Welcome to the
Tufts Health Sciences IRB Office!

IRB Orientation for New Researchers and Research Staff

Tufts

Health Sciences IRB

Instructions:

1. Read through these slides and make a note of any questions you have or any topics you would like us to explain further.
2. If you have any time-sensitive questions, contact us at **IRBoffice@tuftsmedicalcenter.org** or **(617) 636-7512**.
3. Once you have an IRB submission to work on (either a new study or a follow-on submission to an existing study), email us at **IRBoffice@tuftsmedicalcenter.org** to set up a Zoom meeting. *If you don't anticipate having a submission to work on soon but would still like to discuss your questions in a Zoom meeting, that is OK too!*
   - ✓Include your availability over the next several business days
   - ✓Let us know what type of submission you're working on (and the specific study, if it's an existing study)

Introduction to the IRB

What is an Institutional Review Board (IRB)?

- Federally-mandated panel of Tufts Medicine & Tufts University faculty, staff, and community members
  - Scientific Members: MDs, RNs, pharmacists, etc.
  - Non-Scientific Members: Other Tufts staff, community members
- Reviews all **human subjects research** to protect the safety and welfare of research participants
- Ensures that any research study under its jurisdiction is in compliance with federal, state, and institutional regulations
- Promotes high-quality, ethical research

What do IRB Office staff members do?

- Pre-review submissions prior to either convened (full committee) IRB meetings or non-committee review
- Coordinate IRB meetings
- Act as liaisons between the IRB Reviewers and the research community
- Provide guidance to research teams – *We're here to help!*

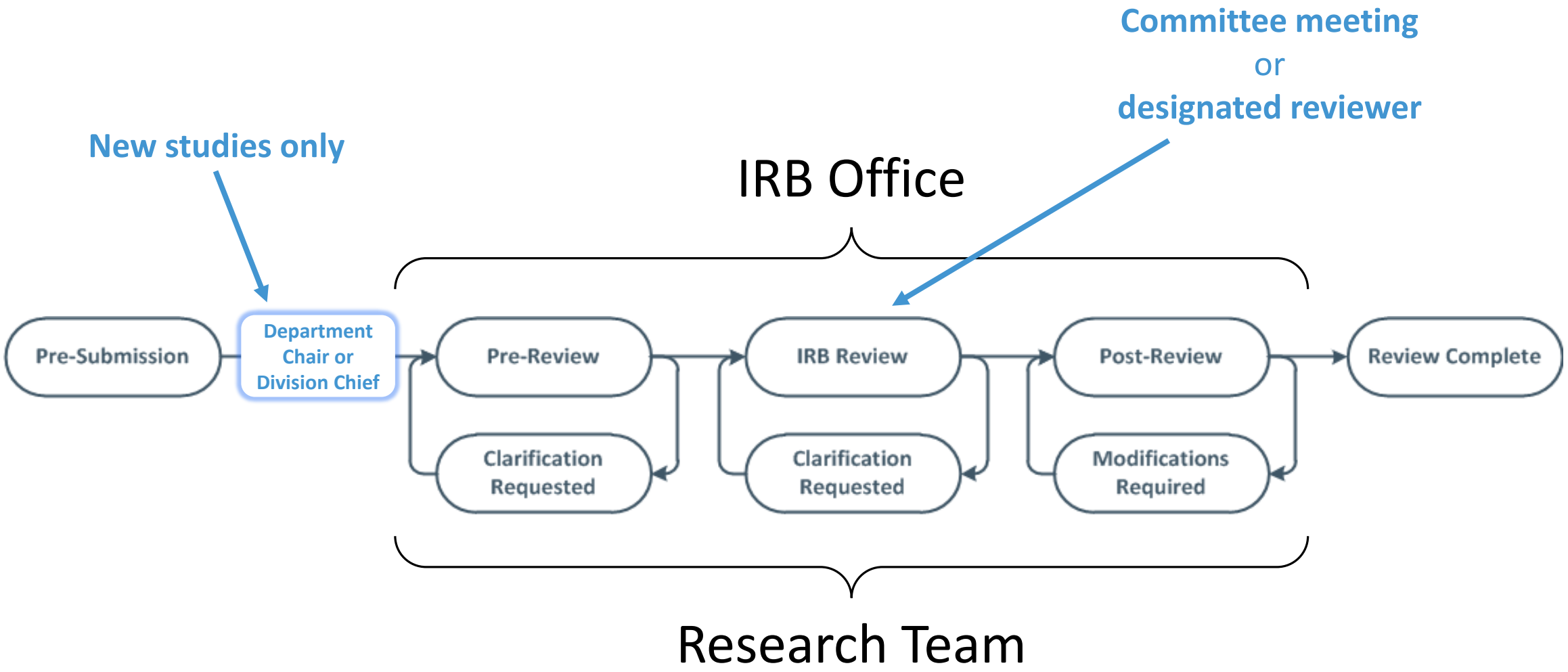
Contact information for IRB Staff:
https://viceprovost.tufts.edu/contact-HS-IRB
Click the **View HS IRB Staff** button at the bottom of the page to see who to contact for different types of questions

How often does the Convened IRB committee meet?

