

How to Respond to IRB Requests

Responding to IRB Requests

1. View and respond to the IRB Requests in the Smartforms.

For a New Study click on Edit Study:

Current State Pre-Review Changes Requested <input type="button" value="Edit Study"/>	Study: Test Study Full Title of Study: Test S (NOTE: Protocol ID: IRB#1
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For an Amendment (AM) click on Edit Amendment and/or Edit Modified Study:

Current State Pre Submission <input type="button" value="Edit Amendment"/> <input type="button" value="Print-Friendly Amendment"/> <input type="button" value="Edit Modified Study"/>	Amendment:Amendment #2 Amendment ID: IRB#11-000042-AM-000 Study Name: Sample Approved Study Principal: A PI1
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For a Continuing Review (CR) click on Edit Continuing Review:

Project State Pre-Review Changes Requested <input type="button" value="Edit Continuing Review"/> <input type="button" value="Printer-Friendly Version"/>	Continuing Review: Continuing Review ID: IRB#12-000 Study ID: IRB#12-000
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The first section of the Smartform will appear.

2. Click on the arrow so it points down.

<< Back	Save Exit Hide/Show Errors Print... Jump To: 1.1 -
Study Title and Key Personnel ▾	
2	▶ Reviewer Notes (0 Notes Total)

If there no IRB Requests for Section 1.1 you will see the message "There are no items to display".

3. Click on Next to view the next Section with an IRB request.

<< Back	3	Save Exit Hide/Show Errors Print... Jump To: 1.1 -
Study Title and Key Personnel ▾		
▼ Reviewer Notes	Next	
Type	Reviewer	Date
There are no items to display		

4. **DO NOT** click on “Click here to respond...” yet, instead:

- a. Make all the requested changes in the Smartform.
- b. Click Save after making changes to the Smartform.
- c. When the changes are complete (make sure to SAVE your changes), click - **Click here to respond...** A dialogue box will open.

4b

The screenshot shows the 'Reviewer Notes' section of a software interface. At the top, there are navigation buttons: '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To: 10.1 - Study Summary - Research Study', and 'Continue >>'. Below this is a 'Filter by' section with a dropdown menu set to 'Type', and buttons for 'Go', 'Clear', and 'Advanced'. A table with the following columns is visible: 'Type', 'Reviewer', 'Date Created', and 'Date Modified'. The table contains one entry: 'IRB Request' by 'IRB Staff1' on '3/5/2012 4:30 PM', with a 'Date Modified' of '3/5/2012 4:30 PM'. Below the table, there is a text field with the value '5.0 Please complete this item to include how much time will be required of the subjects, per visit or contact, and in total for the study.' At the bottom, a red message reads 'Response Required! Click here to respond...'.

5. **When the dialogue box opens:**

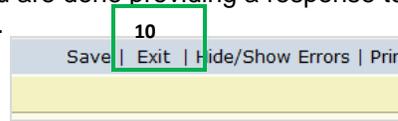
- a. Use the pull down menu to indicate how you are responding.
- b. Write a response to the IRB in the Text box (e.g., Done, Complete). You do not need to repeat the response provided in the Smartform.
- c. Click OK

The screenshot shows a dialog box titled 'Respond to Reviewer Notes' with a 'Help' button in the top right. The dialog contains the following information: 'Author: Yana Gorelik' with a message 'Please revise the consent form to remove the footer. Attach both a marked and clean copy of the revised consent form.' Below this, there are three fields: '* User: A P11', '* Type: Change Request Completed' (with a dropdown arrow), and '* Response: Change Request Completed' (with a dropdown arrow). A text area for writing a response is visible below the 'Response' field. At the bottom of the dialog, there is a 'Required' label, an 'OK' button, and a 'Cancel' button. Annotations '5a', '5b', and '5c' are placed over the 'Type' dropdown, the response text area, and the 'OK' button respectively.

Your response will appear in a green text box.

This screenshot shows the same 'Reviewer Notes' interface as in the previous image. The 'Response Required!' message is no longer present. Instead, a green text box at the bottom of the page contains the text: 'Change Request Completed - Study Staff5 - 4/10/2012 9:46 AM completed'.

10. Repeat steps 3-5 to respond to all IRB Requests. When you are done providing a response to all the IRB Requests, click "Exit" to return to the workspace to submit your response.



11. **PI, PI Proxy, FS:**

Click **Submit Response** to submit the revised application to the IRB for review. The activity "Submit Response" is not available to Study Staff.

Study Staff:

Use the **Send Ready Notification** to let the PI know that the response is ready to be submitted. An email will be sent to the PI, PI Proxies & FS that contains a link to the study workspace. Once in the workspace, the PI can click **Submit Response** to submit the revised application to the IRB for review.

