

How to Respond to a Clarification Request During Initial Local Context Review of External IRB Studies

When relying on an External IRB, the UVM IRB needs to conduct local, institutional reviews in UVMClick prior to releasing approval to begin local research activities (see “How to Request Reliance on an External IRB” [user guide](#)). The required documentation will be requested through a clarification as needed. The PI/Contact/Proxy will receive an email notification from the IRB Reliance Administrator asking for changes to the Click smart forms or submitted documents.

How do you know that the UVM IRB is waiting for a clarification?

The PI (and any assigned proxy or contact) will receive an email notification requesting the required clarifications. 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.

The submission will also appear in your “Dashboard > My Inbox” with a status of Clarification Requested or Modifications Required, and the step of review. An example is shown below.

» Dashboard
Agreements
COI
Facilities
Grants
IACUC
IRB
...

Create ▾
My Inbox
My Reviews

Recently Viewed

- STUDY00002130: External Test Study
- STUDY00002128: Test Study #3
- STUDY00002124: Example Study Title

My Inbox

Filter by ID ▾ Add Filter X Clear All

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY00002127	External IRB	10/21/2022 8:28 AM	11/14/2022 12:07 PM	Clarification Requested (Pre-Review)	Jennifer Dulin

1 items page 1 of 1 25 / page

- Click on the study 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 Modifications Required, along with the step of review. The example below shows Clarification Requested during Pre-Review.

Clarification
Requested (Pre-
Review)

Entered IRB: 10/21/2022 11:41 AM
Last updated: 11/14/2022 12:23 PM

Next Steps

Edit Study

Printer Version

- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews

STUDY00002127: External IRB

Principal investigator: John Smith
Lead principal investigator:
Submission type: Initial Study
Primary contact: John Smith
PI proxies:
PI proxies (Lead site):

IRB office: CHRMS (Medical)
IRB coordinator: Jennifer Dulin
External study ID: 123456

Submitting Department: Med-General

Initial Review Level:

History

Funding

Contacts

Training

Documents

Sites

IRB Assignment Details

Reviews

Snaps

Filter by

Activity

Enter text to search for

Q

+ Add Filter

✕ Clear All

Activity

Author

▼ Activity Date

←

Clarification Requested

Dulin, Jennifer Anne

11/14/2022 12:23 PM

To Respond to Request for Clarifications

- On the History tab, you will see a recent entry that says "Clarification Requested" or "Letter Sent" or "Required Modifications Reviewed". Directly underneath, you will see review comments and/or attached files (blue hyperlink with document title, see below). Review the comments and the content of any attachments (if applicable) for additional information or changes that are required.

****Tip**** If the clarification comments are longer than a few lines, you will see blue text in the bottom right corner that says "read more." Click on this link to expand the entry and see all required clarifications.

History Funding Contacts Training Documents Sites Reviews

Filter by Activity Enter text to search for Q + Add Filter ✕ Clear All

Activity	Author	▼ Activity Date
← Clarification Requested	Dulin, Jennifer Anne	11/14/2022 12:23 PM
Hello Dr. Smith,		
Please see the following clarifications.		
Make all changes to documents using Track Changes, and upload revised versions by hitting "Update" to the left of the previous version in Click.		
1) Study Scope page, Question 13: Please answer "yes"		
2) Local Research Locations: Please add "Main Hospital/ACC" to the list of locations.		
3) Local Site Documents: Please upload your Consent Process Documentation form.		
4) Local Site Documents: Please delete the UCLA approval memo; we do not need approval memos f. . read more ▼		
1-request to rely on external irb 10.25.2021.docx		

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

**Clarification
Requested (Pre-
Review)**

Entered IRB: 10/21/2022 11:41 AM
Last updated: 11/14/2022 12:23 PM

Next Steps

[Edit Study](#)

[Printer Version](#)

[→ Submit Response](#)

3. Depending upon the requested change, you may be required to modify specific fields or upload documents.

****Tip**** When uploading any document:

****Tip**** If you want to REVISE a previously uploaded document, click the UPDATE button, not the +Add button. Do not hit “x” to delete the previous version at any time. It must remain in the Document History.

Example:

Local Site Documents

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

<div><div>+ Add</div></div>				
Document	Category	Date Modified	Document History	
<div><div>Update</div></div> Consent Form(0.01)	Consent Form	11/9/2018	History	

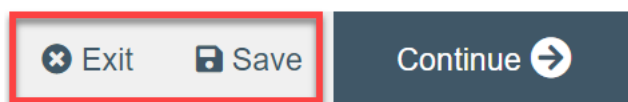
****Tip**** If you want to ADD new materials, click the +Add button, not the Update button.

