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 are listed as a “Study Contact” on the study, you should have received an email notification about the Submission Response and you should have a task in the “Submission Response” folder (green arrow) on your Home Page. If the Task is hidden in that folder, click on the small arrow to display the task (red arrow).

Find the task and Click on the icon under “Open” to access the “Review Response Submission Form”. Skip the next 2 slides to slide # 5.

Note: If you don’t have a “Submission Response” folder or if you don’t have a task for this study in that folder (which indicates that you are not listed as a “Study Contact” on this study), click on “My Studies” (yellow arrow) and proceed to the next slide.
You can use the filter or the “Find by ...” feature to locate the study. Or you can just scroll down.

Locate the study and click on the “Open” icon.
Click on this link to open the Submission Response Form
Stipulation 1 is usually informational. It includes the IRB’s review outcome of the previous round. It also includes instructions on how to proceed and the IRB Analyst’s contact information.

If your Review Response Submission Form has
- Stipulations to make changes to the study Application – Proceed to the next slide
- Stipulations to make changes to Consent Form(s) – Go to the slide # 11
- Stipulations to make changes to Study Documents – Go to the slide # 22
In most cases, the IRB asks you to make changes to a section in the Study Application and presents you with a direct link to that section. If this is the first time in this “Review Response Submission Form” that you’re making a change to the Study Application, you will have a “Revise Existing” button.

- Click on “Revise Existing” to create a revision and make the requested changes (proceed to the next slide).

If there is no link in the “Links to Components” section to take you where you need to go to make your changes, skip to slide # 29.

If there is no “Revise Existing” here, this means that a revision was already created and available for editing. Skip to slide # 10).
Click OK to proceed.
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.
Note: You will notice that the “Revise Existing” link has disappeared since a revision (Version 1.2) had already been created and attached (green arrow). The system will only create a revision once. To let others know that this stipulation has been addressed, click on “Complete Action”.

Once a new revision is 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 make more changes.

In the Text Box, let the IRB know that you have made the changes requested in this stipulation. You can add any additional information here about this stipulation.

- Make sure you frequently save your changes by clicking “Save Form”.
For each of the remaining stipulations, you would (1) click on “Edit/View” to make changes to the linked section, (2) type your response in the text box provided underneath, and (3) click on “Complete Action” button to mark it as completed. (4) Don’t forget to click on “Save Form” to save your work.

<table>
<thead>
<tr>
<th>Stipulation Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Stipulation must be addressed)</td>
<td>please list funding.</td>
</tr>
</tbody>
</table>

If your Review Response Submission Form has
- Stipulations to make changes to Consent Form(s) – Proceed to the next slide
- Stipulations to make changes to Study Documents – Go to the slide # 22
- No Stipulations to make changes to Consent Form(s) or Study Documents – Go to slide # 26
In most cases, the IRB also asks you to make changes to the consent form and presents you with a direct link to that form. If this is the first time you’re making a change, you will have a “Revise Existing” button. Click on “Revise Existing” to create a revision and make the requested changes (proceed to the next slide).

If there is no link in the “Links to Components” section of the stipulation to take you where you need to go to make your changes, skip to slide #29.
Click OK to proceed.
1. Click OK to proceed.

2. You will get the “Informed Consent Document” page. Click on “Check-out Document” to download a copy of the existing consent form and make changes to it.
Download the Consent Document

INSTRUCTIONS

Step 1:
If your browser blocks pop-ups, then after a few moments a bar similar to the one shown below may appear in your browser.

To help protect your security, Internet Explorer blocked this site from downloading files to your computer. Click here for options...

Simply click on the bar and a small drop down list will appear. Click Download File from the list of options.

Step 2:
In a few moments, your browser will prompt you to either Open or Save the file (see example below).
Note: this is not the actual File Download box, it is only a picture. In order to Check-out the document and edit it, you will need to Save it to your workstation.

The system will take you to this page. You will also get a pop-up asking you to open or save the word (rtf) document. Click on “Open”.

Do you want to open or save Consent_323148.rtf (254 KB) from inspir.bu.edu?

[Buttons: Open, Save, Cancel]
This will open the copy of the consent form as a Word document. Click on “File”, then on “Save As” and save it on your desktop with a familiar name that you can find later. You can start making changes to this document now or make them later. Just remember to always save your work.
Now back to INSPIR, you need to press “Complete Checkout” to let everyone know that it is checked out by you and so that the system would give you the option to check it in later when it is ready to be uploaded.
The system will bring you back to “Informed Consent Document” page. It will now have you as the person who has the document checked out. It also presents you with the “Check-in Document” button so you can check it in when the document is ready.

