



Winter 2016

Tufts Medical Center / Tufts University Health Sciences IRB News

### Welcome to the **Winter 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

*Important new form! Important new form! Important new form!*

#### **NEW! Reportable New Information Form**

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The *Unanticipated Problem and Adverse Event (AE) Reporting* policy & form have been replaced with a new [Reportable New Information form](#). This new policy and form will:

- Eliminate the requirement to report on-site SAEs that do NOT meet the criteria for an “unanticipated problem” (*UP = unexpected, & related/possibly related, & places subjects or others at greater risk of harm*)
- Better instruct Investigators and research teams about which items need to be reported to the IRB quickly (within 5 business days)
- Define reportable deviations as “*Failure to follow the protocol that harmed a subject or placed subject at risk of harm.*”

You can start using the new form now. We will not accept the old form after **April 1, 2016**.

#### **Tip Recruitment of Employees and Students**

If your study recruitment methods target employees or students, including the posting of advertisements in areas that are only (or mostly) accessible to employees/students, sending recruitment materials via employee/student listservs, etc., there are additional requirements for IRB review:

- Detail your recruitment methods and targeted population in your study protocol (or site-specific appendix) and other applicable documents
- Provide a *Letter of Support* from the appropriate official for the recruitment of this group for your study

*Note:* Incidental enrollment of an employee or student from public recruitment advertisements is not considered targeted recruitment of employees or students per IRB requirements.

### Update Validation of Documents

The IRB has updated its policy on the validation of subject materials. **Only Informed Consent Forms will be validated with a stamp.** All other subject materials will be listed on the approval letter, but will not be validated and copies will not be provided.

To ensure documents are easily identifiable:

- List all documents being submitted in the cover letter (along with the document name and version)
- Include a version number or version date on each document
- The document name referenced in the cover letter should match the name on the document itself

### New Tufts IRB staff newly CIP Certified

Congratulations to Ashley Rhoads (Coordinator for Minimal Risk Research) and Nila Mitra (IRB Analyst II) who passed the Certified IRB Professional (CIP) examination and received CIP certification!

Passing this rigorous exam demonstrates knowledge and expertise in IRB regulations, procedures, and research ethics.

Over 50% of the Tufts Health Sciences IRB office staff has earned this certification!

### Tip Submission Document Organization

Submissions to the IRB office should be well organized and include:

- Cover letter with a list of documents being submitted (signed by the PI)
- The list of documents in the cover letter should include each document name and version date. The document's name and version date should appear on the document.
- Paper copies of documents should be separated from one another using paper clips, binder clips, staples, or rubber bands (*please do not submit* as one stack of paper where the documents are not separated from one another, as this could lead to difficulty distinguishing the documents)
- Electronic copies of documents should be in editable (WORD) format when possible (if you do not have the WORD version, please submit PDFs, not scanned copies)
- If submitting electronic documents on a password protected device, please provide the password
- If submissions are not properly organized, you may be asked to come to the IRB Office to sort or resubmit

### Tip International Study Checklist

When conducting a study where research activities are occurring outside of the US, all applicable items in the [International Research Checklist](#) must be addressed in the study Protocol or other applicable study documents.

See [our website](#), including the [International Research Guidance](#) for more information.

### Tip IRB Approval

You can always call the IRB office ext. 6-7512 with any questions. However, please remember that having a discussion with the IRB office staff does not equal IRB approval. If IRB approval is required, you will need to submit your request or study in writing to the IRB office in order to obtain an IRB approval letter.

**Tip** Offsite research by Tufts Affiliated Investigators

If you are conducting research at a Non-Tufts institution, even when the research is reviewed and approved by another institution's IRB, the Tufts IRB must determine whether your activities require review by the Tufts IRB or if an [Institutional Assurance Agreement \(IAA\)](#) should be executed.

Please contact the Tufts IRB to discuss any applicable projects.

**New** CR deadlines

Continuing Review submission deadlines are now available on the [IRB website](#). Now you can predict when your continuing review will be due! Just refer to this web page and your study's IRB approval expiration date (which can be found on your last IRB approval letter).

**Tip** Submitting an updated Investigator's Brochure or Device Information

Use the [Amendment cover letter template](#) to submit an updated Investigator's Brochure or updated device information to the IRB.

The PI should consider whether the protocol, Site-Specific Appendix, and/or informed consent forms need to be revised to reflect any new safety information. A statement about the PI's determinations should be included in your amendment cover letter.

**Tip** Submitting an Amendment

When submitting an amendment, it is important to include an [Amendment Cover Letter](#) that lists:

- Amendment number or identifier
- Changes and the rationale for these changes
- Each submitted document (name & version date)
- PI's original signature

In addition, submit all pertinent documents, including tracked and updated versions, if applicable. Submit electronic copies of ICFs if you want them validated electronically by the IRB.

**Tip** Increasing Study Enrollment

To increase the number of subjects you are approved to enroll, submit the request as a [study amendment](#) including the following:

- Explain the rationale for the increase
- Confirm there are adequate resources to cover this increase in enrollment
- Provide documentation from the sponsor confirming the sponsor approves the increase
- Contact Research Administration to see if the contract needs to be revised to reflect the increase in enrollment

### New "Ask the IRB"

**Question:** I recently submitted a study, and I've been told it requires SRC review. What is the SRC and why does my study have to be reviewed by the SRC before IRB review can occur?

**Answer:** The [Scientific Review Committee](#) (SRC) reviews select clinical research proposals to ensure they meet an acceptable standard of scientific rigor and merit prior to IRB review.

Studies that are greater than minimal risk and have not undergone an independent scientific peer review are selected to be reviewed by the SRC. Please be sure to describe any prior scientific review in your cover letter.

### New IRBook Club

What if we lived in a world where all crime was predicted...and all offenders were arrested *before* committing a crime?


Come discuss the issue of free will, conspiracy, and alternate realities in Phillip K. Dick's Minority Report at the Winter IRBookclub.

**Friday, April 1st** from 12:00-1:00  
IRB Conference Room, Tupper 1

RSVP to [irboffice@tuftsmedicalcenter.org](mailto:irboffice@tuftsmedicalcenter.org) before March 18<sup>th</sup>!

### 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](#) 

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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.

