



Office for Research Protections

newsletter

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Fall Edition

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Announcements

New Reporting System for Terminated/Expired Protocols

Beginning in the month of September 2003, as part of ORP's transition to an electronic protocol management system, ORP will begin sending electronic notices to investigators informing them of closed and expired protocols. At the same time, ORP will discontinue sending individual notices of closed and expired protocols to College Deans and Department Heads. Instead, a summary report of all closed and expired protocols will be sent to each Dean and Department Head twice per month for IACUC protocols and once per month for all Human Participant, Biosafety and Isotope protocols. The first report to the Deans and Department Heads will be sent in October 2003.

New Adverse Event Reporting Policy

The Biomedical and Social Science Institutional Review Boards have recently approved an adverse event policy. This policy will replace the existing policy and defines adverse events according to significance. There are significant adverse events, trends, and mild and moderate events, which all have guidelines defined for how and when to report. There are new event forms and tracking logs available on the ORP website (<http://www.research.psu.edu/orp/>) for investigator use.

Office for Research Protections

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ORP—Serving the Penn State Research Community

The Office for Research Protections' goal is to promote a successful partnership of shared responsibility between the researchers, the compliance committees, and the University to protect research participants, researchers, and the local community. ORP strives to make Penn State a model for conducting outstanding research in an atmosphere that promotes trust, respect, and cooperation from both the academic community and the general public.

Navigating and complying with the increasingly complex regulations governing research can be difficult. Yet, the level of accountability expected from research institutions has increased dramatically, and failure to comply can make an institution ineligible for future funding from federal, state, or private sources.

ORP is in place to help University faculty, staff, and students obtain approval for proposed research projects and conduct research within the legal boundaries. ORP provides the following services:

- consultation with researchers about the conduct of their research and their research proposals
- preliminary screening of proposals for compliance with the regulations
- scheduling of research proposal reviews by the compliance committees
- maintenance of review proceedings records and
- educational seminars.

ORP administratively manages the five University compliance committees that review research proposals:

- the Biomedical Institutional Review Board (IRB)
- the Social Science Institutional Review Board (IRB)
- the Institutional Animal Care and Use Committee (IACUC)
- the Institutional Biosafety Committee (IBC) and
- the University Isotopes Committee (UIC).



Additionally, ORP coordinates committee activities with other administrative units (including the Animal Resource Program, Environmental Health and Safety, Office of Sponsored Programs, University Health Services, Office of Physical Plant, and University Relations); represents the Vice President for Research in applying for assurance renewals and research program accreditations, making mandatory reports, and hosting inspectors from governmental oversight agencies; and maintains all committee records, research proposals, and related documents.

ORP is responsible for all campus locations except for the College of Medicine located at the Hershey Medical Center. Although the College of Medicine maintains its own compliance committees and separate federal assurances, ORP maintains close communication with all Penn State campuses to ensure consistent policy throughout the Penn State System.

One of ORP's goals, however, is to serve you, the researcher. We want to ensure that you are able to conduct your research study, whenever possible. Sometimes it can be difficult to understand why and how the regulations impact your research proposal. When you have questions, ORP staff members are available to assist you in preparing your research project so that it is in compliance with federal, state and local regulations, as well as, University Policies.

Research vs. Class Project – When to Submit to ORP

Mary wanted to present the results of a class project at the Undergraduate Research Fair. However, when she submitted her work, she was asked for documentation of IRB approval for her research. Mary had not submitted her research to the IRB for approval prior to carrying out her project. In fact, she had never heard of the IRB before. Without IRB approval, Mary was denied the ability to present her work at the exhibit. Mary contacted the ORP with her problem and inquired about obtaining IRB approval. Unfortunately, according to federal regulations, the IRB could not retroactively approve her research project.

This scenario is hypothetical, but very similar situations do occasionally occur. To help avoid such unfortunate circumstances, the ORP encourages instructors to adequately inform their students about the need to submit to the IRB (*for work with human participants*) or to the IACUC (*for work with animals*) when doing work that falls under the definition of research.

