

Tufts Medical Center and Tufts University Health Sciences (TUHS) CITI Institutional Instructions Health Sciences Campus (HSC) IRB Course

Investigators and research team members at Tufts Medical Center and TUHS who conduct research involving human subjects must complete a mandatory training program prior to beginning research and must undergo continuing education on an annual basis.

The 2008 continuing education must be completed before 31 December 2008.

The 2007 continuing education was to be completed before 31 December 2007; existing PI/new research team members must complete this before proceeding to the HSC Continuing Education 2008

Learner Groups (Choose Only One):

1. New HSC PI/New Research Team Members
2. HSC Continuing Education 2008
3. HSC Continuing Education 2007
4. New HSC IRB Committee Members
5. Current HSC IRB Committee Members

1. New HSC PI/New Research Team Members: All new research team members at Tufts Medical Center and TUHS are required to complete the following four (4) Basic Modules in the CITI program before beginning human subject research:

- *Privacy and Confidentiality* (SBR)
- *History and Ethical Principles* (Biomedical module)
- *IRB Regulations and Review Process* (Biomedical module)
- *Informed Consent* (Biomedical module)

and any one (1) additional module of their choice.

Education modules include:

1. Lectures sponsored by the IRB office.
2. Tufts Medical Center/TUHS or off-site lectures related to IRB/human subject protection topics.
3. Modules from the Collaborative CITI program

It is the responsibility of the person attending a lecture to confirm with the IRB that it will count toward continuing education. This should be done prior to attending the lecture. A certificate of completion or attendance is also required and is to be retained as noted below.

Individuals are to retain their certificate of completion. Principal Investigators are required to retain a copy of education certificates for all research team members: These documents are subject to audit.

2. HSC Continuing Education 2008 for Existing PI/ Research Team Members: Each year, all research team members must complete two (2) education modules as part of ongoing training. The requirements for the 2008 continuing education are to complete the CITI module, “Workers as Research Subjects – A Vulnerable Population,” **and** any one (1) additional module. Please see above for more information about the education modules.

3. HSC Continuing Education 2007 for Existing PI/Research Team Members:

Please note: The 2007 continuing education for Existing PI/ Research Team Members was to be completed before 31 December 2007. The requirements for the 2007 continuing education were to complete the CITI Basic Module, “Conflicts of Interest in Research Involving Human Subjects,” **and** any one (1) additional module. Please see above for more information about the education modules.

Individuals are to retain their certificate of completion. Principal Investigators are required to retain a copy of education certificates for all research team members: These documents are subject to audit.

IRB Members

IRB members at Tufts Medical Center and TUHS are required to complete mandatory training and orientation at the time of initial appointment to the IRB, and are to undergo continuing education each year.

4. New HSC IRB Committee Members: At the time of initial appointment, new IRB members are required to complete the following five (5) Basic Modules in the CITI program:

- *Privacy and Confidentiality (SBR)*
- *History and Ethical Principles (Biomedical module)*
- *IRB Regulations and Review Process (Biomedical module)*
- *Informed Consent (Biomedical module)*
- *The IRB Member Module – “What Every New IRB Member Needs to Know”*

and one (1) other module chosen by the IRB member.

Education modules include:

1. Lectures sponsored by the IRB office.
2. Tufts Medical Center/TUHS or off-site lectures related to IRB/human subject protection topics.
3. Modules from the CITI program

It is the responsibility of the member attending a lecture to confirm with the IRB that it will count toward continuing education. This should be done prior to attending the lecture.

It is also the responsibility of the IRB member completing the education module to send a copy of the certificate of completion to the IRB office and to retain a copy of the certificate for each module completed.

5. Current HSC IRB Committee Members: As continuing education for 2008, all current IRB members are required to complete the following modules in the CITI program:

- Genetic Research in Human Populations
- International Research (NOT the SBR module)*
- Hot Topics: Data and Safety Monitoring: New NIH and NCI Policies*

For the “Genetic Research in Human Populations” module, IRB members are to retain a copy of the certificate of completion for their files and are responsible for sending a copy of the certificate of completion to the IRB office (email is acceptable).

* The “International Research” and under Hot Topics “Data and Safety Monitoring: New NIH and NCI Policies” do not have self-tests; a certificate of completion will not be generated. Instead, each IRB member is to submit written confirmation to the IRB office (email is acceptable) that those modules were completed. Members must also retain a copy of all documents for their own files.

This requirement is to be completed before 31 December 2008.

To Start the Course:

- Enroll in a Learner Group appropriate for your role in human subjects research for the Health Sciences Campus (HSC)
- On the Learner’s Menu, click on the “**Grade Book**” link
- Complete the required modules and associated quizzes

You must select the “**Submit Exam**” button from the quiz to receive a score and save it onto the program. If you exit the quiz without doing so, you will have to take the quiz again because an incomplete status will remain in the Grade Book. You will not be able to advance to the next module until you have taken the quiz and saved it.

Once you complete the required modules and receive a passing grade, you have the option to take Optional modules.

Please note: There are modules that are required by CITI and are not listed here. Please complete those modules as part of the training.

To Complete the Course:

- The minimum passing score for the quizzes is **70%**. A running tally is compiled in the Grade Book. If you want to improve a score on a quiz, you may repeat any quiz in which you didn’t score 100% correct.
- Print or download a **Course Completion Report** as evidence that you have met your institutional requirements. **Please note:** if you did not meet the passing grade, you will not be able to print a completion report.

Questions:

- Problems and questions regarding your requirements should be addressed to the IRB main office at (617) 636-7512 or via email at IRBoffice@tuftsmedicalcenter.org.
- Technical issues should be addressed to citisupport@med.miami.edu or (305) 243-7970.