



Creating and submitting a modification

Human Research Protection Program

(Last Updated: 01/29/2024)



This PowerPoint will guide you through how to create and submit a modification to an approved IRB protocol.

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. At the top, there are navigation tabs: Dashboard, Admin, COI, IRB (highlighted with a red box and callout 1), and Settings. Below these are sub-tabs: Submissions (highlighted with a red box and callout 2), Meetings, Reports, Library, Institutional Profiles, Help Center, and Central Actions. The main content area is titled 'IRB' and contains a search bar (callout 3) and a filter dropdown menu (callout 4) with options: In-Review, Active, New Information Reports, External IRB, Relying Sites, and All Submissions (highlighted with a red box). Below the filter is a search input field with a search icon and '+ Add Filter' and 'x Clear All' options. A table of studies is displayed below, with columns: ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. The first row is highlighted with a red box and callout 5, showing a folder icon, ID 'STUDY2023-0039', Name 'New Study 9.19.2023', Date Modified '12/14/2023 3:51 PM', State 'Off', PI First Name 'Denise', PI Last Name 'Puga', and Coordinator First Name.



Creating a modification

1. Select **Create Modification/CR**

Approved

Entered IRB: 12/1/2022 11:25 AM
Initial approval: 12/1/2022
Initial effective: 12/1/2022
Effective: 12/9/2022
Approval end: 11/30/2023
Last updated: 4/6/2023 10:44 AM

Next Steps

View Study

Printer Version

1

Create Modification/CR

Report New Information

Modification/Update

1. Select **Modification/Update*****
2. Identify the **modification scope** (*must select at least one option, or both if applicable*):
 - Select **Study team member information** to add new study personnel
 - Select **Other parts of the study** for all other modifications to the protocol

*** Do not select *Modification and Continuing Review* unless you are confident that your study requires a continuing review. Most minimal risk studies approved after January 20, 2019 do not require a continuing review, but still must undergo an Administrative Check In (instructions on how to create and submit an Administrative Check In can be found [here](#)). To identify if your study requires a continuing review or an administrative check in, please reference your initial approval letter.

You Are Here: Test > _IRBSubmission

Creating New: IRB Submission

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ⓘ

Continuing Review

Modification / Update

Modification and Continuing Review

[Clear](#)

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

Modification scope:

Study team member information

Other parts of the study

How to discard a modification

1. Once you select **Save** or **Continue** on the **Modification/Continuing Review** page, you will not be able to edit your purpose or scope on this page.
2. If an incorrect response was chosen for either “*What is the purpose of this submission?*” or “*Modification scope*” and the form has been saved, then click **Exit** to leave the submission and select **Discard** from the study record workspace. A new Modification/CR request will need to be created to continue with the modification request.

1

Modification / Continuing Review

Editing: MOD00000018

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ⓘ

Continuing Review

Modification / Update

Modification and Continuing Review

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

Modification scope:

Study team member information

Other parts of the study

Active Modification For This Study

✕ Exit Save Continue →

2

Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Create Ad Hoc Certifications

Add Comment

Add Private Comment

Discard

Manage Tags

Complete the Modification Summary

1. Complete the **Modification Summary** page

IMPORTANT! Provide a brief summary of the modification and a revised copy of your protocol document. All modifications must be added to the written protocol. It is not sufficient to provide the modification in Question 3. The revised protocol must be attached to the Basic Study Information page. If the revised protocol is not provided, the modification will be returned.

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

The screenshot shows a web interface for editing a modification. The breadcrumb trail is 'You Are Here: Test > Modification / Update #7 for S...'. The page title is 'Editing: MOD00000018'. The left sidebar has a menu with 'Modification / Continuing Review' and 'Modification Summary' (highlighted with a red circle '1'). The main content area is titled 'Modification Information' and contains three sections: 1. 'Study enrollment status:' with five checkboxes; 2. 'Notification of subjects:' with two checkboxes and an information icon; 3. '* Summarize the modifications:' with a large text input area. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue' (highlighted with a red circle '2').

Validation and Compare icons are visible in the top left of the interface.

