HRPO IRB Approvals

- “Approval Date” on IRB Approval NOT necessarily the approval date for PDS or an application.

- “Next IRB Approval Due Before” = Expiration Date

Example:
- “Approval Date” on IRB Approval = 9/7/11
- “Next IRB Approval Due Before” = 8/10/12
- Approval Date in PDS and application = 8/11/11
Freedom of Information Act Requests

- If the PI does not respond, NIH will release the information
- The only things that can be redacted are:
  - Proprietary / patentable / commercial or financial information
    - Provide an adequate and convincing written justification for withholding the information
  - Information that would constitute a clearly unwarranted invasion of personal privacy
    - NIH will redact this information
    - Examples: SSN, birthdates, home addresses & phone numbers, sources & amounts of pending support, sources of private support, % of effort on the project, institutional base salary information

GWAS and dbGaP

- GWAS -> Genome-Wide Association Studies
- dbGaP -> The database of Genotypes and Phenotypes
- Teri Medley is the “authorized institutional signing official” who will review and approve
- Once approved by NIH and data is accessed, annual & close-out progress reports are required
Coming Soon!
Revised Proposal Certification Form (PC Form)

Notable Changes

1. New: “Subawarding Entity (When WU Is Subrecipient)” field on General Info A page of PDS that will populate the PC Form.
Notable Changes

2. To save space, form will only print selected options in sections: Proposal Type, Purpose and Document Type.

3. Key Personnel and Other Significant Contributors will be listed separately. These will be the only two sections on page 2.

4. Human Subjects section re-vamped
   a. Check-boxes removed.
   b. URLs added for assisting with human subjects research determination.
   c. Human Subjects Education yes/no check boxes removed.

5. Revised verbiage/questions in Export Controls section.
**Revised Proposal Certification Form (PC Form)**

**Notable Changes**

6. PI Signature section revamped.
   a. Now includes Conflict of Interest verbiage. Additional PI initials no longer required!
   b. Will include NIH fellowship assurances, if applicable, based on agency code (2-17004). Eliminates need for NIH Fellowship Addendum form!
   c. Sponsor/mentor signature line will be populated if NIH fellowship, based on agency code.
   d. Signature lines will be populated for each PI if it is a multiple PI application.

7. Remove blank page that displays on the PC form.
PI Role of “BASIC” in eRA Commons

• Being phased-out by NIH
• A PI’s “BASIC” account cannot be used to submit an application -> it will get an error
• Must create an entirely new account

NIH Operates Under A Continuing Resolution

• Enacted 10/4/11
• Continues government operations through 11/18/11 at the FY11 level minus 1.5%
• Until FY12 appropriations enacted, NIH will issue non-competing awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level)
• Consistent with our practice during the CRs of FY 2006 - 2011
• Upward adjustments to awarded levels will be considered after FY 2012 appropriations are enacted
• Reference: NOT-OD-12-004
NIH Budget News

- President’s 2012 Budget Request $31.987 billion
  - Increase of 2.4% from FY 2010
  - Areas of emphasis:
    - Technologies to accelerate discovery
    - Enhancing the evidence for health care decisions
    - New Innovator Award and Early Independence Award

Breakdown of FY 2012 President’s Budget Request for NIH – $31.987 Billion

- Research Project Grants (52.3%)
- Research Centers (9.46%)
- Other Research (5.58%)
- Research Training (2.48%)
- R&D Contracts (11.07%)
- Intramural Research (10.56%)
- Research Mgmt & Support (4.8%)
- All Other (3.62%)
Closing out the Era of ARRA

• Timely Quarterly and Closeout Reports Required
  - All standard closeout documents apply to ARRA funded awards (Final Progress Report, Final Invention Statement, Final FFR), even if ARRA funded a Supplement to a non-ARRA parent.

More at: http://www.grants.nih.gov/recovery/

Accelerating Unspent ARRA Awards

• NIH has always expected ARRA grantees to expend funds in a timely and expeditious manner
• OMB Memorandum M-11-34 Issued 9/15/2011 directs agencies to assure ARRA funds are spent by 9/30/2013 – only provides limited options to extend availability of funds
  - Grantees should assure all ARRA funds are drawdown and all financial reports (cash and expenditure) are reconciled before 9/30/2013.
  - When considering initial 12-month extensions that extend into late FY2013, grantees should not extend beyond 6/30/2013 to allow financial closeout by 9/30/13.
• Anticipate that NIH will update guidance previously provided in Notice OD-10-067 to eliminate/restrict the ability for a second no-cost extension.
• The OMB Memorandum allows Federal agencies to request waivers from the September 30, 2013 deadline in limited cases due to special circumstances of a project (e.g., where programs are long-term by design).
Revised Multiple-PD/PI Policy Allows PD/PI Change with Prior Approval

