



## FY14 Mid-Year Hard Close Information

The process of closing the books for fiscal 2013 has begun. Key closing dates and important deadlines are outlined in the 2014 Mid-Year Hard Close Memo and the Year End Close checklist is available to assist you in the year-end close process. Please take special notice of the information contained in this document, and share it with your staff and others that you deem appropriate. If you have questions or need further information, please do not hesitate to contact either the Controller's Office at 368-2126.

Both the memo and the checklist can be found on the Controller's Office website at <http://www.cwru.edu/finadmin/controller/>.

## Spring Courses in the Master's in Clinical Research (CRSP)

The Clinical Research Scholars Program (CRSP) has many educational, informative, relevant, and wonderful spring courses that may be of interest to you, your staff, and/or other medical personnel.

The following are a list of the CRSP courses offered this spring:

- CRSP 407, Statistical Methods: Logistic Regression and Survival Analysis
- CRSP 412, Communication in Clinical Research – Grant Writing
- CRSP 500, Design and Analysis of Observational Studies
- CRSP 502, Leadership Skills for Clinical Research Teams
- CRSP 504, Managing Research Records – A System's Approach
- CRSP 505, Investigating Social Determinants of Health

For more information, please contact Angela Bowling ([axb710@case.edu](mailto:axb710@case.edu), 368-2601), the Educational Administrator for the program.

## Avoiding Problems with Suspension and Debarment

Federal regulations require Case Western Reserve University to conduct business only with vendors, subcontractors, subawardees and individuals who are in good standing with the federal government. Anyone who is not in good standing with federal agencies cannot work on or provide services for government grants or contracts. People and entities who are subject to these restrictions are generally described as having been "debarred," "suspended" or "excluded."

To avoid inadvertent problems, visit <http://www.sam.gov> and verify that study staff, collaborators and vendors are not debarred, suspended or otherwise ineligible to receive federal funds.

## Researcher Profiles

We are continuing to update our online researcher profiles. Please take the time to fill in the new form so it can be posted on the website. If you need a copy of the form, please send an email to [dentres@case.edu](mailto:dentres@case.edu).

- Bonus! If you complete the profile and include keywords, we can forward any related funding opportunities directly to you. Help us help you get funded!

## Educational Opportunities

CAPS Classes – Check out the latest CAPS classes!

<http://www.case.edu/its/training/capsregistration.html>

- Upcoming classes
  - Effective Interpersonal Communication – December 4, 1:00-3:30pm
  - Running and Interpreting Financial Reports and Reconciliation – December 9, 2:00-3:30pm
  - Sponsored Projects: Project Monitoring – December 11, 2:30-3:30pm
  - Purchasing from A to Z – Anytime online!
  - Financial Journals – Anytime online!
  - Financial Cashiering – Anytime online!

### Research Administration Seminar Series

Check out <https://research.case.edu/Education/Onlinecalendar.cfm> to see the latest offerings from CWRU and UH on various research topics. Upcoming sessions include:

- Sparta Training – Multiple sessions
- Informed Consent Series Part 8: Conflicts of Interest and Informed Consent – December 6
- How to Use ResearchMatch as a Recruitment Tool – December 12, January 9
- Clinical Research Forum – December 18
- iRIS Training: New Protocol Submissions – December 19, January 16
- How Do You Know When an IND is Required? Application Submission Steps – January 7
- Maintaining Your Investigational New Drug (IND) with the FDA: Keys for Success – January 21
- iRIS Training: Submitting Protocol Amendments – January 23
- iRIS Training: Submitting Continuing Reviews – January 30
- RESCHEDULED: Informed Consent Series Part 6: Involving Children in Research – February 7
- How Do You Know When an IDE is Required? Application Submission Steps – February 11
- Maintaining your Investigational Device Exemption (IDE) with the FDA: Keys for Success – February 25

### All About Grants Podcasts from the NIH

The Office of Extramural Research (OER) presents conversations with NIH staffers. Designed for investigators, fellows, students, research administrators, and others, the podcasts provide insights on a variety of topics. The podcasts are in mp3 and updated every other week on the NIH OER site: [http://grants.nih.gov/podcasts/All\\_About\\_Grants/index.htm](http://grants.nih.gov/podcasts/All_About_Grants/index.htm).

