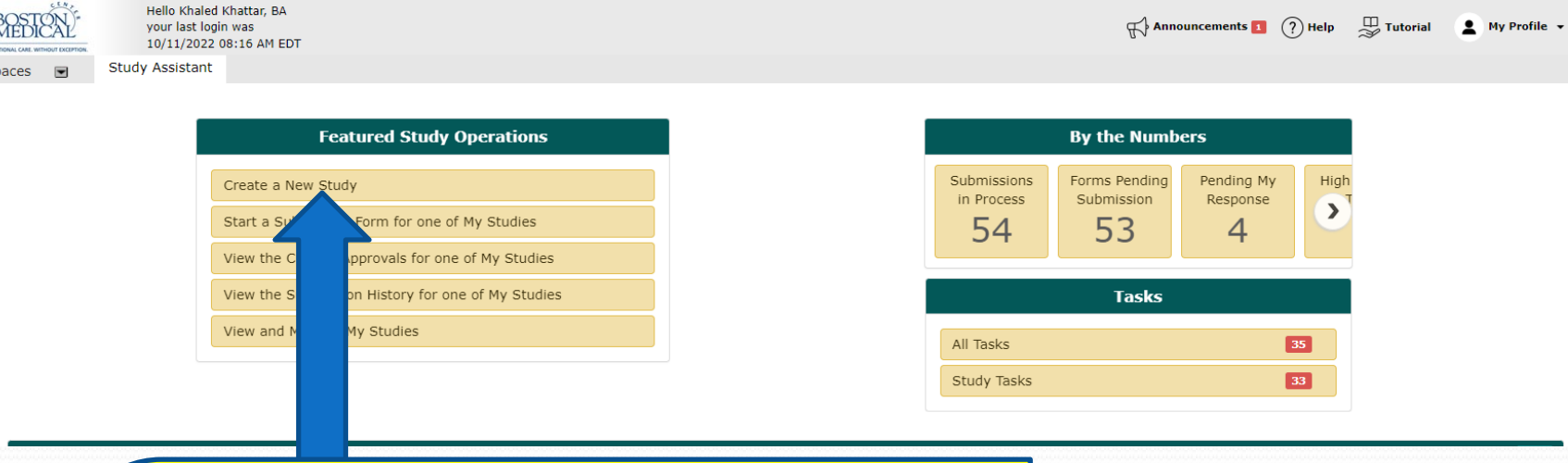
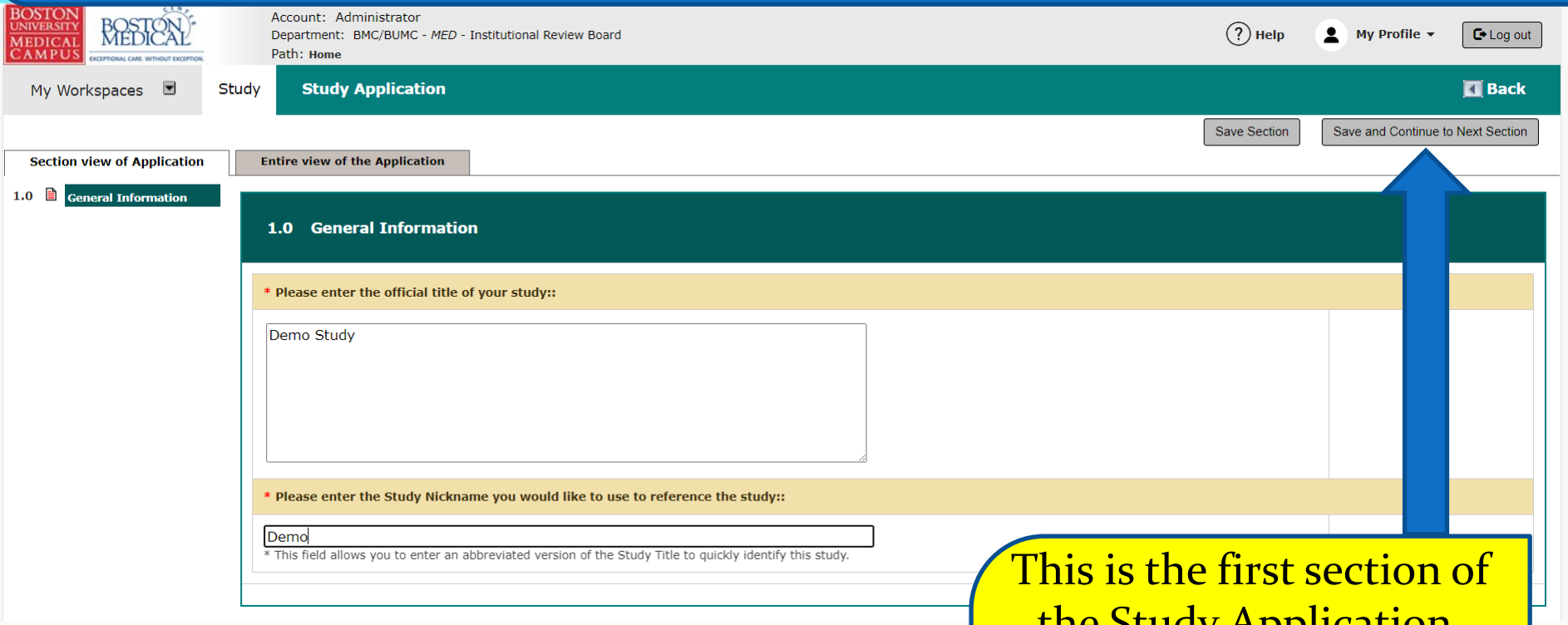
How to create a new study draft in INSPIR II



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

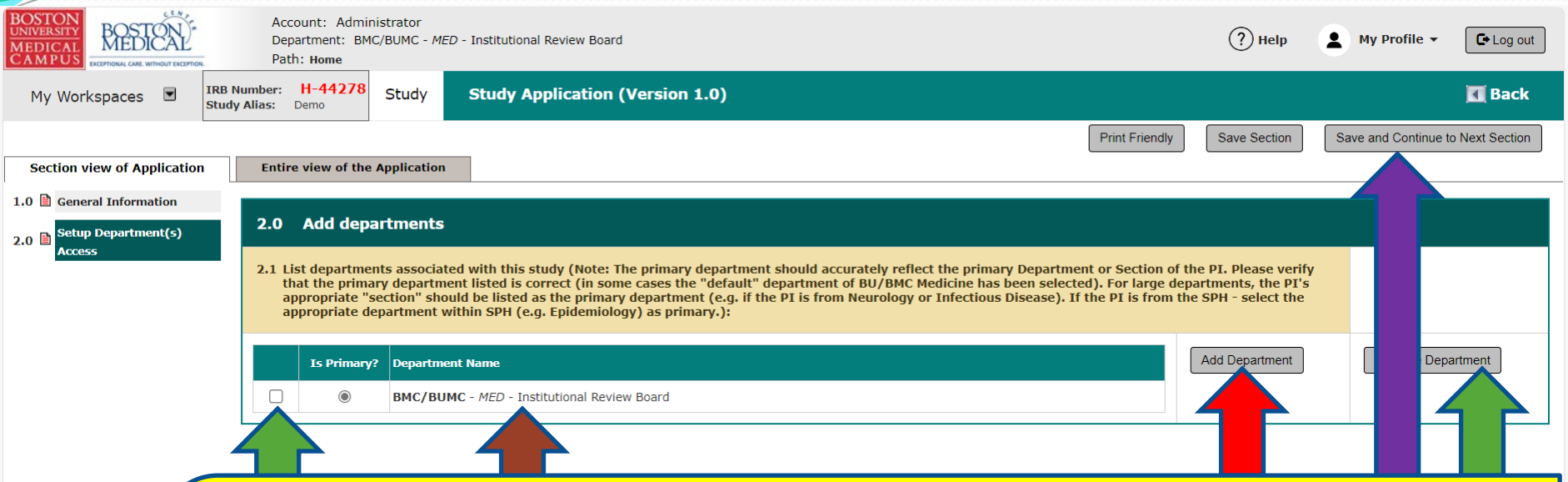
Click on "**Create a New Study**"

The system will create and open a new Study Application form.



