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1. Overview

Purpose

Recognizing that a vital component of a comprehensive human research protection program is an education program for all individuals involved with human subjects research, Drexel University is committed to providing training and an ongoing educational process for Institutional Review Board (IRB) members, the staff of the IRB and Human Research Protection Program (HRPP) Office, investigators, and members of their research team related to ethical concerns and regulatory and organizational requirements for the protection of human subjects.

2. Training/Ongoing Education of IRB Chair(s), Members, and Staff

2.1 Orientation

New IRB members, including alternate members, must undergo an IRB orientation program. New members will first meet with the HRP Executive Director or designee for an orientation session. Prior to this orientation meeting, new members are sent a set of PowerPoint Modules that provide an overview of IRB function, ethics, regulations, HIPAA, IRB 111 Review Criteria and operations. At orientation, the new member will be given a review of resources, information, checklists and education presentations.

New members are required to complete Collaborative Institutional Training Initiative (CITI) training for Human Subjects Protections. Prior to orientation with the HRP Executive Director, members may attend the first IRB meeting as an observer. A Q&A session, as applicable, is scheduled to discuss any questions the new member has about the process, checklist, or study. This offers an opportunity for them to become familiar with the role of primary reviewer preparation and then to hear the presentation of the assigned primary reviewer in the IRB meeting, discussion, and vote.

2.2 Initial CITI Education

IRB members and HRP and IRB administrators and staff will complete the required modules in the CITI Course for the Protection of Human Research Subjects; renewal is required every three (3) years. The modules are grouped by categories of research. Researchers, IRB Members, and Staff are only required to complete one group of modules that best fits the type of research they normally conduct or review.

Optional modules should be completed to the extent they are applicable to the role, e.g., Good Clinical Practice (GCP), Responsible Conduct of Research (RCR), Export Compliance, Undue Foreign Influence, Clinical Research Coordinator (CRC), Public Health Research, Community-Engaged and Community-Based Participatory Research.

2.3 Continuing Education for IRB Members

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB.

In addition to initial training requirements, continuing education is delivered to IRB members regularly. Drexel University uses the following activities as a means for offering continuing education to IRB members, and to HRP and IRB administrators and staff:

- IRB Meeting educational presentations included on meeting agenda.
- Email communications to all IRB Members and personnel of additional regulatory updates, recent publications, and guidance as they are released.
- The HRP website that includes:
  - copies of education handouts;
  - dates of upcoming educational offerings of interest to members & staff;
  - links to other training resources;
  - references from governmental sites (OHRP, FDA, NIH, DOE, EPA);
  - educational offerings from OHRP and other IRBs;
  - a link to CITI; and
  - Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) and topical informational sites (FDA Drugs, Medline Plus tutorials, and Certificates of Confidentiality).
- Periodic webinar offerings.
- Periodic sessions with the IRB personnel and IRB members to include HRP Informational Sessions as well as training topics.
- Identification and dissemination by the Executive Director of new information that might affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via email, mail, or during IRB meetings.

The Drexel University HRP has available electronic copies of IRB Management & Function of IRB Member Handbook, resources for IRB Members, Staff, and researchers.

The activities for continuing education vary on a yearly basis depending on operating budget and areas of need, as determined by HRP Executive Director. Fulfillment of training requirements is included as part of the evaluation of the performance of IRB members/alternates.

3. Training/Ongoing Education of Investigators and Research Team

As stated previously, a vital component of a comprehensive human research protection program is an education program for all individuals involved with research subjects. Drexel University is committed to providing training and an ongoing educational process for investigators and members of their research team related to ethical concerns and regulatory and organizational requirements for the protection of human subjects.

3.1 Education and Training Requirements

Investigators, key personnel, and other members of the research team must complete the Drexel University required core modules in the CITI Course in the Protection of Human Research Subjects, including Health Information Privacy and Security, as applicable, at least every three years.

Additional modules should be completed to the extent they are applicable to the research team member's role and study, e.g., Good Clinical Practice (GCP), Responsible Conduct of Research (RCR), Export Compliance, Undue Foreign Influence, Clinical Research Coordinator (CRC), Public Health Research, Community-Engaged and Community-Based Participatory Research.

Final Drexel University IRB approval will not be granted for i) initial applications and ii) personnel modifications adding new study personnel to the study until education requirement(s) have been completed for the new personnel.

3.1.1 Documentation of Equivalent Education for Non-English Speakers

The Drexel University IRB will consider alternate training documentation for non-English speakers. Contact the IRB to discuss potential equivalent training options when needed.

3.1.2 Ongoing Research Education and Training Requirements

Continuing education requirements in the Protection of Human Research Subjects (as described above) must be completed for all individuals engaged in human subjects research at least every three (3) years by completing a CITI Refresher Course. Continuing education is tracked through CITI.

3.1.3 HRP/IRB Monitoring of CITI Training

Final approval of initial study submissions will not be granted until all appropriate members of the research team have completed the designated applicable CITI course(s).

Modifications adding new team members will not be approved until the new member(s) of the research team has completed the designated applicable CITI course(s).

3.2 Additional Educational Opportunities

The HRP Executive Director and other IRB Staff make a number of presentations to Drexel University researchers. These presentations include:

- Requests from study teams for additional training,
- Requests for class presentations on IRB Overview as part of an undergraduate or graduate level class.

In addition, the HRP Executive Director collaborates with the Executive Director for Research Quality Assurance to identify research training needs. The Office of Research and Innovation facilitates ongoing training. Training opportunities include:

- Clinical Research Training Series covering topics including informed consent, regulatory administration, training, protocol compliance, and reporting requirements,
- Training presentations for new ORI procedures and guidelines.

- Dissemination of educational materials and resources via the ORI newsletter and bulletins.

4. Responsibilities

4.1 Office for Research & Innovation Responsibilities and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining these procedures, applicable tools, and training. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

4.2 IRB Chair, Members, and Staff Responsibilities

The IRB Chairs, committee members, and HRP personnel are responsible for completing the required trainings as outlined in these procedures and as required for their role and expertise.

4.3 Principal Investigator and Faculty Mentor Responsibilities

The Principal Investigator (and Faculty Mentor as applicable) is ultimately responsible for the conduct and oversight of the project. Please refer to ORI-002, Principal Investigator Eligibility and Responsibilities, for a listing of the PI and Department Responsibilities. The PI is responsible for following these procedures, ensuring appropriate approvals and oversight, and ensuring study personnel have appropriate training and experience prior to performing study procedures.

5. Resources

- Clinical Research Guidelines and Tools
- CITI Program Training
- ORI-005 Research Education and Training Procedures
- ORI-005 Training Matrix

6. Revision

Version 001/Effective Date 11/10/2025 – Original Document: Education and Training