

## Protocol Application Process

All protocol submissions require the following forms:

1. IRB Protocol Cover Sheet with signature/s
2. IRB Protocol Application *or* Application for Exempt Status

### When applicable:

- Additional study material (i.e. recruiting materials, consent forms, questionnaires, debriefing statements etc.)
- Additional material that the IRB committee will need to review the protocol (i.e. thesis proposal, background information on research topic, explanation of unique circumstances)

The required IRB forms can be found at:

[www.tufts.edu/central/research/IRB/Forms.htm](http://www.tufts.edu/central/research/IRB/Forms.htm)

### Informed Consent

Guidance on the informed consent process and examples of informed consent can be found at:

[www.tufts.edu/central/research/IRB/InformedConsent.htm](http://www.tufts.edu/central/research/IRB/InformedConsent.htm)

### Educational Requirement

Prior to submitting for Exempt, Expedited or Full Review, researchers **must** complete an on-line educational tutorial and test. All investigators (faculty, research staff & assistants, students, and faculty advisors) are required to complete the Collaborative IRB Training Initiative (CITI) program.

The CITI program can be found at:

[www.tufts.edu/central/research/IRB/citi.htm](http://www.tufts.edu/central/research/IRB/citi.htm)

When all requirements are completed, a Course Completion Report will be sent to the IRB office. Be sure to print a copy for your records. The certificate is valid for 5 years.

## Requirements for Approval of Human Subject Research

The Code of Federal Regulations outlines the procedure and the standards for review of protocols. The core factors to consider for all human subject research are:

- Risks to subjects are minimized;
- Risks to subjects are reasonable in relation to anticipated benefits;
- Selection of subjects is equitable;
- Informed consent is adequate and appropriately documented;
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
- Appropriate safeguards have been included to protect vulnerable subjects.

### Further Information Regarding Human Subject Research Policy

- Code of Federal Regulations [www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)
- Office of Human Research Protection [www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/)

**Tufts SBER IRB Website:**  
<http://www.tufts.edu/central/research/IRB>



## Social, Behavioral & Educational Research

# Institutional Review Board

## (SBER IRB) Medford Campus

Contact the staff at the SBER IRB Administration Office for assistance in navigating the approval process prior to conducting human subject research.

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## What is the IRB?

The IRB is a committee of Tufts faculty and staff, and at least one individual outside the Tufts University community that reviews all human subject research protocols. The purpose of the IRB is to protect the rights of human participants. The composition of the committee and the approval process are dictated by the US Department of Health and Human Services; specifically the Office for Human Research Protections (OHRP): [www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/)

## What Must Be Reviewed?

To determine if it is necessary to submit to the IRB, there are 2 important questions that must be addressed:

### 1. Is it research?

According to Code of Federal Regulations 45 CFR 46.102(d), research is defined as, "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

### 2. Are there human subjects involved?

The Code of Federal Regulations 45 CFR 46.102(f) defines a human subject as, "a living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention, or interaction with the individual, or
2. Identifiable private information".

Any research that does not meet **both** of these criteria is excluded from review by the IRB. If you are not sure, please contact the IRB Administrator for guidance.

## Types of Review

The type (level) of review is largely (although not exclusively) dependent on the level of risk that the research poses to participants. The three types of review, as defined by OHRP in order of increasing levels of risk are:

### Exempt Review

Your research *may* qualify for Exemption from review if it poses no more than minimal risk to participants. To view the list of six acceptable categories to determine if your research meets the criteria for Exempt Review please refer to: [www.tufts.edu/central/research/IRB/Exemption.htm](http://www.tufts.edu/central/research/IRB/Exemption.htm)

### Expedited Review

If your research does not qualify for Exemption, yet poses only minimal risk to participants, it may qualify for an Expedited Review. This means that only a select number of committee members review your protocol. To view the list of acceptable categories and to determine if your research meets the criteria for Expedited Review please refer to: [www.tufts.edu/central/research/IRB/ExpeditedReview.htm](http://www.tufts.edu/central/research/IRB/ExpeditedReview.htm)

### Full IRB Review

If your protocol poses greater than minimal risk to participants then it *must* be reviewed during a convened IRB committee meeting. The committee meets once a month (September – July) according to the schedule on the following page. There are strict submission deadlines for protocols requiring Full IRB Review. Please refer to the schedule and ensure that protocols are submitted before 1PM on the due date.

## Submission Deadlines

### Exempt & Expedited Review Submission

These protocols are processed on a rolling basis so there are no specific submission deadlines. Please allow a minimum of one week for Exempt Review and a minimum of two weeks for Expedited Review before receiving **initial** feedback from the office of the IRB. Allow additional time for requested changes to be submitted and reviewed before final approval is granted. **Research CANNOT begin before final approval is granted.**

### Full IRB Review Submission

For all protocols that require **Full IRB Review**, the submission deadlines (2 weeks before the meeting) are listed below. In order to ensure your protocol is given appropriate consideration, **all** materials must be submitted with your application by **1PM** on the dates indicated.

Submission Deadline	SBER IRB Meeting Date
September 7, 2011	September 21, 2011
October 5, 2011	October 19, 2011
November 2, 2011	November 16, 2011
November 30, 2011	December 14, 2011
January 11, 2012	January 25, 2012
February 1, 2012	February 15, 2012
February 29, 2012	March 14, 2012
March 21, 2012	April 4, 2012
April 11, 2012	April 25, 2011
May 2, 2012	May 16, 2012
May 30, 2012	June 13, 2012
July 5, 2012	July 18, 2012
August 2011 no meeting **	

\*\* Note: Because there is no August meeting, appropriate planning for summer research and/or application for continuing review is essential.