Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Winter 2017 Tufts Health Sciences IRB News

Welcome to the Winter 2017 edition of Tufts MC / TUHS IRB News

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

Attention New Coordinators & PIs:

If you are new to the IRB process and would like some guidance and to meet the IRB staff, please schedule an orientation meeting with the IRB office to familiarize yourself with our website, go over the types of IRB review, discuss meeting deadlines, IRB tips, and more! Or you could schedule an appointment to review the study submission you are working on. We are always happy to meet with you & answer your questions!

As a reminder, we have office hours every Tuesday from 2-4pm, but you don't need to wait until Tuesday - Contact us to schedule an appointment for any time that is convenient for you! Call IRB ext. 6-7512.

Training Video Simulations

The Office of Research Integrity (ORI) has developed two interactive video simulations, which are fun and informative ways to train individuals and groups about promoting research integrity, protecting human research participants, and avoiding questionable clinical research/laboratory practices. Please take the time to check out these interactive videos, which allow you to assume the role of one of four characters and make choices that will determine the outcome of the story:

The Research Clinic

The Lab

These video simulations are not required and do not replace CITI education requirements.

Updated Form 5 (Continuing Review form)

The Form 5 was revised to include an option to check "None" for a study's funding source, clarify the criteria for exclusion of non-English speaking subjects, and options for Principal Investigators to confirm study documentation is maintained by the research team.

New Investigator's Brochure (Cover Letter)

The IRB Office has created a template cover letter that investigators may use to submit an updated Investigator's Brochure. We also updated the Amendment (Cover Letter) to include information from the Investigator's Brochure (Cover Letter) so researchers have the option of using either template cover letter to submit an updated Investigator's Brochure for their study.

Updated Form 10 (IAA/IIA Request form)

The Form 10 is used to request Tufts to consider implementing an IRB Authorization Agreement (IAA) where the Tufts Health Sciences IRB will either assume or cede oversight to another IRB. This form has been revised to request documentation from the designated site at the institutional level confirming they are amenable to the proposed agreement. This will ensure that the designated site has already considered and is amenable to the proposed agreement.

Updated Preparatory to Research Form

We updated this form to improve the layout and provide definitions to help you complete the form. As a reminder, this form is required when you plan to access protected health information (PHI) for purposes *preparatory* to research, such as preparing a research protocol, assessing feasibility of a research study, developing a hypothesis, or identifying prospective participants who would meet eligibility criteria for a proposed project.

New ¡Opción española para módulos CITI!

The CITI Program website has added Spanish language options for both the *Biomedical Researchers* learner group and the *Social & Behavioral Research* learner group - the two learner group options that the Tufts Health Sciences IRB accepts for mandatory human subject research education.

In order to view the CITI modules in Spanish, choose “Add a Course” and select the Spanish option.

Updated Request for Exemption Form

The Request for Exemption Form has been updated for submission of research eligible for Exempt review.

Please note that when you are completing the request for exemption form, the form serves as your protocol and, in general, a separate protocol should not be submitted.

Please contact the IRB Office with any questions about whether your research might be eligible for Exempt review.

New *Translators Wanted!* for Short Forms

Do you know someone who speaks & writes in Japanese, Tagalog, or Slovenian? If so, we are looking to add these short forms to our website!

If you know someone who would be willing to forward or back translate the short form, let us know or forward them our office contact information.

In addition, if you (or someone you know) would be willing to translate our short form into any other language that we do not currently have posted, please let us know! See the list of the current short form languages available on our website. Once we have the short form forward and back translated, the IRB will approve it to post for general use.

Ask the IRB…

Question: After my study has gone to a Scientific Review Committee (SRC) meeting and I have responded to SRC comments, how long until my study is approved by the SRC to proceed to IRB review?

Answer: It depends. Sometimes the response can be reviewed and approved within a few days by the SRC over email, while other times the response may need to be reviewed and approved at a convened SRC meeting.

Question: My study went through the SRC process, I responded to SRC comments, and my study was approved by the SRC. Now it has proceeded to the IRB and there are additional comments. Why were these

comments not brought up during the SRC review?

Answer: The SRC review focuses on the scientific and statistical aspects of the study, while the IRB review focuses on the ethical and regulatory aspects of the study - two completely different types of review. The SRC and IRB reviews are not done concurrently for this reason.

New Tip sheet: Responding to IRB comments

The IRB Office has created a new tip sheet with some helpful tips for responding to IRB comments. Be sure to follow these tips when responding to IRB comments & stipulations to ensure your study is reviewed and approved as quickly as possible!

Tip Version Control

Whether submitting materials for a continuing review or amendment, please be sure to submit the most recent versions of all documents. If revising a document, submit both a tracked and clean/updated copy of the most recent IRB approved version. If a document is not being revised, submit copies of the most recent version. Proper version control can allow for a more efficient review period and eliminate extra work for your research team!

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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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

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