INSPIR II Introductory Training

Navigating the BMC/BU Medical Campus IRB Electronic System

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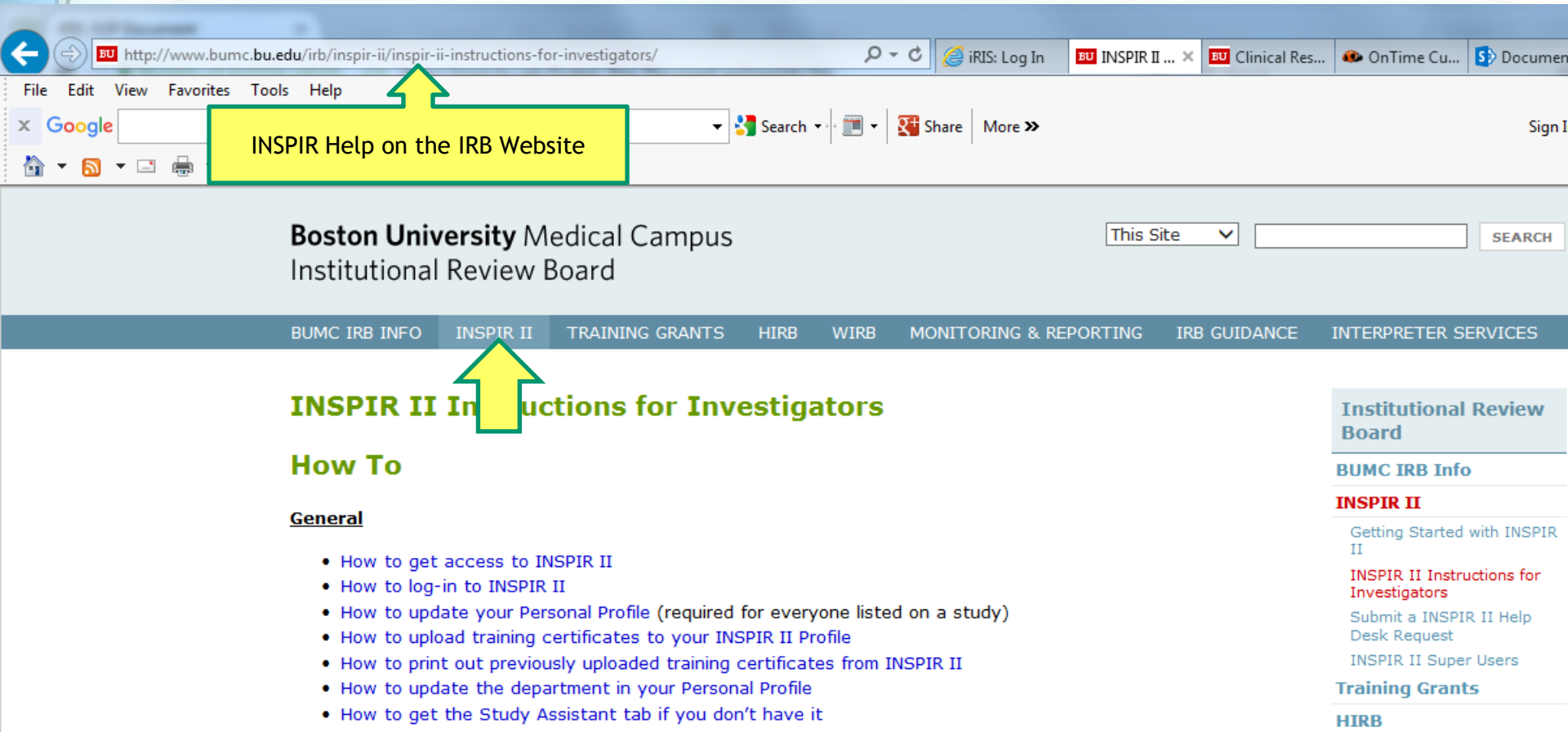
INSPIR II

- INSPIR II Help Resources
  - On the IRB Website
  - In the INSPIR System and Forms
- INSPIR II Access
  - Get Access to INSPIR
  - Login into INSPIR
  - Update your INSPIR Profile
- How to perform some basic INSPIR II functions
  - Create a new IRB Application Draft
  - Create and attach consent forms and study documents
  - Complete signoff list and submit to the IRB
  - Check status and Submissions History
  - Respond to stipulations in a Review Response
  - Amendments, Continuing Review, and other forms

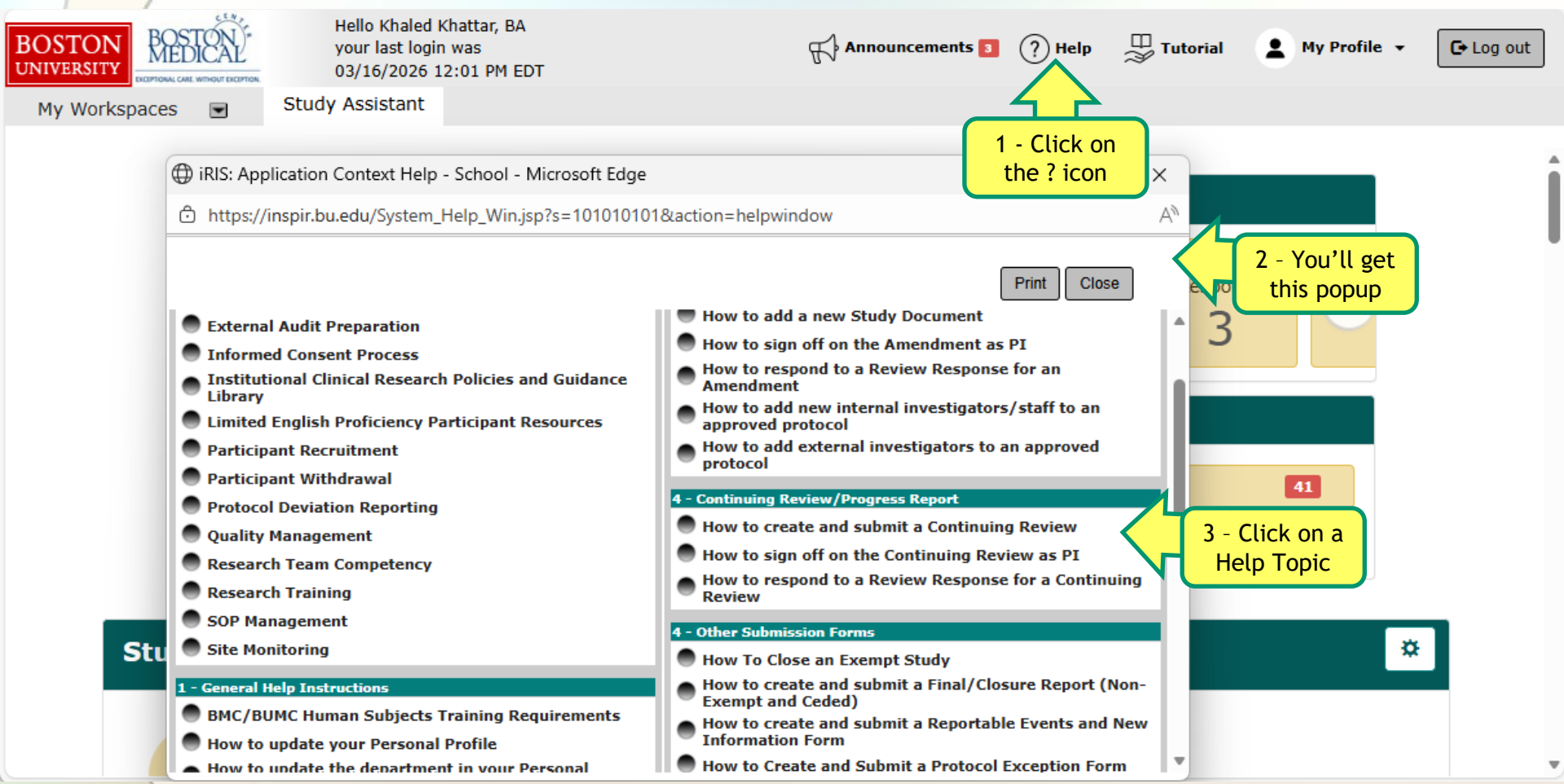
INSPIR II Help Resources

- On the IRB Website

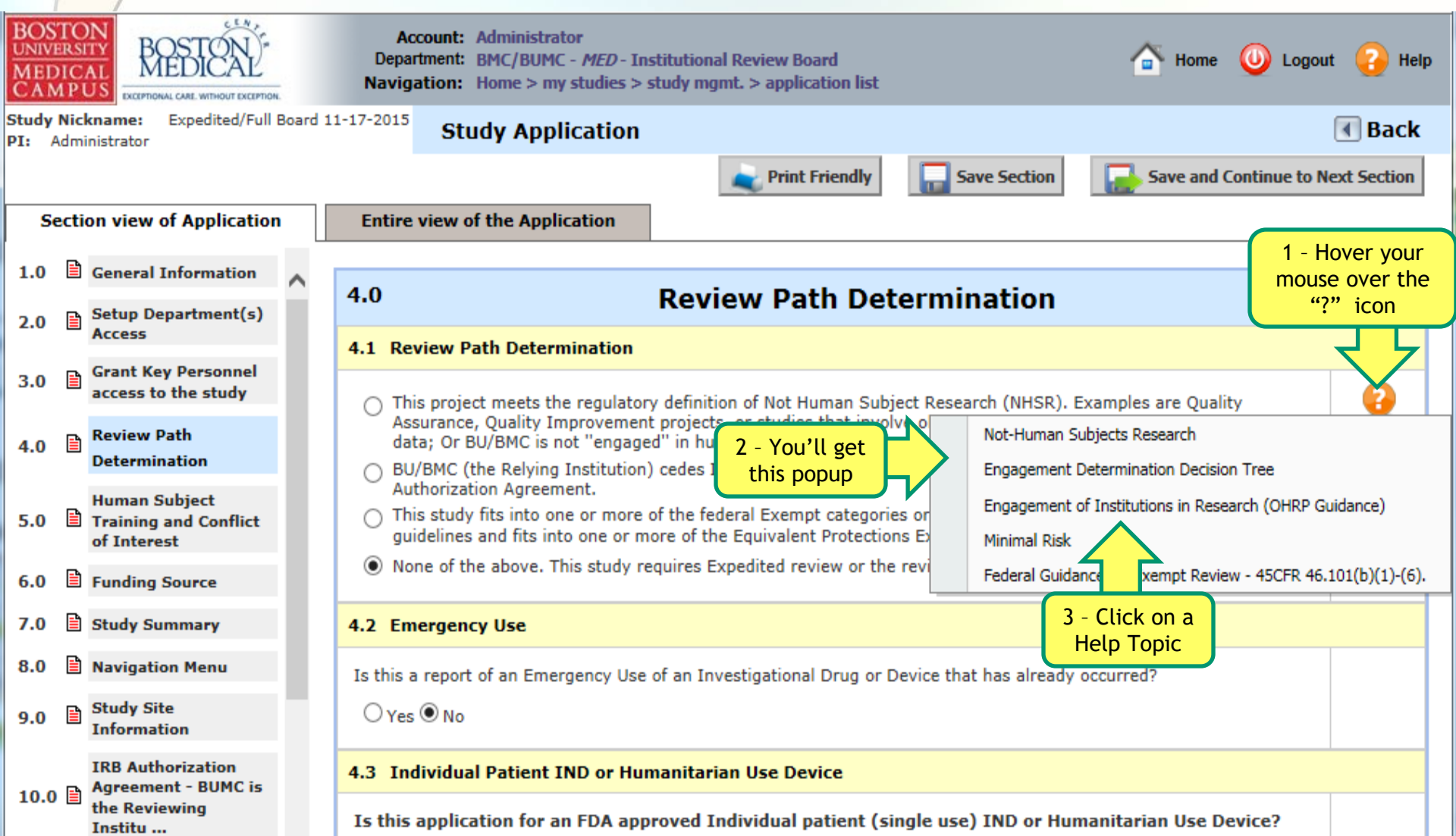
Visit www.bumc.bu.edu/irb and click on "INSPIR II" then on "**INSPIR II Instructions for Investigators**".



- In the INSPIR System and Forms
  - The “Help” icon on your INSPIR Home Page



- In the INSPIR System and Forms
  - The “Help” icon in the form you’re working on for help on that section



- INSPIR II Access
  - Get Access to INSPIR
    - There is only one way for an INSPIR user account to be created; and that's by logging into INSPIR for the first time. If the study team cannot find you in INSPIR to add you to their study, this means that you have never logged in to INSPIR before to create your INSPIR account.
    - You will need a BU username and Kerberos password, or a BMC username and BMC password to login to the INSPIR system.
    - If you have a BU username and Kerberos password, your BU username is the text part of your BU email address before "@bu.edu"; for example, if your BU email address is "jdoe@bu.edu", then your username is "jdoe"
    - If you have a BMC username and BMC password, your BMC username is usually the first 2 letters of your first name followed by the first 5 or 6 letters of your last name; for example, if your first name is Jane and last name is Doe, then your BMC username is likely to be "jadoe" (same credentials BMC personnel use to login to BMC EPIC).
    - Please use the step-by-step instructions in this link to troubleshoot your INSPIR Access:
      - How to get access to INSPIR II

https://inspir.bu.edu/

Search...

Type “https://inspir.bu.edu” in the web browser’s address bar and click “Enter”; or click on this link: https://inspir.bu.edu. This will bring you to this INSPIR II log-in page

- You can Login using your BU username (e.g. “jdoe” if your BU email is “jdoe@bu.edu”) along with your BU Kerberos password

OR

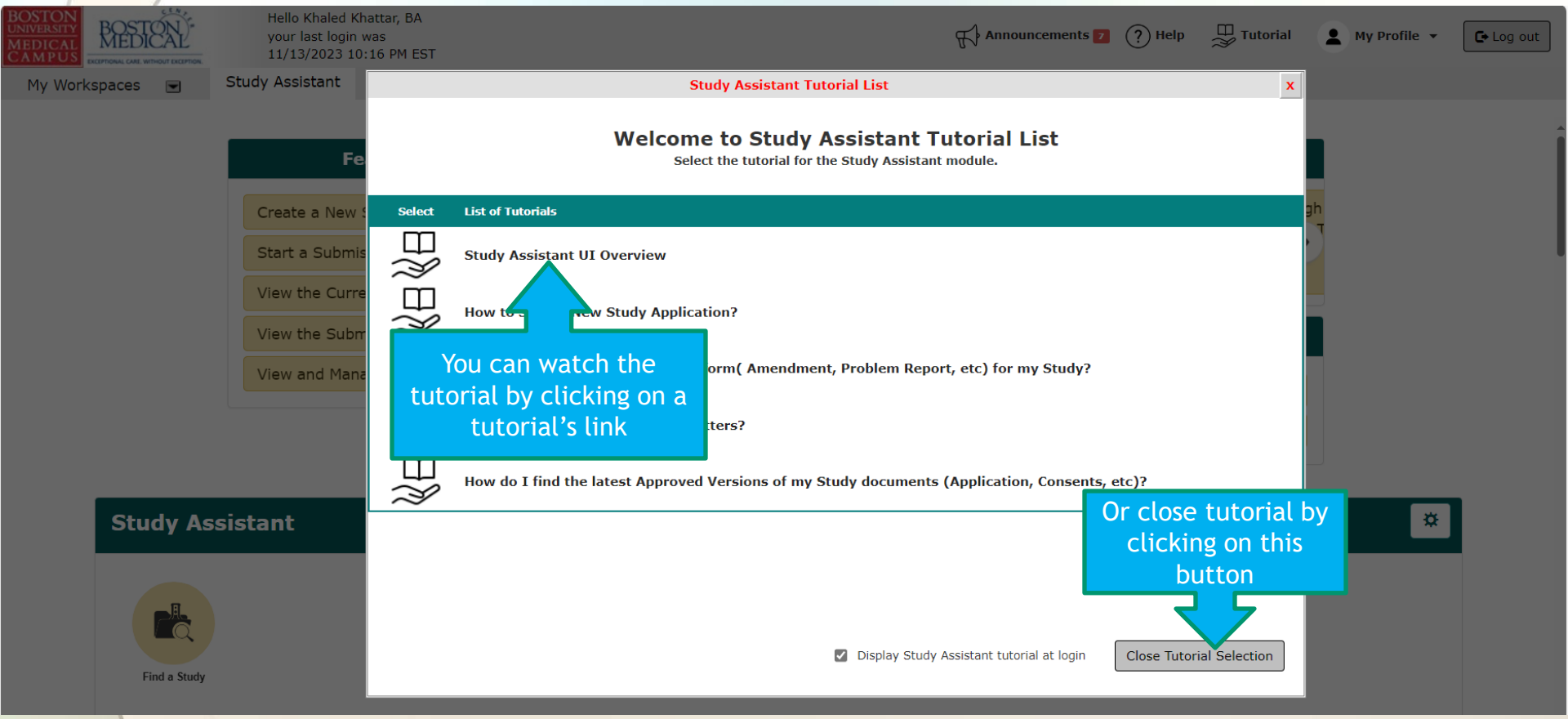
- You can Login using your BMC username (first 2 letters of your first name followed by the first 5 or 6 letters of your last name, same one you use in EPIC) along with your BMC password.

Type in your username and password and then click on “Log In”.

