



## FROM THE ASSOCIATE PROVOST FOR RESEARCH

### Mark Your Calendar: August 6th, Faculty Orientation

The Office of the Associate Provost for Research is hosting a Research Orientation for all faculty, trainees and staff who are involved or interested in the research process. The faculty orientation is scheduled for Thursday, August 6<sup>th</sup> from 3-5 PM in Basic Sciences Building Room 402.

This orientation is specifically focused on tools and processes available for both seasoned investigators and those new to the research enterprise at MUSC (<http://research.musc.edu/>). Often, when research teams move to a new university or individuals start up a research program, they have difficulty finding clear guidance to fully understand 1) the overall process of research grant development and application; 2) the support systems that are available to help; and 3) the role of different research offices and how they may be defined at any given institution.

Our goal is to provide information on navigating the research system at MUSC and understanding the roles of different support offices. Our hope is that this information will offer members of the MUSC community a more seamless process of conducting scientific research and nurturing the art of discovery.

### Drug Discovery/Bioengineering Buildings construction is underway

Work in the former Visitor Parking Lot (G Lot) has started on two new research buildings. The Drug Discovery Building (DDB) and the Bioengineering/Cancer Genomics Building (BEB) will go up side-by-side in a construction contract that combines the work to achieve significant economies of scale and scheduling.

The two new research buildings are financed with a combination of federal grants and State of South Carolina Research Infrastructure funds that are designated specifically for research construction. These funds are restricted and may not be used for operations, maintenance, education or any other purpose.

The anticipated completion time for construction is Fall 2011, with occupancy at the end of 2011 or early 2012. Recent and impending activities related to starting construction are listed below.

#### June, 2009

- Award contract to Brasfield Gorrie (B-G) Construction Company out of Birmingham, Alabama.
- Contract is for \$73,000,000 for both buildings-- another \$5-7M of "after construction costs" are expected.

- Contract period is 27 months (July 2009 thru Oct 2011).
- Work hours 7:00 a.m. until 5:30 p.m., 5 days per week, as weather and other factors permit.

### **July, 2009**

- B-G mobilize on site.
- Secure perimeter of construction site.
- Install erosion control to site.
- Relocate site utilities,
- Remove trees from site (as many as possible being given to City (the palmettos) or to Legare Farms (oaks and crepe myrtles).
- Removing brick wall at bus stop.
- Demolishing surface lot.

### **August, 2009**

- First test piles driven 2<sup>nd</sup> week in August

### **September, 2009**

- Early- mid September production pile driving begins: for DDB, 550 piles @ 12 per day, as weather and other factors permit; for BEB, 441 piles @ 12 per day, as weather and other factors permit.
- Expect pile driving to last total of 3 months.

## **CITI MIAMI log-in system will change in mid-August**

The method for logging in to the Collaborative Institutional Training Initiative (CITI MIAMI) will change late August 2009. More information will be forth soon. MUSC and the CITI Program Office, located at the University of Miami, have collaborated to develop a more secure and efficient log-in system that will eliminate the need to create a new username and password combination for access to the CITI training.

Under the new system, all users, whether first time or previously registered, will access CITI MIAMI by using their current MUSC NetID and password. The link to CITI MIAMI will be on MUSC's Intranet Research Support Services website (<http://research.musc.edu/researchresources.html>) under the "Regulatory and Compliance" heading. When the CITI MIAMI link is selected, a gray box will open, asking for a NetID and password. After you correctly enter your information, you will be directed to the CITI MIAMI home page.

For MUSC users who are already registered with the CITI MIAMI website with either a VA or MUSC affiliation, the MUSC NetID log-in will be your new log-in for both affiliations.

Non-MUSC users who wish to take the CITI training will need to complete a Non-MUSC User Application for a NetID that is available through the Office of the Chief Information Officer (OCIO). This procedure requires the non-MUSC individual to be sponsored by an MUSC employee. The sponsor must contact the appropriate "registration authority" (see: <http://www.musc.edu/infoservices/idam/contacts.html>) to provision and deliver the NetID.

MUSC and CITI MIAMI have worked diligently to match current users with their NetIDs, allowing instant access to existing records. If any issues or questions arise, please contact Summer Young, MUSC Compliance Training coordinator at [youngsn@musc.edu](mailto:youngsn@musc.edu) or 792-0319 or Cynthia Teeter, MUSC Compliance Director at [teeter@musc.edu](mailto:teeter@musc.edu) or 792-8740.

Also, please note that on Monday, August 3, at 8 AM, the CITI Program web site will be taken offline for a system upgrade. The expected downtime will approximately five days. All users should complete their work and log-off before 8 AM on August 3, and regain access on or after August 8.

### **RPG Retreats will be offered Aug. 14 and Oct. 9 – help investigators refine competitive research proposals**

The Office of Research Development (ORD) offers new and established investigators and research trainees the opportunity to participate in Research Project Grant Retreats (RPG Retreats). Individuals who want constructive criticism on a research grant application are encouraged to sign up to present. Researchers at any phase of career development—from scientist-in-training to senior investigator—are encouraged to attend. The opportunity to learn by example is significant.

The next RPG Retreat will take place Friday, August 14, from 2 PM until 6 PM, in the Hollings Cancer Center Auditorium (Rm. 120). The presenters will be Teresa Kelechi, PhD, Associate Professor of Nursing; Ryan Kendall, PhD, Postdoctoral Fellow; Adam Smolka, PhD, Professor of Medicine; and Kirstin Wallace, PhD, Assistant Professor of Biostatistics, Epidemiology and Bioinformatics. The agenda available online at <http://research.musc.edu/rpg.html>.

Two slots to present at the following RPG Retreat on Friday, October 9 are available. The event will be from 2 P to 6 PM with location to be announced. The timing of the October RPG Retreat is excellent for investigators who are planning to revise and resubmit a proposal to NIH in November.

RPG Retreats are part of the Office of Research Development's portfolio of institutional services offered at no cost to participants.

Please visit the RPG web page at <http://research.musc.edu/rpg.html> for more information, including Guidelines for Presenters. You can also register at this site to present or attend. For questions, please contact Peggy Schachte, Director, MUSC Office of Research Development, 792-0868, e-mail [schachte@musc.edu](mailto:schachte@musc.edu).

### **New Faculty Welcome will be August 4<sup>th</sup>**

A New Faculty Welcome Event, sponsored by the Faculty Senate and MUSC Administration, will occur Tuesday, August 4, from 4:30 pm to 6:00 pm in Room 402 of the Basic Science Building. The University President, Provost and Faculty Senate President will make brief remarks and new faculty will be individually introduced via a slide show and posters, followed by a reception in the 4<sup>th</sup> Floor lobby.

Please save the date and plan to attend – everyone is invited! To RSVP, please contact Heather Ferguson at [fergush@musc.edu](mailto:fergush@musc.edu) or 792-5828.

### **MUSC's myPeerReview database entries are on the rise**

The Office of Research Development (ORD) offers a searchable on-line database of MUSC faculty with peer review experience. myPeerReview is a service to MUSC researchers and trainees, especially new investigators, who are looking for mentoring or advice with regard to submitting a grant proposal or scientific paper for publication.

To develop myPeerReview initially, ORD garnered information from biographical sketches regarding service on grant and editorial review panels at the national level. Types of reviews range from ongoing service on a standing study section or editorial board to special emphasis panels and ad hoc reviews.

In July ORD updated myPeerReview, which now includes a total of 526 peer review committee entries and 1170 journal entries.

Sponsors of interest include: National Institutes of Health, Agency for Healthcare Research and Quality, National Library of Medicine, Health Services and Resources Administration, Department of Defense, American Cancer Society, American Heart Association, Juvenile Diabetes Association International, National Science Foundation, National Aeronautics and Space Administration and Department of Energy. Examples of journal editorial service include: Journal of Neuroscience Research, The Journal of Nutrition, Behavior Modification and the American Journal of Epidemiology.

