

How to Respond to a Clarification or Modification Request

During the Pre-Review process, RPO staff may need to return the submission to researchers for clarifications or edits. The PI/contact/Proxy will receive an email notification from the IRB Regulatory Analyst asking for changes to the Click Smart form or IRB submitted protocol documents.

How do you know a clarification is required?

The PI (and any assigned proxy or contact) will receive an email notification requesting a clarification on a submission. An example of that email is below.

Notification of Requested Clarifications

To: Jane Doe

Link: [STUDY00000036](#) Click here to open the study/protocol

P.I.: [John Smith](#)

Title: Cure for the Common Cold

Description: Clarifications have been requested on this submission. This requires a response from you. For additional details, click on the link above to review and provide clarification.

- Click on the study/protocol hyperlink. Depending on your login status at the time, the system may require your UVM NetID /password login credentials.
- The submission will appear with a status of “Clarification Requested” or “Required Modifications” along with the step it relates to.

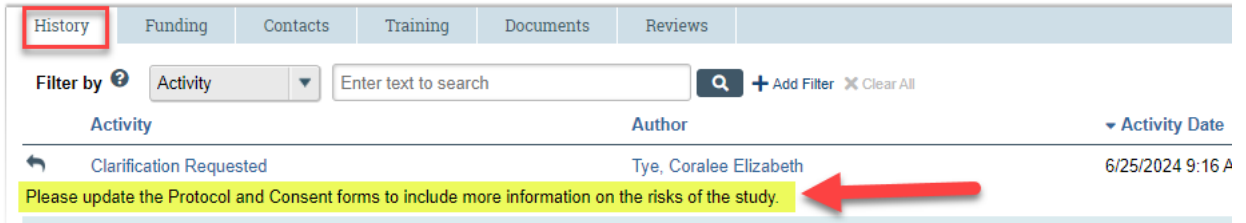
This example is looking for clarification during the Designated Review workflow stage.



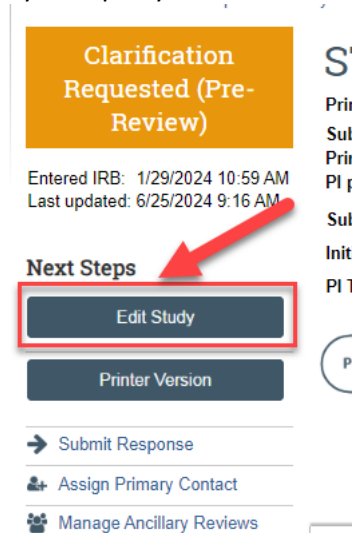
The screenshot shows the UVM IRB system interface. At the top, there are navigation tabs: Submissions, Meetings, Reports, Library, and Help Center. Below this, the breadcrumb trail reads: IRB > Submissions > Expedited Study. The main heading is 'STUDY00002706: Expedited Study'. To the left of the main content, there is a sidebar with a 'Next Steps' section containing 'Edit Study' and 'Printer Version' buttons. The main content area displays submission details: Principal investigator: [Name], Submission type: Initial Study, Primary contact: [Name], PI proxies: [Name], Submitting Department: Med, Initial Review Level: [Level], and PI Title: Professor. To the right, it shows IRB office: CHRBSS (Behavioral) and IRB coordinator: Coralee Tye. Below the details is a workflow diagram showing the stages: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. The 'Pre-Review' stage is highlighted with an orange box and labeled 'Clarification Requested'. Below the workflow diagram is a 'History' section with tabs for Funding, Contacts, Training, Documents, and Reviews. The 'Reviews' tab is selected, showing a table with columns for Activity, Author, and Activity Date. The first row shows 'Clarification Requested' by Tye, Coralee Elizabeth on 6/25/2024 9:16 AM. Below the table, there is a yellow box with the text: 'Please update the Protocol and Consent forms to include more information on the risks of the study.'

To Respond to Request for Clarifications


1. On the History tab, you may see a recent entry that says, “Clarification Requested” or “Letter Sent” or “Required Modifications Reviewed”. Directly underneath, you will see comments and/or attached files. Review the comments and the content of any attachments (if applicable). The comments and attachments (if applicable) should provide you with the additional information or changes that are required.



2. Click the dark grey button called “Edit Study” to open your forms.

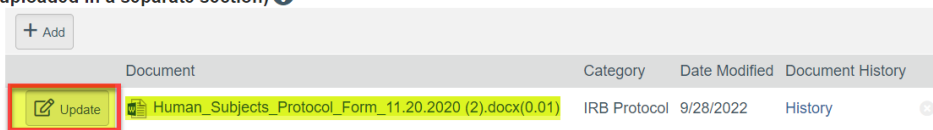


****Tip**** If you need to upload a new version of a previously uploaded document:

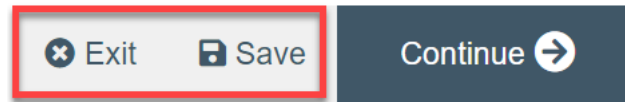
- Click the UPDATE  Update button. Do not delete previous document versions (do NOT click the x). Do not click the +Add button unless you are adding a new document type.