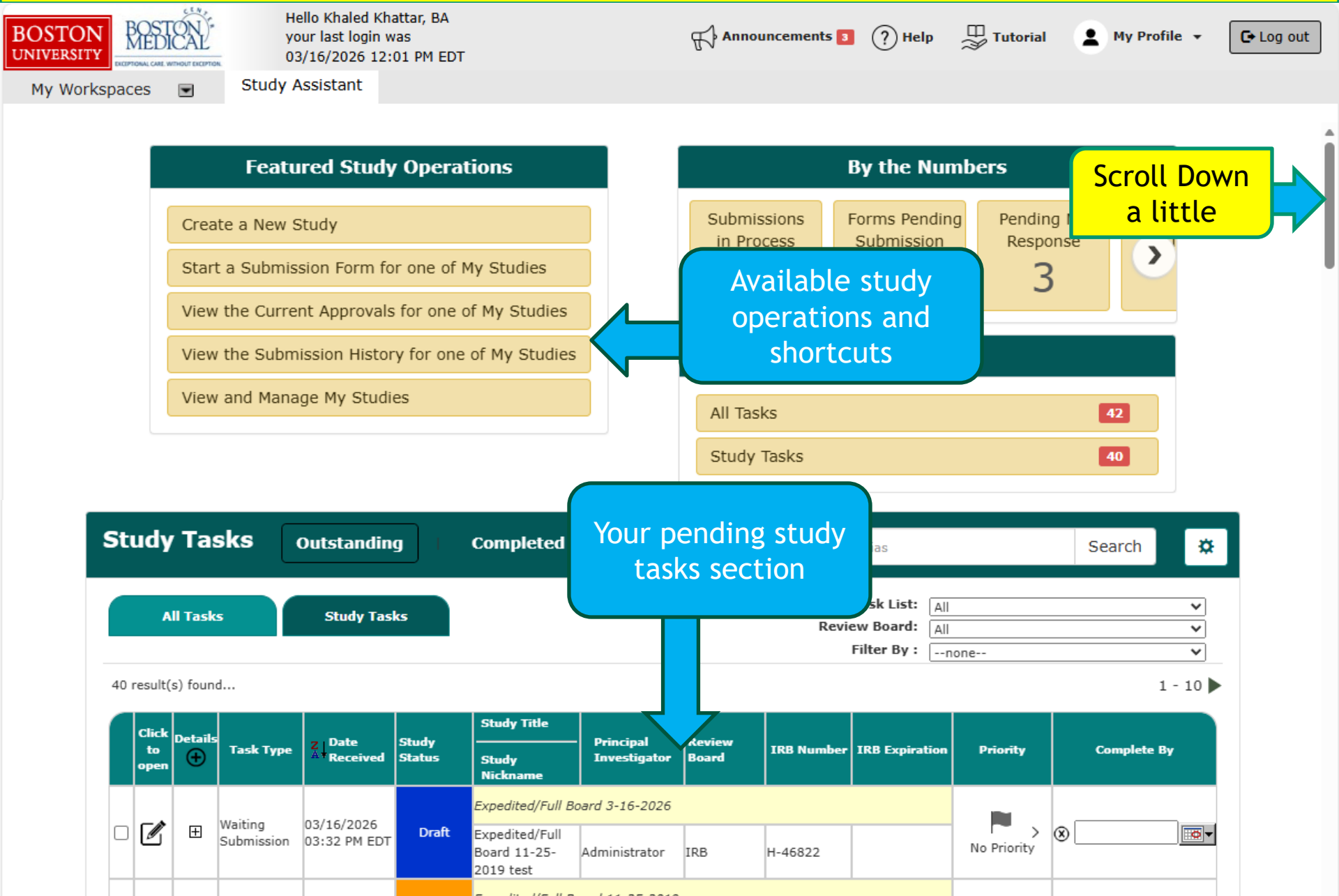
It is a violation of BU’s and BMC’s Institutional policy to log in using someone else’s username and password or to give your username and password to someone else

Logging in brings you to your personal HOME Page

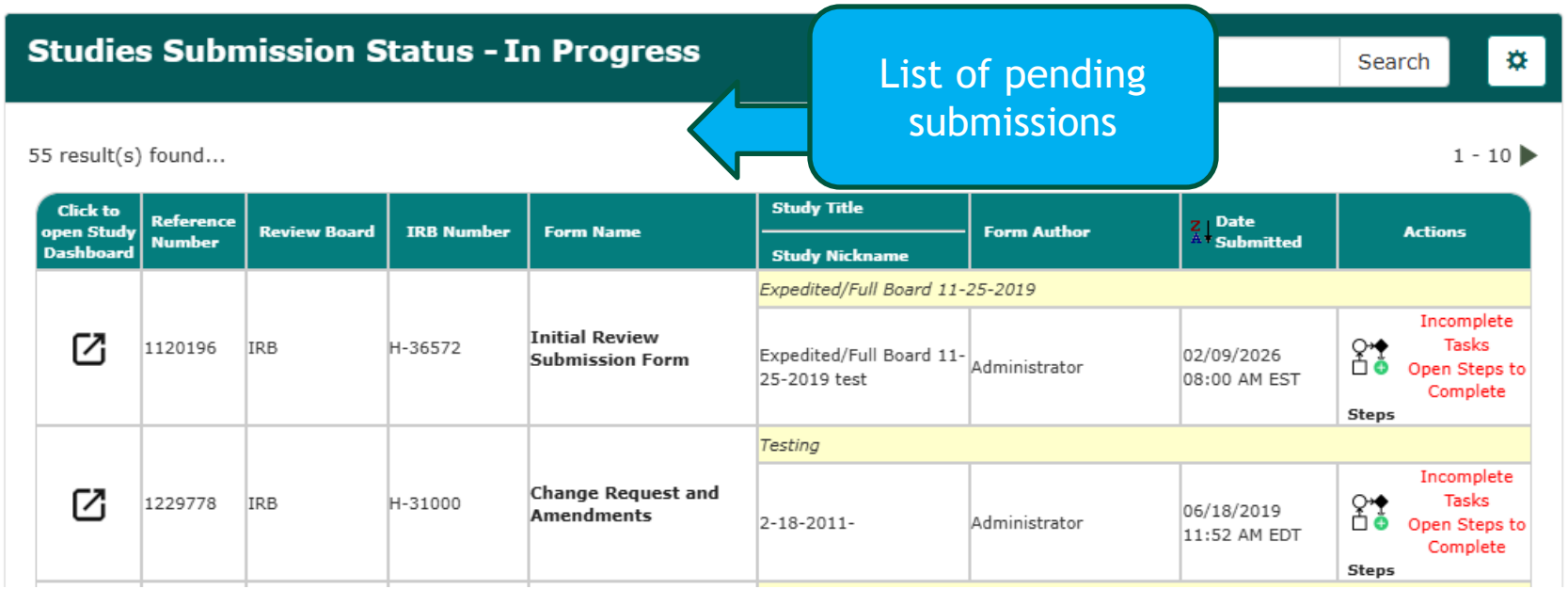
If you still have the "Display Study Assistant Tutorial at login" box checked, you will get the tutorial popup below.

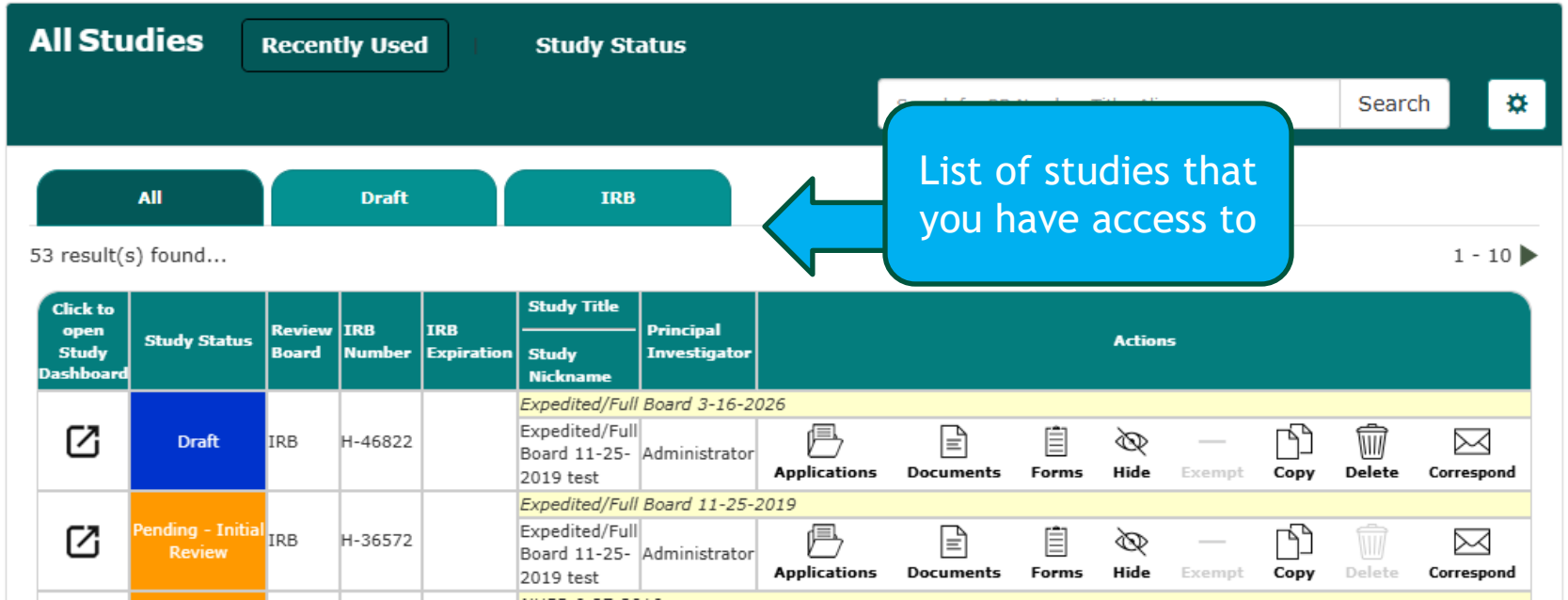


This is how your HOME Page will look like when the tutorial popup is closed

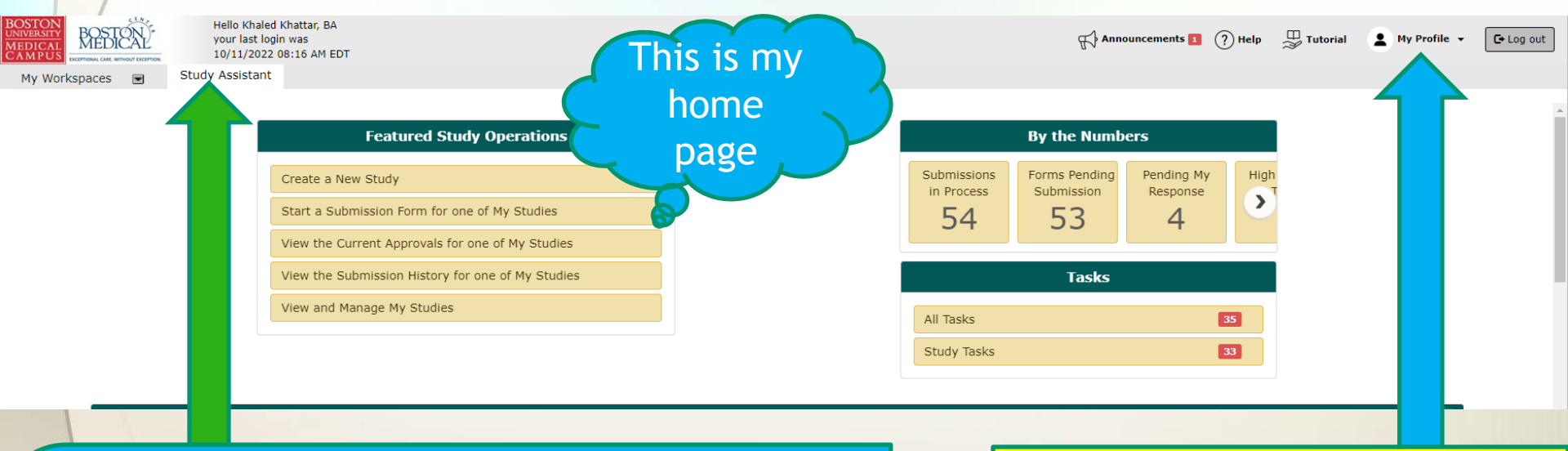


Other sections available on your HOME page





- INSPIR II Access
  - Update your INSPIR Profile
    - The first thing you should do when you login for the first time is to update your INSPIR Account Information.



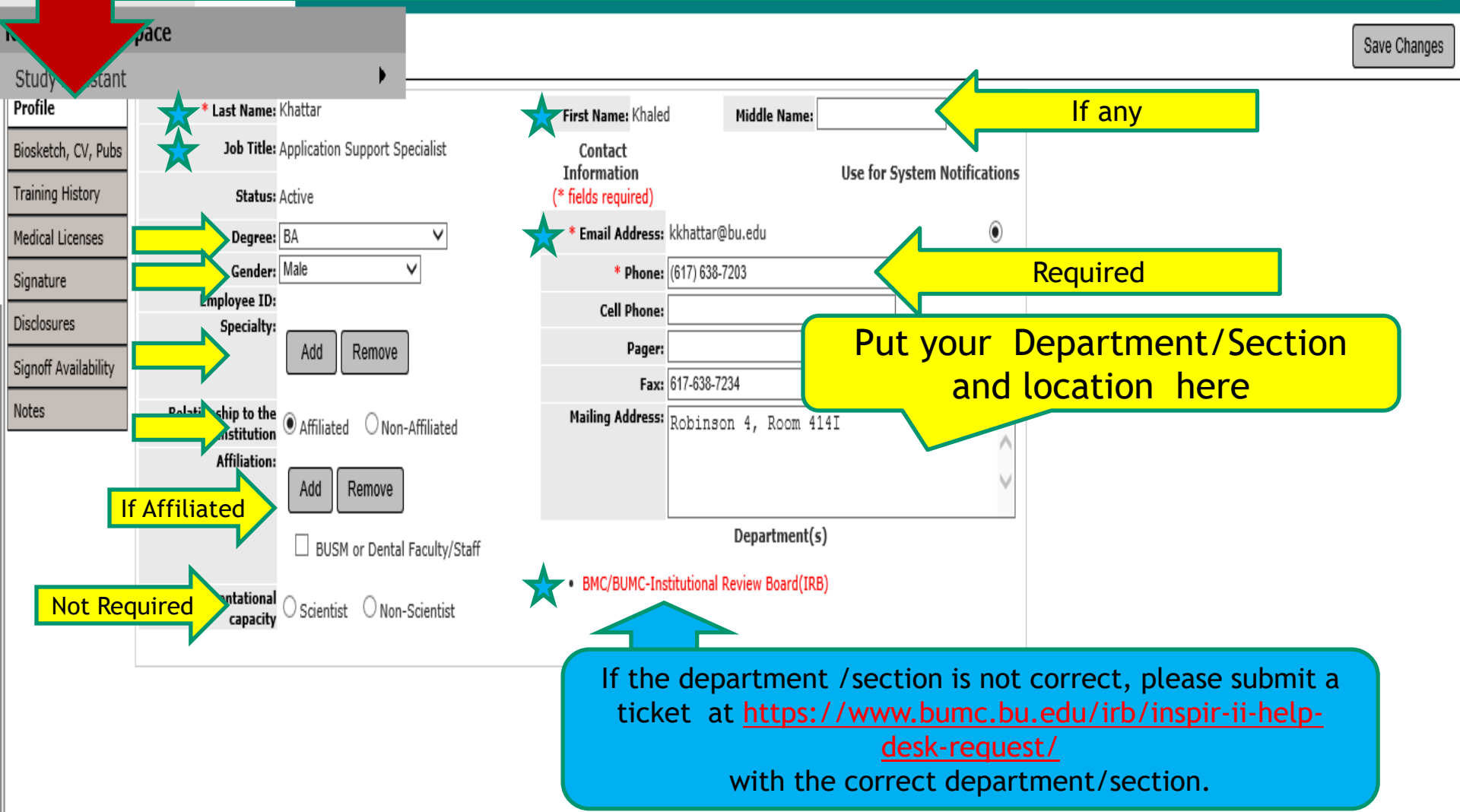
Note: If you don't see "Study Assistant", submit the ticket in the link below and provide us with your department and institution information: https://www.bumc.bu.edu/irb/inspir-ii-help-desk-request/

Hover your mouse pointer over "My Profile" to extend the dropdown list and then click on My Account

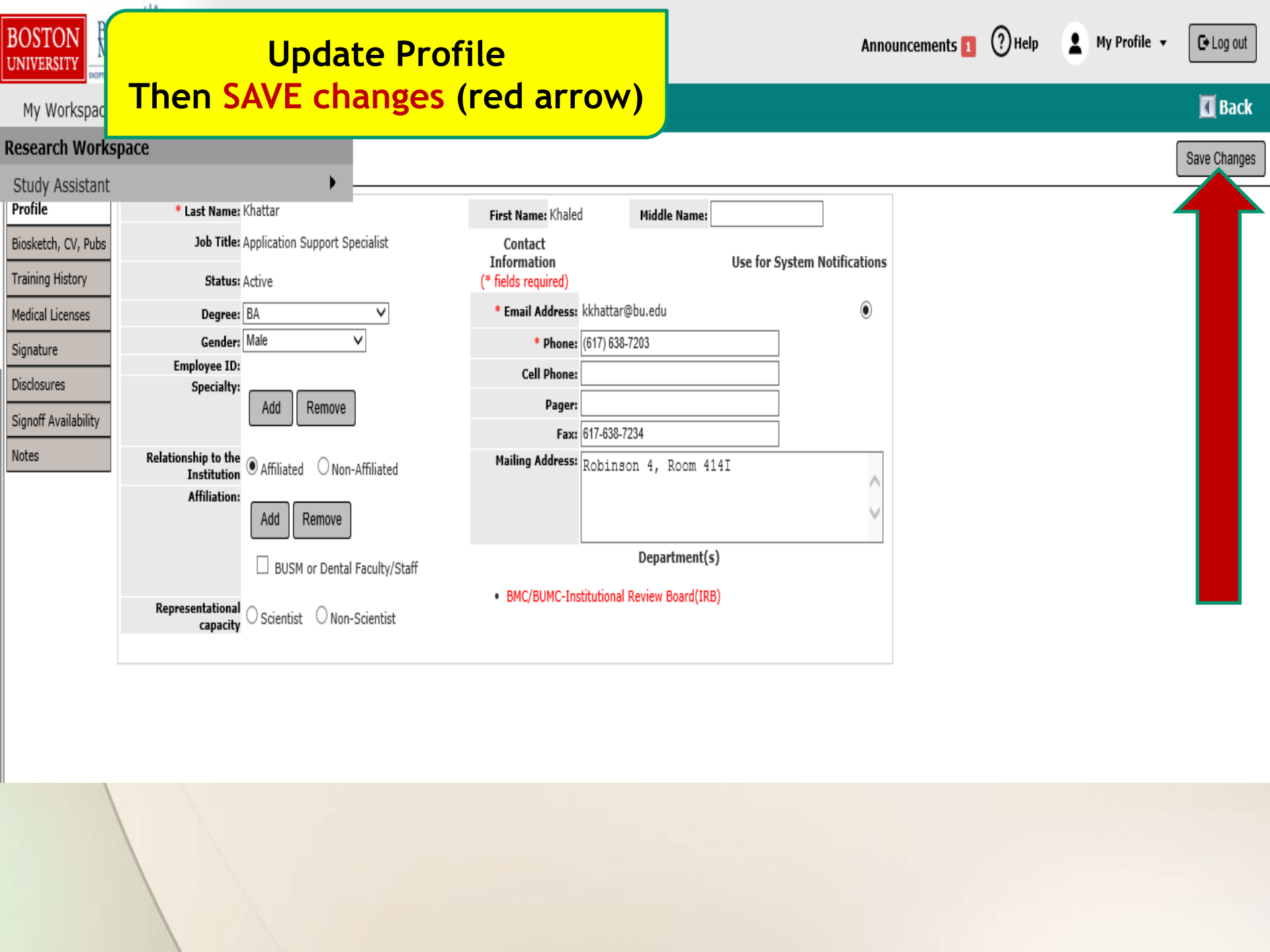
This is My Account Page sub-page: Profile

