND SAFETY

IMPORTANT CLASS OFFERING!

Environmental Health and Safety will conduct a Shipping of Infectious Substances Under IATA class. Recurrent training is required every two (2) years. The present class provides general awareness and function-specific training on the shipping requirements for the transport of infectious substances and/or diagnostic specimens by air. Some safety training is included to supplement that already provided through the Wake Forest University Health Sciences (WFUHS) Exposure Control Plan for Bloodborne Pathogens. Further, this class reviews requirements of the U.S. Department of Transportation (DOT) and the Centers for Disease Control and Prevention (CDC) for shipping of hazardous (biological) materials. Included are the requirements of the International Air Transport Association (IATA). The class will be held on Wednesday, October 26, 2005 from 9:00-10:30 in Hanes 1064. Please contact Jennifer Evans, EH&S Education Specialist, at 6-6084 or jeevans@wfubmc.edu to be enrolled.

CLOSEOUT PROCEDURES FOR LABORATORIES USING HAZARDOUS MATERIALS

Failing to close out labs properly could cost departments extra dollars. Whenever a Principal Investigator leaves WFUHS or moves to different laboratory facilities, hazardous materials must be managed carefully. Applicable institutional, local, state, and federal guidelines and regulations must be observed.

Planning for the proper disposal of all hazardous materials must be accomplished with the assistance of Environmental Health and Safety. Hazardous materials may include (but are not limited to):

- Chemicals
- Biological materials
- Tissues
- Radioisotopes
- Contaminated equipment

The primary responsibility for the proper management of all hazardous materials rests with the Principal Investigator. Beyond the investigator, responsibility lies with the WFUHS department. If the process of disposal, shipping, or intramural transfer of hazardous materials requires the services of EH&S (outside of the scope of normal EH&S activities) or an outside contractor, the responsible department may be charged.

EH&S is not responsible for costs incurred by individuals or departments as a result of lab closeouts or transfers. This includes the cost of lab or equipment decontamination, if not accomplished or arranged by the responsible Principal Investigator.

Questions? Contact the EH&S Director, David A. Brown @ 6-9375 or dabrown@wfubmc.edu.

WFU ACUC SEMI-ANNUAL SITE VISITS TO OCCUR IN OCTOBER

The WFU Animal Care and Use Committee (ACUC) begun its first semi-annual site visits of animal facilities for this academic year during October. It will take 2-4 weeks to conduct all of these visits.

ACUC teams will visit all Animal Resources Program housing and support space, satellite housing space, and many procedure rooms in individual laboratories on all of the WFU campuses. Procedure rooms are defined as **"any room where a live animal is used as part of an experiment/surgery."** **ACUC visits of all animal facilities, including procedures rooms, are required** for the institution to remain compliant with the federal regulations and to continue receiving research funding.

If you have any questions, please contact the Animal Monitoring and Oversight Specialist, David Cannon, at 6-4127. David will be happy to address any concerns you may have concerning your space or animals.

RECOVERING THE COST OF ANIMALS IN RESEARCH GRANT PROPOSALS

The cost of supporting research animals can be underestimated easily, with devastating effects on grant budgets and the ability to complete the research that was proposed. Animal purchases, housing costs, and funds for any other activity which is provided by the research team in support of animals, such as special environmental enrichment, are recovered as direct costs - the part of the total research budget that is managed by the principal investigator. Shortfalls in the recovery of animal costs, therefore, have an immediate effect on a research laboratory's bottom line. Given NIH's cost-cutting mode where whole budgets are often reduced by a percentage, sound budgeting practices are crucial.

"Best Practices" for proposing animal costs include the following:

- Carefully estimate the current costs for the proposed animal purchases and housing.
- **Make your best effort to anticipate the growth of animal costs during the life of the research project.** Is it known that animals may be in short supply during the life of the project? Will changes in housing during the course of the project alter your costs?
- **Include ALL of your animal-related costs.** Have you included the costs for the unique food, bedding, or housing that your research staff are providing or expect to receive from the Animal Resources Program? Have you included costs for providing for the special needs of singly housed animals?