Developed by ORD in conjunction with Satya Phanse and John Imholz of MUSC's Information Services, myPeerReview is available on the MUSC Research Website at <http://research.musc.edu/myPeerReview.html>

ORD invites all members of the MUSC research community to improve and expand the database by adding, updating and/or correcting their information. As always, ORD welcomes your comments and suggestions about this service as well as other ORD activities and offerings. Please email your queries concerning the database to Janet Johnson ([johnsjn@musc.edu](mailto:johnsjn@musc.edu)).

### **ORSP revises Grant Administrator assignments for college & departments**

In order to maintain adequate service levels and to keep the research administration workload evenly distributed, the Office of Research and Sponsored Programs (ORSP) recently revised its grant administrator service assignments for MUSC's colleges and departments. The revised assignments are based on a review of historical data and projections for optimal service delivery. The current list of assignments is available on line at [http://research.musc.edu/orsp/gc\\_areas.html](http://research.musc.edu/orsp/gc_areas.html).

Please note the revised grant administrator/college & departmental assignments were effective Monday, July 20<sup>th</sup>, 2009. Careful measures were taken to minimize the impact on the MUSC research community.

For questions, please contact your assigned Grant Administrator in ORSP, or call 792-3838 for assistance.

### Updated NIH Award Terms for Grants funded by the American Recovery and Reinvestment Act of 2009 (“Recovery Act” or “ARRA”)

On July 8, 2009, the National Institutes of Health announced amended HHS Standard Terms of Award for grants awarded via the American Reinvestment and Recovery Act (ARRA) ([http://grants.nih.gov/grants/policy/NIH\\_HHS\\_ARRA\\_Award\\_Terms.pdf](http://grants.nih.gov/grants/policy/NIH_HHS_ARRA_Award_Terms.pdf))

The new starting deadline for reporting quarterly progress is **October 10, 2009**, with additional deadlines each calendar quarter for the life of the ARRA-funded grant award (**Jan 10, April 10, July 10, and Oct 10**). The reporting data points are contained in the government’s guidance found here: <http://www.recovery.gov/sites/default/files/OMB+Final+Cover+Memo.pdf>.

MUSC’s Office for Research and Sponsored Programs (ORSP) will submit these reports on behalf of the Principal Investigators for each quarter of the project period. The reports will be cumulative.

ORSP will be providing more guidance and assistance to departments and Principal Investigators regarding the required ARRA quarterly reporting. In coordinating this reporting, ORSP’s intent is to minimize the impact on the recipient PIs and their home departments. More information and up-to-date announcements can be found at the MUSC ARRA home page: <http://research.musc.edu/stimulus/index.html>.

For questions, please contact your assigned Grant Administrator in ORSP, or call 792-3838 for assistance.

Source: NIH Notice NOT-OD-09-120: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-120.html>

### College of Nursing launches Community Engaged Scholars Program

The MUSC College of Nursing’s Center for Community Health Partnerships (CCHP) will implement a Community Engaged Scholars Program in August 2009. This program will provide training, pilot funds, and mentorship for teams consisting of an academic and community partner(s) who will pursue community-based participatory research (CBPR).

The goal of the Community Engaged Scholars Program is to increase the number and capacity of academic-community partnerships to conduct research with mutual ownership of the processes and products. The ultimate goal is to improve the health of our communities in South Carolina and beyond.

Six teams were selected to participate in the inaugural year of the program. These teams represent academic disciplines from across the MUSC campus and partners from various community sectors. MUSC’s first Community Engaged Scholars are:

1. **Dr. Susan Newman** – Assistant Professor, College of Nursing, and **Gwen Gillenwater** – Executive Director, disAbility Resource Center (*Unmet health needs of individuals with disabilities in the Tri-County area*)

2. **Dr. Carol Wagner** – Professor, Pediatrics/College of Medicine, **Joyce Winkler, MPH** – Director of Nursing, Eau Claire Community Health Center Cooperative, **Gloria Warner, MA** – Chief Operations Officer, Eau Claire Community Health Center Cooperative, and **Carolina Rodriguez-Cook** – Research Assistant, Eau Claire Community Health Center Cooperative (*Importance of Vitamin D as it relates to health status and disease*)
3. **Dr. Renata S. Leite** – Assistant Professor, College of Dental Medicine, and **Angela C. Brown** – President, Red Top Improvement Association (*Periodontal disease prevention in the Gullah community*)
4. **Dr. Holly Wise** – Associate Professor, Division of Physical Therapy, College of Health Professions, and **Cindy Dodds, MHS, PT** – Pediatric Physical Therapist, Pattison's Academy (*Improving the quality of life for children with severe disabilities in the Lowcountry*)
5. **Dr. Kristin Wallace** – Assistant Professor, Biostatistics, Bioinformatics & Epidemiology, **Dr. Katherine Sterba** – Assistant Professor, Biostatistics, Bioinformatics & Epidemiology, **Debbie Bryant, MSN** – Director, Outreach Services, Hollings Cancer Center, **Rev. Remus Harper** – Pastor, Mt. Carmel African Methodist Episcopal Church, and **Rev. Jeannette Jordan** – Pastor, The Church, Christian Disciples of Christ (*Cancer prevention and wellness in the faith-based, African-American community*)
6. **Dr. Janet Grossman** – Professor, College of Nursing, and **Charlotte Anderson** – Director, 211 Hotline, Trident United Way (*Youth & Community suicide prevention*)

Source: CoN CCHP, <http://www.musc.edu/nursing/cchp/cescholars.htm>.

### NIH loan repayment program applications are due December 1

Starting September 1, the National Institutes of Health (NIH) will accept new applications for five Loan Repayment Programs (LRPs). The LRPs offer as much as \$35,000 a year to repay qualified educational debt for health professionals who are pursuing careers in clinical, pediatric, contraception and infertility, or health disparities research. The programs also provide coverage for Federal and state tax liabilities.

**Please note:** LRP awards are not research grants, not included in CRISP (or RePORTER) and not awarded to the institution. Rather they are loan repayments made directly to the individual. They are also competitive.

Applicants must have a doctoral-level degree, devote 50% or more of their time to nonprofit- or government-funded research, and have educational debt equaling at least 20% of their institutional base salary. Applicants must be US citizens, permanent residents, or US nationals.

The five programs offering loan repayment are the Clinical Research LRP, Pediatric Research LRP, Contraception and Infertility Research LRP, Clinical Research for Individuals from Disadvantaged Backgrounds LRP, and Health Disparities Research LRP.

All applications for 2010 awards must be submitted electronically by December 1, 2009. For details and online application information, visit <http://www.lrp.nih.gov/>. The LRP Information Center staff is available to answer questions Monday through Friday, 9AM to 5PM, call 866-849-4047 or email [lrp@nih.gov](mailto:lrp@nih.gov).

MUSC investigators who have experience with the Loan Repayment Programs, either as successful awardees or as peer reviewers, have offered to provide advice to new applicants. For information in this regard, please contact Peggy Schachte at [schachte@musc.edu](mailto:schachte@musc.edu) or 792-0868.

Source: NOT-OD-09-107 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-107.html>, July 18, 2009; or NIH LRP website, <http://www.lrp.nih.gov/>

### **Francis Collins is nominated as NIH director**

President Obama has nominated Francis S. Collins, MD, PhD, to become the new director of the National Institutes of Health (NIH). The nomination requires Senate confirmation. Formerly, Dr. Collins served as the director of the National Human Genome Research Institute (NHGRI) at the NIH for 15 years. He is known for his landmark discoveries of disease genes such as cystic fibrosis, and his visionary leadership of the Human Genome Project, which helped to unravel the human genetic code. Among Collins' other notable accomplishments is his bestselling book, "The Language of God: A Scientist Presents Evidence for Belief". He recently founded the BioLogos Foundation, which according to the foundation Web site attempts "to address the escalating culture war between science and faith in the United States." For additional information, go to [www.whitehouse.gov/the\\_press\\_office/President-Obama-Announces-Intent-to-Nominate-Francis-Collins-as-NIH-Director](http://www.whitehouse.gov/the_press_office/President-Obama-Announces-Intent-to-Nominate-Francis-Collins-as-NIH-Director) and [www.aamc.org/newsroom/pressrel/2009/090708a.htm](http://www.aamc.org/newsroom/pressrel/2009/090708a.htm).

