Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Winter 2018 Tufts Health Sciences IRB News

Welcome to the Winter 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

Important Update: 6 month delay to the revised Common Rule

The US Department of Health and Human Services announced a **6 month delay** in the final rule that was initially planned to be effective January 19, 2018:

- The new effective date and general compliance date of the revised common rule is **July 19, 2018**
- A further delay is being considered (for example, January 21, 2019)
- We are unable to implement any of the burden-reducing changes at this time (such as eliminating continuing review or revising the exemption categories)
- Please contact the IRB Office with any questions at IRBOffice@tuftsmedicalcenter.org or ext. 6-7512

Reminder: GCP Training

NIH announced that, effective January 1, 2017, NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP).

Effective January 2018, GCP training is required for ***all*** clinical trials (all studies that meet the NIH definition of clinical trial) regardless of funding source.

Acceptable GCP training includes:

- CITI GCP training
- Any other GCP training approved by "TransCelerate", a mutual recognition program for GCP training.

The PI is responsible for compliance with GCP training, and documentation of GCP training for each research team member must be retained in your study files.

Confidentiality and Data Security for your Research

The IRB Office, in collaboration with Tufts Medical Center Information Services (IS), Tufts University Technology Services (TTS), & Tufts Medical Center Internal Audit & Corporate Compliance, created new guidance, "Confidentiality and Data Security Guidelines for Electronic Research Data".

Refer to these guidelines when you are developing your study plan for maintaining confidentiality and security for electronic records, and when you have questions about properly securing and maintaining your electronic research data.

Payment and Reimbursement Information for Participants in your Research

The FDA has updated their information sheet about payment and reimbursement for research subjects to clarify that reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging are acceptable under current practices. This update is in response to inquiries FDA received from stakeholders about appropriate reimbursement practices.

Louis Lasagna Award Winner 2017

IRB Chair Andreas Klein, MD and Justin Fongemie, PharmD

Congratulations to Cardiology Clinical Pharmacy Specialist **Justin Fongemie, PharmD**, the 2017 recipient of the Louis Lasagna, MD Outstanding Institutional Review Board (IRB) Member Award!

This award is given to an IRB member who best exemplifies Dr. Lasagna's extraordinary care, concern, and compassion for research subjects and his advocacy for candor, honesty, and integrity in the design and execution of clinical research.

Justin has served as a pharmacy representative on the IRB since 2015. He was commended for his thoughtful and careful reviews of studies, his role in the accreditation of our Human Research Protection Program and bringing his pharmacy expertise to the IRB review process.

Tip to Prevent Non-Compliance Issues

Create a plan so your study records are complete even if you leave your position.

Study Coordinators should:

- Save study documents on a secure shared drive or other central location that you know the PI and future research team members will be able to access (don't save documents on your desktop, a flash drive, or personal drive).
- Save study related e-mails and attachments with the study documents *(Print & file or save electronically by selecting the e-mail or group of e-mails you want to save, choose "File", then "Save as Adobe PDF" – you can also append additional e-mails to this file of saved e-mails. Alternatively, save e-mails to an Outlook archive saved on a shared drive).*
- Use a clear and consistent method of assigning version dates to documents and save each version of forms and documents.
- Leave the PI and new coordinator with detailed instructions that provide information about the status of ongoing studies, a list of your tasks & responsibilities, where study documents are retained, your method of assigning versions, and other details to help with a smooth transition!

Do a *Quick Check* of Your ICF Before & After the Subject Signs!

Follow this step-by-step process to help make sure the informed consent form (ICF) is correctly completed and signed for each subject. This quick check will help you avoid common consent form errors & non-compliance.

Before the subject signs, check:

1) **Version & Validation**: Make sure you have the most recent ICF version approved by the IRB, and that it has the IRB validation approval date on it.
2) **Every Page**: Make sure the ICF includes every page before you give it to a subject.
3) **Short Forms**: Print & use the Short Form Quick Reference Checklist every time you use a Short Form to consent a non-English speaker.

New Checklists to Help You Review Your New Study Submission!

Decrease IRB turnaround time by completing our new *optional* checklist for Reviewing your IRB New Study Application before Submitting it to the IRB!

Using this checklist will help the IRB to review and approve your study as quickly as possible:

CHECKLIST: Reviewing your IRB New Study Application before Submitting it to the IRB

You can also use this new protocol checklist to make sure your protocol includes all relevant sections:

CHECKLIST: Protocol Checklist

After the subject signs, check:

4) **Participant Signature & Date**: The subject signed & dated in the correct place, and that the date is correct.
5) **PI/Representative Signature & Date**: The PI (or representative) signed & dated in the correct place, and that the date is correct. *The representative must be noted as a research team member who will consent subjects in the protocol or Site-Specific Appendix.*
6) **Choices**: Make sure the subject has made his/her choices on any extra questions being asked, for example about banking specimens for future use.

Do not start any research activity with the subject or file the ICF until you have completed this quick check!

Continuing Review Tip:

Here are some helpful tips for completing Continuing Review Form 5, section A (enrollment status):

- If your study is permanently finished enrolling subjects for this study, please complete the applicable boxes under questions 1-4.
- If your study is open to enrollment and consenting subjects, please indicate this on question 5.
- If your study has never enrolled subjects, questions 6-8 might apply.

Tip: Maintaining Audit-Ready Study Files

The Tufts Health Sciences IRB has been conducting routine internal audits of PI study files. We wanted to remind you that the study file should "tell a story" to any auditor looking at the files. To have the full story, you need to:

- Keep a copy of the signed submissions to the IRB and all of the correspondence to and from the IRB. This means if the IRB requested revisions to documents, you should keep a copy of the IRB's request and the documents you provided in response to the request.
- Keep any original documents provided by the IRB. Keeping all correspondence will ensure your study file is complete and help you to be in compliance with all regulatory requirements.

Ask the IRB…

Question: **When do version dates need to be updated on study documents?**

Answer: Version dates should be updated when any changes are made to study documents. If you are submitting them unchanged at continuing review, the version date should stay the same.

Question: **During continuing review, do I have to submit all Reportable New Information (RNI) forms and Amendments that were already reviewed since the last continuing review?**

Answer: No. You should answer applicable questions about them when completing the Form 5 to provide a summary (i.e. section G for Amendments and section J for Reportable New Information). But you do not need to submit the same amendments or RNI forms that were previously submitted to and reviewed by the IRB.

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 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,

IRB Staff Updates

Welcome!

Kim Garabedian has joined the IRB staff as the IRB Analyst for continuing reviews and amendments working with the IRB-BLUE committee.

Congrats!

Tori Zupkofska has been promoted to the IRB Analyst position and works on continuing reviews and amendments working with the IRB-RED committee.

Anya Barytol has been promoted to the Coordinator for Minimal Risk Research and works on new minimal risk

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!

research studies, quality assurance/quality improvement projects, graduate student projects, and IRB reliance agreements.

Jaime Pellerin, Coordinator for Minimal Risk Research, will be leaving the institution to pursue a position related to her interest in nutrition. Best wishes to Jaime!

Contact us!

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

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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.**

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