

WAKE FOREST
UNIVERSITY

SCHOOL of MEDICINE
THE BOWMAN GRAY CAMPUS

OFFICE OF RESEARCH

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

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RESEARCH INFORMATION BULLETIN Vol. 18, No. 5, May/June 2004

SALLY A. SHUMAKER, PH.D. NAMED ASSOCIATE DEAN FOR RESEARCH

William B. Applegate, M.D., M.P.H., Senior Vice President and Dean, appointed Dr. Sally A. Shumaker as the Associate Dean for Research effective May 7, 2004. Dr. Shumaker's responsibilities include oversight of all extramural research grant and contract activities including oversight of Grants Administration and the Animal Care & Use Committee; the Institutional Review Board; Industry Relations; the Animal Resources Program and Environmental Health & Safety. She will foster collaboration with department chairs and center directors by assisting faculty members with future grant and contract development. Dr. Shumaker is a nationally and internationally recognized expert in clinical research, with primary areas of expertise in women's health, behavioral science, health-related quality of life and conducting multi-center clinical trials. Throughout her career, Dr. Shumaker has worked to promote the development of younger faculty members and to provide the infrastructure needed to enhance the success of all faculty. She is particularly well known for her national and local contributions toward the promotion of the careers of women in medicine. Please join the Office of Research in welcoming Dr. Shumaker.

INTERIM DEPUTY ASSOCIATE DEAN

The Office of Research welcomes back Mr. Lawrence D. Smith as the Interim Deputy Associate Dean for Research. Mr. Smith retired as Associate Dean for Research in June 2001 after 19 ½ years of service; he has agreed to assist as we recruit for the Assistant Dean for Research position vacated by Dr. Sheila Vrana on June 1st. Mr. Smith will be in the office in the afternoons to assist with the day to day operations including grant and contract review and approval. His wisdom and experience are invaluable to the Office and we are grateful to have him back with us.

DIRECTOR OF GRANTS ADMINISTRATION NAMED

Effective June 1, 2004, Kim Vargas has assumed the role of Director, Grants Administration. Kim is also signatory authority for Wake Forest University Health Sciences in all matters relating to grants and contracts. The timely new position will ensure a successful and smooth transition until the new Assistant Dean for Research position is filled. Congratulations Kim!

CONCERN LINES

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

**REGULATORY COMMITTEE
DEADLINES**

ANIMAL CARE AND USE
COMMITTEE -
JULY 2 AND AUGUST 6, 2004

INSTITUTIONAL REVIEW BOARD -
NOON - FRIDAYS

**INTRAMURAL RESEARCH
SUPPORT COMMITTEE
DEADLINES**

*REGULAR AND INTERIM -
AUGUST 20, 2004

* Clinical studies or other
research involving humans
are encouraged

**WAKE FOREST BAPTIST REACHES \$114 MILLION
IN NIH FUNDS**

Wake Forest University School of Medicine gained nearly \$10 million in funding from the National Institutes of Health (NIH) for FY03 which ended on September 30, 2003, reaching \$114,768,124 and ranking 36th overall among 125 American medical schools. The Department of Public Health Sciences remained second in the nation among similar departments, bringing in nearly \$28 million. The Department of Physiology and Pharmacology moved up from fifth in FY02 to third among similar departments, with more than \$16 million in funding. "In today's environment, increasing funding by \$10 million is a significant accomplishment for any institution," said Sally A. Shumaker, Ph.D., Associate Dean for Research. "I am proud of the hard work and contribution by our faculty and their commitment to research excellence." Eight other departments ranked among the top 25 nationally within their specialties: Cancer Biology, 14th, Obstetrics and Gynecology, 21st, Radiologic Sciences and Anesthesia, both 22nd, Pathology and Surgical Sciences, both 23rd, and Family and Community Medicine, 25th. - Bob Conn

FACULTY ALERT: GCRC COMPETITIVE RENEWAL

If you conduct human research of any kind or plan to do so between 2006 and 2011, take advantage of the General Clinical Research Center! The GCRC provides supplemental resources free of charge for investigator-initiated studies. The GCRC is in the process of preparing a renewal application to the NIH for an additional five years of funding.

A formal call for abstracts will be mailed soon. Respond by sending an abstract by July 1 if you would like your clinical research to be included in the grant request.

What does the GCRC have to offer? Since the last renewal, a five-bed outpatient Geriatric GCRC has been added. This unit and the Main GCRC are up-to-date research centers with exam rooms, metabolic kitchen, processing lab, molecular genetics lab, computer center, administrative offices and trained professionals. The GCRC can also supplement investigators' NIH funding for lab tests.

