

• VISION & TRANSITION

• POLICY

# Current Issues at NIH

Spring 2006

• COMPLIANCE

• ELECTRONIC ADMINISTRATION

## THE PAST

"The mind must be prepared not only by scientific training and technological know-how, but also by the awareness of social needs."

Louis Pasteur,  
Saturday Review

## THE PRESENT

"We live in a time when the words *impossible* and *unsolvable* are no longer part of the scientific community's vocabulary.

Each day we move closer to trials that will not just minimize the symptoms of disease and injury but eliminate them."

Christopher Reeve,  
Testimony to US House of Representatives

## THE FUTURE

The future is not some place we are going to, but one we are creating. The paths are not to be found, but made, and the activity of making them, changes both the maker and the destination.

John Schaar,  
Futurist

4

# AGENDA

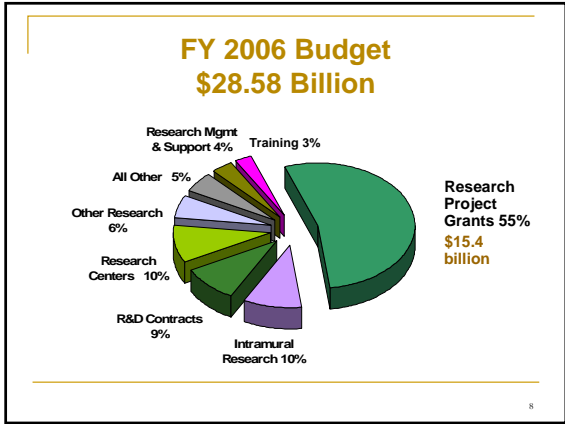
- THE FUTURE
  - Watch for These "Hot Topics" in FY2006!
- THE PRESENT
  - Recent Policy Issues Affecting the Grants Process!
- THE PAST
  - Past Policy Issues that Continue to Affect our Present and Impact our Future
- CONTACTS & ELECTRONIC RESOURCES
  - Helpful NIH Contact Information & Web Pages

# THE FUTURE

Policy Issues that Affect Today's Grants Process and Continue to Impact Our Future

- NIH Budget & FY 2006 Funding Policy
- Multiple PIs
- Focus on New Investigators
- Electronic Receipt of Applications
- eRA Commons
- Paperless Notification Process
- NRSA Application & FY 2006 Budget News

# THE NIH BUDGET & FY2006 FUNDING POLICY



### FY2006 Financial Policy for Grant Awards: RPGs & Other Grant Programs

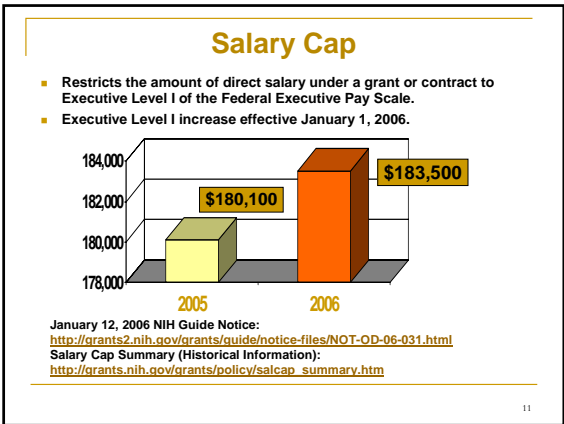
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-025.html>

NIH appropriation for FY2006 includes a 1% across-the-board reduction to non-emergency, discretionary programs

- RESEARCH PROJECT GRANTS (RPGs)
  - Non-competing awards are awarded at 97.65% of the amount indicated for the FY2006 budget period (Future years will be adjusted by the same factor.)
  - Competing RPGs will be managed to an average award amount equal to FY 2005 levels
- OTHER GRANT PROGRAMS (excluding Kirschstein-NRSA)
  - Other grant programs are managed in accordance with the policies to be established by each Institute and Center.
  - Questions regarding adjustments applied on individual grant awards may be directed to the identified Grants Management Specialist

### FY 2007 President's Budget Request

- Request for \$28.578 billion (No change from FY 2006 appropriation)
- Estimated 9,337 competing RPGs (+275 over FY 2006)
- Investment in several trans-NIH strategic initiatives and priorities, including:
  - Biodefense
  - Enhanced Support for New Investigators
  - NIH Roadmap for Biomedical Research
  - Genes, Environment and Health Initiative
  - Clinical and Translational Sciences
  - Management Innovations
  - AIDS
- NIH Summary of the FY 2007 President's Budget: <http://officeofbudget.od.nih.gov/pdf/Press%20info%20final.pdf>



### Small Business Innovation Research/Small Business Technology Transfer Research (SBIR/STTR) Program

- SBIR reauthorized through FY 2008
  - Set aside remains at 2.5%
  - Commercialization plan required for Phase II applications
  - New SBA data collection requirement for Phase II applications
- STTR reauthorized through FY 2009
  - Electronic SF424R&R application through Grants.gov effective 12/1/2005
  - Phase II awards increase to \$750,000
  - Commercialization plan now required for Phase II applications
  - New SBA data collection requirement for Phase II applications

## What Can You Expect in FY2006?

- Trans-NIH
  - Roadmap (FY2004 - )
  - NIH Strategic Plan for Obesity Research (FY2005 - )
  - Neurosciences Blueprint (FY2006 - )
- Initiatives are posted in the NIH Guide for Grants & Contracts: <http://grants1.nih.gov/grants/guide/index.html>

13

## FY2006 and Beyond: Science Management and Administration



- Portfolio management and trans-NIH science investments
  - Public Access Policy
  - Knowledge Management
  - Office of Portfolio Analysis and Strategic Initiatives (OPASI)
- Facilitating multidisciplinary collaborative research: Multiple PIs
- New Investigators

14

## Public Access Policy

NIH-funded investigators are requested to submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs from NIH.

