PennERA Upgrade

An upgrade to the PennERA (Electronic Research Administration) system is scheduled to begin on Friday evening, April 15 with a planned go-live on Wednesday, April 27, 2005*. The upgrade will affect all current users of the PennERA system, including users of Proposal Tracking, SPIN Plus, and the Human Subjects and Lab Animal Protocol Tracking modules.

During the upgrade, the Office of Research Services (ORS) will be unable to create new or update existing proposals/awards and grant accounts. No AIS documents will be created after April 15 and no updates to regulatory protocol information will be possible until April 27. A read-only PennERA environment and the BEN Protocol Status Report will be available for reference during the upgrade; however, this information will be static as of April 15. No updates will be made during the upgrade process to proposal/award information in the Data Warehouse or to the protocol information in the BEN Protocol Status Report.

ORS staff will be in training during the week of April 18-22. We would like to encourage your patience as ORS staff acclimates to the new system. While we do not anticipate excessive delays with business operations, we do expect to experience some slowdown during this transitional period. We appreciate your patience as we strive to improve the way we do research administration at Penn.

End-user support

To coincide with the PennERA system upgrade, an end-user support structure has been implemented to support users:

- Help Line—Users dial 6-2900 (on campus) or 215-746-2900 (off campus); hours are 9AM-5PM, Monday-Friday. This single help-desk number can be used for all operational and technical questions.
- E-mail—Questions can be e-mailed to pennerahelp@pobox.upenn.edu.
- Web—A web form is available from the PennERA Help page at http://project.pennera.upenn.edu/help.asp. Users enter
information that will automatically be directed to subject matter and technical experts in the same manner as the Help Line.

**More information about PennERA**

Additional updates about PennERA will be provided throughout the project. For the most current information, please visit the PennERA web site at [http://www.pennera.upenn.edu](http://www.pennera.upenn.edu). If you have any questions, comments, or suggestions, please send an e-mail to pennera@pobox.upenn.edu.

*The projected release date is predicated on the availability and performance of the software products from the vendor from whom we purchased applications. We have every expectation that all software releases as well as testing and training components of the implementation will support release in that timeframe. Alternate release date is June 1, 2005.*

--Robin H. Beck,
Vice President of Information Systems and Computing

--Andrew B. Rudczynski, Ph. D.,
Executive Director of Research Services and Associate Vice President of Finance

--Joseph R. Sherwin, Ph.D.,
Director of the Office of Regulatory Affairs

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**NSF Web Site Redesigned**

If you’ve visited the NSF web site ([http://www.nsf.gov](http://www.nsf.gov)) since January 31, you’ll have noticed that the site has been redesigned. NSF has improved many functions and added some new ones.

One of the new features that should prove useful to faculty and staff is a page of “Specialized Information for the Research and Education Community” ([http://www.nsf.gov/funding/research_edu_community.jsp](http://www.nsf.gov/funding/research_edu_community.jsp)). A new funding section includes an alphabetical index and upcoming due dates ([http://www.nsf.gov/funding/](http://www.nsf.gov/funding/)). A note to those with browser bookmarks for NSF—some features, including the NSF Directorates, have moved or changed names.

**Federal Plan Will Allow Multiple PIs on Grants and Contracts**

In January, Office of Science and Technology Policy Director John Marburger issued a memo to federal agencies mandating that all federal research agencies “should accommodate the recognition of two or more principal investigators on research projects” funded by grants and contracts. The policy would not replace the use of a single principal investigator when appropriate but establishes “the appropriateness of multiple principal investigators in this era of complex multidisciplinary research.”

The details of the policy and its implementation have not been finalized. A work group of the National Science and Technology Council that includes representatives from federal agencies will “develop an implementation strategy that meets the needs of both the research community and the funding agencies.”


**New Search Features for NIH Guide**

National Institutes of Health NIH Guide announcements can now be found much more easily. NIH has improved the browse interface for Requests for Applications (RFAs), Program Announcements (PAs), and Notices. All announcements in each category may also be viewed by using selections in the drop-down box at the top of each listing page. Clicking on header links allows resorting of the lists online. In addition, a new “Ad Hoc” search page is available that allows individualized queries with various selection criteria.

