



How to respond to requests for clarifications from the IRB

Human Research Protection Program



This PowerPoint will guide you through how to respond to requests for clarification from the IRB.



Responding to clarification requested

Log into Huron:

1. From the **Dashboard**
2. Click on **My Inbox**
3. Select the **folder symbol** or the **Name** of the submission to open and review the request for clarifications.

State informs what actions are pending for the submission.

IRB Stage

TEXAS A&M UNIVERSITY

Hello, Heather Cline [Switch User](#)

1 Dashboard COI IRB

Page for Heather Cline [Help](#)

2 My Inbox My Reviews

3

Recently Viewed

Recent Pinned

No pinned item to display.

My Inbox

Filter by ID [Add Filter](#) [Clear All](#)

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY2023-0043	HRPP staff	6/21/2023 2:16 PM	6/26/2023 2:16 PM	<u>Clarification Requested (Pre-Review)</u>	Denise Puga

Review the Clarification Requested

1. The **History** tab lists the activities taken on a submission including clarifications requested from the IRB reviewer or coordinator.
2. Under the History tab, review the **Clarification Requested**.

Note: the clarification will be directly embedded in this location, but you can also click on the blue link labeled with *Clarification Requested* to open the requests in a separate window.

STUDY2023-0027: Factor A

Principal investigator: Denise Puga
 Submission type: Initial Study
 Primary contact: Denise Puga
 PI proxies: Kelly Drake

