



Welcome to the Fall 2017 edition of Tufts MC / TUHS IRB News

Updates and useful information from the IRB office for Investigators, Study Coordinators, and other research team members

Update AAHRPP SUCCESS!



The Tufts Health Sciences Human Research Protection Program has received full accreditation from the Association for the Accreditation of Human Research Protection Programs ([AAHRPP](#))!

The AAHRPP Council on Accreditation awarded Tufts Medical Center and Tufts University Health Sciences this initial Full Accreditation for 3 years effective September 18, 2017.

As the "gold seal," AAHRPP accreditation offers assurances to research participants, researchers, sponsors, government regulators, and the general public that an HRPP is focused first and foremost on excellence in the protection of human subjects.

Update Certificates of Confidentiality (CoC) Policy for NIH funded studies

CoCs protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in other specific situations.

Under the updated policy, NIH funded researchers will be automatically issued a CoC through their award. NIH funded researchers will no longer have to request a CoC, nor will they receive an actual certificate.

All research that was commenced or ongoing on or after December 13, 2016 and is within the scope of this policy is deemed to be issued a Certificate through this policy.

The NIH has [suggested consent language](#) describing the CoC Protections.

For more information:

- [NIH CoC Kiosk](#)
- [Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality](#)
- ["Open Mike" Blog: Letter from NIH's Deputy Director of Extramural Research](#)

Reminder SIRB

The NIH has implemented a [Single IRB \(sIRB\) policy](#) to enhance and streamline

Reminder GCP Training

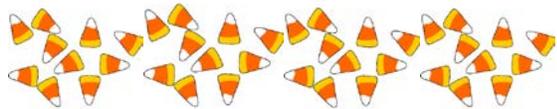
[NIH announced](#) that, effective January 1, 2017, NIH-funded investigators and staff who are

the IRB review process for multi-site research so that research can proceed as quickly as possible without compromising ethical principles and protections for human research participants.

Applicants will be expected to include a plan for the use of a sIRB in the grant applications and contract proposals they submit to the NIH (for due dates on or after January 25, 2018).

Contact the IRB with any questions about choosing an IRB of record for your Multi-site research study.

Complete a [Form 10](#) when requesting Tufts serve as the IRB of record or for Tufts to cede oversight to another IRB.



involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP).

GCP training is required for all NIH funded studies that meet the NIH's definition of a [clinical trial](#).

As of 01 January 2018, GCP training will be 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.

Educational Opportunity! Tufts CTSI Seminar

Expert Feedback on Changing Policies for NIH-funded Studies

Are you an NIH grant applicant, awardee, researcher, or research administrator? Are you ready for the regulatory changes scheduled to take effect in 2018?

Mark your calendar for [Expert Feedback on Changing Policies for NIH-funded Studies](#), a seminar featuring joint presentations by regulatory experts from the Tufts Health Sciences Institutional Review Board (IRB) and the Tufts University and Tufts Medical Center Offices of Research Administration, followed by an interactive Q&A session. Anyone planning to apply for an NIH grant early next year is strongly encouraged to attend.

The seminar will take place Tuesday, December 5, from 1:00-3:00PM in the Behrakis Auditorium, 150 Harrison Avenue, Boston.

A live webcast will also be available. To register, please click [here](#).

Educational Opportunity!

Learn About 2018 Regulatory Changes at the Virtual PRIM&R Research Conference

Public Responsibility in Medicine and Research (PRIM&R) will host its [2017 Advancing Ethical Research Conference on November 5-8](#). The conference will focus on regulatory changes scheduled to take effect in 2018, including the revised Common Rule.

Interested in attending? Tufts CTSI is sponsoring live-streaming access to the event, including keynote presentations, panel discussions, and breakout sessions. [Register here](#) for instructions on how to access the live stream.

The event will include keynote presentations, panel discussions, and breakout sessions! If you are not able to view the conference live, as long as you register you will be able to access all conference materials for up to 30 days after the conference.

Make sure to register now so you don't miss this excellent opportunity!!



Completeness of 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. You should also 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.



Study Title for Sponsored Studies

The IRB approval letter can only reference one study title. When a Sponsor provides more than one title (for example, a short title and long title) please be sure to specify the title you would like us to use on formal IRB correspondence by using the preferred title on the IRB forms you complete (Form 1, Site-Specific Appendix, Form 6, etc.).



Ask the IRB...

Question: I received my continuing review approval including a validated ICF with new validation dates. Do subjects have to be **re-consented** to the newly validated ICF? No changes were made to the ICF.

Answer: No, the IRB does not require subjects be re-consented if no changes were made to the ICF content, even if you updated the version date. Check with the study Sponsor about their requirements, and contact the IRB Office with any questions.



Ask the IRB...

Question: What is the difference between the terms Coded, De-Identified, and Anonymous?

Answer:
Coded: Direct personal identifiers have been removed and replaced with words, letters, figures, symbols, or a combination of these for purposes of protecting the identity of the source, but the original identifiers are retained in such a way that they can be traced back to the source by someone with the code.

De-identified: All direct personal identifiers are permanently removed, no code or key exists to link the information or materials to their original source, and the remaining information cannot reasonably be used by anyone to identify the source.

Anonymous data: Personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved.

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, 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

[Alison \(Ali\) Rosin](#) has joined the IRB staff as our IRB Administrative Assistant. Welcome Ali!

Jonathan Delgado, IRB Analyst who worked on amendments/continuing reviews, has left the institution to study for the Massachusetts Bar Exam. Best wishes to Jon!

If you'd be interested in joining the IRB Office Staff, please see the [IRB Analyst I posting](#) for more information.



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.

