

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.

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	Forms Pending Submission	Pending My Response	High
54	53	4	>

Tasks

All Tasks	35
Study Tasks	33

When you login into INSPIR II (<https://inspir.bu.edu/>), you will get to this page. This is your Home page

Click on **“Study Tasks”** to check if you already have a **“Submission Response”** task (shortcut) for this specific study that will allow you to respond to the stipulations.

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

BOSTON UNIVERSITY MEDICAL CAMPUS | BOSTON MEDICAL CENTER | Hello Administrator your last login was 11/16/2023 02:55 PM EST | ? Help | Tutorial | My Profile | Log out

My Workspaces | Study

Study Tasks | Outstanding | Completed

Search for RB Number, Title, Alias | Search

All Tasks | Study Tasks

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

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

Click to open	Details	Task Type	Date Received	Study Status	Study Title	Principal Investigator	Review Board	IRB Number	IRB Expiration	Priority	Complete By
<input type="checkbox"/>		Submission Response	11/17/2023 02:10 PM EST	Pending - Initial Review	Dummy Study for Demo	Administrator	IRB	H-44279		No Priority	<input type="text"/>
<input type="checkbox"/>		Waiting Submission	11/16/2023 11:16 PM EST	Exempt - limited IRB review	Testing	Administrator	IRB	H-31000		No Priority	<input type="text"/>
<input type="checkbox"/>		Waiting Submission	11/08/2023 11:06 AM EST	Exempt - limited IRB review	Testing	Administrator	IRB	H-31000		No Priority	<input type="text"/>
<input type="checkbox"/>		Submission Routing Signoff	07/12/2022 07:02 AM EST	Exempt - limited IRB review	Testing	Administrator	IRB	H-31000		No Priority	<input type="text"/>
<input type="checkbox"/>		Waiting Submission	05/24/2021 10:55 AM EST	Draft	Separate Protocol 8/17/2018	Administrator	IRB				
<input type="checkbox"/>		Waiting Submission	10/23/2020 10:30 PM EST	Draft	testing 2	Khattar, Khaled, BA					
<input type="checkbox"/>		Waiting Submission	09/21/2020 09:38 AM EST	Draft	Testing Migration MSD						
<input type="checkbox"/>		Waiting Submission	03/19/2020		Test Interface	Administrator	IRB				

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

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
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- View and Manage My Studies

By the Numbers

Submissions in Process	Forms Pending Submission	Pending My Response	High T
54	53	4	>

Tasks

All Tasks	35
Study Tasks	33

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

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

Search for RB Number, Title, Alias Search

All Studies Recently Used Study Status

All Draft IRB

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

Click to open Study Dashboard	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Actions
	Pending - Initial Review	IRB	H-44279			
	Exempt - limited IRB review	IRB	H-31000			
	Draft	IRB	H-44278			
	Closed - Ceded Review	IRB	H-37307		Velos# HRB123 - Active in Velos for Interface Testing	
	Draft	IRB	H-36572		Expedited/Full Board 11-25-2019	
	Draft	IRB	H-38072		Separate Protocol 8/17/2018	
	Draft	IRB	H-44153		Single patient	
					Review 10-29-2015	
					Review 10-29-2015	
					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 **BOSTON MEDICAL CENTER** Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

Help My Profile Log out

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

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
	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

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

Print Friendly Refresh Constant Fields Save Form

Form
Administrator

Previous Submission

Recommendations
No recommendation entered.

Stipulations
Comments that must be addressed
No Stipulation entered.
Comments
No Stipulation entered.

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

Stipulation 1 out of 6:

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

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

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)

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

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

Do you accept this Stipulation?
 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 # 14](#)).

You will get the confirmation popup.

The screenshot shows a web application interface for a study management 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, Path: Home > find study > study mgmt.), and navigation links (Help, My Profile, Log out). Below the header, there are tabs for 'My Workspaces' and 'Study Assistant'. The main content area displays a 'Review Response Submission' form. A yellow callout box with a blue arrow points to a 'CONFIRM' button in a white 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 shows a table with columns 'Operation', 'Action Status', and 'Component Name'. The 'Action Status' for 'Modify Existing Attachment' is 'Action Not Complete'. Below the table, there are radio buttons for 'Do you accept this Stipulation?' (N/A, Yes, No) 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 Study Assistant Review Response Submission

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

Help My Profile Log out

Print Friendly 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)

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:

Confirm the adding a revision.
Are you sure you want to create a revision?

