

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) 63532

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 69374

Promotions for Two Members of OR

Dr. William Applegate has announced that Sally Shumaker, Ph.D., professor and associate dean for research, has been appointed to senior associate dean for research of WFUHS. David Friedman, Ph.D., professor of physiology and pharmacology, was also appointed to associate dean for research.

“Dr. Shumaker has completely reorganized the scope of our Office of Research, instituting a number of key services to further support our science faculty,” said Dr. Applegate. “Dr. David Friedman has led the development of our research infrastructure in our downtown research park.”

Drs. Shumaker and Friedman have both been faculty members at WFUHS since 1990. We congratulate both of them for this recognition of their accomplishments.

NIH Raises Salary Cap

Effective January 1, 2008, Executive Level I salary rose from \$186,600 to \$191,300. All NIH budgets submitted from this point forward should use the new cap of \$191,300. The ability to obtain the highest salary can be lost if the NIH budget is not filled out properly. When a PI's institutional base salary exceeds the capped amount, place the actual salary, rather than the current limit, in the institutional base salary box of the table on Form Page 4 of the PHS 398 form. Then, if the salary limit is raised between the time of submission and award, the new salary limit will be applied to the formerly reported salary. Complete details can be found at: <http://grants.nih.gov/grants/guide/index.html>.

In The Spotlight

Hugo Caldas, Ph.D., Assistant Professor of Neurosurgery, has received a 2-year grant entitled “Dual Use of Mesenchymal Stem Cells in Both Detection and Delivery of an Oncolytic Virus to Brain Tumors” from the Dana Foundation. There is a 2-step vetting process for this award, and overall competition for this program is limited from each U.S. medical school. Dr. Caldas was selected from among the 86 scientists who were invited to submit full applications. We congratulate him for this noteworthy accomplishment.



The International Menopause Society (IMS) has established an IMS/Bayer Schering Pharma Thomas Clarkson Prize, in honor of **Thomas B. Clarkson**, D.V.M., Professor of Pathology/Comparative Medicine. The prize of 3,000 euros will be given in recognition of the best young investigator’s work in menopause and cardiovascular health. The inaugural award will be presented at the annual IMS meeting in Madrid in May 2008. We commend Dr. Clarkson on this enduring tribute to his long career of pioneering research in women’s health, especially in cardiovascular disease and menopause.



David Friedman, Ph.D., Professor of Physiology/Pharmacology and Associate Dean for Research, received the prestigious Science Educator Award from the Society for Neuroscience. This annual award honors an outstanding neuroscientist for his or her significant contributions to educating the public about neuroscience. “Dr. Friedman has been instrumental in fostering scientist-teacher partnerships and advocating for the use of animals in research through a variety of channels,” said David Van Essen, president of the Society. “More recently, his public education efforts have extended to reach journalists and state legislators, influencing both the media and new legislation.” Congratulations to Dr. Friedman for this recognition of his contributions to improving public health through his research and advocacy.



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CONCERN LINES

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

ANIMAL CARE AND USE
COMMITTEE DEADLINES
FEBRUARY 1, MARCH 7, APRIL
4, MAY 2, JUNE 6, 2008

INSTITUTIONAL REVIEW BOARD
NOON ON FRIDAYS

INTRAMURAL RESEARCH SUP-
PORT COMMITTEE DEADLINES

FEBRUARY 8, 2008
CROSS CAMPUS

FEBRUARY 22, 2008
MEDICAL STUDENT SUMMER
RESEARCH AND FACULTY
FOREIGN TRAVEL

APRIL 11, 2008
REGULAR AND INTERIM

CONFLICT OF INTEREST REVIEW
COMMITTEE DEADLINES

MANAGEMENT PLANS
2ND MONDAY OF EACH MONTH

CIRC MEETINGS
4TH WEDNESDAY OF EACH
MONTH

RESEARCH ADMINISTRATORS
SESSIONS

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

February 14, March 13,
April 10, May 8, September
11, October 9, November
13, December 11, 2008

IRIS: A New Tool for Research Collaboration

The Office of Research and Academic Computing announce a new resource for the WFUHS research community. **IRIS** (Institutional Research Interest System) is an internal web-based tool that researchers and their staff can utilize to search the title, abstract, and/or population of studies involving human subjects which have been approved by the WFUHS IRB. **IRIS** is located at <http://iris.wfubmc.edu>. This link can be found on the Office of Research website (<http://www1.wfubmc.edu/or/>) and the Faculty homepage (<http://infinet.wfubmc.edu/depts/faculty/>).

IRIS was developed in response to the October 2006 Faculty Research Retreat. At that retreat, faculty identified collaboration as an important component of the research community at WFUHS and supported recommendations to facilitate collaboration. **IRIS** is the first of two new tools to help researchers find potential collaborators. The second tool, the Faculty Database, is targeted for release later in 2008. For further information, please contact the IRB office at 716-4542 or Scott Mann in Academic Computing at 716-9361.

