2002 NIH Update

- **Hot** Topics
- Pre-Award News
- Post Award News
- Compliance News
- What's New in the World of eRA?

Human Embryonic Stem Cell Research

Stem Cell Research Policy

<u>Criteria for Federally-Funded Research</u>:

- Derivation of the cells from the blastocyst (early embryo) must have been initiated prior to 9 p.m. EDT August 9, 2001
- Embryo was created for reproductive purposes and no longer needed
- Informed consent from donors to use the cells for research
- No financial inducements for the donation

OER Stem Cell Web Site

http://grants.nih.gov/grants/stem_cells.htm

Listing of FAQs by topic:

- *Research Funding Opportunities*
- *Administrative Issues*
- *Training*
- *Grant Application Assistance*
- *Research Prohibitions*
- *Institutional Review Board Issues*
- *Acquisition of Stem Cells*
- *Intellectual Property Issues*
    (Topic list as of 7/26/2002)

Biodefense

NIH Plan for Biodefense Research, FY2003

Research Facilities Construction

- ☐ Build BSL-3 and BSL-4 labs (including at the comprehensive research centers)

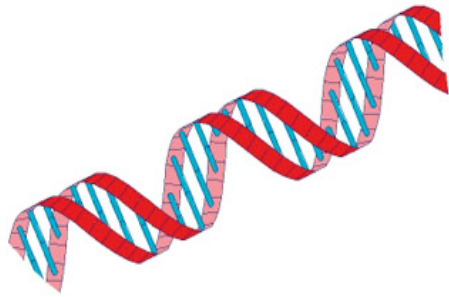**Basic Research on Agents of Bioterrorism**

- ☐ Support research programs in at least 4 comprehensive extramural centers in FY03
- ☐ Conduct genomic sequencing and proteomic analysis on up to 25 pathogens
- ☐ Expand training programs

Drugs/Vaccine/Diagnostic Discovery and Development

- ☐ Test and develop candidates for next-generation anthrax vaccine
- ☐ Engage industry through challenge grants
- ☐ Establish repositories for diagnostic and drug reagents
- ☐ Develop animal models, establish high-containment facilities and services

Clinical Research

- ☐ Expand clinical trials infrastructure (VTEUs)
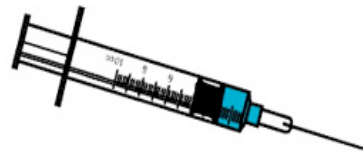- ☐ Conduct smallpox, anthrax, and ebola clinical trials

Genomics
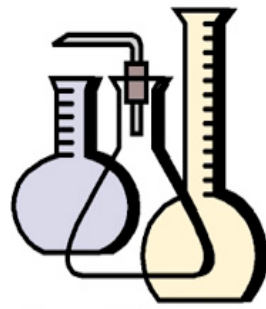
Basic Research

Antimicrobials

Biodefense Research Priorities

Diagnostics

Vaccines

Expansion of Research Capacity

Select Agents

Select Agent Rule

- Public Health Security and Bioterrorism Response Act of 2002 (H.R. 3448)
  - Signed by the President on June 12, 2002
  - Includes <u>possession and use</u> of agents
  - Requires registration of
    - Facilities
    - Individuals
  - Generation of a SA list by the USDA

Select Agent Interagency Working Group

- Lead agency: CDC

- Participating agencies: NIH, FDA, USDA, CIA, FBI, DOD, DOJ, DOT, DOC, EPA, US Postal Service, Office of Homeland Security

For more information on Select Agents:

- Current CDC Select Agent Rule
  http://www.phppo.cdc.gov/nltn/sar.asp
- Public Health Safety and Bioterrorism Preparedness and Response Act of 2002
  http://www.cdc.gov/od/ohs/lrsat/bioterro.htm
- Proposed Revisions to Select Agent List
  http://www.access.gpo.gov/su_docs/fedreg/a020823c.html
- *NIH Guidelines for Research Involving Recombinant DNA Molecules*
  http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html
- FAQs About Institutional Biosafety Committee
  http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm

Health Insurance Portability and Accountability Act of 1996 (HIPAA) – effective April 13, 2003

Guidance for grantees currently in development

New IOM Report Published -

Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct , July 2002.

Proposed OMB Changes

- Proposed changes in cost principles (Circulars A-21, A-87, and A-122) is an effort to make the descriptions of similar cost items consistent with one another;

- Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107)

- Standard data elements for program announcements through E-Grants in Fed Biz Opps; and

- Standard format for program announcements.

- Revision of Circular A-133, proposes to increase audit threshold from $300,000 to $500,000

Loan Repayment

- The LRP provides for the repayment of the educational loan debt of qualified health professionals who agree to conduct biomedical research.

- Payments will be a contract (not a grant) and disbursed directly to the financial institution holding the education loan

- Will cover up to $35,000/year (principal & interest), plus Federal taxes

See Oct 10 NIH Guide (NOT-OD-03-004)
 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-004.html
And Oct 10 NIH Guide (NOT-OD-03-005)
 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-005.html

Loan Repayment Program:

"What Does the Future Hold?"

