NYIT Policy on Required Education in the Protection of Human Research Participants—Release Date: January 1, 2015

Office of Sponsored Programs and Research, New York Institute of Technology

1. Research Conducted under FWA 00000708

The New York Institute of Technology (NYIT) is committed to maintaining the highest ethical standards in research. The purpose of this policy is to ensure that all persons who participate in the conduct and review of research involving human subjects under NYIT's Federalwide Assurance for the Protection of Human Subjects, FWA 00000708, and its Department of Defense Addendum, F50535, have received appropriate training in the protection of human subjects. NYIT's training program is outlined below.

2. Regulatory Basis for Training

Under the terms of NYIT's FWA, when the Institution becomes engaged in research involving human subjects, whether federally supported or not, the Institution and the Institutional Review Boards upon which it relies to review the research are required to adhere to the ethical principles in the Belmont Report and to comply with the Federal (Department of Health and Human Services) Policy for the Protection of Human Subjects, also known as the Common Rule.[1] Although the Common Rule does not mandate investigator or IRB member training in the protection of human subjects in research, the Institution holding the FWA is responsible for ensuring that these parties understand and comply with the Common Rule.

The Department of Defense follows the DHHS and FDA regulations on human subjects research, but it also requires that the research be reviewed by the IRB under DoD regulations.[2] Under NYIT's DoD Addendum, the Institution is responsible for conducting initial as well as continuing education in research ethics for personnel who "review, approve, oversee, or manage" DoD-supported human subject research. The training and retraining requirement applies to all members of the study team of a human subject protocol that receives DoD funding: research investigators, their research staff, IRB Chairs, Co-Chairs, IRB members, management, and other staff. The DoD requires documented retraining every three years.

2.1. Training of Key Personnel

Under an NIH policy that became effective October 1, 2000[3], all individuals who will be involved as "key personnel" in the design or conduct of NIH-funded human subject research, including human subject research that is exempt from Institutional Review Board (IRB) approval[4], must fulfill a requirement for education in the protection of human research participants. The requirement extends to key personnel of consortium institutions and alternate performance sites. The content of the education program is not prescribed by NIH but, rather, is left to the discretion of the institution(s) where the research is conducted. NIH expects all key personnel to receive the training before beginning research involving human subjects.

The NIH Office of Extramural Research (OER) online tutorial, "Protecting Human Research Participants"[5], is currently considered by the NIH to satisfy its training requirement, and NYIT has for a number of years accepted that tutorial or its predecessor, the NCI "Human Participant Protections Education for Research Teams" course, as satisfying the requirement. Effective September 1, 2015, with few exceptions (concerning which, see 'Equivalent Training' below), NYIT will no longer accept the NIH tutorial as fulfilling the requirement. Instead, CITI training (q.v.) will be required for all new studies and for most key personnel.

2.2. Training of IRB Members

Common Rule[6] and FDA regulations[7] require that an Institutional Review Board (IRB) "be sufficiently qualified through the experience and expertise of its members…to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects"; that, "In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice"; and that, "If an IRB regularly reviews research that involves a vulnerable category of subjects, …consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects…An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB." IRB member training, if any, is not prescribed by regulation but is, instead, left to the institution's discretion.

Hitherto, NYIT has required IRB members to complete the NCI or NIH OER on-line training, or its equivalent, prior to service on its IRBs. Effective September 1, 2015, new NYIT IRB members will be required to complete CITI training, prior to service. Current members have until December 31, 2015 to re-certify.

3. Collaborative Institutional Training Initiative (CITI)

NYIT has a license from the Collaborative Institutional Training Initiative (CITI)[8] of the University of Miami (UM), under which it is able to offer online training to NYIT faculty, staff and students. CITI was founded in 2000 as a collaboration between the UM and the Fred Hutchinson Cancer Research Center to develop a web-based training program in human research subject protection. The CITI Program has since expanded to include courses in other curricular areas including Animal Care and Use, Biosafety and Security, Export Control, Good Clinical Practice, Information Privacy and Security, Responsible Conduct of Research, and Conflicts of Interest. (Training in these areas is also available under NYIT's license.)

The CITI Program in Human Subjects Research (HSR) includes "Basic" courses with a Biomedical or a Social-Behavioral-Educational focus; advanced courses including IRB Member and IRB Administrator modules; and "Refresher" courses for re-certification purposes. Basic HSR courses cover the historical development of human subject protections as well as current information on regulatory and ethical issues. Basic modules are appropriate for all persons involved in HSR, or who have responsibilities for setting policies and procedures with respect to such research, including IRBs. HSR module topics include: basics of IRB regulations and the review process, assessing risk to participants, avoiding group harms, conflicts of interest, cultural competence, FDA-regulated research, genetic research, HIPAA-regulated research, informed consent, international research, Internet research, IRB member responsibilities, IRB chair responsibilities, records-based research, research in schools, research with protected populations, research with vulnerable subjects, unanticipated problems and reporting, and students in research.