- **Twice per month**
- New studies should be submitted at least 2 weeks before the meeting. **https://viceprovost.tufts.edu/HS-IRB-Meeting-Dates-Deadlines**
  - Meeting this deadline does *not* guarantee that the study will be reviewed at that meeting – substantive pre-review comments must be resolved before the meeting
  - You will see two sets of meeting dates and deadlines: one for the Red Committee (2nd Tuesday of each month) and one for the Blue Committee (4th Thursday of each month)
  - There's no difference between the Red and Blue committees and it doesn't matter which one reviews your study

Not all studies require Convened IRB committee review – many submissions will be reviewed on a rolling basis instead

How does IRB review work?

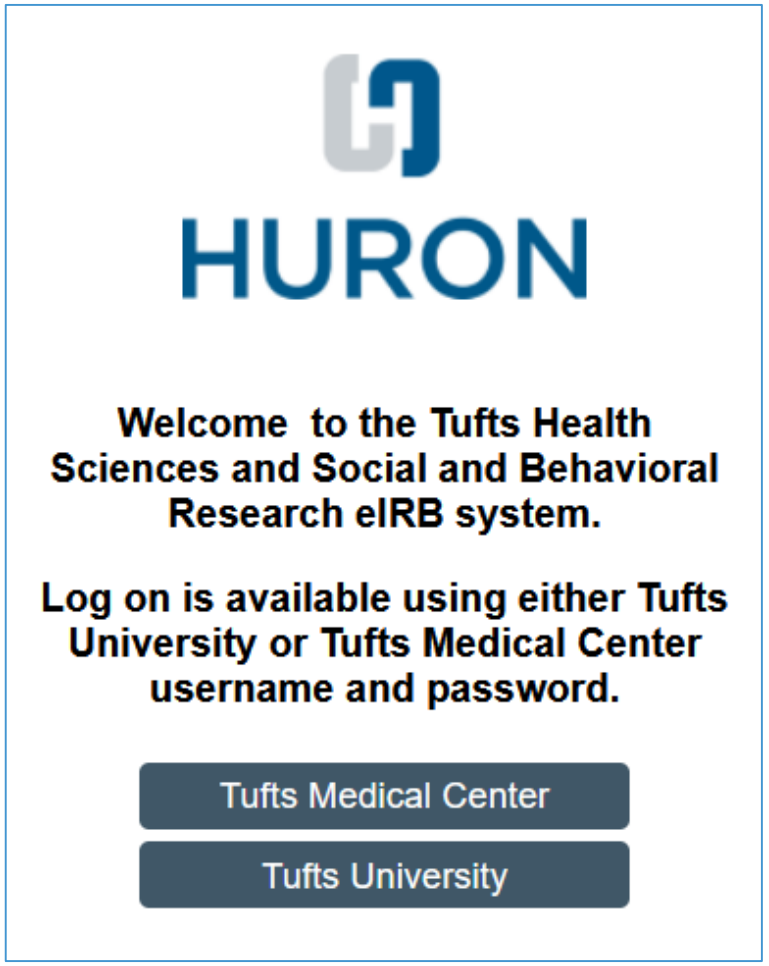


Where do I create a submission?

Electronic IRB (eIRB)
submission system:
https://eIRB.tuftsmedicalcenter.org

- If you get an error message that there is no account for you, email researchIT@tuftsmedicalcenter.org
- **MelroseWakefield and Lowell General researchers:** If you don't have a Tufts MC email account, contact us at IRBoffice@tuftsmedicalcenter.org

Note: Tufts MC Studies with any Funding must be created in CTMS first. If these are created directly in eIRB, the submission may need to be redone.