- Program continues to be refined
- Multiple receipt dates can be anticipated in the future
- Possible changes to eligibility criteria
- Possible growth in the number awarded
- All changes will be announced in NIH Guide

Grantees can sign up for listserv to receive information on next application cycle.
http://www.lrp.nih.gov/

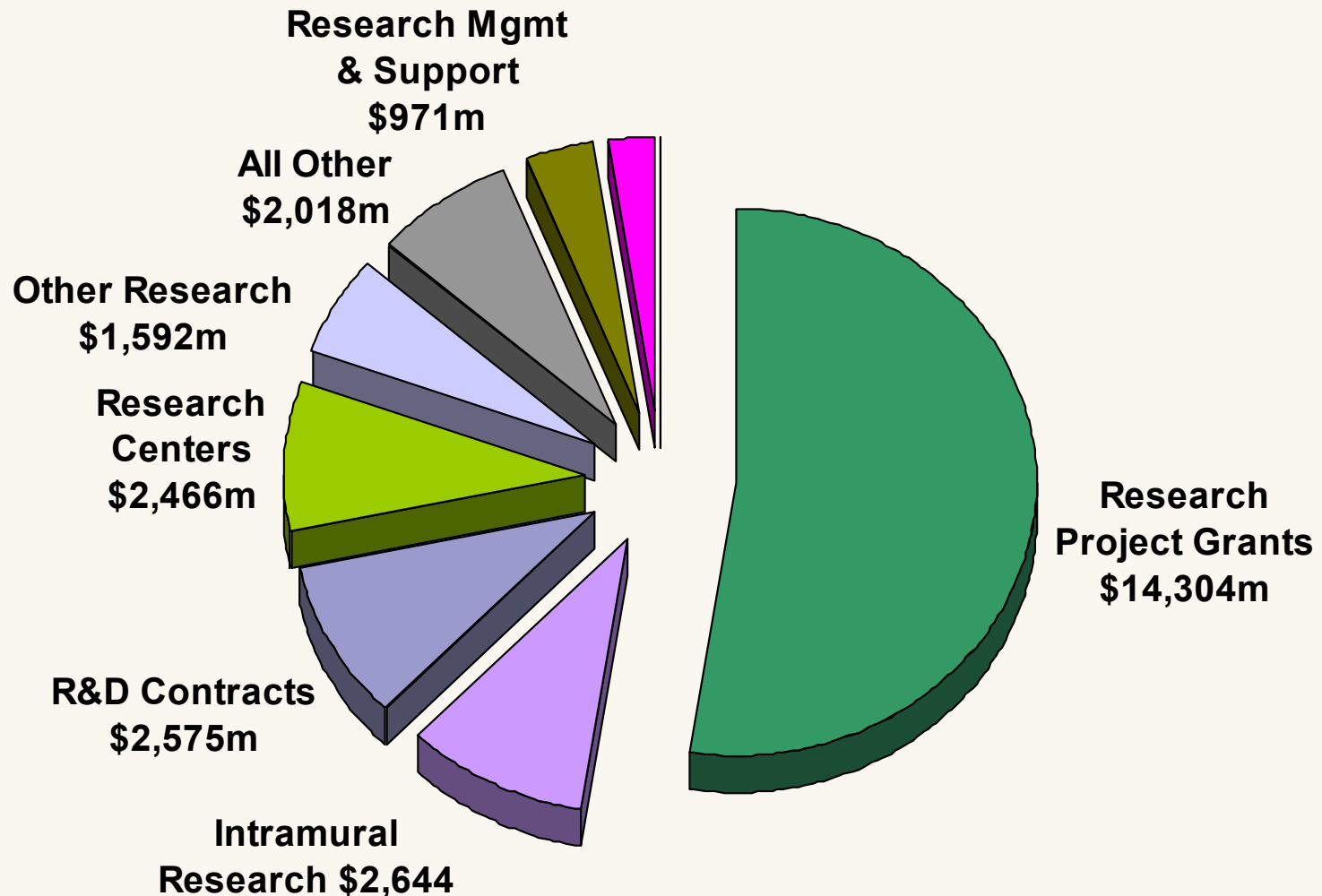# The NIH Budget

FY 2003 President's Budget Request

- Increase of 16.7% over the FY 2002 appropriation

- 9,854 Estimated Competing RPG awards

- The FY 2003 budget completes the President's commitment to double the FY 1998 appropriation level in five years

- New proposal to double the NIH budget yet again

Research Initiatives in FY 2003 President's Budget Request

- Bioterrorism
- Cancer
- Diabetes
- Minority Health and Health Disparities
- Parkinson's Disease

FY 2003 President's Budget Request $27.3 Billion

Research Mgmt & Support $971m

All Other $2,018m

Other Research $1,592m

Research Centers $2,466m

R&D Contracts $2,575m

Intramural Research $2,644

Research Project Grants $14,304m

Other Updates

Non-competing Continuation Grant Progress Report

Last pre-printed "hard copy" Face Pages mailed in June 2002 for November 2002 start dates

Beginning with December 2002 start dates grantees must use website
http://era.nih.gov/userreports/pr_due.cfm