Contact the Animal Resources Program (713-7394) for current animal per diem rates, trends in cost growth and other animal budgeting issues.

NEWS FROM THE ANIMAL RESOURCES PROGRAM

Congratulations to Ms. Gaye Hodges, of the Animal Resources Program, on obtaining her CMAR certification. This professional certificate is the highest recognition one can receive from the American Association for Laboratory Animal Science (AALAS) in conjunction with the Laboratory Animal Management Association and the Institute of Certified Professional Managers. The CMAR program, Certified Manager of Animal Resources, consists of a series of four exams, and is designed to raise competency and professionalism in the field of laboratory animal resources management. Ms. Hodges is one of only ninety-five people world-wide who have earned this title. In addition, Ms. Hodges was promoted to the new Operations Manager position for the Downtown Campus, which is scheduled to open in January 2006. Ms. Hodges will train with Mr. Bruce Rose, Operations Manager, Bowman Gray and Reynolda Campuses, until her move to the new campus upon its completion.

NEWS FROM NIH

NIH ANNOUNCES INITIAL PLANS TO TRANSITION TO THE SF424(R&R) APPLICATION AND ELECTRONIC SUBMISSION THROUGH GRANTS.GOV - NOT-OD-05-067

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-067.html>

This Notice announces NIH's initial plans to: 1) transition from the PHS398 application to the SF424 Research and Related (R&R) application; **and**, 2) simultaneously transition to electronic submission via Grants.gov by the end of 2007.

NIH Transition Plan

The simultaneous transition to electronic submission and a new set of application forms is a huge initiative involving numerous funding mechanisms and tens of thousands of applications ranging widely in size and complexity. The transition relies upon many pieces for its success: technical development of eRA and Grants.gov systems; trans-agency resolution of policy and operational issues; communication, training and outreach; and the acceptance of the change by our research partners in the extramural community. NIH is committed to doing all it can to make this happen.

NIH will transition to the SF424 (R&R) form and electronic submission through Grants.gov by individual research program/funding mechanism. Funding Opportunity Announcements (also known as Requests-for-Applications and Program Announcements) will be issued in the NIH Guide and posted in Grants.gov as mechanisms are transitioned. The transition by mechanism will include **all** active Funding Opportunity Announcements for that program/mechanism. Applications in response to these announcements will require electronic submission through Grants.gov.

Initial plans/milestones for submission dates and mechanisms are as follows:

December 1, 2005 —Small Business Innovative Research (SBIR) and Small Business Technology Transfer Programs (STTR) (R41, R42, R43, R44)

December 15, 2005 —Support for Conferences & Scientific Meetings (R13 & U13)

January 25, 2006 —Academic Research Enhancement Awards (AREA) (R15)

June 1, 2006 —Small Grant Programs (R03) & Exploratory/Development Research Grant Awards (R21)

October 1, 2006 —Research Project Grant Program (R01)

NIH will continue to communicate transition plans for other programs/mechanisms as they evolve and will provide the community with ample notice of impending events. In general, announcements will be made in the NIH Guide for Grants and Contracts at least 4-6 months before the transition of a particular funding mechanism/research program. For more details about the electronic submission process, go to the NIH Office of Extramural Research's website at <http://era.nih.gov/ElectronicReceipt/>.

