


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.



BOSTON UNIVERSITY

MEDICAL CAMPUS






BOSTON MEDICAL CENTER


EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Hello Administrator

your last login was

11/16/2023 02:55 PM EST

 Help
  Tutorial
  My Profile

 Log Out

My Workspaces

Study

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” .

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MEDICAL

EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Hello Khaled Khattar, BA
your last login was
10/11/2022 08:16 AM EDT

Announcements 1

Help

Tutorial

My Profile

Log out

My Workspaces

Study Assistant

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.

Search for RB Number, Title, Alias Search

All Recently Used Study Status

56 result(s) found...

1 - 10

Click to open Study Dashboard	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Study Type	Study Administrator	Applications	Documents	Forms	Hide	Exempt	Copy	Delete	Correspond
	Pending - Initial Review	IRB	H-44279		Du...										
	Exempt - limited IRB review	IRB	H-31000		Test...										
	Draft	IRB	H-44278		De...										
	Closed - Ceded Review	IRB	H-37307		Int...										
	Draft	IRB	H-36572		Expedited/Full Board 11-25-2019										
	Draft	IRB	H-38072		Expedited/Full Board 11-25-2019										
	Draft	IRB	H-44153		Separate Protocol 8/17/2018										
					Separate Protocol 8/17/2018										
					Single patient										
					Single patient										
					Review 10-29-2015										
					Review 10-29-2015										
					ing Checklist Expedited/Full Board 12-2-2016										
					my Expedited/Full Board 2022										
					Reviews 8/17/2018										
					Reviews 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

BOSTON UNIVERSITY
MEDICAL CAMPUS

SEVER
BOSTON MEDICAL
EXCEPTIONAL CARE WITHOUT EXCEPTION

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

? Help My Profile Log out

My Workspaces Study Submissions Back

Study Status: Pending - Initial Review IRB Number : H-44279 Study Alias: 11/17/2023 PI: Administrator

IRB Number : H-44279 Study Title : Dummy Study for Demo

Submissions Study 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

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
	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 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 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 forget to update the protocol.

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.)

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

Study Assistant

Review Response

Submission Form - (Version 1.0)

Back

Refresh Constant Fields

Save Form

Form

Stipulation 9 out of 9:

Description:
Please make changes to the Initial Review

Stipulation Type: (Stipulation must be addressed)

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

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?

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.

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

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 displays a web application interface for a medical review process. 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, a sidebar on the left contains 'My Workspaces' and 'Form' tabs. The main content area shows a 'Review Response Submission' form. A yellow callout box with a blue arrow points to a confirmation popup. The popup contains the text: 'Confirm the adding a revision. Are you sure you want to create a revision?' and two buttons: 'CONFIRM' and 'CANCEL'. 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 in the background shows the status of various components, with 'Initial Review Submission Form' marked as 'Action Not Complete'.

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

My Workspaces
Form

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

Study Assistant

Review Response Submission

Print Friendly Refresh Constant Fields Save Form

Back

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 Section: Initial Review Submission	Revise Existing

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

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)' in a web application. 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 has a green header bar with 'Initial Review Submission Form - (Version 1.1)' and a 'Back' button. Below this, there are buttons for 'Print Friendly', 'Refresh Constant Fields', 'Save Form', and 'Exit Form'. The main content area has a dark green background with white text. It includes a 'Note' about the submission packet, instructions on how to create and attach consent forms, and instructions on how to upload and attach study related documents. A blue box with a warning icon and the text 'Modifications Required: Please make changes to the Initial Review' is highlighted. Below this, there is a form with fields for 'Study Title', 'IRB Number', 'Principal Investigator', 'PI Name', 'PI Email Address', and 'PI Phone Number'. An orange arrow points from the text in the first block to the 'Modifications Required' box. A blue arrow points from the 'Save Form' button to the text in the second block.

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

My Workspaces

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 for Boston University Medical Campus. The top navigation bar includes the university logo, account information (Administrator), and a breadcrumb trail: Home > find study > study mgmt. The main header shows the current form: Initial Review Submission Form - (Version 1.0). A green arrow points to the 'Initial Review Submission Form (Version 1.1)' link in the table, indicating that a revision has been created. A yellow arrow points to the 'Compare Form Version' button, and an orange arrow points to the 'Save Form' button. A blue arrow points to the 'Edit/View' icon in the table, which is used to open the new revision. The table lists the following actions:



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)

Below the table, there is a section for 'Do you accept this Stipulation?' with radio buttons for N/A, Yes, and No. A text box is provided for 'Provide an explanation on how you addressed this Stipulation:'. The stipulation description is: 'Please make changes to the Initial Review'. The stipulation type is 'Stipulation must be addressed'.

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).

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, the user is logged in as 'Administrator' from 'BMC/BUMC - MED - Institutional Review Board'. The path is 'Home > find study > study mgmt.'. The form title is 'Review Response Submission Form - (Version 1.0)'. Below the title, there is a section for 'Links to Components' with a table showing the status of various components. A yellow callout box points to the 'Revise Existing' button in the 'Action' column of the 'Study Application (Version 1.0)' row. Another yellow callout box points to the 'Links to Components' section, indicating that if there is no link, the user should contact the assigned IRB Analyst. A third yellow callout box points to the 'Revise Existing' button, indicating that if it is not present, a revision has already been created and the user should skip to slide # 23.

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

Study

Review Response Submission Form - (Version 1.0)

My Work

Form

2 out of 7:

Describe

Please describe the changes in more details ...

Stipulation: (Stipulation must be addressed)

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

Do you accept this Stipulation?

☐ N/A ☒ Yes ☐ No

Font Family 12

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.

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

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 Boston Medical Center IRB system. A yellow callout box with the text 'Click on “CONFIRM” button to proceed.' has a blue arrow pointing to a confirmation popup. The popup contains the text: 'Confirm the adding a revision. Are you sure you want to create a revision?' and two buttons: 'CONFIRM' and 'CANCEL'. The background form shows a table with columns 'Operation', 'Action Status', and 'Component Name'. The 'Action Status' for 'Modify Existing Attachment' is 'Action Not Complete'. The 'Component Name' is 'Study Application (Version 1.0)'. The form also includes a 'Stipulation 2 out of 7' section and a 'Do you accept this Stipulation?' section with radio buttons for 'N/A', 'Yes', and 'No'.

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.

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.

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

My Workspaces Study **Study Application (Version 1.7)** Back

Section view of Application Entire view of the Application

1.0 General Information

2.0 Information

Information for your study::

Information you would like to use

Abbreviated version of the Study Application

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.

16.0 Confidentiality

17.0 HIPAA Compliance

18.0 Cost/Payment

19.0 Biological Sample Collection

20.0 Drugs or Biological Agents

21.0 Devices

22.0 Retention of Samples or Data

23.0 Study Attachments

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

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.

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/BUHC - 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

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
Links to Components (These are the items that are linked to this stipulation)	Modify Existing Attachment	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.

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.



Account: Administrator

Department: BMC/BUMC - MED - Institution

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

Board

Response

[Help](#)

[My Profile](#) ▼

[Log out](#)

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

Study **Study / Section (Version 1.1)**

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 Menu
9.0 Study Site Information
10.0 Purpose
11.0 Subject
12.0 Design/Pr
13.0 Risks & Be
Justification
14.0 Data & Saf
ing
15.0 Consent Pr
16.0 Privacy an
Confidenti
17.0 HIPAA Cor
18.0 Cost/Paym
19.0 Biological
Collection
20.0 Drugs or B
Agents
21.0 Devices
22.0 Retention of Samples or
Data
23.0 Study Attachments

7.0 Study Summary

7.1 Provide a brief summary of the project that is 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 "Study Attachments" section (green arrow), 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	<input checked="" type="checkbox"/> 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:

Print Friendly Refresh Constant Fields Save Form

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.

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

Study Assistant

Review Response S

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 Name	Action
Modify Existing Attachment	Action Not Complete	Study Consent Main Consent Form (Version 1.0)	Revise Existing

Do you accept this Stipulation?
☐ No ☒ Yes ☐ No

Font Family 12

Log out

Back

Save Form

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 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:

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

X

* 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 shows a web application interface with a 'Study Consent Revision' dialog box open. The dialog box contains the following fields:

- * 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

At the bottom of the dialog box are two buttons: 'Close, don't save any changes' and 'Save Consent'.

In the background, a browser's 'Downloads' popup is visible, showing a file named 'Main Consent Form.rtf' with an 'Open file' link. A yellow arrow points from the 'Download Consent' button in the dialog box to the 'Downloads' popup.

The background application interface includes a top navigation bar with 'My Workspaces', 'Study Assistant', and 'Review Response Submission Form - (Version 1.0)'. Below this is a table with columns 'Operation', 'Action Status', and 'Component'. The table has one row with 'Modify Existing Attachment' and 'Action Not Complete'. There is also a 'Do you accept this Stipulation?' section with radio buttons for 'N/A', 'Yes', and 'No'.

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:

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

Download Consent: Download

Select the document to upload: Choose File No file chosen

Close, don't save any changes Save Consent

View Document RTF

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 titled 'Open' is overlaid on the form. The dialog shows a list of files in the 'Desktop > Consent Forms > Consent Templates' folder. The files are listed in a table with columns for Name, Status, and Date modified. A blue arrow points to the 'Open' button at the bottom right of the dialog.

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

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)


The screenshot shows a web application interface with a 'Study Consent Revision' popup. The background shows a 'Form' section with a 'Stipulation 5 out of 9' warning and a table with columns 'Operation', 'Action Status', and 'Component'. The popup has the following fields:

- *Consent Title: Main Consent Form
- *Version Number: 1.1
- *Version Date: 11/17/2023 (with a green arrow pointing to the date field)
- Sponsor Version: (empty)
- *Category: Adult Consent
- *Language: English
- Description: (empty text area)
- Comments: (empty text area)
- Download Consent: Download button
- Select the document to upload: Choose File Main_Cons..._Template.rtf (with a blue arrow pointing to the filename)

At the bottom right of the popup are two buttons: 'Close, dont save any changes' and 'Save Consent' (with a grey arrow pointing to it). A 'View Document' button with a PDF icon is also visible in the top right corner of the popup.


(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





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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/BOMC - 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 (indicated by a large yellow arrow)
- Select the document to upload:** Choose File (No file chosen)

The background shows a form for 'Stipulation 7 out of 9'. It includes a table with columns: Operation, Action Status, and Component. The 'Action Status' for 'Modify Existing Attachment' is 'Action Not Complete'. Below the table is a section 'Do you accept this Stipulation?' with radio buttons for N/A, Yes, and No. A 'View Document' button is also visible in the top right of the popup.

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' dialog box open. The dialog box contains 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

At the bottom of the dialog box are two buttons: 'Close, don't save any changes' and 'Save Document'.

A yellow arrow points from the 'Download' button in the dialog box to a browser's 'Downloads' popup. The popup shows a list of downloaded files:

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

Each file has an 'Open file' link next to it. A 'See more' link is at the bottom of the popup.

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 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 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:

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 response submission forms. A file explorer window is open, displaying a list of files. A blue arrow points to the 'Dummy Flyer' file, and another blue arrow points to the 'Open' button. The background shows a 'Review Response Submission Form' with various fields and buttons.

Study Document Revision:

Document Title: Flyer

Open

File Explorer: Desktop > Consent Forms > Velos Test

Name	Status	Date modified
Adult Consent Form Template	✓	6/22/2022 10:37 AM
Continuing_Review_Submission_Form_4	✓	5/27/2021 10:22 PM
Dummy Device Brochure	✓	4/13/2016 8:18 AM
Dummy FDA document	✓	4/11/2016 2:08 PM
Dummy Flyer	✓	4/11/2016 2:09 PM
Dummy Investigator brochure	✓	4/13/2016 8:19 AM
Dummy In Consent	✓	4/11/2016 2:09 PM
Materials Handed Out to Subjects	✓	4/11/2016 2:17 PM
Protocol	✓	4/11/2016 2:09 PM
Short Form	✓	4/11/2016 2:19 PM
Approval Letter	✓	3/14/2014 9:20 AM
Search and INSPIR-II Interface S...	✓	4/11/2016 2:20 PM

File name: Dummy Flyer

Open Cancel

View Document

Print Friendly Refresh Constant Fields Save Form

Back

My Workspaces

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

Study Assistant

Review Response Submission Form - (Version 1.0)

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
Modify Existing Attachment	Action Not Complete

Do you accept this Stipulation?

N/A Yes No

Provide an

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:

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

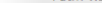

Select the document to upload: Choose File Dummy Flyer.rtf




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
 

- 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



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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

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This will open 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. On the right, there are links for Help, My Profile, and Log out. Below the navigation bar, there is a section for 'My Workspaces' and a table with IRB details: IRB Number: H-44279, Study Alias: 11/17/2023, and PI: Administrator. The main title of the page is 'Review Response Submission Form - (Version 1.0)'. A 'Print Friendly' button is located in the top right corner. The main content area has a green header that says 'Form has been Completed!' and a subtitle 'Instruction of Form has Been Completed Screen'. A yellow callout box with a blue arrow points to three buttons: 'Signoff and Submit', 'Return to Form', and 'Exit Form'. The text inside the callout box reads: 'To submit to the IRB, click on “Signoff and Submit” or “Notify PI to Signoff” (if you are not the PI)'. The 'Form' tab is selected in the top left corner.

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)

Back

Print Friendly

Form

Form has been Completed!

Instruction of Form has Been Completed Screen

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

Signoff and Submit

Return to Form

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. Once the PI signs off, it will proceed to the IRB.
- Clicking on “Return to Form” will take you back to the Review Response Submission Form.
- Clicking on “Exit Form” will take you back to where you started.