Welcome to the Institutional Research Interest System
IRIS allows researchers to search active human subject research studies at Wake Forest University Health Sciences in order to discover collaborators by research interest. To begin, enter a keyword or phrase below and use the options to determine the type and scope of your search.

Keyword(s): Pediatric Dermatology

Do not use quotes or operators such as AND or OR. Instead use search type below to select an option.

How to Search: All keywords Help

Where to Search: Title, Abstract, and Subject Population Search

2 Non-Industry Sponsored Studies were returned. For additional information, click a study's IRB Number.

IRB#	PI	Short Title	Full Title	Abstract	Subject Population	Contact PI
IRB0000027	Feldman, Steven	Acne-Adherence	Measuring Adherence in Subjects with Acne Vulgaris in a Clinic Population Subtitle: Topical Benzoyl Peroxide for Acne	STUDY TITLE: Measuring Adherence in Subjects with Acne Vulgaris in a Clinic Population Subtitle: Topical Benzoyl Peroxide for Acne Objectives: To evaluate adherence rates to topical benzoyl peroxide 5% gel in subjects with mild to moderate ...	Approximately 20 male and female subjects age 13 to 18 with mild to moderate acne vulgaris will be recruited.	sfeldman@wfubmc.edu
IRB00004402	Feldman, Steven	Written Action Plans for Atopic Dermatitis	Written Action Plans: Potential for Improving Outcomes in Children with Atopic Dermatitis	Purpose We propose to develop a written education plan for parents of children with atopic dermatitis to guide them through the management of their child's chronic illness between health-care visits. Background One specific tool for self-management t ...	We will survey 10-20 pediatric dermatologists and physicians with expertise in managing atopic dermatitis. We will also survey 10-20 parents of children with atopic dermatitis; these children will be patients in the dermatology clinic. We will also show	sfeldman@wfubmc.edu

New Budget Review Process for GCRC Grants

The National Institutes of Health (NIH) is transforming how clinical and translational research is conducted at academic health centers across the country through a new consortium funded by Clinical and Translational Science Awards (CTSA.)

This transformation has begun within the WFUHS Translational Sciences Institute (TSI) and will require changes in the structure and function of the GCRC. The GCRC is fully committed to providing services to our investigators during and beyond this transition.

Due to recent changes made by the NIH in the level of funding for the CTSA mechanism, several GCRC operational changes including a GCRC pre-review and review process for investigators' access to services will be implemented effective January 1, 2008. Please contact Marcy Poletti at 6-9755 if you have any questions. The changes are as follows:

- All grant applications and budgets requesting GCRC services must be reviewed and approved by GCRC administration prior to their submission to the Office of Research.

- RO1 grants must request ancillary lab, and imaging support, as well as other large requests for services such as meals, dietary data, etc. from their funding center.
- Pharmacy and contrast charges will no longer be supported.
- In keeping with the GCRC mission, pilot studies and junior faculty will be given first priority in financial support of ancillary testing.
- All protocol applications will be assessed for additional opportunities for cost sharing.
- GCRC administration will perform an annual assessment of protocol budget requests and year to date census. While making every attempt to continue support, annual adjustments to GCRC support may be required to meet NIH budgetary constraints.

2007 MEDICAL STUDENT RESEARCH DAY WINNERS

FIRST PLACE

Darnell Josiah, Class of 2008

“Oncolytic Virus Therapy for GBM Delivered by Adipose-Derived Mesenchymal Stem Cells”

SECOND PLACE

Shannon Rosati, Class of 2008

“Continuous Delivery of Interferon-Gamma Sensitizes Neuroblastoma to the Anti-Tumor Activity of Temozolomide through the Modulation of O6-Methylguanine-DNA Methyltransferase Expression”

THIRD PLACE

Bryant Cameron Webb, Class of 2010

“From Politics to Parity: Using a health disparities index to measure the efficacy of health legislation”

FOURTH PLACE

Kristin Dew, Class of 2010

“Biofilms in Pneumococcal Otitis Media”

HONORABLE MENTION

Ashley Brown, Class of 2010

“High-Fidelity Simulation Enhances Medical Student Learning”

TRANSLATIONAL SCIENCE INSTITUTE AWARDS

Steven Newton, Class of 2010

“Effects of Angiotensin-(1-7) on Glioblastoma Multiforme”

Rebekah Wilson, Class of 2010

“Adherence to Topical Hydrocortisone 17-Butyrate .1% in Adult Patients with Atopic Dermatitis”

Elfriede Agyemang, Class of 2010

“HIV-Related Knowledge, Attitudes, Disclosure and Stigma Issues among Antenatal Women In Ghana”



DECEMBER 2007 IRSC AWARDEES

**Alexander H. Claiborne,
PhD**

Department of Biochemistry

“Targeting Unique Coenzyme A Biosynthetic and Redox Functions in Bacillus anthracis”

Debra I. Diz, PhD

**Hypertension and Vascular
Research Center**

“Development of a Colony of Malignant Hypertensive Rats”

Iris J. Edwards, PhD

**Department of Pathology
Section on Tumor Biology**

“Inhibition of Prostate Cancer Growth by Decorin”

