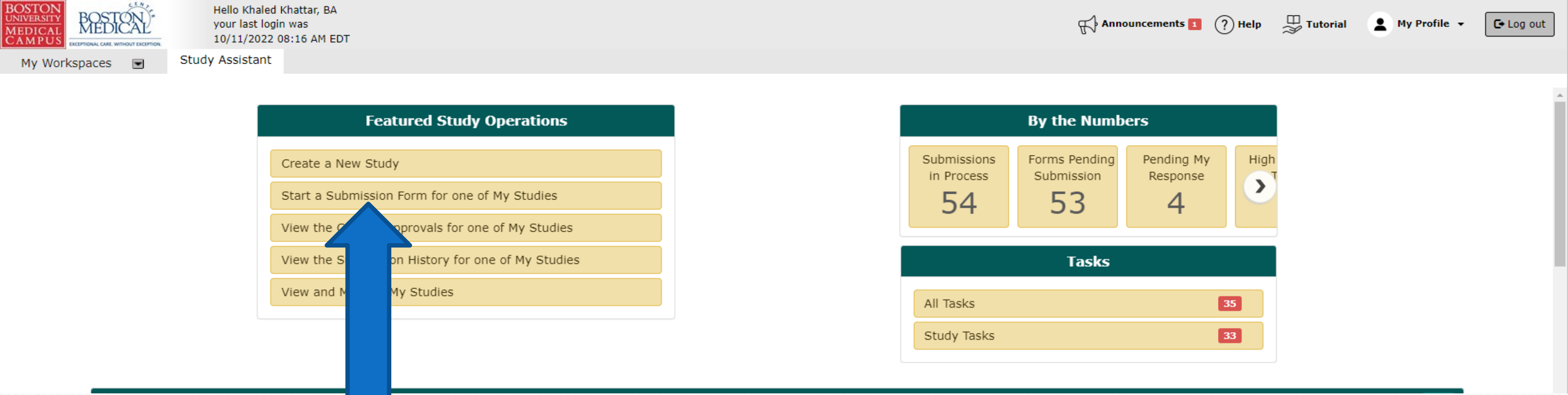
# Adding/Removing Internal Investigators from an Already Approved Study (Section 3.0)

# Internal Investigators

- These are BU/BMC faculty, staff, or students
- Boston Public Health Commission and Boston Healthnet Community Health Center investigators are also considered “internal” investigators for BUMC IRB studies
- To be listed, all internal investigators and study staff MUST have a BU or a BMC username and password and had previously logged in to INSPIR (at least once).
- Investigators from other institutions are not considered Internal Investigators. They need to be added to your approved study as External Investigators in the Study Application, by submitting a “Change Request and Amendments” form instead of this form.

# Internal Investigators

- An "Internal Study Personnel Change Form" can be submitted to add/remove internal investigators from Section 3 at any time.
- An "Internal Study Personnel Change Form" can be submitted
  - While another "Internal Study Personnel Change Form" is pending
  - While another "Change Request and Amendments" form is pending
  - While a "Continuing Review" form (Progress Report) is pending
- An "Internal Study Personnel Change Form" cannot be used to add External Investigators – a standard amendment called "Change Request and Amendments Form" must be submitted
- The addition/removal of an internal personnel occurs once the IRB approves the "Internal Study Personnel Change Form", and not before.

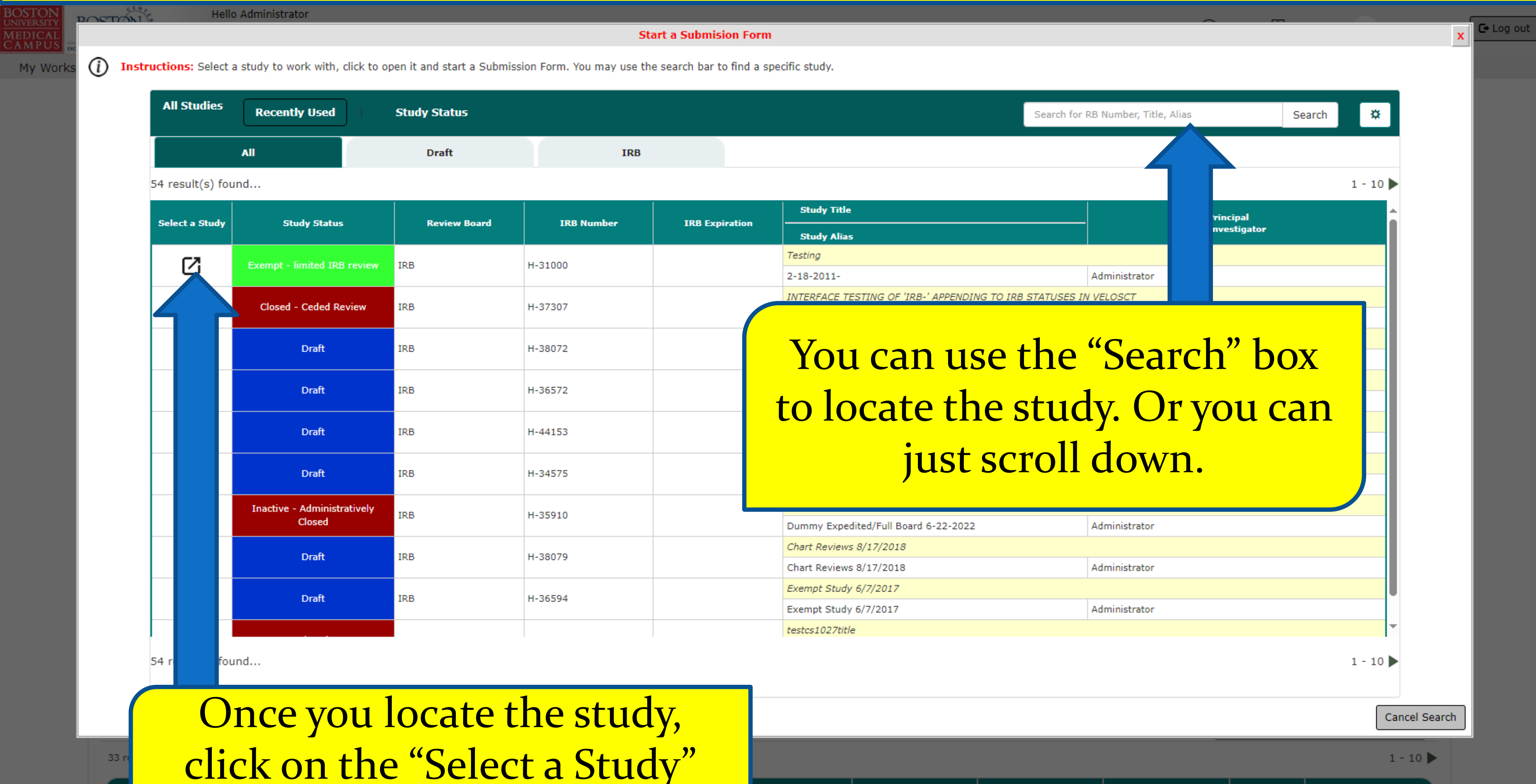



When you login into INSPIR II (https://inspir.bu.edu/), you will get to this page. This is your Home page

Click on “**Start a Submission Form for one of My Studies**”

# This opens the “Start a Submission Form” pop-up page.

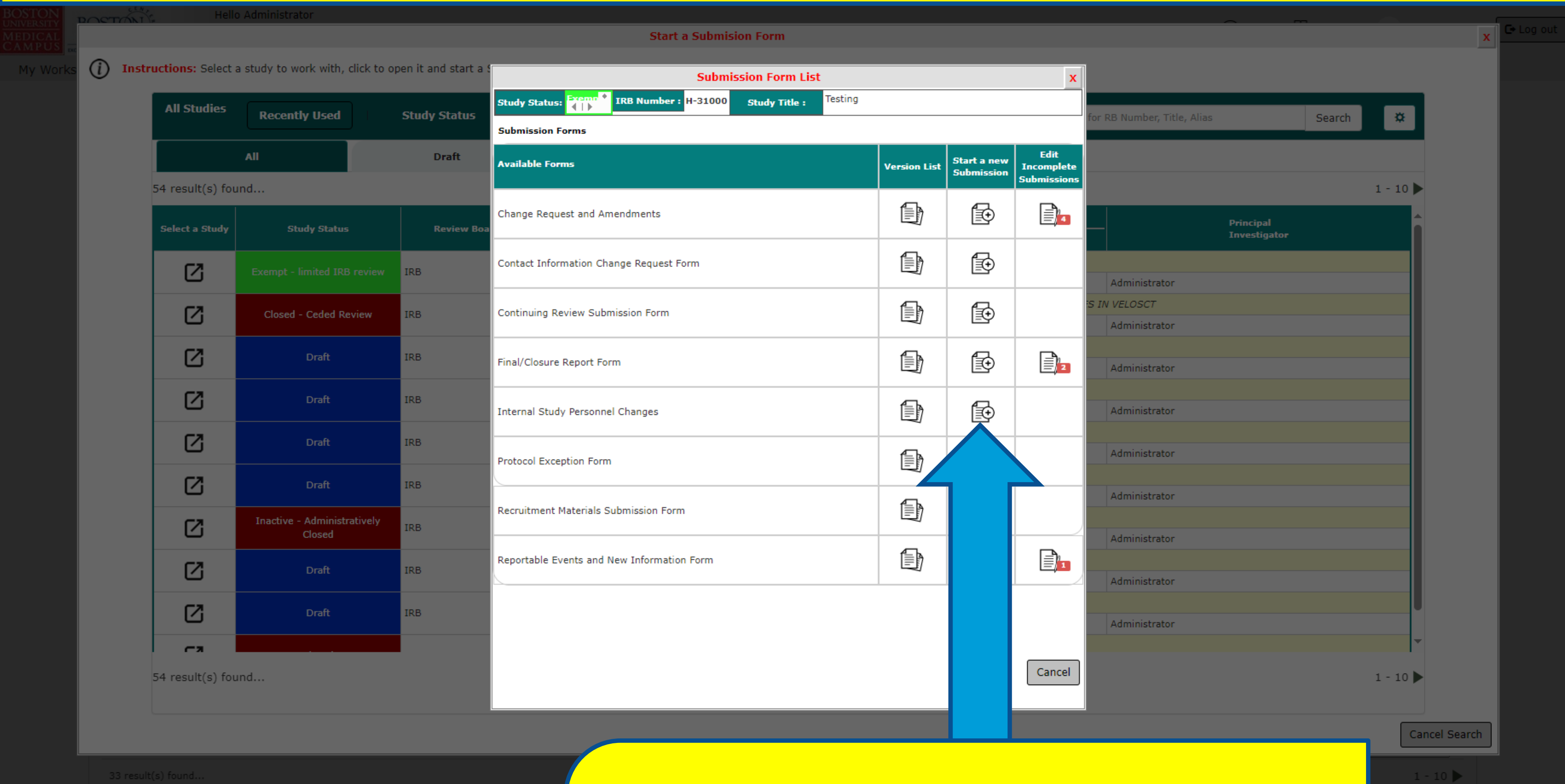
- **Locate the study that you want to add/remove personnel.**




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

Once you locate the study, click on the “Select a Study” icon

# This opens the "Submission form List" popup.




**Click on "Start a New Submission" icon that corresponds to the "Internal Study Personnel Changes"**- blue arrow

This opens a new "Internal Study Personnel Changes" form and will bring you to the Amendment information page. In section 1.2 describe the changes requested (e.g. We want to add Dr. Jane Doe as a Co-Investigator)
Then scroll down to complete the next section (1.3) of the form. (yellow arrow)

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

Internal Study Personnel Changes ion 5.0)

Back

Print Friendly | Refresh Constant Fields | Save Section | Save and Continue to Next Section

Section view of the Form | Entire view of the Form

1.0 Amendment Information

1.2 Amendment for KSP changes only

*All investigators engaged in human su earch, including supervising principal investigators, co-investigators, participating clinicians and research st application, they must be in complianc e [requirements](#) for training in human subjects and Good Clinical Practices (if applicable), and they must have completed the financial interest disclosure forms and submitte o the appropriate office for Boston Medical Center or Boston University.*

*Use the Study Contacts section to desi study personnel in addition to the Principal Investigator who need to receive email notifications. If the Principal Investigator is a student, resident, or fellow, the Super ncipal Investigator must be listed in the Study Contacts section.*

*If you ONLY need to add an administra stant (i.e., an individual who has no contact with subjects or identifiable data but needs to access your INSPIR application), you do not need to submit this form. Instead, see www.bumc.bu.edu/irb/files/2016/10/How-to-add-Administrative-Assistant.pdf.*

Briefly describe below the requested c the "3.0 Grant key study personnel (KSP) access to the study" section of the application. Make sure you list the names and roles of ALL personnel to be added or removed s section. (Don't forget to add/remove them appropriately in the next section 1.6) These changes will only take effect if and when the IRB administratively approves this ame

See the [IRB policy](#) for detailed instru dd BU-CRC Students, Faculty and Employees.

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1. Replacing the study PI
2. Replacing the study Supervising PI
3. Adding new personnel to the study
4. Removing existing personnel from the study
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***Please note:*** *This form can only be used to add/delete personnel to the KSP section (Section 3.0) of the application. To add non-BMC/BU investigators to the study, or to make any other changes to the study, you will need to submit the "Change Request & Amendments" form instead.*

In section 1.3, check the box(es) for one or more options:

- To replace the current PI with someone else, check "Changing Principal Investigator" box.
- To replace the Supervising PI with someone else, check the "Changing Supervising Principal Investigator (formerly known as Faculty Sponsor)" box.
- To add new study personnel (other than the PI or Supervising PI), check the "Adding study personnel" box.
- To remove an existing study personnel, check the "Removing study personnel" box.

**1.3 Type of personnel changes**

**Please indicate the type of change (choose all that apply):**

☐ Changing Principal Investigator

☐ Changing Supervising Principal Investigator (formerly known as Faculty Sponsor)

☐ Adding study personnel

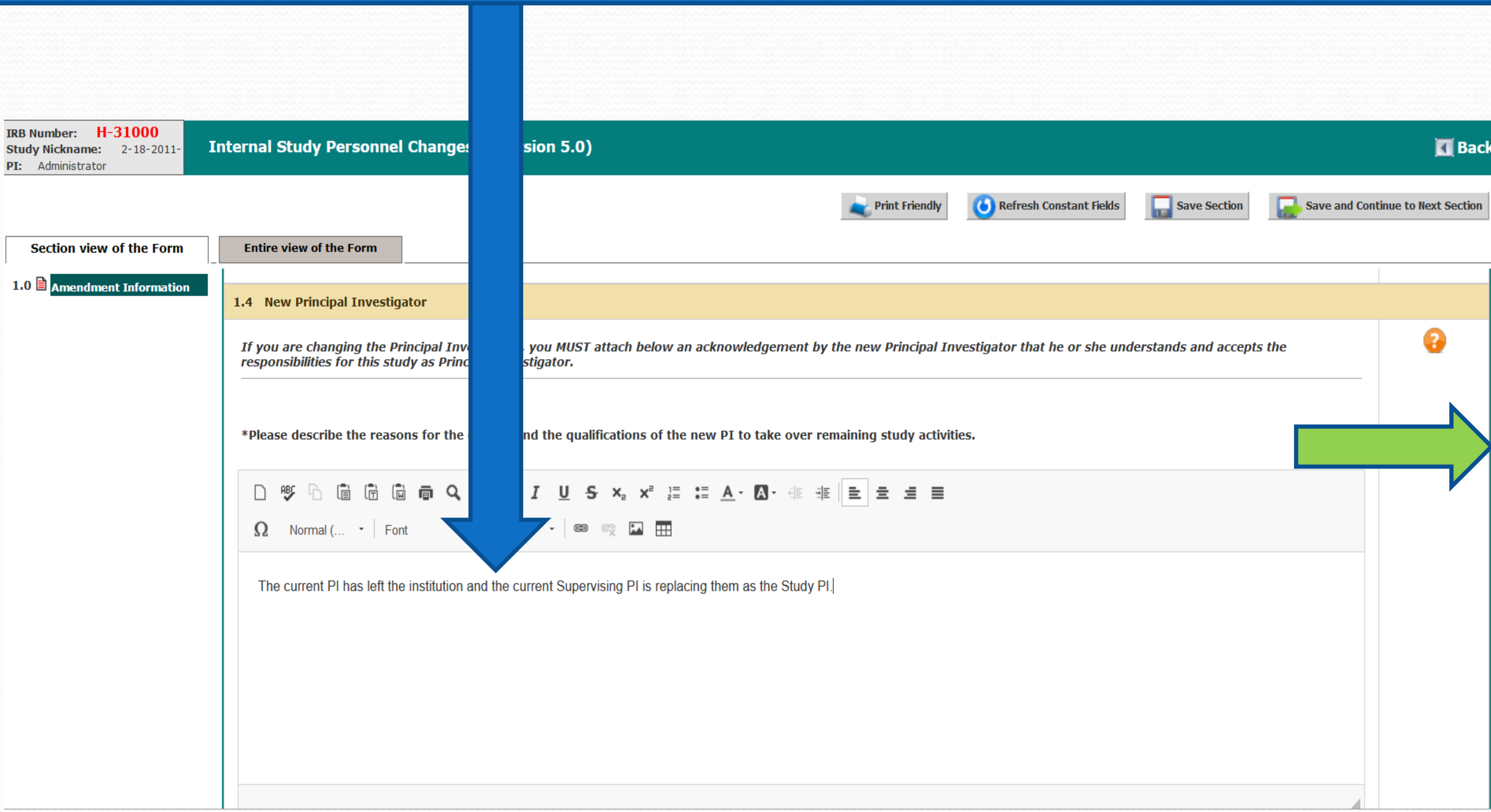
☐ Removing study personnel

Depending on what boxes you have checked, the corresponding section will appear in this form to be completed. Scroll down in the form to address the next section.