- Applies to:
  - Currently funded NIH research projects
  - Previously-supported NIH research projects if they are accepted for publication on or after May 2, 2005.
- Does Not Apply to:
  - Book chapters, editorials, reviews, or conference proceedings.
  - Publications resulting from non-NIH-supported research projects should not be submitted

**Note:** In an effort to drive knowledge activities and achieve science management goals, the NIH strongly encourages the Research community to respond to this request.

Effective May 2, 2005

15

## Public Access Policy Resources

- Public Access Policy Website:  
<http://www.nih.gov/about/publicaccess/>
- NIH Manuscript Submission (NIHMS) System  
<http://www.nihms.nih.gov>
- Public Access Policy in the *NIH Guide*:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html>
- Authors' Manual:  
[http://www.nih.gov/about/publicaccess/publicaccess\\_Manual.htm](http://www.nih.gov/about/publicaccess/publicaccess_Manual.htm)
- Questions and Answers:  
[http://www.nih.gov/about/publicaccess/publicaccess\\_QandA.htm](http://www.nih.gov/about/publicaccess/publicaccess_QandA.htm)
- Public Access Policy Mailbox:  
[PublicAccess@nih.gov](mailto:PublicAccess@nih.gov)

16

## Knowledge Management – What Are We Talking About?

- **Definition** = Formalization of the management of the enterprise's intellectual assets (human, organizational, relationship)
- **Definition** = Distribution, access, and retrieval of unstructured information about "human experiences" between interdependent individuals or among members of a workgroup.
  - Involves identifying a group of people that have a need to share knowledge; developing technological support to enable sharing; and creating a process for transferring and disseminating that knowledge.

17

## Knowledge Management – How Would NIH Benefit From Application of KM?

- Disease coding
- Peer review
  - Referral and assignment of applications
  - Identification of peer reviewers
  - Identification of potential Conflict of Interest
- Portfolio analysis
  - Scientific trend analysis
  - Clinical relevance recognition tools
- Need-to-know-based security screening
- Clinical Center – clustering of clinical research
- Office of Technology Transfer – patent and royalties management

18

## Office of Portfolio Analysis and Strategic Initiatives (OPASI)

- **Function:** Enhance the NIH priority-setting process while improving trans-agency coordination
- **The NIH Roadmap will be integrated into OPASI.**
- **Will be achieved through:**
  - Sound decision-support systems
  - Rigorous and uniform sources of evidence
  - Broad public and scientific input
- **Will result in:**
  - Identification of cross-cutting research requiring common investment
  - Optimal balance between scientific opportunity and public health concerns
  - Enhanced accountability to Congress, scientists, patients, and the public

19

# MULTIPLE PIs

20

## NIH Plans to Recognize Multiple Principal Investigators

- In 2006, the National Institutes of Health (NIH) will begin to implement a Federal-wide policy to allow more than one Principal Investigator (PI) on individual research awards.
- The NIH will make the multiple-PI option available for applications submitted in response to a selected group of Requests for Applications (RFAs) and Program Announcements (PAs) with May-June 2006 receipt dates.
- This presents a new and important opportunity for investigators seeking support for projects or activities that clearly require a "team science" approaches and which do not fit the single-PI model.
- **Implementation Plans:**  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-036.html>

21

22

## FOCUS ON NEW INVESTIGATORS

23

24

## Pathways to Independence (K99/R00)

<http://grants.nih.gov/grants/guide/pa-files/PA-06-133.html>

- Designed to facilitate receiving an R01 award earlier in an investigator's research career.
- The primary, long-term goal of the PI Award Program is to increase and maintain a strong cohort of new and talented, NIH-supported independent investigators
- The Pathway to Independence Award will provide up to five years of support consisting of two phases.
  - The initial phase will provide 1-2 years of mentored support for highly promising, postdoctoral research scientists.
  - This phase will be followed by up to 3 years of independent support contingent on securing an independent research position.
- It is anticipated that 150 to 200 PI Awards will be issued for this program in the initial year.

Questions and Answers

[http://grants.nih.gov/grants/new\\_investigators/QsandAs.htm](http://grants.nih.gov/grants/new_investigators/QsandAs.htm)

25

## NIH/CSR Pilot Study for New Investigators Begins

### Speedier NIH Review of Research Applications Planned

- Pilot is designed to shorten the time to the next review for some new investigators who are not successful in a R01 grant submission and are readily able to address the concerns raised and issues identified in the Summary Statement.
- To qualify for this pilot, special conditions must be met. For example:
  - A new or first resubmission of an R01 application must be submitted for the February 1 or March 1, 2006 date.
  - The application must be reviewed in one of the participating Study Sections.
  - The Principal Investigator must agree that the resubmitted application be assigned to the same Study Section; no change in review venue is permitted for the resubmission.
  - The July 20, 2006 receipt date must be met; late applications will not be considered.
- Qualifications for special resubmission dates are listed in the following NIH Guide Notice: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-013.html>

26

## ELECTRONIC RECEIPT OF APPLICATIONS

27

## NIH's Electronic Receipt Goal

By the end of September 2007, NIH plans to:

- Require electronic submission through Grants.gov for all NIH grant applications.
- Transition from the PHS 398 application form to SF424 family of forms data set.
  1. SF424 Research and Research-Related (SF424 [R&R])
  2. SF424 Discretionary (of limited use for NIH)

Revised Timeline:

[http://era.nih.gov/ElectronicReceipt/files/Electronic\\_receipt\\_timeline\\_Ext.pdf](http://era.nih.gov/ElectronicReceipt/files/Electronic_receipt_timeline_Ext.pdf)

Announced in the NIH Guide, Aug. 19, 2005:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-067.html>

28

## Why Transition to Electronic Receipt?

- Eliminates the burden of paper-based data collection
- Resulting efficiencies may allow NIH to shorten the cycle from application receipt to award
  - AREA Grants an early win!
- Electronic validations improve data quality
- Reductions of scanning, printing, and data-entry costs
- Grant image is consistent, clear and in color

29

## Why Transition to SF424 (R&R)?

- SF424 (R&R) is the government-wide data set for research grant applications
  - Applicants can use standard forms regardless of the program or agency to which they are applying
  - Reduces administrative burden on the Federal grants community

30

## Why Transition Now?

- **Public Law (PL) 106-107**
  - **Federal Financial Assistance Management Improvement Act of 1999**
    - Improve the effectiveness and performance of Federal financial assistance programs
    - Simplify Federal financial assistance application and reporting requirements
    - Improve the delivery of services to the public
- **President's Management Agenda (2002)**
  - "Agencies to allow applicants for Federal Grants to apply for, and ultimately manage, grant funds online through a common web site, simplifying grants management and eliminating redundancies . . ."

31

## Why Transition Now?

- OMB has set the following FY 2006 Goal for Agencies: Post 75% of Funding Opportunities in Grants.gov "Find" on "Apply"
- The PHS 398 OMB clearance expires in September 2007

32

## This is a Huge Transition for All of Us!

- The simultaneous transition to electronic application submission and a new set of application forms is a huge initiative for NIH with an aggressive time table
- It involves:
  - Many funding mechanisms
  - Tens of thousands of applications ranging widely in size and complexity
  - Numerous communications from NIH staff and applicant organizations regarding the new submission process and application form set
- The transition relies upon many pieces for its success:
  - Technical development of eRA and Grants.gov systems
  - Trans-agency resolution of policy and operational issues
  - Lots of communications, training and outreach
  - Acceptance of change by NIH staff
  - Acceptance of change by our research partners in the extramural community.

33

## Multiple Systems Working Together

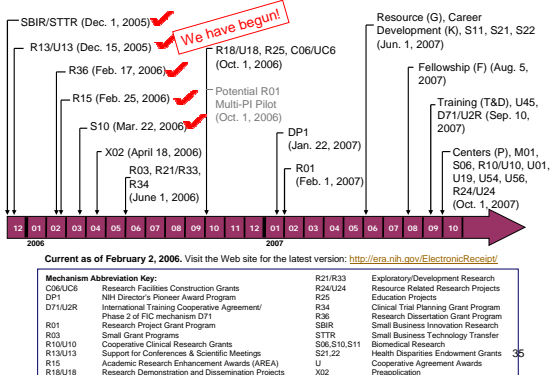
- **Grants.gov** – the Federal government's single on-line portal to find and apply for Federal grant funding.
  - Used by all 26 Federal grant-making agencies.
- **eRA Commons** – the NIH electronic Research Administration system that allows applicants/grantees to electronically receive and transmit application and award information.
  - Used by NIH and other HHS components.

**Important!**

Each system has its own registration requirements and validation process.

34

## NIH Planned Transition Dates of Mechanisms for Electronic Submission using the SF424 (R&R)



35

## Registration Requirements

- Both Grants.gov (organization only) and eRA Commons (organization and PI) registration is required for electronic submission.
- These are separate processes that can be done simultaneously.
- All registrations must be **completed prior to application submission**.
- Failure to complete the required registrations prior to application submission may result in delay of review assignment and funding consideration.
- See <http://era.nih.gov/ElectronicReceipt/preparing.htm> for additional information.

It is critical for institutions to begin these registrations at least 2-4 weeks before applications are due!

36

## Software Requirements

- PureEdge viewer downloaded (free) from Grants.gov site at <http://www.grants.gov/DownloadViewer>
- PDF generation software
  - Grants.gov lists some available tools and software <http://www.grants.gov/assets/PDFConversion.pdf>.
- MAC users will need to use PC emulation software or download free CITRIX client application to take advantage of the CITRIX service offered by Grants.gov in partnership with NIH. <http://www.grants.gov/MacSupport>
  - PureEdge has committed to providing a platform independent viewer by November 2006. PureEdge viewer downloaded (free) from Grants.gov site at <http://www.grants.gov/DownloadViewer>

37

## New Business Process: Posting Funding Opportunity Announcements (FOAs)

- Funding Opportunity Announcements will continue to be posted in the NIH Guide and Contracts (<http://grants2.nih.gov/grants/guide/>)
  - Button added to the NIH Guide announcements allowing applicants to access the Grants.gov application package directly from the NIH Guide 
  - NIH will continue to use RFAs and PAs, but all solicitations will be referred to as funding opportunity announcements (FOA) in Grants.gov
- FOAs will simultaneously be posted to Grants.gov along with the appropriate application package
  - Note that you must search Grants.gov by opportunity number rather than CFDA number for NIH opportunities.

