NIH UPDATE 2001

Outline

- Administrative and Policy Issues
- Budget and Legislative Mandates
- Institutional Compliance
- Electronic Research Administration
- Important Reminders
- Fundamentals

Revision of the NIH Grants Policy Statement (NIHGPS) Background

- The NIHGPS (Rev. 3/01) is effective for all NIH grants and cooperative agreements with budget periods beginning on or after 3/1/01
- The NIHGPS published 10/1/98 remains the standard term and condition for all grants and cooperative agreements with budget periods that began between 10/1/98 and 2/28/01
- See NIH Guide 2/27/01

Revision of NIHGPS Organization

- The document is now in three sections:
  - *Part I – General Information*
  - *Part II -Terms of Award*
  - *Part III - Contacts*

- The pages are numbered consecutively

Revision of NIHGPS
Availability and Maintenance

- Availability: Copies will not be printed or mailed. The NIHGPS is available on-line in both HTML and PDF versions

- Maintenance: Interim changes will be published in the NIH Guide. Concurrently, conforming changes will be made in both electronic versions of the NIHGPS, with a date indicator showing the change's effective date.

Revision of NIHGPS Changes in Policy #1

- The separate requirement for approval of significant rebudgeting has been eliminated. It is now incorporated as an indicator of a change in scope.
- Effective 3/1/01 for all NIH awards.
- This eliminates the need to reply to question #2 of the four SNAP questions.

Revision of NIHGPS Changes in Policy #2

- The term “collaborator” has been changed to “co-investigator.” This change is intended to more accurately describe the role of individuals who are involved with the principal investigator (PI) in the scientific development or execution of the project
- This will be reflected in the next revision of the 398 application
- This ***does not change*** the role and/or responsibilities of the PI as detailed in the NIHGPS or the PHS 398 application

Revision of NIHGPS Changes in Policy #3

- The criteria to allocate costs normally assignable to multiple projects (“closely related work”) has changed. A grantee may allocate costs normally assignable to multiple projects to one of those projects or else treat multiple projects as a single cost objective regardless of the funding IC or whether the awards involve the same or different PIs

- However, identifying projects as “closely related” continues to be a prior approval requirement

Revision of NIHGPS Changes in Policy #4

- For grantees subject to A-21, the 10/98 NIHGPS states that they may not rebudget from direct costs to accommodate an F&A rate increase unless the rate in effect at the time of award was provisional

- This requirement is now eliminated from the NIHGPS

- Grantees may rebudget between direct and F&A costs (in either direction) without NIH prior approval, provided there is no change in scope

Revision of NIHGPS Changes in Policy #5

- The addition of a foreign component requires prior approval for all recipients, regardless of terms of award

Revision of NIHGPS Changes in Policy #6

- A statistical sampling basis is now acceptable for physical inventory of equipment.

Revision of NIHGPS Expanded or Clarified Coverage

- It is stated explicitly that it is the grantee organization's responsibility to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved assurance and IRB approval of the research, consistent with 45 CFR 46
- A clinical hold placed by the Food and Drug Administration (FDA) is added as an example of change of scope

Revision of NIHGPS
Expanded or Clarified Coverage (cont.)

- A list of actions that require prior approval is provided in table format
- Clarifying language on the use of 1099 forms for both fellowship and training grants is included
- The allowability of foreign travel costs purchased under a code share is discussed.

Revision of NIHGPS
Expanded or Clarified Coverage (cont.)

- A continued and increased emphasis on timely and accurate reporting is reflected throughout the document

Financial Conflict of Interest Clarifications/Reminders

- Prior to the expenditure of any NIH funds under a new award, organizations must notify the Chief GMO of the awarding NIH IC of any conflicting financial interests and assure that the interest has been managed or reduced or eliminated
- As other conflicting interests are subsequently identified, organizations must notify the Chief GMO within 60 days of the identification
- Organizations must make additional information available to NIH upon request

Financial Conflict of Interest Clarifications/Reminders

- Grantees also must ensure that consortium agreements address whether the consortium participant's employees will be subject to the financial conflict of interest requirements of the collaborating organization or to those of the grantee
- Discussion in the new NIHGPS on how Institutional Review Boards (IRBs) are considering investigator financial conflict of interest