Note: If you did not check the "Changing Principal Investigator" box in section 1.3 of the form, skip the next instructions to slide # 22.

# Changing Principal Investigator

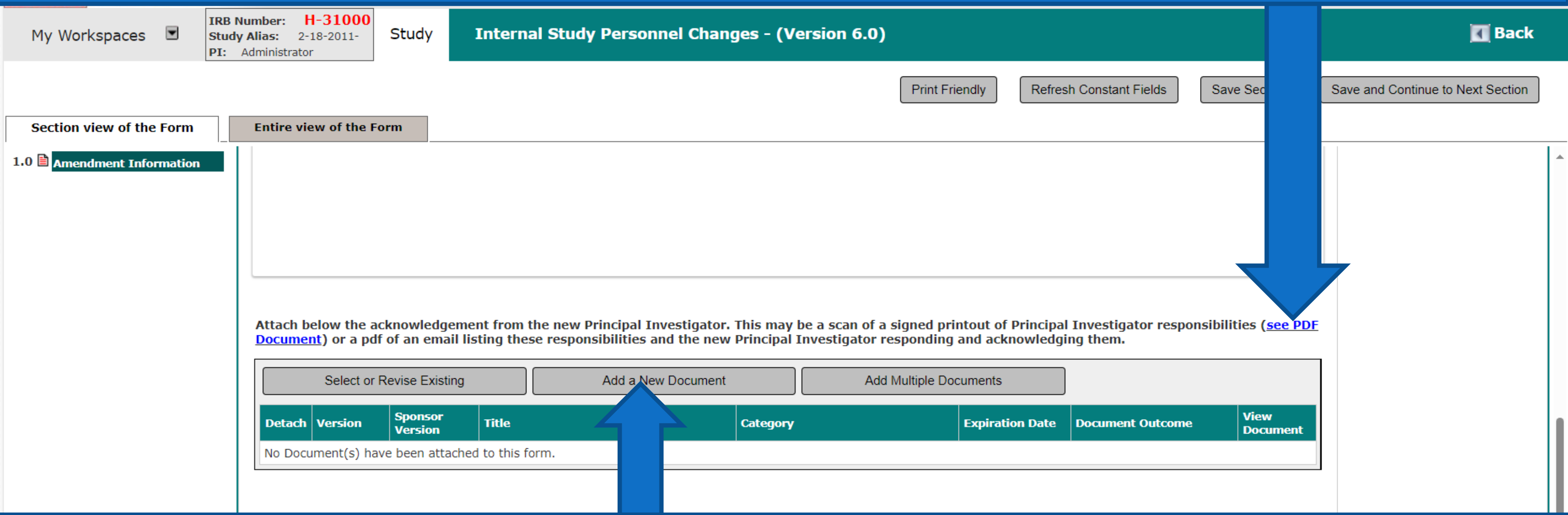
In section 1.4, describe the reason for the requested PI change (blue arrow). Then scroll down. (green arrow)



Next, you need to download the "Principal Investigator Responsibilities" document, have the new PI sign it, and attach it to this submission:

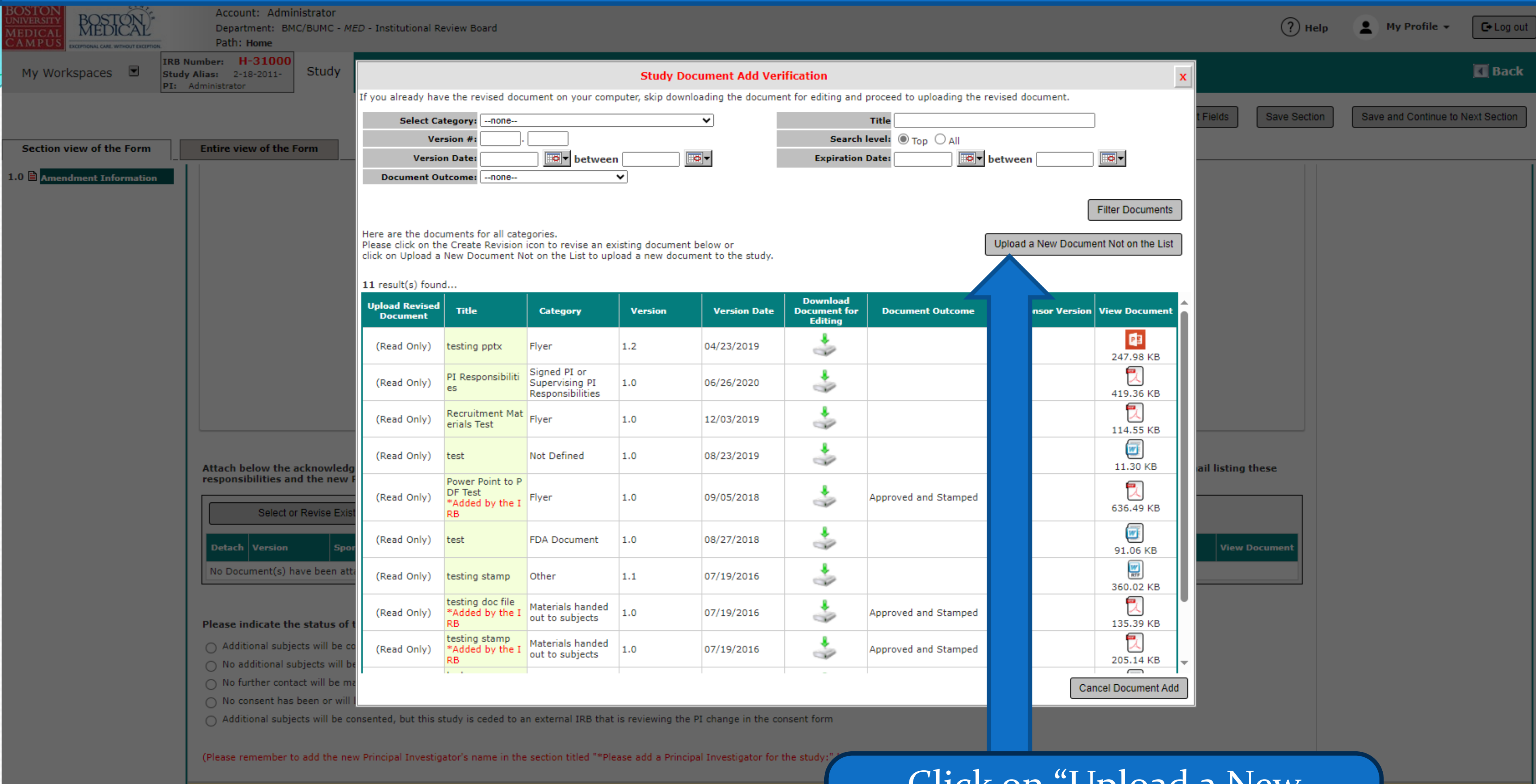
1. Click on "see PDF Document" link to open this document.
2. Save the document to your Desktop
3. If you have Adobe, the new PI can e-sign it and save it again to your Desktop. If you don't have Adobe, you can print it out, have the new PI sign the printout, and then scan the signed document and save it to your Desktop.

Alternatively, you can use a PDF of an email listing these responsibilities and the new Principal Investigator responding and acknowledging them.



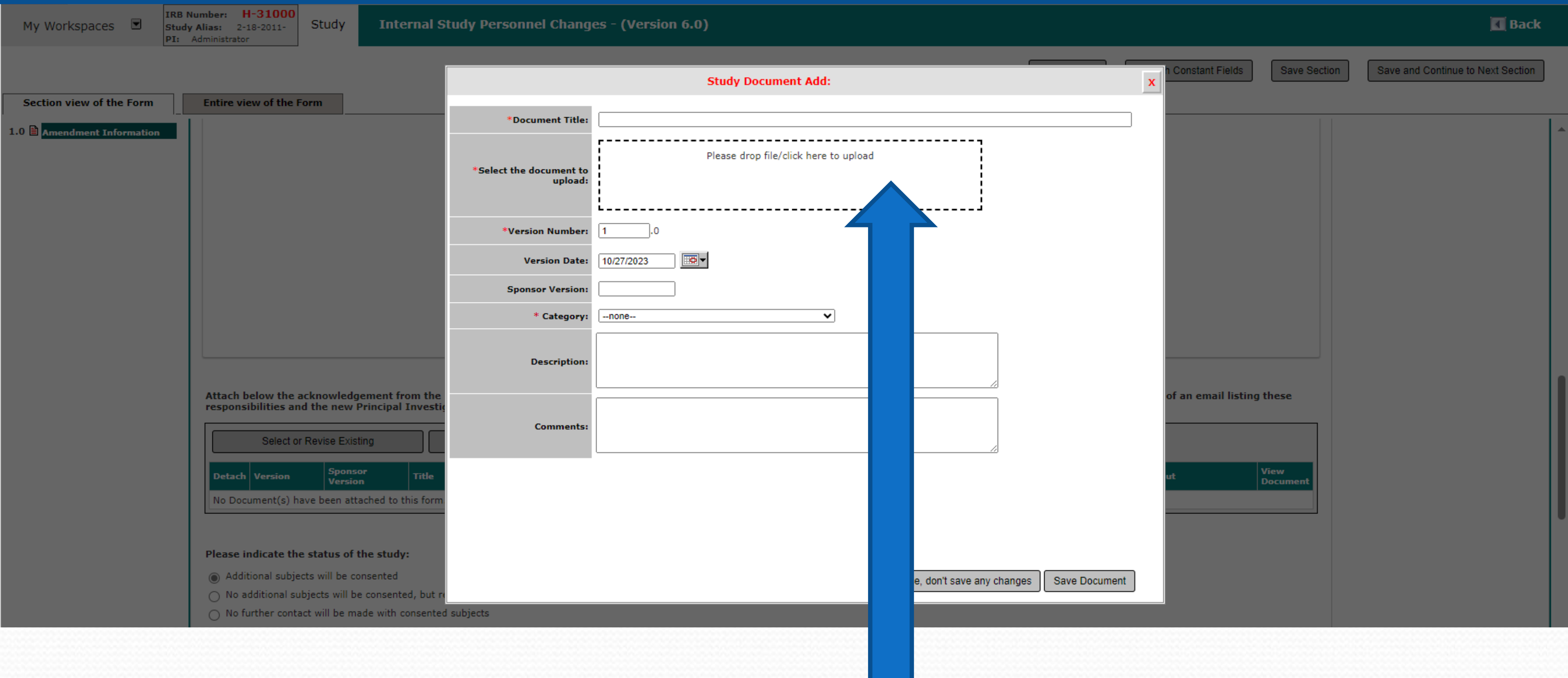

Once you have a signed "Principal Investigator Responsibilities" document saved on your Desktop, click on "Add a New Document" to attach it to this submission.

# This opens the “Study Document Add Verification” pop-up.




Click on “Upload a New Document Not on the List” button

# This opens the “Study Document Add” pop-up.

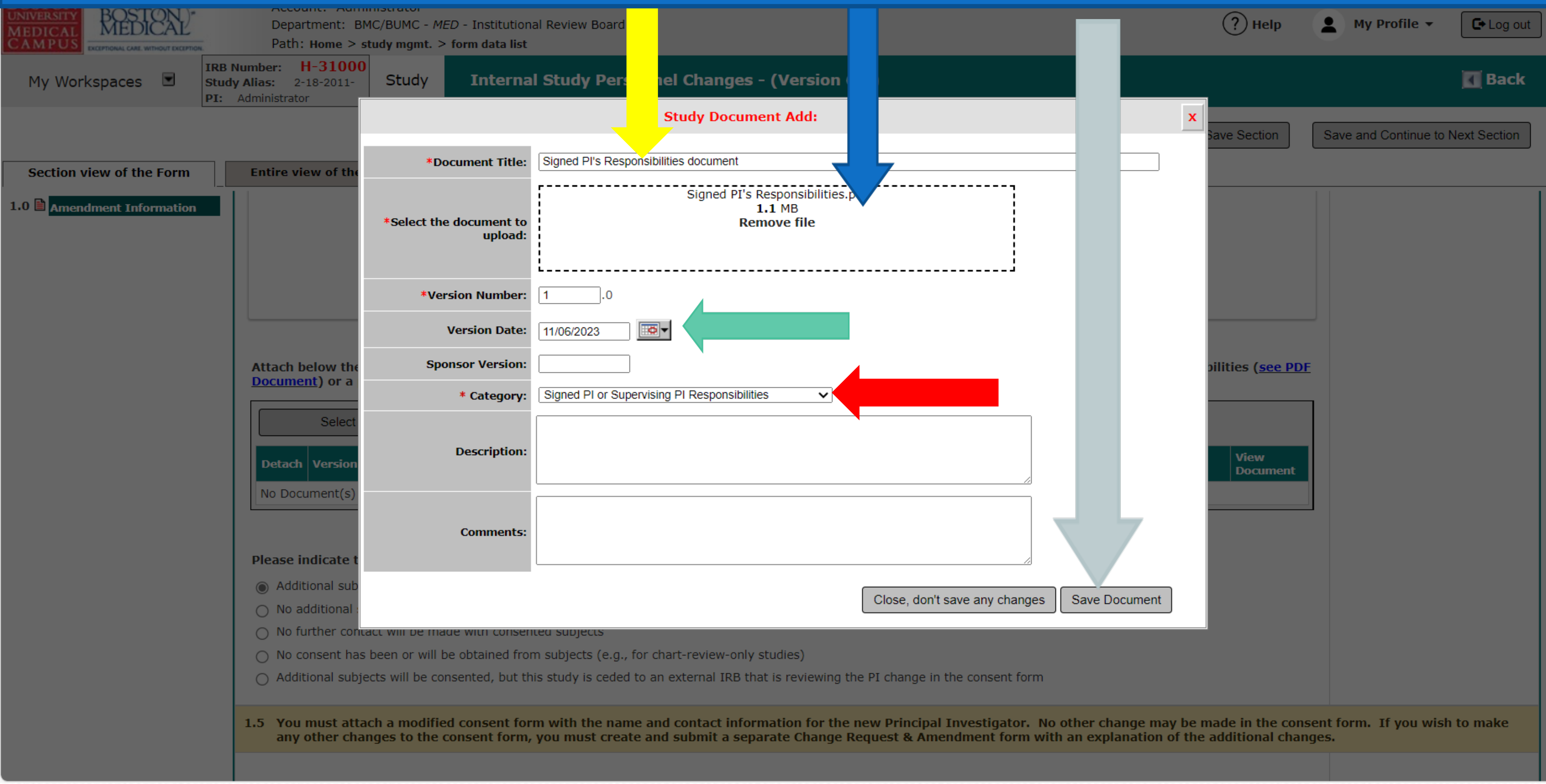



Drag and drop the signed “Principal Investigator Responsibilities” document in the “Select the Document to upload” box; or click inside this box and follow your system’s prompts to navigate to where you saved the document to upload it.

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

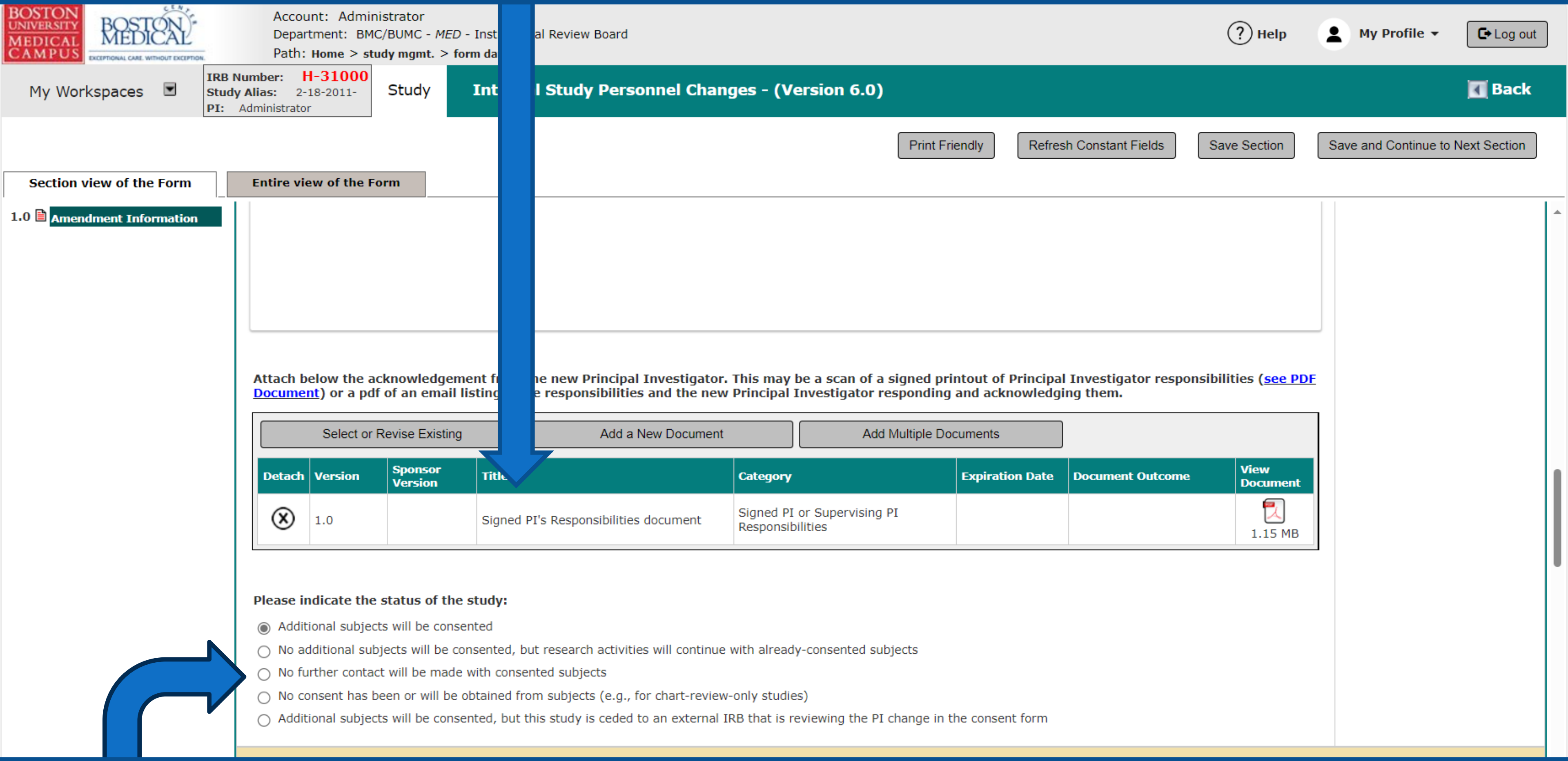
- Notice the uploaded document’s name is now appearing in the popup (blue arrow)

1. Type in a meaningful document title (yellow arrow)
2. Change the “Version Date” to today’s date (green arrow)
3. Select “Signed PI or Supervising PI Responsibilies” for the “Category” (red arrow)
4. Click on the “Save Document” button (Grey arrow)



This will bring you back to the "Internal Study Personnel Change Form".