- Revised policy acknowledges that it may not be essential to require peer review to change from single- to multiple-PD/PI award, or from a multiple- to single-PD/PI award
- Requires a prior approval request sent to the IC GMO by the AOR
- Justification must be based on scientific needs of the project; request will not be considered if based on administrative convenience
- Revised policy is consistent with prior approval requirements for a change in PD/PI (see Grants Policy Statement, Section 8.1.2.6)
- Guide NOT-OD-11-118 specifies the information to be included in the prior approval request
- Change may not be implemented without GMO approval and revised NoA


Appeals Policy

Effective with Competing Applications submitted on/after 1/25/2011; (i.e., October 2011 Council Round)

- Formal appeal letter must be submitted by the Authorized Organization Representative (AOR) or document concurrence of the AOR; requests to withdraw an appeal letter must likewise include AOR concurrence

- ICs can establish deadlines for appeals; however no letter can be accepted before the summary statement has been made available to the PD/PI or later than 30 calendar days after the relevant Council meeting


Appeals Policy (cont)

An appeal letter will only be accepted if the letter:

1) Describes flaws in the review process for application in question
2) Explains reason for the appeal
3) Is based on one or more of the following issues
   - Evidence of bias on the part of one or more peer reviewers
   - Conflict of interest on the part of on or more peer reviewers (see 42 CFR 52h.5)
   - Lack of appropriate expertise within the Scientific Review Group (SRG)
   - Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially

- Appeals based solely on differences of scientific opinion will not be accepted
- Questions on the Notice should be directed to ReviewPolicyOfficer@mail.nih.gov

Mandating Use of the Commons to Submit No-Cost Extension Notifications

- Effective October 1, 2011, NIH is requiring grantees to use the No-Cost Extension feature in the eRA Commons to notify NIH when they exercise their one-time authority to extend, without additional funds, the final budget period of a grant.
  - Once the eRA Commons link is closed, such an action becomes a prior approval request and must be submitted for consideration to the Grants Management office of the NIH awarding component.

For more see: NOT-OD-11-098
Change in the NIH Continuous Submission Policy for Reviewers with Recent Substantial Service

NOT-OD-11-093

- This Notice announces the lengthening of the window of time during which peer reviewers who have served six times in 18 months (recent substantial service) can submit their applications under the NIH continuous submission policy.

- Previous window was 10/1 – 9/30

- Effective July 8, 2011: For peer reviewers in this category, the window is adjusted to begin on August 16th and extend to September 30th of the next year.

For more see: NOT-OD-11-093, NOT-OD-08-026, NOT-OD-09-114, NOT-OD-09-155, NOT-OD-10-090 and NOT-OD-11-036

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NIH Grants Policy Statement Revision - FY2012

- Effective October 2011, revision supersedes the October 1, 2010 version
  - Incorporates policy changes since 10/01/10, public policy changes, clarification of existing policies
  - Incorporates new business process changes, minor edits for clarity in response to user input, and updated URLs when applicable.
- New GPS to be published in late October.
Research Performance Progress Report (RPPR)

- RPPR at NIH
  - Implementation plan posted January 21, 2011
    - Will implement in an electronic environment
  - Refining agency specific reporting and implementation requirements
    - With goal to minimize impact on grantees
  - Expect to pilot in January 2012
  - Participating in Federal-wide data dictionary workgroup

Closeout Final Reports

*Grantees are strongly encouraged to submit closeout documents electronically through the eRA Commons!*

- Failure to submit timely reports may affect future funding to the organization.
- Documents are due within 90 days of project period end date:
  - Final Federal Financial Report (FFR) SF-425 Expenditure Data (submitted through eRA Commons)
  - Final Inventions Statement & Certification
  - Final Progress Report
- Grantees must ensure there are no discrepancies between the final FFR expenditure data (in eRA Commons) and the FFR cash transaction data in the Payment Management System.
Closeout
NIH Centralized Processing Center

- Centralized office accepts receipt of all non-financial, paper-based closeout documents
  - Final Progress Report
  - Final Invention Statement and Certification
- If not using eRA Commons Closeout Module, mail closeout documents to the Central NIH unit at:
  NIH Centralized Processing Center
  6705 Rockledge Drive, Room 2207, MSC 7987
  Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)
  Bethesda, MD 20817 (for other courier/express mail only)

Non-Competing Continuation Progress Reports

- Failure to submit complete and timely progress reports may affect future funding to the organization
- Non-SNAP annual progress reports are due two months prior to the anniversary date (paper submission)
- SNAP progress reports (e-SNAP) are due 45 days prior to the anniversary date (electronically submitted through eRA Commons eSNAP Module)
- All grantees have access to a searchable list to determine which progress reports are due at:
  http://era.nih.gov/userreports/pr_due.cfm
Use Correct Application Forms

Remember to use the latest version of forms available for your Funding Opportunity Announcement (FOA)

- Identify form version by the Competition ID
- Competition ID ADOBE-FORMS-B2 currently used for most new FOA postings
  - Includes: fix for modular budget issue, updated construction budget form and support for up to 30 subaward budgets
- Fellowship, Training and a few other programs will continue to use ADOBE-FORMS-B1
  - These programs don’t use the forms fixed in B2

FAQs: [http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#find1](http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#find1)
Tips for Submission Success