Who may submit protocols? Either MDs or PhDs can be principal investigators (with an MD serving as responsible-physician). The NIH GCRC program gives top priority to research funded by the NIH, but also accepts investigator-initiated studies funded by foundations, industry and other sources. Only a small number of industry-initiated protocols can be included. All protocols must be approved by the IRB and the GCRC.

If you would like a GCRC brochure, please contact Ms. Teresa Reagan at 716-9750.

RESEARCH ADMINISTRATORS MONTHLY MEETINGS

Research administrators will not meet during the months of July and August. Meetings will begin again in September and take place the 2nd Thursday of every month at 10:00 am in Commons Conference Rooms 2 & 3. The Office of Research is soliciting ideas to be presented. If you have topics related to research administration in the medical school that you would like to see presented, or if you would like to be added to research administrators email list, email Amy Comer at acomer@wfubmc.edu. This email list is also used by the Office of Research to relay information relating to research administration when needed.

TECHNOLOGY-BASED INTERNSHIP PROGRAM

Be a mentor. Be an influence. Be the spark that starts the burning interest. Host an intern this summer. Be a part of the Winston-Salem Chamber of Commerce Technology Council's Technology-based Internship Program. If you are searching for a qualified intern, look no further! For more information, contact Annessa Warehime at 728-9244 or awarehime@winstonsalem.com

LAB IN NEED OF SUPPLIES



A Nuclear Medicine lab is in search of supplies and equipment to restock their lab due to the relocation of one of their PIs to another institution. The following items are needed:

- beakers of various sizes
- graduated cylinders of various sizes
- pH meter
- balances for measuring chemicals
- incubator for tissue culture
- pipetman any size
- PCR equipment
- centrifuge low and high speed
- fume hood for evacuating chemical fumes
- fume hood for tissue culture
- microscope (does not need bells and whistles, to observe cells and tissue staining)
- liquid nitrogen tank for building a supply of cell lines -- size does not matter
- carboys of any size
- bottles of all sizes for preparing media and buffers

If your lab has any of the above supplies to donate, please contact Robin King at 63385 or roking@wfubmc.edu.

SEEKING POSITION

WAKE FOREST PRE-MED UNDERGRADUATE STUDENT SEEKS RESEARCH POSITION AS PART OF UNDERGRADUATE STUDIES (NO PAY NECESSARY). ESPECIALLY INTERESTED IN CARDIOLOGY RELATED RESEARCH. CURRENT LAB SKILLS INCLUDE: SPECTROSCOPY ANALYSIS; COLUMN CHROMATOGRAPHY; CRYSTALLIZATION; DISTILLATION; EXTRACTION; FILTRATION; PCR; RESTRICTION DIGESTS; CLONING WITH PLASMID VECTORS; cDNA ATTAINMENT AND APPLICATION; SDS-PAGE; GEL ELECTROPHORESIS; BLOTS – SOUTHERN, NORTHERN, WESTERN; ENZYME ASSAYS; DNA SEQUENCING – DIDEOXY CHAIN METHOD. CONTACT CHRIS NELSON, NELSCM2@WFU.EDU.

REMINDERS



Face Pages:

All face pages, cover sheets etc., for grant applications should be signed by the Principal Investigator before routing to the Office of Research for review and approval.

Delivering Grants to the Office of Research:

Grant applications brought to the Office for signature should be left in the "Grants Drop-Off" basket at Angela Horton's desk. Please do not put grant applications in individual mailboxes. The Office also discourages sending original grant applications via interoffice mail.



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

TAKE A TOUR OF THE WOMEN'S HEALTH CENTER WEBSITE

The WHCoE website, with sunny yellow-and-orange banners and easy-to-read layout, resides within the WFUBMC Women's Health pages at www.wfubmc.edu/women. Here are some of the site's notable features: On the WFUBMC Women's Health page, the WHCoE offers a listing of *New Programs* at the Medical Center and *Other Links* to sites related to women's health.

The WHCoE updated Women's Health Referral Resource this spring. The resource lists over 100 WFUBMC health care providers with clinical services or programs that offer care sensitive to gender differences in health, are provided exclusively for women, or meet the expressed desires of women patients. The list is subdivided by topic for easy searching and provides contact information for each service or provider. All health care providers on this list responded to our annual survey. If you provide a women's health clinical service or program and would like to be added, please contact Natalie Barrett (nbarrett@wfubmc.edu). Periodic updates will be posted online at the site.

