How to Create and Submit an Amendment in INSPIR II
Login into INSPIR II and from your Home page, click on “My Studies” and proceed to the next slide.
Locate the study and click on the "Open" icon.

<table>
<thead>
<tr>
<th>Click to open</th>
<th>Study Status</th>
<th>IRB Number</th>
<th>IRB Expiration</th>
<th>Principal Investigator</th>
<th>Study Title/Study Nickname</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pending - Initial Review</td>
<td>H-32615</td>
<td>-</td>
<td>Administrator, BA</td>
<td>testing Oracle upgrade.. 9-16-2012</td>
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<tr>
<td></td>
<td>Approved / Open - Expedited</td>
<td>H-31000</td>
<td>2-18-2011</td>
<td>Administrator, BA</td>
<td>Testing</td>
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<td>Draft</td>
<td>H-32617</td>
<td>2-18-2011</td>
<td>Administrator, BA</td>
<td>Copy of Testing testing...</td>
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<td>Khattar, Khaled, BA</td>
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<td>Khattar, Khaled, BA</td>
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<td>Demo Protocol Demo</td>
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<td>testing 10-10-2012 testing 10-10-2012</td>
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<td>Administrator, BA</td>
<td>testing Drugs</td>
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</table>
There are no pending “Change Request & Amendments” forms in “Outstanding Submissions” (yellow arrow).

(“Internal Study Personnel Changes” forms and “Continuing Review Forms” are allowed)

This opens the “Submissions/Study Management” page for the protocol. From here you can:

a. Make sure that there are NO current “Change Request & Amendments” form pending.

b. Create an Amendment.
If you have determined there are no “Change Request & Amendments” forms in Outstanding Submissions, then you can go ahead and create an amendment by clicking on “Change Request & Amendments” link [green arrow] from the Column titled SUBMISSION 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 1.1 and then use the scroll bar (red arrow) to scroll down to the next section of the form.

1.0 Amendment Information

1.1 Study Information:

IRB Number:
H-31000

Study Title:
Testing

Principal Investigator:
Administrator, BA

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.

If the study expiration is within 6 weeks, please do not fill out and submit this amendment. Instead, create a Continuing Review form and make any changes to the application, consent form, or study documents within the Continuing Review Form and submit it to the IRB for review.

You cannot submit multiple amendments (this form) at the same time. You need to wait until an amendment had been approved by the IRB before creating a new amendment.

You cannot submit an amendment while there is a Continuing Review form being reviewed, and vice versa.

For complex amendments or amendments involving changes to multiple sections of the IRB application, please submit a TRACK CHANGES version in MS WORD for the changes made to the IRB application. Click the help (?) Icon for instructions.

Amendment Reason:
--none--

Does this amendment change the risk/benefit ratio?
Yes No
If there are changes to be made to the study application, click on this grey bottom 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.
This will bring into a copy (revision) of the study application.

If you get this popup, then you will need to convert to the newly published study application form:
1- Click “OK” to close the popup (green arrow)
2- Click on the “Convert to the New Form Version” button (red arrow)

If you don’t get this popup, then you are in the new form. Please skip to screen # 13.
When converted, the system will hide all sections except the first three. Don’t worry, nothing is lost!

Start clicking “Save and Continue to the Next Section” until all sections reappear and you have made all your changes along the way.
Please note: this example is of an exempt study. 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.

Click on any sections 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, click on “Back” (green arrow) so that the system will automatically take you back to the “Attaching Study Application” page (next slide).
Note the new version number (1.1). If you want to go back to the application for more editing, click on “Edit/View” icon (yellow arrow). If you’re done for now with your changes, follow step 1 and 2 below (blue arrows).

1- Make sure this radio button is checked (by default)

2- Click “Save Attachment” to attach this new revision of the study application to the amendment
Note the new revision (version 1.1) attached here in the amendment. You can now access this version from this screen by clicking on the “Edit/View” icon.

Scroll down here to complete the rest of the form.
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:

- Add a new consent Form
- Revise a 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:
- Add a new document
- Revise an existing 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.
If you want to go back into the amendment, click on “Amendment Information”.

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.