4. NYIT Requirement for CITI Training in Human Subjects Research

Effective September 1, 2015, all NYIT researchers, staff, and others involved in the design and conduct of research involving human subjects (collectively, "Key Personnel"), irrespective of the source of funding, if any; all Institutional Review Board members and IRB administrators; and all other staff responsible for approval and oversight of such research, must complete the following modules of the applicable "Basic" course in HSR, unless equivalent training approved by the relevant IRB has been successfully completed:

Course	Track
1. "Belmont Report and CITI Course Introduction"	Biomedical or Social-Behavioral-Educational
2. "History and Ethical Principles"	Biomedical or Social-Behavioral-Educational
3. "Basic Institutional Review Board Regulations and Review Process"	Biomedical
4. "Informed Consent"	Biomedical or Social-Behavioral-Educational
5. "Conflicts of Interest in Research Involving Human Subjects"	Biomedical or Social-Behavioral-Educational
6. At least nine (9) other Biomedical or Social-Behavioral-Educational modules of the participant's choosing.†	Biomedical or Social-Behavioral-Educational

†For IRB members and staff one of these nine modules must be the "IRB Member" module. For IRB Chairs and Co-Chairs, the standalone "IRB Chair" course is also required.

Two tracks—a Biomedical track ("Biomed") and a Social-Behavioral-Educational track ("SBE")—are offered. Researchers should select the track that corresponds to the type of research typically conducted. The Biomedical track would be appropriate for medical, physiological, or pharmacological studies. The SBE track would be suitable for studies of sociological, psychological, anthropological, or educational phenomena including observational and survey research and population and/or epidemiological studies.

Each module takes approximately 15-20 minutes to complete. Therefore the training requirement will take 3½-4½ hours to complete. A passing score of 80% or better is required to complete the course. Participants are expected to go back and repeat the quizzes if a low score is received on any particular module. If a wrong answer is given, the correct answer is provided and participants can re-take the quiz.

Institutional Officials at facilities where HSR is conducted, and persons approving such studies at school, college, or departmental levels, are required to complete at least the first five modules listed above. An Institutional Official who is key personnel must complete the training requirements for Key Personnel.

Training is valid for three years. After taking a "Basic" course and prior to the expiration of the three-year period, participants must complete the appropriate CITI "Refresher" course as specified below.

5. Equivalent Training

Under certain circumstances, NYIT may permit the use of alternative training, such as the NIH OER on-line tutorial entitled "Protecting Human Research Participants"[5], for key personnel on human subject studies conducted under its auspices. These may include cases in which a collaborating organization or individual is not affiliated with NYIT; where an individual has access to a comprehensive training program equivalent to that offered by CITI; where the research is of no more than minimal risk; where the individual has limited literacy or lacks fluency in a language in which CITI training is available; or where other circumstances render completion of the CITI Program difficult. In such instances, the organization or individual should prepare a description of the alternative education program and submit it to the Office of Sponsored Programs and Research. Based on the justification submitted by the investigator in the corresponding IRB application, the applicable IRB shall determine whether the alternate training should be approved for specified individuals and document the decision in the protocol file and/or the IRB minutes.

6. Continuing Education

Continuing education is required of all Key Personnel, IRB administrative staff and IRB members, and Institutional Officials. An appropriate CITI "Refresher" course must be completed every three years. Refresher courses (Biomed Refresher 1, 2, or 3; SBE Refresher 1 or 2) are taken in sequential order

within each track. A passing score of 80% or better is required to complete a Refresher course. Participants are expected to repeat the quizzes if a low score is received on any particular module.

Depending on the nature of the research conducted and the level of involvement of the individual, additional specialized training may be appropriate. The CITI "Good Clinical Practices" course is recommended for all persons who conduct or review clinical research. Facilities and individuals are encouraged to supplement CITI training with participation in local and external training programs.

7. Access to the CITI Program

NYIT faculty, staff, and students wishing to obtain access to the Collaborative Institutional Training Initiative (CITI) Program of computer-based instruction should contact NYIT's Office of Sponsored Programs and Research (Tel: 516-686-7488; E-mail: grants@nyit.edu) for assistance. The Program is housed at the University of Miami. CITI is in use by hundreds of institutions and organizations, including leading academic medical centers, and it was designed, and is updated and maintained, by nationally-recognized IRB professionals. The Program consists of a series of topic-specific modules, each followed by a short quiz. CITI training may be completed at one's own pace using work or home computers. Training need not be completed in one session, but quizzes should be taken immediately after completing each module. Although a passing score of 80% is required, one may retake any of the quizzes to improve.

References

[1]45 CFR 46, subpart A.
[2]32 CFR 219.
[3]NOT-OD-01-061.
[4]45 CFR 46.101(b).
[5]http://phrp.nihtraining.com/.
[6]45 CFR 46.107(a).
[7]21 CFR 56.107(a).
[8]https://www.citiprogram.org/.