Extramural Salary Cap

- FY 2001 is the 12th consecutive year for the salary cap
- Restricts the amount of **direct salary** under a grant or contract to Executive Level I of the Federal Executive Pay Scale - currently at a **rate** of $161,200 per year
- See NIH Guide 1/11/01

FINANCIAL STATUS REPORTS: REMINDER AND INFORMATION ON TIMELINESS AND ACCURACY REQUIREMENTS

NIH grantees are required by 45 CFR 74.71 to submit three closeout reports for every award: Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.

- Recipients that submit reports at the 3-month mark will be considered out of compliance if that period exceeds 90 calendar days.

FINANCIAL STATUS REPORTS: REMINDER AND INFORMATION ON TIMELINESS AND ACCURACY REQUIREMENTS (cont.)

- FSRs should be accurate at the time of submission, with revisions made rarely, only to provide updated information.
- Revisions should not be used as a mechanism to correct routinely incomplete or erroneous FSRs.

See NIH Guide, February 22, 2001

FORMAT OF GRANT AND COOPERATIVE AGREEMENT APPLICATIONS SUBMITTED TO NIH

- CSR will check competing grant applications for adherence to format requirements
- Applications that do not comply with the specifications for type size, page limits, or margins **will be returned to the institution without review**
- These applications cannot be submitted in a corrected version until the next receipt cycle

- See NIH Guide, 1/8/01

FORMAT OF GRANT AND COOPERATIVE AGREEMENT APPLICATIONS SUBMITTED TO NIH (cont.)

- Provides links to sites with specific format instructions for the 398, 416 and the SBIR and STTR applications
- Announces a dedicated email address (format@mail.nih.gov) for questions regarding format of applications, as well as a site with frequently asked questions about application format (http://www.format.nih.gov)

PHS 398 and 2590 Grant Application Forms

- These forms are being revised
- Until OMB approval is received, the current versions of the PHS 398 and 2590 should be used
- NIH will publish an announcement in the NIH Guide when the new forms are available for use

Changes to A-21

- On 1/5/01, OMB implemented the following changes:
  - Voluntary uncommitted cost sharing should not be included in the organized research base for computing the F&A rate
  - Such effort is also excluded from effort reporting requirements
  - Tuition remission costs of graduate students are allowable and are not contingent upon an employee-employer relationship

President’s FY 2002 Budget Request

- President’s requested budget of $2.751 billion
- Increase of 13.5% over FY 2001

FY 2001 Appropriations

- Provides $20.3 billion to NIH in FY 2001
- Increase of nearly 14% over FY 2000
- Approximately 9,158 new and competing RPG awards for FY 2001

FY 2001 Appropriations: Legislative Mandates

Limitations/Conditions on use of NIH funds:

- Acknowledgement of Federal funding
- Anti-lobbying
- Continued salary limitation - Federal Executive Level I
- Ban on funding of human embryo research

FY 2001 Appropriation:
Legislative Mandates (cont.)

Limitations/Conditions on use of NIH funds:

- Purchase of American-made equipment and products
- Limitation on use of funds for promotion of legalization of controlled substances
- Restriction on distribution of sterile needles

See NIH Guide 1/17/01

Division of Grants Compliance and Oversight

- New Division within the Office of Policy for Extramural Research Administration
- Emphasis on external and internal compliance issues
- Proactive Compliance Site Visits
- Gary Thompson, Director

FY2000 Proactive Compliance Site Visits

- Subject Matter Focus included
  - Roles and Responsibilities
  - Training and Education
  - Financial Management of Sponsored Projects
  - Financial Conflict of Interest
  - Inventions and Patents
  - Clinical Trial Data Safety and Monitoring
  - Clinical Gene Transfer Research
  - Education–Outreach Seminar

Proactive Compliance Site Visits

- Outcome
  - Proactive Compliance Site Visit Compendium to include:
    - Information Reviewed/Discussed at PCSV
    - Summary Observations
    - Examples of Compliance in Action
  - Compendium will be posted on the NIH OER home page http://grants.nih.gov/grants/oer.htm

