

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

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

Account: Department:

Home Logout Help

When you login into INSPiR II, the system will open into your Home page.

My Assistant

Study Assistant

Add a new Study

My Studies

My Appointments

Your current Department is BU - MED - INSTITUTIONAL REVIEW BOARD

Your current review board is IRB Your current committee is Panel Orange

Worklist Filter: All

Move to Complete

Click on "My Studies" to view the list of studies that you have access to.

5 result(s) found...

Open	Task Type	Received	Tasks
<input type="checkbox"/>	Waiting Submission	10/19/2011 11:28 AM EST	<p>Continuing Review Submission Form is waiting to be submitted</p> <p>Study Title: TESING EMAILS Principal: Khaled Khattar, BA Investigator: Khaled Khattar, BA Submission Type: Continuing Review Submission Form Reference Number: 382595 IRB Number: H-29420 IRB Expiration: 02/28/2011</p>
<input type="checkbox"/>	Submission Response	10/17/2011 09:59 AM EST	<p>IRB returned the submission with the outcome of Administrative Deferral</p> <p>Study Title: testing... Principal: Khaled Khattar, BA Investigator: Khaled Khattar, BA Submission Type: Initial Review Submission Form Reference Number: 378075 IRB Number: H-31293</p>

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Account: Khaled Khattar, BA (You are working under someone else's account. Click here to return to your account)
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My Studies Back

Display my studies by:

IRB Number

Filter my studies by study status: All Most Recently Used

Find by IRB Number: Find

Find by Study Nickname: Find

31 result(s) found...

1 - 31

Click to open	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title/ Study Nickname	Copy Study	Delete Study
Open	Draft	H-31302		Administrator	Dummy Exempt Study 2-18-2011 copy	Copy	
Open	Expired	H-29420	02/28/2011		TESING EMAILS	Copy	
Open	Approved / Expedited					Copy	
Open	Draft	H-27006			27006 Copy of CONSENT WORDING	Copy	
Open	Draft			Khattar, Khaled, BA	23592	Copy	
Open	Pending - Initial Review	H-31293		Khattar, Khaled, BA	testing... 4-12-11	Copy	
Open	Inactive - Administratively	H-31003		Khattar, Khaled, BA	testing 3-21-11	Copy	

Locate the study that you want to close and click on the Open icon next to it.

Under "Submissions Forms" (middle section), click on the "Final/Closure Report Form" (red arrow)

Find: Previous Options ▾

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Navigation: Home | Studies

Home Logout Help

IRB Number: **H-25004** Study Nickname: 25004
PI: Khattar, Khaled, BA

Submissions

Study Status: **Approved / Open - Expedited** Study Title: COMPARE FUNCTIONALITIES
Expiration Date: 12/25/2012

Submissions | Study Management

Protocol Items		Submission Forms		Outstanding Submission(s)			
Application	Adverse Event Form	Change Request & Amendments	Continuing Review Extension Form	Track Location	Ref Number	Request Type	Process Submission
Informed Consent	Final/Closure Report Form	Initial Review Submission Form	Internal Study Personnel Changes	There are no outstanding submissions.			
Other Study Documents	Protocol Deviation/Violation Form	Protocol Exception Form					
Miscellaneous							
Study Correspondence							
Submissions History							
Study Notebook							
Forms							
Recruitment Materials							

Click on the "Add a New Form" button . (red arrow)
This will create a new Final/Closure Report form.

IRB Number: H-25004 **Study Nickname:** 25004 **Final/Closure Report Form** Back
PI: Khattar, Khaled, BA

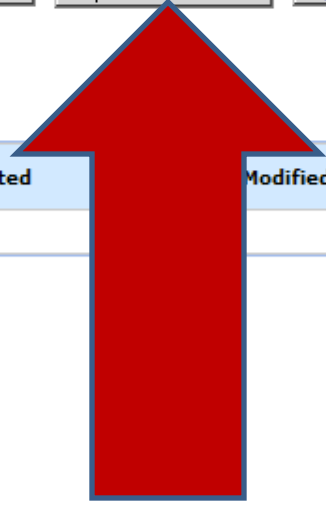
Study Status: Approved / Open - Expedited **Study Title:** COMPARE FUNCTION CAPABILITIES
Expiration Date: 12/25/2012

Export to Excel Add 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...

<input type="checkbox"/>	Show Rev	Edit/View	Created By	Date Created	Modified By	Date Modified
No records have been created.						



