Welcome to the Winter 2020 edition of Tufts MC / TUHS IRB News
Providing updates and useful information from the IRB office for Investigators, Coordinators, and other members of your Research Team

It’s been a great first couple of months using our new eIRB system and we’ve received wonderful feedback about how quick and intuitive it is, as well as environmentally-friendly (paperless)!

Based on some feedback, we wanted to use this newsletter to offer some Tips and Tricks to answer FAQs about the system.

Haven’t heard about eIRB yet and not sure where to start?

The link to eIRB can be found on our website or by visiting https://eirb.tuftsmedicalcenter.org/

IRB Forms Update:
To coordinate with our new eIRB system, we’re in the process of updating many of our forms to prevent duplication of information and to eliminate signature lines. Be sure to download forms and templates directly from the eIRB library for each new submission to ensure you are using the most up-to-date version. For guidance on what Forms to upload and where to put them in the eIRB, refer here.
Tip: How to find a study and see its current status

When searching for a study in eIRB, an easy way to find it is to click the ellipsis (…) symbol and select “All Submissions”. Then use the Wildcard (%) symbol before typing in the study number, PI Name or part of the study name. You can change the search type in “Filter by”. For example:

![IRB search interface]

Curious about what is going on with your study and where it is in the review process? The **big orange box** in the top left corner will tell you the current status of your study.

This study is awaiting Department Chair / Division Chair review & sign off before it gets passed on to the IRB.

This step happens after the PI hits “Submit” on a new study.
Tip: Determining what the Study Status (big orange box) means

- **Pre-Submission** – PI still needs to review & click Submit
- **Dept/Div Review** – Dept Chair / Division Chief needs to Submit Department or Division Review
- **Pre-review** – IRB staff is currently reviewing
- **Clarification Requested** – IRB has requested Clarifications from the PI
- **Acknowledged** – Reportable New Information (RNI) has been acknowledged
- **Active** – The study is active
- **Approved** – The submission has been approved by the IRB
- **Closed** – The study team closed study
- **Discarded** – The study team discarded the submission
- **External IRB** – this study was approved by another IRB
- **Human Research, Not Engaged** – IRB determined Tufts is not engaged for this project; no further review needed
- **Lapsed** – IRB approval for the study has expired
- **Modifications Required** – Designated Reviewer determined that changes were needed for submission to be approved
- **Non-Committee Review** – The submission is being reviewed by a Designated Reviewer (IRB Chair/Vice Chair)
- **Not Human Research** – the project is not human subjects research “NHSR”; no further review needed
- **Pending sIRB Review** – External IRB study awaiting external IRB’s approval

Tip: How to find the contact for Department/Division review

Department/division sign-off is needed before a new study is submitted to the IRB. Here’s how to find the name of the department/division reviewer for your study:

When you click the blue “Edit Study” or “View Study” bar on the left side of the study workspace, you will see the tab at the top with “Jump To”. Click “Jump To” for a drop down menu and select “Study Department/Division.”

Under “*Study Department/Division”, your Department/Division will appear in blue text – click this and you’ll be brought to the page shown at the right. Click the “Properties” tab.

Scroll down until you see “IRB Ancillary Reviewers” and you will see the contact information for your

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<th>IRB Ancillary Reviewers:</th>
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<tbody>
<tr>
<td>Name</td>
<td>E-mail</td>
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<tr>
<td>First &amp; Last Name</td>
<td><a href="mailto:emailaddress@tuftsmedicalcenter.org">emailaddress@tuftsmedicalcenter.org</a></td>
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Tip: How to submit Not Human Subjects Research “NHSR”

Quality Improvement projects and analysis of publicly-available or fully de-identified data may be considered Not Human Subjects Research. (Refer to viceprovost.tufts.edu/HSIRB/review-process/nhsr/ for more guidance on what types of projects may be NHSR.)

To submit a request through eIRB for a NHSR determination:
1. Create a new study in eIRB. The Principal Investigator must meet the PI Eligibility Policy criteria.
2. Fill in the information requested in the eIRB submission “smart form.”
   - Instead of a Protocol, attach a Cover Letter detailing the purpose and activities of the research and the nature of any data/specimens being used. (Refer to our website for a full list of points to include.)
   - On the Local Site Documents page, attach:
     i. A signed Conflict of Interest form. This can be a scanned PDF file.
     ii. Supporting documents (such as a letter from the source of data/specimens, or a letter of support for recruitment)

Click “Submit” to send the project for Department/Division sign-off and IRB Review.