Jason M. Grayson, PhD

**Department of Microbiology
and Immunology**

“Mechanisms of Lymph Node Contraction Following Acute Infection”

Jorge P. Figueroa, MD, PhD

**Department of Obstetrics and
Gynecology**

“Prenatal Glucocorticoid and Postnatal Blood Pressure”

Kylie Kavanagh, VMS, MVS

Department of Pathology

“Improving Cellular Chaperone Proteins in Obese Insulin Resistant Female Vervet Monkeys: A Potential Mechanism by which Insulin Sensitivity is Increased with Dietary N-3 Polyunsaturated Fatty Acid Supplementation”

Marlena Moors Westcott, PhD

**Department of Microbiology and
Immunology**

“Characterization of the Phagosomal Environment that Interferes with Listeria Monocytogenes Entry into the Cytosol of Murine Dendritic Cells”

WFU Translational Science Institute Update

The past few months have been very productive for the WFU Translational Science Institute (TSI.) The **Clinical and Translational Science Award (CTSA)** application was submitted to the NIH on November 5, 2007. It is estimated that the WFU CTSA application was one of approximately 35 submitted in this round and reviews are scheduled for February 2008. Currently, 24 Academic Health Centers have received CTSA's and we anticipate an additional 12 awards will be funded from the current round.

The TSI is rapidly growing with more than 200 members including faculty and administration from WFUHS, WFU Reynolda campus, and TSI partners including Virginia Tech, East Tennessee State University (ETSU), Mission Hospitals in Asheville, and the Center for Creative Leadership (CCL) in Greensboro. We are pleased and excited to have such a strong foundation for the Institute.

In conjunction with several WFUHS departments and TSI partners, the Institute recently awarded 3, out of 25 applications, **TSI Translational Scholars** through the newly developed K12 program. The program provides salary, educational, and supply support for each scholar (highlighted in our previous Pursuit issue.) Additionally, funds were provided for 12, out of 64 applications, **TSI Team Research Awards**.

These highly competitive grants, spanning a range of biomedical interests, aim to foster a multidisciplinary team approach in research. Their funding was made possible by TSI institutional support and by matching funds from WFUHS departments and centers and TSI partners including the WFU Reynolda campus, the Virginia Tech Office of Research, the Virginia Tech College of Engineering, and the Virginia-Maryland Regional College of Veterinary Medicine.

Many activities are planned in the upcoming year including **TSI Synergy Symposia** on Metabolic Syndrome/Obesity and Inflammation scheduled for spring '08 and a Healthcare Analytics Symposium slated for fall '08. A workshop on Team Science – co-facilitated by CCL and WFUHS – will be held in the spring of 2008. Also, the TSI Education and Career Development Program will launch the revised **Clinical and Population Translational Science Master's** program and the **Molecular Medicine and Translational Science PhD** program in the fall of 2008.

The TSI website is now available at <http://www1.wfubmc.edu/tsi>. Information about TSI programs, a directory of staff/administration and listing of activities and awards are posted and will be updated regularly with new information.

Local Foundation Proposals Require Prior Approval

Grant applications to local foundations (e.g., Kate B. Reynolds Charitable Trust, The Duke Endowment and the Winston-Salem Foundation) must be coordinated with the Development Office prior to submission.

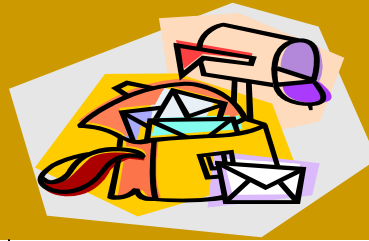
Due to the potential number of interested applicants, these funding agencies require the Medical Center to internally coordinate requests and communication. These foundations also require consultations prior to submission of a proposal.

Please contact H. Jeffrey Swaim, Senior Director of Corporate & Foundation Relations, (hjswaim@wfubmc.edu

or 6-3040) with any questions related to these organizations. He works with faculty and staff to facilitate inquiries and the submission of all funding requests. It is crucial to involve the Development Office at the beginning of the planning process in order to comply with the foundation requirements.

Grant applications to these agencies involve advance planning, but the program officers are very willing to guide us successfully through the application process provided we follow defined institutional procedures.

Ask Dr. OR



Dear Dr. OR,
Who are "senior/key personnel" and how do they differ from "other significant contributors?" What about consultants?

Signed,
Having an Identity Crisis

Dear Crisis,
Senior/key personnel are those "who contribute to the scientific development or execution of a project in a substantive measurable way." The program director/principal investigator (PD/PI) is always considered senior/key personnel. The PD/PI may designate other senior/key personnel as appropriate.

"Other significant contributors" are people who will be involved in the project, but without measurable effort (zero person months or "as needed".) Biosketches of other significant contributors are required; however, other support information is not.

A "consultant" is someone "hired to give professional advice or services for a fee." Generally, a consultant is not considered senior/key personnel. The budget justification should explain the consultant's role and estimate the number of days of anticipated consultation; the expected rate of compensation; and travel, per diem, and related costs.

