Review Response Submission Form

• This form is used to reply to the IRB and address the issues/stipulations raised when the IRB conditionally approves the submission, defers it, returns it as Incomplete submission, or for administrative modifications.
If you don’t have a “Submission Response” task under the “Incomplete Task” tab, click on “My Studies” and proceed to the next slide.

If you have a “Submission Response” task under the “Incomplete Task” tab, click on the icon under Open to access the “Review Response Submission Form”. Skip the next 2 slides to slide # 5.
Locate the study and click on the “Open” icon.
Click here to open Submission Response Form
Scroll down to read the stipulations.
In most cases, the IRB asks you to make changes to a section and presents you with a direct link to that section. If this is the first time you’re making a change, you will have an “Add Revision” icon. Click on “Add Revision” to create a revision and make the requested changes (proceed to the next slide).

If there is no “Links to Components” section to take you where you need to go to make your changes, skip to slide # 12.

If there is no “Add Revision” here, then that means that a revision was already created and available for editing. Click on “Edit/View” and skip to slide # 8).
Click OK to proceed.
The system will create a revision (if one didn’t exist), and take you to the section where you need to make your changes. You can also make changes to any of the other sections listed on the left. Make sure your changes are saved by clicking on “Save and Continue to the Next section”. When you finish making your changes, click on the “Back” button to take you back to the Review Response Form.
Once a new revision had been created, you can directly go to the section that has been associated to a stipulation by clicking on the Edit/View icon to open the new revision and go directly to that section to make your changes.

Note: You will notice that the “Add Revision” link under “Revise” has disappeared since a revision had already been created (Version 1.1) and attached. The system will only create a revision once.
For each of the remaining stipulations, you would (1) click on “Edit/View” to make changes to the linked section (if available), (2) click on “N/A”, “Yes”, or “No”, and (3) type your response in the text box provided underneath. (4) Don’t forget to click on “Save Form” to save your work.

If you want a place where you can tell the IRB something that is not related to any of these stipulation, or a one place where you can list all the changes that you have made, scroll down to the very bottom.
You can list here all the changes you made as a result of this response including changes to the application, Consent forms and Study Documents. You can also address any or all stipulations here, if you prefer.

To save your changes and close this form, click on “Save Form”. Skip to slide # 25.
In some instances, you would not have a link in any of the stipulations to take you where you need to go to make your changes. In such cases, you can directly access the Initial Review Submission Form, Application, Consent Forms, or the Study Documents and make your changes directly to them (see next few slides).
Scroll up to the top of the “Review Response Submission Form” and click on the “Click here to view a revised copy of the Initial Review Submission Form”
This will take you to the Initial Review Submission Packet.

Click “Save and Continue to the Next section”
If you don’t need to make changes to the application, click on “Save and Continue” and skip to slide # 21.

If you need to make changes to the application, check first if there is a read/write version that you can make your changes to by clicking on “Edit/View”. If the application revision is read/write, then go to slide # 18, skip slide # 19, and then go to slide # 20.

If the version under “Edit View” is read only, then you need to create a revision before you can make your changes. To do so, click on “Click here to create a revision to the attached application” button. Proceed to the next slide.
Click on “Add revision” to create a new revision that you can edit.

Note: If the “Add Revision” is absent from this screen, this is an indication that a revision has already been created and can be used to make changes. In this case, skip to screen # 19.
Click “OK” to confirm. This might take a few seconds to open.
A new revision will open. This revision should be read/write and will allow you to make changes (except to section 3).

You can click on a section on the left to open and edit it. Make sure your changes are saved in each section by clicking on “Save and Continue to the Next section”. When you finish making your changes, click on the “Back” button to take you back to the previous screen.
This will bring you back here. Notice the new revision (1.1).

Make sure the “Select” radio button is checked before clicking on “Save Attachment”. This will attach the newest revision of the application to the Initial Review Submission Form.
This should take you back to the “Initial Review Submission”. Notice the new revision (1.1) attached here. To make more changes to the application, you would click on “Edit/View”.

When you’re done making changes to the application, click on “Save and Continue”.
Click on “Save and Continue” when you’re done.

If you need to add a new consent form or make changes to an existing one, click on one of these buttons. Click on one of the links below for instructions on how to:
- Add a new consent Form
- Revise a consent form
Click on “Save and continue” when you’re done.

If you need to add a new study document or make changes to an existing one, click on one of these buttons. Click on one of the links below for instructions on how to:
- Add a new document
- Revise an existing document
Form has been Completed!

Click “Exit Form”
We’re back in the “Review Response Submission Form.”

You can address more stipulation and when you’re done, click on “save Form.”
Form has been Completed!

Click on one of these buttons to proceed:

- Exit Form
- Signoff and Submit
- Return to Form
If you decided to send later, here is where you send it to the PI for signoff and then to the IRB, when you are ready.