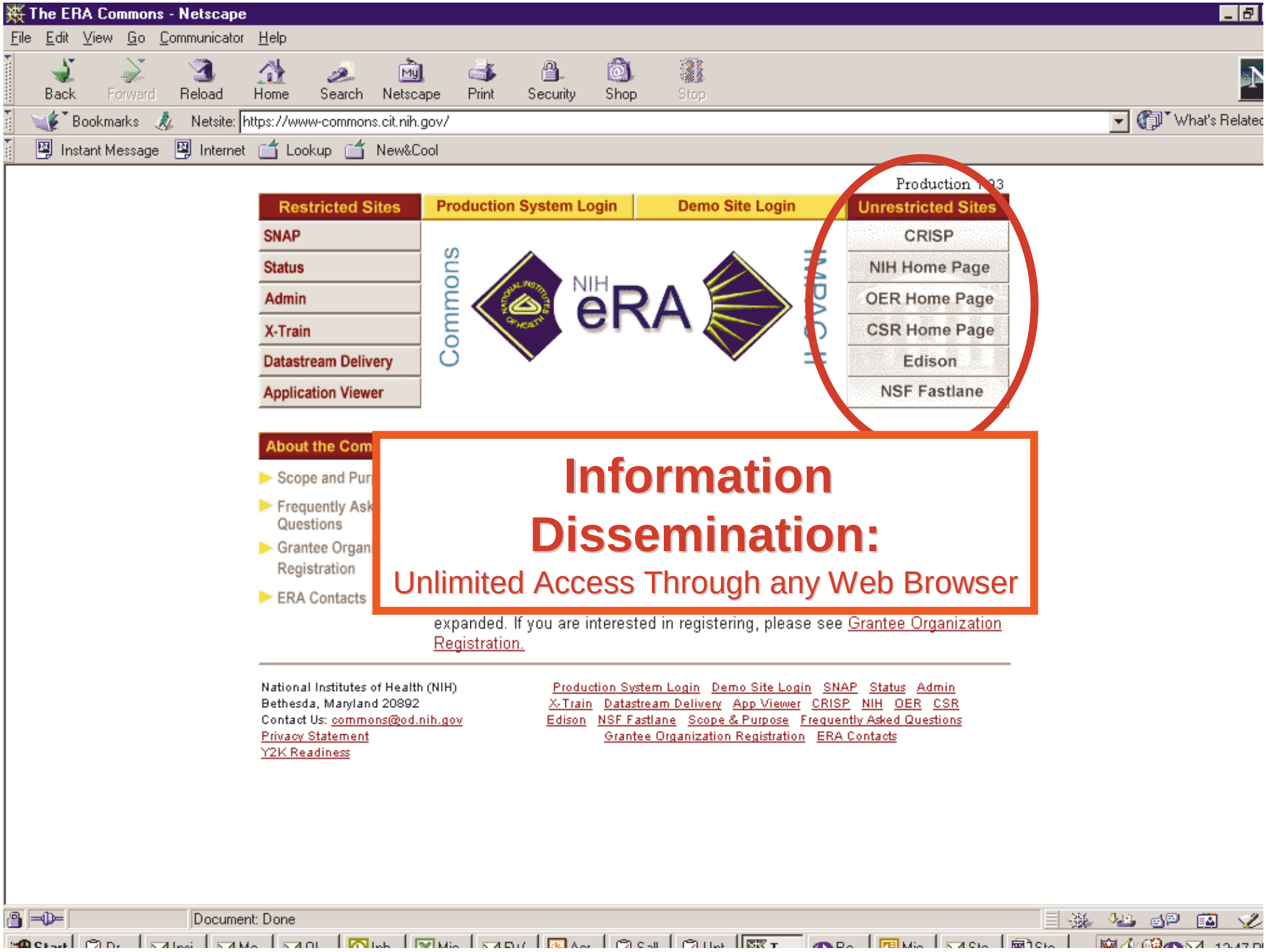
Dimension of Current NIH Extramural Research Administration*