Biographical sketches are needed for all three categories of personnel, but "other support" details are not required for "other significant contributors" or "consultants."
[Quotes taken from the NIH "Extramural Nexus" Newsletter, 11/07 issue; <http://grants.nih.gov/grants/partners/1107Nexus.htm>]

Dear Dr. OR,
A re-budgeting form was recently returned to me requesting that the justification be typed and not hand-written. Can you tell me the reason for this request?

Signed,
Poor Penmanship

Dear Poor Penmanship,

In order to process re-budgeting requests, the Grants Administrator reviewing the request must be able to fully read and understand the justification. A typed justification makes for a more thorough and concise review.

Dear Dr. OR,
I approached a subject about participation in a research study. He verbally agreed to participate, but asked his wife to sign the consent for him since she handles all the family "paperwork." Is this OK if the spouse signs the consent form for the research subject?

Signed,
Unsure

Dear Unsure,
A LAR (legally authorized representative) can sign the consent, in lieu of an adult, ONLY if the subject is incompetent to do so. The process of using a LAR to obtain informed consent must be included in your IRB application and approved prior to obtaining consent.

Dear Dr. OR:
My study takes place in the ICU setting, and by nature, most of my patients are unable to provide informed consent. The IRB has given me permission to obtain consent using a legally authorized representative (LAR.) Is the spouse of a patient the LAR?

Signed,
Confused

Dear Confused:
The spouse of a patient MAY or MAY NOT be the LAR. State law determines that the LAR is (in order):

1. Guardian (of the person or general guardian, not guardian of the estate)
2. Health care agent appointed pursuant to a health care power of attorney
3. Spouse
4. Next of kin
5. Other family member

If the patient does not have a guardian or health care power of attorney, then the spouse would be next in line as the LAR.

Send questions for Dr. OR to Penny Gatsis (pgatsis@wfubmc.edu.)

Controller's Corner

We would like to welcome Shawnee Haney to our Grants staff as of September 24, 2007. Shawnee is assisting Pediatrics, Cancer Biology, Radiation Oncology, Radiation Physics, Radiation Biology and the Cancer Center. We are now fully staffed and will do our best to keep departmental assignments stable as well.

Controller's Office Website:

If it's been a while since you visited our webpage, please consider doing so. There are many procedures listed that describe how we can best assist you in the management of your chartfields. The most frequently reviewed topics are:

- Procedures for Account Management
- Procedures for Collection of Sponsored Funds
- Procedures for Managing Subcontracts under Sponsored Research Projects
- Important Information about Cost Transfers
- Cost Transfer Explanation and Justification Form

A direct link to the Sponsored and Special Funds section:
http://infinet.wfubmc.edu/depts/wfuhs_control/sponsored&specialfunds.htm

Pre-award account forms:

There are now 2 different kinds of Pre-Award accounts available for departments to utilize depending upon the award type:

- Pre-award Accounts on New Awards
- Pre-Award Accounts on Subaward Continuations

Pre-award Accounts for New Awards has been in existence since January 2007 and applies to all new sponsored projects, including competing renewals. These forms also apply to industry projects for which there are fully executed agreements but no checks have arrived.

Please see the policy on our website for a complete description.

Pre-Award Accounts on Subaward Continuations is a newer policy issued in November 2007. These forms are to be used for continuation years of subcontracts when we have not yet received official documentation of the continuation. Set up of Pre-award accounts will allow you to enter HR actions and apply all charges to the correct chartfield, thus reducing cost transfers and other paperwork. Please see the policy on our website for a complete description.

Efforts:

Efforts have now been released for monthly paid staff and faculty. Please remember to certify your July 1 - December 31, 2007 effort within the 30 day window. If you worked on any projects during this period that do not appear on your pre-filled report, you will need to add them. If you had any cost shared effort, you will need to include those chartfields as well although they may not appear on your preprinted report. If you are unable to enter your chartfield, please contact your grant accountant as it may simply need to be added to the system. It is extremely important that you certify your effort correctly. Re-opening any certification for changes is an audit "red flag" as the auditors will want to know why your original certification was incorrect. Since we certify effort after the fact, changes should rarely, if ever, be needed.

Animal Resources Program News

Congratulations to Ms. Vickie Hardy, in the Animal Resources Program, on obtaining her Certified Manager of Animal Resources (CMAR) certification. This professional certificate is the highest level of recognition one can receive from the American Association for Laboratory Animal Science (AALAS) in conjunction with the Laboratory Animal Management Association (LAMA) and the Institute of Certified Professional Managers (ICPM). The CMAR program requires passing a series of four exams, and is designed to raise competency and professionalism in the field of laboratory animal resources management. Ms. Hardy is one of only about 130 people world-wide who have earned this title. The Animal Resources Program is proud to have such an ambitious and dedicated Operations Manager. Vickie is truly an asset to this program.

InfoEd Electronic Submission Training

The InfoEd eRA portal is a web-based system designed to manage the administrative tasks involved in executing sponsored research proposal activities which enables faculty, administrators and staff to efficiently track grants through their lifecycle. Attendees will learn all necessary steps in preparing and creating, for institutional approval, the submission of electronic grant proposals to NIH.