Blue star fields can't be changed

Yellow arrow fields need to be updated: Degree, Specialty, Primary Number, Location , and Affiliation. (Please list section or center within the department in the Mailing Address)



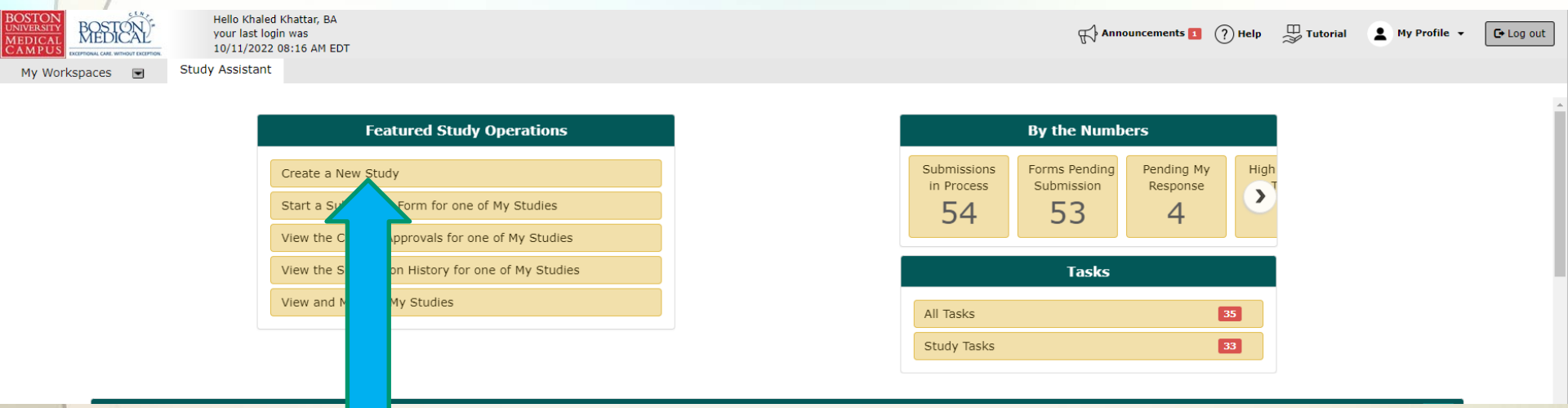
If the department /section is not correct, please submit a ticket at https://www.bumc.bu.edu/irb/inspir-ii-help-desk-request/ with the correct department/section.


Update Profile
Then SAVE changes (red arrow)
BOSTON UNIVERSITY
Announcements 1
Help
My Profile
Log out
My Workspac
Back
Research Workspace
Study Assistant
Save Changes
Profile
Biosketch, CV, Pubs
Training History
Medical Licenses
Signature
Disclosures
Signoff Availability
Notes
* Last Name: Khattar
First Name: Khaled
Middle Name:
Job Title: Application Support Specialist
Contact Information
(* fields required)
Use for System Notifications
Status: Active
Degree: BA
Gender: Male
* Email Address: kkhattar@bu.edu
* Phone: (617) 638-7203
Employee ID:
Cell Phone:
Specialty:
Add
Remove
Pager:
Fax: 617-638-7234
Relationship to the Institution
Affiliated
Non-Affiliated
Mailing Address: Robinson 4, Room 414I
Affiliation:
Add
Remove
BUSM or Dental Faculty/Staff
Department(s)
BMC/BUMC-Institutional Review Board(IRB)
Representational capacity
Scientist
Non-Scientist

Summary

- Once you update your personal profile make sure that you "save the changes"
- No one can update your profile for you- you must update your own profile. It is a violation of BU and BMC's Institutional policy to give someone your username and password or to use someone else's user-name and password.
- It is only necessary to update your personal profile once (unless something in your profile changes). It does not need to be updated for each protocol submitted.
- For each new study submitted, all study personnel will need to have an updated personal profile.

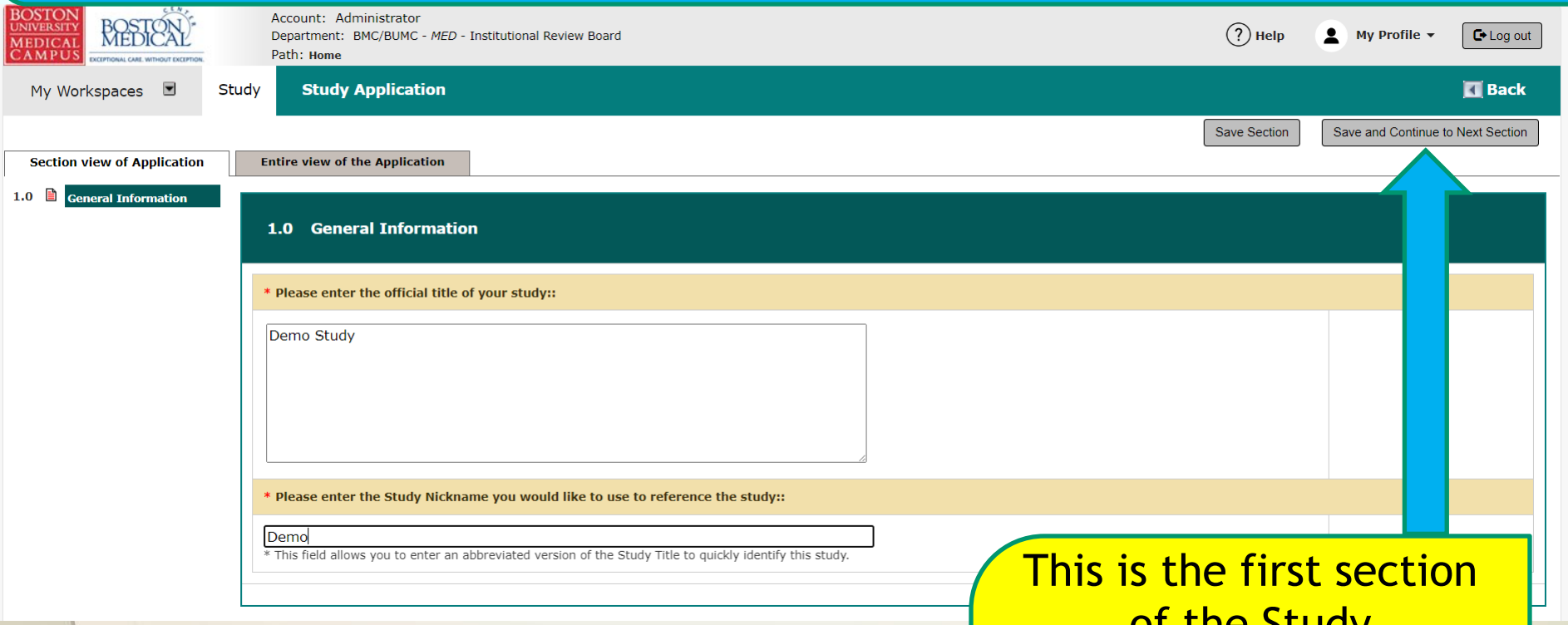
- How to perform some basic INSPIR II functions
  - Create a new IRB Application Draft



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

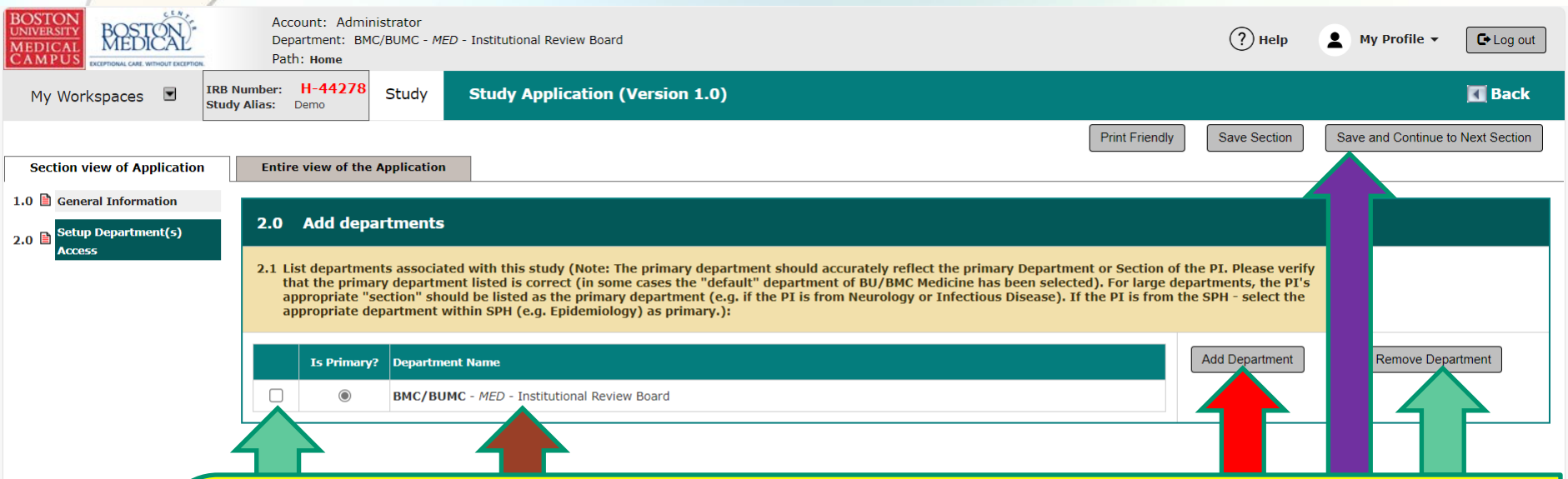
Click on **"Create a New Study"**

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



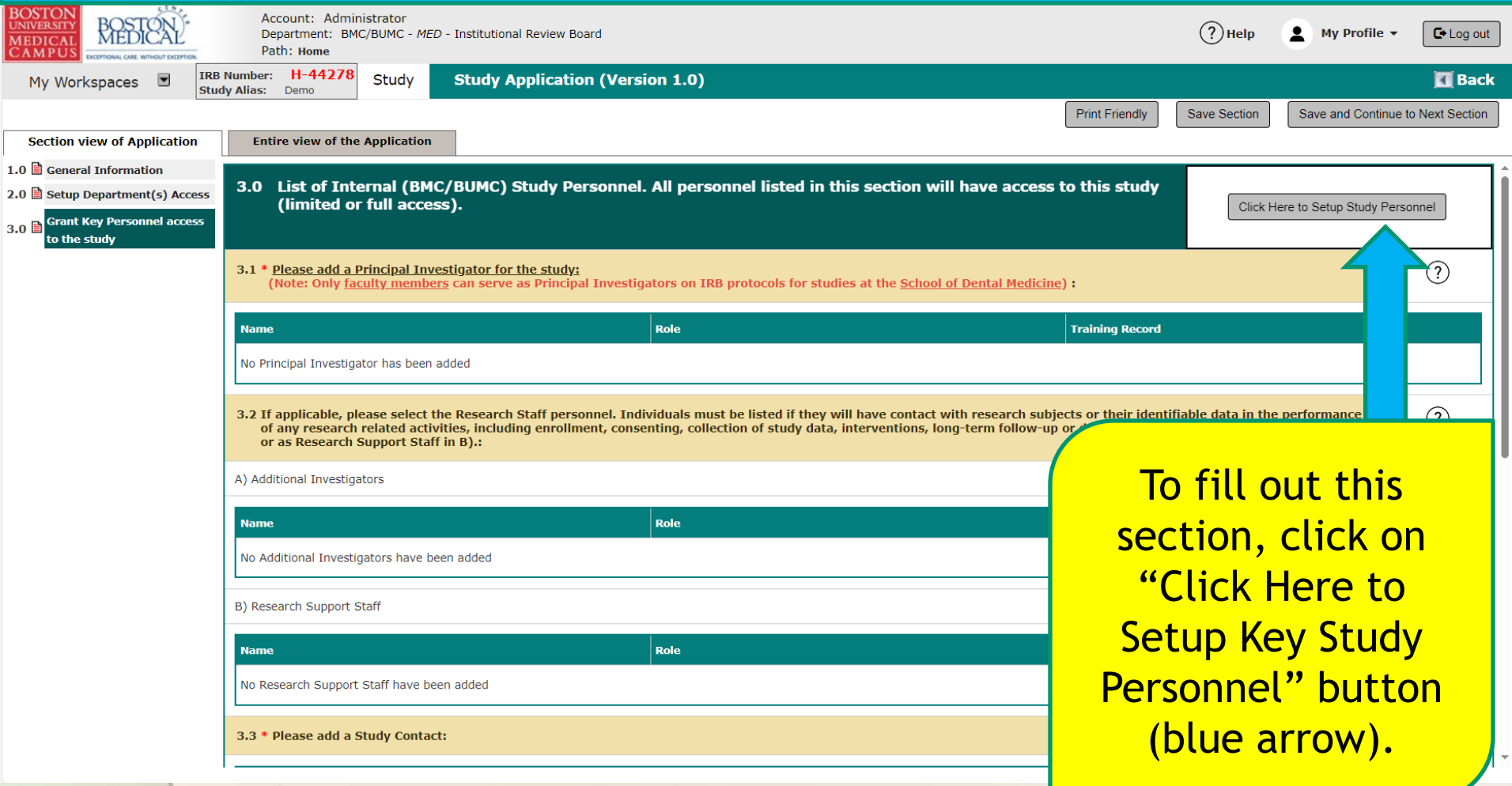
This is the first section of the Study Application. Type in the title and a nickname for the study. Then click on "Save and Continue to the next Section" button to proceed.

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.



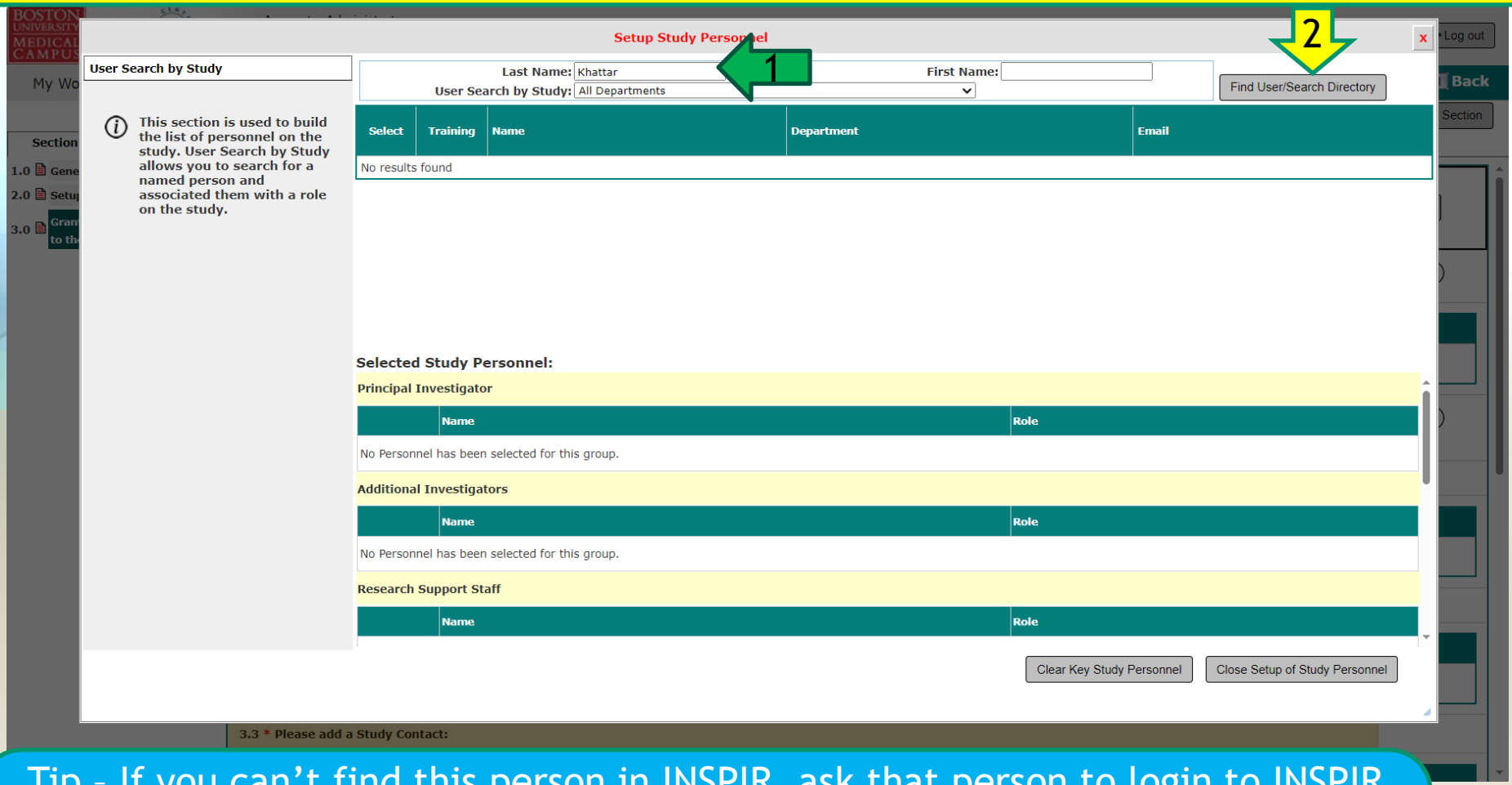
To fill out this section, click on “Click Here to Setup Key Study Personnel” button (blue arrow).

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.