NIH RELEASES FINAL EMPLOYEE ETHICS RULES

The National Institutes of Health has announced final ethics regulations for its employees, including a ban on outside consulting with "substantially affected organizations" such as pharmaceutical, biotechnology or medical device manufacturing companies, health care providers and insurers, and supported research institutions. The new rules, developed by the Department of Health and Human Services, take into account public comments, including those of the American Association of Medical Colleges, and staff concerns about the reporting of certain financial interests, stock divestiture, outside activities, and awards. Among the final regulations: a requirement that senior-level NIH employees and their spouses divest financial holdings "in substantially affected organizations in excess of \$15,000"; a limit on the amount and type of monetary awards that employees can receive from outside sources; and strengthened reporting requirements. The final regulations will allow, subject to prior approval, outside activities with scientific organizations, service on data and safety monitoring boards, Grand Rounds lectures, and scientific grant review. The final regulations are consistent with earlier proposals that enable NIH staff members to engage in compensated academic outside activities such as teaching courses at universities, writing general textbooks, performing scientific journal reviews or editing, and providing general lectures to physicians and scientists as part of a continuing professional education program.

Information: http://www.nih.gov/about/ethics_COI.htm

NIH TO DISCONTINUE MAILING TWO TYPES OF DOCUMENTS

Over the next two grant review cycles, the NIH will discontinue mailing the following two kinds of documents:

Summary Statements: Beginning October 1, 2005, NIH will no longer send hard copies of the Summary Statements to Principal Investigators and Individual Fellow applicants. Summary Statements are accessible electronically to PIs and Fellows in the eRA Commons within approximately 8 weeks of the Scientific Review Group (SRG) meeting.

Review Outcome "Mailers": Beginning February 1, 2006, the NIH will no longer send hard copies of the notification letter (also known as a "mailer") to PIs and Fellows regarding the review outcome of an application by the SRG. When the SRG rosters and meeting dates become available, they may be accessed through <http://www.csr.nih.gov/Committees/rosterindex.asp> (Center for Scientific Review [CSR] reviews) or <http://era.nih.gov/roster/> (Institute/Center reviews). Scores will be posted in the eRA Commons approximately 5 working days after the SRG meeting.

At this time, the NIH will continue to send assignment and change of assignment mailers. However, this information is also accessible through the eRA Commons.

In order to avoid delays in the e-notification process, it is vital that all Grantee Organizations, Principal Investigators, and Individual Fellows register in the eRA Commons and periodically check e-mail addresses for accuracy.

NOTE: This process does not apply to applications for the Agency for Healthcare Research and Quality or the Centers for Disease Control and Prevention.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-075.html>

PLEASE NOTE THAT THE OFFICE OF RESEARCH CANNOT ACCESS SUMMARY STATEMENTS. THESE CAN ONLY BE ACCESSED BY THE PI.

CHANGE IN POLICY FOR INCLUSION OF CLINICAL PRACTICE COMPENSATION IN INSTITUTIONAL BASE SALARY CHARGED TO NIH GRANTS AND CONTRACTS – NOT-OD-05-061

On August 4, 2005 the National Institutes of Health announced a change in NIH grants requirements regarding the inclusion of clinical practice compensation received from outside sources in determining the institutional base salary of the researcher (which is used to determine the amount of funding provided to institutions under federal grants and contracts for such researchers).

A research institution receiving federal funds under a grant or contract may now include in the institutional base salary of a researcher any clinical practice compensation received from an outside source if **all** of the following requirements are met:

- Clinical practice compensation must be set by the institution.
- Clinical practice activity must be shown on the institution's payroll or salary appointment forms and records approved by the institution.
- Clinical practice compensation must be paid through or at the direction of the institution.
- Clinical practice activity must be included and accounted for in the institution's effort reporting and/or payroll distribution system.

The institution must assure that all financial reports and supporting documents associated with the combined institutional base salary and resulting charges to NIH grants are retained and made available to federal officials or their duly authorized representatives as required by law.

The new requirements permit more flexibility in the inclusion of clinical practice compensation in institutional base salary than was allowed under prior guidance. The NIH announcement can be found at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-061.html>.

