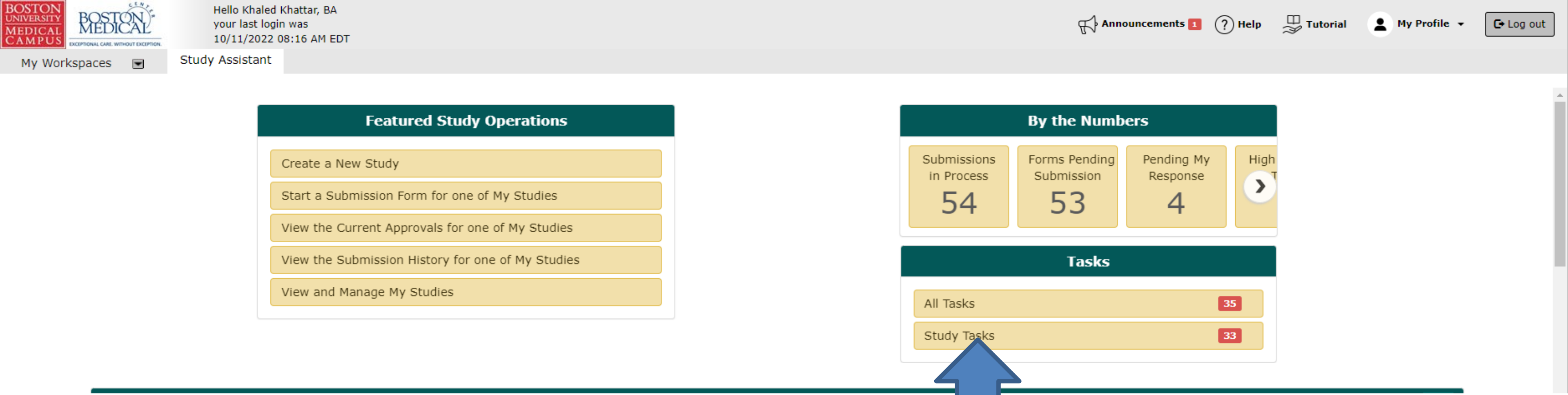
Review Response Submission Form

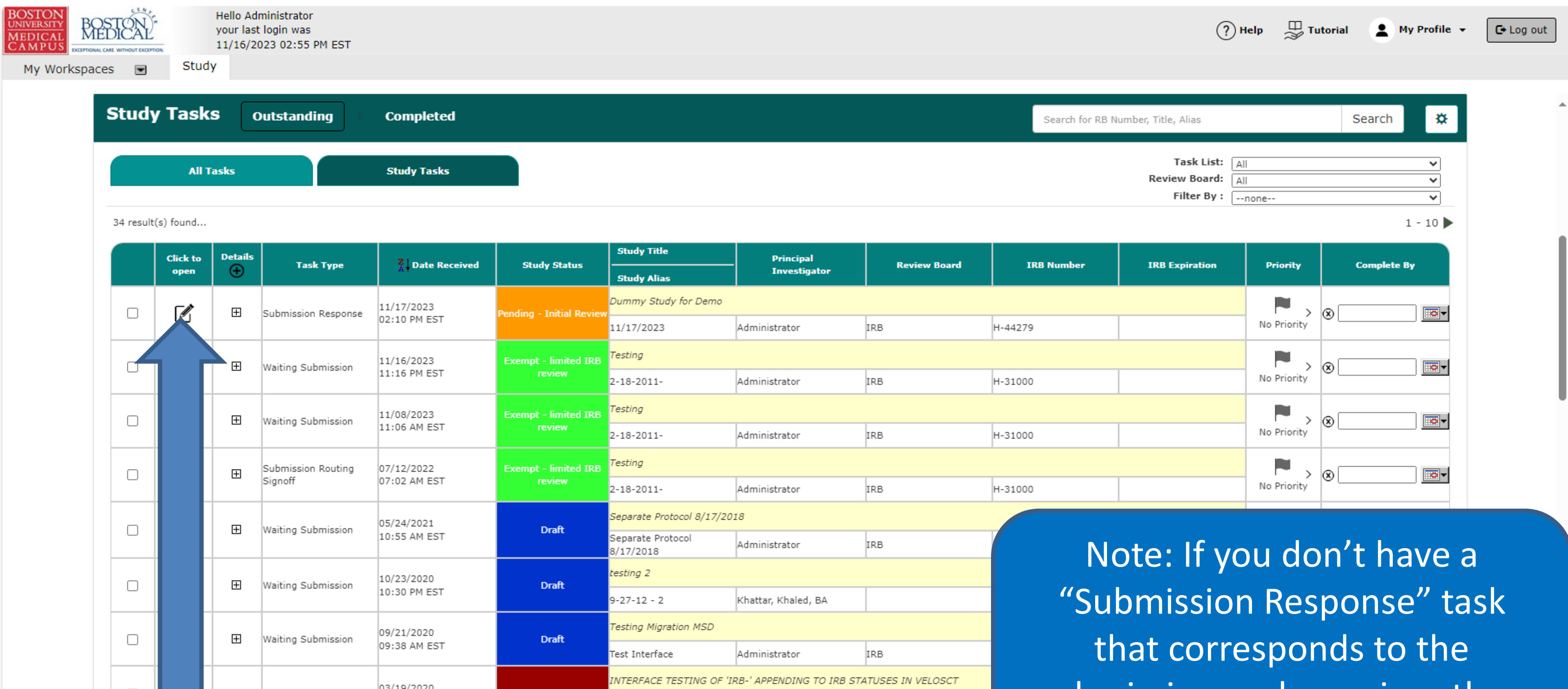
- This form is used to reply to the IRB and address the issues/stipulations raised when the IRB conditionally approves the submission, defers it, returns it as Incomplete submission, or for administrative modifications.



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

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

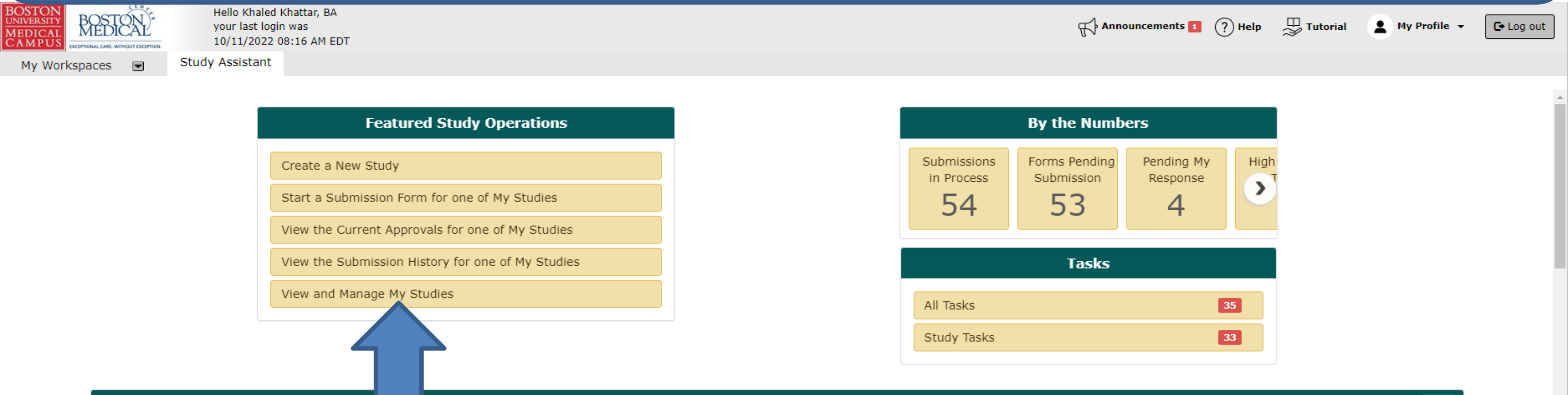
If you are listed as a "Study Contact" on the study, the system will list a task for you in the "Study Tasks" tab and would be listed with the "Submission Response" as the Task Type. This task will allow you to create the "Review Response Submission Form".



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” .

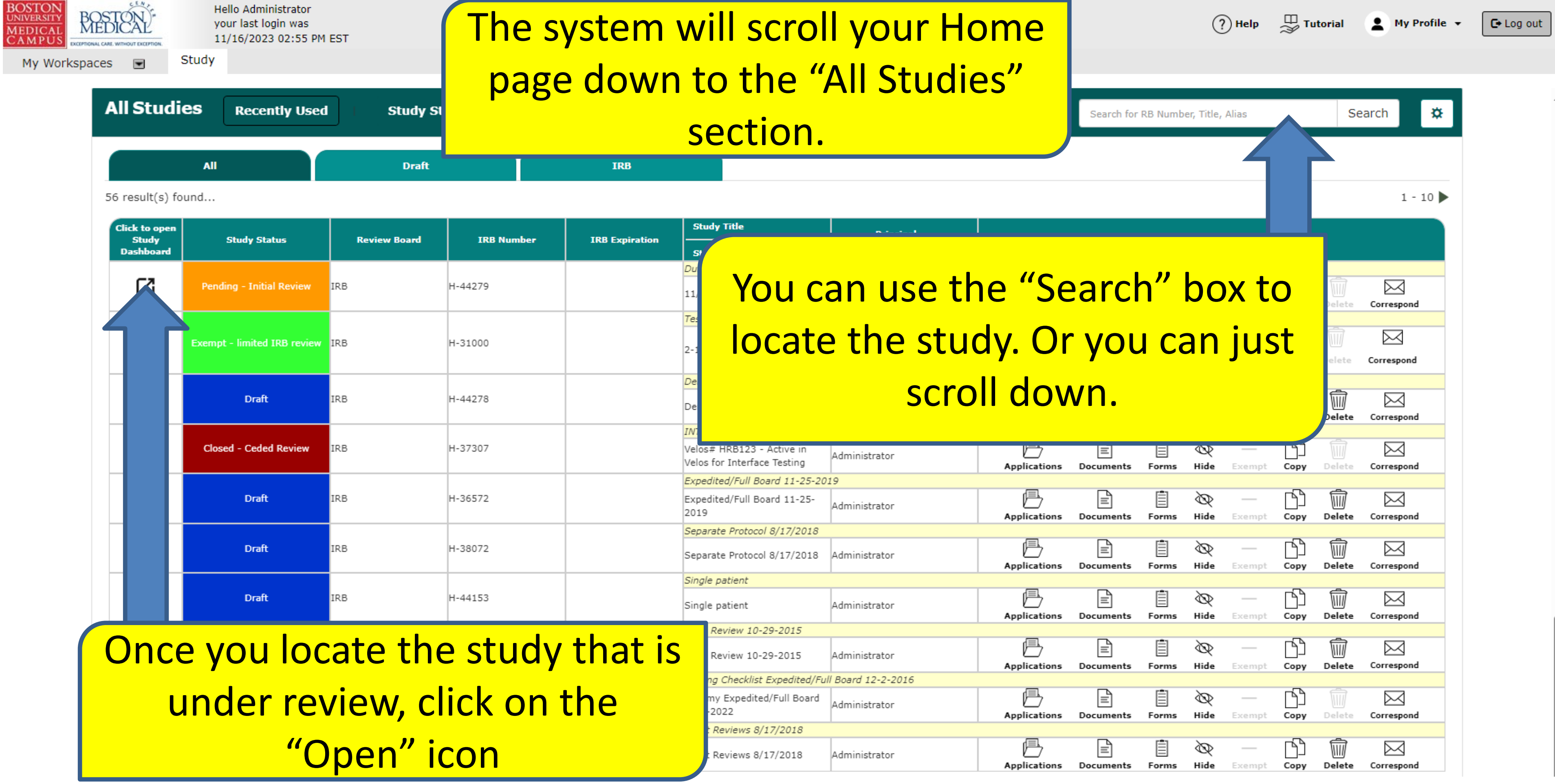


After logging into INSPIR II, from your Home page, click on “View and Manage My Studies” and proceed to the next slide.

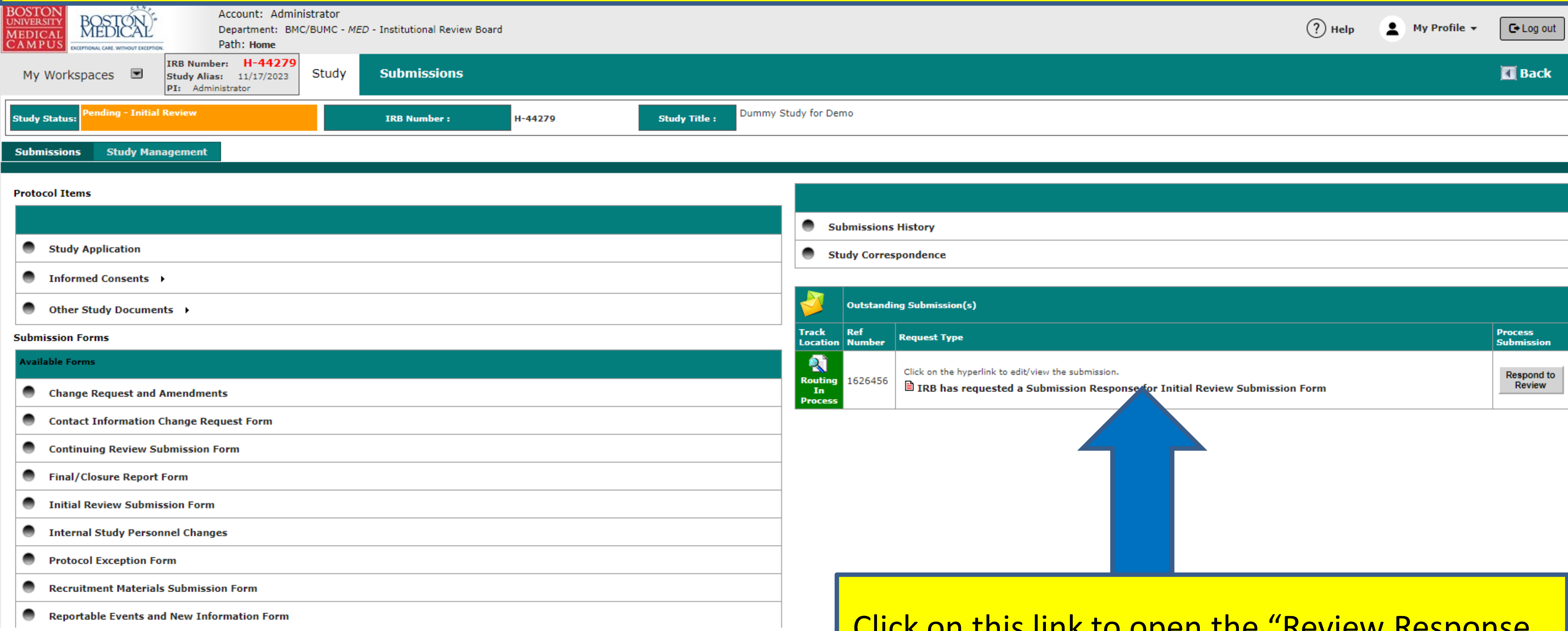
The system will scroll your Home page down to the “All Studies” section.

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

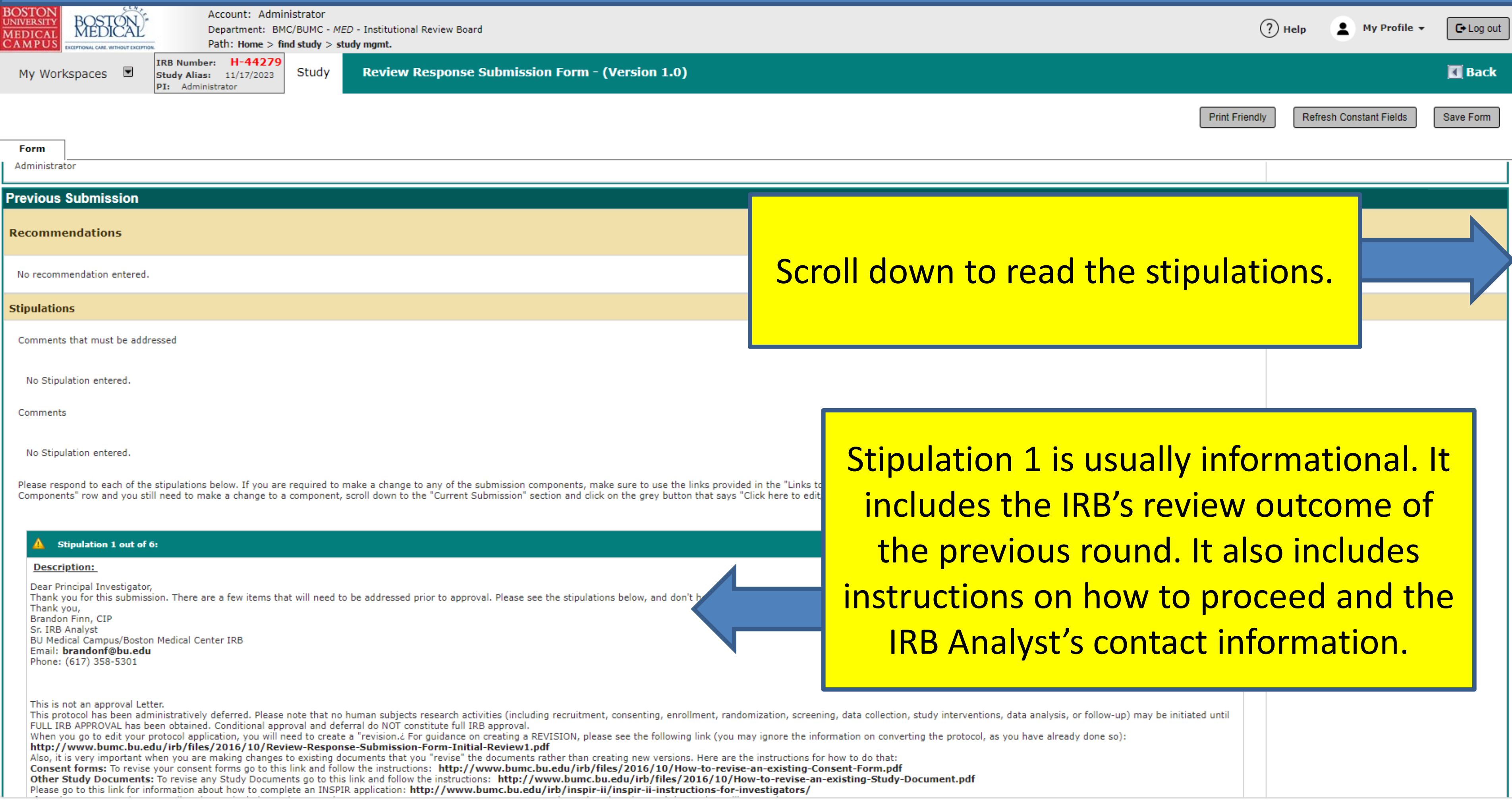


This opens the “Submissions/Study Management” page for the study.



