



NIH Update for FDP

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Office of Policy for Extramural Research
Administration





NIH Leadership Transitions

- Current Leadership
 - Dr. Raynard S. Kington: NIH Director (Acting)
 - Dr. Lawrence Tabak: Principal Deputy Director (Acting)
 - Dr. Sally Rockey: Deputy Director for Extramural Research (Acting)
 - Dr. Norka Ruiz-Bravo: Special Assistant to the NIH Director
- Future Leadership
 - HHS Secretary-designate: Senator Thomas Daschle (nominated but not confirmed)
 - NIH Director: Unknown (not yet nominated)



FDP Update

Policy and Peer Review Changes





FY 2009 Salary Cap

Effective January 1, 2009, salary and wages on NIH grants limited to an annual rate of \$196,700 (equal to Executive Level I).

- An individual's base salary is NOT constrained by the legislative provision for a limitation of salary. An institution may pay an individual's salary amount in excess of the salary cap with non-Federal funds.
- Grantees should provide information on full salary needs (if more than the cap) so NIH can adjust based on future limits
- Salary Cap Summary (historical information):
http://grants.nih.gov/grants/policy/salcap_summary.htm



New Registration Process for Reviewer Reimbursement

- Simplified system for reviewers to receive honoraria and reimbursement for expenses related to participation in NIH peer review meetings.
- Beginning January 17, 2009, reviewers must update their Personal Profile in the eRA Commons.
 - Provide Residential address, phone number, and e-mail.
 - Link to the Secure Payee Reimbursement System and provide Social Security Number, bank routing number, and bank account number.
- All information will be kept secure and confidential.
- Registration does NOT require annual renewal.



Enhancing Peer Review: Summary of Recommendations





Peer Review Implementation Update

First stage of Peer Review Changes will begin with applications submitted in January and February 2009

- **Improve Scoring.**
 - Applications will receive an overall score from each panel member from 1-9, averaged, and multiplied by 10. Thus priority scores will range between 10-90.
 - Priority scores will be percentiled against an appropriate base and reported in whole numbers.
- **Improve Critiques.**
 - Reviewer critiques will be compiled into a summary statement that will be shorter and more focused than currently due to standardized organization and reporting of strengths and weaknesses. Discussed applications will also receive a summary of the panel discussion.
 - ALL applications (including streamlined applications) will receive feedback.

More at: <http://grants.nih.gov/guide/notice-files/NOT-OD-09-023.html>



Peer Review Implementation Update (continued)

- Assist New and Early Stage Investigators
 - NIH commits to identifying Early Stage Investigators (ESIs) so that appropriate consideration of their career stage can be applied during review and award selection stages.
 - Identification of ESIs will occur in the Personal Profile section of the eRA Commons. – **Stay Tuned!**
 - **ESI Definition:** A new or first time investigator who is within 10 years of completing his/her terminal research degree or medical residency (or equivalent).
 - For R01 applications in FY2009, NIH expects to support New Investigators at success rates equivalent to that of established investigators submitting new applications.
 - Majority of New Investigators are expected to be Early Stage Investigators
 - Applications will be clustered during initial peer review to the extent possible.



Peer Review Implementation Update (continued)

- Limit all original new (i.e. never submitted) and competing renewal applications to only one resubmission.
 - Applies to all applications submitted for January 25, 2009 due date and beyond.
 - Previously submitted applications will be allowed two resubmissions (“grandfathered”) until January 7, 2011.
 - Based on recommendations from the Peer Review Oversight Committee to increase the number of high quality and first resubmissions that can be funded earlier.
 - Reduces applicant burden of multiple resubmissions.
 - Removes delays in funding for meritorious science.



FDP Update

eSubmission Activities



Electronic Submission: *Update*

The NIH Transition from PureEdge to Adobe Reader forms continues...

- Past:
 - Submissions of Adobe forms during Fall 2008 pilot phase were successful.
- Present:
 - First set of NIH Adobe-based grant application forms now available from Grants.gov for download and submission.
 - Transition of “K” awards to electronic submission
- Future:
 - Adding recent OMB-approved changes to PHS 398 and SF424 (R&R) forms not yet implemented on electronic application forms.
 - Transition of “F”, “T”, and Complex mechanisms



NIH Transition Schedule from PureEdge to Adobe for Standard Submission Dates

Activity Code	Final PureEdge Submission Deadline	First Adobe Submission Deadline
C06/UC6, R18/U18, R25, Gs, S1, S21, S22, SC1, SC2, SC3	9/25/2008	1/7/2009 (AIDS)
R01	11/5/2008	1/7/2009 (AIDS)
R03, R21, R33, R21/R33, R34, R36	11/16/2008	1/7/2009 (AIDS)
R15	10/25/2008	1/7/2009 (AIDS)
R13/U13	1/7/2009 (AIDS)	4/12/2009
SBIR/STTR	1/7/2009 (AIDS)	4/5/2009

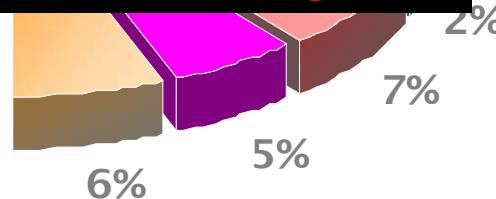


Future Transitions to Electronic Submission with Adobe Forms

- Career Development (K): February 12, 2009
- Fellowship (F): August, 2009 **(RECENT CHANGE!)**
- Training (T): September 25, 2009
- Complex: December 2009

