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# NIH Update

## Fall 2004





# Major Trends in Public Health

- ◆ Shift from acute to chronic diseases
- ◆ Aging population
  - ★ Increasing prevalence of chronic degenerative diseases
  - ★ Multiple coexisting morbidities
  - ★ Increasing Disabilities (MSK, Vision, Hearing)
- ◆ Health Disparities
- ◆ Emerging and re-emerging diseases
  - ◆ Obesity. Diabetes
  - ◆ Infectious diseases

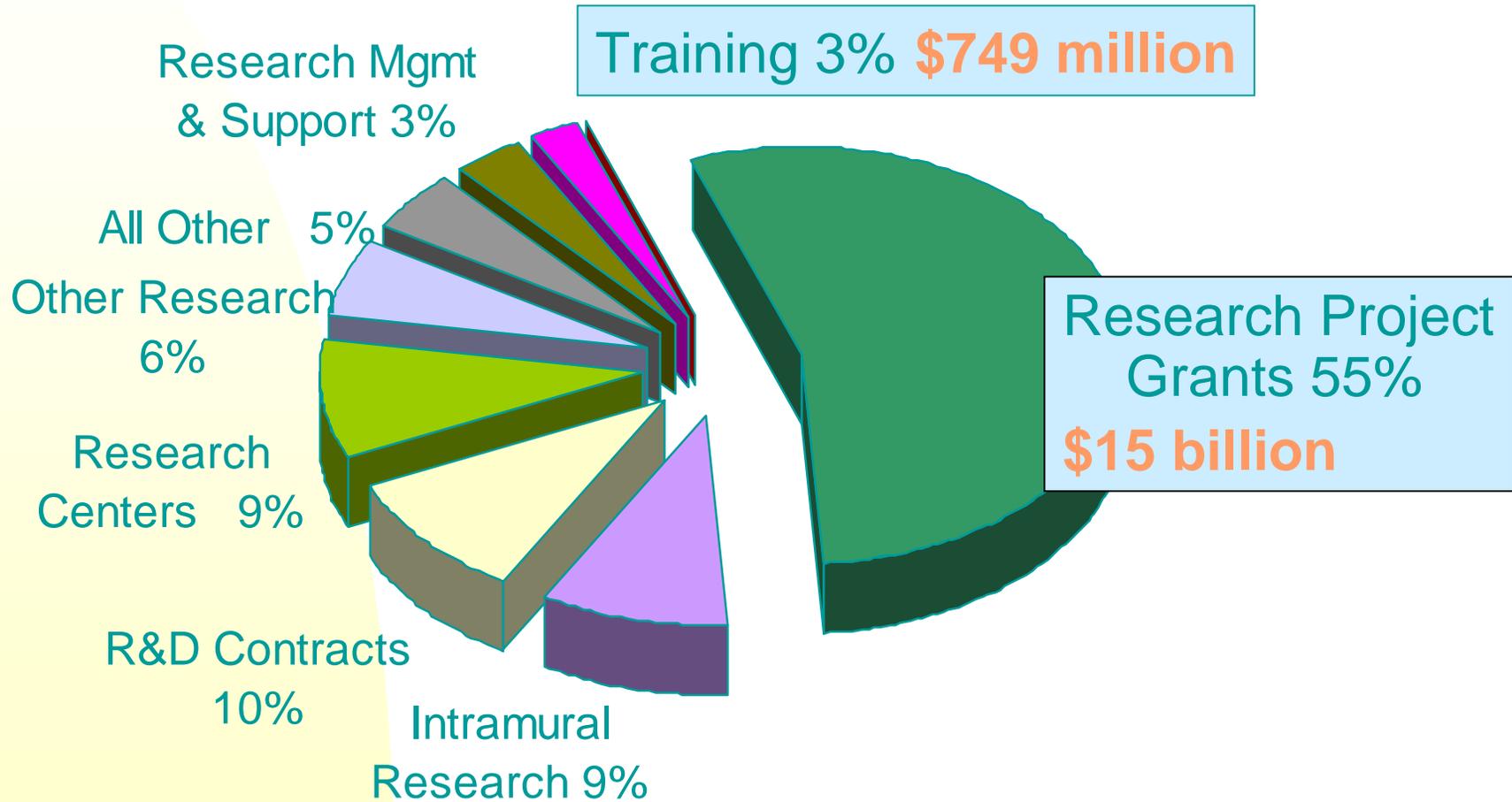


# The NIH Budget



# FY 2004 Budget

\$28.04 Billion

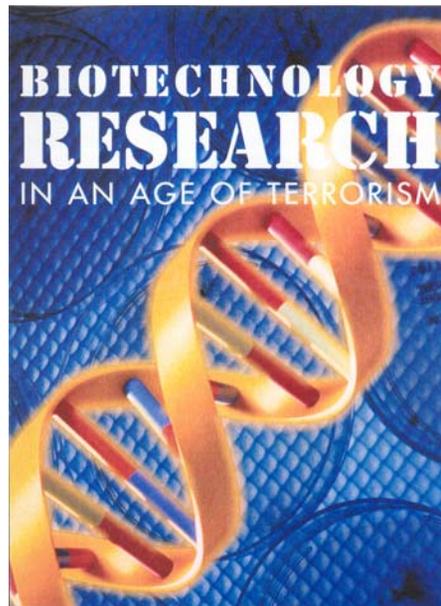


# FY '05 President's Budget Request



- ◆ \$28.757 billion
  - ◆ ~ 2.6% increase over FY 2004
- ◆ Approximately 10,400 competing RPG awards
  - ◆ ~ 260 increase over FY 2004
- ◆ Major initiatives
  - ◆ NIH Roadmap
  - ◆ Obesity
  - ◆ Biodefense
  - ◆ AIDS

# National Science Advisory Board for Biosecurity (NSABB)



# National Science Advisory Board for Biosecurity (NSABB)



New Board to provide advice and guidance regarding biological research that has the potential for misuse and could pose a biologic threat to public health or national security