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

This should open the “Review Response submission Form”.



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

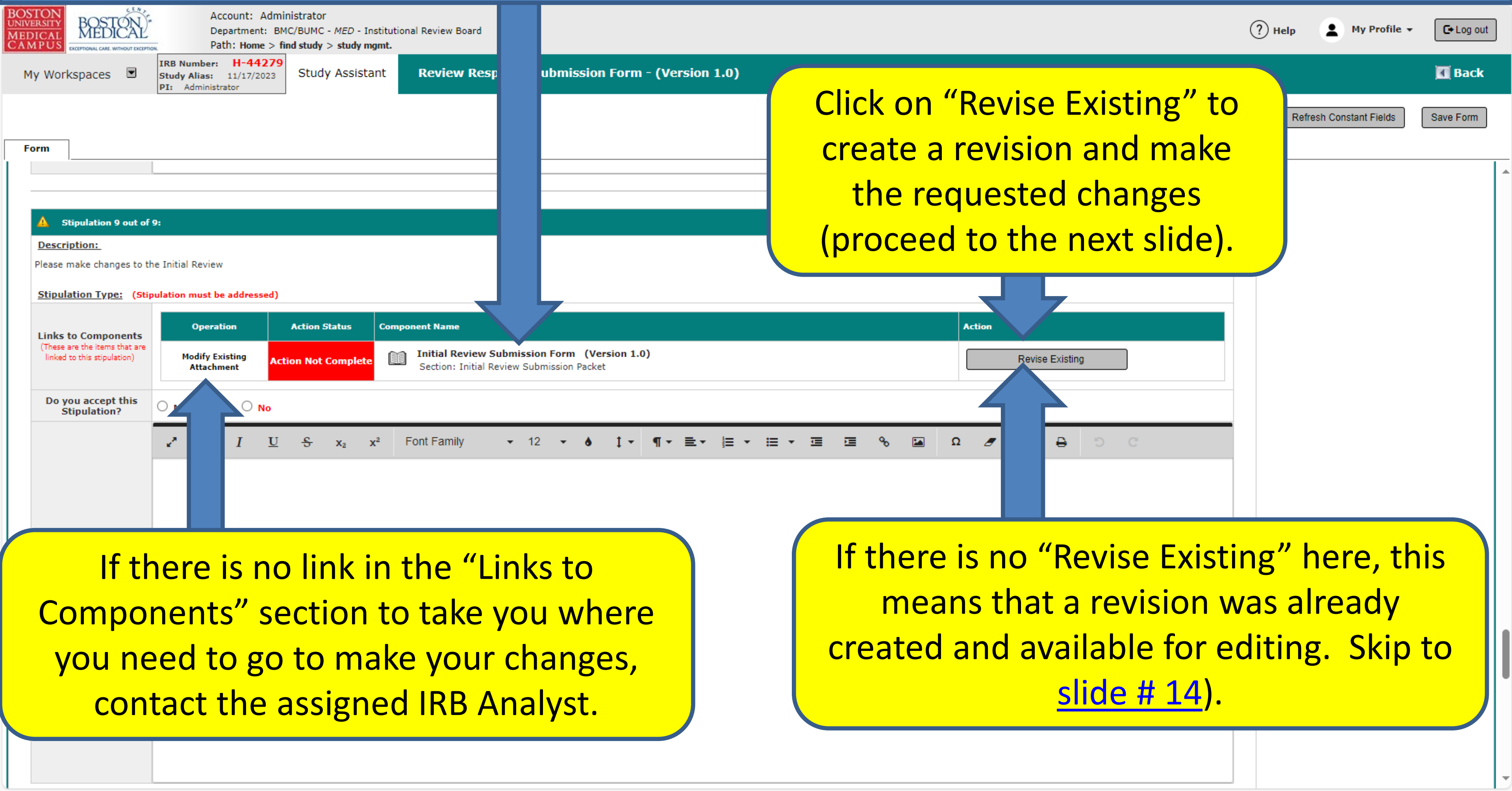
Once you have addressed all stipulations and you are ready to submit the "Review Response" back to the IRB, please go to slide # 45 and follow the rest of the instructions.

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.)



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

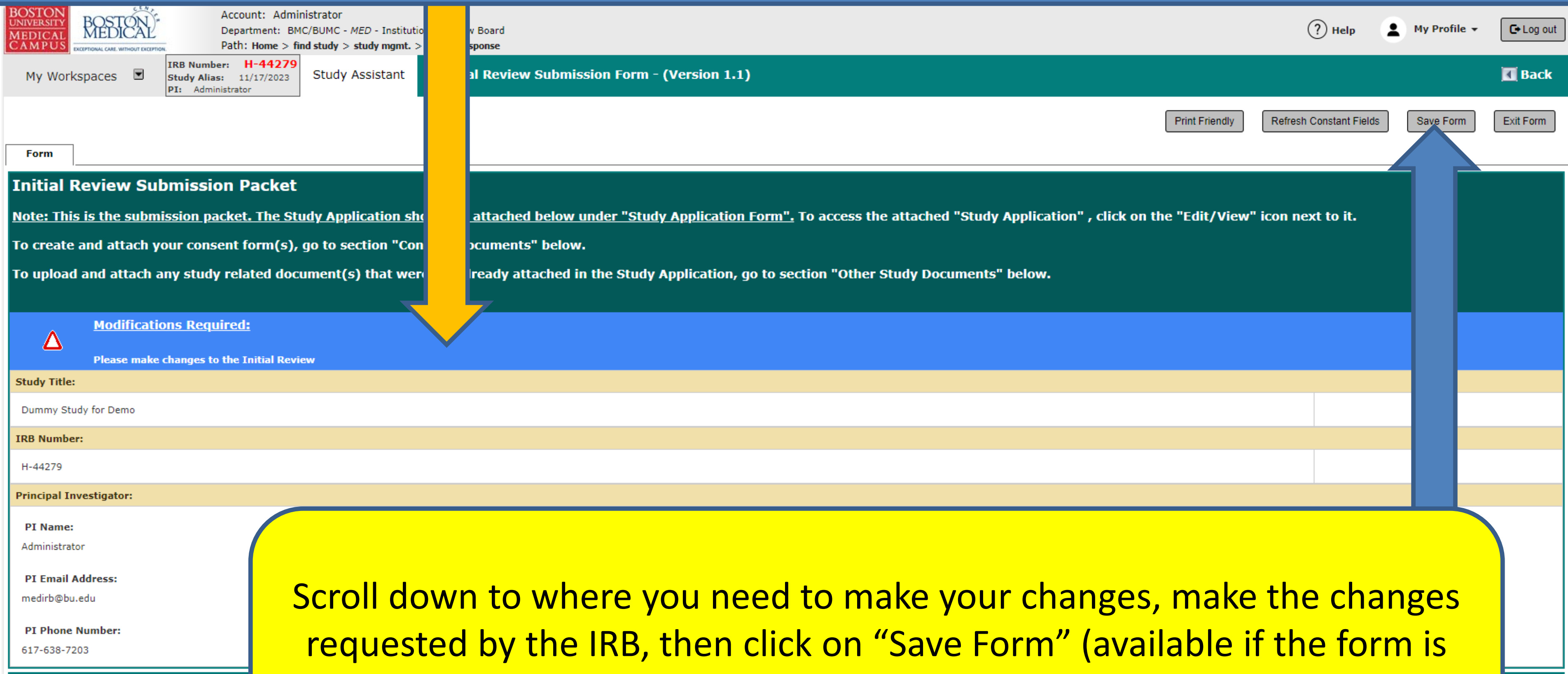
If there is no link in the “Links to Components” section to take you where you need to go to make your changes, contact the assigned IRB Analyst.

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

You will get the confirmation popup.

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.

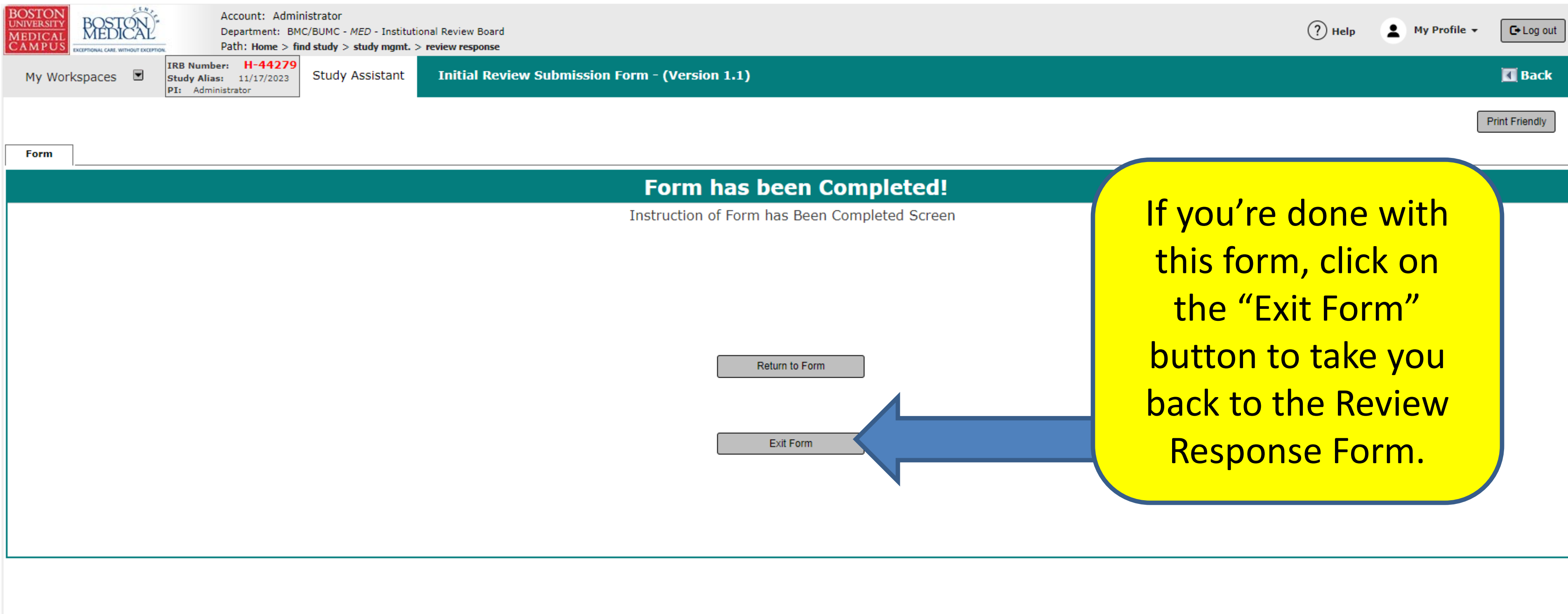
The system will create a revision (if one didn't exist) of the Submission form (in this example, it's the "Initial Review Submission Form") and will take you to the section/question where you need to make your changes. It also lists the stipulation (in a blue box) so that it's accessible to be read and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



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) .

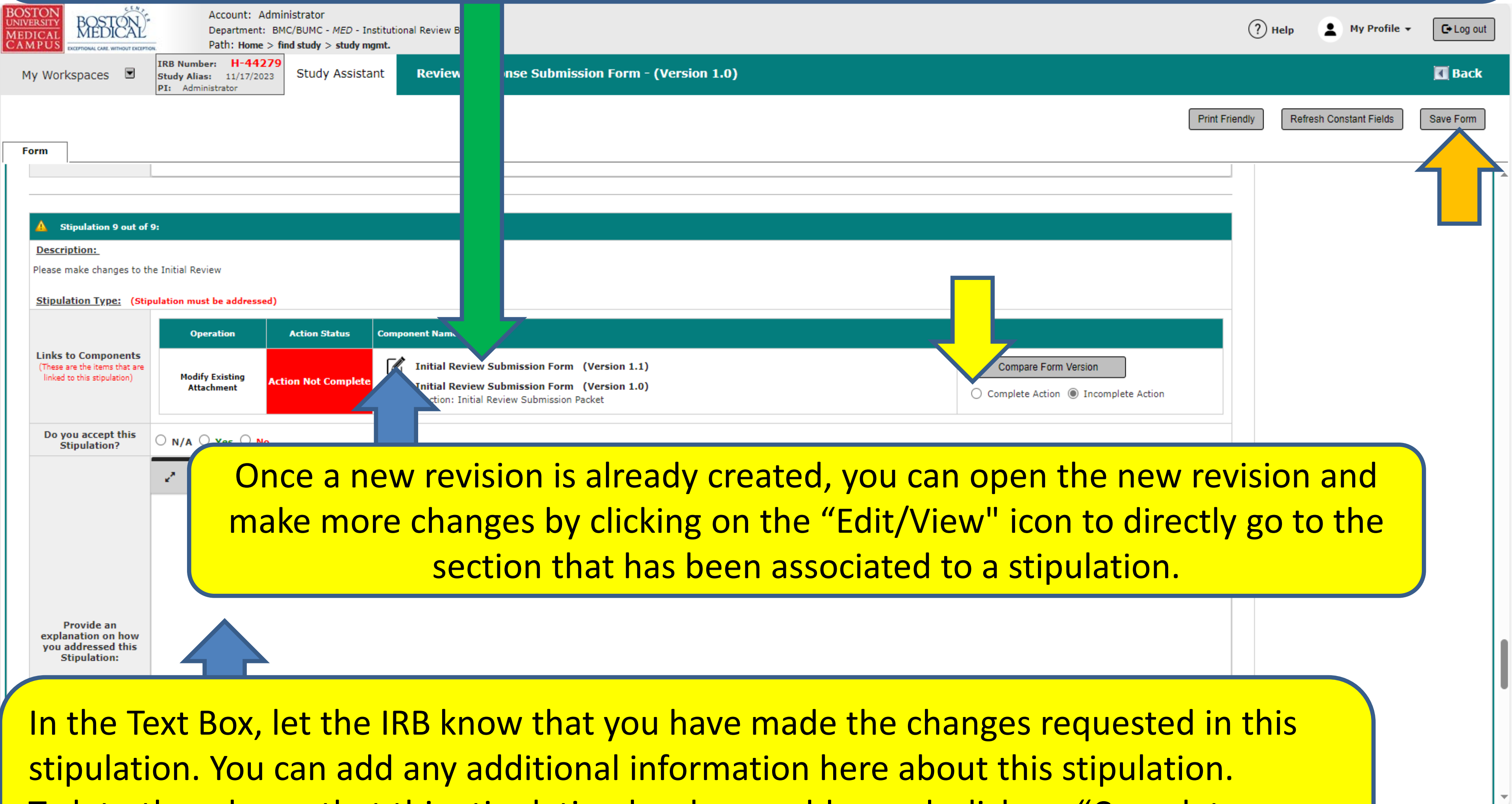
Note: We used the submission form “Initial Review Submission Form” (green arrow) as an example in these slides. Yours might be a different submission form (such as an “Amendment”, “Continuing Review”, “RENE”, “Final/Closure Report”, etc.), but all work the same

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



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

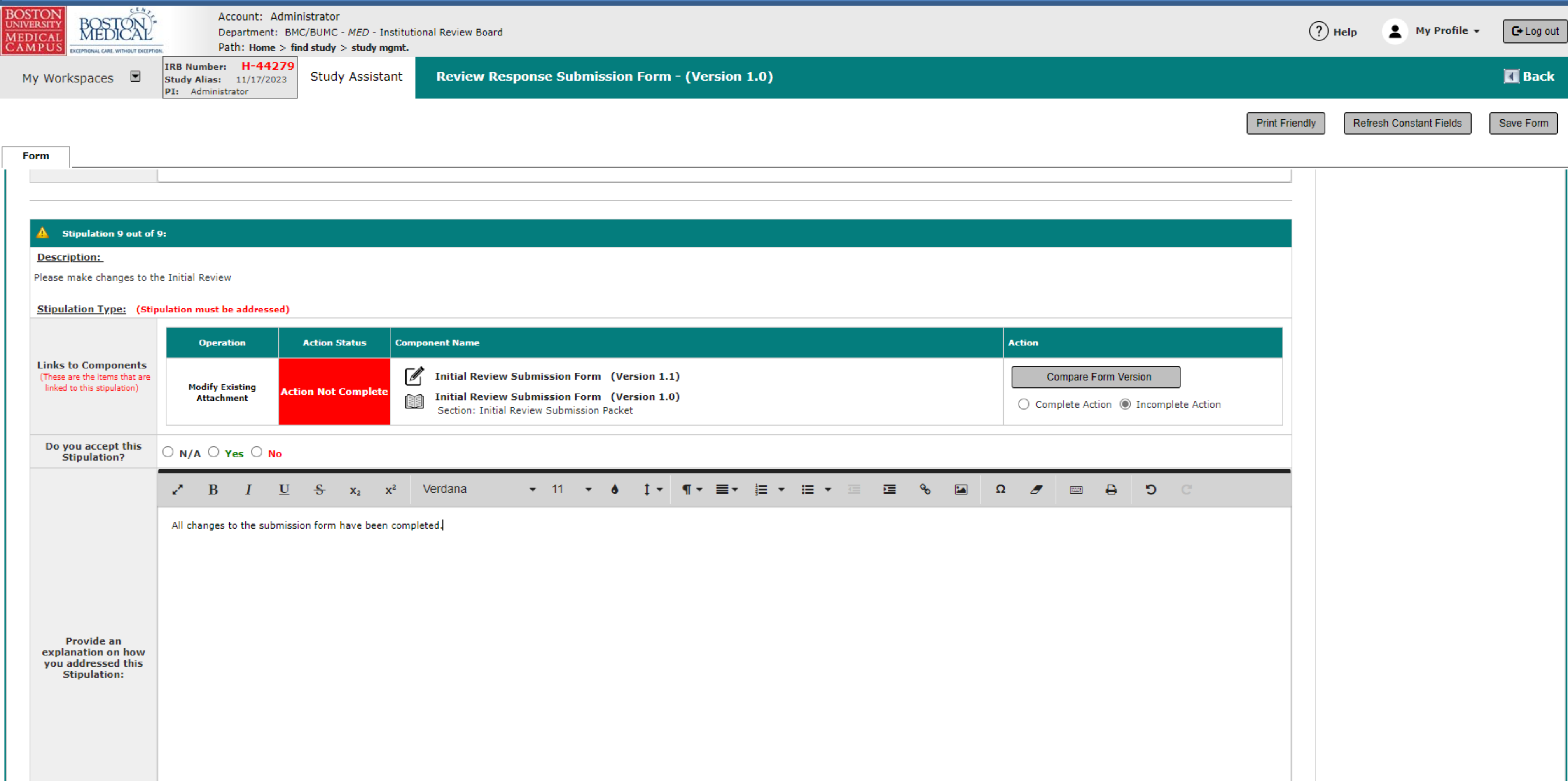
Note: You will notice that the "Revise Existing" link is not there since a revision (Version 1.1) had already been created and attached (green arrow). The system will only create a revision once.