Research Funding Opportunities

For all funding information contact Angela Horton, Office of Research, 60780, unless noted otherwise in the funding announcement

L'OREAL USA

POSITION: Applications for Women in Science Fellowship Program

DESCRIPTION: For the third year in a row, L'Oreal USA is launching the application process for its For Women in Science Fellowship program. The program, which is open to women postdoctoral scientific researchers only, is designed to support the aspirational goals of young women interested in pursuing careers in the life and physical sciences as well as math, engineering, and computer science. This year, the American Association for the Advancement of Science will be responsible for disbursement of the L'Oreal USA Fellowship award funds (five \$20,000 grants), and for monitoring reports from the fellows after their selection. Qualifying applicants are invited to visit the L'Oreal USA Web site to download the application form and to get additional information on criteria and eligibility.

http://www.lorealusa.com/fwis/fwis_home.aspx

CROHN'S AND COLITIS FOUNDATION

POSITION: Biomarkers of Colon Cancer in Inflammatory Bowel Disease

DESCRIPTION: The Foundation is seeking applications to identify biomarkers for colon cancer in patients with IBD. The proposed studies can focus on the exploration of possible candidate biomarkers to be identified through blood tests, stool tests or tests on simple biopsies of the rectum (no colonoscopy). Potential groups of biomarkers include antibodies against proteins found in precancerous lesions or early cancers, proteins, or DNA from cancerous or pre-cancerous lesions that are shed into the stool, and/or identification of genetic mutations that predispose IBD patients to develop colon cancer. This RFA is limited to human investigation and excludes basic in vitro research or preclinical studies in animal models. Awards are for up to \$143,000 total costs per year for up to two years. More information can be found at <http://www.cffa.org/science/research/requestforapps>.

DEADLINES: Letter of Intent - November 1, 2005
Full Application - January 14, 2006

CHARLES E. CULPEPER BIOMEDICAL PILOT INITIATIVE GRANTS PROGRAM

DESCRIPTION: Through this program, Goldman Philanthropic Partnerships seeks to encourage the creation of promising new approaches to the challenges facing patients with life-altering diseases and those who care for them. Biomedical Pilot Initiative Grants encourage the investigation of novel ideas with the potential to lead to breakthroughs in medical research. Applicants include new investigators seeking to establish independent research careers as well as established investigators pursuing new research paths. The initiative is designed to encourage the investigation of novel ideas that further Goldman Philanthropic Partnerships' interest in cures for disease, particularly in the areas of molecular genetics, bioengineering, and molecular pharmacology. Research into complementary and alternative medicine will also be considered. Because the purpose of the grants is to explore new and even untested hypotheses, substantial preliminary information is not required. Grants of up to \$25,000 will be made on a one-time basis, with the possibility for renewal for a second year upon re-application. Visit the Goldman Philanthropic Partnerships Web site <http://www.goldmanpartnerships.org/> for guidelines, FAQs, information on previous grantees, and an application form.

DEADLINE: November 16, 2005

NIH LOAN REPAYMENT PROGRAMS - NOW ACCEPTING APPLICATIONS

NIH is now accepting applications for the five 2005 Loan Repayment Program (LRPs). LRPs can repay up to \$35,000 a year of qualified educational debt for health professionals pursuing careers in clinical, pediatric, contraception and infertility, or health disparities research. The programs also provide coverage for Federal and State tax liabilities. Applicants must have a doctoral-level degree, devote 50% or more of their time to non-profit or government funded research, and have educational debt equaling at least 20% of their institutional base salary. U.S. citizens, permanent residents, or U.S. nationals may apply. The programs are the Clinical Research LRP, Pediatric Research LRP, Contraception and Infertility Research LRP, Clinical Research for Individuals from Disadvantaged Backgrounds LRP, and Health Disparities Research LRP. All applications for the 2006 awards must be submitted online by **December 1, 2005**. Additional information and online applications are available at <http://www.lrp.nih.gov>.