Also, subscribe to the new YouTube Channel for exciting videos about the NIH and grants -

<http://www.youtube.com/user/NIHgrants/>

**Fig 1**

*Listed by application deadline*

*December 3, 2013*

*Updates since last email are highlighted in yellow*

*While every effort is made to ensure the correctness of deadline dates shown, please consult the program website to confirm application due dates.*

Rolling Deadline (4<sup>th</sup> Thursday of Each Month) Sponsor: DentaQuest Foundation

<http://www.dentaquestfoundation.org/sites/default/files/uploads/Innovation%20Fund%20for%20Oral%20Health%20FY%202013.pdf>

Innovation Fund for Oral Health

- x The DentaQuest Foundation envisions specific, long-term changes, within the systems that we work to impact.

IADR Innovation in Implant Sciences Award

- x The Award is intended to help investigators pursue innovative and novel research in oral care that involves, but is not limited to, dental implant therapy

DH Sponsor – CWRU ACES+ Program

4, 201

<http://www.case.edu/admin/aces/opportunity.html>

ACES+ Advance Opportunity Grants

<http://grants.nih.gov/grants/guide/pa>

## Research on Malignancies in the Context of HIV/AIDS

- x The purpose of this funding opportunity announcement (FOA) is to continue advancing our understanding of the risks, development, progression, diagnosis, and treatment of malignancies observed in individuals with an underlying Human Immunodeficiency (HIV) infection or Acquired Immune Deficiency Syndrome (AIDS). The NCI and NIDCR encourage research in areas such as the study of the etiologic factors, cofactors, immunopathogenesis, diagnosis, and consequences of both AIDS and non-AIDS defining malignancies in diverse populations in the context of an underlying HIV infection. This FOA encourages research efforts that will: (i) provide information on the clinical outcomes of such cancers in the affected population; and (ii) identify specific contributions resulting from HIV infection and its potential interaction with other pathogens for the development and pathogenesis of these cancers. Ultimately, such efforts could inform screening approaches and therapies targeted to the affected population.

July, 2011



HIV/AIDS R01

– Sponsor – NIH

R03: <http://grants.nih.gov/grants/guide/files/PA-13-314.html>

R21: <http://grants.nih.gov/grants/guide/files/PA-13-315.html>

Small Grants on Primary Immunodeficiency Diseases

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Research Prevention Travel Awards

- x The IADR is inviting applications from young investigators who have submitted an abstract which has a

<http://grants.nih.gov/grants/guide/files/PA-13-379.html>

Establishing Outcome Measures for Clinical Studies of Oral and Craniofacial Diseases and Conditions (R01)

- x Study outcomes or endpoints used in a clinical trial or study must provide reliable and valid signals for the efficacy of the intervention being tested or to clearly document disease prevalence and/or progression. The lack of defined, valid outcome measures has limited clinical studies of some oral and craniofacial diseases and conditions. This funding opportunity announcement (FOA) aims to address this problem by supporting research that will establish well-founded clinical outcome measures to be used in oral and craniofacial research. The developed outcome assessment(s) may be used to characterize a disease, its progression or severity, or it may serve as a clinical endpoint to measure treatment efficacy in future studies. This FOA also encourages development of clinician-reported, patient-reported or observer-reported (i.e., parent or caregiver reported) outcome measures to capture clinical differences that are meaningful to individuals affected by a disease or condition.

