

University of Miami Policy on Education in Human Subjects Protection for Key Personnel Involved in Human Subjects Research

Introduction

Background

This document describes the modifications of the University of Miami's policy for certification and re-certification for the performance of human subjects research. The University's certification was first begun in 1999. Initially, certification could be obtained by attendance at seminars on human subjects protections. With the development of the on-line CITI Program (see below), the University modified its policy to require completion of the CITI "Core" course. The CITI program has now added new components that are described below. These new components form the basis for this modified policy.

The CITI Program

The CITI program, hosted and coordinated at the University of Miami, was developed by experts in bioethics and IRB process from around the country. Many University of Miami researchers have already been certified by completing the CITI "Core" course. CITI has now added a Continuing Education course for re-certification.

Since the original "Core" curriculum was mainly oriented to biomedical research, a second CITI "Core" curriculum has been added for social/behavioral research. These "Core" curricula will be referred to below as either biomedical or social/behavioral.

Key Personnel

Individuals defined as key personnel must fulfill educational certification requirements before they can perform research involving human subjects. Key personnel are defined as individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project.

Certification

Certification of Key Personnel Performing Biomedical Research

- The certification for these individuals is essentially unchanged. They will continue to require certification through the original CITI Biomedical Course.

Certification of Key Personnel Performing Social/Behavioral Research

- Those individuals involved in social/behavioral research who were certified through the CITI Biomedical Course before 1/1/03 will be required to be certified again through the CITI Social/Behavioral Course no later than 6/30/04. Those who were or will be certified with the CITI Biomedical Course from 1/1/03-12/31/03 will be required to be certified again through the CITI Social/Behavioral Course no later than 6/30/05. Thus, individuals who have been certified through

the CITI Biomedical Course will be permitted to continue performing research until the dates indicated above under their previous certification.

- For any protocol that is to be submitted to an IRB, all individuals intending to be key personnel in social/behavioral research who have not been certified must become certified by completing the new CITI Social/Behavioral Course.

Certification of Key Personnel Performing both Biomedical and Social/Behavioral Research

- If individuals submit protocols to both behavioral and medical IRBs, the CITI Biomedical Course will be the standard. However, the University's Social/Behavioral IRB reserves the right to require completion of additional modules of the CITI Social/Behavioral Course relevant to the research to be performed.

Certification of Key Personnel from other Institutions

- Researchers from outside the University of Miami who are included as key personnel on the IRB submission form must also be certified either by the University's criteria or those of their own institutions. The Principal Investigator is responsible for determining that those key personnel have been certified and providing assurance of this.

Certification of Graduate Students

- All graduate students who are considered key personnel are required to be certified through the appropriate CITI course (see above).

Certification of Undergraduate Students

- Undergraduate students who are key personnel will meet the University's training requirements by another mechanism. Their instructors are required to fulfill the University's training requirements and to adhere to the University of Miami Policy on Class Projects Involving Human Participants. This includes certifying to the IRB that the undergraduate students have been provided appropriate education in human subjects protections. The IRB still reserves the right to require certain undergraduate students to fulfill the standard CITI requirements if it deems this necessary.

Re-Certification

- All re-certification is obtained by the completion of the CITI Continuing Education Course.
- If the CITI Biomedical Course was completed prior to 1/1/03, the CITI Continuing Education Course must be completed by 6/30/04 to remain certified to conduct human subjects research at the University of Miami.

- If either the CITI Biomedical Course or the CITI Social/Behavioral Course was completed between 1/1/03 and 12/31/03, the re-certification deadline is 6/30/05.
- Subsequent re-certification is required within two years of the previous re-certification deadline.

In addition to these policies, IRBs at the University of Miami always reserve the right to require any additional education in human subjects protections it deems necessary for the performance of a research study.

To obtain information on the process for completing certification or re-certification, please contact the CITI Office by e-mail (citisupport@med.miami.edu) or by phone at 305-243-7970. Other questions about this policy should be addressed to Jay Sosenko, M.D., at 305-243-6415.