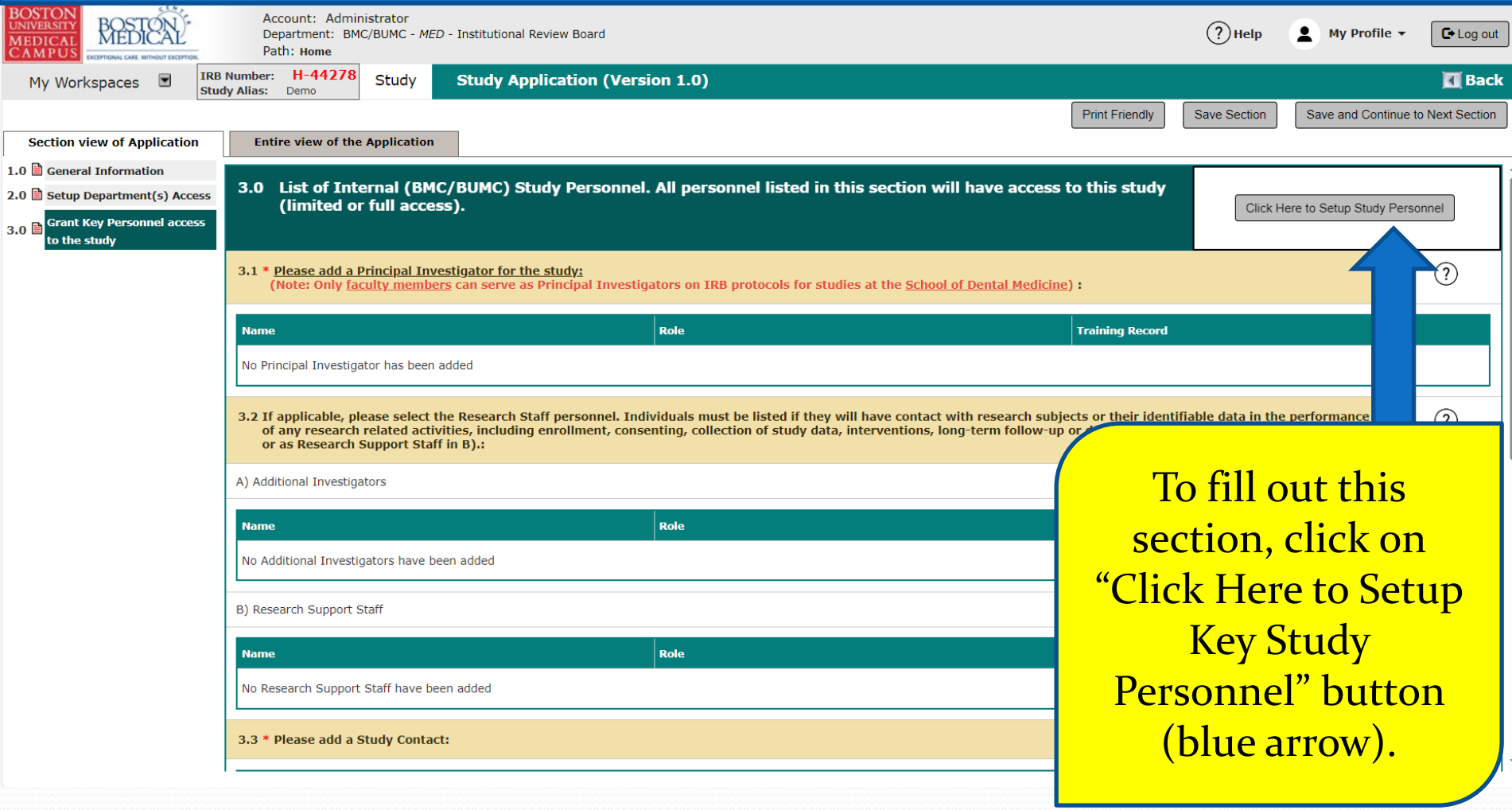
This is the first section of the Study Application. Type in the title and a nickname for the study. Then click on "Save and Continue to the next Section" button to proceed.

The system will start building the Study Application section by section. You can click on these sections/tabs in the left panel to jump back to them.



Make sure you have the right department listed here (brown arrow). If not, check the small box to the left and click on “Remove” (green arrows). Then click on “Add” to add the right department (red arrow). You can add multiple departments if multiple ones are involved. When you’re done click on “Save and Continue…” (purple arrow)

The system will open Section "3.0 Grant Key Personnel access to the study". In this section, you need to enter all internal personnel. Only those entered here will have access to this study.



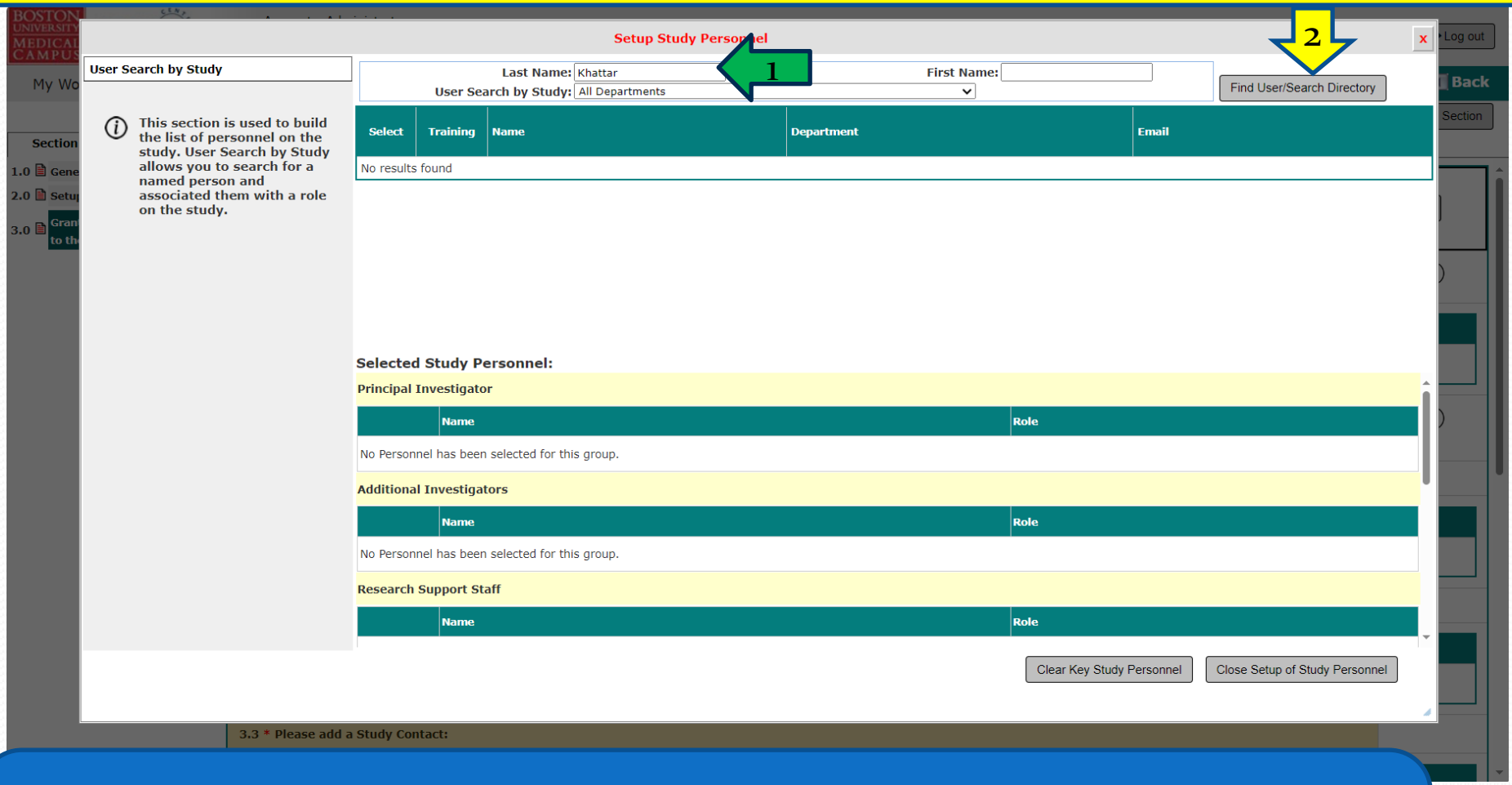
To fill out this section, click on "Click Here to Setup Key Study Personnel" button (blue arrow).

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 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.

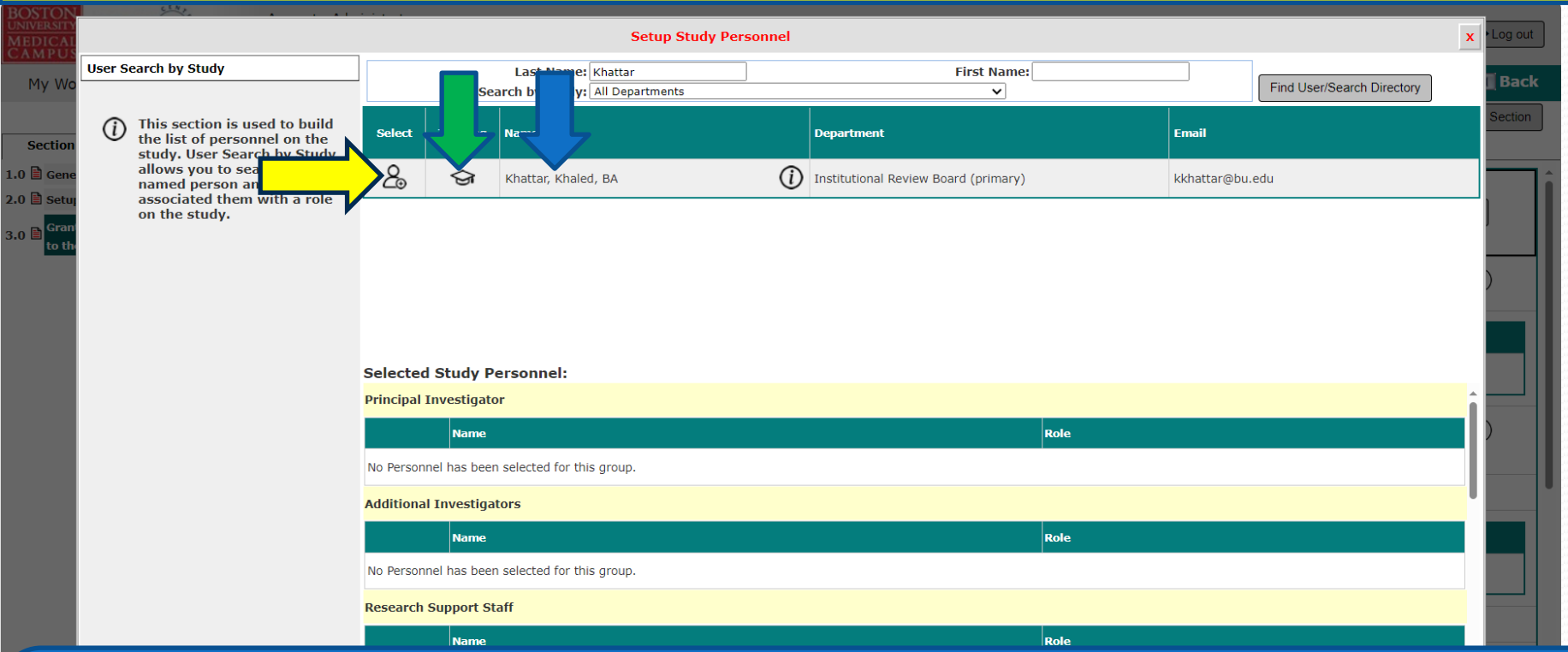
The system will open the “Setup Study Personnel” popup.
1- Enter the last name (green arrow)
2- Click on the “Find User/Search Directory” button (yellow arrow) to search for the person.