This will bring you to a Section by Section view of the Final Report form. Complete Section 1 and then click on **SAVE AND CONTINUE TO THE NEXT SECTION (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.

X Find: Previous Next  Options ▾

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Department: BU - MED - INSTITUTIONAL REVIEW BOARD
Navigation: Home > my studies > study mgmt. > study closure list

Home X Logout ? Help


IRB Number: **H-25004** Study Nickname: 25004
PI: Khattar, Khaled, BA

Final/Closure Report Form

Back

 Printer Friendly  Refresh Constant Fields  Save and Continue to the Next Section

Section view of the Form Entire view of the Form

1.0  Subject Enrollment

1.0 Subject Enrollment

1.1 Study Information:


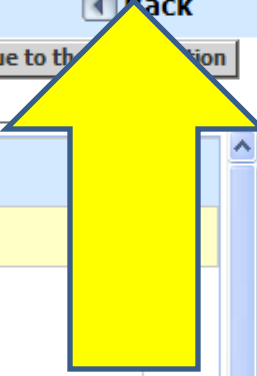
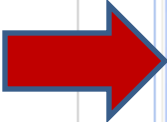
IRB Number:
H-25004

Study Title:
COMPARE FUNCTION CAPABILITIES

Principal Investigator:
Khaled Khattar, BA

1.2 For the column entitled "Approved by this IRB", enter the number of subjects enrolled into the study at all sites where YOU have IRB approval to conduct this research.

	Approved by this IRB	Worldwide (See instructions above)
Total Approved by IRB	<input type="text"/>	<input type="text"/>



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IRB Number: H-25004 Study Nickname: 25004
 PI: Khattar, Khaled, BA

Final/Closure Report Form

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Printer Friendly Refresh Constant Fields Save and Continue to the Next Section

Section view of the Form

Entire view of the Form

1.0 Subject Enrollment

Principal Investigator:
Khaled Khattar, BA

1.2 For the column entitled "Approved by this IRB", enter the number of subjects enrolled into the study at all sites where YOU have IRB approval to conduct this research.

	Approved by this IRB	Worldwide (See instructions above)
Total Approved by IRB	<input type="text" value="50"/>	<input type="text" value="100"/>
Total enrolled at time of last review	<input type="text" value="20"/>	<input type="text" value="40"/>
Total enrolled <u>since</u> last review	<input type="text" value="10"/>	<input type="text" value="20"/>
Total enrolled to date	<input type="text" value="30"/>	<input type="text" value="60"/>

If you have more than one subject group (i.e. intervention group and control group, etc.) please provide the breakdown in the text box below (under PR2) of how many subjects have been enrolled in each group.

You will need to add subjects and total numbers manually- INSPIR II does not auto-calculate fields

Complete each section and then **SAVE AND CONTINUE TO NEXT SECTION**
(yellow arrow)


IRB Number: **H-25004** Study Nickname: 25004
PI: Khattar, Khaled, BA

Final/Closure Report Form

[Back](#)[Printer Friendly](#)[Refresh Constant Fields](#)[Save and Continue to the Next Section](#)

Section view of the Form

Entire view of the Form

1.0  Subject Enrollment

Principal Investigator:

Khaled Khattar, BA

1.2 For the column entitled "Approved by this IRB", enter the number of subjects enrolled into the study at all sites where YOU have IRB approval to conduct this research.

	Approved by this IRB	Worldwide (See instructions above)
Total Approved by IRB	<input type="text" value="50"/>	<input type="text" value="100"/>
Total enrolled at time of last review	<input type="text" value="20"/>	<input type="text" value="40"/>
Total enrolled <u>since</u> last review	<input type="text" value="10"/>	<input type="text" value="20"/>
Total enrolled to date	<input type="text" value="30"/>	<input type="text" value="60"/>

If you have more than one subject group (i.e. intervention group and control group, etc.) please provide the breakdown in the text box below (under PR2) of how many subjects have been enrolled in each group.

This will bring you to the final page.

- If you are not the PI, you will see this screen and it will be your last one for this submission. By clicking “Notify PI to Sign-off” it goes to the PI for sign-off and then is submitted to the IRB.
- If you are the PI, skip to the next screen instead, and there will be a couple more screens before you’re done.

Section view of the Form

Entire view of the Form

- 1.0 Subject Enrollment
- 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

Notify PI to Signoff

If you are the PI, you will see this screen.
By clicking "sign-off and submit", the system will take you to the signoff sheet for sign-off and then it is submitted to the IRB.

