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Office of Research Services

-- Research Administration News --

Special Interest Articles:

- **NEW FEDERAL REGULATION** regarding select agents and toxins
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- Clinical Trials, Confidentiality Agreements
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Industry-Sponsored Clinical Trials – Change in Facilities and Administrative (F&A) Cost Recovery Rate

Effective July 1, 2003, the University's Facilities and Administrative (F&A) cost recovery rate for industry-sponsored clinical trials will be increased to 26% of total direct costs of the project, from the current rate of 23.6%. The 26% rate, which is the University's negotiated off-campus F&A cost recovery rate, will provide the University and the Schools with F&A cost reimbursements that more closely approximate the University's actual costs. The decision to increase the rate was made in consultation with senior officials of the University schools that conduct clinical trials, and with members of the Human Research Advisory Committee.

Also, effective immediately, the University will adopt the NIH's definition of a "clinical trial," for the purpose of assigning the F&A cost recovery rate to industry-sponsored clinical trial proposals. The NIH definition is: "a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious and effective. Clinical trials of experimental drug, treatment device of behavioral intervention may proceed through four phases....." The definition goes on to define the four phases of clinical trials that proceed through epidemiological studies. The full definition is available at http://grants.nih.gov/grants/peer/tree_glossary.pdf.

We ask that you communicate this F&A cost rate change and the updated definition to all faculty and business administrators in departments that conduct industry-sponsored clinical trials. The new rate will apply to industry-sponsored clinical trials for which proposals are submitted on or after July 1, 2003.

It is very important that faculty understand that, in developing the budgets for clinical trials, all appropriate costs, including minimal expected faculty effort and corresponding salary, and F&A costs, must be included in the total costs proposed to sponsors. We recognize that the sponsors of clinical trials frequently approach an investigator with a pre-determined budget amount. Faculty should be cautioned that an internal budget that accounts for all institutional costs must be developed, in order to determine if it is financially feasible to participate in the clinical trial.

The Human Research Advisory Committee will monitor the effects that this change may have on the ability of schools to recover more of their costs associated with the conduct of clinical trials.

Thank you for your cooperation in communicating this information to faculty and staff for whom it is relevant.

SELECT AGENTS and TOXINS NEW FEDERAL REGULATION 42 CFR 73

On June 12, 2002 President Bush signed the "**Public Health Security and Bioterrorism Preparedness and Response Act of 2002**" (Public Law 107-188). The law is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Law requires that all persons possessing biological agents or toxins deemed a threat to public health notify the Secretary, Department of Health and Human Services (HHS). The Law also requires all persons possessing biological agents or toxins deemed a threat to animal or plant health and to animal or plant products to notify the Secretary, US Department of Agriculture (USDA). Penn completed the notification process in the Fall of 2002.

On December 13, 2003, new rules were published in the Federal Register by the Departments of Health and Human Services (HHS) and Agriculture (USDA) for facilities or entities that possess, use, or transfer select agents or toxins. These rules became effective on February 7, 2003.

The Office of Environmental Health & Radiation Safety (EHRS) provides the University oversight (Responsible Official) required by the regulations. The **list of HHS and USDA select agents and toxins** is currently available on the EHRS website. To comply with regulations, each Principal Investigator (PI) possessing, using, or intending to transfer or receive any "select agent" is responsible for registering with EHRS and the appropriate federal agency (CDC or APHIS). Application packets must be reviewed and approved by the director of EHRS prior to submission to federal agencies. The director of EHRS submits all applications to CDC and/or APHIS. **Transfers, sending or receiving of any select agent (intramural or extramural) is prohibited without EHRS approval.**

Contact an [EHRS biosafety officer](#) at 215-898-4453 for more information on the registration process.

Any questions regarding this new law should be forwarded to EHRS at ehrs@ehrs.upenn.edu

Where can I get more information about administering my grants?