Links to these new resources are available from the main NIH Guide Funding Opportunities and Notices page: [http://grants.nih.gov/grants/guide/index.html](http://grants.nih.gov/grants/guide/index.html).

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**Effort Reports were due April 8th!**

Any Reports that have not been submitted are delinquent. Please submit immediately.
Frequently Asked Questions for the NIH
Requirement for Education on the Protection of Human Subjects
(Updated: March 9, 2005 by NIH)

Questions About Who Must Comply with the Policy:

1. Who needs to receive required human subjects education?
   Individuals who will be involved in the design and conduct of NIH-funded human subjects research must fulfill the education requirement.

2. Does the education requirement apply to awards that do not involve human subjects?
   No, but it is important for all investigators, even those working with tissues or specimens derived from human sources to understand when proposed research triggers regulatory and policy requirements. Please note:
   - “Human subject” as defined in 45 CFR part 46 means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information.
   - Research using human specimens, tissues, or data that are unidentifiable may not be considered human subjects research. See: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.
   - Investigators who conduct studies with human specimens, tissues, or data that are determined not to involve human subjects are not required to receive the required education.

3. Are investigators involved in human subjects research that is described by one or more of the exemptions in 45 CFR 46 required to comply with the education requirement?
   Yes. Investigators who conduct human subjects research that is exempt from Institutional Review Board (IRB) review and approval (six exempt categories defined in 45 CFR part 46.101(b)) must comply with the education requirement.

4. Does the education requirement apply to new Key Personnel involved in human subjects research whose names are added on non-competing Progress Reports?
   Yes. NIH expects that all Key Personnel will receive the required education before beginning research involving human subjects. If Key Personnel are added to an award in a non-competing year, documentation that they have received the required education should be included in the non-competing Progress Report.

5. Do individuals identified as Key Personnel who are not involved in the design and conduct of the human subjects portion of an award need to comply with the education requirement?
   No. Investigators who are identified as Key Personnel, but are not involved in the design and conduct of human subjects research do not need to comply with this requirement.

6. Does the education requirement apply to Key Personnel involved in human subjects research supported by an NIH award if they will not be compensated by the award?
   Yes. The education requirement applies to all individuals involved in the design and conduct of human subjects research supported by an NIH award whether or not they receive compensation from the award.

7. Do Key Personnel on foreign awards or on foreign subcontracts have to comply with the education requirement?
   Yes. The education requirement applies to all investigators involved in the design or conduct of research involving human subjects. If the grantee organization has difficulty obtaining documentation that Key Personnel on foreign subcontracts have received the required education, NIH staff may consider issuing awards that restrict third party participation until this documentation is provided to NIH. This will streamline issuing awards in situations where third party participation is not essential to the start of the project. See the September 5, 2001 NIH Guide Notice for additional information.

8. Do third party (subcontract) Key Personnel or consultants need to comply with the
education requirement?
Yes. Third party Key Personnel and consultants must comply with the education requirement if they are involved in the design and conduct of research involving human subjects.

Questions About Award Mechanisms:

1. Does the education requirement apply to Research and Development contract awards?
Yes. The education requirement applies to Research and Development Contract awards that include human subjects research. The contracting officer will request documentation that all Key Personnel involved in human subjects research have received the required education prior to the award of a new contract.

2. Does the education requirement apply to NRSA research fellowship awards?
Yes. The education requirement applies to individual fellowship applications that describe human subjects research. For individual fellows, the Institute/Center that will be funding the fellowship application will request the necessary information prior to issuing the award (Just-In-Time).

4. Does the education requirement apply to NRSA training grants?
Trainees on NRSA training grants are required to receive training in the responsible conduct of research (RCR), which may include the protection of human subjects as a topic. Trainees involved in the design or conduct of human subjects research only need to provide additional documentation of having received the required human subjects education if their required RCR training does not include the protection of human subjects as a topic.