NIH Guide Notice: August 13, 2002
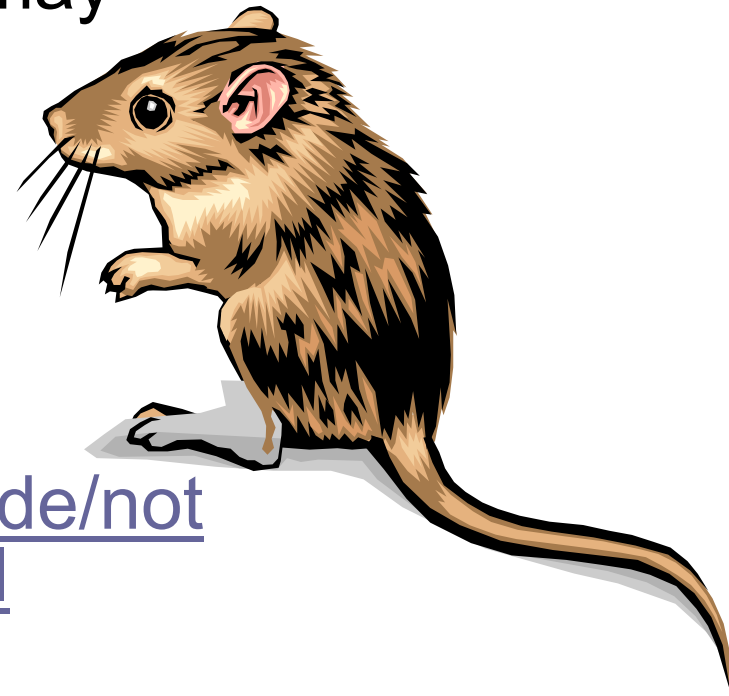http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-066.html

Change in PHS Policy on Humane Care and Use of Laboratory Animals

As of October 1, 2002 receipt date, IACUC approval information may be provided "just-in-time"

NIH Guide, August 8, 2002

http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html

Hottest Topic in NRSA News: New Name

National Research Service Award Program

Ruth L. Kirschstein National Research Service Awards

Enacted via Public Law 107-206, signed 8/2/02

Revised Ruth L. Kirschstein Individual National Research Service Award Application

- The revised application for an Individual National Research Service Award (PHS 416-1) and Progress Report for Continuation Support

  (PHS 416-9) are now available and may be used by applicants.

Receipt Dates for Revised 416-1 and 416-9 (cont'd)
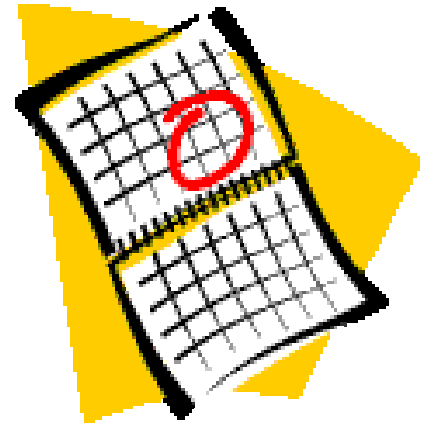
- For December 2002 receipts, both versions (rev. 12/98 and rev. 6/02) will be accepted.

- For April 2003 receipt date, use of the new version (rev. 6/02) is <u>required</u>.

Notable Changes in PHS 416-1

- The forms will only be available electronically

- Fillable forms using Adobe Acrobat

- Human Subjects – specific instructions provided for use of human subjects in research

- New format pages for women and minority enrollment

- Vertebrate Animals –now under the "just-in-time" procedures

Notable Changes in PHS 416-1 (cont')

- Face Page – Human Subjects Research box and Vertebrate Animals box modified

- Personal Data Page – updated Race and Ethnicity Categories

- New Format Pages – Targeted/Planned Enrollment Table and Inclusion Enrollment Report

Intellectual Property

Invention Reporting Requirements of Grantee/Contractors
Administrative Requirements (per 37CFR, 401.14)

- Implement Employee Agreements ⇨ as needed
- 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

Grantee/Contractor Reporting of Intellectual Property Utilization

- Effective January 1, 2002, invention utilization reporting requirements will change
- Most substantive change involves the addition of a question that requires the commercial name of any FDA approved products, utilizing any invention, that have reached the market during the annual reporting period

See NIH Guide 12/13/2001,
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-019.html

Rights To Subject Inventions Made Through Funding Agreements To Foreign Entities

Implementation of this policy will be deferred for twelve months.

NIH Guide, August 8, 2002

http://grants2.nih.gov/grants/guide/noticefiles/NOT-OD-02-065.html

NIH Guide, March 14, 2002

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-039.html

Pre-Award and Post-Award Administration

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, October 16, 2001

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

Applications and Forms:
PHS 398 and 2590 - New Requirements for Reporting Race and Ethnicity

Investigators must follow new OMB standards for collecting data on race and ethnicity

Requires asking subjects minimum of 2 questions:

- Ethnicity
- Race with option to select more than one

Applications and Forms: Application Format

The Center for Scientific Review will check competing applications for adherence to format.

Requirements:

Type size

Page limits

Margins

NIH Guide May 4, 2001,

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01037.html

Applications and Forms: Questions?

Dedicated e-mail address for questions on format:

format@mail.nih.gov

Frequently asked questions on format:

http://www.format.nih.gov

# Change of Receipt Dates for AIDS or AIDS-Related SBIR and STTR Applications

As of March 2002, the receipt dates for SBIR (R43 and R44) and STTR (R41 and R42) applications that propose AIDS or AIDS-related research will become the same as for all other AIDS applications: May 1, September 1, and January 2.

