Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Summer 2018 Tufts Medical Center / Tufts University Health Sciences IRB News

Welcome to the Summer 2018 edition of Tufts MC / TUHS IRB News

Providing updates and useful information from the IRB office for Investigators, Coordinators, and other members of your Research Team

Important Update: Revised Common Rule

The revised Common Rule will go into effect on **January 21, 2019**.

In the meantime, the IRB has implemented certain burden-reducing provisions (effective **July 19, 2018**), one of which is the elimination of continuing review for certain minimal risk research projects. The IRB Office now conducts a brief **administrative annual review** at the time of continuing review for non-FDA, minimal risk research. The revised Form 5 leads you through the process of determining whether continuing review is needed for your study, or if you will only need to submit a partially completed Form 5 (with no other documents) for administrative annual review.

Review the Common Rule Changes page on the IRB website for additional information and consult our PowerPoint Presentation for guidance on completing the Form 5.

Please contact the IRB Office with any questions.

New: SMART IRB Web Page

Learn about the SMART IRB Reliance Agreement on our new web page! SMART IRB is a Reliance Agreement Platform that streamlines IRB review and oversight of multi-site studies. SMART IRB can be used for a range of research from large multi-site clinical trials to two-site collaborations. Our new web page will help you navigate the SMART IRB process. Follow the step-by-step instructions for submitting a request to the Tufts Health Sciences IRB to obtain institutional approval for a proposal to use the SMART IRB Reliance Agreement.

SMART IRB Participating Institution

Update: Short Form Quick Reference Checklist

Print and complete the updated Short Form Quick Reference Checklist when enrolling non-English speakers using Tufts Health

Tip: PI Eligibility Policy & Change in PI

The Tufts Health Sciences IRB does not recognize *Co*-Principal Investigators, or "Co-PIs". Only one Principal Investigator (PI) can be listed as the responsible PI. Do not list any

Sciences IRB approved short forms.

The Short Form Quick Reference Checklist has been updated to more clearly describe the options for who can serve as an interpreter/translator during the short form consent process. It also specifies that the English ICF must be signed by both the witness and the investigator obtaining consent.

research team members as "Co-PI" on IRB Forms or study materials. Other research team members may be named Co-Investigator (Co-I) or Sub-Investigator (Sub-I) instead.

If you would like to change the PI on an existing study, first verify that the newly proposed PI is eligible per the PI Eligibility Policy. Then submit an Amendment (Cover Letter) signed by the former PI and the proposed new PI, along with the proposed PI's Conflict of Interest (COI) Form, and tracked and clean versions of any study documents that require revisions as a result of the change.

Tip: Header and Footer in Consent Forms

Make sure the header and footer are the same on every page of the Informed Consent Form (ICF). This will ensure that when you update the version date or study title, this change will be made on every page of the ICF.
Sometimes the header or footer is not automatically the same for each page because the link is broken between different pages.
To fix this, click on the header or footer on the page that is not automatically updating. This will automatically open the "Design" function in the Toolbar. Then under the "Navigation" section, click on "Link to Previous" on each page of the ICF. This should ensure that the footers and headers are the same throughout.

New: Departing Coordinator Checklist

The IRB posted a new checklist for Study Coordinators who are leaving their position at Tufts, who work on active studies with the Tufts Health Sciences IRB.

This Departing Coordinator Checklist will help ensure the smooth transfer of studies to the new Coordinator before you leave your position.

We encourage you to modify this checklist for use in your department or group.

Ask the IRB…

Question: Do I need to submit a continuing review if I plan to close out the study?

Answer: No, a continuing review is only required if you plan to keep the study active. (However, sometimes at continuing review it is discovered that the study is eligible for close out with the IRB.) The easiest way to close your study with the IRB is to complete and submit a Study Close Out Letter to the IRB.

Ask the IRB…

Question: Does the PI need to be copied on emails from research team members to the IRB?

Answer: Yes! The PI should always be copied on emails about their study. It is the PI's responsibility to oversee all research-related correspondence and have a full understanding of what is happening with their study.

Ask the IRB…

Question: Should I list research team members from non-Tufts, collaborating institutions on the IRB Form 1 for new studies?

Answer: Investigators from other institutions should not be listed on the Form 1. It if has been confirmed that collaborating investigators are engaged in human subject research and a reliance agreement is required, their names should be listed on the Form 10 (reliance agreement form).

If another IRB is overseeing the activity of the collaborating investigators, they do not need to be listed on any form submitted to the Tufts Health Sciences IRB.

The protocol should accurately specify the role and research activities for all collaborators, regardless of whether they are engaged in research or not.