- 60,000 applications X 25 pages X 5 copies
  = 7,500,000 pages
  – submitted by grantees annually
- 7,500,000 pages X 30 copies
  = 225,000,000 pages
  – handled by NIH staff annually

*Numbers are estimates only

ERA Benefits to Grantee & NIH Staff

	Grantee Users	NIH staff
Improved Resource Allocation	• Reduction in paper & handling costs	• Reduction in duplication/disposal costs • Fewer staff required for processing and oversight
Improved Work Efficiency	• Ad lib. monitoring of status information • Improved information retrieval	• Reduction in number of telephone inquiries • Improved information retrieval
Improved Quality of Data	• Most accurate grantee representation – Prof./Inst. profiles • Data validation – User interface & system	• Minimize duplicate versions of people • Minimize grantee contact to verify information
Improved Response Time	• Rapid, confidential viewing of documents – Sum. Stmt./Score	• Purposeful notification of cognizant staff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Bethesda, Maryland 20892
Contact Us: commons@od.nih.gov
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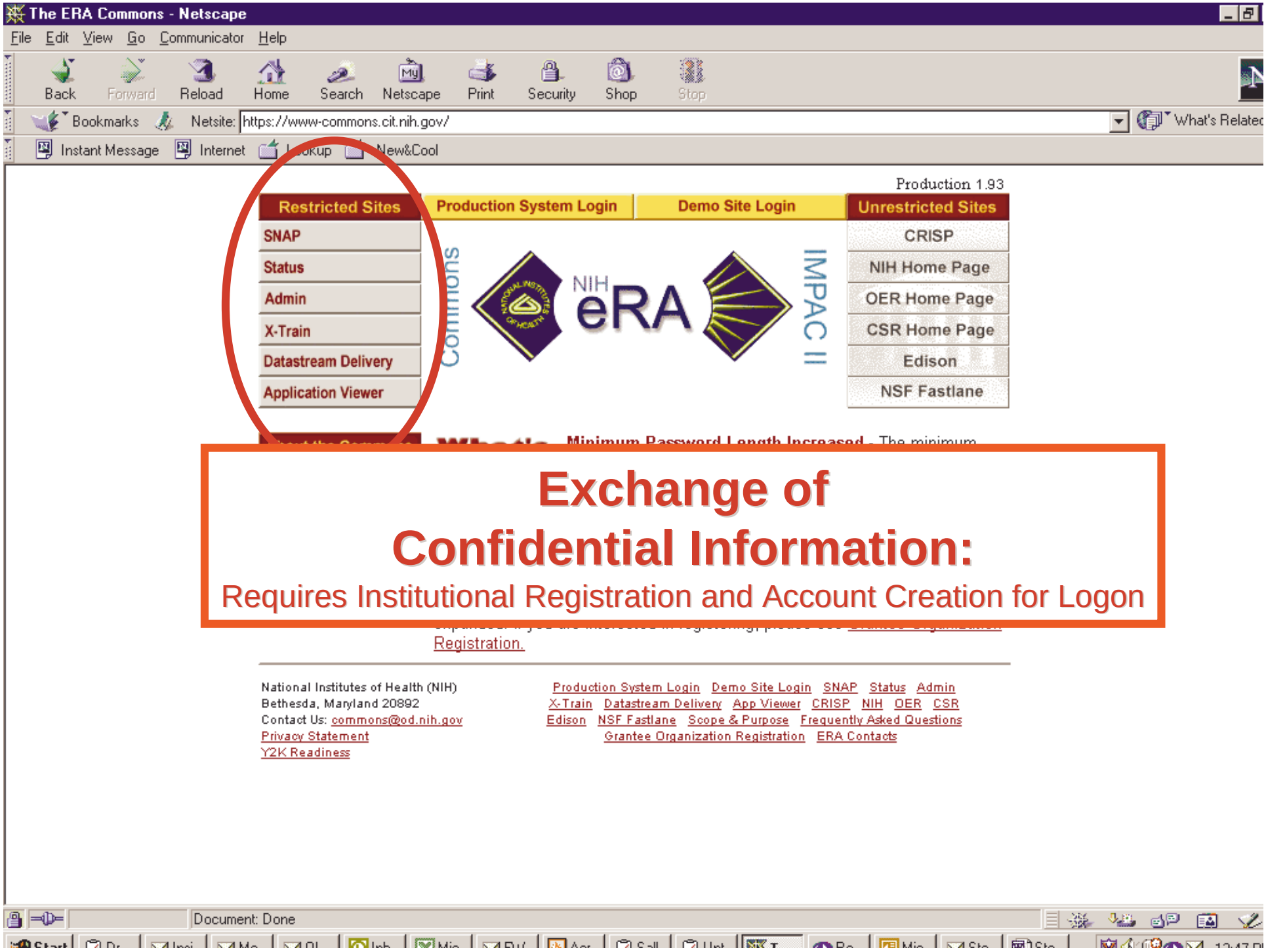
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Confidential Information:
Requires Institutional Registration and Account Creation for Logon
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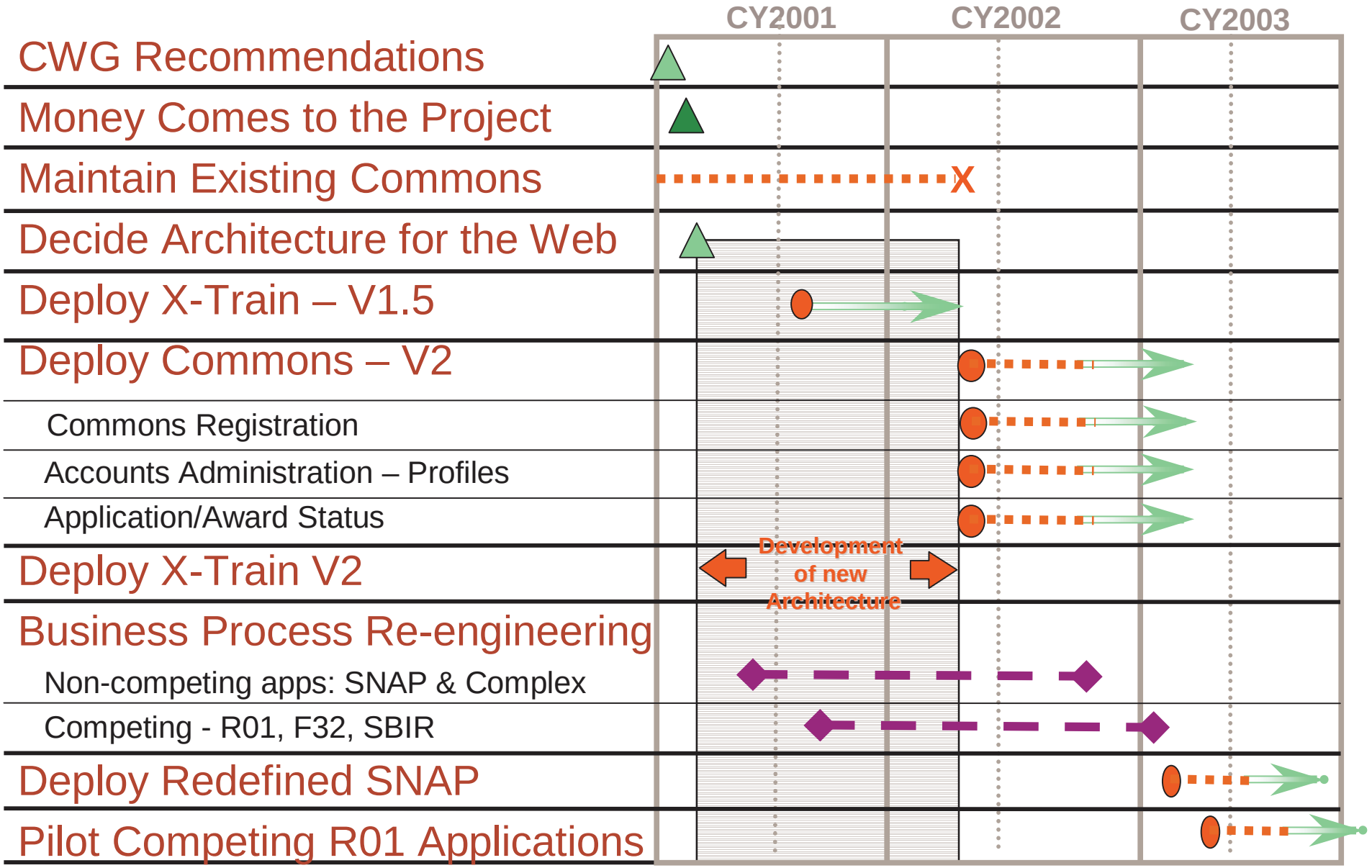
Production System Login Demo Site Login SNAP Status Admin
X-Train Datastream Delivery App Viewer CRISP NIH OER CSR
Edison NSF Fastlane Scope & Purpose Frequently Asked Questions
Grantee Organization Registration ERA Contacts
Document: Done