Tip: How to get back to the Main Study page from Continuing Review or Modification pages

Click on the double arrows (the “breadcrumb trail”) at the top of the screen. This will display a dropdown menu where you can click on the main study title. This will take you back to the main study page.

Tip: How to find the option to “Submit”, Assign a Primary Contact or a PI Proxy

The PI or PI Proxy are the only ones who can click “Submit” for a submission.

On the left hand side of the PI’s work space, the PI can Submit, assign a Primary Contact, and/or assign a PI Proxy.

The Primary Contact can access the study in eIRB and will receive eIRB notifications for the study.

The PI Proxy is able to submit items on behalf of the PI. The PI Proxy must be a member of the research team.
**Tip: Informed Consent Form (ICF) formatting**

Since the validation stamp is added to the ICF directly through the eIRB, we want to make sure the final version of the ICF looks the way you want it to look when presented to the subject.

When uploading your final Microsoft (MS) Word version of an ICF to eIRB, **review the document** to make sure the formatting, spacing, font, etc. are correct.

**Tip: Tips on responding to pre-review comments and requests for revisions**

Once you are ready to submit your response to IRB comments, click **Edit Study** (or Edit Modification/CR) on the left side of the workspace.

Use the **Add** button to add a new document.

Use the **Update** button to replace an older version of a document with a revised version. The older version will still be accessible in the document history.

Include tracked versions and clean versions for any documents you revise. (Remember to delete all comments from clean versions!)

Name documents to clearly show what they are (i.e. Protocol, ICF tracked).

Click **Save** at the top or bottom of the screen before you click **Exit**.

Click **Submit Response** on the left side of the workspace, under all the blue buttons. **The submit option will only show up for the PI** (or PI Proxy if the PI has assigned a PI Proxy).

In the Notes box, type in any responses to comments that aren’t reflected in your revised documents.

Then, click **OK**.
Tip: Who should I notify when I add a Comment?

Checking “PI/PI Proxy/Primary Contact” sends an e-mail to the PI, PI Proxy, and Primary Contact

Checking “Study Team” sends an e-mail to all of the research team members listed in eIRB

Checking “IRB Coordinator” sends an e-mail to the IRB office staff

(Please note that this is not the research coordinator)

Tip: Uploading Password-Protected documents

Avoid uploading password-protected documents to eIRB. If you have to, though, please provide the password to access the document in the form of a comment. You may do so by selecting “Add Comment” on the left hand side of the submission workspace, under Next Steps.

Next Steps

View Modification/CR
Printer Version
View Differences

Add Comment
Add Privato Comment
Manage Tags

View CITI Training

Your comment is visible to anyone with access to this submission.

1. Comment:

The password for the Investigator’s Brochure is: IRB2020
**Tip: Submitting Continuing Review for a WIRB/external IRB study**

**Step 1:**
After WIRB/the external IRB completes the Continuing Review for a study each year, Tufts IRB needs the updated study documents and enrollment information.

**Step 2:** Fill in the information in the window that pops up. Under “Supporting documents,” upload the most recent external IRB approval letter.

**Step 3:** Click “Update Study Details” on the left side of the study workspace.
Type in a brief summary (e.g. “Uploading most recent study materials”) in the box labeled “Summarize the updates.”

Fill in the required information in the study shell, and upload the most recently-approved version of each study document.
Contact the IRB Office with any other questions you have about the eIRB!

Give us a call at ext. 6-7512 or stop by our office on Tupper 1 – we have extended open office hours to help you navigate the new eIRB and are available anytime during our open hours.

You can also refer to eIRB Guidance for Study Teams where you can find video tutorials and tip sheets.

Contact us!

Bookmark our IRB Staff page for guidance to contact the staff member who can best provide assistance with specific questions.

Follow us on Twitter

View our Archived IRB Newsletters

Tufts Health Sciences IRB website: http://viceprovost.tufts.edu/HSCIRB/

Tufts eIRB website: https://eirb.tuftsmedicalcenter.org

Do you know someone who would like to receive IRB News? Click here to send a request to add Investigator/Research Team Member to the IRB Distribution List.

Contact our office at 617-636-7512 Monday to Friday, 8:30 am to 5 pm or stop by during IRB Drop-In Hours Tuesday 2 to 4 pm. We are located in the Tupper Building at 15 Kneeland Street, 1st floor.

Tufts University

Tufts Medical Center