- ◆ Will advise heads of Federal entities that conduct/support life sciences research
- ◆ Managed by NIH
- ◆ Further information and updates available at:  
<http://www.biosecurityboard.gov>

Stay tuned.....



# Public Access to NIH Research Information



# Comment Period on Proposed Public Access Policy



- ◆ NIH intends to request that grantees and PIs provide NIH with electronic copies of all final version manuscripts resulting from NIH funded research upon acceptance for publication
- ◆ NIH plans to archive these manuscripts in PubMed Central (PMC)
- ◆ Six months after publication—or sooner if the publisher agrees—the manuscript will be made available freely to the public through PMC
- ◆ **Public comments accepted for 60 days from publication of the Federal Register Notice.**

NIH Guide, September 3, 2004

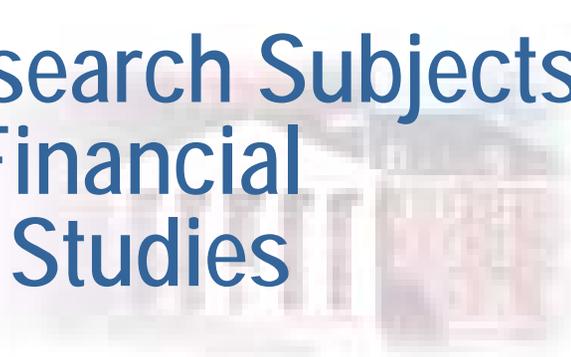
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-064.html>



# Protecting Research Subjects



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



- ◆ New guidance document 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/finreltn/finalguid.pdf>

HHS press release:

