Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Fall 2016 Tufts Medical Center / Tufts University Health Sciences IRB News

## Welcome to the Fall 2016 edition of Tufts MC / TUHS IRB News

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

### New AAHRPP *Update*

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs. To earn accreditation, organizations must provide evidence - through policies, procedures, and practices - of their commitment to scientifically and ethically sound research and to continuous improvement.

We have submitted our application for accreditation. The next step is to prepare for the Site Visit, which will take place possibly late December/early January. As Principal Investigator or member of the research team, you may be selected to be interviewed during the on-site evaluation.

Early preparation is key for the site visit! Over the course of the next couple of months we will be posting weekly tips to help you prepare. So, please bookmark our AAHRPP Site Visit Preparation page and check it weekly to keep up with the latest tips!

### Tip Therapeutic Misconception

*Therapeutic misconception* occurs when an individual (subject, researcher, or IRB member) fails to fully appreciate that the purpose of the research is scientific exploration, not personal care. Individuals often do not recognize that the research is being conducted to answer a scientific question, not to benefit (or provide treatment to) subjects in response to their individual needs.

Eliminate the use of words like “treatment”, “medication”, “medicine”, and “therapy” when referring to the investigational intervention in recruitment material and consents, as these words contribute to the therapeutic misconception.

Check out the optional module in CITI called “Consent and Subject Recruitment Challenges: Therapeutic Misconception” that describes therapeutic misconception, the factors that contribute to it, and strategies for reducing it.

### Updated Form 8 (WIRB Submissions)

The Form 8 (WIRB Submissions) has been revised.

Investigators/research teams will now request the Investigational Drug Services (IDS)

### New Study Close Out Letter Template

The IRB Office is introducing a new Study Close Out Letter. The letter includes a checklist where the PI can simply check “Yes” or “N/A” in response to questions about the status of the study, and then sign it.

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| "Research Pharmacy" review *before* submitting the Form 8 to the IRB office. The Pharmacy Review will be submitted with the Form 8.<br><br>Please see the instructions on our website that explain how to request IDS review. | Using the Close Out Letter template will streamline study closure requests.<br><br>The Study Close Out Letter can be found on the Template page of the IRB website. |
| **New** Investigator's Manual and Human Research Protection Plan (HRPP)<br><br>Take a look at our new Investigator's Manual and Human Research Protection Plan (HRPP)!<br><br>The Investigator's Manual is a useful guide for Investigators and research teams that includes IRB policies and procedures as well as information that will help you submit and manage your research studies.<br><br>The HRPP provides an overview of the components of Tufts Health Sciences Human Research Protection Plan for the conduct of research at Tufts Medical Center and Tufts University Health Sciences.<br><br>Together, these documents have replaced the old IRB Operations Manual. | **New** Information for Participants Website<br><br>The IRB has created a new website to provide education that is aimed at research participants to help them make an informed decision about participating in research. Investigators and research team members are encouraged to provide the link to this website to potential and active study participants.<br><br>The website includes information about participating in research studies, describes the informed consent process, provides a list of questions that participants should consider asking when making the decision to take part in a research study, links to websites to search for research studies to participate in, and links to a series of brochures and videos published by the New England Research Subject Advocacy Group to support communication between researchers and participants. |
| **Tip** Retaining documents from the IRB Office<br><br>Be sure to retain all correspondence with the IRB and your Sponsor in your study files as described in the record retention section of Post-Approval Responsibilities.<br><br>Now is a good time to review your study files to ensure you are retaining records appropriately. If you find that correspondence is missing, the IRB may be able to assist you. To request documents from the IRB study file, submit a formal request to the IRB Office:<br><br>• A letter, signed by the PI, requesting documents from the IRB study file<br>• Specify each document you are requesting, with submission/approval dates, if known (for example, "Approval Letter and validated documents for | **New** "Ask the IRB"<br><br>Question: What do I submit to the IRB if I am conducting a quality improvement (QI) project?<br><br>Answer: If you plan to conduct a quality improvement project, please submit a cover letter describing the following:<br><br>• Dissemination goals<br>• Generalizability of the data or results<br>• Intent of the project<br>• Funding source<br>• Letter of support from the organization you are working with<br><br>Some QI activities have both a research and QI goal and Human Subjects Research regulations may apply. Refer to Quality |

amendment submitted on 10/1/11")
- Explain how you will ensure record retention going forward

Maintaining a copy of all correspondence associated with a study is essential to compliance and will ensure you are prepared for an audit.

Improvement Activities FAQs for more information.

If you are not sure if the proposed project is a quality improvement project, contact the IRB Office to discuss your project.

**New** NIH Statement Regarding Good Clinical Practice (GCP) Training

The NIH recently announced that, effective January 1, 2017, it is expected that NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials be trained in GCP every three years. The announcement can be found ***here.***

GCP helps assure the safety, integrity, and quality of clinical trials and provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting and outlines the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors.

- The Tufts CITI training program includes a GCP Training Course that complies with this NIH statement.
- GCP training does not replace the IRB requirements for CITI training, rather it is a no-cost optional module that would be in addition to the current required IRB CITI training.
- Proof documenting completion of the GCP Training Course is the responsibility of the individual research team member, and the PI should retain this documentation for each research team member in the study files.
- Although investigators and coordinators are *not* required to complete GCP training, ***the strong expectation by NIH is for individuals involved in NIH funded clinical trials to be trained in GCP by January 1, 2017.***
- We recommend that NIH-funded investigators include a statement regarding the GCP training status for themselves and their staff in upcoming NIH progress reports and grant applications.

*To access the CITI GCP Training Course (14 modules):*

1. Sign in to www.citiprogram.org
2. Under *My Learner Tools* for Tufts University/Tufts Medical Center choose "Add a Course"
3. Answer each question, being sure to Click "Yes" on **Question 3** to add "Good Clinical Practice and ICH (GCP) – Basic Course"
4. Hit the "Submit" button
5. GCP should now be listed as a course option under *My Learner Tools* for Tufts University/Tufts Medical Center Courses for you to complete

**Update** IRB Staff

*Welcome!*

Viktoria (Tori) Zupkofska has joined the IRB staff as the IRB Administrative Assistant.

**Tip** Preparatory to Research

If you plan to access Protected Health Information (PHI) for purposes *preparatory to research* (such as preparing a research protocol, assessing the feasibility of a study, developing a hypotheses, etc.), submit a Review Preparatory to Research Form to the IRB office.

The IRB must review and grant a waiver of HIPAA authorization if you plan to access PHI for research purposes.

## 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**.

Tufts University

Tufts Medical Center