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

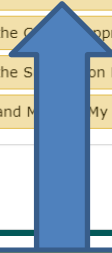My Workspaces ▼   Study Assistant

Featured Study Operations

Create a New Study

Start a Submission Form for one of My Studies

View the C...   ...provals for one of My Studies

View the S...   ...on History for one of My Studies

View and M...   ...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 **"Start a Submission Form for one of My Studies"**

2

This opens the "Start a Submission Form" pop-up page.

Start a Submision Form

Instructions: Select a study to work with, click to open it and start a Submission Form. You may use the search bar to find a specific study.

All Studies | Recently Used | Study Status

Search for RB Number, Title, Alias | Search

| All | Draft | IRB |

54 result(s) found...   1 - 10 ▶

Select a Study	Study Status	Review Board	IRB Number	IRB Expiration	Study Title / Study Alias	Principal Investigator
⬈	Exempt - limited IRB review	IRB	H-31000		Testing / 2-18-2011-	Administrator
	Closed - Ceded Review	IRB	H-37307		INTERFACE TESTING OF 'IRB-' APPENDING TO IRB STATUSES IN VELOSCT	
	Draft	IRB	H-38072			
	Draft	IRB	H-36572			
	Draft	IRB	H-44153			
	Draft	IRB	H-34575			
	Inactive - Administratively Closed	IRB	H-35910		Dummy Expedited/Full Board 6-22-2022	Administrator
	Draft	IRB	H-38079		Chart Reviews 8/17/2018 / Chart Reviews 8/17/2018	Administrator
	Draft	IRB	H-36594		Exempt Study 6/7/2017 / Exempt Study 6/7/2017	Administrator
					testcs1027title	

54 result(s) found...   1 - 10 ▶

Cancel Search

You can use the "Search" box to locate the study. Or you can just scroll down.

Once you locate the study, click on the "Select a Study" icon

3

This opens the "Submission Form List" popup.

Start a Submision Form

Submission Form List

| Study Status: Exempt | IRB Number : H-31000 | Study Title : | Testing |

Submission Forms

Available Forms	Version List	Start a new Submission	Edit Incomplete Submissions
Change Request and Amendments	📄	📄	📄
Contact Information Change Request Form	📄	📄	
Continuing Review Submission Form	📄	📄	
Final/Closure Report Form	📄	📄	📄
Internal Study Personnel Changes	📄	📄	
Protocol Exception Form	📄	📄	
Recruitment Materials Submission Form	📄	📄	
Reportable Events and New Information Form	📄	📄	📄

Cancel

Click on "Start a New Submission" icon that corresponds to the "Reportable Events and New Information Form "- blue arrow

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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.

BOSTON UNIVERSITY / BOSTON MEDICAL

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

Announcements 1 | ? Help | My Profile ▾ | Log out

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

Study | Reportable Events and New Information Form - (Version 12.0) | ◀ Back

Print Friendly | Refresh Constant Fields | Save Section | Save and Continue to Next Section

Section view of the Form | Entire view of the Form

1.0 📄 Reportable Events and New Information

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 - Initial Report

**must be submitted within 7 days of investigator learning of event

☐ Unanticipated Problem - Follow-up Report

☐ Major Protocol Deviation

(also select Unanticipated Problem if this deviation suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.)
**must be submitted within 7 days of investigator or research staff learning of event

☐ DSMB, DMC, or other safety monitor's report WITH recommended changes to the study

(if NO recommended changes, do not file this form; instead, report at the time of Continuing Review)
**must be submitted within 7 days of investigator receiving report

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

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

🏠 Home   ⏻ Logout   ❓ Help

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

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

Reportable Events and New Information Form - (Version 9.0)

◀ **Back**

🖨 Print Friendly   🖊 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

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.

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🔍 100% ▾

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 the "Reportable Events and New Information 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)**