Research is defined as a “systematic investigation designed to develop or contribute to generalizable knowledge” (Federal Register, 56, p. 28013). Dissemination of findings includes, but is not limited to, honor’s, master’s, and doctoral theses; presentation at a scientific meeting or conference; submission to or publication in a scientific journal; and Internet postings. If the project falls under this definition of research, review and approval of a human participants research protocol by the IRB or of an animal research protocol by the IACUC is required.

Class related instructional assignments that do not fit within the definition of research do not need to be submitted to the IRB or IACUC for review. However, if either knowledge contribution or dissemination is a possibility, IRB or IACUC review and approval must be obtained prior to contact with research participants.

Additionally, it is important to keep in mind that if student work will fall under the definition of research, instructors should discuss the IRB or IACUC submission process early in the class schedule to allow adequate time for IRB / IACUC review and approval prior to the start of the research. Generally, IRB or IACUC review takes three weeks. Research may not begin until approval is granted.

Guidelines regarding class projects and research can be found on the ORP website at <http://www.research.psu.edu/orp/hum/guide/IV.html>.

Ensuring Animal Welfare: Penn State's AAALAC Accreditation

Adapted in part from information published on the AAALAC website (<http://www.aaalac.org>)

The Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accredited The Pennsylvania State University on February 13, 2001. AAALAC promotes the humane treatment of animals in science through a voluntary accreditation program through which "research programs demonstrate that they not only meet the minimums required by law, but are going the extra step to achieve excellence in animal care". To date, more than 650 organizations have earned accreditation through AAALAC, indicating a commitment to animal welfare and appropriate animal use in research.

To become accredited, Penn State had to carry out an extensive self-assessment of all aspects of the animal research program. AAALAC evaluators reviewed the self-assessment and conducted a four-day site-visit at the University to ensure that regulations and standards of care were being met. Penn State is currently in the process of renewing its accreditation. AAALAC conducted site visits at the University Park campus the week of July 27th, 2003. The site team will make its recommendation to the AAALAC Council. The AAALAC Council will meet this fall to review the recommendation and make a final decision regarding our accreditation status.



AAALAC accreditation offers several benefits to Penn State:

- 1) Signals a quality program: Accreditation demonstrates that Penn State is serious about setting, achieving, and maintaining high standards for animal care and use.
- 2) Enhances scientific validity: Reliable results in scientific research involving animals depend on superior animal care. Accreditation engages scientists, managers, and administrators in a rigorous assessment of the Penn State program, ultimately resulting in better research practices and outcomes.
- 3) Demonstrates accountability: Accreditation demonstrates a willingness to go above and beyond what is required by law to conduct animal research in a humane manner. It tells the Penn State community that we are committed to responsible animal research.
- 4) Provides assurances to funding sources: Many funding sources view AAALAC accreditation as a commitment to program excellence, and as an assurance that animal use will be justified and humane and regulations will be followed.

HIPAA Regulations in Place for Human Participant Research

As of April 14, 2003, research projects working with protected health information are subject to federal regulations in the Health Insurance Portability and Accountability Act (HIPAA). HIPAA was designed to improve the efficiency and effectiveness of the healthcare system, as well as to increase the accountability of healthcare providers with respect to the confidentiality of patient information.

HIPAA relates directly to what is called Protected Health Information (PHI). PHI is defined as identifiable health information created or received by an organization covered under the HIPAA regulations (generally healthcare providers and insurance companies).

HIPAA impacts all researchers at Penn State who plan to create or use PHI in their research. Such research activities might include medical chart reviews, epidemiological studies, behavioral studies, social science studies, and clinical research. They may or may not involve the provision of treatment or diagnosis.

How do you know if your research will use PHI? When evaluating the data you will collect, ask yourself three main questions:



- 1) Is the health information resulting from a clinical encounter (like a physician visit)?
- 2) Is the physician or other individual performing the clinical treatment part of a covered entity (under HIPAA)?
- 3) Does the covered entity perform standard transactions electronically (e.g., billing for healthcare services)?

If your research will use PHI, you will find that HIPAA impacts:

- 1) your ability to access PHI records and databases maintained by covered entities and
- 2) your responsibilities to protect the privacy of PHI once it is in your possession.