FR 5, 201 (R01) HHS, 201 – Sponsor: NIH 4

<http://grants.nih.gov/grants/guide/files/PA-13-292.html>

Behavioral and Social Science Research on Understanding and Reducing Health Disparities

- x Given the extensive scientific literature documenting health inequities, this announcement calls for research to address and to improve understanding of the causes of health disparities. In so doing, the announcement stresses the explicit employment of concepts and models from the behavioral and social sciences to guide applications in basic social and behavioral, and applied social and behavioral research by focusing on three action areas: public policy, health care, and disease/disability prevention.

strategy, a number of steps are necessary, such as characterization of the intervention, determination of suitable outcome measures, and identification of the optimum population and randomization approach. Applicants must provide a clear and compelling rationale for pursuing study and development of the intervention, as well as for other critical aspects of the research design (e.g., dose or schedule, choice of



integrated system in simulated clinical settings or in the context of actual clinical settings. Applicants that focus upon significant interrelated patient safety issues while simultaneously addressing frequent and high cost care that oc

**FD** ~~R03 ORA 201~~ – Sponsor: ~~NIH~~ **R03**

<http://grants.nih.gov/grants/guide/files/PA-11-328.html>

NIDCR Small Research Grants for Oral Health Data Analysis and Statistical Methodology Development (R03)

- x The goal of this funding opportunity announcement is to support meritorious research projects that involve secondary data analyses of existing oral or craniofacial database resources, or to develop ~~new~~ **statistical** methodology for analyzing oral and craniofacial data using existing oral or craniofacial databases.

**FD** ~~R03 ORA 201~~ – Sponsor: ~~NIH~~ **R03**

<http://grants.nih.gov/grants/guide/files/PA-11-329.html>

**NEW! Clarifying notice:** <http://grants.nih.gov/grants/guide/noticefiles/NOT-DE-14-001.html>

NIDCR Clinical Trial or Biomarker Clinical Evaluation Study Planning Grant

- x The NIDCR will support clinical trial or biomarker clinical evaluation study planning grants (R34) for comprehensive planning, design and documentation of ~~investigated~~ **investigated** Phase I, II, III, or IV interventional clinical trials, or biomarker clinical evaluation studies that involve prospective collection of specimens and clinical outcomes. ~~Interventonal~~ **Interventional** behavioral studies, sometimes referred to as Stage I, II, III or IV studies, are included. The goal of the R34 grant program is to give investigators the time and funds necessary to complete detailed clinical trial or study planning and written supporting documentation prior to U01 funding and full implementation of a clinical trial or study. The R34 grant will provide up to one year of support. R34 awardees who complete their planning activities and have compelling justification to proceed to a clinical trial or biomarker clinical evaluation study can submit a cooperative agreement application (U01) for clinical trial implementation or biomarker clinical evaluation study (details are presented ~~in PA39~~ **in PA39**). If the investigators conclude that a clinical trial or biomarker clinical evaluation study is not warranted, the reasons for not proceeding with the U01 implementation application must be documented in the final progress report to the NIDCR that summarizes the R34 award activity.

**FD** ~~R03 ORA 201~~ – Sponsor: ~~NIH~~ **R03**

R03 - <http://grants.nih.gov/grants/guide/files/PA-11-328.html>

R21 - <http://grants.nih.gov/grants/guide/files/PA-11-329.html>

Healthy Habits: Timing for Developing Sustainable Healthy Behaviors in ~~Child~~ **Child** and Adolescents

- x Encourages applications targeting basic or applied research, depending on the state of the science. Where there is evidence of the value of an approach to developing healthy sustainable behavior, but there are key questions that are yet to be answered, then an intervention of limited scale would be appropriate. Before the large, rigorous and ~~well~~ **well** designed studies that are required to address these questions can be implemented, important ~~early~~ **early** phase research and development must be ~~complete~~ **complete** in order to elucidate the optimal research strategy, a number of steps are necessary, such as characterization of the intervention, determination of suitable outcome measures, and identification of the optimum population and randomization approach. Applicants must provide a clear and compelling rationale for pursuing study and development of the intervention, as well as for other critical aspects of the research design (e.g., dose or schedule, choice of endpoints of interest, etc). Applications that ~~leverage~~ **leverage** existing research infrastructures, for example through follow-ups or use of relevant existing data sets or ancillary studies to existing ~~studies~~ **studies**, are also encouraged.