- Carefully follow the specific guidelines found in the Application Guide and the Funding Opportunity Announcement (FOA)
  - Instructions in the FOA trump those found in the Application Guide
- Check your application for common errors before you submit
- Submit early!
  - Think days, not hours or minutes before deadline

Tips for Submission Success

- NIH eliminated the 5-day grace period for receipt of letters for reference for Ks (as of 6/1/2011) and Fs (as of 4/08/2011)
  - Letters of reference will be due on application due date
  - Applicants are encouraged to request letters only from individuals able to submit them on time.
- Correct any errors before the submission deadline
  - If errors are found in the submission process, you must submit a changed/corrected application before the deadline
- View your application in Commons
  - YOU are responsible for verifying that your error-free application is viewable in the eRA Commons and correctly reflects your submission
  - If you can’t VIEW it, NIH can’t REVIEW it!
Looking Ahead

- Change of Grantee or Training Institution (Type 7 applications)
  - working to transition to electronic applications
- Administrative Supplements (Type 3 applications)
  - working to transition to electronic applications
- Changes to how users log in to eRA Commons
  - Federated authentication
  - Future changes to improve security

Looking Ahead

- Changes in system for Delegations
- Changes to Financial Conflict of Interest module to meet compliance needs
- Transition to Research Performance Progress Report
Helpful NIH Resources

NIH Regional Seminars 2012

- NIH Regional Seminars for administrators and researchers new to NIH
  - Indianapolis, Indiana (exact date to be determined)
- Faculty: NIH policy officials, grants management, program and review staff, eRA Commons trainers, OHRP, OLAW
- Information at: http://grants.nih.gov/grants/seminars.htm
Frequently Asked Questions

- FAQs include questions about:
  - Application/progress report preparation, funding initiatives, policies, human subjects, animals, disaster response, etc...
  - [http://grants.nih.gov/grants/frequent_questions.htm](http://grants.nih.gov/grants/frequent_questions.htm)
  - Key word search

Tools to Search NIH Funding

- Research Portfolio Online Reporting Tools (RePORT) [http://report.nih.gov](http://report.nih.gov)
  - Provides access to reports, data and analysis of NIH research activities, including ARRA-specific data queries, and more
  - Quick links to “Frequently Requested Reports,” FAQs

- RePORT EXPENDITURES & RESULTS (RePORTER) [http://projectreporter.nih.gov/reporter.cfm](http://projectreporter.nih.gov/reporter.cfm)
  - Tool used to search information from NIH project databases and funding records, PubMed abstracts and full-text articles, and invention reporting (iEdison, Interagency Edison)
  - Replaces CRISP
Summary of Helpful NIH Web Pages

- Office of Extramural Research (OER) Web Page
  http://grants.nih.gov/grants/oer.htm
- NIH Grants Policy Statement (Rev. 10/10)
- NIH Extramural Nexus – newsletter for the extramural community
  http://nexus.od.nih.gov/all/nexus-by-date/
- Rock Talk
  http://nexus.od.nih.gov/all/rock-talk/
- Grant Application Basics
  http://grants.nih.gov/grants/grant_basics.htm

Summary of Helpful NIH Web Pages

- Applying Electronically
- Annotated SF424 (R&R) Application Forms (General and Small Business)
  http://grants.nih.gov/grants/ElectronicReceipt/communication.htm#forms
- Ten Checks to Help Avoid Common Application Errors
  http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm#10checks
- Do I have the right electronic forms for my NIH application?
NIH OER Listservs

• NIH Guide for Grants and Contracts:
  – Official publication for NIH Grant Policies, Guidelines & Funding Opportunities

• Office for Human Research Protections (OHRP):
  – Office for Human Research Protections (OHRP)

• Office of Laboratory Animal Welfare (OLAW):
  – http://grants.nih.gov/grants/olaw/references/list.htm

• eSubmission:
  – Separate listservs available for scientists and administrators

Grants Information: Who to Contact!

• General Application Questions:
  – E-Mail: GrantsInfo@nih.gov
  – Phone: 301-435-0714

• Grants.gov Customer Support:
  – E-Mail: support@grants.gov
  – Webpage: http://grants.gov/
  – Phone: 800-518-4726

• eRA Commons Helpdesk:
  – Phone: 301-402-7469 or 800-504-9552
Grants Information: Who to Contact (cont…)

- Division of Grants Policy:
  - E-Mail: GrantsPolicy@mail.nih.gov
  - Phone: 301-435-0949

- Division of Grants Compliance & Oversight:
  - E-Mail: GrantsCompliance@mail.nih.gov
  - Phone: 301-435-0949

Office of the Vice Chancellor for RESEARCH

Be Informed!
Be Up-to-Date!
Be in the Know!

Listservs
NIH Extramural Update
http://grants2.nih.gov/grants/nexus.htm

NIH Weekly Guide
http://grants.nih.gov/grants/guide/listserv.htm

RESADM-L
http://www.ncura.edu/data/newsroom/newsletters/pdf/apr96/eid.html

Research News
http://researchnews.wustl.edu/