

URA Weekly Update for the Week Ending April 10, 2009

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URA General Information

URA Grants.gov Web Page – More help is on the way! We have redesigned the URA [Grants.gov](#) page which will be posted on April 14. {It is at NSIT now for formatting/posting.} We've cleaned up the format, made it easier to navigate the page, posted all the NIH ARRA checklists/summaries, added a quick and easy to use [URA Mail box](#) to link to the webshare, and a separate page that has the [Basic Essentials/Survival Guide](#) of all information one would need to put together a SF424 application. We hope this new page consolidated page will help out individuals who have never submitted a Grants.gov application before. Please check out <http://researchadmin.uchicago.edu/proposals/gg.shtml> on Tuesday.

URA Training Group email address –. We've created a new mailing list URA-Training@lists.uchicago.edu } for anyone to use who may have questions – easy to difficult – on research administration. If you are new and have not met with Cyndie or Aaron, please do so. We really want to help.

Reminders:

Use the new ETF for your NIH ESNAP submissions

We have created a new [ETF](#) (eSNAP Transmittal Form). Please begin to use this form immediately. There are additional fields that are required for data entry into TRACS. We've also added imbedded help and have written instructions. The new form and instructions are available on the [URA website](#).

NIH Commons Accounts

Anyone with the role of PI/PD on an NIH Grants.gov submission must have an NIH Commons Account. It but takes us a few minutes to create one...but we need to know who needs on. Please send an email to ERA-HELP@lists.uchicago.edu to request an account. We need their name and UC email address. If they already have an account from another institution, we can create an affiliation – all we need it their Commons user name and email address to create the affiliation.

NIH ARRA internal deadline

Internal deadlines for the **NIH Competitive Revision** Applications are:

- Administrative forms/draft science Due in URA, Friday, April 10 by 5:00pm
- Final ready to submit applications Due in URA, Thursday, April 16 by 5:00pm

Internal deadlines for the **NIH Challenge Grant** opportunity are:

- Administrative forms/draft science Due in URA, Friday, April 17 by 5:00pm
- Final ready to submit applications Due in URA, Thursday, April 23 by 5:00pm

Clinical Trial Vs Clinical Research

We've seen an uptick in the number of questions between clinical trial vs. clinical research. Please review the definition below. If you have any questions, please contact your URA Manager.

A **clinical trial** is operationally defined as a prospective study involving human subjects that is designed to answer specific questions about the effects or impact of particular biomedical or behavioral interventions. Such studies may include drugs, treatments, devices, or behavioral or nutritional strategies.

In the area of molecular or imaging diagnostics, a study is a clinical trial if it uses the information from the diagnostic test in a manner that somehow affects medical decision-making for the study subject. In this way the information from the diagnostic test may have an impact on some aspect of outcome, and assessment of this outcome may be a key goal of the

trial. By contrast, studies that do not use information from the diagnostic test in any manner that can affect the outcome of study subjects, but whose objective is only gathering data on the characteristics of a new diagnostic approach, are not clinical trials and are not covered by DSM policy, unless performing the diagnostic test itself imposes some risk on study subjects.

Behavioral clinical trials include studies of interventions with the goals to increase behaviors (e.g., cancer screening, physical activity, fruits and vegetable intake), eliminate or reduce behaviors (e.g., smoking, sun exposure) and /or improve coping and quality of life or reduce the negative sequelae of treatment. Observational studies and those that do not test interventions are not considered clinical trials.

If the proposed study does not fit any of the above, it is clinical research.

Agency Updates & News

Stimulus Website Updates – please make sure to check the Researchfunding.uchicago.edu site for updates. Many agencies are posting their deadlines. We are continually posting new information. Any forms, checklists, and administrative tools will be posted at the URA.Grants.gov site.

National Science Foundation

NSF awards provided by the ARRA will include specific conditions identifying the funding as coming from the Recovery Act and will reference specific awardee reporting requirements. Additionally, we will be required to separately account for ARRA funds. These funds cannot be commingled with non-Recovery Act Funds. NSF has posted an FAQ on ARRA funding: <http://www.nsf.gov/pubs/2009/nsf09038/nsf09038.jsp>

If you have additional questions, please contact your URA Manager or Lynda.

NIH Competitive Revisions Update

NIH published on April 10 a [notice](#) regarding competitive revisions for parent awards for which the activity code of the application has not transitioned to electronic submission. This includes Program Project grants (P01), Center grants (e.g., P20, P30, P50), Cooperative Agreements (e.g., U01), Training Grants (e.g., T32) and Institutional Career Development Awards (K12). Applications for all of these grants are still submitted in paper and revision applications must be prepared using the paper forms found in the PHS 398 instructions for preparing a research grant application (see <http://grants.nih.gov/grants/funding/phs398/phs398.html>).

Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

At the time of submission, two additional copies of the application and all copies of the appendix material should be sent to the Referral Officer of the NIH Institute or Center that is administering the parent award. Contact information for Institute/Center Referral Officers or Review Chiefs can be found on the Institute or Center web sites at

http://grants.nih.gov/recovery/ic_supp.html

Note: Paper applications will not be accepted for competitive revisions using activity codes that have transitioned to electronic submission.