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