This PowerPoint provides guidance for maintaining study records when an **External IRB** serves as the IRB of Record.

Getting started

1. Navigate to the **IRB workspace**
2. Select **Submissions** tab
3. Select **All Submissions** tab
4. Note: **Filter by** allows you to sort through your studies by name, PI first and last name, and submission type.
5. Open your study by selecting the **folder symbol** or the **name** of the study.

Last modified: 12/14/2023

How would you like to proceed?

Please read carefully over the following list and select the option that is best for you:

1. **Provide the Texas A&M IRB with changes that have been approved by the IRB of Record,** including updates to the IRB protocol, master templates, and funding source**.** Please continue to the next slide.

   Important: Changes to study procedures or master templates must be approve by the IRB of Record before submission to the Texas A&M IRB, and documentation of that approval must be provided.

2. **Inform the Texas A&M IRB of local changes that occur at the Texas A&M site,** including updates to study personnel and revisions to local recruitment materials. Please click here to be directed to slide 11.

Creating a modification

1. Select **Update Study Details**

Use this feature only if you are reporting **changes that have been approved by the IRB of Record.**

Active

Entered IRB: 3/13/2024 12:03 PM
Initial approval: 4/15/2021
Initial effective: 4/15/2021
Effective: 4/15/2021
Approval end: 4/14/2026
Last updated: 2/13/2026 1:00 AM

Next Steps

View Site

Printer Version

Create Site Modification

1 Update Study Details

Report New Information

Study Update Information

1. **Summarize the updates:** Describe the changes to the IRB-approved protocol or master templates that were reviewed and approved by the IRB of Record, including affected documents, sections revised, and confirmation of approval.

2. Click **Save**

3. Click **Continue**

Navigate the IRB Application to make edits

After selecting **Continue** on the **Study Update Information** page, you will be taken to the application to make edits.

1. Use the page navigator on the left side of the screen to locate any pages that need to be edited. The page currently being viewed will be shown highlighted in orange. To view a specific page, click the desired page on the navigator.

2. Click **Save** after making any edits to ensure your work is saved.

Basic Study Information

If the IRB of Record approved changes to the IRB protocol, please attach the most recently approved IRB protocol that incorporates all approved revisions.

How to attach the most recently approved IRB protocol:

1. Click **Update** in Question 8, "Attach the Protocol," and attach the revised IRB protocol.

2. Click **Save**

3. Click **Continue**

Basic Study Information

External IRB

Study Funding Sources

Study Scope

Devices

Study-Related Documents

Multi-site or Collaborative study

5. * Will an external IRB act as the IRB of record for this study? ⊙
   ● Yes ○ No

6. Lead principal investigator: ⊙
   [...]

7. * Which IRB should oversee this study? ⊙
   ○ IRB - Dentistry
   ● IRB - TAMU CS
   Clear

8. Attach the protocol: ⊙

   [+ Add]

Document	Category	Date Modified	Document History
📄 2. PROTOCOL REVISION [✎ Update]	IRB Protocol	8/5/2024	History ⊗

   ①

   [⊗ Exit] [💾 Save] [Continue ⊙]

How to attach documents

Please attach all documents that were reviewed and approved by the external IRB as part of the modification being reported to the Texas A&M IRB. This includes newly approved and/or revised documents, and the external IRB's approval letter confirming approval.

1. Navigate to the **Local Site Document** page

2. Select **+Add** to attach a *new* study document or **Update** to attach a *revised* study document. It is important that you select the correct option to ensure good document management.

3. Once you have finished uploading all your documents, click **Save** and then **Exit**.

Important final step:

Email your IRB coordinator to notify them that you are reporting new changes to an externally approved IRB protocol. IRB Coordinators are assigned to specific colleges or units, please consult [this list](#) to determine the liaison for your department.

Please include the following information in your email:

- Principal Investigator (PI) name

- Study number

- Study title

If this step is not completed, the Texas A&M IRB will **not** be notified of the changes being submitted.

Creating a modification

1. Select **Create Site Modification**

Active

Entered IRB: 3/13/2024 12:03 PM
Initial approval: 4/15/2021
Initial effective: 4/15/2021
Effective: 4/15/2021
Approval end: 4/14/2026
Last updated: 2/13/2026 1:00 AM

Next Steps

View Site

Printer Version

Create Site Modification

Update Study Details

Report New Information

Modification/Update

1. Select **Modification/Update**

2. Select both **Study team member information** <u>AND</u> **Other parts of the study**.

Complete the Modification Summary

1. Complete the **Modification Summary** page:

   Q1 – Indicate the study enrollment status

   Q2 – Indicate whether study participants need to be notified of the changes being submitted, if applicable. *If not applicable*, skip question.

   Q3 – Provide a summary of the local changes that occur at the Texas A&M site

2. Select **Save** and then **Continue**

Navigate the IRB Application to make edits

After selecting **Continue** on the **Modification Summary** page, you will be taken to the application to make edits. Please note that only Local pages will be accessible.

1. Use the page navigator on the left side of the screen to locate any pages that need to be edited. The page currently being viewed will be shown highlighted in orange. To view a specific page, click the desired page on the navigator.

2. Click **Save** after making any edits to ensure your work is saved.

Adding study personnel requires two steps:

Step 1: Add the individual to the **Local Study Team Members** page (see next slide).

