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 in order 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 6).
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 list a task for you under “Below are your incomplete IRB Tasks:”, tucked in the “Continuing Review Due” folder. This task will allow you to create the Continuing Review form.

Click on the folder icon next to “Continuing Review Due” to expand and display the list of tasks.

Note: If you don’t have a “Continuing Review Due” folder under the “Below are your incomplete tasks:” title, then skip to slide # 6.
1- Locate the “Continuing Review Due” task for the study that you want to renew, and  
2- click on the “Open” icon next to it.

Note: If you don’t have a task in the “Continuing Review Due” folder that corresponds to the study that you want to renew, then skip to slide # 6.
This will bring you to the “Continuing Review Form Selection” page.

1- Click on “Continuing Review Submission Form” radio button (blue arrow), and
2- Click on the “Continue button” (green arrow)
3- Skip to page 10 of these instructions

If you want to close the study instead of renewing it, then click on the “Final/Closure Report Form” radio button and follow the instructions in this link:
After logging into INSPIR II, from your Home page, click on “My Studies” and proceed to the next slide.

Only follow the instructions in pages 6 to 9, if the system did not list a task for you under your “Below are your incomplete IRB tasks” in the “Continuing Review Due” folder.
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” (green arrow).

If you don’t see the new Continuing Review Form here, click on the “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.

1.1 The IRB will no longer accept changes to be made to the study application, consent forms, or study documents as part of the Continuing Review. All such changes should be made and submitted to the IRB using a separate “Change Request & Amendments” form, which can be submitted at the same time as the Continuing Review form if there are no other previous amendments currently awaiting IRB approval.

Please note: The consent forms (and other subject materials that are stamped) will only have an Approval Date. There will no longer be an Expiration Date. When changes are made to consent forms as part of a “Change Request & Amendment” submission, the revised consent form will be stamped with a new Approval Date, and the previously-approved consent will be voided.

Click on the Help (?) icon on the right for step by step instructions/screenshot.

PLEASE NOTE: Do not use this form to submit a Final report. If you want to submit a final report, please use the “Final Report/Closure” Form instead. For more information, click here

1.2 Study Information:

IRB Number:
H-31000

Study Title:
Testing

Principal Investigator:
Administrator

1.3 What is the status of this study?

- Study only involves existing data, documents, and/or pathological specimens
- Intending to enroll but no one has yet been enrolled, no records collected
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.

<table>
<thead>
<tr>
<th>Section view of the Form</th>
<th>Entire view of the Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 The Continuing Review Submission Form will be used as a Pro ...</td>
<td>Form has been Completed!</td>
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<tr>
<td>2.0 Subject Demographics</td>
<td>Exit Form</td>
</tr>
<tr>
<td>3.0 Has Study Been Monitored or Audited?</td>
<td>Signoff and Submit</td>
</tr>
<tr>
<td>4.0 Adverse Events, Serious Adverse Events, and Unanticipated Pr ...</td>
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<tr>
<td>5.0 Protocol Status</td>
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<tr>
<td>6.0 Study Progress</td>
<td></td>
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<tr>
<td>7.0 Identification of New Risks</td>
<td></td>
</tr>
</tbody>
</table>

If you want to go back into the Continuing Review form, click on any of the sections on the left.

**Note:** Your Continuing Review Form might look different and might have less or more sections than this example depending on your answers and type of study.

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.
The PI will then receive a Submission Sign-off sheet (that looks like this).

1. The PI can review the Continuing review (PR) form by clicking on the “open” icon - yellow arrow
2. Then clicks on the “Approve” radio button. (orange arrow)
3. Then sign off (entering user ID and password and “save sign-off to authenticate. (red arrows)