Types of Studies

Not Human Subjects Research Projects

- The IRB must make all determinations about whether a project is Not Human Subjects Research (NHSR) before the project begins
  - Review is usually quick – we may need to ask clarifying questions and ensure you are following institutional policies (handling of confidential research data, recruiting employees or students, etc.)
- We have a brief **NHSR Request Form** to be submitted in place of a full Protocol
- Supporting documents sometimes needed:
  - Letters from data/specimen source
  - Letters of support from collaborating institutions, IRB approvals
  - Data collection forms, surveys, questionnaires, etc.
- **Instructions:**
  - **https://viceprovost.tufts.edu/not-human-subject-research-determinations**
  - **Detailed eIRB Instructions**

Defining Human Subjects Research

1. **Research:** a systematic investigation designed to develop or contribute to **generalizable knowledge**

   Some **Quality Improvement & Quality Assurance** projects are also Research:

   - Assessing **internal** practices or systems → Not Research
   - Contributing to **scientific knowledge** → Research

Use the **Quality Improvement Self-Assessment Tool** to find out whether you need to submit to the IRB: **https://is.gd/Tufts_HSIRB_QI**

- *This is the **only** exception to the policy that all NHSR projects must be submitted to the IRB.*

Human Subjects Research definition: 45 CFR 46.102(e,l)

Defining Human Subjects Research

2. **Human Subject:** a **living** individual about whom an investigator:
   - Collects data by **interaction** or **intervention** with the individual, *and/or*
   - Uses or generates **identifiable, private information** or **identifiable biospecimens**.

   Research on pre-existing **de-identified** data or specimens doesn't involve Human Subjects

   - Researcher must have ***no way to access any identifiers***
   - **Medical chart review** → **Human Subjects Research**, even if the researcher doesn't *record* the identifiers they're accessing

Human Subjects Research definition: 45 CFR 46.102(e,l)

Minimal Risk Human Subjects Research

Minimal risk: no greater risk of harm than daily life or routine clinical examinations

Reviewed on a rolling basis, rather than at a Convened IRB Meeting

- **Exempt** research includes *most* surveys, interviews, and medical chart reviews, with some exceptions
  - Exempt from the Common Rule for Research, but not exempt from other laws (e.g. HIPAA) or from institutional policy
  - Submit Form 7 (Request for Exemption) in place of a full Protocol
- Instructions: **https://viceprovost.tufts.edu/exempt-submission-requirements**

Minimal Risk Human Subjects Research

Minimal risk: no greater risk of harm than daily life or routine clinical examinations

Reviewed on a rolling basis, rather than at a Convened IRB Meeting

- **Expedited** research includes other minimal-risk procedures: non-invasive data/specimen collection, small blood draws, low-risk clinical trials of approved treatments, etc.
- Instructions: **https://viceprovost.tufts.edu/expedited-and-full-committee-review**
  - Use our **Protocol Template**, or our **Site-Specific Appendix** if the protocol cannot be edited

Greater than Minimal Risk Research

Examples of what may elevate a study to Greater than Minimal Risk level:

- Investigational new drug or device
- Biopsy, invasive specimen collection
- Large or frequent blood draws
- Research-related radiation

Instructions: **https://viceprovost.tufts.edu/expedited-and-full-committee-review**

- Use our **Protocol Template**, or our **Site-Specific Appendix** if the protocol cannot be edited

- Reviewed at a Convened IRB Meeting
  - *Minor modifications may qualify for expedited review*
- May need **Scientific Review** by the Scientific Review Committee (SRC) before IRB review

Scientific Review Committee (SRC)

SRC is a separate committee that reviews research proposals to ensure they meet an acceptable standard of scientific rigor and merit **prior to IRB review**.

- SRC review is required for **greater than minimal risk studies** *without* prior documented scientific peer-review
  - Usually, SRC review applies to **investigator-initiated** studies
  - For **industry-sponsored** or **federally-funded studies**, scientific peer review has usually already taken place
- IRB staff will automatically route the study to the SRC for you if needed (you do not need to do anything)
  - SRC meetings occur on the 1st and 3rd Tuesday of every month (2 meetings per month).
  - SRC approval is required *before* IRB review can begin
- For more information, visit the following webpage that describes the SRC process: **https://viceprovost.tufts.edu/scientific-review-committee**

Using Other IRBs

- Submit to us in eIRB for permission ***before*** submitting to any external IRB
  - Include **Form 10B**, which needs to be signed by your department chair or division chief
- These requests are reviewed on a case-by-case basis and may be declined
- **Submit early!** These need extra time for institutional review & for setting up an agreement with the other IRB
- **Instructions:**
  - **External-IRB Guidance Checklist for Local Study Team**
  - **Detailed eIRB Instructions**

WCG IRB (WIRB)

- A commercial IRB we have a standing contract with
- A Tufts MC or Tufts University study can always go to WCG IRB if it meets the following criteria:
  - Multi-Center
  - Industry-sponsored (or sponsored by a non-federal foundation)
  - Sponsor-initiated (sponsor wrote the protocol)
  - Must NOT be a Phase 1 / Pilot / First-In-Human study
- You still need to **submit in eIRB first** so that we can check ancillary reviews (e.g. pharmacy review, Grants & Contracts review of the ICF)
  - Instead of Form 10B, include **Form 8**, which needs to be signed by your department chair or division chief
- **Instructions:**
  - **WCG IRB Guidance Checklist for Local Study Team**

