



NIH Update – 5/2010

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**Office of Policy for Extramural Research
Administration**



ARRA Reminder Notices

- See reminders for spending and no-cost extensions for ARRA awards:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-067.html>

- Spending should be timely and expeditious and in accordance with expected pace of research
- Standard NIH Terms of Award apply in addition to ARRA specific terms.
- Grantee has authority to extend project period end dates up to 12 months. (This is separate from the non-ARRA parent for Type 3 awards.)
 - Additional (prior approval) extensions will only be considered in limited circumstances



ARRA Reminders

- Supplements
 - Scientific/Program progress should be addressed separately in the annual progress report (Type 5); if no T-5 address in final progress report
 - Special progress reporting for Summer Experience program
 - Separate closeout documents are required for each supplement and competitive revision
 - Special financial closeout requirements for grants with multiple ARRA-funded supplements



Federal Financial Report SF-425

- Effective 1/1/10 NIH grantees are to report cash transaction data via the Payment Management System (PMS) using the FFR cash transaction data elements
- Additional information and training available on the Division of Payment Management website: <http://www.dpm.psc.gov/>.
- Transition of FSR data to FFR is on hold
 - NIH pilot of new eFFR feature in the Commons scheduled to start end of 7/2010
 - Grantees should continue to use eFSR system until further notice.



NIH's Role on Registration & Reporting of Results in ClinicalTrials.gov

Responsible Parties are solely responsible for the content, quality and timeliness of registration and results reporting in accord with FDAAA.

Responsible Parties are required to affiliate their applicable clinical trials with their Institution's organization account or their own individual account, as appropriate. They will no longer be registered in an NIH IC organization account. NIH ICs cannot in any way substitute for the Responsible Party in fulfilling its statutory duties.



FCOI: Advanced Notice of Proposed Rulemaking (ANPRM)

- “NIH Requests Comments on Proposed Amendment of Regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors”
 - Published May 8, 2009 in the NIH Guide to Grants and Contracts: NOT-OD-09-099
- Federal Register (Vol. 74, No. 88) May 8, 2009
- 60-day comment period – closed July 7, 2009
 - 78 comments received and considered
- All comments are posted at:
 - <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=NIH-2008-0002>



Notice of Proposed Rulemaking (NPRM)

- NIH has considered comments submitted in response to the ANPRM and on behalf of the Department of Health and Human Services and the Public Health Service has prepared a NPRM which proposes changes to the regulations
- The NPRM is under review and clearance
- NPRM will be published in the Federal Register for public comment
- A Final Rule is expected to be published this year



Electronic Submission of SNAPS (Streamlined Noncompeting Award Process)

- Beginning with SNAP progress reports due on/after August 1, 2010, the National Institutes of Health (NIH) will **require** use of the eRA Commons eSNAP module for the submission of all SNAP progress reports. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-093.html>
- SNAP provisions expanded to include those previously only in eSNAP (e.g., no IRB/IACUC dates submitted; due 45 days instead of 60 day before anniversary)
- To accommodate implementation of mandated use of eSNAP, in July 2010 NIH will automatically enable all grantees to submit eSNAPs. It is important that the grantee not click "disable."



Return to a Two-day “Error Correction Window” for Grant Applications Effective May 8, 2010

- Effective May 8, 2010, NIH, AHRQ, NIOSH, and FDA will return to a two (2) business day “error correction window” (i.e., the time allowed after the submission deadline for an applicant to address NIH system-identified errors/warnings) for electronic and competing paper-based PHS 398 grant applications.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-088.html>



Required Use of xTrain for Appointment and Termination Notices – January 2011

- Beginning January 1, 2011, the National Institutes of Health (NIH) will require the use of the xTrain Commons module to electronically prepare and submit the PHS 2271 Statement of Appointment form and PHS 416-7 Termination Notice for the following institutional research training, fellowship*, education, and career development awards:
 - Kirschstein-NRSA undergraduate institutional training grants (T34 – appointment forms only)
 - Kirschstein-NRSA predoctoral and postdoctoral institutional training grants (T32, T35, T90, TL1, and TU2)
 - Kirschstein-NRSA fellowships (F30, F31, F32, and F33 – termination notices only)*
 - National Library of Medicine institutional training grants (T15)
 - Research education awards (R25, R90)
 - Institutional career development awards (K12, KL2, KM1)

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-072.html>



Web Page on NIH Extramural Response to Natural Disasters

Part of NIH's commitment to the health of the biomedical community in the impacted areas, and concern for the health and safety of people and animals in the programs we oversee.

Includes:

- Links to Recent Guide Notices and event-specific web page
- Links to other Federal web sites for disasters
- NIH Emergency Contact Information
- Examples of extramural assistance provided to previous natural disasters and emergencies
- Frequently Asked Questions



Thank You!

Any Questions?