

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

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	Forms Pending Submission	Pending My Response	High
54	53	4	>

Tasks

All Tasks	35
Study Tasks	33

When you login into INSPIR II (<https://inspir.bu.edu/>), you will get to this page. This is your Home page

Click on **“Study Tasks”** to check if you already have a **“Continuing Review Due”** task (shortcut) for this specific study that will allow you to create the Continuing Review form.

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

Search for RB Number, Title, Alias Search

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 Study Alias	Principal Investigator	Review Board	IRB Number	IRB Expiration	Priority	Complete By
<input type="checkbox"/>			Submission Routing Signoff	07/12/2022 08:02 AM EDT	Exempt - limited IRB review	Testing 2-18-2011-	Administrator	IRB	H-31000		No Priority	<input type="text"/>
<input type="checkbox"/>			Waiting Submission	05/24/2021 11:55 AM EDT	Draft	Separate Protocol 8/17/2018 Separate Protocol 8/17/2018	Administrator	IRB	H-38072		No Priority	<input type="text"/>
<input type="checkbox"/>			Waiting Submission	10/23/2020 11:30 PM EDT	Draft	testing 2 9-27-12 - 2	Khattar, Khaled, BA				No Priority	<input type="text"/>
<input type="checkbox"/>			Waiting Submission	09/21/2020 10:38 AM EDT	Draft	Testing Migration MSD Test Interface	Administrator	IRB	H-39402		No Priority	<input type="text"/>
<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 Velos# HRB123 - Active in Velos for Interface Testing	Administrator	IRB	H-37307		No Priority	<input type="text"/>
<input type="checkbox"/>			Continuing Review Due	12/12/2019 03:31 AM EST	Exempt - limited IRB review	Testing 2-18-2011-	Administrator					<input type="text"/>
						Exempt Study						



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.

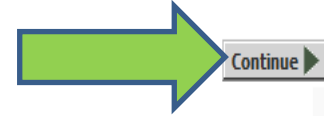
- 1- Locate the “Continuing Review Due” task for the study that you want to renew, and
- 2- click on the “Open” icon next to it.

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



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

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 9 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:
<http://www.bumc.bu.edu/irb/files/2016/10/How-to-Crete-and-Submit-a-Final-Report.pdf>

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

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

My Workspaces | Study Assistant

Featured Study Operations

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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.

Search for RB Number, Title, Alias Search

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

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		Applications Documents Forms Hide Exempt Copy Delete Correspond
	Inactive - Administratively Closed	IRB	H-31293		testing signoff	Khattar, Khaled, BA	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	IRB	H-35016		testing 2		Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	IRB	H-38079		9-27-12 - 2	Khattar, Khaled, BA	Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	IRB	H-41022		test initiate irb through Velos 6-8-21		Applications Documents Forms Hide Exempt Copy Delete Correspond
	Draft	IRB	H-41826	06/09/2022	test-study-nickname	Khattar, Khaled, BA	Applications Documents Forms Hide Close Exempt Copy Delete Correspond
	Expired	IRB			MASTER 2020 DRAFT APPLICATION		Applications Documents Forms Hide Exempt Copy Delete Correspond

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

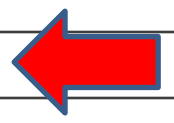
This opens the "Submissions/Study Management" page for the study.

Protocol Items

- Protocol Items
- Study Application
- Informed Consent
- Other Study Documents

Submission Forms

- Submission Forms
- Initial Review Submission Form
- Change Request & Amendments
- Internal Study Personnel Changes
- Continuing Review Submission Form
- Final/Closure Report Form
- UPSER/Adverse Event Form
- Protocol Deviation/Violation Form
- Protocol Exception Form
- StudyFinder Form



Submissions History

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	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).

Study Status: **Exempt - limited IRB review** IRB Number: H-31000 Study Title: Testing

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. 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.

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Section view of the Form

Entire view of the Form

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

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 \(?\) icons on the right for step by step instructions/screenshots.](#)

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 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 is a navigation bar with two tabs: "Section view of the Form" (selected) and "Entire view of the Form". The main content area is a light blue banner that reads "Form has been Completed!". Below the banner, there are two buttons: "Exit Form" (with a red X icon) and "Signoff and Submit" (with a hand icon). A large blue arrow points from the "Exit Form" button to a callout box on the right that says "Click on 'Exit' to exit this form now and come back later." Another large blue arrow points from the "Signoff and Submit" button to a callout box on the right that says "Click on 'Signoff and Submit' or 'Notify PI for Signoff' if you're ready to submit to the IRB." On the left side, there is a vertical list of sections, each with a document icon and a number: 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 left callout box to this list of sections.

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 1

Administrator as Principal Investigator
Do you Approve or Deny this submission? Approve Deny **2**

Comments: Click here to add comments.
Save Signoff **3**