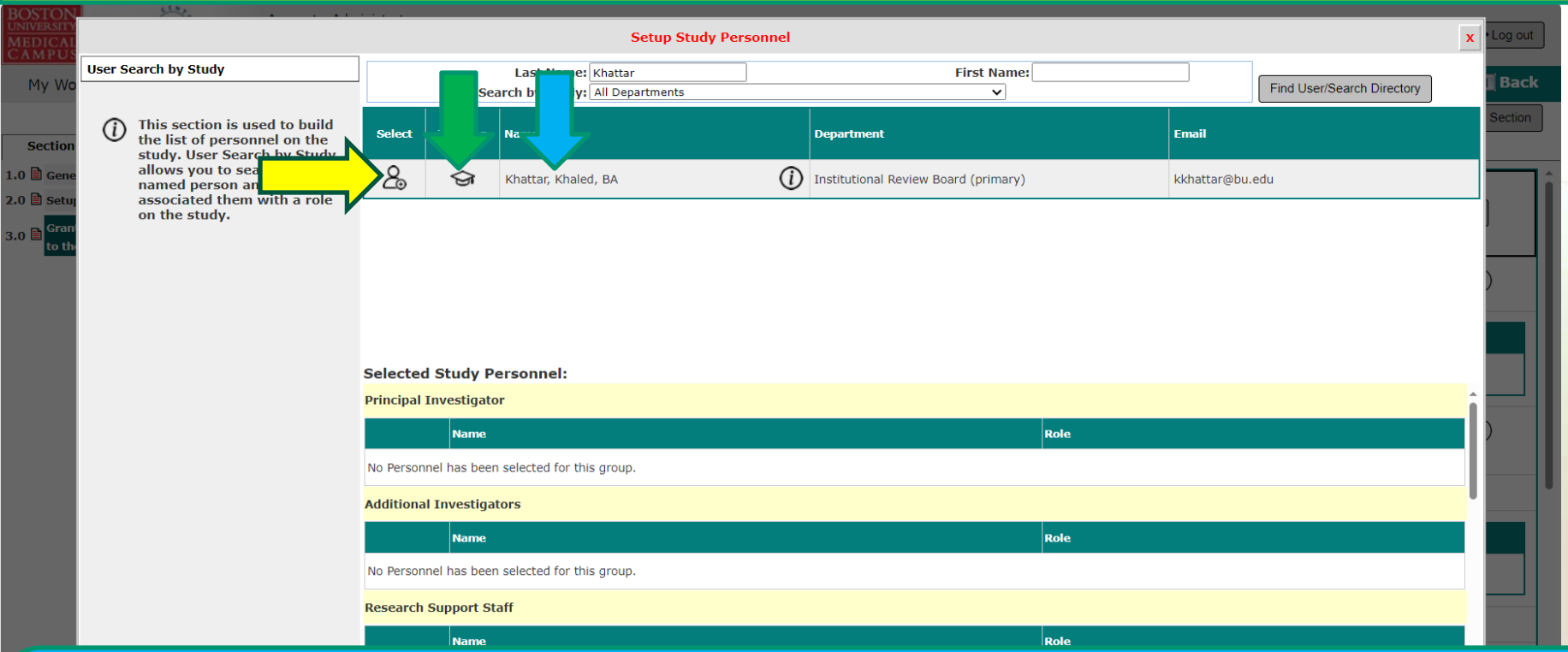
The system will open the “Setup Study Personnel” popup.
1- Enter the last name (green arrow)
2- Click on the “Find User/Search Directory” button (yellow arrow) to search for the person.



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)

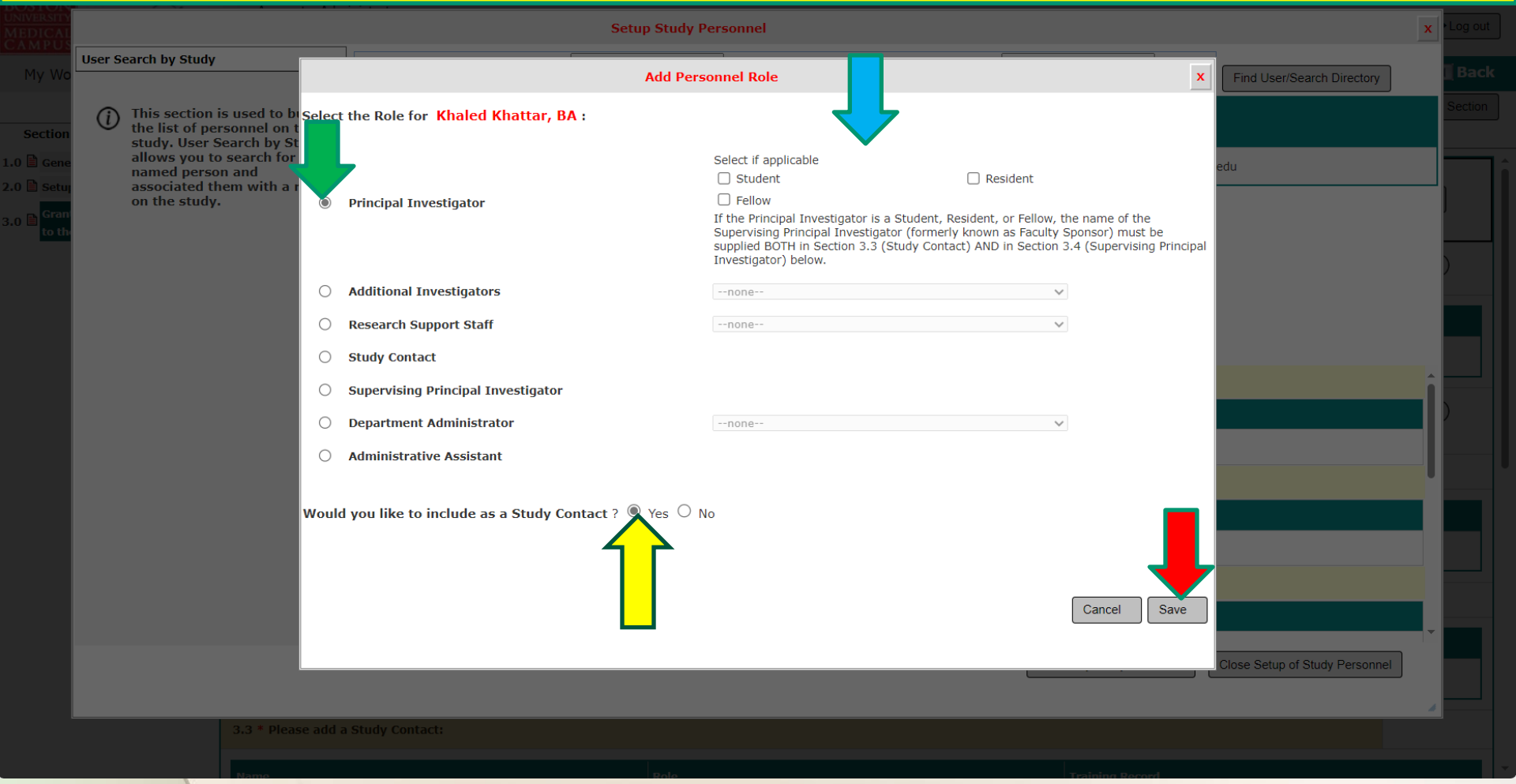
1. First check that they are up-to-date with training by clicking on the training icon (green arrow). If they don't have the required IRB training, please do not add them.
2. Click on the "Select" icon (yellow arrow) to select this person.



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

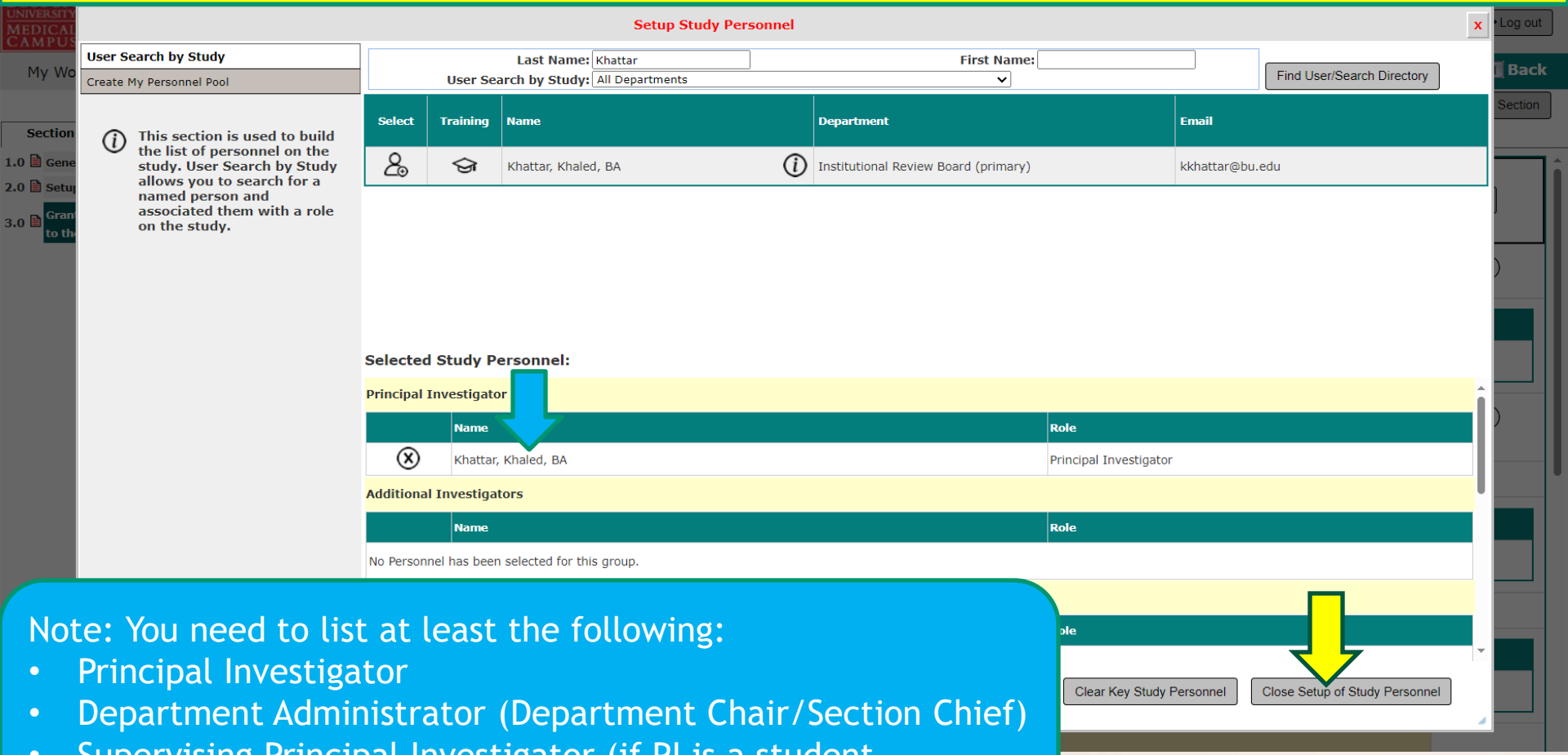
This will open the “Add Personnel Role” popup.

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.

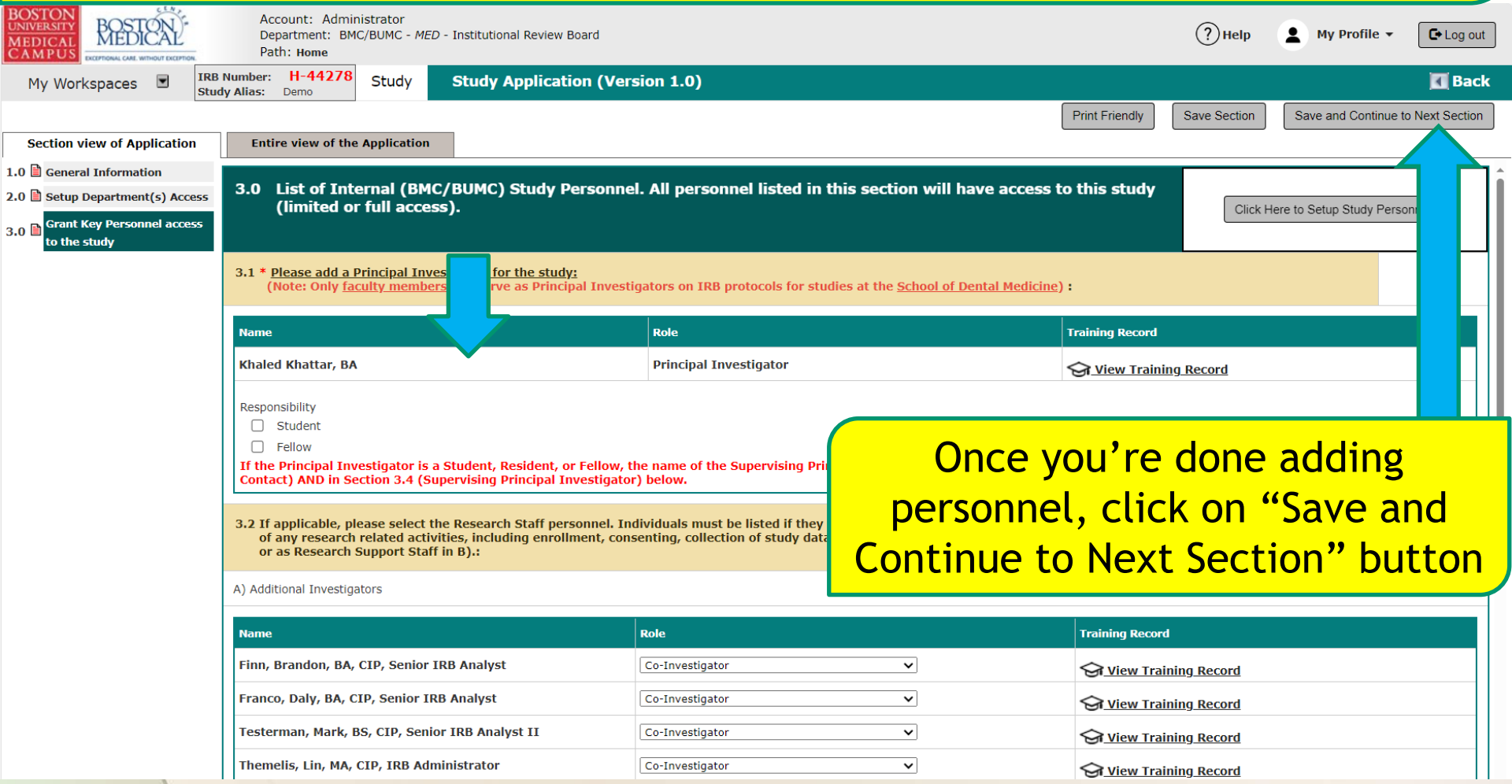
- Note that the person just added is showing up in the appropriate section/role (green arrow).
- To add more personnel, repeat steps in slides 7 – 10.
- If you are done selecting all study personnel, you would click on “Close Setup of Study Personnel” button (yellow arrow).



Note: You need to list at least the following:

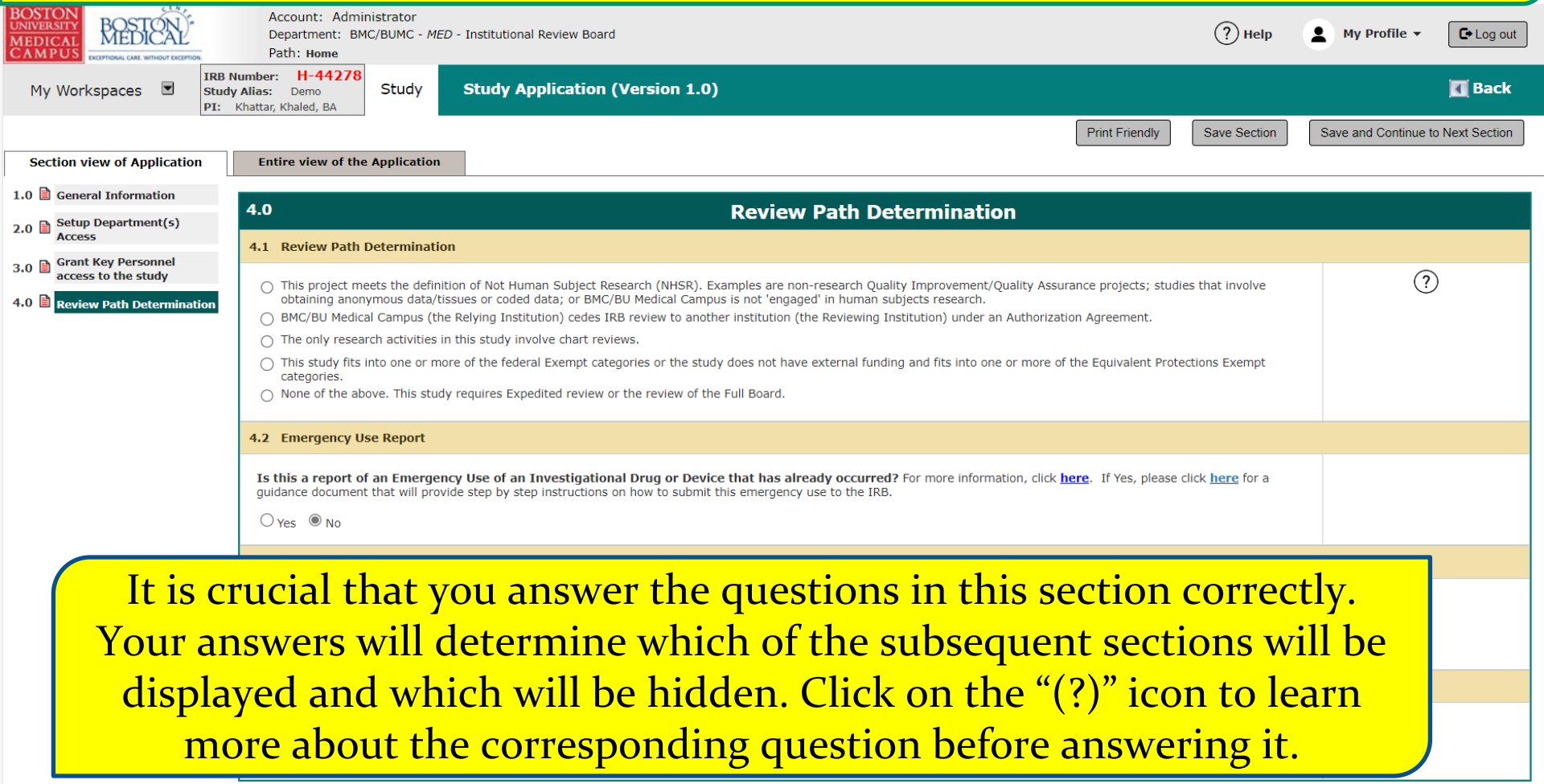
- Principal Investigator
- Department Administrator (Department Chair/Section Chief)
- Supervising Principal Investigator (if PI is a student, resident, or fellow)

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.

