

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” .

BOSTON
UNIVERSITY
MEDICAL
CAMPUS

BOSTON
MEDICAL

EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Hello Khaled Khattar, BA

your last login was

10/11/2022 08:16 AM EDT

My Workspaces

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.

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

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

BOSTON UNIVERSITY MEDICAL CAMPUS **STATE OF MASSACHUSETTS BOSTON MEDICAL CENTER**

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 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
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”.

**BOSTON
UNIVERSITY
MEDICAL
CAMPUS**

**BOSTON
MEDICAL
CENTER**

 Help
 My Profile
 Log out

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

Review Response Submission Form - (Version 1.0)

 **Back**

Print Friendly Refresh Constant Fields Save Form

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
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->

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 shows a web application interface for a medical review system. 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 has a 'Form' tab and a 'Review Response Submission' section. A yellow callout box with a blue arrow points to a confirmation popup. The popup contains the text 'Confirm the adding a revision.' and 'Are you sure you want to create a revision?'. Below the text are two buttons: 'CONFIRM' and 'CANCEL'. The background interface includes a table with columns 'Operation', 'Action Status', and 'Component Name'. The 'Action Status' column has a red 'Action Not Complete' status. There are also buttons for 'Print Friendly', 'Refresh Constant Fields', and 'Save Form'.

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

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 and user information: Account: Administrator, Department: BMC/BUMC - MED - Institution, Path: Home > find study > study mgmt. >. Below this, there are tabs for 'My Workspaces' and 'Form'. The 'Form' tab is active, showing the 'Initial Review Submission Packet'. A note states: '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.'

A blue box highlights the 'Modifications Required:' section, which contains the text: 'Please make changes to the Initial Review'. An orange arrow points from the text in the first paragraph to this blue box. A blue arrow points from the 'Save Form' button to a yellow callout box.

The form fields include:

- Study Title: Dummy Study for Demo
- IRB Number: H-44279
- Principal Investigator: Administrator
- PI Name: Administrator
- PI Email Address: medirb@bu.edu
- PI Phone Number: 617-638-7203

Buttons at the top right include 'Print Friendly', 'Refresh Constant Fields', 'Save Form', and 'Exit Form'.

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 'Form has been Completed!' page in the IRB system. The page has a teal header with the text 'Form has been Completed!' and 'Instruction of Form has Been Completed Screen'. Below the header, 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.' The page also includes a sidebar with 'My Workspaces' and a top navigation bar with 'Home > find study > study mgmt. > review response'.

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 shows the Boston University Medical Campus IRB system interface. At the top, there is a header with the university logo and navigation links. Below the header, a sidebar on the left contains 'My Workspaces' and 'Study Assistant' information. The main content area displays 'Stipulation 9 out of 9' with a description: 'Please make changes to the Initial Review'. Below this, a table lists actions for 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 in the top right. A blue arrow points to the 'Edit/View' icon in the table. A yellow callout box explains that once a new revision is created, you can open it and make more changes by clicking on the 'Edit/View' icon. Another yellow callout box explains that in the text box, you should let the IRB know you have made the changes requested in this stipulation and add any additional information. A final yellow callout box states: '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.

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

Study Assistant

Review

Initial Review Submission Form - (Version 1.0)

Back

Print Friendly Refresh Constant Fields Save 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 (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).



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 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 is a section 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 structure:

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 'N/A', '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 'Revise Existing' button to another yellow callout box. A fourth blue arrow points from the 'Revise Existing' button to a yellow callout box.

Annotations:

- 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.
- 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 header with user information (Administrator, BMC/BUMC - MED - Institutional Review Board), a sidebar with 'My Workspaces', and a main content area with a table of components. The table has columns for Operation, Action Status, and Component Name. The 'Study Application (Version 1.0)' component is highlighted, showing its section and question details. Below the table, there are radio buttons for 'Do you accept this Stipulation?' and a text area for 'Provide an explanation on how you addressed this Stipulation:'.

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

Review Response Submission Form

Print Friendly Refresh Constant Fields Save Form

Back

Form

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 1.0) Section: Study Summary Question: Provide a brief summary Do NOT copy from a gra

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 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.

The screenshot shows the Boston University Medical Campus Study Application interface. At the top, the user is logged in as 'Administrator' with account details: 'Department: BMC/BUMC - MED - Institutional Review Board' and 'Path: Home > study mgmt. > change request list > change request'. The main header indicates 'Study Application (Version 1.7)'. A sidebar on the left lists application sections: General Information, Confidentiality, HIPAA Compliance, Cost/Payment, Biological Sample Collection, Drugs or Biological Agents, Devices, Retention of Samples or Data, and Study Attachments. The main content area shows a 'New Form Version has been published' popup. The popup contains an information icon, a message stating '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.', and a 'Convert to New Form Version' button. A yellow callout box on the left explains that if the user doesn't get this popup, they are already in the newest form version and should skip to page #22. A green arrow points to the 'Convert to New Form Version' button, and another yellow callout box explains that if the user does get this popup, they need to click the button to convert to the newly published form and continue to the next page.