Class Descriptions

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. It is recommended an individual take InfoEd 101 prior to registering for this session.

InfoEd Update is for experienced InfoEd users. It addresses added system features and functionalities within the latest release, and new guidelines for building a budget.

InfoEd NIH Electronic Submission Training

The following workshops are designed to provide a more “hands on” interaction; therefore, space is limited as each participant will be assigned a computer. All of these workshops will be held in Classroom B of Carpenter Library. (Note: Scheduled workshops may be cancelled if fewer than 5 people registered for the session. A notice to all attendees will be sent via email, prior to any cancelled training.)

It is recommended an individual take the InfoEd 101 prior to registering for InfoEd 102 or any classes involving program updates.

InfoEd 101

1/31 - 1-3 pm
2/11 - 1-3 pm
2/26 - 9-11 am
3/11 - 1-3 pm
3/20 - 9-11 am
3/25 - 1-3 pm

InfoEd 102

1/29 - 1-3 pm
2/7 - 1-3 pm
2/28 - 9-11 am
3/27 - 9-11 am

InfoEd Update

2/21 - 9-11 am
3/18 - 9-11 am

GRANTS ADMINISTRATION 2008 WORKSHOP SCHEDULE

Work smart...get funded. How to compete more effectively for sponsored funding

Participants will learn the basics of identifying funding opportunities, building a relationship with sponsors and understanding the various proposal components (introduction, goals, objectives, literature review, preliminary studies, and methodology.) Individuals who attend the session can expect to: Compete more effectively for sponsor funding, research funding opportunities and sponsor funding history to increase submission success, and to write compelling narrative that will find favor with peer reviewers.

Date: January 31, 2008

Time: 2:30 - 5:00 pm

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

Presenter: Kris Rhodes

Legal Fundamentals for Federal Grants

Legal Fundamentals for Federal Grants and Contracts provides a fundamental background of the legal compliance requirements associated with federal grants, with an emphasis on implications of federal costing and administrative requirements of applied award administration. The workshop specifically addresses OMB Circulars, Code of Federal Regulations, Federal Acquisition Regulation, Award Notices, Agency Guidelines, and Institutional Policies and how the compliance requirements intersect and impact award administration.

Date: March 6, 2008

Time: 1-5 p.m.

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

Presenter: Kris Rhodes

IRB & ACUC 2008 Workshop Schedule

Clinicaltrials.gov

Public Law 110-85, which was enacted on September 27, 2007 amends the Public Health Service Act to expand the scope of clinical trials that must be registered in ClinicalTrials.gov. It also increases the number of registration fields that must be submitted, requires certain results information to be included and sets penalties for noncompliance. The Office of Research has developed new guidance for investigators and study team members to assist them when submitting information to clinicaltrials.gov. Come and learn about the new requirements and how this affects you.

Date: January 30, 2008
Time: 10:00 – 11:00 am
Location: Commons 1 & 2, G-floor, Nutrition Building
Presenters: Cheryl Byers/Paula Means

Study Coordinator 101

This is a hands-on workshop designed to cover IRB policies and procedures, federal regulations, GCPs 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.

Date: April 24, 2008
Time: 1:30 - 4:20 pm
Location: E24, Hanes Building
Presenter: Cheryl Byers

IRB Update

Get the latest updates on policies and practices within the IRB. (Note: It is not necessary to register for these sessions.)

Date: February 19, 2008
Time: 10:00 – 11:00 am
Location: Commons 1 & 2, G-floor, Nutrition Building
Presenter: Cheryl Byers

Date: May 22, 2008
Time: 1:00 - 2:00 pm
Location: Commons 1 & 2, G-floor, Nutrition Building
Presenter: Cheryl Byers

AAALAC Site Visit Preparation

These sessions are for individuals interested in reviewing material for the AAALAC site visit. The target audience is any WFU personnel who work with animals and the purpose is to explain what AAALAC is, why a site visit will be conducted, and what to do to be well prepared for the visit. (Note: It is not necessary to register for these sessions.)

Date: January 29, 2008
Time: 11-12 noon
Location: Reynolda Campus - Winston 221 (McDonald Seminar Room)
Presenter: David Lyons

Date: February 1, 2008
Time: 10:00 – 11:00 am
Location: Commons 1 & 2, G-floor, Nutrition Building
Presenter: David Lyons

How to Prepare for an IACUC Inspection

These sessions will cover how to prepare your laboratory for 'internal' semi-annual inspections and 'external' inspections by groups such as USDA and AAALAC. (Note: It is not necessary to register for these sessions.)