Submission Tips

CITI Research Education

- Required for **all** members of the research team
  - Not required for Not Human Subjects Research projects
- Must be completed before the submission can be approved
  - We will still review the submission in the meantime; only final approval will be held
- Two choices of human subjects protection courses: **Biomedical Researchers** or **Social-Behavioral Researchers**
- Courses from other institutions may partially transfer over if you add Tufts to your existing CITI account
- A completed course is valid for **4 years**

Registration instructions: **https://viceprovost.tufts.edu/human-subjects-research-protection-education-requirements**

General Tips

- Describe your planned procedures **in detail** – as a rule of thumb, another investigator should be able to conduct the study for you using your protocol
- **Proofread!** Are all details consistent between & within documents?
- **Track your changes** when revising any study documents
  - If there are separate Tracked and Clean versions of the document from previous submissions, replace them with the revised Tracked and Clean versions. (If not, you only need to submit the Tracked version.)
- The quicker (and more thoroughly) you respond to IRB comments and stipulations, the sooner your submission will be approved
  - Respond point-by-point to each comment so you can be sure not to miss any
  - If you have questions about IRB comments, **ask us – don't guess!**
  - **Tip Sheet: How to Respond to IRB Comments**

Informed Consent (Non-Exempt Research)

- Informed consent must be obtained before *any* study-related procedures are done
  - If you need to check eligibility before consent (e.g. with a chart review or questionnaire), you must request a **waiver of consent** for these procedures in the protocol
- Obtaining informed consent is a **process**, not just signing a form
  - Check the participant's understanding
  - Allow time for the participant to ask questions and consider their decision
- More information: **https://viceprovost.tufts.edu/HS-IRB-informed-consent**

Documenting Consent (Non-Exempt Research)

- Always use the current IRB-approved Informed Consent Form (ICF), which will be in **PDF format** with a **validation stamp** at the bottom
- For non-English speakers, we have pre-approved **short forms** in many languages – you will need an interpreter to explain the full details
- Make a copy of the signed consent form:
  - Keep one copy for study records
  - Give the other copy to the participant
- More information: **https://viceprovost.tufts.edu/HS-IRB-informed-consent**

Drafting an Informed Consent Form (ICF)

1. Use our **ICF Template** as a guide.
2. Use simple language & simple sentences (**8th-grade reading level**)
   - Avoid technical/scientific language, or define high-level terms
   - The ICF should be seen as a **teaching tool** for research participants rather than a legal document
3. Use **2nd person** "you" language instead of "I," "they," or "subject"
4. Make sure information from the Protocol is fully and accurately described in the ICF (i.e. number of subjects, procedures, risks, etc.)
5. Differentiate **voluntary research activities** from procedures that are already being done for standard clinical care

Always upload a **Microsoft Word** copy of the ICF to the Consent field in eIRB.
PDFs of the ICF are not accepted.

Informed Consent (Exempt Research)

- A full informed consent process and signed ICF are not required for Exempt research
- Our policy: If there are **interactions** with participants, there must be a consent process
  - ➢ Provide a **written** consent information sheet that participants can save
    - ○ Use our **Consent Information Sheet Template** as a guide
    - ○ Always provide the current IRB-approved information sheet, which will be in **PDF format** with a **validation stamp** at the bottom
    - ○ Don't (only) copy the approved text into the first page of an online survey; you must provide the validated document
  - ➢ Provide an opportunity to ask questions before deciding whether to participate (list PI's contact information on the information sheet)

