1.0 Purpose
The purpose of this SOP is to describe training requirements for all personnel involved in conducting human participant research.

2.0 Policy
It is the policy of the IRB that all personnel involved in the conduct of exempt and non-exempt human participant research must receive training in the protection of human participants.

2.1 Collaborative IRB Training Initiative (CITI)
Training in the protection of human participants is primarily accomplished through completion of this web-based training program.

a. Personnel to be certified
Research personnel listed on the IRB application and consent document(s) by name must complete one of the existing CITI trainings. Research personnel are classified as follows:

1. PIs
2. Supervising Investigators (if any) and Key Personnel
3. Participating Personnel
4. Limited Research Worker

b. Training tracks
1. Behavioral/Social Science: Basic Course to be completed by PIs, Supervising investigators, key and participating personnel at UNL who conduct behavioral or social science studies.

2. Biomedical: Basic Course to be completed by PIs, Supervising Investigators, and participating personnel at UNL who conduct biomedical studies (e.g., exercise science, nutrition, or any study determined by the IRB).

3. Limited Research Worker: Abbreviated CITI training.

c. Student research
All graduate students conducting human participant research (exempt and non-exempt) and undergraduates who have responsibility for project design and integrally involved in data collection must take the basic CITI course.
D. **External investigators or subcontract recipients**
The IRB will accept certificates of training from other institutions when research personnel include external investigators or subcontract recipients who have been trained elsewhere and are under the legal jurisdiction of that institution with respect to compliance with federal regulations. A copy of any certification must be provided to the HRPP office.

E. **New research personnel added to IRB-approved research via a Request for Change or Application for Continuing Review**
All new employees serving as investigators, participating personnel, and Limited Research Workers must complete CITI training prior to addition as research personnel to any research study. The IRB will accept certificates of training from prior institutions only if the other institution utilized the CITI training system.

F. **IRB approval of research**
All research personnel must be CITI trained/certified prior to IRB approval of initial research applications, continuing review applications, and 5-year continuing review forms.

*NOTE: Current project personnel whose prior certification may have lapsed must renew certification prior to IRB approval of any new application of annual continuing review.*

G. **Access to the CITI training program**
A link to the CITI Training Program is available through the HRPP website (http://research.orr/otraining.shtml). Following registration, the individuals will be able to immediately access the system.

H. **Test data confidentiality**
Individual test scores are confidential. The webmaster and staff supporting the distance learning software at the University of Miami where the data are processed and stored have access to individually identifiable quiz scores. Additionally, the IRB staff will have access to the individual test scores to determine if the test taker achieved the minimum passing score. Aggregate, anonymous quiz data will be used by course faculty to help improve course content and quiz questions. There will be no further disclosure of individually identifiable quiz results or aggregate institutionally identifiable results beyond that mentioned above.

I. **Minimum passing score required for certification**
The IRB requires a passing score of 75% overall to receive CITI certification.

J. **CITI certification renewal**
Certification for training using the CITI course is valid for 3 years from the original date of completion. Certification must be renewed at that time in order for the individual to be listed as an authorized study personnel in new IRB applications or continuing review forms. Certification renewal is available through the CITI Continuing Education Course.

To renew certification:

1. UNL faculty, students, and staff must complete the appropriate track Continuing Education Course or the initial course.
2. The IRB requires a passing score of 75% overall to receive a renewal of CITI certification.

2.2 Other training requirements

A. All research personnel listed on the IRB application are expected to read The Belmont Report, which is posted on the OHRP website (www.hhs.gov/ohrp).

B. All research personnel listed on the IRB application are expected to read UNL IRB policies, which are applicable to their research and, which can be accessed on the HRPP website (http://research/orr/forms.shtml).

C. All research personnel listed on the IRB application are expected to be reasonably familiar with the requirement of Health and Human Services regulations at 45 CFR §46, which can be accessed on the HRPP website (www.hhs.gov/ohrp).

2.3 Other Available Training

The HRPP website, which is regularly updated and contains links to OHRP and other websites, serves as the primary educational resource and outreach tool for the campus. In addition, the IRB staff conducts workshops on an on-going basis for investigators and protocol coordinators and IRB Policy updates appear on the HRPP website.