Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Welcome to the Fall 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

As previously reported, some additional revisions of the Common Rule will be effective as of **January 21, 2019**.

The IRB implemented the burden-reducing provisions (effective **July 19, 2018**), one of which is the elimination of continuing review for certain studies. The IRB now conducts a brief **administrative annual review** at the time of continuing review for qualifying studies. The revised Form 5 (section E) leads you through the process of determining whether your study is eligible for continuing review or administrative annual review. Refer our continuing review/administrative annual review website page for additional information.

On **January 21st, 2019**, the Common Rule changes will affect the minimal risk research categories.
For more information about these changes please refer to the IRB website and review the IRB PowerPoint presentation.

Please contact the IRB Office with any questions.

New: Site-Specific Appendix and Protocol Template

The Site-Specific Appendix has been revised to be consistent with the Protocol template. Revisions to the Site-Specific Appendix include:

1. Expansion of the Vulnerable Populations section to include additional populations your study could enroll.
2. Formatting capabilities, which allow sections of the Site-Specific Appendix to expand.

Note: *Remember to click "Enable Content" when you open the document to enable the expandable text.*

In tandem with the Site-Specific Appendix, the Protocol template has been revised for consistency. Revisions include:

1. Expansion of the Multi-Site Research section to provide additional information regarding collaborations with other institutions.
2. An additional section on screening data collection.

Important Update: Click IRB Electronic Submission System is coming!

We are excited to announce the kickoff of implementation for our new eIRB management system. Over the next 7 months, we will be reaching out to investigators, research teams, and committee members to get feedback on how to seamlessly implement the electronic system. We are hoping to go live with the new system early summer of 2019.

Please start using the revised Site-Specific Appendix and protocol template for your new study submissions effective immediately.

> ***Note***: *It is not required for you to submit this new version of the Site-Specific Appendix for amendments or continuing reviews/administrative annual reviews for ongoing studies. The previously IRB-approved versions can be used for ongoing studies.*

New: Check Out New Versions of the IRB Forms

Look out for new versions of these IRB Forms! The following forms were updated to include a new *Point of Care Pregnancy Testing* section:

Updated Forms:

- Form 1 **Version Date:** 08/16/2018
- Form 5 **Version Date:** 08/30/2018
- Form 8 **Version Date:** 08/14/2018
- Form 9 **Version Date:** 10/12/2018
- Form 10 **Version Date:** 08/27/2018
- Form 11 **Version Date:** 04/03/2018

New: "Where to Start" Webpage

Don't know "where to start" with your IRB submission? Check out our new "Where to Start" page on the home page of the IRB website. There you will find links to instructions for different types of submissions, such as new study, continuing review/administrative annual review, single IRB, amendment, etc. The page also includes IRB Office Staff contact information in case you have any questions along the way.

New: Regulatory Binder Tabs

The IRB website has a new template for tabs to be used in your study file. These tabs are meant to guide you as to what you are required to retain in your study file, as well as educate you on best practices for document retention.

New: Educational Presentations

The IRB Office is creating a set of educational presentations for the Tufts research community.
Check out the presentations that have already been posted on the IRB website:

- ✓ Final Revisions to the Common Rule- Impact on Continuing Review
- ✓ Final Rule – Will these Changes Affect Minimal Risk Research?
- ✓ Common Audit Findings and How to Avoid Them

Tip: How to Avoid Common Audit Mistakes

- Develop and follow a consistent method for identifying document versions, whether embedded in the text of the file, or in the file name. Please note you can use the following self-audit checklists to conduct routine quality assurance inspections of your study files:
  - **File Review Checklist:** https://viceprovost.tufts.edu/HSCIRB/files/TUHS-IRB_PI-Review-Checklist_Protected.docx
  - **Participant File Checklist:** https://viceprovost.tufts.edu/HSCIRB/files/TUHS-IRB_PI-Participant-Checklist_Protected.docx
- Be sure to maintain copies of all correspondence with the IRB in your study binder / files, including emails with the IRB since they often contain important information like study stipulations.
- Develop and follow a plan to distribute revised study documents to your research team members at other sites. This plan should include a procedure to verify that proper documents are enforced at the local site.

