How to Create and Submit a Continuing Review Form (Progress Report) in INSPIR II
Creating and Submitting a Continuing Review Form

• If you are listed as the “Study Contact” on the study, the system will send you a notification reminder about the Continuing Review, and at the same time, it will create a task for you in your “Incomplete Tasks” on your “Home” page inorder to use it to complete the Continuing Review Form (If you have a task there, continue to the next page).

• If you are not listed as a “Study Contact” on the study, you will not have the task on your “Home” page, but you can still create and submit the Continuing Review Form (if you don’t have a task there, skip to page 5).
Login into INSPIR II and start from your “Home” page. If you are listed as a “Study Contact” on the study and it’s time for renewal, the system will create a task for you under your “Incomplete Tasks” that will allow you to create the Continuing Review form.

1- Locate the “Continuing Review Due” task for the study, and
2- click on the “Open” icon next to it.
This will bring you to the “Continuing Review Form Selection”.

1. Click on “Continuing Review Submission Form” radio button (blue arrow), and
2. Click on the “Continue button (green arrow)
3. Skip to page 9 of these instructions

If instead of renewing the study you want to close it, then click on “Final/Closure Report Form” and follow the instructions in this link:

Only follow the instructions in this and the next page if you are not listed as a “Study Contact” on the study and so the system did not create a task for you under your “Incomplete Tasks” that will allow you to create the Continuing Review form.

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.
If you see the “Continuing review Form” here, this means that someone else had already created the Continuing Review Form and you can open it by clicking on the link. If you don’t see the Continuing Review Form here, click on “Continuing Review Submission Form” (red arrow).
If you see the new “Continuing Review Form” here, this means that someone else had already created the Continuing Review Form and you can open it by clicking on “Edit/View”. If you don’t see the new Continuing Review Form here, click on “Add a New Form” button (red arrow).
This will bring you to a Section by Section view of the Continuing Review form.
Complete Section 1 and then click on SAVE AND CONTINUE (yellow arrow) to proceed to the next section. As you complete each section the sections will be added to the left hand column (green arrow).
Use the scroll bar (red arrow) to scroll through each section of the form. Answer all questions.

1.0 The Continuing Review Submission Form will be used as a Progress Report to request renewal of the study, and at the same time include any necessary changes to the Study Application, Consent Form(s), and Study document(s) that had occurred since the last IRB review. Use this form to submit a Final report. If you want to submit a final report, please use the "Final Report/Closure" Form instead.

You will need to complete Section 8 of this form to attach a revised version of the Study Application, all Consent Forms that will still be used and all Study Documents that are still valid. These will be reviewed as part of this submission and approved or stamped accordingly by the IRB. Any changes to the study, should be made here in Section 8 once this form has been created, and not in a separate amendment.

Once this Continuing Review Submission Form has been created, you should not create any amendments until this form has been finalized and approved by the IRB. Any changes to the study, should be made here in Section 8 once this form has been created, and not in a separate amendment.

IF YOU ALREADY HAVE AN AMENDMENT IN REVIEW THAT HASN'T BEEN PROCESSED, YOU SHOULD RETRACT IT AND ADD THE AMENDMENT DESCRIPTION TO THE CONTINUING REVIEW FORM IN SECTION 8.

Creating and submitting an amendment while a Continuing Review is still pending, or vice versa, is not allowed.

Click on the Help (?) icons on the right for step by step instructions/screenshots.

1.1 Study Information:

IRB Number:
H-31000

Study Title:
Testing

Principal Investigator:
Administrator, BA
You will need to add subjects and total numbers manually—INSPIR II does not auto-calculate fields.

Complete each section and then click on “Save and Continue” (yellow arrow) for the next section to appear. Answer all questions.

### DESCRIPTION TO THE CONTINUING REVIEW FORM IN SECTION 8.

Creating and submitting an amendment while a Continuing Review is still pending, or vice versa, is not allowed.

Click on the Help (?) icons on the right for step by step instructions/screenshots.

#### 1.1 Study Information:

| IRB Number: | H-31000 |
| Study Title: | Testing |
| Principal Investigator: | Administrator, BA |

#### 1.2 Subject Enrollment

For the column entitled “Approved by this IRB”, enter the number of subjects enrolled into the study at all sites where YOU have IRB approval to conduct this research.

<table>
<thead>
<tr>
<th>Approved by this IRB</th>
<th>Worldwide (See instructions above)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Approved by IRB</td>
<td>100</td>
</tr>
<tr>
<td>Total enrolled at time of last review</td>
<td>22</td>
</tr>
<tr>
<td>Total enrolled since last review</td>
<td>53</td>
</tr>
<tr>
<td>Total enrolled to date</td>
<td>75</td>
</tr>
</tbody>
</table>
Once you have visited all the sections of the Continuing Review Form and answered all the questions, the system will take you to this page.

Click on “Exit” to exit this form now 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 Continuing Review form, click on any of the sections on the left.
The PI will then receive a Submission Sign-off sheet (that looks like this). The PI can review the documents by clicking on the “open” icon:

- Continuing review (PR) form - yellow arrow
- IRB application (green arrow)
- Then clicks on “Approve” radio button. (orange arrow)
- Then sign off (entering user ID and password and “save sign-off to authenticate. (red arrow)