Example:

Other attachments:

<div><div>+ Add</div></div>			
Document	Category	Date Modified	Document History
There are no items to display			

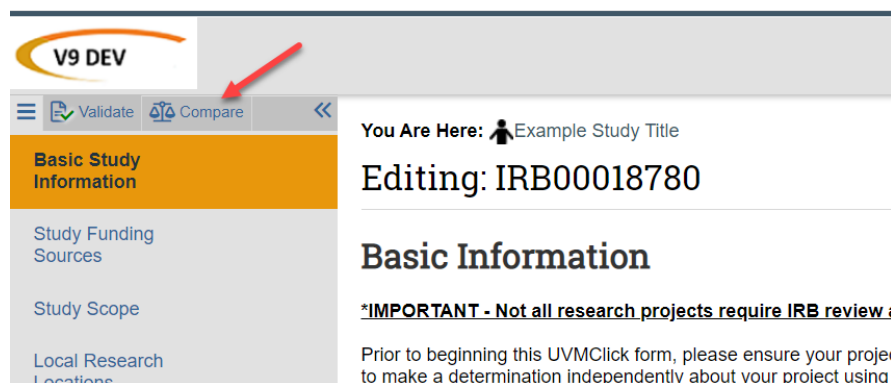
4. Once you have edited the applicable fields, select “Save”. Then select “Exit”.



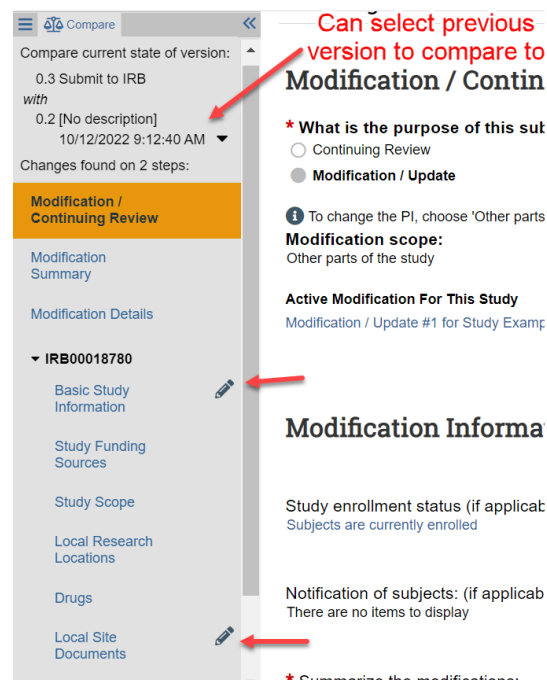
Important! The response has not yet been submitted back to the IRB for review.

Comparing your Updated Submission to Previous Versions

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



2. 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.



3. 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) ?

The screenshot shows a document titled "Human_Subjects_Protocol_Form_11.20.2020.docx(v3)" with a category of "IRB Protocol" and a date modified of "10/12/2022". A red arrow points to the "History" link, with a note: "Document versions can be compared here". Below this, a "Differences" section shows a comparison between version 1.2 (MOD00010568) and the current version. A red arrow points to the "Changed:" section, with a note: "Protocol was modified 1 hour ago".

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

Resource History for Human_Subjects_Protocol_Form_11.20.2020.docx

Title: Human_Subjects_Protocol_Form_11.20.2020.docx
File: Human_Subjects_Protocol_Form_11.20.2020.docx
Owner: John Smith
Author:
Content Type: Document
Version: v3
Description:

History:

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

Compare

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

Submitting the Clarification back to the RPO Office

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

The screenshot shows a screen titled "Clarification Requested (Designated Review)". Below the title, it says "Entered IRB: 9/28/2022 11:45 AM" and "Last updated: 9/28/2022 3:46 PM". Under the heading "Next Steps", there are three buttons: "Edit Study", "Printer Version", and "Submit Response". The "Submit Response" button is highlighted with a red border. Below these buttons are two links: "Assign Primary Contact" and "Assign PI Proxy".

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. Click on blue hyperlinks.

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	Study Scope	

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

- When submitting a response, you have the opportunity to optionally add notes and/or upload supporting documents (do not use this to upload documents required to be in the Smart Forms). These are not required fields. Clicking OK will remove this submission from your “My Inbox,” and place it in the IRB Reliance Administrator’s “My Inbox” for processing.

Submit Response

1. Notes:

Optional

2. Supporting documents:

Optional

Add

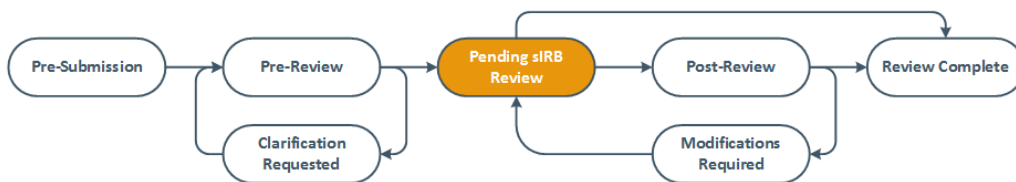
Name

There are no items to display

OK

Cancel

Note: The status will change from “Clarification Requested” or “Modifications Required” to an IRB Review status.



Approval to Begin Local Activities

Once the IRB has all of the required documentation, including the site approval memo from the External IRB, approved local consent(s), and all local Ancillary Reviews are completed, you will receive a memorandum that states that you are approved to begin local activities and the IRB review status will be “Review Complete”.