NIH Guide, March 7, 2002

http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-036.html

Expanding Expanded Authorities

Expanded Authorities
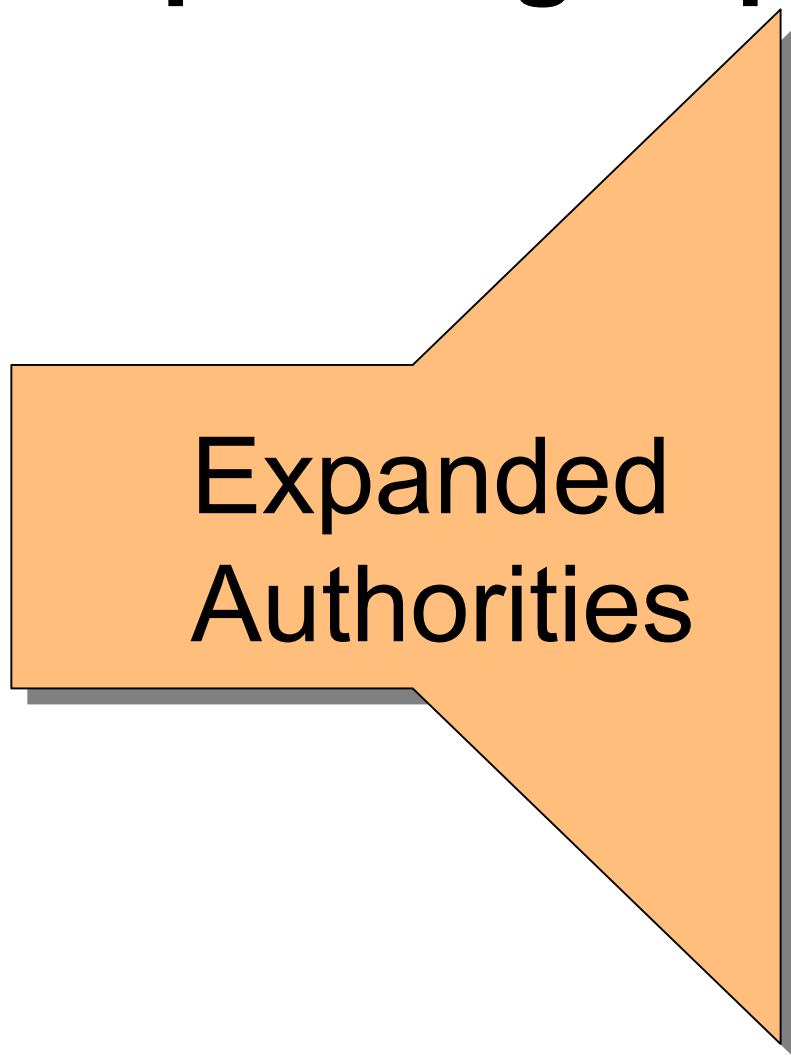
conditions for all mechanisms

NIH standard terms and

Excludes automatic carryover for mechanisms that currently do not have this authority

See NIH Guide, September 28, 2001,
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-070.html

Requirement for Education in the Protection of Human Subjects

NIH education requirement remains in effect for all key personnel** involved in human subject research

** Key personnel are defined as those staff who are significantly involved in the design and conduct of the research.

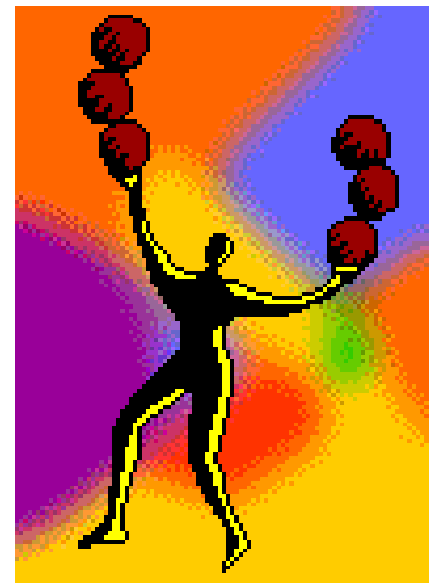# NIH Announces Statement On Certificates Of Confidentiality

- Certificates are issued by NIH to protect identifiable research information from forced disclosure
- They constitute an important tool to protect the privacy of research study participants
- Information is available at the Certificate Kiosk
- NIH Guide March 15, 2002 , http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-037.html

Financial Conflict of Interest

The grantee must:

- Notify Chief GMO to assure that the conflict of interest is being managed, reduced, or eliminated
- Provide additional information, if requested
- Address FCOI in consortium agreements

See the following NIH Guide Notices for additional info:

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

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

NIH Analysis of COI policies at:

http://grants1.nih.gov/grants/policy/coi/nih_review.htm

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"

- If submitting an itemized budget, grantees should request actual institutional-based compensation and include justification

  See NIH Guide, 12/10/2001, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html
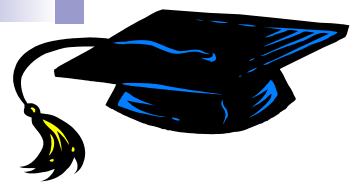
Graduate Student Compensation (cont.)

- NIH staff will review and determine appropriate level at the time of award

- Revised budgets (modular or itemized) will not be accepted solely to adjust this compensation level

- 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

NRSA - What's New?

Part-time Training

- NRSA legislation revised in FY2001 to include part-time training "in cases of disability or pressing family need" will apply to both fellows and trainees

- Will require awarding IC prior approval

- Must continue to be at least 50%, less than 50% would require leave of absence from NRSA support

Discipline Coding

- Old "Discipline/Specialty/Field Codes" now called "Field of Training (FOT)"

FY 2003 Proposed NRSA Budget and Policy Changes

- Proposed stipend increase – proposing 10% for Predoc and entry-level Post-doc, smaller increases for other Post-doc levels

- Discussing increase in Postdoc institutional allowance

- Discussing potential change in leave policy

F&A Costs for Foreign and International Organizations

Grants to foreign organizations and foreign consortium participants are now eligible to receive F&A cost

8% F&A -**less equipment**

- F&A costs are provided to support the costs of compliance with DHHS and NIH requirements.
- NIH will not support any capital expenses (facilities), or normal general operations related to foreign and international organizations.

