

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. 16, No. 7 August 2002

JUST IN TIME SUBMISSION FOR ACUC PROTOCOLS

The National Institutes of Health (NIH) announced the amendment of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals to allow "just-in-time" verification of Institutional Animal Care and Use Committee (IACUC) approval of animal use in PHS-funded research. In the past, verification of IACUC approval of an animal research project had to be complete within 60 days of submission of an application to NIH and prior to peer review of the proposal. The change in policy requires verification of approval "any time prior to award unless specifically required by a funding component." *Effective September 1, 2002*, the new policy permits us to wait until *after* NIH-peer review is complete to begin the review process. NIH will give universities adequate notice, prior to an award, of the need to conduct the review. NIH hopes the change will reduce some of the regulatory burden on universities by permitting the applicants and IACUC to focus substantive review on proposals likely to be funded by NIH. NIH will modify the Grants Policy Statement and 398 application form and instructions to reflect the new policy.

ACUC EXPLORES ELECTRONIC SUBMISSION

The WFU Animal Care and Use Committee (ACUC) is making strides to improve its use of electronic systems to reduce cost and streamline processes by exploring the electronic transfer of protocols. August will be a trial month for electronic protocol review to troubleshoot and refine procedures. An electronic copy of the protocol in Microsoft Word or Adobe Acrobat for the PC, in addition to the 22 hard copies was required for the recent protocol deadline. If all goes well, the new procedures for the upcoming deadline on September 6th will be as follows:

The electronic version may be transmitted as an attachment via email to Beverly Greenwood at bgreenwd@wfubmc.edu or on a floppy disk, zip disk (250 or 100 MB) or CD along with the original and 3 hard copies. The electronic version of the protocol will be made available to ACUC members for review via secure electronic transmission, which will reduce paper usage and increase the speed of communication. All animal users will be notified before September 1st on protocol submission requirements.

CONCERN LINES

ANIMAL CARE & USE -
716-5899
RESEARCH CONDUCT -
716-0338
COMPLIANCE -
1-877-880-7888

**REGULATORY COMMITTEE
DEADLINES**

ANIMAL CARE AND USE COMMITTEE -
SEPTEMBER 6 AND OCTOBER 4, 2002

INSTITUTIONAL REVIEW BOARD -
NOON - FRIDAYS

**INTRAMURAL RESEARCH
SUPPORT COMMITTEE
DEADLINES**

*REGULAR AND INTERIM -
SEPTEMBER 24 & NOVEMBER 26,
2002

* Clinical studies or other
research involving humans
are encouraged

DEAR DR. OR

Dear Dr. OR:

My research team has been quite successful in recruiting subjects for a clinical trial of an investigational new drug. The sponsor will permit our site to accrue additional subjects. Does the IRB need to know about this?

Signed,
On a Roll

Dear On a Roll:

Yes. Any change in the approved protocol - such as an increase in the number of subjects - or informed consent document must be approved in advance by the IRB. So, for example, if a study was approved for 20 subjects and any additional subjects are to be recruited, the IRB needs to review study progress and plans for additional accrual. Also, the research agreement will need to be amended to provide for this additional work. Note also that NIH and departmentally sponsored studies are subject to the same requirement: that any change in the protocol requires IRB review and approval.

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

ADOBE SITE LICENSE

Wake Forest University Health Sciences departments can now take advantage of a new licensing program for Adobe software. Departments are eligible to purchase Adobe products at significant savings over both standard commercial and academic pricing. The Office of Research no longer has licenses available for Adobe. To obtain a copy of the software, call the help desk at 6-HELP, provide an account number, and the software will be installed for a nominal fee.

AHRQ NOW HAS GRANTS DATABASE

The Agency for Healthcare Research and Quality now has a searchable grants awarded database--much like the CRISP database at NIH. The AHRQ database is termed GOLD [Grants Online Database], and has FY01 awards at present. Grants awarded in FY00 and 02 are being added. The GOLD website is: www.gold.ahrq.gov.