To view the Referral Resource or to access a printable version of the list, visit the *Meet Our Doctors* page at www.wfubmc.edu/women.

Also listed on the WHCoE site: Professional and community events, and Women's Health News & Resources. Learn more about Education, Leadership & Mentoring, and Research Programs, the Research Support Core, and the WHCoE Resource Center catalogue by following the links. We also update the "Upcoming Events" section frequently. For more information about who we are, where we are, and how to contact us, visit our introduction page.

NATIONAL WOMEN'S HEALTH REPORT CARD

According to the 2004 edition of *"Making the Grade on Women's Health: A National and State-by-State Report Card,"* small gains and key setbacks characterize the current status of women's health in the U.S. The report, the third to be issued by the National Women's Law Center and the Oregon Health & Science University, provides thumbnail sketches of factors related to women's access to health care, wellness and prevention, and living in a healthy community. A total of 27 health status benchmarks are considered, largely taken from the U.S. Department of Health and Human Services "Healthy People" initiative. Each benchmark is ranked on "strength of policy in 2004" as well as "change from 2001," when the Report Card was first issued. Data are presented for each state and nationwide. North Carolina ranks 38th in the U.S. on the Report Card. The only areas judged to have improved in our state since 2001 were Medicaid spousal impoverishment, women's protections in clinical trials and external review of their health data, tobacco sales rate to minors, and state funding for tobacco prevention. Other categories, including breast and cervical cancer treatment, violence against women assistance, and HMO members' direct access to OB-GYN care, showed no change from 2001. The Report Card can be accessed at www.nwlc.org/details.cfm?id=1861§ion=health.

MENTAL HEALTH: NEW ADDITION TO NATIONAL WOMEN'S HEALTH INFORMATION CENTER WEBSITE

The latest addition to the wealth of information on the National Women's Health Information Center's website is devoted to women's mental health. The new section features discussions of depression, mind/body wellness, menopause, and mental health disabilities, as well as medical news, support group and hotline contacts, and listings of events of interest. To access all of this information, visit www.4woman.gov/mh/.

CONGRATULATIONS!

The Women's Health Center of Excellence congratulates Dr. Deborah Best, Professor of Psychology at the Reynolda Campus, on her promotion to Dean of the College (effective July 1). Dr. Best, who chaired the Department of Psychology from 1994 to 2002, is well-known for her work on gender stereotypes, cross-cultural psychology, and cognitive development in young children. She currently leads the "Digital Bridge Initiative," a project with Habitat for Humanity of Forsyth County investigating the effects of providing computers to children who live in Habitat-built homes. We look forward to working with Dr. Best in the future.

Dr. Angela Hattery, Associate Professor of Sociology at the Reynolda Campus (and cross-appointed in the Department of Public Health Sciences), was recently awarded a 3-year Z. Smith Reynolds Foundation Fellowship. The fellowships are designed to affirm and reward the university's most able and promising young faculty members by supporting and encouraging professional development. Dr. Hattery's research has been focused in two main areas: the intersection of work and family (*Women, Work, and Family: Balancing and Weaving*, Sage 2001) and intimate partner violence (IPV) (*Violence in Intimate Partner Relationships*, currently under review with Lynne Rienner). Her current work on IPV (with Professor Earl Smith) is framed by a race, class, gender paradigm and is focused on the qualitative experiences of battering—for both the victim and the offender—in African-American and Latino communities.

RACIAL AND ETHNIC DIFFERENCES IN NC: 2004 UPDATE NOW AVAILABLE

The North Carolina Department of Health and Human Services has just released their report "*Racial and Ethnic Differences in Health in North Carolina: 2004 Update*". The complete report is available online at <http://www.schs.state.nc.us/SCHS/pdf/RaceEthnicRpt.pdf>.

As Secretary of NC Dept of Health and Human Services Carmen Hooker Odom writes in the Executive Summary, "Race is considered as a marker of health problems, not as a risk factor or a cause. Describing racial and ethnic differences in health allows targeting of resources and culturally appropriate health improvement programs toward populations most in need." Sections of the report particularly relevant to women's health include teen pregnancies, live births, and risk factors during pregnancy. This report will serve as a useful guide to those who wish to conduct research on racial and ethnic differences, or to document statewide trends.