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).

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

My Workspaces My Workspaces Study Assistant

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

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

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

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

Study Assistant

Initial Review Submission Form - (Version 1.1)

Form

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.

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)

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) Action: Initial Review Submission Packet

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:

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).

If you have more stipulations with links to the submission form, repeat slides # 9 – 15.

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

Print Friendly 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)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Initial Review Submission Form (Version 1.1)	<input type="button" value="Compare Form Version"/> <input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action
		Initial Review Submission Form (Version 1.0) Section: Initial Review Submission Packet	

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:

All changes to the submission form have been completed.

- 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.

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 Profile Log out

Refresh Constant Fields Save Form

Form

2 out of 7:

Describe
Please describe the stipulation 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

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 a web application interface for a study management 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 (Home > find study > study mgmt.). A yellow callout box with a blue border and a blue arrow pointing to a confirmation popup contains the text: "Click on 'CONFIRM' button to proceed." The confirmation popup is a white dialog box with the title "Confirm the adding a revision." and the question "Are you sure you want to create a revision?". It features two buttons: "CONFIRM" and "CANCEL". The background interface shows a form titled "Review Response Submission Form" with various sections, including a table with columns "Operation", "Action Status", and "Component Name". The table contains one row with "Modify Existing Attachment" under "Operation" and "Action Not Complete" under "Action Status". Below the table, there are radio buttons for "N/A", "Yes", and "No" under the heading "Do you accept this Stipulation?".

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

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

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

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

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

Study Application (Version 1.7)

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

Section view of Application Entire view of the Application

1.0 General Information
2.0 Information

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

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. 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/BUMC - 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.							

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

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).

The screenshot shows the 'Review Response Submission Form - (Version 1.0)' interface. At the top, there are navigation links for 'My Workspaces', 'Study Assistant', and 'Review Response Submission Form - (Version 1.0)'. A user profile section shows 'Account: Administrator', 'Department: BMC/BUMC - MED - Institutional Review Board', and 'Path: Home > study mgmt.'. There are also buttons for 'Help', 'My Profile', and 'Log out'. Below the navigation, there are buttons for 'Print Friendly', 'Refresh Constant Fields', 'Save Form', and 'Signoff and Submit'. The main content area is titled 'Form' and contains a stipulation section. The stipulation is titled 'Stipulation 2 out of 9:' and has a description: 'Please describe in more details ...'. Below the description, there is a table with the following columns: 'Operation', 'Action Status', and 'Component Name'. The table contains two rows: 'Modify Existing Attachment' with 'Action Not Complete' status, and 'Study Application (Version 1.1)' with a blue arrow pointing to it. Below the table, there are radio buttons for 'Do you accept this Stipulation?' with options 'N/A', 'Yes', and 'No'. At the bottom, there is a rich text editor with a toolbar.

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

Proceed to the next slide.

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

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

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

My Workspaces

Section view of Application | Entire view of the Application

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
ring
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 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.....

Print Friendly | Save Section | Save and Continue to Next Section

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.

The screenshot shows the IRB system interface. At the top, there is a header with the Boston University Medical Campus logo and user information: Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board, Path: Home > find study > study mgmt. There are also links for Help, My Profile, and Log out. Below the header, the main content area is titled "Review Response" and "Submission Form - (Version 1.0)". There are buttons for "Print Friendly", "Refresh Constant Fields", and "Save Form".

The main form area is titled "Stipulation 2 out of 7:". It has a "Description:" field with the text "Please describe in more details ...". Below that is a "Stipulation Type:" field with the text "(Stipulation must be addressed)".

There is a table with the following columns: Operation, Action Status, and Component Name. The table contains one row:

Operation	Action Status	Component Name
Modify Existing Attachment	Action Not Complete	Study Application (Version 1.1) Study Application (Version 1.0)

Below the table, there is a "Do you accept this Stipulation?" field with radio buttons for N/A, Yes, and No. There is also a "Provide an explanation on how you addressed this Stipulation:" field.

Annotations on the screenshot include:

- A green arrow pointing to the "Study Application (Version 1.1)" component name.
- A yellow arrow pointing to the "Complete Action" radio button.
- An orange arrow pointing to the "Save Form" button.
- A blue arrow pointing to the "Do you accept this Stipulation?" field.