After IRB Approval

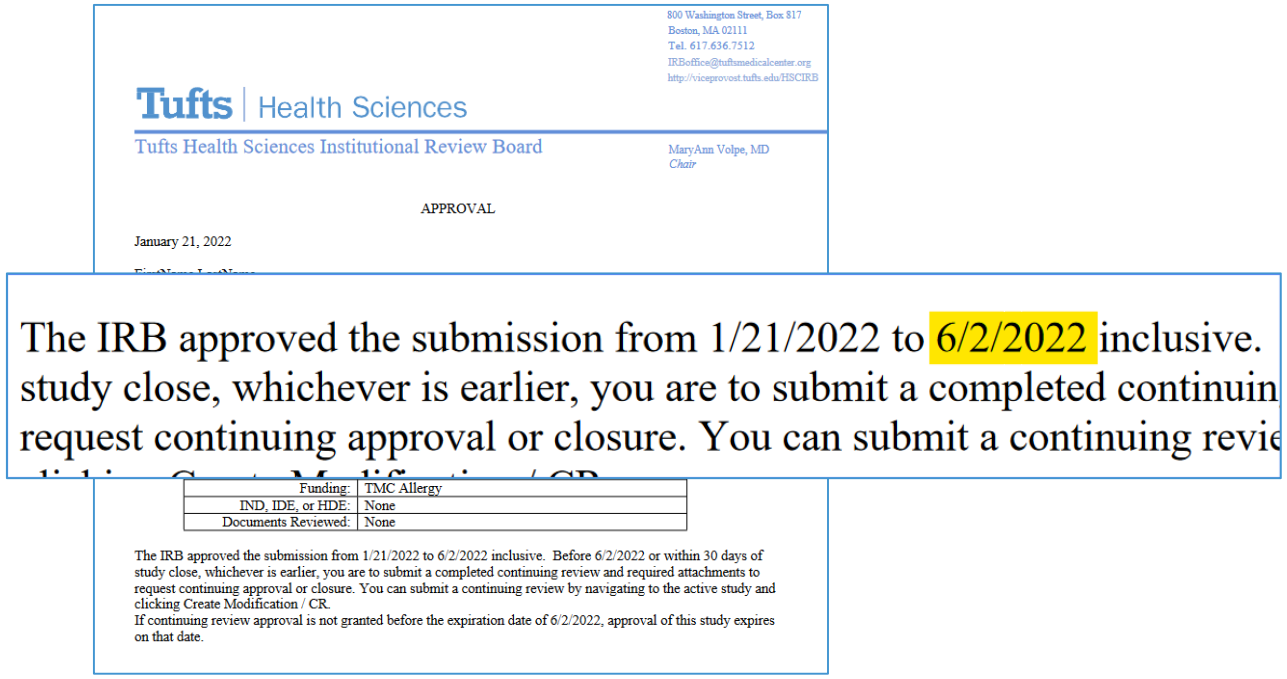
Investigator Manual

- Posted on our website (**https://viceprovost.tufts.edu/HS-IRB-policies**) and linked in every approval letter
- Includes a full list of Post-Approval Responsibilities
- Also explains policies about:
  - Definition of Research Personnel
  - Human Research Protection Training
  - Financial Conflict of Interest Disclosures
  - Obtaining and documenting consent

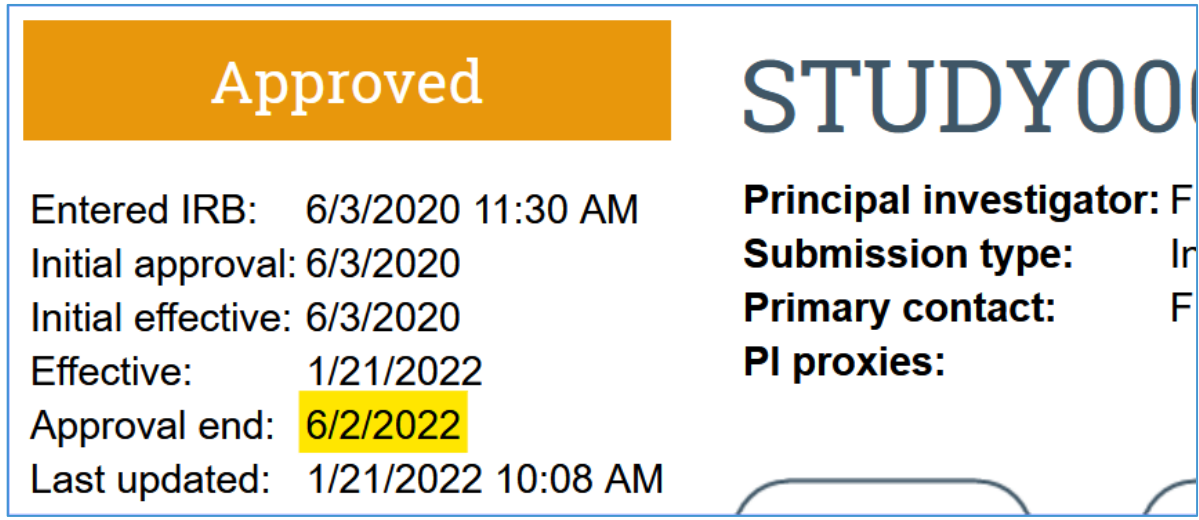
…and more!