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)

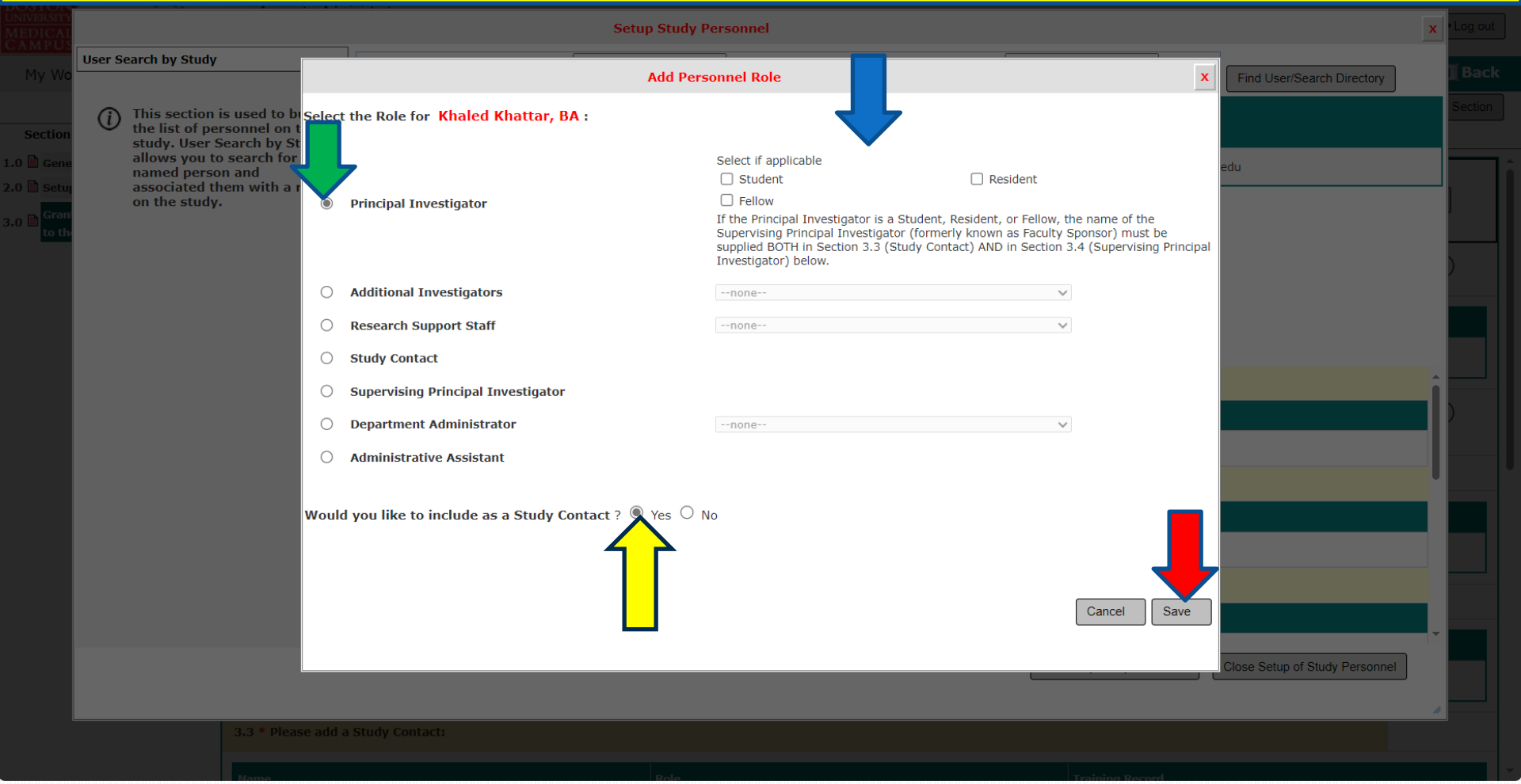
1. First check that they are up-to-date with training by clicking on the training icon (green arrow). If they don't have the required IRB training, please do not add them.
2. Click on the "Select" icon (yellow arrow) to select this person.



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

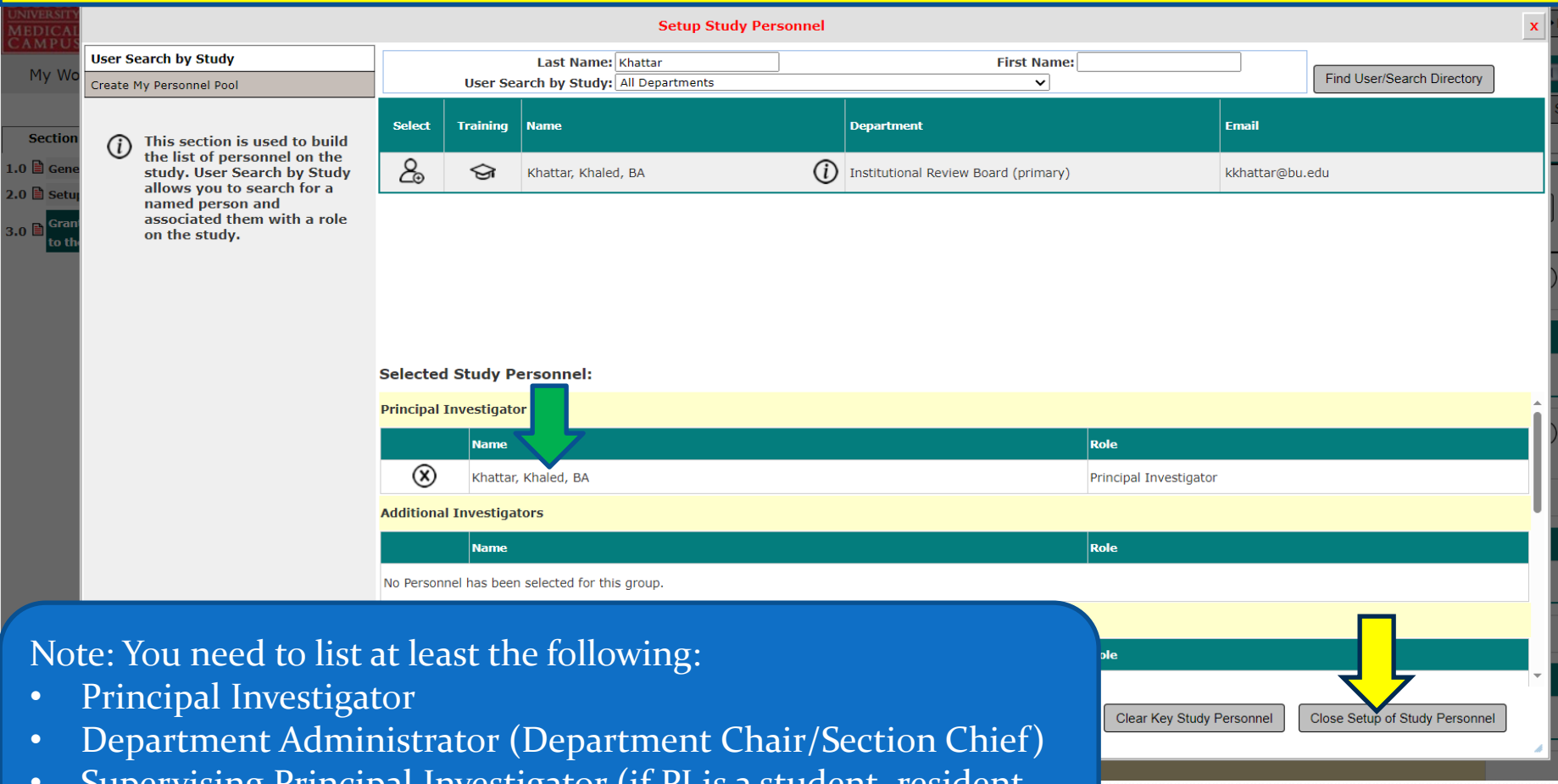
This will open the “Add Personnel Role” popup.

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 check boxes or 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.

