How to Create and Submit an Amendment in INSPIR II
Login into INSPIR and from your Home page, click on “My Studies” to list all the studies that you have access to.
Locate the study and click on the "Open" icon.
The page opens the “Submissions/Study Management” page for the protocol.

- Multiple submissions of “Change Request & Amendments” forms is not allowed. Make sure that there are no pending “Change Request & Amendments” forms in “Outstanding Submissions” (yellow arrow). If there is already one listed here, please use it to make the additional changes.

(“Internal Study Personnel Changes” forms and a “Continuing Review Form” are allowed to be submitted at the same time a “Change Request & Amendments” form is submitted)
If you have determined there are no “Change Request & Amendments” forms in Outstanding Submissions, then you can go ahead and create a new amendment by clicking on “Change Request and Amendments” link [green arrow] from the Column titled “Available Forms” (red arrow).
Click on the “Add a New Form” button. (red arrow) This will create a new Change Request & Amendments form.
This will bring you to the Change Request & 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. Use the scroll bar (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 the Next Section” (green arrow) to save and proceed.
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 # 16.
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 this case, click on the “Edit/View” icon and skip to page # 14.
Click "OK" 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 new form. Please skip to page # 14.

If you do get this popup (this is very rare), 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.
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!

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).

This page only applies if you need to convert to the newly published study application form (this is very rare).
Click on any section on the left (yellow 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 application is complete, keep clicking “Save and Continue” (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 screen by clicking on the “Edit/View” icon.

The system automatically takes you back to the “Change Request and Amendments form” page and attach the revised Study Application to the amendment’s submission components (assuming the Study Application was completed).
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 consent forms, 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 the next section” to close this form and/or send it to the PI for sign off.
Click on "Exit" 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.

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