5. Does the education requirement apply to responses to RFPs, RFAs and PAs as well as to investigator initiated grant applications?
Yes. The education requirement applies to all NIH awards that include human subjects research.

Questions About Documentation:

1. When, in the award process, should documentation of the required human subjects education be provided to NIH?
The Institute/Center that would be funding the project will request documentation that all Key Personnel have received the required education prior to issuing the award. The information should be submitted to your Grants Management Official with other Just-In-Time requirements and must contain the signature of an authorized institutional official.

2. Will an award be delayed until documentation of completion of the required education is provided?
Yes. The award may be delayed in its entirety or NIH Staff may choose to issue an award restricting all human subjects research until documentation of completion of the education requirement has been received. If problems are encountered investigators should contact the program official or grants management specialist. Contractors and prospective contractors should consult with the project officer or contract officer.

3. Does the documentation that the required education has been received need to be a part of the document signed by an institutional official?
Yes. The documentation must be signed by an institutional official. It is, however, not required that the Principal Investigator also sign the documentation (see the September 5, 2001 NIH Guide Notice).

4. Do Key Personnel who have already submitted documentation of having received the required education for one award need to re-submit the documentation when involved in human subjects research supported by another award?
Yes. Individuals involved in the design and conduct of human subjects research supported by more than one award must provide certification that they have received the required education once for each award.
5. Can the same certificate of completion of the human subjects education be used on more than one application or contract proposal?

Yes. As long as the education is current, the same certificate may be submitted to NIH to fulfill the human subjects education requirement.

6. How frequently do Key Personnel need to provide documentation of having received the required education?

Key Personnel only need to provide this documentation once for each competing award.

7. If new Key Personnel involved in human subjects research are included in a non-competing Progress Report, does documentation of their compliance with the education requirement need to be provided?

Yes. Documentation of compliance with the education requirement must be provided for all Key Personnel involved in human subjects research once for each competing award. If Key Personnel are added to an award in a non-competing year, documentation that they have received the required education should be included in the next non-competing Progress Report.

8. If the NIH computer-based training module on Protection of Human Subjects is taken to meet the education requirement, will NIH provide copies of the certificate of completion?

No. After completing the training module, the trainee may print out a certificate of completion that may be provided as documentation of compliance with the requirement. NIH cannot provide additional copies of the certificate. Investigators who misplace their certificate of completion of the NIH computer-based training module may need to take the training again to obtain a new certificate.

Questions about Human Subjects Education Programs:

9. Does NIH specify which educational programs should be used to fulfill the human subjects education requirement?

No. The NIH does not endorse any specific educational programs. We believe that institutions are in the best position to determine what programs are appropriate for fulfilling the education requirement. Institutions may require a particular program or may choose to develop a program to meet the requirement. The "NIH Bioethics Resources on the Web" site: http://www.nih.gov/sigs/bioethics/specific.html lists several courses that institutions may direct Key Personnel involved in human subjects research to complete.

10. How often do investigators involved in the design and conduct of human subjects research need to complete the education?

The NIH policy is silent on the frequency of education. The intent of the education requirement is for investigators to keep abreast of development in human subjects protection. We believe that institutions and investigators are in the best position to determine when additional education is warranted.

For Further Information, Please Contact OEPMailbox@mail.nih.gov.
Did You Know.......??

...Faculty are required to certify their own effort report (see Sponsored Projects Policy No. 2114). Whether the effort form is electronic (some faculty are participating in the ERS Pilot) or paper, the faculty member must certify his or her own effort form.

...Cost transfers can be a red flag to auditors that awards are not being managed properly. Be cognizant of Sponsored Projects Policy No. 2113. All cost transfers (including salary) must be done within 90 days from the time the expense was incurred. Waiting until an effort report is generated may not conform to the policy.

...Books are not an allowable cost to a federal sponsored project if that book is available in the University’s Library. The rational is that an allocable portion of the Library’s acquisition costs are included in the University’s F&A rate. Purchasing the same book on a federal award and applying the F&A rate to that expense would be considered double charging the federal government auditors.