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 **BOSTON MEDICAL** EXCEPTIONAL CARE. WITHOUT EXCEPTIONS.

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	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:

Rich text editor toolbar: Bold, Italic, Underline, Strikethrough, x₂, x², Font Family, 12, Paragraph, List, Bulleted List, Indent, Outdent, Link, Unlink, Image, Table, Undo, Redo.

- 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.

The screenshot shows the IRB system interface. At the top, there is a header with the Boston University Medical Campus logo and user information: Account: Administrator, Department: BMC/BUMC - MED - Institutional Review Board, Path: Home > find study > study mgmt. Below the header, there are navigation buttons: My Workspaces, Study Assistant, Review Response S, Log out, Back, and Save Form. The main content area shows a stipulation: "Stipulation 5 out of 9: Description: Please fix this statement in the Main Consent form. Stipulation Type: (Stipulation must be addressed)". Below the stipulation, there is a table with columns: Operation, Action Status, Component Name, and Action. The table contains one row: "Modify Existing Attachment", "Action Not Complete", "Study Consent Main Consent Form (Version 1.0)", and "Revise Existing". A blue arrow points from the "Revise Existing" button to a yellow callout box. Another blue arrow points from the "Links to Components" section to a yellow callout box. Below the table, there is a section for "Do you accept this Stipulation?" with radio buttons for "No", "Yes", and "No". At the bottom, there is a rich text editor toolbar with various icons for text formatting and editing.

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

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.

Print Friendly Refresh Constant Fields Save Form

Form

Stipulation 5 out of 9:

Description:
Please Fix this statement in the Main Consent form

Stipulation Type: (Stipulation must be addressed)

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

Do you accept this Stipulation?
 N/A Yes No

Provide an explanation on how you addressed this Stipulation:

Confirm the adding a revision.
Are you sure you want to create a revision?

CONFIRM CANCEL

Click on "Confirm" button to proceed.

The “Study Consent Revision” popup will open.

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

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

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

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

Print Friendly Refresh Constant Fields Save Form

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:

Select the document to upload: No file chosen

Stipulation 5 out of 9:

Description:
Please Fix this statement in the Main Consent form

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component
Modify Existing Attachment	Action Not Complete	Stu

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

Do you accept this Stipulation? N/A Yes No

Provide an explanation on how you addressed this Stipulation:

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:** (empty)
- * Category:** Adult Consent
- * Language:** English
- Description:** (text area)
- Comments:** (text area)
- 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'. A yellow arrow points from the text above to a 'Downloads' popup in the browser. The popup shows a file named 'Main Consent Form.rtf' with an 'Open file' link and a 'See more' link. The background shows a 'Review Response Submission Form - (Version 1.0)' with a table of operations and a stipulation section.

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

Study Alias: 11/17/2023
PI: Administrator

Print Friendly Refresh Constant Fields Save Form

Study Consent Revision

* Consent Title: Main Consent Form

* Version Number: 1 .1

* Version Date: 11/17/2023

Sponsor Version:

* Category: Adult Consent

* Language: English

Description:

Comments:

Download Consent: Download

Select the document to upload: Choose File No file chosen

Close, don't save any changes Save Consent

View Document RTF

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:

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 a study management system. The main window is titled "Review Response Submission Form - (Version 1.0)". A file selection dialog box is open, showing a list of files in the "Consent Templates" folder. The files listed are:

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 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

A blue callout box at the bottom contains the following steps:

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 displays a web application interface with a 'Study Consent Revision' popup window. The popup contains the following fields and elements:

- * Consent Title:** Main Consent Form
- * Version Number:** 1 .1
- * Version Date:** 11/17/2023 (highlighted with a green arrow)
- Sponsor Version:** (empty)
- * Category:** Adult Consent
- * Language:** English
- Description:** (text area)
- Comments:** (text area)
- Download Consent:** Download
- Select the document to upload:** Choose File Main_Cons...Template.rtf (highlighted with a blue arrow)
- Buttons:** Close, don't save any changes; Save Consent (highlighted with a grey arrow)
- View Document:** View Document (RTF)

The background shows a 'Form' with a table of components and a 'Do you accept this Stipulation?' section.

