OFFICE OF RESEARCH PROTECTIONS

2025 ANNUAL REPORT

University of Pittsburgh

Pitt Research

Office of Research Protections (ORP)

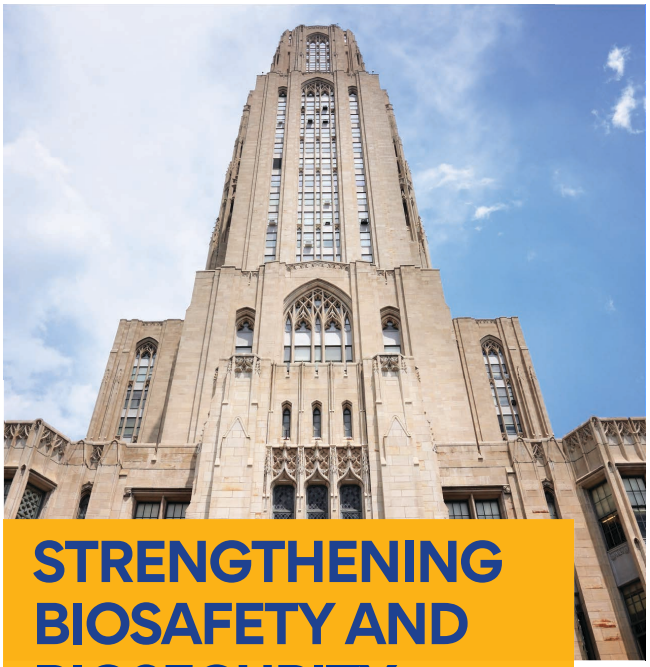
WHO WE ARE

The Office of Research Protections (ORP) supports investigators in the ethical design and conduct of research, ensuring that all studies comply with applicable laws, regulations, and ethical standards. ORP fulfills this mission through a combination of educational initiatives, prospective protocol review, investigator consultations, and oversight of ongoing research activities.

- This **comprehensive guide** provides an overview of ORP's history, operational functions, and organizational structure.
- The accompanying **organizational chart** highlights the dedicated professionals who carry out the office's mission.

ACHIEVEMENTS IN FY 2025

The U.S. government has intensified scrutiny of research involving infectious pathogens as indicated by revised federal policy on Dual Use Research of Concern (DURC), and a new Executive Order titled "Improving the Safety and Security of Biological Research."



STRENGTHENING BIOSAFETY AND BIOSECURITY OVERSIGHT

ORP has taken several measures to address this increasing scrutiny. ORP organized a blue-ribbon advisory panel comprised of national experts in biosecurity, coordinated a comprehensive review of existing institutional policies and practices, and organized a site visit by the advisory panel.

Following the panel's recommendations, oversight of biosafety and biosecurity functions was transferred from Environmental Health and Safety to ORP, enhancing operational efficiency and ensuring tighter integration of biosafety oversight with other research regulatory functions.

ORP has initiated multiple improvements to meet evolving federal biosafety requirements, including:

- **Process Mapping** of all biosafety-related functions to improve workflow efficiency and programmatic clarity;
- **Adoption of Salesforce** to streamline communications between biosafety personnel and research teams;
- **Upgrades to public-facing informational resources**, including webpages regarding DURC compliance and other biosafety requirements.

ACHIEVEMENTS IN FY 2025

ORP has taken several other measures to improve operational efficiencies and provide financial savings for the University.