The policy change was effective 10/01/2001,
see NIH Guide March 29, 2001:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-028.html

Updated Resource

- Revised "Grants Administration Information Sources" is now available at: http://grants.nih.gov/grants/policy/grants_info.pdf

- Provides updated contact information for Grants Administration individuals at all NIH ICs

Compliance News

Division of Grants Compliance and Oversight

- Established August 28, 2001

- Division within the Office of Policy for Extramural Research Administration, OER

- Emphasis on external and internal compliance activities

Audit/Review Oversight

- A-133 audits
- CFO audits
- IG and GAO reviews
- OMA reviews

Other Compliance Activities

- Provide direction and advice to ICs and institutions on compliance issues

- Focal point for financial conflict of interest notifications

- Institutional compliance cases
  - Corrective action plans

- Outreach
  - Educational seminars
  - National and regional meetings

- Proactive Compliance Site Visits

NIH Proactive Compliance Site Visits: Objective/Purpose

Objective

- Move from reactive noncompliance to proactive compliance

Purpose

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

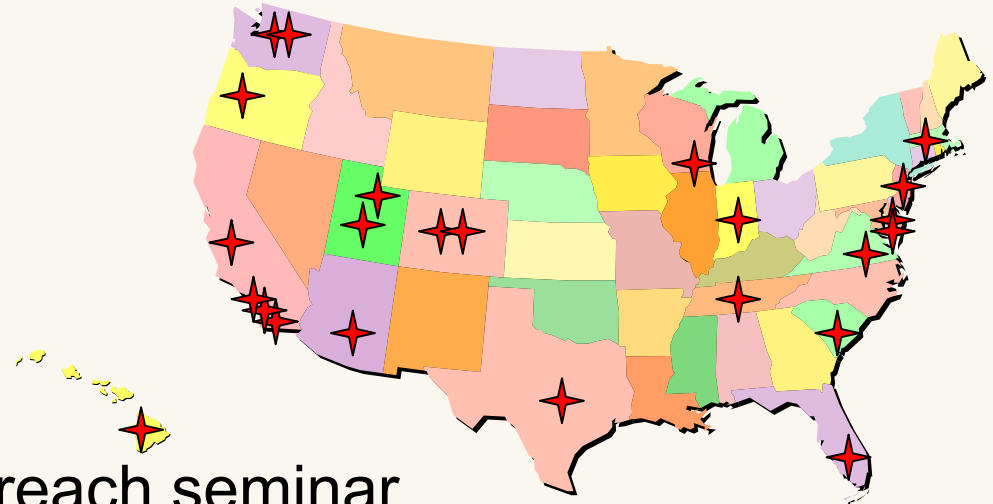# Proactive Compliance Site Visit Summary: FY2000-FY2002

26 institutions:

> 20 universities/medical schools
>
> 4 non-profits (3 AIRI institutions)
>
> 2 hospital

Geographic diversity

Expanded education-outreach seminar

NIH Proactive Compliance Site Visit Program has…

- Initiated the process of moving from reactive to proactive
- Confirmed that:

  - Compliance is an ongoing and dynamic process and is more likely to be present and effective if it is established as an institutional expectation

  - Site visits build a foundation of partnership

  - Recipients are committed to properly administering sponsored activities although institutional oversight is not always evident

Outcome

Proactive Compliance Site Visits: A Compendium

    Subject matter focus

    Regulations/policies/guidelines

    Summary observations

    Examples of compliance in action

Available on Grants Compliance and Oversight page
http://grants.nih.gov/grants/compliance/compliance.htm