Source: AAMC STAT, July 13, 2009.

### **Recovery Act quick link on the NIH RePORT website**

NIH's Research Portfolio Online Reporting Tool (RePORT) (<http://report.nih.gov/index.aspx>) provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH-supported research. On the website, several quick links are provided, one including the Recovery Act quick link (<http://report.nih.gov/recovery/>), which features:

- NIH Grants Funded by the American Recovery and Reinvestment Act of 2009
- Recovery Act-Funded Supplement Providing Summer Research Experiences
- NIH Recovery Act Solicitations and Cumulative FY 2009 Grant Funding
- Download ALL NIH Recovery Act Project Information

For additional information regarding RePORT and its quick links, please visit the RePORT website at <http://report.nih.gov/index.aspx>.

Source: NIH RePORT website

### **NIH guidelines for reviewers are available online for all mechanisms**

Have you ever wished that you could know in advance what the reviewers of your NIH proposal will be looking for when they read your grant? As part of the *Enhancing Peer Review* project, the Office of Extramural Research has made publicly available a comprehensive set of guidelines for all major grant mechanisms.

The offerings include General Guidelines for Study Section Chairs and Reviewers as well as guidelines and critique templates for Research Project Grants (RPGs, e.g., R01s, R03s and R21s), Program Project Grants (PPGs), Small Business research grants, Fellowships (F awards), Career Development awards (K awards, including K99/R00s), Training Grants (T32s), and Shared Instrumentation Grants (S10s). All the guidelines and templates are posted online in PDF file format; some are also posted as Microsoft Word docs.

Any junior or senior investigator preparing an NIH grant submission or resubmission can benefit by reviewing the instructions to the reviewers and review criteria in order to make sure that the proposal covers all key points in a direct, obvious and clear presentation. Bookmark this valuable information at the following link:

[http://grants.nih.gov/grants/peer/reviewer\\_guidelines.htm#k\\_awards](http://grants.nih.gov/grants/peer/reviewer_guidelines.htm#k_awards)

### **NSF requests input for 2011 Emerging Frontiers in Research and Innovation (EFRI) topics**

The National Science Foundation (NSF) invites the research community to submit suggestions for topics for the FY 2011 Program Solicitation in Emerging Frontiers in Research and Innovation (EFRI). Suggestions should address an emerging transformational area of research and innovation. Topic ideas should provide forward-looking views and identify opportunities in emerging frontiers of research and innovation. Topics or areas of opportunity should be those that cannot be supported through other programs at NSF.

All the information submitted will remain confidential. There will be no feedback to or discussion with submitters. September 15, 2009 is the deadline for submitting topic ideas online at <http://www.nsf.gov/eng/efri/efri2011/>.

Source: *EFRI 2011 Topic Suggestions*, <http://www.nsf.gov/eng/efri/efri2011/>

## South Carolina Clinical & Translational Research Institute (SCTR)

### News and Announcements

- SCTR earns \$20 million Clinical & Translational Science Award from the National Institutes of Health. SCTR joins 39 previously funded academic medical research institutions within a national network working together to reduce the time it takes to translate laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train the next generation of researchers. The NIH will grant a total of 60 CTSA's through 2012 to round out this exclusive network  
"This award is the result of the collaborative efforts of clinicians, researchers, educators and staff across the state of South Carolina, all with the shared vision of improving the health of the state's citizens," said Kathleen Brady, MD, PhD, SCTR Director and CTSA Principal Investigator.
- Are you starting a new research study? **MUSC Approval Plan for Research (MAP-R)** is a new research tool that is designed to guide you through the MUSC research approval process. The MUSC Approval Plan will provide you with a comprehensive list of applications and links that you will need to complete for your research study. Please visit <https://sctrweb2.musc.edu/mapr/> to complete a MAP-R!
- The SCTR Pilot Projects Selection Committee announces the 2009 SCTR Pilot Project awards. The funded projects represent multiple Colleges and Schools at MUSC, USC and Clemson; and range from Cancer Drug Discovery to Novel Methods for Exercise for SLE Patients. Also, some of the projects will be co-funded by MUSC and USC in the true spirit of SCTR's multi-institutional collaboration. Please visit the SCTR website for a complete listing (<http://sctr.musc.edu/index.php/programs/pilot-projects>).
- **August Research Lunch-n-Learn** will be held on Wednesday, August 19<sup>th</sup> from 12-1 PM in the Colbert Library, Room 109. This month there will be a presentation by Susan Rittmann from MUSC Office's of Compliance. The topic to be discussed is "Budget Negotiations with Sponsors." Please feel free to bring your lunch!
- **MUSC HERO Campaign** launches this September with the goal of increasing recruitment and participant diversity for all MUSC research studies. Make sure your study is registered on [www.MUSCHERO.com](http://www.MUSCHERO.com)!
- For a monthly listing of **research events**, please visit TEACH'S Calendar of events. <http://muschealth.com/activecalendar/CalendarNOW.aspx?fromdate=7/1/2009&todate=7/31/2009&display=Month>
- **REDCap (Research Electronic Data Capture) Database** is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: an intuitive interface for data entry, audit trails for tracking data manipulation and export procedures, procedures for importing data from external sources, advanced features such as branching logic and calculated fields, and automated export procedures for seamless data downloads to common statistical packages such as SPSS, SAS, Stata, R. <http://sctr.musc.edu/index.php/redcap>

### MUSC awarded \$20M clinical and translational award from the NIH

On July 14, the National Center for Research Resources (NCRR), part of the National Institutes of Health (NIH), expanded the national consortium for transforming clinical and translational research. The Clinical and Translational Science Awards (CTSAs) were awarded to seven more academic health centers, bringing the consortium to 46 member institutions. This national network of medical research institutions is working to accelerate the process that develops laboratory discoveries into treatments for patients, to engage communities in clinical research and to train a new generation of clinical and translational research.

The seven institutions receiving new CTSA funding include:

- **Medical University of South Carolina (Charleston)**
- Mount Sinai School of Medicine (New York City)
- New York University School of Medicine (New York City)
- University of Arkansas for Medical Sciences (Little Rock)
- University of Florida (Gainesville)
- University of Illinois at Chicago
- University of Texas Medical Branch (Galveston)

MUSC and the South Carolina Clinical and Translational Research (SCTR) Institute will receive \$20 million in research funding during the next five years. This will fund 11 programs on campus and through the partnerships with the University of South Carolina, Health Sciences South Carolina, Clemson University, South Carolina State University, Claflin University, Greenwood Genetics Center, South Carolina Research Authority, and VA medical centers. The award provides these programs with more infrastructure support, better research training, and greater access to top clinical trials. For additional information regarding the distributions of the CTSA award, please go to <http://www.nih.gov/news/health/jul2009/ncrr-14.htm>.

Source: AAMC STAT, July 20, 2009.

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SEARCH FOR  
INKLINGS ON THE  
WEB!