Example:

12. * Attach the protocol:
(e.g. industry protocol, human subjects protocol, or exempt form Note: other attachments such as consent form and recruitment materials will be uploaded in a separate section) ?



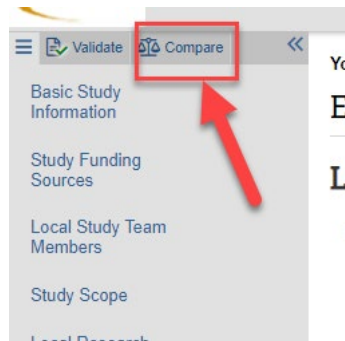
3. Depending upon the requested change, you will be required to modify the specific fields or uploaded documents in your form. Once you have edited the applicable fields, select “Save”. Then select “Exit”.



Important! The response has not yet been submitted back to the IRB Office for review.

Comparing your Updated Submission to Previous Versions

4. To see the modifications made to your study please use the Compare function.



5. On the comparison page, you can select the previous version of the submission for comparison. The pencil icons will show which parts of the study have been edited.

Can see previous versions to compare to

Local Site Documents ⓘ

Compare current state of version:
0.3 Changes submitted to IRB
with
0.2 Submit to IRB
1/29/2024 10:59:44 AM

Version	Description	Date
0.3	Changes submitted to IRB	6/25/2024 9:15:08 AM
0.2	Submit to IRB	1/29/2024 10:59:44 AM
0.1	[No description]	1/29/2024 10:54:18 AM

Can see where edits were made

1. **Consent forms:** (include all consents, consent addenda, and information s

Document

medical_consent_template_4.3.2023.docx(0.02)

References

• modified 2 minutes ago • version 0.3+ (Changes submitted to IRE

Changed: medical_consent_template_4.3.2023.docx

2. **Recruitment materials:** (add all recruitment letters, recruitment emails, s

Document

dsRoberts Rules Made Simple.pptx(0.01)

3. **Other attachments:** (See "Suggested attachments" below)

Document

Data_Management_and_Security_Plan_06-06-2023 (11).docx(0.0

ⓘ Suggested attachments:

- HIPAA Authorization Form
- Study surveys/questionnaires
- Data Management and Security Plan
- Letters of support

6. Differences can be viewed by clicking on the pencil icon to take you to that section.

12. * Attach the protocol:

(e.g. industry protocol, human subjects protocol, or exempt form Note: other attachments such as consent form and recruitment materials will be uploaded in a separate section) ?

Document versions can be compared here

Protocol was modified 1 hour ago

By clicking on the document history, you can compare document versions.

Compare	Date	Version	Person	Action	Notes	Uploaded File
<input type="checkbox"/>	10/12/2022 9:14 AM	v3	John Smith	File Uploaded & Edited		Human_Subjects_Protocol_Form_11.20.2020.docx
<input type="checkbox"/>	9/28/2022 3:45 PM	v2	John Smith	File Uploaded & Edited		Human_Subjects_Protocol_Form.docx
<input type="checkbox"/>	9/28/2022 11:13 AM	0.01	John Smith	Created		Human_Subjects_Protocol_Form_11.20.2020 (2).docx

7. To exit the comparison view, click EXIT on the bottom right-hand side of the screen.

Submitting the Clarification back to the RPO Office

8. Click the activity on the left that says “Submit Response” to send this submission back to the RPO Office for review and processing.

Submissions Meetings Re

IRB > Submissions > Expedited Study

Clarification Requested (Pre-Review)

Entered IRB: 1/29/2024 10:59 AM
Last updated: 6/25/2024 9:25 AM

Next Steps

Edit Study

Printer Version

Submit Response

Assign Primary Contact

Manage Ancillary Reviews

Manage Guest List

STU

Principal

Submission

Primary c

PI proxies

Submitting

Initial Rev

PI Title:

Pre-Subr

History

If there are any required fields that you forgot to enter, the Submit process will display them. You can use the pop-up to Jump To those particular screens quickly and enter the missing data.

Error/Warning Messages			Refresh
Message	Field Name	Jump To	
⊖ This is a required field; therefore, you must provide the required information.	Drug Involved	Study Scope	
⊖ This is a required field; therefore, you must provide the required information.	Device Involved		

NOTE: These Errors/Warning Messages only appear if required field entry was missed.

9. When submitting a response, you have the opportunity to optionally add notes and/or upload supporting documents. Clicking OK will remove this submission from your “My Inbox,” and place it in the RPO Office “My Inbox” for processing.

Submit Response

1. Notes:

Optional

2. Supporting documents:

Optional

+ Add

Name

There are no items to display

OK Cancel

Note: The bubble will change from “Clarification Requested” to “IRB Review”.

