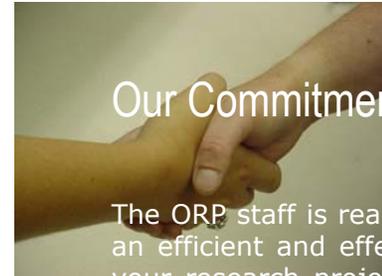




The Pennsylvania State University
212 Kern Graduate Building
University Park, PA 16802-3301
814.865.1775
www.research.psu.edu/orp/



Our Commitment to You:

The ORP staff is readily available to facilitate an efficient and effective review process for your research projects. We promise to exceed your expectations in providing excellent customer service. Your comments and suggestions are always welcome.

This publication is available in alternative media on request.

The Pennsylvania State University is committed to the policy that all persons shall have equal access to programs, facilities, admissions, and employment without regard to personal characteristics not related to ability, performance, or qualifications as determined by University policy or by state or federal authorities. It is the policy of the University to maintain an academic and work environment free of discrimination and harassment against any person because of age, ancestry, color, disability or handicap, national origin, race, religious creed, sex, sexual orientation or veteran status. Discrimination or harassment against faculty, staff or students will not be tolerated at The Pennsylvania State University. Direct all inquiries regarding the nondiscrimination policy to the Affirmative Action Director, The Pennsylvania State University, 201 Willard Building, University Park, PA 16802-2801; Tel 814-865-4700/V, 814-863-1150/TTY



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Who we Are

The Office for Research Protections (ORP) was established in 1990. The responsibilities of the office include facilitating the research review process, providing guidance on research integrity issues and serving as a resource for the research community. ORP administers five University review committees formed to ensure that research is conducted in accordance with federal, state and local regulations and guidelines.

They are:

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

Each committee is comprised of faculty, staff and community representatives appointed by the Vice President for Research, and includes both scientist and non-scientist members in order to provide comprehensive review of research proposals.

The ORP is responsible for all colleges and campus locations except for the College of Medicine, which 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.

About the IRB

The IRB's primary responsibility is to ensure the protection of human participants. Anyone performing research studies involving human participants at Penn State must submit to one of the following committees for review and approval prior to initiating their research:

- The Social Science IRB reviews human-participant research that involves questionnaires, surveys, interviews, focus groups, etc.
- The Biomedical IRB reviews human-participant research that involves the scientific study of normal or abnormal physiology and development; studies that evaluate the safety, effectiveness, or usefulness of a medical product, procedure, or intervention; and studies that involve any invasive procedures (e.g., saliva, tissue, urine, or blood samples; dietary manipulation; exercise studies; etc.).

The IRB holds monthly meetings to discuss full review proposals. Expedited and exemption reviews are assigned to at least one committee member for review. The estimated review time is approximately three weeks. Prior to approval, research personnel listed on the protocol application must complete the online IRB Basic Training Seminar, located at <http://www.research.psu.edu/orp/hum/train/intro.html>.

About the UIC

The primary responsibility of the UIC is to ensure that Penn State complies with regulations established by the Nuclear Regulatory Commission (NRC) and the Pennsylvania Department of Environment Protections for containing, controlling and transporting radioactive materials. Anyone utilizing radioactive materials must submit an authorization request to the UIC for review and approval prior to starting their research.

Visit our Website!

www.research.psu.edu/orp



ORP has a website located at the following URL: <http://www.research.psu.edu/orp>. A few of the many useful items available on the website are:

- IRB, IACUC, UIC and IBC applications (available for download and completion on your personal computer)
- description of types of review
- model consent forms and instructions
- online training programs
- committee and university policies and guidelines
- meeting dates
- relevant links
- FAQs
- information on research ethics and conflict of interest
- much more!

Other Resources:

Vice President for Research: 814-863-9580

Office of Intellectual Property: 814-865-6277

Office of Sponsored Programs – 814-865-1372

Animal Resource Program: 814-865-1495

Environmental Health and Safety: 814-865-6391

University Health Services – 814-865-6556

Office of Occupational Medicine: 814-863-8492

Office of Physical Plant – 814-865-1701

Important Definitions:

Conflict of Interest

Conflict of interest refers to situations in which financial considerations may compromise, or have the appearance of compromising, an employee's professional judgment in conducting, evaluating, or reporting on research/scholarship, instruction, outreach, or technology transfer programs. The bias such conflicts may conceivably impart can affect not only the collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of licensees, choice of protocol, involvement of human participants, and the use of statistical methods. The ORP administratively oversees the disclosure of potential conflicts and manages the conflict-of-interest review committees.