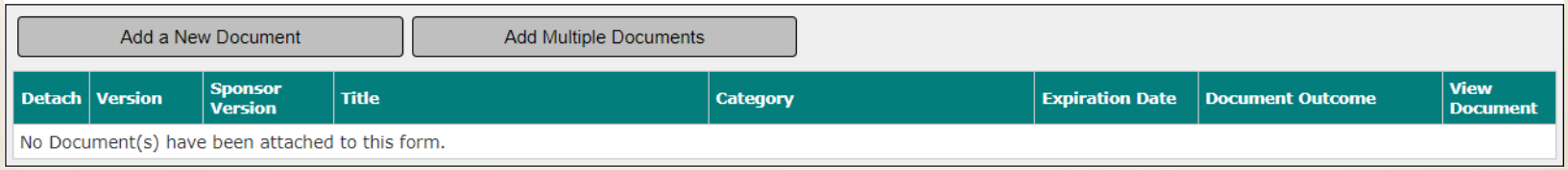
As you click “Save and Continue to Next Section”, the rest of the sections will appear in the left-hand column. Sections that have not been visited will not appear there until later.

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.

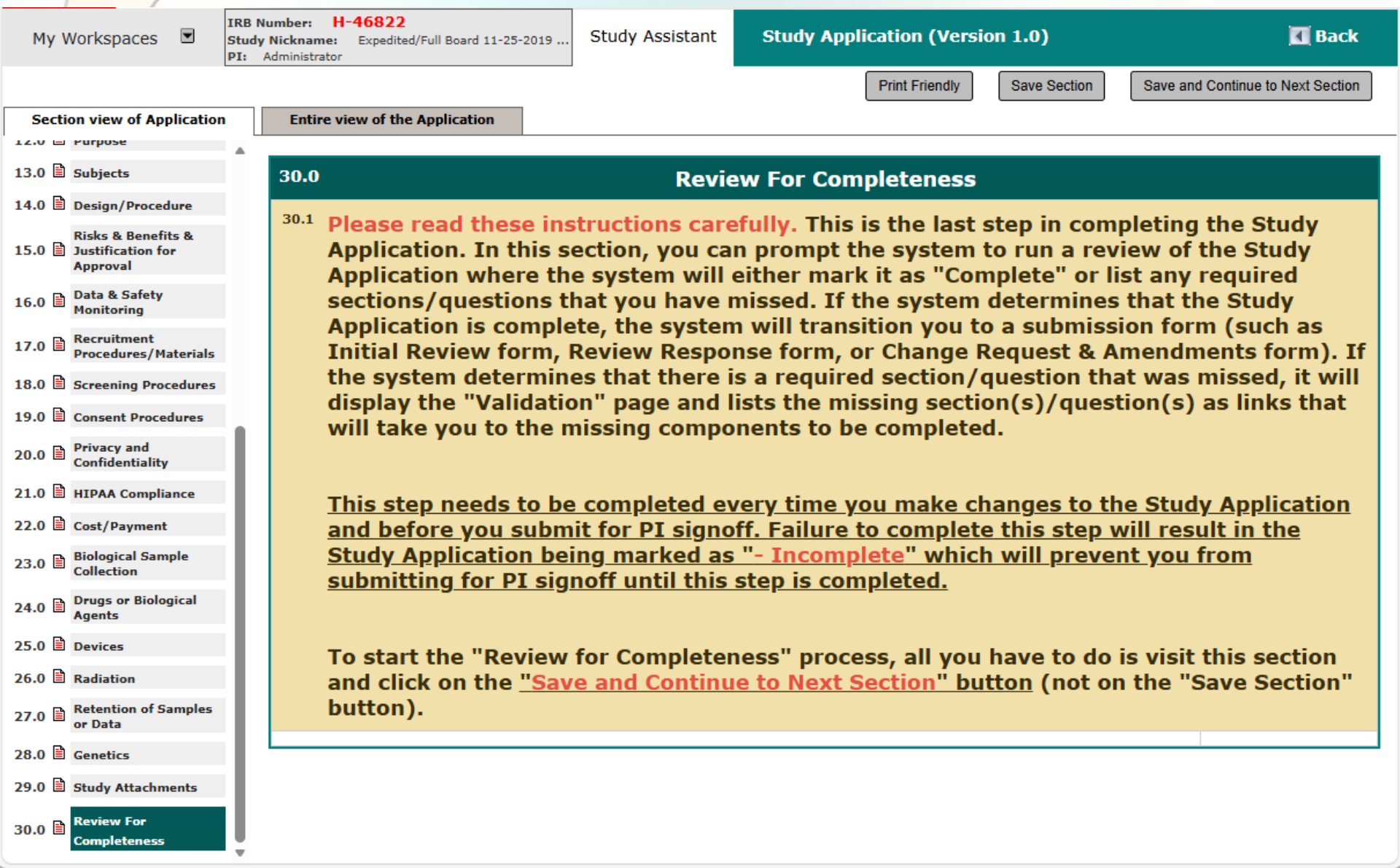
Draft Protocol (cont.)

- 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.

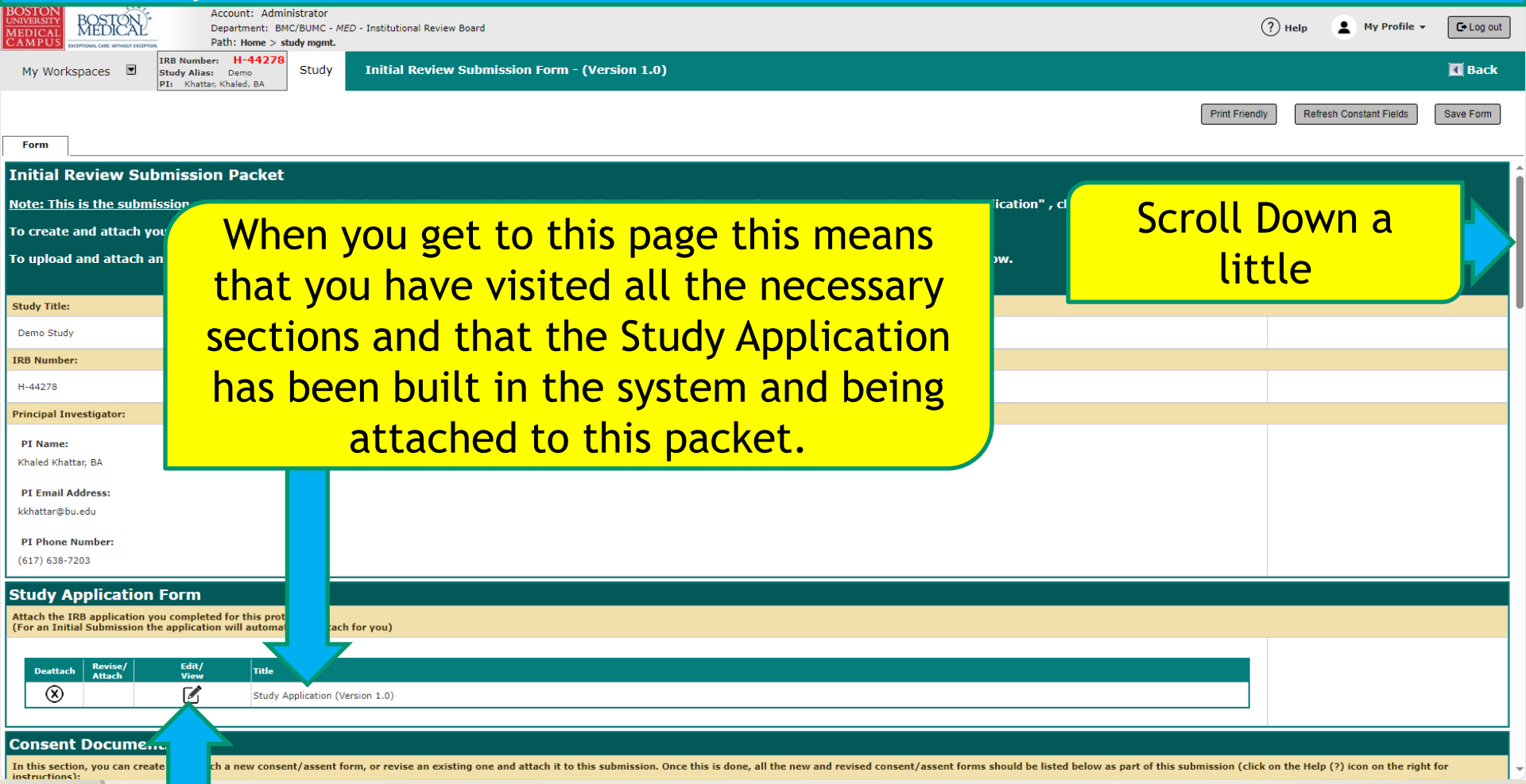


- We'll show you later how to upload a document in this table. Detailed instructions can be found in the following link:
- How to add a new Study Document

When all sections have been visited, you will reach the “Review For Completeness” section. Clicking on “Save and Continue to Next Section” will prompt the system to review the Study Application before proceeding to attach it to the “Initial Review Form” packet.

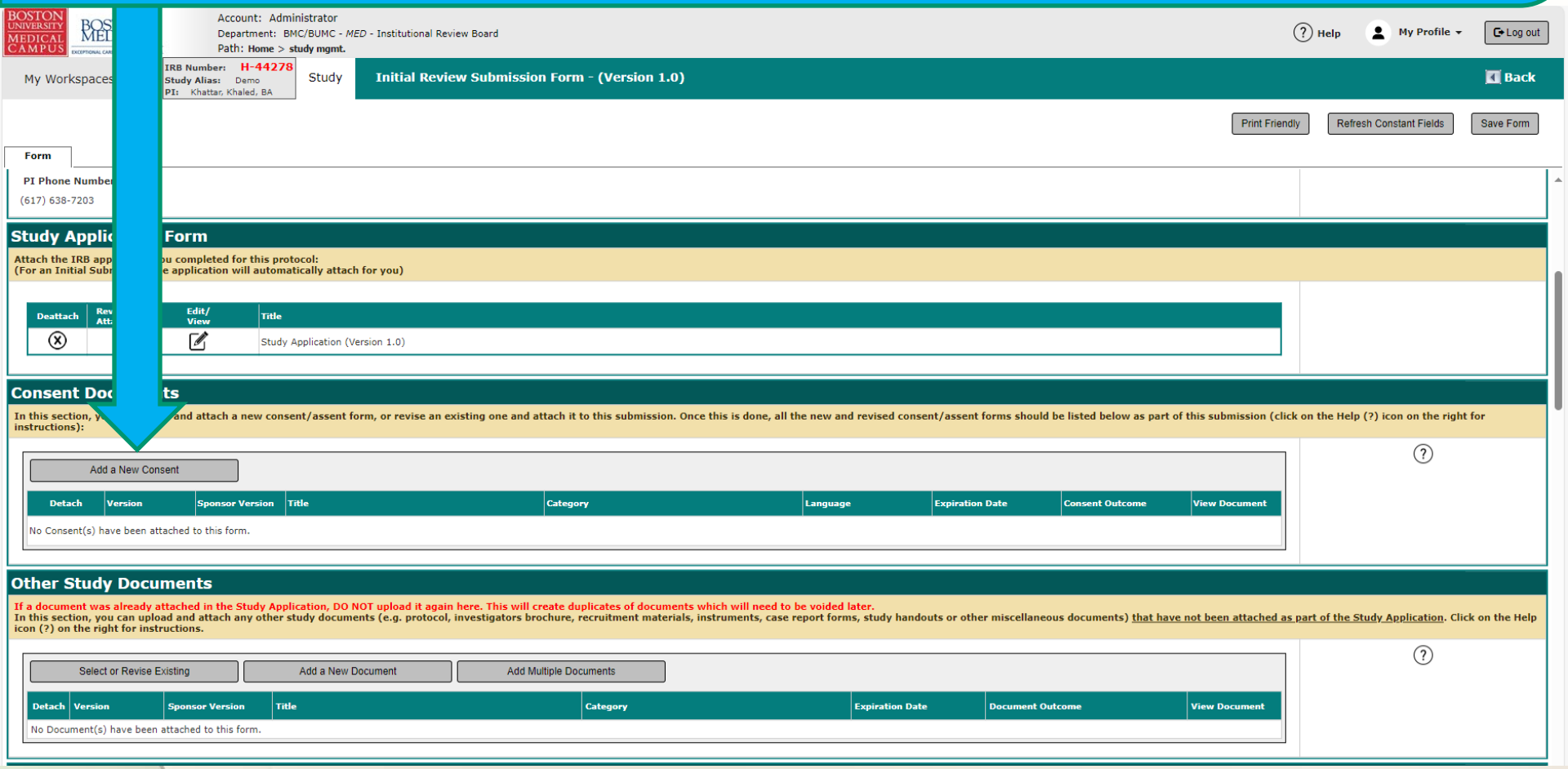


When you finish filling out all the sections in the Study Application, the system will transition you to the “Initial Review Submission Form”.

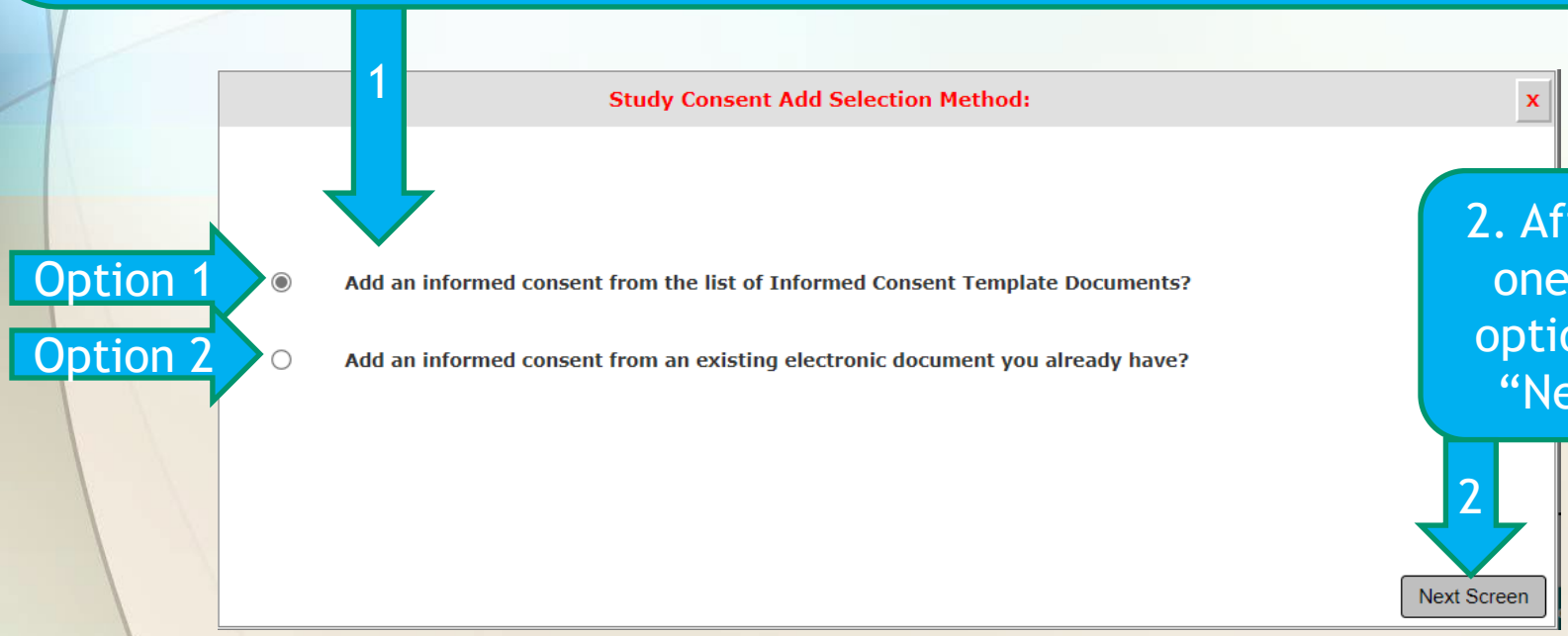


This is where all consent forms should be generated and attached to the submission. To add a new consent form, click on the grey button. For detailed instructions, follow the instructions in this link:

- How to add a new Consent Form



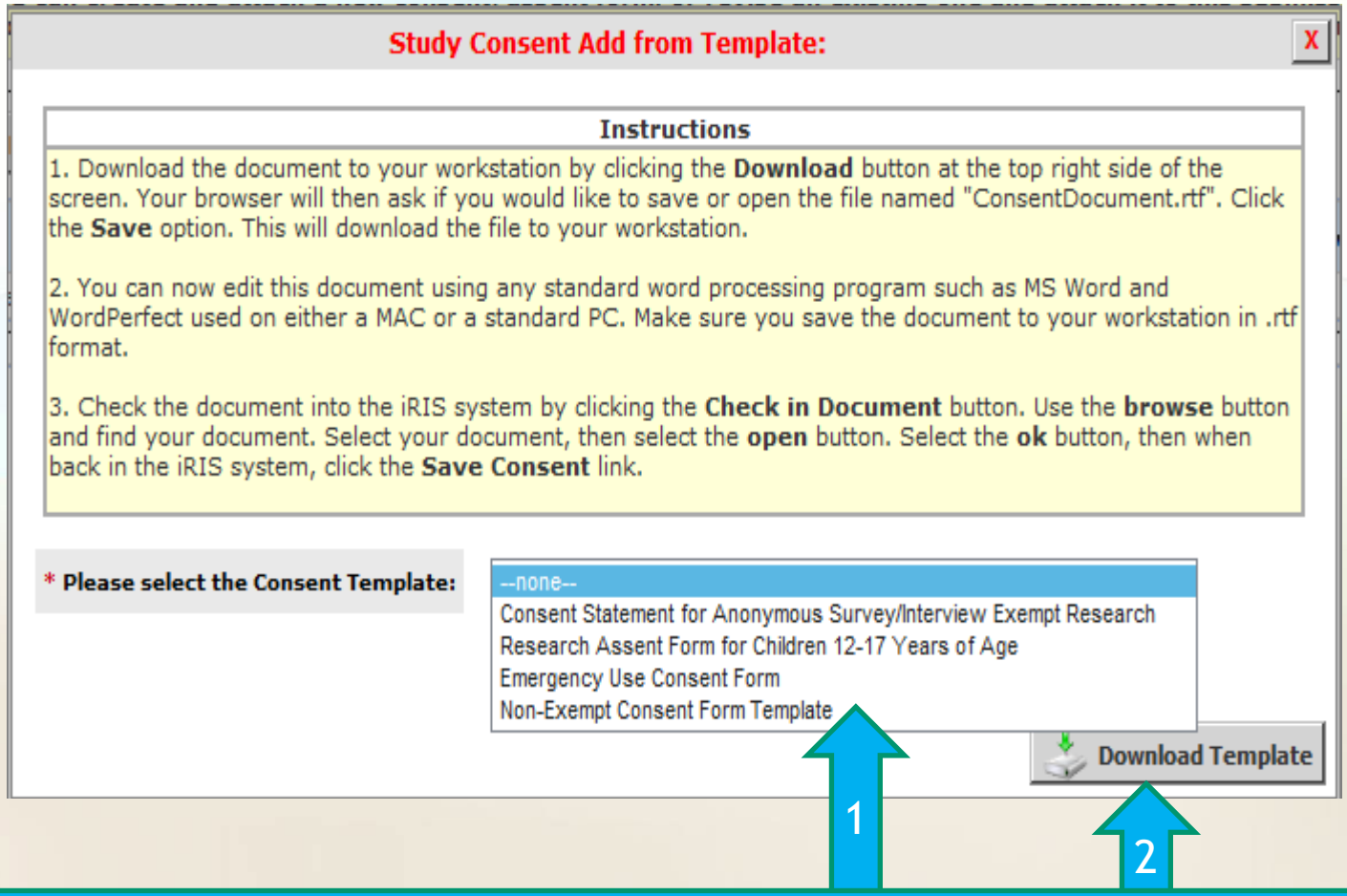
1. Select one of the two options shown (instructions for these two options will follow):
- Option 1 – Select to download an RTF Word document of the Consent Form template with all the template languages included in it.
- Option 2 - Select to upload a consent form Word document that you already have, such as a revised consent form template that you have already downloaded or a Foreign language consent form.



