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.

	Task		Outstanding	Completed					Search for RB N	lumber, Title, Alias		Search				
	All Ta	asks		Study Tasks						Task List: Review Board: Filter By : -	All					
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				
	open	Ð		AT		Study Alias	Investigator									
		Ŧ	Submission Routing	07/12/2022	Exempt - limited IRB	Testing					▶ ,	· > (x)				
	٢		Signoff	08:02 AM EDT	review	2-18-2011-	Administrator	IRB	H-31000		No Priority	°				
	_			05/24/2021 11:55 AM EDT	05/24/2021	05/24/2021	05/24/2021	05/24/2021		Separate Protocol 8/17/20	018					~
		Ŧ	Waiting Submission		Draft	Separate Protocol 8/17/2018	Administrator	IRB	H-38072		No Priority	⊗				
				10/23/2020		testing 2										
		Ŧ	Waiting Submission	11:30 PM EDT	Draft	9-27-12 - 2	Khattar, Khaled, BA				No Priority	⊗				
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		Ŧ	Waiting Submission	03/19/2020 01:40 PM EDT	Closed - Ceded Review							⊗				
						Velos# HRB123 - Active ir 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	CAL MEDICAL your last	aled Khattar, BA login was J22 08:16 AM EDT Int		T Announcem	eents 💶 ? Help	Tutorial	💄 My Profile 👻	
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All Tasks 35		View the Submission History for one of My Studies		Tasks				
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.

All Studi	All) ∣ Study S Draft	pag	e dowr	n to the ' section	"All Studio	es"	Search for	r RB Number,	; Title, Alias		Se	earch 🌣
Click to open Study Dashboard	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Principal				Actions		_	
Exempt - limited IRB review IRB			H-31000		²⁻ You d	box t	to) Delete	Correspond				
	Inactive - Administratively Closed	RB	H-31293		⁴⁻ locat	e the stu	ldy. Or	r yoı	ı ca	n ju	st		Correspond
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you want to close, click on the "Open" icon

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



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			IRB Expiration Date:	02/16/2015										
Subm	ssions Study Manag	jement		_										
	ol Items					^								
Protoc	ol Items						S S	ubmission	is History					
۲	Study Application						S	tudy Corre	espondence					
۲	Informed Consent						e							
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Submi	ssion Forms						Track Location	Ref Number	Request Type	Process Submission				
Submi	ssion Forms								Click on the hyperlink to edit/view the submission.	Send				
۲	Initial Review Submissio	n Form						800080	Internal Study Personnel Change	Submission				
۲	Change Request & Amen	dments					Rout	-						
۲	Internal Study Personne	l Changes	i				II Proc		u see the "Final/Closure Report Form"					
۲	Continuing Review Submission Form							this means that someone else had already created the Final/Closure Report Form and you						
۲	Final/Closure Report Fo	m							pen it by clicking on the link.	1.5.5				
۲	UPSER/Adverse Event F	orm						-	don't see the Final/Closure Report F					
۲	Protocol Deviation/Violation Form						here, click on "Final/Closure Report Form" (re arrow).							
۲	Protocol Exception Form								v).					
۲	StudyFinder 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- Fi PI: Administrator	nal/Closure Report Form - (Version 2.0)	🖪 Back										
Section view of the Form	Image: Save Section Image: Save Sect	nd Submit										
[.												
1.0 🗎 Final/Closure Report	1.0 The Final/Closure Report Form will be used as a Progress Report to request the closure of											
2.0 🖹 Subject ollment	the study.											
3.0 Subje pographics	1.1 Study Information:											
4.0 or Audited?												
Adverse Events Serious 5.0 Adverse Events, and MINOR Deviations	IRB Number: H-31000											
6.0 🖹 Study Closure	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 have less or more sections services and the section is service and the section is set and the											
than this example depending on your answers and												
ty	pe of study.											
	O No funding obtained											
	O Industry contract never executed											
	Sponsor closed study before any subjects enrolled at BU/BMC	9										
	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)

BOSTON UNIVERSITY MEDICAL CAMPUS CAMPUS Commas CM windor trans.	rator UMC - <i>MED</i> - Institutional Review Board	? Help	В Му Г	Profile 🔻 🏾 🏾 🏾	€ Log out
My Workspaces 🗷 Study Submission	I Routing Signoff			l	🖪 Back
Study Title: Submission Reference Number:					Save Signoff
				Create PDF	- Packet
Submission Form(s):	Include in PDF Packet Last Approved Separate Window Submission Component Name				
	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				