Research Misconduct

Research misconduct is defined as (1) fabrication, falsification, plagiarism or other practices that seriously deviate from accepted practices within the scientific community for proposing, conducting, or reporting research or other scholarly activities; or (2) material failure to comply with applicable federal requirements for protection of researchers, human participants, or the public, or for ensuring the welfare of laboratory animals; or (3) failure to disclose all real or perceived conflict of interests; or (4) failure to comply with other applicable legal requirements governing research or other scholarly activities. It does not include disputes regarding routine, non-creative works of authorship, honest error, or honest differences in interpretations or judgments of data, and is not intended to resolve bona fide scientific disagreement or debate.

As defined in Penn State Policy RA10 "Handling Inquiries/Investigations Into Questions of Ethics in Research and in Other Scholarly Activities", there are established procedures for addressing allegations and handling inquiries/investigations of research misconduct. The ORP provides administrative support and oversight of this process.

About the IACUC

The primary responsibility of Penn State's IACUC is to ensure that University activities utilizing vertebrate animals are conducted according to established regulations governing the humane care and use of animals in teaching and research. Anyone utilizing whole-bodied animals for the purpose of teaching, research, demonstration/observation, or for any other activity under the auspices of Penn State must submit the proposed use to the IACUC for prior review and approval. Relevant regulations include the Animal Welfare Act, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the Guide for Care and Use of Laboratory Animals.



About the IBC



The primary responsibility of the IBC is to review research activities involving the use of materials that have the potential to pose a danger to the health and safety of the researchers, the Penn State Community, and/or the nearby community. Anyone utilizing biohazardous materials in teaching or research at Penn State must submit proposed use to the IBC for review and approval prior to utilizing the materials. In addition to the use of biohazardous materials, Penn State policies address infectious-waste disposal and the handling of human blood and tissue samples.

Services we Provide



Consulting:

The ORP has a staff of IRB and IACUC/UIC/IBC coordinators who are here to assist students, staff and faculty members in writing research proposals. In addition, the coordinators provide answers to questions regarding the review and approval process, recommend the appropriate review type, assist in the development of applications and consent forms, and serve as liaisons between the researcher and committees for additional information requests. Call us today to make an appointment with one of our committee coordinators!

Our staff assistants can help you determine the status of your proposal and can also answer questions about policies and guidelines, meeting dates, proposal deadlines and types of review.

CONTACT INFORMATION:

- Candice Yekel, Director
- Paula Morgan, Administrative Assistant
- Jodi Mathieu, IRB Coordinator for Social Science Research
- Stephanie Krout, IRB Assistant for Social Science Research
- Mary Becker, IRB Coordinator for Biomedical Research
- Melissa Conrad, IRB Assistant for Biomedical Research
- Tracie Kahler, IRB Coordinator for Continuing Reviews
- William Greer, IACUC, IBC and UIC Coordinator
- Melanie Freeman, IACUC Assistant
- Erica Kresovich, IBC and UIC Assistant
- Laura Young, Receptionist
- Michelle Stickler, Educator
- Jennifer Stewart, Multimedia Training Specialist

Education:



ORP offers both live and online training in a variety of topics designed to help researchers comply with regulations and conduct research responsibly. Some online training programs are required prior to the approval of a research application. Other training is simply available for your information. View the latest listing of available training programs at: <http://www.research.psu.edu/orp/>.

The ORP educator provides live training for faculty, staff, and students on topics related to the responsible conduct of research such as research misconduct, conflict of interest, responsible authorship, data integrity, etc. Contact our educator if you would like to have one or more of these topics addressed in a workshop, seminar, or class.

The ORP committee coordinators are also available to lead discussions regarding research involving human participants or animals, the review and approval process, and/or regulatory issues pertaining to the conduct of research.

