Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-007-1	01/31/2017	HSO	IRB	Page **1** of **3**

1. **PURPOSE**

    1.1. Training on the protection of **human subjects** is a critical component of all **research** endeavors. Therefore, training is required for all researchers. The purpose of this **policy** is to describe the training and educational requirements for all individuals **engaged in human subjects research**.

2. **DEFINITIONS**

    2.1. **Collaborative Institutional Training Initiative (CITI):** is an on-line educational training course that provides relevant, up-to-date information on the protections of human research subjects in the format of instructional modules. The modules are divided into two groups: social/behavioral and biomedical.

3. **POLICY**

    3.1. The **Principal Investigator (PI)** and Research Staff (Study Team Members) should be qualified for their research roles by education and experience including knowledge of all applicable laws, regulations, and guidance for the protections of human research subjects.

    3.2. UGA has chosen to subscribe to the CITI program for all of its online research based training. All UGA researchers who are engaged in human research must complete an educational program on ethics and procedures for the use of human subjects in research from CITI before the IRB may review a submission. See *Policy and Procedure: Engagement Determination*.

    3.2.1. The specific module required is based upon the type of research being conducted, either social/behavioral or biomedical.

    3.2.2. Effective January 1, 2017, all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials must complete the additional CITI training on Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH).

    3.2.3. CITI provides additional modules that may be required for a particular submission or by a federal funding agency or sponsor contract (e.g., for research involving special/vulnerable populations, Internet research, or Good Clinical Practice for clinical trials).

    3.3. Non-UGA Collaborators may either complete CITI training or complete equivalent training from their affiliated **institutions**.

    3.4. Individuals must earn an overall 80% grade or better to pass the course.

    3.5. Certification is valid for five years. At that time, it is necessary to complete a Refresher Course. However, NIH-funded investigators and staff who are involved in clinical trials are required to maintain their GCP training every three years through Refresher Course(s).

3.6. The PI is responsible for ensuring that all personnel are properly trained before submitting an initial study or a ***modification*** to add study team members.

3.7. If education requirements are not satisfied, a submission will not be considered complete by the IRB. The review process will only commence once the submission has been determined to be complete.

4. **PROCEDURES: Researchers**

4.1. The researcher will log in to CITI via the UGA GeaR website http://gear.ovpr.uga.edu/.

4.2. From the CITI home page, the researcher will choose University of Georgia Courses under the Main Menu.

4.3. To select a course to complete, the researcher will choose "Add a Course or Update Learner Groups."

4.4. Under the heading "Human Subjects Courses (IRB)," the researcher will choose the appropriate course related to the research to be conducted – either Social and Behavioral Research or Biomedical.

   4.4.1. Researcher may also choose additional modules based on the research to be conducted such as ***Children***, International, Internet, ***Prisoners***, and Good Clinical Practice for Clinical Trials

4.5. The researcher will complete all modules in each course related to the research to be conducted and as required by a federal funding agency or sponsor contract.

4.6. CITI records should be visible in the electronic application system the following day upon completion.

   4.6.1. If CITI completion records are not visible in the electronic application system the following day, researcher should contact the IRB Staff for assistance.

4.7. Certification for Non-UGA Collaborators must be attached when adding the researcher to the application.

   4.7.1. If the Non-UGA Collaborator needs access to the UGA CITI training portal, contact the IRB Staff for assistance.

5. **PROCEDURES: IRB Staff**

5.1. The IRB Staff ensures training is current for UGA and Non-UGA researchers before an IRB submission is reviewed.

5.2. If a researcher has difficulty with CITI training records not populating in the electronic application system correctly, the IRB Staff will assist by communicating with the researchers and CITI for resolution.

    5.2.1. If no resolution is possible, the IRB Staff may manually add CITI training records, if necessary.

  5.3. IRB staff is available to provide in-person training, Question and Answer presentations, workshops, and round-table discussions at the request of any department/unit, faculty/instructor or student group.

6. MATERIALS

  6.1. None

7. RESOURCES

  7.1. UGA CITI Login Portal, http://gear.ovpr.uga.edu/applications-and-databases/uga-citi-login-portal/

  7.2. Policy and Procedure: Engagement Determination