NIA

POSITION: Paul B. Beeson Career Development Awards in Aging - RFA-AG-06-005

DESCRIPTION: This program provides three to five years of mentored career development support to clinically-trained faculty members in strong research environments to enable them to gain skills and experience in aging research, under the guidance of a mentor or mentors, and to establish an independent program of research in this field. It also includes an annual meeting that allows opportunities to partner with national mentors and fellow awardees. The mechanisms are the NIH K08 (Mentored Clinical Scientist Development Award) and K23 (Mentored Patient-Oriented Research Career Development Award). Eligible Principal Investigators include individuals with a clinical doctoral degree who have completed specialty training, who are U.S. citizens or permanent residents of the U.S. by the time of award, and who have not received R01 or similar support as a Principal Investigator.

DEADLINES: Letter of Intent - October 24, 2005
Full Application - November 23, 2005

NCCAM, NCI, OFFICE OF DIETARY SUPPLEMENTS

POSITION: Basic and Preclinical Research on Complementary and Alternative Medicine (CAM) - PA-05-141

DESCRIPTION: The Institutes invite applications for funding of basic, mechanistic and/or preclinical research in all domains of CAM, in order to elucidate the underlying mechanisms of action of CAM therapies and to provide a stronger foundation for ongoing and planned clinical studies. This initiative encourages CAM and conventional researchers to focus on opportunities in CAM research to employ cutting-edge technologies to strengthen the knowledge bases needed to improve clinical practice. This PA will use the NIH R01, R21 and R15 award mechanisms. The complete program announcement can be found at <http://grants.nih.gov/grants/guide/pa-files/PA-05-141.html>.

DEADLINES: February 1, 2006, June 1, 2006 and October 1, 2006

GRANT AND CONTRACT PROPOSAL WATCH

| | Fiscal Year 06 July - Aug | Fiscal Year 05 July - Aug | % Change |
|---------------------|------------------------------|------------------------------|-------------|
| Proposals Submitted | 135 | 134 | 0.7% |
| Dollars Requested | \$39,756,761 | \$50,788,788 | (21.7%) |

For all funding information contact Angela Horton, Office of Research, 60780, unless noted otherwise in the funding announcement

Research Funding Opportunities

Research Funding Opportunities

For all funding information contact Angela Horton, Office of Research, 60780, unless noted otherwise in the funding announcement

REMINDER "THREE DAY RULE" FOR APPLICATIONS

Applications must be submitted to the Office of Research for review and institutional signature no less than **three days prior** to the agency deadline.

KEY FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES

(DHHS) INSTITUTES - (<http://www.nih.gov/icd/>)

AHRQ - Agency for Healthcare Research and Quality

NCCAM - National Center for Complementary and Alternative Medicine

NCI - National Cancer Institute

NCRR - National Center for Research Resources

NEI - National Eye Institute

NHLBI - National Heart, Lung and Blood Institute

NHGRI - National Human Genome Research Institute

NIAAA - National Institute on Alcohol Abuse and Alcoholism

NIA - National Institute on Aging

NIAID - National Institute of Allergy and Infectious Diseases

NIAMS - National Institute of Arthritis and Musculoskeletal and Skin Diseases

NIBIB - National Institute of Biomedical Imaging and Bioengineering

NICHD - National Institute of Child Health and Human Development

NIDA - National Institute on Drug Abuse

NIDCD - National Institute on Deafness and Other Communication Disorders

NIDDK - National Institute of Diabetes and Digestive and Kidney Diseases

NIDCR - National Institute of Dental and Craniofacial Research

NIHES - National Institute of Environmental Health Sciences

NIGMS - National Institute of General Medical Sciences

NIMH - National Institute of Mental Health

NINDS - National Institute of Neurological Disorders and Stroke

NINR - National Institute of Nursing Research

NLM - National Library of Medicine

ORWH - Office of Research on Women's Health

PURSUIT STAFF

AMY COMER

KAREN KLEIN

PAULA MEANS

