



## Quick Step By Step Instructions for How to Respond to an HS Review in IRAP

1. An email will be sent to the PI and the PI's delegates from the IRB Reviewer.
  - a. There will generally be a Word document of the letter from the IRB or Office of the IRB attached to this email. Save the letter to your computer.
  - b. Use the letter to provide your point-by-point response to the IRB or Office of the IRB. Use spacing, bold font, or differing font color to distinguish your response from the questions. Save the response letter to submit into IRAP.
2. Log into IRAP ([irap.uab.edu](http://irap.uab.edu))
3. Click on IRB/Human Subjects
4. Search for the IRB Project via one of the options below based on your role:
  - a. If you are the PI, named as key personnel on the protocol, or have been named as a delegate of one or more key personnel – Click on Search For>Enter the IRB Project Number (IPN) in the Record Number field>Search by “IRB-XXXXXXXX” or “\*XXXXXXXX”.
  - b. If you are the PI – you may click on “Show List” to see all of your projects.
  - c. If you are the delegate of one or more of the study's key personnel (including the PI) with access to HS – you may click on Show List>Click on the People Icon and select the name of the PI for the record that you are looking for.
5. Click on the yellow folder icon of the project that requires a response.
6. The project will open to the screen that shows all Submissions for the life of the project. The submission that needs a response will be in a status of “Additional information required,” and beneath it will be a blue hyperlink that reads, “Respond to Change Requests.”
  - a. If the status of the submission is not “Additional information required” – please contact the individual that sent you the review results email, they will update the record so you can respond.
  - b. If you can see the status of “Additional information required” but cannot see the hyperlink that says “Respond to Change Requests” – first make sure that you can see the green “Edit Mode” text at the top right of the record and the “Add New” button. If you can see both of these – check for a Response to Info/Mod Request immediately under the submission with a status of “Additional information required”. It could be that the response has been started, if there is a submitted date next to the response, the response has been submitted. If a response has been started but has not yet been submitted, click the “Response to Info/Mod Request” link to the response to continue responding.
  - c. If you see a red “View” box, you are a delegate without edit access or someone else is editing the record. Contact [IRAP@uab.edu](mailto:IRAP@uab.edu) for help.
7. Click on the “Respond to Change Requests” hyperlink>Select “Response to Info/Mod Request” in the popup window dropdown list. Click Save.

8. The Response submission has now been created. It will contain all of the documents that were included in the submission that this response is related to. DO NOT DELETE ALL DOCUMENTS.
  - a. If the letter from the IRB or Office of the IRB requests changes to documents, revise your documents using tracked changes whenever possible. This allows the reviewer to see additions and texts that were deleted.
  - b. Save a clean version and tracked version of any document that you revise for your response.
  - c. When naming the documents you are including with your response, follow the IRB's naming conventions located at <http://www.uab.edu/research/administration/offices/IRB/Guidance/Pages/IRAP-Naming-Conventions.aspx>.
  - d. To add documents to your response, click on the blue "Add" hyperlink directly above the Document/Form list. In the pop up, you can add documents. Browse and select the document. Using the IRAP Naming Conventions, add document name in the name field and select the correct document category from the picklist. When finished adding, naming and selecting the document category click on upload. The pop up will refresh and additional documents can be added. You will be unable to see all of the documents that you have uploaded until you close out of the pop up window and the submission.
  - e. Make sure to add the response letter (described in 1.a above) to your submission as well.
  - f. If you are replacing documents that were in a previous submission or removing documents altogether, you should delete documents from the response submission by clicking on "Remove" on the line next to the document.
9. When finished adding all documents, click on close. The pop up window will close and the submission page will refresh and show all of your documents.
10. Click on the "Submit" button near the top right of the screen to send your response to the Office of the IRB.
11. You may click Done in the upper left corner to close out of the record.

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