Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Summer 2016 Tufts Health Sciences IRB News

Welcome to the Summer 2016 edition of Tufts Health Sciences IRB News

Updates and useful information from the IRB office for Investigators, Coordinators, and other members of your research team

★★★New IRB Website Re-Launch! ★★★

We are pleased to announce the release of our newly redesigned Tufts Health Sciences IRB website. By updating our website, we have improved navigation, streamlined menus, and provided easier access to the information you need. No content has been removed from the website.

Please feel free to provide your feedback and suggestions as we strive for continuous improvement irboffice@tuftsmedicalcenter.org.

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Update Revised IRB Forms

The IRB has updated some of our IRB forms. Please use the updated forms for your IRB submissions:

- Form 1 (New Study)
- Form 5 (Continuing Review)
  Note: If Tufts Health Sciences IRB is the IRB of record for an external study site or sites, a Form 5 should be completed and submitted for *each* site.
- Form 6 (Tissue Banking)
  Note: The tissue banking policy and tissue banking informed consent form (ICF) worksheet have also been updated to streamline the information:
  - Tissue Banking Policy
  - Tissue Banking ICF Worksheet
- Form 7 (Retrospective Record / Database / Specimen Review)

New Protocol Template

Check out the revised "Protocol Template" page on the IRB website. The page lists several protocol templates you may use to write a protocol for your research study. The page includes a completely revamped protocol template that can be used for any study as

New Amendment Cover Letter is **REQUIRED**!

The IRB now requires use of the template amendment cover letter for each amendment.

Including this letter with your submission will ensure that all required information is present, which will help the IRB review and approve

well as a link to the FDA and NIH's template for Phase 2 and 3 IND/IDE studies.

your amendment faster.

New FDA Guidance Expanded Access

The FDA has finalized guidance on "expanded access", which includes emergency use of an investigational drug.

The following was released by the FDA:

- Guidance describing Form FDA 3926 (for physicians requesting IND for expanded access)
- Q & As for expanded access to investigational drugs for treatment use
- Guidance about charging for investigational drugs
- Patient and physician fact sheets

Please also refer to the IRB's emergency use page for information about emergency use and expanded access.

New NIH Human Subjects Research Quick Decision Tool

The NIH has released a quick decision tool for investigators to aid in determining whether their research activity is human subjects research.

Although we encourage the use of this tool, please remember that at Tufts Medical Center and Tufts University Health Sciences, it is an institutional requirement for investigators to submit proposed projects to the IRB to receive a formal human subjects determination letter.

Tip Advertisements and Recruitment Material

When creating recruitment material for subjects, it is important to make sure the information is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document or the protocol.

A copy of the *final* version of all recruitment documents should be submitted to the IRB, so the IRB can evaluate the relative size of the type used, color, and other visual effects. For example, statements about payment should not be emphasized (by using a bold type or larger font).

Please see the guidance on our website for more information on direct advertising material for recruitment of study subjects.

Update IRB Staff

Welcome!

Ben Thomas, MPH has joined the IRB staff as the IRB Analyst for continuing reviews and amendments working with the IRB-BLUE committee.

Jon Delgado, JD has joined the IRB staff as the IRB Analyst for continuing reviews and amendments working with the IRB-RED committee.

Congratulations!

Congratulations to Anya Barytol, MA our new Assistant IRB Coordinator, and Jaime Pellerin, our new IRB Coordinator for Minimal Risk Research.

Feel free to contact Anya or Jaime with any questions about minimal risk research.

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 Health Sciences 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

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