Large Animals
Date: March 7, 2008
Time: 10:30 - 11:30 am
Location: Commons 1 & 2, G-floor, Nutrition Building
Presenter: David Lyons

Small Animals
Date: March 7, 2008
Time: 11:30 - 12:30 pm
Location: Commons 1 & 2, G-floor, Nutrition Building
Presenter: David Lyons

IRB UPDATES

IRB Fees

Effective January 1, 2008, contracts for human subjects research sponsored by for-profit entities (including pharmaceutical companies) must include the new IRB fee structure. Historically, the IRB invoiced industry sponsors \$2000 for the initial review of IRB applications reviewed by the full board. The fee structure has been expanded to bring the institution up to industry standard and will include the following:

- \$2000 for initial IRB review by the full board
- \$1000 for initial IRB review of expedited applications
- \$500 for each continuing review

The IRB does not currently charge for the review of amendments, study-associated promotional material and adverse events.

IRB fees will be invoiced from the **IRB approval date** as opposed to the date the contract is fully executed with Industry Relations. Sponsors should be informed of this change in IRB processes.

The IRB is fully electronic!

2 years after implementing eIRB, our online submission and review system, the IRB is fully electronic! More than 1,100 studies have been electronically submitted and approved since the first submission in October 2005. In addition, nearly 900 studies that were originally submitted in paper have been migrated into the electronic format, allowing the entire human subjects research active study base to leverage eIRB's paperless routing and data access capabilities. As a result, the IRB has been running fully electronic board meetings since Fall of 2007. We consistently look for ways to improve eIRB to facilitate research at WFUBMC and will continue to do so.

A special thanks to Scott Mann, Academic Computing Analyst/Programmer IV, the IRB staff, and Administration for your help and support. Also, we want to thank the research community for without all of you, our success would not have been possible.

ACUC UPDATES

eIACUC Postponed

Plans to implement an electronic protocol submission system for the Institutional Animal Care and Use Committee (IACUC) that parallels one now in place for the Institutional Review Board (IRB) are on hold at least until July. Constraints on funds and personnel critical to the project have pushed back the project until later in 2008.

AAALAC Coming Soon!

The triennial site visit by the Association for the Assessment and Accreditation of Laboratory Animal Care International is expected in February or March of 2008. The announced visit will be for three days to evaluate the animal program. WFU has been accredited by AAALAC since 1966. To learn more about the upcoming visit, attend an informal AAALAC Site Visit Preparation workshop being held on each of our campuses:

Downtown campus, Jan 10, 1-2PM; Friedberg Campus, January 16, 1-2PM; Bowman Gray Campus, Commons 1&2, 10-11AM; Reynolda Campus, January 29, Winston 221, 11-12 noon.

All items in compliance, says USDA

The Animal Resources Program and the IACUC are pleased to report "all items in compliance" on all campuses according to USDA Inspection Reports. This year's inspection occurred over two visits; one in August conducted at the WFU Primate Center, Friedberg Campus and the other in November conducted at the Bowman Gray, Downtown and Reynolda Campuses. We are pleased to be recognized as an institution with a faculty and staff who are devoted to the high quality and humane care of animals in research.

WFU Constructs National Training Program for IACUC

New training debuts April 1 on the federal Office of Research Integrity web site aimed at IACUC members who inspect animal facilities. The site delivers an online, user-driven, training course via a "virtual walk-through" of laboratory animal facilities that simulates an actual inspection. The multi-media approach guides users through a dynamic virtual inspection comprised of 360 degree panoramic images of actual facilities. The training aims to supply regulatory knowledge in an engaging visual context that makes learning easier and directly relevant to the task at hand. Congratulations to David Lyons, PI of the ORI grant supporting this project.

NIH NEWS

Modified Application Submission, Referral and Review for Appointed NIH Study Section Members – NOT-OD-08-026

The NIH is implementing an alternate plan for submission and review of research grant applications from appointed members of chartered NIH study sections in order to recognize their outstanding service and to minimize disincentives to study section service. The timing of Study Section meeting and most standard due dates for grant application overlap, thus reviewers are under pressure to review applications and prepare their own applications simultaneously. Beginning February 5, 2008 the alternate submission and review procedures will be available for appointed members of NIH Study Sections. The alternate process is limited to 1) appointed members of chartered standing Study Sections and 2) applications that would normally be received on standard submission dates, but not special receipt dates (RFAs and some PARs). This continuous submission process will enable appointed members of chartered NIH Study Sections to submit their application as soon as they are fully developed. The applications will be reviewed no later than 120 days after receipt. NIH plans to analyze this opportunity on an ongoing basis in order to assess feasibility and satisfaction. A series of FAQs have been prepared and are available at <http://cms.csr.nih.gov/>.

NIH Policy of Late Submission of Grant Applications – NOT-OD-08-027

NIH expects that grant applications will be submitted on time, according to the standard deadlines and receipt dates.

- For applications that are required to use paper format these are submission or postmark dates. Applications are on time if they are sent on these dates.
- For applications that are required to use electronic submission this requires successful submission to Grants.gov by 5:00pm local time on the date indicated.
- For both paper and electronic submissions, when these dates fall on a weekend or holiday, they are extended to the next business day. However, Requests for Applications (RFAs) and Program Announcements with Special Referral Considerations (PARs) with special receipt dates always must be received on the dates designated in the announcement to be on time.