2. After selecting one of the two options, click on "Next Screen"

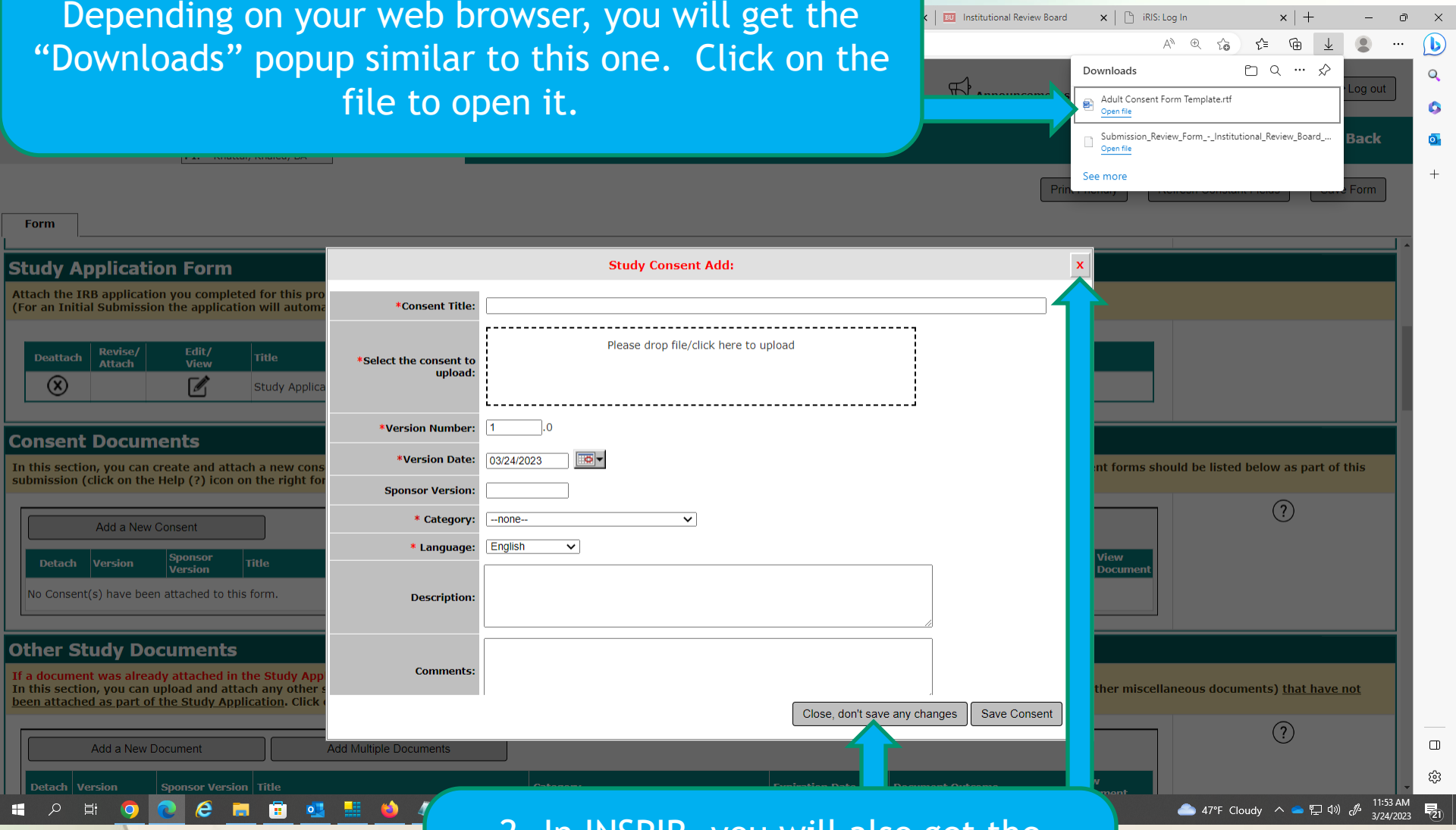
- If you selected option 1, proceed to slide # 4 for instructions.
- If you selected option 2, proceed to slide # 10 for instructions.

If option 1 was selected:

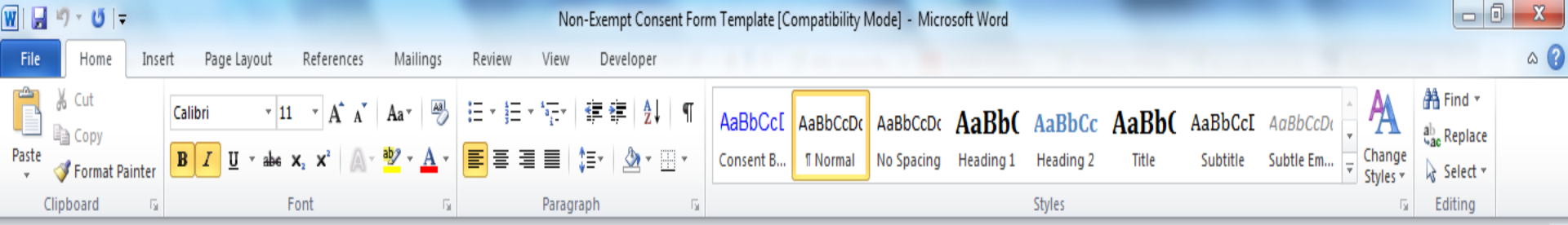


You will see this popup. From the “Please select the Consent Template” drop down list, 1. Select one of the available templates.
2. Click on “Download Template” button.

1. The selected Consent template will download. Depending on your web browser, you will get the "Downloads" popup similar to this one. Click on the file to open it.



2. In INSPIR, you will also get the "Study Consent Add" popup. Close this popup since you will not upload the document at this time.



BOSTON UNIVERSITY SCHOOLS OF MEDICINE, PUBLIC HEALTH, DENTAL MEDICINE AND THE BOSTON MEDICAL CENTER

BOSTON MEDICAL

BOSTON UNIVERSITY MEDICAL CAMPUS

RESEARCH CONSENT FORM

(Type your Research Consent Form Description/Title" here)

Title of Project:

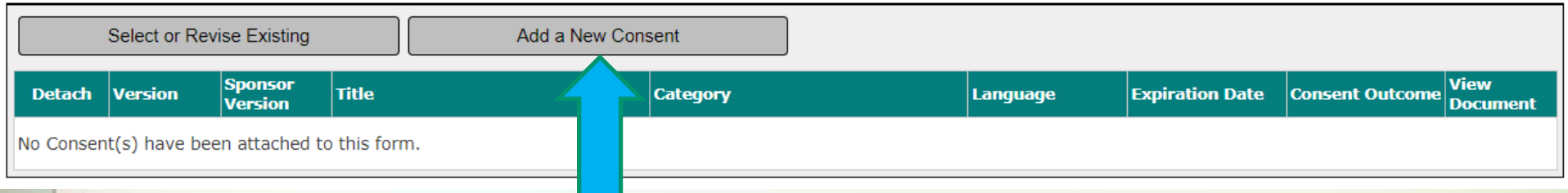
Principal Investigator:

This is a template for completing a research consent form.

The consent form template should open in Word. Make sure you "save as" this file on your Desktop or somewhere you can find later. Start making your changes and don't forget to save your changes.

Instructions for option # 1

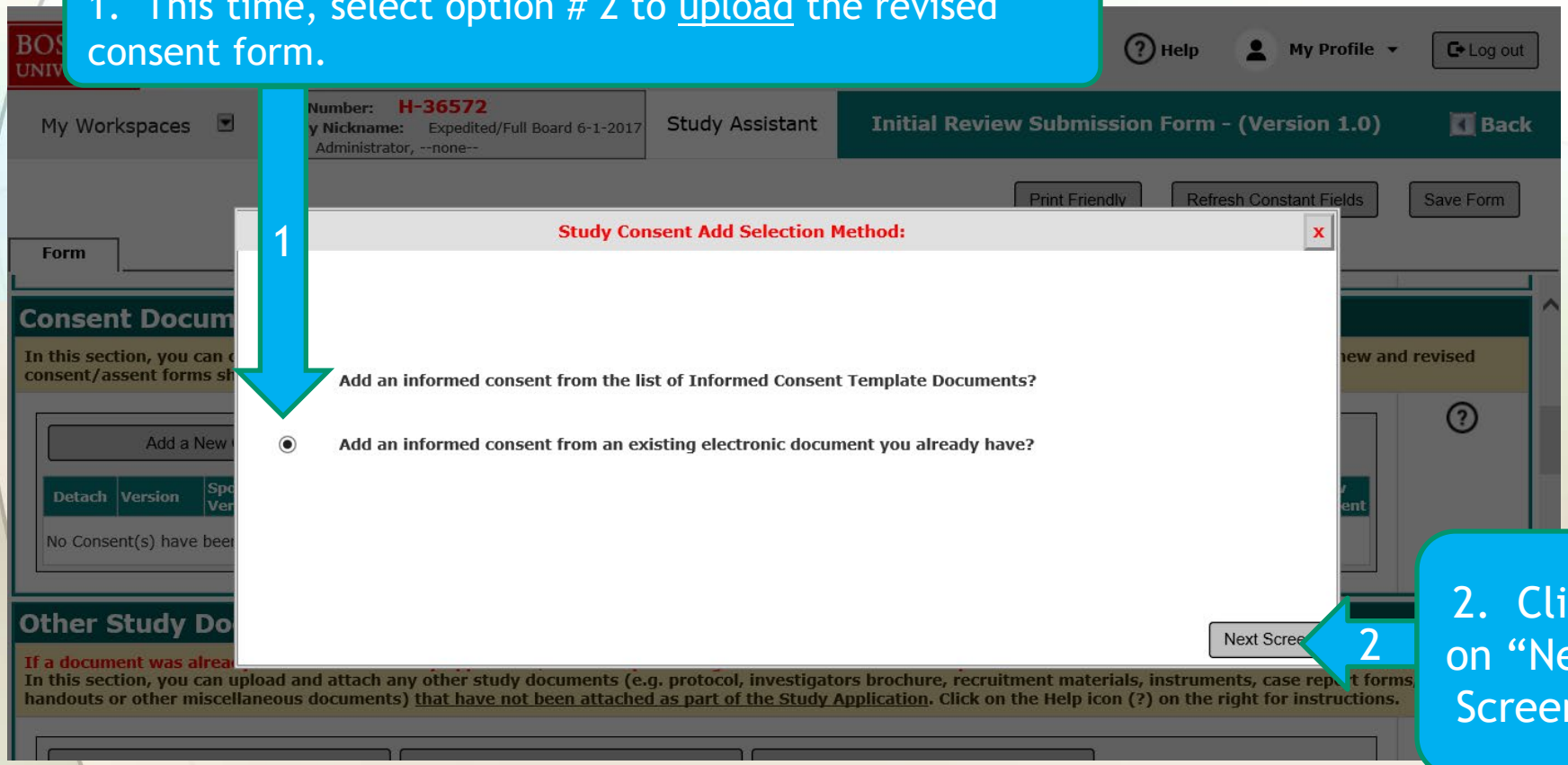
In INSPIR, go back to where you started, to the screen where you can add a new consent form.



Click again on the “Add a New Consent” button.

Instructions for option # 1

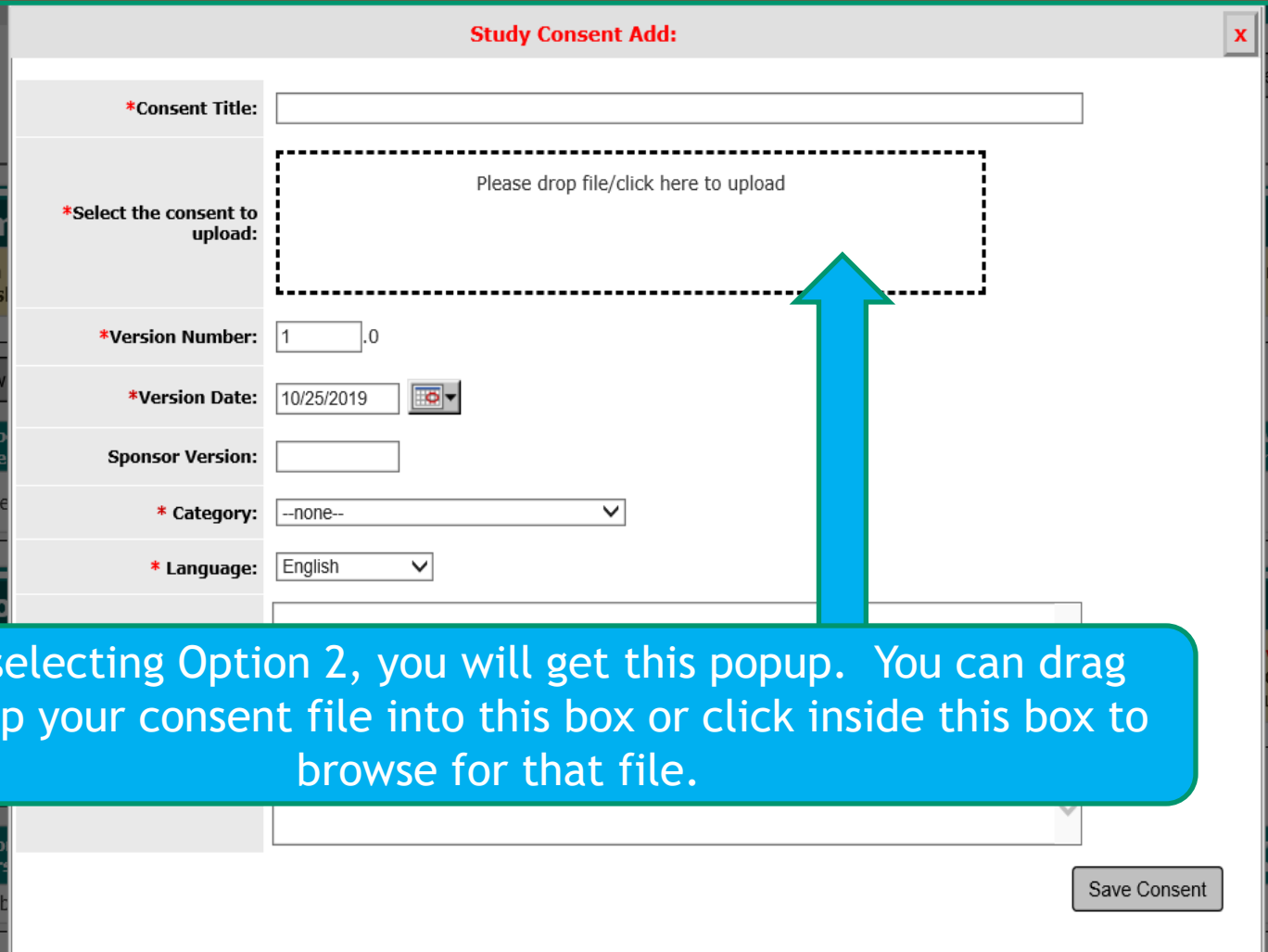
1. This time, select option # 2 to upload the revised consent form.



