Human Subjects Office /Institutional Review Board Overview and Educational Resources



UI Institutional Review Boards

The Institutional Review Board (IRB) is an independent, autonomous, ethical review committee that oversees human subjects research conducted by UI faculty, staff and students. The UI IRBs include:

- IRB-01 (biomedical research)
- IRB-02 (social/behavioral/educational research)
- IRB-03 (research at VA Health Care System)
- IRB-04 (research funded by Department of Defense) -inactive

Researchers select an IRB based on the department in which they conduct their research and the nature of the study.

The UI IRB may enter into reliance agreements for UI investigators to rely on a commercial or academic IRB, or for external investigators to rely on the UI IRB. This is called a single, central or external IRB model.

Human Subjects Office

The Human Subjects Office (HSO) is the administrative office for the IRB and the UI Human Research Protection Program (HRPP).

HSO staff review HawkIRB applications, conduct compliance monitoring and provide educational guidance and resources. HSO staff provide support for ClinicalTrials.gov registration and reporting and provide guidance and oversight for the use of a Single, Central or External IRB model. The HSO also includes the Conflict of Interest in Research Office.

Educational Resources

Resource	Description
Researcher Handbook	Electronic roadmap to navigate the complex UI research environment
Research Navigation Tool for New Faculty and Research Scientists	This tool is used to begin the onboarding process for new UI faculty and research scientists. It provides information about programs for research support.
Ul IRB Standard Operating Procedures and Researcher Guide	Reference document for UI IRB policies and procedures and guidance for researchers
HawkIRB (eResearch Application)	For submission of all IRB application forms. Integrated with UI Human Research Protection Program (HRPP) units.
HawkIRB Trainings	Learn to navigate in the HawkIRB system and prepare forms for IRB approval. Recordings available in the IRB ICON Course for Researchers.
IRB ICON Course for Researchers	A collection of resources available to anyone with a HawkID. Includes: HawkIRB trainings, IRB Overview, IRB Efficiency Initiative information sessions and demonstrations, and recordings on a wide variety of additional topics
IRB Office Hours	Virtual drop-in via Zoom, no appointment necessary. Spring/Fall (twice a week); Summer (once a week)
IRB Connection Newsletter	Articles and announcements for the UI research community (Principal Investigators, research team members, HawkIRB Delegates and by request.
Class and Small Group Presentations	A standard IRB overview presentation (recording available in IRB ICON Course for Researchers) or lecture tailored to meet the needs of the students/group.
Human Subjects Research: An Overview for Researchers	Provides a general overview of UI IRB structure and approval/training requirements
Faculty Advisor Responsibilities	Outlines the Faculty Advisor responsibility for overseeing research conducted by student PIs
Course-Related Student Project Policy and Checklist	Regarding exception from IRB approval for certain projects conducted as a course requirement for research methods courses. Use checklist to confirm exception.
Glossary of Terms and Acronyms	Defines common acronyms and terms for UI human subjects research
Support for Single or External IRB Models	Guidance for establishing reliance agreements for lead or relying sites for federally funded, multi-site research and industry-sponsored research
Support for Clinical Trials Registration and Reporting	Guidance for registration and results reporting for applicable clinical trials (ACT)
PI Transfer / Departure Checklist	Separate checklists (funded research or internal, departmental or unfunded research) provide guidance and notify the Division of Sponsored Programs (DSP) and/or the Human Subjects Office (HSO).

HawkIRB: eResearch Application System



HawkIRB is a homegrown eResearch application system. People with a HawkID can click the tile on the Human Subjects Office website to access this system. Use the following features/resources to prepare HawkIRB applications:

- Help Messages associated with most questions
- Carousel index with links to (1) What you need to start, and (2) Why the IRB needs this information
- Workflow communication during IRB review process
- All forms for submission plus a mechanism to check the status of other HRPP committee reviews

Human Subjects Protection Training

All UI researchers must complete a one-time, human subjects protection (HSP) training in the CITI Program.



See <u>Training Requirements</u> and follow instructions in the <u>UI CITI Program Users Guide</u> to register for required and optional courses.

Other trainings available: Responsible Conduct of Research (RCR), Good Clinical Practice (GCP), HSP Training Refresher, VA HSP Training and Refresher, and Export Controls.

Graduate and Undergraduate students must complete the <u>student PI training requirement</u> in the IRB ICON Course for Researchers.