OTHER EVENTS OF INTEREST

July 12-13, 2004

Women Across the Life Span: A National Conference on Women, Addiction and Recovery
Sponsored by: Center for Substance Abuse & Treatment, Substance Abuse and Mental Health Services Administration (SAMHSA), Dept. Health and Human Services
Baltimore Marriott Inner Harbor
Details: conferences.jbs.biz/women_and_childwelfare/lifespan/index.htm, or email ADixon@jbs1.com
Registrations received before July 2: \$200

July 29-31, 2004

Role of Families in Preventing and Adapting to HIV/AIDS
Sponsored by: Office of AIDS Research, National Institute of Mental Health, NIH
Details: Dr. Willo Pequegnat (phone 301-443-6100; fax 301-443-9719; email wpequegn@nih.gov)

August 12-15, 2004

Women of Color, Taking Action for a Healthier Life: Progress, Partnerships and Possibilities – Washington, D.C.
Sponsored by: Office of Research on Women's Health, Dept. Health and Human Services
Details: www.4woman.gov/mwhs or call: Elizabeth David at (202) 205-0571, Adrienne Smith at (202) 690-5884, or Frances Ashe-Goins at (202) 690-6373

NOTICE

The Research Support Core would like to alert investigators who are planning grant submissions for July 1 that editing services will not be available from June 10-June 30, and budget services will not be available from June 28-June 30. As always, Core services are first-come, first-serve. Contact the Core Director, Dr. Kristie Foley, if you have any questions (kfoley@wfubmc.edu).

DEAR DR. OR

Dear Dr. OR:

In recruiting subjects to be in my study I am finding that many are already participating in other research studies. Can a subject be in more than one study at a time?

Signed
Double Dipping

Dear Double,

When evaluating a subject's eligibility, he/she should always be asked whether he/she is currently or recently been enrolled in other research studies, even if this is not specifically prohibited by your protocol. While there are no regulatory requirements that prohibit this, investigators must consider subject safety, scientific integrity, and protocol requirements when faced with this problem. Safety issues can range from anemia in normal volunteers resulting from multiple blood donations to potentially life-threatening drug interactions in subjects taking part in interventional research. Issues associated with the scientific integrity of a study can arise when the intervention in one study, say weight loss resulting from participating in an exercise study, can impact the results of a second study, such as blood sugar control in a diabetes drug study. Finally, protocol requirements must be adhered to that, for what ever reason, specifically exclude subjects who are currently or who have recently taken part in other research studies.

In general, it is not recommended to allow subjects to participate in more than one study at a time, especially if the studies are interventional trials. If an investigator believes it may be appropriate for a subject to be in more than one study, or if an investigator discovers that an enrolled subject is taking part in another research study, he/she should immediately contact the principal investigator of the other study. A decision on the subject's participation should be based on the safety and welfare of the subject, scientific issues related to the studies, and protocol requirements. The IRB must be notified of any protocol deviation or any unanticipated problem that arise as a result of a subject taking part in multiple research studies.

Dear Dr. OR:

I am in the process of becoming an investigator under a sub-contract with another institution. The prime institution is requesting only a budget. What forms do I need to route to the Controllers Office and Office of Research?

Signed;
Ready to Collaborate

Dear Collaborate:

WFUSM requires that you route the Institutional Review and Certification Form, budget, statement of work, and checklist for Institutional approval. A letter of intent to take part in a sub-contract will be provided by the Office of Research. If the prime institution requests other information it should be included in the routing as well.

Dear Dr. OR:

I am preparing to submit an R01 grant application with two 2 sub-contracts with other organizations. I have received all the information from the subs, but am confused about which forms to include in my application to NIH. Please advise.

Signed:
Ready to Submit

Dear Submit:

You will need to include an initial budget period (form page 4) and entire proposed project period (form page 5) for each participating organization if the application is not in a modular format. Biographical sketches for key personnel from the participating organization and a resource section for each are also needed. In section H, you will need to explain the programmatic, fiscal and administrative arrangements with each organization and include a Statement of Intent for each sub-contract organizationsigned by the authorized institutional official.

CONTROLLER'S CORNER - GRANTS MANAGEMENT

FRIENDLY REMINDERS

Effort Reporting

Effort reporting is a major audit concern across the nation at many university campuses. The Controller's Office sends effort reports for review to biweekly staff every 2 weeks and to salaried staff every 6 months. It is imperative that these effort reports are verified and signed by the employee within 2 weeks. Effort reporting is a federal requirement. Improper reporting has resulted in universities having to pay millions of dollars in fines. Please take the time to evaluate your effort and ensure that you are exerting the amount of effort that you are certifying on these reports. Your signature on the report documents that you have done this review and should not be changed retroactively. If you have expended effort but your salary has been paid differently we may have to adjust the distribution but the effort reports should not have to be altered. Distribution and effort may not always be the same especially in cases where the federal salary cap applies. Also, include projects with no salary support.