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.



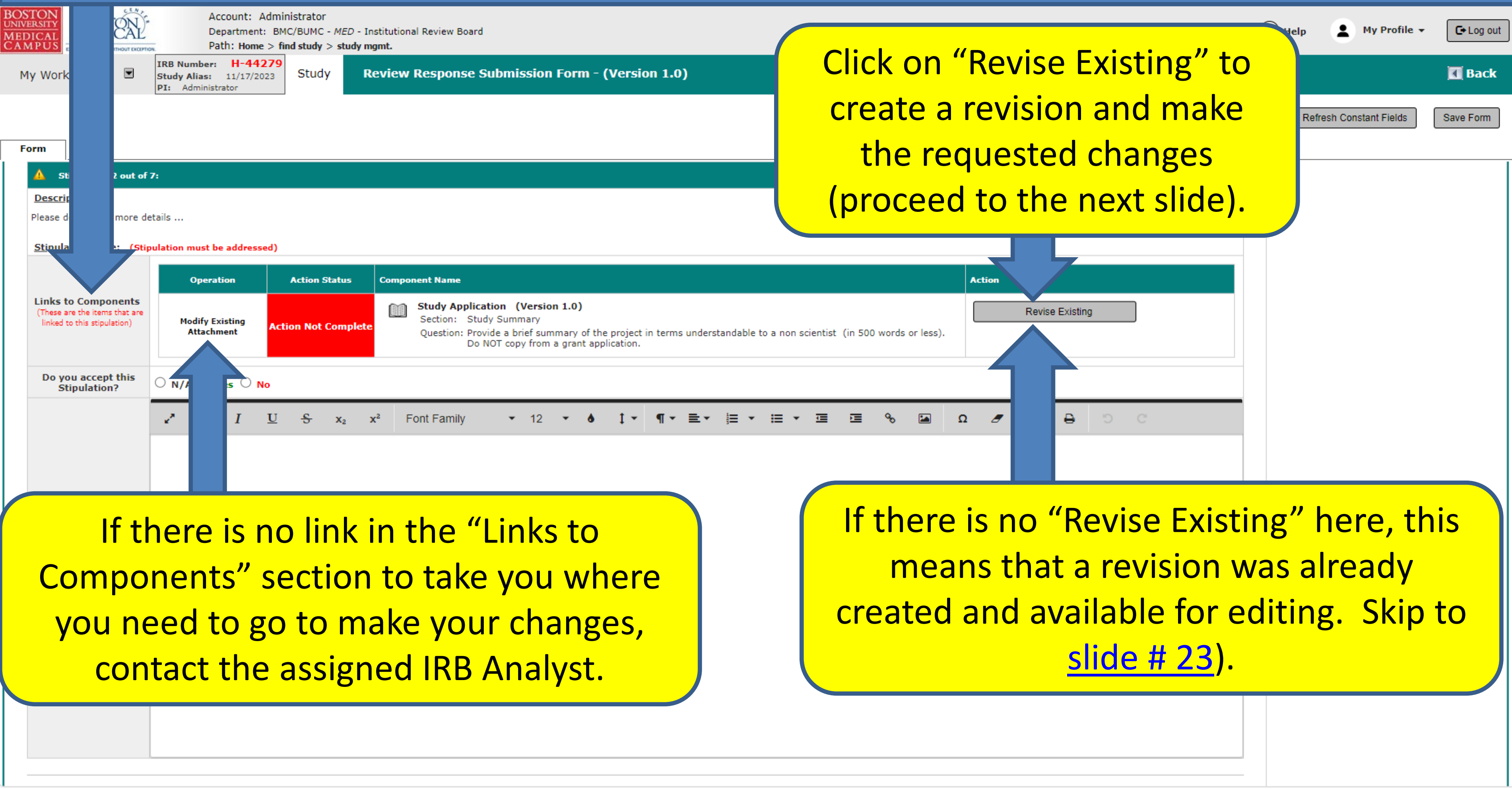
- When you’re done with this type of stipulations, go back to slide # 8 for more options.

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.

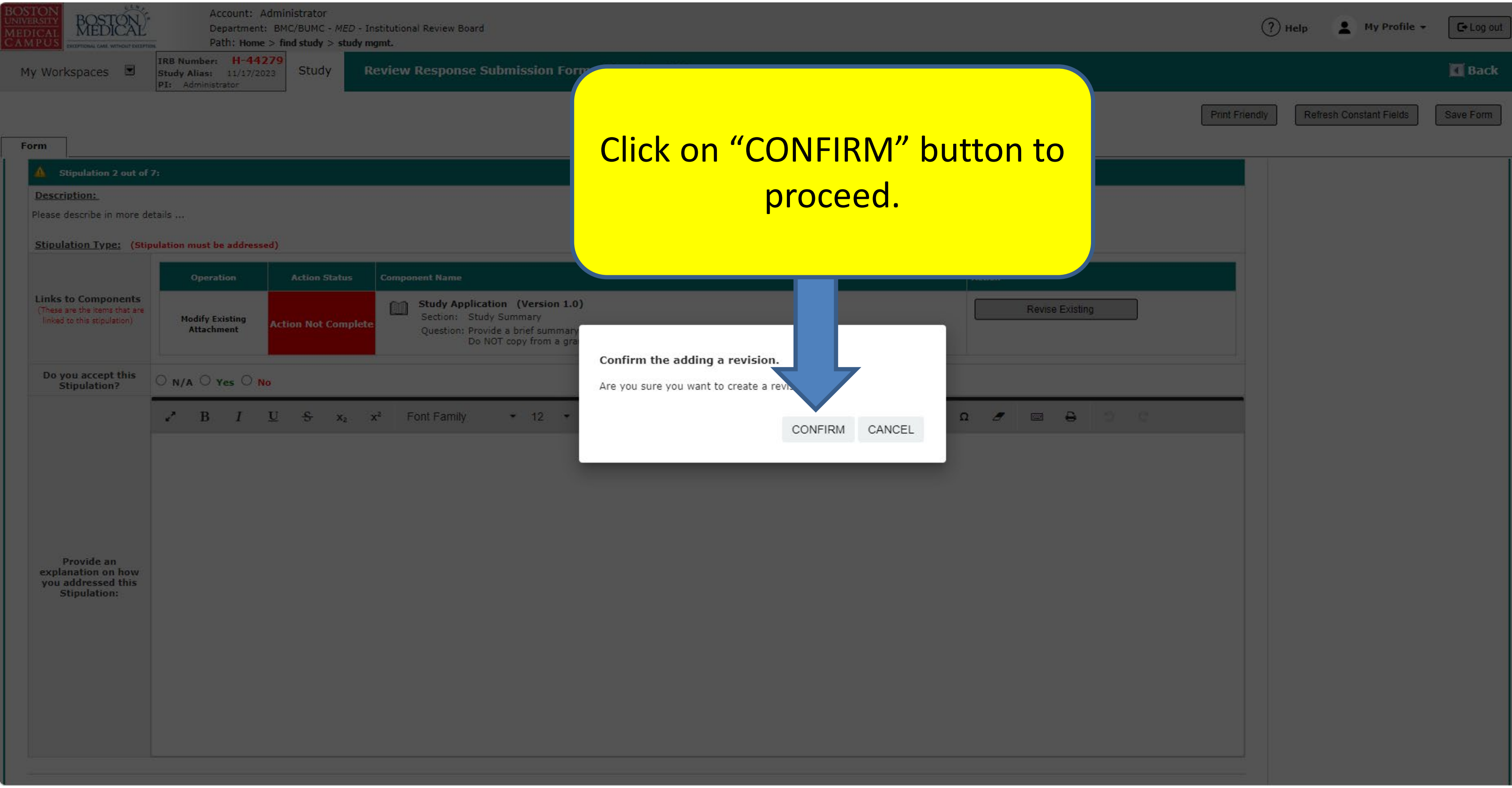


Click on "Revise Existing" to create a revision and make the requested changes (proceed to the next slide).

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.

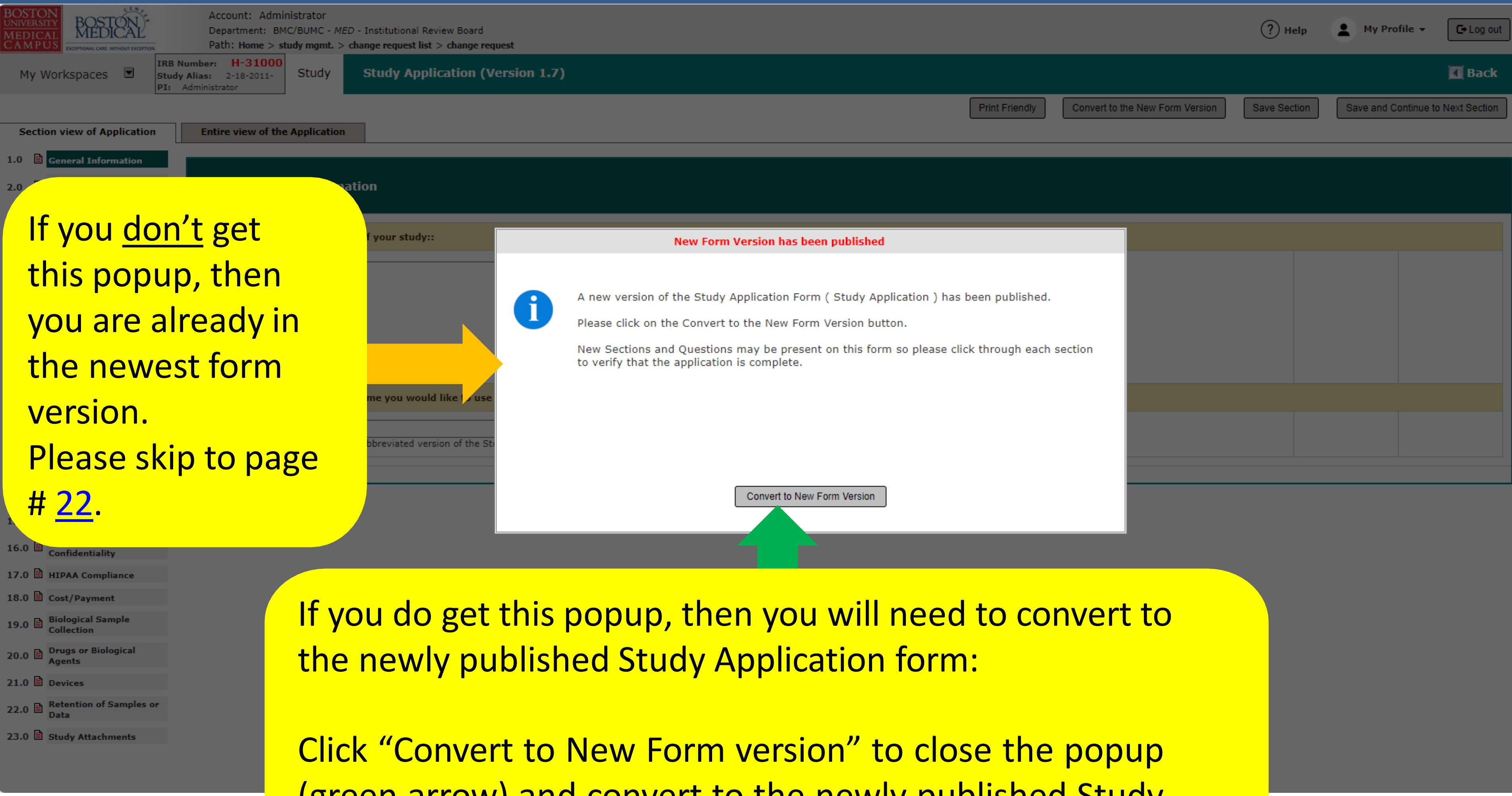
If there is no "Revise Existing" here, this means that a revision was already created and available for editing. Skip to slide # 23).

You will get the confirmation popup.



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.

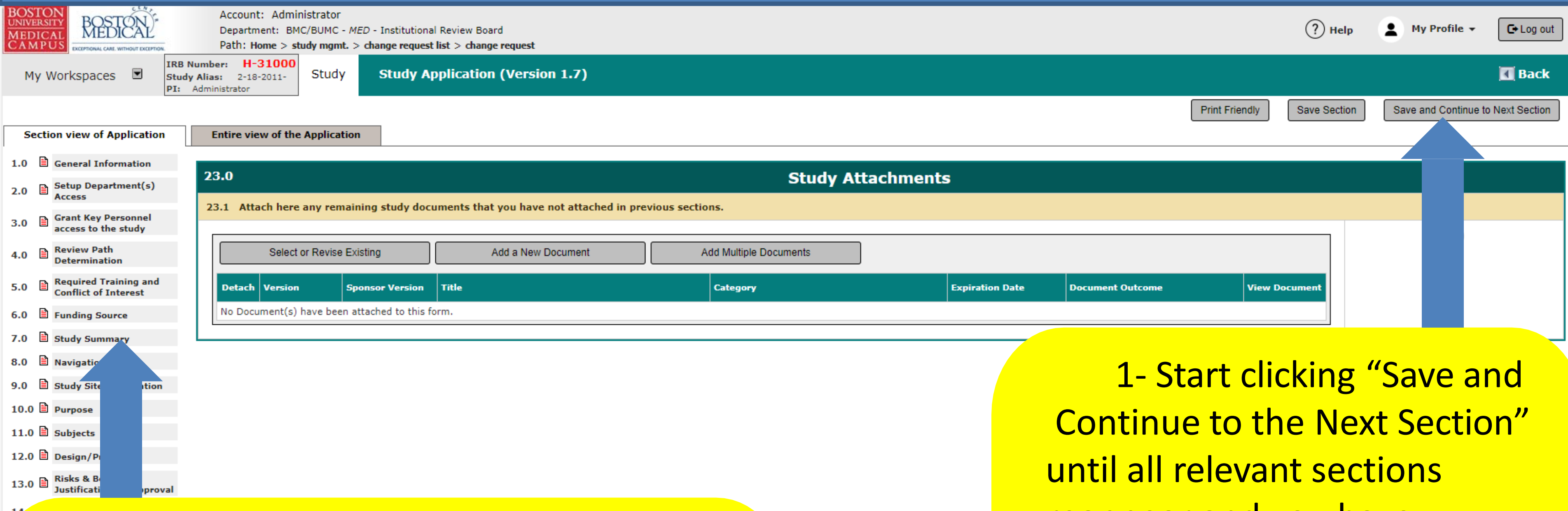


If you <u>don’t</u> get this popup, then you are already in the newest form version.
Please skip to page # 22.

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.

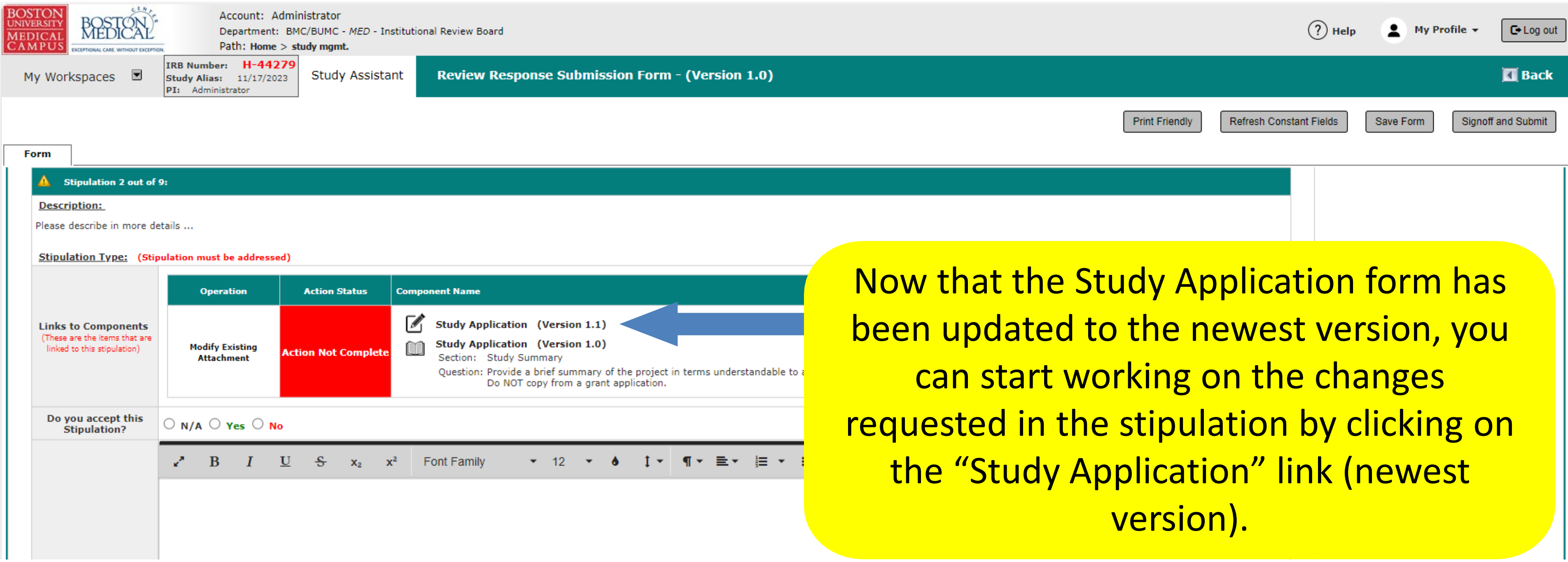


The system will start converting to the new form section by section. If a section has a new question that is required, the system will stop there and hide all subsequent sections until you answer the new question. Don't worry, nothing is lost in these hidden sections!