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:** **?**

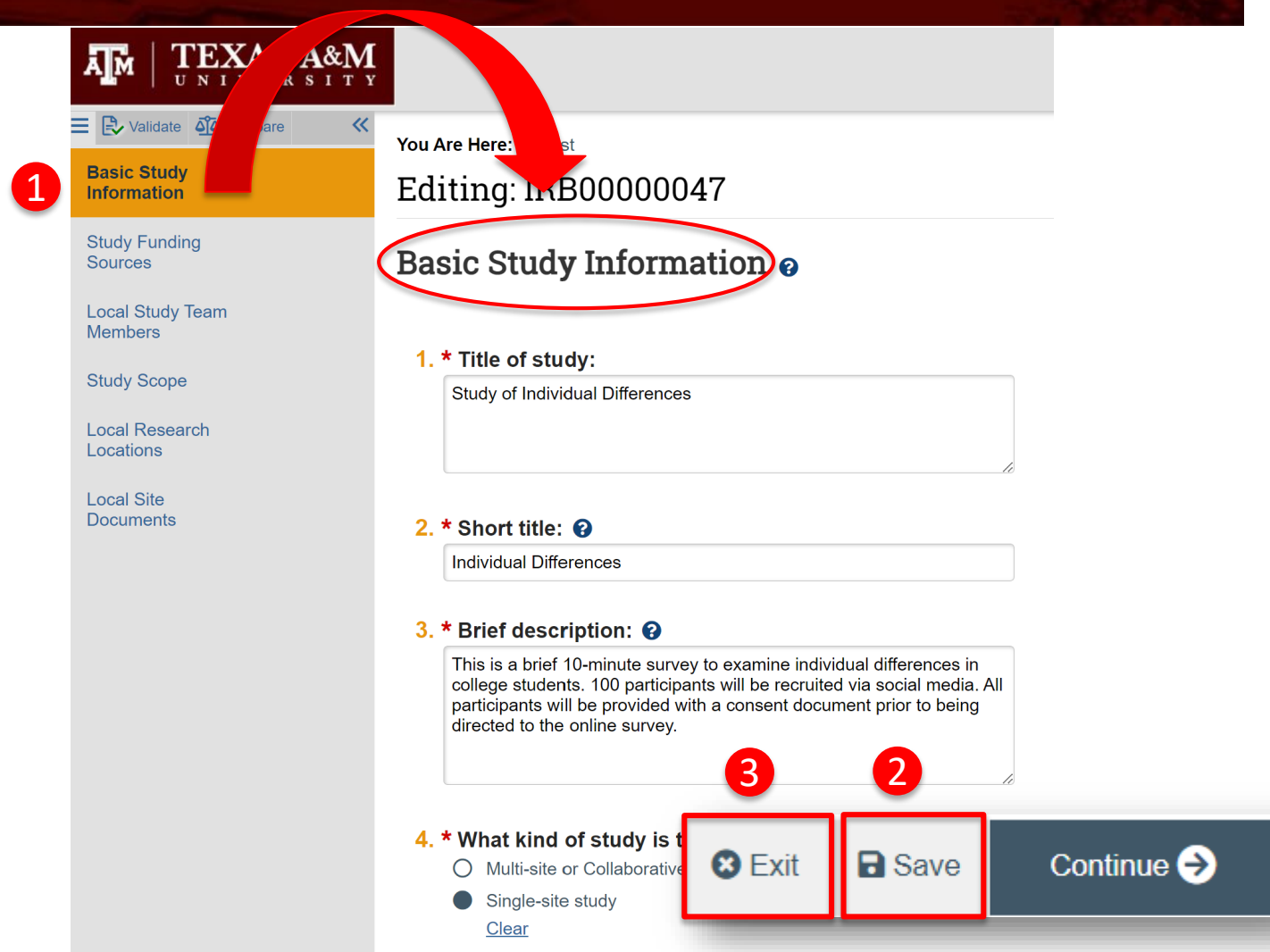
2

Exit Save Continue →

Navigate the IRB Application to make edits

Once **Continue** is selected on the **Modification Summary** page, you will be brought 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.
3. Once all edits have been made and saved, click **Exit**.



The screenshot shows the IRB application interface. The left sidebar contains a page navigator with the following items: **Basic Study Information** (highlighted in orange), Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, and Local Site Documents. A red circle with the number '1' is next to the 'Basic Study Information' link. The main content area shows the 'Editing: IRB00000047' page. The 'Basic Study Information' section is circled in red. It contains three required fields: 1. * Title of study: (text box containing 'Study of Individual Differences'), 2. * Short title: (text box containing 'Individual Differences'), and 3. * Brief description: (text area containing 'This is a brief 10-minute survey to examine individual differences in college students. 100 participants will be recruited via social media. All participants will be provided with a consent document prior to being directed to the online survey.'). A red circle with the number '3' is next to the 'Brief description' label. Below the fields are four buttons: 'Exit' (circled in red with a red circle '3'), 'Save' (circled in red with a red circle '2'), 'Continue' (circled in red with a red circle '2'), and a 'Clear' link. A red arrow points from the 'Basic Study Information' link in the sidebar to the 'Basic Study Information' section in the main content area.