...NSF’s current maximum consulting rate is $524.00 per day (exclusive of indirect cost, travel, per diem, clerical services, fringe benefits and supplies) as specified in Article 5 of the NSF GC-1.

...At a minimum, the NIH expects that all Key Personnel will receive the required education before beginning research involving human subjects. If Key Personnel are added to an award in a non-competing year, documentation that they have received the required education should be included in the non-competing Progress Report.

Training Opportunities:

ORS Quizzes and FAQ’s:

Take a moment to look at our quizzes or FAQ section for more guidance on administering 5-funds here at Penn. Both can be accessed by clicking Training on our home page (http://www.upenn.edu/researchservices/).

Research Compliance Tutorials and Other Education:

For further guidance on administering 5-funds here at Penn, please visit the Research Compliance Training and Education page at http://www.upenn.edu/researchservices/rc/pages/training.htm.
ORS Monthly Quick Quiz

1) OMB Circular A21 mainly covers which –
   a) Cost Principles
   b) Administrative Requirements for Grants and Other Agreements
   c) Audits

   For answer, click here or visit http://www.whitehouse.gov/omb/circulars/index-education.htm.

2) Effort Reporting information is available in one location on ORS’s website.
   a) True
   b) False

   For answer, click here or visit http://www.upenn.edu/researchservices/effortreportingA.html.

3) The Sponsored Programs Manual includes chapters titled “Preparation of Proposals” and “Guidelines for Cost Transfers”.
   a) True
   b) False

   For answer, click here or visit http://www.upenn.edu/researchservices/Manual.html.

New Research Compliance Tutorials Now Available

Newly added to the ORS Web Site are tutorials on the subjects of Allowability, Cost Transfers & Documentation; Export Controls, and Effort Reporting. Please take a few moments to view these tutorials. The tutorials and other compliance related information can be found at http://www.upenn.edu/researchservices/rc/pages/training.htm.
Getting to Know......
Flossie Perry, Receptionist/Administrative Assistant

Years at Penn: 15 years

Years in Research Services: 6 years

What she does: Meet and Greet visitors, answer questions and telephones, and direct telephone calls to appropriate person. Filing, typing, etc.

Hobbies/Interests: Cooking, reading, and helping others.

Favorite Restaurant: Little Italy In N.J.

Favorite ways to spend a vacation: Going to North Carolina to visit other family members and spending time with family.

What Co-workers say:
...Flossie is always ready to pitch in when others need help
...She loves the Holidays and is the best decorator in the office.

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The Pre-award staff is responsible for processing proposals, reviewing, negotiating, and accepting awards (except for corporate contracts), as well as, providing post-award non-financial administration for these accounts. Questions concerning issues such as no-cost extensions, carryover requests and other administrative matters should be directed to the appropriate pre-award contact. Questions concerning industrial clinical trial agreements and sponsored research agreements should be addressed to the Corporate Contracts Group.

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Contact Information for all areas is provided below.

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About Our Organization...

Our Mission

The Office of Research Services (ORS) oversees the administrative support of the University's externally funded research and is responsible for implementation of University policies established for this purpose. An important part of the ORS mission is service to the research faculty, through the provision of information and advice for the development of applications, and assistance in the administration of awarded grants and contracts.

In this role, ORS

• Supports the schools and centers in the development of proposals for grants and contracts;
• Reviews and approves all proposals before submission to the potential sponsor;
• Coordinates negotiations of awards;
• Accepts awards for the University, including the signing of contracts;
• Provides oversight and guidance to faculty and staff concerning the proper management of sponsored projects;
• Prepares all financial reports to sponsors.

In addition to these functions, ORS is responsible for billing of contracts management of letters of credit for payment of grants, preparation of the facilities & administrative and employee benefit rate proposals and rate negotiations, management of the effort reporting system, and oversight of service center rate development. ORS reports jointly to the Vice President for Finance & Treasurer and Vice Provost for Research.

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