FALL GCRC CLINICAL RESEARCH SERIES**OPENING SPEAKER**

"Recruitment Challenges"

Sharon Jackson, Ph.D.

Associate Professor, Public Health Sciences

GCRC Demographic Expert

Wednesday, September 4, 2002

12 noon

Nutrition Education Wing, Conference Rooms 1, 2 & 3


Lunch will be provided; come early

NEWS FROM NIH

NIH EXPANDS TO SIX-DIGIT APPLICATION NUMBERS

The growth of NIH funding has resulted in record numbers of grant applications and awards. The National Cancer Institute (NCI) reached a milestone in June with the assignment of application number CA99999. The next number assigned to NCI was the first at NIH to use 6 digits in its serial number. Application numbers are assigned sequentially within NIH Institutes and Centers. NIH does not expect other Institutes or Centers will reach six digits before 2003.

NIH GUIDANCE ON THE USE OF CARBON DIOXIDE FOR ANIMAL EUTHANASIA



Public Health Service (PHS) policy requires local Animal Care and Use Committees (ACUCs) to assure that euthanasia of research animals is conducted in accordance with the Report of the American Veterinary Medical Association on Euthanasia, unless justified for scientific reasons. In all circumstances, the principle of minimizing pain and distress should be applied.

The use of CO₂ is generally accepted as an euthanasia agent for small laboratory animals under the following conditions: 1) high concentrations are distressing to some species, so pre-filling the chamber is not recommended, 2) death must be verified after euthanasia and preferably assured by subsequent thoracotomy, 3) chambers must not be overcrowded, and 4) compressed CO₂ in cylinders is the only allowed source of CO₂. In addition, all unintended recovery of animals after apparent death from CO₂ must be reported by WFUHS to the Office of Laboratory Animal Welfare.

For the complete PHS notice see <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-062.html>.

For the Report of the AVMA on Euthanasia see <http://www.avma.org/resources/euthanasia.pdf>

VIGILANCE: UPDATES FROM WFUSM ENVIRONMENTAL HEALTH AND SAFETY

TIPS ON WORKING WITH AIR AND WATER REACTIVE MATERIALS

- Determine if materials you wish to use are listed in the REACTIVE CHEMICALS POLICY. If so, review available reference literature to obtain specific safety information, document the process in an SOP, and submit a Chemical Safety Application and the SOP to the Chemical Safety Committee.
- Always minimize the amount of material involved in the experiment; the smallest amount sufficient to achieve the desired result should be used. Scale-ups should be handled with great care, giving consideration to the reaction vessel size, cooling, heating, stirring and equilibration rates. You will receive assistance in determining if the proposed procedure and facilities are adequate to ensure safety.
- Excessive amounts of these reactive compounds should not be purchased, synthesized, or stored in the laboratories. The key to safely handling reactive chemicals is to keep them isolated from the substances that initiate their violent reactions.
- Do not work alone. Activities with reactive chemicals should be performed during the normal work day or when other employees are immediately available.
- Perform all manipulations of air or water reactive materials in a chemical fume hood. Factors to be considered in judging the adequacy of the hood include its size in relation to the reaction and required equipment, the ability to fully close the sash, and the composition of the sash.
- The reaction equipment must be properly secured. Reaction vessels should be supported from beneath with tripods or lab jacks, and shields or guards must be clamped or secured.
- Handle water-sensitive compounds away from water sources. Light-sensitive chemicals should be used in light-tight containers.

WILD POLIO VIRUS SURVEY AND INVENTORY

The Centers for Disease Control and Prevention (CDC) will initiate a survey and inventory to identify wild poliovirus in October, 2002 as part of the WHO program to prevent reintroduction of wild polioviruses from the laboratory into the community. The survey will alert laboratories to the impending eradication of polio and encourage disposal of all unneeded wild poliovirus materials. The inventory will enable CDC to maintain a list of laboratories in which wild poliovirus may be present, keep them informed of biosafety developments, and permit notification of the eradication efforts and when to implement containment requirements.

