Highlights of the 2009 NIH Annual Update

Jane Tolbert

ORPA

June 16, 2009

NIH Funding – FY 2009

- NIH received a total of $30.4 billion (an increase of 3.2% from FY 2008)
- 9800 new and competing RPGs
- Average competing award expected to increase by 3%
- Average non-competing award expected to remain at previously committed level
- 1% increase in NRSA stipend levels
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-066.html

New Tools to Search NIH Funding

- New reports, data and analyses website released in March 2008 and expended significantly in January 2009.
- NIH-wide Research Portfolio Online Reporting Tool (RePORT)
- Includes info on success rate, funding estimates for certain research areas, funding by Institution etc.

http://report.nih.gov/

Recovery (ARRA) Act

- ~$10 billion for NIH to spend within the next two years ($8.2 billion for extramural funding)
- In addition to NIH's "regular" budget"
- Funding opportunity information available at: http://www.grants.nih.gov/recovery/

ARRA Award Features

- Requires recipients to account for, track, monitor, report on, provide for audit of, and closeout ARRA funding separately from non-ARRA funds
- All ARRA awards will include a banner at the top of the NIH Notice of Award
- Special ARRA terms and conditions (http://www.grants.nih.gov/grants/policy/NIH_HHS_ARRA_Award_Terms.pdf)

NIH Priorities

- Roadmap for Medical Research (http://nihroadmap.nih.gov/)
- Blueprint for Neuroscience Research (http://neuroscienceblueprint.nih.gov/)
- Continued Focus on New Investigators
- Assistance for Early Stage Investigators

Reminder - Definition of "New Investigator"

- Definition has been updated to provide more detailed guidance
- A "new" investigator may not have successfully competed as a PD/PI of most research grants
- PIs who did not initially compete for a major research grant but were later designated as PD/PI are still considered "new"
- All PD/PIs must meet the new investigator definition to receive special consideration on multi-PI grants

http://grants.nih.gov/grants/new_investigators/resources.htm

Reminder - Shortened Review for New Investigators

- NIH continues to focus on new investigators
- New investigators who are unsuccessful in an initial R01 submission may shorten the time to next review (if they can address the concerns addressed in the Summary Statement in that time frame)
- Resubmissions for the next cycle must be submitted by March 20, July 20, or November 20

http://grants1.nih.gov/grants/guide/notice-files/not-od-07-083.html

Enhancing Peer Review

- Changes so far:
  - Phase out A2 application
  - Identification of Early Stage Investigator (ESI) Applications

New Policy for resubmission Applications

- NIH limiting 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 until January 7, 2011
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html

Identification of Early Stage ESI Applications

- Encourage earlier transition to research independence
- Counter trend of increasing time spent in training phase of career
- Strongly encourage New Investigators, particularly ESIs to apply for R01s
- Support New Investigators at success rates equivalent to established investigators submitting new applications

Early Stage Investigator - Definition

- A new investigator who is within ten years of completing the terminal research degree or is within ten years of completing medical residency
- For multiple PD/PI applications, ALL PD/PIS must meet ESI requirements
- Status applies only to R01s
- ESIs are also eligible for the shortened review cycle offered to New Investigators.

Enhancing Peer Review

- Changes happening soon:
  - Enhanced review criteria
    - Significance
    - Investigator(s)
    - Innovation
    - Approach
    - Environment
  - New scoring system
    - 9 point scale – 1=Exceptional, 9=Poor
    - Will be implemented for FY10 funding consideration and ARRA opportunities

Enhancing Peer Review

- Changes happening soon:
  - Structured critiques
    - Decrease variability
    - Increase quality of info in critiques
    - Succinct, better organized
    - Ensure that reviewers address all criteria and considerations
    - Bulleted comments
  - Clustering of new investigator applications

Enhancing Peer Review

- Changes happening later (January 2010)
  - **Shorter Research plans (!)**
  - Changes to three parts of the application
    - Biographical sketch
    - Research Plan
    - Resources

Enhancing Peer Review

- Biographical Sketch
  - Personal statement
  - Publications limited to 15
    - 5 most recent
    - 5 best
    - 5 most relevant to application

Enhancing Peer Review

- Restructured Research Plan
  - Specific Aims – 1 page
  - Research Strategy (includes "old" Background & Significance, Research Design & Methods, Preliminary Studies/Progress Report)
  - R01 – Research Strategy – 12 pages
  - R21 – Research Strategy – 6 pages
  - Introduction – 1 page

Enhancing Peer Review

- Facilities & Other Resources
  - Environment – address how scientific environment will contribute to probability of success etc

For more information on enhancing peer review see http://enhancing-peer-review.nih.gov/

NIH and Grants.gov

- **Compatible versions of Adobe Reader are currently 8.1.1, 8.1.2, 8.1.3, 8.1.4, 8.1.5, 9.0, 9.1 and 9.1.1 (http://www.grants.gov/help/download_software.jsp#adobe811)**
- **New Parent R21 and R03 application packages released. These must be used for submissions on or after May 16, 2009.**
- New PHS 398 and SF 424(R&R) Application forms expected in Fall 2009 (no details yet)

Timeline for grants.gov transition

- Transition from Pure Edge to Adobe forms complete for existing FOAs (no more Pure Edge)
- K awards have transitioned to Adobe
- F awards will transition August 8, 2009
- Ts and Complex mechanisms still on hold

Common Errors

- Use of special characters in file name
- Not using PDF format
- Missing eRA Commons user name
- Missing organization name for senior/key personnel
- Missing FWA/Animal Assurance number
- Missing Cognizant Agency information
- R&R Budget form – senior/key person effort must be greater than zero

Reminder - NIH Policy for Late Application Submission

- Generally not accepted except in unusual circumstances
- Permission not granted in advance
- Must be accompanied by a cover letter
- For regular standard submission dates application must be received within two weeks of the deadline
- For expedited submission dates application must be received within one week of the deadline
- Late applications are not accepted for special receipt dates

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-027.html

Reminder - Submission of Additional Grant Application Materials

- Submission of additional materials prior to review
- Original application is kept intact with additional materials sent to reviewers separately
- Materials must be submitted to Scientific Review Officer with consent of the Institution's AOR/ SO

  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-082.html

Reminder - NIH Policies on Submission of Similar, Identical or Essentially Identical Applications

- Submission of identical applications to one or more components of NIH or PHS is not allowed
- NIH will not review any new or resubmission application containing one or more of the specific aims in a similar, identical or essentially identical application until the peer-review process for the original application is complete.
- Applications must be modified to comply with the new FOA

Changes to K-award Policies

- K-awardees may request NIH permission to reduce their full-time appointment to less than full-time (under certain circumstances and for limited time)
- Under certain circumstances, K-awardees may request permission to reduce their professional effort to less than 75%
- Short –term career development experience at another institution for 3 months or less allowable without NIH approval
- Leave of absence of up to 12 months permitted (without award support)
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-036.html

NIH Salary Cap

- Effective January 1, 2009, the salary cap was increased to $196,700

- UR guidelines available at: http://www.rochester.edu/orpa/PropInfo/NIHCAP09.pdf

NRSA Stipend Levels

- FY 2009 levels increased 1% from FY 2008:
  http://grants1.nih.gov/grants/guide/notice-files/
  NOT-?.html
- Policy for tuition, fees and trainee related expenses:
  http://grants1.nih.gov/grants/guide/notice-files/
  NOT-OD-06-093.html
- Parental leave policy – up to 60 days of parental leave
  http://grants.nih.gov/grants/guide/notice-files/NOT-
  OD-08-064.html

Public Access Policy (now permanent)
http://publicaccess.nih.gov/

- Mandates public access to results of NIH funded research to advance science and improve public health
- Final peer-reviewed manuscript must be submitted to PubMed Central
- Manuscript will be made publicly available no later than 12 months after official publication
- Compliance demonstrated by use of the PMC ID#

X-Train

- X-Train is a new system to improve the administration of NIH Training Grants
  - Allows electronic submission of appointment and termination notices
  - Available through NIH Commons
  - UR Pilot?

  Full Production expected in 2009

Reminder - Clinical trials.gov and Registration Requirements

- Effective December 26, 2007, all ongoing trials of drugs or devices for serious or life-threatening diseases are to be registered
- Other trials to be registered within one year
- New trials to be registered within 21 days of first patient enrollment
- Responsibility for registration (i.e. who should register) depends on the type of trial
- Contact Eric Rubinstein at 6-4284 with questions on registration
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-030.html

Closeout

- NIH encourages electronic submission via Commons
- Closeout documents required within 90 days of the end of the project
    - FSR (electronic submission <u>required</u>)
    - Final Invention Statement
    - Final Progress Report
- Late reports may affect future funding to PI and/or institution

    http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-051.html

OIG Audit Work Plan (same as last year!)

- Cost transfers, effort reporting
- Administrative & clerical salaries
- Use of Data & Safety Monitoring Boards in Clinical Trials
- NIH monitoring of extramural COI
- Grantee management of Financial COI

Other Items

- Revised NIH Grants Policy Statement in progress (no release date yet)

- NIH Commons – Profile Maintenance for PIs
  - PIs should keep their profiles up-to-date (contact information) – particularly important for classification as Early Stage Investigators (ESI)
  - Profile data is used for other electronic processes (Summary statements, eNotifications)

Other Items

- New Registration Process for Peer Reviewer Reimbursement
  - Replaces CCR system; reviewers must log in via Commons and link to the Secure Payee Reimbursement System (SPRS) to provide payment info
  - Effective January 17, 2009
    http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-033.html

Other Items

- Protecting Confidentiality in the NIH Peer Review Process
  - NIH is now password protecting data on the compact disks sent to reviewers
  - Specific instructions for accessing data will be sent to reviewers with the CDs.
    http://grants1.nih.gov/grants/guide/notice-files/not-od-08-071.html

NIH Resources

- Office of Extramural Research Home Page:
  http://grants.nih.gov/grants/oer.htm
- Searchable database of Pas, RFAs and Notices:
  http://grants.nih.gov/grants/guide/index.html
- Grants Policy Statement:
  http://grants.nih.gov/grants/policy/nihgps_2003/
- Extramural Nexus Newsletter:
  http://grants.nih.gov/grants/nexus.htm
- NIH Guide for Grants & Contracts listserv:
  http://grants.nih.gov/grants/guide/listserv.htm
- eSubmission listserv:
  http://era.nih.gov/ElectronicReceipt/listserv.htm

NIH Resources

- CRISP Database
  http://report.nih.gov/crisp/index.aspx
- Grant Application Basics
  http://grants.nih.gov/grants/grant_basics.htm