**Tufts Health Sciences IRB**

**Checklist: Reviewing your New Study Application before submitting it to the IRB**

The IRB recommends using this checklist to review your new study application before submitting it to the IRB. This will help the IRB to review and approve your study as quickly as possible:

Confirm that all [applicable documents](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/LQS1LUR5G8OKF4J4QRFNHTUN2D/Documents%20and%20Forms%20to%20upload%20to%20eIRB%20030920.docx) are uploaded into [eIRB](https://eirb.tuftsmedicalcenter.org), specifically the following commonly missed documents (please note that missing these documents could prevent a study from being placed on an IRB meeting agenda):

Data and Safety Monitoring Board (DSMB) charter (this might be called the Data and Safety Monitoring Committee (DSMC), Safety Monitoring Committee, etc., and if the protocol, Site-Specific Appendix (SSA), or any other study document mentions any of these, then the charter needs to be included in your submission)

Site-Specific Appendix (for multi-site studies)

Informed Consent Form (ICF)

Confirm the Principal Investigator meets the [Tufts PI Eligibility requirements](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/21PNFU0UK3NKJC8Q86PI61R695/PI%20Eligibility_020119.pdf)

(Fellows, Residents, PhD candidates/students, graduate students, trainees, and other employees or staff members in learning positions are not eligible to serve as the PI)

Review the [eIRB](https://eirb.tuftsmedicalcenter.org) smart form to make sure:

All research team members listed have appointments at / are employed by Tufts Medical Center or Tufts University (if not, call the IRB Office ext. 6-7512 for advice)

Make sure your enrollment goals match what is listed in the ICF and protocol and that they are high enough to account for withdrawals and screen failures.

For drug or device studies make sure to:

Upload the Investigator’s Brochure (for investigational drugs)

Upload the latest version of the package insert (FDA approved drugs). Confirm you are submitting the latest version by downloading it from this website: [FDA Approved Drug Products website](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process).

Upload the Operator’s Manual (device)

Upload the FDA letter that describes the IND (drug) or IDE (device) # (If you do not have this, ask the study Sponsor)

If you think your study drug is IND exempt, confirm that it meets all requirements under **21 CFR 312.2(b)(1)** and explain how “the research does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product”. You can do this by attaching a document to the Drugs page of the [eIRB](https://eirb.tuftsmedicalcenter.org) smart form.

If you think your study device is IDE exempt, specify which IDE criteria it meets. You can do this by adding a comment to eIRB or by attaching a document to the Devices page of the [eIRB](https://eirb.tuftsmedicalcenter.org) smart form. Refer to the [Device Decision Tree](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/I2EISPBUF5S4BF1NAS4A28MGDA/Device%20Decision%20Tree.docx) for the IDE exemption categories.

If you think the study device is a [*Non-significant risk (NSR)*](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)device, upload the FDA or Sponsor’s determination documenting that to the Devices page of the [eIRB](https://eirb.tuftsmedicalcenter.org) smart form.

For Investigator Initiated Studies, review the protocol to make sure:

The Tufts Health Sciences IRB [Protocol Template](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/55G6R9KOEMO4T59EERP27KJP2C/HRP-503%20-%20TEMPLATE%20PROTOCOL_081920.docx) or another protocol template has been used that includes relevant sections. Use the [Protocol Worksheet](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/PRJFG2L6TBNKP97H785SRCJI6E/Protocol%20Worksheet.docx) to confirm all relevant sections are present.

References are included and the references support the study’s hypothesis and risk/benefit assessment.

Review each informed consent form (ICF) to make sure:

The Tufts Health Sciences IRB [ICF Template](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/BLF6CF7PL17KB0IM15ULBI0BE6/HRP-590%20-%20ICF%20Template_HS%20IRB.docx) has been used

Each procedure, test, visit, etc. a subject will undergo is described in the protocol and ICF, and the information is consistent (for example, a procedure described in the ICF must also be described in the protocol, and vice-versa). To assist with this review, compare the *Procedures* sections or *Study Timeline* of the ICF and protocol side-by-side.

All reasonably foreseeable risks from the protocol and Investigator’s Brochure, Operator’s Manual, package insert, etc. are included in the ICF. Include physical, psychological, social, legal, or other risks associated with the research, and information about their likelihood and seriousness.

If your study includes randomization, the risks associated with each study group must be described in the protocol (or Site-Specific Appendix) and ICF.

If your study includes a standard of care control group, describe the standard of care in the protocol (or Site-Specific Appendix) and in the ICF.

If subjects will be asked to change or delay their standard of care (such as restricting regular medication use until after the study), the risks associated with this and the care subjects will receive to minimize these risks must be described in the protocol (or Site-Specific Appendix) and ICF.

Complete an [informed consent checklist](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/HIHLSJAN3MP4B1CQP2LSPD9QAE/HRP-351%20-%20WORKSHEET%20-%20Elements%20of%20Consent%20Checklist_072215.docx) for each ICF to ensure all elements are present.

Complete a [Tissue Banking Worksheet](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/TU05MQ1UTPM4131K434IEUDG71/Tissue-Banking-Worksheet.docx) for each tissue banking consent or section of the main ICF.

For international research studies, complete the [International Research with Human Subjects checklist.](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/4FUMCVJNRQF4T54J3AVET8NU33/International%20Research%20Checklist_071519.docx)

Read the IRB forms, informed consent form (ICF), and protocol to ensure information is consistent throughout all documents in the submission (in particular, carefully review the schedule of procedures to make sure everything is consistent).

Feel free to “Add a Comment” in eIRB to describe any additional information you would like to convey about the study, such as information about the urgency of the submission

Feel free to refer to the [IRB Member Review Forms](https://viceprovost.tufts.edu/reviewer-forms-checklists-worksheets), which are the forms the IRB uses when reviewing studies.

Call the IRB office ext. 6-7512 with any questions. You are welcome to set up an in person meeting or speak with an IRB Administrator over the phone any time you have questions or need assistance!