<http://www.hhs.gov/news/press/2004pres/20040512.html>

# OHRP Guidance on Research Involving Coded Private Information and Biological Specimens



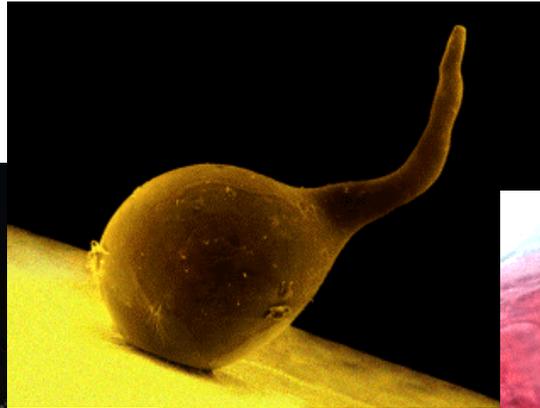
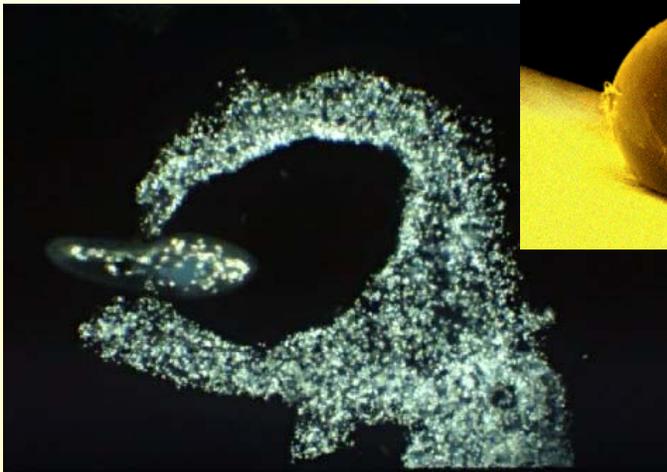
- ◆ Office for Human Research Protections (OHRP) issued guidance on August 10, 2004
- ◆ NIH is assessing how best to implement the OHRP Guidance
- ◆ Stay tuned...

OHRP Guidance, August 10, 2004

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>



# Model Organisms



# New 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)



# Other Changes to Application Instructions

# Change in Direct Cost Limitation on Solicited Applications



Effective April 30, 2004,

Applications (RFAs) that include a limitation on direct costs are to exclude from that limit the facilities and administrative (F&A) costs requested by consortium participants.

NIH Guide notice, April 30, 2004:

<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-040.html>

# Centralized Receipt of Non-Competing Progress Reports



- ◆ Effective with non-competing progress reports due on/after October 1, 2004
- ◆ Does NOT change the mailing address used for all new and competing grants nor that process
- ◆ Only for NIH progress reports
- ◆ Goal of improving efficiency

NIH Guide Notices, July 23 and September 2, 2004

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-054.html>

<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-063.html>

# Revisions to the PHS 398 and 2590 Forms



*Application for a*  
**Public Health Service Grant**  
PHS 398



*Progress Report for a*  
**Public Health Service Grant**  
PHS 2590

# PHS 398 Revision

(Coming soon!)



- ◆ Extensively rewritten with a focus on clarity, simplicity, & plain language
- ◆ Reorganized into 3 Parts
  - ◆ Part I: Instructions (now are truly just application instructions)
  - ◆ Part II: Supplement Instructions for Preparing the Human Subjects Section of the Research Plan
  - ◆ Part III: Policies, Assurances, Definitions & Other Information

# PHS 398 Revision

(Coming soon!)



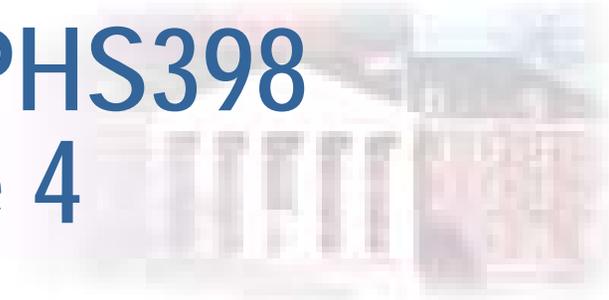
## ◆ Notable changes:

- ◆ Face Page: Adding “Clinical Trials Indicator”

- ◆ Form Page 2

- ★ **Description** now includes separate instruction for PI to clearly describe public health relevance
- ★ Created designated area for Stem Cell information
- ★ Added new section for “Other Significant Contributors”

# Sample Section of New PHS398 Budget Page, Form Page 4



- ◆ Separated Consortium DC & F&A Costs
- ◆ Instructions revised to use Subtotal for Face Page Item 7a

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
<b>SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b> <i>(Item 7a, Face Page)</i>		\$
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
<b>TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b>		\$

# PHS 398 Revision

(Coming soon!)