IRB office: IRB 1
 IRB coordinator: Denise Puga

PI Department: Vice President For Research



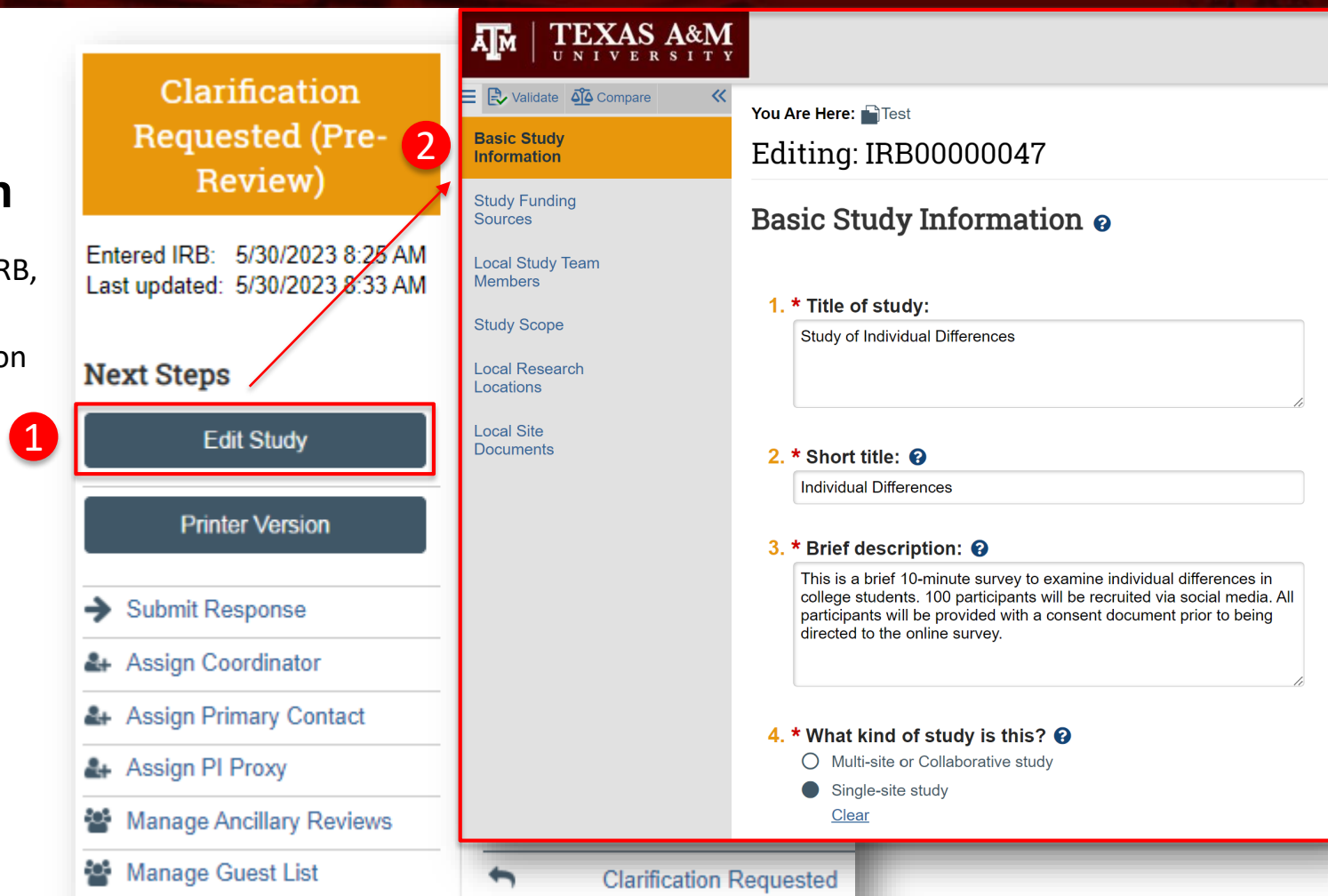
1

2

History	Funding	Contacts	COI	Documents	Reviews	Snapshots
Filter by Activity <input type="text" value="Enter text to search"/> + Add Filter ✕ Clear All						
Activity	Author	Activity Date				
Clarification Requested 1. Study Funding Source (Q 3). Please provide additional information about the sponsor. 2. Provide additional protocol information. Please see the attached supporting documents. The document contains comments that request additional clarifications/information. Requested Protocol Changes	Puga, Denise A	5/30/2023 8:33 AM				

How to Edit the application

1. If changes are needed or requested by the IRB, click the **Edit Study**.
2. This will give you access to the IRB application and allow for any edits to be made.



The screenshot shows the IRB application interface. On the left, a sidebar contains a yellow box with the text "Clarification Requested (Pre-Review)" and a red circle with the number "2" next to it. Below this, the "Next Steps" section is highlighted with a red box and a red circle with the number "1" next to it. The "Edit Study" button in the "Next Steps" section is also highlighted with a red box. A red arrow points from the "Edit Study" button to the "Basic Study Information" section of the main application area. The main application area shows the "Basic Study Information" section with the following fields:

- 1. * Title of study: Study of Individual Differences
- 2. * Short title: Individual Differences
- 3. * Brief description: 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.
- 4. * What kind of study is this?
 - Multi-site or Collaborative study
 - Single-site study
 - [Clear](#)

The top of the application area shows the Texas A&M University logo and the text "You Are Here: Test" and "Editing: IRB00000047". The bottom of the application area shows a "Clarification Requested" button.

How to navigate the application

1. The page navigator will appear on the left side of the screen. The page currently being viewed will be shown highlighted in orange.
 - Click on the page that requires edits to be made.
 - Make your edits on the page selected
2. Once the edits have been made, click **Save** and:
 - **Continue** to navigate to other pages in the application; or
 - **Exit** to return to the IRB workspace

The screenshot displays the IRB application interface. On the left, a page navigator lists several sections: Basic Study Information, Study Funding Sources (highlighted in orange), Local Study Team Members, Study Scope, Local Research Locations, and Local Site Documents. A red circle with the number '1' is placed next to the 'Study Funding Sources' item. A red arrow points from this item to the main content area. The main content area shows the 'Editing: STUDY2023-0027' page. It features a 'Study Funding Sources' section with a dropdown menu for 'Maestro Funding Source' and a table with columns for 'M-Number', 'Project Name', 'PI Last Name', and 'PI First Name'. Below the table, there are two 'View' buttons and a 'Clear' button. A red circle with the number '2' is placed next to the 'Continue' button in the bottom right corner of the application window.

How to revise your protocol

During the review process, you may be asked to edit your protocol document. To do this:

1. Read the **clarification requested**: the request contains important information about what steps need to be completed.
2. Click the attached supporting document. This will automatically download a copy of the revised protocol to your computer.
3. Open the downloaded document from your computer.

The screenshot shows a web interface with a navigation bar at the top containing tabs for History, Funding, Contacts, COI, Documents, Reviews, and Snapshots. Below the navigation bar is a filter section with a 'Filter by' dropdown set to 'Activity', a search input field with the placeholder 'Enter text to search', and a '+ Add Filter' button. A 'Clear All' link is also present. The main content area displays a table with columns for Activity, Author, and Activity Date. A single row is visible with the following data: Activity: Clarification Requested, Author: Puga, Denise A, Activity Date: 5/30/2023 11:45 AM. Below the table, a text block contains the message: 'Edits to the protocol template are needed. Please see the attached supporting document, i.e., "Requested Protocol Changes", for additional information. Once all changes have been made, please attach the revised protocol template in the Basic Study Information page.' A red box highlights a document icon and the text 'Protocol Requested Changes' below this message. Two red callout boxes with numbers 1 and 2 are positioned to the left of the screenshot. Callout 1 points to the text message, and callout 2 points to the highlighted document link.

