How to Create and Submit a “Change Request and Amendments” Form in INSPIR II

- You should not create a “Change Request and Amendments” form while another “Change Request and Amendments” form is still pending IRB review. The system will prevent you from submitting it.
- A Revision of a Study Document should be made (and attached) only in the “Change Request and Amendments” form and not in the Study Application.
When you login into INSPIR II (https://inspir.bu.edu/), you will get to this page. This is your Home page.

Click on “Start a Submission Form for one of My Studies”
This opens the “Start a Submission Form” pop-up page.

You can use the “Search” box to locate the study. Or you can just scroll down.

Once you locate the study, click on the “Select a Study” icon.
This opens the study into the “Submissions” tab.

Click on “Start a New Submission” icon that corresponds to the “Change Request and Amendments” - blue arrow

• NOTE: You should not create a new “Change Request and Amendments” submission form while another “Change Request and Amendments” form is still pending IRB review. To check if you already have one pending IRB review or one that is still in draft form and can be used instead of creating a new one, click on the “Version List” icon (orange arrow)
This will bring you to the Change Request and Amendments form. This is section 1.0. Complete question 1.2 “Amendment Description”. Make sure you click on “Save Section” (green arrow) every time you update this section; otherwise, you will lose your work. Scroll down (red arrow) to scroll down to the next question in this section.
Next, you need to answer 3 questions about whether or not you will be making changes to the Study Application, adding or revising one or more consent forms, and/or adding or revising one or more study documents. If you answer “Yes” to any of these 3 questions, the appropriate section will be included in the next section. Complete these questions and then click on “Save and Continue to Next Section” (green arrow) to save and proceed.

1. Do these changes require revisions to the application?
   - Yes
   - No

2. Do these changes require revisions to the consent form(s), or the addition of a new consent form(s)?
   - Yes
   - No

3. Do these changes require revisions to any other study documents (protocol, survey, exempt information sheet, etc.), or the addition of new documents?
   - Yes
   - No
If you wanted to make changes to the Study Application and therefore you have answered “Yes” to question # 1) in the previous section, you should have question “2.1 Changes to the Application” visible.

To make changes to the Study Application, click on this grey bottom to create a revision of the Study Application and attach it.

If no changes will be made to the Study Application, you should not have this question. In this case, skip to page # 14.
The system will open the “Attaching Study Application” popup.

You will get a popup. Click on “Add Revision” to create a new revision and make changes to it.

Note: If you don’t see “Add Revision” on the right, this means that a revision was already created, and you can use that one to make your changes. In that case, you would click on the “Edit/View” icon and skip to page # 10.
Click “Confirm” to proceed. The system will create a revision (read-write copy) of the Study Application and open it for editing.
If you don’t get this popup, then you are already in the newest form version. Please skip to page # 12.

If you do get this popup, then you will need to convert to the newly published Study Application form:

Click “Convert to New Form version” to close the popup (green arrow) and convert to the newly published Study Application form. Continue to the next page.
This page only applies if you need to convert to the newly published Study Application form.

The system will start converting to the new form section by section. If a section has a new question that is required, the system will stop there and hide all subsequent sections until you answer the new question. Don’t worry, nothing is lost in these hidden sections!

1- Start clicking “Save and Continue to the Next Section” until all relevant sections reappear and you have answered all new questions (you can also make some or all your amendment’s changes along the way).
Click on any section on the left (orange arrow), to jump to that section and make your changes. Once you made all your changes to the application and you have saved all the changed sections and the Study Application is complete, keep clicking “Save and Continue to Next Section” (green arrow) until the system automatically takes you back to the “Change Request and Amendments form” page (next slide).

Please note: this is just an example. Your screen will look different depending on the type of your study. And depending on the branching, you will see less or more sections on the left.
If the new revision of the Study Application was completed, it should now appear (be attached) here in the amendment. If you want to make more changes to the Study application, you can now access this version from this form by clicking on the “Edit/View” icon.
If you wanted to add a new consent form or revise one or more of the existing consent forms and therefore you have answered “Yes” to question # 2) in the previous section 1.0, you should have question “2.2 Add/Modify a Consent Form” visible.

If you need to make changes to the consent form(s), click on the “Select/Revise Existing” button. If you need to add a new consent form, click on the “Add a New Consent” button. Click on one of the links below for instructions on how to:

- Revise a consent form
- Add a new consent Form

If you are not adding or revising any study documents, you should not have this question. In this case, skip to the next page.
If you wanted to add a new study document or revise one or more of the existing documents and therefore you have answered “Yes” to question # 3 in the previous section 1.0, you should have question “2.3 Add/Modify a Study Attachment” visible.

If you need to make changes to the consent form(s), click on the “Select/Revise Existing” button. If you need to add a new consent form, click on the “Add a New Document” button. Click on one of the links below for instructions on how to:

- Revise an existing document
- Add a new document

If you are not adding or revising any study documents, you should not have this question. In this case, skip to the next page.
When you’re done with the amendment, click on “Save and Continue to Next section” to close this form and/or send it to the PI for sign off.
The system automatically takes you to the “Form has been Completed!” page.

If you want to go back into the amendment, click on “Amendment Information”.

Click on “Exit Form” to exit this form and come back later.

Click on “Signoff and Submit” or “Notify PI for Signoff” if you’re ready to submit to the IRB.