- Notice that the PI Responsibilities document is now appearing in this form.

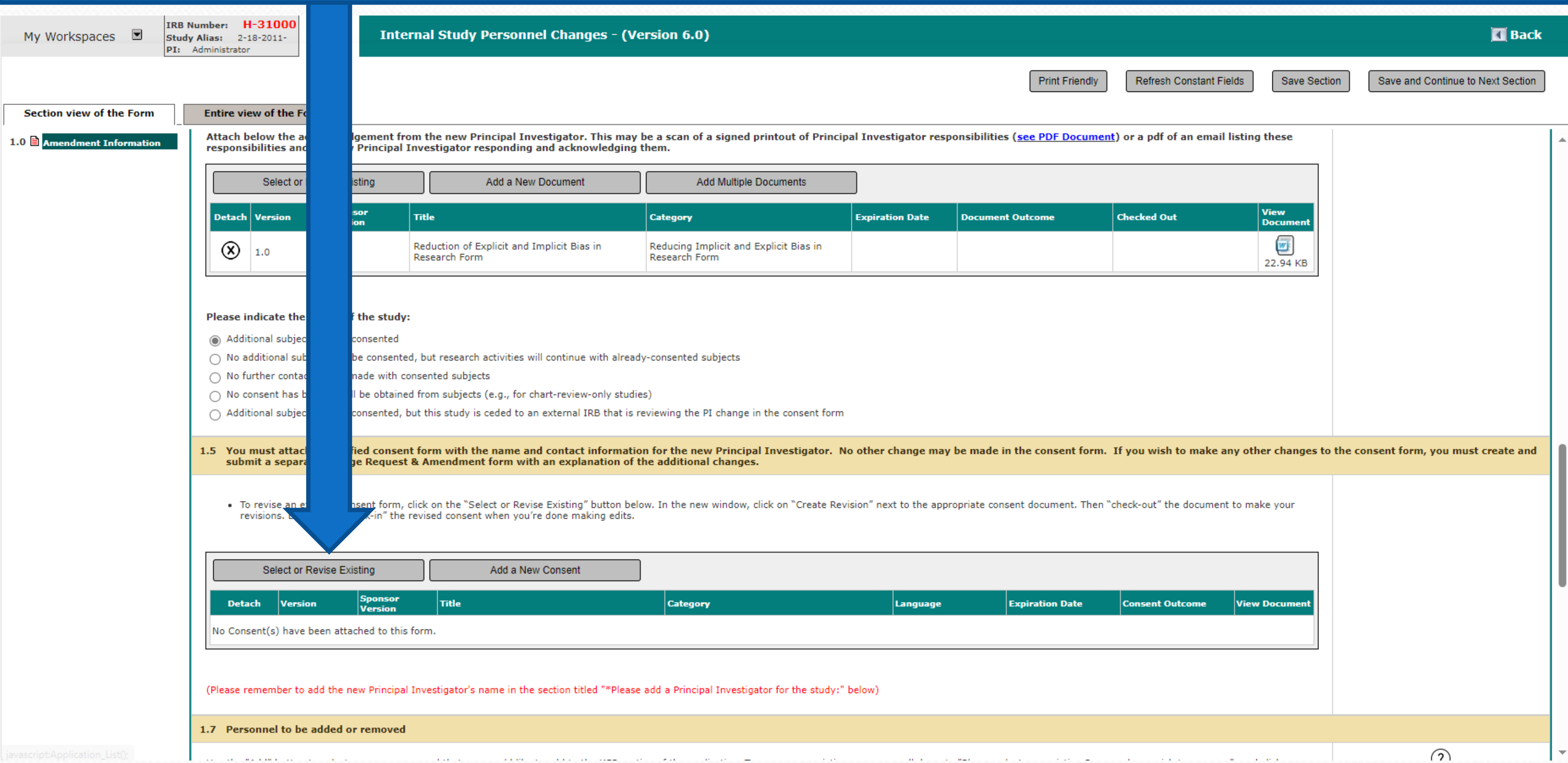



Next, you need to select one of the options under "Please indicate the status of the study".

- If you selected option 1, "Additional subjects will be consented", section 1.5 needs to be completed. Proceed to the next slide.
- If you selected any of the remaining four options (other than "Additional subjects will be consented"), skip the next instructions and go to slide # 22.

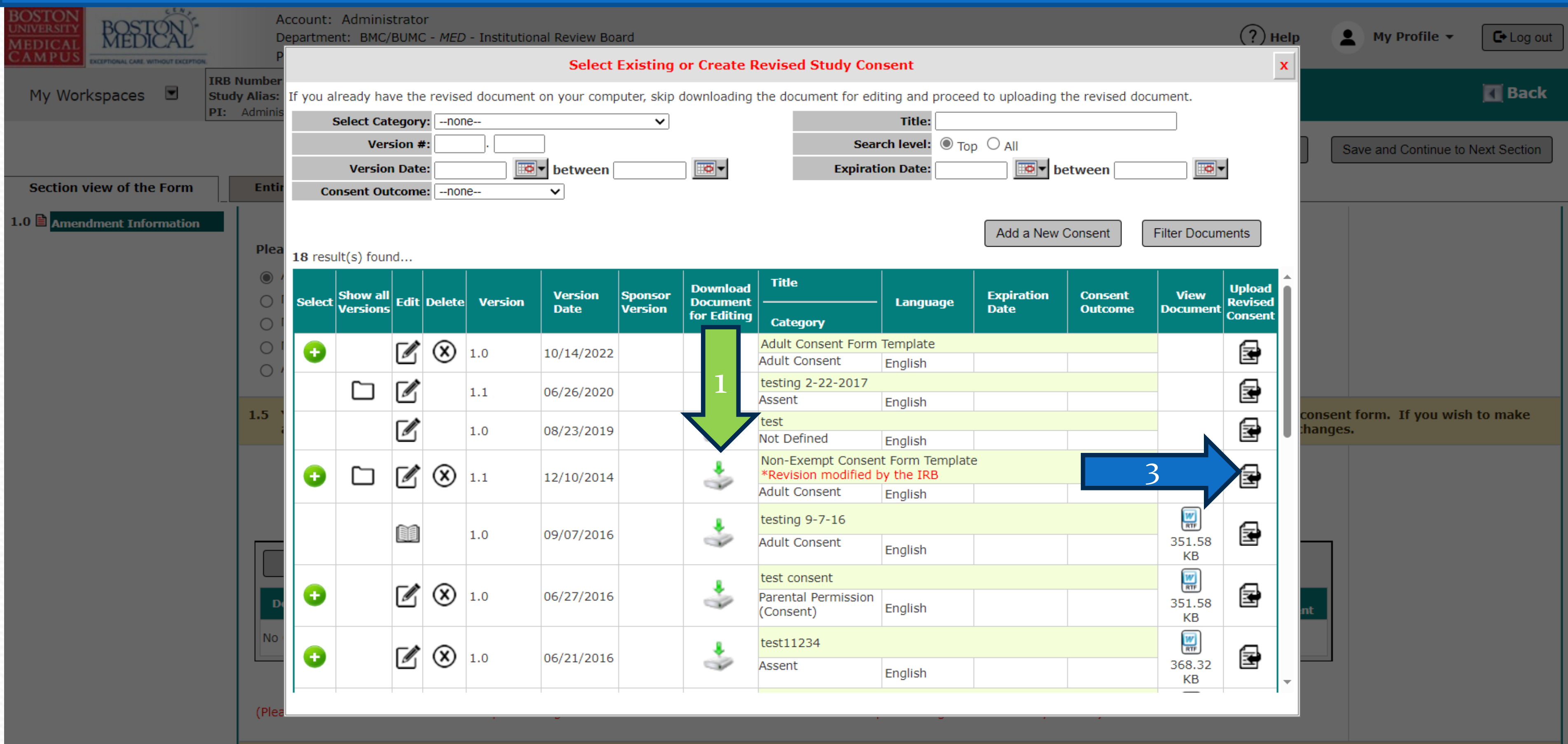
If you selected option 1, “Additional subjects will be consented”, section 1.5 will appear.

- In this section you need to revise any approved consent forms to include the new PI’s name and contact information. To revise a consent form, click on the “Select or Revise Existing” button. (blue arrow)



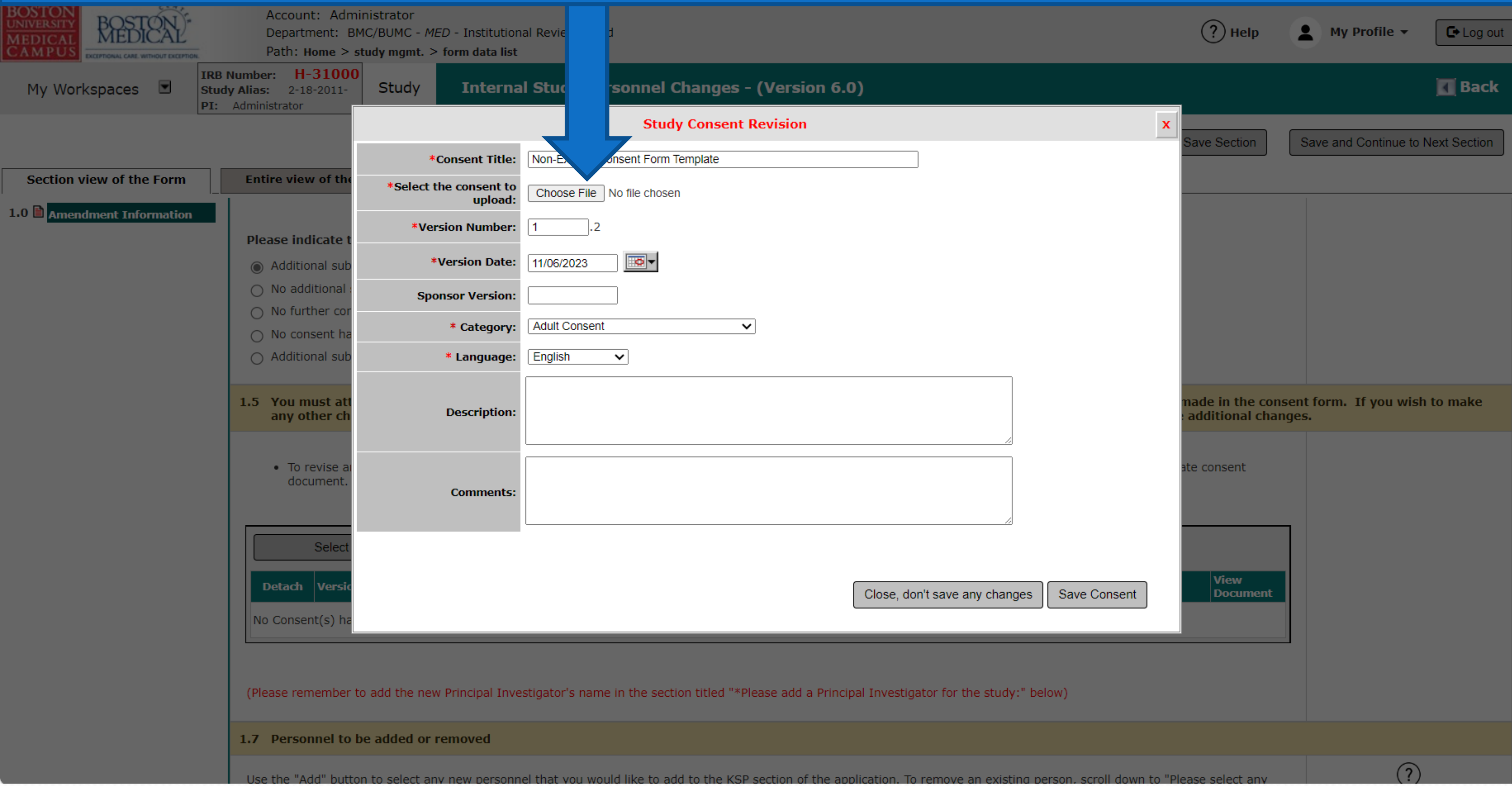
Clicking on the “Select or Revise Existing” button, will display a popup similar to the one shown below.

1. Scroll down and find the consent form that you want to revise, then click on the “Download document for Editing” icon that correspond to that consent form to download a copy for editing (green arrow).
2. Once you finish your edits to the consent form, save it on your desktop
3. Come back to this screen and click on “Upload Revised Consent” icon (blue arrow) that correspond to that consent form to upload your revised consent form



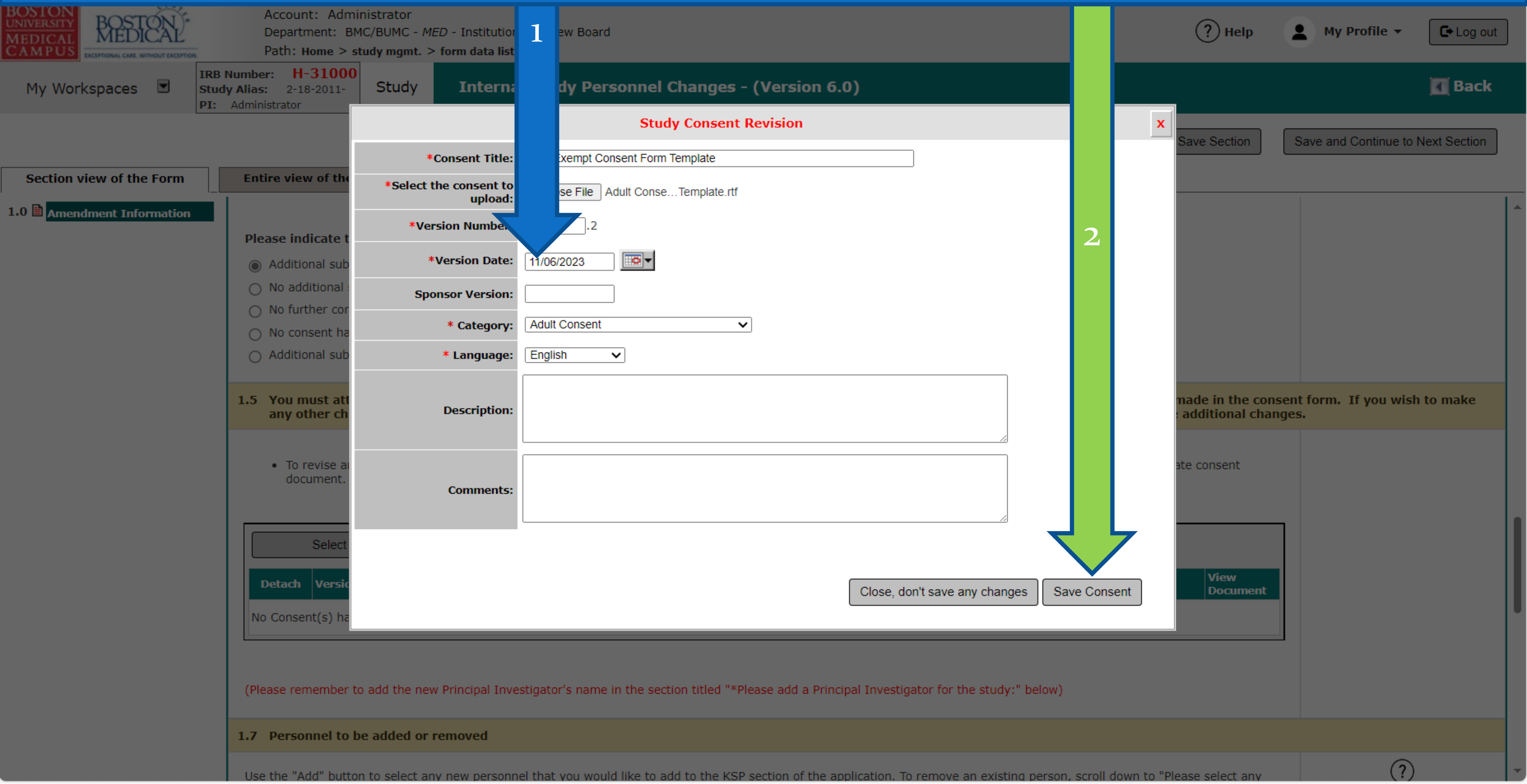
Clicking on the “Upload revised Consent” icon , will open the “Study Consent Revision” popup displaying the selected consent form cover sheet.