Timeline is subject to change due to Grants.gov form development delays

- Electronic
- Training (T)
- Fellowship (F)
- Career Dev. (K)
- Complex





Business Process and Form Changes for “K” Applications

- Applicants must use the SF424 (R&R) Detailed Budget Component to provide the following limited information only:
 - Senior/Key Person costs (base salary, person months, requested salary, and fringe) for only the candidate.
 - Research Development Support costs in F.1 (Other Direct Costs/Materials and Supplies).
 - Budget Justification
- Reference letters for mentored “K” awards must be submitted directly by referee through the eRA Commons.
- Biosketch revision now requires “Research Support” information similar to other NIH RPG applications.
- Complete instructions available in Part I, Section 7 of the SF424 (R&R) Application Guide for NIH and other PHS Agencies.



FDP Update

Other NIH Activities



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



NIH Regional Seminars on Program Funding and Grants Administration

2009 Regional Seminars:

Seminar #1: April 16-17, 2009 in Atlanta, GA

Seminar #2 – June 25-26, 2009 in Las Vegas, NV

Electronic research administration labs offered in conjunction with the two-day seminar.

- Yearly seminars to educate research administrators, investigators new to NIH, and trainees.
- Due to the popularity of these seminars and availability of space - ***Early Registration is Highly Recommended!***
- Seminar and Registration Information:
<http://grants.nih.gov/grants/seminars.htm>

Interested in hosting?
Contact us!



Community Outreach

- **HealthierUS.gov**
 - HHS Initiative to promote healthy lifestyles and improve community health and wellness.
 - Web site highlights important health topics such as:
 - Encouragement for increasing physical activity
 - Recommendations for eating a nutritious diet
 - Tips on avoiding risky behaviors
 - Information on preventive health screenings





Thank You!

Any Questions?



Appendix

Other Items of Interest to FDP Members





Updated Guidance from OHRP

- Final Guidance on Engagement of Institutions in Human Subjects Research
 - Published October 23, 2008 in Federal Register.
 - Finalizes previous draft guidance and describes:
 - Scenarios that, in general, would result in an institution being considered engaged in a human subjects research project.
 - Scenarios that would result in an institution being considered not engaged in a human subjects research project
 - IRB review considerations for cooperative research in which multiple institutions are engaged in the same non-exempt human subjects research project.



Updated Guidance from OHRP (continued)

- Revised Guidance on Research Involving Coded Private Information or Biological Specimens
 - Provides guidance on when coded private information or specimens is or is not research involving human subjects.
 - Reaffirms OHRP policy that, under certain limited conditions, this research is not human subjects research.
 - Clarifies distinction between:
 - Research involving coded private information or specimens that does not involve human subjects, and
 - Human subjects research that is exempt from the requirements of HHS regulations.



Financial Conflict of Interest (FCOI) Activities

As requested by Congress, NIH developed an Advanced Notice of Proposed Rule Making (ANPRM) to gather public comment on possible revisions to the FCOI regulation.

- After OMB reviews the ANPRM, it will be posted in the Federal Register for public comment for a period of 60 days.



Topics covered in ANPRM

1. Expanding the scope of the regulation and disclosure of interests
 - Should NIH require Investigators to disclose all financial interests related to their Institutional responsibilities when they receive an NIH award?
2. Identification and management of conflicts by Institutions
 - For research involving human participants, should Investigators who are involved in participant selection, the informed consent process, and clinical management of a trial, be prohibited from having a Significant Financial Interest in any company whose interests could be affected by their research or clinical trial? If so, what special circumstances – such as limited availability of specially qualified Investigators – may justify waiving this condition?



Topics covered in ANPRM (con't)

3. Definition of “significant financial interest” (SFI)

- Should the current exemptions be maintained?
 - If so, are current de minimus levels reasonable? Should they be the same for all types of research?
 - If not, which exemptions should be reconsidered?

4. Assuring Institutional compliance

- Should independent confirmation of an Institution’s compliance with the regulation be required? What would this look like?

5. Requiring Institutions to provide additional information

- Should Institutions be required to submit to the PHS funding component additional information on any identified conflict?



Topics covered in ANPRM (con't)

6. Defining Institutional conflict of interest

- How would Institutional conflict of interest be defined?
- What would an Institutional conflict of interest policy address in order to assure the PHS of objectivity in research?



eRA Commons FCOI Module/ reporting tool

- Enables grantees to report identified FCOIs to NIH through the eRA Commons
- System allows institutions to:
 - Initiate and send a new FCOI report electronically through the eRA Commons
 - Search previously created records
 - Edit a previously submitted record
 - Respond to a request for additional information
 - Rescind a previously submitted record
 - View history of actions
- Limited pilot of system begun in October, 2008. Will be expanded as appropriate – **Stay Tuned!**



Web-based Tutorial on FCOI

- Reviews requirements of and responsibilities for compliance with Federal FCOI regulations
- Designed for use by:
 - **Institutional officials** responsible for managing NIH-funded grants, cooperative agreements and/or contracts
 - **Individuals** who are responsible for the design, conduct or reporting of NIH-supported research.
- Includes quizzes to test understanding and certificate of completion

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-106.html>