Tip Sheet: For those New to the IRB Process

Welcome to the Tufts Health Sciences IRB Office!

What is an IRB?

An Institutional Review Board (IRB) is a federally-mandated panel of Tufts' faculty, staff, and community members that review all human subject research to protect the safety and welfare of research participants. The IRB helps to ensure that any research study under its jurisdiction is in compliance with federal, state, and institutional regulations. Only the IRB has the authority to approve human subject research.

The Tufts Health Sciences IRB is committed to helping promote research among students, faculty, and staff at Tufts Medical Center and Tufts University. Please contact us with questions about IRB proposals, IRB submissions and forms, and your ongoing research studies.

What do IRB Office staff members do?

IRB Office staff pre-review submissions, coordinate convened IRB meetings, provide guidance to Investigators and research team members, and act as liaisons between the IRB Reviewers and the research community.
The Tufts Health Sciences IRB Office staff has expertise in IRB administration, many years of experience, and we're here to help you!

When should I call the IRB Office?

Anytime! *Call the IRB Office ext. **6-7512** with any questions!*

- *Always* call about urgent items: An urgent issue or urgent deadline request
- A "Just in Time" IRB review request for a grant funded project
- Issues or potential issues with participants
- Reportable New Information *(things you need to report to the IRB right away)*
- Which forms to submit
- Questions about how to complete IRB forms
- Questions about policies, procedures, regulations, drugs, devices, etc.

What is the Institutional Scientific Review Committee (SRC), and which studies are reviewed by the SRC?

The SRC reviews all greater than minimal risk studies without documented prior scientific peer review to ensure that they meet an acceptable standard of scientific rigor and merit *prior* to IRB review. Generally, SRC review applies to single-site investigator-initiated studies. SRC review is separate from IRB review and occurs before the IRB review.

Things to Remember:

1. The IRB website contains important information about the IRB review process, policies, meeting dates and deadlines, forms and templates, staff contact information, and more!
    - Investigator Manual
    - Post Approval Responsibilities
    - Submitting New Studies
    - Submitting Continuing reviews
    - IRB Meeting Dates & Deadlines (this applies to greater than minimal risk studies)
    - Continuing Review Deadlines
    - Tip Sheet: How to Respond to IRB Comments
    - Inspection/Audit Tips
    - Information for Research Participants
    - Policies
    - FAQs

2. Helpful checklists & worksheets:
    - International Research Checklist
    - Short Form Reference Checklist (when enrolling non-English speaking participants)

- Informed Consent Checklist (when drafting the consent for your study)
- Tissue Banking Worksheet (banking specimens for future use that is not specified in your current study)
- File Review Checklist & Participant File Checklist (to conduct self-audits of your study files)
- Departing PI Checklist (when a PI is leaving the institution, to ensure their research is closed our or transferred appropriately)

3. Be sure to check out the following for updates, tips, and deadlines:
   - Quarterly Newsletters (e-mail IRBOffice@tuftsmedicalcenter.org to be added to our e-mail distribution list)
     IRB Twitter Page Follow us on Twitter @TuftsMCTUHS_IRB

We welcome and encourage you to contact the IRB Office with any questions at (617) 636-7512