Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Summer 2017 Tufts Health Sciences IRB News

Welcome to the Summer 2017 edition of Tufts MC / TUHS IRB News

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

Update Tufts Health Sciences IRB Undergoes Not-For-Cause FDA Inspection

The U.S. Food and Drug Administration (FDA) conducted a not-for-cause inspection of the Boston Tufts Health Sciences Institutional Review Board (IRB) and IRB office from June 22nd to June 26th, 2017.

The FDA spent 3 days assiduously reviewing studies, IRB meeting minutes, and various documents from the last five years. The inspector issued no findings. This is the best possible determination that the FDA could have made, and we're very pleased with, and proud of, the outcome!

Sponsors often ask whether the FDA has issued a 483 with findings to the IRB. Now, thanks to the hard work of our IRB Chair, Vice-Chairs, IRB Members, and IRB Office Staff, you can let sponsors know that the FDA has not issued a 483 to the Tufts Health Sciences IRB in over 10 years!

Update AAHRPP Site Visit

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) conducted a site visit on June 28th and 29th, 2017.

AAHRPP Site Visitors reviewed 36 study files and interviewed 55 members of the Tufts Health Sciences Human Research Protections Program (HRPP), including Investigators, research team members, research administrators, IRB office staff, and IRB members.

The Site Visitors were impressed with the Tufts Health Sciences HRPP's strong and committed human research protection program, noting the culture of collaboration.

Our sincere thanks to all of you for helping to make our AAHRPP site visit a success!

Tip NIH Policy Changes

NIH has made policy changes to improve the stewardship of NIH funded clinical trials. NIH expanded its definition of clinical trial to include any prospective study investigating a

Update Form 5 (Continuing Review form)

The Form 5 has been revised to provide guidance that the cover letter for continuing reviews should indicate which documents being submitted are:

health-related biomedical or behavioral intervention, which may include placebo or other controls.

Read more about the changes here: Clinical Trial Requirements for Grants & Contracts

These changes include:

- Good Clinical Practice (GCP) Training for NIH funded Clinical Trials
- Clinical Trial Specific Funding Opportunities
- Single IRB Policy for Multi-site Research
- Clinicaltrials.gov Registration & Reporting

- New Documents
- Revised Previously Approved Documents
- Unchanged Previously Approved Documents

The name and version of each listed document should match the name and version on the document itself.

Tip Record Retention

Before submitting your study documents to the IRB office, you must keep the signed copies of *all* of the documents for your study file. This includes forms and cover letters with signatures on them.

A blank form/letter (without signature) for your own study file is not accepted.

Movies with a research theme!

Thanks to **Elizabeth A. Grimm, JD, CHRC,** Supervisor, for Cancer Clinical Trials Neely Center for Clinical Cancer Research for the following excellent movie recommendations concerning clinical research:

- The Doctor - http://a.co/0lv0aGT
- Living Proof (Herceptin/Her2+ Breast Cancer Trials): http://a.co/byrlZtq
- Miss Evers' Boys (Tuskegee): http://a.co/ayaIrgY
- Wit (Stage 4 Ovarian Cancer – High Dose Chemo Trial) - http://a.co/jbpplJU

IRB Staff Update

Ben Thomas, IRB Analyst (amendments/continuing reviews) has left the institution to pursue medical school.

Viktoria (Tori) Zupkofska, IRB Administrative Assistant, has been promoted to the IRB Analyst position.

Congratulations Ben and Tori!

If you'd be interested in joining the IRB, please see the IRB Administrative Assistant posting for more information.

Ask the IRB…

Question: My study is a **retrospective** medical chart review and I am done looking at records for it. Should I list it as closed to enrollment on the Form 5?

Answer: No, a **retrospective** medical chart review should not be listed as "closed to enrollment" on a Form 5, because it would not have actually enrolled subjects with an informed consent form. Instead, please check off the medical chart review/secondary analysis section of the Form 5, and continue to submit a Form 7 for the continuing review until you complete the study and close it with the IRB.

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