- ◆ Harmonizing paper & electronic submissions by adding NIH Commons ID on face page, key personnel section & biosketch
- ◆ Will continue to keep policies & definitions in sync with NIH GPS
- ◆ Expect OMB Clearance soon
- ◆ **Existing forms will be accepted until new ones become available**

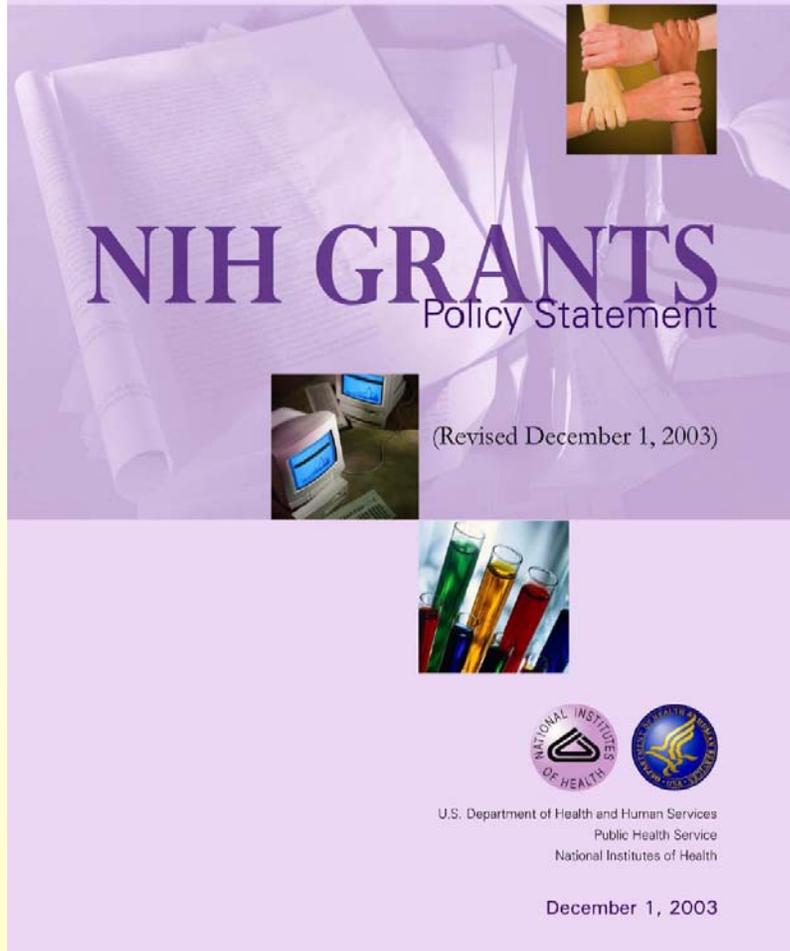
# PHS 2590 Revision

(Coming soon!)



- ◆ Included information on electronic submission via e-SNAP
- ◆ Incorporated refined definition of Key Personnel
- ◆ Incorporated new category “Other Significant Contributors” throughout instructions
- ◆ For SNAP—modified instructions to now require submission of *complete* Other Support Pages if changes in active support are noted
- ◆ Form pages available in fillable Word & PDF formats
- ◆ Expect OMB Clearance soon
- ◆ **Existing forms will be accepted until new ones become available**

# Revised NIH Grants Policy Statement



## NIH GRANTS Policy Statement

(Revised December 1, 2003)



U.S. Department of Health and Human Services  
Public Health Service  
National Institutes of Health

December 1, 2003

# Revised NIH Grants Policy Statement



- ◆ Published December 1, 2003
- ◆ New NIH Grants Policy Statement includes:
  - ◆ Revisions to NIH policies since March 2001
  - ◆ Clarifications
  - ◆ Public Policy Changes
  - ◆ Index

