

Review Response Submission Form

- This form is used to reply to the IRB and address the issues/stipulations raised when the IRB conditionally approves the submission, defers it, returns it as Incomplete submission, or for administrative modifications.

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 **“Submission Response”** task (shortcut) for this specific study that will allow you to respond to the stipulations.

If you are listed as a “Study Contact” on the study, the system will list a task for you in the “Study Tasks” tab and would be listed with the “Submission Response” as the Task Type. This task will allow you to create the “Review Response Submission Form”.

Hello Administrator
your last login was
11/16/2023 02:55 PM EST

? Help
Tutorial
My Profile
Log out

My Workspaces
Study

Study Tasks
Outstanding
Completed

Search for RB Number, Title, Alias
Search

All Tasks
Study Tasks

Task List: All
Review Board: All
Filter By: --none--

34 result(s) found...
1 - 10

	Click to open	Details	Task Type	Date Received	Study Status	Study Title Study Alias	Principal Investigator	Review Board	IRB Number	IRB Expiration	Priority	Complete By
☐			Submission Response	11/17/2023 02:10 PM EST	Pending - Initial Review	Dummy Study for Demo 11/17/2023	Administrator	IRB	H-44279		No Priority	
☐			Waiting Submission	11/16/2023 11:16 PM EST	Exempt - limited IRB review	Testing 2-18-2011-	Administrator	IRB	H-31000		No Priority	
☐			Waiting Submission	11/08/2023 11:06 AM EST	Exempt - limited IRB review	Testing 2-18-2011-	Administrator	IRB	H-31000		No Priority	
☐			Submission Routing Signoff	07/12/2022 07:02 AM EST	Exempt - limited IRB review	Testing 2-18-2011-	Administrator	IRB	H-31000		No Priority	
☐			Waiting Submission	05/24/2021 10:55 AM EST	Draft	Separate Protocol 8/17/2018 Separate Protocol 8/17/2018	Administrator	IRB				
☐			Waiting Submission	10/23/2020 10:30 PM EST	Draft	testing 2 9-27-12 - 2	Khattar, Khaled, BA					
☐			Waiting Submission	09/21/2020 09:38 AM EST	Draft	Testing Migration MSD Test Interface	Administrator	IRB				
☐			Waiting Submission	03/19/2020		INTERFACE TESTING OF 'IRB-' APPENDING TO IRB STATUSES IN VELOSCT						

Note: If you don't have a “Submission Response” task that corresponds to the submission under review, then proceed to the next slide.

1. Locate the “Submission Response” task for the submission under review, and
2. Click on the “Open” icon next to it. Skip the next slides to [slide # 7](#).

Only follow the instructions in slides 4 to 6, if the system did not list a “Review Response” task for you in the “Study Tasks” tab because you are not one of the “Study Contacts” .

BOSTON UNIVERSITY

MEDICAL CAMPUS

CELEST

BOSTON MEDICAL

EXCEPTIONAL CARE. WITHOUT EXCEPTION.

My Workspaces

Hello Khaled Khattar, BA

your last login was

10/11/2022 08:16 AM EDT

Study Assistant

Study Assistant

Announcements 1

Help

Tutorial

My Profile

Log out

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

By the Numbers

Submissions in Process

54

Forms Pending Submission

53

Pending My Response

4

High T

>

Tasks

All Tasks

35

Study Tasks

33

After logging into INSPIR II, from your Home page, click on “View and Manage My Studies” and proceed to the next slide.

4

The system will scroll your Home page down to the “All Studies” section.

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

Once you locate the study that is under review, click on the “Open” icon

All Studies Recently Used Study Status

Search for RB Number, Title, Alias Search

56 result(s) found... 1 - 10

Click to open Study Dashboard	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Actions
	Pending - Initial Review	IRB	H-44279			
	Exempt - limited IRB review	IRB	H-31000			
	Draft	IRB	H-44278			
	Closed - Ceded Review	IRB	H-37307		Velos# HRB123 - Active in Velos for Interface Testing	
	Draft	IRB	H-36572		Expedited/Full Board 11-25-2019	
	Draft	IRB	H-38072		Separate Protocol 8/17/2018	
	Draft	IRB	H-44153		Single patient	
					Review 10-29-2015	
					Review 10-29-2015	
					Review Checklist Expedited/Full Board 12-2-2016	
					Review Expedited/Full Board 2022	
					Review 8/17/2018	
					Review 8/17/2018	

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

Once you locate the study that is under review, click on the "Open" icon

This opens the “Submissions/Study Management” page for the study.

BOSTON UNIVERSITY
MEDICAL CAMPUS

BOSTON MEDICAL
EXCEPTIONAL CARE WITHOUT EXCEPTION.

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

? Help My Profile Log Out

My Workspaces

IRB Number: H-44279
Study Alias: 11/17/2023
PI: Administrator

Study Submissions

Back

Study Status: Pending - Initial Review

IRB Number : H-44279

Study Title : Dummy Study for Demo

Submissions

Submission Management

Protocol Items

Study Application

Informed Consents

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

Recruitment Materials Submission Form

Reportable Events and New Information Form

Submissions History

Study Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
Routing In Process	1626456	Click on the hyperlink to edit/view the submission. IRB has requested a Submission Response for Initial Review Submission Form	Respond to Review

Click on this link to open the "Review Response Submission Form".

This should open the “Review Response submission Form”.

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

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > find study > study mgmt.

Help My Profile Log out

My Workspaces Study **Review Response Submission Form - (Version 1.0)** Back

Form Administrator

Previous Submission

Recommendations

No recommendation entered.

Stipulations

Comments that must be addressed

No Stipulation entered.

Comments

No Stipulation entered.

Please respond to each of the stipulations below. If you are required to make a change to any of the submission components, make sure to use the links provided in the "Links to Components" row and you still need to make a change to a component, scroll down to the "Current Submission" section and click on the grey button that says "Click here to edit."

Stipulation 1 out of 6:

Description:

Dear Principal Investigator,
Thank you for this submission. There are a few items that will need to be addressed prior to approval. Please see the stipulations below, and don't h
Thank you,
Brandon Finn, CIP
Sr. IRB Analyst
BU Medical Campus/Boston Medical Center IRB
Email: brandonf@bu.edu
Phone: (617) 358-5301

This is not an approval Letter.
This protocol has been administratively deferred. Please note that no human subjects research activities (including recruitment, consenting, enrollment, randomization, screening, data collection, study interventions, data analysis, or follow-up) may be initiated until FULL IRB APPROVAL has been obtained. Conditional approval and deferral do NOT constitute full IRB approval.
When you go to edit your protocol application, you will need to create a "revision.& For guidance on creating a REVISION, please see the following link (you may ignore the information on converting the protocol, as you have already done so):
<http://www.bumc.bu.edu/irb/files/2016/10/Review-Response-Submission-Form-Initial-Review1.pdf>
Also, it is very important when you are making changes to existing documents that you "revise" the documents rather than creating new versions. Here are the instructions for how to do that:
Consent forms: To revise your consent forms go to this link and follow the instructions: <http://www.bumc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Consent-Form.pdf>
Other Study Documents: To revise any Study Documents go to this link and follow the instructions: <http://www.bumc.bu.edu/irb/files/2016/10/How-to-revise-an-existing-Study-Documents.pdf>
Please go to this link for information about how to complete an INSPIR application: <http://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/>

Scroll down to read the stipulations.

Stipulation 1 is usually informational. It includes the IRB's review outcome of the previous round. It also includes instructions on how to proceed and the IRB Analyst's contact information.

Stipulation Types

Below are the list of the most common types of stipulations. You would read each stipulation in your “Review Response Form” and determine which type it is. Then you would follow the corresponding instructions (slides) and come back to this slide when you finish that set of slides. Repeat these steps until you have addressed all stipulations.

Types of stipulations:

- Stipulations to make changes to the Submission Form – Go to [slide # 9](#) - 15
- Stipulations to make changes to the study Application (only available in the “Initial Review Submission form” or “Change Request and Amendments form”) – Go to [slide # 16](#) - 24
- Stipulations to make changes to Consent Form(s) – Go to [slide # 25](#) - 34
- Stipulations to make changes to Study Documents – Go to [slide # 35](#) – 44

Once you have addressed all stipulations and you are ready to submit the “Review Response” back to the IRB, please go to [slide # 45](#) and follow the rest of the instructions.

How to address stipulations with links to the Submission Form

* Depending on your submission, the submission form can be an “Initial Review”, “Amendment”, “Continuing Review”, “RENE”, “Final/Closure Report”, etc.), but these instructions will work the same.

* If a stipulation is missing a link, please contact the assigned IRB Analyst so they can setup the missing link in that stipulation.

Note: We used here the submission form “Initial Review Submission Form” (green arrow) as an example in the following slides. Yours might be a different submission form (such as an “Amendment”, “Continuing Review”, “RENE”, “Final/Closure Report”, etc.)

The screenshot shows the IRB system interface for Boston University Medical Campus. At the top, the header includes the university logo, user information (Administrator, BMC/BUMC - MED - Institutional Review Board), and navigation links. The main content area displays a submission form titled "Initial Review Submission Form - (Version 1.0)". A green arrow points from the top text to this form. Below the form title, there is a section for "Stipulation 9 out of 9:" with a description and a "Stipulation Type" dropdown. A table titled "Links to Components" lists the submission form and its status. A red arrow points from the "Action Not Complete" status to a yellow callout box. Another red arrow points from the "Revise Existing" button to a yellow callout box. A third red arrow points from the "Do you accept this Stipulation?" section to a yellow callout box. The interface also includes a "Form" tab, a "My Workspaces" section, and a "Help" link.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > find study > study mgmt.

My Workspaces ☒ TRB Number: H-4279
Study Alias: 11/17/2023
PI: Administrator

Study Assistant Review Response Submission Form - (Version 1.0)

Click on “Revise Existing” to create a revision and make the requested changes (proceed to the next slide).

Stipulation 9 out of 9:
Description:
Please make changes to the Initial Review
Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Initial Review Submission Form (Version 1.0) Section: Initial Review Submission Packet	Revise Existing

Do you accept this Stipulation? ☐ Yes ☒ No

If there is no link in the “Links to Components” section to take you where you need to go to make your changes, contact the assigned IRB Analyst.

If there is no “Revise Existing” here, this means that a revision was already created and available for editing. Skip to [slide # 14](#)).

You will get the confirmation popup.

The screenshot shows a web application interface for a medical institution. At the top, there is a header with the Boston University Medical Campus logo, user information (Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board), and navigation links (Help, My Profile, Log out). Below the header, there is a sidebar with 'My Workspaces' and a main content area. The main content area displays a 'Review Response Submission' form. A yellow callout box with a blue arrow points to a 'CONFIRM' button in a confirmation popup. The popup text reads: 'Confirm the adding a revision. Are you sure you want to create a revision?' with 'CONFIRM' and 'CANCEL' buttons. The background form includes sections for 'Stipulation 9 out of 9', 'Description', 'Stipulation Type', 'Links to Components', and 'Do you accept this Stipulation?'. A table with columns 'Operation', 'Action Status', and 'Component Name' is visible, showing 'Modify Existing Attachment' with 'Action Not Complete' status. The bottom of the form has a rich text editor with various formatting options.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > find study > study mgmt.

My Workspaces ☒ Study Assistant Review Response Submission

Form

Stipulation 9 out of 9:

Description:

Please make changes to the Initial Review

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name
Modify Existing Attachment	Action Not Complete	Initial Review Submission Form Section: Initial Review Submission

Links to Components
(These are the items that are linked to this stipulation)

Do you accept this Stipulation? ☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

CONFIRM CANCEL

This will create a read-write version of your submission form that you can edit, and it will take you to the right section/question.

The system will create a revision (if one didn't exist) of the Submission form (in this example, it's the "Initial Review Submission Form") and will take you to the section/question where you need to make your changes. It also lists the stipulation (in a blue box) so that it's accessible to be read and followed (orange arrow).

The screenshot shows the 'Initial Review Submission Form - (Version 1.1)' interface. At the top, there is a header with the Boston University Medical Campus logo, user information (Account: Administrator, Department: BMC/BUMC - MED - Institution, Path: Home > find study > study mgmt. >), and navigation links (Help, My Profile, Log out). Below the header, there is a sidebar with 'My Workspaces' and a 'Form' tab. The main content area is titled 'Initial Review Submission Packet' and contains a note about the submission packet. A blue box with a warning icon and the text 'Modifications Required: Please make changes to the Initial Review' is highlighted. A yellow arrow points from the text in the first paragraph to this blue box. A blue arrow points from the 'Save Form' button to the text in the second paragraph. The form fields include 'Study Title' (Dummy Study for Demo), 'IRB Number' (H-44279), and 'Principal Investigator' (PI Name: Administrator, PI Email Address: medirb@bu.edu, PI Phone Number: 617-638-7203).

Account: Administrator
Department: BMC/BUMC - MED - Institution
Path: Home > find study > study mgmt. >

IRB Number: **H-44279**
Study Alias: 11/17/2023
PI: Administrator

Study Assistant

Initial Review Submission Form - (Version 1.1)

Print Friendly Refresh Constant Fields Save Form Exit Form

Initial Review Submission Packet

Note: This is the submission packet. The Study Application should be attached below under "Study Application Form". To access the attached "Study Application", click on the "Edit/View" icon next to it.

To create and attach your consent form(s), go to section "Consent Documents" below.

To upload and attach any study related document(s) that were not already attached in the Study Application, go to section "Other Study Documents" below.

Modifications Required:
Please make changes to the Initial Review

Study Title:
Dummy Study for Demo

IRB Number:
H-44279

Principal Investigator:
PI Name: Administrator
PI Email Address: medirb@bu.edu
PI Phone Number: 617-638-7203

Scroll down to where you need to make your changes, make the changes requested by the IRB, then click on "Save Form" (available if the form is only one page) or "Save and Continue to Next Section" (if the form has multiple sections) .

Note: We used the submission form “Initial Review Submission Form” (green arrow) as an example in these slides. Yours might be a different submission form (such as an “Amendment”, “Continuing Review”, “RENE”, “Final/Closure Report”, etc.), but all work the same

When you reach the end of the form, the system will bring you to the “Form has been Completed!” page

The screenshot shows the top navigation bar of the IRB system. On the left, there are logos for Boston University Medical Campus and Boston Medical Center. The user's account information is displayed: Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board, and Path: Home > find study > study mgmt. > review response. On the right, there are links for Help, My Profile, and Log out. Below the navigation bar, there is a green header with the text 'Initial Review Submission Form - (Version 1.1)'. A 'Print Friendly' button is located in the top right corner. The main content area has a green header with the text 'Form has been Completed!' and 'Instruction of Form has Been Completed Screen'. Below this, there are two buttons: 'Return to Form' and 'Exit Form'. A large blue arrow points from a yellow callout box to the 'Exit Form' button. The callout box contains the text: 'If you're done with this form, click on the "Exit Form" button to take you back to the Review Response Form.'

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > find study > study mgmt. > review response

Help My Profile Log out

My Workspaces IRB Number: H-44279 Study Alias: 11/17/2023 PI: Administrator Study Assistant Initial Review Submission Form - (Version 1.1) Back

Form

Print Friendly

Form has been Completed!
Instruction of Form has Been Completed Screen

Return to Form

Exit Form

If you're done with this form, click on the "Exit Form" button to take you back to the Review Response Form.

Note: You will notice that the “Revise Existing” link is not there since a revision (Version 1.1) had already been created and attached (green arrow). The system will only create a revision once.

The screenshot displays the IRB system interface. At the top, the header includes the Boston University Medical Campus logo, account information (Administrator), and navigation links. The main content area shows a stipulation titled "Stipulation 9 out of 9:" with a description: "Please make changes to the Initial Review". Below this, a table lists components associated with the stipulation. A green arrow points to the "Initial Review Submission Form (Version 1.1)" row, which has an "Action Not Complete" status. A yellow arrow points to the "Compare Form Version" button. An orange arrow points to the "Save Form" button. A blue arrow points to the "Edit/View" icon in the table row. A yellow callout box explains that once a new revision is created, users can open it and make more changes by clicking the "Edit/View" icon. Another yellow callout box explains that users should provide an explanation of how they addressed the stipulation in a text box and click "Complete Action" (yellow arrow) to let others know the stipulation has been addressed. A final yellow callout box instructs users to frequently save changes by clicking "Save Form" (orange arrow).

Operation	Action Status	Component Name
Modify Existing Attachment	Action Not Complete	Initial Review Submission Form (Version 1.1)
		Initial Review Submission Form (Version 1.0)

Compare Form Version

Complete Action Incomplete Action

Do you accept this Stipulation? ☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

In the Text Box, let the IRB know that you have made the changes requested in this stipulation. You can add any additional information here about this stipulation. To let others know that this stipulation has been addressed, click on “Complete Action” (yellow arrow).

- Make sure you frequently save your changes by clicking “Save Form” (orange arrow).



Account: Administrator

Department: BMC/BUMC - MED - Institutional Review Board

Path: [Home](#) > [find study](#) > [study mgmt.](#)

[?](#) Help
[My Profile](#) ▾
[Log out](#)

- When you're done with this type of stipulations, go back to [slide # 8](#) for more options.

- When you're done with this type of stipulations, go back to [slide # 8](#) for more options.

How to address stipulations with links to the Study Application

- *This type of link is only available when the submission is an “Initial Review Submission Form” or a “Change Request and Amendments” form.
- * If a stipulation is missing a link, please contact the assigned IRB Analyst so they can setup the missing link in that stipulation.

In most cases, the IRB asks you to make changes to a section in the Study Application and presents you with a direct link to that section (in the “Links to Components” row). If this is the first time in this “Review Response Submission Form” that you’re revising the Study Application, you will have a “Revise Existing” button.

The screenshot shows the 'Review Response Submission Form - (Version 1.0)' interface. At the top, there is a header with user information: Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board, Path: Home > find study > study mgmt. Below this, there are fields for IRB Number: H-44279, Study Alias: 11/17/2023, and PI: Administrator. The main content area is titled 'Form' and contains a table with the following data:

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Application (Version 1.0) Section: Study Summary Question: Provide a brief summary of the project in terms understandable to a non scientist (in 500 words or less). Do NOT copy from a grant application.	Revise Existing

Below the table, there is a section for 'Links to Components' with a note: '(These are the items that are linked to this stipulation)'. There is also a section for 'Do you accept this Stipulation?' with radio buttons for 'Yes' and 'No'. A blue arrow points from the 'Links to Components' section to the 'Revise Existing' button. Another blue arrow points from the 'Revise Existing' button to a yellow callout box. A third blue arrow points from the 'Links to Components' section to a yellow callout box.

Callout 1 (Top Right): Click on “Revise Existing” to create a revision and make the requested changes (proceed to the next slide).

Callout 2 (Bottom Left): If there is no link in the “Links to Components” section to take you where you need to go to make your changes, contact the assigned IRB Analyst.

Callout 3 (Bottom Right): If there is no “Revise Existing” here, this means that a revision was already created and available for editing. Skip to [slide # 23](#)).

You will get the confirmation popup.

The screenshot displays the 'Review Response Submission Form' in the IRB system. A yellow callout box with the text 'Click on “CONFIRM” button to proceed.' has a blue arrow pointing to the 'CONFIRM' button in a confirmation popup. The popup text reads: 'Confirm the adding a revision. Are you sure you want to create a revision?' with 'CONFIRM' and 'CANCEL' buttons. The background form includes a table with the following data:

Operation	Action Status	Component Name
Modify Existing Attachment	Action Not Complete	Study Application (Version 1.0) Section: Study Summary Question: Provide a brief summary of the study. Do NOT copy from a grant proposal.

Other visible elements include the 'Stipulation 2 out of 7' section, a 'Do you accept this Stipulation?' section with radio buttons for N/A, Yes, and No, and a 'Links to Components' section.

This will create a read-write version of the Study Application that you can edit, and it will take you to the right section/question.

Note: Every few months or as needed, the IRB adds new questions to the Study Application and publishes it. The “Convert to the New Form Version” is the system’s way to bring your Study Application up to the most recent version.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > study mgmt. > change request list > change request

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

Study Application (Version 1.7)

Print Friendly Convert to the New Form Version Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Information

If you don't get this popup, then you are already in the newest form version. Please skip to page # [22](#).

New Form Version has been published

A new version of the Study Application Form (Study Application) has been published.
Please click on the Convert to the New Form Version button.
New Sections and Questions may be present on this form so please click through each section to verify that the application is complete.

Convert to New Form Version

If you do get this popup, then you will need to convert to the newly published Study Application form:

Click “Convert to New Form version” to close the popup (green arrow) and convert to the newly published Study Application form. Continue to the next page.

This page only applies if you need to convert to the newly published Study Application form.

Account: Administrator
Department: BMC/BJMC - MED - Institutional Review Board
Path: Home > study mgmt. > change request list > change request

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

My Workspaces

Study Application (Version 1.7)

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 Review Path Determination
5.0 Required Training and Conflict of Interest
6.0 Funding Source
7.0 Study Summary
8.0 Navigation
9.0 Study Site Information
10.0 Purpose
11.0 Subjects
12.0 Design/Protocol
13.0 Risks & Benefits Justification Approval
14.0

23.0 Study Attachments

23.1 Attach here any remaining study documents that you have not attached in previous sections.

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
No Document(s) have been attached to this form.							

The system will start converting to the new form section by section. If a section has a new question that is required, the system will stop there and hide all subsequent sections until you answer the new question. Don't worry, nothing is lost in these hidden sections!

1- Start clicking "Save and Continue to the Next Section" until all relevant sections reappear and you have answered all new questions. Keep clicking on this button until all sections are revisited and the system transitions you back the "Review Response Form"

This page only applies if you need to convert to the newly published Study Application form.

The system automatically takes you back to the “Review Response Submission Form” page and attach the new version of the Study Application (assuming the Study Application was completed).

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

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

? Help My Profile Log out

My Workspaces IRB Number: **H-44279**
Study Alias: 11/17/2023
PI: Administrator

Study Assistant **Review Response Submission Form - (Version 1.0)** Back

Print Friendly Refresh Constant Fields Save Form Signoff and Submit

Form

Stipulation 2 out of 9:

Description:
Please describe in more details ...

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name
Modify Existing Attachment	Action Not Complete	Study Application (Version 1.1)
		Study Application (Version 1.0) Section: Study Summary Question: Provide a brief summary of the project in terms understandable to ... Do NOT copy from a grant application.

Links to Components
(These are the items that are linked to this stipulation)

Do you accept this Stipulation? ☐ N/A ☒ Yes ☐ No

Font Family 12

Now that the Study Application form has been updated to the newest version, you can start working on the changes requested in the stipulation by clicking on the “Study Application” link (newest version).

Proceed to the next slide.

The system will create a revision (if one didn't exist) of the Study Application and take you to the section/question where you need to make your changes. It also lists the stipulation (in blue box) so that it's accessible to be read and followed (orange arrow).

Account: Administrator
Department: BMC/BUMC - MED - Institution
Path: Home > find study > study mgmt. >

IRB Number: H-4279
Study Alias: 11/17/2023
PI: Administrator

My Workspaces

Section view of Application

Entire view of the Application

Print Friendly Save Section Save and Continue to Next Section

7.0 Study Summary

7.1 Provide a brief summary of the project... understandable to a non scientist (in 500 words or less). Do NOT copy from a grant application.

Modifications Required:

Please describe in more details ...

Click here to access the text editor.

test.....

You can also make changes to any of the other sections listed on the left. Make sure your changes are saved by clicking on “Save and Continue to the Next section”.

It's a good practice to have the system check for completeness every time you make a change to the “Study Application”. You can do this by visiting “Review for Completeness” section, then click on “Save and Continue to Next Section” button.

Note: You will notice that the “Revise Existing” link is not there since a revision (Version 1.1) had already been created and attached (green arrow). The system will only create a revision once.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > find study > study mgmt.

IRB Number: H-44279
Study Alias: 11/17/2023
PI: Administrator

My Workspaces

Review Response

Stipulation 2 out of 7:

Description:
Please describe in more details ...

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name
Modify Existing Attachment	Action Not Complete	☒ Study Application (Version 1.1) ☐ Study Application (Version 1.0) Section: Study Summary Description: Provide a brief summary of the project in terms understandable to a non scientist (in 500 words or less). Do NOT copy from a grant application.

Compare Application Version

Complete Action ☐ Incomplete Action ☒

Do you accept this Stipulation?
☐ N/A ☒ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

Once a new revision is already created, you can open the new revision and make more changes by clicking on the “Edit/View” icon to directly go to the section that has been associated to a stipulation.

In the Text Box, let the IRB know that you have made the changes requested in this stipulation. You can add any additional information here about this stipulation. To let others know that this stipulation has been addressed, click on “Complete Action” (yellow arrow).

- Make sure you frequently save your changes by clicking “Save Form” (orange arrow).

Repeat steps in slides 16 – 24 for any other stipulations that have a link to the Study Application”

BOSTON UNIVERSITY MEDICAL CAMPUS EXCEPTIONAL CARE WITHOUT EXCEPTION

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > find study > study mgmt.

Help My Profile Log out

My Workspaces My Workspaces

IRB Number: **H-44279**
Study Alias: 11/17/2023
PI: Administrator

Study Assistant

Review Response Submission Form - (Version 1.0)

Back

Print Friendly Refresh Constant Fields Save Form

Form

Stipulation 4 out of 9:

Description:
Update the Study Type in the funding section....

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Application (Version 1.0) Section: Funding Source Question: Study Type	<button>Revise Existing</button>

Links to Components
(These are the items that are linked to this stipulation)

Do you accept this Stipulation?
☐ N/A ☒ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

Font Family 12

- When you're done with this type of stipulations, go back to slide # 8 for more options.

How to address stipulations with links to a Consent Form

* If a stipulation is missing a link, please contact the assigned IRB Analyst so they can setup the missing link in that stipulation.

In most cases, the IRB also asks you to make changes to the consent form and presents you with a direct link to that form.

[illegible]

Form

Description:

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Consent Main Consent Fo	Revise Existing

Confirm the adding a revision.

Do you accept this Stipulation? ☐ N/A ☒ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

Confirm the adding a revision.

Are you sure you want to create a revision?

CONFIRM

CANCEL

Click on “Confirm” button to proceed.

The “Study Consent Revision” popup will open.

- It is recommended that you download a copy of the latest revision of the consent form from INSPIR for editing. You can download it by clicking on “Download” icon (orange arrow) then proceed to the next slide.
- If you already have the revised consent form on your computer ready to be uploaded, click on “Choose File” and skip the next slides to slide # 30.

Account: Administrator

Department: BMC/BUMC - MED - Institutional Review Board

Path: Home > find study > study mgmt.

My Workspaces

IRB Number: **H-44279**

Study Alias: 11/17/2023

PI: Administrator

Study Assistant

Review Response Submission Form - (Version 1.0)

Help

My Profile

Log out

Back

Print Friendly

Refresh Constant Fields

Save Form

Form

Stipulation 5 out of 9:

Description:

Please Fix this statement in the Main Consent form

Stipulation Type: (Stipulation must be addressed)

Links to Components

(These are the items that are linked to this stipulation)

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Do you accept this Stipulation?

☐ N/A

☐ Yes

☐ No

Provide an explanation on how you addressed this Stipulation:

Study Consent Revision

*Consent Title:

Main Consent Form

*Version Number:

1

1

*Version Date:

11/17/2023

Sponsor Version:

*Category:

Adult Consent

*Language:

English

Description:

Comments:

Download Consent:

Download

Select the document to upload:

Choose File

No file chosen

Close, don't save any changes

Save Consent

View Document

RTF

28

The selected consent document will download. Depending on your system and web browser, you will get the “Downloads” popup similar to this one. Click on the file to open it.

The screenshot displays a web application interface for managing consent forms. A modal dialog titled "Study Consent Revision" is open, showing fields for "Consent Title" (Main Consent Form), "Version Number" (1), "Version Date" (11/17/2023), "Sponsor Version", "Category" (Adult Consent), and "Language" (English). It also includes text areas for "Description" and "Comments", a "Download Consent" button, and a "Select the document to upload" section with a "Choose File" button. The background shows a "Review Response Submission Form - (Version 1.0)" with a table of stipulations. A yellow arrow points from the "Download Consent" button to a browser's "Downloads" popup, which lists "Main Consent Form.rtf" with an "Open file" link.

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Save the consent document to your computer then start making your changes. Don't forget to save it again when you're done editing. When you are ready to upload the revised consent form from your computer, come back here and proceed to next slide.

Notice that this revised consent document will now be given a new Version Number (the system will increment the version number by + .1) (yellow arrow)

Note: If you used track changes in your document, make sure that you accept all changes and save it before uploading the document.

My Workspaces ☒ IRB Number: **H-44279** Study Assistant Review Response Submission Form - (Version 1.0) Back

PI: Administrator

Form

Stipulation 5 out of 9:

Description:

Please Fix this statement in the Main Consent form

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Do you accept this Stipulation? ☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

Download Consent: Download

Select the document to upload: Choose File No file chosen

Close, don't save any changes Save Consent

Click on the "Choose File" button to navigate on your computer to where you last saved your revised consent document to upload it (orange arrow)

This opens the “Open” pop-up or a different popup depending on the system that you are using.

The screenshot shows a web application interface for reviewing a consent form. The background is a dark grey sidebar with navigation links like 'My Workspaces', 'Study Assistant', and 'Review Response Submission Form - (Version 1.0)'. The main content area is a light grey form titled 'Study Consent Revision' with a 'Consent Title' field set to 'Main Consent Form'. A file dialog box is open over the form, showing a list of files in the 'Consent Templates' folder. A blue arrow points from the bottom of the screen to the 'Open' button in the dialog box.

Study Consent Revision

*Consent Title: Main Consent Form

Open

Desktop > Consent Forms > Consent Templates

Search Consent Templates

Name	Status	Date modified
Blood-Draw-Consent-Form	✓	5/22/2014 9:51 AM
Consent Statement for Anonymous Sur...	✓	4/2/2014 11:07 AM
Consent Use Consent Form	✓	4/2/2014 11:07 AM
Information Sheet Template	✓	12/12/2016 2:17 PM
Consent_Form_Template	✓	5/27/2014 3:16 PM
Consent Form Template	✓	5/22/2014 8:57 AM
Consent Form for Children 12-17 ...	✓	4/2/2014 11:06 AM
Consent Form for Children 12-17 ...	✓	4/2/2014 11:07 AM

File name: All files

Open Cancel

1. Navigate to the consent document that you want to upload
2. Click on the document to highlight it
3. Click on “Open”

- This will bring you back to the “Study Consent Revision:” popup.
- Notice the uploaded consent document’s name is now appearing in the popup (blue arrow)
1. Change the “Version Date” to today’s date (green arrow)
 2. Click on the “Save Document” button (Grey arrow)

PI: Administrator

Print Friendly Refresh Constant Fields Save Form

Form

Stipulation 5 out of 9:

Description:

Please fix this statement in the Main Consent form

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Links to Components
(These are the items that are linked to this stipulation)

Do you accept this Stipulation? ☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

Font

Study Consent Revision

*Consent Title: Main Consent Form

*Version Number: 1 .1

*Version Date: 11/17/2023

Sponsor Version:

* Category: Adult Consent

* Language: English

Description:

Comments:

Download Consent: Download

Select the document to upload: Choose File Main_Cons..._Template.rtf

View Document RTF

Close, don't save any changes Save Consent

(1) Type your response in the text box provided underneath, and (2) click on “Complete Action” button to mark it as completed. (3) Don’t forget to click on “Save Form” to save your work





BOSTON UNIVERSITY

MEDICAL CAMPUS



BOSTON MEDICAL CENTER

EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: Administrator

Department: BMC/BUMC - MED - Institutional Review Board

Path: [Home](#) > [find study](#) > [study mgmt.](#)

Help

My Profile ▾

Log out

My Workspaces

IRB Number: **H-44279**

Study Alias: 11/17/2023

PI: Administrator

Study Assistant

Review Response Submission Form - (Version 1.0)

Back

- When you're done with this type of stipulations, go back to [slide # 8](#) for more options.

- When you're done with this type of stipulations, go back to [slide # 8](#) for more options.

How to address stipulations with links to a Study Document

* If a stipulation is missing a link, please contact the assigned IRB Analyst so they can setup the missing link in that stipulation.

In most cases, the IRB also asks you to make changes a study document and presents you with a direct link to that form.

Department: BMC/BORC - MED - Institutional Review Board
Path: Home > find study > study mgmt.

IRB Number: **H-44279**
Study Alias: 11/17/2023
PI: Administrator

My Workspaces

Study Assistant

Review Response S

Form

Stipulation 7 out of 9:

Description:
Fix a sentence in the Flyer

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Document Flyer (Version 1.0)	Revise Existing

Links to Components
(These are the items that are linked to this stipulation)

Do you accept this Stipulation?

Font Family 12

If this is the first time you're making a change, you will have a "Revise Existing" button. Click on "Revise Existing" to create a revision and make the requested changes (proceed to the next slide).

If there is no link in the "Links to Components" section to take you where you need to go to make your changes, contact the assigned IRB Analyst.

The “Study Document Revision” popup will open.

- It is recommended that you download a copy of the latest revision of the study document from INSPIR for editing. You can download it by clicking on “Download” icon (orange arrow) then proceed to the next slide.
- If you already have the revised study document on your computer ready to be uploaded, click on “Choose File” and skip the next slides to slide # 40.

The screenshot displays the INSPIR system interface. A 'Study Document Revision' popup window is open, featuring the following fields:

- Document Title:** Flyer
- Version Number:** 1.1
- Version Date:** 11/17/2023
- Sponsor Version:**
- Category:** Flyer
- Description:**
- Comments:**
- Download Document:** Download
- Select the document to upload:** Choose File No file chosen

A large yellow arrow points to the 'Download' button. The background shows a form for 'Stipulation 7 out of 9' with a table of links to components and a section for accepting the stipulation.

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Do you accept this Stipulation? ☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

The selected study document will download. Depending on your system and web browser, you will get the “Downloads” popup similar to this one. Click on the file to open it.

The screenshot shows a web application interface with a 'Study Document Revision' form in the foreground. The form contains fields for Document Title, Version Number, Version Date, Sponsor Version, Category, Description, and Comments. It also has a 'Download Document' button and a 'Select the document to upload' section. In the background, a browser's 'Downloads' popup is visible, showing a list of files including 'Flyer (1).rtf', 'Flyer.rtf', and 'Main Consent Form.rtf'. A yellow arrow points from the text in the top blue box to the 'Downloads' popup.

My Workspaces ☒ IRB Number: **H-44279** Study Alias: 11/17/2023 Study Assistant Review Response Submission Form - (Version 1.0) PI: Administrator

Form

Stipulation 7 out of 9:

Description:

Fix a sentence in the Flyer

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Do you accept this Stipulation? ☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

Download Document: Download

Select the document to upload: Choose File No file chosen

Close, don't save any changes Save Document

Downloads

- Flyer (1).rtf Open file
- Flyer.rtf Open file
- Main Consent Form.rtf Open file

See more

Save the study document to your computer then start making your changes. Don't forget to save it again when you're done editing. When you are ready to upload the revised study document from your computer, come back here and proceed to next slide.

Notice that this revised study document will now be given a new Version Number (the system will increment the version number by + .1) (yellow arrow)

Note: If you used track changes in your document, make sure that you accept all changes and save it before uploading the document.

My Workspaces ☒ IRB Number: **H-44279** Study Assistant Review Response Submission Form - (Version 1.0) Back

Study Alias: 11/17/2023
PI: Administrator

Print Friendly Refresh Constant Fields Save Form

Form

Stipulation 7 out of 9:

Description:
Fix a sentence in the Flyer

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Do you accept this Stipulation? ☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

Font

Study Document Revision:

* Document Title: Flyer

Version Number: 1 .1

Version Date: 11/17/2023

Sponsor Version:

* Category: Flyer

Description:

Comments:

Download Document: Download

Select the document to upload: Choose File No file chosen

View Document

Close, don't save any changes Save Document

Click on the "Choose File" button to navigate on your computer to where you last saved your revised study document to upload it (orange arrow)

This opens the “Open” pop-up or a different popup depending on the system that you are using.

The screenshot shows a web application interface for reviewing a response submission form. The top navigation bar includes the Boston University Medical Campus logo, user information (Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board, Path: Home > find study > study mgmt.), and a 'Log out' button. The main content area displays the 'Review Response Submission Form - (Version 1.0)' with a 'Document Title' field containing 'Flyer'. A file explorer window is open, showing the 'Velos Test' folder. The file 'Dummy Flyer' is selected. A blue arrow points from the 'Open' button in the file explorer to a blue callout box containing three numbered steps: 1. Navigate to the study document that you want to upload, 2. Click on the document to highlight it, 3. Click on 'Open'.

1. Navigate to the study document that you want to upload

2. Click on the document to highlight it

3. Click on “Open”

This will bring you back to the “Study Document Revision:” popup.

- Notice the uploaded study document’s name is now appearing in the popup (blue arrow)

1. Change the “Version Date” to today’s date (green arrow)
2. Click on the “Save Document” button (Grey arrow)

My Workspaces

IRB Number: **H-44279**
Study Alias: 11/17/2023
PI: Administrator

Study Assistant

Review Response Submission Form - (Version 1.0)

Back

Form

Stipulation 7 out of 9:

Description:

Fix a sentence in the Flyer

Stipulation Type: (Stipulation must be addressed)

Links to Components

(These are the items that are linked to this stipulation)

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Do you accept this Stipulation?

☐ N/A ☐ Yes ☐ No

Provide an explanation on how you addressed this Stipulation:

Study Document Revision:

*Document Title: Flyer

Version Number: 1.1

Version Date: 11/17/2023

Sponsor Version:

* Category: Flyer

Description:

Comments:

Download Document: Download

Select the document to upload: Choose File Dummy Flyer.rtf

View Document

RTF

Close, don't save any changes

Save Document

(1) Type your response in the text box provided underneath, and (2) click on “Complete Action” button to mark it as completed. (3) Don’t forget to click on “Save Form” to save your work





 Account: Administrator
 Department: BMC/BUMC - MED - Institutional Review Board
 Path: [Home](#) > [find study](#) > [study mgmt.](#)

[Help](#)
[My Profile](#)
[Log out](#)

- When you're done with this type of stipulations, go back to [slide # 8](#) for more options.

How to submit the “Review Response Submission Form” to the IRB

Before submitting to the IRB, we recommend that you take a last look at the “Current Submission Components” section by scrolling down (blue arrow) to the very end of the “Review Response Submission Form”. This is what the PI will see in their signoff page. It’s also what the IRB will see when reviewing your response. So please make sure that all your submission components are listed in this table.

My Workspaces

IRB Number: **H-44460**
Study Nickname: ECG-AI in CA
PI: Ruberg, Frederick Lief, MD

Study Assistant

Review Response Submission Form - (Version 2.0)

Back

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Notify PI to Signoff

Section view of the Form

Entire view of the Form

1.0

Review Response Submission Form

1.5 Current Submission Components (Overview)

Show submission component(s) in round: 3 Current Round

Items in Folder View

Add New Component

Compare Item(s)

Create PDF Packet

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	All Submission Components Previous Rounds & Currently Attached
Submission Form(s)						
☐	☐					IRB - Review Response Submission Form - (Version 2.0)
☐	☐					Initial Review Submission Form - (Version 1.1)
☐	☐					Initial Review Submission Form - (Version 1.0)
Application						
☐	☐					Study Application - (Version 1.1)
☐	☐					Study Application - (Version 1.0)
Document(s)						
Category : Device Brochure						
☐	☐					Device Brochure - (Version 1.0)
Category : External IRB Approval Letter						
☐	☐					WIRB approval - (Version 1.0)
Category : HIPAA Form						
☐	☐					HIPPA waiver letter - (Version 1.0)
Category : Letter						
☐	☐					Risk determination letter - (Version 1.0)
Category : Protocol						
☐	☐					Protocol - (Version 1.0)

If everything looks good and you are ready to submit to the IRB, click on the “Save and Continue to Next Section” button (green arrow).

This will open the “Form has been Completed!” page.

The screenshot shows the 'Review Response Submission Form - (Version 2.0)' interface. At the top, there is a header bar with 'My Workspaces' on the left, a box containing 'IRB Number: H-44460', 'Study Nickname: ECG-AI in CA', and 'PI: Ruberg, Frederick Lief, MD', the role 'Study Assistant', and a 'Back' button. Below this is a teal bar with the title 'Review Response Submission Form - (Version 2.0)' and buttons for 'Print Friendly' and 'Signoff and Submit'. The main content area has two tabs: 'Section view of the Form' and 'Entire view of the Form'. On the left sidebar, under 'Section view of the Form', there is a link '1.0 Review Response Submission Form' with a green arrow pointing to it. The main content area displays a large teal banner with the text 'Form has been Completed!' and 'Grant Key Personnel access to the study'. Below this, a yellow box contains the instruction: 'To submit to the IRB, click on “Signoff and Submit” or “Notify PI to Signoff” (if you are not the PI)'. To the right of this box are two buttons: 'Signoff and Submit' and 'Exit Form'. A blue arrow points from the yellow box to the 'Signoff and Submit' button, and an orange arrow points from the 'Exit Form' button back to the yellow box.

My Workspaces

IRB Number: **H-44460**
Study Nickname: ECG-AI in CA
PI: Ruberg, Frederick Lief, MD

Study Assistant

Review Response Submission Form - (Version 2.0)

Back

Print Friendly

Signoff and Submit

Section view of the Form

Entire view of the Form

1.0 Review Response Submission Form

Form has been Completed!

Grant Key Personnel access to the study

To submit to the IRB, click on “Signoff and Submit” or “Notify PI to Signoff” (if you are not the PI)

Signoff and Submit

Exit Form

- Clicking on “Signoff and Submit” or “Notify PI to Signoff” (if you are not the PI), will route this submission for PI signoff (blue arrow). Once the PI signs off, it will proceed to the IRB.
- Clicking on “Review Response Submission Form” (green arrow) will take you back to the Review Response Submission Form.
- Clicking on “Exit Form” (orange arrow) will exit this form.