When retroactively changing effort the following documentation is required:

- Why is it necessary to alter the certification report?
- What has changed?
- Why was it missed before?

Approving responsibilities:

When you are signing off on Request for Payments or clicking to approve a requisition or HR items in the PeopleSoft system, please verify that all of the information is correct before sending to the Controller's Office. We see increased coding errors and as a result receive requests to change personnel in HR. It is our responsibility to review the requests but it is also the responsibility of those signing to verify the correct code or chartfield is used. Here is a check list to use when you are reviewing any item:

- Is this coded correctly?
- Is this grant active and is this the correct year?
- Is this a valid expense for this grant?
- Is this the appropriate funding source for this charge? (Does it belong to this grant or is it a departmental charge?)
- Is there enough money available for this charge?
- If there are not enough funds, have you initiated rebudgeting procedures and included a note that these have been started?

-- NEWS FROM THE INSTITUTIONAL REVIEW BOARD --

THE TOP 10 REASONS WHY THE IRB MUST DELAY APPROVING YOUR RESEARCH PROTOCOL

1. Your consent form does not have a Wake Forest University Health Sciences header or logo at the top.

The header should be prominently displayed at the top of the consent form and should be clearly separated from the protocol title.

2. Your consent form does not name the Steadfast Insurance Company as the provider of the WFUHS institutional liability policy.

WFUSH changed coverage to Steadfast Insurance approximately 2 years ago, but protocols are submitted with the name of the prior insurer.

3. Approval signatures are missing on the front page of the application.

IRB review of your protocol cannot proceed without the signature approval of your Department or Section Head.

4. The date of last human subject protection education program is not provided for key personnel listed on the protocol submission.

ALL key personnel listed on the protocol submission - including collaborating investigators, coordinators, fellows, residents, or students - must have completed a human subject protection education program such as the CRICC program.

5. Bio-Sketches for the PI and all key collaborators are missing from the application.

This information is needed in the NIH format for the PI and all co-investigators listed on the submission.

6. The application forms, consent form, and the research protocol have not been proof-read.

The job of the IRB members and staff is made much more difficult by protocols that contain spelling and grammatical errors. Such errors often result in the consent form containing nonsensical or erroneous information, for example using inulin in place of insulin. "Cut and paste errors" result in similar problems, such as including sections that refer to investigational drug in a protocol that involves only standard care. Consent forms should be written in the second person (i.e. "You will receive" not "I will receive"). The consent form should maintain the second person throughout the consent form, with the possible exception of the final paragraph indicating agreement to participate that precedes the signature area.

7. The RESEARCH PROTOCOL is missing from the application packet.

The research protocol describes in detail the background, rationale, and methodology of the study, as well as detailed information about how research subjects will be recruited. This is distinct from and in addition to the information provided on the IRB submission forms. For industry sponsored studies, the drug company protocol may be provided. NIH-supported research must also include the grant application.

8. A diskette containing electronic copies of all required documents was not submitted with the application packet, the submitted diskette does not contain all the required documents, the documents on the diskette are not accessible because they are password protected, or the diskette is corrupt and not readable.

The IRB posts all documents on its internal web site for inspection by members during its review. If electronic files are not provided, the review cannot proceed. Documents should be in Microsoft Word or Adobe Acrobat format and not password protected. The diskette should be checked prior to submission to ensure it contains all required documents and that it is readable.

9. The consent form is missing key sections.

Federal law mandates that consent forms must contain certain specific elements. The IRB web site has an excellent template available for use by all PIs, which contains all the required elements. The use of appropriate headers makes each section distinct and helps make the information clear to the subject.

10. Sections in the consent form are inappropriately combined.

Combining sections can result in confusion. This is especially true when the language describing Benefits, Costs, Compensation, and Liability are not listed separately in the consent form. Each of these elements should appear in a separate section.

ACCOUNTING FOR DISCLOSURES

Federal regulations allow an IRB to approve the alteration or waiver, in whole or in part, of the requirement for individual authorization for the use or disclosure of protected health information [45CFR164.512(i)] as long as the following conditions are met:

The use or disclosure of protected health information involves no more than minimal risk to the privacy of the individuals based on:

- An adequate plan to protect the identifiers from improper use and disclosure.
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the study. Or if there is adequate health or research justification for retaining the identifiers, or if retaining the identifiers is required by law.
- Adequate written assurance that the protected health information will not be reused or disclosed to any other persons or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information is allowed under regulation.
- The research could not practicably be conducted without the waiver or alteration.
- The research could not practicably be conducted without access to and use of the protected health information.

