	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Training Requirements	#6.1

The purpose of this SOP is to describe who must complete training on the protections of human research subjects and what type of training is acceptable.

I. General Requirements

The UNCW Institutional Review Board (IRB) requires researchers to complete the online Basic Course for Human Research Protections, or an equivalent course, prior to granting approval to conduct human subjects research.

II. Scope

A. This SOP pertains only to projects that meet the definition of human subjects research as identified by 45 CFR §46.102, regardless of the source of funding, if any.

B. This SOP pertains to all persons (UNCW faculty, staff, students, or non-UNCW collaborators) involved in the design and/or conduct of research projects involving human subjects. Examples of persons involved in the design and conduct of research projects include persons engaged in planning the study, writing survey/interview/focus group questions, recruiting subjects, administering study procedures, and analyzing identifiable data. In particular, all individuals who will obtain informed consent from research subjects and who will otherwise directly interact with subjects must have completed the required training.

III. Procedures

A. Training Website

UNCW subscribes to the Collaborative Institutional Training Initiative (CITI) Program, designed to demonstrate the highest ethical standards and to comply with all laws and regulations. The website can be found at http://www.citiprogram.org/. Other forms of training must be approved on a case-by-case basis by the IRB chair or designee.

B. Certification of Training

The IRB office receives certification of training directly through the CITI Program website for users who indicate affiliation with UNCW when they register an account with the CITI Program. Non-UNCW collaborators subject to the training requirement must submit documentation of completion to the IRB office. The IRB office will maintain a record of all training documentation received. IRB staff will not request review of a human subject research application by an IRB co-

chair or designee until IRB staff has confirmed completion of training and/or received all relevant training documentation.

C. Refresher Training

The UNCW IRB does not currently require investigators to complete refresher training. However, UNCW researchers who collaborate with researchers from other institutions may be required to complete refresher training if the collaborating institution's IRB requires refresher training.

IV. References to Other Applicable SOPs

V. Responsibilities

Title	Responsibility
IRB Co-chair or designee	Responsible for determining if alternate training courses are acceptable.
Research Compliance Specialist	Responsible for conducting initial reviews of human subjects research applications and ensuring documentation of training is on file.
Principle Investigator (PI)	Prior to submission of an application to the IRB, the principle investigator is responsible for completing the required training, ensuring all other persons on the research team involved in the design and conduct of human subjects research have completed the required training, and providing documentation of completion to the IRB upon request by IRB staff.
Other investigators	Required to complete the required training and are required to provide the principal investigator with documentation of training completion upon request by the principal investigator.

VI. Resources

A. UNCW IRB Website: http://uncw.edu/sparc/integrity/irb.html
B. U.S. Department of Health & Human Services, Office of Human Research Protections website: https://www.hhs.gov/ohrp/
C. 45 CFR 46 ("Common Rule"): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
D. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html