Step 2: Provide information about the individual's:

- Study role and delegated duties, and
- Qualifications to perform those duties

How to complete Step 2:

If you completed the *Request to Rely on External IRB Template*:

- Update the template to include the required personnel information (see the table in **Section 1: Study Personnel**). Attach the updated template to **Question 3** on the **Local Site Documents** page (see Slide 17 for instruction on how to attach new or revised study documents) .

- **If you did not complete the *Request to Rely on External IRB Template*:**
  Use the ***Supplemental Resource: Study Personnel*** . Once completed, attach the table to **Question 3** on the **Local Site Documents** page (see Slide 17 for instruction on how to attach the document on how to attach new or revised study documents) .

Local Study Team Members

To add Texas A&M study team members:

1. Click **+Add**

   ? **I am trying to add study personnel to an IRB protocol, why am I not able to locate them in the system?**

   Some TAMU members (such as undergraduates, visiting scholars, and adjunct/affiliate professors) need to opt into their information being fed into Huron before they are active in the system. If you are not able to locate a member of your research team, have that individual visit the following website: **https://raes.dor.tamu.edu**. *Note*: It will take 24 hours before their information is active in Huron.

2. Complete the **Add Study Team Member** ❷ smart Form
   - Q1 – Type the name of the team member being added or click the ellipsis […]
   - Q2 – Identify the role of the team member
   - Q3 – Identify if the team member will be involved in collecting consent.
   - Q4 – Identify if the team member has a conflict of interest.

Important! All personnel being added must have completed CITI training. Instructions for how to complete CITI training may be found on the HRPP website.

To remove Texas A&M study team members :

3. Click the **X** to the right of the team member.
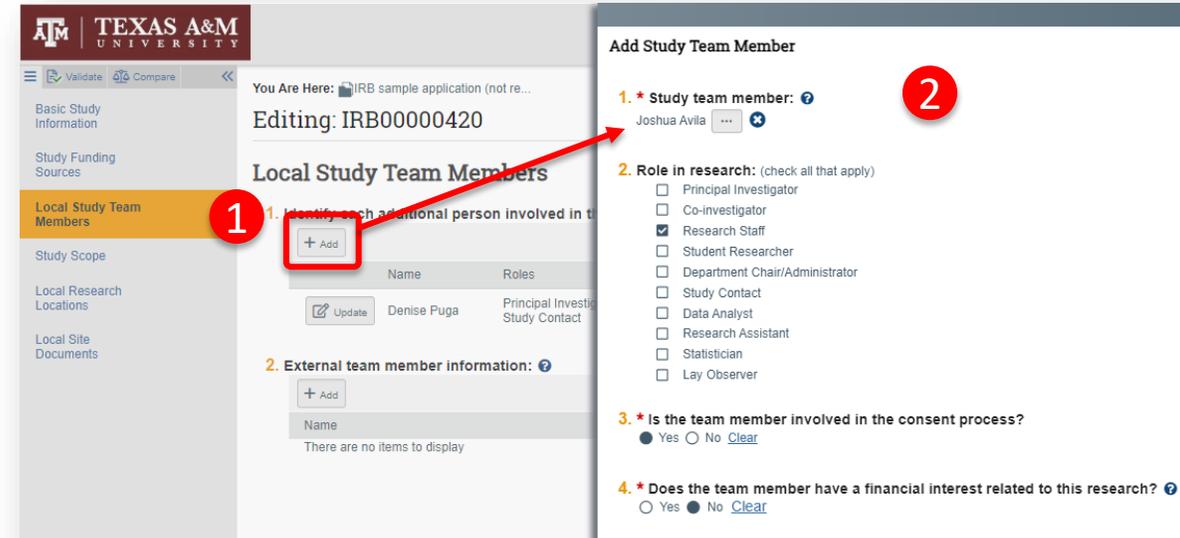
Click **X** to Remove study personnel

How to attach new or revised study documents

If you need to add a new or revised study document:

1. Navigate to the **Local Site Document** page

2. Select **+Add** to attach a _**new**_ study document or **Update** to attach a _**revised**_ study document. It is important that you select the correct option to ensure good document management.
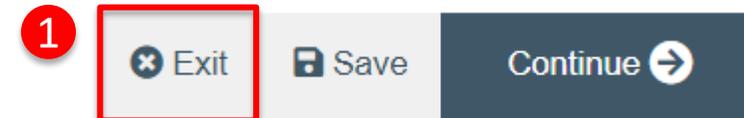
3. Click **Save**

Submitting your changes to the IRB

Once you have finished editing the IRB application and saved all your edits:

1. Select **Exit** to be directed to the IRB Workspace

2. Click **Submit**

   IMPORTANT! The PI or PI Proxy must click *Submit* for the submission to be received by the IRB.
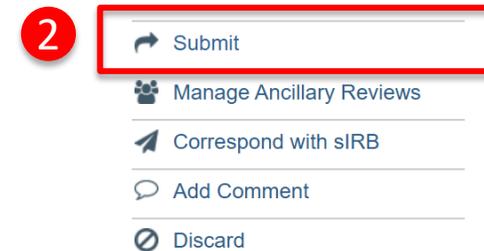
3. Click **OK**

Pre-Submission

Entered IRB: 3/3/2026 12:31 PM
Last updated: 3/3/2026 12:31 PM

Next Steps

Edit Modification

Printer Version

Submit

Manage Ancillary Reviews

Correspond with sIRB

Add Comment

Discard

Visit the FAQ webpage

Please take a moment to visit the frequently asked questions webpage **Huron FAQ – Division of Research (tamu.edu)** to learn more about Huron functionality.