Click “Save Consent” to close this window for now.
This will bring you back to the Review Response Submission Form. Note that it tells everyone that it is checked out by you (green arrow).
- When you are ready to upload the revised consent form, click on the “Edit/View” (note and pencil) icon (yellow arrow) and proceed to the next slide.
This will bring you back to the “Informed Consent Document” screen. Click on “Check-in Document” button to upload the revised consent form. You would browse and select that document from your desktop.
When you successfully select the revised consent document, the screen would change and it will no longer be checked out by you.

Make sure you change the version date to today’s date.

Then click “Save Consent” to save your changes and close this window.
This will bring you back to the Review Response Submission Form. (1) Type your response in the text box provided underneath, and (2) click on “Complete Action” button to mark it as completed. (3) Don’t forget to click on “Save Form” to save your work.

If your Review Response Submission Form has
• Stipulations to make changes to Study Documents – Proceed to the next slide
• No Stipulations to make changes to Study Documents – Go to slide # 26
In most cases, the IRB also asks you to make changes to a study document that you have attached and presents you with a direct link to that document.
- If this is the first time you’re making a change to this document, you will have a “Revise Existing” icon. Click on “Revise Existing” to create a revision and make the requested changes (proceed to the next slide).

And in rare cases, the IRB might ask you to remove/delete a study document. In this case you would click on “Remove” instead.

If there is no link in the “Links to Components” section to take you where you need to go to make your changes, skip to slide # 29.
Click OK to proceed.
You will get the “Study Documents” screen. Click on “Check-out Document” to download a copy of the existing study document and make changes to it.

This is similar to the consent form process. You can follow the same steps, slides 14-20 and then return here and proceed to the next section.
This will bring you back to the Review Response Submission Form. (1) Type your response in the text box provided underneath, and (2) click on “Complete Action” button to mark it as completed. (3) 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”.
Click on one of these buttons to proceed

- Clicking “Exit Form” will take you back to where you started, either to your Home page (see slide # 1) or to the “Submissions” tab of the study (see next slide).
- Clicking “Notify PI to Signoff” will notify the PI to sign off. If you are the PI, you will have the “Signoff and Submit” button instead. Clicking on “Signoff and Submit” button will take you to the “Submission Routing Signoff” page where you can signoff as the PI.
- Clicking “Return to Form” will take you back to the Review Response Submission Form.
If you decided to “Exit Form” and send later, here is where you send it to the PI (or yourself if you are the PI) for signoff when you are ready.
In some instances, you would not have a link in the stipulation to take you to the form or document where you need 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).
If your Review Response Submission Form has:

- Stipulations to make changes to the study Application – Proceed to the next slide
- Stipulations to make changes to Consent Form(s) – Go to the slide # 35
- Stipulations to make changes to Study Documents – Go to the slide # 37
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 the “Study Application” link.

If the version in the “Study Application” link” is read only, then you need to create a revision before you can make your changes. To do so, click on the icon in the “Revise/Attach” column. Proceed to the next slide.
Click OK to proceed.
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 Review Response Submission Form.
You are back in the “Current Submission Components” Section of the “Review Response submission Form.

If your Review Response Submission Form has

• Stipulations to make changes to Consent Form(s) – Go to the next slide
• Stipulations to make changes to Study Documents – Go to the slide # 37
• No Stipulations to make changes to Consent Form(s) or Study Documents – follow the instructions in slides 26 through 28.
If you need to make changes to the Consent form, you need to create a revision before you can make your changes.

- To do so, click on the icon in the “Revise/Attach” column. Follow the instructions in slides #12 to #20 and then return here and go to the next slide.
You are back in the “Current Submission Components” Section of the “Review Response submission Form.”

<table>
<thead>
<tr>
<th>Compare</th>
<th>Include in PDF Packet</th>
<th>Unattach</th>
<th>Revise/Attach</th>
<th>Revisions</th>
<th>All Submission Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Previous Rounds &amp; Currently Attached</td>
</tr>
</tbody>
</table>

**Submission Form(s)**
- IRB - Review Response Submission Form - (Version 4.0)

**Application**
- Initial Review Submission Form - (Version 1.2)

**Consent Form(s)**
- Study Application - (Version 1.3)

**Document(s)**
- Adult Consent Form (English) - (Version 1.2)

*Added by the IRB.

If your Review Response Submission Form has:
- Stipulations to make changes to Study Documents – Go to the next slide
- No Stipulations to make changes to Consent Form(s) or Study Documents – follow the instructions in slides 26 through 28.
If you need to make changes to a Study Document, you need to create a revision before you can make your changes.

- To do so, click on the icon in the “Revise/Attach” column.
- Follow the instructions in slides #23 and #24 and then return here and go to the next slide.
You are back in the “Current Submission Components” Section of the “Review Response submission Form.

If you are done with all the changes to this submission components, follow the instructions in slides 26 through 28.