Section 3. **Education & Training**

3.1 Training and Continuing Education of the IRB Chair, IRB Members, and Staff

Recognizing that a vital component of a comprehensive human research protection program is an education program, the medical school is committed to providing training and continuing education for IRB members, HRPP/IRB staff, and investigators and their research staff, related to ethical concerns and regulatory and medical school requirements for the protection of human subjects.

3.1.1 Orientation

New IRB members, including alternate members, meet with the IRB chair, HRPP director, or a designated staff member for an informal orientation session. At the session, an overview of the federal regulations is reviewed and an orientation to IRB processes is provided. Also, the new member is provided with access to:

- The medical school *Human Research Protection Program (HRPP) and Institutional Review Board (IRB) Handbook*, which serves as the policies and procedures for the HRPP and IRB.
- The Belmont Report.
- *Institutional Review Board Member Handbook* by Amdur and Bankert, or a comparable resource
    - A resource list of federal regulations and guidance relevant to the IRB.
    - Medical school policies and procedures for the protection of human subjects.
    - Tools such as checklists used by IRB reviewers.

3.1.2 Initial Training and Education

New IRB members and HRPP/IRB staff must complete the modules of CITI courses that are required by the medical school: Protection of Human Research Subjects (biomedical or social behavioral track, as applicable), and Conflicts of Interest. Appointments of new members to the IRB do not become effective until the orientation and initial education requirements are completed.

3.1.3 Continuing Training and Education

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 and education continues for IRB members throughout their service on the IRB.

Beyond the initial training and education requirements, IRB members and HRPP/IRB staff must also satisfy continuing education requirements on an annual basis. The

medical school offers continuing education via a variety of means including, but not limited to, the following:

- In-service education and training at IRB meetings.
- Education and training workshops.
- Distributing copies of appropriate publications.
- Distributing 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 or during IRB meetings.
- Providing support for webinars and conferences.
- Access to the IRB resource library maintained by the HRPP.

IRB members and HRPP and IRB administrators and staff are also required to complete the modules of CITI courses that are required by the medical school every four years as part of the medical school continuing education requirements.

The activities for continuing education vary on a yearly basis depending on operating budget and areas of need, as determined by the HRPP director. The HRPP director in collaboration with the IRB chair determine which continuing education activities are mandatory for IRB members and staff in a given year, and establishes a mechanism to track whether each individual has satisfied the requirements. Members and staff who are unable to attend education sessions are provided with the materials provided in the session and, whenever possible, the opportunity to remediate the training that they missed. If a remediation session is not possible (eg, a webinar or conference), then an equivalent educational opportunity may be offered at the discretion of the HRPP director.

IRB members who have not fulfilled their continuing education requirements are not assigned as primary or secondary reviewer until the requirements are fulfilled. Failure to complete training may result in the individual being removed or not renewed as an IRB member. Fulfillment of training requirements is included as part of the evaluation of the performance of IRB members/alternates.

3.2 Continuing Training and Education of Investigators and Research Staff

Investigators and research staff whose responsibilities include interaction with human subjects or their identifiable data must complete the modules of CITI courses that are required by the medical school: Protection of Human Research Subjects (biomedical or social behavioral track, as applicable), Health Information Privacy and Security; and Conflicts of Interest. Evidence of current training for each investigator and member of the research staff with the date of completion within four years of the application date must be included as part of every new research study application and application for continuing review. Training is verified by HRPP/IRB staff at the time of initial application and continuing review.

New research applications are not be reviewed until the Principal Investigator and all investigators and research staff with human subject responsibilities have completed the required modules of CITI courses.

While applications for continuing review are accepted and reviewed if CITI training is not current, final study approval may be withheld or participation by a research staff member may be restricted until the Principal Investigator and all investigators and research staff have completed the training requirement.

3.2.1 Equivalent Training

3.2.1.1 External Investigators

If external investigators or research staff provide documentation verifying that they have successfully completed human subject research training that they believe equivalent to that required by the medical school, they may request that the medical school accept their training as equivalent to the required CITI courses. The HRPP director reviews the documentation and determines if it satisfies medical school requirements.

3.2.1.2 Refresher Training

Medical school investigators and research staff who attend a PRIM&R, OHRP, FDA, or other conference where the primary focus is human subjects' protection, and provide documentation verifying attendance, may request that the medical school accept this training in lieu of completion of the refresher CITI course(s). The HRPP director reviews the documentation and determines if it satisfies medical school requirements.