Office of Research Protections (ORP) Annual Report
2023-2024 Academic Year

Major Achievements:

Maintained Strong Regulatory Compliance, as Documented by Governmental Inspections

Over the past year, multiple regulatory inspections were conducted by government entities, as detailed below. Each inspection concluded with commendatory remarks and no findings of noncompliance. These outcomes affirm the robustness of research regulatory compliance at Pitt.

- **Radiation Safety Program Inspections:** Throughout the year, eight inspections were conducted by the Pennsylvania Department of Environmental Protection with no findings of noncompliance.
- **Institutional Review Board Inspection:** The Food and Drug Administration (FDA) inspected the Institutional Review Board from May 16-24, 2024, and found no instances of noncompliance with FDA regulations or the University's internal policies.
- **Animal Care and Use Program Inspections:**
    - The Department of Defense (DOD) inspected the animal care and use program on September 6, 2023, and commented, “The [Pitt] staff were professional and knowledgeable. The strong collegial culture at the institute was impressive. The Animal Care and Use Review Office recommends continued funding of the supported animal research to appropriate DOD agencies."
    - The United States Department of Agriculture (USDA) inspected the animal care and use program in January 2024, without any findings of noncompliance with the Animal Welfare Act and Regulations.

Renewed Licensure Required for Research Activities

The University is required to periodically renew its licensure and provide comprehensive written descriptions of its research programs to government entities to permit the continuation of specific types of research.

- Completed renewal of the Broad Scope Radioactive Material License (renewal required every 10 years).
- Renewed the Public Health Service Animal Welfare Assurance (renewal required every 4 years).

Provided Improved Training in Ethics and Compliance for Investigators

The Office of Research Protections continues to enhance training for investigators to ensure the execution of ethical and regulatory-compliant research.

- Finalized an NSF-funded training program on research security in collaboration with partners at other institutions.
- Launched a new website on Responsible Conduct of Research.
- Introduced a new website on Research Security and Trade Compliance.
- Prepared the University community for implementation of upcoming research security requirements through education via frequent newsletter articles and presentations.
- Socialized the interim research governance policy through multiple presentations and changes in the IRB application to highlight acceptable data storage.
- Provided eleven presentations on the responsible conduct of research.
- Promoted onboarding and offboarding requirements for arriving/departing investigators through various mechanisms, increasing compliance.

- Created a series of short videos to aid investigators in writing protocols submitted to the Biosafety Committee.
- Collaborated with Health Sciences Information Technology to promote a new FDA-compliant data capture system (REDCap).
- Participation in a number of policy committees including a UPMC Committee related to use of clinical data in research (Epic Research Module).

Improved University Processes to Assure Regulatory Compliance

The Office of Research Protections engages in collaborative efforts with various other departments to ensure continuous improvement that bolsters regulatory compliance and refines the University's ethical practices.

- Accreditation was obtained for a new residency program in diagnostic imaging physics, with the intent of providing a pipeline of health physicists for the University. A grant was obtained from the American Association of Physicists in Medicine to defer the costs of the program.
- The MyIBC and Animal Research Online protocol management systems were updated to assure functionality as the lifespan of dependent operating system processes ends.
- Forms and processes were devised to aid investigators in the entry of projects into the FDA-compliant REDCap system.
- Implemented ImageTwin and Parallax software systems to enhance our capabilities in conducting assessments of image manipulation for research integrity purposes and scrutinizing foreign engagements, respectively.
- Collaborated with legal and DLAR to implement a process to allow an investigator to conduct a clinical trial of a therapy in dogs in collaboration with a local veterinary clinic.
- Collaborated with Pitt-IT to implement a secure cyber environment necessary for projects entailing controlled unclassified information.
- A variety of systems processes were implemented to assure that appropriate permits are secured prior to imports of biologics.
- Enhanced processes were implemented across multiple University systems to broaden the scope of export control procedures.
- The cataloging of conflict of interest data was improved to facilitate the retrieval of information.
- Compliance with Diversity, Equity, and Inclusion standards was enhanced in Office of Research Protections. All staff received training on creating accessible content, and the Institutional Review Board implemented screening procedures to ensure diverse representation among committee members.