When you receive an approval

- See the Investigator Manual for a full list of Post-Approval Responsibilities
- Check your approval letter and finalized documents for any discrepancies
- Check the study's **expiration date**…
  in the approval letter:



or in eIRB:



Amendments / Modifications (MODs):

All changes to an approved study (even minor changes) must be submitted to the IRB, including changes to:

- Research procedures
- Research documents
- Research team members

- New documents or changes to a study cannot be used until the IRB approval letter is provided *(unless to **prevent an immediate hazard** to a subject, and if that occurs, you should contact us about that right away).*
- Update the **version dates** to ensure version control and avoid non-compliance
  - Remember to turn Tracked Changes on before updating the version date!

More information: **https://viceprovost.tufts.edu/modification**

Continuing Review

- For **non-exempt** research, approval typically expires after exactly **one year**
  - IRB determinations for **Exempt** and **NHSR** projects never expire
- **Continuing Review** submission is due **60 days** prior to expiration
  - ➢ eIRB will send up to 3 automated reminder emails (90, 60, and 30 days prior to the expiration date) to the PI, Primary Contact, and PI Proxy if one is assigned
- Even if you are not making any changes, you *must* submit a combined **Modification and Continuing Review (MODCR)** in case changes are requested by the IRB.
- If your study expires prior to receiving IRB approval, **all research activity must stop immediately** until the IRB approval has been granted *(unless to **prevent an immediate hazard** to a subject, and if that occurs, you should contact us about that right away).*

More information: **https://viceprovost.tufts.edu/continuing-review**

Reportable New Information (RNI):

- Must be submitted to the IRB within **5 business days** of *becoming aware* of the information
- Submit by clicking the **"Report New Information" button** in eIRB
- Must fit one of the categories of RNI listed under "Report New Information" in eIRB and on our website, *see link below*
  - Examples: non-compliance, confidentiality breach, harm to subjects
- **Unanticipated problems** should only be reported if they're unexpected *and* probably related to the research procedures (you do NOT need to report Adverse Events that don't meet this definition)
- Include a detailed **corrective & preventative action plan** for non-compliance

For more information and to review the criteria for RNI:
https://viceprovost.tufts.edu/reportable-new-information

Closing a Study

Close your study once all four milestones have been met:

1. Study is permanently closed to **enrollment**
2. All subjects have completed all study-related **interventions**
3. **Collection** of private identifiable information is complete
4. **Analysis** of private identifiable information is complete

- Close the study by making a **Continuing Review** submission in eIRB
- Please submit a closure rather than just allowing approval to lapse

Instructions for Closing a Study with the IRB

Using elRB

eIRB Instructions

Go to **https://viceprovost.tufts.edu/eIRB-Tips-HS-IRB-Studies** to find:

- Video tutorials
- Tip sheets
- Instruction worksheets, which you can download to plan out your responses without logging into eIRB
- Slide decks
- FAQs

eIRB Tip #1: Library

Click on the **Library tab** to access all of our templates, IRB forms, Standard Operating Procedures (SOPs), checklists, IRB Newsletters, etc.

Always **download a new copy** of any IRB form or template you need, to make sure you are using the most up-to-date version

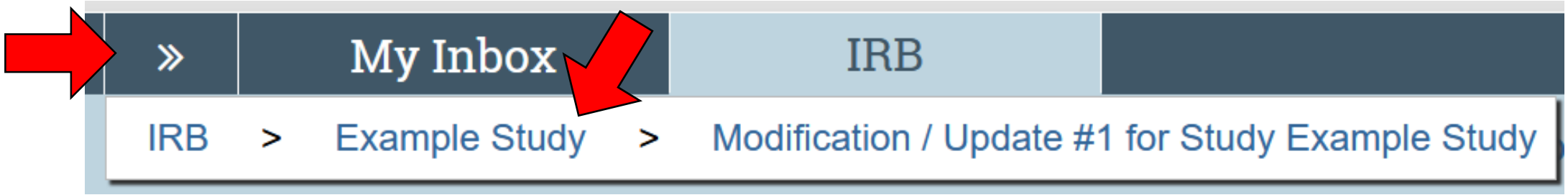
You can also find the same documents on our website:

- **https://viceprovost.tufts.edu/HS-IRB-Forms-Templates**
- **https://viceprovost.tufts.edu/HS-IRB-Policies**
- **https://viceprovost.tufts.edu/HS-IRB-Newsletter**

eIRB Tip #2: Breadcrumb Trail

When you are within a follow-on submission (e.g. a modification or continuing review) for an existing study, and you want to get back to the study's main page, use the "**Breadcrumb Trail**" feature:

- Click on the ≫ button in the top-left corner of the page
- Click on the main study title



eIRB Tip #3: Naming Documents

The Name you enter for documents in eIRB will be the way they are referred to in the study's Approval Letter.