NIH eRA Commons
Implementation Plans: 2001-2003



Timely and Accurate Submission of Financial Status Reports (FSR)

- Except for those awards under SNAP and awards requiring more frequent reporting, the FSR is required annually.
- When required annually, the report must be submitted for each budget period no later than 90 days after the close of the budget period.
- NGA will specify if more frequent reporting is required

Reporting: Inventions and Final Closeout

- Each invention must be reported to NIH in grant applications, progress reports, and in the final invention statement and certification form.
- Final Closeout Reports
  - Final Financial Status Report
  - Final Invention Statement and Certification
  - Final Progress Report
- Failure to submit timely and accurate closeout reports may affect future funding

398 Issues

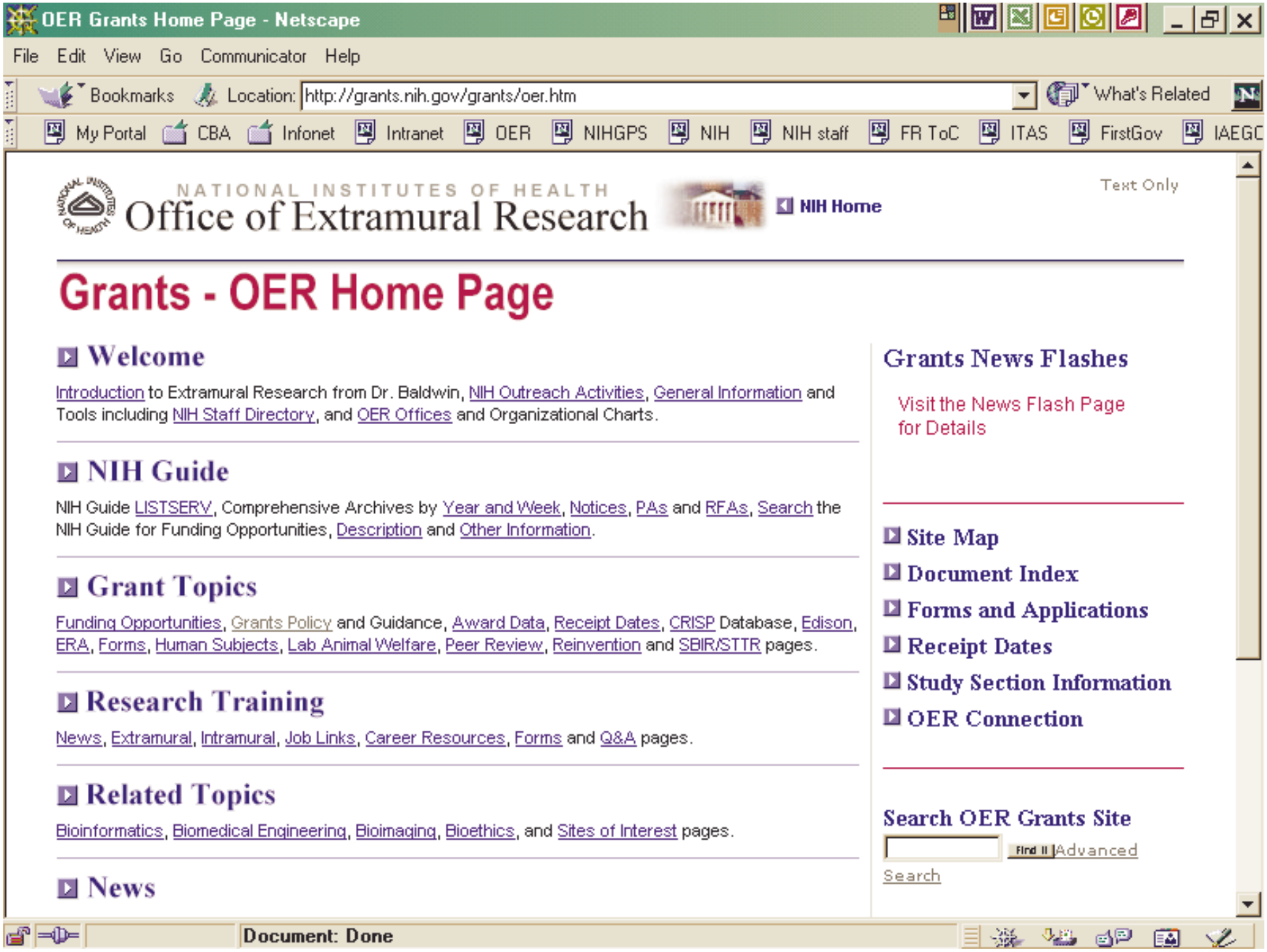
- Grantee must list the actual salary in effect at the time of submission (for non modular applications)
- Grantee should include actual escalation rates (for non modular applications)
- Grant applications should be complete timely and conform with all instructions (398 kit, program announcement)
- Submit a separate noncompeting continuation application for Minority Supplement recipients

