



Spring 2017

Tufts Health Sciences IRB News

Welcome to the Spring 2017 edition of Tufts Health Sciences IRB News
Updates and useful information from the IRB office for Investigators, Study Coordinators,
and other research team members

Update AAHRPP Site Visit

The institution is in the process of applying for [accreditation](#) from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The next step in the process is our site visit, where AAHRPP site visitors will evaluate our human research protection program's performance.

Our AAHRPP site visit will take place on Wednesday, June 28th & Thursday, June 29th

As Principal Investigator or member of the research team, you may be selected to be interviewed during the on-site evaluation. AAHRPP will provide a list of individuals selected in late May/early June. If you are selected, we will provide you with additional information.

In the meantime, visit our [AAHRPP Site Visit Website](#) page for more information on how to prepare and sample interview questions.



Update GCP Update

[NIH announced](#) that, effective January 1, 2017, NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP).

GCP training is required for all NIH funded studies that meet the NIH's definition of [clinical trial](#).

As of May 1, 2017, IRB approval for new studies and continuing review will not be granted for NIH funded clinical trials until the PI certifies completion of GCP training for the PI and research team.

As of 01 January 2018, GCP training will be required for *all* clinical trials (all studies that meet the NIH definition of [clinical trial](#)) regardless of funding source.

Acceptable GCP training includes:

- [CITI GCP training](#)
(Note: CITI expects to add a GCP course for Social Behavioral research in June)
- Any other GCP training approved by "[TransCelerate](#)", a mutual recognition program for GCP training.

The PI is responsible for compliance with GCP training, and documentation of GCP training for each research team member must be retained in your study files.

New ClinicalTrials.gov Form

New Federal Regulations regarding **clinicaltrials.gov** went into effect on April 18, 2017.

In order to ensure compliance, a new [ClinicalTrials.gov](http://www.clinicaltrials.gov) form is now **required** at time of IRB submission for all new studies that utilize an informed consent form. This new form, which will ensure your study is reviewed to evaluate whether posting is required, can be found at:

<http://viceprovost.tufts.edu/HSCIRB/files/clinicaltrials.gov-form.docx>.

If you have any questions about clinicaltrials.gov or how to register a study, please contact:

Tufts Medical Center
Meghan Coughlin
mcoughlin@tuftsmedicalcenter.org

Tufts University Health Sciences
Kirby Johnson
kirby.johnson@tufts.edu

New Tufts Medical Center [Clinical Trials Website](#) Posting Requirement

Tufts Medical Center Research Administration now requires all studies that utilize a consent form & enroll subjects at Tufts Medical Center to be posted on the clinical research recruitment website.

A [Clinical Research Recruitment Website Form](#) must be submitted to the IRB at the time of initial IRB submission and with each continuing review submission. The form can be found at:

<http://viceprovost.tufts.edu/HSCIRB/files/clinical-research-recruitment-website.docx>.

Please keep in mind that the audience for this posting is the general public.

(If you are a Tufts University Health Sciences Investigator, posting your study on this website is optional.)

New QA/QI Audits

In order to attain AAHRPP accreditation, we have implemented a Quality Assurance/Quality Improvement (QA/QI) program. The IRB office will conduct audits of Investigators' study files. The studies are randomly selected using an algorithm. In addition to helping fulfill AAHRPP requirements, we hope these audits will be beneficial to PIs and research teams because they will help ensure your study files are complete and compliant with the regulations.

Please refer to the [IRB website](#) for tips for being prepared for an audit. We have posted the checklists we use during these audits [File Review Checklist](#) and a [Participant File Checklist](#) that you can use as self-audit tools for your study files.

If selected, you will be notified by IRB staff before the audit with instructions on how to prepare.

Tip Recruitment & Subject Materials

As a reminder, all material that are seen or given to subjects must be submitted to the IRB for review. This includes any emails sent to them, study information sheets, surveys, focus group guides, verbal screening scripts, etc. The plan for using subject materials should be detailed in the Protocol (when, where and how they are used).