Find:

Previous Next Options ▾



Account: Khaled Khattar, BA (You are working under someone else's account. Click here to return to your account)
Department: BU - MED - INSTITUTIONAL REVIEW BOARD
Navigation: Home > my studies > study mgmt. > study closure list

Home Logout Help

IRB Number: **H-25004** Study Nickname: 25004
PI: Khattar, Khaled, BA

Final/Closure Report Form

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Printer Friendly Signoff and Submit

- Section view of the Form**
- 1.0 Subject Enrollment
- 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

Entire view of the Form

Form has been Completed!

Exit Form

Signoff and Submit

The PI will then receive a Submission Sign-off sheet (that looks like this).
 The PI can review the Final Report by clicking on the “open” icon (yellow arrow)
 Then sign off (entering user ID and password and then clicking on “save sign-off” to authenticate.
 (red arrow)

Submission Signoff Sheet Back

Save Signoff

Study Title: COMPARE FUNCTION CAPABILITIES
Submission Reference Number: 410275

Submission Form(s):



Open	Type	Document Name	Version	Date Submitted into Workflow
	Submission Form	Final/Closure Report Form	Version 1.0	01/06/2012 02:38 PM EST

Submission Attachments below:

No Attachment found:

Khaled Khattar, BA as Principal Investigator
 do you Approve or Deny this submission?

Approve
 Deny

This form requires your electronic signature.
 Please enter your User ID & Password:

User ID:

Password:



Save Signoff

You can check the status from the "Study Submissions" page where you would click on the icon under "Track Location" (blue arrow)

Find: Previous Next Options ▾

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Department: BU - MED - INSTITUTIONAL REVIEW BOARD

Navigation: [Home](#) > [my studies](#)

Home Logout Help

IRB Number: **H-25004** Study Nickname: 25004 Back
 PI: Khattar, Khaled, BA

Study Status: Approved / Open - Expedited Study Title: COMPARE FUNCTION CAPABILITIES
 Expiration Date: 12/25/2012

Submissions | Study Management

Protocol Items	Submission Forms	Outstanding Submission(s)											
<ul style="list-style-type: none"> Application Informed Consent Other Study Documents <li style="background-color: #e6f2ff; padding: 5px;"> Miscellaneous Study Correspondence Submissions History Study Notebook <li style="background-color: #e6f2ff; padding: 5px;"> Forms Recruitment Materials 	<ul style="list-style-type: none"> Adverse Event Form Change Request & Amendments Continuing Review Submission Form Final/Closure Report Form Initial Review Submission Form Internal Study Personnel Changes Protocol Deviation/Violation Form Protocol Exception Form 	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #e6f2ff;"> <th style="font-size: small;">Track Location</th> <th style="font-size: small;">Ref Number</th> <th style="font-size: small;">Request Type</th> <th style="font-size: small;">Process Submission</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; background-color: green; color: white;"> Routing In Process</td> <td style="text-align: center;">410275</td> <td style="font-size: small;">Click on the hyperlink to edit/view the submission. Final/Closure Report Form</td> <td style="text-align: center; vertical-align: middle;"><input type="button" value="Retract Submission"/></td> </tr> </tbody> </table>	Track Location	Ref Number	Request Type	Process Submission	 Routing In Process	410275	Click on the hyperlink to edit/view the submission. Final/Closure Report Form	<input type="button" value="Retract Submission"/>			
Track Location	Ref Number	Request Type	Process Submission										
 Routing In Process	410275	Click on the hyperlink to edit/view the submission. Final/Closure Report Form	<input type="button" value="Retract Submission"/>										



You are now all set.

Convert Select

Favorites MSN MSNBC Hotmail Traffic for Boston, Massa...

Electroni... INSPIR II... IRIS: Log In IRIS: ... X http://dc... Boston U... NIH Certi...

Find: tilton Previous Next Options



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IRB Number: **H-25004** Study Nickname: 25004
 PI: Khattar, Khaled, BA

Workflow - Submission Tracking

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Printer Friendly

Status	View Details	Date Received / Date Completed		Event Description
In Process		01/06/2012 03:02 PM EST	+	IRB received the submission
Completed		01/06/2012 03:02 PM EST 01/06/2012 03:02 PM EST	+	All study personnel have been verified with up to date training records.
Completed	Routing Signoff	01/06/2012 02:56 PM EST 01/06/2012 03:02 PM EST	+	Khaled Khattar, BA as Principal Investigator review and apply signoff
Completed		01/06/2012 02:32 PM EST 01/06/2012 02:56 PM EST	+	Final/Closure Report Form is waiting to be submitted