Human Subjects Research Training for IRB Members, PIs and the Research Team

Ethical considerations are essential in planning and implementing any research study involving humans. The University of Texas at Tyler (UT Tyler) has a formal agreement known as the Federal Wide Assurance (FWA) with the Department of Health & Human Services that states UT Tyler will be responsible in protecting the rights and welfare of human subjects involved in research through adherence to related principles regarding research conducted with human subjects.

These principles are operationalized through established policies and procedures that are reflected in UT Tyler’s IRB Handbook. Of utmost importance is the knowledge and skills required to do human subjects research within a solid ethical framework. In order to facilitate meeting this standard of knowledge, UT Tyler has purchased a license to the Collaborative Institutional Training Initiative (CITI), a comprehensive educational program that is used nationally and world-wide “to provide educational content that promotes the quality of and public trust in the research enterprise” (Mission statement: CITI). The main website for CITI can be accessed at https://www.citiprogram.org/

I. Minimum training requirements for Principal Investigators (PI), co-investigators, student assistants, and anyone else directly related to the implementation of the research protocol have been established and are as follows:

a. For socio-behavioral PIs: PIs, co-investigators, and any student or other assistant who will be involved with sample recruitment and other sampling procedures, data collection, and identifiable (via direct or indirect identifiers) data and/or data analyses are required to do the following if the IRB protocol is considered to be socio-behavioral research:

i. Socio-Behavioral Course: 9 modules
   1. Belmont Report and CITI Course Introduction
   2. History and Ethical Principles
   3. Defining Research with Human Subjects
   4. The Federal Regulations
   5. Assessing Risk
   6. Informed Consent
   7. Privacy and Confidentiality
   8. Unanticipated problems and Reporting Requirements in Social and Behavioral Research
   9. Populations in Research Requiring Additional Considerations and/or Protections
Additional supplemental course(s) may be required if a special population is used, such as cognitively impaired or research in primary/secondary schools, or special method is used, such as internet or community-based participatory action research, or a special topic, such as stem cells/tissue research.

b. For biomedical PIs: PIs, co-investigators, and any student or other assistant who will be involved with sample recruitment and other sampling procedures, data collection, and identifiable (via direct or indirect identifiers) data and/or data analyses are required to do the following if the IRB protocol is considered to be biomedical research:

i. Bio-Medical Course: 9 modules
   1. Belmont Report and CITI Course Introduction
   2. History and Ethics of Human Subjects Research
   4. Informed Consent
   5. Social and Behavioral Research (SBR) for Biomedical PIs
   6. Records-Based Research
   7. Research and HIPAA Privacy Protections
   8. Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
   9. Populations in Research Requiring Additional Considerations and/or Protections

Additional supplemental course(s) may be required if a special population is used, e.g., cognitively impaired or research in primary/secondary schools, or special method is used, such as internet or community-based participatory action research, or a special topic, such as stem cells/tissue research.

c. Those individuals, e.g., student research assistants (RA), who are handling de-identified data for data analysis purposes are exempt from these requirements under the condition that the PI accepts responsibility for oversight and monitoring of the student RA for the ethical conduct of research as described in the required training for the PI and research team. The PI may require students to take any of the CITI modules as it relates to their functions on the research team.
2. **Minimum training requirements** for IRB members who are affiliated with UT Tyler, include the following:
   a. Socio-behavioral course
   b. Biomedical course
   c. Any supplemental modules necessary to complete a thorough review of a particular protocol

3. **Minimum training requirements** for IRB members who are not affiliated with UT Tyler include the following module(s):
   a. Community member
   b. Any supplemental modules necessary to complete a thorough review of a particular protocol; for example, a physician external member may be required to have socio-behavioral and/or biomedical courses if review of a particular protocol requires that particular knowledge.

4. **The timing, frequency, and documentation of CITI training will be as follows:**
   a. CITI training must be completed at least every three years or more often as required per protocol.
   b. The Office of Research & Scholarship IRB Coordinator will verify certification prior to final protocol approval.

The CITI training site can be accessed at: [https://www.citiprogram.org/](https://www.citiprogram.org/)

Once an account is established, completion of courses and modules can be done as required.