

## 7.1. Frequently Asked Questions for Training in Human Subject Protection

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

[NYIT policy](#) requires training in the protection of human subjects for all researchers, key personnel, Institutional Review Board members, IRB staff and institutional officials involved in human subject research. The required training is a computer-based program known as the Collaborative Institutional Training Initiative (CITI). CITI is a widely used and well-respected web-based training program designed and maintained by nationally known IRB professionals. In 2016 CITI joined the Biomedical Research Alliance of New York (BRANY) to better address the educational needs of investigators, staff, and students in the global research community. It is in use at hundreds of institutions and organizations, including leading academic medical centers. The CITI Program consists of topic-specific modules, each one followed by a short quiz. CITI's program content now includes nearly two dozen subject areas. Researchers select the track that corresponds to the type of research typically conducted, one emphasizing biomedical research and the other, social, behavioral, and educational research. The educational materials comprising each module may either be read on-screen or printed out. The training requirement may be completed at one's own pace using office or home computers.

### 1. What is CITI?

The Collaborative Institutional Training Initiative, or CITI, is an educational program for the protection of human subjects in research. It was developed by IRB professionals and is focused on bioethics and human subject research. There are two core courses, one in biomedical research and one in social, behavioral, and educational research. The courses consist of modules, each one followed by a short quiz.

### 2. Who must take the CITI Training Program?

All researchers and key personnel who interact with human subjects or who work with identifiable human subject data must take the training. IRB members, IRB administrative staff, and other institutional officials must also complete specified training. An institutional official who is also key personnel must complete the requirements for key personnel. For a list of the requirements for each group, click [here](#).

### 3. Is there a fee?

NYIT pays an annual fee for all NYIT users. Individual users are not assessed a fee for CITI training.

### 4. How do I access the on-line CITI training modules?

For access to the NYIT training portal, visit the [CITI website](#). For a list of required modules, click [here](#).

### 5. Which CITI training modules should I take?

Researchers should select the Basic track that corresponds to the type of research typically conducted: **Biomedical Research**, for medical, physiological, or pharmacological studies; or **Social-Behavioral- Educational Research**, for studies of sociological, psychological, anthropological, or educational phenomena including observational and survey research, and population and/or epidemiological studies.

Researchers taking a refresher course should select **Refresher** modules that reflect their selections for the Basic course(s). The Biomedical Research track includes three corresponding sets of refresher modules. The Social-Behavioral-Educational Research track includes two corresponding sets of refresher modules.

### 6. How does CITI work?

When you log in, you are taken to a "Learner's Menu" where you may select either the Basic or Refresher Course. From there, you will be taken to the Grade Book where you may begin the next required module. The course software will keep track of your progress. When you have finished the quiz for a module, the software will provide a

link to the next module or the opportunity to view the Grade Book. You are also allowed to go back and re-take a quiz if a response is incorrect. The software displays the correct answer.

Modules may be completed in one session or in multiple sessions. The required modules must be completed in the order in which they are listed. Optional modules may be completed in any order.

After you have completed all of the modules for your learner group, CITI will provide you with a certificate of completion for a score of 80% or better, and notification will be sent to OSPAR at NYIT.

#### **7. How long will it take me to complete the training?**

Each Basic module takes approximately 10-30 minutes to complete. The required modules of the Basic course take a total of 3½-4½ hours to complete. Refresher courses take a total of 1½-2 hours to complete.

Modules are designed to be taken sequentially. You do not have to complete the training in a single session. The CITI program allows you to log off at any time and it will keep a record of your training.

#### **8. How will the IRB know if my training is complete?**

OSPAR has access to the CITI course completion report. Additionally, your application to the IRB should contain certificates of completion for all study personnel, which the IRB Administrator will check.

#### **9. How do the changes to the Common Rule affect my training?**

All learners who complete the course after January 21, 2019 have the new revisions to the common rule automatically updated in the modules. Anyone who was certified before January 21, 2019 can take the *New Revisions to the Common Rule Course* if they have an active protocol.

#### **10. Will NYIT accept certificates of training from other institutions?**

Except as specified in the [NYIT policy](#) under **Equivalent Training** all human subject researchers at NYIT must complete the CITI course. Those who were grandfathered in with NIH or other training must now complete CITI training. Investigators of full-board and expedited protocols will be required to recertify at the time of renewal. Faculty members affiliated with other institutions can affiliate with NYIT, and modules already completed at the previous institution will pre-populate and be accessible to put toward NYIT's training.

#### **11. When do I have to renew my training?**

Continuing education, consisting of a 1½-2-hour CITI Refresher course, is required every three years.

#### **12. What if I forget my CITI username or password?**

If you have forgotten your CITI username or password, go to the CITI website and follow the prompts for 'Forgot Username or Password'. The system will send your username and password to your e-mail address.

#### **13. What if I have further questions?**

Please contact: Eileen Gazzola, Sponsored Programs and Research; New York Institute of Technology, Tel:516-686-7488; E-mail: [egazzola@nyit.edu](mailto:egazzola@nyit.edu)

## FAOs 2 & 4:

### **CITI Program: Learner Groups and Module Requirements**

#### **New Courses Added- Revisions to the Common Rule**

(This course provides a detailed review of the regulatory changes to 45 CFR46, Subpart A, “Federal Policy for the Protection of Human Subjects” – aka the Common Rule and is mandatory for all investigators who currently have an active protocol).

#### Biomedical Researchers and Key Personnel:

*Belmont Report and CITI Course Introduction* - Required

*History and Ethics of Human Subjects Research* - Required

*Basic Institutional Review Board (IRB) Regulations and Review Process* - Required

*Informed Consent* - Required

*Conflicts of Interest in Research Involving Human Subjects* - Required

At least nine (9) additional Biomedical modules of your choice

#### Social-Behavioral-Educational (SBE) Researchers and Key Personnel:

*Belmont Report and CITI Course Introduction* - Required

*History and Ethical Principles* - Required

*The Regulations* - Required

*Informed Consent* - Required

*Conflicts of Interest in Research Involving Human Subjects* - Required

At least nine (9) additional SBE modules of your choice

#### Biomedical and Health Sciences Research IRB Members and IRB Staff:

*Belmont Report and CITI Course Introduction* - Required

*History and Ethics of Human Subjects Research* - Required

*Basic Institutional Review Board (IRB) Regulations and Review Process* - Required

*Informed Consent* – Required

*Conflicts of Interest in Research Involving Human Subjects* - Required

*IRB Member Module* - Required<sup>1</sup>

Eight (8) other Biomedical modules of your choice

#### Education, Social Science, and Behavioral Research IRB Members and IRB Staff:

*Belmont Report and CITI Course Introduction* - Required

*History and Ethical Principles* – Required

*The Regulations* - Required

*Informed Consent* - Required

*Conflicts of Interest in Research Involving Human Subjects* - Required

*IRB Member Module* - Required<sup>1</sup>

Eight (8) other SBE modules of your choice

#### Institutional Officials:

*Belmont Report and CITI Course Introduction* - Required

*History and Ethics of Human Subjects Research* - Required

*Basic Institutional Review Board (IRB) Regulations and Review Process* - Required

*Informed Consent* - Required

*Conflicts of Interest in Research Involving Human Subjects* - Required

<sup>1</sup>For IRB Chairs and Co-Chairs, the standalone *IRB Chair* course (3 modules) is also required.