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## RESEARCH OPPORTUNITIES & DEADLINES

### ALTERNATIVE & COMPLEMENTARY MEDICINE

**Other index terms:** Cancer, Clinical Research, Nursing, Nutrition & Dietary  
**Title:** Developmental Projects in Complementary Approaches to Cancer Care and Treatment (R21) (R03)  
**Agency:** National Cancer Institute (NCI)  
 National Institute of Nursing Research (NINR)  
**Application Deadline:** Standard dates apply, please see  
<http://grants1.nih.gov/grants/funding/submissionschedule.htm>  
**PA Identifications:** PA-09-167, PA-09-168  
**CFDA Numbers:** 93.395, 93.361  
**Links:** <http://grants.nih.gov/grants/guide/pa-files/PA-09-167.html> (R21)  
<http://grants.nih.gov/grants/guide/pa-files/PA-09-168.html> (R03)

This Funding Opportunity Announcement (FOA), issued by the National Cancer Institute (NCI), and the National Institute of Nursing Research (NINR), of the National Institutes of Health, invites applications for basic, pre-clinical, and clinical complementary cancer research. The research should relate to the areas of prevention, diagnosis, and treatment of cancer as well as management of cancer symptoms and side effects due to conventional cancer treatment. In addition, this FOA encourages the development and application of emerging and innovative technologies, including identification of novel therapeutics in the pharmacopoeia of Traditional Medical Systems (as defined by the World Health Organization), use of complementary approaches to improve the therapeutic ratio of standard and investigational anti-cancer therapies, and research on lifestyle modifications (e.g. diet, exercise, mind-body approaches) for their impact on cancer outcomes (e.g., response to conventional cancer therapy, survival). The overarching goals of these FOAs are to encourage investigators to submit high quality, preliminary research of humans that will advance the science of Complementary and Alternative Medicine (CAM) and provide a solid foundation and justification for future research project (R01) grant applications to definitively determine the efficacy of CAM approaches.

#### Specific Research Objectives for the R21

The intent of this initiative is to encourage and support the development of basic and clinical (prevention, therapeutic, and palliative) cancer research in complementary approaches. Another goal of this initiative is to facilitate communication and collaboration between practitioners in complementary approaches and the conventional cancer research communities.

For the purpose of this FOA, applicants may consider complementary approaches as they relate to the prevention, diagnosis, and treatment of cancer, cancer-related symptoms, and side effects of conventional treatment. In addition, applicants may consider research that focuses on the potential interactions of complementary approaches with conventional cancer therapies. Complementary approaches that are considered appropriate to this announcement include (but are not limited to) those involving nutritional approaches, natural products, mind-body approaches, energy therapies, herbal medicines, and interventions based upon those within traditional medical systems (as defined by the World Health Organization), such as traditional Chinese medicine or ayurvedic medicine. Topics of programmatic interest include, but are not limited to:

- Approaches related to management of cancer-related symptoms and side effects of conventional treatment;
- Exploratory studies of complementary approaches in combination with conventional regimens, and outcome, effectiveness, and quality of life assessments.
- Design and pilot testing of interventions for comparative studies of complementary modalities as interventions for end of life and palliative care (e.g., relaxation therapy, music therapy);

- Development of methodologies to improve assessment of the impact of complementary approaches to treatment; e.g., instrument development, biobehavioral markers, acceptance of longitudinal designs or prevention;
- Feasibility studies of behavioral interventions that incorporate principles of cultural competency, in particular within populations that utilize culture-specific traditional methods of treating cancer;
- Applications relevant to understudied populations (i.e. the use of complementary approaches in children or older adults). Descriptive studies of the prevalence of complementary and alternative medicine (CAM) use in understudied populations including the impact of such use on the primary modality of treatment are also appropriate;
- Nutritional approaches in the prevention and treatment of cancer as well as to prevent disease recurrence;
- Preclinical studies of candidate-complementary approaches with appropriate models to demonstrate efficacy and toxicity, and improvement over current clinically approved cancer treatment and disease management;
- Preclinical studies to advance understanding of mechanism of actions as well as drug-drug interactions;
- Isolation and pharmacological studies of active ingredients from herbal or other traditional medicine preparations, including a defined reconstitution of more than one pure ingredient, such as drug-drug interaction; and
- Applications that seek to clarify markers of exposure to bioactive food components and their biological response in specific targets are also appropriate.

CAM research is integrated through various program areas of the Extramural Divisions and Intramural research programs ([http://www.cancer.gov/cam/research\\_portfolio.html](http://www.cancer.gov/cam/research_portfolio.html)), such as:

- pre-clinical studies of candidate CAM with appropriate models to demonstrate efficacy and toxicity, and improvement over current clinically approved cancer treatment and disease management;
- preclinical studies of mechanism of actions and drug-drug interactions;
- clinical studies of CAM to improve the therapeutic index of conventional systemic or surgical therapies for cancer by either improving efficacy or decreasing toxicity of conventional therapy;
- research on symptom management during active treatment and/or at the end of life; and
- survivorship research.

The National Institute of Nursing Research (NINR) also encourages applications that are consistent with its strategic plan and research themes for the future. In keeping with its research themes, projects that may lead to improved strategies for managing the effects of illness to improve quality of life, reducing health disparities, and enhancing the end-of-life experience for patients and their families are particularly welcome. For further information on NINR's strategic plan, the applicant may refer to <http://www.ninr.nih.gov/research/diversity/mission.html>.

### **Specific Research Objectives for the R03**

This FOA aims to support pilot projects, and allow CAM researchers to ascertain preliminary data that could provide the basis for more extended research that can otherwise not be achieved in the area of CAM research. While definitive and costly studies are best supported by other mechanisms, a small grant (R03) can provide resources for essential tasks such as preliminary assessments of alternative or new medical systems or techniques, encourage innovative applications of new CAM approaches, and ascertain pilot data that can be essential for larger R01 projects.

CAM research is integrated through various program areas, of the Extramural Divisions and Intramural research programs ([http://www.cancer.gov/cam/research\\_portfolio.html](http://www.cancer.gov/cam/research_portfolio.html)), such as:

- pre-clinical studies of candidate CAM with appropriate models to demonstrate efficacy and toxicity, and improvement over current clinically approved cancer treatment and disease management;
- preclinical studies of mechanism of actions and drug-drug interactions;
- clinical studies of CAM to improve the therapeutic index of conventional systemic or surgical therapies for cancer by either improving efficacy or decreasing toxicity of conventional therapy;
- research on symptom management during active treatment and/or at the end of life; and
- survivorship research;

R03 small grants encourage investigators to initiate research in areas not typically explored by R01 investigators. Moreover, it can foster coordination of small research project collaborations, and promote collaborative research between national and international studies for comparative or validation trials. This is particularly relevant to initiate research on CAM practices that are identified via the **NCI Best Case Series Program** ([http://www.cancer.gov/cam/bestcase\\_intro.html](http://www.cancer.gov/cam/bestcase_intro.html)) as warranting NCI-initiated research (for further details, go to: [http://www.cancer.gov/cam/research\\_information.html](http://www.cancer.gov/cam/research_information.html)). Examples of such therapeutic regimens include the treatment approach of the P. Banerji Homeopathic Research Foundation (<http://www.pbhrfindia.org/>), insulin potentiation therapy, and macrobiotic lifestyle as per the Kushi Institute (<http://www.kushiinstitute.org/>). Research of these approaches is high-risk and previous efforts to stimulate investigations via single contract mechanisms have not been fruitful. The small grant R03 mechanism can provide support for preliminary explorations of these approaches.

**Broad areas of Complementary and Alternative Medicine (CAM)-related research activities appropriate for this FOA include, but are not limited to, the following;**

- Alternative Medical Systems
- Botanical Extracts
- Medicinal herbs and herbal mixtures
- Energy Therapies
- Exercise Therapies
- Manipulative and Body-Based Methods
- Mind-body Interventions
- Nutritional Therapeutics
- Pharmacological and Biologic Treatments

For further details, go to: [http://www.cancer.gov/cam/research\\_information.html](http://www.cancer.gov/cam/research_information.html)).

The common characteristic of the small grant (R03) is provision of limited funding for a short period of time. Examples of the types of projects that ICs support with the R03 include, but are not limited to, the following:

- Pilot or feasibility studies
- Secondary analysis of existing data
- Small, self-contained research projects
- Development of research methodology
- Development of new research technology
- Nature of the research opportunity
- Pertinent background information that establishes the need for the research

## BIostatistics & EPIDEMIOLOGY

**Other index terms:** Bioinformatics, Genetics  
**Title:** Novel Statistical Methods for Human Gene Expression Quantitative Trait Loci (eQTL) Analysis (R01)  
**Agency:** National Institute of Mental Health (NIMH)  
**LOI Deadline:** August 16, 2009  
**Application Deadline:** September 16, 2009  
**RFA Identification:** RFA-RM-09-006  
**CFDA Number:** 93.310  
**Link:** <http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-09-006.html>

This FOA solicits applications to develop innovative statistical methods to detect the influence of genetic variation on tissue-specific gene expression and regulation. The goal of the FOA is to seek proposals to develop statistical methods to appropriately analyze the forthcoming complex data sets generated by the NIH Roadmap initiative entitled "Genotype-Tissue Expression (GTEx) Project". Applicants are encouraged to take advantage of existing tissue-specific gene expression datasets and/or simulated datasets, but will also be strongly encouraged to utilize GTEx-generated data, if and when it is available.

