

Section 7:

Required Human Subjects Training

All DF/HCC investigators and research personnel who participate in the design, conduct, or reporting of human subject research must complete a course in human subject protections. Members of the IRB and SRC must also complete training. Furthermore, anyone listed as “key personnel” on an NIH grant needs to complete a human research education program.

DF/HCC has selected the CITI (Collaborative Institutional Training Initiative) educational program to satisfy this requirement. Other forms of human subject protection training are accepted on a case-by-case basis. Initial and continuing education (every 3 years) in human subject protections are required for participation in DF/HCC research.

It is the Overall Principal Investigator’s responsibility to make sure the human subject training requirements are met for all individuals listed on the protocol. Lack of training may delay the approval of research.

7.1 The CITI Program

The CITI program consists of case-based learning of ethical concepts and regulations in a web-based learning environment. Experts in bioethics and the IRB community developed the program. The modules include reading material that can be viewed on screen or printed, followed by a brief online quiz. The format is “open-book.”

Completion of the CITI Basic program takes about 4 to 6 hours. Completion of the CITI Refresher takes approximately 1 hour. Users are not required to complete the exam in one sitting. Please note that registrants who begin a course but do not log in again for 30 days will be deleted from the system and will have to re-register.

You can register to take the CITI course at www.citiprogram.org.

7.2 Software Requirements

Users will need to have Internet Explorer 5.0 or higher (preferred) or Netscape Navigator 6.2 or higher, MS Word or other word-processing software capable of viewing files in the RTF format, and Adobe Acrobat Reader software, Version 5.0.

7.3 Courses

The CITI program offers four courses. The courses are:

- Biomedical Course (Group 1)
- Social/Behavioral (Group 2)
- Biomedical Minimal Risk or Exempt Course (Group 3)
- Combined Social/Behavioral and Biomedical Course (Group 4)

The specific course required depends on the function of the registrant. Individuals who overlap two areas (e.g. therapeutic clinical and behavioral research) need to complete the Combined Social/Behavioral and Biomedical Course (Group 4) in order to do research in both areas or to review studies in both areas. From the DF/HCC perspective Study Coordinators and Research Nurses must complete the full Biomedical Course (Group 1), regardless of the nature of the research, as their roles in the research process are often expanded.

For questions regarding human subject protections training, please contact the CTEO at (617) 582-8480 or by email (cteo@dfci.harvard.edu).

7.4 Certification

The CTEO receives automatic electronic notification when a course is completed. This information is added to the DF/HCC training database. If you need official documentation of human subjects training for grant purposes, please contact the CTEO education coordinator at (617) 582-8480 or (cteo@dfci.harvard.edu).

7.5 DF/HCC Training List

Individuals who complete the required training receive a training certificate and are included on the DF/HCC Training List.

All DF/HCC investigators and research staff have access to the DF/HCC Training List. A link to the training list may be found on the CTEO section of the DF/HCC website.

7.6 Continuing Education

Since regulatory requirements change and research presents new ethical challenges, ongoing education is needed. Continuing education is required every three years. Individuals must complete the CITI Refresher course, or another approved training program, by their three-year anniversary. Subsequent re-certification is required within three years of the previous re-certification anniversary. As a courtesy, the CTEO sends reminder notices to individuals 60 and 30 days prior to the anniversary/expiration date.

It is the Overall Principal Investigator's responsibility to make sure the human subject training requirements are met by all individuals listed on the protocol. Lack of re-certification training by an individual listed on the protocol may result in the temporary suspension of research activities for that specific individual. Research staff will be re-instated once they complete the continuing education course and the overall PI or designee files the appropriate paperwork with OHRS.