Tip: When to Submit Updated Investigator's Brochures to the IRB

New editions of Investigator's Brochures (IBs) should be submitted to the IRB as they are received by the research team. Once a research team is notified of an update in the IB, it is important that it is assessed to see if it impacts other study documents, and submitted to the IRB as an amendment in a timely manner. Even if your study is now closed to enrollment and you no longer need to submit the Form 2 at continuing review, it is still required that you submit updated IBs since the changes might impact subjects who are on the study drug, and/or have previously taken the study drug.

Please be reminded that the IRB Office is still paper-based at this time, and we require a paper copy of all study documents when they are submitted for review. Please note that multiple pages may not be printed on one sheet of paper, as documents must be legible. You may, however, print double-sided.

As a reminder, if subjects are still taking the study drug(s), Form 2 and accompanying documents are required at continuing review, including a copy of the current version of the IB. This is required even if the IB is not being updated with the continuing review submission.

Ask the IRB…

***Question*:** How should I submit a response to the IRB?

Answer: Please review the Tip Sheet: Responding to IRB Comments. This tip sheet contains essential information that

Ask the IRB…

Question: When is my continuing review (CR) / administrative annual review (AAR) submission deadline?

Answer: In order to ensure your study is given appropriate review in a timely

can help speed up the review process for your project. When you submit your response, be sure to reference the IRB number.

manner, continuing review (CR) / administrative annual review (AAR) submissions must be submitted by the deadlines listed on this webpage.

Ask the IRB…

Question: All IRB forms are locked for editing. How can I track changes on Request for Exemption or Form 7 when I submit my response?

Answer: Print two copies of each updated document. On one of the copies please physically **highlight** the sections that have been revised.

*NEW** ASK A STUDY COORDINATOR:

Would you like to get your question answered by another research coordinator? If you are looking for advice from a person who has been in your shoes, the IRB can help get your question answered by another coordinator experienced in your field of work.

Some of these questions will be posted in upcoming issues of this newsletter.

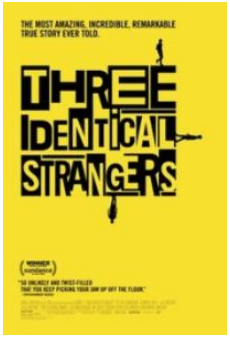
Feel free to send your questions to irboffice@tuftsmedicalcenter.org with the subject line "Ask a Study Coordinator"

Attention! Welcome New Research Participant Advocate

Kieran F. Reid, PhD, MPH, an Assistant Professor at the Friedman School of Nutrition Science and Policy at Tufts University and a Scientist III in the Nutrition, Exercise Physiology, and Sarcopenia Laboratory at the Jean Mayer USDA Human Nutrition Research Center on Aging (HNRCA) will serve as a resource for study volunteers and a liaison to Principal Investigators (PIs) and research teams, and can assist with issues relating to: informed consent forms and processes, participant safety, regulatory statutes, participant satisfaction , etc. Investigators, and study team members, and research participants are encouraged to call the Research Participant Advocate at **617-556-3081**.

Attention! Human Subjects Research Issues in the Movies!

"Three Identical Strangers" is a fascinating documentary about triplets adopted shortly after birth by three separate families. Regardless of separation, brothers had similar habits and quirks, which not only stoked the media firestorm, but also, led to discussions about genetics and the influence of environment. "Three Identical Strangers" takes its audience on an engrossing, heartbreaking journey into the lives of individuals whose lives became experiments for scientist on a quest to unravel how identity is shaped.



Attention! New Coordinators & PIs

Please add new PIs and Coordinators to the IRB email distribution list to receive IRB newsletters and other important IRB information. Email IRBOffice@tuftsmedicalcenter.org to request for someone to be added.
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 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!

IRB Staff Updates

Rebecca Elias, MPH, has been promoted to Assistant IRB Coordinator and works on new minimal risk submissions.
Congratulations, Rebecca!

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

Please Note! New Entrance for the IRB Office (15 Kneeland Street)!

The IRB Office has a new street entrance at 15 Kneeland Street (Tupper Building)! To gain entrance into our new office space from 15 Kneeland Street, press the buzzer on the left side of the doorway (pictured below). **For security reasons, you will be required to show your Tufts-issued ID in order to gain entry to the office.** The administrative assistant will buzz you into the IRB office through an intercom system. The new drop boxes for IRB Submissions and pick-ups are located in our new office foyer. You will no longer access the IRB office through the Tupper 1 lobby entrance.

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 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