

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

Note: If you want to close the study instead of renewing it, then:

- To close an “Exempt”, “Exempt – no IRB review”, “Exempt – limited IRB review”, “NHSR”, or “Not Engaged”, follow the instructions in this link: [How To Close an Exempt Study](#)
- To close an “Expedited”, “Full Board”, or “Ceded Review” study, follow the instructions in this link: [How to create and submit a Final/Closure Report](#)

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 in the “Study Tasks” tab and would be listed with the “Continuing Review Due” as the Task Type. This task will allow you to create the Continuing Review form.

My Workspaces Study

Study Tasks
Outstanding
Completed

All Tasks
Study Tasks

Task List: All
Review Board: All
Filter By: --none--

33 result(s) found... 1 - 10

	Click to open	Details	Task Type	Date Received	Study Status	Study Title	Principal Investigator	Review Board	IRB Number	IRB Expiration	Priority	Complete By
						Study Alias						
<input type="checkbox"/>			Submission Routing Signoff	07/12/2022 08:02 AM EDT	Exempt - limited IRB review	Testing					No Priority	
						2-18-2011-	Administrator	IRB	H-31000			
<input type="checkbox"/>			Waiting Submission	05/24/2021 11:55 AM EDT	Draft	Separate Protocol 8/17/2018					No Priority	
						Separate Protocol 8/17/2018	Administrator	IRB	H-38072			
<input type="checkbox"/>			Waiting Submission	10/23/2020 11:30 PM EDT	Draft	testing 2					No Priority	
						9-27-12 - 2	Khattar, Khaled, BA					
<input type="checkbox"/>			Waiting Submission	09/21/2020 10:38 AM EDT	Draft	Testing Migration MSD					No Priority	
						Test Interface	Administrator	IRB	H-39402			
<input type="checkbox"/>			Waiting Submission	03/19/2020 01:40 PM EDT	Closed - Ceded Review	INTERFACE TESTING OF 'IRB-' APPENDING TO IRB STATUSES IN VELOSCT					No Priority	
						Velos# HRB123 - Active in Velos for Interface Testing	Administrator	IRB	H-37307			
<input type="checkbox"/>			Continuing Review Due	12/12/2019 03:31 AM EST	Exempt - limited IRB review	Testing					No Priority	
						2-18-2011-	Administrator					
						Exempt Study						

- 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 “Continuing Review Due” task that corresponds to the study that you want to renew, then skip to slide # [5](#).

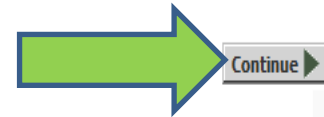
This will bring you to the “Continuing Review Form Selection” page.

IRB Number: **H-31000**
PI: Administrator, BA

Continuing Review Form Selection

Back

Study Status: **Approved / Open - Expedited** IRB Number: **H-31000** Study Title: Testing
IRB Expiration Date: 02/16/2015



Continue



Select a Form or go to the Study Management Page.

<input type="radio"/>	Continuing Review Submission Form
<input type="radio"/>	Final/Closure Report Form
<input type="radio"/>	Go to the Study Management Page

To renew this study:

- 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

Only follow the instructions in pages 5 to 8, if the system did not list a “Continuing Review Due” task for you in the “Study Tasks” tab because you are not one of the “Study Contacts” .

BOSTON UNIVERSITY MEDICAL CAMPUS
BOSTON MEDICAL
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Hello Khaled Khattar, BA
your last login was
10/11/2022 08:16 AM EDT

My Workspaces Study Assistant

Announcements **1** Help Tutorial My Profile Log out

Featured Study Operations

- Create a New Study
- Start a Submission Form for one of My Studies
- View the Current Approvals for one of My Studies
- View the Submission History for one of My Studies
- View and Manage My Studies

By the Numbers

Submissions in Process 54	Forms Pending Submission 53	Pending My Response 4	High T
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Tasks

All Tasks	35
Study Tasks	33

After logging into INSPIR II, from your Home page, click on “View and Manage My Studies” and proceed to the next slide.

The system will scroll your Home page down to the “All Studies” section.

You can use the “Search” box to locate the study. Or you can just scroll down.

Once you locate the study that you want to renew, click on the “Open” icon

page down to the "All Studies" section.

You can use the "Search" box to locate the study. Or you can just scroll down.

51 result(s) found...

Click to open Study Dashboard	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Principal	Actions
	Exempt - limited IRB review	IRB	H-31000		testing signoff		
	Inactive - Administratively Closed	IRB	H-31293		testing signoff		
	Draft	IRB	H-35016		testing signoff		
	Draft	IRB	H-38079		testing signoff		
	Draft	IRB	H-41022		testing signoff		
	Draft	IRB	H-41022		testing signoff		
	Expired	IRB	H-41826	06/09/2022	testing signoff		

This opens the “Submissions/Study Management” page for the study.

