Welcome to the Summer 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

eIRB Update:
A New Electronic IRB System, being implemented over the last 9 months in conjunction with Tufts University, will go live at the end of September beginning with a pilot group of departments.
The system will streamline the application process, improve communication and create better transparency during the IRB review cycle.
In person, online, PDF and video training will be widely available.
Stay tuned for additional information!

IRB TIPS - Tips from office staff on all things IRB

Tip: Educational Opportunity!
Clinical Research Coordinator (CRC) Training on CITI

There are 2 CRC training courses available for Clinical Research Professionals on CITI. The CRC Foundations course delivers basic CRC training that includes the operational and regulatory essentials that CRCs need. It also provides a basis for learners who will later move on to the advanced course.

In the Advanced course, learners will gain a deeper understanding of the CRC’s role by exploring key operational, leadership, regulatory, and technical elements associated with daily work.

To add these courses, log in to CITI, choose “Add a Course”, and choose “Clinical Research Coordinator Training” Foundations or Advanced.

Tip: Is Consent Required for Exempt Studies?
A signature for consent is not required for Exempt studies. However, the institutions recommend obtaining consent in exempt studies whenever possible. Consent for exempt studies can be obtained through an information sheet (this can be via email or as a preamble to a survey or questionnaire).

If a paper survey or questionnaire is administered, participants should receive the consent information sheet separately, so they can keep this after completing the survey. If the survey is administered by email, the consent information sheet should be presented in the body of the email (or as a separate attachment) so the participants can refer to the email if they have questions.

When you draft an information sheet, include all required elements of consent. You can find the list of elements on the IRB website [see “Other Documents” “Consent Documentation”].
**Tip: Responsibilities of the PI Coordinating a Multi-Site Research Project for which Tufts Health Sciences IRB serves as the single IRB of Record**

Before you assume a responsibility as the overall PI for a study where Tufts Health Sciences IRB will serve as the single IRB of record for multiple sites, please review “Expectations when Tufts Health Sciences IRB serves as the IRB of record for a non-Tufts site”. This document describes the additional responsibilities you will be taking on as the overall PI of a multi-site study.

Once a reliance agreement has been executed for other sites to rely upon Tufts Health Sciences IRB, the Tufts PI is considered the ‘overall PI’ for the multi-site research study and assumes overall responsibility for the conduct of the study at all sites. This includes the collection of all regulatory information needed by the Tufts Health Sciences IRB and the notification/communication of all IRB-related matters to and from all relying sites.

For example, if a reportable event occurs at a relying site, the relying site PI must inform the overall PI so this event can be reported to the Tufts Health Sciences IRB.

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**Tip: Submitting Current Information with Continuing Reviews**

When you are preparing your continuing review submission, it is important that the information and study materials being submitted include the most recent up-to-date information.

If your study is being updated at the time of continuing review, submit an amendment/modification [Amendment/Modification Cover Letter](#) along with your continuing review submission so they can be reviewed together.

If there are any planned or pending modifications to your study at the time of continuing review, you must *bring this to the IRB’s attention*.

As a reminder, at the time of continuing review, you are asked to confirm the following:

- All modifications have been submitted to the IRB
- The PI is submitting any new and relevant information, published or unpublished, about risks associated with the research

If you fail to submit the most recent information and changes to the study at the time of continuing review, this could have implications for the participants.

For example, a pending modification could include new information, such as an update to the study risks that could affect the safety of a participant or their decision to continue to participate. It is important that subjects are made fully aware of new information as soon as possible.

If you are unsure of how to submit your continuing review with a modification or planned changes, please refer to the [Amendment/Modification](#) page on the IRB website or contact the [IRB office](#) for guidance.
**Question:** How soon can I expect approval for my study?

**Answer:** If we identify issues or have any questions during our pre-review, we will contact you. The IRB’s ability to review and approve studies quickly also depends on how quickly and thoroughly you respond to IRB questions. Our turnaround time varies based on your response time, type of submission (e.g. minimal risk study or greater than minimal risk study), number of studies submitted to the IRB, meeting dates, etc.

If you have any questions about a specific project please contact the IRB office so we can provide you with information specific to your research.

**Question:** I need a letter of support for my grant proposal confirming that Tufts is willing to act as the IRB of record for multiple sites. What do I need to do?

**Answer:** Submit a cover letter to the IRB with the following information:

- Principal Investigator name
- Study title
- Description of study
- Anticipated number of sites
- Names of the sites (if known)
- Funding source
- Description of research procedures at each site (if known)

The proposal will be reviewed, and if the institution decides to allow the Tufts Health Sciences IRB to serve as the single IRB of record for multiple sites, we will provide you with language for your grant proposal.

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**New: HeLa Genome Data Use Agreement**


German researchers published a paper on the first sequence of the full HeLa genome which was met with concerns by researchers, advocates, and the Lacks family. NIH and the Lacks family had discussions about the NIH and the Lacks family had discussions about the concerns that this might reveal data about the family’s disease risk. The Lacks family will now have a say in reviewing applications for controlled access to this whole genome data. All NIH-funded researchers working with the full genome will include data in a shared database and are asked to kindly give acknowledgment to the Lacks family for their contributions to science and medicine.

HeLa cells are the most widely used human cell lines today and have helped with the most important scientific research & advances over the past 60 years.

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**New: OHRP Video about Research Participation**

**New OHRP Video for the Public:**

Research Use of Information and Samples from Patient Care

OHRP has posted a new video on its public outreach website, About Research Participation. The short video explains secondary research use of leftover materials from medical care to help members of the general public understand this important type of research and that it is a regular occurrence.

View the new video here: [https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos](https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos)

OHRP’s educational materials are free to the public, and are available in both English & Spanish. You can use and share them with research participants or people considering research participation.
**IRB Updates!**

**Renee Brody** IRB Administrator I – Responsible for New Minimal Risk Research; Resident, Fellow & Graduate Student Projects; Western IRB (WIRB); and Amendments

**Caitlin Farley** IRB Administrator II – Responsible for New Minimal Risk Research; Resident, Fellow & Graduate Student Projects; Western IRB (WIRB); Amendments; and International Research

**Anya Barytol** IRB Administrator II, *Single IRB Specialist* – Responsible for processing reliance agreements; requests to cede review to another institution or for Tufts Health Sciences IRB to assume oversight over non-Tufts sites

**Victoria Nuon** IRB Administrator I – Responsible for Continuing Reviews; Amendments; and Study Close-Outs

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**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 specific study submission you are working on.

*We are always happy to meet with you in person to answer questions!*

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**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/HSIRB/](http://viceprovost.tufts.edu/HSIRB/)

*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.

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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.