



Policy Name: Education and Training Requirements for Individuals Involved in Human Research			
Approved		Date: 11/01/08	
Effective Date: 02/20/09	Page 1 of 3	Section: HRPP 5.3	Policy Number: N/A
Replaces Policy: N/A			Dated: N/A

I. POLICY

A. Introduction

All individuals involved in human research must complete the initial 17 basic modules focused on biomedical or behavioral/social research when commencing such research.

Beginning in Fall of 2008, all individuals involved in human research must complete the MIAMI CITI COURSE REFRESHER MODULE 101 every three years providing a mechanism of continuing education. Individuals with a Ralph H. Johnson VAMC appointment are required to complete similar continuing education modules at the CITI site on an annual basis and this will satisfy the MUSC requirement for Continuing Education in Human Research Protection

B. CITI

MUSC is registered for training of individuals involved in human research through the Miami Collaborative Institutional Training Initiative or CITI <http://www.musc.edu/citi>

This process will be monitored through CATTs (Computerized Annual Training and Tracking System)

C. Background

The ethical conduct of research on human subjects is an essential component of our research mission. The principles of the ethical conduct of research are delineated in the following documents

1. [Declaration of Helsinki](#)
2. [Nuremberg Code](#)
3. [Belmont Report](#)
4. [Code of Federal Regulations-PHS \(45 CFR Part 46\)](#)
5. Code of Federal Regulations-FDA (21 CFR Parts 50 and 56)

- a) [Web-Based](#)
- b) [PDF Part 50](#)
- c) [PDF Part 56](#)

6. [VA handbook 1200.5](#)

As recipients of federal funding, MUSC is required to ensure that individuals performing or overseeing research on human subjects are educated on the ethical conduct of research. Specific guidelines have been issued by the Office for Human Research Protection OHRP in the United States Public Health Service regarding the responsibilities of individuals and institutions for compliance with the ethical conduct of research.

II. PROCEDURES

A. WHO MUST COMPLETE THE EDUCATION REQUIREMENT?

All individuals involved in human research. Exempt protocols do not mean exempt from IRB review and educational requirements.

B. INDIVIDUALS INVOLVED IN HUMAN RESEARCH

- 1. [Definitions from 45 CFR Part 46](#)
- 2. In order to help you assess whether participation in the educational activity is required, below are definitions from the Code of Federal Regulations. Additional information is available at http://grants.nih.gov/grants/policy/hs_educ_faq.htm.
 - a) “**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

MUSC/VA comment: In practical terms, if publication, presentation at a scientific meeting, or other scholarly purpose of the work is intended, it is probably research. If unsure, consult the Director of the Office of Research Integrity.

b) “**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.”

MUSC/VA comment: This means that use of tissues from living patients or examination of their medical records for the purpose of research qualifies as research on a human subject. If unsure, consult the Director of the Office of Research Integrity.

III. REFERENCES