Newly updated

NIH eRA Objective:
Full Electronic Grants Administration

Applicant/Grantee Interface – NIH Commons
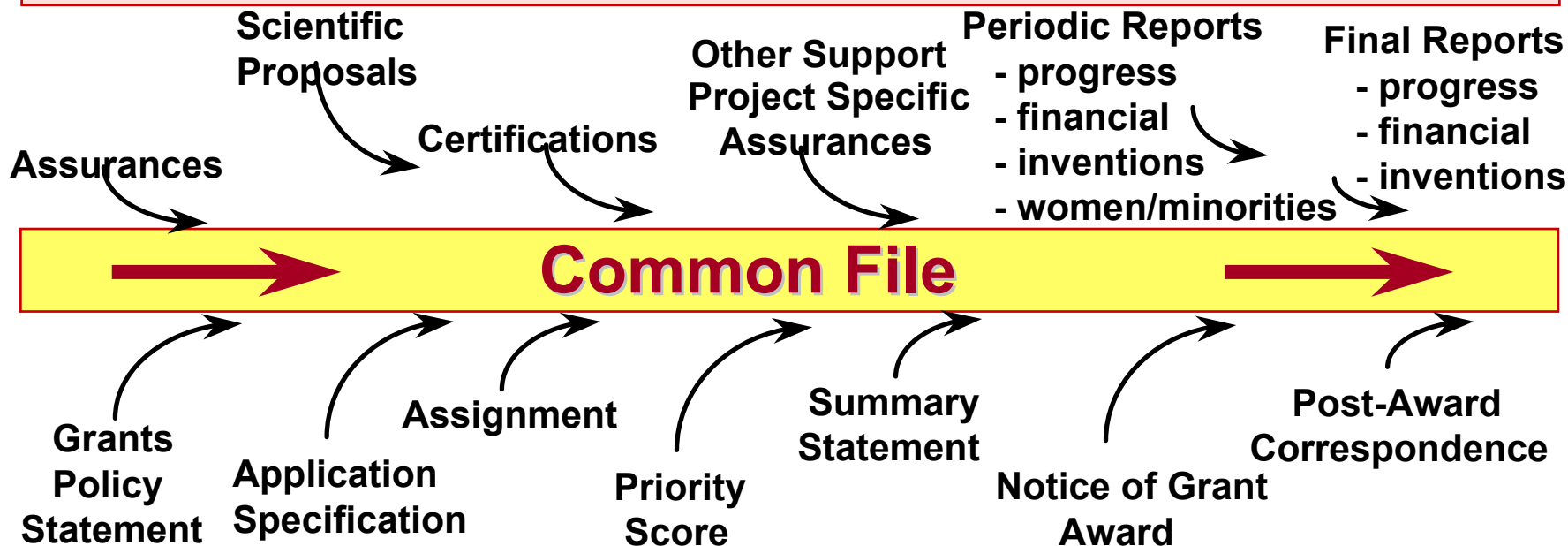
225,000,000
Pieces of Paper

NIH Grants Database Interface – IMPAC II

1.6 million transactions daily

NIH Institutes and Centers

NIH eRA Objective:
Full Electronic Grants Administration

Applicant/Grantee Interface – NIH Commons

Scientific Proposals

Other Support Project Specific Assurances

Periodic Reports
- progress
- financial
- inventions
- women/minorities

Final Reports
- progress
- financial
- inventions

Certifications

Assurances

Common File

Grants Policy Statement

Application Specification

Assignment

Priority Score

Summary Statement

Notice of Grant Award

Post-Award Correspondence

NIH Grants Database Interface – IMPAC II
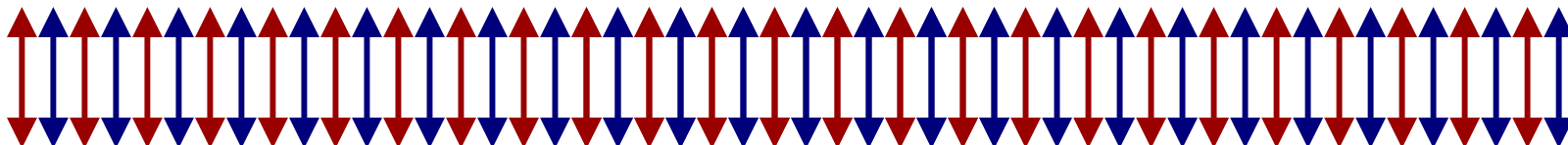
NIH Institutes and Centers

NIH ERA Components

Unrestricted Interfaces

- NIH and OER Web Sites - http://www.nih.gov/grants
- CRISP on the Web – Awards Database – http://crisp.cit.nih.gov

Restricted Interfaces – https://commons.era.nih.gov

- Commons Registration – Secure access for grantee institutions
- Accounts Administration – Secure access for grantees
- Application/Award Status – Monitor pending grant applications
- Institutional & Professional Profiles – Maintain repetitive information about institutions and investigators
- Competitive Application – Competing Grant Application
- Trainee Appointments (X-Train) – Appointment and administration of grantee trainees
- Submission of non-competing progress reports (e-SNAP)
- Financial Status Report (FSR)
- Interagency Edison – Invention Reporting

Commons Working Group (CWG)

