Tufts Medical Center (Tufts MC) and Tufts University Health Sciences (TUHS) IRB
Western IRB (WIRB) Submission Policy

Policy/Procedure

Phase II (IIa, IIb, or II), III, or IV protocols undertaken at Tufts MC/TUHS may be eligible for submission to WIRB for review and approval. A Principal Investigator may choose to submit such a study to either the Tufts MC/TUHS IRB or WIRB; there is no obligation to use WIRB. Only industry (for-profit) sponsored or non-federally funded foundation sponsored, multi-centered, sponsor initiated (defined as sponsor created, designed, and developed) studies are eligible for WIRB review. WIRB review would be in place of IRB review performed by the convened Tufts MC/TUHS IRB.

A research study may only be reviewed by the Tufts MC/TUHS IRB or WIRB, not both. It is not permissible for an investigator to submit a study not approved by one IRB to the other IRB. In addition, it is not permissible for a study to be submitted to both the Tufts MC/TUHS IRB and WIRB, with the intent of withdrawing the submission from the other IRB.

If the study involves a test article that has been issued an IND or IDE number, the IND or IDE number must be issued to the sponsor of the study and not an investigator. If a determination must be made by the IRB regarding the need for an IND or IDE for a test article (21 CFR 312 or 21 CFR 812) the study will not be eligible for WIRB review. Arrangements for sub-sites under a Tufts MC or TUHS primary site are the responsibility of the Principal Investigator to pursue separately with WIRB, independent of his/her relationship with Tufts MC or TUHS. The institutions reserve the right to deny any study submission to WIRB.

The details of this policy and the attendant procedures apply to each study a Principal Investigator intends to submit to WIRB.

Before submitting a study to WIRB, Principal Investigators are required to submit documents to the Tufts MC/TUHS IRB office electronically, on a flash drive or CD, so that it may be verified that the study is eligible for WIRB review. Hard copy submissions or documents sent via electronic mail will not be accepted. Among the documents to be submitted electronically are the completed and Principal Investigator signed Tufts MC/TUHS WIRB submission form (Form VIII), a complete copy of the sponsor’s protocol including appendices and supplemental documents, a signed institutional Conflict of Interest form from the Principal Investigator (each research team member must complete a research COI form; the Principal Investigator is to submit his or her signed COI form along with the COI form of any research team member(s) with “YES” responses on their completed COI form), the sponsor’s template informed consent form, and signed approval information from all required institutional committees, e.g., radiation safety committee. Each document should be scanned and saved separately. The Principal Investigator is to retain all original signed Forms, letters, etc., in his/her study file. Documents requiring the Principal Investigator signature that have been signed by someone other than the Principal Investigator will be returned to the Principal Investigator.
The designated IRB office staff person will forward the protocol and informed consent form to the Tufts MC Office of Clinical Research Administration (OCRA) for review of the research-related injury language.

In addition, the IRB office staff person will forward submitted documents to the pharmacy for pharmacy review.

The Principal Investigator assumes responsibility for the accuracy of information submitted on Form VIII. The IRB office will perform a pre-screen of the information submitted by the Principal Investigator. Documents requiring the Principal Investigator’s signature that have been signed by someone other than the Principal Investigator will be returned to the Principal Investigator. Applications submitted with missing, inaccurate, or inconsistent information will also be returned to the Principal Investigator; a returned submission may invalidate the study’s eligibility for WIRB review. A submission that proceeds to WIRB with inaccurate information may invalidate the study’s eligibility for WIRB review.

The designated IRB office staff person will perform a pre-screen of the submitted documents related to criteria for submission to WIRB and to verify that all required institutional committee approvals have been received. S/he will include any Tufts MC / TUHS institutional committee review comments as an appendix to Form VIII. In addition, the OCRA will confirm research-related injury language is acceptable and is in accordance with the contract language. S/he will print and sign the Form VIII and send a scanned signed copy of Form VIII to the PI and the designated person in the OCRA. The original Form VIII signed by the IRB office staff person will be retained in the IRB office.

