

THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES	IRB Policy Number: 021.1
Title: <i>Human Subjects Protections Training Requirement</i>	Page: 1 of 2
Written by: _____ Laura W. Knight, MPH; Sr. IRB Administrator	Date this issue: July 2008 Previous issue(s): 021.0 (12/07)
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I. PURPOSE

The purpose of this policy is to define the training requirements for Institutional Review Board (IRB) members, investigators and research personnel involved in human subjects research under the jurisdiction of the NSMC IRB.

To increase the Federal commitment to the protection of human research participants, several new initiatives to strengthen government oversight of research with human subjects were announced by HHS Secretary Shalala on May 30, 2000. On October 1, 2000, the NIH required education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Before funds can be awarded for competing applications or contract proposals involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research.

Although the mandate from the DHHS applies only to NIH grants and contracts, the NSMC IRB policy extends this mandate to include all human subjects research conducted under the jurisdiction of the NSMC IRB in order to comply with our Federal Wide Assurance (FWA) with the Office of Human Research Protection (OHRP), U.S. Department of Health & Human Services. This Assurance includes a requirement that all research personnel working with human participants will receive training in ethical guidelines and regulations. "Research personnel" is defined as persons who have direct and substantive involvement in proposing, performing, reviewing, or reporting research and includes students fulfilling these roles as well as their faculty advisors.

II. SCOPE

As of May 1, 2008, all investigators and research personnel, originally listed or later added to a project through an amendment, participating in the conduct of human subjects research under the jurisdiction of the NSMC IRB, and all current IRB Members must complete, or have completed within the past three (3) years, the NSMC approved basic education program developed by the Collaborative Institutional Training Initiative (CITI).

III. DEFINITIONS

Collaborative Institutional Training Initiative (CITI): An internet-based set of educational modules on the protection of human participants in research. It is sponsored by a consortium of IRB professionals and researchers from universities and medical schools across the country and is administered by the University of Miami.

IV. POLICY

A. Initial Training - CITI Basic Course

This internet-based course in human research protection and bioethics is designed specifically for all personnel that have a significant involvement in the planning, conduct, and analysis of any scientific activity that employs human research participants. The course consists of training

modules that are divided into two tracks: Biomedical Research and Social/Behavioral Research. The learning objectives of the CITI course are:

1. To provide an understanding of the historical perspectives, ethical principles, and Federal regulations associated with the conduct of research with human participants;
2. To provide a clear understanding of what constitutes informed consent and how it must be applied in research involving humans;
3. To provide basic information on the regulations and policies governing research with investigational drugs, biologics, and devices;
4. To provide a clear understanding of the ethical issues and Federal regulations in force during the conduct of Social/Behavioral research, records based research, and genetics research with human participants; and
5. To provide Investigators conducting research at VA facilities a clear understanding of the special procedural and regulatory policies for human research at VA research facilities.

B. Continuing Education – CITI Refresher Course

All researchers and their staff and all current IRB members are required to complete, at a minimum, the CITI Refresher Course every three (3) years in order to keep current in issues relating to human subjects protection.

Other non-CITI training programs will not be accepted. CITI training conducted through another institution will be accepted on a case-by-case basis. CITI training conducted through any Partners institution (e.g., BWH, MHG, DFCI, Newton-Wellesley, McLean, etc) will be accepted and these CITI training records can be transferred to NSMC.

The NSMC IRB office automatically receives notice once personnel complete the CITI Basic and/or CITI Refresher courses when the institution selected at registration is NSMC. Personnel are required to maintain a copy of their CITI completion report as documentation of the required CITI training course.

Investigators and Research Personnel

As of May 1, 2008, the NSMC IRB will not approve any protocol, either initially or at continuing review, unless all listed Investigators and research personnel have completed or updated their CITI training, as applicable.

IRB Members

As of May 1, 2008, all NSMC IRB members must have completed or updated their CITI training, as applicable, in order to maintain active membership on the IRB.

V. REFERENCES

1. [NIH Required Education In The Protection Of Human Research Participants](#)
2. [Frequently Asked Questions for the Requirement for Education on the Protection of Human Subjects](#)
3. Collaborative IRB Training Initiative (CITI) Training: <http://www.citiprogram.org>