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*

LOCAL PANEL ON HORMONE REPLACEMENT THERAPY – AUG. 14 – HAWTHORNE INN

Physicians and researchers from WFUBMC will answer questions about hormone replacement therapy (HRT) at a public meeting from 6 p.m. to 8 p.m. Aug. 14 at the Hawthorne Inn and Conference Center, 420 High Street in Winston-Salem. The panel will include experts in cancer, cardiology and women's health. Questions can be submitted in advance by calling 336-713-4222 or by sending an email to whcoe@wfubmc.edu. Questions will also be taken at the event. Attendees will receive a free information packet including, "What To Ask Your Doctor." Wake Forest is one of two centers in the state conducting the Women's Health Initiative, a large research study to learn more about women's health. Recently, the study found that the risks of taking estrogen plus progestin outweigh the benefits for many women. About 7 million women in the United States take this combination of hormone replacement therapy.

Contact: 336-713-4220.

WOMEN'S HEALTH SEMINAR SERIES 2002-2003 – STICHT CENTER AUDITORIUM

Tuesday, Sept. 10, Noon,

"Update on the Women's Health Initiative"

Sally Shumaker, PhD, Associate Dean, Faculty Services & Career Development, Professor, Public Health Sciences, WFUBMC.

SAVE THE DATES! GRAYLYN CONFERENCE OCT. 10-11

In the wake of the new WHI and HERS follow-up results, the importance of understanding more about hormone replacement therapy and its effects on postmenopausal women's health is greater than ever. So this year's Graylyn Conference on Women's Health, entitled "Hormone Replacement Therapy and Coronary Heart Disease: Primary versus Secondary Prevention," is especially timely. Once again, Dr. David Herrington has assembled a faculty of 16 world-renowned experts to consider basic science, epidemiologic, and clinical aspects of this important public-health issue. Our special speaker, Jane Brody from the *New York Times*, will provide a consumer and public safety perspective to our theme. Don't miss this excellent opportunity for networking and pursuing extramural collaborations.

The brochure and registration form can be seen and printed out at our page on the Women's Health Center of Excellence website: www.wfubmc.edu/women/profed/brochure.pdf, or call Allie Richardson at 6-9124 to receive a brochure or to answer any questions. Graylyn's intimate setting means that space is limited, so register soon!

Women's Health continued.....

WOMEN'S HEALTH IN SPORTS AND EXERCISE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Child Health and Human Development (NICHD), and the Office of Research on Women's Health (ORWH) encourage investigator-initiated research grant applications to study women's health in sports and exercise. The purpose of this program announcement (PA) is to stimulate and foster a wide range of basic, translational, and patient-oriented clinical studies. Improvement in our basic knowledge of the pathophysiology of sports injuries in women will help to solve the puzzle of why female athletes are more susceptible to certain types of injury. In addition, translational studies will be helpful in developing optimal prevention, rehabilitation, and training strategies for injuries and overuse syndromes in the female athlete throughout the life spectrum. This pathophysiology may also be applicable to women with disabilities, as compensation for disability often includes some athletic activity.

Deadlines: October 1, 2002, February 1, and June 1, 2003

Contact: James S. Panagis, M.D., M.P.H., Director Orthopaedics Program, NIAMS

Email: jp149d@nih.gov

AMERICAN ASSOCIATION OF OBSTETRICIANS AND GYNECOLOGISTS FOUNDATION (AOGF) SCHOLARSHIP

The American Association of Obstetricians and Gynecologists Foundation (AOGF) Scholarship wishes to identify potential future academic leaders and to stimulate their development through the support of advanced scientific scholarships. The award will provide research training and experience for a candidate of proven ability who exhibits significant evidence of talent and dedication to an academic career. Research training may be either laboratory based or clinical and may focus on biology fundamentals, disease mechanisms, interventions, epidemiology, or translational research. At least 90 percent of the candidate's efforts should be spent in research and research training, which may be conducted in facilities either within or outside of the sponsoring department of obstetrics and gynecology.