eRA feedback from the extramural community

- Definition of user requirements

- Definition of future priorities

- Assistance with testing and deployment

Representatives from 18 institutions

- Diverse skills

  14 Research Administrators

  6 IT Technologists

  4 Active Research Faculty

- Diverse institutional representation

  13 NCURA members

  11 SRA members

  10 FDP institutions represented

  13 COGR institutions represented

CWG-Related Issues

- Commons V 2.0 User Interface
- Streamlining Noncompeting Progress Reporting – Type 5 Awards
- Review of Financial Status Report Software
- Review and Potential Streamlining of the Competitive Application Process
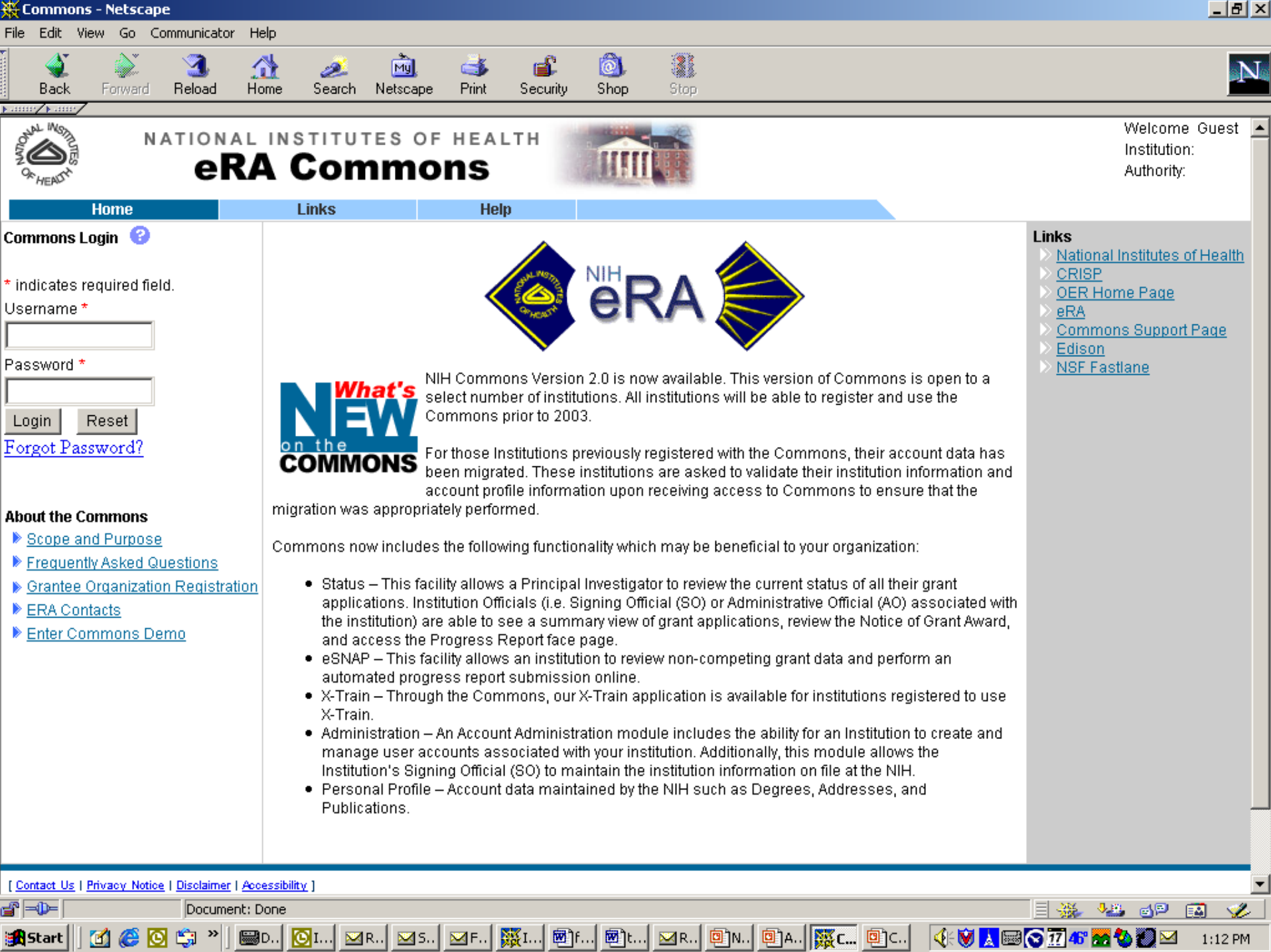
NATIONAL INSTITUTES OF HEALTH
eRA Commons

| Home | Links | Help | |

Commons Login ?

* indicates required field.

Username *

Password *

Login   Reset

Forgot Password?

About the Commons

▶ Scope and Purpose
▶ Frequently Asked Questions
▶ Grantee Organization Registration
▶ ERA Contacts
▶ Enter Commons Demo

Links

▶ National Institutes of Health
▶ CRISP
▶ OER Home Page
▶ eRA
▶ Commons Support Page
▶ Edison
▶ NSF Fastlane

What's NEW on the COMMONS

NIH Commons Version 2.0 is now available. This version of Commons is open to a select number of institutions. All institutions will be able to register and use the Commons prior to 2003.

For those Institutions previously registered with the Commons, their account data has been migrated. These institutions are asked to validate their institution information and account profile information upon receiving access to Commons to ensure that the migration was appropriately performed.

Commons now includes the following functionality which may be beneficial to your organization:

- Status – This facility allows a Principal Investigator to review the current status of all their grant applications. Institution Officials (i.e. Signing Official (SO) or Administrative Official (AO) associated with the institution) are able to see a summary view of grant applications, review the Notice of Grant Award, and access the Progress Report face page.
- eSNAP – This facility allows an institution to review non-competing grant data and perform an automated progress report submission online.
- X-Train – Through the Commons, our X-Train application is available for institutions registered to use X-Train.
- Administration – An Account Administration module includes the ability for an Institution to create and manage user accounts associated with your institution. Additionally, this module allows the Institution's Signing Official (SO) to maintain the institution information on file at the NIH.
- Personal Profile – Account data maintained by the NIH such as Degrees, Addresses, and Publications.
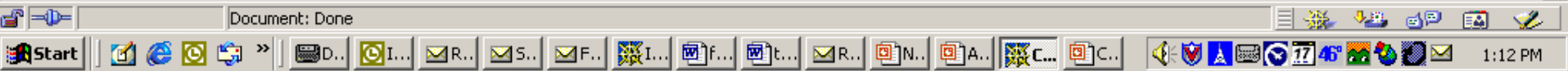
NIH Commons V 2.0 User Interface

Deployment of new User interface – October 2002

- New GUI (user interface) standards
- Production deployment to all grantee institutions
- Interfaces
  - Commons registration
  - Accounts administration
  - Application/award status
  - X-Train (Trainee Appointments)
- October 14, 2002: Production deployed to CWG
- Open Registration: December 10, 2002

All institutions to register whether submitting electronically or in paper

- Improve data quality for electronic and paper submissions

e-Notification (Type 5 Notification)

Phase 1 - OER Website

http://era.nih.gov/userreports/pr_due.cfm

- Launched August 13, 2002. See Guide Notice OD-02-066

- Provides institution-specific list of Type 5s according to Due Date

- Records drop off the list as NIH staff indicate "received" in IMPAC II

- Mailing of Face pages discontinued as of December 2002 start dates. See NIH Guide Notice OD-02-047.

e-Notification (cont.)

