| Policy Title | Investigator Training |
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| Last Updated | May 17, 2022 |
| Responsible Office | IRB Office |
| Contact Information | IRB Office<br>Email: irb@kennesaw.edu<br>Phone: 470-578-4941 |

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

2. **Definitions**
   2.1. **Collaborative Institutional Training Initiative (CITI) Program:** 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.

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. All KSU 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 Program before the IRB may approve a submission.
      3.2.1. The specific module required is based upon the type of research being conducted: Social, Behavioral, Educational Research with Human Subjects or Biomedical Research with Human Subjects.
      3.2.2. Effective January 1, 2017, all NIH-funded investigators and staff who engage 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 Program 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-KSU Collaborators may either complete CITI Program training or complete equivalent training from their affiliated institutions.
   3.4. Individuals must earn an overall 75% grade or better to pass each course.
   3.5. Certification is valid for three years. At that time, it is necessary to complete one or more Refresher Courses.
   3.6. The PI is responsible for ensuring that all research staff are trained and have up to date certifications before submitting a study or a modification to add study team members in addition for the duration of the project.

4. **Procedures: PI and Research Staff**
   4.1. PI and Research Staff may access CITI via KSU IRB website or directly at citiprogram.org.

4.2. PI and Research Staff must register an account with CITI and affiliate the account with Kennesaw State University.

4.3. PI and Research Staff must complete the Social, Behavioral, Educational Research with Human Subjects course or the Biomedical Research with Human Subjects Course.

    4.3.1. Course entitled Students Conducting Minimal Risk Research does not satisfy the training requirement and will not be accepted by the IRB. 4.4. For all non-KSU research staff, the PI must attach a certificate or completion report to the submission form.

    4.3.2. Non-KSU research staff, who do not have access to training through an affiliated institution, may affiliate with KSU on the CITI website to gain access to the supported courses.

5. Procedures: IRB Staff

5.1. The IRB Staff ensures training is current and appropriate for KSU and Non-KSU researchers before an IRB submission is reviewed using pre-review checklist.

5.2. IRB Staff may identify supplemental modules during pre-review to be required for research involving special/vulnerable populations, Internet research, or Good Clinical Practice for clinical trials.

5.3. 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.

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

Resources:

Pre-Review Checklist
CITI Program website https://about.citiprogram.org/