Review Response Submission Form for Continuing Review 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.
Log in into the INSPIR website. This will bring you to your Home page.

Under the “Below are your incomplete IRB tasks”, click on the “Submission Response” folder icon (blue arrow) to display the tasks. If you have a task in that folder, click on the “Open” icon (green arrow) to access the “Review Response Submission Form”. Skip the next 2 slides to slide # 5.

If you don’t have a task in the “Submission Response” folder, click on “My Studies” (orange arrow) and proceed to the next slide.

Note: In order to get the tasks for this study in your “Incomplete Tasks” (and receive all study notifications), you need to be also listed as a Study Contact on this study before you can get them. Refer to these instructions if you want to be added as one: [http://www.bumc.bu.edu/irb/files/2016/10/How-to-add-Administrative-Assistant.pdf](http://www.bumc.bu.edu/irb/files/2016/10/How-to-add-Administrative-Assistant.pdf)
Locate the study and click on the “Open” icon.
Click here to open Submission Response Form
Scroll down to read the stipulations.

Note: The first stipulation is usually informational and is used by the IRB analyst to communicate to you the review outcome and to provide instructions. Please read it carefully before skipping to the next stipulation.
There are 4 types of Stipulations

- A Stipulation that requires changes to the Continuing Review Form and a link to the component/section is provided to take you there (slides 7-10).
- A Stipulation that only asks for clarification and requires no changes to be made, and therefore, there is no link to any of the components/sections (slide 11).
- A Stipulation that requires changes to the Continuing Review Form; but there is no direct link provided to take you there (slides 12-16).
Stipulations that require changes to the Continuing Review Form and a link to the “Continuing Review Submission Form” is provided in the “Links to Components” section (yellow arrow) of the stipulation. If you don’t have such a stipulation, skip to slide # 11.

For these types of stipulations, you would click on the “Revise Existing” button (green arrow) to create a revision of the Continuing Review form and make changes to it. But if there is no “Revise Existing”, that means a revision already exists and attached, and you would click instead on the “Edit/View” icon (blue arrow) to access it and make your changes.
If you get this popup, click on “OK”
This will take you to the linked component/section in the Continuing Review form (in this example, the stipulation was linked to section 2.1). Make all the changes requested and when you’re done updating this form, click on “Save and Continue”, then click on “Exit Form”.
You’re back in the Review Response Form. If you want to go back to make more changes, click on “Edit/View” (green arrow) and make these changes. When you’re done with all the changes requested in this stipulation, (1) click on “N/A”, “Yes”, or “No”, and (2) type your response in the text box provided underneath. (3) Don’t forget to click on “Save Form” to save your work.
Stipulations that only ask for clarification and require no changes to be made, and therefore, there is no link to any of the components/sections. If you don’t have such a stipulation, skip to slide #12.

In this type of stipulations, you only need to answer the IRB question or give your explanation in the text box provided. When you’re done click on “Save Form”. 
Stipulations that require changes to the Continuing Review Form, but there is no direct link provided to take you there. If you don’t have such a stipulation, skip to slide # 17.

In this type of stipulations, you need to manually go to the component/section to make the changes requested. To do so, scroll to the bottom of the Review Response form.

Note that there is no “Links to Components” section here.
Scroll down to the bottom of the “Review Response Submission Form” and click on the “Click here to view a revised copy of the Continuing Review Submission Form”
If you get this popup, click on “OK.”
If you get this popup, click on “OK”, and start making any changes needed to the Continuing Review.

Make all the changes requested and when you’re done updating this form, click on “Save and Continue”, then click on “Exit Form”
This form allows you to respond to recommendations, stipulations, or other issues identified during the review process. Please make the appropriate revisions to your submission and attach the new versions to this submission form in the appropriate area.

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

This will bring you to the Review Response.
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 “Response Comments” at the very bottom of the Review response form. Otherwise, skip to the next slide.

You can list here any additional changes you have made or comments you want to give.
Exiting the Review Response Form and Submitting it
To save your changes and close this form, click on “Save Form”.
If you want to exit this form and come back later, click “Exit Form”.

If you want to return to the form, click “Return to Form”.

If you want to exit this form and submit to the IRB, click “Notify PI for Signoff” or “Signoff and Submit”.

Form has been Completed!
If you decided to send later, you can come back here by clicking on “My Studies”, locating this study, then by clicking on the “Open” icon. This will bring you to this page. When you are ready, click on “Send Submission” to send the Review Response to the PI for signoff and then to the IRB.