1. Click on the “Choose File” button to upload your revised copy of the consent form and follow your system’s prompts to navigate to where you saved the document to upload it.



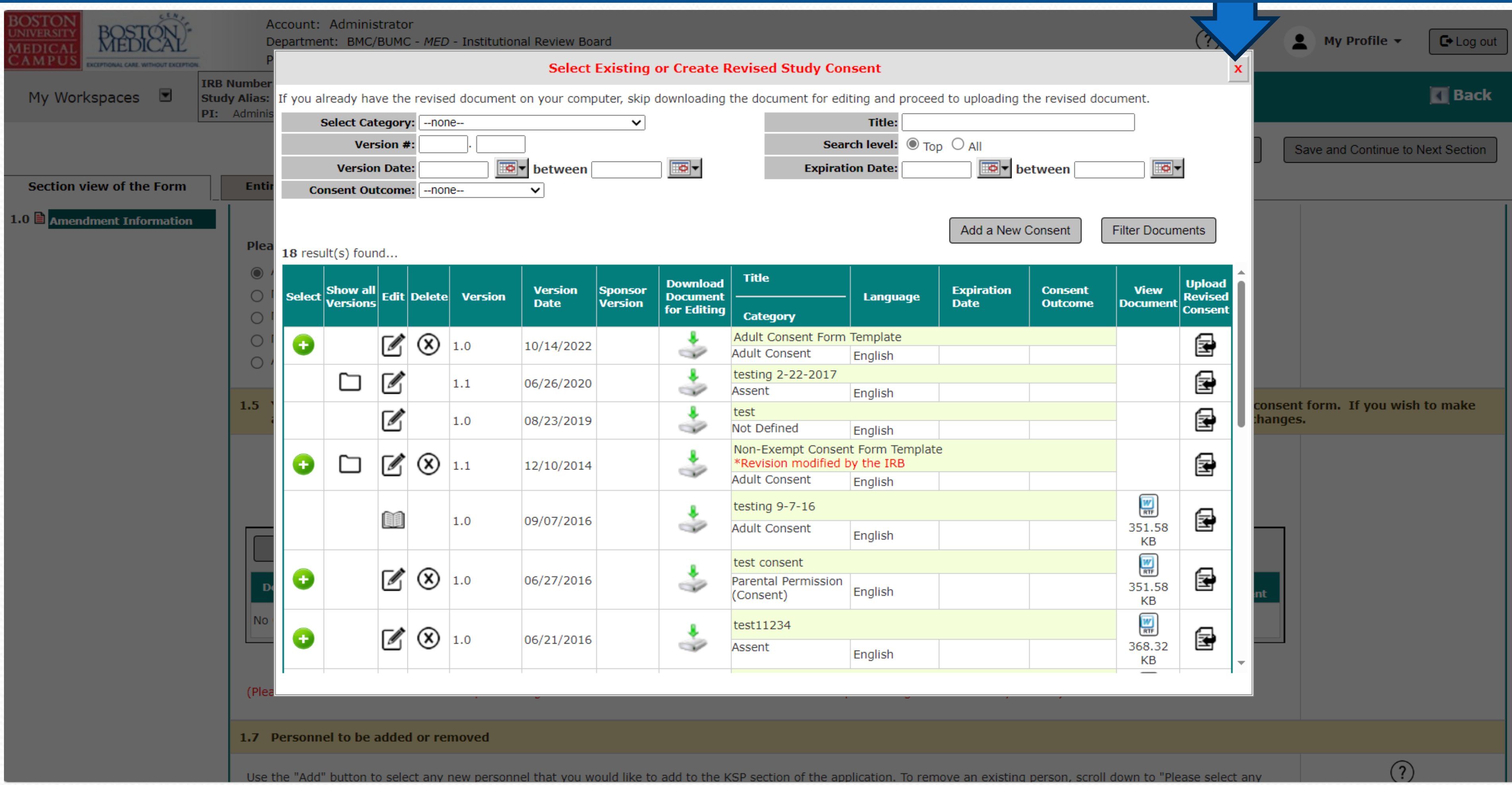
This will take you back to the "Study Consent Revision:" popup.

1. Change the Version Date to today's date (blue arrow) and change any other field in this screen, if needed.
2. Click on the "Save Consent" button (green arrow).



This will bring you back to the "Select Existing or Create Revised Study Consent" page.

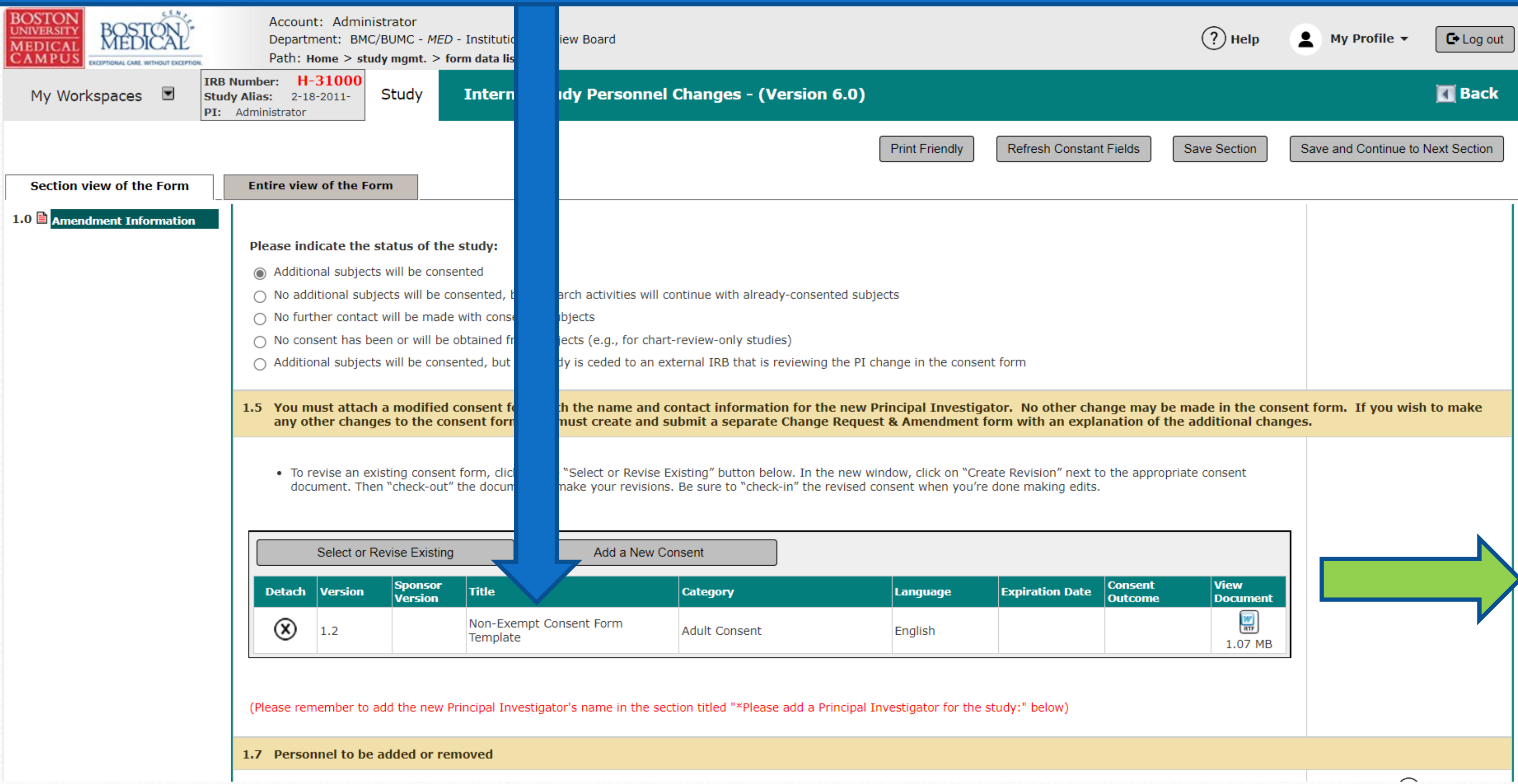
- If you have more consent forms that you need to revise and attach, repeat the instructions in slides 17-20.
- If you are done revising consent forms, then close this page (blue arrow)



This will take you back to the “Internal Study Personnel Changes” Form.

The revised consent form(s) should appear in the table in section 1.5 (blue arrow).

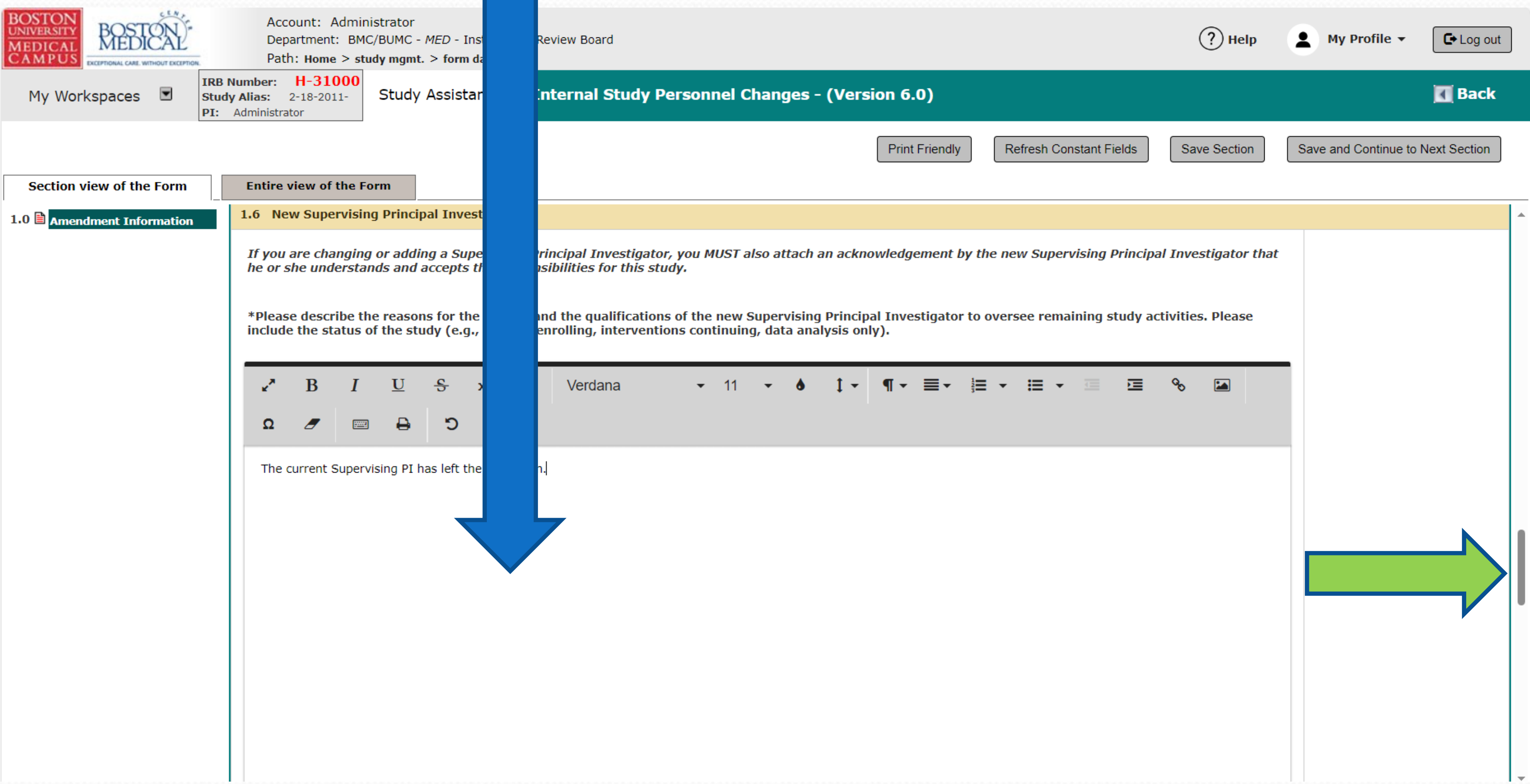
1- Scroll down to the next section (green arrow).



Note: If you did not check the "Changing Supervising Principal Investigator (formerly known as Faculty Sponsor)" box in section 1.3 of the form, skip the next instructions to slide # 29.

# Changing Supervising Principal Investigator (formerly known as Faculty Sponsor)

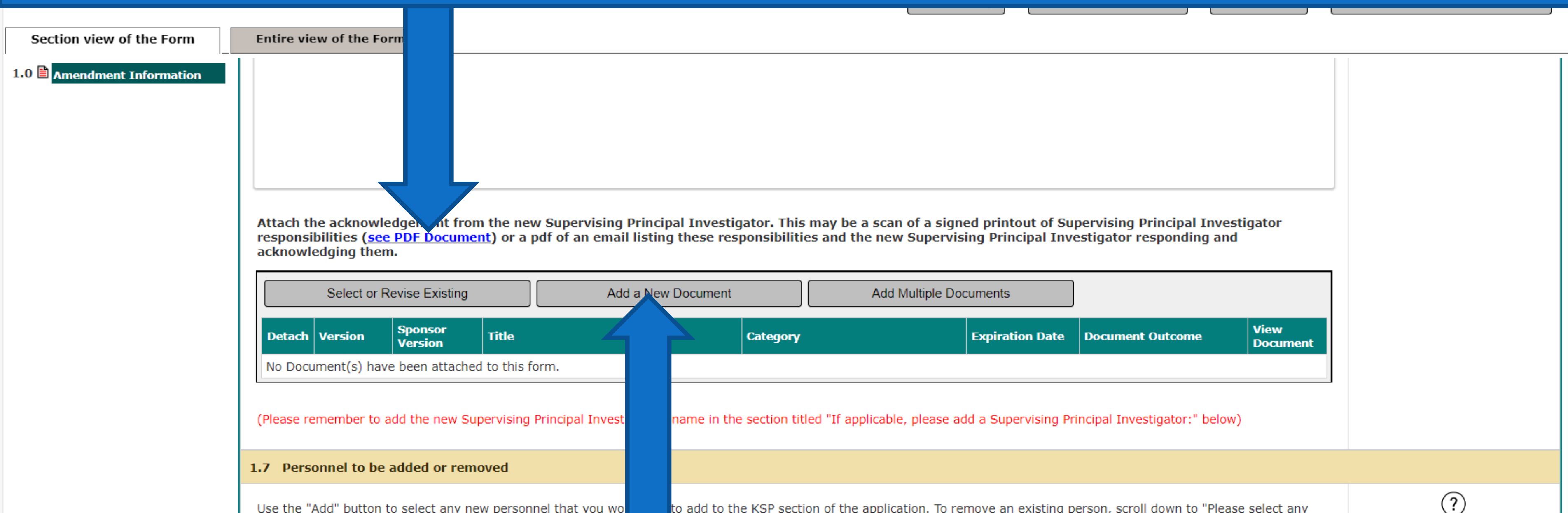
In section 1.6, describe the reason for the requested Supervising PI change (blue arrow). Then scroll down. (green arrow)



Next, you need to download the “Principal Investigator Responsibilities” document, have the new Supervising PI sign it, and attach it to this submission:

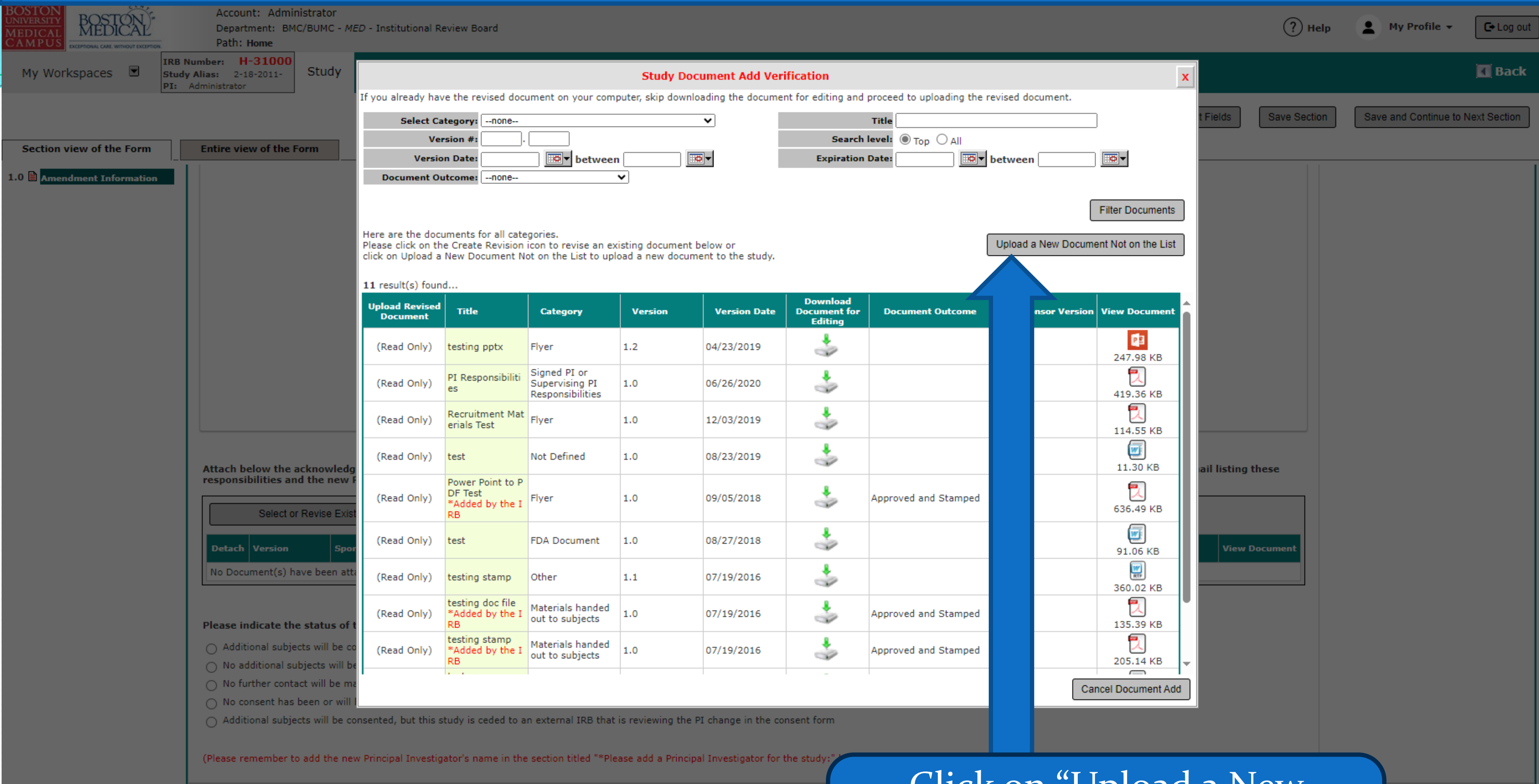
1. Click on “see PDF Document” link to open this document.
2. Save the document to your Desktop
3. If you have Adobe, the new Supervising PI can e-sign it and save it again to your Desktop. If you don’t have Adobe, you can print it out, have the new Supervising PI sign the printout, and then scan the signed document and save it to your Desktop.

Alternatively, you can use a PDF of an email listing these responsibilities and the new Supervising Principal Investigator responding and acknowledging them.



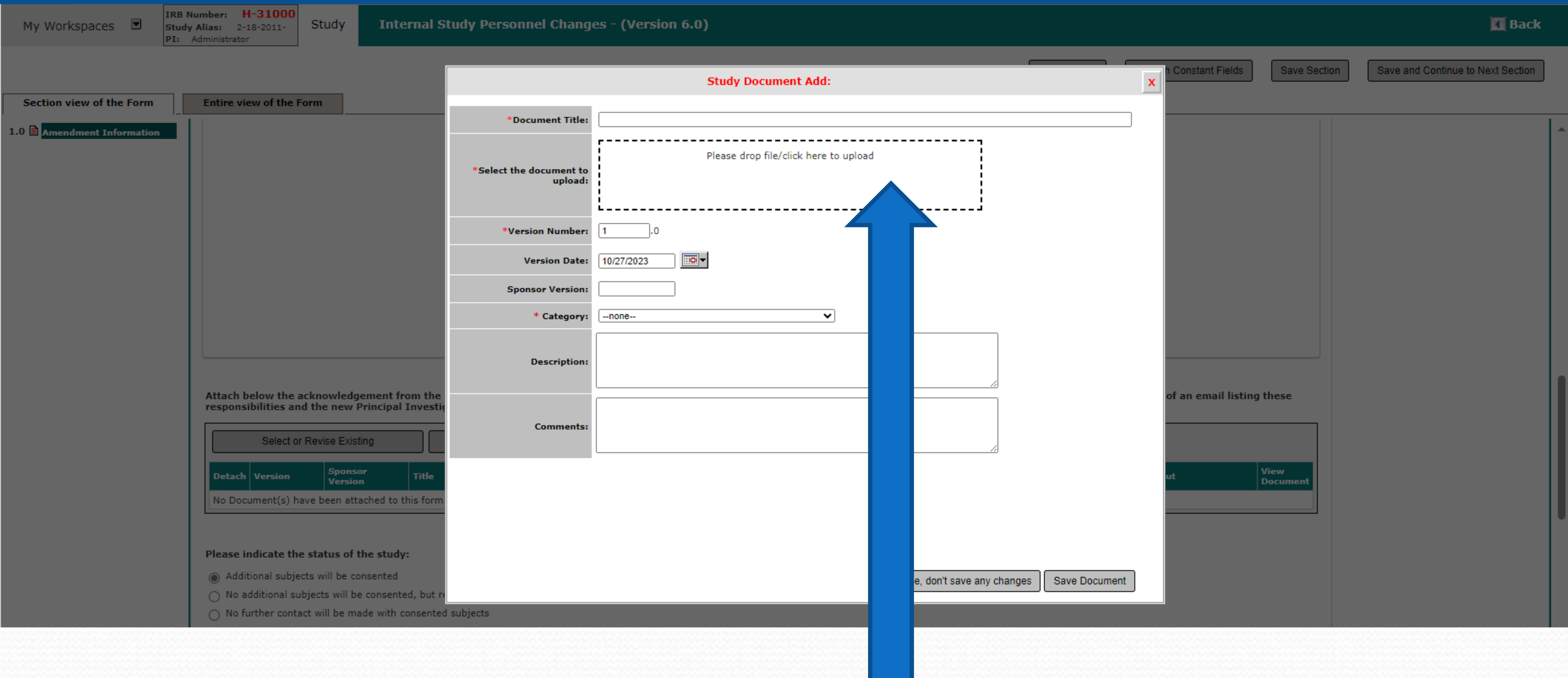

Once you have a signed “Principal Investigator Responsibilities” document saved on your Desktop, click on “Add a New Document” to attach it to this submission.

# This opens the “Study Document Add Verification” pop-up.




Click on “Upload a New Document Not on the List” button

# This opens the “Study Document Add” pop-up.

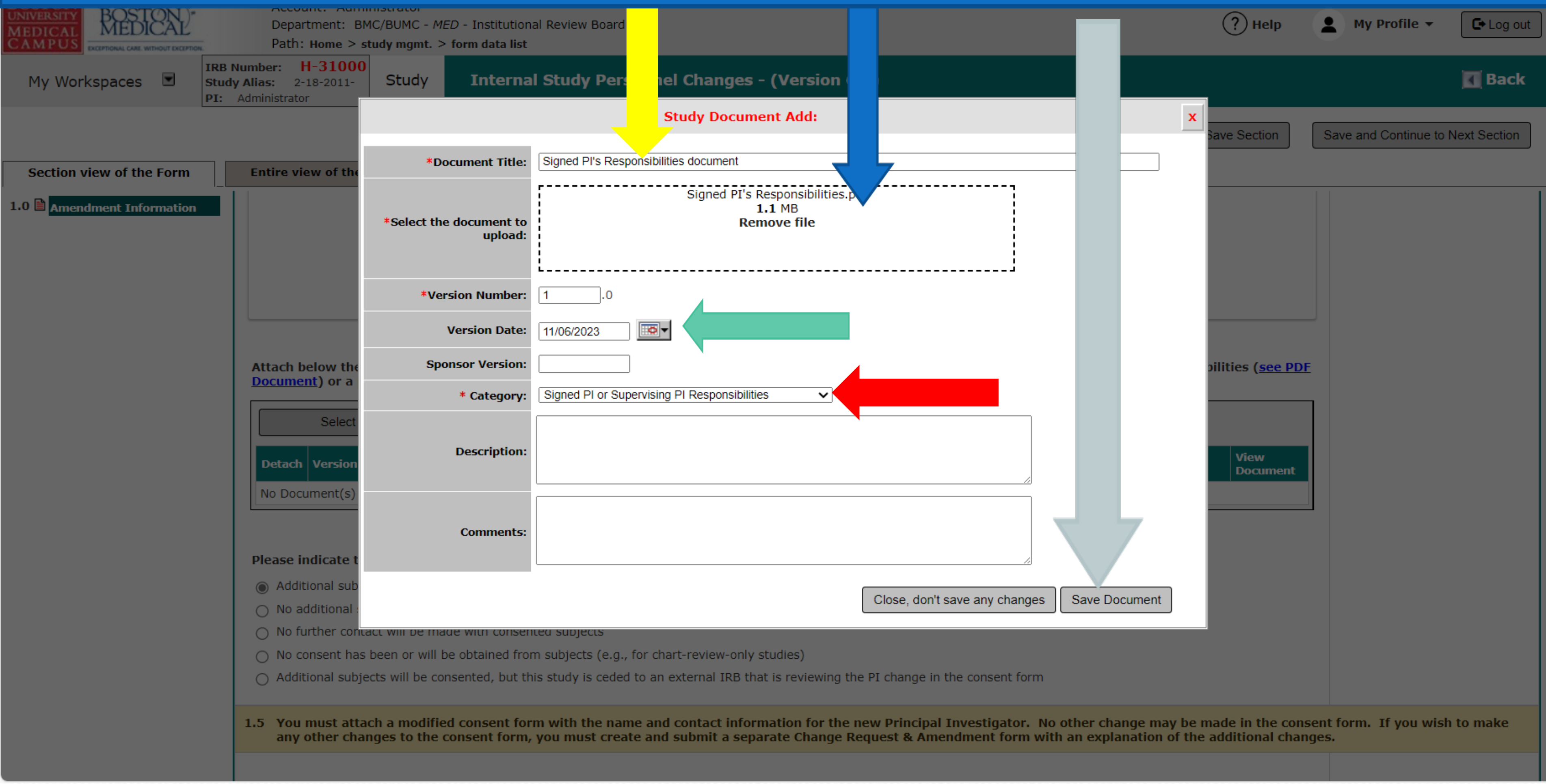



Drag and drop the signed “Principal Investigator Responsibilities” document in the “Select the Document to upload” box; or click inside this box and follow your system’s prompts to navigate to where you saved the document to upload it.

This will bring you back to the "Study Document Add:" popup.

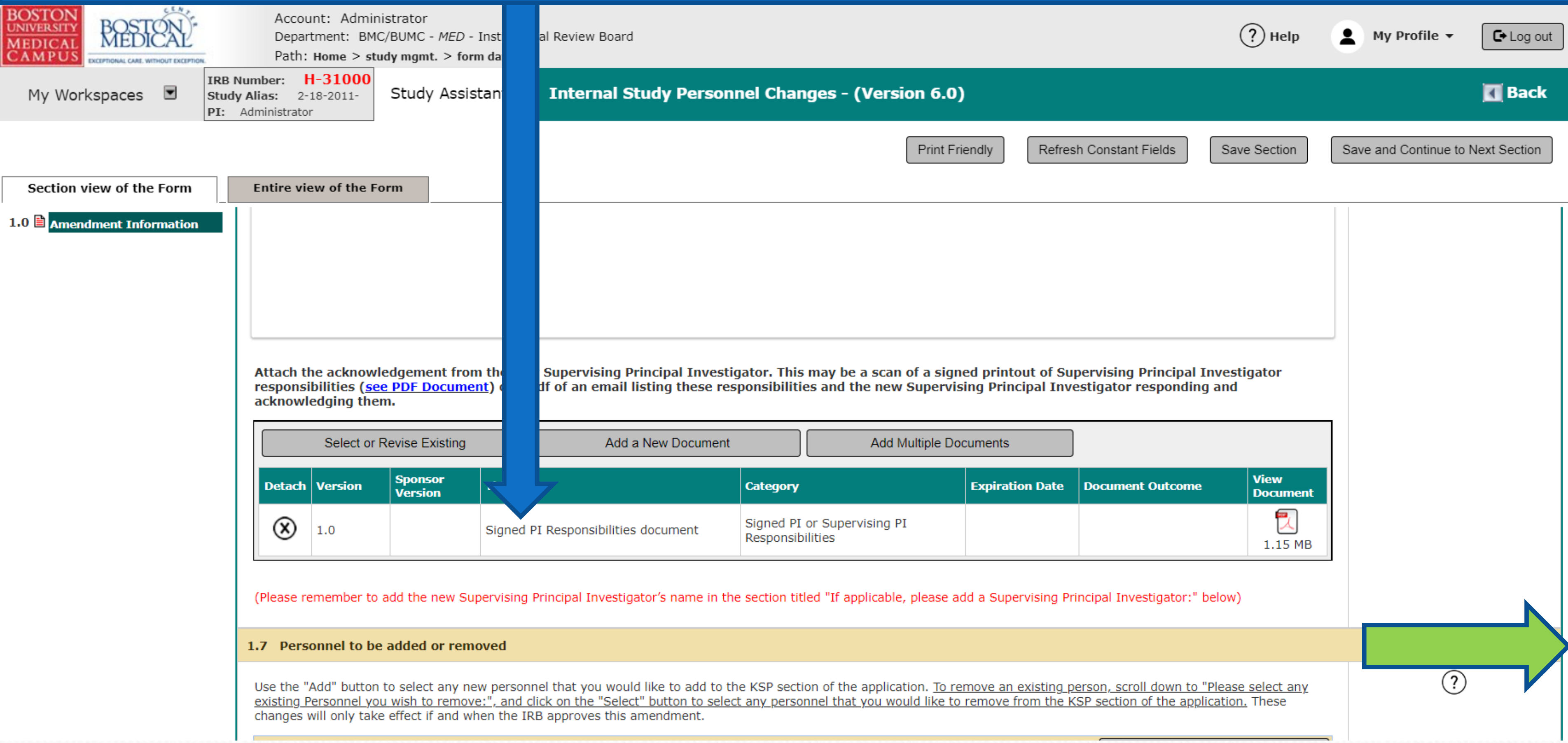
- Notice the uploaded document's name is now appearing in the popup (blue arrow)

1. Type in a meaningful document title (yellow arrow)
2. Change the "Version Date" to today's date (green arrow)
3. Select "Signed PI or Supervising PI Responsibilies" for the "Category" (red arrow)
4. Click on the "Save Document" button (Grey arrow)



This will bring you back to the “Internal Study Personnel Change Form”.

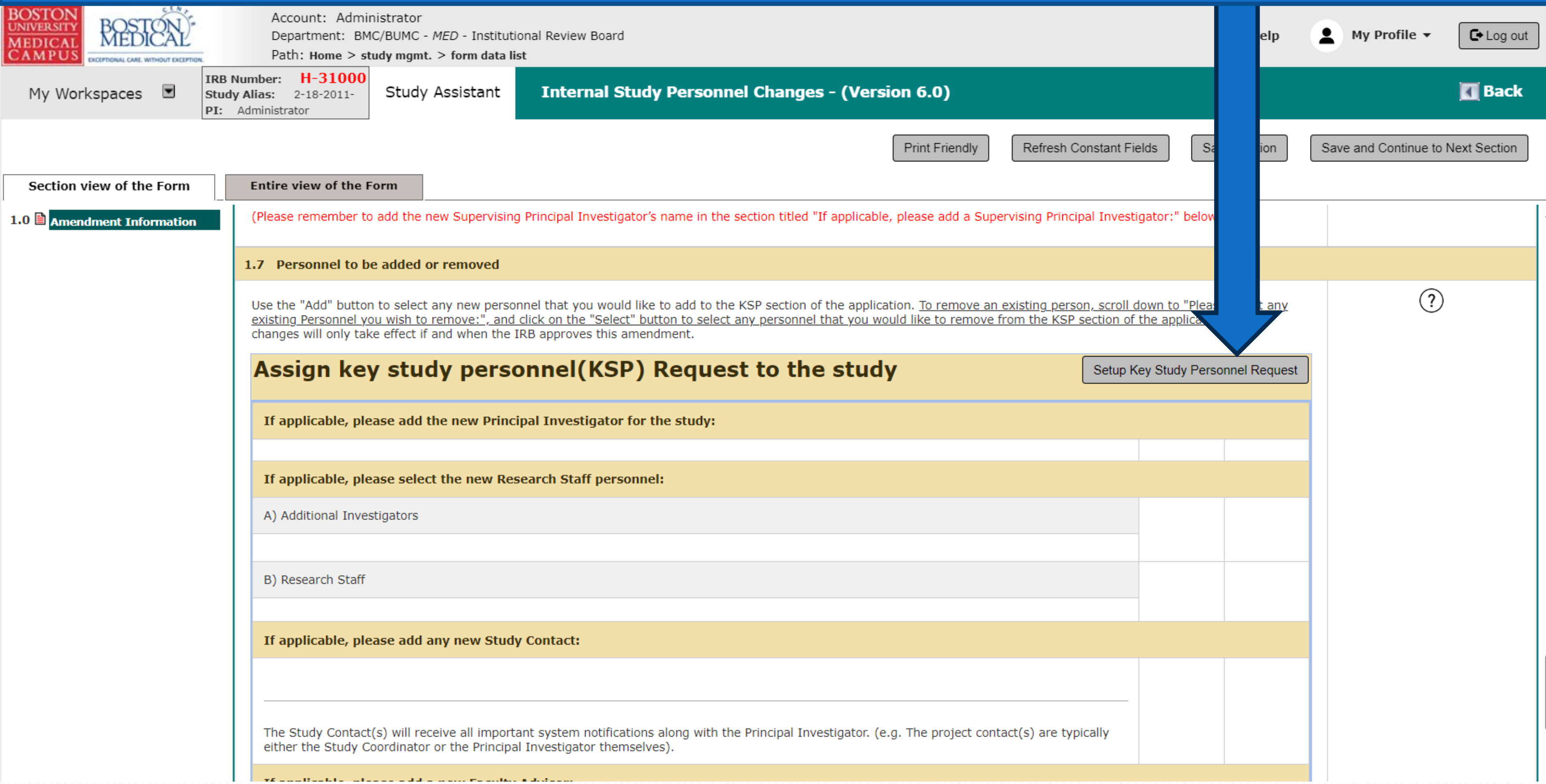
- Notice that the PI Responsibilities document is now appearing in this form (blue arrow)
- Scroll down to the next section (green arrow).



