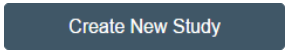
UT Health San Antonio | Enterprise Research Management System (ERMS)

# External Study Submission Quick-Guide

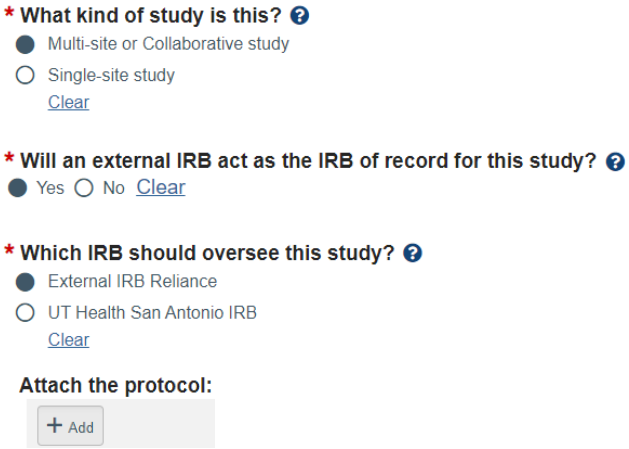

The circled numbers correspond to the relevant pages below:


1. Navigate to the IRB Tab located at the top of the page.

2. Select the **Create New Study** button:




3 Complete the **Basic Study Information** fields, ensuring that the following information is selected and completed:




**Other attachments should be uploaded under other applicable sections (e.g. 10 & 11 )**

4 On the **Basic Site Information** tab, provide a description of all activities our site will perform.
**If your site will be conducting all portions of the research, type "ALL".**

5 Select the IRB of record.

6 On the **Study Funding Sources** tab, indicate your source of funding.

7 Using the "Add" button, add the **Local Study Team Members** (Research Team Members) who will be participating in this study.
**If you wish to add a Research Team Member as a PI Proxy, this person must be listed as a Local Study Team Member.**

**Use the help features for adding correct personnel and research roles.**

8 Complete the **Study Scope** to identify if your study involves an investigational **Drug/Device.**

9 Add additional **Local Research Locations** relevant to the study. For example, University Health.

10 On the **Study Related Documents** tab, provide all consent form templates, study-related recruitment materials, and other study-related documents (e.g. data collection materials).

11 On the **Local Site Documents** tab, attach consent forms and recruitment materials that specifically pertain to our site.

Local Site Documents consist of the following:
HRP-211a – Form A
HRP-211b – Institutional Form
Local site consent form
- Incorporate HRP-901a – Local Context Information and HIPAA. (using tracked changes)
- For NCI CIRB studies only, use HRP-901b – NCI CIRB Boilerplate language.

Include additional forms as annotated in the Institutional Supplement forms.
**All forms are in the ERMS-IRB Library under Templates.**
Do not include the HIPAA waiver or HIPAA authorization unless the external IRB of record will not act as the privacy board and provide these reviews. Most IRBs will provide these reviews, including commercial IRBs.

**You may now click "Finish" to return to the Pre-Submission page. See page 2 for instructions to submit.**

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# Next Steps

Dashboard | Agreements | COI | IRB

Pre-Submission

## Next Steps

Edit Study

Printer Version

- Submit
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Manage Related Agreements
- Create Ad Hoc Certifications
- Add Comment
- Discard
- Manage Tags

## Submit

Once all applicable information has been provided, and a Contact/PI Proxy has been assigned, you may now submit your study.

## Adding a PI Proxy

This function will allow the addition of a **PI Proxy**. A **PI Proxy** has the ability to act on behalf of the PI. Only a PI or a **PI Proxy** may submit a study.

**Note:** If you wish to add an individual as a **PI Proxy**, this person must be listed as a **Local Study Team Member**

## Edit Study

If you feel something has been incorrectly filled out, or a person was not added, this will allow you to revise your application prior to submission.

## Manage Guest List

Using this feature will allow added personnel to view the submission and its status.

**Note:** This feature is different from a **PI Proxy**

## Need Help?

The Help button is also present within the Next Steps fields shown on the left. Once accessed, clicking the button will provide additional help text!