Ask the IRB…

Question: Should I list the names of research team members in the protocol document?

Answer: We recommend avoiding references to specific names in the protocol document. Instead, refer to the research team members by their role (i.e., Principal Investigator, Co-Investigator, Coordinator, etc.). Specifying names in the protocol will increase the number of future protocol modifications / amendments needed, since you will need to revise your protocol document every time you have a change in your research team.

Ask the IRB…

Question: I plan to analyze data collected for a closed study. The original study accessed subject identifiers, but for the new project, data will be de-identified. Would this project be considered human subjects research?

Answer: This project **would** be considered human subjects research (and would be an exempt study) ***if*** the PI for the new project had access to subject identifiers while working on the original study (i.e., if the PI was part of the research team for the original study that accessed identifiable data).

The study **would not** be considered human subjects research ***if*** the investigator never had access to identifiable information and will independently analyze data for his/her own research (without sharing analysis with the institution that provided the data).

Attention! New Funding Opportunity: CTRC Voucher Program

Do you need modest financial support to complete a clinical study or generate preliminary data to support a proposal for a larger, more definitive study? Tufts CTSI is pleased to announce a new Clinical and Translational Research Center (CTRC) Voucher Program that offers up to $5,000 per selected study to be used to offset the costs associated with use of CTRC space, sample processing services, and personnel for research study participant evaluations.

The application period for the initial competition of the CTRC Voucher Program is now open. Review the application and eligibility requirements and submit your proposal by **Friday, August 31, 2018**.

If you have any questions, please email voucher@tuftsctsi.org.

Tip: Adding new Research Team Members

Research team members are those responsible for the design, conduct, or reporting of the research, such as the PI, Co-Is, research nurses, coordinators, project managers, etc.

The IRB needs to be informed of changes to the research team. The IRB must acknowledge the addition of a new research team member *before* that new research team member starts working on a study. In order to add a new research team member, submit one of the following to the IRB:

- Change in Research Team Cover Letter – can be utilized when study documents (i.e. protocol, ICF, recruitment materials, etc.) do **not** need to be updated as a result of the change in research team.
- Amendment Cover Letter – must be utilized when study documents (i.e. protocol, ICF, recruitment materials, etc.) **do** need to be updated as a result of the change in research team.

Once a change in research team request is reviewed and approved by the IRB, the PI will receive an acknowledgement email or an IRB approval letter.

Tip: Continuing Review / Administrative Annual Reviews

- If your study is eligible for Administrative Annual Review, supplemental documents that were previously required at continuing review are no longer required. However, please be reminded that you are still required to submit Amendments and Reportable New Information (RNI)to the IRB.

- If your study is eligible for **Administrative Annual Review**, and you are still using informed consent forms (ICFs) with an expiration date, submit Microsoft Word document versions of the ICFs. We will provide you with a validation stamp on the ICFs with the expiration date removed.

- If your study is not eligible for Administrative Annual Review and a **Continuing Review** is required, you do not need to sign the Investigator Acknowledgment twice. The Form 5 Section F *Investigator Acknowledgment* signature is intended for those who are eligible for Administrative Annual Review, and are not completing the remainder of Form 5. If you are completing the Form 5 in its entirety, the PI should sign the Section O *Investigator Acknowledgment* at the end of the form.

Attention! New Coordinators & PIs

New PIs and Coordinators should be added to the IRB email distribution list to receive IRB newsletters and other important IRB information.

Please email IRBOffice@tuftsmedicalcenter.org to request for someone to be added.

If you know someone who is new to the IRB

Attention! Research on the move!

The IRB Office space is undergoing renovations!

We will have a new street entrance at 15 Kneeland Street - planned in early September - around Labor Day!

We will provide you with additional details as the date approaches!

process, please let them know they can schedule an orientation meeting with the IRB office staff to review our website, types of IRB review, discuss meeting deadlines, IRB tips, and more!

You can also schedule an appointment to review a study submission you are working on. We are always happy to meet with you in person to answer questions!

Please Note: 310 Forms

The IRB Office will no longer provide the HHS Optional Form 310 to Investigators along with IRB approval letters as documentation of IRB approval or an IRB exemption determination.

Instead, Investigators will submit a copy of the IRB approval letter to the funding agency, if needed.

IRB Office Staff Updates:

Ali Rosin has been promoted to the Assistant IRB Coordinator and works on new minimal risk submissions. *Congratulations, Ali!*

Contact us!

Bookmark our IRB Staff page for guidance to contact the staff member who can best provide assistance with specific questions.

Follow us on Twitter

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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