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.

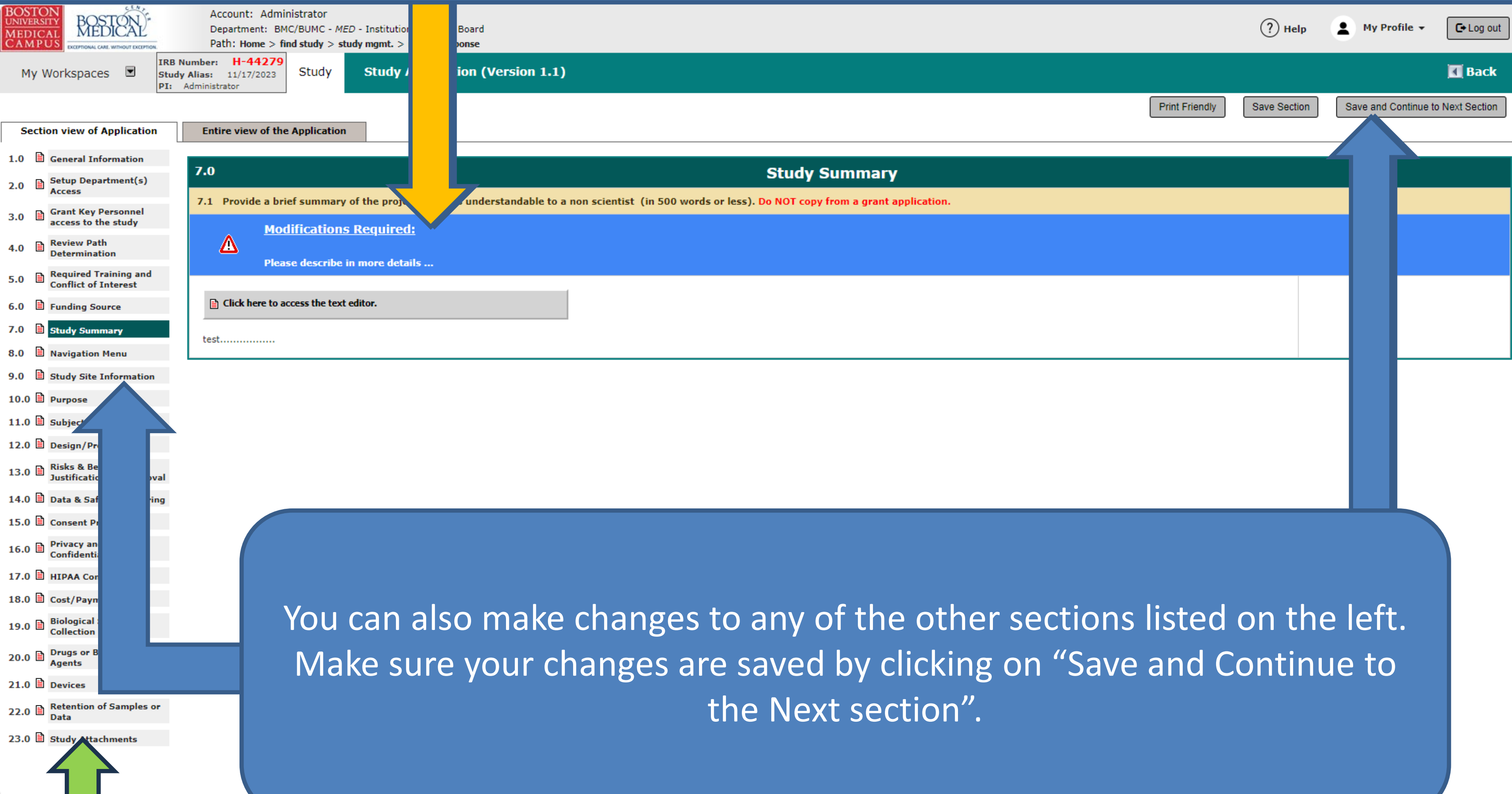
The system automatically takes you back to the “Review Response Submission Form” page and attach the new version of the Study Application (assuming the Study Application was completed).



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.

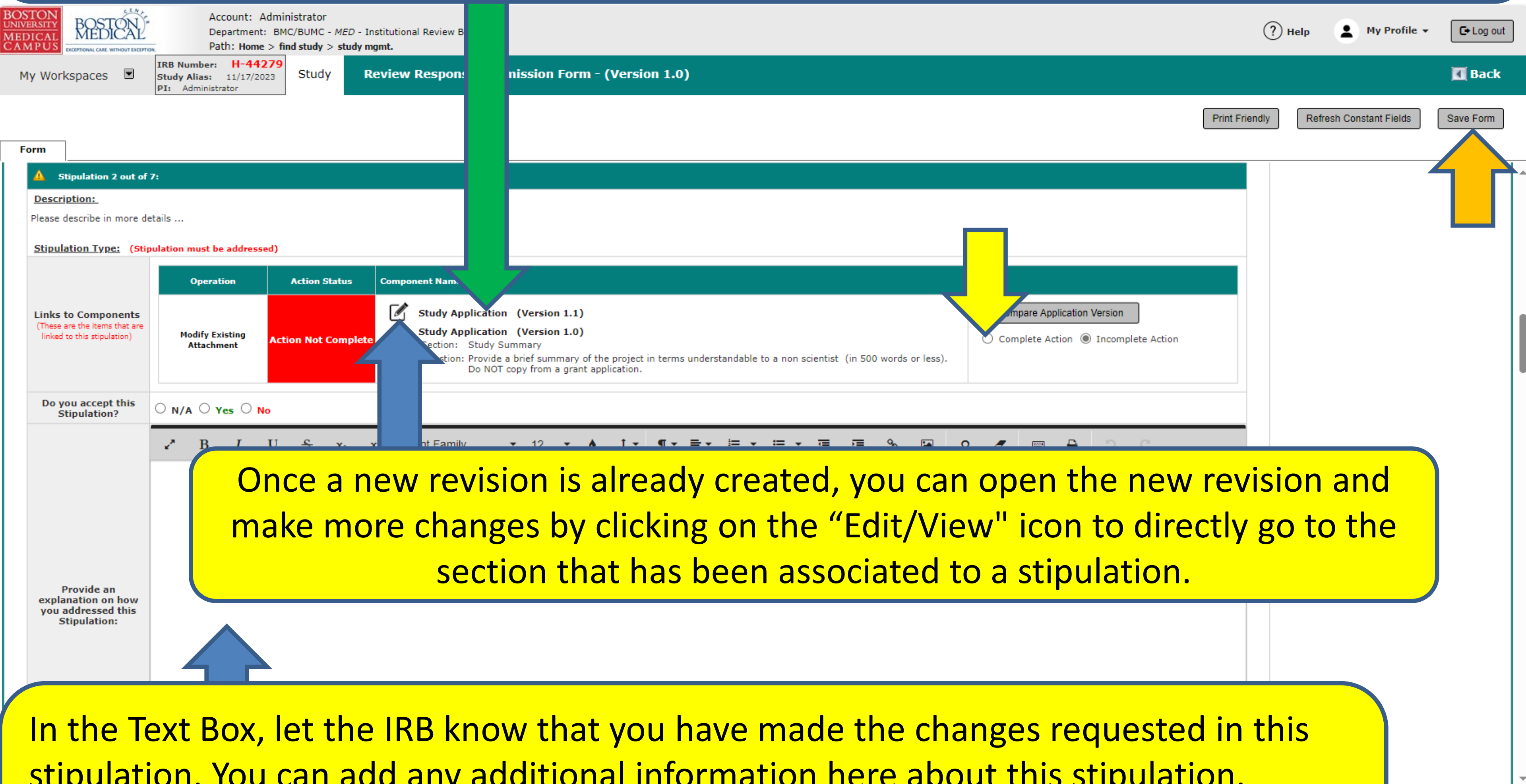
The system will create a revision (if one didn't exist) of the Study Application and take you to the section/question where you need to make your changes. It also lists the stipulation (in blue box) so that it's accessible to be read and followed (orange arrow).



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.

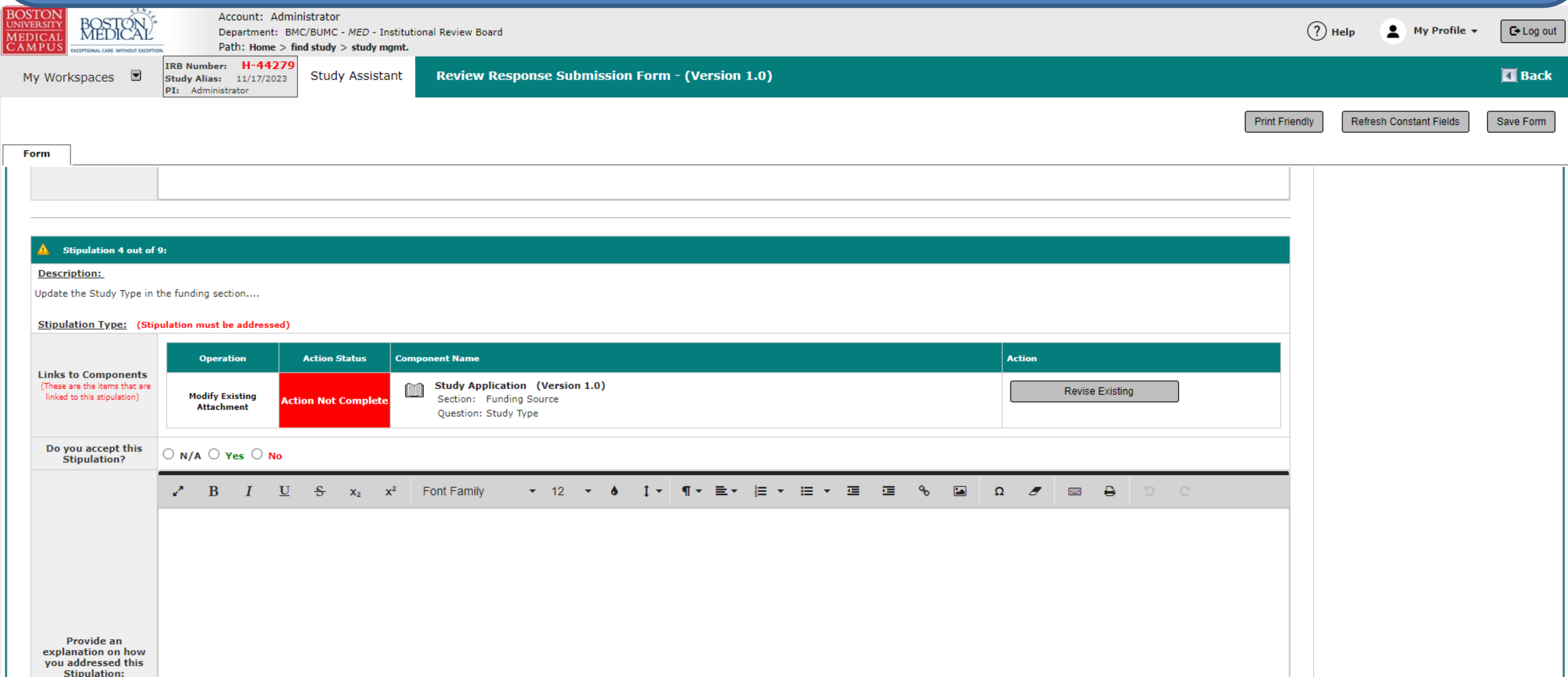
Note: You will notice that the "Revise Existing" link is not there since a revision (Version 1.1) had already been created and attached (green arrow). The system will only create a revision once.



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”

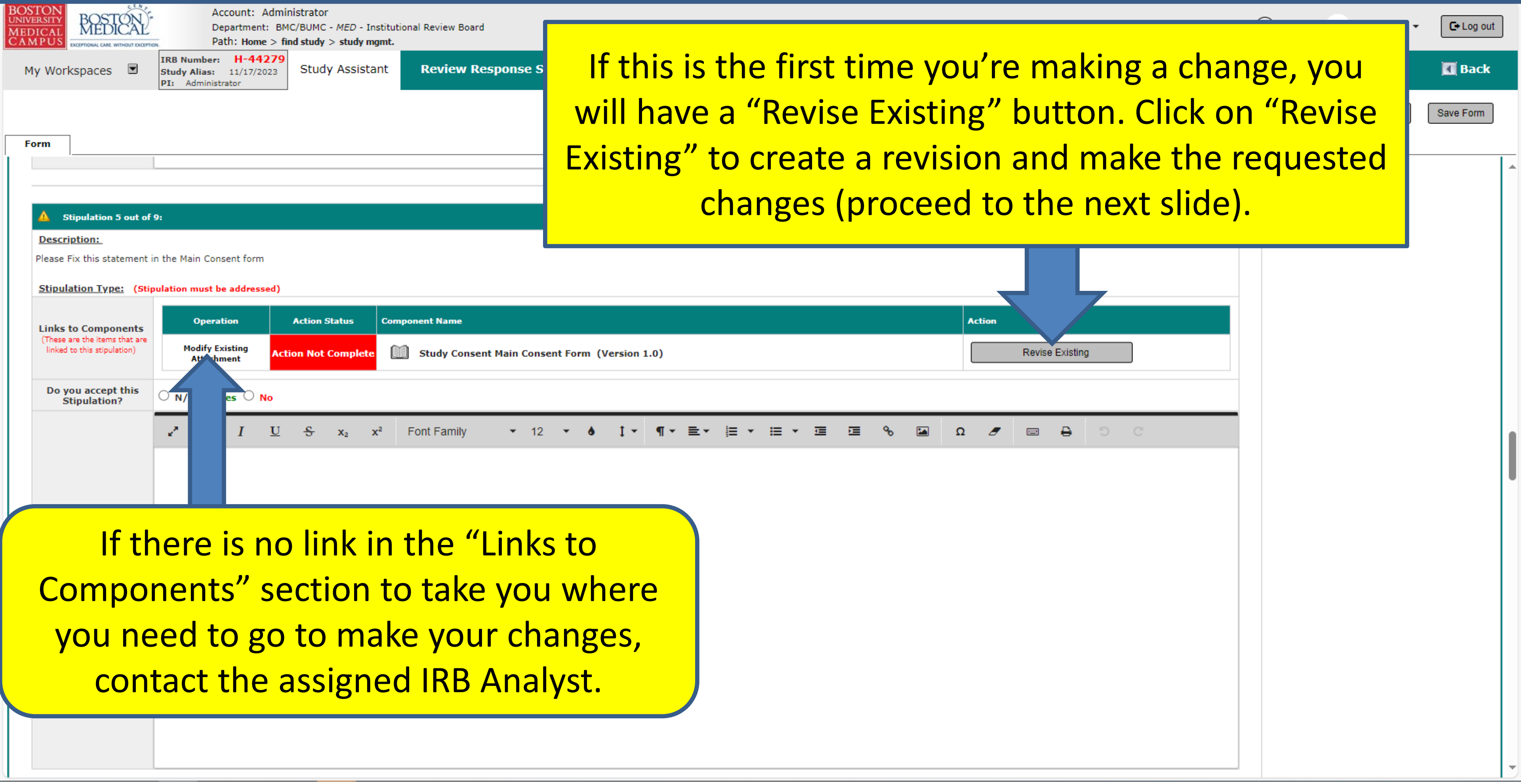


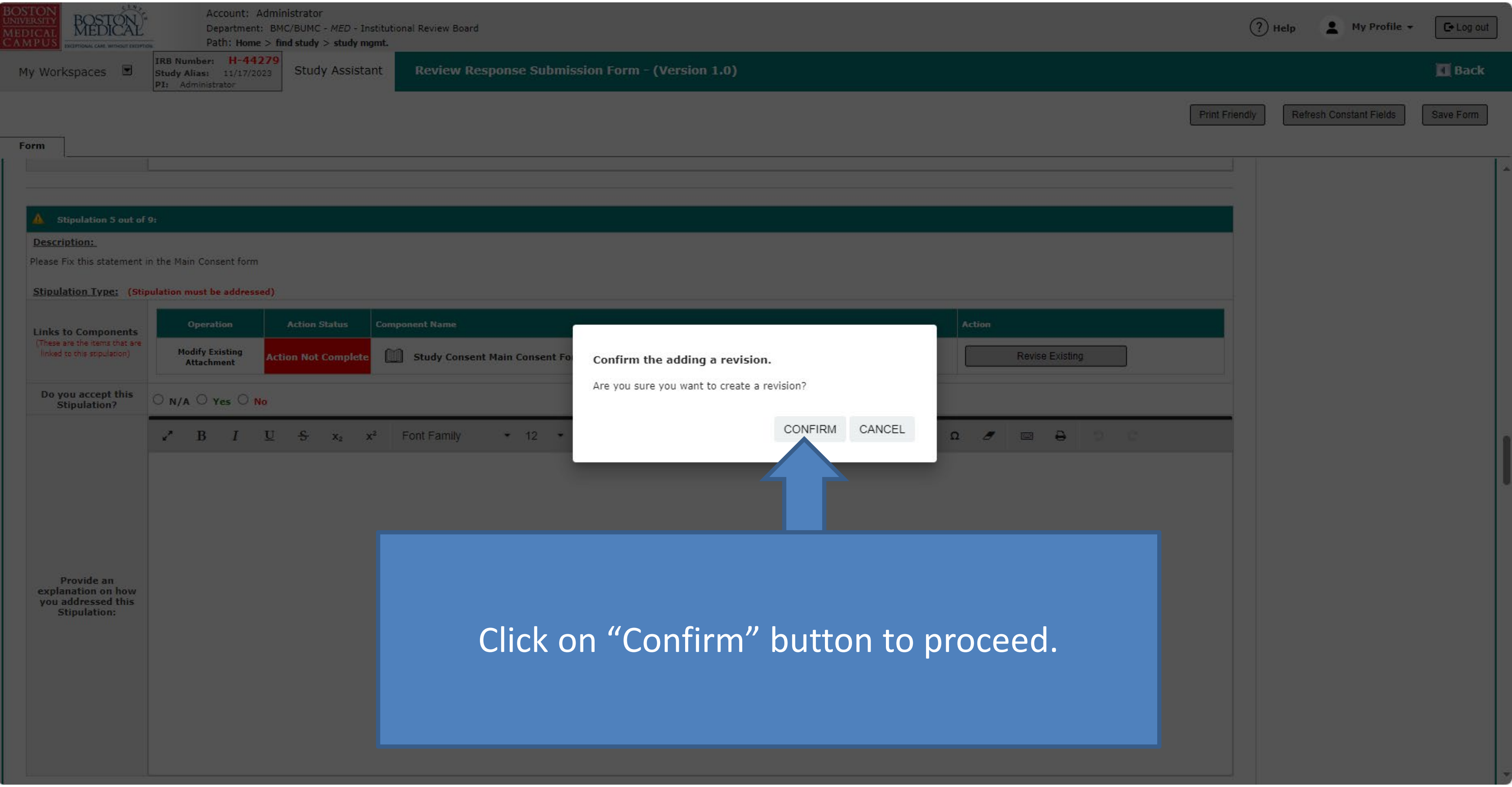
- When you’re done with this type of stipulations, go back to slide # 8 for more options.