- **Mechanism of Support.** This FOA will utilize the R01 grant mechanism.
- **Funds Available and Anticipated Number of Awards.** The total amount of funds available for these awards is \$1 million total costs per year for two years; we anticipate making two to three awards.
- **Budget and Project Period.** The total project period may not exceed two years. Direct costs are expected to be \$200,000 to \$300,000 per year per award.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application.
- **Number of Applications.** Applicants may submit more than one application, provided each application is scientifically distinct.

This RFA seeks proposals to develop innovative and advanced statistical methods to appropriately analyze the forthcoming complex data sets to assess the influence of genetic variation on tissue-specific gene expression and regulation. Applicants are encouraged to take advantage of the availability of the SNP and tissue specific gene expression data (both chip- and next-generation sequencing based RNA expression data) from multiple tissues generated by the GTEx pilot project. However, since the data generated from the GTEx pilot may not be available until very late in the funding period, if at all, analyses based on existing human genotype-gene expression datasets, and simulation-based studies, are also appropriate. In terms of the data resources, applicants are encouraged to use the data generated by GTEx if/when it is available; they may also use existing data through collaborative efforts, the GTEx portal of NCBI (<http://www.ncbi.nlm.nih.gov/gtex/>), or simulated data sets. All proposed analyses must have relevance to human eQTL mapping, and those that focus entirely or predominantly on human data, or those that involve direct comparison of human data to other mammalian systems, have the highest programmatic priority.

Examples of research areas that applicants may work on include the following (note this is not an all-inclusive list, and applicants are encouraged to address more than one area):

- Extend existing methods, such as regression approaches, or develop new methods, such as structural equations, Bayesian models, or causal inference models, as a framework to integrate analysis of genotype and gene expression for eQTL identification, for simultaneous analysis of multiple genetic variants, for joint analysis of gene expression levels in multiple tissues, and for analysis of regulatory networks.
- Extend existing models or develop new ones to make predictions about the functional relevance of genetic variants to gene regulation, in terms of expression levels, gene splicing, and/or regulatory networks.
- Modify existing data reduction tools to make analytical procedures more efficient.
- Develop methods to use multiple datasets or multiple tissue types to reduce the number of false negative results.
- Develop creative methods to quantify RNA expression levels from next-generation sequencing generated data, compare it to chip-based estimates, and evaluate its impact on the ability to identify eQTLs.
- Model and explore the overlap in eQTLs between different tissues.
- Model and explore the incremental identification of new eQTLs as the number of tissues is increased.
- Compare the ability to identify eQTLs in samples obtained under different conditions (for example, the same organ from autopsy and surgery cases).
- Model and explore the influence that having expression data from multiple tissues from each donor has on statistical power to detect *trans*-eQTLs.
- Develop new methods to take diverse population structure into account in data analysis.

**CANCER**

**Other index term:** Clinical & Translational Research  
**Title:** Developmental Research in Cancer Prognosis and Prediction (R21), (R33)  
**Agency:** National Cancer Institute (NCI)  
**Application Deadline:** Standard dates apply, please see  
<http://grants1.nih.gov/grants/funding/submissionschedule.htm>  
**PA Identifications:** PA-09-158; PA-09-159  
**CFDA Numbers:** 93.394, 93.395  
**Links:** <http://grants.nih.gov/grants/guide/pa-files/PA-09-158.html> (R21)  
<http://grants.nih.gov/grants/guide/pa-files/PA-09-159.html> (R33)

This Funding Opportunity Announcement (FOA), issued by the National Cancer Institute (NCI), National Institutes of Health (NIH), encourages research applications from institutions and organizations to evaluate the utility and pilot the application of new strategies for determining prognosis or predicting response to therapy for cancer. The purpose of this FOA is to develop newly discovered biomarkers from initial correlative observations into assays or test systems suitable for use in clinical trials or other types of confirmatory clinical research studies. This program will provide tools whose purpose is to improve clinical decision-making in the care of cancer patients.

- **Mechanism of Support.** This FOA will use the NIH Exploratory/Developmental (R21) grant mechanism and runs in parallel with a FOA of identical scientific scope, [PA-09-159](#), that encourages applications under the Exploratory/Developmental Phase II Grant (R33) mechanism.
- **Funds Available and Anticipated Number of Awards.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the mechanism, numbers, quality, duration, and costs of the applications received.
- **Budget and Project Period.** The total project period for an application submitted in response to this funding opportunity may not exceed two years. Direct costs are limited to \$275,000 over an R21 two-year period, with no more than \$200,000 in direct costs allowed in any single year.
- **Application Research Plan Component Length:** The R21 application Research Plan component of the PHS398 (Items 2-5) may not exceed 15 pages, including tables, graphs, figures, diagrams, and charts.
- **Specific Research Objectives:** The objective of this FOA is to continue the development of novel prognostic and predictive biomarkers beyond the point of initial discovery into new laboratory assays and test systems that will be suitable for application in clinical trials or in larger clinical research studies such as those supported by R33 awards, in which the clinical utility of the biomarker can be evaluated.

**CHILD & ADOLESCENT HEALTH**

**Other index term:** Cardiovascular  
**Title:** Barth Syndrome Foundation Announces 2009 Request for Research Proposals  
**Agency:** Barth Syndrome Foundation  
**Application Deadline:** October 31, 2009  
**Link:** <http://www.barthsyndrome.org/english/View.asp?x=1635>

The **Barth Syndrome Foundation**, a nonprofit organization that strives to save lives through education, advances in treatment, and pursuit of a cure for Barth syndrome, has announced the availability of funding for research internationally on the natural history, biochemical basis, and treatment of Barth syndrome.

Barth syndrome is a serious X-linked genetic condition associated with cardiomyopathy, neutropenia, skeletal muscle weakness, exercise intolerance, growth delay, and diverse biochemical abnormalities (including defects in mitochondrial metabolism and phospholipid biosynthesis). Because many clinical and biochemical abnormalities of Barth syndrome remain poorly understood, the foundation is seeking proposals for research

that may shed light on any aspect of the syndrome.

The foundation is most interested in providing "seed money" to be used by experienced investigators for the testing of initial hypotheses and collection of preliminary data leading to successful long-term funding by the National Institutes of Health and other major granting institutions around the world. In addition, the foundation is especially interested in attracting new investigators to the very interesting field of Barth syndrome research.

The foundation anticipates awarding several one- or two-year grants of up to \$40,000 each. Complete program guidelines are available at the Barth Syndrome Foundation Web site (<http://www.barthysyndrome.org/english/View.asp?x=1635>).