How to attach your revised protocol

Modifications to approved procedures (e.g., participant enrollment, consent process, recruitment) **require** that you update your protocol document. Attach an updated protocol to the Basic Study Information page:

1. Navigate to the **Basic Study Information** page
2. Click **Update** on **Attach the Protocol** (this can be either Question 7 or 8)
3. Click **Choose File** and attach your revised protocol and then click **OK**

The screenshot shows the 'Basic Study Information' page for 'STUDY 2023-0027'. The left sidebar has a red box labeled '1' around the 'Basic Study Information' tab. The main content area has a red box labeled '3' around the 'Attach the protocol' section, which includes a '+ Add' button and a list of documents. A red box labeled '2' is around the 'Update' button in the document list. An 'Add Attachment' dialog box is open on the right, with a red box labeled '1' around the 'File to attach:' field and a 'Choose File' button. The dialog also has fields for 'Name' and 'Version number'.

Adding/removing TAMU personnel

To add TAMU 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?

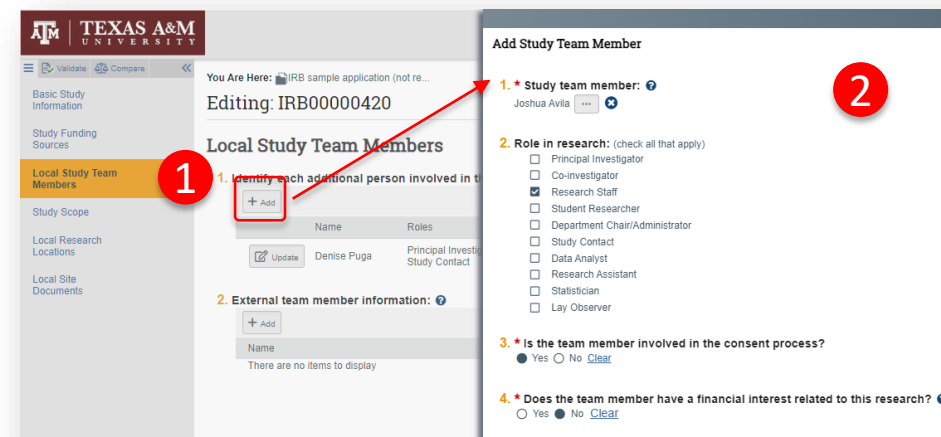
Some TAMU members (such as undergraduates, visiting scholars, and adjunct/affiliate professors) need to opt into their information being fed into Huron before they are active in the system. If you are not able to locate a member of your research team, have that individual visit the following website: <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 and log into the new [Texas A&M SSO CITI URL](#)

To remove study team members:

3. Click the X to the right of the team member.



Click **X** to Remove

How to attach new or revised study documents

If you need to add a new or revised study document in response to a clarification requested:

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**, then **Exit** to navigate back to the study Workspace.

The screenshot shows the 'Local Site Documents' page for 'Factor A' in the 'Editing: STUDY2023-0027' workspace. The sidebar on the left contains navigation options: Basic Study Information, Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, and **Local Site Documents** (highlighted with a red circle 1). The main content area shows three sections: 1. **Consent forms:** (include an HHS-approved s) with a '+ Add' button (highlighted with a red circle 2) and a document entry 'Study Consent (1)' with an 'Update' button (highlighted with a red circle 3). 2. **Recruitment materials:** (add all material to) with a '+ Add' button and a document entry 'Flyer(1)' with an 'Update' button. 3. **Other attachments:** with a '+ Add' button and a document entry 'Survey (1)' with an 'Update' button. The top of the page has 'Validate' and 'Compare' buttons and a 'You Are Here: Factor A' breadcrumb.

Submitting your modification 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**



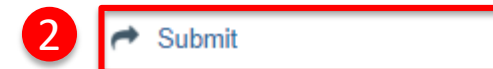
Pre-Submission

Last updated: 5/22/2023 10:08 AM

Next Steps

Edit Study

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://tamu.edu/huron/faq) to learn more about Huron functionality.