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:

This will bring you back to the Review Response Submission Form.

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

Study Alias: 11/17/2023
PI: Administrator

Print Friendly Refresh Constant Fields Save Form

Form

Stipulation 5 out of 9:

Description:
Please Fix this statement in the Main Consent form

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name
Modify Existing Attachment	Action Not Complete	Study Consent Main Consent Form (Version 1.1)
		Study Consent Main Consent Form (Version 1.0)

Compare Consent Version
 Complete Action Incomplete Action

Do you accept this Stipulation?
 N/A Yes No

Provide an explanation on how you addressed this Stipulation:

Font Family 12

1

2

3

If you have more stipulations with links to a consent form, repeat [slides # 22 – 34](#).

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

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)**

Print Friendly Refresh Constant Fields Save Form

Form

Stipulation 5 out of 9:

Description:
Please Fix this statement in the Main Consent form

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Consent Main Consent Form (Version 1.1)	<input type="button" value="Compare Consent Version"/> <input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action
		Study Consent Main Consent Form (Version 1.0)	

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 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.

The screenshot shows a web interface for an Institutional Review Board (IRB). At the top, there is a navigation bar with 'MEDICAL CAMPUS' and 'MEDICAL' logos, and a breadcrumb path: 'Department: BMC/BMC - MED - Institutional Review Board > Path: Home > find study > study mgmt.'. Below this, there are fields for 'My Workspaces', 'IRB Number: H-44279', 'Study Alias: 11/17/2023', and 'PI: Administrator'. A 'Study Assistant' role is also indicated. A 'Review Response S' button is visible. A yellow callout box with a blue arrow pointing to the 'Revise Existing' button contains the text: '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)'. Below this, a stipulation is shown: 'Stipulation 7 out of 9: Description: Fix a sentence in the Flyer. Stipulation Type: (Stipulation must be addressed)'. A table titled 'Links to Components' (with a note: '(These are the items that are linked to this stipulation)') has the following data:

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

Below the table, there is a 'Do you accept this Stipulation?' section with a radio button for 'No'. A blue arrow points from the 'Revise Existing' button in the table to the 'Do you accept this Stipulation?' section. Another yellow callout box with a blue arrow pointing to the 'Do you accept this Stipulation?' section contains the text: '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.' At the bottom of the page, there is a rich text editor toolbar with various icons for text formatting and editing.

BOSTON UNIVERSITY MEDICAL CAMPUS BOSTON MEDICAL CENTER

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 Assistant Review Response Submission Form - (Version 1.0) Back

Study Alias: 11/17/2023
PI: Administrator

Print Friendly Refresh Constant Fields Save Form

Form

Stipulation 7 out of 9:

Description:
Fix a sentence in the Flyer

Stipulation Type: (Stipulation must be addressed)

Links to Components <small>(These are the items that are linked to this stipulation)</small>	Operation	Action Status	Component Name	Action
	Modify Existing Attachment	Action Not Complete	Study Document Flyer (Version	Revise Existing

Do you accept this Stipulation? N/A Yes No

CONFIRM CANCEL

Provide an explanation on how you addressed this Stipulation:

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.

The screenshot displays a web application interface with a modal window titled "Study Document Revision:". The modal contains the following fields and controls:

- Document Title:** Text input field containing "Flyer".
- Version Number:** Text input field containing "1" followed by ".1".
- Version Date:** Date picker set to "11/17/2023".
- Sponsor Version:** Empty text input field.
- Category:** Dropdown menu set to "Flyer".
- Description:** Large text area.
- Comments:** Large text area.
- Download Document:** Button labeled "Download" with a yellow arrow pointing to it.
- Select the document to upload:** "Choose File" button and "No file chosen" text.
- Buttons:** "Close, don't save any changes" and "Save Document" at the bottom right.

The background interface shows a form with a stipulation description: "Fix a sentence in the Flyer". Below this is a table with columns "Operation", "Action Status", and "Component". The "Action Status" column contains a red "Action Not Complete" label. A "View Document" button with a Word icon and "RTF" text is visible in the top right of the modal.

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 and controls:

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

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

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

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

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.

