Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Welcome to the Spring 2019 Edition of Tufts Health Sciences IRB News

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

IMPORTANT UPDATES — The latest in the IRB Office

Update: Studies Involving Review or Analysis of HIV Data

If you are putting together a new study involving the review or analysis of HIV data, please note the following:

- If identifiable HIV status, testing, or treatment information is being obtained for your study (including recording, receiving or disclosing identifiable HIV testing results among researchers and/or institutions), *written consent is required* before obtaining this information.

Be sure to clearly state how data related to HIV status, treatment, etc. will be collected in the Protocol / Site-Specific Appendix (SSA), and informed consent form (as applicable).

If information is being shared among researchers and/or institutions, an agreement may be required. Contact Grants & Contracts for Tufts MC and MTA for Tufts University for information about developing an agreement.

Please note that any study that involves HIV testing continues to require consent before conducting this testing.

For more information, please refer to Massachusetts State Law Section 70F.

IRB TIPS — Tips from office staff on all things IRB

Tip: Protocol Clarification Letters

Study Sponsors sometimes provide a "Protocol Clarification Letter" or "Administrative Clarification" memo. These documents usually clarify something related to the protocol

Tip: Requesting an Agreement for Transferring Data and/or Specimens

An agreement may be required to allow a researcher to share data and/or specimen with a collaborator (a person or entity not associated

document that will be updated with the next protocol amendment.

When you receive something like this from the Sponsor, the PI (or PI and Study Coordinator) should review it and consider the following:

- Should we notify the research team (or anyone else) about this? If so, how? (e.g., a meeting)
- Is there anything we need to do to make sure we follow this new information?
- If it relates to something important, ask the Sponsor when the protocol will be revised to include this information.

Please include these details in the cover letter when you submit this to the IRB.

with the study or the researcher's institution).

❖ To submit a request for an **Agreement for Tufts Medical Center** complete the following applicable questionnaires:

- Data Use Agreement (DUA) Questionnaire
- Material Transfer Agreement (MTA) Questionnaire for Outgoing Materials
- Material Transfer Agreement (MTA) Questionnaire for Incoming Materials

❖ To submit a request for an **Agreement for Tufts University** please contact:

Material Transfer Agreements (MTAs):

- mta@tufts.edu
- Data Use, Collaboration, or Non-Disclosure Agreements:
  Emily Rezendes, Staff Counsel,
  Office of University Counsel
  emily.rezendes@tufts.edu

Tip: Emergency Use

The Emergency Use website page has been redesigned to include a streamlined way to request the IRB to review and acknowledge Emergency Use of an investigational product. The redesigned website page includes:

- *New* Emergency Use Form A brief form that guides you through all you need to answer and submit for your emergency use
- Template: Letter of Support from Physician not Involved in the Emergency Use. This is a sample letter for an uninvolved physician to affirm specific points related to the proposed emergency use

As a reminder, emergency uses only apply in the following circumstances:

Tip: What if I did not track changes in my document when I made revisions?

Don't worry! If you have a copy of the original document, you can still make a tracked changes version. Just use the "Compare" function in Microsoft Word as follows:

1. Go to "Review" and click "Compare"
2. In the drop down menus find your original document and then compare it to your new document.
3. Microsoft Word will then make a new document showing all the revisions you made in tracked changes.
4. Save this document as your new tracked changes version

- Patient is in a life-threatening or severely debilitating situation
- No standard treatment is available
- There is no time to obtain IRB approval

Tip: The Difference Between a Waiver of Documentation of Consent and a Waiver of Consent

A waiver of documentation of consent and a waiver/alteration of consent are not the same – be sure that you are requesting the correct type of waiver in the IRB submission form.

A waiver of documentation of consent removes the requirement to obtain the research participant's *signature* on the consent form (i.e., consent will be verbal or documented in other ways). An IRB may waive the requirement for the investigator to obtain signed consent form if <u>one of the following</u> is applicable for the study:

- The only record linking a participant to the research is the consent from in studies where the principal risk is a breach of confidentiality
- The research is minimal risk and only involves procedures for which consent is not normally sought
- Participants are members of distinct cultural group or community in which signing forms is considered unusual.

A waiver/alteration of consent is a full or partial waiver of the elements of informed consent. In order for an IRB to waive or alter consent <u>all of the following conditions</u> must be met:

- The research in its entirety involves no more than minimal risk to participants
- The waiver or alteration will not adversely affect the rights or welfare of participants.
- The research could not practically be carried out without the waiver or alteration.
- Wherever appropriate, participants will be provided with additional pertinent information after participation.

WHAT'S NEW IN THE IRB — The Latest in the IRB Office

New: Amendment Cover Letter

Minor revisions have been made to the Amendment Cover Letter to clarify the "Re-consent" section and to address the content enabling issues that were occurring for some users.

The IRB Office is Hiring!

IRB Administrator I - Responsible for processing continuing reviews, amendments and study close-outs

IRB Administrator I – Responsible for new minimal risk submissions

Use the updated version located here: Amendment Cover Letter	**IRB Administrator II** – Single IRB Specialist

Attention!

If you know someone who is new to the IRB process, please let them know they can schedule an orientation meeting with the IRB office staff. We will meet with them 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!

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

View Archived IRB Newsletters

Tufts Health Sciences IRB website: http://viceprovost.tufts.edu/HSCIRB/

Do you know someone who would like to receive IRB News? Click here to send a request to add Investigator/Research Team Member to the IRB Distribution List.

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