

# How to Create and Submit a Protocol Exception Form

### Featured Study Operations

- Create a New Study
- Start a Submission Form for one of My Studies
- View the Approvals for one of My Studies
- View the Submission History for one of My Studies
- View and Manage My Studies

### By the Numbers

Submissions in Process	Forms Pending Submission	Pending My Response	High T
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”**

# This opens the “Start a Submission Form” pop-up page.

**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
<input checked="" type="checkbox"/>	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 VELOSC		
	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		Administrator
	Draft	IRB	H-36594		Chart Reviews 8/17/2018		Administrator
					Exempt Study 6/7/2017		
					Exempt Study 6/7/2017		Administrator
					testcs1027title		

54 r... 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

# This opens the “Submission Form List” popup.

**Submission Form List**

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

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 “Protocol Exception Form”- blue arrow

This will bring you to a Section view of the Protocol Exception 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 CENTER** Account: Administrator  
Department: BMC/BUMC - MED - Institutional Review Board  
Path: Home

My Workspaces IRB Number: H-31000 Study **Protocol Exception Form - (Version 2.0)** 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 Protocol Exception Information**

Submitting this exception request does not constitute IRB approval. This exception must be reviewed and approved by the IRB PRIOR to the PI initiating the action. If the exception requires "urgent" review, please contact the IRB at 617-358-5372.

**1.1 Study Information:**

RB Number:  
H-31000

Study Title:  
Testing

Principal Investigator:  
Administrator

**1.2 Describe the exception and provide justification below (for more information, click [here](#)):**

**1.3 Does this exception change the risk/benefit ratio of the study for this subject?**

Yes  No

**1.4 If you have a Sponsor / Funding Agency that needs to be notified of this exception, have you done so?**

Yes  
 No  
 N/A - Not a sponsored study/the sponsor doesn't require notification

**1.5 Attachments**

?

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

The screenshot displays the user interface of the Boston Medical Center Institutional Review Board (IRB) system. At the top, the Boston University and Boston Medical Center logos are visible, along with user information: Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board, and Path: Home. Navigation links include My Workspaces, Announcements, Help, My Profile, and Log out. The main header shows the current study: Protocol Exception Form - (Version 2.0). Below the header, there are buttons for Print Friendly and Signoff and Submit. The main content area features a large green banner that reads "Form has been Completed!" with the subtext "Grant Key Personnel access to the study". At the bottom of this banner are two buttons: "Signoff and Submit" and "Exit Form". On the left side, there is a sidebar with a "Section view of the Form" tab selected, showing a list of sections. A callout box on the left points to this sidebar, stating: "If you want to go back into the Protocol Exception Form, click on any of the sections on the left." Another callout box on the right points to the "Signoff and Submit" button, stating: "Click on 'Signoff and Submit' or 'Notify PI for Signoff' if you're ready to submit to the IRB." A third callout box on the right points to the "Exit Form" button, stating: "Click on 'Exit Form' to exit this form and come back later."

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

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

Protocol Exception Form - (Version 2.0) [Back](#)

Print Friendly Signoff and Submit

Section view of the Form Entire view of the Form

Protocol Exception 1.0 Information Submitting this except ...

**Form has been Completed!**  
Grant Key Personnel access to the study

Signoff and Submit Exit Form

If you want to go back into the Protocol Exception Form, click on any of the sections on the left.

Click on “Signoff and Submit” or “Notify PI for Signoff” if you’re ready to submit to the IRB.

Click on “Exit Form” to exit this form and come back later.

The PI will then receive a Submission Sign-off sheet (that looks like this).

1. The PI can review the Protocol Exception Form by clicking on the “Protocol Exception 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)

The screenshot shows the 'Submission Routing Signoff' page. At the top, the user is identified as 'Administrator' from the 'BMC/BUMC - MED - Institutional Review Board'. The page title is 'Submission Routing Signoff'. Below the header, there are navigation options like 'My Workspaces' and 'Study'. The main content area shows submission details: 'Study Title: Testing' and 'Submission Reference Number: 1628080'. A table lists 'Submission Form(s)' with columns for 'Include in PDF Packet', 'Compare to Last Approved', 'View in Separate Window', and 'Submission Component Name'. One row is visible for 'Protocol Exception Form'. Below the table, there are radio buttons for 'Approve' and 'Deny', a 'Comments' field, and a 'Save Signoff' button. Three numbered arrows point to these elements: a yellow arrow labeled '1' points to the 'Protocol Exception Form' link in the table; an orange arrow labeled '2' points to the 'Approve' radio button; and a red arrow labeled '3' points to the 'Save Signoff' button.

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

Announcements 1 Help My Profile Log out

My Workspaces Study Submission Routing Signoff Back

Save Signoff

Study Title: Testing  
Submission Reference Number: 1628080

Create PDF Packet

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input checked="" type="checkbox"/>			Protocol Exception Form

Submission Form(s)

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

Comments: Click here to add comments.

Save Signoff