NIH Guide notice that highlights specific changes:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-009.html>

NIH Grants Policy Statement (12/03 revision)

[http://grants.nih.gov/grants/policy/nihgps\\_2003/index.htm](http://grants.nih.gov/grants/policy/nihgps_2003/index.htm)

# Revised Grants Policy Statement – Highlights



- ◆ **Expanded Authorities:** applies to all mechanisms and is a standard term of award
- ◆ **Audit:** threshold for A-133 audits have increased from \$300,000 to \$500,000 for fiscal years ending after 12/31/03
- ◆ **Closely Related Work:** no longer requires NIH prior approval
- ◆ **Key Personnel:** expanded definition to describe contribution of key personnel as “measurable” whether or not salaries are requested.

# Revised Grants Policy Statement – Highlights



- ◆ **Clinical Practice Plan (IBS):** Clinical practice plan appointment compensation may be considered in the base salary as long as *all* criteria are met.
- ◆ **Consortium:** grantee is responsible for including applicable requirements of the policy statement in the written agreements and written agreements must include a reference to financial conflict of interest, intellectual property, and data sharing requirements

# Revised Grants Policy Statement – Highlights



- ◆ USA PATRIOT Act
- ◆ Select Agents Law
- ◆ HIPAA
- ◆ Human Embryonic Stem Cells
- ◆ Fetal cells/tissues (FDA jurisdiction) and associated responsibilities for grantees
- ◆ Definitions: NIHGPS and PHS 398 glossaries-similar definitions were merged



# Grants Policy Statement – Clarification

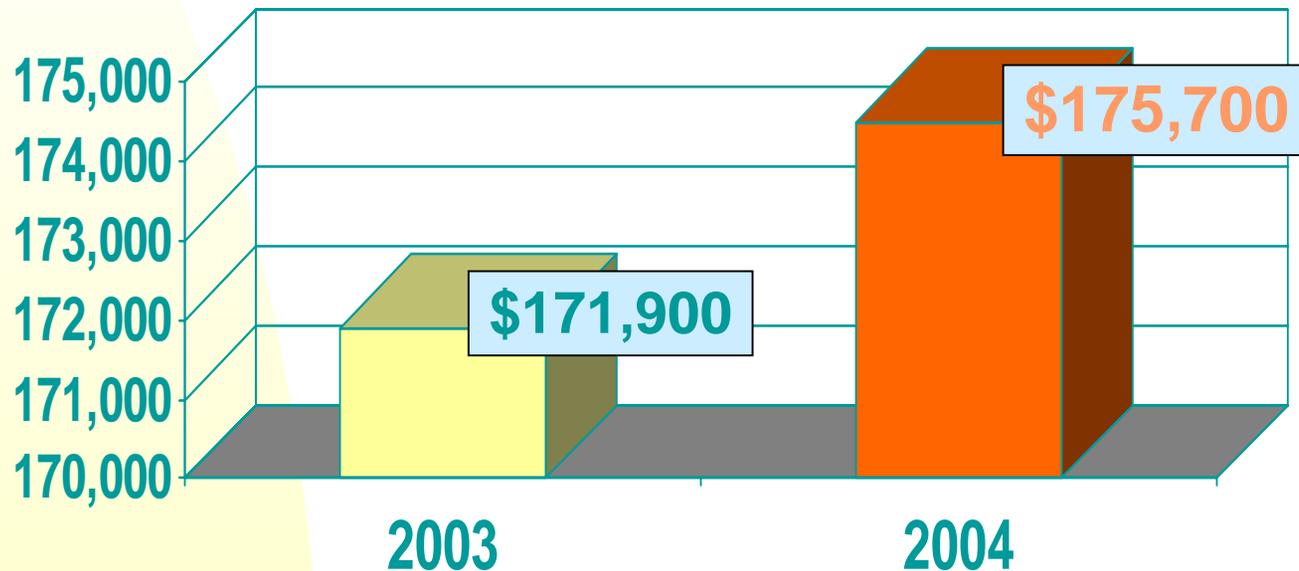
- ◆ Invention, licensing and patent costs are unallowable as a direct cost unless specifically authorized on the grant award.
  - ◆ They may be allowable as F&A costs, provided they are authorized under applicable cost principles and are included in the negotiation of F&A cost rates.