38

## Using Standard Forms to Apply Through Grants.Gov is a Very Different Model

- The application form and instructions will now be part of a package that NIH posts on Grants.gov along with each funding opportunity announcement (FOA).
- Applicants will download the application package for the specific funding opportunity announcement from within Grants.gov .
- This specific application package MUST be used to apply for the accompanying solicitation.
  - Some fields of application are pre-filled from announcement

39

## On-Time Submission

- On-time submission has 2 elements:
    1. Application accepted by Grants.gov by 8:00pm ET on the submission date
    2. Verify application image within 2 days of availability in the NIH Commons
  - During initial transition period, NIH validation errors may be corrected within 1 week period after receipt date
- \* NIH's late application policy still in effect

40

## NIH's Transition Strategy

- NIH is transitioning by individual research program/funding mechanism
- ALL applications in response to these announcements for transitioned mechanisms require electronic submission through Grants.gov on the SF424 family of forms
- Mechanisms not yet transitioned will continue to require paper PHS 398 submission
- NIH will announce plans to transition mechanisms in NIH Guide for Grants and Contracts

41

## Advice From Experience

**Important!**

### Read and follow all application instructions!

- Failure to follow instructions has resulted in applicants having to submit corrected applications.
- Two most common problems with applications to date:
  - There are application fields not marked as mandatory on the federal-wide form but that are required by NIH
    - Example: The credential field of the R&R Senior/Key Person Profile component MUST contain the PI's assigned eRA Commons User ID for NIH to process the application submission
  - All non-Pure Edge attachments MUST be in PDF format
    - NIH systems cannot accommodate other types of documents

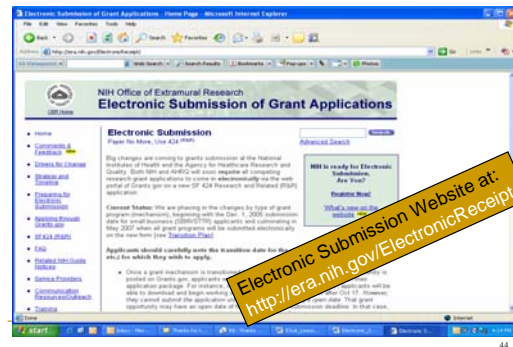
42

## Advice From Experience

- Register now to be prepared!
- Allow time for corrections.
- See it through to verification in eRA Commons to complete the application process.
- When seeking support, be prepared to provide identifying information for your application and organization.

43

## Where to Find More Information



44

## Where To Go For Help

- General information on Electronic Submission and the SF424 (R&R):
  - <http://era.nih.gov/ElectronicReceipt>
- Grants.gov registration, submission and Pure Edge behavior questions:
  - Visit: <http://www.grants.gov/CustomerSupport>
  - Grants.gov Customer Service
    - E-mail: [support@grants.gov](mailto:support@grants.gov)
    - Phone: 1-800-518-4726
- eRA Commons registration and post submission questions on Commons functionality
  - Support Page: <http://era.nih.gov/commons/index.cfm>
  - eRA Commons Help Desk
    - E-mail: [commons@od.nih.gov](mailto:commons@od.nih.gov)
    - Phone: 1-866-504-9552 OR 301-402-7469
- Forms transition and questions on NIH's overall plan for electronic receipt
  - NIH Grants Information
    - E-mail: [grantsinfo@nih.gov](mailto:grantsinfo@nih.gov)
    - Phone: 301-435-0714

45

## eRA COMMONS

46

## eRA Commons' Functionality

- Administration
- Just-In-Time (JIT) Information
- Request for No-Cost Extensions
- Financial Status Reports (FSR)
- Closeout
- Electronic Streamlined Non-Competing Award Process (eSNAP) (Note: eSNAPs increased fourfold from FY 2004 to FY 2005)
- Internet Assisted Review (IAR)
- Demo Facility

47

## eRA Commons' Functionality: Important for Investigator Access

- Status
  - Priority Score\*
  - Summary Statement\*
  - E-Submission application
  - NOGA
  - View all applications

\* This is the only place for PIs to access this information.

48

## What's in the Future? Organizational Hierarchy

- Ability for organizations, such as Institutes and Centers (ICs) and grantee institutions, to define different levels to their organization for different business areas and assign particular roles and rights associated with each.
- Allow grantees to:
  - Define hierarchy structure of their organization
  - Assign rights to hierarchy levels
  - Allocate staff within the hierarchy
  - Staff will be able to view only the grants and projects to which they are given access

49

## PAPERLESS NOTIFICATION PROCESS

50

## NIH Moves Toward Paperless Notification Process

- The NIH announced it is eliminating mailing of the following paper notifications:
  - Summary Statements – Effective October 1, 2005
  - Peer Review Outcome Letters – Effective February 1, 2006

- PIs and Fellows can access this information through the eRA Commons.

In order to avoid delays in the e-notification process, it is vital that grantees and PIs register in the eRA Commons and periodically check e-mail addresses for accuracy. PIs should consult with their business office for creating a Commons account.

- eRA Commons Home Page: <https://commons.era.nih.gov/commons/>
- NIH Guide Notice, September 8, 2005: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-075.html>

51

## NRSA: APPLICATION & FY2006 BUDGET NEWS

52

## PHS 416-1 Kirschstein-NRSA Application:

### Revised Instructions & Forms Available

- The newly revised "Application for an Individual Fellowship Ruth L. Kirschstein National Research Service Award" (PHS 416-1, rev. 10/05) instructions and forms are now available and will be accepted for submission/receipt dates on or after January 5, 2006.
- All applications received for submission dates on or after May 10, 2006 must use only the new instructions and forms; otherwise, those applications will be returned to the applicant.
- The newly revised instructions and forms are available at <http://grants.nih.gov/grants/forms.htm>.

NIH Guide Notice for PHS 416-1  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-016.html>

53

## PHS 416-9 Kirschstein-NRSA Continuation Progress Report:

### Revised Instructions & Forms Available

- The newly revised "Progress Report for Continuation Support of an Individual Fellowship Ruth L. Kirschstein National Research Service Award" (PHS 416-9, rev. 10/05) instructions and forms are now available and will be accepted for submission immediately.
- All progress reports received on or after June 1, 2006 must use the new version.
- The newly revised instructions and forms are available at <http://grants.nih.gov/grants/forms.htm>.