Phase II - NIH Commons "pull technology"

- Status Interface will provide AO with list of Type 5's according to Due Date

- Each Type 5 will include link to pre-populated face pages (PHS 2590 & PHS 416-9)

Phase III - NIH Commons "push technology"

- Commons Registration includes new e-mail address for "push" notifications

- Later release – "push" to individual PIs and list to AOs

Streamlining Noncompeting Award Process (SNAP Progress Report)

e-SNAP: Pilot Deployment November 2002

- ☐ Optional sign-off by business official
- ☐ Flexible routing for approvals prior to
  submission to NIH
- ☐ Submit 45 days before budget period start date
- ☐ Separate data area for science highlights
- ☐ Ability for interim updates
- ☐ Eliminate IRB and IACUC review dates
- ☐ Assurances and certifications part of institutional
  profile

Electronic Financial Status Report (eFSR)

Commons-based submission and approval of FSRs

eFSR: Pilot Deployment November 2002

- ☐ Deployment critically dependent on shut down of mainframe system (IMPAC I) 12/31/02
- ☐ Full implementation critically dependent on Commons registration

  Open Registration begins December 10, 2002

- ☐ See <u>NIH Guide</u> Notice OD-03-008; November 1, 2002

Reengineering the Competitive Application

November 2001 CWG meeting

- Streamlining data requirements
  - Advantages offered by implementation of profiles
  - Advantages offered by recategorizing of information
  - Opportunities to question need for information

January 2002 CWG meeting

- Streamlining business process
  - Receipt, referral, review
  - Just-in-time submissions
  - Application schedule and content

Design/develop of Electronic Competing Grant Application

- Pilot datastream deployment possible near end of FY03

File Edit View Go Communicator Help

Back Forward Reload Home Search Netscape Print Security Shop Stop

Bookmarks Location: http://era.nih.gov What's Related

Instant Message Internet Lookup New&Cool

eRA
Home page

About eRA | Newsletters | Project Management | Business Areas | Tech Corner

Reference Shelf
- Glossary
- Frequently Asked Questions
- Documents
- Site Index

Key Links
- NIH
- Commons
- IMPAC II
- Federal Commons
- Invention Reporting (iEdison)
- CRISP on the Web

Welcome to eRA

The Electronic Research Administration (eRA) integrates NIH's Commons and IMPAC II projects.

About eRA

eRA Overview, Objectives, Goals, Operating Principles, Where eRA Fits Into NIH, System Architecture, More...

Project Management

Overview, Advocates, Management Committees, More...

Initiatives

2002 Core Initiatives, Accomplishments, Priorities

Contact Us

Report a Technical Problem

Opinions? Questions? Ask eRA

Get Involved

Project Plans

Implementation Plans

Bug / Enhancement Tracking

Legacy Retirement

Business Areas

All Business Areas

Budget Management

Committee Management (CM)

Data Integrity

Electronic Council Book (ECB)

eRA Interface to the Extramural Community (Commons)

Grants Management (GM)

Infrastructure

IC Technical Perspective

Paperless Business Practices (Scanning)

Receipt, Referral, & Assignment (RR)

Reporting

Review (REV)

Project News

IMPAC II 2002 Deployment Schedule Announced
IMPAC II will move to a bi-monthly release schedule beginning in January.

New Production Environment Enhances System Performance
A new production and development environment available in January will increase system speed, enable faster backups and recovery, and support additional database instances.

All *Inside eRA* Headlines

Start ... S. C. F. E. F. I. R. C. c. A. e. U. B. U. L. e. C. 52° 1:06 PM

File   Edit   View   Go   Communicator   Help

Back   Forward   Reload   Home   Search   Netscape   Print   Security   Shop   Stop

Bookmarks   Location: http://era.nih.gov/eranews/index.cfm   What's Related

Instant Message   Internet   Lookup   New&Cool

eRA
Home page

Newsletters
▶ Latest *Inside eRA*
▶ Latest *Inside eRA for Partners*
▶ *Inside eRA* Back Issues
▶ *Inside eRA for Partners* Back Issues

Reference Shelf
▶ Glossary
▶ Frequently Asked Questions
▶ Documents
▶ Site Index

Key Links
▶ NIH
▶ Commons
▶ IMPAC II
▶ Federal Commons
▶ Invention Reporting (iEdison)
▶ CRISP on the Web

About eRA   **Newsletters**   Project Management   Business Areas   Tech Corner

eRA News

Latest *Inside eRA*
The newsletter for Federal employees

Subscription center

Back issues

Latest *Inside eRA for Partners*
The newsletter for NIH Research Partners

Subscription center

Back issues

Feedback and Help, Accessibility, Privacy

Start   1:07 PM

NIH eRA User Support

- Questions about
  - ☐ eRA design
  - ☐ Deployment schedule
  - ☐ Advice on implementation planning
  - ☐ Commons registration
  - ☐ User support
- eRA Help Desk:

    (866) 504-9552 or (301) 402-7469

    Mon–Fri, 7:30-5:30 Eastern Time

    commons@od.nih.gov

Thank you!

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