After the Principal Investigator receives the signed Form VIII for the study, the Principal Investigator may submit the application directly to WIRB via the WIRB website or as hard copy documents. The Principal Investigator and research team members are to communicate directly with WIRB and submit all future study-related documents (e.g., changes among research team members, advertisements, amendments/revisions, continuing review, AEs/SAEs, unanticipated events, protocol deviations/violations, non-compliance,) directly to WIRB without submitting copies to Tufts MC/TUHS IRB office. All Tufts MC/TUHS institutional policies pertaining to the institutional informed consent form (ICF) format (including the template Introduction), research-related record retention, consent procedures, COI, SAE reporting, the HIPAA research authorization form, institutional inspection/monitoring, research education, etc., apply to studies submitted to WIRB for review. Please note: ICF templates for Tufts MC/TUHS have been sent to WIRB; the institutional ICF Participant’s Statement is not a required component of the ICF for WIRB studies. Researchers are reminded to retain a copy of all correspondence with the Tufts MC/TUHS IRB and/or WIRB in their study files.

**WIRB Submission Process**

The Principal Investigator (PI) must certify that s/he has read and understands the internal WIRB process and requirements and has reviewed them with the research team; this is documented by signing the Tufts MC/TUHS Form VIII. Original signature documents are to be retained by the PI and a scanned copy of each signed document is to be submitted to the IRB office, as described below.

For each study, the following documents are to be submitted to the Tufts MC/TUHS IRB office electronically, on a flash drive or CD, preferably in Portable Document Format (PDF). Each document
should be scanned and saved separately. The CD or CD case is to be labeled with the PI’s name, telephone number, protocol number, and the study sponsor:

1. A completed Form VIII signed by the PI and Department Chair/Division Chief, as appropriate. Every field in Form VIII must be completed; incomplete forms will be returned to the PI and will result in delays. Responses are not to refer to other documents.

2. A copy of the complete study protocol, including any appendices and supplemental documents, as provided by the sponsor.

3. A copy of the sponsor’s template informed consent form (ICF) with Tufts MC introductory language and Radiation Safety Officer recommended language, if applicable, included.

4. If a drug/biologic/substance (including placebo) is involved in the study: Completed and PI-signed Form II(s), including a copy of the Investigator’s Brochure, package insert, MSDS, etc.

5. If a device is involved in the study: Completed and PI-signed Form III(s), including a copy of the test article Operator/User Manual, device specifications, etc.

6. A signed institutional Research Conflict of Interest form from the PI. Each research team member must complete the research COI form, and the PI is to submit his or her signed COI form along with the COI form of any research team member(s) with “YES” responses on their completed COI form.

7. Documentation of approval (as required) from each required institutional committee (see below).

Please ensure documents are not password protected or please provide access passwords. E-mailed or paper documents will not be accepted. It is not required that the WIRB application be submitted to the IRB. Documents requiring the PI’s signature that have been signed by someone other than the PI will be returned to the PI.

Scanners and CD drives with write capability are available in the IRB office, if needed. Please call the main IRB office (ext. 6-7512) if access to these resources is needed.

**Institutional Committee Reviews**

As with all studies submitted to the Tufts MC/TUHS IRB, approval from the required applicable institutional committees must be obtained by the PI prior to submission of the application to the IRB office.

Institutional committees include:

1. **Radiation Safety Committee (RSC):** Approval is required if the study involves research-related ionizing radiation exposure. If subjects will be exposed to ionizing radiation as a result of study participation, a Form IV is to be submitted to the RSC. After review and approval from the RSC, the original Radiation Safety Officer (RSO) signed Form IV will be provided to the PI as confirmation of approval. The PI is to scan the signed Form IV and submit it as noted above. The PI is to retain the original signed Form IV in his/her study file.
If the study involves exposure to ionizing radiation; however, in the PI’s assessment the exposure is part of standard care, the PI is to send a copy of the protocol and template ICF to the RSO, who will either confirm the PI’s assessment or will request a Form IV. If a Form IV is required, the instructions above are to be followed. If the RSO confirms the PI’s assessment, a copy of the RSO’s letter or e-mail confirmation is to be scanned and submitted on the CD. The PI is to retain the original signed letter from the RSO in his/her study file.

2. Institutional Biosafety Committee (IBC): Approval is required if the study involves biohazardous materials that include pathogenic microorganisms, infectious materials, biological toxins, recombinant DNA, and select agents. After review and approval from the IBC, an original signed letter will be provided to the PI by the IBC as confirmation of approval. The PI is to scan the signed approval letter and submit it as noted above. The PI is to retain the original signed letter from the IBC in his/her study file.

Pharmacy: If the study involves drugs, substances (including placebo), or biologics, a Form II is to be submitted for each drug/substance/biologic administered as part of the study, including required attendant drug/substance/biologic information (e.g., Investigator's Brochure, package insert, MSDS). The IRB office will facilitate the Pharmacy review for the PI. The PI is to retain the original signed Form II(s) in his/her study file. Documents requiring the PI’s signature that have been signed by someone other than the PI will be returned to the PI.

