

How to Create and Submit a Final/Closure Report in INSPIR II to close a study

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 you can use to close it.

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 Final/Closure Report form.

My Workspaces ▾ Study

Study Tasks Outstanding Completed

All Tasks Study Tasks

Task List:
 Review Board:
 Filter By:

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	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	Administrator	IRB	H-38072		No Priority	<input type="text"/>
<input type="checkbox"/>			Waiting Submission	10/23/2020 11:30 PM EDT	Draft	testing 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	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	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	Administrator					
						Exempt Study						



1- Locate the “Continuing Review Due” task for the study that you want to close, 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 close, then skip to slide # 5.

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.

 Continuing Review Submission Form Final/Closure Report Form Go to the Study Management Page

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

- 1- Click on “Final/Closure Report Form” radio button (blue arrow)
- 2- Click on the “Continue” button (green arrow)
- 3- Then skip the next 4 slides to slide # 9.

If you want to renew the study instead of closing it, then click on “Continuing Review Submission Form” and follow the instructions in this link:

<http://www.bumc.bu.edu/irb/files/2016/10/How-to-Create-and-Submit-a-Progress-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		
	Inactive - Administratively Closed	IRB	H-31293		testing signoff	Khattar, Khaled, BA	
	Draft	IRB	H-35016		testing 2		
	Draft	IRB	H-38079		9-27-12 - 2	Khattar, Khaled, BA	
	Draft	IRB	H-41022		test initiate irb through Velos 6-8-21		
	Draft	IRB	H-41826	06/09/2022	test-study-nickname	Khattar, Khaled, BA	
	Expired	IRB			MASTER 2020 DRAFT APPLICATION		

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 close, click on the "Open" icon

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

IRB Expiration Date: 02/16/2015

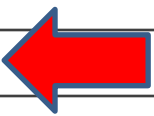
Submissions Study Management

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 Change	<input type="button" value="Send Submission"/>



If you see the "Final/Closure Report Form" here, this means that someone else had already created the Final/Closure Report Form and you can open it by clicking on the link. If you don't see the Final/Closure Report Form here, click on "Final/Closure Report Form" (red arrow).

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

Final/Closure Report Form

Back

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

Copy Form Add a New Form Compare Two Versions Delete Selected Form(s)



List of records associated with form: Final/Closure Report Form.

To view previous versions click on the folder icon.

0 result(s) found...

✓	Show Rev	Edit/View	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
No records have been created.										



If you see the "Final/Closure Report Form" here, this means that someone else had already created the Final/Closure Report Form and you can open it by clicking on "Edit/View". If you don't see the Final/Closure Report Form here, click on the "Add a New Form" button (red arrow).

This will bring you to a Section by Section view of the Final/Closure Report 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.

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Navigation: Home > my studies > study mgmt.

IRB Number: **H-31000**

Study Nickname: 2-18-2011-

PI: Administrator

Final/Closure Report Form - (Version 2.0)

Back

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 Final/Closure Report
- 2.0 Subject Enrollment
- 3.0 Subjectographics
- 4.0 Has Study Been Monitored or Audited?
- Adverse Events Serious Adverse Events, and MINOR Deviations ...
- 6.0 Study Closure
- 7.0 Identification of New Risks

1.0 The Final/Closure Report Form will be used as a Progress Report to request the closure of the study.

1.1 Study Information:

IRB Number: H-31000

Study Title: Testing

Principal Investigator: Administrator

1.2 What is the status of this study? For more information, click [here](#)

ns, long-term follow-up and analysis using personally-identifiable is closed.

s were enrolled), please check here.

ver started at BU/BMC below:

- No funding obtained
- Industry contract never executed
- Sponsor closed study before any subjects enrolled at BU/BMC
- Other - Explain in the text box below:

Note: Your Final/Closure Report form might look different and might have less or more sections than this example depending on your answers and type of study.

Once you complete all sections, the system will take you to the “Form has been Completed” page.

IRIS: Final/Closure R... x

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Navigation: Home > my studies > study mgmt.

Home Logout Help

Final/Closure Report Form - (Version 2.0) Back

Print Friendly Signoff and Submit

Section view of the Form Entire view of the Form

1.0 Final/Closure Report

2.0 Subject Enrollment

3.0 Subject Demographics

4.0 Has Study Been Monitored or Audited?

Adverse Events Serious

5.0 Adverse Events, and MINOR Deviations ...

6.0 Study Closure

7.0 Identification of New Risks

Form has been Completed!

Instruction of Form has Been Completed Screen

Exit Form

Signoff and Submit

Click on “Exit Form” 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.

If you want to go back into the Final/Closure Report form, click on any of the sections on the left.

Note: Your Final/Closure Report 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 Final/Closure Report form by clicking on the “Final/Closure Report 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)

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

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: 806236

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"/>	Final/Closure Report Form

Submission Form(s):

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

Comments: Click here to add comments.

Save Signoff