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.

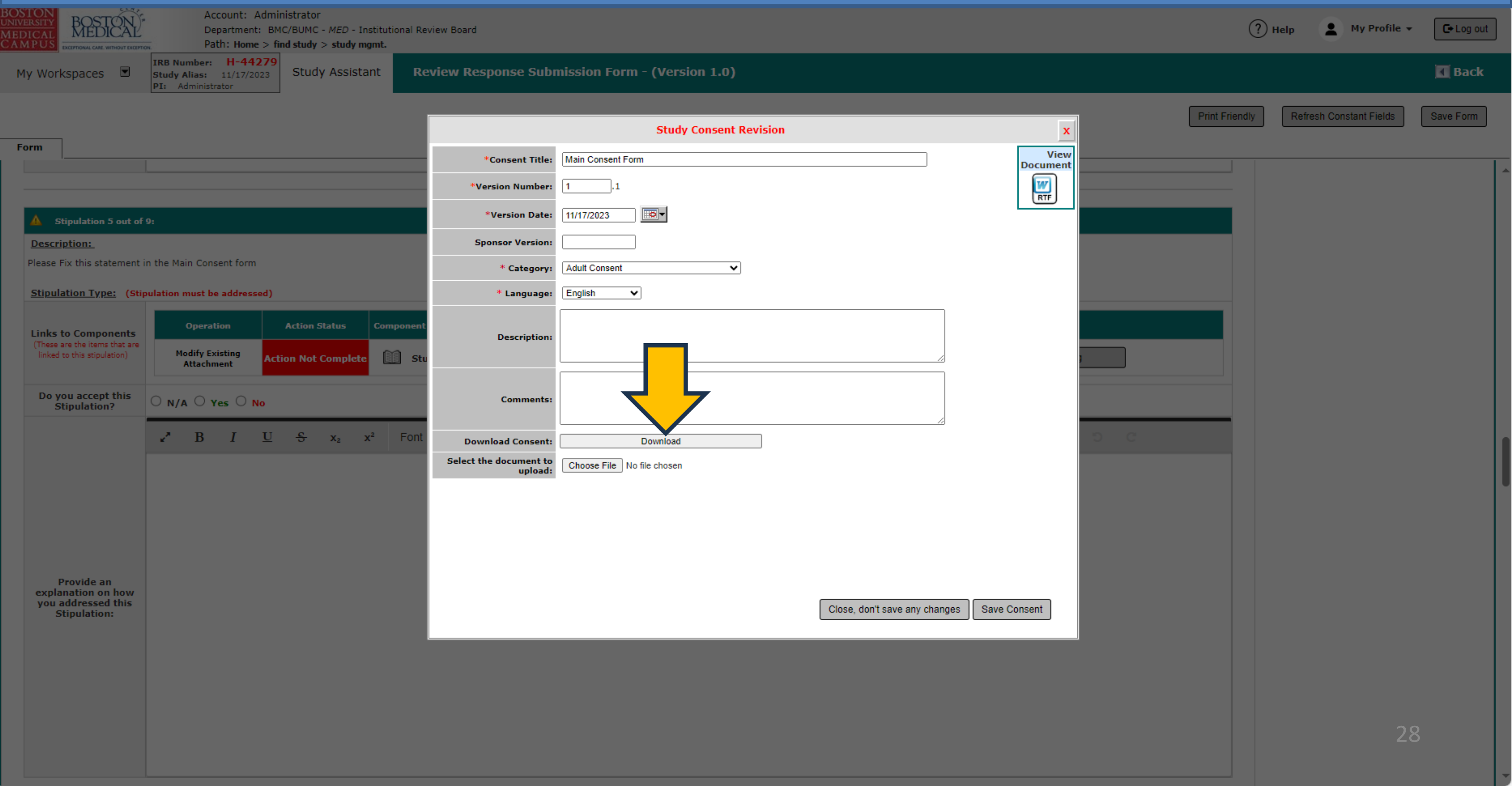




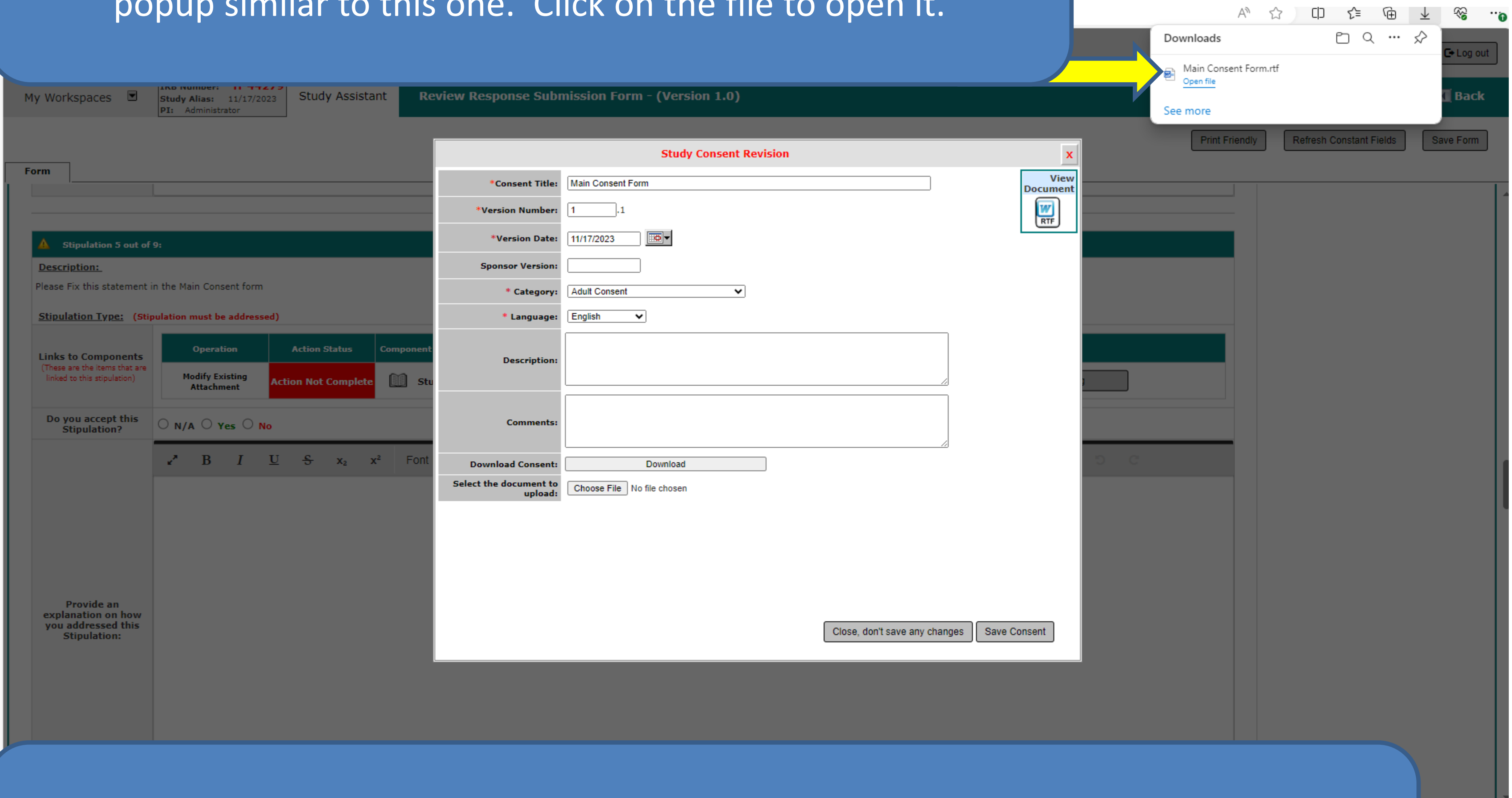
Click on “Confirm” button to proceed.

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 <u>slide # 30</u>.



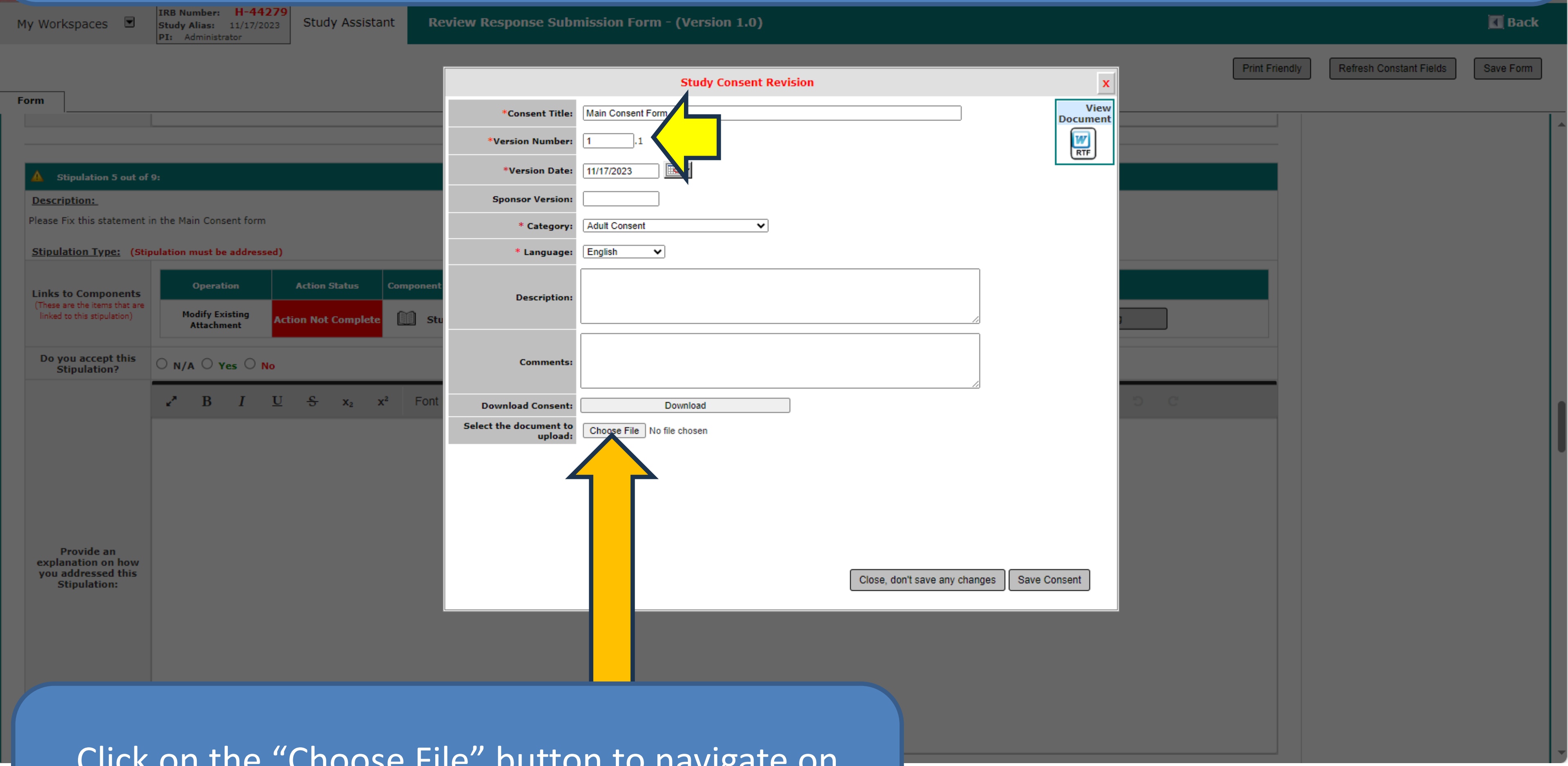
The selected consent document will download. Depending on your system and web browser, you will get the "Downloads" popup similar to this one. Click on the file to open it.



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.

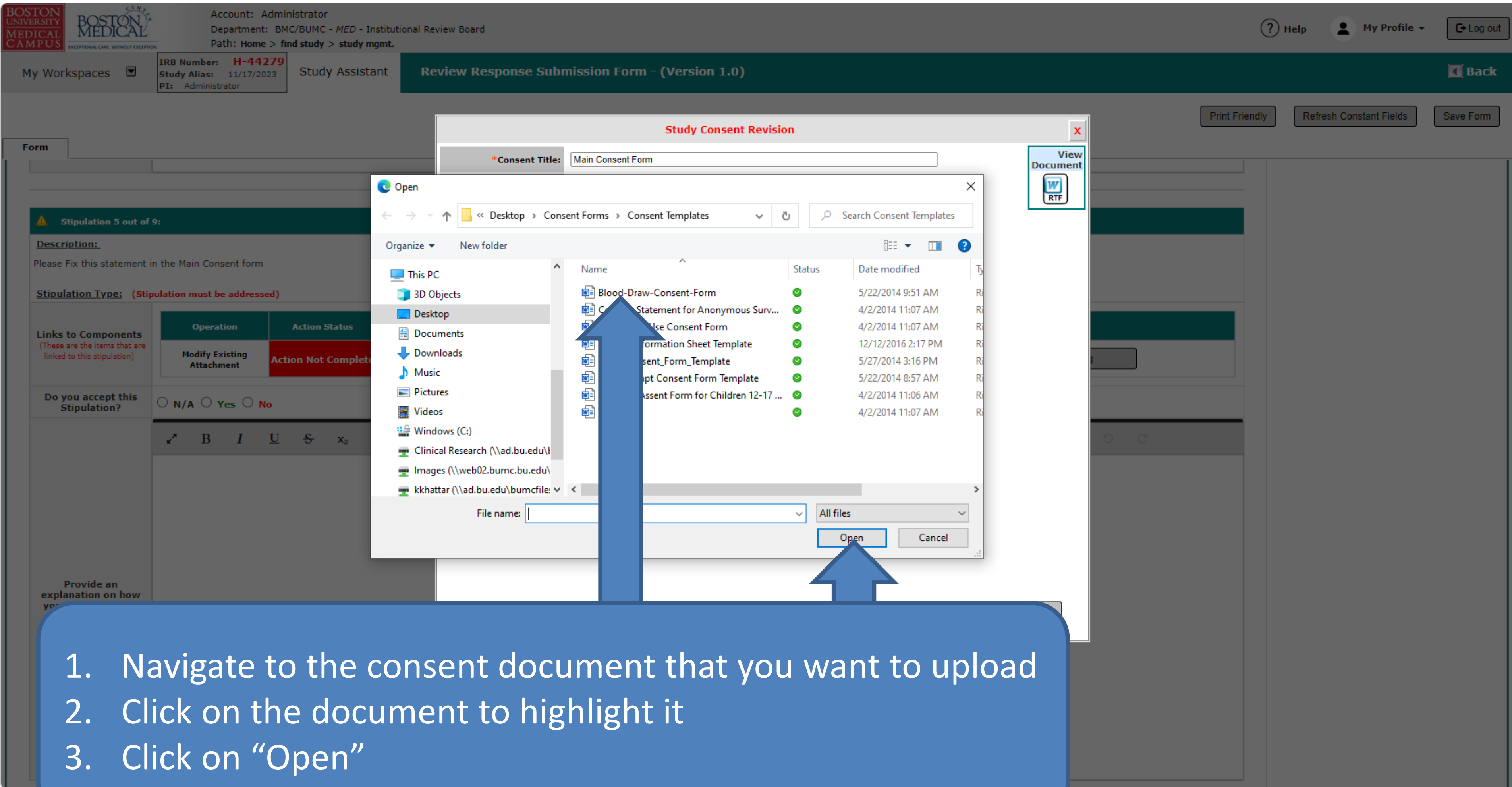
Notice that this revised consent document will now be given a new Version Number (the system will increment the version number by + .1) (yellow arrow)

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



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.