2. Click on "Next Screen"

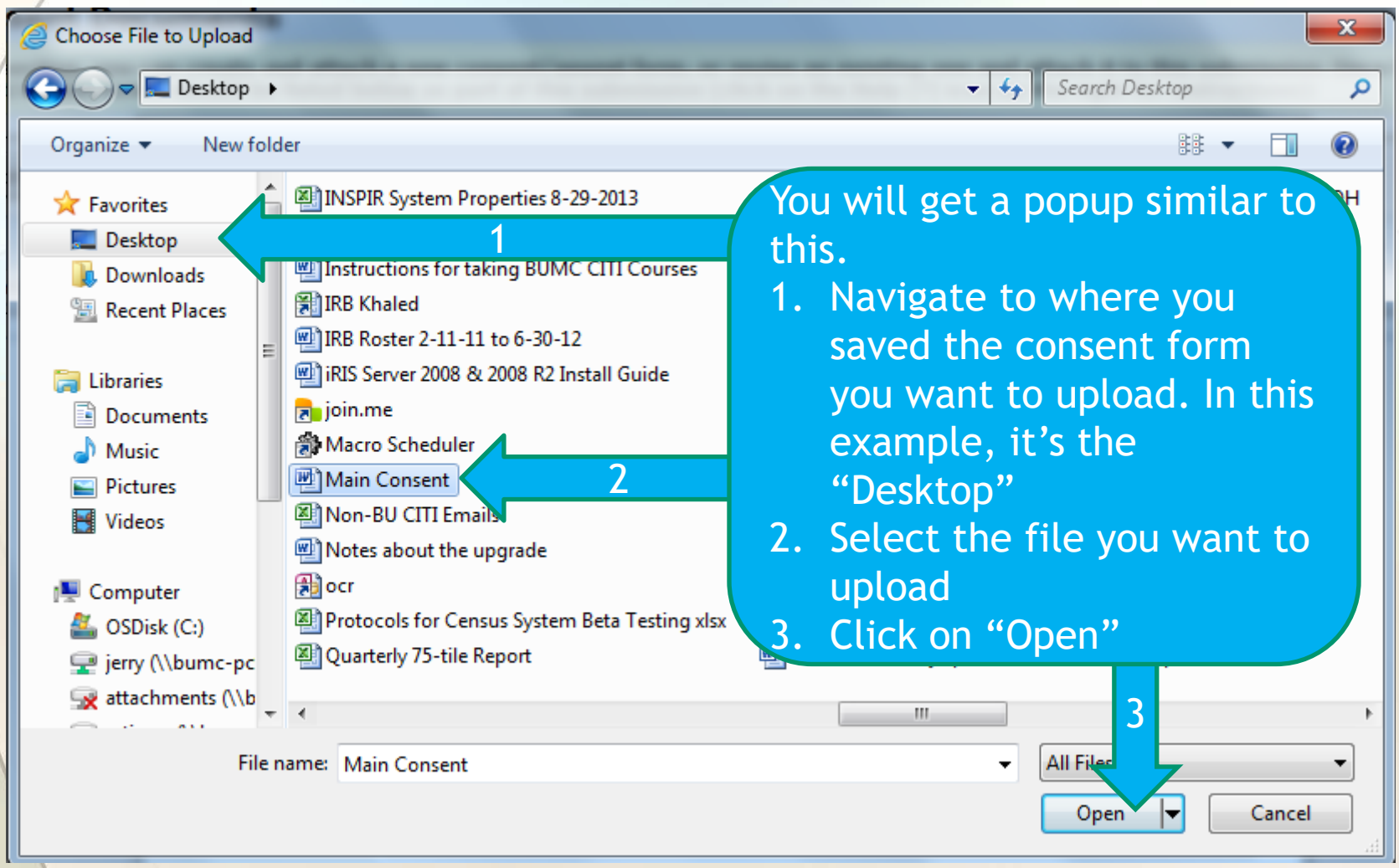
Instructions for options # 1 and # 2

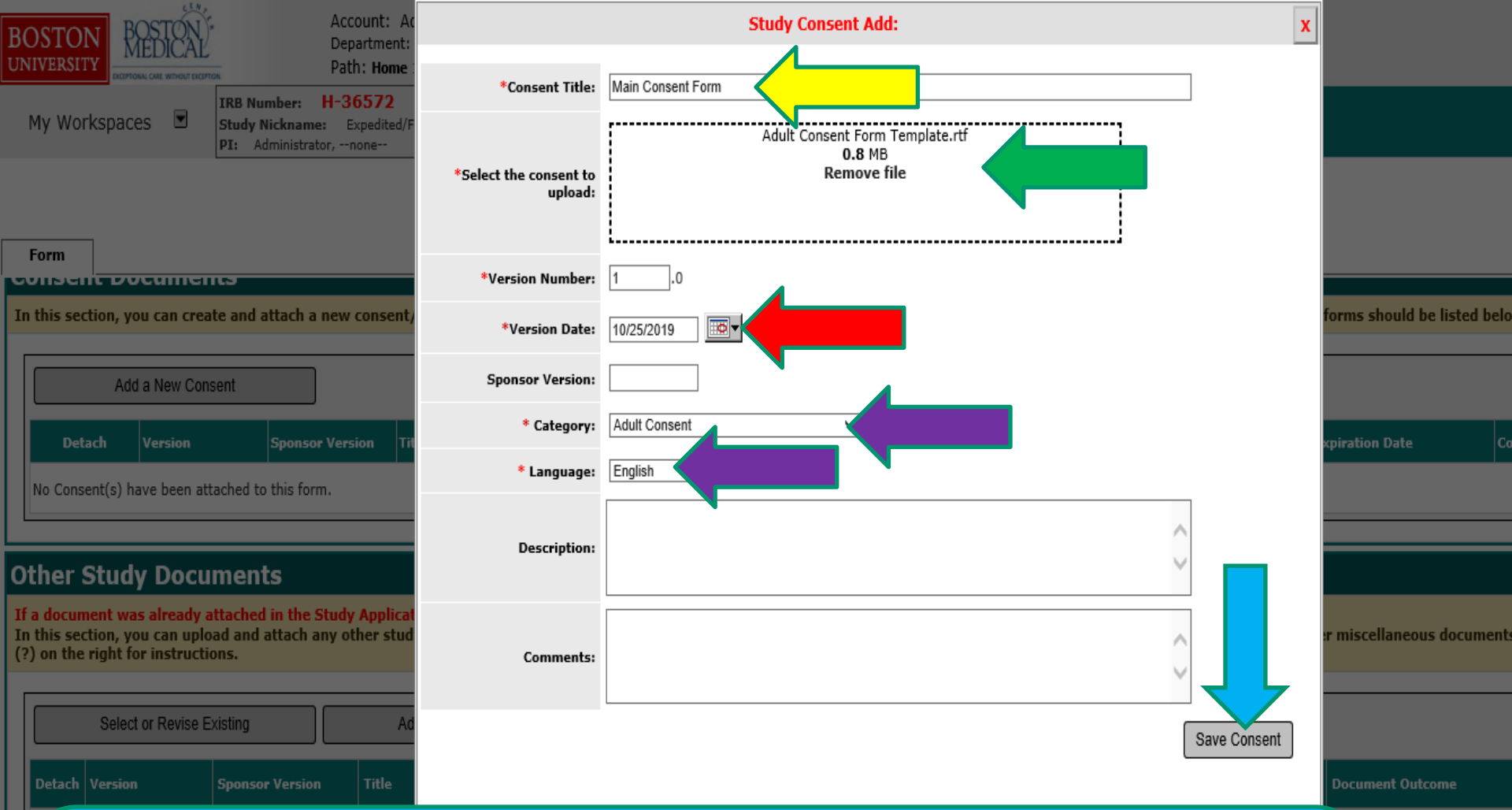
Before uploading, make sure that the consent form that you want to upload is clean (i.e. Track changes had been all accepted, there are no comments on the right margin, Headers and Footers are there, etc…). In other words, it should look the way you want the final consent form to look minus the approval stamp which will be applied later when it is approved by the IRB.



After selecting Option 2, you will get this popup. You can drag and drop your consent file into this box or click inside this box to browse for that file.

Instructions for options # 1 and # 2 – continued
If you dragged and dropped the consent file into the box, go to the next slide.
If you clicked inside the box to browse, you will get this popup.



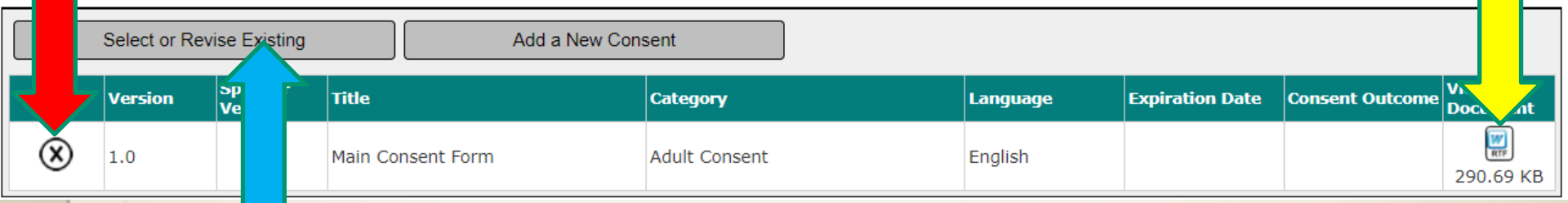


The system will bring you back to this popup. Note the name and path of the file to be uploaded (green arrow). Type in a title to your consent form (yellow arrow) and make sure the version date is current (red arrow). Also, select the appropriate category and language (purple arrows). Make all the necessary changes to this popup and then click on “Save Consent” (blue arrow).

Instructions for options # 1 and # 2 - continued

This will bring you back to where you started in the form.

The consent form that you have just uploaded should appear on this table/list. You can verify that you have uploaded the right consent form by clicking on the "View Document" icon to open it (yellow arrow). You can detach (not common) from this submission any consent form that you don't want to submit to the IRB by clicking on the (X) icon next to it (red arrow).



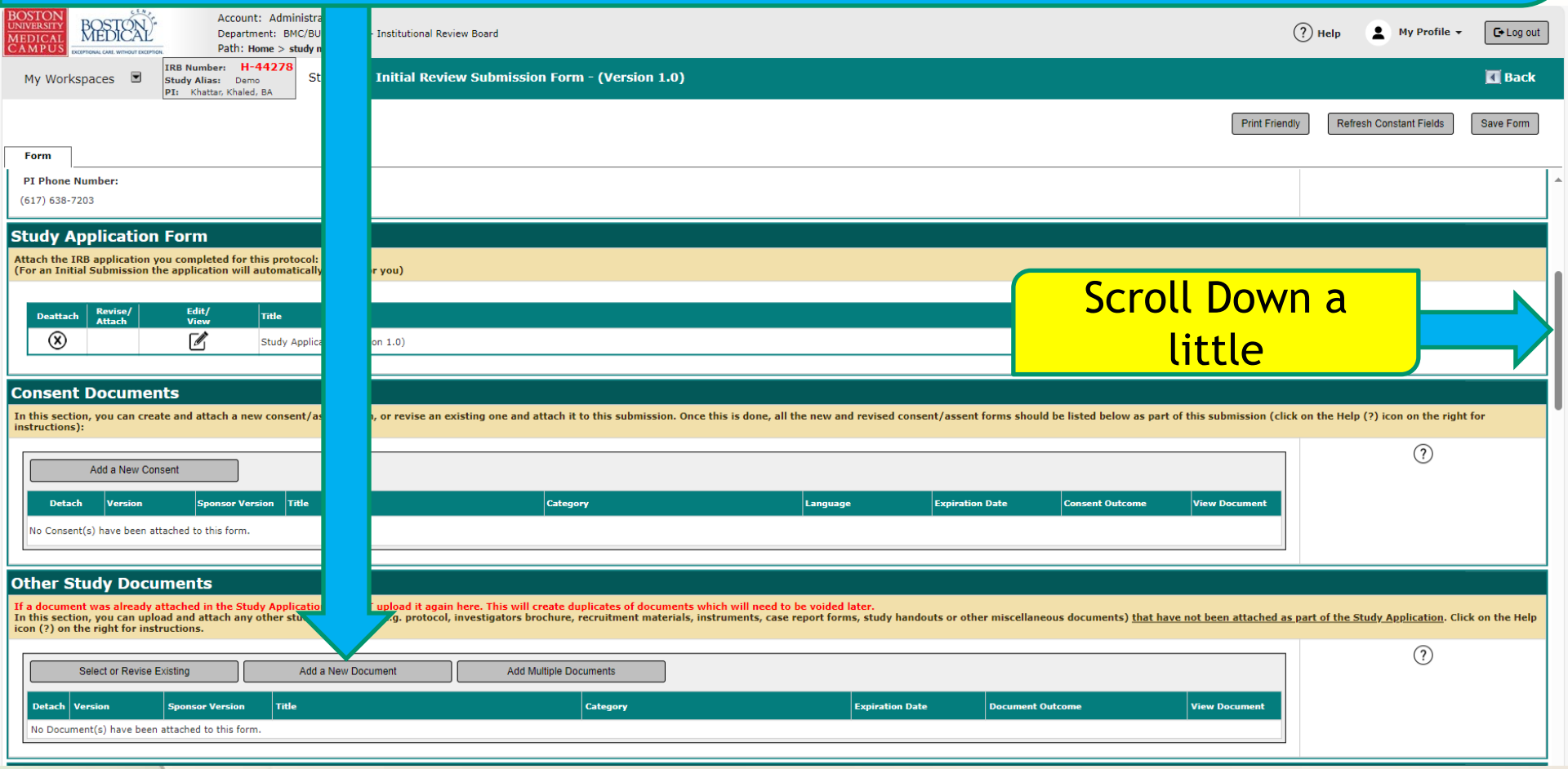
To revise the consent form that you have just uploaded or to attach to this form a different existing consent form, click on "Select or Revise Existing" and follow the instructions in this link:

- How to revise an existing Consent Form

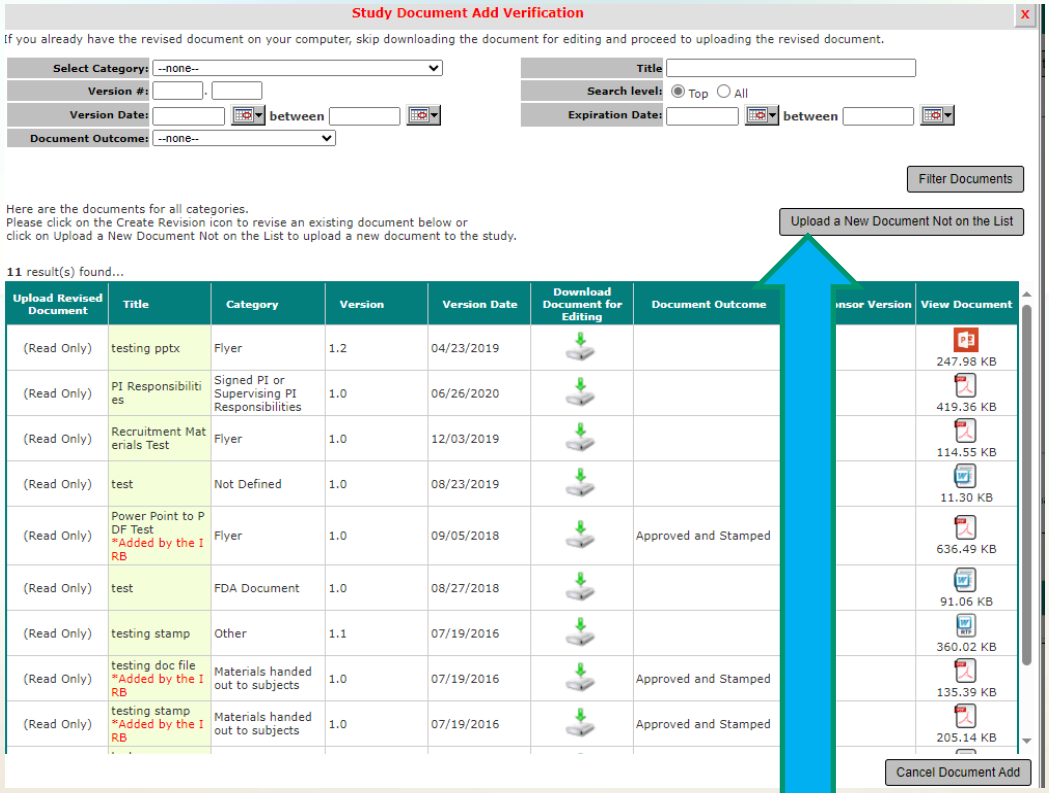
You're done adding the consent form. You can start over if you have additional Consent forms.

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 . For detailed instructions, follow the instructions in this link :

- How to add a new Study Document

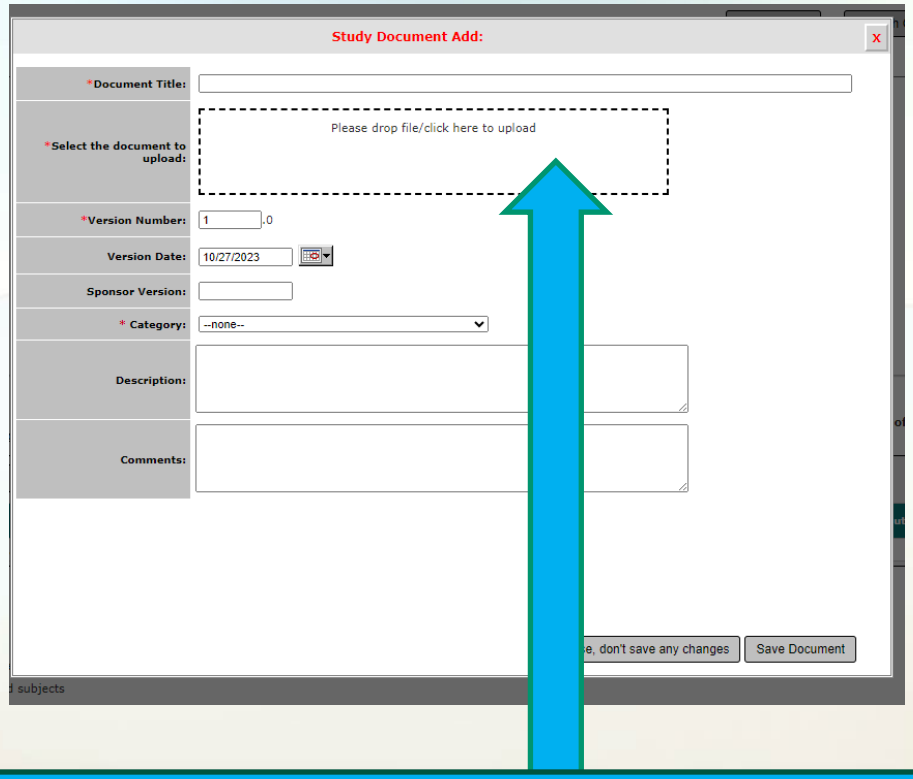


This opens the “Study Document Add Verification” pop-up.