INCREASING COST SAVINGS AND IMPROVING OPERATIONAL EFFICIENCIES

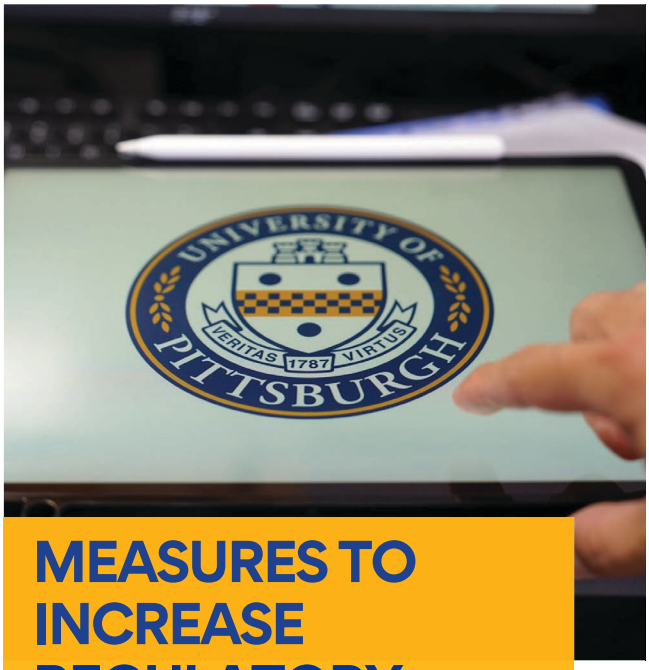
- **Radiological Security and Infrastructure Modernization:** ORP partnered with the U.S. Department of Energy's Office of Radiological Security (ORS) to improve campus safety by removing two legacy cesium irradiators—avoiding over $1 million in decommissioning costs—and replacing them with X-ray devices, 50% funded by ORS. An additional $300,000 in ORS-funded security upgrades is being applied to remaining irradiators, significantly reducing radiological risk and enhancing long-term security.

Other Operational Efficiencies Implemented:

- Developed artificial intelligence tools to support IACUC protocol review.
- Created mechanisms to flag IRB submissions involving University-owned intellectual property.
- Enhanced oversight and compliance processes for the import of biologic materials
- Implemented infrastructure and protocols for managing Controlled Unclassified Information (CUI).
- Upgraded internal databases to improve data management and accessibility.
- Streamlined the review and approval process for multicenter human subject studies.

ACHIEVEMENTS IN FY 2025

ORP has taken many other measures to improve regulatory compliance.



MEASURES TO INCREASE REGULATORY COMPLIANCE

- **Improved Visitor Authorization:** ORP is collaborating with the Policy Office to formalize the current visitor process into institutional policy, while developing guidance, training, and enhanced procedures to strengthen compliance with the current process..
- **Education Regarding Research Security:** A website devoted to research security was implemented, and a Research Security Module, condensing the federal modules, was deployed on the Pitt CITI platform, allowing tracking of investigators who completed this training.

Other Measures to Increase Regulatory Compliance:

- **Research Integrity Policy Update:** ORP is collaborating with the Policy Office to update the Research Integrity Policy (RI-07) to align with new federal requirements.
- **Improved Electronic Consent (e-Consent) of Human Research Participants:** ORP developed guidance and collaborated with Health Sciences IT (HSIT) to create training and resources that support compliant e-consent implementation.
- **Development of an Electronic Regulatory (eReg) System for Clinical Trials:** ORP collaborated with HSIT to implement a 21 CFR Part 11–compliant eReg system to streamline management of regulatory documents for clinical trials.

KEY METRICS

New protocol submissions declined across all major committees in fiscal year FY25 compared to prior years, likely reflecting a broader decrease in new research funding. Despite this, overall protocol review volume—including amendments and renewals—remained relatively stable.

New Protocol Submissions				
Committee	**FY 25**	**FY 24**	**FY 23**	**FY 22**
Institutional Review Board	1515	1608	1541	1714
Institutional Animal Care & Use Committee	386	487	454	410
Institutional Biosafety Committee	88	95	86	112

All Protocol Submissions (including modifications and renewals)				
Committee	**FY 25**	**FY 24**	**FY 23**	**FY 22**
Institutional Review Board	7923	8445	9053	9014
Institutional Animal Care & Use Committee	2822	2800	2749	2850
Institutional Biosafety Committee	1406	1276	1314	1254

KEY METRICS

Compliance-related activities increased, with notable growth in research integrity reviews (assessments, inquiries, and investigations), visitor authorizations, and conflict of interest evaluations.

Other Key Metrics				
Metric	**FY 25**	**FY 24**	**FY 23**	**FY 22**
Research Integrity Reviews	34	29	18	16
Visitor Reviews	322	285	331	265
Technology Control Plans	25	29	13	7
FDA Submissions	245	249	259	268
Conflict of Interest Reviews	1576	1310	1257	1774