Pitt Research
Office of Research Protections (ORP)
Major Accomplishments, FY 2023

University Policy Drafting and Implementation

- ORP implemented University Policy RI-11, "Institutional Conflict of Interest"(ICOI), which was signed by Chancellor Gallagher on June 18, 2022. A slate of committee members was recommended to the University Senate and ratified. The ICOI committee members were trained and monthly committee meetings have been convened since October, 2022.
- ORP managed the drafting of University Policy RI-13, "Drones," and presented the policy to major stakeholders including the University Senate. Chancellor Gallagher signed Policy RI-13 on March 27, 2023. An implementation webpage has been developed.
- ORP initiated drafting of a University Policy "Human Data and Biological Samples Sharing." Benchmarking was completed and weekly committee meetings have been conducted. A final draft policy should be complete by the Fall.
- ORP initiated drafting of an interim University Policy "Data Governance." A final draft should be complete by August, 2023.
- ORP assisted in drafting interim University Policy RI 12, "Research and Clinical Training with Human Cadavers." ORP will participate in writing the final policy in Fall, 2023.

Research Security

- Pitt is co-recipient of an NSF grant to develop research security training for the U.S. academic community. ORP is working with partners at other institutions to finalize a training module by November, 2023.
- ORP provided background information to prepare the Pitt community for research security requirements stipulated in NSPM-33. These efforts including hosting presentations by Dr. Rebecca Keiser, Chief of Research Security and Policy at NSF, as well as Mr. Alan Kohler, Assistant Director of Counterintelligence, FBI. Additional on-campus briefings occurred, as well as regular updates in ORP's monthly newsletter.
- ORP coordinated other Pitt departments in establishing mechanisms to permit research requiring adherence to Controlled Unclassified Information (CUI) regulations.

Effective Management of Research Compliance Programs

- Over the past year, the human and animal research programs were fully re-accredited, and the University's Broad Scope Radioactive Materials license was renewed.
- Inspection of the University's animal program by the USDA in December, 2022 revealed no deficiencies. Several inspections related to use of radiation on Campus and in UPMC facilities also resulted in no citations.

Enhanced Strategies for Investigator Education

- All new faculty members at Pitt receive an email from the ORP Vice Chancellor inviting them to a custom onboarding with the ORP divisions they will need to interact with. Sixty-nine new investigators completed onboarding in FY 2023.
- ORP circulates a monthly newsletter that is widely read by University members. The newsletter is distributed to over 20,000 University members, and over the past six months had an average open rate of 54%, and an average click rate of 26%.
- A new Quality Assistance Review process was launched for human subject studies, to provide formative feedback to investigators.
- Presentations on regulatory topics were increased in frequency to accommodate investigator requests.

- New guidelines on Responsible Conduct of Research were formulated and posted. A web-based version of the guidelines is in development for a new website on the Responsible Conduct of Research. This website will also provide research security information.
- Several ORP websites were revised to provide updated information.

Multicenter Clinical Trials

- ORP has been engaged with a working group in the School of Medicine to enhance clinical trial capabilities at Pitt/UPMC.
- ORP established through Purchasing Services a standing agreement with several contract research organizations to facilitate Pitt clinical investigators engaging their services.
- ORP enhanced training regarding regulatory compliance for multicenter trials, including improved webpages and documentation templates.
- ORP has been collaborating with Health Sciences IT in establishing a data capture system (REDCap) that is compliant with FDA regulations.
- The IRB's "reliance team" that manages multisite studies expanded its capabilities. NIH allows investigators to budget direct costs for management of multicenter trials by the IRB, a requirement that was enforced at Pitt in FY 2023. The reliance team had 325 investigator consultations in the past year, and received $131,070 in grant direct costs to support its operations.