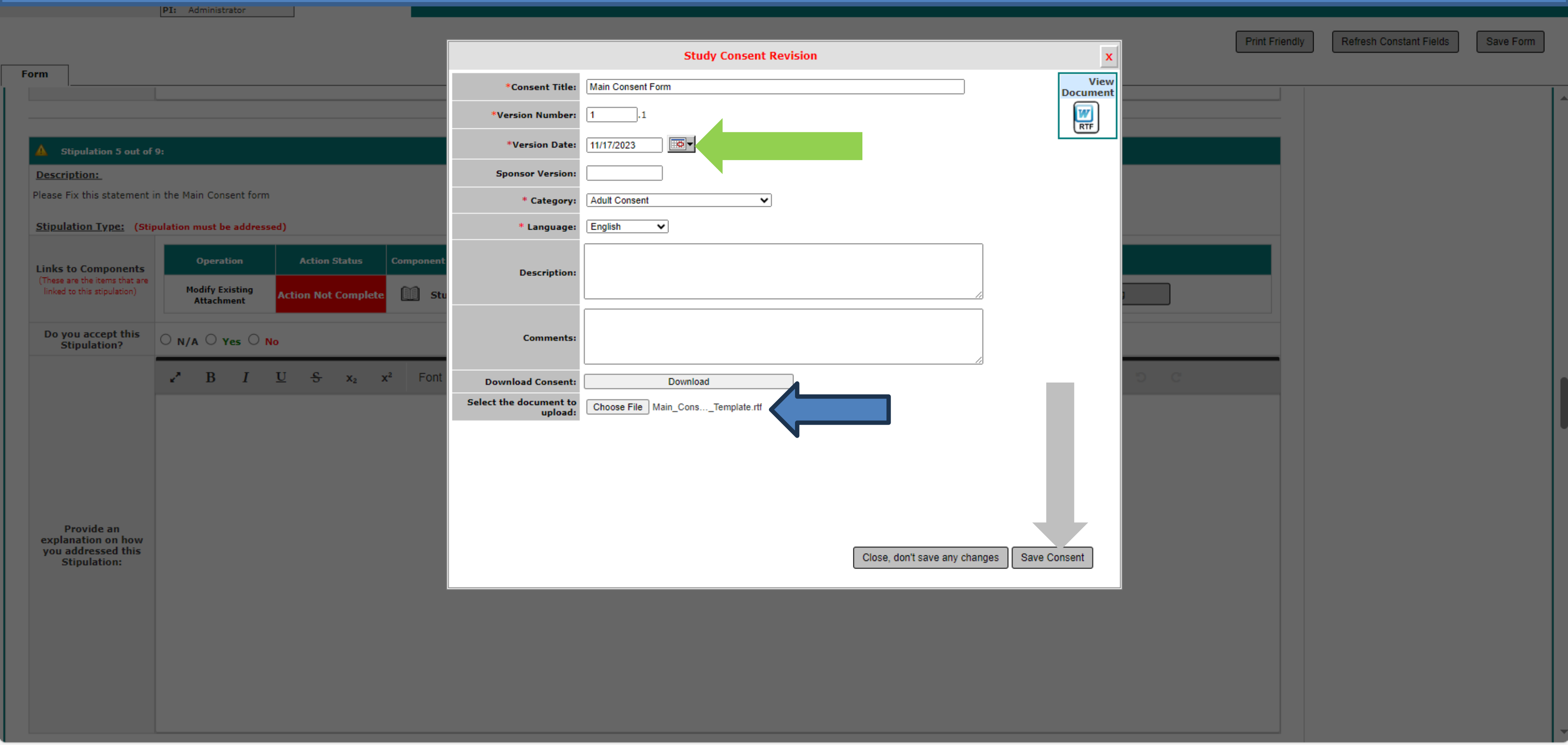


1. Navigate to the consent document that you want to upload
2. Click on the document to highlight it
3. Click on “Open”

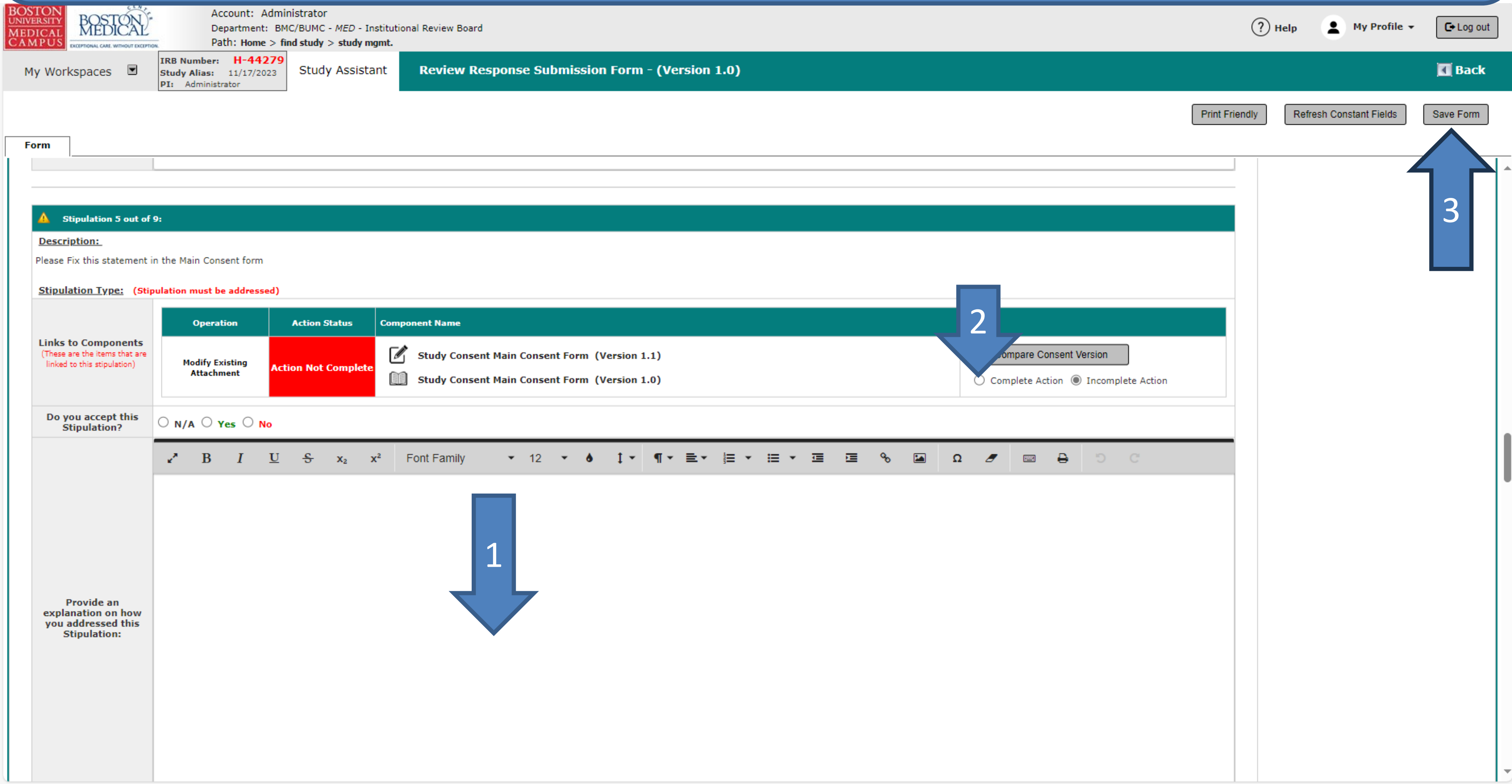
This will bring you back to the “Study Consent Revision:” popup.

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

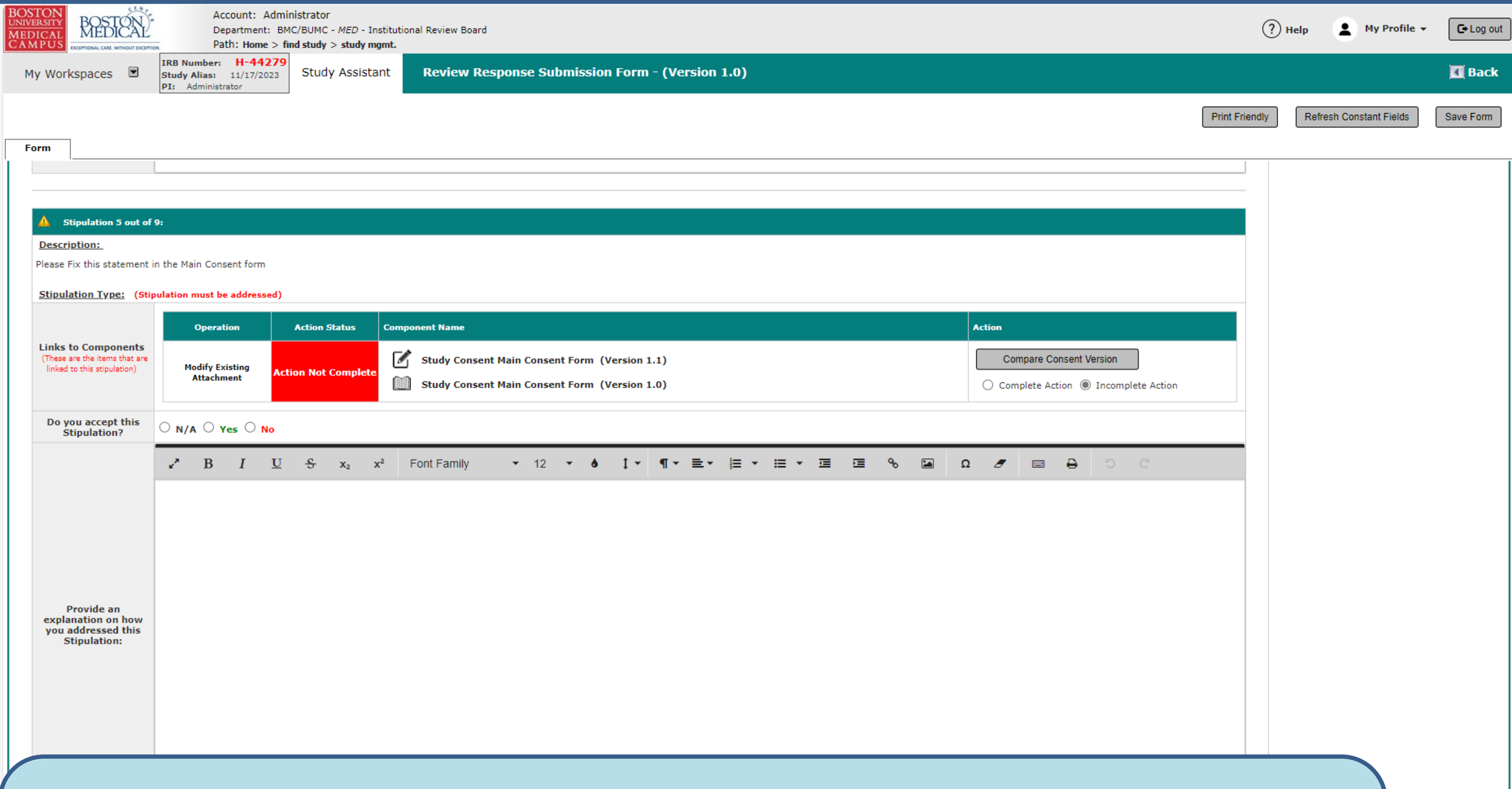
1. Change the “Version Date” to today’s date (green arrow)
2. Click on the “Save Document” button (Grey arrow)



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



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

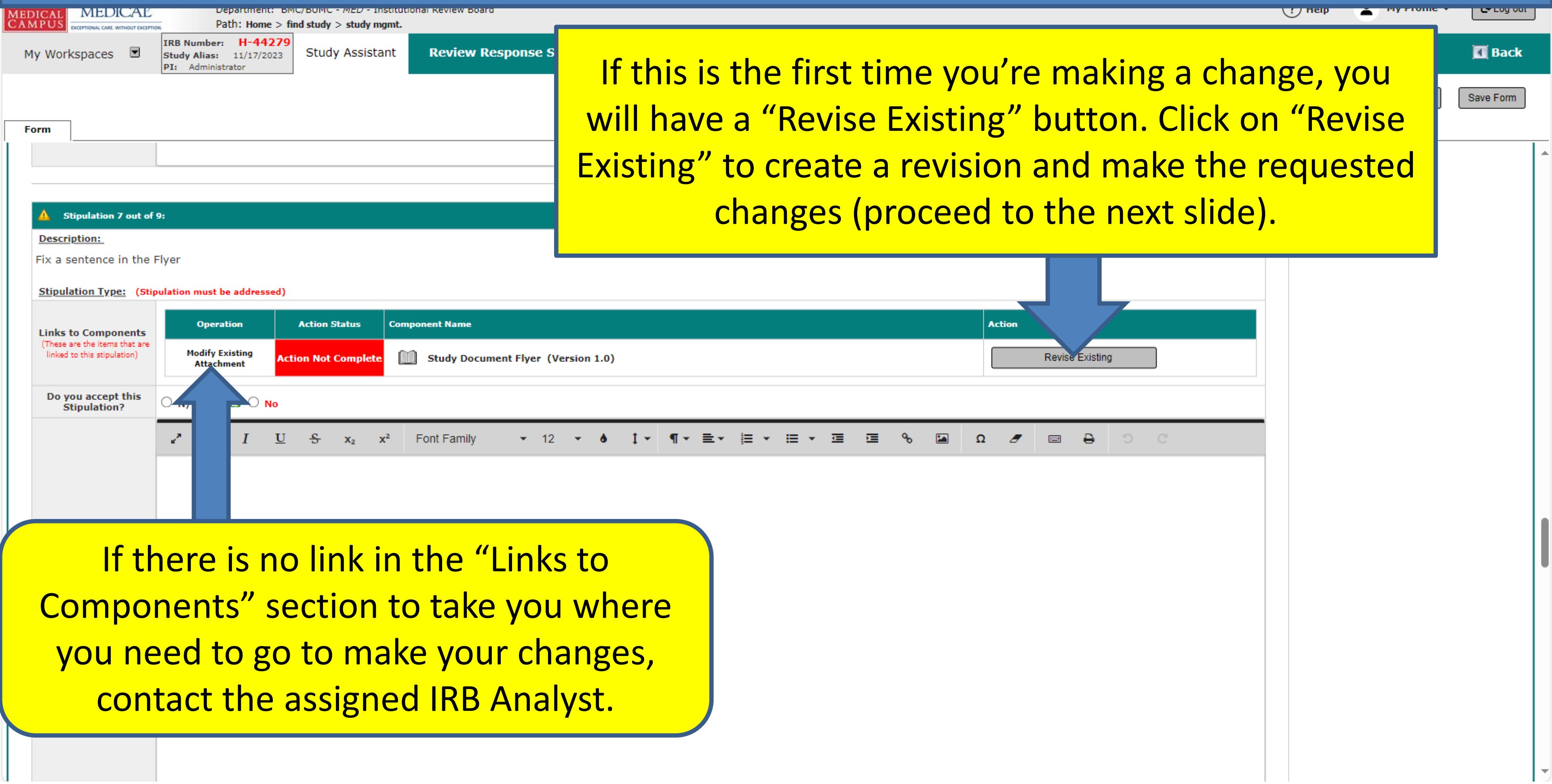


- When you're done with this type of stipulations, go back to slide # 8 for more options.

How to address stipulations with links to a Study Document

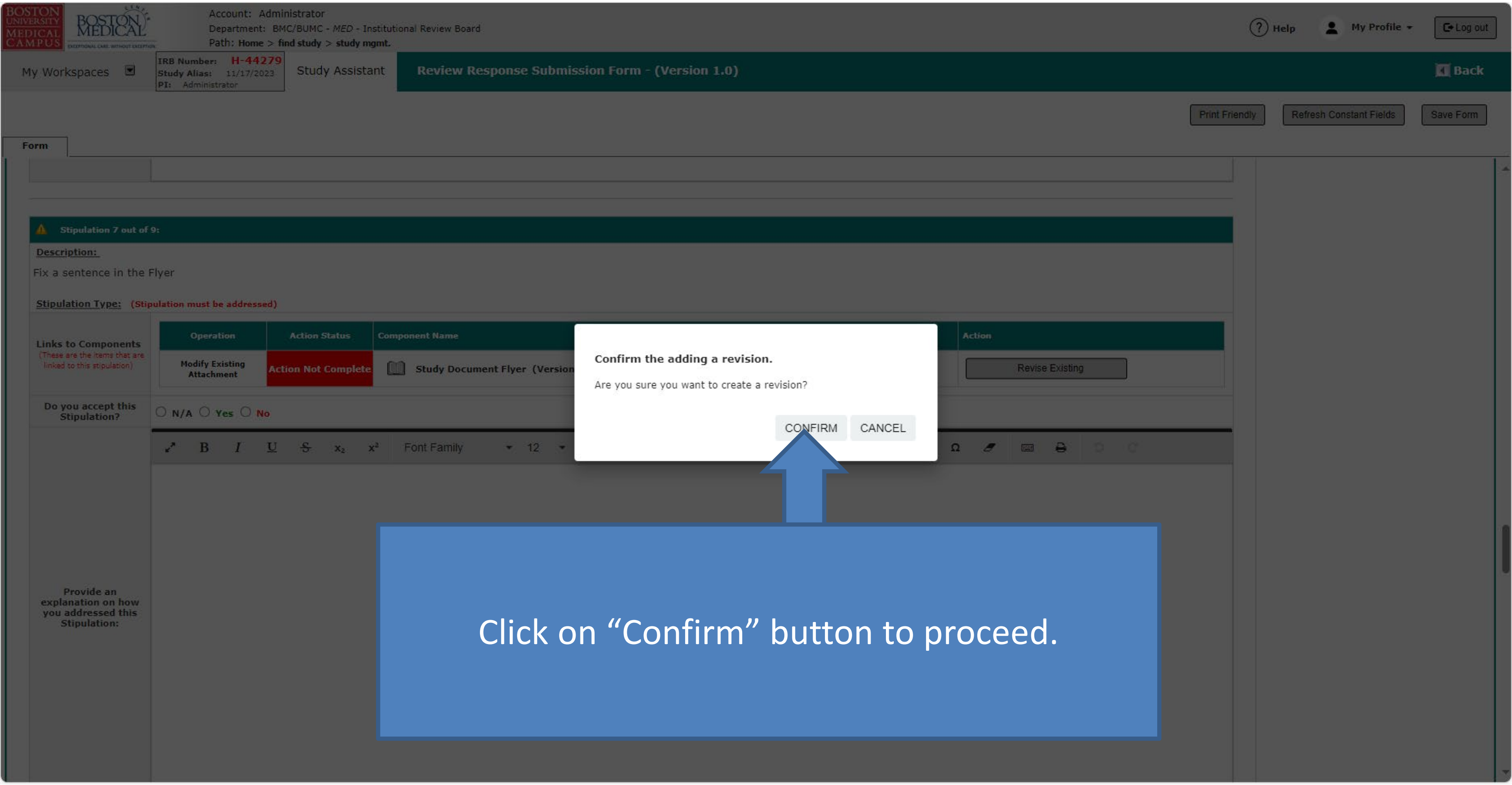
* If a stipulation is missing a link, please contact the assigned IRB Analyst so they can setup the missing link in that stipulation.

