

How to Create and Submit a Reportable Events and New Information Form (RENI)

Welcome Khaled Khattar, BA (Last Login: 11/20/2017 11:44 AM EST)

Study Assistant

Add a New Study	My Studies	Find a Study	Submit a Form	My Current Approvals	Upcoming Renewals	My Appointments
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Below are your incomplete Study tasks:

Waiting Submission	11
Below are your incomplete IRB tasks:	
Continuing Review Due	12
Submission Response	3

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

Open Dashboard	1
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My Studies Back

Display my Studies by:

Filter my Studies by study status: All Most Recently Used

Find by IRB Number:

Find by Study Nickname:

13 result(s) found... 1 - 13

Click to open	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title/ Study Nickname	Copy Study	Delete Study
	Pending - Initial Review	H-32615		Administrator, BA	testing Oracle upgrade.. 9-16-2012		
	Approved / Open - Expedited	H-31000		Administrator, BA	Testing 2-18-2011		
	Draft	H-32617		Administrator, BA	Copy of Testing 2-18-2011		
				Khattar, Khaled, BA	testing... 4-12-11		
				Khattar, Khaled, BA	Test 10-12-11 - Test 10-12-11 - Test 10-12-11 - Test 10-12-11 - Test 10-12-11 - Test 10-12-11 - Test 10-12-11 - Test 10-12-11 10-12-11		
	Draft			Khattar, Khaled, BA	Demo Protocol Demo		
	Expired	H-31173	12/25/2013	Khattar, Khaled, BA	Testing 3-16-2011 3-16-2011		
	Draft			Administrator, BA	testing 10-10-2012 testing 10-10-2012		
	Draft	H-31302		Administrator, BA	Dummy Exempt Study 2-18-2011 copy		
	Draft			Administrator, BA	testing 2 9-27-12 - 2		
	Inactive - Administratively Closed	H-32108		Administrator, BA	testing 11-6-2012 11-6-2012		
					testing Drugs		

Locate the study and click on the "Open" icon.

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

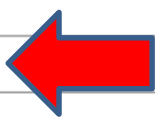


Protocol Items

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

Submission Forms

- Available Forms
- Change Request and Amendments
 - Contact Information Change Request Form
 - Continuing Review Submission Form
 - Final/Closure Report Form
 - Initial Review Submission Form
 - Internal Study Personnel Changes
 - Protocol Exception Form
 - Reportable Events and New Information Form
 - StudyFinder Form



- Submissions History
- Study Correspondence

Outstanding Submission(s)			
Track Location	Ref Number	Request Type	Process Submission
	1081680	Click on the hyperlink to edit/view the submission. Continuing Review Submission Form	Send Submission
	1081676	Click on the hyperlink to edit/view the submission.	Send Submission



If you see the "Reportable Events and New Information Form" link here, this means that someone else had already created the Reportable Events and New Information Form and you can open it by clicking on the link. If you don't see the Reportable Events and New Information Form link here, click on "Reportable Events and New Information Form" under "Available Forms" to create one (red arrow).

Subforms Attachments

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

Reportable Events and New Information Form

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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
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No records have been created.



If you see a pending "Reportable Events and New Information Form" here, this means that someone else had already created the Reportable Events and New Information Form and you can open it by clicking on "Edit/View".
If you don't see the Reportable Events and New Information Form, click on the "Add a New Form" button to create one (red arrow).

This will bring you to a Section by Section view of the Reportable Events and New Information 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.



Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Navigation: Home > my studies > study mgmt.

Home Logout Help

IRB Number: H-31000
Study Nickname: 2-18-2011-
PI: Administrator

Reportable Events and New Information Form - (Version 9.0)

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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 Reportable Events and New Information
- 2.0 Report Date
- 3.0 Unanticipated Problems (UPs) Details
- 4.0 Need for protocol or consent form modifications
- 5.0 Attachments



1.0 Reportable Events and New Information

For information about reporting requirements, click [here](#)

1.1 Study Information:

IRB Number: H-31000	
Study Title: Testing	
Principal Investigator: Administrator	

1.2 Report Type

- Unanticipated Problem associated with fatal or life-threatening event - Initial Report
****must be submitted within 2 days of investigator learning of event**
- Unanticipated Problem NOT associated with fatal or life-threatening event - Initial Report
****must be submitted within 7 days of investigator learning of event**
- Unanticipated Problem - Follow-up Report



Once you complete all sections, the system will take you to this page.



Account: Administrator
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Home Logout Help

IRB Number: H-31000
Study Nickname: 2-18-2011-
PI: Administrator

Reportable Events and New Information Form - (Version 9.0)

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Print Friendly

Signoff and Submit

Section view of the Form

Entire view of the Form

- 1.0 Reportable Events and New Information
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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 Reportable Events and New Information Form, click on any of the sections on the left.

Note: Your Reportable Events and New Information 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 Reportable Events and New Information Form by clicking on it (yellow arrow)
2. Then clicks on the "Approve" radio button. (orange arrow)
3. Then enters User ID and password. (red arrows)
4. Then clicks "Save Signoff" to authenticate, signoff, and submit to the IRB. (blue arrows)

EMSPROD/CMS/IRB/STUDIOS/STUDIOS

Submission Routing Signoff

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Save Signoff

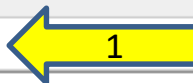
Study Title: Testing

Submission Reference Number: 1081098

Create PDF Packet

Submission Form(s):

Include in PDF Packet	Submission Component Name
<input type="checkbox"/>	Reportable Events and New Information Form



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

Approve Deny

Comments: [Click here to add comments.](#)

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

User ID:

Password:



Save Signoff