Activity	Author	Activity Date
Clarification Requested	Puga, Denise A	5/30/2023 11:45 AM

Edits to the protocol template are needed. Please see the attached supporting document, i.e., "Requested Protocol Changes", for additional information. Once all changes have been made, please attach the revised protocol template in the Basic Study Information page.

[Protocol Requested Changes](#)

How to revise your protocol

The document provided by the IRB may include one or both of the following:

- 1. Comments in the margin** requesting clarifications.
 - The comments will appear in the exact location on the Word document where the clarifications are being requested. Please provide the information being requested in the location indicated.
 - Use Track Changes to capture all edits to the protocol document. Instructions on how to use Track Changes in Word can be found [here](#).
- 2. Track Changes** suggesting edits.
 - Suggested track changes are intended to help clarify or enhance information presented in the protocol document. Please be aware that you have the option to either accept or decline the suggested edits.
 - Instructions on how to accept/decline tracked changes can be found [here](#).

1

2

1. Purpose and rationale of the study:
This study is designed to test a novel theory.

2. Study population: 20 TAMU students will be recruited for this study. The students must 18 and older and have access to a mobile device.

Does your study population involve children under the age of 18? Yes No

a) How many participants will be enrolled? 20
b) How many subject records will be obtained or received? N/A
c) How many subject specimens will you receive? N/A

Puga, Denise A
Please provide additional information about the purpose and rationale of the study.

How to attach your revised protocol

Once you have finished editing your protocol and have addressed all the requests for clarifications, save a copy of the revised protocol document for your files and upload a copy to your initial application in Huron.

How to upload your revised protocol document:

1. Navigate to the **Basic Study Information**. To do this, click *Edit Study* from the study workspace.
 - *Note:* You may revisit [Slide 5](#) for instructions on how to complete this task.
2. Click **Update** under **Attach the protocol** (i.e., the last question on the page).
3. Click **Choose File** to attach the revised protocol document.
4. Click **OK**

The screenshot displays the 'Editing: STUDY2023-0027' interface. On the left, a sidebar menu has 'Basic Study Information' highlighted with a red box and a red circle containing the number '1'. Below this, other menu items like 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations', and 'Local Site Documents' are visible. The main content area shows the 'Basic Study Information' form with several fields: 'Title of study' (Pilot Study to Test the effectiveness of Factor A), 'Short title' (Factor A), 'Brief description' (This study examines how Factor A improves students...), 'What kind of study is this?' (Single-site study selected), 'Will an external IRB act as the IRB?' (No selected), 'Local principal investigator' (Denise Puga), and 'Attach the protocol' (with an '+ Add' button). At the bottom of the form, an 'Update' button is highlighted with a red box and a red circle containing the number '2'. To the right, an 'Add Attachment' dialog is open, showing a 'File to attach:' field with a 'Choose File' button highlighted by a red box and a red circle containing the number '3'. Below this are fields for 'Name' and 'Version number'.

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
 - Note: You may revisit [Slides 5 and 6](#) for instruction on how to complete this task.
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 displays 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 box and labeled '1'). The main content area shows three sections: '1. Consent forms: (include an HHS-approved s...)' with a '+ Add' button (labeled '2') and an 'Update' button for 'Study Consent (1)'; '2. Recruitment materials: (add all material to...)' with a '+ Add' button and an 'Update' button for 'Flyer(1)'; and '3. Other attachments:' with a '+ Add' button and an 'Update' button for 'Survey (1)'. The bottom navigation bar includes 'Exit', 'Save', and 'Continue' buttons, with the 'Exit' button labeled '3'.

Submit response to the IRB

1. Click **Submit Response** from the Study Workspace
2. The **Submit Response** smart form will appear. Use this form to provide the IRB with any additional comments or documentation.
3. Click **OK**
 - Note: Once OK is selected, your response will immediately appear in the History tab and it will be available to all with access to the submission.

The screenshot shows the IRB system interface. On the left, the 'Study Workspace' for 'Factor A' is visible. A red box labeled '1' highlights the 'Submit Response' button in the 'Next Steps' section. On the right, the 'Submit Response' smart form is displayed, with a red box labeled '2' highlighting the 'Notes' field. The form includes a 'Supporting documents' section with an '+ Add' button and a table with a 'Name' header and the text 'There are no items to display'.