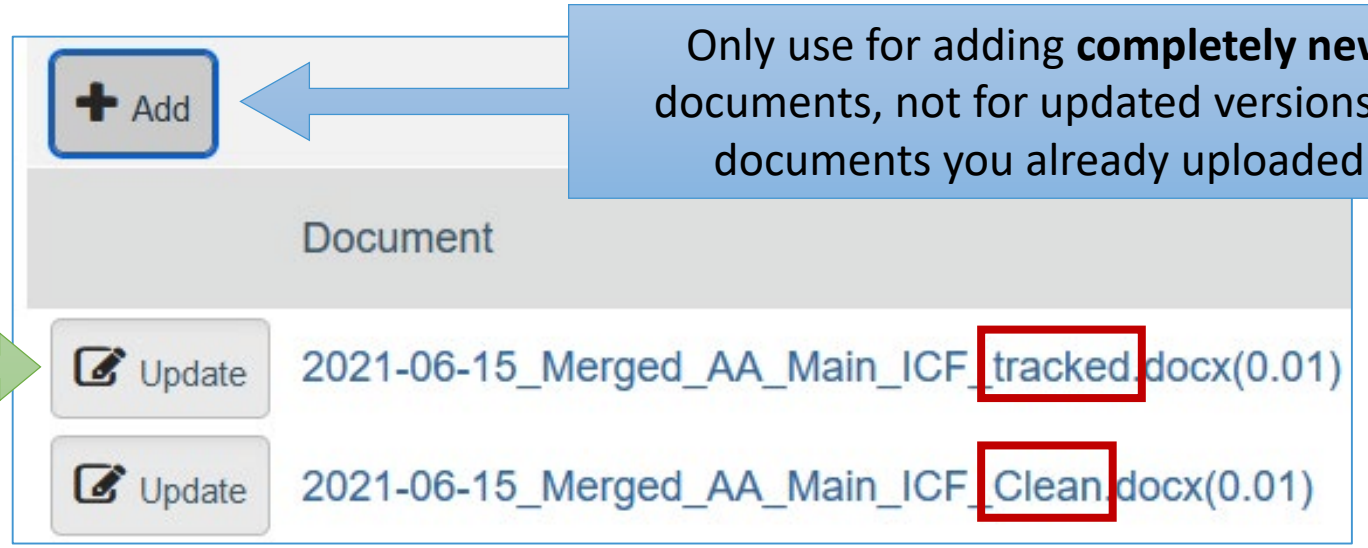
Optional: Enter the name you want listed on the approval letter

The filename from your computer. If #2 is left blank, this is what will appear on the approval letter.

Not listed on the approval letter, but still useful for viewing in eIRB

eIRB Tip #4: Updating Revised Documents

Use the “Update” button to replace an existing document with an updated/revised version.



Only use for adding **completely new** documents, not for updated versions of documents you already uploaded

Use this for updated versions. The original version will still be accessible!

Always replace the old Tracked-Changes version with the new Tracked-Changes version, and replace the old Clean with the new Clean

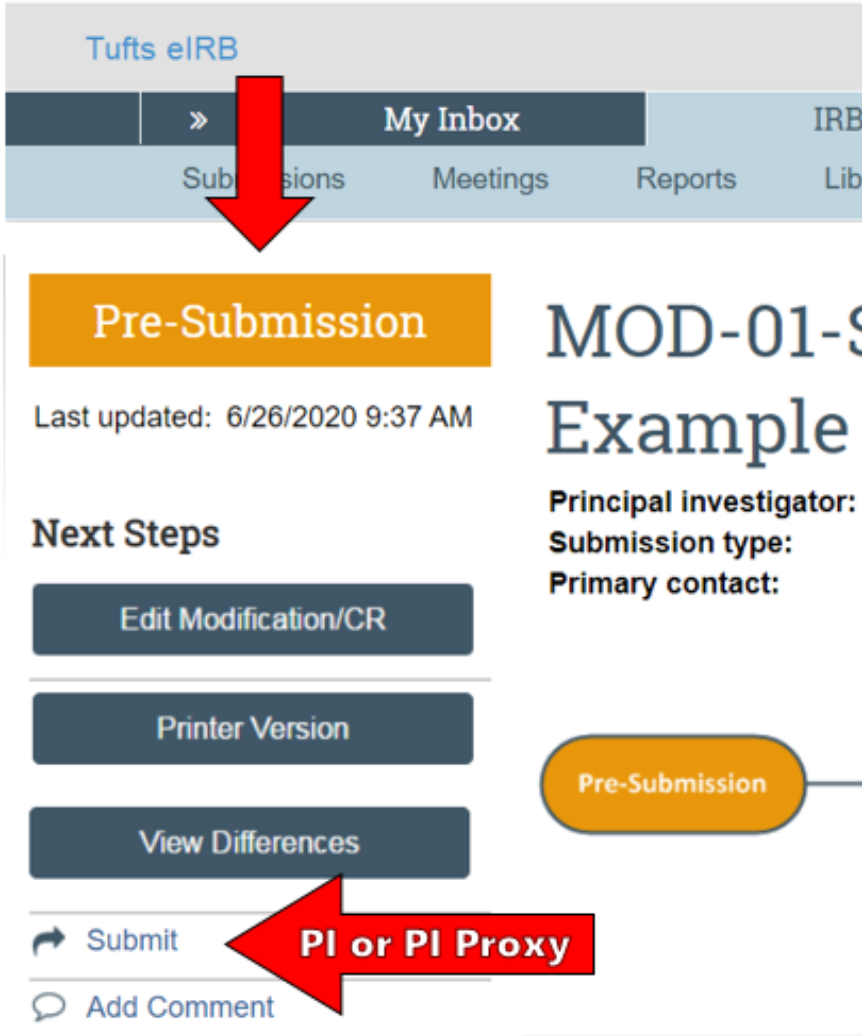
eIRB Tip #5: Remember to submit!