Contact: Mrs. Nora P. Smith, Administrative Director, AGOS and AOGF

Email: nps@Virginia.edu

FEMALE HEALTH AND EGG QUALITY - NICHD

NICHD invites applications for a program on female health and egg quality. This program will utilize the cooperative agreement mechanism to better understand the impact of poor nutrition, extreme exercise, smoking, certain assisted reproductive technologies, and other adverse health situations upon reproductive processes prior to and around the time of fertilization in females. The central focus of this program is to establish measurable, identifiable characteristics of high-quality human and nonhuman eggs that have full developmental potential. It is thought that a high-quality egg is an important starting point for the development of a healthy embryo, placenta, and fetus. It is also thought that low egg quality can lead to certain forms of infertility, abnormal embryonic and fetal development, low birthweight, and longterm adult diseases and disorders in the offspring. The Barker hypothesis on fetal origins of adult diseases suggests that there can be adverse in utero effects on the fetus may lead to certain adult diseases such as heart attacks, diabetes, and chronic high blood pressure. This present initiative is based upon the concept that the Barker hypothesis may also pertain to adverse effects on the developing egg before and around the time of fertilization. Among the ultimate beneficiaries of this program will be women who have difficulty attaining healthy pregnancies and producing healthy offspring owing to low egg quality.

Deadline: October 16, 2002

<http://grants1.nih.gov/grants/guide/rfa-files/RFA-HD-02-018.html>

Research Funding Opportunities

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

BURROUGHS WELLCOME FUND

POSITION: Clinical Scientist Awards in Translational Research

DESCRIPTION: The program's goal is to foster the development and productivity of outstanding physician-scientists who will strengthen translational research -- the two-way transfer between basic research and patient care. The awards are intended to give recipients the freedom and flexibility to explore fundamental scientific questions, apply the resulting knowledge at the bedside, and bring insights from the clinical setting back to the laboratory for further exploration. The Fund is interested in supporting investigators who will bring novel ideas and new approaches to translational research. Proposed activities may draw on the many recent advances in the basic biomedical sciences that provide a wealth of opportunities for studying and alleviating human diseases. Large-scale clinical trials, epidemiological studies, and health services research are not eligible for support. Grants are for up to \$150,000 per year for up to five years.

DEADLINE: September 3, 2002

LEUKEMIA AND LYMPHOMA SOCIETY

POSITION: Career Development Program

DESCRIPTION: The Society is dedicated to the conquest of leukemia, lymphoma, Hodgkin's disease and myeloma through research. The following career development awards are available:

Scholar - these awards are for highly qualified individuals who have demonstrated over a period of not less than five years their abilities to conduct original research on leukemia, lymphoma and myeloma. They must hold a faculty position and have obtained substantial support for their research from a national agency. This program is designed to aid the individual rather than the project. Awards are for up to \$100,000 per year for up to 5 years.

Scholar in Clinical Research - the scholar must have held a faculty or equivalent position for at least three years at the time of review and have demonstrated an ability to conduct original clinical research on the prevention, diagnosis or treatment of leukemia, lymphoma, or myeloma. Applicants must have concomitant support for all relevant research costs. The proposed studies should translate new concepts in the basic biomedical, epidemiological or preventive sciences into clinical practice. Preference will be given to applicants whose research involves a clinical trial or new or innovative applications. Awards are for \$100,000 per year for up to 5 years.

Special Fellow - These special fellows must have completed more training and education in the field than the requirements for a fellowship, but less than necessary for a scholarship. The applicant should have at least two years of postdoctoral research training at the time of review. Applicants may have concurrent research support or rely on their sponsors for research support. Awards are for \$50,000 per year for up to 3 years.

Fellow - fellows are beginning investigators with minimal or no experience working in fields relevant to leukemia, lymphoma or myeloma. A Fellow applicant must not have had more than two years of postdoctoral research training at the time of review. Fellows are encouraged to embark on an academic career involving clinical or fundamental research in or related to leukemia, lymphoma or myeloma. Awards are for \$40,000 per year for up to 3 years.