# Important Reminders

# Salary Cap

- ◆ Restricts the amount of **direct salary** under a grant or contract to Executive Level I of the Federal Executive Pay Scale
- ◆ Executive Level I increase effective January 1, 2004



February 13, 2004 NIH Guide Notice

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-025.html>



# 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

See NIH Guide, 12/10/2001

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html>

Reminder

# 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>

Reminder

# Financial Conflict of Interest

When a conflict of interest is identified, the grantee must:

- ◆ Notify Chief GMO to assure that the conflict of interest is being managed, reduced, or eliminated
- ◆ Provide additional information, if requested

FCOI requirements must be addressed in consortium agreements

See the following NIH Guide Notices for additional information:

<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html>

<http://grants2.nih.gov/grants/guide/notice-files/not95-179.html>

Reminder

# 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*

Reminder

# Revised Policy on Amended Applications



- ◆ No longer time limit on submission of revised applications
- ◆ Limit of 2 revisions remains in effect
- ◆ Applies to all NIH extramural funding mechanisms

NIH Guide Notice May 7, 2003

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html>

# 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
  - ◆ **New Business Process Beginning 10/1/2004:** Centralized Receipt of ALL NIH Progress Reports:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-054.html>

# Non-competing Continuation Grant Progress Reports



- ◆ It is important that progress reports be complete and timely
- ◆ 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 reports

NIH Guide, August 5, 2003:

<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-054.html>

# Applications and Forms: Questions?



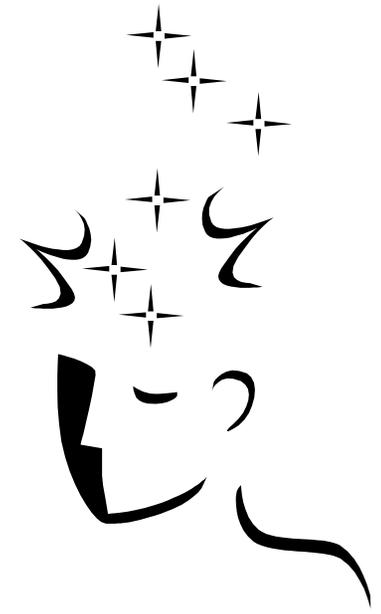
Dedicated e-mail address for questions on format:  
[format@mail.nih.gov](mailto:format@mail.nih.gov)

Frequently asked questions on format:  
<http://www.format.nih.gov>





# Intellectual Property



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

Reminder

## 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

# 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

# Compliance



# Common Institutional Compliance Issues

- ◆ Misuse of funds
- ◆ Unallowable costs
- ◆ Misallocation of costs
- ◆ Deficient effort reporting
- ◆ Inadequate subrecipient monitoring
- ◆ Delinquent closeout
- ◆ Noncompliance with assurances



# Common Contributors to Compliance Problems



- ◆ Inadequate resources
- ◆ Lack of understanding of roles and responsibilities of institutional staff
- ◆ Inadequate staff training and education
- ◆ Outdated or nonexistent policies and procedures
- ◆ Inadequate management systems (e.g., effort reporting, financial management)
- ◆ Perception that internal control systems are not necessary

# Proactive Compliance Site Visits



## Purpose:

- ◆ To assess the level of understanding of certain Federal/NIH requirements
- ◆ To assist in ensuring compliance with Federal/NIH requirements



## 37 institutions visited since FY 00:

- ◆ 29 universities/medical schools
- ◆ 6 non-profits (3 AIRI institutions)
- ◆ 2 hospitals



# Outreach and Resources

# OER Outreach Activities and Resources

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

- OER Home
- Funding Opportunities
- Applications & Forms
- Awarded Grants
- Grants Policy
- eRA
- About OER

[ [Workshops and Seminars](#) | [Additional Resources](#) ]