An accounting of each disclosure of the protected health information is required under a waiver of authorization granted by the Institutional Review Board [45CFR164.528(a)]. The accounting for each disclosure must include the following:

- The date of the disclosure.
- The name of the entity or person who received the protected health information and, if known, the address of such entity or person.
- A brief description of the protected health information disclosed.
- A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure.

If you have any questions or concerns about a waiver of authorization or the accounting of disclosures made under a waiver of authorization, please contact the WFUBMC Privacy Office at 713-HIPA or the Institutional Review Board at 716-4542.

VIGILANCE:**UPDATES FROM WFUSM ENVIRONMENTAL HEALTH AND SAFETY****LABORATORY CLOSEOUT**

Whenever a principal investigator leaves either the institution or a laboratory room, he/she must clean the laboratory of all chemical, biological, and radioactive materials and contamination. The Laboratory Checkout Form (<http://www.wfubmc.edu/ehs/docs/labclose.doc>) provides a documented and comprehensive way to ensure that all of the Principal Investigator's responsibilities have been completed. Recently, a vacated lab contained several hazardous materials including dry sodium metal and a bulging container of ether that had not been disposed of prior to the P.I. leaving the institution. These materials presented a hazard to the EH&S responders as well as the workers renovating the lab. Any laboratory that is not closed-out properly will be quarantined until appropriately cleaned. For questions, contact the Chemical Safety Office at 777-3099.

CERTIFICATE OF ENVIRONMENTAL COMPLIANCE

Many agencies (DOD, EPA, USAMRMC) sponsoring research require information on the health, safety and environmental practices of the Principal Investigator and the host research site. This may be a short statement, a signed Certificate of Environmental Compliance, or it may require a more sophisticated description of the WFUHS policies and practices. EH&S requires basic information from the PI prior to signing such compliance documents. An evaluation of the risks associated with the research project is necessary.

The Principal Investigator must contact EH&S at least 5 working days before the application must be submitted. The following information will be helpful to the process:

- A short description of the research project
- A list of hazardous chemicals, biohazardous materials and radioactive materials (including Chemical Safety, Biosafety, and Radiation Safety Committee approval numbers).
- The location of the laboratory rooms where the work will take place.

PPD SKIN TESTING

TB infection rates have declined in the United States over the past five years. However, some public health officials are concerned that the decline may not continue. Increases have been seen in individuals from countries of high incidence, certain geographical areas of the United States, and in certain racial/ethnic minority groups.

The tuberculin skin test is currently the only widely used method for identifying infection with *M. tuberculosis* in persons who do not have tuberculosis disease. Exposure to researchers and staff could occur through work with tissue that could aerosolize the organism or contact with visitors.

Testing is offered through Employee Health on Mondays, Tuesdays, Wednesdays and Fridays. Skin testing should be done on an annual basis. Individuals who work with non-human primates must be tested every six months.

NEWS FROM NIH

USE OF CURRENT PHS 398, 2590 AND RELATED FORMS

The Research and Research Training Grant Applications and Related Forms (PHS-398, 2590, 2271, 3734) Exp. 5/2004, currently in use remain authorized until further notice from NIH. The revised versions have been submitted to OMB for review and approval. Once OMB approval is received, the new forms will become available for use and will be accessible on the NIH and Office of Research websites. There will be a transition period when both the new and old forms will be accepted by NIH.

CHANGE IN DIRECT COST LIMITATIONS ON SOLICITED APPLICATIONS

NIH has announced a revision of its policy on direct cost limitations on solicited applications published after April 30, 2004. Applications in response to those Program Announcements (PAs) and Requests for Applications (RFAs) that include a limitation on direct cost are to exclude from that limit the facilities and administrative (F&A) costs requested by consortium participants. The F&A costs requested by the consortium will be reflected in the PHS 398 application according to current instructions, and F&A costs awarded under these programs will continue to be awarded under the current practice. However, these consortium F&A costs will not be counted as a direct cost when determining if an applicant is in compliance with a direct cost limitation on a solicited application. This does not change the NIH policy on the acceptance of applications requesting direct costs of \$500,000 or more for any one year.