## CLINICAL RESEARCH

**Other index term:** Hearing & Communication Disorders  
**Title:** NIDCD Definitive Phase III Clinical Trial Planning Grant (R34)  
**Agency:** National Institute on Deafness and Other Communication Disorders (NIDCD)  
**Application Deadline:** Standard dates apply, please see <http://grants1.nih.gov/grants/funding/submissionschedule.htm>  
**PAR Identification:** PAR-09-142  
**CFDA Number:** 93.173  
**Link:** <http://grants.nih.gov/grants/guide/pa-files/PAR-09-142.html>

- **Purpose.** The goal of this FOA is to provide support to complete the development of a comprehensive research protocol for large-scale, multicenter Phase III Definitive Clinical Trials (DCT). The planning grant is designed to permit early peer review of the proposed clinical trial in terms of its rationale, general design, organizational structure and implementation plan. The planning grant is used to support the development of a detailed Manual of Procedures (MOP), which is required for submission when applying for a Phase III Definitive Clinical Trial ([PAR-08-205](#)). The planning grant will provide support to establish the research team, develop tools for data management and oversight of the research, define recruitment strategies, and develop and finalize the MOP. The Planning Grant is NOT intended to support small Phase I/II Preliminary Clinical Trials. Applications for Phase I/II Preliminary Clinical Trials should use the NIDCD Phase I/II Preliminary Clinical Trials in Communication Disorders ([PAR-08-204](#)).
- **Mechanism of Support.** This FOA will utilize the R34 funding mechanism.
- **Funds Available and Anticipated Number of Awards.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary.
- **Budget and Project Period.** The total project period for an application submitted in response to this FOA may not exceed two years. Direct costs are limited to \$275,000 over a two-year period, with no more than \$200,000 in direct costs allowed in any single year.
- **Application Research Plan Component Length:** The R34 application Research Plan component of the PHS398 (Items 2-5) may not exceed 25 pages, including tables, graphs, figures, diagrams, and charts. See [http://grants1.nih.gov/grants/funding/funding\\_program.htm](http://grants1.nih.gov/grants/funding/funding_program.htm)

## HEALTH DIFFERENCES & DISPARITIES

**Other index term:** Cancer  
**Titles:** Exploratory/Developmental Grants Program for Basic Cancer Research in Cancer Health Disparities (R21)  
Basic Cancer Research in Cancer Health Disparities (U01)  
**Agency:** National Cancer Institute (NCI)  
**LOI Deadline:** Not Applicable  
**Application Deadlines:** June 23, 2009; November 23, 2009; June 23, 2010; November 23, 2010; June 23, 2011; November 23, 2011  
**CFDA Numbers:** 93.393, 93.396, 93.399  
**PAR Identifications:** PAR-09-160; PAR-09-161  
**Links:** <http://grants.nih.gov/grants/guide/pa-files/PAR-09-160.html> (R21)  
<http://grants.nih.gov/grants/guide/pa-files/PAR-09-161.html> (U01)

Through this Funding Opportunity Announcement (FOA), the Center to Reduce Cancer Health Disparities (CRCHD) and the Division of Cancer Biology (DCB), at the National Cancer Institute (NCI), invite grant applications from investigators interested in conducting basic research studies into the causes and mechanisms of cancer health disparities. These awards will support pilot and feasibility studies, development and testing of new methodologies, secondary data analyses, and innovative mechanistic studies that investigate biological/genetic bases of cancer health disparities. This FOA is also designed to aid and facilitate the growth of a nationwide cohort of scientists with a high level of basic research expertise in cancer health disparities research and to provide resources for those investigators that may need additional support on their path to successfully compete for R01/R01\* funding in basic research in understanding cancer health disparities.

- **Mechanism of Support.** This FOA will use the NIH Exploratory/Developmental (R21) grant mechanism and runs in parallel with an FOA of identical scientific scope, PAR-09-161, which encourages applications under the Cooperative Agreement (U01) mechanism.
- **Funds Available and Anticipated Number of Awards.** Awards issued under this FOA are contingent upon the availability of funds. Budgets of up \$275,000/two years (not to exceed to \$200,000/year) direct costs are allowed.
- **Budget and Project Period.** The total project period for an application submitted in response to this funding opportunity may not exceed two years. Direct costs are limited to \$275,000 over an R21 two-year period, with no more than \$200,000 in direct costs allowed in any single year.

### Background

Cancer health disparities represent a major public health concern in the United States. Regardless of socioeconomic factors, minority populations have higher overall incidence rates and worse outcomes than the overall population. Understanding the causes of genomic/genetic/epigenetic variability between ethnic groups that impact cancer susceptibility and/or response to therapy, is vital to reducing the observed cancer outcome gaps in this country. Several recent studies (2006-2007) suggest there may be a biological basis for the observed unequal burdens of cancer across the racial/ethnic populations. The NCI specifically encourages evidence-based mechanistic investigations of factors that are designed to increase our understanding of the basic biology of cancer health disparities.

### Specific Research Objectives

Research applications should focus on basic cancer research and cancer health disparities, consistent with the research interests of both the Division of Cancer Biology (DCB, <http://dcb.nci.nih.gov/>), and the Center to Reduce Cancer Health Disparities (CRCHD, <http://crchd.cancer.gov/>). The DCB supports research in the broad areas of cancer cell biology, cancer etiology, cancer immunology and hematology, DNA and chromosome aberrations, structural biology, and the tumor microenvironment. The CRCHD supports cancer health disparity research focused on basic, hypothesis-driven studies that explicitly address the unequal burden of cancer amongst racial/ethnic minorities or other underserved populations across the cancer continuum (prevention, early detection, diagnosis, treatment and survivorship).

For this FOA, the NCI is particularly interested in the interplay of race/ethnicity with cancer biology, such as the use of biospecimens from different racial/ethnic groups or the use of ancestral markers in determining more genetically defined measures of race and ethnicity. These awards will provide support for pilot or feasibility studies, for development and testing of new methodologies, development and testing of new research technology, secondary analysis of existing data, self-contained research projects, and innovative studies that provide a basis for more extended research (see also <http://dccps.nci.nih.gov/smallgrants/>).

Research topics of interest include but are not limited to:

- Examination of ethnic differences in HPV strain types/infection prevalence;
- Studies of polymorphisms in liver detoxification enzymes;
- Examination of differences in gene expression profiles in triple negative breast tumors in African-American women;
- Studies on the role of TP53 haplotypes in lung cancer among African-Americans;
- Genetic/epigenetic susceptibility differences between ethnic populations; and
- New animal and cell culture models/systems designed to investigate cancer disparities

## HEALTH INFORMATICS

**Other index terms:** Clinical & Translational Research, Community Care & Outreach, Health Services Research  
**Title:** NLM Applied Informatics Grants (G08)  
**Agency:** National Library of Medicine (NLM)  
**LOI Deadline:** June 1, 2009  
**Application Deadline:** July 1, 2009  
**CFDA Number:** 93.879  
**RFA Identification:** RFA-LM-09-001  
**Link:** <http://grants.nih.gov/grants/guide/rfa-files/RFA-LM-09-001.html>

- **Purpose.** The National Library of Medicine (NLM) offers Applied Informatics grants to health-related and scientific organizations that wish to optimize the utility and use of clinical and research information. These grants are for organizations that wish to exploit the capabilities of information technology to bring usable, useful biomedical knowledge to end users by translating the findings of informatics and information science research into practice through novel or enhanced systems and services.
- **Mechanism of Support.** This FOA will utilize the G08 grant mechanism.
- **Funds Available and Anticipated Number of Awards.** NLM anticipates making 3 – 5 awards, spending approximately \$800,000 to support this program. Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.
- **Budget and Project Period.** Individual awards may not exceed \$150,000 for one year, \$300,000 over two years or \$450,000 over three years, in direct costs. The total amount requested need not be the same in each year of a multi-year project. The project period can be one to three years. This program does not cover costs for facilities and administration, also called overhead or indirect costs.

These grants can be used to support a variety of health-related information activities relating to clinical or scientific information, including but not limited to:

Designing, deploying and evaluating a unique digital information resource that has the potential to meet national needs. This might involve such activities as

- Integrating digital information that comes from different sources to create tailored views
- Introducing tools and techniques into existing online resources that help users visualize and understand the information they find
- Improving the usability of interfaces

Fundamental features of a project proposal for this program include discussion of the following points:

- The information problem and its context, supported by published evidence
- Rationale for the system, resource or service
- Evidence of a user-centered approach to development and deployment
- A timeline and milestones for the proposed work
- Outcome-oriented evaluation of the proposed system or service
- Plan for disseminating the results of the project
- Plan for supporting the system after grant funding ends

These grants are not merely grants for technology or online access to publications. They should bring to end-users the high-quality scientific or health-related information they seek. Applicants should describe their approach to providing systems and services, address mechanisms for promoting use of the proposed system, provide details of training and evaluation plans, and discuss their plans for managing and supporting the work after grant funding ends. Applicants who propose to create a web-based resource should discuss how they will address content features such as selection, source credibility, currency, accuracy and completeness.