# Adding New Internal Investigators to a Study and/or Removing Existing Study Personnel from the Study

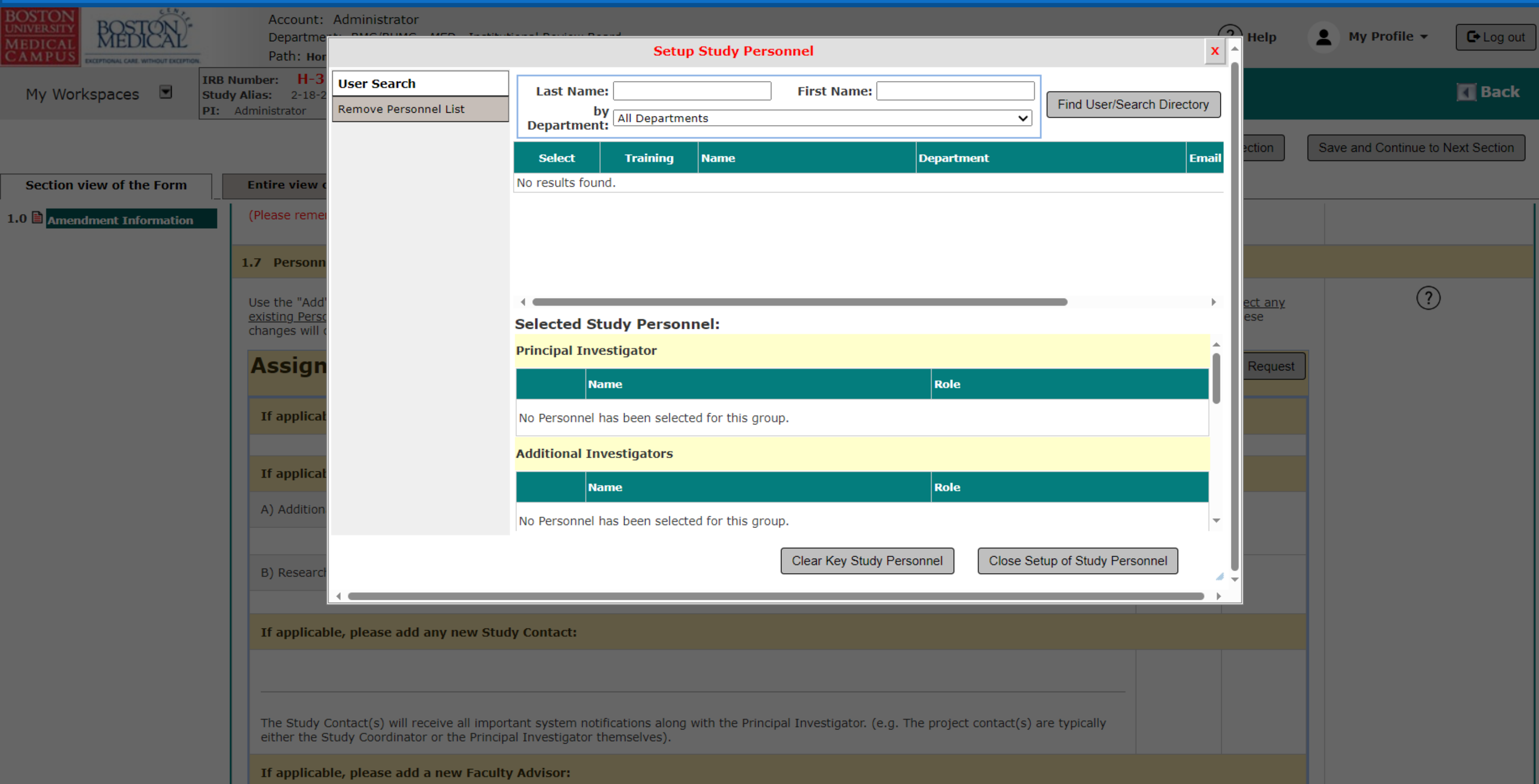
Section 1.7 “Personnel to be added or removed”, should be filled out in this form without exceptions.

- To fill out this section, click on “Setup Key Study Personnel Request” button (blue arrow).



This will open the “Setup Study Personnel” popup.

- If you are adding new study personnel to your study, proceed to the next slide.
- If you are only removing existing personnel from your study, skip the next instructions to slide # 38.



Note: If you are only removing existing personnel from your study, skip the next instructions to slide # 37.

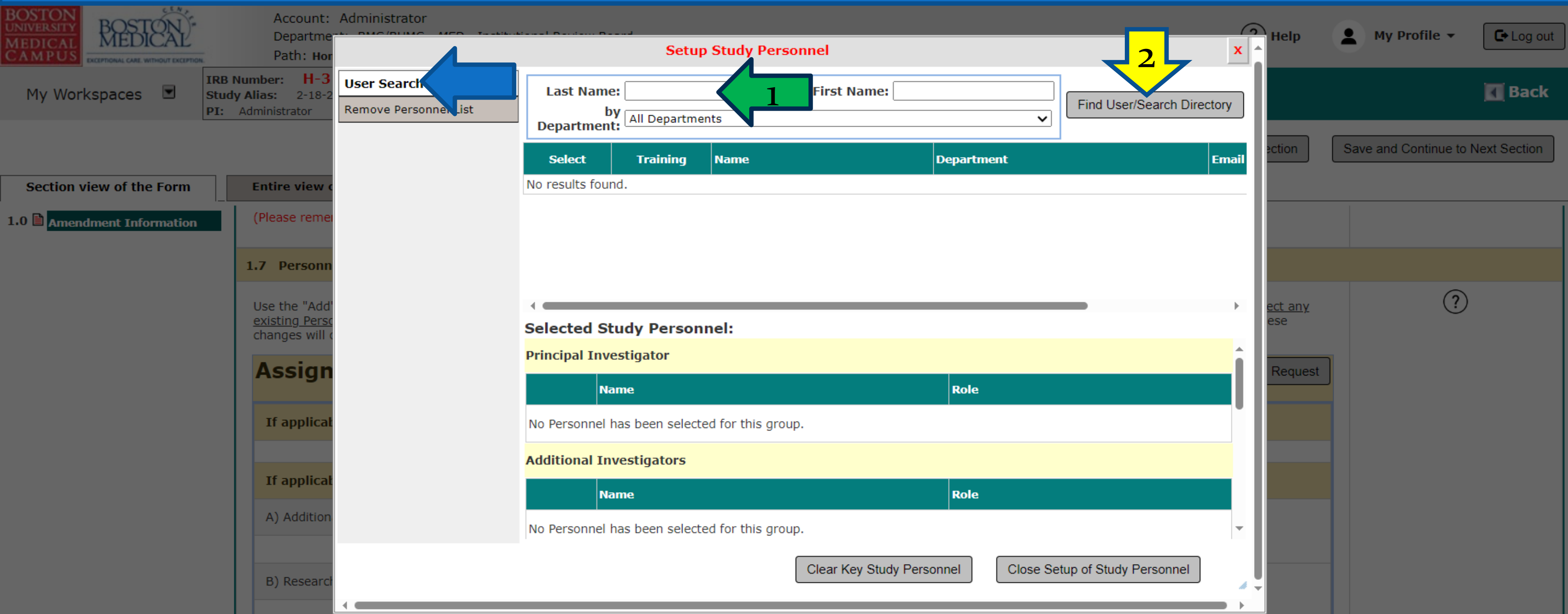
# Adding New Internal Investigators to a Study

# Notes for adding New Investigators

- “Study Contact” is not a real study role. So, anyone that is listed as a Study Contact will also need to be listed under another study role such as “Additional Investigators” or “Research Staff”, if they are not already listed there.
- If the new investigator(s) that are being added will need to receive email notifications about the protocol and be assigned tasks in their INSPIR Home page, you will also have to give them the “Study Contact” Role.

Make sure you are in the "User Search" tab (blue arrow).

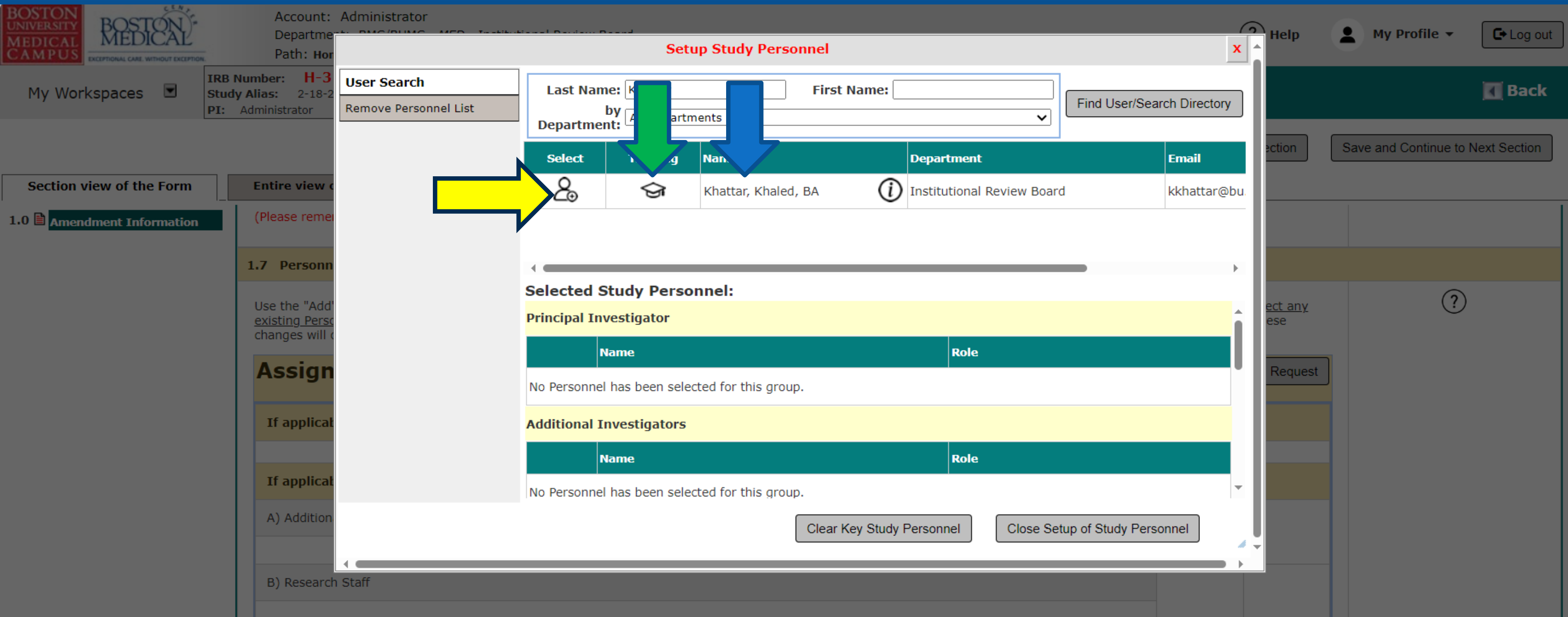
1- Enter the last name (green arrow)
2- Click on the "Find User/Search Directory" button (yellow arrow) to search for the person.




Tip – If you can't find this person in INSPIR, ask that person to login to INSPIR for the first time and their INSPIR account will be created. They can use the step-by-step instructions in the link below to login and create their INSPIR account: http://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf

If the person you are looking for has an INSPIR account, their name will show up like in the screenshot below (blue arrow)

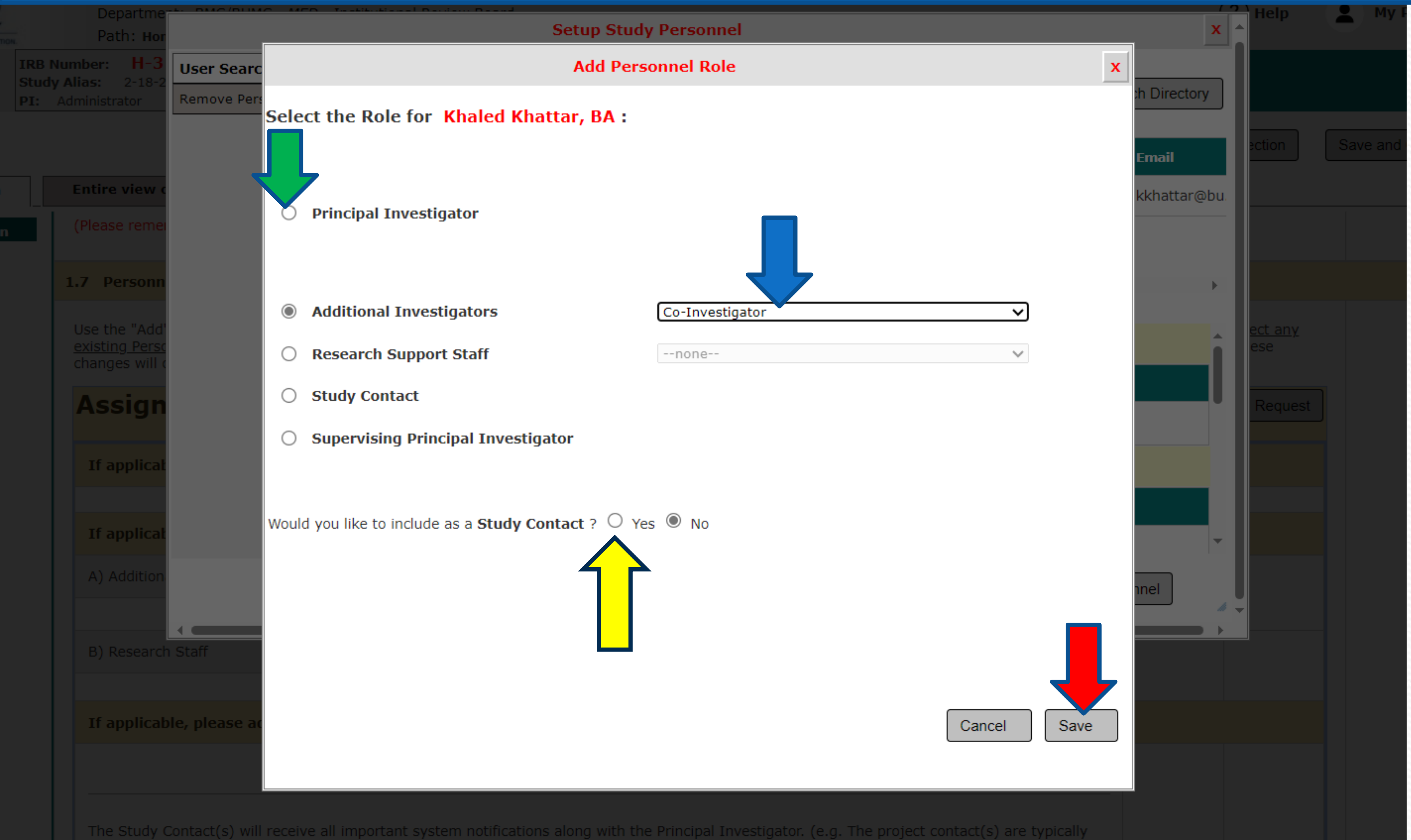
1. First check that they are up-to-date with training by clicking on the training icon (green arrow). If they don't have the required IRB training, please do not add them.
2. Click on the "Select" icon (yellow arrow) to select this person.




