Office of Research Protections

FY 2026 Annual Report

The Office of Research Protections (ORP) supports the University of Pittsburgh's research mission by ensuring the integrity, safety, and regulatory compliance of its research enterprise. In addition to the routine study review and compliance oversight functions highlighted on pages 3-4, the accomplishments described below reflect the innovations and novel contributions of ORP's nine divisions during fiscal year 2026.

I. Policy Development

ORP contributed to the development of University and national policies in FY 2026.

- **The Research Misconduct Policy (RI-07) was completely rewritten** to incorporate new federal regulations effective January 1, 2025. The revised policy cleared the Senate Research Committee, Faculty Assembly, and Senate Council; was communicated to the Faculty and Staff unions; and was submitted to the Office of Research Integrity (ORI) for approval to meet the mandated implementation date of January 1, 2026.
- **The Academic Visitor Policy was developed and unanimously approved** by the Senate Council following a full Faculty Senate review process. The policy will take effect upon the Chancellor's signature.
- **A response to a Request for Information (RFI) for a Proposed NIH Genomic Data Sharing Policy** was prepared and submitted. Other organizations used the Pitt submission as a template for their submissions.

II. Measures to Improve Regulatory Compliance

ORP divisions implemented new measures to strengthen regulatory compliance across the University.

- **A Research Security Refresher Training Module was developed and deployed on the CITI platform.** The streamlined module satisfies federal training expectations under Section 10634 of the CHIPS and Science Act and is more relevant to the day-to-day work of Pitt researchers than the module produced by NSF. Automated compliance verification for the module was integrated into the grant submission workflow through PERIS.
- **CMMC Level 2 Certification was achieved** in collaboration with Pitt Digital, establishing compliance with Department of Defense cybersecurity requirements for controlled unclassified information (CUI). This certification will enable the University to accept research grants and contracts that require the handling of CUI.
- **Financial Conflict of Interest (FCOI) subrecipient disclosure requirements were streamlined and expanded** from PHS-only awards to all federal, nonprofit, and foundation awards. The revised process replaces two lengthy forms and hard-copy collection with a single one-page form and an AirTable-based online system, significantly reducing administrative burden on departments and subrecipient investigators.
- **Malign Foreign Talent Recruitment Program (MFTRP) certification was integrated into myDisclosures,** enabling automated detection of potential compliance concerns and supporting federal requirements for senior/key personnel certifications at the time of proposal submission.
- **DOJ Bulk Sensitive Data Rule guidance was published** to equip investigators with resources to navigate emerging data security obligations associated with international research activities. In addition, webinars and newsletter articles were used to inform the research community about evolving restrictions on collaborations and engagements involving countries of concern.
- **Security for irradiators was strengthened through partnerships with the Department of Energy.** Through one program, a non-operational cesium irradiator was removed from the Hillman Cancer Center at minimal cost to the University. Through a separate program, enhanced biometric security measures are being implemented for all irradiators.

- **Advarra eReg was launched and mandated** as of March 1, 2026, for studies conducted under faculty-held IND/IDE applications and NIH-defined clinical trials, standardizing electronic regulatory file management across the human research enterprise.
- **An ancillary IRB review process was established** for all studies with an international nexus, ensuring systematic oversight of compliance for research involving foreign collaborators or institutions.
- **Public Access to Institutional Biosafety Committee meeting minutes** was established, as required by a new NIH policy.
- **An Emergency and Disaster Response Plan for the Human Research Protection Program was developed and implemented,** with a coordinated educational session delivered jointly by ORP, the Office of Public Safety and Emergency Management, and the Division of Laboratory Animal Resources.
- **ORP initiated a campus-wide seminar series** featuring topics of broad interest to the research community on research ethics and regulatory compliance. Several hundred University members have attended each session.

III. Technology & Process Innovation

ORP continues to modernize processes to improve efficiency and reduce administrative burden.

- **An AI-assisted IACUC pre-review tool was developed** through a collaboration between the IACUC, ORP IT, Huron, and Pitt Digital. The tool uses AI to help investigators strengthen protocol submissions prior to formal review. The development and validation methodology was published in LabAnimal (November 2025) and presented at three national and international conferences.
- **An AI guidance framework for human subjects research was implemented** in partnership with Pitt Digital, establishing institutional standards for the responsible use of AI in research involving human participants.
- **A Human Subjects Research Determination Tool was implemented** to standardize information collection for projects that may not constitute human subjects research and to enable more efficient IRB resource allocation. Approximately 500 determination letters have been issued to date, with all submissions monitored for quality.
- **An enterprise license for Proofig AI was acquired** to enable pre-publication detection of image duplication and manipulation, proactively supporting research integrity at the point of manuscript submission. A collaboration was established with the Health Sciences Library to provide investigators with training in using the tool.
- **Biorisk Management training and occupational health databases were migrated** from a standalone Microsoft Access system to an enterprise Tableau platform, enabling real-time dashboards and reporting. An automated protocol review tool was also built to check training and medical surveillance compliance during IACUC protocol review, saving up to two hours per complex protocol; a companion self-service tool allows investigators and staff to check their own compliance records prior to submission.
- **A REDCap Compliance Activities database was launched to process clinical trial monitoring reports,** which replaced the legacy Access system.
- **myDisclosures and PittPRO systems were upgraded** to current vendor specifications, extending operational life through 2034 and bridging to a planned enterprise Research Suite.
- **Visual Compliance was integrated with the University's purchasing system,** enabling automated screening of vendors and collaborators against export control and sanctions databases.
- **Mapping of the processes involved in approving an animal study was conducted**, and bottlenecks were identified. Efforts are underway to eliminate these bottlenecks and improve efficiency.
- **The Biorisk Management Division transitioned from Environmental Health & Safety to ORP**, enabling improved integration with other ORP divisions while maintaining uninterrupted support for the IACUC, IBC, DLAR, and other institutional stakeholders. In addition, several divisional processes have been updated to improve efficiency and enhance service delivery.

