Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Winter 2015 Tufts Medical Center / Tufts University Health Sciences IRB News

Welcome to the Winter 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 Good Clinical Practices and ICH (GCP) Basic Course Now Available on CITI

To access the GCP course:

- Select "Add a Course or Update Learner Groups" after logging into your CITI account.
- Indicate YES to Question #3, "Would you like to take the GCP - Basic Course?"

The GCP course is **not a substitute** for completing Tufts Human Subjects Protection Education requirements. It is additional, optional education for study personnel engaged in executing a drug, device, biologic and/or behavioral intervention research study.

If you are required to complete GCP training for a sponsored research study, **please confirm with the Sponsor** that CITI's GCP course will fulfill your training requirement.

Reminder Human Subjects Protection Education Requirements

As of January 1, 2015, PIs and all listed study staff were required to complete the revised education requirements in CITI.

All listed research team members must complete either the Biomedical or SBER course **before** new studies, continuing reviews, or amendments can be approved.

CITI certification will be **valid for 4 years**.

For additional information, please visit the Research Education page of our website:

- Step-by-step instructions for registering with CITI and completing the updated requirements
- Frequently Asked Questions

Tip Study Team Personnel Changes

Need to change the PI for a study or add/remove a research team member?

Use the Change in Research Team Cover Sheet Template to notify the IRB of the amendment.

Tip For Investigators Who Use Western IRB (WIRB)

If you are accessing identifiable health information about potential subjects *before* consent, please complete WIRB's HIPAA Partial Waiver Request form so WIRB can grant a partial HIPAA waiver for your study.

Tip How to figure out when your Continuing Review application is due!

Your continuing review application is due on the last business day of the month, 2 months before the study expires. You can find the expiration date on your last approval letter, under "IRB Approval Valid Until."

For example, if your study expires in May 2015 your continuing review application will be due 3/31/15:

IRB Approval Valid Until: 5/1/15 – 5/31/15
Submit Continuing Review by: 3/31/15

Tip Getting Amendments Approved: Part 1

Keep IRB turnaround time in mind when submitting an amendment for review:

- Turnaround time for amendments that can be expedited in the IRB office is typically 7-10 business days.
- Turnaround time is closer to 14-21 days for amendments that require full committee review.

See future Newsletters for additional tips

New Revised Short Forms for Enrolling Non-English Speakers

The IRB approved short forms posted for use have been revised to eliminate the Investigator signature line.

- If the potential subject decides to participate, the English ICF must be signed by the *Investigator* and *witness* (interpreter)
- The short form must be signed by the *subject* and *witness*

To help you remember: Each person will sign the form in the language(s) they understand—subjects sign the short form, investigators sign the English consent form, and interpreters sign both forms.

Please be sure to print the Short Form Quick Reference Checklist to help guide you through the steps for enrolling a non-English speaker using a short form.

New Post Your Study on Tufts Medical Center Clinical Trials Website

If you haven't already posted your study on the Tufts Medical Center Clinical Trials search website, please consider posting it. Posting your study on this site does not require IRB approval, and there is no cost associated with posting Tufts Medical Center studies*. Please download the form and get further information about how to post your study: http://intra/nmresearch/

*Non Tufts Medical Center studies cost $250 to post.

New Assistant IRB Coordinator

Please welcome Jaime Pellerin, the new Assistant IRB coordinator in the IRB office. She will facilitate reviews of minimal risk research and WIRB studies.

Jaime has a BA in Nutritional Science from the University of New Hampshire and previously worked at Spaulding Rehabilitation Center as a Diet Technician.

Visit our website for a complete listing of IRB Office Staff.

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**.

Tufts University

Tufts Medical Center