Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 208.1	TITLE: Training Requirements for Research Personnel	Date Effective: 09/01/2020 Last Revision Date:

I. Purpose

The Institutional Review Board requires all individuals working with human subjects in research complete training in the protection of human subjects. This requirement reflects the Board's commitment to the protection of the rights and welfare of human subjects in research, regardless of funding source.

II. Scope

This procedure applies to any investigator or research personnel involved in human subjects research at Western Carolina University, regardless of funding source. Collaborating investigators employed at external institutions that do not have requirements for human research protection training must comply with the stated training requirement, or provide evidence of current equivalent training.

III. Definitions

Applicable Clinical Trial:

1. Pediatric post-market surveillance of a device
2. Clinical trials funded in whole or in part by the National Institutes of Health in response to any type of application for funding, including competing renewals, submitted on or after January 18, 2017.
3. A clinical trial initiated on or after September 27, 2007 that:
    a. Involves the study of a drug, biologic, or device that is regulated by the FDA
    b. AND is controlled
    c. AND at least one of the following applies:
        i. At least one site is in the U.S. or its territories
        ii. The drug, biologic, or device is a product manufactured in and exported from the U.S. or one of its territories for study in another country
        iii. The study has a FDA IND or IDE number
    d. AND is none of the following:
        - A Phase 1 drug trial (Phase 1/Phase 2 trials are considered applicable)
        - Primary purpose is to assess device feasibility
        - An expanded access study

Human Subject: living individual about whom an investigator conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Research Personnel: any individual who is involved in conducting human subjects research studies. Such involvement may include:

- obtaining information about living individuals by intervening or interacting with them for research purposes;
- obtaining identifiable private information about living individuals for research purposes;
- obtaining the voluntary informed consent of individuals to be subjects in research; and
- studying, interpreting, or analyzing identifiable private information or data for research purposes.

Research: systematic investigation designed to develop or contribute to generalizable knowledge

IV. Procedure

1. Training for every member of the research team must be complete before the Board will review a research protocol.
2. The required training is provided through Collaborative IRB Training Initiative (CITI). CITI is an external website, not managed by Western Carolina University.
3. The investigator must complete and pass the module titled Social/Behavioral Research. A passing score is 80%. The certificate will be valid for five (5) years. When the certificate is due to expire, training must be renewed.
4. Investigators conducting an NIH funded Applicable Clinical Trials must complete and pass the Good Clinical Practice (GCP) module, in accordance with the National Institutes of Health. A passing score is 80%. The certificate will be valid for three (3) years. When the certificate expires, training must be renewed.
    a. The Good Clinical Practice series has four modules. The investigator shall select the appropriate module based on the research. GCP modules include:
        i. GCP – Social and Behavioral Research Best Practices for Clinical Research
        ii. GCP – FDA Focus
        iii. GCP for Clinical Trials Involving Investigational Medical Devices
        iv. GCP for Clinical Trials Involving Investigational Drugs
5. Training may be renewed by taking the Social/Behavioral Refresher or the GCP Refresher course, which is valid for an additional three (3) years. Alternatively, the investigator may retake either acceptable course again, which will be valid five (5) years or (3) years, respectfully, from date of completion. The refresher courses will populate one (1) time. When the Refresher certificate expires, the full Social/Behavioral Research or Good Clinical Practice course needs to be completed again.
6. CITI will send reminder emails to users whose certificates are about to expire.

IV. Responsibilities

Investigators

V. References

45 C.F.R. § 46.103(a) (2018)

Dep't of Health, Educ. and Welfare, Belmont Report, DHEW Pub. Nos. (OS) 78-0013,14 (April 18, 1979)

National Institutes of Health, DHHS, Policy on Good Clinical Practice Training, NOT-OD-16-148, (September 16, 2016)