Please be sure to "title" each participant document in the header or footer and provide a version date. This is important to ensure that the IRB appropriately references these materials as approved on the IRB approval letter.

Tip How to locate the current package insert for a drug

If your research study includes the use of a study drug, be sure to submit the most recent version of the package insert with your initial and continuing review submissions.

Bookmark this helpful link to the FDA database of approved drug products to locate current drug labeling - package inserts: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>

Tip Are you an IRB Expert?

Did you know?

If you are submitting study modifications to the IRB, the [Amendment Cover Letter](#) must be included with your submission?

The [Amendment Cover Letter](#) is a **required** cover letter template that includes the necessary information to help the IRB review and approve your modifications in a timely manner.

Tip Tips from a Clinical Research Coordinator
Follow these steps to help ensure appropriate re-consenting of subjects!

- 1) Always check your IRB approval letter to see if subjects need to be re-consented. If you use a checklist for processing approvals, consider including this as something to check.
- 2) Send a notification e-mail about the need to re-consent to the whole team, including the PI, Co-Is, nurses, etc. Add information in large bold letters that says which subjects (e.g., all subjects vs. only those on active intervention) must be re-consented and when (e.g., ASAP or at their next scheduled clinic visit). Include a summary of what the changes entail (updates to risks, new visits/procedures/drugs, etc.) in the e-mail.
- 3) If an Outlook calendar reminder is used to let the research team know the next time the subject is due to be in clinic, make sure the reminder includes the need to re-consent the subject.
- 4) If the subject comes infrequently and their visit is a few months after IRB approval of the updated ICF, it is helpful for the PI and research team to review the most recently approved ICF with the tracked changes to refresh their memory about what changes were made.

This tip is courtesy of Elizabeth Grimm, JD, CHRC, Supervisor of Cancer Clinical Trials in the Neely Center for Clinical Cancer Research.

Would you like to share a tip with other Investigators or research team members? If so, e-mail IRBOffice@tuftsmedicalcenter.org with the subject line "IRB Newsletter Tips"

Tip Are you conducting a quality improvement (QI) project?

Quality assurance/quality improvement initiatives:

- Are intended to improve or assess internal practices, programs, or systems and
- Are not designed to contribute to generalizable knowledge*

*Generalizable knowledge is not explicitly defined by HHS but is understood to refer to information that is intended to be applied outside of the program, process or system being studied.

If you plan to conduct a quality improvement project, please submit a cover letter to the IRB describing the following:

- Dissemination goals
- Generalizability of the data or results
- Intent of the project
- Funding source
- Letter of support from the organization you are working with

Some QI activities have both a research and QI goal and Human Subjects Research regulations may apply. Refer to [Quality Improvement Activities FAQs](#) for more information.

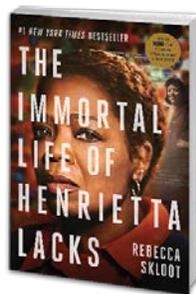
If you are not sure if the proposed project is a quality improvement project, contact the [IRB Office](#) to discuss your project.

Human Subjects Research Issues in the Movies!

HBO has produced a [television film](#) based on Rebecca Skloot's [book](#) *The Immortal Life of Henrietta Lacks*, which documents the story of a woman who was diagnosed with cervical cancer in the 1950's. Her cancer cells (later known as HeLa) would change the course of cancer treatment.

The story brings up important bioethical issues since neither Lacks nor her family gave her physicians permission to harvest her cells, nor were they aware at the time how the cells would be used for medical research and commercial purposes.

The film stars Oprah Winfrey and Rose Byrne and can be watched on HBOGo and OnDemand.



Ask the IRB...

Question: When do I need to submit a copy of the grant with my IRB submission?

Answer: At continuing review and when there is a federal award where Tufts Medical Center or Tufts University is receiving direct federal funding.



Question: How do I ensure the quickest turnaround time for a new study submission to the IRB?

Answer: Follow the tips from this IRB Tip Sheet: [Tip sheet: Responding to IRB comments](#)



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.