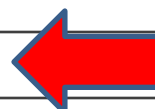
Submissions Study Management


Protocol Items

Protocol Items
<input type="radio"/> Study Application
<input type="radio"/> Informed Consent
<input type="radio"/> Other Study Documents

Submission Forms

Submission Forms
<input type="radio"/> Initial Review Submission Form
<input type="radio"/> Change Request & Amendments
<input type="radio"/> Internal Study Personnel Changes
<input type="radio"/> Continuing Review Submission Form
<input type="radio"/> Final/Closure Report Form
<input type="radio"/> UPSER/Adverse Event Form
<input type="radio"/> Protocol Deviation/Violation Form
<input type="radio"/> Protocol Exception Form
<input type="radio"/> StudyFinder Form



<input type="radio"/> Submissions History			
<input type="radio"/> Study Correspondence			
 Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
	800080	Click on the hyperlink to edit/view the submission. Internal Study Personnel Changes	<input type="button" value="Send Submission"/>



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).

My Workspaces ☒

IRB Number: **H-31000**

Study Alias: 2-18-2011-

PI: Administrator

Study

Continuing Review Submission Form

Back

Study Status: Exempt - limited IRB review

IRB Number : H-31000


Study Title : Testing

Copy Form








Add a New Form

Compare Two Versions

Delete Selected Form(s)

List of records associated with form: Continuing Review Submission Form.
 To view previous versions click on the folder icon .

3 result(s) found...

<input type="checkbox"/>	Show Rev	Edit/View	Details	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Status	Total En...	Created By	Date Created	Last Modified By	Last Date Modified
<input type="checkbox"/>				1239876							Mary-Tara Roth	07/16/2019 09:12:25 AM	Administrator	11/06/2023 07:23:24 AM
<input type="checkbox"/>				1082877					Actively enrolling	50	Administrator	02/19/2019 09:35:49 AM	Administrator	02/19/2019 09:35:49 AM
<input type="checkbox"/>				904876				01/30/2017 02:11:05 PM EST	Actively enrolling	20	Administrator	01/30/2017 02:10:32 PM	Administrator	01/30/2017 02:10:32 PM

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. Depending on the study's IRB Classification, this section might look different from what you see below. Complete Section 1 and then click on **SAVE AND CONTINUE (yellow arrow)** to proceed to the next section. As you complete each section (if there are more than one section) the sections will be added to the left hand column **(green arrow)**. Use the scroll bar to scroll through each section of the form. Answer all questions.

My Workspaces ☒

IRB Number: **H-31000**

Study Nickname: 2-18-2011-

PI: Administrator

Study Assistant

Continuing Review Submission Form - (Version 8.0)

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Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Signoff and Submit

Section view of the Form

Entire view of the Form

1.0 Continuing Review/Status Check-In Submission Form

1.0 Continuing Review/Status Check-In Submission Form

1.1 Study Information:

IRB Number:

H-31000

Study Title:

Testing

Principal Investigator:

Administrator

IRB Classification:

Exempt

Once you have visited all the sections of the Continuing Review Form and answered all the questions, the system will take you to the “Form has been Completed” page.

The screenshot shows a web interface for a Continuing Review Form. At the top right, there are two buttons: "Print Friendly" and "Signoff and Submit". Below these, there are two tabs: "Section view of the Form" (selected) and "Entire view of the Form". On the left, a sidebar lists seven sections: 1.0 The Continuing Review Submission Form will be used as a Pro..., 2.0 Subject Demographics, 3.0 Has Study Been Monitored or Audited?, 4.0 Adverse Events, Serious Adverse Events, and Unanticipated Pr..., 5.0 Protocol Status, 6.0 Study Progress, and 7.0 Identification of New Risks. A large blue arrow points from the bottom callout box to the sidebar. The main content area has a light blue header that says "Form has been Completed!". Below this header, there are two buttons: "Exit Form" (with a red X icon) and "Signoff and Submit" (with a document icon). Two blue callout boxes with arrows point to these buttons. The top callout box points to the "Exit Form" button and contains the text: "Click on 'Exit' to exit this form now and come back later." The bottom callout box points to the "Signoff and Submit" button and contains the text: "Click on 'Signoff and Submit' or 'Notify PI for Signoff' if you're ready to submit to the IRB."

Print Friendly Signoff and Submit

Section view of the Form Entire view of the Form

1.0 The Continuing Review Submission Form will be used as a Pro ...

2.0 Subject Demographics

3.0 Has Study Been Monitored or Audited?

4.0 Adverse Events, Serious Adverse Events, and Unanticipated Pr ...

5.0 Protocol Status

6.0 Study Progress

7.0 Identification of New Risks

Form has been Completed!

Exit Form

Signoff and Submit

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.

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.

- 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 “Continuing Review Submission Form ” link - yellow arrow
 - 2. Then clicks on the “Approve” radio button. (orange arrow)
 - 3. Then signs off by clicking “Save Signoff ” button. (red arrows)

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Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

?

Help

My Profile

Log out

My Workspaces

Study

Submission Routing Signoff

Back

Save Signoff

Study Title: Testing
Submission Reference Number: 1239876

Create PDF Packet

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input checked="" type="checkbox"/>			
<input type="checkbox"/>		<input checked="" type="checkbox"/>	Continuing Review Submission Form

Administrator as Principal Investigator
Do you Approve or Deny this submission?

☐ Approve ☐ Deny

Comments: Click here to add comments.

Save Signoff

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