398 Issues (cont.)

- Include certification that key personnel have received training in human subjects protections
- For clinical trials, include the data safety monitoring plan and complete the table on gender and minority accrual
- Appropriately identify key personnel and provide pertinent information (e.g., biosketch)
- Include all human/animal assurances (especially for type 2 and 5s)
- Provide complete information

A-133 Audit

- Data collection form and copies of the reporting package must be submitted to the Federal Audit Clearinghouse
- Audit reports should **not** be sent directly to the GMO
- HHS/NIH will impose sanctions that may result in the loss of Federal funds on grantees that are delinquent in complying with the provisions of A-133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Grants - OER Home Page
Welcome
Introduction to Extramural Research from Dr. Baldwin, NIH Outreach Activities, General Information and Tools including NIH Staff Directory, and OER Offices and Organizational Charts.
NIH Guide
NIH Guide LISTSERV, Comprehensive Archives by Year and Week, Notices, PAs and RFAs, Search the NIH Guide for Funding Opportunities, Description and Other Information.
Grant Topics
Funding Opportunities, Grants Policy and Guidance, Award Data, Receipt Dates, CRISP Database, Edison, ERA, Forms, Human Subjects, Lab Animal Welfare, Peer Review, Reinvention and SBIR/STTR pages.
Research Training
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Forms and Applications
Receipt Dates
Study Section Information
OER Connection
Search OER Grants Site
Find It! Advanced Search
Document: Done

Information Sources

- Your Office of Sponsored Projects
- ✓ Notice of Grant Award (terms of award)
- ✓ NIH Grants Policy Statement
- ✓ NIH Guide for Grants and Contracts
- ✓ NIH Office of Extramural Research Homepage
- ✓ Welcome Wagon Letter
- Grants Information at grantsinfo@nih.gov

What if I have a Question?

- Can my question be answered at my institution?
- Can my question be answered by written policy or regulations?
- Should my question be answered by an office at NIH? Should I call the Grants Management Specialist or Program Official indicated on the Notice of Grant Award?

Who Do I Call at NIH?

- See the NIH Grants Administration Information Sources (located on the OER Grants Policy and Guidance page) -- Resource for locating NIH extramural staff

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

For Policy Questions

- If I tried the above sources and still have a general policy question unanswered, call the Division of Grants Policy, OPERA, 301/435-0949

Award Conditions & Information for NIH Grants

- Standard NIH Award Terms and Conditions, Grant Payment Information and OIG Hotline information

http://grants.nih.gov/grants/policy/awardconditions.htm