Additional information about the programs listed can be found at:

<http://www.leukemia-lymphoma.org>.

DEADLINE: September 16, 2002 - electronic submission required.

NIDDK

POSITION: Racial and Ethnic Differences in the Etiology of Type 2 Diabetes in the United States - PA-02-117

DESCRIPTION: The Institute seeks research applications to enhance the understanding of the underlying metabolic and physiologic mechanisms that contribute to the racial and ethnic differences in the incidence and pathophysiology of type 2 diabetes in the United States. The overall objective of this PA is to determine the metabolic and physiologic reasons for disparities in the incidence of type 2 diabetes in minority race-ethnic populations. This PA will use the NIH research project grant (R01) and the Exploratory/Development Research Grant (R21) award mechanism.

DEADLINES: October 1, 2002, February 1 and June 1, 2003

NIA, NCI, NIDDK, NIEHS

POSITION: Age-Related Prostate Growth: Biologic Mechanisms - PA-02-116

DESCRIPTION: Substantial data currently exist showing that prostate volume increases with age in middle-aged and older men, following a post-pubertal plateau. In addition, the incidence and prevalence of prostate disease increase with age, and are very high in elderly men. The Institutes invite research applications addressing biologic mechanisms related to aging processes that underlie the initiation and progression of prostate growth processes in middle-age, and the pathophysiological connections of the growth process with the prostate diseases prevalent in older men, benign prostatic hypertrophy (BPH) and prostate cancer. This PA will use the NIH research project grant (R01) and the Exploratory/Development Research Grant (R21) award mechanism.

DEADLINES: October 1, 2002, February 1 and June 1, 2003

Research Funding Opportunities

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

GRANT AND CONTRACT PROPOSAL WATCH

	Fiscal Year 02 July - June	Fiscal Year 01 July - June	% Change
Proposals Submitted	1028	916	12
Dollars Requested	\$516,531,071	\$325,265,673	59

Research Funding Opportunities

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

NATIONAL HEADACHE FOUNDATION

POSITION: Research Grants

DESCRIPTION: The Foundation supports research in the field of headache and pain. The Foundation is interested in supporting research grants that are objectively sound and whose results can contribute to the better understanding and treatment of headache and pain. More information can be found at <http://www.headaches.org>.

DEADLINE: December 1, 2002

Are you receiving Pursuit monthly, but your co-worker is not? If additional people in your office are interested in receiving Pursuit, contact Amy Comer, 64549 to be put on the mailing list.

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

AHRQ - Agency for Healthcare Research and Quality
NCCAM - National Center for Complementary and Alternative Medicine
NCI - National Cancer Institute
NCNR - National Center of Nursing Research
NCRR - National Center for Research Resources
NEI - National Eye Institute
NHLBI - National Heart, Lung and Blood Institute
NHGRI - National Human Genome Research Institute
NIAAA - National Institute on Alcohol Abuse and Alcoholism
NIA - National Institute on Aging
NIAID - National Institute of Allergy and Infectious Diseases
NIAMS - National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB - National Institute of Biomedical Imaging and Bioengineering
NICHD - National Institute of Child Health and Human Development
NIDA - National Institute on Drug Abuse
NIDCD - National Institute on Deafness and Other Communication Disorders
NIDDK - National Institute of Diabetes and Digestive and Kidney Diseases
NIDCR - National Institute of Dental and Craniofacial Research
NIEHS - National Institute of Environmental Health Sciences
NIGMS - National Institute of General Medical Sciences
NIMH - National Institute of Mental Health
NINDS - National Institute of Neurological Disorders and Stroke
NLM - National Library of Medicine
ORWH - Office of Research on Women's Health

PURSUIT STAFF

SHEILA VRANA, PH.D.
 DAVID LYONS, PH.D.
 AMY COMER



BACK TO
 SCHOOL
 TIME!!