Operational Efficiencies and Expansions

- To address health physics oversight requirements for the radiation safety program, a residency program has been proposed. Required documentation was submitted for accreditation of the program; if accredited, the program will begin recruitment in Fall 2023.
- A legacy irradiator was decommissioned, with funding negotiated through federal programs by ORP to reduce by over $200,000 the cost of removing the device.
- ORP is collaborating with UPMC to establish capabilities for theranostic procedures, which involve a precision targeting of cancer cells with radiation. In the past year, this collaboration has permitted the use of Lu-177 to treat castration-resistant prostate cancer. Over 200 Lu-177 treatments were provided in FY 2023.
- Use of the E2Open restricted party software tool managed through ORP was expanded to additional offices and for additional purposes.
- A new protocol management system, *My*IACUC, is being implemented to replace a legacy system for managing animal research protocols. The new system will provide efficiencies for investigators and will improve compliance oversight.
- The *My*IBC system used for managing protocols involving recombinant DNA is being upgraded for integration in the PERIS™ initiative.
- ORP has established MOUs and additional agreements with Carnegie Mellon University, the Veterans Administration, and other local institutions to permit increased collaborations in animal research.
- An IRB educational coordinator was recruited to facilitate onboarding of IRB protocol coordinators and to ensure consistency in protocol reviews.
- Business processes in ORP's Conflict of Interest division were streamlined and automated, with automated queries replacing those historically managed through emails. The new system also permits better recordkeeping for transactions.
- A new ancillary review process was established through MyRA to provide additional oversight of biologic imports, as well as more robust reporting of agents imported.
- ORP protocol management systems were migrated from physical servers to virtual servers, allowing greater expansion capability and lower maintenance costs.

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Major Metrics, FY 2023

1) Protocol Reviews by Committees (New + Modified Protocols)

Area	New Submissions and Modifications			
	FY 23	FY 22	FY 21	FY 20
IRB	7379	6943	7519	6934
IACUC	2749	2850	2798	3040
IBC	604	623	566	722

Analysis: total reviews (new and modified protocols) by the IRB, IACUC, and IBC have remained constant.

2) Investigator Consultations/Queries Resolved

Area	Total Queries Resolved			
	FY 23	FY 22	FY 21	FY 20
IRB	1070	976	576	609
Clinical Trials	1040	637	683	---
MyDisclosures	920	1572	2023	---

Analysis: Investigator consultations and questions regarding human subject research remain high, particularly for clinical trials. Inquiries related to *My*Disclosures continue to fall, as familiarity with the system increases.

3) ORP Communications: Monthly Newsletter

	Q1 FY 22	Q2 FY 22	Q3 FY 22	Q4 FY 22	Q1 FY 23	Q2 FY 23	Q3 FY 23	Q4 FY 23
% Opened	17.1	26.3	29.3	19.8	44.5	33.1	51.7	56.7
% Clicked	0.5	14.3	14.6	0.7	30.5	15.6	34.3	18.5

Analysis: A key communication tool used by ORP is its monthly newsletter, which is sent to monthly to > 20,000 University members. Readership has progressively increased over time.

4) Other Key Metrics

	FY 23	FY 22	FY 21	FY 20
IACUC: Review of New Grants for Congruency with Protocols	178	173	215	211
IRB: Reportable New Information (reports of unexpected events and protocol deviations)	321	284	386	542
Radiation Safety: Lab Audits	1768	1747	1767	1786
Conflict of Interest: Total Transactions Reviewed	1178	1762	1578	1303
Trade Compliance: Export Control Reviews	3001	2695	2106	1939
Trade Compliance: Visitor Agreements	331	265	84	272
Number of New FDA Approvals (IND/IDE)	17	21	44	29

Analysis: Most key metrics have remained consistent over the past four years. Visitor agreements have continued to increase, as travel resumes following the pandemic and compliance with the visitor registration requirement increases. Export control reviews continue to increase because of increased awareness of the University community of their importance. Conflict of interest transactions declined in FY 2023 as automation and streamlined processes eliminated the need for some reviews