



Spring 2016

Tufts Medical Center / Tufts University Health Sciences IRB News

### Welcome to the Spring 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

#### Tip Study Document Formatting

All study documents and especially the Protocol, Informed Consent Form and other participant facing documents, must include a version date, page numbers and clear title.

This aids in the IRB review and documentation as well as the research team's version control and organization of study documents.

#### New Wards of the State

A new Tufts Health Sciences IRB Policy on [Wards of the State](#) has been uploaded to our website!

This policy provides instructions for studies that plan to enroll children who are wards of the state.

#### New Emergency Use Website Page

The IRB has revamped the [Emergency Use IRB website page](#). The page now includes a [quick reference guide](#) on what to submit to the IRB for emergency use situations and an ICF template specifically tailored for emergency use situations.

#### New Certification of Translation Form

The [Certification of Translation Form](#) has been created for use with studies that include translated documents to document the translator credentials and information for forward and back-translations, as applicable.

Please see the Tufts Translation Policy in the [Tufts IRB Operations Manual](#) for more information.

#### Tip Payment/Incentives

For all studies that include payment/incentives provided to research subjects for study participation, the protocol and Informed Consent Form must include:

- specific amounts/items/incentives at each visit and the total amount for the study, as well as the payment schedule
- form of payment, if monetary (cash, gift card, ClinCard)

The protocol should also include:

- local value and average household income if international/otherwise applicable
- value of non-monetary incentives such as gifts/items, extra credit, access to services

### **New** [Tips for Being Prepared for an Inspection](#)

The IRB has posted some tips for investigators and research teams preparing for an inspection or audit. These include advice about what to do before the inspection, when scheduling the inspection, and during the inspection. Consider using this [tip sheet](#) as a basis for developing your own inspection plan.

To help keep you “audit ready,” [self-audit tools](#) have also been posted to guide research teams in conducting routine quality assurance inspections of study files.

### **Tip** [Submitting Electronic Documents for New Submissions](#)

All new submissions are triaged among various IRB staff members therefore study documents should not be emailed directly to a staff member unless they have instructed you to do so for the specific submission.

For new submissions that require electronic documents (initial review, continuing review, amendments) please e-mail the documents to the IRB Office Administrative Assistant, [Anya Barytol](#), or provide a CD or USB thumb drive (with password) in addition to the hard-copy submission.

### **Update** [Request for Exemption Form](#)

The [Request for Exemption Form](#) has been updated for submission of research eligible for [Exempt review](#).

Please note that this form will serve as your protocol and, in general, a separate protocol should not be submitted.

Please contact the IRB Office with any questions about whether your research might be eligible for exempt review.

### **Update** [New Subpoena for Belfast Project](#)

Boston College has been served with [a new subpoena from British authorities](#) for the tape recordings from the Belfast Project, continuing a legal battle that highlights the often unrecognized risks to participants in social-behavioral research.

The project was a collection of oral histories examining the [“The Troubles”](#), a time of sectarian violence in Northern Ireland, conducted by investigators at Boston College.

### **New** [IRB Office Renovations](#)

The IRB Office is undergoing renovations during the month of May.

Please excuse our appearance during this time.

We will make every effort to maintain our usual timely response during office renovations.

Participants included IRA members during the time of the “The Troubles” who were promised that project records would be released only upon their death. However, authorities in Britain have since subpoenaed the records that may contain information about unprosecuted crimes, particularly the murder of a British informant.

The project was determined to be Non-Human Subjects Research and did not receive IRB review.

### New "Ask the IRB"

**Question:** I'm submitting a study that is similar to one I submitted a while ago. Can I just edit the same IRB submission form that I used with the previous study for this new study?

**Answer:** No, you should go to the [Forms and Templates page of our website](#) to download the most recent version of the submission form. The IRB accepts only the most recent version of the IRB submission forms for new initial submissions and continuing review submissions for previously approved studies.

We update the forms regularly in an effort to collect the information from investigators that is needed for review in the most efficient and convenient way.

### Update IRB Staff Monica Cheng

Monica Cheng, IRB Analyst (amendments/continuing reviews/SRC) will be leaving the institution to pursue a Physician's Assistant degree.

*Congratulations Monica!*

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

### Coming Soon IRB Website Re-launch

The Tufts Health Sciences IRB website is undergoing a redesign with an expected release date in early Summer.

### 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 MC / TUHS IRB website: <http://viceprovost.tufts.edu/HSCIRB/irb-regulations/>

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[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.

