



Fall 2014

Tufts Medical Center / Tufts University Health Sciences IRB News

### Welcome to the Fall 2014 edition of Tufts Health Sciences IRB News

Updates and useful information from the IRB office for Investigators, Coordinators, and other members of your research team

#### **New** [International Research Guidance & Checklist](#)

When conducting international research, Tufts researchers must ensure that studies not only meet the ethical and regulatory requirements for conducting research at Tufts, but also respect the cultural norms and research regulations in the host country.

To help researchers comply with these standards, and increase transparency about the IRB's expectations for international research, the Tufts Health Sciences IRB has developed an International Research Guidance and Checklist:

• [Guidance: International Research with Human Subjects](#)

• [Checklist: International Research with Human Subjects](#)

These documents are tools for researchers to use when developing their protocols and IRB applications. IRB staff and IRB reviewers will also use these documents to guide their reviews of international research.

#### **Reminder** [Human Subjects Protection Education Requirements](#)

Human Subjects Protection Education Requirements via the CITI Program have been updated for all Tufts MC and TUHS researchers (click [here](#) for the September 4<sup>th</sup> announcement).

**Plan Ahead!** The revised CITI requirements must be completed **before January 1, 2015**.

PIs and all listed study staff must complete the education requirements before new studies, continuing reviews, or amendments can be approved.

CITI certification will be **valid for 4 years**.

Register for or Update your Learner Group in CITI to 1 of these 2 options:  
Biomedical Researchers (16 modules)  
Social-Behavioral-Educational Researchers (13 modules)

For additional information and step-by-step instructions for registering with CITI and completing the updated requirements, please visit the [Research Education](#) page of the Tufts Health Sciences IRB website.

### Tip Avoid Over-Enrollment

Every subject who signs an informed consent form (ICF) is considered enrolled in the study and counts towards your total enrollment whether or not the subject completes the study. Dropouts and withdrawals also count towards total enrollment.

To avoid over-enrollment:

Consider incomplete participation, subject dropout, and withdrawals when estimating the total enrollment goal for your study.

Put systems in place to track enrollment numbers throughout the course of the study.

If you notice that the study is nearing the total enrollment goal, submit an amendment to the IRB for an increase in the total enrollment goal.

Submit amendments to request an increase in enrollment goals **before** your initial enrollment goal has been reached.

**New** All IRB Forms have been updated to reflect current CITI requirements

The IRB will no longer accept outdated IRB submission forms! Always check the IRB website for the latest version of [IRB Forms](#).

### Tip Avoid Enrolling Ineligible Participants

If your study has multiple eligibility criteria, create an eligibility checklist. Always ensure that the eligibility checklist is complete **before** enrolling a subject in the study.

Eligibility checklists do not require approval by the IRB.

### Tip When to Report Protocol Deviations

Report protocol deviations to the IRB as soon as they occur or as soon as they are discovered in your study. Do not wait until continuing review to submit past deviations to the IRB.

## Contact us!

**Bookmark** our [IRB Staff](#) page for guidance to contact the staff member who can best provide assistance with specific questions.

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Tufts MC / TUHS IRB website: <http://viceprovost.tufts.edu/HSCIRB/irb-regulations/>

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Send us their name and e-mail address so we can add them to our IRB distribution list: [irboffice@tuftsmedicalcenter.org](mailto:irboffice@tuftsmedicalcenter.org)

Contact our office at **617-636-7512** Monday to Friday, 8:30 am to 5 pm or stop by during IRB Drop-In Hours Tuesday 2 to 4 pm. We are located in the Tupper Building at 15 Kneeland Street, 1st floor.