The NIH Office of Extramural Programs promotes personal interactions with all segments of the research community, including business partners and supports a variety of outreach activities in all regions. Outreach activities are limited to, the following:

## Workshops and Seminars

- [NIH Regional Seminars on Program Funding and Grants Administration](#)  
These 2 day seminars for faculty and administrators include topics on
  - o funding opportunities for new investigators
  - o application preparation
  - o the review process
  - o grant administration issues
  - o hot policy topics and more...
- [National Animal Welfare Workshops](#)  
The Office of Laboratory Animal Welfare (OLAW), sponsors workshops on incorporating the Public Health Service Policy into Animal Welfare Education ensuring high-quality management of institutional animal care and use programs.
- [Office for Human Research Protections \(OHRP\) Workshops](#)  
The DHHS Office for Human Research Protection offers workshops on
  - o responsibilities of researchers
  - o Institutional Review Boards (IRBs)
  - o institutional officials for the protection of human subjects in research.OHRP also offers self-instructional materials at <http://ohrp.osophs.dhhs.gov/educmat.htm>.
- [NIH Small Business Research Conferences](#)  
The Office of Extramural Programs offers conferences addressing the needs of small business researchers interested in the SBIR/STTR programs. Presentations given at past conferences are available on this site.

# NIH Regional Seminars on Program Funding and Grants Administration



- ◆ NIH holds 2 Regional Seminars a year
- ◆ 2005 seminars:
  - ◆ April 7-8, 2005 in Albuquerque, NM
  - ◆ June 23-24, 2005 in West Lafayette, IN
- ◆ Geared towards research administrators, investigators new to NIH, and trainees
- ◆ Seminar information:  
<http://grants.nih.gov/grants/seminars.htm>



## **Grants Information**

<http://grants.nih.gov/grants/oer.htm>

**Phone: 301-435-0714**

**E-Mail: GrantsInfo@nih.gov**



NIH  
eRA



# eRA Statistics NIH Commons



	<b>May '03</b>	<b>Dec. '03</b>	<b>Sept. '04</b>
<b>Institutions</b>	425	737	1,732
<b>eSNAPs</b>	165	633	2,833
<b>FSRs</b>	7,000	20,656	35,610
<b>JIT</b>	N/A	N/A	554
<b>No Cost Ext.</b>	N/A	N/A	2,894
<b>Users</b>	3,100	8,177	24,632

# Commons Functionality



## ◆ Profiles

- ◆ Institutional Profile (IPF)
- ◆ Professional Profile (PPF)

## ◆ Status

- ◆ View status of pending/awarded applications
- ◆ View and access priority score/summary statement (PI only)
- ◆ View NIH staff contact information for each application
- ◆ Link to study section rosters and dates of meetings
- ◆ Link to NGA and other grant related documents

## ◆ e-SNAP

- ◆ Submission of non-competing progress report
- ◆ Open to all Institutions October 2004

# Commons Functionality



- ◆ **FSR (Financial Status Reports)**
  - ◆ Submission of financial status reports
  - ◆ Same system is used by NIH Office of Financial Mgmt.
- ◆ **IAR (Internet Assisted Review)**
  - ◆ Reviewer submission of critiques and preliminary scores prior to study section meeting
- ◆ **Demo Facility**
  - ◆ Anyone can use (don't need a Commons Acct)
  - ◆ Contains all functionality of production system
  - ◆ User creates their own training accounts & institution
  - ◆ Standard data populates new accounts
  - ◆ Great for on-campus training classes

# Commons Functionality

## New Features (11/03)



### Submit Extensions

- ◆ Grantees can now submit notification to NIH of the initial no-cost extension of the final budget period in a previously approved competing segment.
- ◆ Automatically updates budget/project period end dates in the NIH database.
- ◆ Automatically generates e-mail notifications to assigned NIH staff and the grantee institution.
- ◆ Have until the current budget/project end date to submit (10 day window required for hard copy notifications has been waived for electronic notifications.)