Office of Research Services Web Site:

www.upenn.edu/researchservices/

Research Investigator's Handbook:

www.upenn.edu/researchservices/rih/intro.html

A Quick Guide for Faculty:

www.upenn.edu/researchservices/pdfs/newfacbk.pdf

University of Pennsylvania Cost Sharing Policy:

www.upenn.edu/researchservices/rs/costshare.html

Contact an Office of Research Services Staff Member:

www.upenn.edu/researchservices/rs/contact.html





PennERA: Preparation for Implementation of Phase I

The PennERA (Electronic Research Administration) team is currently finalizing the implementation for Phase I of the project. As part of Phase I implementation, the Human and Animal Protocol and Proposal Tracking modules of the PennERA system will be released to the Office of Research Services (ORS) and the Office of Regulatory Affairs (ORA). SPIN Plus, a funding opportunities application, will be available to the entire Penn community. A valid PennKey and password and a standard web browser will be required to access these applications.

A projected July 2003 release date is based on a "window of opportunity" that appears to best balance the introduction of changes with the least disruption of critical year-end operational activities. The planning assumption behind a release date is of course predicated on the availability and performance of the software products from the vendors 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 time frame.

Training will be provided on the Human and Animal Protocol and Proposal Tracking modules for those who will have access as part of this release, including ORS and ORA, and to a limited extent OEHRs, ORSS, OHR, and ULAR. An online tutorial and a quick reference guide will be available to SPIN Plus users. More details on training will be provided as implementation approaches.

Changes

When the new applications are released, the following complementary changes will be made:

- BEN Reports—Changes to BEN Reports will be to the protocol information being displayed in BEN Reports only. Changes to the Financial Reports in BEN Reports are not anticipated at this time.
- AIS form—The current AIS form will be redesigned to reflect the newly automated account setup process.
- Proposal Transmittal and Approval Form—The current Proposal Transmittal will be updated to reflect changes in data elements, as well as to incorporate information for compliance purposes.
- Protocol Tracking and Proposal Tracking applications—These applications will provide the ability to set up automatic alerts by project to signal when grants and protocol approvals are about to expire.
- BEN Financials—Minor changes will be made to the Freeze Grant and Fund Attributes screens and certain reports specific to ORS Post-Award accounting to display the sponsor code, which is being converted from a 4- to a 5-digit number.
- GRAM—Minor cosmetic changes to GRAM are anticipated.

In preparation for implementation, ORS and ORA staff will be going through a transitional period as they acclimate to the new systems. We do not anticipate excessive delays with business operations, but 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.

More Information about PennERA

Stay tuned next month for details about implementation dates for Phase I. Additional updates about PennERA will be provided throughout the project. For the most current information, please visit the PennERA project web site at <http://www.pennera.upenn.edu/>. If you have any questions, comments, or suggestions, please send an e-mail to pennera@pobox.upenn.edu.

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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

Confidentiality Agreements For Evaluation of Clinical Trial Materials

When faculty researchers are considering participation in a clinical trial sponsored by a pharmaceutical company, the pharmaceutical company will usually provide to the faculty researcher information about the investigational drug or device covered by the clinical trial. This information is provided in order to allow the faculty researcher to evaluate the value of participating in the clinical study as an investigator. Given the enormous investments being made for the development of new therapeutic agents, the information provided may be of significant commercial value and the pharmaceutical company will usually require the prospective investigator to review such information under terms and conditions imposed by a signed confidentiality agreement.

In considering the acceptance of confidential information under such agreements, faculty researchers should consider the following:

1. The policy of the University of Pennsylvania is that such confidentiality agreements are a matter between the faculty researcher and the pharmaceutical company. The University will not sign such agreements and shall not bear any liability for maintaining the confidentiality of information provided to the faculty researcher under such confidentiality agreements. Making confidential information available solely to the faculty researcher protects other University personnel from the potential liability of having violated confidentiality obligations. As a general rule, the University research environment is not well suited for maintaining the secrecy of commercially valuable information.
2. Faculty should be wary of unreasonable terms and conditions under such agreements. For example, it is preferable to limit the obligations of confidentiality to include materials provided to the faculty research in writing. Requirements that verbal disclosures be kept confidential are ambiguous and difficult to enforce. In addition, the agreement should not contain any terms relating to ownership of intellectual property or unreasonable limits on future publications. The terms and conditions should relate only to the purpose of maintaining the confidentiality of materials provided to the faculty researcher in order for them to evaluate the prospect of participating in the clinical trial. Another point to keep in mind is that the materials provided should be limited to technical information truly needed to evaluate participating in the trial and should exclude needless information of a financial or business nature. Finally, the term of the confidentiality agreement should be for a period of about three years. Time periods greater should be carefully considered before accepting them.
3. The Office of Human Research has a University of Pennsylvania template Confidentiality Agreement for the purpose of allowing faculty researchers to receive information from pharmaceutical sponsors. <http://www.med.upenn.edu/ohr/agreements.htm>. OHR can provide guidance and review for confidentiality agreements provided to faculty for such purposes. Confidentiality agreements provided to faculty for other purposes are handled by the Center for Technology Transfer. <http://www.finance.upenn.edu/ctt/>



Frequently Asked Questions...

What is the Federal Demonstration Project (FDP)?



The Federal Demonstration Partnership (FDP) is a cooperative initiative among federal agencies and institutional recipients of federal funds. It was established to increase research productivity by streamlining administrative processes and minimizing the administrative burden on principal investigators while maintaining effective stewardship of federal funds. On July 1, 1996, the University of Pennsylvania became a member of the FDP. If you are a researcher and a recipient of federal grants, you have benefited from FDP successes, which include ninety-day pre-award spending authority, institutionally approved no-cost extensions up to one additional year, and automatic carryover of unobligated funds from one budget period to the next. In its current phase (Phase IV), the FDP boasts ninety institutional members, ten federal agencies, and two professional organizations. Given the ever-increasing federal regulatory environment and the strain on the relationship between academe and the federal government, FDP provides a unique forum for dialogue, demonstration, and debate among all the key players.

More information regarding the FDP, the participating agencies, and the resulting benefits for award administration at Penn can be obtained at www.thefdp.com or <http://www.upenn.edu/researchservices/spmanual/fdp.html>.

How Does Penn Rank in Research \$ Received?

Penn is ranked ninth nationally in research expenditures (per NSF survey for federal fiscal year 2001 which is the latest survey available).

<http://www.nsf.gov/sbe/srs/nsf03316/pdf/tabb32.pdf> expenditures include all research sources as reported by the institution.

In the area of federal awards, Penn was ranked third in federal obligations for federal fiscal year 2001.

<http://www.nsf.gov/sbe/srs/infbrief/nsf03317/start.htm>.

Regarding NIH funding, during federal fiscal year 2002, Penn ranked second as a University.

<http://grants1.nih.gov/grants/award/trends/rnk02all1to100.htm>

Pre-Award Administration Staff

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. Greg Curley is now responsible for Account Information Sheets (AIS's) for all industrial clinical trials and sponsored research agreements.

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- Institute for Environmental Medicine – SOM
- Institute for Human Gene Therapy – SOM
- Institute for Neurological Sciences – SOM
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- Neurology – SOM
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- Gastrointestinal – SOM
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- Neurosurgery - SOM
- Orthopedic Surgery – SOM
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- Microbiology – SOM
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- Account Information Sheets for Corporate Contracts

Post Award Administration Staff

The main functions handled by these ORS staff members are the preparation of financial invoices and reports, coordination of audits, collection of receivables, cash management functions, and close outs of funds. The Federal Compliance Group handles facilities and administrative costs, employee benefit rates, effort reporting, and compliance issues. Contact Information for all areas is provided below.

FEDERAL COMPLIANCE GROUP:

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 - Surgery
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About Our Organization...

Our Mission

The Office of Research Services 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, Research Services

- 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, Research Services is responsible for billing of contracts management of letters of credit for payment of grants, preparation of indirect cost and employee benefit rate proposals and rate negotiations, management of the effort reporting system, and oversight of service center rate development. The office reports jointly to the Vice President for Finance and Vice Provost for Research.

Office of Research Services Quick Contact List:

ORS General Phone Numbers: 215-898-7293 (General Information, Proposals, Awards)
215-898-7269 (Financial Reports & Invoices, Accounting)

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