



Spring 2018

Tufts Health Sciences IRB News

Welcome to the Spring 2018 edition of Tufts Health Sciences IRB News
Updates and useful information from the IRB office for Investigators, Study Coordinators,
and other Research Team Members

Tufts Health Sciences IRB Website Survey: *Please tell us what you think!*

Do you use the Tufts Health Sciences IRB website? <http://viceprovost.tufts.edu/HSIRB/>

If so, tell us what you think! Take this quick 5 minute survey. Your answers will be completely confidential. <https://is.gd/TuftsIRBSurvey>

Congratulations! to the Tufts Health Sciences IRB Office Team!

The IRB Office was named a 2018 Tufts MC [True Blue](#) team recipient for the extraordinary effort they put into obtaining an important five-year accreditation by the Association for the Accreditation of Human Research Protection Programs for the Tufts Health Sciences Human Research Protection Program (HRPP). This accreditation is extremely important to continue safe and excellent human subject research.



Update: Amendment Cover Letters!

The IRB has updated the amendment cover letters to clarify some of the questions and to make the letters easier to fill out. Please take a look at these on our [website](#) and start using them immediately:

- [Amendment \(Cover Letter\)](#)
- [Adding/removing members of the research team](#) (when there are no other changes to the study documents)



New: Spanish Resources on Protections for Research Participants

OHRP has expanded the Spanish-language materials available on its public outreach website, **About Research Participation**, hhs.gov/about-research-participation. From the main page, users can choose to view the site in English or Spanish. The Spanish pages include **short videos** about participating in research and a **printable list of questions** that potential volunteers can ask researchers. New to the site is a **series of infographics** to help Spanish-speaking members of the public understand the protections that exist for research participants.

Study coordinators and research staff can use these materials to facilitate and improve the informed consent process. We hope the availability of these materials in Spanish will be a valuable resource for the research community as well as the general public. Please consider sharing this information with other human research protection professionals!

Important Update: Revised Common Rule

The U.S. Department of Health and Human Services (HHS) announced a **Notice of Proposed Rulemaking (NPRM)** proposing an additional 6 month delay in the compliance date for the revisions to the Federal Policy for the Protection of Human Subjects (the “Common Rule”).

If finalized, the new compliance date will be January 21, 2019.

The NPRM also proposes to allow institutions to implement three “burden-reducing provisions” during this delay period:

1. Use of the revised definition of “research,” which deems four categories of activities as not research
2. Allowance for no annual continuing review for certain categories of research
3. Elimination of the requirement for IRB review of grant applications for research

Comments are due by May 21, 2018.

New: [Tufts Health Sciences IRB Statement of Compliance](#)

The IRB Office has posted a new [Tufts Health Sciences IRB Statement of Compliance](#) to replace the FWA memo.

You may provide this statement to your sponsor in lieu of the IRB membership roster (which is confidential). This statement serves to acknowledge that Tufts Health Sciences IRB operates in accordance with applicable laws, regulations, and policies governing IRB Operations.



Reminders:

- **Microsoft Word Electronic Documents**
If you are submitting anything with an Informed Consent Form (ICF), please email the [IRB Office Account](#) the Microsoft Word document version of the ICF(s). We need ICFs in this format in order to provide our IRB validation stamp once the study is approved. Electronic Word documents also allow us to make any edits to ICFs with suggested revisions to increase clarity and efficiency during pre-review!
- **Version Control**
Please be reminded to always use the most recently IRB-approved version of study documents. Check the most recent IRB Approval Letter for this information. Whenever you submit an Amendment, always verify you are tracking changes on the most recently IRB-approved version of the document to avoid non-compliance.

Tip: Re-Consenting Subjects

When submitting updated consent forms, specify whether the revisions might relate to participants' willingness to continue to participate in the research study. In some instances, re-consent may not be required.

For example:

- Minor administrative changes, such as a newly added research team member
- If a procedure or study visit is being added that does not affect previously enrolled subjects

If the PI determines re-consent is not necessary, provide the rationale in the [Amendment Cover Letter](#) to the IRB.