NIH Guide Notice for PHS 416-9:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-017.html>

54

## FY 2006 Ruth L. Kirschstein – NRSA Stipend & Other Budgetary Level Changes

NIH Guide Notice, January 9, 2006:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-026.html>

### STIPENDS:

- Revised stipend levels for Postdocs at 0 and 1 years of experience.
  - All other levels remain the same as FY 2005.
- In effect for all Kirschstein-NRSA awards made on or after October 1, 2005.
- Retroactive adjustments or supplementation to stipend levels and/or other budget categories made prior to Oct. 1, 2005 are not permitted.

### INSTITUTIONAL ALLOWANCES:

- Individual Fellows Sponsored by non-Federal, Public, & Private Institutions:
  - Postdoctoral Fellows - \$7000 (and increase of \$500 from FY 2005)
- Individual Fellows Sponsored by Federal and For-Profit Institutions:
  - Postdoctoral Fellows - \$5,900 (and increase of \$500 from FY 2005)
- No additional changes to Institutional Allowances
- Applies to all competing and non-competing NRSA awards made with FY 2006 funds.
- Any FY 2006 awards issued using previously-approved levels will be revised.

### TRAINING RELATED EXPENSES:

- There are no changes from FY 2005 levels.

55

## THE PRESENT (and the Past)

Policy Issues that Affect Today's Grants Process and Continue to Impact Our Future

- Outreach to Grantee Community
- Response to Hurricane Katrina
- PHS 398 & PHS 2590: Application/Progress Report FAQs & Important Reminders
- Career Award Reminders
- Other Policy Reminders
- News from OLAW
- OHRP Guidance
- Compliance & Audit Issues
- NIH Contacts and Electronic Resources

## OUTREACH TO GRANTEE COMMUNITY

57



- January 2006 Inaugural Issue
- Bi-monthly Newsletter produced by the NIH Office of Extramural Research (OER) for the grantee community
- Updates on NIH policies and activities
- An opportunity to gain a better understanding of the operation of extramural programs.
- Two-way communications portal — we will be listening to you and plan to modify the content of the *Nexus* accordingly.
- To subscribe to the *NIH Extramural Nexus*, send a plain text email to [Listserv@list.nih.gov](mailto:Listserv@list.nih.gov) including only the words **Subscribe EXTRAMURALNEXUS** in the body of the message.

58

## NIH Regional Seminars on Program Funding and Grants Administration

- NIH holds 2 Regional Seminars a year to educate research administrators, investigators new to NIH, and trainees
- 2006 seminars:
  - March 30-31, 2005 in Boston, MA
  - May 31-June 1, 2006 in Riverside, CA
- Seminar and Registration Information: <http://grants1.nih.gov/grants/seminars.htm>

Due to the popularity of these seminars and availability of space -  
Early Registration is Highly Recommended!

59

**Workshops and Seminars:**  
<http://grants1.nih.gov/grants/outreach.htm>

## RESPONSE TO HURRICANE KATRINA

61

## RESPONSE TO HURRICANE KATRINA

NIH Grants Hurricane Recovery  
Contact: George Gardner, Division of Grants Policy, OPERA, OER, OD  
Questions may be addressed to a central mailbox address ([nihggr@nih.gov](mailto:nihggr@nih.gov)) or by phone at 301-435-8140.

NIH website dedicated to post-Katrina information for biomedical research community:

<http://grants.nih.gov/grants/katrina/index.htm>.

- Letters to NIH Research Community
- Related Federal Web Sites
- Research Community Information
- Links for Affected Institutions
- Frequently Asked Questions
- NIH Guide Notices

62

## PHS 398 (Rev. 09/04) (Competing Grant Application) and PHS 2590 (Rev. 09/04) (NonCompeting Progress Report)

NIH Guide Notice, November 2, 2004:  
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-006.html>  
Revised instructions and forms:  
<http://grants.nih.gov/grants/forms.htm>

63

## PHS 398 (Rev. 09/04) Competing Grant Application: Looking to the Future

- Modifications to the PHS 398 are currently underway as a result of significant changes to the NIH grants process (i.e.: multiple PIs, transition to the SF 424 R&R by Sept. 2007, etc.)
- Grantees are advised to watch for the following in FY 2006:
  - Revised PHS 398 Instructions
  - Changes to accommodate consistent business processes
- Sources of Information include:
  - NIH Guide to Grants & Contracts, <http://grants.nih.gov/grants/guide/index.html>
  - PHS 398 Webpage (Includes instructions, forms, & recent changes) <http://grants.nih.gov/grants/funding/phs398/phs398.html>

64

## Applications and Forms: Questions and Contacts

Dedicated e-mail address for questions on format:

[format@mail.nih.gov](mailto:format@mail.nih.gov)

Additional Forms & Formatting Contacts:

- For questions relating to application/forms submission and policy, please contact:
  - NIH GrantsInfo Office at [grantsinfo@nih.gov](mailto:grantsinfo@nih.gov) or (301) 435-0714 <http://grants.nih.gov/grants/forms.htm#help>.
- For technical assistance regarding the use of the PHS forms:
  - E-mail the PHS Forms Help Desk at: [phsforms@peacetech.com](mailto:phsforms@peacetech.com).
- For additional questions concerning format specifications, (e.g., font typeface and size, line and character spacing per inch, page limits, and margins):
  - E-mail the following dedicated address at [format@mail.nih.gov](mailto:format@mail.nih.gov).