IV. Accolades for Exemplary Performance

External inspections and accreditation site visits affirmed the strengths of ORP programs and activities.

- **AAALAC International accreditation was renewed with the distinction of "Exemplary,"** the highest accolade conferred by AAALAC, following a four-day site visit in October 2025. The ORP Animal Research Protection division led all aspects of preparation, including Program Description submission and multiple pre-visit community outreach sessions. In addition, no findings of noncompliance were identified during the USDA's April 2026 inspection of the animal research program.
- **The Diagnostic Imaging Physics Residency Program received re-accreditation.** This program was established by the Radiation Safety Division to expand the pipeline of diagnostic imaging health physicists, with its inaugural resident set to graduate in June 2026.
- **The Federal Select Agent Program's three-year renewal inspection** was completed in December 2025, with a simultaneous CDC Import Permit Program inspection. Of the 15 departures identified, 14 have been formally closed as of May 2026. Select Agent Tier 1 Suitability Assessment processes were also substantially improved through engagement with the HR Business Process Improvement group.
- **The AAHRPP accreditation process advanced to Step 1 and Step 2 application acceptance,** reflecting the maturity and rigor of the University's Human Research Protection Program.

ORP FY 2026 — Research Activity Metrics

In addition to the achievements described above, ORP continues to fulfill its mandated responsibilities by prospectively reviewing research studies to ensure they are conducted ethically and in accordance with applicable regulatory requirements. ORP also conducts additional compliance reviews to assess and support regulatory compliance.

Estimated *Values in the shaded column represent FY 2026 full-year estimates based on activity through April 2026.*

New Protocol Submissions

	FY 2023	FY 2024	FY 2025	FY 2026 (through April)	FY 2026 (estimated)
IRB	1,416	1,463	1,382	1,345	**1,611**
IRB – Multisite (Pitt primary IRB)	19	29	11	8	**10**
IRB – Multisite (other institution primary)	156	137	124	118	**142**
IACUC	454	487	386	326	**391**
IBC	86	95	88	84	**101**

Total Reviews

	FY 2023	FY 2024	FY 2025	FY 2026 (through April)	FY 2026 (estimated)
IRB	10,050	8,613	8,054	7,811	**9,373**
IACUC	2,749	2,800	2,822	2,155	**2,586**
IBC	1,314	1,276	1,406	1,165	**1,398**

Other Key Metrics

	FY 2023	FY 2024	FY 2025	FY 2026 (through April)	FY 2026 (estimated)
Clinical Trials					
New FDA Submissions (IND/IDE)	17	7	12	12	**14**
Total FDA Submissions	259	249	245	239	**287**
Clinical Trial Monitoring Visits	163	202	180	136	**163**
Conflict of Interest					
Referrals Reviewed	1,124	1,125	1,358	1,325	**1,590**
Conflict Management Plans (new/revised)	92	89	110	75	**90**
Radiation Safety					
Laboratory Audits	1,768	1,540	1,648	1,323	**1,588**
Radioactive Packages Received	213	173	163	119	**143**
Research Security & Trade Compliance					
Visitor Agreements	331	285	322	206	**247**
Other Agreements	172	198	183	418	**502**
Foreign Influence Reviews	11	25	6	25	**30**
Technology Control Plans	13	29	25	38	**46**
Total Export Control Reviews	2,342	14,132	4,692	3,240	**3,888**

Despite delays in the release of federal research funding, protocol submission volumes have remained relatively stable compared to prior years. As federal funding is released, we anticipate a corresponding influx of new protocols, and final FY 2026 figures are likely to exceed those of previous years.

Heightened research security concerns, driven by new federal regulations and restrictions, have led to a steep increase in workload for the Research Security and Trade Compliance Division, most notably in foreign influence reviews and technology control plans. The Division has also experienced a significant rise in investigator consultations as the research community seeks guidance on interpreting and complying with evolving regulatory requirements.

The Conflict of Interest Division has similarly seen increased demand, recording the highest number of COI referrals reviewed in the past four years — a trend that reflects both the growth of industry-sponsored research activity and the expanding scope of disclosure obligations under federal policy.