EXTENDING THE EXPIRATION DATE OF RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITIES AND RESEARCH SUPPLEMENTS FOR INDIVIDUALS WITH DISABILITIES

The NIH continues to emphasize the use of administrative supplements to attract underrepresented minorities and individuals with disabilities to the sciences and to careers in biomedical, behavioral, clinical, and social science research. The complete Program Announcement's for these programs can be found at <http://grants.nih.gov/grants/guide/pa-files/PA-01-079.html> and <http://grants.nih.gov/grants/guide/pa-files/PA-01-080.html>. The NIH has announced that these programs will remain active until replaced by subsequent program announcements

Research Funding Opportunities

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

AMERICAN LUNG ASSOCIATION

POSITION: Research Grants

DESCRIPTION: The ALA research program fosters basic, clinical and behavioral research designed to find cures and to prevent and relieve the suffering associated with lung disease. The following grants and awards are available:

Biomedical Research Grants – these grants provide seed monies for investigators researching the mechanisms of lung disease and general lung biology. Awards are for up to \$40,000 per year for up to two years.

Clinical Patient Care Research Grant – these grants provide seed monies for investigators working on traditional clinical studies examining methods for improving patient care and treatment for lung disease. Awards are for up to \$40,000 for up to two years.

Social-Behavioral Research Grant – these grants provide seed monies for investigators working on epidemiological and behavioral studies examining risk factors affecting lung health. This grant includes studies concerning the ethical, legal, and economic aspects of health services and policies. Awards are for up to \$40,000 for up to two years.

DeSouza Research Award – this award focuses on one or more of three areas of interest: bronchiectasis; infection with atypical Mycobacteria, particularly Mycobacterium avium; and infection with Nocardia species. The award supports clinical, laboratory, or epidemiological research relating to these three conditions. Award are for \$100,000 for up to three years.

Career Investigator – this award is intended to support the career development of established independent investigators who show great promise for a national leadership role in investigative work related to lung disease biology, traditional clinical studies related to patient care and behavioral and psychosocial matters relevant to lung disease. Awards are for up to \$60,000 per year for up to three years.

Lung Health Dissertation Grant – these grants provide pre-doctoral support for students with an academic career focus and/or nurses pursuing a doctoral degree. Research areas of particular interest to the ALA are: psychosocial, behavioral, health services, health policy, epidemiological, biostatistical and educational matters related to lung disease. Awards are for \$21,000 per year for up to three years.

Additional information on the programs is available at <http://www.lungusa.org>.

DEADLINE: September 1, 2004

BURROUGHS WELLCOME FUND

POSITION: Career Awards

Career Awards in the Biomedical Sciences – these awards are intended to foster the development of biomedical researchers who are early in their careers and to help them make the critical transition to becoming independent investigators. Awards provide \$500,000 to bridge advanced postdoctoral training and the first three years of faculty service. Additional information on this program be found at <http://www.bwfund.org>.

DEADLINE: October 1, 2004

GLAXOSMITHKLINE

POSITION: Drug Discovery and Development Research Grants

DESCRIPTION: GlaxoSmithKline, a leader in HIV research and therapies, is offering research grants of up to \$150,000 for innovative HIV/AIDS drug research, including therapies aimed at treating infection as well as prophylactic vaccines or microbicides designed to prevent transmission of the virus. The research grants are for one year and carry no obligation to the recipient's organization for licensure, patenting, or transfer of confidential information, although GSK may discuss the possibility of future collaboration with some applicants. Complete information can be found at <http://dddresearchgrant.com>.

DEADLINE: July 31, 2004

CHARLES A. DANA FOUNDATION

POSITION: Program in Human Immunology

DESCRIPTION: The Dana Foundation wishes to stimulate research that deals directly with patients. This research will provide new information more broadly about the disease process and about the immune system. Relevant science to disease might originate from many quarters, but the intent is to support scientists who have begun significant immunological research with patients, and who have preliminary data to qualify them to carry out the work and ensure that the proposal will proceed. This new program will consider complementing groups of two or three investigators, including investigators from different institutions, who need to work in collaboration to pursue challenging immunological questions in patients. Interested researchers may provide **brief (2-page)** descriptions and NIH-style CVs for a preliminary assessment of a plan that would be funded at a level of \$100,000 direct costs per year for 3 years, per investigator. Investigators selected to provide full proposals will be notified and given details of requirements.

More information can be found at <http://www.dana.org/grants/health/humanimmunologyinquiries.cfm>

DEADLINE: September 1, 2004

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, 2004

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AMERICAN CANCER SOCIETY

POSITION: Research Grants and Fellowships

Electronic submission is required for all applications. Information can be accessed at <http://www.cancer.org>, click on "Professionals", then "Research Programs and Funding".

