Policy Name: **Education and Training Requirements for Individuals Involved in Human Research**			
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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 every two years 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.

D. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>)

E. INTERNATIONAL COMMITTEE ON HARMONISATION – GOOD CLINICAL PRACTICES (ICH – GCP)

ICH-GCP is often referenced as a requirement by sponsors of corporate trials. However, there are differences in the ICH-GCP and FDA regulatory requirements. The Office of Research and Sponsored Programs (ORSP) strives to either qualify the ICH-GCP requirement with “as adopted by FDA” or negotiate the ICH-GCP reference completely out of the agreement/award terms.

When ICH-GCP is a firm requirement of the sponsor, the IRB manager and the affected PI will be promptly notified. At that point, a review must be conducted among the various parties (PI, IRB, and ORSP) to determine if it is reasonable to agree to ICH-GCP terms in the agreement/grant award for the PI and the IRB.

If there are cogent reasons for agreeing to the ICH-GCP requirement (i.e., international trial or other identifiable reason) and all parties (PI, IRB, and ORSP) agree, then ORSP will accept the ICH-GCP and sign/execute the agreement/accept the award.

At that point the IRB will take the necessary steps to ensure MUSC's compliance with the ICH-GCP requirements. Additionally, the PI will need to attest that he/she understands his/her and affected staffs obligations in conducting the study/trial in complete accordance with ICH-GCP. As evidence of this understanding, PIs, other investigators, and other named study staff involved with the study will complete the ICH-GCP CITI module.

F. MEMORANDUM OF UNDERSTANDING

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

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.

C. VERIFICATION OF THE COMPLETION OF EDUCATION AND TRAINING REQUIREMENTS

1. The MUSC Compliance office maintains the records of education and other courses completed by MUSC personnel.

2. Prior to release of a new study or continuing renewal of an existing study, the IRB Staff accesses the records maintained by University Compliance and verifies that the education requirements for all personnel on the study are current.

III. REFERENCES