



External IRB Study Update Guidance

Human Research Protection Program

(Last Updated: 3/03/2026)



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.

The screenshot shows the IRB workspace interface. The top navigation bar includes 'Dashboard', 'Admin', 'COI', 'IRB', and 'Settings'. The 'IRB' tab is selected and highlighted with a red box and a red circle containing the number 1. Below this, the 'Submissions' tab is also highlighted with a red box and a red circle containing the number 2. The main content area shows the 'IRB' workspace with a search bar (3) and a filter dropdown (4) set to 'All Submissions'. A table of studies is displayed below, with the first row containing a folder icon (5), the ID 'STUDY2023-0039', the name 'New Study 9.19.2023', the date '12/14/2023 3:51 PM', and the PI names 'Denise' and 'Puga'.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name
STUDY2023-0039	New Study 9.19.2023	12/14/2023 3:51 PM		Denise	Puga	



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 approved 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**

The screenshot shows a mobile application interface for creating a new IRB submission. The top navigation bar includes a 'You Are Here' breadcrumb trail with a folder icon and the text '> IRBSubmission'. Below this, the title 'Creating New: IRB Submission' is displayed. The main content area is titled 'Study Update Information' and contains a single instruction: '1. * Summarize the updates:'. This instruction is highlighted with a red circle containing the number '1'. Below the instruction is a large, empty text input field. The left sidebar of the application shows a menu item 'Study Update Information' which is currently selected.

✕ Exit

💾 Save

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.

The screenshot displays the IRB application interface. On the left, a page navigator lists several sections: **Basic Study Information** (highlighted in orange), External IRB, Study Funding Sources, Study Scope, Devices, and Study-Related Documents. A red circle with the number '1' is placed next to the 'Basic Study Information' item. A large red arrow points from this item to the main content area. The main content area shows 'You Are Here: Editing: IRB00003985'. Below this, the 'Basic Study Information' section is circled in red. It contains two required fields: '1. * Title of study:' and '2. * Short title:'. At the bottom of the screen, a navigation bar contains three buttons: 'Exit', 'Save', and 'Continue'. The 'Save' button is highlighted with a red box and a red circle with the number '2' above it.

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
1 Update	2. PROTOCOL REVISION	IRB Protocol	8/5/2024 History ✕

✕ 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**.

Basic Site Information

Additional Local Funding Sources

Local Study Team Members

Local Research Locations

Local Site Documents

Editing: IRB00003985 [Go to forms menu](#)

Local Site Documents

1. Consent forms: (include an HHS-approved sample consent document, if applicable)

2 + Add

Document	Category	Date Modified	Document History
Update Final (2).doc(0.01)	Consent Form	8/5/2024	History ✕

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

+ Add

Document	Category	Date Modified	Document History
Update Advertisement	Recruitment Materials	8/5/2024	History ✕

3. Other attachments:

+ Add

Document	Category	Date Modified	Document History
Update IRB Approval.pdf(0.01)	External IRB Correspondence	8/5/2024	History ✕

✕ Exit
Save

 Continue

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

1

Create Site Modification

Update Study Details

Report New Information

Modification/Update

1. Select **Modification/Update**
2. Select both **Study team member information** AND **Other parts of the study**.

Modification /
Continuing Review

Creating New: IRB Submission

Modification

* What is the purpose of this submission? ?

Modification / Update

[Clear](#)

i To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team and research location information

Other parts of the site

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**

1

You Are Here: Test > Modification / Update #7 for S...

Editing: MOD00000018

Modification Information

- 1. Study enrollment status:**
 - No subjects have been enrolled to date
 - Subjects are currently enrolled
 - Study is permanently closed to enrollment
 - All subjects have completed all study-related interventions
 - Collection of private identifiable information is complete
- 2. Notification of subjects:** (check all that apply)
 - Current subjects will be notified of these changes
 - Former subjects will be notified of these changes

i Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.
- 3. * Summarize the modifications:** **?**

2

Exit Save 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.

The screenshot displays the IRB application interface. On the left, a sidebar contains a page navigator with the following items: **Basic Site Information** (highlighted in orange), Additional Local Funding Sources, Local Study Team Members, Local Research Locations, and Local Site Documents. A red circle with the number '1' is positioned to the left of the sidebar. The main content area shows the 'Basic Local Site Information' page, which is also circled in red. The page title is 'Editing: IRB00003985'. Below the title, there are two required fields: '1. * Local principal investigator:' and '2. * Brief description of activities this site will perform:'. A red arrow points from the 'Basic Site Information' link in the sidebar to the 'Basic Local Site Information' page. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue'. The 'Save' button is highlighted with a red box and a red circle with the number '2' above it.

