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.
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 & 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. Complete Section 1.2 and then use the scroll bar (red arrow) to scroll down to the next section of the form.

1.0 Amendment Information

An amendment is any change or modification to a currently approved IRB protocol. Amendments to a research protocol or consent form must be approved by the IRB before a researcher can apply the amendment to subjects, except where necessary to eliminate apparent hazards to the human subjects. For more information, click here.

1.1 Study Information:

IRB Number:
H-31000

Study Title:
Testing

Principal Investigator:
Administrator

1.2 Note: This Amendment cannot be used to add/remove study personnel from "3.0 Internal Study Personnel" section. To add/remove personnel from section 3.0, you need to submit the "Internal Study Personnel Changes" form instead. For instructions on how to submit the "Internal Study Personnel Changes" form, click on the (?) icon below.

Other than changes to the "3.0 Internal Study Personnel" section, this amendment can be used to make changes to the study application, consent form(s), and study documents.

You cannot submit multiple "Change Request & Amendments" forms (this form) at the same time. You need to wait until a "Change Request & Amendments" form had been approved by the IRB before creating a new one.

Amendment Description:

Please describe the amendment in detail below. Include an explanation for why these changes are necessary. If the risk/benefit ratio of the study is changing, but you are not changing the consent form, explain the reasons below.
If there are changes to be made to the study application, click on this grey button to create a revision of the application and attach it.
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 screen #13.
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 screen #13.

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 screen shot.
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 screen shot only applies if you need to convert to the newly published study application form (this is very rare).
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 you also need to add a new consent form or study document, or revise an existing consent form or study document, scroll down.

Note the new revision (version 1.5) attached here in the amendment. You can now access this version from this screen by clicking on the “Edit/View” icon.
If you need to add or make changes to the consent form(s), click on the appropriate button. Click on one of the links below for instructions on how to:

- Revise a consent form
- Add a new consent Form
If you need to add or make changes to a Study Document, click on appropriate button. Click on one of the links below for instructions on how to:

- Revise an existing document
- Add a new document

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".