Institutional Review Board Policies and Procedures Manual

SECTION 6: REQUIRED EDUCATION AND TRAINING FOR HUMAN SUBJECTS RESEARCH

6.1 HUMAN SUBJECTS RESEARCH EDUCATION AND TRAINING

Education and training in the protection of human research participants is required for anyone engaged in human subjects research (i.e., investigators, research personnel, IRB members and ORIC staff). Institutional investigators and research personnel must conduct human subject research in an ethical manner and in compliance with applicable federal regulations, IRB and Institutional policies, and Illinois laws. In addition, effective 2017, training in Good Clinical Practice (GCP) is required for all research personnel involved in the conduct, management and oversight of a clinical trial.

A. Required Education and Training

i. Human Subjects Protection

Consistent with the NIH policy, any individual involved in the design or conduct of human subjects research at the Institution must fulfill required training in the protection of human research participants before beginning research and periodically thereafter. This required education includes an overview of the history of protections, the applicable federal and state regulations and the three ethical principles outlined in The Belmont Report. The required education and training is structured to promote discussion of how these regulations and guiding principles must be incorporated as part of the ethical conduct of research. This required education can be accomplished by completing the CITI Program Biomedical or Social

Principal Investigators are responsible for maintaining documentation of this Human Subjects Protection Training for all study personnel and ensuring it is renewed accordingly.

a. IRB approval of any research study will not be issued unless all research personnel are in compliance with the required training in human subjects protection.

b. Non-Institutional personnel engaged in research at our Institution are expected to follow the Institution's requirements for education as described in this policy.

c. All investigators and research personnel must complete continuing education in human subjects protection periodically (i.e., at least every 3 years).

ii. Good Clinical Practice

Effective January 2017, training in Good Clinical Practice (GCP) is required for all research personnel involved in the conduct, management and oversight of a ***clinical trial.*** The NIH definition of a clinical trial is "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on biomedical or behavioral outcomes."

GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The principles were developed in 1996 by the International Conference on Harmonisation (ICH) in collaboration with representatives from the European Union, Japan, and the United States. The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.

GCP principles describe the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with these GCP principles provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.

To fulfill the GCP training requirement, the CITI Program GCP modules are to be completed. All investigators and research personnel must complete continuing education in GCP periodically (i.e., at least every 3 years). The Principal Investigator is responsible for maintaining documentation of this GCP training for all study personnel and ensuring it is renewed accordingly.

IRB approval of any clinical trial (per the NIH definition) will not be issued unless all research personnel are following the GCP training requirements.

B. Research Community Training in Human Subject Protection Principles

i. ORIC Targeted training

ORIC staff offers targeted, individual sessions intended to provide assistance, education, and feedback to members of the research community. This assistance includes education on IRB processes and requirements and guidance on IRB application materials. ORIC staff is available during office hours on a weekly basis for one-on-one meetings to answer questions and provide assistance to research personnel as they prepare or revise their submissions for IRB review.

ii. Department or Individual Specific Training

Training on all aspects of human research protections and IRB processes is available at the request of departments or investigators. ORIC staff is available to provide specialized training to address department-specific research submissions.

6.2 REQUIRED EDUCATION FOR IRB MEMBERS AND STAFF

A. IRB Member Training and Orientation

i. Initial Education and Training

The IRB Chair and ORIC staff are responsible for providing orientation to new members appointed to the IRB. All new IRB members are expected to complete the on-line CITI Training Courses. All IRB members are required to become familiar with the Belmont Report, The Nuremberg Code, the Declaration of Helsinki, federal regulations and guidelines pertaining to research involving human subjects, HIPAA Privacy Rule, as well as other applicable federal and state regulations. Prospective IRB members are first invited to attend an IRB meeting to observe how the meetings function and what is expected of IRB members. Once an individual becomes a new member, they will have an orientation with ORIC staff. In this session the new member meets the ORIC staff, and staff present and review with them the IRB Member Handbook. Additional orientation sessions and follow up sessions with staff are scheduled as needed. Finally, to assist them with their reviews, new IRB members are paired with seasoned members of the IRB when first assigned to review a submission and until the new member is ready to review on their own.

iii. Continuing Education

IRB members are required to recertify their human subjects protection education periodically. This can be achieved through completion of the CITI program modules or attendance at the monthly IRB meetings, at which ongoing education and training is provided through discussions of protocols and by the IRB Chair and ORIC Staff. Furthermore, IRB members are provided with updates on new federal and state laws and Institutional guidelines and policies, as needed. Members of the IRB are routinely provided with relevant articles from scientific literature and appropriate educational materials via email, or during convened Board meetings, to stay informed of contemporary issues.

B. ORIC Research Compliance Coordinator Education and Training

Each newly hired ORIC staff member receives intensive and individualized training and orientation. ORIC Research Compliance Coordinators (ORIC Coordinator) are responsible for ensuring all protocols to conduct research involving human subjects at our Institution are following applicable federal, state, and local regulations and policies by completing comprehensive analyses of all submissions to the IRB. ORIC Coordinators are also responsible for documentation of all IRB deliberations and providing ongoing guidance to research personnel throughout the IRB review process. Initial training and continuing education is critical to ensuring ORIC Coordinators are equipped with the knowledge required to successfully carry out their responsibilities.

i. Initial Training

All new ORIC Coordinators are required to complete the required human subject protections training as indicated above. ORIC Coordinators are also trained on the Belmont Report, The Nuremberg Code, the Declaration of Helsinki, federal regulations, and guidelines pertaining to research involving human subjects, HIPAA Privacy Rule, as well as other applicable federal and state regulations. Furthermore, ORIC Coordinators undergo a comprehensive orientation to learn the IRB review process, the submission process, protocol tracking and review, and Institutional policies and procedural documents related to the conduct of human subjects research at our Institution.

In particular, during the orientation and probation period, all assignments completed by a new ORIC Coordinator are reviewed by an Assistant or Associate Director before being forwarded on for IRB review. This process allows the ORIC Coordinator to receive real time feedback on their process and review of the assigned protocols to confirm that they are able to:

a. Process IRB submissions based on correct understanding of regulatory and Institutional policy and procedures.

b. Familiarize themselves with review checklists, and requirements for IRB meeting approval letters and minutes.

c. Develop skills to proficiently document important steps in the review process.

d. Issue approvals promptly, accurately, and with all relevant documentation.

e. Appropriately incorporate feedback received in order to work independently with minimum supervision in the future.

f. Complete reviews within the departmental processing goal target.

iv. Continuing Education

a. Education Sessions and Staff Meetings

ORIC staff attend weekly staff meetings and periodic continuing education sessions. ORIC staff is encouraged to discuss important issues and commonly asked questions from the research community and present on topics of interest to facilitate a deeper level of understanding of IRB processes, federal and state regulations, and ethical issues relating to human subjects protections.

b. Workshops, In-Services, Conferences

ORIC staff are encouraged and expected to attend formal educational sessions from ad hoc workshops on a given policy matter, in-services with invited speakers from the research community on current trends in biomedical research or ethics, and conferences related to human subjects research, such as those presented by AAHRPP, FDA, OHRP, and PRIM&R.