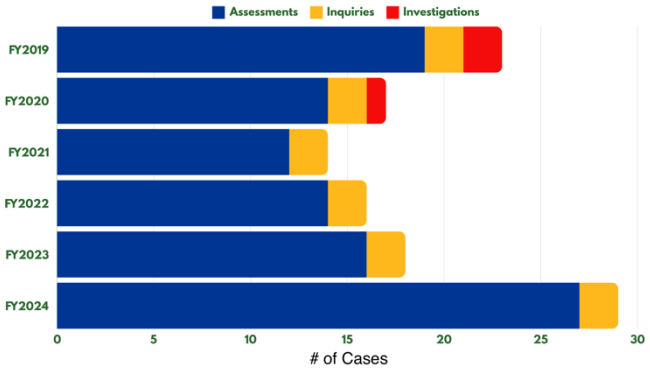
Office of Research Protection Members are National Leaders

Several ORP members are leaders of national organizations focused on ethics and regulatory compliance.

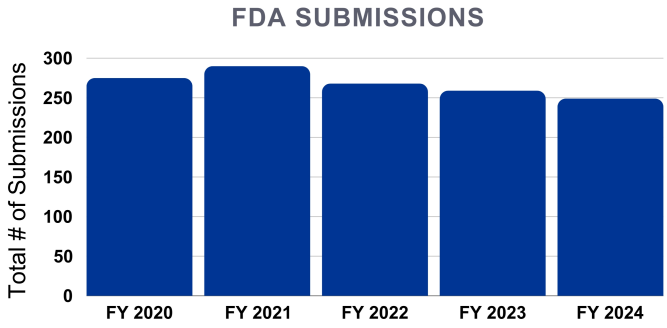
- Allen DiPalma was recruited as a key participant in the NSF-funded SECURE Center.
- Allen DiPalma serves on the COGR Board and is often recruited to provide presentations on research security.
- Lara Paciello was appointed to the Pennsylvania Radiation Protection Advisory Committee.
- Kelly Dornin is a member of the steering committee for the Research Compliance Network, a consortium of professionals engaged in quality improvement for human subject research.
- Justin Snyder is a member of the PRIM&R Education Committee

Key Metrics for Office of Research Protections, FY 2020- FY 2024

Increase in Research Integrity Concerns

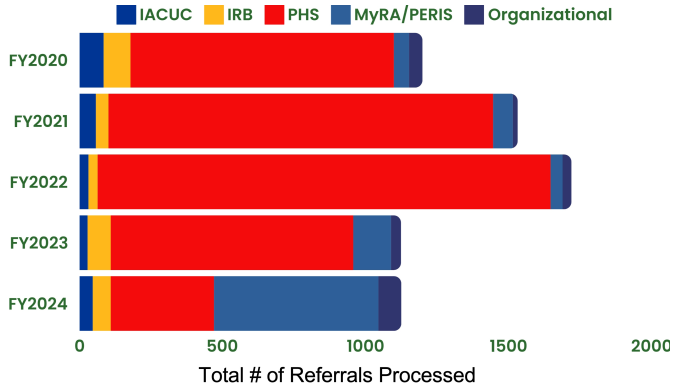


Stable FDA Submissions for Clinical Trials



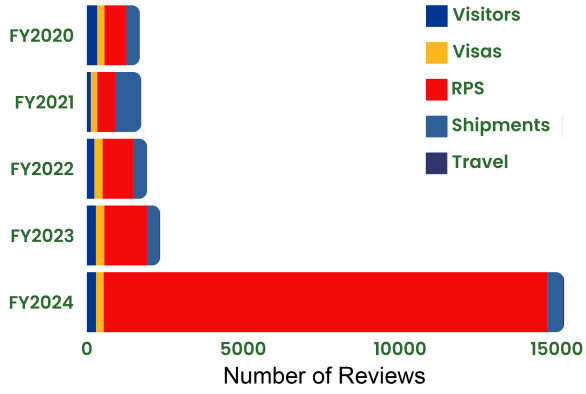
Refinements in COI Reviews

The number of COI reviews was stable from FY 2023, following a decline resulting from process refinement.



Increases in Export Control Reviews

The number of export control reviews, particularly restricted party screenings (RPS), increased to address research security recommendations.



Stable Protocol Submissions

The total number of reviews (new protocols, amendments, renewals) conducted by the IRB, IACUC and IBC remained stable in FY 2020-FY 2024 . Values are expressed as a percentage relative to the submissions in FY 2020. In FY 2024, the following number of reviews were completed by each committee: 8445 (IRB), 2800 (IACUC), 1276 (IBC).