[eIRB](https://eirb.tuftsmedicalcenter.org/) tip sheet: **Create New Not Human Subjects Research (NHSR) Study** (New Study Submission to Health Sciences IRB)

This worksheet describes the information you will need to submit a new NHSR study in eIRB – you can refer to the Tips column while you are entering your study into eIRB, or you can use this as a worksheet to gather information about your study in one place before you enter it into eIRB.

How to search in the drop down fields: Click on the ellipsis […] and use the percent sign % before and/or after the name you are search for. For example if you are searching for Tufts Medical Center Division of Cardiology, search %Cardiology% or if you are searching for a name, you could search %Laura% or %Potter%.

Questions with a star (\*) are required questions. You will not be able to proceed to the next page if you do not provide your response for these questions.

|  |  |  |
| --- | --- | --- |
| **Field** | **Tips** | **Insert information about your study** |
| Basic Study Information |
| 1. Title of Study
 | Copy/Paste this from the NHSR Form to avoid typos or spelling errors – this is the formal, long title.  |  |
| 1. Short title
 | This is your study nickname – sometimes an acronym or catchy name you use to refer to the study. eIRB will list your study with this title in lists of submissions you can view. Note this short title is how the study will be referred to throughout the system, so make sure it is a title that makes sense in relation to the study. |  |
| 1. Brief Description
 | A brief summary of your study. |  |
| 1. What kind of study is this?
* Multi-site or Collaborative study
* Single-site study
 | **Multi-Site / Collaborative Study:** A study in which two or more institutions coordinate to complete the research activities outlined in the protocol. **Single-Site Study:** A study in which only one institution completes all research activities outlined in a specific protocol. |  |
| 1. Will an external IRB act as the IRB of record for this study?
* Yes
* No
 | Choose “**No**” – Not Human Subjects Research determinations do not require Tufts to cede review to an external IRB.  |  |
| 1. Will your IRB act as the single IRB of record for other participating sites?
* Yes
* No
 | (This question is added if you choose “Multi-site or Collaborative study” for question # 4.)Choose “**No”** – Tufts IRB does not assume oversight for Not Human Subjects Research determinations. Each participating site should get their own IRB determination. |  |
| 1. Local Principal Investigator
 | This is the Tufts PI. Refer to the [PI eligibility policy](https://viceprovost.tufts.edu/principal-investigator-eligibility-policy).  |  |
| 1. Does the local PI have a financial interest related to this research?
* Yes
* No
 | Review the PI’s completed [Research Financial Disclosure form](https://viceprovost.tufts.edu/hs-irb-forms) – if they have a financial interest to disclose, choose Yes. If not, choose “No.”You will be asked to attach this form on the Local Site Documents page.  |  |
| 1. Which IRB should oversee the study?
* HS IRB
* SBER IRB
 | **HS IRB** = Tufts Health Sciences IRB**SBER IRB** = Tufts Social, Behavioral & Educational IRBIf you are at Tufts Medical Center, choose HS IRB. If you are at Tufts University, choose HS IRB if your study is biomedical; choose SBER IRB and switch to the appropriate [SBER Tip Sheet](https://viceprovost.tufts.edu/eirb-tips-sber-irb-studies) if your study is social, behavioral, or educational.  |  |
| 1. Is this study investigator initiated?
* Yes
* No
 | A study is an investigator-initiated study when the study is designed, initiated, and managed by an individual investigator or team of investigators. Generally, the investigator acts as the study sponsor. Funding for an investigator-initiated study may come from a variety of sources including internal funds, external grants, and commercial interests.  |  |
| 1. Is this study a Clinical Trial?
* Yes
* No
 | Choose **“No”** – Clinical Trials are always Human Subjects Research.  |  |
| 1. Is this an Industry Funded, Multicenter, Clinical Trial?
* Yes
* No
 | Choose **“No”** – Clinical Trials are always Human Subjects Research.  |  |
| 1. Is this study a “First in Human” use of the investigational product (drug or device)?
* Yes
* No
 | Choose **“No”** – this refers to a type of Clinical Trial, which is always Human Subjects Research.  |  |