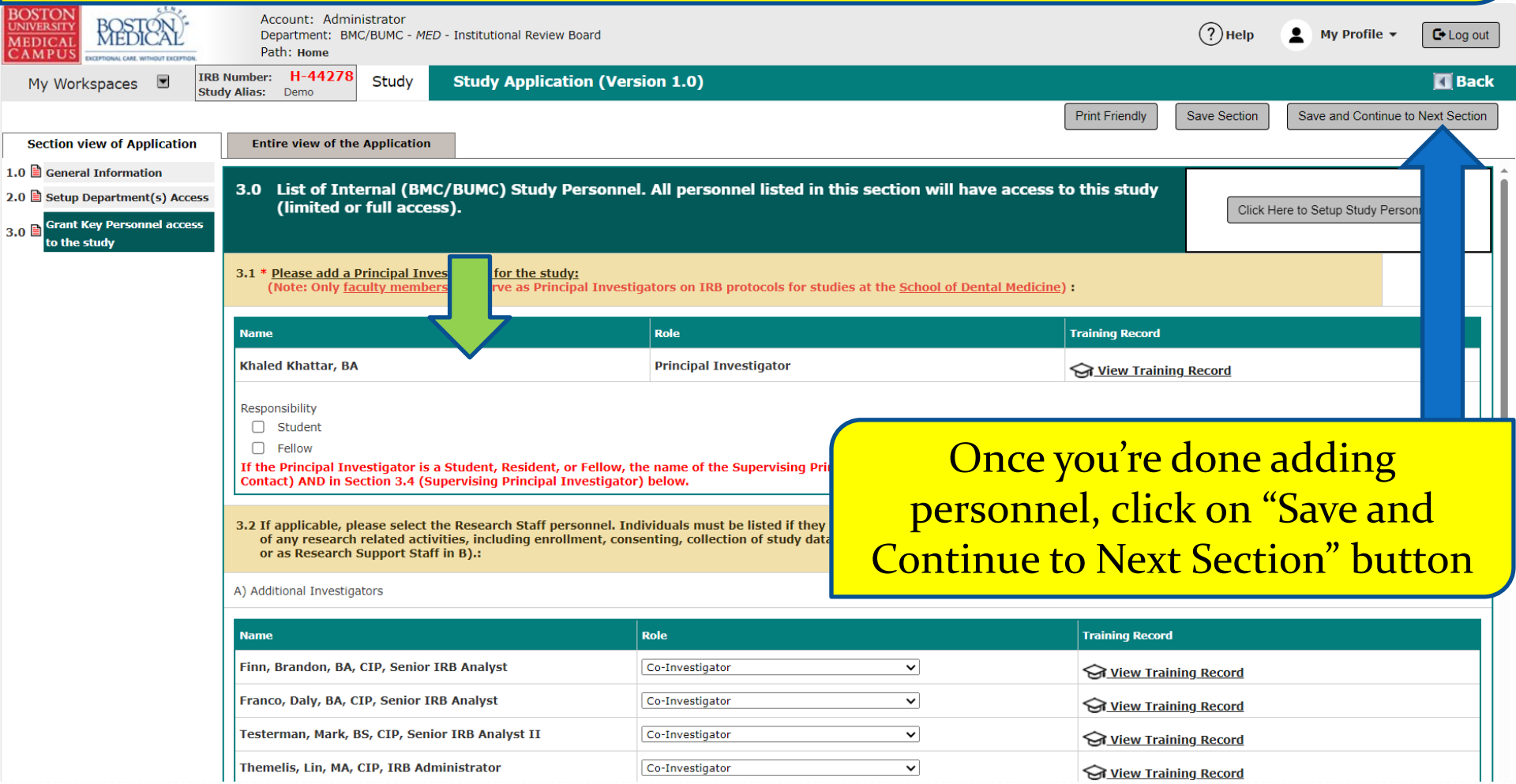
- Note that the person just added is showing up in the appropriate section/role (green arrow).
- To add more personnel, repeat steps in slides 7 – 10.
- If you are done selecting all study personnel, you would click on "Close Setup of Study Personnel" button (yellow arrow).



Note: You need to list at least the following:

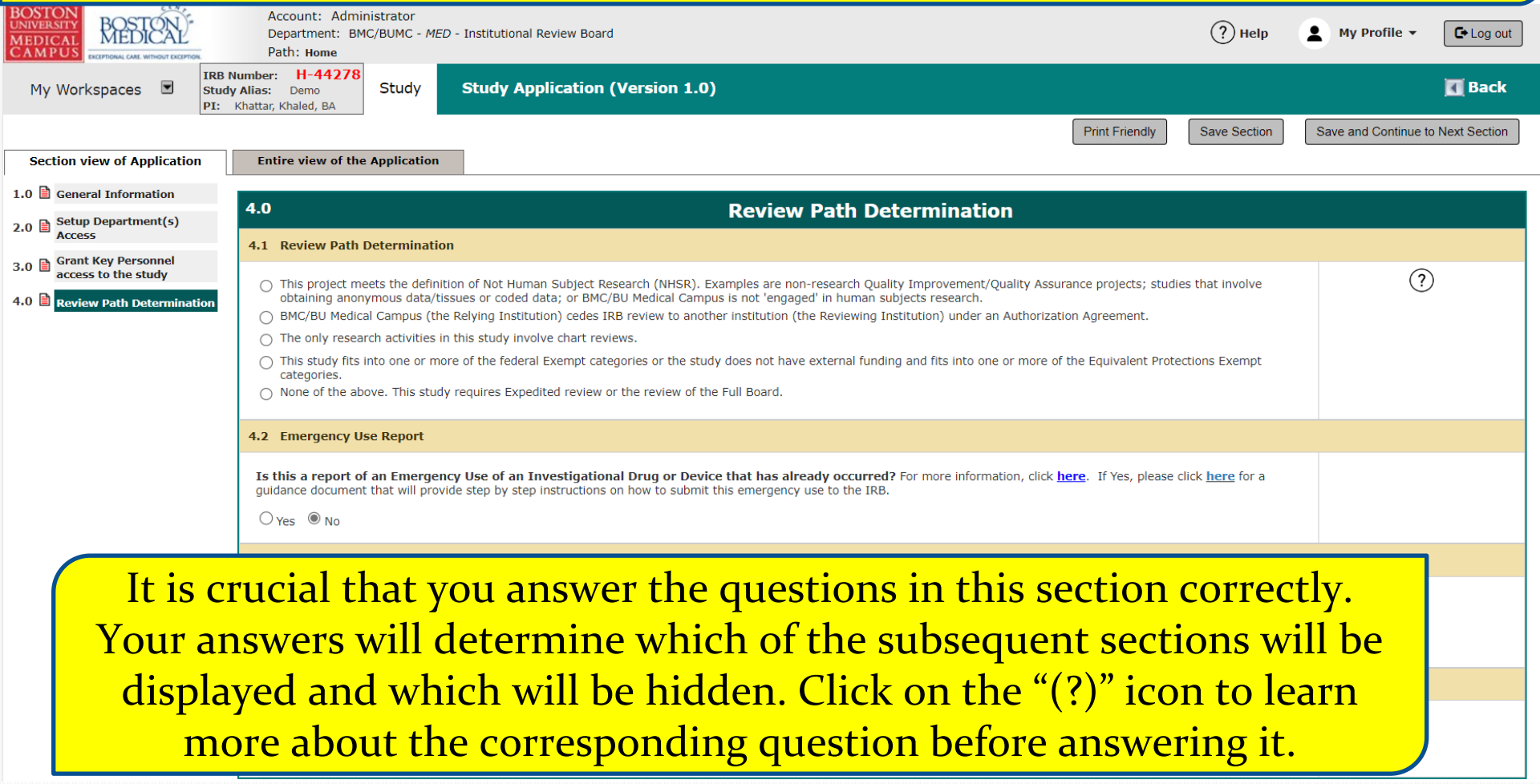
- Principal Investigator
- Department Administrator (Department Chair/Section Chief)
- Supervising Principal Investigator (if PI is a student, resident, or fellow)

This will bring you back to Section "3.0 Grant Key Personnel access to the study". All your study personnel and their roles should now be listed in this section (green arrow)



Once you're done adding personnel, click on "Save and Continue to Next Section" button

The system will transition you to Section 4.0 “Review Path Determination”



It is crucial that you answer the questions in this section correctly. Your answers will determine which of the subsequent sections will be displayed and which will be hidden. Click on the “(?)” icon to learn more about the corresponding question before answering it.

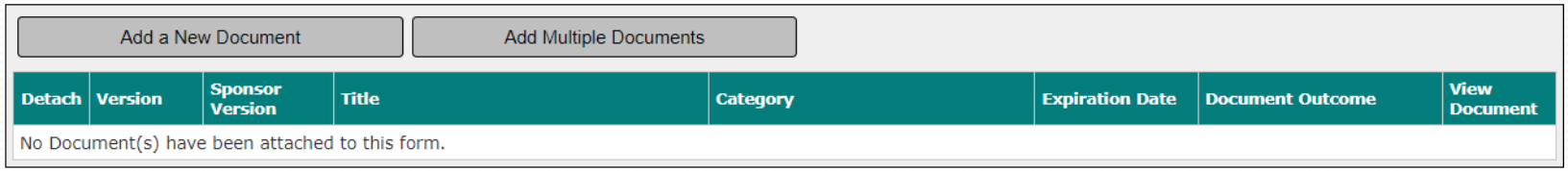
As you click “Save and Continue to Next Section”, the rest of the sections will appear in the left-hand column. Sections that have not been visited will not appear there until later.

Draft Protocol

- Section 4 “Review Path Determination” is the first section that will determine the branching for the study.
- Depending on your responses in this section, the rest of the sections will either appear or will be hidden.
- If you change your mind as you are “building” your draft and then you later make changes that will affect the branching, the system will “HIDE” all sections AFTER you reach the branching change and you will need to revisit these sections, Section by Section, and review those pages and then click “Save and Continue…” repeatedly until all the sections re-appear. The system did not delete your answers. If you click “Save and Continue…” they will reappear, unless that section is no longer required after the changes that you have made. New sections might also appear and need to be completed.

