



Summer 2014

Tufts Medical Center / Tufts University Health Sciences IRB News

Welcome to the Summer 2014 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 [Enrolling Subjects with Impaired Decision-Making Capacity](#)

Subjects with impaired decision making capacity are a vulnerable population. If you want to include subjects who are unable to consent for themselves, you need to provide the rationale for this to the IRB.

The IRB needs to specifically review and approve the enrollment of subjects with impaired decision-making capacity for a research study. Please refer to the [IRB operations manual](#) for more information about enrolling this subject population.

Tip [Enrolling Non-English Speakers and Short Form Checklist](#)

If you plan to enroll non-English speakers into your study, you need to use either a fully translated IRB approved consent, or an IRB approved [short form](#).

When using a short form to enroll a non-English speaker, consider printing the [Short Form Quick Reference Checklist](#), which will walk you through each step to properly enroll non-English speakers.

New [Form VII](#)

Form VII has been revised to gather more complete and accurate information about medical record/chart/database review studies. The form has also been re-formatted so it is easier to complete.

Research News at Tufts [What's it Like to be an IRB Member?](#)

The Office of the Vice Provost of Research interviewed IRB members in an effort to shed light on the processes of the IRB and members' experiences.

New [Site-Specific Appendix](#)

The Site-Specific Appendix has been revised with updated payment and adverse event reporting sections.

New [Amendment Information Page](#)

Please take a look at the IRB's new web page that explains how to submit an amendment. Consider using the optional letter templates when you submit your next amendment.

Would you like to learn how to write consents at an 8th grade reading level?

Program for Readability in Science & Medicine (PRISM) Training

Take this free [online PRISM training course](#) to learn how to improve the readability of consent forms and other participant materials.

Please complete the [Annual IRB Satisfaction Survey](#)

Please take a few minutes to complete our survey about your experience with the IRB over the last year.

Feel free to include your ideas for future issues of IRB News!

We appreciate your feedback!

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/>

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.