# Commons Functionality

## New Features (cont)



### ◆ **Just-In-Time Submission**

- ◆ Grantees can now electronically submit the 4 data elements included in the just-in-time submission
  - ★ IACUC approval date
  - ★ IRB approval date
  - ★ Other support page for key personnel
  - ★ Human subjects education information for key personnel involved with human subjects
- ◆ Currently allows only a single submission per grant--requires all data at the same time. (Future enhancement will allow multiple submissions.)

# Commons Functionality: E-SNAP



- ◆ Electronic submission of non-competing SNAP Progress Reports through web interface
- ◆ In pilot since November 2003
- ◆ Open to all Institutions October 2004
- ◆ Also testing potential business process redesigns so interested grantees will be required to sign an agreement before participating

# Commons Functionality: E-SNAP



- ◆ **Difference from Paper Submission**
  - ◆ 45 day submission deadline (vs 60 days with hard copy)
  - ◆ Incorporates centrally stored grantee information (in the Institutional Profile) and PI information (in the Person Profile)
  - ◆ For publications that are available electronically, can include link rather than submit hard copy reprint
  - ◆ Key Personnel Data Page—system stores previous submission to allow easy updates in future yrs

# Commons Functionality: E-SNAP



- ◆ **Difference from Paper Submission (cont)**
  - ◆ Testing business process change re: submission of IRB and/or IACUC approval dates
  - ◆ Approval dates will not be required at time of e-SNAP submission. Instead grantees agree to provide data on a quarterly retrospective basis. Goal is to assure full compliance. NIH expects the data to fully support a permanent change in the business process; i.e., eliminating the need for routine reporting for SNAP progress reports
  - ◆ Retrospective data collection will be required until NIH has collected & analyzed data from a larger population of participating grantees

# Future Plans

- ◆ New Query/Reporting Tool (Est. Fall '04)
  - ◆ Canned Queries
  - ◆ Ad Hoc Queries
- ◆ Organizational Hierarchy—ability for institutions to customize access to data based on organizational structure
- ◆ Continued improvements to existing functionality



# Electronic Proposal -Competitive Grant Application Process (CGAP) and Grants.gov



- ◆ CGAP Pilots ongoing since October 2003
  - ◆ 55 applications submitted electronically
  - ◆ 46 processed all the way through review
- ◆ Go Live
  - ◆ Feb/March Receipt Dates
  - ◆ Only for R01, R03, R21's & Modular
  - ◆ Still piloting full budget proposals & other types of submissions
- ◆ Grants.gov
  - ◆ Piloted with Pioneer Awards
  - ◆ System-to-system testing this fall
- ◆ Interested in participating? Contact Scarlett Gibb at [gibbs@mail.nih.gov](mailto:gibbs@mail.nih.gov) or Jennifer Flach at [flachj@mail.nih.gov](mailto:flachj@mail.nih.gov)

# NIH eRA User Support



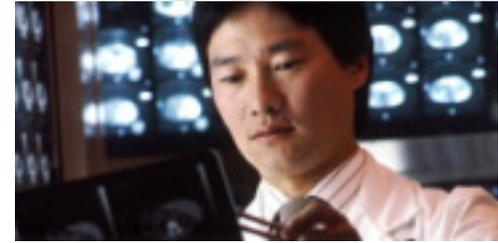
Commons Support Page:  
<http://era.nih.gov/commons>

- ◆ Release notes
- ◆ User guides
- ◆ Deployment plans
- ◆ User tips
- ◆ FAQs

eRA Help Desk:

Mon–Fri, 7:30-5:30 Eastern Time

- ◆ (866) 504-9552 (Voice-Toll Free)
- ◆ (301) 402-7469 (Voice-Local)
- ◆ (301) 451-5675 (Fax)
- ◆ (301) 451-5939 (TTY)
- ◆ [commons@od.nih.gov](mailto:commons@od.nih.gov)



# NIH

**Supporting  
Discovery to  
Improve  
Human Health**





# Questions?

Office of Policy for Extramural Research  
Administration

301-435-0938  
[GrantsPolicy@mail.nih.gov](mailto:GrantsPolicy@mail.nih.gov)

# Guide Notices