Upon review and acceptance of the submission, an IRB office staff person will e-mail the Form VIII to the PI with an IRB office staff member’s signature.

WIRB Submission

Please note the following regarding your submission to WIRB:

- WIRB will not accept an application from Tufts MC/TUHS without a Form VIII signed by the PI, Department Chair/Division Chief, and IRB office staff person.
- Submit a HIPAA Research Authorization Form (RAF), if applicable.
- The WIRB application asks, “Does this site have an obligation to use another IRB?” This refers to the Tufts site having an obligation to any IRB other than the Tufts MC / TUHS IRB.

WIRB applications may be downloaded from the WIRB website: [http://www.wirb.com](http://www.wirb.com)

WIRB has a shorter submission form for those studies that have previously been reviewed by WIRB for other sites. The PI or a research team member is to contact WIRB directly to ascertain whether the short form is allowable: 1-800-562-4789 or clientservices@wirb.com. Care should be taken to submit the correct form, as submitting the short form when the study has not been previously reviewed will lead to delay and extra effort.

All questions regarding completion of WIRB forms are to be addressed directly to WIRB by the PI or his/her research team.

WIRB will acknowledge receipt of the submission by email to the PI and the designated IRB office staff person. WIRB will provide a tracking number to follow the progress of the submission.
WIRB may ask questions of the PI with regard to the submission. The PI or his/her designee is to address these questions directly with WIRB. The responses to these questions are not to be directed to the Tufts MC/TUHS IRB office.

If WIRB approval is granted, the PI and research team members are to communicate directly with WIRB regarding the study and are to submit all future documents (e.g., changes among research team members, advertisements, amendments/revisions, continuing review, AEs/SAEs, unanticipated events, protocol deviations/violations, non-compliance,) directly to WIRB for review/approval without submitting copies to the Tufts MC/TUHS IRB office.

WIRB will send all approvals to the PI. The designated Tufts MC/TUHS IRB office staff person will be copied on the following by WIRB:

- Initial Approval
- Continuing Review Approval
- SAE review
- Safety report review

WIRB will also notify the designated Tufts IRB office staff person of any non-compliance findings. Non-compliance will be reviewed by the Tufts MC/TUHS IRB according to the institutional IRB Operations Manual. Determination to notify the Office of Human Research Protection (OHRP), US Food and Drug Administration (FDA), etc., and notification to federal agencies will be addressed by Tufts MC/TUHS according to IRB policy.

WIRB will send an invoice for services rendered directly to the study sponsor. If information is needed regarding the appropriate sponsor contact for the invoice, please contact the OCRA.

WIRB invoices that are not paid by the sponsor within sixty (60) days will become the responsibility of the PI’s department/division.

The following are to be submitted to WIRB for initial review of a research study:

- Signed copy of Form VIII, as noted above.
- WIRB Initial Review Submission Form
- Protocol*
- Current professional license for the PI, showing the expiration date*
- Curriculum Vitae (CV) for the PI and each Co-Investigator*
- ICF, including the Tufts MC/TUHS institutional Introduction language.
- HIPAA RAF
- Other materials to be provided to subjects that are not included in the protocol, including advertisements, contact letters, informational brochures, questionnaires, subject diaries, etc.

* Any commercially available validated instruments cited in the protocol that are used without modification are not listed individually on the Certificate of Approval; however, approval of the protocol does extend to the uses of such industry standard forms as described in the approved protocol.
For studies involving a drug, substance, or biologic provide a copy of each of the following to WIRB:

- Investigator's Drug Brochure†
- Background Information for Food Supplements†
- FDA Form 1572 (if applicable)
- Documentation from the sponsor or FDA verifying the IND #, if one is required for the research†
- IBC approval information, if applicable.
- Current Massachusetts Controlled Substances Registration

For studies involving a device, provide a copy of the Operator/User Manual and one of the following:

- Copy of the letter from the FDA granting the IDE† OR
- A letter from the sponsor confirming that the study is a non-significant risk device study as defined by the FDA;† OR
- A letter from the sponsor explaining why the investigation is exempt from the IDE requirements under 21CFR 812.2(c) or otherwise exempt. †

† Materials may be omitted if WIRB is already in receipt of a current version. This may include recruitment and other subject materials.

The following is the current WIRB fee schedule for Tufts MC/TUHS: