

TO: Tufts Medical Center and Tufts University Research Community

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SUBJECT: Updated Tufts Medical Center / Tufts University Human Subject Research Education Requirements

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Investigators and research team members (“researchers”) at Tufts Medical Center and Tufts University who conduct research involving human subjects must complete a mandatory training program prior to beginning research and must undergo continuing education on a regular basis.

In an effort to bring our research education practices into alignment across Tufts Medical Center and all Tufts University campuses, and to simplify compliance with new and continuing education requirements, we are pleased to announce the following changes to the Human Subjects Research Education Requirements:

- Once researchers complete the revised education requirements, CITI training will be valid for 4 years. Annual recertification will no longer be required.
- The CITI education requirements are now more comprehensive and allow researchers to choose education based on the type of research they conduct.
- All researchers engaged in human subjects research will need to complete the revised education requirements by January 1, 2015. Credit for previously completed CITI courses can be counted toward the new training requirement.

Further details about the updated requirements:

CITI will notify researchers when their education certificate is near expiration. Once their education has expired, researchers will complete CITI’s “Refresher Course,” which will be valid for another 4 years. This process repeats every 4 years, cycling between the Basic Education Course and Refresher Courses.

Researchers will no longer register for CITI learner groups according to campus (e.g. *Tufts HSC PI/Research Team Members: Health Sciences Campus only* or *New SBER PI/New Research Team Members, including Students: Medford/Somerville Campus Only*). Instead, researchers will register for a learner group according to the type of research they conduct: “Biomedical Researchers” or “Social/Behavioral/Educational (SBE) Researchers.”

This change will allow users to complete education that is relevant to their research activities, regardless of their campus location. Researchers who conduct both Biomedical and SBE research will register with the learner group most closely related to the majority of their research activities.

All researchers will complete the CITI “Basic Education Course” for their user group. For Biomedical researchers, this consists of 16 modules. For SBE researchers, this consists of 13 modules. To ensure that researchers receive credit for meeting their past human subject research education requirements, all previously completed CITI modules can be counted toward their initial Biomedical/SBE Basic Education Course requirements.

The list of modules for each Basic Education Course is available at the end of this announcement. Once researchers have completed all the modules in their course, they will have access to a completion certificate, and their education will be valid for 4 years from the date of completion.

**All researchers engaged in human subject research activities at Tufts Medical Center or Tufts University must complete either the Biomedical or SBE Basic Education Course by January 1, 2015.** Compliance with educational requirements will be audited by staff within the Boston and Medford IRB offices.

Acceptance of equivalent human subject research education for community partners or collaborating researchers at other institutions will be made on a case-by-case basis.

We appreciate your work to ensure compliance with federal regulations and institutional policies, as well as your commitment to the appropriate and ethical conduct of human subject research.

Detailed instructions regarding the transition to the new education requirements can be found on both the [Tufts Health Sciences IRB](#) and [Tufts SBER IRB](#) websites.

#### **Basic Biomedical (Biomed) Course Modules**

- Belmont Report and CITI Course Introduction
- History and Ethics of Human Subjects Research
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Social and Behavioral Research (SBR) for Biomedical Researchers
- Records-Based Research
- Genetic Research in Human Populations
- Research with Protected Populations – Vulnerable Subjects: An Overview
- Vulnerable Subjects – Research Involving Prisoners
- Vulnerable Subjects – Research Involving Children
- Vulnerable Subjects – Research Involving Pregnant Women, Human Fetuses, and Neonates
- Avoiding Group Harms – U.S. Research Perspectives
- Avoiding Group Harms – International Research Perspectives
- FDA-Regulated Research
- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
- Research and HIPAA Privacy Protections

#### **Basic Social-Behavioral-Educational (SBE) Course Modules**

- Belmont Report and CITI Course Introduction
- History and Ethical Principles – SBE
- Defining Research with Human Subjects – SBE
- The Regulations – SBE
- Assessing Risk – SBE
- Informed Consent – SBE
- Privacy and Confidentiality – SBE
- Research with Prisoners – SBE
- Research with Children – SBE
- Research in Public Elementary and Secondary Schools – SBE
- International Research – SBE
- Internet Research – SBE
- Unanticipated Problems and Reporting Requirements in Social and Behavioral Research