NLM Applied Informatics grant projects must result in an operational service activity. This may involve installation of a whole system, the testing of a prototype followed by a fuller implementation, establishing connectivity of existing system components, or enhancing features of an existing system or resource. A small planning activity may be included within the proposed project. Development projects must demonstrate the involvement of intended users, and present a plan for training them and gathering feedback from them.

Evaluation is a key feature of any application in this grant program. Where possible, applicants are encouraged to design evaluations that measure real outcomes for users. Applicants proposing outreach initiatives are encouraged to make use of resources such as Measuring the Difference: a Guide to Planning and Evaluating Health Information Outreach <http://nnlm.gov/evaluation/guide/>, or to find evaluation consultants to work with them. Applicants who propose to create a web-based resource or service should discuss how they will track use, growth, user characteristics and content features such as currency, accuracy, timeliness and completeness.

Dissemination of results to a larger community of interest is a fundamental feature of this grant program. Applicants should explain how they will share what they learned with others, and indicate what kinds of access to resources or services they will provide to interested parties outside the participating organizations.

The following types of projects are considered outside the scope of NLM's Applied Informatics grant program:

- Installation of Online library catalogs
- Electronic health record systems, single-purpose or closed clinical systems such as a stand-alone laboratory system or picture archiving system (PACS)
- Digitization of print materials
- Projects that duplicate NLM products and databases such as Go Local consumer health initiatives or biomedical literature indexing projects

## INFECTIOUS DISEASES

**Other index terms:** Bioengineering & Bio-imaging, Drug Discovery & Development  
**Title:** Partnerships for Development of Vaccines for Selected Pathogens (R01)  
**Agency:** National Institute on Allergy and Infectious Diseases (NIAID)  
**LOI Deadline:** June 26, 2009  
**Application Deadline:** July 27, 2009  
**RFA Identification:** RFA-AI-09-016  
**CFDA Number:** 93.856  
**Link:** <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-09-016.html>

This Funding Opportunity Announcement (FOA) issued by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) invites research applications for projects that will

advance development of vaccines against five pathogens that have a significant impact on public health: cytomegalovirus, respiratory syncytial virus, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Clostridium difficile*. The formation of collaborative partnerships between academic (or non-profit) researchers from different disciplines or with industry is strongly encouraged, but not required.

- **Mechanism of Support.** This FOA will utilize the R01 grant mechanism.
- **Funds Available and Anticipated Number of Awards.** The NIAID intends to commit \$4.0 million in total costs in FY2010 to fund three to five applications in response to this FOA. Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary.
- **Budget and Project Period.** An applicant may request a project period of up to five years and a budget for direct costs of no more than \$500,000 in any single year.
- **Application Research Plan Component Length:** The R01 application Research Plan component of the PHS398 (Items 2-5) may not exceed 25 pages, including tables, graphs, figures, diagrams, and charts. See [http://grants1.nih.gov/grants/funding/funding\\_program.htm](http://grants1.nih.gov/grants/funding/funding_program.htm)

### Partnerships

A key component of this FOA is the formation of collaborative partnerships, which may be between academic researchers from different disciplines or between academic and industry researchers. For the purpose of this FOA, "industry" is defined as large or small, domestic or foreign, pharmaceutical, biotechnology, bioengineering, and chemical companies. Since academic organizations are often the source of new candidate products, this FOA will support partnerships between industry and collaborator(s) from academic (or non-profit) research organizations. For this FOA, partnerships are strongly encouraged, but not required.

Applications submitted in response to this FOA will include a Product Development Plan (PDP) to assist reviewers and program staff in project evaluation. The PDP will define the general goals of the project, intended use/indication of the proposed therapeutic or diagnostic, and biodefense/public health gap the product is intended to fill. Additionally, the PDP will detail the stage-specific product development activities that will be performed during the project period and outline plans for further development after completion of the project.

The Principal Investigator of the project may be affiliated with industry, an academic organization or non-profit research organization.

### Research Goals and Objectives

To facilitate the development and testing of candidate vaccines, it is imperative that promising basic research findings/technologies be translated rapidly into new approaches and strategies for product development. The involvement of experts from diverse disciplines (e.g., biochemists, structural biologists, protein chemists, pharmacologists, immunologists, molecular biologists, engineers and clinicians) within academia and industry is needed to enable development of well-designed candidates for vaccines.

The objectives of this FOA are:

1. To support research that will advance the development and/or production of vaccines specific for the pathogens described above. Developmental research is not required to result in a "final" product but must advance the development of a candidate product; and
2. To stimulate scientifically sound, original, and innovative research requiring a comprehensive team and multidisciplinary effort that will facilitate advancement of a promising candidate product or platform technology through the product development pathway.

To most effectively achieve these objectives, **applications must include *in vivo* efficacy data in at least one animal model with accompanying general safety and immunogenicity data.** It is understood that the animal studies may involve a vaccine or endpoint that does not precisely replicate the planned human vaccine.

**NOTE:** While clinical development strategies may be included within an overall product development plan, **this FOA will NOT support Phase I, II, and III clinical trials or field trials.** Applications requesting support for clinical trials will be viewed as unresponsive to this FOA and will not be reviewed. However, utilization of appropriate human cell lines and human derived material in pre-clinical studies in support of complying with regulatory requirements is considered responsive and is encouraged.

For all vaccine projects, approaches should consider the ultimate potential of candidate vaccines to induce safe and protective responses in a diverse population. Projects may include, but are not limited to, one or more of the following areas:

- Improvement of existing candidates, including assessment of alternate formulations, stabilization, immunopotential, regimen optimization and evaluation of novel adjuvants.
- Evaluation of novel vaccine strategies, such as recombinant DNA; reverse genetics leading to live-attenuated strains and vectors; chimeras and mono- or multi-valent subunits.
- Advanced preclinical studies, including: safety and toxicology studies; further efficacy testing in animal models; assessment of host response; determination of clinically-relevant correlates of immunity and surrogate endpoints.

## INFECTIOUS DISEASES

**Other index term:** Global & International Health  
**Title:** International Collaborations in Infectious Disease Research (ICIDR) (U01)  
**Agency:** National Institute of Allergy and Infectious Diseases (NIAID)  
**LOI Deadline:** June 23, 2009  
**Application Deadline:** July 23, 2009  
**RFA Identification:** RFA-AI-09-010  
**CFDA Number:** 93.856  
**Link:** <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-09-010.html>

- **Purpose.** This Funding Opportunity Announcement (FOA) encourages applications from U.S. institutions proposing collaborative research with foreign [non-U.S.] investigators and organizations to study infectious diseases of the greatest public health significance in resource-constrained countries. This work is expected to increase scientific knowledge on public health related issues, enhance relevant research experience for U.S. and foreign investigators, promote the development of research capacity, and encourage future collaborative relationships.
- **Mechanism of Support.** This FOA will utilize the U01 cooperative agreement grant mechanism.
- **Funds Available and Anticipated Number of Awards.** The NIAID expects to award \$6.3 million in total costs in response to this FOA to support 5 to 9 new and/or competing renewal grants.
- **Budget and Project Period.** The total project period for an application submitted in response to this funding opportunity may not exceed five years. Direct costs are limited to \$500,000 in year 1. Future year recommended levels are limited to 3% escalation costs.