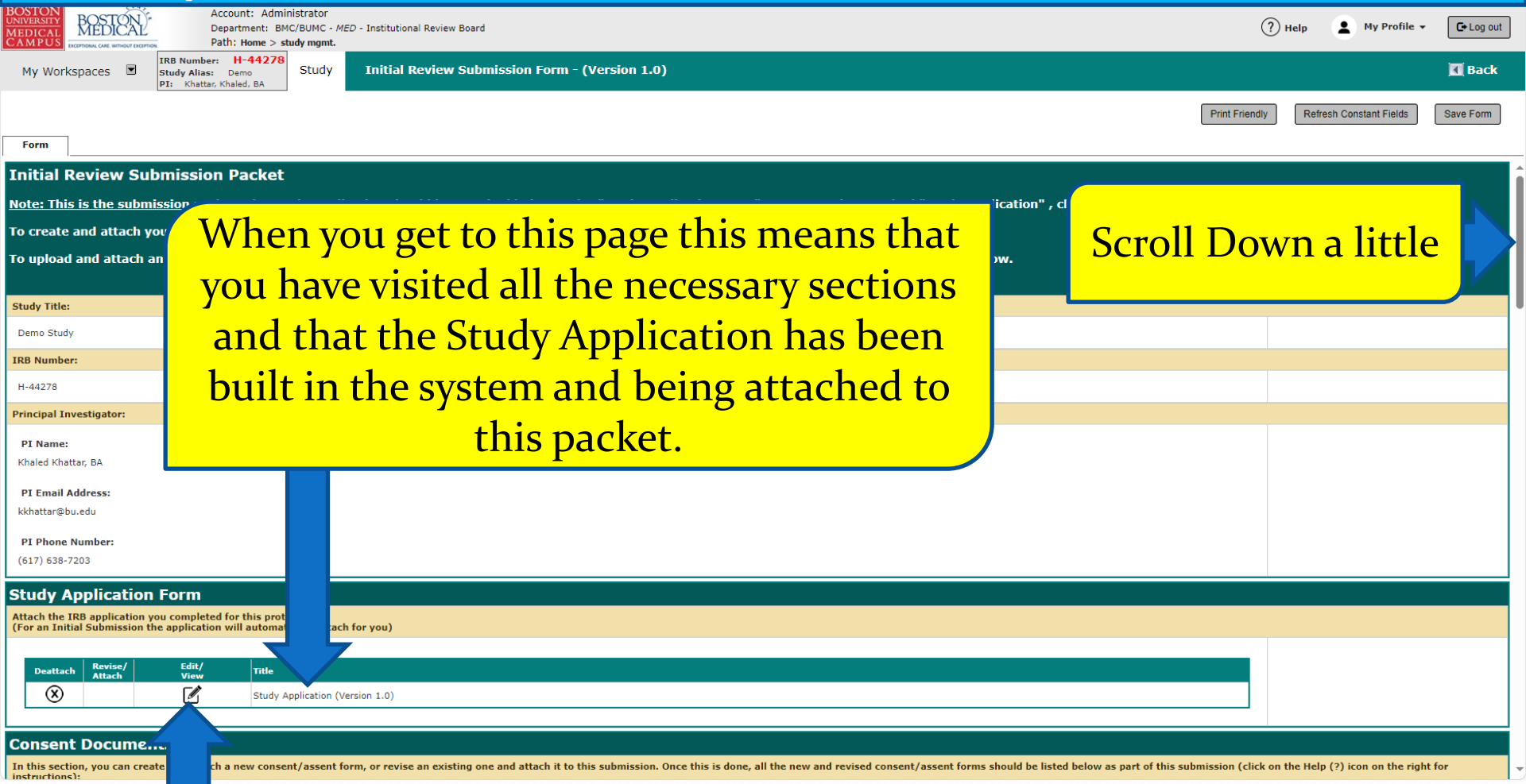
Draft Protocol (cont.)

- In many sections, you will encounter the Study Document table (see screenshot below) where you can add documents in the Study Application. This is optional (unless it's required), as you can add your study documents all at once when the system transitions you to the "Initial Review Submission Form" in the "Other Study Documents" section.



- If you decide to add a study document within the Study Application, please follow the instructions in this link: https://www.bumc.bu.edu/irb/files/2016/10/How-to-Add-a-New-Study-Document.pdf

When you finish filling out all the sections in the Study Application, the system will transition you to the "Initial Review Submission Form".



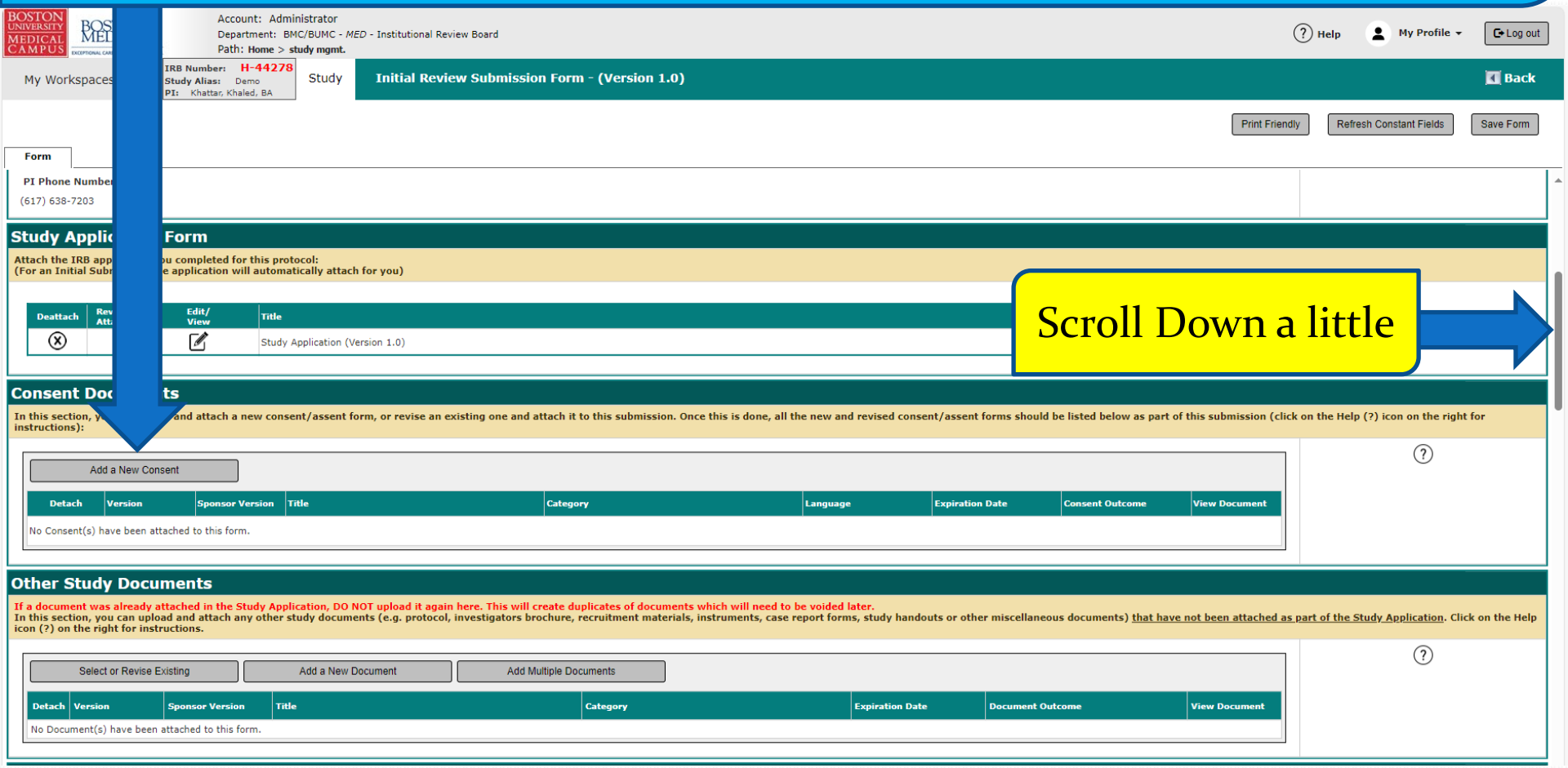
When you get to this page this means that you have visited all the necessary sections and that the Study Application has been built in the system and being attached to this packet.

Scroll Down a little

Next time you need to access the Study Application, click on the icon under "Edit/View"

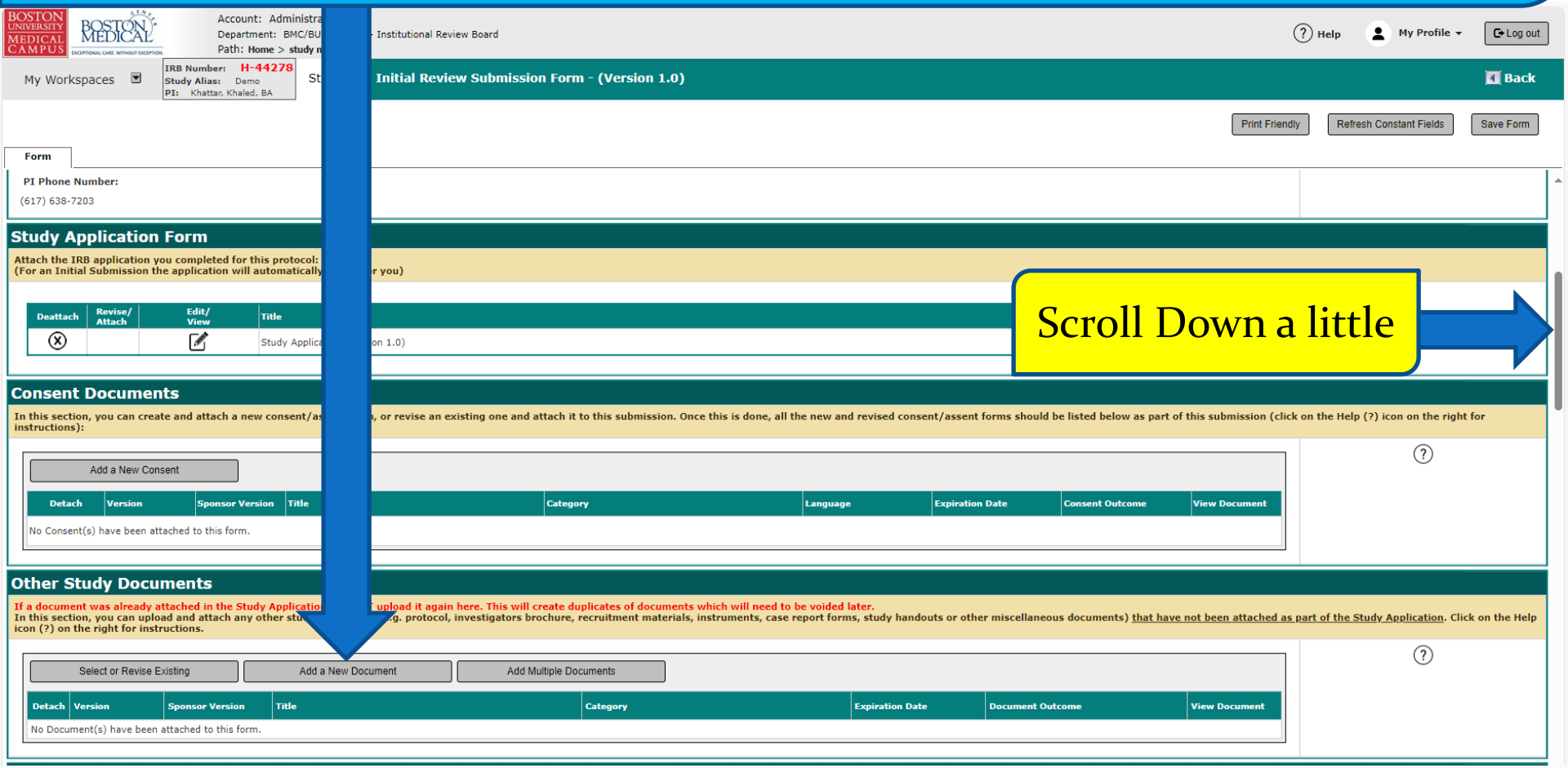
This is where all consent forms should be generated and attached to the submission. To add a new consent form, click on the grey button. Follow the instructions in this link:

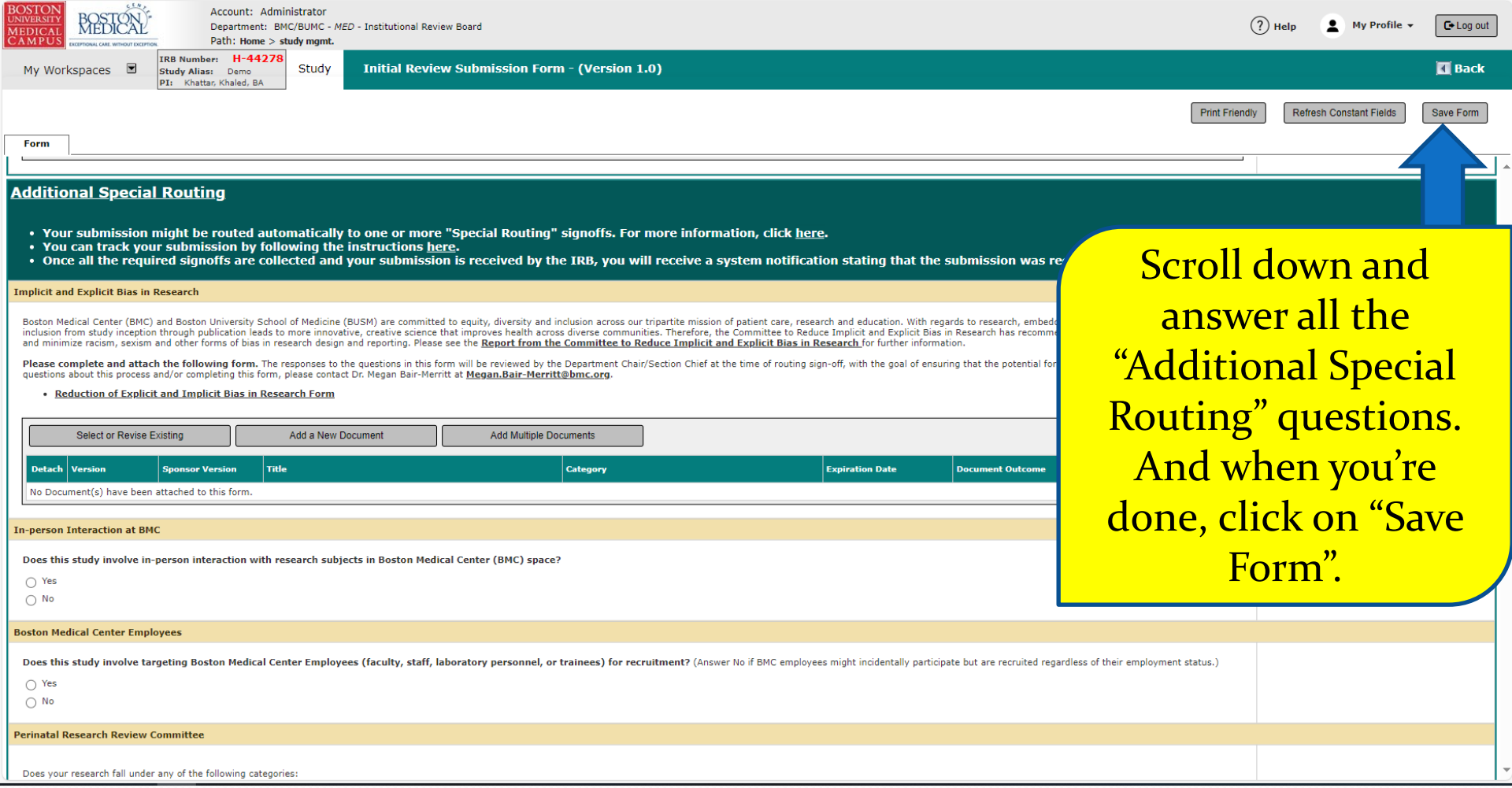
- How to add a new Consent Form



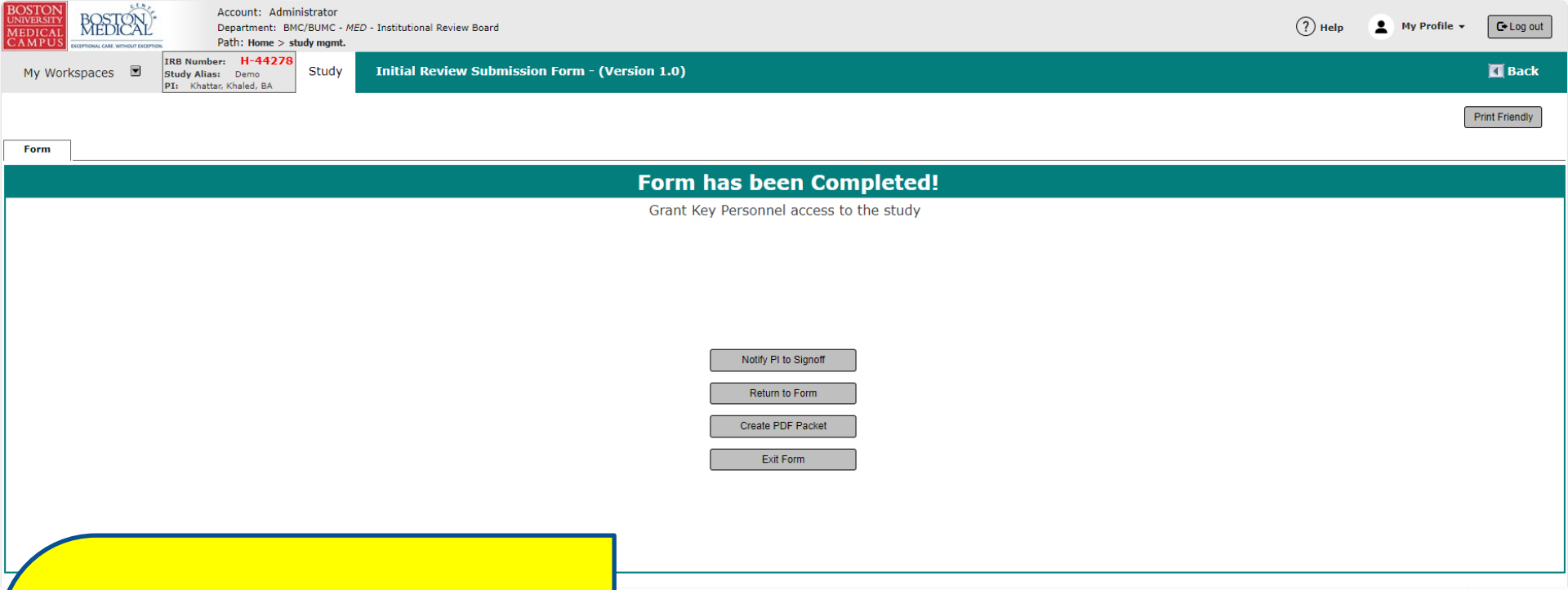
This section is where any additional study documents are uploaded and attached to the submission. To add a new study document, click on the grey button. Follow the instructions in this link:

- How to add a new Study Document



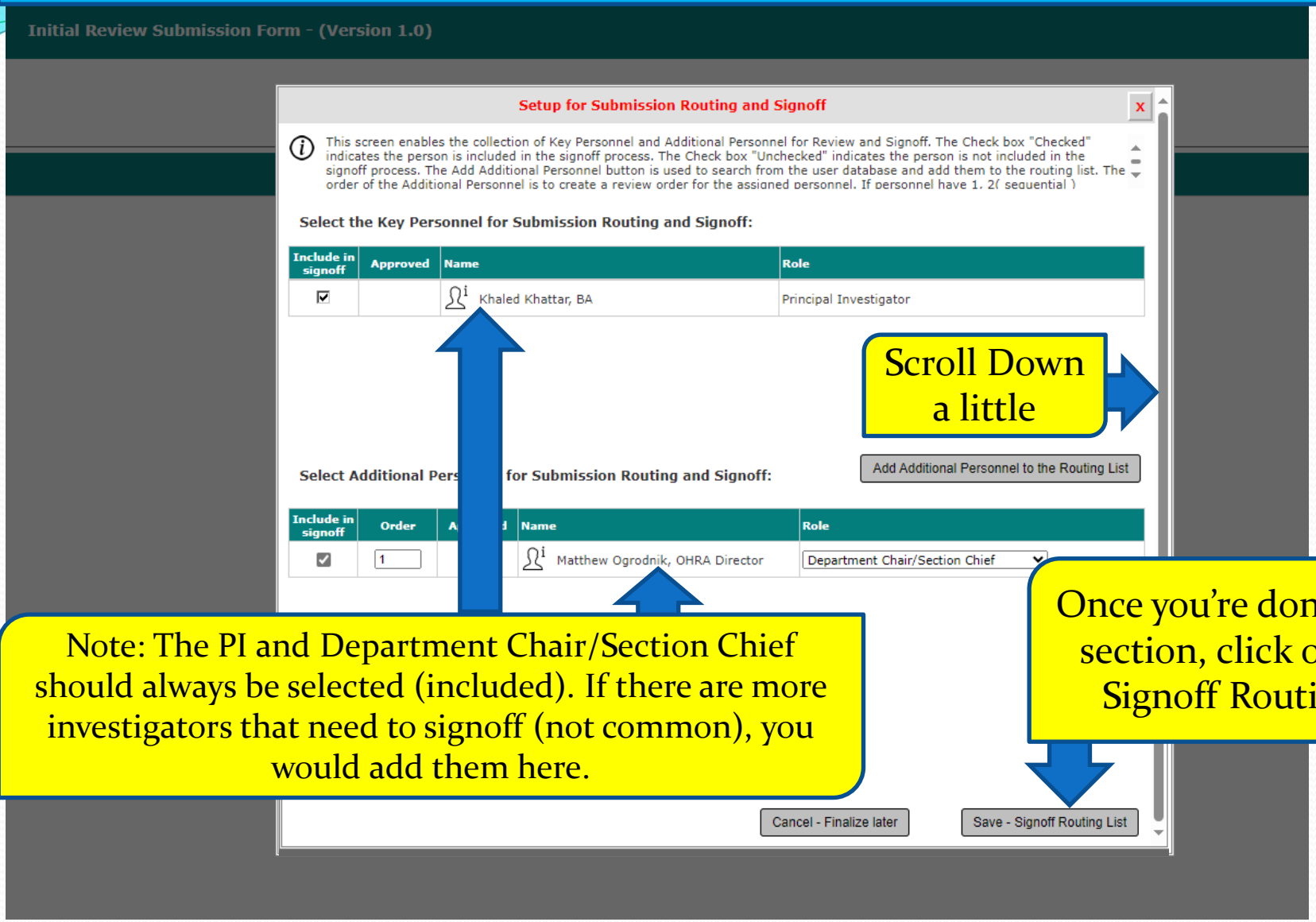


Scroll down and answer all the "Additional Special Routing" questions. And when you're done, click on "Save Form".



You can click on “Exit Form” to exit this submission and complete later. If you’re ready to submit, click on “Signoff and Submit” (not visible here) if you are the PI; or if you are someone other the PI, click on “Notify PI to Signoff”.

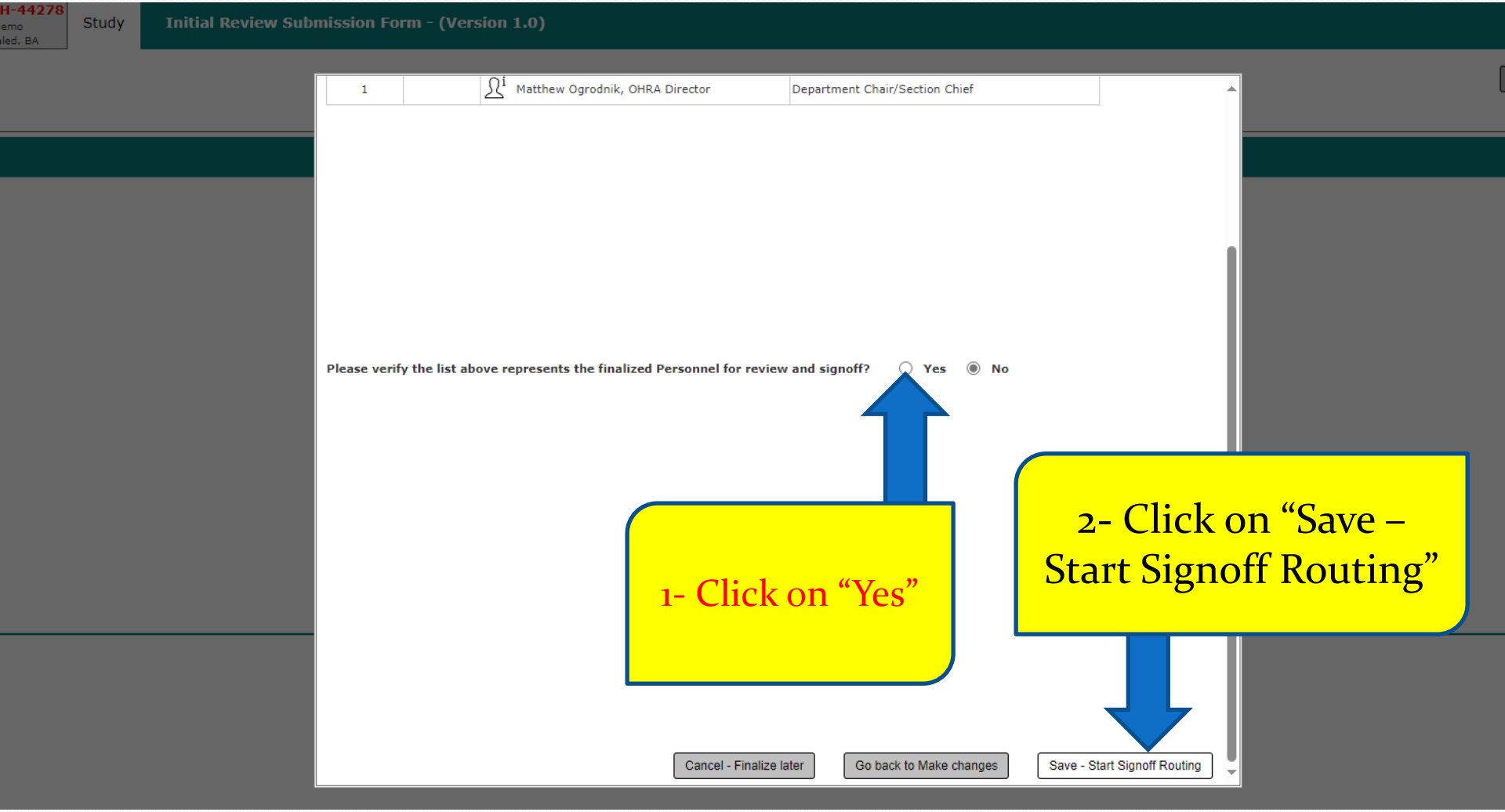
If you have clicked in the previous screen on either “Signoff and Submit” or “Notify PI to signoff”, the system will bring you to this screen to setup signoff list.



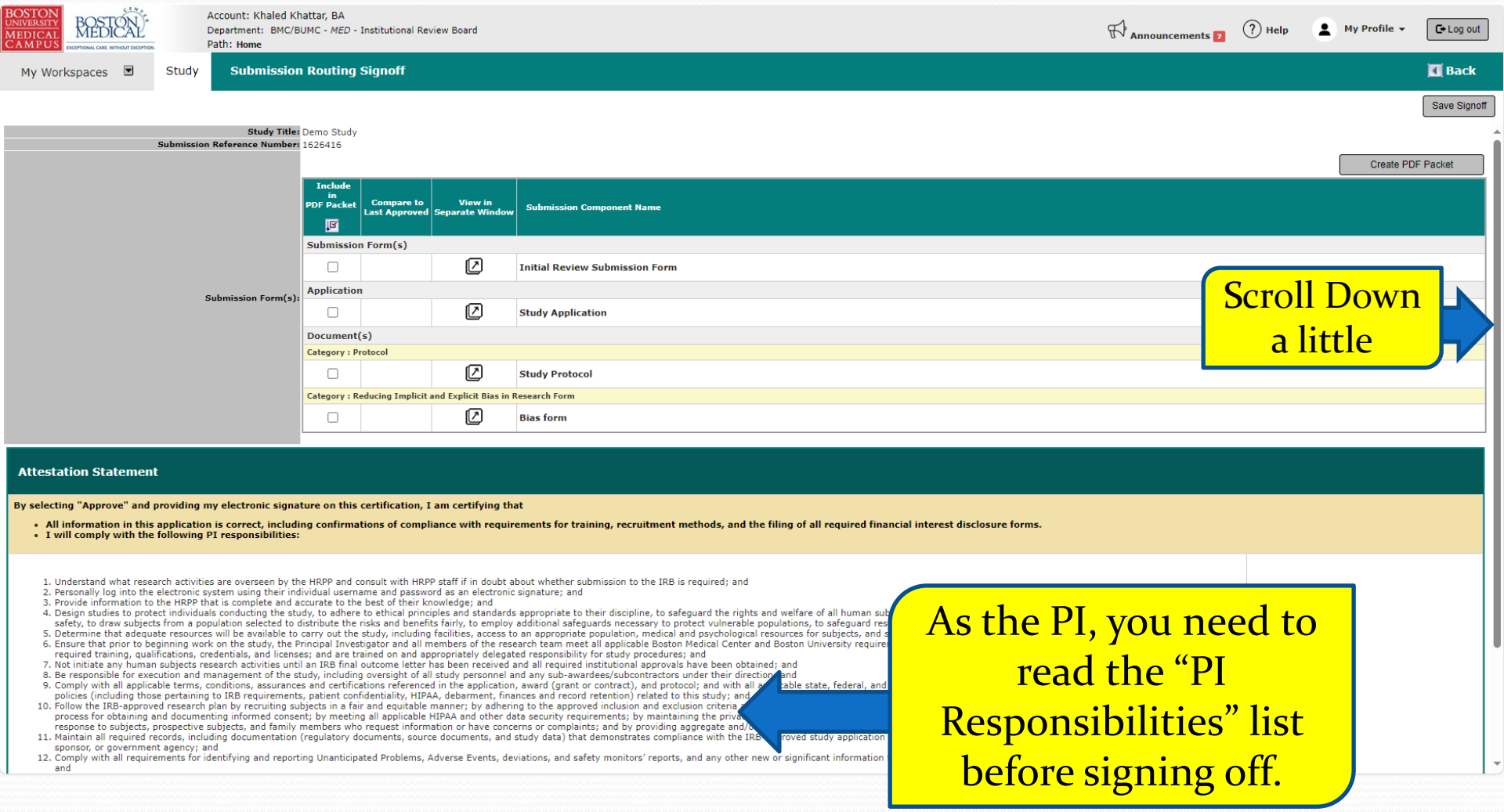
Note: The PI and Department Chair/Section Chief should always be selected (included). If there are more investigators that need to signoff (not common), you would add them here.