Tip: Sending Data/Specimens to another institution

If you plan to send Tufts data or specimens to another institution, your study might require a data use agreement (DUA) or material transfer agreement (MTA). The agreement is required under the Privacy Rule and must be finalized before there is any use or disclosure of data or specimens to an outside institution or party for the purposes of research. To find out if your study requires a DUA or MTA, contact:

- Tuftsmcgrants&contra@tuftsmedicalcenter.org for Tufts Medical Center studies
- MTA@tufts.edu for Tufts University studies

Tip: What is Payer of Last Resort?

By law, Medicare/Medicaid is considered a “payer of last resort” which means that they will technically pay for any remaining medical costs incurred by eligible individuals after all other insurance has paid the claim.

If you have a study where a Sponsor says something like “*We will attempt to bill your insurance, if insurance denies/does not cover the cost, the Sponsor will cover the costs,*” this is a red flag and in violation of the law. This is in violation of the law because in this case the Sponsor is acting as the “payer of last resort.” Also, another issue here is that Medicare/Medicaid could technically pay for the costs for eligible participants while other study participants would have their costs covered by the Sponsor – this is not allowed because Medicare/Medicaid cannot be charged for services that are being given to others for free.

If you ever come across this issue with one of your studies, please contact the Compliance Department and the IRB office so we can help you resolve this issue.

Tip: What to Submit at Continuing Review when you Study is Closed to Enrollment

The following items are still required with your continuing review submission when a study is permanently closed to subject enrollment:

- [Form 5 \(Continuing Review Form\)](#)
- Protocol/Site-Specific Appendix
- [Conflict of Interest \(COI\) Form](#)
- Any previously required Forms and corresponding documents that are still relevant to the study (e.g., [Form 2](#) if subjects are still receiving study drug, [Form 6](#) if subjects' specimens are still being banked, etc.)
- Study documents that are going to be used *going forward* (e.g., Follow-up questionnaires)

Informed Consent Forms and recruitment materials do not need to be submitted for studies that are closed to subject enrollment unless you plan to use them going forward (for example, submit the ICF if you plan to use it to re-consent subjects).

Ask the IRB...

Question: Can you copy research coordinators on continuing review reminder notices sent to the principal investigator?

Answer: Our office does not have a way to email the rest of the research team. We individually send Principal Investigators 1st, 2nd, and 3rd notices. Please encourage the PI to forward these notices to you as soon as possible in order to submit continuing reviews to the IRB office before the [deadline](#).



Ask the IRB...

Question: How do I know when my continuing review is [due](#)?

Answer: It may be helpful to record [submission deadlines](#) from our website on your calendar, listing all applicable studies for each deadline. The study expiration date is listed on the approval letter, so you can add this information into your calendar deadline as soon as you receive the approval letter to alert you when the continuing review deadline is approaching. The IRB Office begins distributing continuing review reminder notices two months before the month your study expires. For instance, if your study was approved in August, you will begin receiving notices in June.

Question: How should I name my study documents?

Answer: Please be sure to include and appropriately label *all* documents in your submission to the IRB. In order to avoid confusion and to distinguish the difference between other documents, a name should be given that matches the title of the document.

Attention! Training Requirement for Point of Care Pregnancy Testing

In order for us to be compliant with CLIA regulations, all people performing urine pregnancy tests must be trained annually. This applies only to tests being performed by staff in the clinic, not tests being sent to the Tufts MC laboratory or to a central laboratory. If you currently perform pregnancy tests, or if you think you might in the future, you must attend one of the trainings.

We will be holding two training sessions in Stearns auditorium:

Friday, May 18th at 2:00 p.m.

Thursday, May 24th at 10:00 a.m.

RSVP to: Douglas Reichgott dreichgott@tuftsmedicalcenter.org

Attention! New Coordinators & PIs

New PIs and Coordinators should be added to the IRB e-mail distribution list to receive this newsletter and other important updates.

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

If you know someone who is new to the IRB

IRB Staff Updates

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

If you or someone you know is interested in joining the IRB Office Staff, please see our [IRB Administrative Assistant job posting](#).

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!



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? 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.