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



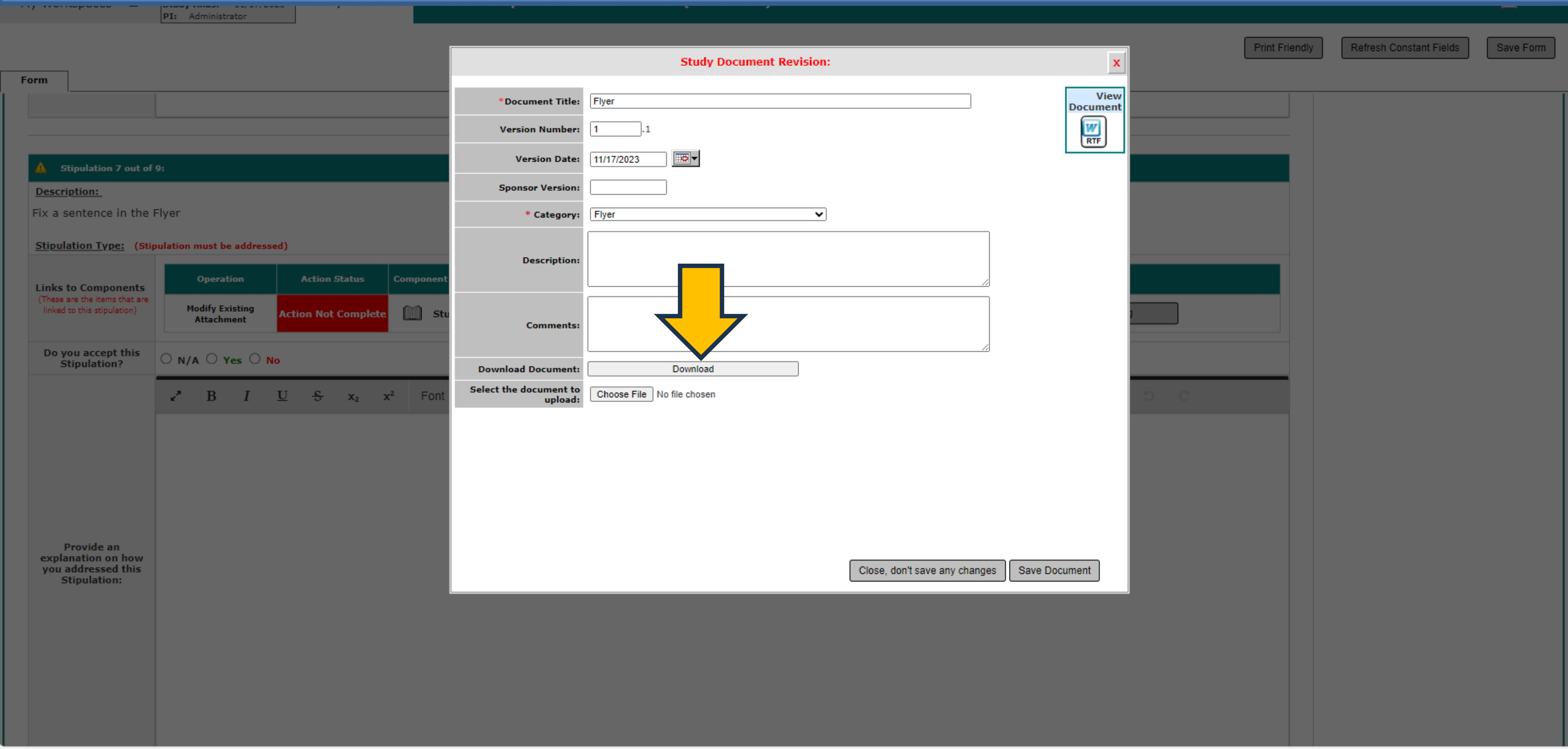
If this is the first time you're making a change, you will have a "Revise Existing" button. Click on "Revise Existing" to create a revision and make the requested changes (proceed to the next slide).

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.

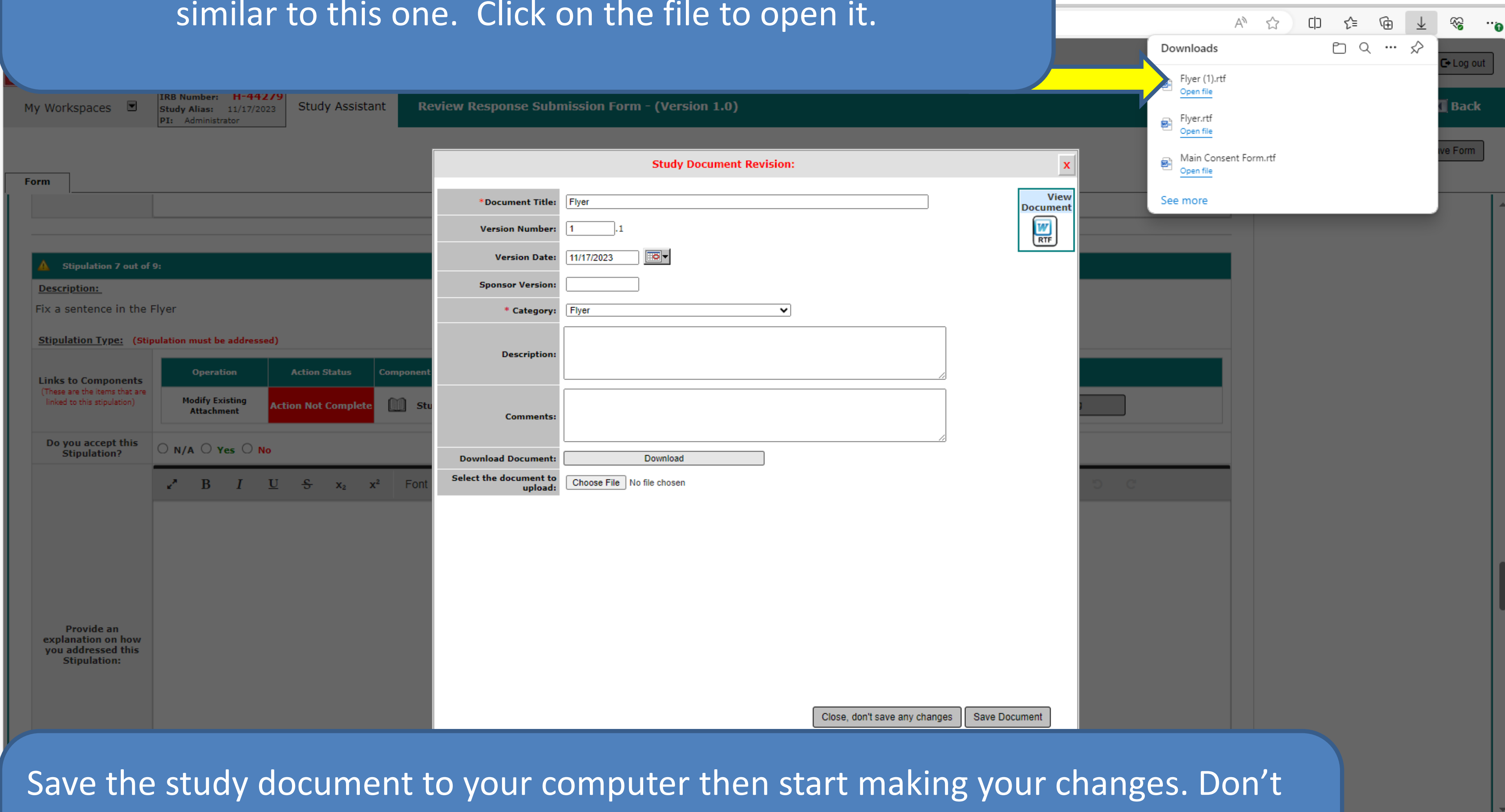

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home > find study > study mgmt.
Help
My Profile
Log out
My Workspaces
IRB Number: H-44279
Study Alias: 11/17/2023
PI: Administrator
Study Assistant
Review Response Submission Form - (Version 1.0)
Back
Print Friendly
Refresh Constant Fields
Save Form
Form
Stipulation 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 Name
Action
Modify Existing Attachment
Action Not Complete
Study Document Flyer (Version
Revise Existing
Do you accept this Stipulation?
N/A
Yes
No
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 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 <u>slide # 40</u>.



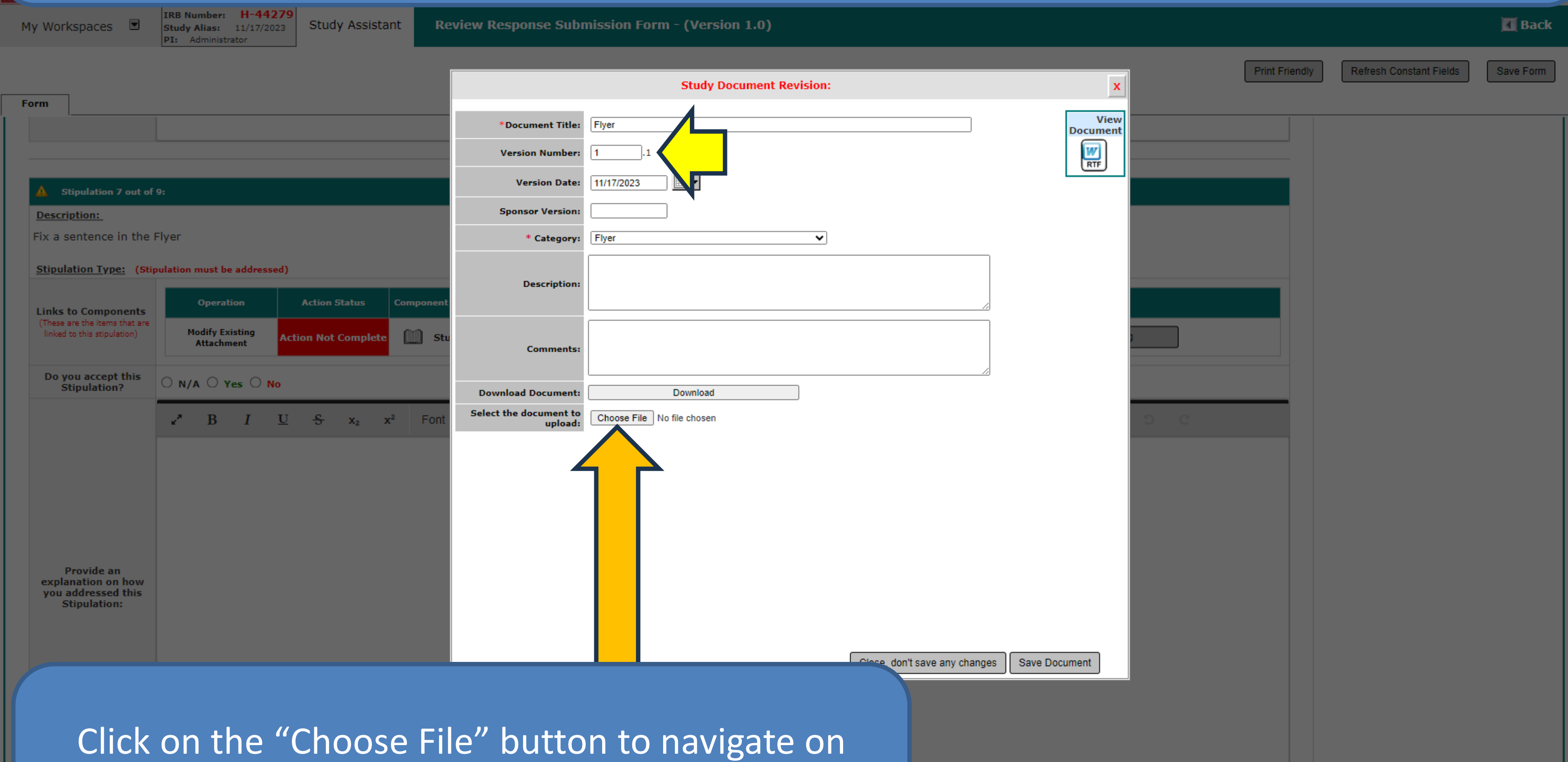
The selected study document will download. Depending on your system and web browser, you will get the "Downloads" popup similar to this one. Click on the file to open it.



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.

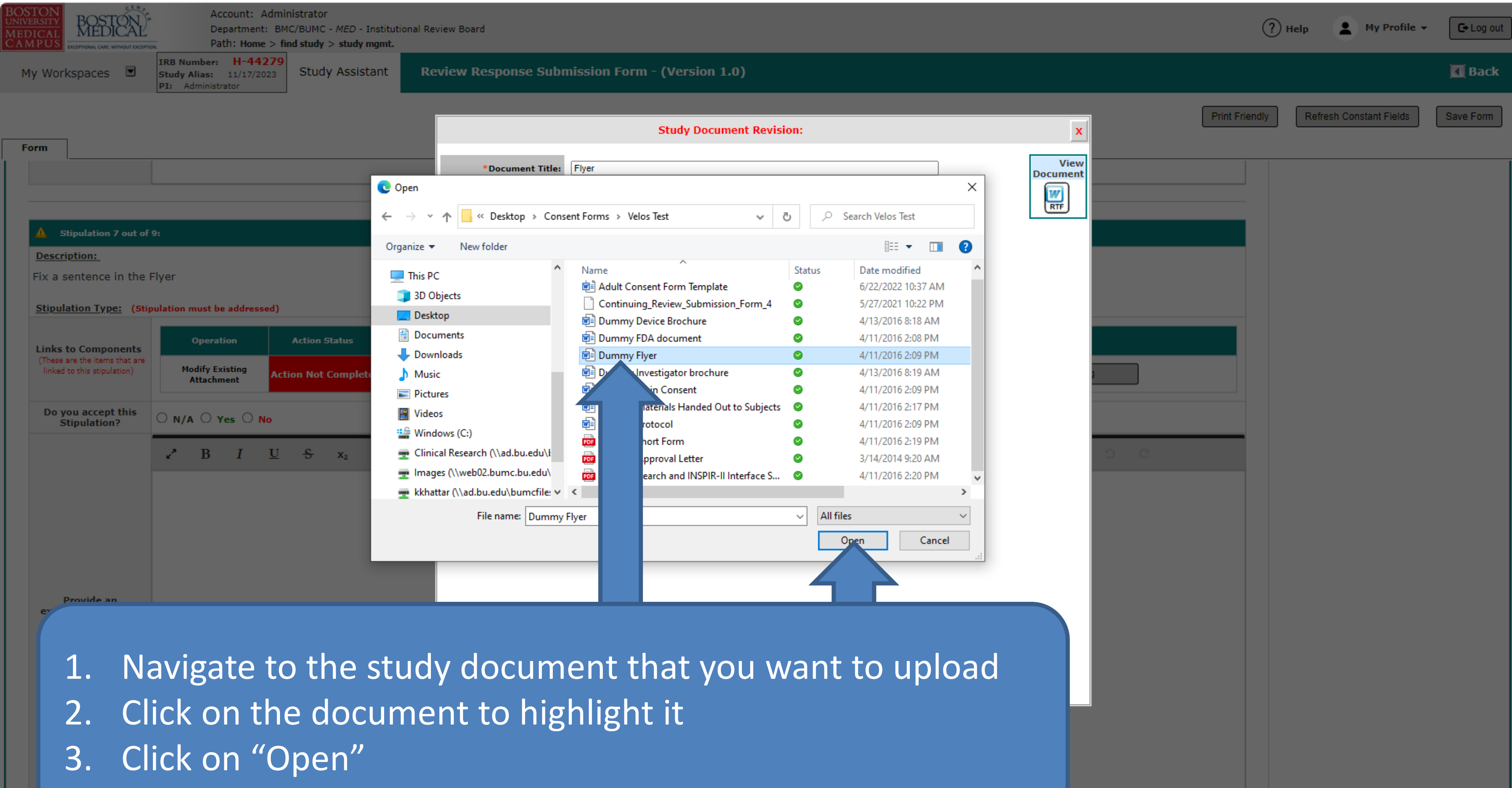
Notice that this revised study document will now be given a new Version Number (the system will increment the version number by + .1) (yellow arrow)

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



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.