65

## IMPORTANT APPLICATION REMINDERS

66

## Change in Calculation of Direct Costs for Applications with Consortium F&A Costs

All applications that involve consortium/contractual facilities and administrative (F&A) costs are to exclude the facilities and administrative (F&A) costs requested by consortium participants from the total direct cost request.

NIH Guide Notice, November 2, 2004:  
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html>

Effective for all applications that have submission/receipt dates on or after Dec 1, 2004

67

## Graduate Student Compensation

- Ties compensation on research grants to the zero level NRSA postdoc stipend in effect at the time of award
- Compensation continues to include "salary or wages, fringe benefits and tuition remission"
- No adjustments will be made to noncompeting award levels or future years
- Grantees may rebudget to accommodate the higher level
- This policy was effective with awards issued on or after 12/10/2001:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html>

68

## Applications and Forms: Restriction on Submission

Prior approval is required for competing applications that request \$500,000 total direct costs or more for *any* budget period.

NIH Guide Notice, October 16, 2001:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>

69

## Other Support

- NIH requires **complete** and **up-to-date** other support information before an award can be made
  - Complete means **all** sources of research support (including outside the applicant organization)
- Grantees must report changes in other support as part of the annual progress report

NIH Guide, February 13, 2003:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-029.html>

70

## NIH Policy on Late Submission of Grant Applications

- NIH expects grant applications to be submitted on time
- Late applications
  - Generally are not accepted, except in rare instances
    - Unaccepted late applications will be returned without review
  - Are only considered for standing receipt dates
  - Permission is **not** granted in advance
  - Must be accompanied by a cover letter with compelling reasons for the delay
  - Window of consideration for late applications is two weeks
- NIH will not consider accepting late applications for the Special Receipt Dates for RFAs and PARs

NIH Guide, January 27, 2005  
<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-05-030.html>

71

## Non-Competing Continuation Progress Reports

**REMINDER—Don't Be Late!**  
A recent OIG study concluded that major contributing factors to late awards were late and/or incomplete progress reports.

- An annual progress report is due two months prior to anniversary date.
- All grantees have access to searchable list of due progress reports at:  
[http://era.nih.gov/userreports/pr\\_due.cfm](http://era.nih.gov/userreports/pr_due.cfm)
- NIH e-mails 2 progress report reminders to the PI
  - Two months prior to the due date
  - Two weeks after the due date for overdue report
- NIH Guide, August 5, 2003:  
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-054.html>
- Centralized Receipt of ALL NIH Progress Reports – effective 10/1/04  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-054.html>

72

## CAREER AWARD REMINDERS

73

## Policy on Concurrent Support for Mentored Career Awardees

Mentored career awardees (K awardees) may now hold concurrent support from an NIH career award and an NIH research grant.

NIH Guide, November 14, 2003:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-007.html>

Information About Career Development Awards:

<http://grants.nih.gov/training/careerdevelopmentawards.htm>

74

## Policy on Concurrent Support for Mentored Career Awardees

- May reduce level of effort on career awards in last two years of support and replace with an NIH research grant or subproject -- awardee must remain in mentored situation
- Awardee must serve as a PI or subproject Director
- Effort required on career award may be reduced to no less than 50% and be replaced by effort from the research award so total level of research commitment remains at  $\geq 75\%$  for the duration of the mentored career award
- Applies to K01, K07, K08, K22, K23, and K25, and individuals mentored through institutional K12 awards
- Policy effective for competing research applications submitted on or after February 1, 2004

75

## Revised Definition of Full Time Appointment for Career Awards

- Require 75% commitment of full-time professional effort
- Revised policy allows recipient to meet required commitment of total professional effort as long as:
  1. the individual has a full-time appointment with the applicant organization
  2. the minimum percentage of the candidate's commitment required for the proposed Career award experience is covered by that appointment
- Applies to all existing Career Development Award announcements for all applications and resubmissions submitted on/after October 1, 2004

NIH Guide Notice, August 3, 2004:

<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-056.html>

76

## OTHER POLICY REMINDERS

77

## NIH Policy on Sharing of Model Organisms for Biomedical Research



Investigators submitting an NIH application/proposal beginning with the October 1, 2004 receipt date are expected to include a specific plan for sharing and distributing unique model organism research resources generated using NIH funding in the application/proposal OR state appropriate reasons for why such sharing is restricted or not possible.



NIH Guide Notice: May 7, 2004

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>

FAQs and sample sharing plans available at:

[http://grants.nih.gov/grants/policy/model\\_organism/index.htm](http://grants.nih.gov/grants/policy/model_organism/index.htm)

78

## NIH Policy on Data Sharing

Investigators submitting a research application requesting \$500,000 or more of direct costs in any single budget period to NIH on or after October 1, 2003 must include a plan for sharing final research data for research purposes, or state why data sharing is not possible.

NIH Guide Notice, February 26, 2003:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

NIH Guide Notice, October 16, 2001:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>

79

## INVENTION REPORTING & INTELLECTUAL PROPERTY

80

## Invention Reporting Requirements of Grantee/Contractors per the Bayh-Dole Act

Administrative Requirements (per 37CFR, 401.14)

- Implement Employee Agreements ⇨ at employment
- Disclose Each Invention ⇨ within 60 days
- Resolve Election or Waive of Title ⇨ within 2 years
- File Patent ⇨ within 1 yr. of election
- Provide License to the Govt. ⇨ upon title election
- Indicate Govt. Support on Patent ⇨ with patent appl.
- Share Royalties With Inventor ⇨ when available
- License Small Businesses ⇨ where feasible
- Product Manufacturing in U.S. ⇨ required
- Report on Invention Utilization ⇨ annually

81

## Intellectual Property

- Information on reporting requirements and policy, as well as electronic systems to fulfill reporting requirements, may be found at Interagency Edison, <http://www.iedison.gov>.
- All foreign grantees, contractors, consortium participants and/or subcontractors are reminded that they must comply with Bayh-Dole invention reporting requirements.