The long standing NIH policy on late applications is stated in the application instructions:

- Permission for a late submission is not granted in advance.
- In rare cases, late applications will be accepted but only when accompanied by a cover letter that details compelling reasons for the delay.
- While the reasons are sometimes personal in nature, an objective evaluation of their merit requires that some details be provided. It is not sufficient, for example, to state simply that there has been an unforeseen circumstance that delayed submission. Specific information about the timing and nature of the cause of the delay is necessary so that a decision can be made. Only the explanatory letter is needed, no other documentation is expected.

NIH does not expect to accept any applications received beyond the window of consideration. The windows of time for consideration have been carefully chosen so that the late applications can be processed with the cohort of on-time applications.

NIH will consider accepting late applications based on the acceptability of the explanation and the processing time required.

Regular Standard Submission Dates – To be considered applications must be received at the NIH within two weeks of the standard submission date.

Expedited Standard Submission/Receipt Dates – To be considered applications must be received at the NIH within one week of the standard submission date.

Special Receipt Dates for RFAs and PARs - NIH will not consider accepting late applications for the special receipt dates.

Appendices to Paper PHS 398 to be Submitted on CD – NOT-OD-08-031

In an effort to further utilize electronic technology, NIH is implementing the requirement that paper applications provide appendix material only on CDs. **All paper PHS 398 applications submitted for May 25, 2008 and subsequent due dates must provide appendix material on CD only**, and include five identical CDs in the same package with the application. Paper applications submitted for due dates prior to May 25, may voluntarily provide the appendix on five identical CDs; if submitting CDs it is not necessary to include a paper appendix.

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Paper appendices will no longer be accepted for applications submitted for the May 25th and subsequent deadlines. A summary listing of the items included in the appendix is encouraged but not required. When including a summary it should be the first file on the CD. When preparing CDs:

- Use PDF format, preferably not scanned documents.
- Label each disk with the PD/PI name and application title
- If burning CD-ROM disks on a Mac, select the ISO 9660 format.
- Do not use compression techniques for the electronic files.
- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

Appendices should not be used to circumvent the page limitations of the Research Plan. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Revised PHS 398 and 2590 Forms and Instructions now Available

Although NIH continues to transition from the PHS 398 to the SF424(R&R) and electronic submission, the paper PHS 398 is required for all grant mechanisms that have not transitioned. A new revised version of the PHS 398 is now available and must be used for all applications received for the May 25, 2008 deadline and subsequent deadlines. The PHS 2590 forms and instructions have also been revised and the new version must be used for all progress reports due on or after March 1, 2008. The 2590 forms are for progress reports that are not eligible to be submitted electronically via eCOMMONS. The new forms and instructions are available at <http://grants.nih.gov/grants/oer.htm>

Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research

In accordance with Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008), the NIH voluntary Public Access Policy (NOT-OD-05-022) is now mandatory. The law states:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

1. The NIH Public Access Policy applies to all peer-reviewed articles that arise, in whole or in part, from direct costs 1 funded by NIH, or from NIH staff, that are accepted for publication on or after April 7, 2008.

2. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy.

3. PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal articles. Its content is publicly accessible and integrated with other databases (see: <http://www.pubmedcentral.nih.gov/>).

4. The final, peer-reviewed manuscript includes all graphics and supplemental materials that are associated with the article.

5. Beginning May 25, 2008, anyone submitting an application, proposal or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing applicable articles that arise from their NIH funded research. This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

Change in Name for NIH Scientific Review Staff

The NIH has recently made a change in the designation of the extramural staff responsible for the management of the peer review process for grant applications and contract proposals; they also are the designated federal official responsible for the peer review meeting. Instead of Scientific Review Administrator, these individuals will be known as **Scientific Review Officers**. This new title is a more appropriate reflection of their major focus on scientific rather than administrative activities.

Over the next several months documents, websites, and other information items will be updated with the new title.

Faculty Foreign Travel Awards Program

The Faculty Foreign Travel Awards Program seeks to encourage career development through participation in international scientific endeavors.

Applications will be competitively evaluated by the Intramural Research Support Committee. Potential for career development and unique scientific, academic, or clinical opportunities will be the primary criteria.

Awards are limited to one-half of allowable travel costs (maximum of \$1,500.) Eligible applicants include assistant professors, associate professors and professors who lack access to funds for travel. Preference will be shown to junior faculty. For details to go <http://www1.wfubmc.edu/or>. The deadline for submission is February 22, 2008.

