



### Welcome to the Fall 2015 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** [Proposed Changes to the Common Rule](#)

The Department of Health and Human Services (HHS) has released a [Notice of Proposed Rule Making \(NPRM\)](#) and is requesting feedback from the research community.

Feel free to contact the [IRB office](#) with any comments about the NPRM.

#### **New** [Post-Approval Responsibilities](#)

To aid investigators with study management, the IRB has created a list of [Post-Approval Responsibilities](#) to describe investigator responsibilities upon receiving IRB approval.

The list of [Post-Approval Responsibilities](#) is posted on the IRB website and will be provided with your initial and continuing review approval documents.

#### **Updated** [Form 5 \(Continuing Review\)](#)

The IRB has revised the Form 5 (Continuing Review). The updated version of the form can be found on the [Forms page of the IRB website](#) and should be used going forward.

Revisions to the form include:

- A copy of a de-identified ICF signed by a subject will be required at submission with each continuing review, if applicable
- All documents in a submission must be submitted as a paper copy (documents cannot be submitted only in electronic form)
- Section D. *Current Study Status* has been revised to further explain the different options

#### **Tip** [Avoid Study Approval Expiration](#)

It is important to be aware of the study approval and expiration dates because once a study approval has lapsed, no research activities may continue, including:

- Participant recruitment and enrollment
- Data collection
- Data analysis

To avoid non-compliance, make note of the study's expiration date (this date can be found on the last approval letter) and be sure to submit the continuing review on time each year. The IRB also sends courtesy notices to the PI with the deadline for continuing review starting 2 months prior to expiration.

Please contact the IRB Office at 617-636-7512 if you have questions about expired studies.

**New [IRB Reliance options](#) and [Requests to Cede/Assume IRB Review](#)**

Are you interested in learning about the different options for requesting the Tufts Health Sciences IRB to give up (cede) oversight of a study to another IRB or to take on (assume) oversight of a study?

Take a look at our new website page: [Requests to Cede/Assume IRB Review](#) which includes useful information, such as:

- A table that describes [IRB reliance options](#) and which options might apply to your study
- Individual website pages for each reliance option with detailed information and instructions
- [Form 9](#) to submit new network studies under an established central IRB agreement
- [Form 10](#) to request the Tufts Health Sciences IRB cede or assume oversight for a research study

**New [Departing PI Checklist](#)**

The IRB has created a checklist for Investigators who are leaving Tufts and have active studies in the IRB.

This checklist describes different options for ensuring your research studies are closed out, transferred to a new PI, and/or transferred to a new institution *before* you leave Tufts.

This checklist can be found on the [Forms page of the IRB website](#).

**Updated [Form 8 \(WIRB Submissions\)](#)**

If you are submitting a new study to WIRB, WIRB must invoice the Sponsor directly.

We have updated our WIRB Form 8 to include new information about invoicing for WIRB studies. The updated version of the form can be found on the [Forms page of the IRB website](#) and should be used going forward.

Please consult with your Research Administrator if you have any WIRB billing questions.

**Updated [ICF templates](#) & [New ICF Checklist](#)**

The IRB has revised the Informed Consent Form templates to include [Greenphire ClinCard](#) and radiation risk template language. Please use the current versions going forward.

In addition, please use the [Elements of Informed Consent Checklist](#) when creating consent forms.

The ICF templates and Elements of Informed Consent Checklist can be found on the [Informed Consent page of the IRB website](#).

**New [Tissue Banking Checklist](#)**

The IRB has created the [Tissue Banking Checklist](#) to provide guidance when preparing a study for submission that includes tissue banking.

Please see the [Tufts Tissue Banking Policy](#) for more information and to determine if your study includes tissue banking (unspecified future use of specimens).

### Updated [Form 4 \(Radiation\)](#)

The IRB has revised the Form 4 for Research Radiation. The updated version of the form can be found on the [Forms page of the IRB website](#) and should be used going forward.

The old form will not be accepted after December 01, 2015.

### New "Ask the IRB"

**Question:** I submitted my new study for IRB review. When can I start my project?

**Answer:** Any activities considered to be Human Subjects Research can't begin until the study has been reviewed by the IRB and you receive a final approval letter or a notice of exemption from the IRB office.

This includes the collection of data from medical records for research purposes and subject recruitment activities.

If you are not sure if the project you wish to conduct is Human Subjects Research, contact the [IRB Office](#) to discuss your project.

### New IRBook Club

You're invited to the IRB's quarterly book club! Join us for friendly discussions about works of fiction that relate to interesting topics in bioethics.

**Book Selection:** [World War Z](#), by Max Brooks  
**When:** Friday, October 30<sup>th</sup>, 12pm-1pm\*  
**Where:** IRB Office (Tupper 1)

Find out how the zombie apocalypse relates to some of the same bioethics questions you face every day!

\*Light refreshments will be provided.

RSVP by October 23rd by sending your name to [IRBoffice@tuftsmedicalcenter.org](mailto:IRBoffice@tuftsmedicalcenter.org).

Start reading our Winter IRBook Club Selection, [Brave New World](#) by Aldous Huxley, and see our Winter 2016 Newsletter in January for the meeting 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 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](mailto: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.