Research Scholar Grants in Basic, Preclinical, Clinical and Epidemiology Research - these grants support investigator-initiated research projects. Awards are for up to four years and for up to \$200,000 per year. Independent investigators in the first eight years of an independent research career or faculty appointment are eligible to apply.

Research Scholar Grants in Psychosocial, Behavioral and Cancer Control Research - these grants support investigator-initiated research projects. Awards are for up to five years and for up to \$400,000 per year. Independent investigators at any state of their research careers are eligible to apply. However, senior investigators are strongly encouraged to include as co-investigator a faculty member at an early stage in his/her career.

Research Scholar Grants in Health Services and Health Policy Research - these grants support investigator-initiated research projects. Awards are for up to four years and for up to \$200,000 per year. Independent investigators at any state of their research careers are eligible to apply. However, senior investigators are strongly encouraged to include as co-investigator a faculty member at an early stage in his/her career.

Postdoctoral Fellowships - this award is to support the training of researchers who have just received their doctorate to enable them to qualify for an independent career in cancer research (including basic, preclinical, clinical, psychosocial, behavioral, and epidemiologic research). Awards are made for one to three years with progressive stipends of \$37,000, \$39,000 and \$42,000 per year, plus a \$2,000 per year institutional allowance. The Society annually selects several of the top-ranked fellows to receive special 3-year fellowships with an award amount of \$144,000.

Mentored Research Scholar Grant in Applied and Clinical Research - these grants support mentored research by junior faculty within the first four years of their faculty appointment to become independent investigators in clinical, cancer control, epidemiologic, psychosocial, behavioral, health services, or health policy outcomes research. Awards are for up to five years and for up to \$135,000 per year.

Cancer Control Career Development Awards for Primary Care Physicians - this award is made to support primary care physicians with a rank of instructor or assistant professor who are pursuing an academic career with an emphasis on cancer control. Awards are made for three years with progressive stipends of \$50,000, \$55,000 and \$60,000 per year. The grant also provides up to \$10,000 additional funds per year for support of a mentor.

DEADLINE: October 15, 2004

NCI

POSITION: Diet, Epigenetic Events, and Cancer Prevention – PA-04-099

DESCRIPTION: The Institute invites applications for new R01, R21, and R03 grants which are focused on research leading to the elucidation of mechanism(s) by which dietary factors influence epigenetic processes as well as increasing the understanding of these processes in cancer prevention. The objective is to encourage collaboration between nutrition and epigenetic experts to study bioactive food components with cancer preventative properties, and to examine key epigenetic events in cancer processes (i.e., carcinogen metabolism, cell division, differentiation, apoptosis) so that investigators can begin to establish linkages between epigenetics, methylation pattern, and tumor incidence/behavior. It is anticipated that information gained will provide guidance for the development of dietary intervention strategies for cancer prevention. The complete PA can be found at <http://grants.nih.gov/grants/guide/pa-files/PA-04-099.html>

DEADLINES: October 1, 2004; February and June 1, 2005

NIDDK, NHLBI, NIA

POSITION: Heterogeneity of Fat Depots: Underlying Basis and Association with Morbidity – PA-04-098

DESCRIPTION: The Institutes invite investigator-initiated research projects (R01 and R21) to investigate the life cycle of adipocytes and other cell types present in various fat depots, such as macrophages, neurons, and endothelial cells. The goal of this initiative is to increase our understanding of the interactions among the cell populations in order to identify biomarkers of changes in cellular physiology and metabolism brought on by the obese state, which are truly associated with the development of co-morbidities such as diabetes, atherosclerosis, and hypertension. The long term goal of this initiative is to identify markers of obesity associated with disease risk that could yield new targets for therapeutics to disrupt this link. The complete PA can be found at <http://grants.nih.gov/grants/guide/pa-files/PA-04-098.html>.

DEADLINES: October 1, 2004, February 1 and June 1, 2005

GRANT AND CONTRACT PROPOSAL WATCH

	This Fiscal Year	Last Fiscal Year	%
	July - April	July - April	Change
Proposals Submitted	936	828	13.5%
Dollars Requested	\$549,086,788	\$441,570,954	24.3%

Research Funding Opportunities

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REMINDER

"THREE DAY RULE" FOR APPLICATIONS

Applications must be submitted for review and institutional signature not less than three days prior to the agency deadline. For the upcoming **July 1** deadline, applications must have Controller's Office review of the budget and be submitted to the Office of Research by **June 25th**.

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

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

NLM - National Library of Medicine

ORWH - Office of Research on Women's Health

PURSUIT STAFF

AMY COMER

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