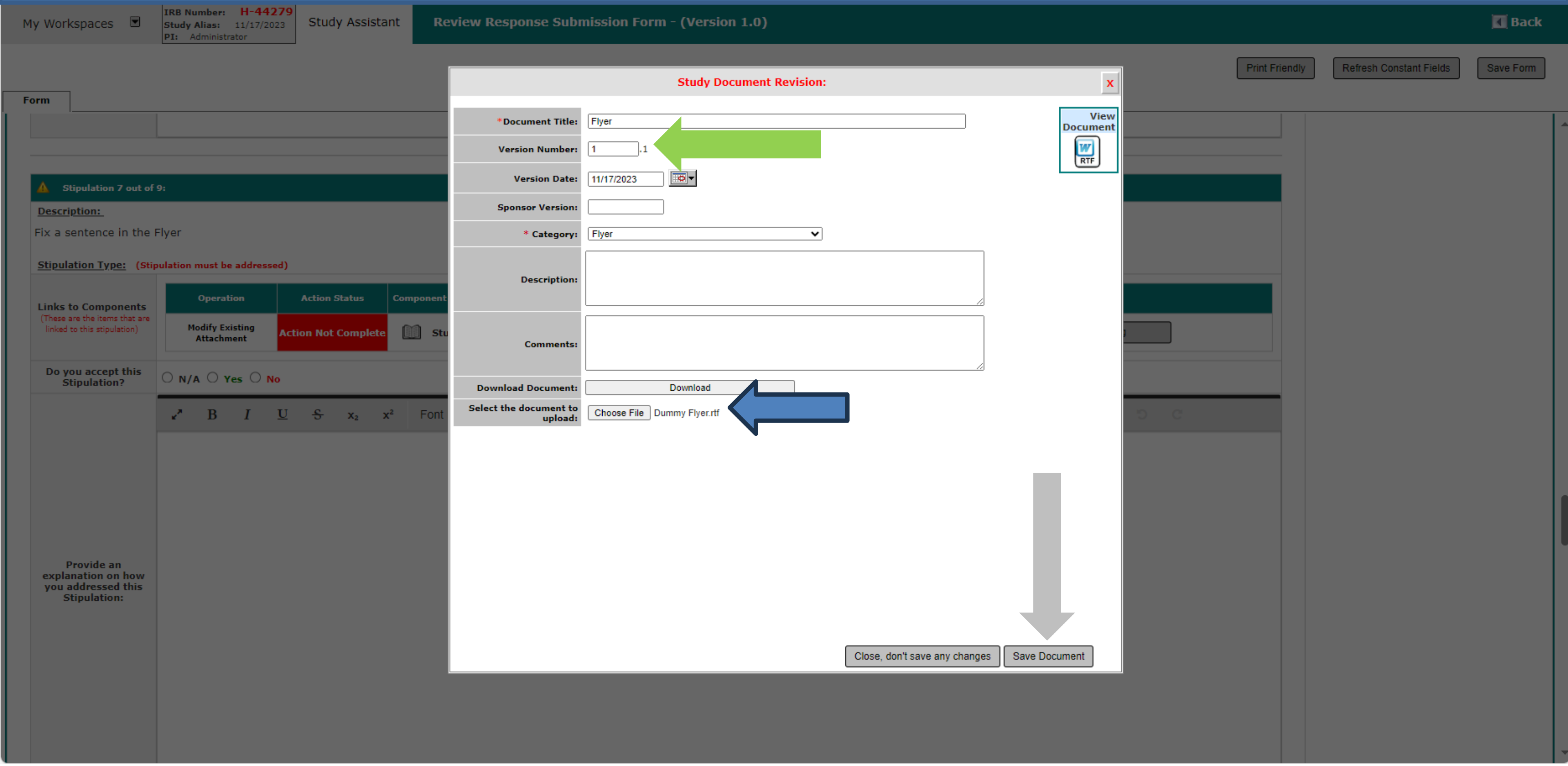


1. Navigate to the study document that you want to upload
2. Click on the document to highlight it
3. Click on “Open”

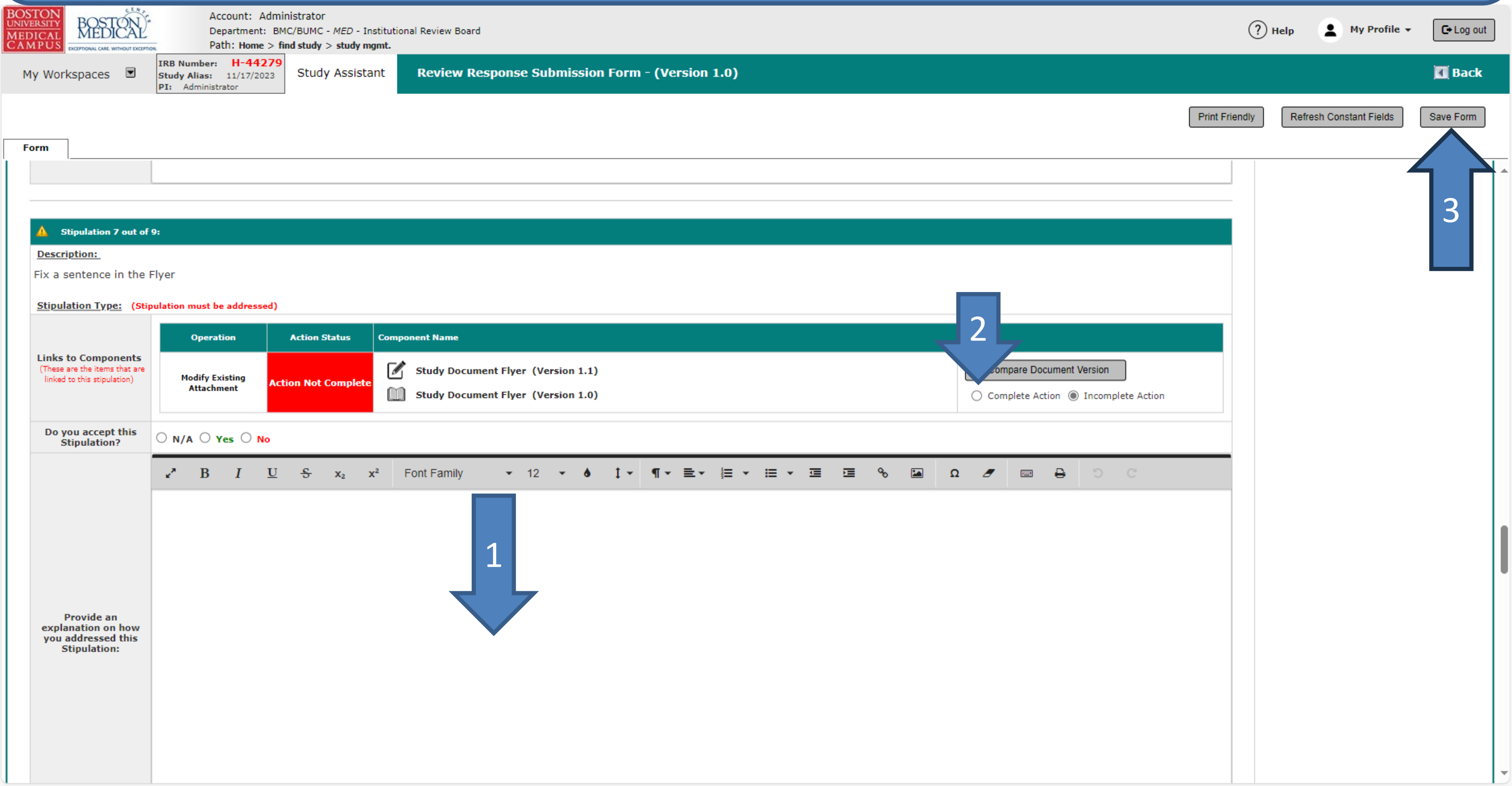
This will bring you back to the “Study Document Revision:” popup.

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

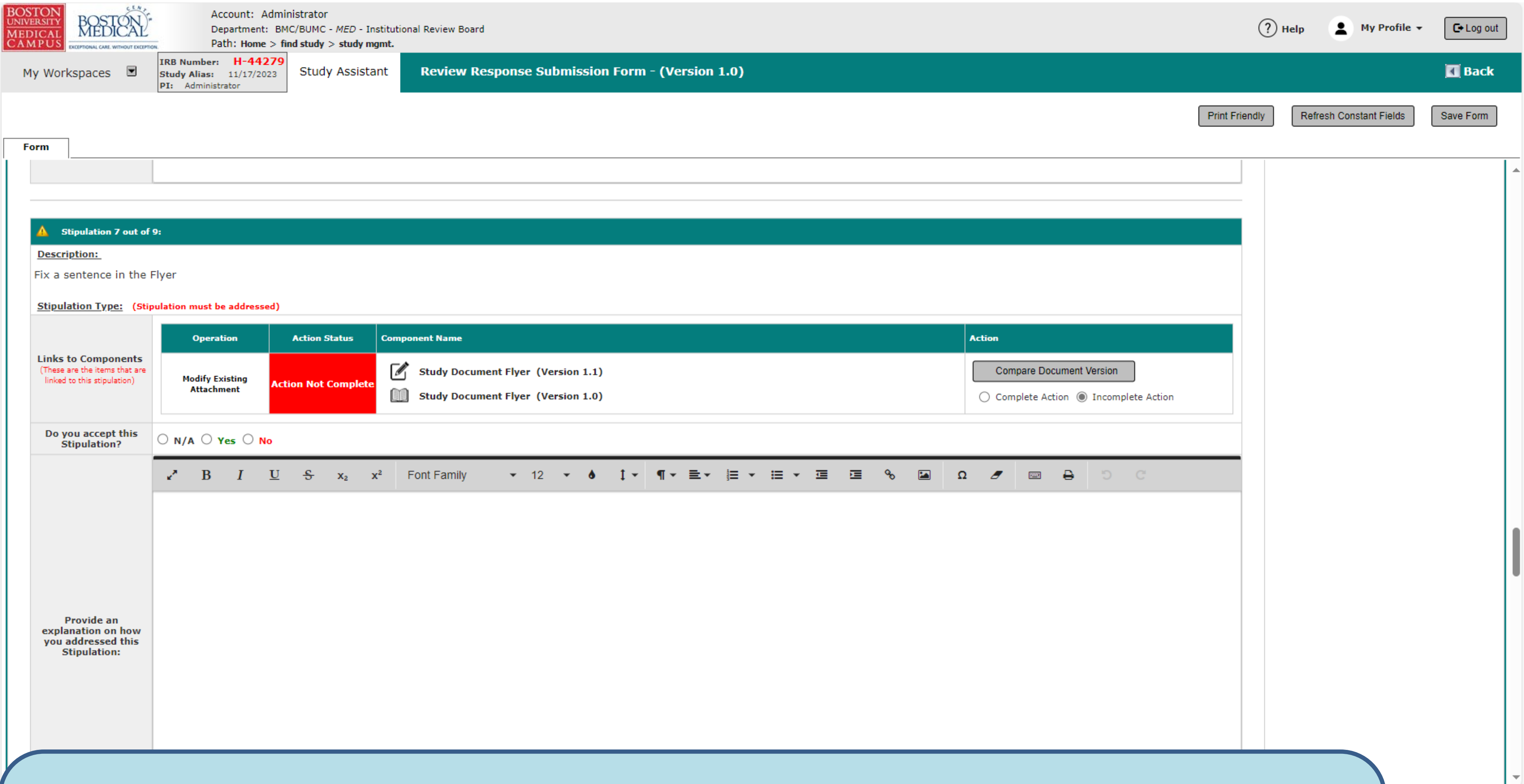
1. Change the “Version Date” to today’s date (green arrow)
2. Click on the “Save Document” button (Grey arrow)



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



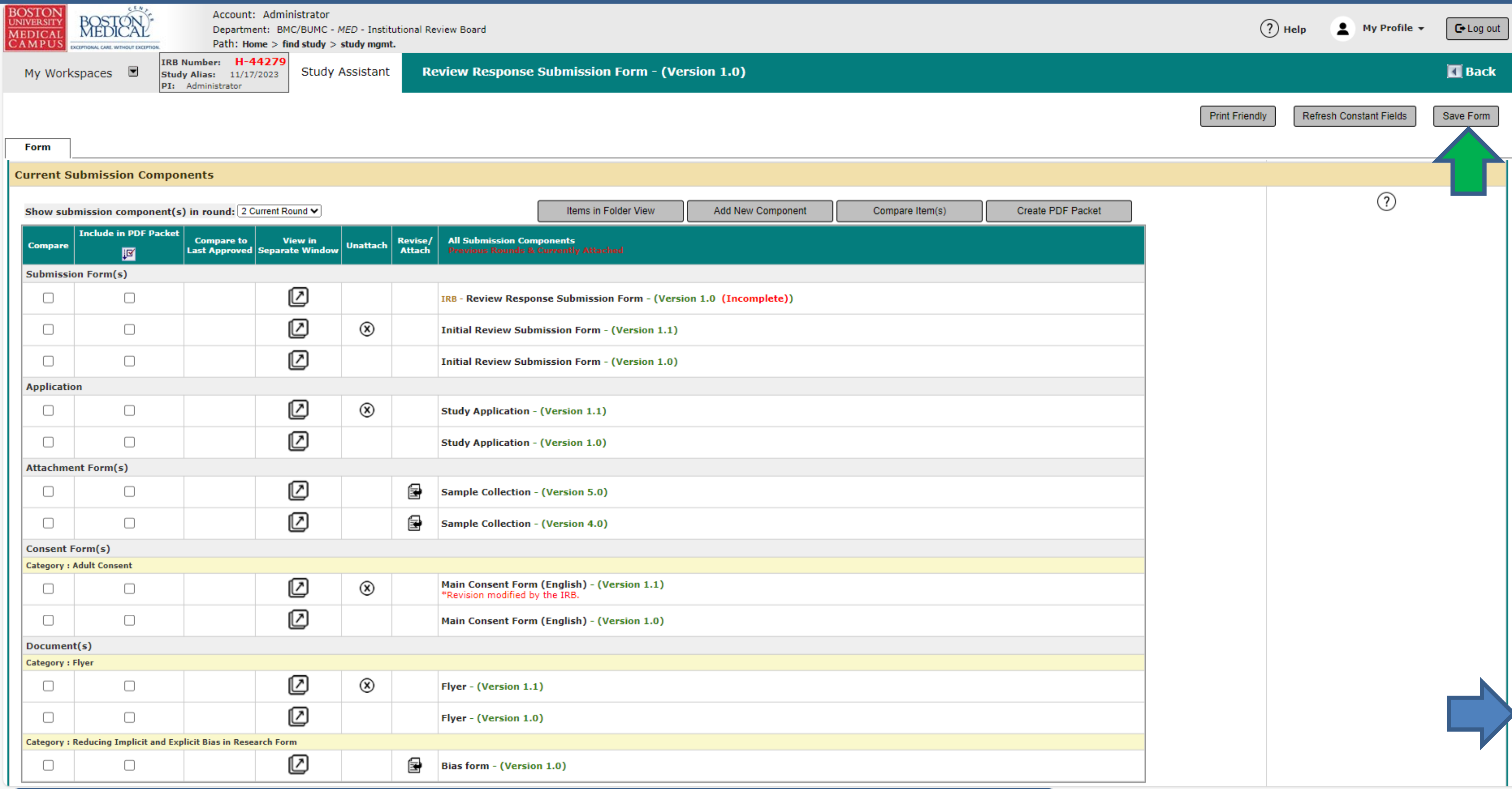
If you have more stipulations with links to a study document, repeat slides # 35 – 44.



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

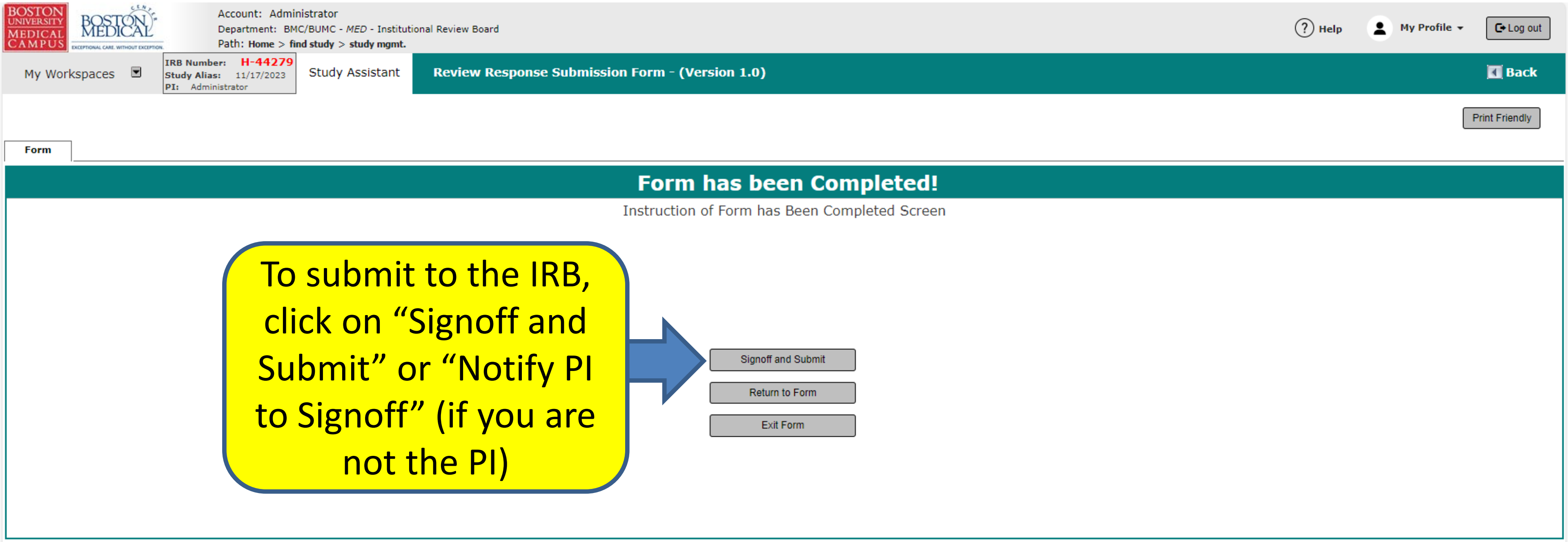
How to submit the “Review Response Submission Form” to the IRB

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.



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.



- Clicking on “Signoff and Submit” or “Notify PI to Signoff” (if you are not the PI), will rout 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.