Tip – If you can't find this person in INSPIR, ask that person to login to INSPIR for the first time and their INSPIR account will be created. They can use the step-by-step instructions in the link below to login and create their INSPIR account: [http://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf](http://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf)

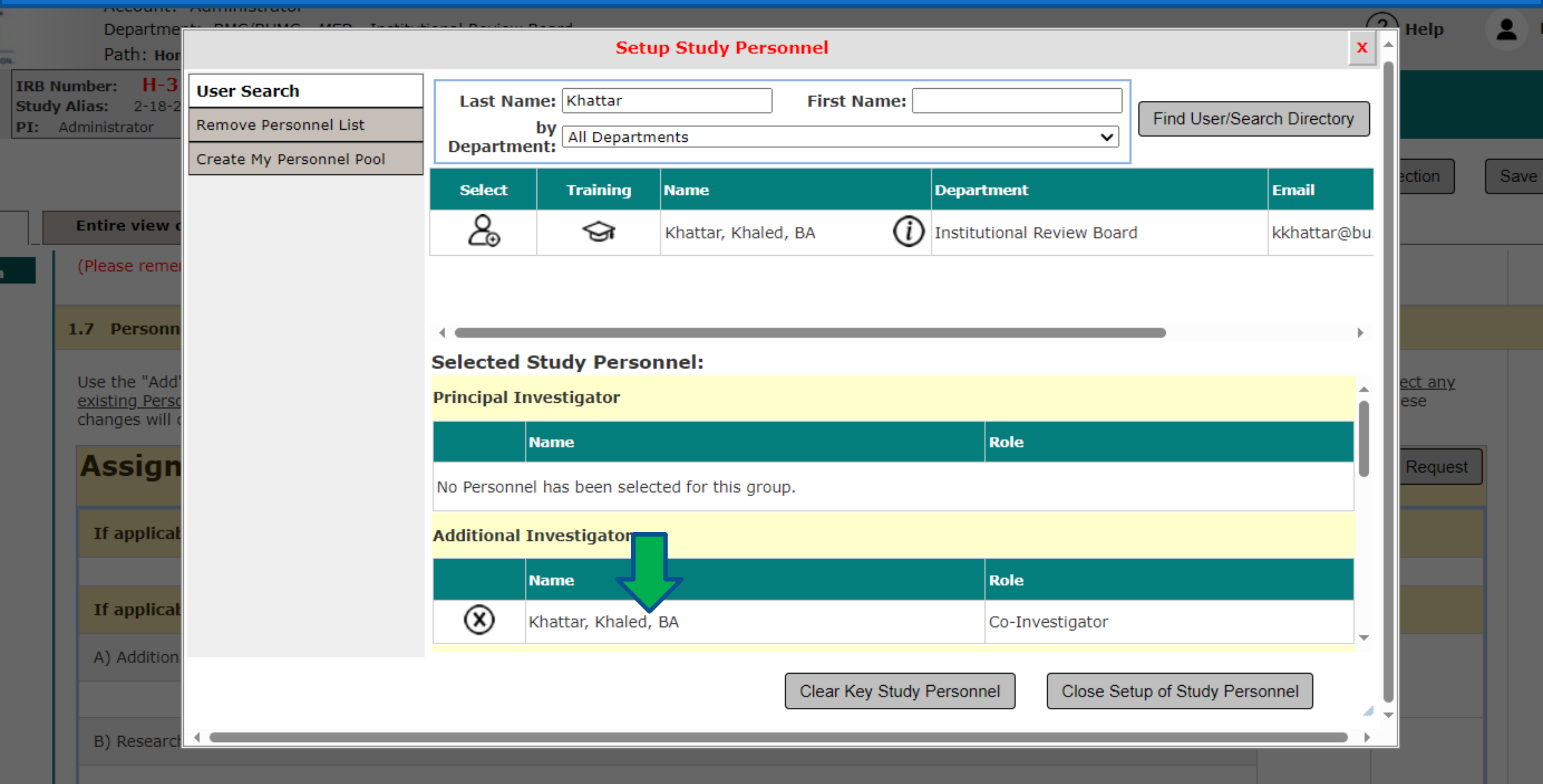
This will open the "Add Personnel Role" popup.

1. Select their role on the study by clicking on one of the listed roles' radio buttons (green arrow).
2. Some roles require that you select the user's role subcategory from a drop-down menu- (blue arrow). Select the user's role subcategory if applicable.
3. If you want this person to get study tasks and all study email notifications, select "Yes" (yellow arrow) for "Would you like to include as a Study Contact ? ", otherwise select "No".
4. When you are done, click on the "Save" button (red arrow).



This will take you back to the "Setup Study Personnel" popup.

- Note that the person just added is showing up in the appropriate section/role (green arrow).
- To add more personnel, repeat steps in slides 34 – 37.
- If you will be removing existing personnel from your study, proceed to the next slide.
- If you will not be removing any existing personnel from your study, skip the next instructions to slide # 42.

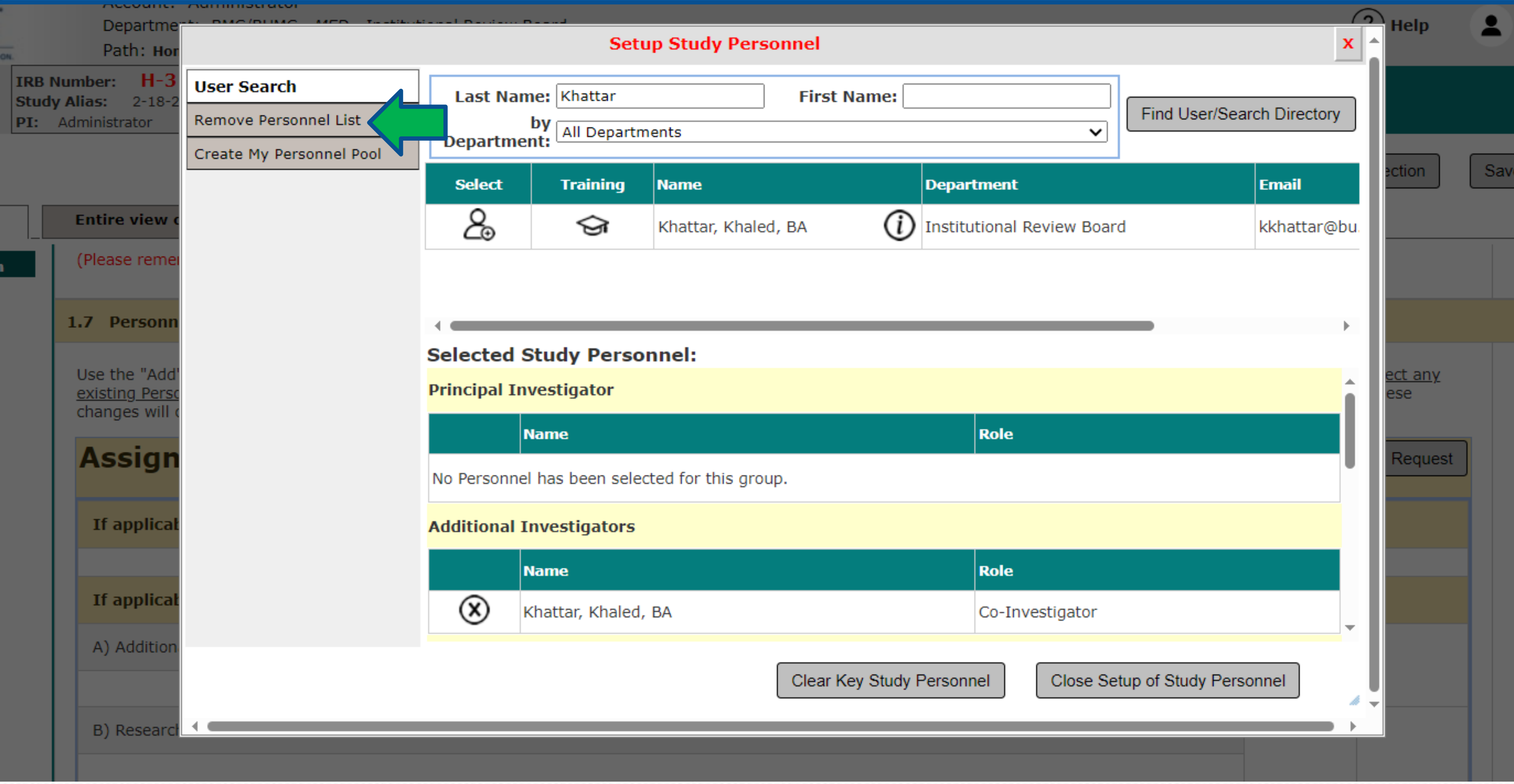


Note: If you will not be removing any existing personnel from your study, skip the next instructions to slide # 42.

# Requesting the Removal of Existing Internal Investigators from the Study

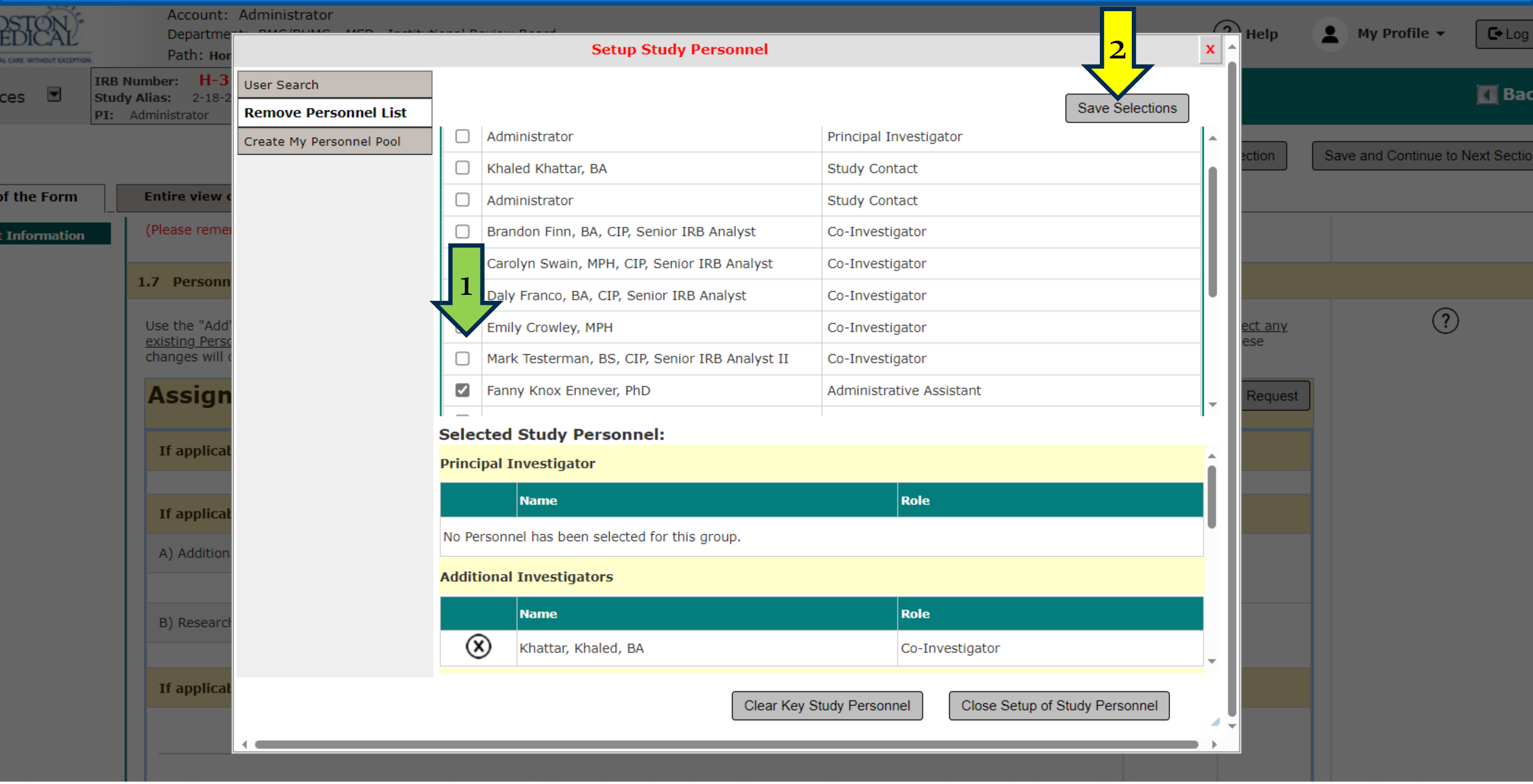
While you still in the “Setup Study Personnel” popup:

1. Click on the “Remove Personnel List” tab (green arrow)



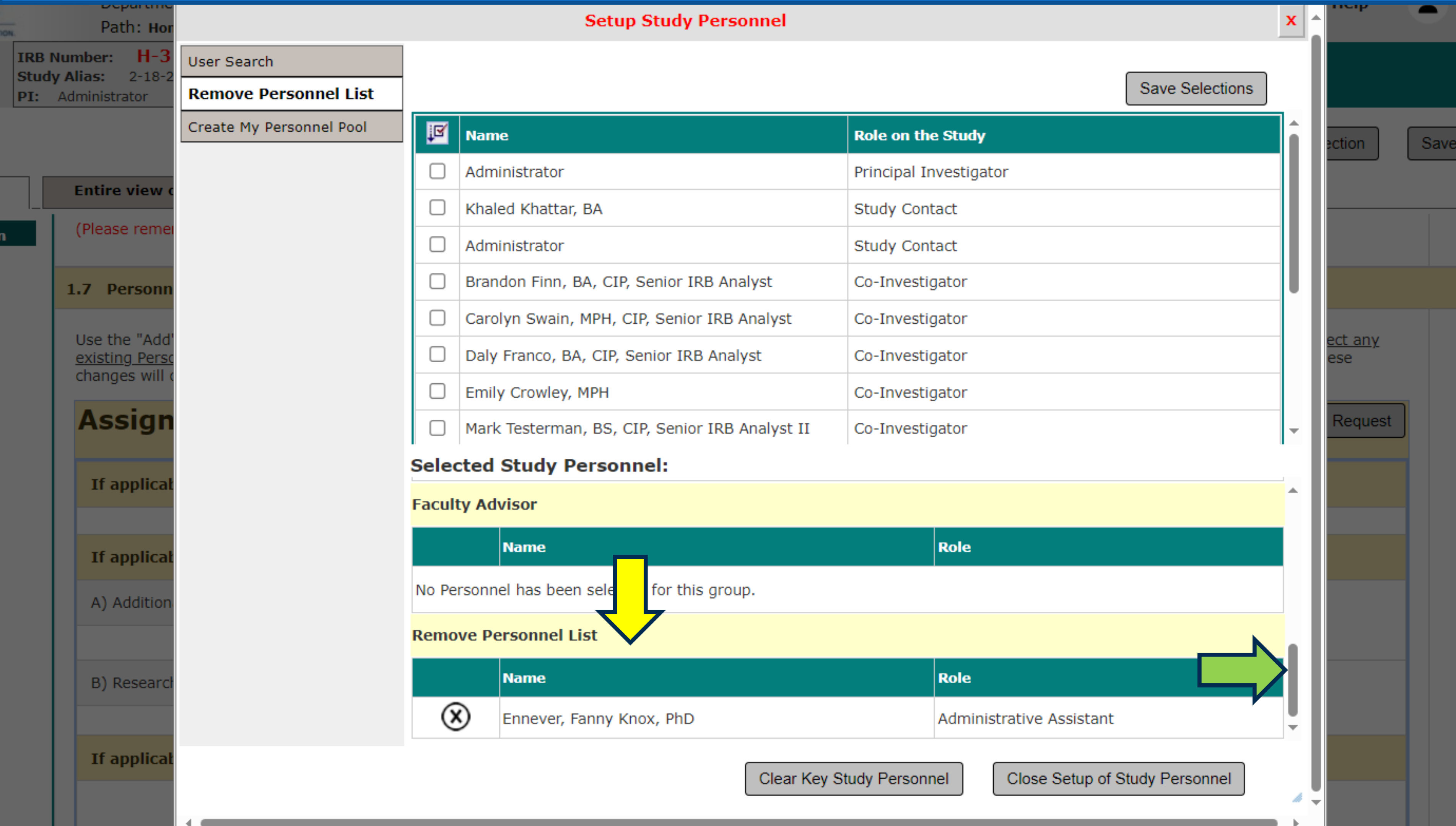
The “Setup Study Personnel” popup will refresh to list all personnel currently listed on your study:

1. Click on the check boxes to select the personnel you want to remove from your study (green arrow)
2. When you’re done selecting all personnel that you want removed, click on the “Save Selections” button (yellow arrow).