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.*

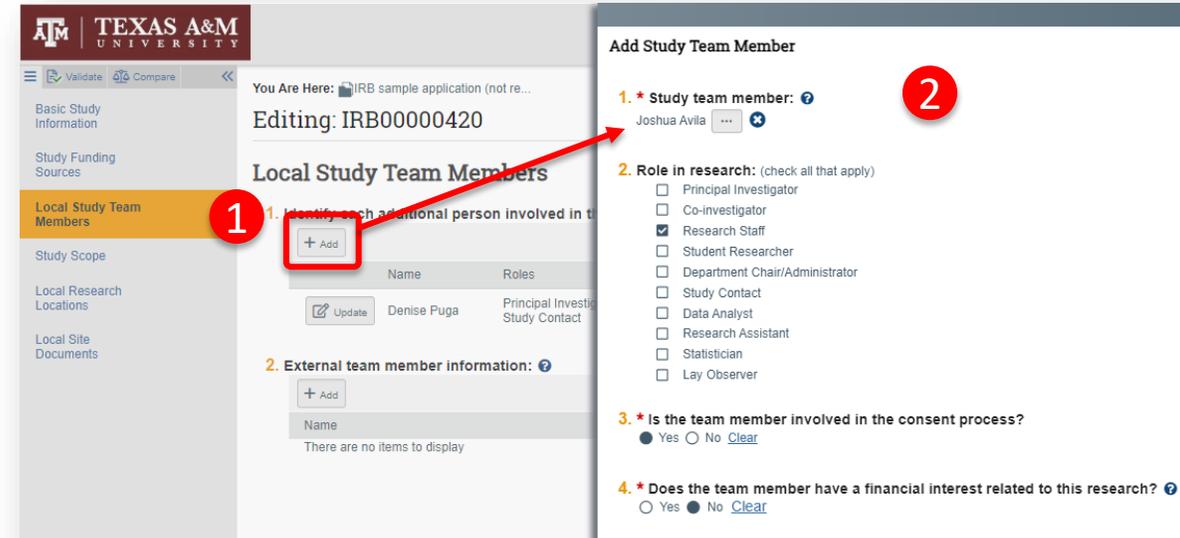
2. Complete the **Add Study Team Member** smart Form

- 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.



3



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**

- Basic Site Information
- Additional Local Funding Sources
- Local Study Team Members
- Local Research Locations
- Local Site Documents**

Editing: IRB00003985

[Go to forms menu](#)

Local Site Documents

1. Consent forms: (include an HHS-approved sample consent document, if applicable)

2 **+ Add**

Document	Category	Date Modified	Document History
Update Final (2).doc(0.01)	Consent Form	8/5/2024	History

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

+ Add

Document	Category	Date Modified	Document History
Update Advertisement	Recruitment Materials	8/5/2024	History

3. Other attachments:

+ Add

Document	Category	Date Modified	Document History
Update IRB Approval.pdf(0.01)	External IRB Correspondence	8/5/2024	History

2

Exit **Save** **Continue**

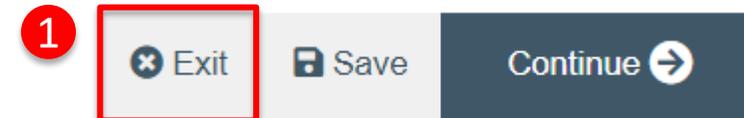
Submitting your changes to the IRB

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**



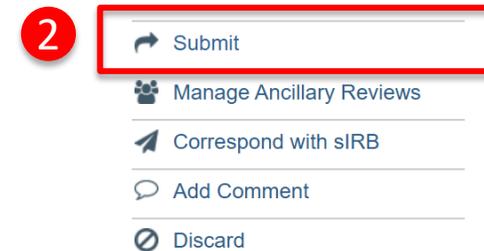
Pre-Submission

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

Next Steps

Edit Modification

Printer Version





Visit the FAQ webpage

Please take a moment to visit the frequently asked questions webpage [Huron FAQ – Division of Research \(tamu.edu\)](https://www.tamu.edu/huron/faq) to learn more about Huron functionality.