**FD** ~~R03 ORA 201~~ – Sponsor: ~~NIH~~ **R03**

<http://grants.nih.gov/grants/guide/files/PA-11-315.html>

Systems Science and Health in the Behavioral and Social Sciences – R21

- x NIDCR supports research that ~~examines~~ **examines** community characteristics, the organization of health care systems, and the social contexts that contribute to oral health. Many of the opportunities for improving oral health lie in achieving behavioral, lifestyle and social ~~changes~~ **changes** objectives that are shared with many other scientific areas. Drawing from the expertise of diverse fields within the social and behavioral sciences presents an important opportunity to develop models and approaches that will produce meaningful improvements in oral health. This approach dovetails with the view of oral health as an essential component of general health as cited in the 2000 Surgeon General's report on oral health in America: <http://www.surgeongeneral.gov/library/oralhealth/> The NIDCR supports systems science projects that explain the determinants of and/or methodologies to improve oral, dental and craniofacial health. Please note the NIDCR will not accept any clinical intervention studies ~~submitted~~ **submitted** through this FOA.

**F11** \_\_\_\_\_ – SponsorNIH 6, 201

<http://grants.nih.gov/grants/guide/files/PA-11-217.html>

Mechanistic Studies of HIV-exposed Seronegative Individuals (HESNI)

- x R21 funding mechanism. The purpose of this initiative is to support mechanistic studies of individuals who are repeatedly exposed to HIV but remain seronegative (HESNI), or demonstrate resistance to infection. The emphasis will be on demonstrating causality, and not simply association.

**F11** \_\_\_\_\_ – SponsorNIH 6, 201

<http://grants.nih.gov/grants/guide/files/PA-11-159.html>

Biomarkers of Infection-Associated Cancers

- x R21 Funding Mechanism: Funding for research that proposes to identify biomarkers for cancers where the etiology of the disease is attributed to infectious agents.

**F11** \_\_\_\_\_ – SponsorNIH 6, 201

**March 20, 2011** – Sponsor: NIH

**4 (2011)**

<http://grants.nih.gov/grants/guide/paras/PAR-13-029.html>

Opportunities for Collaborative Research at the NIH Clinical Center (U01)

- x The goal of this funding opportunity announcement (FOA) is to support collaborative translational research projects aligned with NIH efforts to enhance the translation of basic biological discoveries into clinical applications that improve health. This opportunity is specifically to promote partnerships between NIH intramural investigators (e.g., those conducting research within the labs and clinics of the NIH) and extramural investigators (e.g., those conducting research in labs outside the NIH). This FOA provides support for extramural investigators to take advantage of the unique research opportunities available at the NIH Clinical Center by conducting research projects in collaboration with NIH intramural investigators.

**April 10, 2011** – Sponsor: NIH

**0, 2011**

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<http://grants.nih.gov/grants/guide/paras/RFA-RM-13-006.html>

NIH Pioneer Award Program

- x The NIH Pioneer Award initiative is part of the NIH Common Fund (formerly known as the NIH Roadmap), which supports crosscutting programs that are expected to have exceptionally high impact. All Common Fund initiatives invite investigators to develop bold, innovative, and often risky approaches to address problems that may seem intractable or to seize new opportunities that offer the potential for rapid progress.

**April 10, 2011** – Sponsor: NIH

**7, 2011**

**6, 2011**

<http://grants.nih.gov/grants/guide/paras/RFA-RM-13-007.html>

NIH Director's New Innovator Award Program

- x The NIH Director's New Innovator Award addresses two important goals: stimulating highly innovative research and supporting promising new investigators.