PURPOSE
This Standard Operating Procedure (SOP) is to define the training requirements and review considerations for all research team members, including the Principal Investigator, involved in human subjects research activities, and for Institutional Review Board (IRB) committee members and RIC office staff members administratively supporting the IRB program.

SCOPE
This SOP delineates systematic process activities and functions for compliance with the US Department of Health and Human Service, Office for Human Research Protections (OHRP) and Common Rule requirements, and University of North Texas requirements for the management, coordination, and operation of the Institutional Review Board program. It applies to all staff members whom are engaged in the operations and support of the Institutional Review Board, and to all UNT Researchers performing human subjects research.

DEFINITIONS/ABBREVIATIONS
1. Definitions
   1.1 CITI Training: Web-based training in research ethics and compliance provided by the Collaborative Institutional Training Initiative (CITI).
   1.2 External Collaborator: Any individual proposing to conduct research using any UNT property, facility, participant population who is not UNT a faculty member, staff member, or student. External Collaborators must perform research activities in partnership with a UNT Principal Investigator.
1.3 Human Subjects Research Activity: Any activity that contributes to the scientific development or execution of a human subjects research study in a substantive, measurable way. This includes, but may not be limited to, activities involving recruitment, interaction, or intervention with human subjects, participation in the consent process by either leading it or contribution to it and recording or processing identifiable private information.

1.4 IRB Analyst: Staff member of the Office of Research Integrity and Compliance that perform administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.

1.5 Researcher: Any individual performing various tasks related to the conduct of human subjects research activities, including but not limited to obtaining informed consent from subjects, collecting and analyzing data, interacting with subjects, and communicating with the IRB.

1.6 Principal Investigator: The primary individual responsible for the preparation and conduct of a research grant, sponsored project, or human subjects research study, in compliance with applicable laws, regulations, and institutional policy governing the conduct of research.

2. Abbreviations

2.1 SOP/SOPs: Standard Operating Procedure(s)
2.2 OHRP: Office for Human Research Protections
2.3 RIC: Research Integrity and Compliance
2.4 IRB: Institutional Review Board
2.5 PI: Principal Investigator

RESPONSIBILITIES

This SOP is applicable to all UNT researchers performing human subjects research under the oversight of the UNT Institutional Review Board. This SOP is also applicable to all members of Research Integrity and Compliance and Institutional Review Board members who are involved in record keeping, reviewing, or approving research studies for the Institutional Review Board program.

PROCEDURE

1. The University of North Texas Institutional Review Board (IRB) requires that all individuals working with human subjects in research complete an instructional training program focused on research ethics and research compliance.

   1.1 This reflects UNT’s commitment to the protection of the rights and welfare of human subjects in research and incorporates the requirements of the National Institutes of Health (NIH)

   1.2 Training requirements are applicable to:

       1.2.1 All Researchers engaged in Human Subjects Research Activity.
       1.2.2 All External Collaborators engaged in Human Subjects Research Activity performed in collaboration with UNT Researchers and reviewed by the UNT IRB.
       1.2.3 All RIC staff
       1.2.4 All IRB Committee members

   1.3 Training must be renewed every 3 years.

2. Researcher and External Collaborator Responsibilities

   2.1 Principal Investigators, Researchers, External Collaborators, and other members of
the research team must complete the UNT required core modules in the CITI course in the Protection of Human Research Subjects.

2.1.1 Required courses include:

2.1.1.1 Social and Behavioral Research Investigators course if you are engaged in Social and Behavioral Research.
2.1.1.2 Biomedical Research course if you are engaged in Clinical Research
2.1.1.3 Biomedical Research and Good Clinical Practice courses if you are engaged in Clinical Trials.
2.1.1.4 The UNT Responsible Conduct of Research (RCR) Basic course is required for all personnel working on projects with federal funding. This is in addition to the courses noted above.

2.2 Evidence of training for each member of the research team must be provided with every new research study application and application for renewal. New studies and applications for renewal will not receive final approval if the education requirements are incomplete.

2.3 If an individual can provide documentation verifying that they have successfully completed human subject research training equivalent to that required by this SOP, the individual may request a substitution of the requirements noted above. The RIC Assistant Vice President or designee will review the documentation and determine if it satisfies organizational standards as defined in this SOP. This will be assessed on a case-by-case basis.

2.4 The RIC office is willing to perform one-on-one or specialized training related to human subjects research by request. Individuals requesting specialized training must contact the RIC staff to discuss and schedule the desired training.

3. **RIC Staff and IRB committee member responsibilities**

3.1 All RIC Staff and IRB Committee Members responsible for the review and approval of human subjects research must complete the following CITI Training modules:

3.1.1 Social & Behavioral Research or Biomedical Research course
3.1.2 IRB Administration course
3.1.3 The IRB Chairperson must also complete the IRB Chair course

3.2 Evidence of training must be stored by the RIC office for reference

**REFERENCES**

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. CITI Research Ethics and Compliance Training website

**APPENDICES**

1. IRB Guidelines
2. UNT Human Subjects (IRB) website - Training and Education