Single Site or Multi-site Study: Clarification Requests

Clarification Requests – Step by Step Instructions

The IRB system is available at https://irb.energy.gov

Clarification requests can be anything from making a change in the smartform in IRB system, uploading missing documents, or making changes within the documents (e.g., protocol, consent form) and uploading the new version.

The steps for responding to a clarification request are outlined below. Steps are the same for an initial, modification, or continuing review. Steps for responding to a clarification request can happen during:

- Pre-review
- Designated review

An IRB Coordinator or an IRB member will send a clarification request asking for changes via the IRB system. The system will also send a notification email to the Principal Investigator (PI) and PI proxy (if applicable). The request will also show in the history of the study in the study workspace.

Clarification Request for a Pre-Review of Designated Review

Log in to IRB system.

The study will appear in the My Inbox. It will state it is in a "Clarification Requested" state.

On the study's workspace, click the "Edit Study" button.

Making Changes in the Smartform

If you need to make changes to smartform, the full smartform will open.

- Click on the smartform page where the changes need to be made.
- Make the change.
- Click Save then Exit.

Making Changes to the Documents

If you need to make changes to the document already in the smartform, click on the "Update button" next to the document. **Do not upload a track-changed document**. Click the OK button. See screen shot below:

12. * Attach the protocol: ?

[Add]

Document
[Update] HRP-503-Protocol
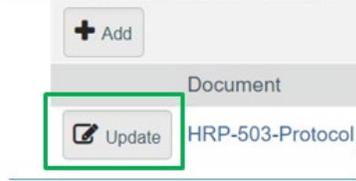
- You will know when the new version has been uploaded since it will show the date you modified the document.

1. * Attach the protocol: ?

[Add]

Document	Category	Date Modified	Document History	
[Update] HRP-503-TEMPLATE-Protocol with Instructions_test.docx(0.02)	IRB Protocol	8/29/2022	History	✖

- If you want to see the history of when you updated the documents through the lifetime of the study, click "History" on the document line.

1. * Attach the protocol: ?

[Add]

Document	Category	Date Modified	Document History	
[Update] HRP-503-TEMPLATE-Protocol with Instructions_test.docx(0.02)	IRB Protocol	8/29/2022	History	✖

Title: HRP-503-TEMPLATE-Protocol with Instructions_test.docx
File: HRP-503-TEMPLATE-Protocol with Instructions_test.docx
Owner: PI Hendricks
Author:
Content Type: Document
Version: 0.02
Description:

History:

Compare	▾ Date	Version	Person	Action	Notes	Uploaded File
☐	8/29/2022 3:15 PM	0.02	PI Hendricks	File Uploaded & Edited		HRP-503-TEMPLATE-Protocol with Instructions_test.docx
☐	6/20/2022 12:48 PM	0.01	PI Hendricks	Created		HRP-503-TEMPLATE-Protocol with Instructions_test.docx

Save the changes, exit, and it will take you to the Study workspace.

Changes will show in the History, but it is **NOT** submitted to the IRB.

Responding to a Clarification Request

Once you have made all the changes to the study, you will need to submit to the IRB.

On the study workspace, click the "Submit Response" button. Enter the comments and click "OK" button.

Printer Version

➔ Submit Response

&+ Assign Primary Contact

&+ Assign PI Proxy

👥 Manage Ancillary Reviews
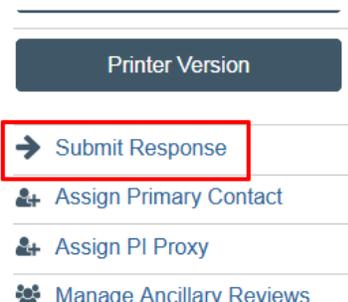
The study goes back to the IRB.

Clarification Request for a Committee Review

Making Changes in the IRB system

Once in the IRB system, the study will appear in the IRB My Inbox. It will state it is in a "Clarification Requested" state.

Since the study is at a committee review state, the study **cannot** be edited. Only a response can be submitted.

On the study workspace, click the "Submit Response" button. Enter the comments and click "OK" button.
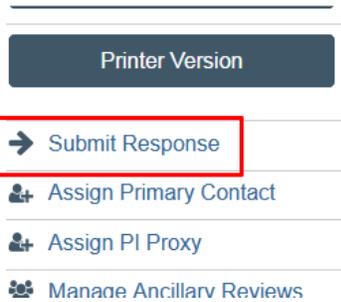
The study goes back to the IRB.

If you need any assistance while submitting to the IRB system, please contact your IRB administrator. If you do not know your IRB administrator, please visit the DOE website that lists the site IRB administrators at https://science.osti.gov/ber/human-subjects/IRBs.