Human Research Protection Education and Training Requirements

Submission of a Curriculum Vitae

All IRB members, investigators, and study staff must submit a current curriculum vitae (CV) to the IRB office. Investigators whose studies qualify for exempt review are not required to submit a CV.

Required human subjects research protection education

All individuals responsible for protecting the safety and welfare of human subjects in research are required to complete human subjects research protection education modules. This education is completed online through Collaborative Institutional Training Initiative (CITI) at:

citiprogram.org

The following individuals must complete required CITI education in human subjects research protection:

- All principal investigators, co-investigators, medical monitors, and study coordinators as listed on the study protocols
- Institutional Review Board Chair, Vice-Chair, and voting members
- Research and Development Committee members responsible for reviewing study protocols
- Woman's Hospital Research Center staff
- Human Research Protection Program Institutional Official
- Human Research Protection Program Organizational Official

The required CITI course curriculum will be available upon registering with CITI online. Initial training certification period is three years, after which CITI will send notification that renewal and a refresher course is due.

Investigators whose studies qualify for exempt review are not required to complete this training. Study investigators conducting non-exempt research that are not current on CITI training education requirements may not submit research proposals for review (initial review or continuing review) until the education requirements have been fulfilled.

IRB Member education

IRB member education begins upon appointment to the board by the Board of Directors. All new IRB member appointees will have an orientation with the Human Protections Administrator (HPA) for education regarding applicable human subjects research regulations (e.g. Common Rule and 21 CFR 50 and 56), the Belmont Report, OHRP and FDA Guidance

documents and reference materials on human subjects research topics, and training regarding local IRB policies and procedures.

The HPA is responsible for presenting education for IRB members and staff at convened IRB meetings for review and discussion. The education may include, but is not limited to, the following:

a. Current federal regulations;
b. Local policies and procedures;
c. Changes in federal regulations;
d. Changes in local policies and procedures;
e. Cases of interest regarding protection of human subjects in research;
f. Other items as requested by the IRB

IRB staff and members are encouraged to participate in the IRB Forum, a listserv providing opportunity for discussion on issues and regulation throughout the IRB community.

Failure to remain current with CITI training requirements may result in removal from the board.

Research and Development (R&D) Committee Members

R&D members responsible for reviewing study protocols for scientific integrity, feasibility, and investigator conflict of interest are required to complete online CITI training. Failure to remain current with CITI training requirements may result in removal from the committee.

Woman's Hospital Research Center (WHRC) Staff

WHRC staff will receive initial and continuing training in the areas germane to their responsibilities, including CITI training in human subjects protection and review of all policies and procedures. Initial training of WHRC staff includes, but is not limited to, the following:

- Attendance at IRB meetings as an observer to learn the process of administering a meeting.
- Review the human subjects research regulations (Common Rule and FDA regulations) and the HRPP policies and procedures
- Complete the online CITI course curriculum for human subjects research

Continued training will include renewal of CITI course curriculum, attendance at meetings and conferences, and review of presentations and educational articles as distributed at the convened IRB meetings.

Required CITI training modules

ROLE	REQUIRED MODULES
Study Investigators	Human Subject Research: • Avoiding Group Harms • Informed Consent • Basic IRB Regulations and Review Process • COI in HSR • Research Involving Pregnant Women • Records-Based Research • Recognizing and Reporting Unanticipated Problems • Populations in Research Requiring Additional Protections • History and Ethics of HSR • HIPAA • The Belmont Report Good Clinical Practice (required only for investigators conducting clinical trials with drugs/devices): • Completing the CITI GCP course • Audits and Inspections of Clinical Trials • Monitoring of Clinical Trials by Industry Sponsors • Reporting Serious Adverse Events • Detecting and Evaluating Adverse Events • Informed Consent in Clinical Trials • The CITI GCP Course for Clinical Trials • Managing Investigational Agents • Investigator Obligations in FDA-Regulated Research • Conducting Investigator-Initiated Studies
Study Coordinators	Human Subject Research: • Avoiding Group Harms • Informed Consent • Basic IRB Regulations and Review Process • COI in HSR • Research Involving Pregnant Women • Records-Based Research • Recognizing and Reporting Unanticipated Problems • Populations in Research Requiring Additional Protections • History and Ethics of HSR

	• HIPAA • The Belmont Report
IRB Members/Staff	<u>Human Subject Research</u> • Avoiding Group Harms • Informed Consent • Basic IRB Regulations and Review Process • COI in HSR • Research Involving Pregnant Women • Research Involving Children • Genetic Research in Human Populations • Records-Based Research • Recognizing and Reporting Unanticipated Problems • Populations in Research Requiring Additional Protections • History and Ethics of HSR • The IRB Member Module • HIPAA • The Belmont Report • Vulnerable Subjects – Workers/Employees
Research & Development Committee Members	<u>Human Subject Research</u> • Avoiding Group Harms • COI in HSR • FDA-Regulated Research • Research Involving Pregnant Women • Research Involving Children • Genetic Research in Human Populations • Records-Based Research • Populations in Research Requiring Additional Protections • History and Ethics of HSR • The Belmont Report • Vulnerable Subjects – Workers/Employees • HIPAA • Financial COI: Overview • Institutional Responsibilities as They Affect Investigators • Institutional COI

Institutional and Organizational Officials	Introduction to Being an Institutional Official; IO Knowledge Requirements: Human Subject Protections; Expectations of the IO; Challenges of Being an IO

Continuing education requirements

Documentation of CITI continuing research education (renewed every three years) is required for all investigators, study coordinators, IRB members, R&D members, and the Institutional and Organizational Officials. Investigators are expected to train all study staff on protection of human subjects in research. For IRB members, continuing education will also be presented by the Human Protections Administrator at the convened IRB meetings. These educational materials will come from PRIMR.org, PRIMR's IRB forum, OHRP Web site educational materials and guidance, or other relevant sources.

If the investigator is required to fulfill CITI continuing education renewal requirements for another IRB, a certificate of completion will suffice for the continuing education requirement here. CITI training must be current for all investigators and study staff for their studies to be submitted for continuing review.

DATE	REVISION
7/11/23	Revised CITI training requirements and listed required modules by group; GCP no longer required for study coordinators