Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Summer 2015 Tufts Medical Center / Tufts University Health Sciences IRB News

Welcome to the Summer 2015 edition of Tufts MC / TUHS IRB News

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

Updated Form 2 (Drugs) & Form 3 (Devices)

The IRB has revised the Form 2 (Drugs) and Form 3 (Devices). The new forms can be found on the forms page of the IRB website. Please start using them immediately. As of 01 September 2015, we will not be accepting older versions of the forms.

Please call the IRB office staff at ext. 6-7512 if you have any questions while you are completing these new forms.

Updated Conflict of Interest (COI) Form

The updated COI Form is now available for use on the IRB Website. See "Ask the IRB" below for information about the COI Form requirements.

New Principal Investigator (PI) Eligibility Policy *and* Jurisdiction of the Tufts IRB Policy

The IRB has posted new policies to clarify who is eligible to serve as a Principal Investigator (PI) at Tufts and the scope of research that is reviewed by the Tufts IRBs.

These policies apply to both the Tufts Health Sciences IRB and the Tufts Social, Behavioral, & Educational Research (SBER) IRB on the Tufts Medford campus. The jurisdiction policy clarifies who may submit to the Tufts IRBs, particularly when investigators conduct research on behalf of organizations other than Tufts.

Please refer to our website to read the PI Eligibility Policy and the Jurisdiction of the Tufts IRB Policy.

New Greenphire/ClinCard IRB Website Page

The IRB has created a new website page with information about using Greenphire ClinCard to pay and/or reimburse subjects.

This page includes IRB approved handouts for subjects for general use. (You no longer need to submit these posted ClinCard subject handouts to the IRB for approval – just use the posted IRB approved versions.)

Tip Avoid Over-Enrollment

When planning out your study design, make sure you request the appropriate number of subjects to enroll (in fact, when in doubt, request approval to enroll the highest number in your anticipated range).

Enrolling beyond the IRB approved number of subjects is considered non-compliance.

This page also includes tips about revising your study to include ClinCard as the payment method as well as template ClinCard language for your informed consent form (ICF).	If, during the course of your study, you believe you will reach the approved number of subjects, submit an amendment to the IRB requesting an increase in enrollment (and make sure to revise all applicable study documents).
New Investigator Post-Approval Responsibilities The IRB has created a list of Post-Approval Responsibilities for all Investigators. This list is meant to serve as guidance when conducting human subjects research and a copy will be provided with each Initial and Continuing Review approval letter.	**Tip** Reducing IRB Turnaround Time: • Make sure your submission is complete and easy to follow. • Submit a cover letter that describes or summarizes your submission. • Track your document revisions so it is easy for the IRB to see what has been changed.
New "Ask the IRB" Question: I completed a Conflict of Interest (COI) Form for Research Administration. Do I need to submit a separate COI form for my study? Answer: Yes. Your COI form on file with Research Administration is different from the study-specific COI form for the IRB. For *each study* the PI is required to submit a COI form to the IRB and keep completed COI forms for the entire research team in the study files. The PI will submit his or her own COI form along with any COI forms for research team members where a "Yes" response is checked.	**Tip** Avoid Using Subject Identifiers when Corresponding with the IRB When submitting documents to the IRB, including serious adverse event reports, make sure to redact subject identifiers by doing the following: *Make a copy of the document, take a black marker and black out the subject's name and any other subject identifiers, then photocopy this redacted (blacked out) copy so the identifiers cannot be read through the black marker.* When corresponding by e-mail, re-read your e-mail to double check that the e-mail and any e-mails in the chain do not include subject identifiers.
New German Short Form A German Short Form has been approved by the IRB and added to the IRB Website for the enrollment of German speaking subjects. Remember to print and use the Short Form Quick Reference Checklist when you are enrolling non-English speakers.	**Just for Fun!** Victor Frankenstein's Institutional Review Board Proposal, 1790 *Harry Potter* and the measures of personality: Extraverted Gryffindors, agreeable Hufflepuffs, clever Ravenclaws, and manipulative Slytherins

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/

Do you know someone who would like to receive IRB News?
Send us their name and e-mail address so we can add them to our IRB distribution list: 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**.

Tufts University

Tufts Medical Center