2008 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 2008. The two-day seminars provide information about the NIH funding process, from opportunity identification and application preparation through post award administration. Presentations are targeted towards research administrators, researchers new to NIH, post docs and trainees. Opportunities for informal interactions between seminar participants and NIH grants management, program, policy and review staff are incorporated into the program and such interactions are highly encouraged. NIH electronic research administration labs are offered on a day adjacent to the two day seminar. The seminars will be held on:

March 25-26, 2008 – San Antonio, Texas - hosted by the University of Texas Health Science Center at San Antonio

June 19 – 20, 2008 – Chicago, Illinois - hosted by University of Illinois at Chicago

Information on programs is available from the NIH Office of Extramural Research regional seminar website at: <http://grants.nih.gov/grants/oer.htm>

NIH FUNDING OPPORTUNITIES

DOD CDMRP Research Funding for 2008

The Fiscal Year 2008 (FY08) Defense Appropriation Act (Public Law 110-116) provides research funding for the following programs managed by the Department of Defense office of Congressionally Directed Medical Research Programs (CDMRP):

- Breast Cancer Research Program \$138 Million
- Prostate Cancer Research Program \$80 Million
- Ovarian Cancer Research Program \$10 Million
- Gulf War Veterans' Illnesses Research Program \$10 Million
- Neurofibromatosis Research Program \$8 Million
- Autism Research Program \$6.4 Million
- Tuberous Sclerosis Complex Research Program \$4 Million
- Peer Reviewed Medical Research Program \$50 Million

Program Announcements are anticipated to be released in early 2008 with detailed descriptions of funding mechanisms, evaluation criteria, submission requirements, and deadlines. Each Program Announcement will be available electronically for downloading from the Grants.gov website (<http://www.grants.gov>) and the CDMRP website (<http://cdmrp.army.mil>) upon its release.

MUSCULAR DYSTROPHY ASSOCIATION (MDA)

The MDA supports basic and applied research into forty diseases of the neuromuscular system with the ultimate goal of identifying the causes of, and effective treatments for, the muscular dystrophies and related diseases, which include spinal muscular atrophies and motor neuron diseases, peripheral neuropathies, inflammatory myopathies, metabolic myopathies, and diseases of the neuromuscular junction. Applicants must have a Ph.D., M.D., or equivalent degree. A maximum award of \$45,000 is available. For additional information go to <http://www.mdaua.org/>

DEADLINE: Letter of Intent – June 15, 2007 (Electronic Submission)

FINANCIAL RESEARCH COMPLIANCE WORKSHOPS

Standard Sessions

3-27-2008 (Special 1:00 pm – 5:00 pm session)
 5-22-2008 - 8:30 am – 12:30 pm
 7-24-2008 - 8:30 am – 12:30 pm
 9-25-2008 - 8:30 am – 12:30 pm
 11-12-2008 - 8:30 am – 12:30 pm

Faculty Only Sessions

2-13-2008 – 10:00 am – 12:00 noon
 2-28-2008 – 11:00 am – 1:00 pm

Please contact Laura Hemrick at lhemrick@wfubmc.edu or 64403 for more information.

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

Women's Health Research Day, April 3rd

Planning is underway for the third annual Women's Health Research Day. It will be held from 8:00 a.m. until 3:30 p.m. in the Commons on April 3rd, 2008. This year's topic is, "Depression: Comorbidities & High Risk Populations." Our agenda features WFUSM researchers and honored guests from the Emory University School of Medicine and the National Institute of Mental Health. We are now accepting poster abstract submissions on ANY women's health topic. A prize of \$100 will be awarded to the best poster of the day. Registration is required of all participants, and a \$25 fee will be charged to cover the cost of lunch and event materials. This fee is waived for students. For more details about registration, poster submissions and for an agenda, please visit <http://www1.wfubmc.edu/whcoe/Research/2008+WHRD.htm> or contact Shannon Golden (6-9714 or sgolden@wfubmc.edu).

Funding Opportunities in Women's Health

Several new funding opportunities in women's health have recently been announced. The National Institute of Child Health and Human Development has just released a program announcement for the "Role of Adipose Tissue as an Endocrine Organ in Reproduction and Infertility" (R21 & R01.)

Additionally, the Nancy R. Gelman Foundation has announced a call for its 2008 Seed Grant Program, which funds projects designed to improve outcomes for women with breast cancer. Grants will be awarded for basic science research proposals and for community-based proposals.

For more details about these announcements and to view a list of others, please visit our website, which is updated regularly: <http://www1.wfubmc.edu/whcoe/>

Scientific Review Service

The WHCOE's Research Program's faculty committee provides scientific reviews of grant proposals upon request. The committee also provides assistance in responding to grant reviews. If you would like your materials reviewed, or if you have questions about the process, please contact the Program Coordinator Shannon Golden (6-9714; sgolden@wfubmc.edu) or the Program Director, Dr. Mark Cline (6-1564; jmcline@wfubmc.edu).

Brown Bag Research Strategy Workshops

These workshops are developed for faculty, and are designed to enhance research skills. They are scheduled at noon in the Cancer Center, rooms 2A & 2B.

Date: February 25th
 Topic: Intramural Funding
 Panelists: Ann Geiger, PhD & Shannon Mihalko, PhD
 Moderator: Paula Means, MPA

Date: April 30th
 Topic: How to Run an Effective Team
 Panelists: Barbara Nicklas, PhD & Martha Alexander-Miller, PhD
 Moderator: Sally Shumaker, PhD

Pursuit Staff

Amy Comer

Penny Gatsis

Karen Klein

Paula Means

Rachel Woodside