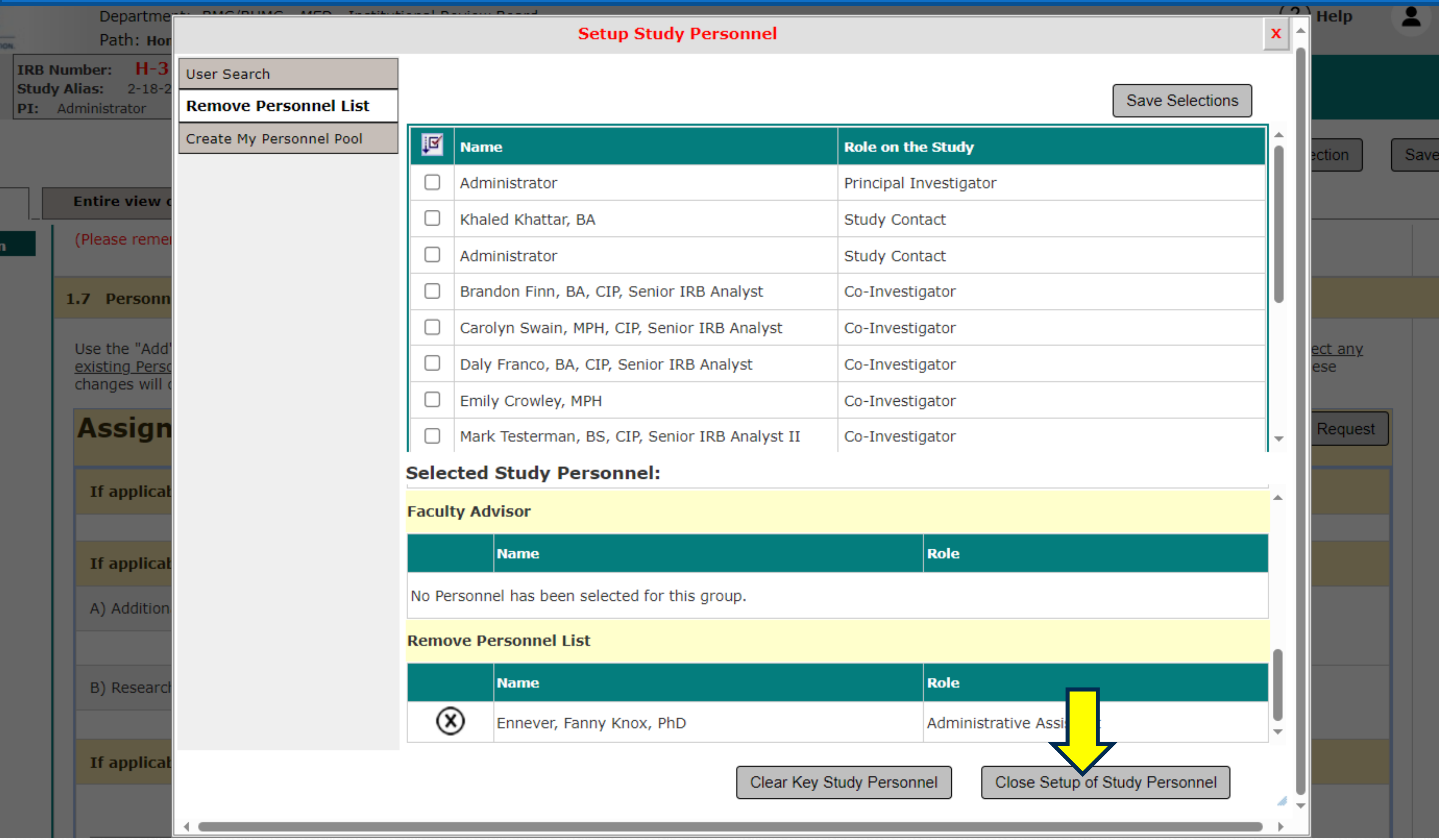
The “Setup Study Personnel” popup will refresh again:

- If you want to select more personnel to be removed repeat steps in slide 40.
- To view the list of personnel that you selected to be removed, scroll down (green arrow)
- You will see all personnel that you selected to be removed under “Remove Personnel List” (yellow arrow).



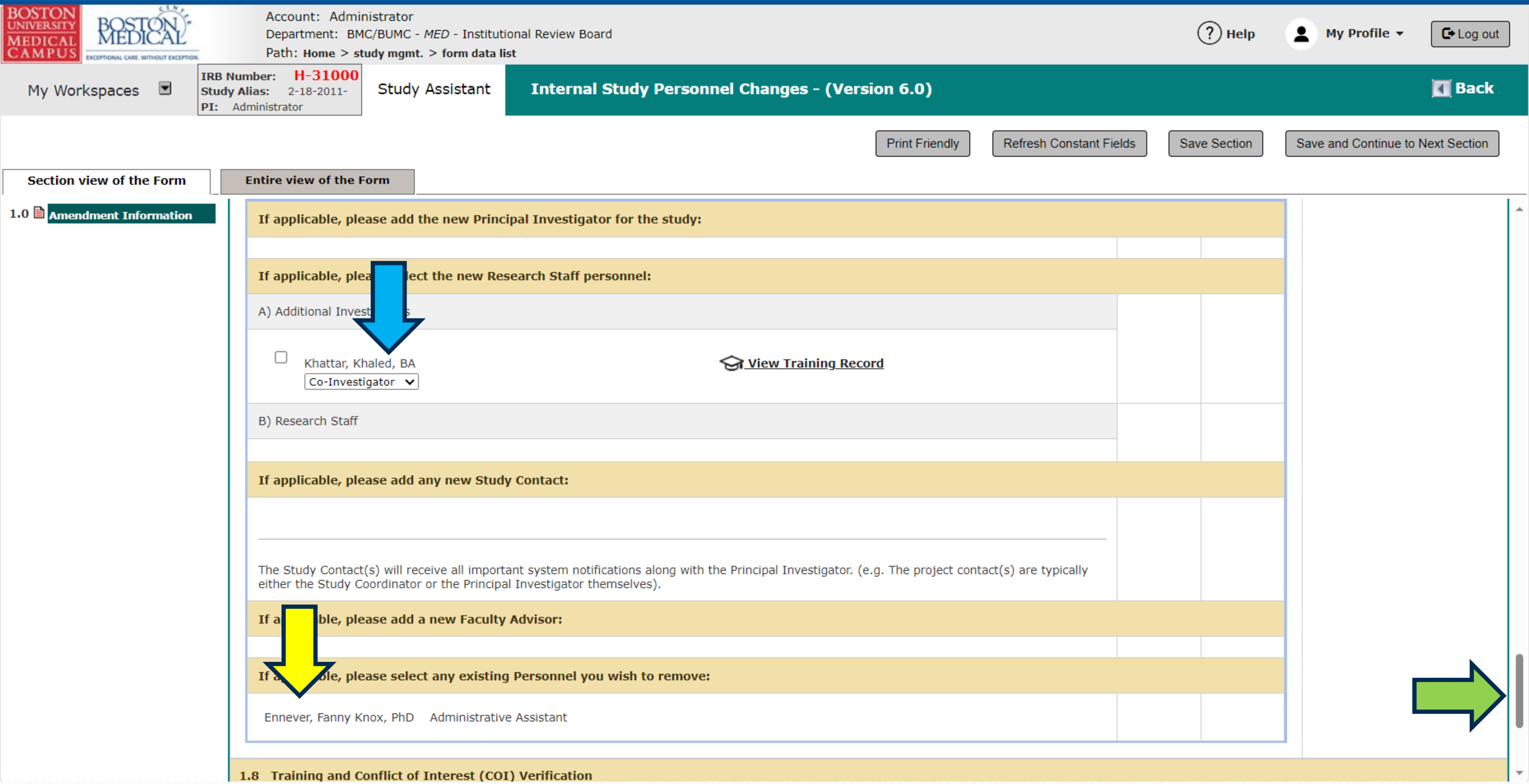
If you are done selecting new personnel to be added and/or selecting existing personnel for removal from the study:

- You would click on “Close Setup of Study Personnel” button (yellow arrow).



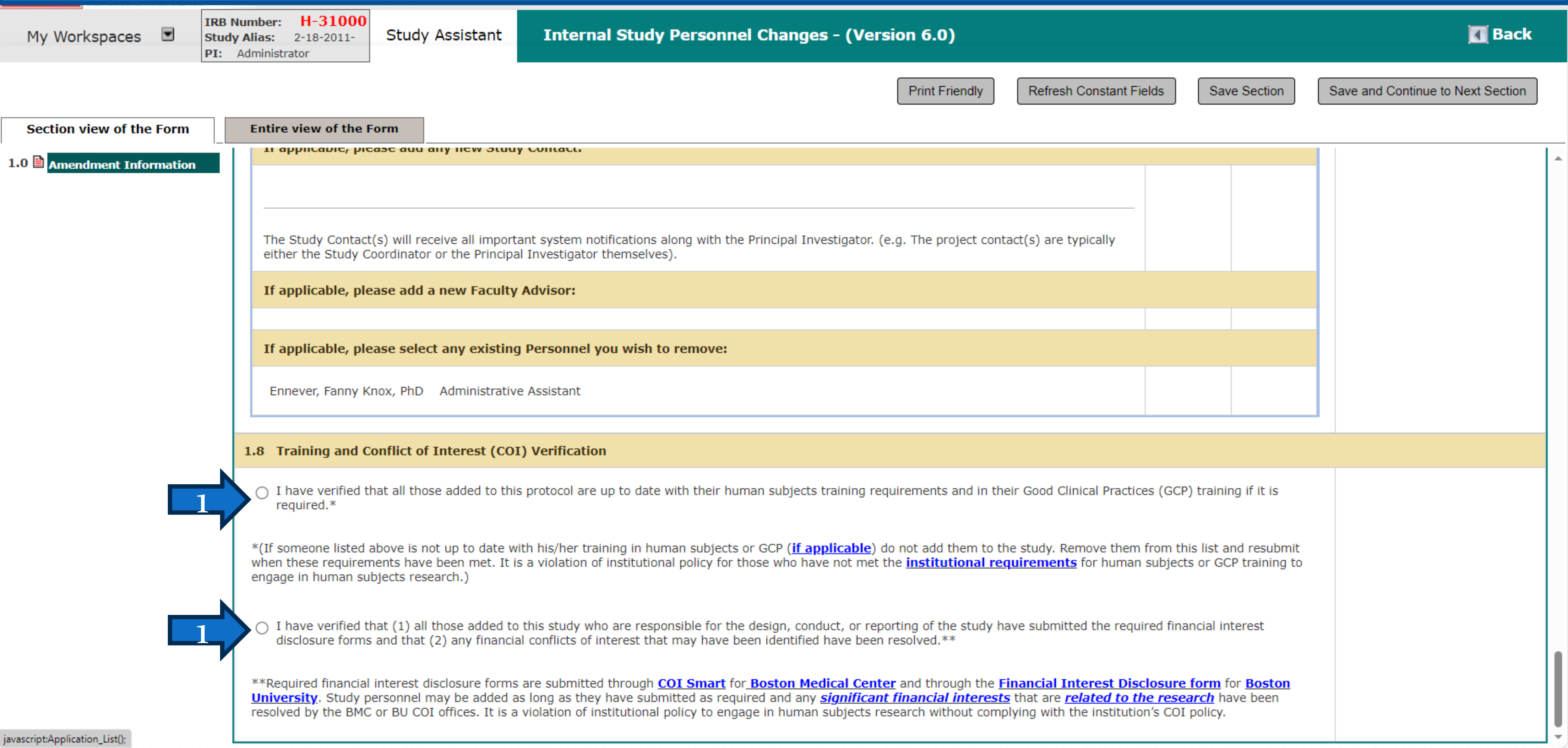
This should bring you back to the “Internal Study Personnel Changes” form.

- Notice that the personnel selected to be added to the study (if applicable), now appears in the appropriate section of this form (blue arrow)
- Notice that the personnel selected to be removed from the study (if applicable), now appears in the appropriate section of this form (yellow arrow).
- Scroll down to proceed (green arrow)



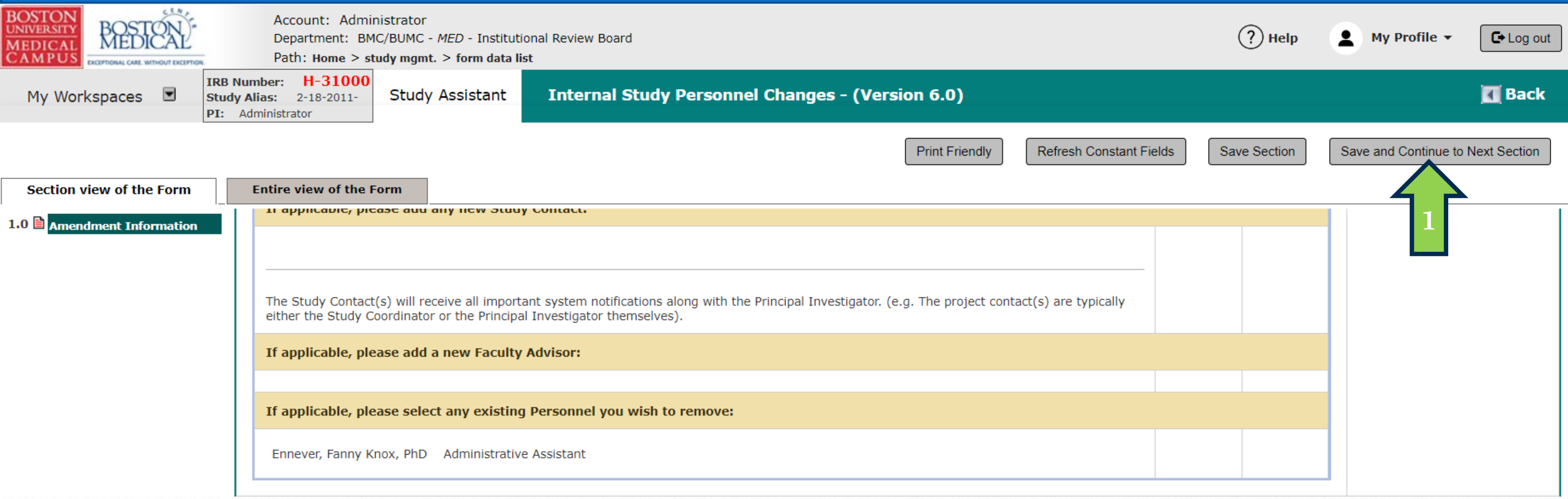
Only if you are adding study personnel to your study, Section 1.8 will be displayed in this form and needs to be completed as explained in this slide. If you are not adding any Study Personnel, Section 1.8 will be hidden and in this case, you would skip this slide to the next.

- Basically, in Section 1.8 (if displayed), you will be attesting that you have verified that the personnel you are adding to this study have completed their required IRB training and submitted Conflict of Interest forms.
- You need to check both radio buttons before the system allows you to submit.
  1. Check the two radio buttons (blue arrows)



Now it's time to save this form and submit it.

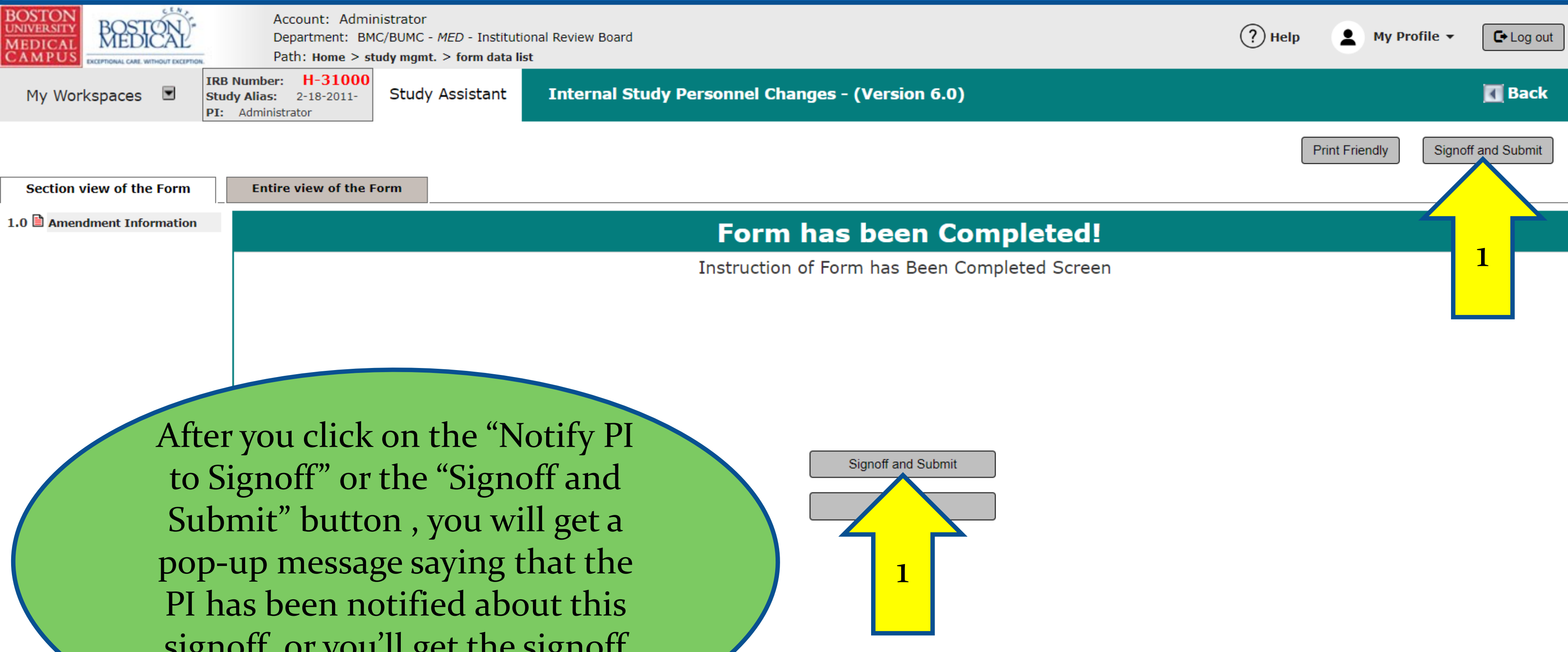
1. Click on "Save and Continue to Next Section" button (green arrow)



This will bring you to the "Form Has Been Completed" page.

1. Click on the "Notify PI to Signoff" or the "Signoff and Submit" button (whichever is available to you) to submit this amendment to the PI for signoff before it goes to the IRB (yellow arrow)

The PI must sign off on these amendments even if the PI completed this form.




After you click on the "Notify PI to Signoff" or the "Signoff and Submit" button , you will get a pop-up message saying that the PI has been notified about this signoff, or you'll get the signoff page if you are the PI.

# PI Signoff

- The PI will receive an email notification that there is a submission (in this case an "Internal Study Personnel Change Form" ) awaiting their signoff
- The PI will also be able to locate this signoff "task" by going to their INSPIR homepage and looking under "All Tasks"
- For instructions on how to sign off as the PI, follow the instructions in the link below:

https://www.bumc.bu.edu/irb/files/2016/10/How-to-sign-off-on-protocol-as-PI.pdf