After you've created a new study or a follow-on submission (modification, continuing review, etc.) the draft will **NOT** automatically be submitted.

If the orange box says Pre-Submission, then the PI or their assigned PI Proxy needs to click Submit.

- See PI instructions for assigning a PI Proxy

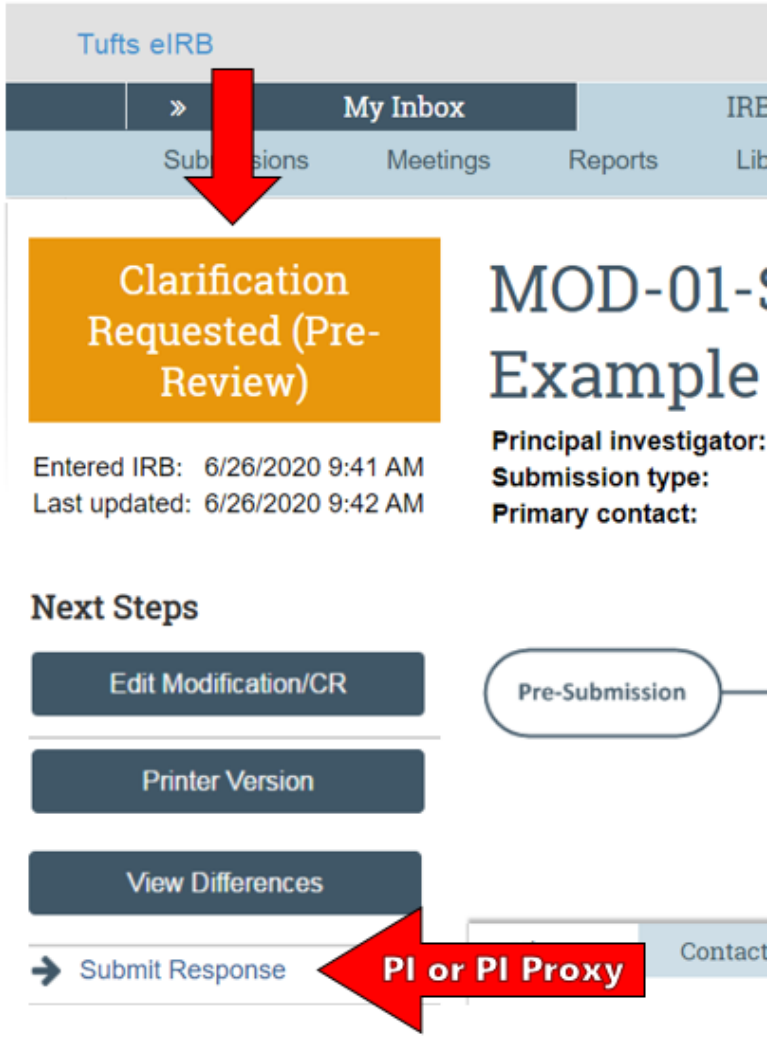
Until you submit, you can keep editing the draft.



eIRB Tip #5: Remember to submit!

The same is true for when the IRB sends you comments to address.

If the orange box says Clarification Requested, then the PI or their assigned PI Proxy needs to click Submit Response once you are done making the requested changes.



Thank You for reading!

Contact the IRB Office with any questions and to set up a Zoom meeting for your first submission:

IRBoffice@tuftsmedicalcenter.org • (617) 636-7512

Check out our archive of **Quarterly Newsletters** for more tips