HIPAA requires a number of new forms and procedures, as well as, training in order to access and utilize PHI for research. The ORP staff can help you identify what you may need to do to be in compliance. You can also read more about the HIPAA regulations and how they affect research at Penn State by reviewing the online training module, HIPAA: The Impact on Research developed by ORP. To access the training, visit <http://www.research.psu.edu/orp/HIPAA/index.htm>.

Promoting the Responsible Conduct of Research (RCR)

As a research university, maintaining integrity in research is of paramount importance not only for continuing excellence in the professions we represent, but also for preserving public trust in our institution. Disregard for integrity in research stands to tarnish the reputation of individual researchers as well as our institution.

In a 2002 report, the Institute of Medicine stated that, "For an institution, [integrity] is a commitment to creating an environment that promotes responsible conduct by embracing standards of excellence, trustworthiness, and lawfulness" (p. 4). The report goes on to say, "For the individual scientist, integrity embodies above all a commitment to intellectual honesty and personal responsibility for one's actions and to a range of practices that characterize the responsible conduct of research, including:

- intellectual honesty in proposing, performing, and reporting research
- accuracy in representing contributions to research proposals and reports
- fairness in peer review
- collegiality in scientific interactions, including communications and sharing of resources
- transparency in conflicts of interest or potential conflicts of interest
- protection of human participants in the conduct of research
- humane care of animals in the conduct of research and
- adherence to the mutual responsibilities between investigators and their research teams" (p. 5).

The research environment in which we work continues to change and become increasingly complex. It becomes more and more difficult to manage all of the issues impacting research such as the ever-growing number of regulations, the increasing commercialization of research, the need to safeguard intellectual property while supporting an environment of openness, the oversight of research staff with varying levels of expertise, and the management of fiscal responsibilities – all while continuing to strive for greater and greater outputs.

Because of the increasing responsibilities placed on researchers, institutions need to play an important role in helping to promote and maintain research integrity. Here at Penn State we are undertaking a Responsible Conduct of Research (RCR) education initiative that will offer numerous methods of reaching out to researchers to increase awareness of research integrity.

The first effort under the RCR initiative, the development of the Guidelines for the Responsible Conduct of Research, is already complete. The Guidelines, which will be available on GURU as RAG16, outline the University's expectations for the ethical conduct of research.

The second initiative is to offer short research and professional ethics educational workshops within each college. These workshops will begin fall semester 2003. Each department within the college will be encouraged to send faculty representatives. Depending on the college, the workshops will cover topics such as conflict of interest, intellectual property, data management, authorship, and human participant and animal research. In the future, other supporting educational materials will also be available through online learning modules.

Michelle Stickler in the Office for Research Protections is coordinating the RCR education initiative. Michelle is also available to make research ethics presentations in the classroom and other forums. Michelle can be reached at 814-865-1775 or mmc115@psu.edu.

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Meet our Staff:

Administration:

- **Candice Yekel**, Director
- **Paula Morgan**, Administrative Assistant
- **Laura Young**, Staff Assistant

Education:

- **Michelle Stickler**, Education Specialist
- **Jennifer Stewart**, Multimedia Training Specialist

Compliance:

Institutional Review Board (IRB)

- **Mary Becker**, Compliance Coordinator II - Biomedical Human Participants
- **Melissa Conrad**, Biomedical IRB Assistant
- **Tracie Kahler**, Compliance Coordinator II - Continuing Reviews for Human Participants
- **Jodi Mathieu**, Compliance Coordinator II - Social Science Human Participants
- **Stephanie Krout**, Social Science IRB Assistant

Institutional Animal Care and Use Committee (IACUC)

- **William Greer**, Compliance Coordinator II - Animal Care and Use, Radioactive and Biohazardous Materials
- **Melanie Freeman**, Animal Care and Use Committee Assistant

Institutional Biosafety Committee (IBC) and University Radioisotopes Committee (UIC)

- **William Greer**, Compliance Coordinator II - Animal Care and Use, Radioactive and Biohazardous Materials
- **Erica Kresovich**, Biosafety and Radioisotopes Assistant

This publication is available in alternative media on request.

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