| 1. Is this an Early Feasibility Study (EFS), a limited clinical investigation of a device early in development?
* Yes
* No
 | Choose **“No”** – this refers to a type of Clinical Trial, which is always Human Subjects Research.  |  |
| 1. Specify the phase of the study (or check N/A if study does not have a phase)
 | Choose **“No”** – this refers to the phases of Clinical Trials, which are always Human Subjects Research.  |  |
| 1. Attach the protocol
 | Attach a completed **Not Human Subjects Research (NHSR) Request Form**, found on our website at <https://viceprovost.tufts.edu/hs-irb-forms> This should be in MS Word format.Please **only** attach the NHSR form here – you will have a chance to attach all other study related documents later in the smart form if needed.Once you choose your file, you can specify a name and version number. **IMPORTANT:** The way you name this document is the way it will be referred to in the Approval Letter.  |  |
| Study Funding Sources |
| 1. Identify each organization supplying funding for the study
 | Click on the +Add button, search for the funding organization using the search tips at the top of this page. If the funding organization is not present, fill out the [New\_Edit Sponsor Request Form](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/DBMEIC4V2J4KD2HEGLE8DV5J4C/New%20or%20Edit%20Sponsor%20Request%20Form%20101619.pdf). If your study is not funded, choose your department or division. You can add multiple funding sources for your study. |  |
| Local Study Team Members |
| 1. Identify each additional person involved in the design, conduct, or reporting of the research.
 | Click +Add, search for Tufts study team members, specify their role or roles, specify whether or not they are involved in the consent process, and specify whether or not they have a financial interest related to this research. [If any research team members has a financial interest to disclose, choose “Yes” here, and attach a ***signed*** copy of their form on the Local Site Documents page in category 3: [Research Financial Interest Disclosure forms](https://viceprovost.tufts.edu/hs-irb-forms)]If the Tufts research team member you are looking to add is not listed in eIRB email ResearchIT@tuftsmedicalcenter.org to add this person. Provide ResearchIT with the name, email address, and title (e.g., MD, MA, etc.) of the person you wish to add. |  |
| 1. External team member information
 | There should be no non-Tufts-affiliated team members on the Tufts study team. If any external collaborators are working on the project, they should follow their own institution’s IRB submission requirements. |  |
| Study Scope |
| 1. Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?
 | This should be **“No”** – studies specifying the use of a drug, biologic, or food are always Human Subjects Research. If the answer is Yes, switch to the [Basic New Study Tip Sheet.](https://tufts.box.com/s/226jlw6r9721v5xwbie7lbtzzdhypt6o)  |  |
| 1. Does the study evaluate the safety or effectiveness of a medical device or use a humanitarian use device (HUD)?
 | This should be **“No”** – studies evaluating a medical device are always Human Subjects Research. If the answer is Yes, switch to the [Basic New Study Tip Sheet.](https://tufts.box.com/s/226jlw6r9721v5xwbie7lbtzzdhypt6o) |  |
| Local Research Locations |
| 1. Total number of subjects expected to enroll at Tufts sites:
 | Enter the expected number of participants to be enrolled at Tufts only, accounting for withdrawals. If no subjects are to be enrolled (i.e., receiving de-identified data) enter the total number of people whose data will be included. |  |
| 1. Identify research locations where research activities will be conducted or overseen by the local investigator:
 | Click +Add, and search for Tufts locations. If the location where the Tufts investigator will conduct or oversee research activities is not listed, add the details to the form. |  |
| 1. International Research: Will any of the research activities take place outside the United States? If Yes, please list the country(ies) where the research will take place:
 | Choose “Yes” only if Tufts will be engaged in research at an international site. Be sure to list any international sites when Tufts is the Sponsor, primary grant recipient, or coordinating site. |  |
| 1. [added if you choose “Yes” to 3]