82

## Closeout Final Reports

Documents are due within 90 days of project period end date

- Final Financial Status Report (FSR)
- Final Inventions Statement & Certification
- Final Progress Report

*Failure to submit timely reports may affect future funding to the organization!*

83

## NEWS FROM THE OFFICE OF LABORATORY ANIMAL WELFARE (OLAW)

84

## News from OLAW

<http://grants1.nih.gov/grants/olaw/olaw.htm>

- Resource Book for the Design of Animal Exercise Protocols available from OLAW
- NIH Requests Information on New Standards for the Care and Use of Laboratory Animals
- New ILAR Report, Guidelines for the Humane Transportation of Research Animals  
The report offers science-based guidelines for humane transportation [http://www.nap.edu/execsumm\\_pdf/11557.pdf](http://www.nap.edu/execsumm_pdf/11557.pdf)
- IACUC 101 and PRIMR/ARENA Annual IACUC Meeting in Boston (March)  
[http://primr.org/education/2006\\_IACUC/overview\\_IACUC06.html](http://primr.org/education/2006_IACUC/overview_IACUC06.html)
- IACUC 101 and 201 Workshops in Richmond, Virginia (April)  
<http://www.research.vcu.edu/events/iacuc101201>



## GUIDANCE FROM THE OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)

86

## OHRP News: MPAs & CPAs Expired

(Multiple Project Assurances & Cooperative Project Assurances)

- Any institution that has not obtained an OHRP-approved FWA as of January 1, 2006 will no longer be covered by an OHRP-approved assurance of compliance until the institution submits, and OHRP approves, an FWA.
- Single Project Assurances (SPAs) currently approved by OHRP will remain in effect for the duration of the project and through all non-competitive award renewals.
- You are strongly encouraged to use the OHRP Electronic Submission System (ESS) for any new IRB/IEC registration or new FWA, as well as for all updates/renewals: <http://ohrp.cit.nih.gov/efile>
- For questions about registering an IRB/IEC or submitting an FWA, please contact your regional coordinator at OHRP: <http://www.hhs.gov/ohrp/dagi-staff.html#staff>

NIH Guide Notice, December 2, 2005:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-015.html>

87

## NIH Implementation of OHRP Guidance on Research Involving Coded Private Information or Biological Specimens

- NIH added definitions and clarifications relevant to the OHRP Guidance to the PHS 398 (rev. 9/04) instructions.
- All grant applications and progress reports involving coded private information or biological specimens submitted on or after January 10, 2005 should follow the revised instructions.

NIH Guide, December 30, 2004:  
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-020.html>  
OHRP Guidance, August 10, 2004:  
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

88

## Guidance for Protecting Research Subjects from Possible Harm Caused by Financial Conflicts of Interest

- Guidance entitled, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection," published May 12, 2004.
- Applies to all human subjects research conducted or supported by HHS agencies or regulated by the FDA.
- Intended for:
  - Institutional Review Boards (IRBs)
  - Investigators
  - Research institutions
  - Other interested parties

Federal Register notice:  
<http://ohrp.osophs.dhhs.gov/humansubjects/finretn/finalguid.pdf>  
HHS press release: <http://www.hhs.gov/news/press/2004pres/20040512.html>

89

## COMPLIANCE ISSUES

90

## Division of Grants Compliance and Oversight, OPERA, OER

### Internal Compliance Activities

- Grants Management Professional Certification Program
- Management Controls Compliance Model
- Audit oversight
- Guidance for NIH grants management staff
  - Compliance issues
  - Policy Interpretation and application

91

## Division of Grants Compliance and Oversight, OPERA, OER

### External Compliance Activities

- Institutional compliance
  - Technical assistance
  - Corrective action plans
- Outreach
  - Educational seminars
  - National and regional meetings
  - NIH Regional Seminars
- Proactive Compliance Site Visits
- Targeted Site Reviews

92

## NIH Proactive Compliance Site Visits

- Assess the level of understanding of certain Federal/NIH requirements 37 grantees visited since FY 2000
  - Roles and Responsibilities
  - Training and Education
  - Financial Management
  - Financial Conflict of Interest
  - Invention and Patent Reporting
  - Administering and Overseeing Clinical Research

93

## NIH Targeted Site Reviews: Financial Conflict of Interest (FCOI)

- In response to increasing public interest
- A new initiative to determine whether grantee institutions have:
  - Fully implemented the FCOI regulations as they pertain to grants (42 CFR Part 50 Subpart F), and
  - Complied with reporting requirements
- Eight completed since FY 2005

94

## Financial Conflict of Interest Summary of Reporting Requirements

1. At the time of application: Investigators must submit significant financial interests to the institution.
2. Prior to the expenditure of funds: The institution must report a financial conflict of interest to the NIH and assure that it has been managed, reduced, or eliminated.
3. Financial conflicts of interest identified after the initial report: The institution must report within 60 days of identification and assure that it has been managed, reduced, or eliminated.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-013.html>

95

## Definition of Investigator

**Investigator** – Principal Investigator (PI) and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding

The term "Investigator" includes the Investigator's spouse and dependent children

### Let's Clarify.....

- An **investigator** is not just the Principal Investigator conducting the PHS sponsored research. It can be...
- **Anyone** (i.e., key personnel, lab technicians, etc.) that is involved in the **design, conduct, or reporting** of the PHS sponsored research