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 Confidentiality
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

New Form Version has been published

i 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/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)** Back

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 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 Form - (Version 1.0)

Print Friendly Refresh Constant Fields Save Form

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 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.

Form

Please Fix this statement in the Main Consent form

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

✓ B I U S x₂ x² Font Family 12

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.

UNIVERSITY
MEDICAL
CAMPUS

EXCEPTIONAL CARE WITHOUT EXCEPTION

BOSTON
MEDICAL

Center

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

Help

My Profile

Log out

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

View Document

Close, don't save any changes

Save Consent

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 for reviewing a consent form. A modal window titled "Study Consent Revision" is open, allowing for updates to the "Main Consent Form". The form includes fields for versioning and categorization, as well as descriptive text and a download option. A browser's download manager is visible, indicating the current document has been downloaded as "Main Consent Form.rtf".

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

Stipulation Type
(Stipulation must be addressed)

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

Provide an explanation on how you addressed this Stipulation:

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.

The screenshot shows a web application interface for reviewing a consent form. A modal window titled "Study Consent Revision" is open, displaying the following fields:

- *Consent Title:** Main Consent Form
- *Version Number:** 1.1 (A yellow arrow points to this field, indicating an automatic increment by .1).
- *Version Date:** 11/17/2023
- Sponsor Version:** (empty)
- *Category:** Adult Consent (dropdown menu)
- *Language:** English (dropdown menu)
- Description:** (text area)
- Comments:** (text area)
- Download Consent:** Download button
- Select the document to upload:** Choose File button (An orange arrow points to this button, indicating where to click to upload the revised document).

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

In the background, the main application interface is visible, showing a header with "My Workspaces", "IRB Number: H-44279", "Study Alias: 11/17/2023", "PI: Administrator", and "Study Assistant". The main content area shows a "Review Response Submission Form - (Version 1.0)" with a "Back" button. A table with columns "Operation", "Action Status", and "Component" is partially visible, showing a row with "Modify Existing Attachment" and "Action Not Complete".

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 main window is titled "Review Response Submission Form - (Version 1.0)". It includes a header with user information (Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board, Path: Home > find study > study mgmt.) and a sidebar with navigation options (My Workspaces, Study Assistant, Back). The main content area displays a "Study Consent Revision" form with a table of consent templates. A blue arrow points to the "Open" button in the file dialog.

Study Consent Revision

*Consent Titles: 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)

The screenshot shows a web application interface with a 'Study Consent Revision' popup. The background shows a 'Form' tab with a 'Stipulation 5 out of 9' section. The popup has the following fields and buttons:

- *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 field)
- * Category:** Adult Consent (dropdown menu)
- * Language:** English (dropdown menu)
- Description:** (text area)
- Comments:** (text area)
- Download Consent:** Download button
- Select the document to upload:** Choose File button, Main_Cons..._Template.rtf (with a blue arrow pointing to the filename)
- Buttons at the bottom:** Close, don't save any changes, Save Consent (with a grey arrow pointing to the 'Save Consent' button)
- Top right button:** View Document (with a document icon)

The background form includes a table with columns 'Operation', 'Action Status', and 'Component'. The 'Action Status' column shows 'Action Not Complete' in red. There is also a section for 'Do you accept this Stipulation?' with radio buttons for 'N/A', 'Yes', and 'No'.

(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/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.

Form

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

Modify Existing Attachment



Study Document Flyer (Version

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 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.

PE: 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

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 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 RTF

Close, don't save any changes Save Document

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 displays 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'.

In the background, a browser's 'Downloads' popup is visible, showing a list of files:

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

A yellow arrow points from the 'Download Document' button in the dialog box to the 'Downloads' 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 Path: 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:

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 ▾



My Workspaces

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

Study Assistant

Review Response Submission Form - (Version 1.0)

Back

Print FriendlyRefresh Constant FieldsSave Form

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 1.1)	<button>Compare Document Version</button>
		Study Document Flyer (Version 1.0)	☐ Complete Action ☒ Incomplete Action

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

Provide an explanation on how you addressed this Stipulation:

B I U S x₂ x² Font Family 12 🔥 ↕ ¶ ▾ ▸ ▹ ► ▻ ▸ ⌂ 🖼️ 🔗 📄 🖨️ ↺ ↻

- 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



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

IRB Number: **H-44279**

Study Alias: 11/17/2023

PI: Administrator

Study Assistant

Review Response Submission Form - (Version 1.0)

Back



46

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 columns for IRB Number, Study Alias, and PI. The table contains one row with IRB Number H-44279, Study Alias 11/17/2023, and PI Administrator. To the right of the table is a 'Study Assistant' button. The main header of the page is 'Review Response Submission Form - (Version 1.0)'. On the right side of the header, there is a 'Back' button. Below the header, there is a 'Form' tab. The main content area has a green header with the text '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 'Notify PI to Signoff' button is not visible in the screenshot.

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

My Workspaces

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