Once you’re done with this section, click on “Save – Signoff Routing List”

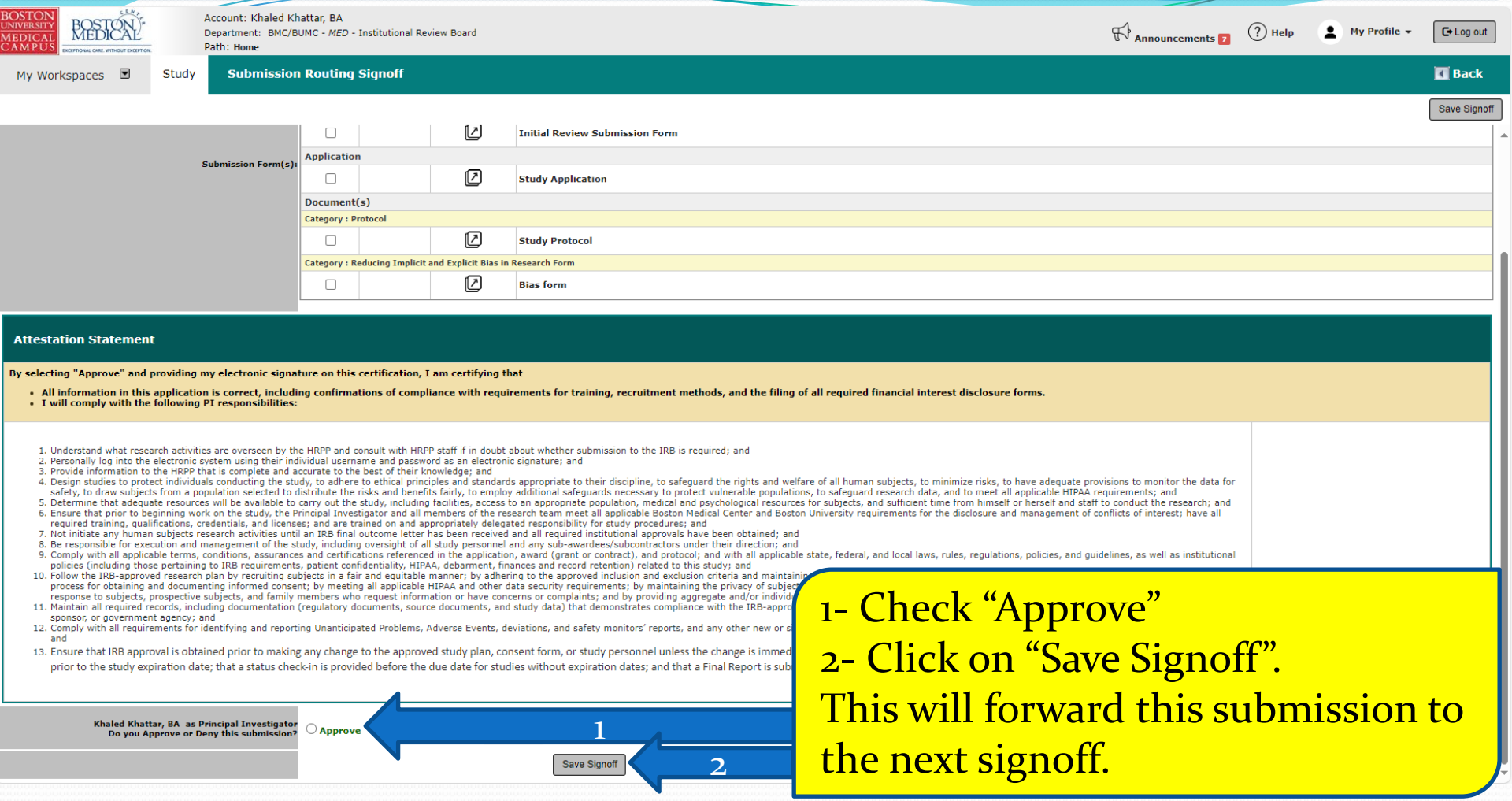
If you have clicked in the previous screen on “Save – Signoff Routing List”, the system will bring you to this screen.



If you are not the PI, skip this slide and the next one to slide # 24. If you are the PI listed on this study, the system will take you to the PI's "Submission Routing Signoff" page.



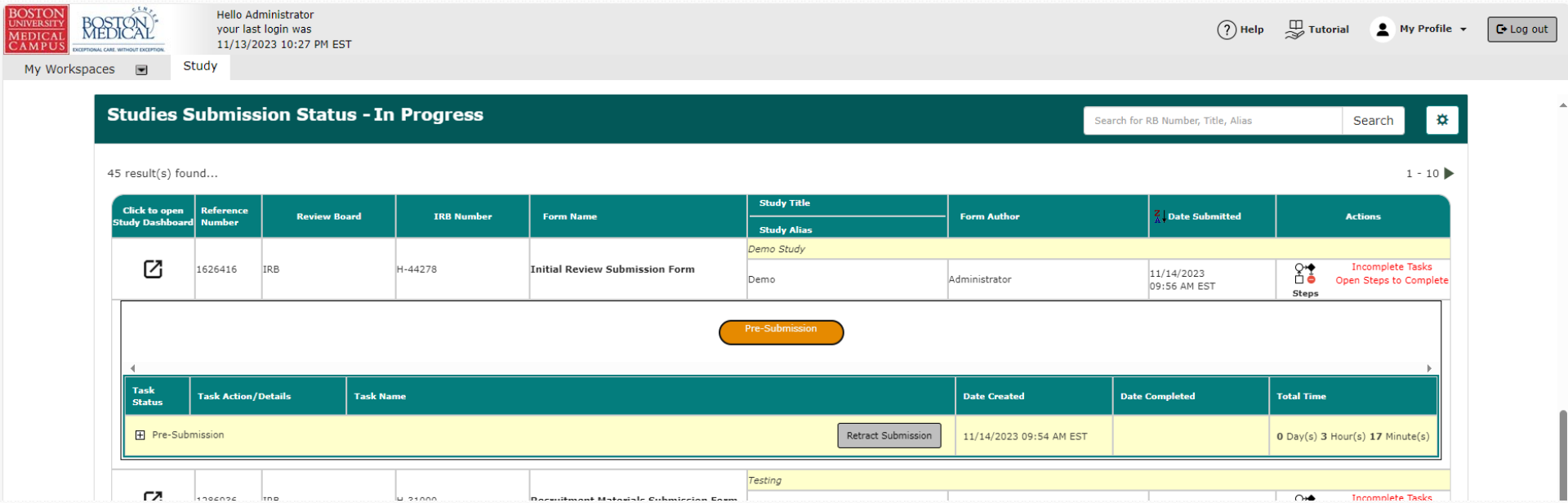
You are still in the PI's "Submission Routing Signoff" page.



1- Check "Approve"
2- Click on "Save Signoff".
This will forward this submission to the next signoff.

Note: Please never "Deny" the submission here. Instead, you or a study team can retract the submission for more changes by following these instruction:
https://www.bumc.bu.edu/irb/files/2016/10/How-to-retract-a-submission.pdf

The system will transition you to the “Studies Submission Status – In Progress” section in your Home page where you can check submission progress including signoff progress.



To access/view this draft once you close out of it, follow the instructions in the link below:

https://www.bumc.bu.edu/irb/files/2016/10/How-to-open-a-draft-INSPIR-II-protocol.pdf

Other INSPIR II Help Resources

(https://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/)

- How to log-in to INSPIR II
- How to update your Personal Profile
- How to get the Study Assistant tab if you don't have it
- How to open a draft INSPIR II protocol
- How to sign off on protocol as PI
- How to sign off on protocol by Department Chairs
- How to add new internal investigators/research staff
- How to add external investigators
- How to respond to a Review Response for an Initial Review
- How to create and submit a Progress Report
- How to respond to a Review Response for a Continuing Review
- How to create and submit an Amendment
- How to respond to a Review Response for an Amendment
- How to add a new Consent Form
- How to revise an existing Consent Form
- How to add a new Study Document
- How to revise an existing Study Document