96

## Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards

- Developed by the HHS OIG
- The compliance program guidance is intended to serve as a set of guidelines for developing and implementing a compliance program or evaluating an existing one
- The compliance program guidance does not:
  - Establish a set of program rules or standards
  - Establish criteria by which to conduct audits or review of regulatory or program compliance

97

## Fundamental Elements of an Effective Compliance Program

- The OIG guidance encourages the development of a compliance program that relies on eight elements:
  - Implementing written policies and procedures
  - Designating a compliance officer and compliance committee
  - Conducting effective training and education
  - Developing effective lines of communication
  - Conducting internal monitoring and auditing
  - Enforcing standards through well-publicized disciplinary guidelines
  - Responding promptly to detected problems and undertaking corrective action
  - Defining roles and responsibilities and assigning oversight responsibility

98

## Compliance is an Institutional Commitment!



Compliance Questions for NIH?: [GrantsCompliance@nih.gov](mailto:GrantsCompliance@nih.gov)

99

## AUDIT ISSUES

100

## Audit Requirement

- All NIH grantees that expend \$500,000 (for fiscal years ending after December 31, 2003) or more in a year in Federal awards are subject to an audit requirement.
- Audits are due no later than 9 months after the end of the grantee's audit period.
- Grantees delinquent in submitting audits risk the imposition of sanctions and potential loss of Federal funds.

101

## Summary of Audit Requirements

Grantee Type	Source of Audit Requirement	Where to Submit Audit Reports
State & Local Governments	OMB Circular A-133	Federal Audit Clearinghouse 1201 E. 10th Street Jeffersonville, IN 47132 Questions: 1-800-253-0696 or <a href="mailto:govs.fac@census.gov">govs.fac@census.gov</a>
Colleges & Universities		
Non-Profits		
Hospitals		
For-Profits	45 CFR Part 74.26 (d)	National External Audit Review Center HHS Office of Audit Services 323 West 8th Street Lucas Place, Room 514 Kansas City, MO 64105 Phone: 800-732-0679 or 916-374-6714
Foreign	NIH Grants Policy Statement (same as For-Profits)	(same as For-Profits)

## NIH CONTACTS AND ELECTRONIC RESOURCES

103

## Summary of Helpful NIH Web Pages

- Office of Extramural Research Administration homepage – Links to Funding opportunities, Grants Policy, Application and Forms, Awarded Grant data  
<http://grants1.nih.gov/grants/oer.htm>
- NIH searchable database of RFAs, PAs, and Guide Notices  
<http://grants1.nih.gov/grants/guide/index.html>
- NIH Grants Policy Statement (Rev. 12/03)  
[http://grants1.nih.gov/grants/policy/nihgps\\_2003/index.htm](http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm)
- eRA Homepage  
<http://commons.era.nih.gov/>
- Electronic Submission of Grant Applications Homepage  
<http://era.nih.gov/ElectronicReceipt/index.htm>
- CRISP database - Search to analyze an Institute's portfolio of funded projects, research areas, and more.  
[http://crisp.cit.nih.gov/crisp/crisp\\_query.generate\\_screen](http://crisp.cit.nih.gov/crisp/crisp_query.generate_screen)
- All About Grants Tutorial (NIAID) - provides information on grant application basics: planning, writing, and managing tips  
<http://www.niaid.nih.gov/ncn/grants/default.htm>

104

## Updated Contact Sources

- Revised “Grants Administration Information Sources” is now available at:  
[http://grants.nih.gov/grants/policy/grants\\_info.pdf](http://grants.nih.gov/grants/policy/grants_info.pdf)
  - Provides updated contact information for Grants Administration individuals at all NIH ICs
- Contact list for NIH Chief Grants Management Officers posted at:  
[http://grants.nih.gov/grants/stafflist\\_gmos.htm](http://grants.nih.gov/grants/stafflist_gmos.htm)

105

## Grants Information: Who to Contact!

### Application-Specific Questions:

#### Administrative:

Contact the Grants Management Specialist at the Awarding Institute/Center

#### Scientific/Programmatic:

Contact designated Program Official/Director at Awarding Institute/Center

#### Review Questions:

Contact the assigned Scientific Review Administrator

106

## Grants Information: Who to Contact!

**General Application Questions:** (Including e-Submission guidelines, resources & referrals, application review & award process, etc.)

E-Mail: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)  
Phone: 301-435-0714

**Customer Support for Grants.gov:** (Including navigating PureEdge forms, aspects of submitting through the system, resources available, etc.)

E-Mail: [support@grants.gov](mailto:support@grants.gov)  
Webpage: <http://grants.gov/>  
Phone: 1-800-518-4726

**eRA Commons Help Desk:** (Including Commons registration help, application verification, Commons functionality questions, etc.)

E-Mail: [commons@od.nih.gov](mailto:commons@od.nih.gov)  
Webpage: <https://commons.era.nih.gov/commons/index.jsp>  
Phone: 301-402-7469 (Toll Free: 866-504-9552)

**Grants Policy Interpretation & Consultation:**

E-Mail: [GrantsPolicy@mail.nih.gov](mailto:GrantsPolicy@mail.nih.gov)  
Phone: 301-435-0949 (Toll Free: 800-518-4726)

**Compliance Issues:**

E-Mail: [GrantsCompliance@mail.nih.gov](mailto:GrantsCompliance@mail.nih.gov)  
Phone: 301-435-0949

107

# THANK YOU!

Presented by:

Joe Ellis

Director of the Office of Policy for  
Extramural Research (OPERA),  
OER, OD, NIH, HHS

George Gardner

Asst. Policy Officer, Office of Policy  
for Extramural Research (OPERA),  
OER, OD, NIH, HHS

108