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

Hello Khaled Khattar, BA your last login was

10/11/2022 08:16 AM EDT

My Workspaces

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



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.

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	All Ta	asks		Study Tasks						Task List: Review Board: Filter By : -	۱۱ ۱۱ none		
33 result(s)	) found											1	
	Click to	Details	Task Type	Z Date Received	Study Status	Study Title	Principal	Review Board	IRB Number	IRB Expiration	Priority	Complete By	
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						Velos for Interface Testing	Administrator	IRB	H-37307	1	No Priority		

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.



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: <u>http://www.bumc.bu.edu/irb/files/2016/10/How-to-Create-and-Submit-a-Progress-Report.pdf</u> Only follow the instructions in pages 5 to 8, if the system <u>did not</u> list a "Continuing Review Due" task for you in the "Study Tasks" tab because you are not one of the "Study Contacts".

Featured Study OperationsCreate a New StudyStart a Submission Form for one of My StudiesView the Current Approvals for one of My StudiesView and Manage My StudiesView and Manage My StudiesStudy Tasks	Workspaces	aled Khattar, BA login was J22 08:16 AM EDT Int		T Announcem	eents 💶 ? Help	Tutorial	💄 My Profile 👻	[
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Study Tasks 33		View and Manage My Studies	All Tasks	5	35			
			Study Ta	asks	33			

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

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Click to open Study Dashboard	Study Status	Review Board	IRB Number	IRB Expiration	Study Title Principal Actions
Ø	Exempt - limited IRB review	IRB	H-31000		<sup>2</sup> You can use the "Search" box to
	Inactive - Administratively Closed	IRB	H-31293		locate the study. Or you can just
	Draft	IRB	H-35016		scroll down.
	Draft	IRB	H-38079		Ch Ch Delete Correspond
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you want to close, click on the "Open" icon

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



🖪 Back

				IRB Expiration Date:	02/16/2015					
Subn	nissions	Study Man	agement		_					
Proto	col Items					 ^				
Proto	ocol Items						S S	Ibmission	ns History	
۲	Study Ap	plication					St	udy Corre	espondence	
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۲	Continuin	ng Review Sub	mission For	m				nis r creat	reans that someone else had already	d vou
۲	Final/Clo	osure Report F	orm					can o	open it by clicking on the link.	.,
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۲	StudyFind	der Form								7



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.

CINIVERSIII	Navigation: Home > my studies > study mgmt.								
IRB Number: H-31000 Study Nickname: 2-18-2011- Final/Closure Report Form - (Version 2.0) PI: Administrator									
Print Friendly       ORefresh Constant Fields       Save Section       Save and Continue to Next Section       Signoff and S         Section view of the Form       Entire view of the Form       Entire view of the Form       Image: Save Section       Image: Save Section									
[.									
1.0 🗎 Final/Closure Report	1.0 The Final/Closure Report Form will be used as a Progress Report to request the closure of the study.								
2.0 🖹 Subject ollment									
3.0 Subje ographics	1.1 Study Information:								
4.0 or Audited?									
Adverse Events Serious 5.0 Adverse Events, and MINOR Deviations	H-31000								
6.0 🖹 Study Closure	Study Title:								
7.0 🗎 Identification of New Risks	Testing								
	Principal Investigator: Administrator 1.2. What is the status of this study? For more information, click <u>here</u>								
Note: Your Final/Clo	osure Report form might look								
different and migh	t baye loss or more sections								
different and migh	t flave less of more sections to were enrolled), please check here.								
than this example depending on your answers and									
type of study.									
	O No funding obtained								
	O Industry contract never executed								
	Sponsor closed study before any subjects enrolled at BU/BMC	9							
O Other - Explain in the text box below:									



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)

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My Workspaces 🗷 Study Submission	Routing Signoff			l	K Back
Study Title: Submission Reference Number:	Testing 806236				Save Signoff
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Submission Form(s):	Include in PDF Packet Last Approved Separate Window Separate Window				
	Submission Form(s)           Image: Submission Form (s)         Image: Submission Form (s)           Image: Submission Form (s)         Image: Submission Form (s)				
Administrator as Principal Investigator Do you Approve or Deny this submission?	2 Comments: Click here to add comments. Save Signoff				