Select the country(ies): | Search for the countries using the search tips above. You can select multiple countries. |  |
| Local Site Documents |
| 1. Consent forms: (include an HHS-approved sample consent document, if applicable)
 | Click +Add and upload the consent documents in Microsoft Word format. **IMPORTANT:** The way you name these documents is the way they will be referred to in the Approval Letter.If you are **prospectively collecting specimens/blood** for the purposes of QA/QI, you must provide project participants with an **Information Sheet**. Use of a consent information sheet is also recommended for other types of QI interactions. You may use this [QA/QI Information Sheet Template](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/6IQBRDQ6B5T434PR1RISCP231E/Template%20Information%20Sheet%20for%20QAQI%20Blood%20Draw%20Project%20043020.docx).Foreign-language versions of materials should be submitted only after English versions are approved.  |  |
| 1. Recruitment materials: (add all material to be seen or heard by subjects, including ads)
 | Click +Add and upload all recruitment material to be seen or heard by subjects, including ads (printed, audio, video) and recruitment materials and scripts. Surveys and other participant-facing materials can be added under #4: Other attachments.Foreign-language versions of materials should be submitted only after English versions are approved.**IMPORTANT:** The way you name these documents is the way they will be referred to in the Approval Letter. |  |
| 1. Research Financial Interest Disclosure forms:
 | Click +Add and upload [Research Financial Interest Disclosure forms](https://viceprovost.tufts.edu/hs-irb-forms).* + - Each member of the study teamshould fill out their own form and sign it. ***Retain all signed forms with your study files.***
		- The Principal Investigator’s**signed** form should be uploaded to this page.
		- If any other study team members has a financial interest to disclose, their **signed** form should be uploaded to this page.
 |  |
| 1. Other attachments:
 | Click +Add and upload other supporting documents, such as: * Evaluation instruments, surveys, and any other participant-facing materials
* Translator Credentials
* [International Checklist](https://viceprovost.tufts.edu/hs-irb-worksheets-checklists)
* Letter(s) of support
* any other materials/[IRB forms](https://viceprovost.tufts.edu/hs-irb-forms) not attached elsewhere.

Choose the appropriate category type for each document. **IMPORTANT:** The way you name these documents is the way they will be referred to in the Approval Letter. |  |
| Study Department/Division |
| Select the Tufts Institutional Department/Division responsible for the oversight of this research (it may differ from the PI's Department/Division): | Tip: Department names start with “TMC” or “TU”For initial study submissions, studies overseen by the Health Sciences IRB require Department/Division Review prior to IRB review. The submission will be routed to the reviewing Department/Division based on the selection above. |  |
| Final Page |
| You have reached the end of the IRB submission form. Read the next steps carefully:1. Click Finish to exit the form.
2. Important! To send the submission for review, click Submit on the next page.
 | Click “Finish.”**IMPORTANT:** Clicking “Finish” does **not** submit the study to the IRB*.* When you are ready to submit, you will click “Submit” on the left menu of the Study Workspace.  |  |
| Study Workspace |
| Left menu | * Here you have the option to “Edit Study” if you need to make further changes before submitting.
* You can also “Assign Primary Contact” (the person who will receive communications along with the PI and can respond to communications about the study).
* You can “Assign PI Proxy” who can do anything the PI can do, including submitting the study, and is authorized to take these actions in the PI’s name.
* You can request “Ancillary Review” if subject-matter expertise is needed as part of the review process. Make sure to select the appropriate TMC- or TU-specific review body.
* You can “Manage Guest List” to give people not on the Study Team access to view the submission. Of note, IRB staff and Members already have access.
* You can “Add a Related Grant” that is affiliated with this IRB submission.
* You can “Add Comment” that will be visible to anyone with access to the submission.
* You can “Copy” or “Discard” the submission.
* You can “Add Reliance Agreements.”
* Finally, you can “View CITI Training” status of all Study Team members.
 |  |
| Submit | If you are creating the submission on behalf of the PI, go to “Add Comment” and send the PI a comment that the submission is ready for their review and submission. The PI will receive an email with the link to the study.When the PI is ready to submit, click “Submit” on the left menu of the Study Workspace.Once you “Submit” the proposal, it will be routed to the study department/division for review. When the department/division reviewer approves the study, the submission status will move to Pre-Review on the Study Workspace diagram. This means the submission has been delivered to the HS IRB for review.  |  |