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

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)

Print Friendly Refresh Constant Fields Save Form

View Document RTF

Open

Document Title: Flyer

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

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)

The screenshot displays a web application interface with a 'Study Document Revision' popup window. The popup contains the following fields and elements:

- * Document Title:** Flyer
- Version Number:** 1.1 (indicated by a green arrow)
- Version Date:** 11/17/2023 (indicated by a green arrow)
- Sponsor Version:** [Empty field]
- * Category:** Flyer
- Description:** [Empty text area]
- Comments:** [Empty text area]
- Download Document:** Download button
- Select the document to upload:** Choose File button, Dummy Flyer.rtf (indicated by a blue arrow)
- Buttons:** Close, don't save any changes; Save Document (indicated by a grey arrow)
- View Document:** View Document button with RTF icon

The background interface shows a 'Review Response Submission Form - (Version 1.0)' with a 'Stipulation 7 out of 9' section. The stipulation description is 'Fix a sentence in the Flyer'. The stipulation type is 'Action Not Complete'. The interface also includes a 'Links to Components' table and a 'Do you accept this Stipulation?' section.

This will bring you back to the Review Response Submission Form.

(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.

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 7 out of 9:

Description:
Fix a sentence in the Flyer

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name
Modify Existing Attachment	Action Not Complete	Study Document Flyer (Version 1.1) Study Document Flyer (Version 1.0)

Compare Document Version
 Complete Action Incomplete Action

Do you accept this Stipulation?
 N/A Yes No

Provide an explanation on how you addressed this Stipulation:

1

2

3

If you have more stipulations with links to a study document, repeat slides # 35 – 44.

BOSTON UNIVERSITY MEDICAL CAMPUS **BOSTON MEDICAL CENTER** 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 Assistant Review Response Submission Form - (Version 1.0) Back
Study Alias: 11/17/2023
PI: Administrator

Print Friendly Refresh Constant Fields Save Form

Form

Stipulation 7 out of 9:

Description:
Fix a sentence in the Flyer

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Document Flyer (Version 1.1)	<input type="button" value="Compare Document Version"/>
		Study Document Flyer (Version 1.0)	<input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action

Do you accept this Stipulation? N/A Yes No

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

Provide an explanation on how you addressed this Stipulation:

Rich text editor toolbar: Bold, Italic, Underline, Strikethrough, x₂, x², Font Family, 12, Paragraph, List, Indent, Link, Image, Undo, Redo.

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

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

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

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](#) [Refresh Constant Fields](#) [Save Form](#)

Form

Current Submission Components

Show submission component(s) in round: **2 Current Round** [Items in Folder View](#) [Add New Component](#) [Compare Item\(s\)](#) [Create PDF Packet](#)

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/ Attach	All Submission Components Previous Rounds & Currently Attached
Submission Form(s)						
<input type="checkbox"/>	<input type="checkbox"/>					IRB - Review Response Submission Form - (Version 1.0) (Incomplete)
<input type="checkbox"/>	<input type="checkbox"/>			<input checked="" type="checkbox"/>		Initial Review Submission Form - (Version 1.1)
<input type="checkbox"/>	<input type="checkbox"/>					Initial Review Submission Form - (Version 1.0)
Application						
<input type="checkbox"/>	<input type="checkbox"/>			<input checked="" type="checkbox"/>		Study Application - (Version 1.1)
<input type="checkbox"/>	<input type="checkbox"/>					Study Application - (Version 1.0)
Attachment Form(s)						
<input type="checkbox"/>	<input type="checkbox"/>					Sample Collection - (Version 5.0)
<input type="checkbox"/>	<input type="checkbox"/>					Sample Collection - (Version 4.0)
Consent Form(s)						
Category : Adult Consent						
<input type="checkbox"/>	<input type="checkbox"/>			<input checked="" type="checkbox"/>		Main Consent Form (English) - (Version 1.1) <i>*Revision modified by the IRB.</i>
<input type="checkbox"/>	<input type="checkbox"/>					Main Consent Form (English) - (Version 1.0)
Document(s)						
Category : Flyer						
<input type="checkbox"/>	<input type="checkbox"/>			<input checked="" type="checkbox"/>		Flyer - (Version 1.1)
<input type="checkbox"/>	<input type="checkbox"/>					Flyer - (Version 1.0)
Category : Reducing Implicit and Explicit Bias in Research Form						
<input type="checkbox"/>	<input type="checkbox"/>					Bias form - (Version 1.0)



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

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

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

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.