**All applications must be focused on a single pathogen or disease entity.**

Topics of interest for this program are limited to research on infectious diseases, including emerging infections that are of the greatest public health significance within the collaborating country. Except as noted below, research on any relevant infectious disease is appropriate. Applications proposing studies on the following diseases and pathogens are specifically encouraged:

- Zoonotic diseases, including Leptospirosis, Brucellosis, Melioidosis, Rickettsioses
- Leprosy and Buruli ulcer
- Viral pathogens, especially Enterovirus 71 and Monkey Pox
- Respiratory diseases, including Tuberculosis, Pneumococcal infections, Influenza, N. meningitides, and S. pneumoniae.
- Sexually transmitted infections: Bacterial Vaginosis, Haemophilus ducreyi and Trichomoniasis
- Parasitic diseases and vectors
- Hepatitis E in pregnant women

- NIAID Category A, B, and C priority pathogens (<http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/CatA.htm>, especially Enterotoxigenic E. coli, Shigella, Hantaviruses, Dengue, Rift Valley Fever, Japanese Encephalitis Virus and West Nile Virus

## RENAL & KIDNEY DISEASE

**Other index terms:** Aging, Biostatistics & Epidemiology, Clinical & Translational Research  
**Title:** Renal Function and Chronic Kidney Disease in Aging (R01), (R21)  
**Agency:** National Institute on Aging (NIA)  
 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)  
**Application Deadline:** Standard dates apply, please see <http://grants1.nih.gov/grants/funding/submissionschedule.htm>  
**PA Identifications:** PA-09-165; PA-09-166  
**CFDA Number:** 93.866  
**Links:** <http://grants.nih.gov/grants/guide/pa-files/PA-09-165.html> (R01)  
<http://grants.nih.gov/grants/guide/pa-files/PA-09-166.html> (R21)

This Funding Opportunity Announcement (FOA) issued by the National Institute on Aging (NIA) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, invites applications that propose basic, clinical, and translational research on chronic kidney disease (CKD) and its consequences in aging and in older persons. Applications should focus on the 1) biology and pathophysiology of CKD in animal models; 2) etiology and pathophysiology of CKD in the elderly; 3) epidemiology and risk factors for the development of CKD with advancing age; and/or 4) diagnosis, medical management and clinical outcomes of CKD in this population. Research supported by this initiative should enhance knowledge of CKD and its consequences in the elderly and provide evidence-based guidance in the diagnosis, prevention, and treatment of CKD in older persons.

### SCOPE OF RESEARCH:

This FOA invites research applications in both animal models and in humans, addressing the etiology, pathophysiology, risk factors, consequences, prevention, or treatment of CKD in older patients. Areas of interest include, but are not limited to, the following areas:

#### Etiology and Pathophysiology

- Contributions of age-related changes in renal vascular structure and function on the development of CKD (e.g., changes in renal blood flow, vascular resistance, and sensitivity to ischemia), and the mechanisms by which these changes occur.
- Mechanisms of kidney fibrosis underlying CKD progression.
- Contributions of cellular senescence and gene polymorphisms to CKD during aging and in older adults and their mechanisms of action.
- Relationship of CKD to age-related changes in renal morphology, pathology, structure (e.g., tubular atrophy, glomerulosclerosis, interstitial fibrosis) and function (e.g., changes in renal hemodynamics, GFR, urine concentrating and diluting ability, secretion of renin and erythropoietin, and activation of vitamin D).
- Roles of oxidative stress and endothelial dysfunction in the development of CKD during aging and in aged adults.
- Possible differences in pathology and pathophysiology of CKD in younger vs. older patients or animals.
- Complications and long-term consequences of CKD in the elderly (e.g., development of osteoporosis, CVD, and anemia; impact on vitamin D metabolism and phosphate balance; effects on coagulation mechanisms; and modulation of secretion of renin and erythropoietin).
- Role of CKD and its complications in functional impairment and disability among older patients.

**Epidemiology, Risk Factors, and Comorbid Interactions**

- Natural history of age-related decline in kidney function, and progression from early stage CKD to ESRD in the elderly.
- Clinical consequences and long-term outcomes of different stages of CKD in older adults, including effects of mild decreases in GFR on long-term health outcomes.
- Role of established CKD risk factors (e.g., hypertension, diabetes and acute kidney injury) and potential new risk factors (e.g., oxidative stress, age-related endothelial dysfunction) in development and progression of CKD in the elderly.
- Studies that distinguish risk factors for progression to different stages of CKD, and the extent to which risk factors are the same or differ across different stages of CKD. Studies on the relationships between acute kidney injury and CKD are encouraged.
- Relationships of comorbidities to development of CKD in the elderly and its progression to ESRD, and the interaction of coexisting diseases with CKD on morbidity and functional outcomes in older patients.
- Relationships of CKD and/or its treatment to cognitive impairment in the elderly.

**Early Detection and Diagnosis**

- Development and validation of new methods or biomarkers to accurately, reliably, and efficiently measure renal function and identify early stages of declining function in older persons or animal models.
- Studies to analyze and improve the performance of current GFR estimating equations in older patients.
- Development and validation of new tests of age-related acute and chronic renal damage, including measures of age-related decline in kidney functions other than glomerular filtration, e.g., kidney endocrine functions.
- Development and validation of screening algorithms for early detection of CKD in community-dwelling elderly, particularly older adults at increased risk for CKD, to optimize timing of screening, frequency of testing, sensitivity and specificity of screening tests, and cost–benefit ratios.

**Prevention and Treatment**

- Efficacy of treatments for CKD risk factors (e.g., cardiovascular disease and diabetes) to prevent or delay onset of CKD in older persons.
- Effects of various interventions applied at early stages of CKD in preventing or slowing further adverse effects in older patients (e.g., risk factor management, vitamin D, dietary regimen such as protein restriction, salt restriction and calorie restriction, and physical activity interventions).
- Testing new treatment approaches in elderly CKD patients who have conditions contributing to its progression (e.g., diabetes/hypertension), e.g., angiotensin-converting-enzyme (ACE) inhibitors, angiotensin receptor blockers and aldosterone blockade; optimal targets for blood pressure and glucose control.
- Testing of clinical strategies for the management of complications and long-term consequences of CKD in older patients (e.g., cardiovascular and peripheral vascular disease, Vitamin D deficiency, hyperphosphatemia, osteodystrophy and hematologic problems).
- Studies evaluating whether interventions to slow progression in CKD are efficacious in preventing or slowing further functional loss when applied at earlier levels of decrease in GFR.
- Development and testing of interventions to maintain functional status, cognitive function, and quality of life among older CKD patients.

**WOMEN'S HEALTH**

**Other index term:** Cancer  
**Title:** Susan G. Komen for the Cure® – 2009-2010 Research Grant Request for Applications  
**Agency:** Susan G. Komen for the Cure®  
**Pre-App Deadline:** June 1, 2009  
**Application Deadline:** July 31, 2009  
**Link:** <http://www.komengrantsaccess.org/> OR [www.komen.org/grants](http://www.komen.org/grants)

Komen's commitment to supporting life-saving research has never been stronger. Building on 27 years of funding research to find the causes and cures of breast cancer, Komen continues its important new focus on research that will speed the translation of discoveries into reductions in breast cancer mortality and/or incidence within the next decade and on addressing disparities in breast cancer across populations.

**Important Changes to Pre-Application Requirements**

The content and requirements for research and training pre-applications are changing! Pre-applications will now require more detailed and specific information about proposed research, such as specific aims and a clear description of the timeline from research results to impact on breast cancer incidence and/or mortality. Read the RFA requirements for pre-applications carefully and start preparing your pre-application early!!

**Research Funding Opportunities**

This year, Komen completes its transition to a two cycle RFA schedule in which recurring research RFAs will be announced each April and May and training RFAs will be announced each September. Announcements about additional special topic RFAs may be made at other times during the year.

**April and May 2009 – Announcement of Research RFAs:**

- Investigator-Initiated Research (IIR): IIR grants provide up to \$600,000 over three years to stimulate exploration of new ideas and novel approaches in breast cancer research and clinical practice that will lead to reductions in breast cancer incidence and mortality within the next decade.
- Career Catalyst Research (CCR) Grants: CCR grants provide unique opportunities for scientists in the early stages of their career to achieve research independence with an independent award of up to \$450,000 over three years.
- Career Catalyst in Disparities Research (CCDR): CCDR awards provide a unique opportunity for scientists in the early stages of their career to achieve research independence. This award provides up to \$450,000 over 3 years for research exploring the basis for differences in breast cancer outcomes and the translation of this research into clinical and public health practice interventions.