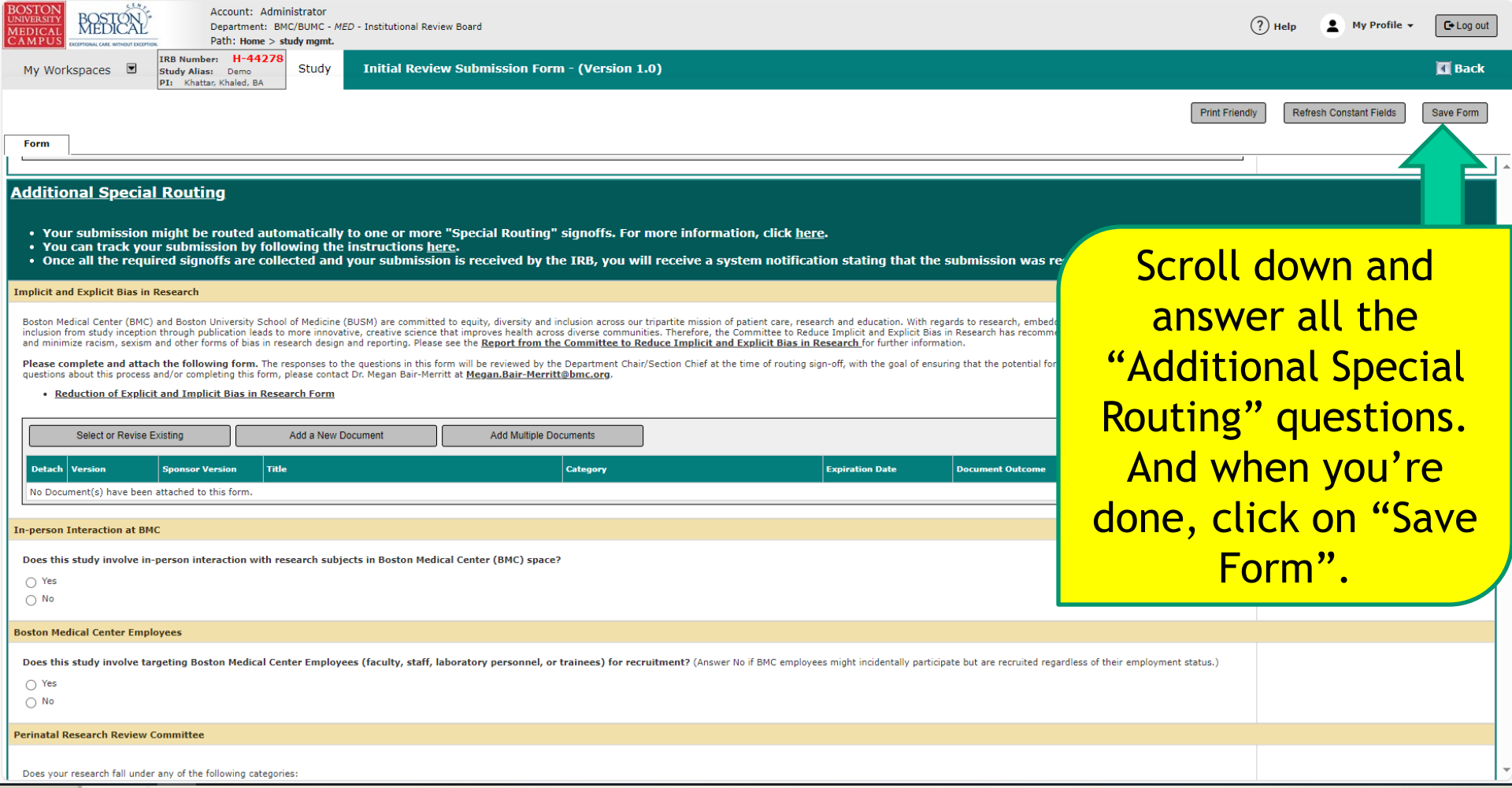
Click on “Upload a New Document Not on the List” button

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

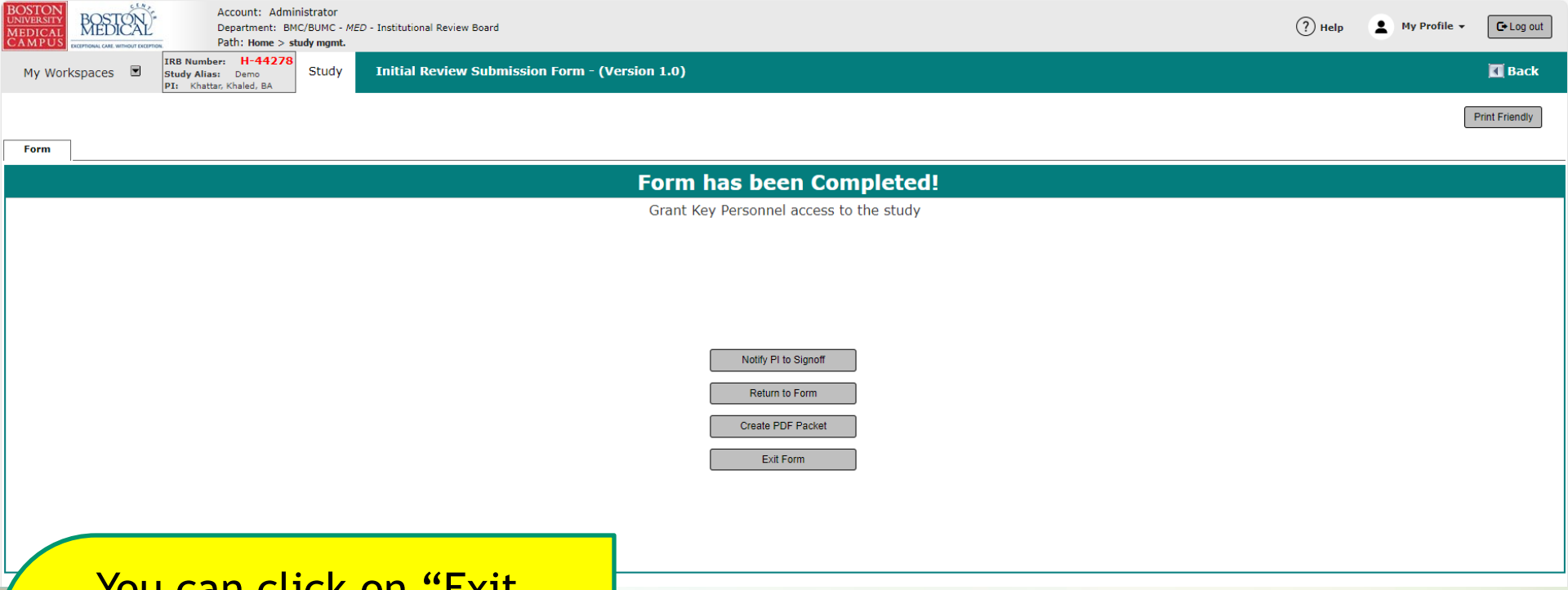


You can either:

- Drag and drop your 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.

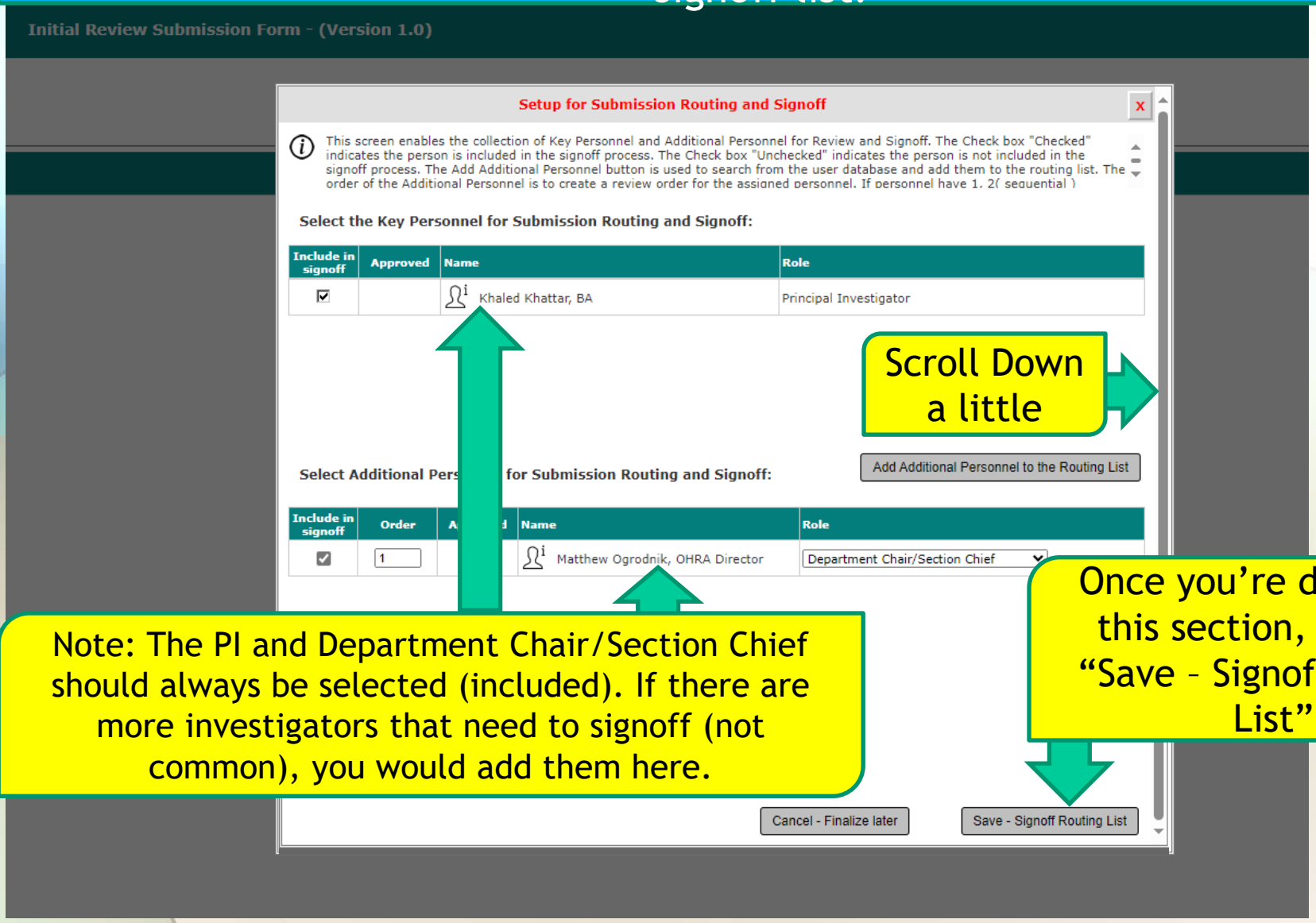


Scroll down and answer all the “Additional Special Routing” questions. And when you’re done, click on “Save Form”.



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”.

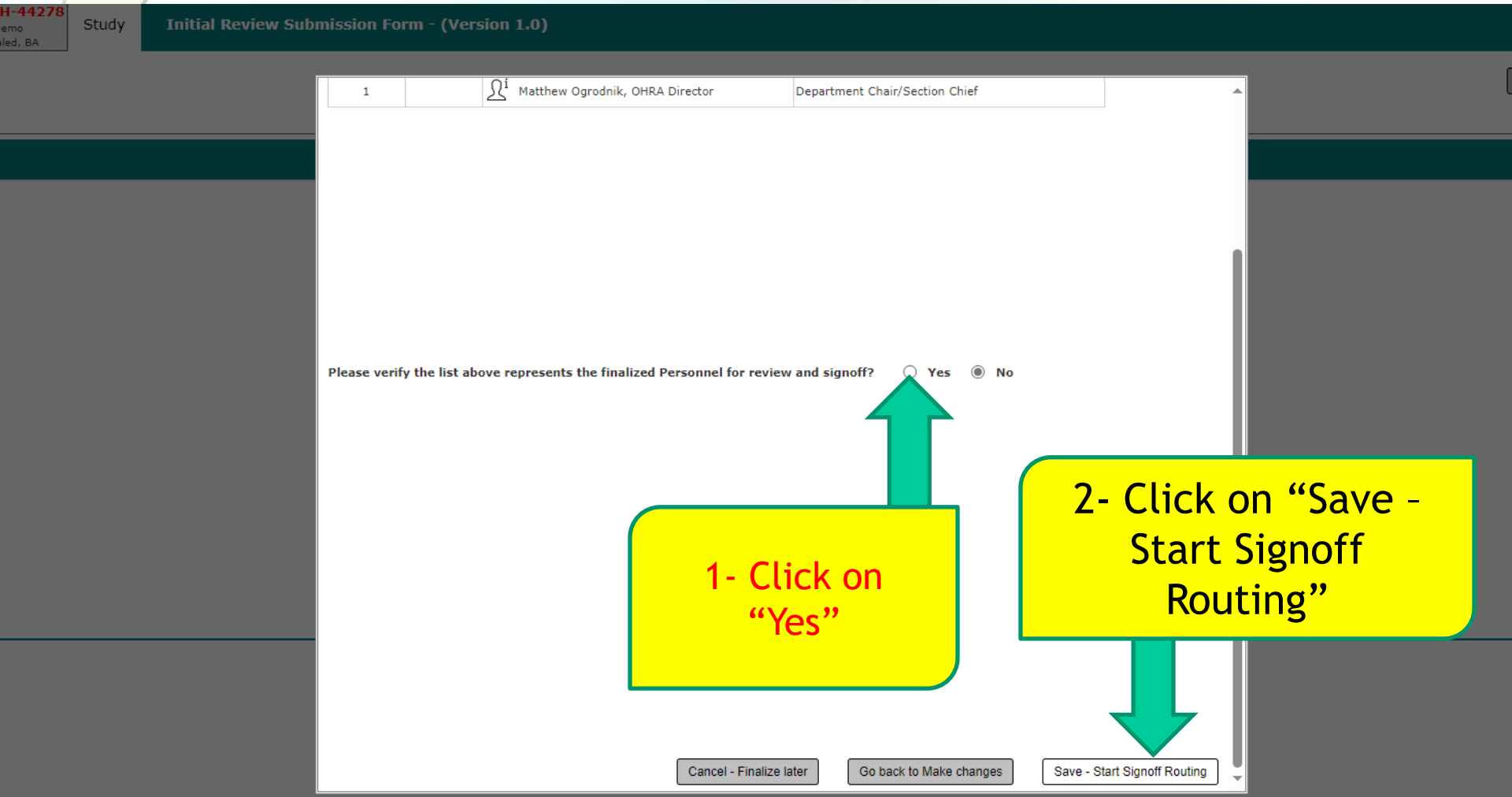
If you have clicked in the previous screen on either “Signoff and Submit” or “Notify PI to signoff”, the system will bring you to this screen to setup signoff list.



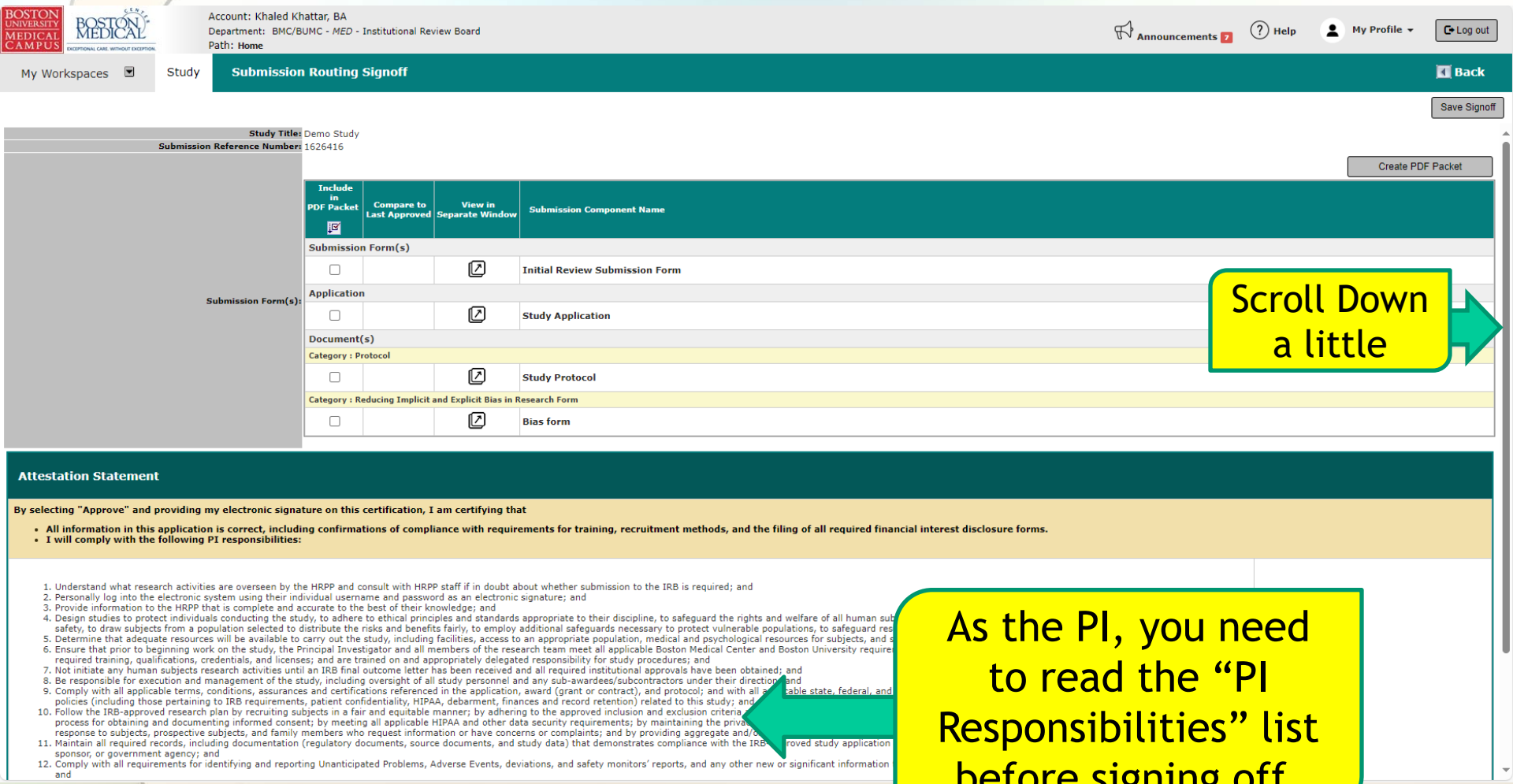
Note: The PI and Department Chair/Section Chief should always be selected (included). If there are more investigators that need to signoff (not common), you would add them here.

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

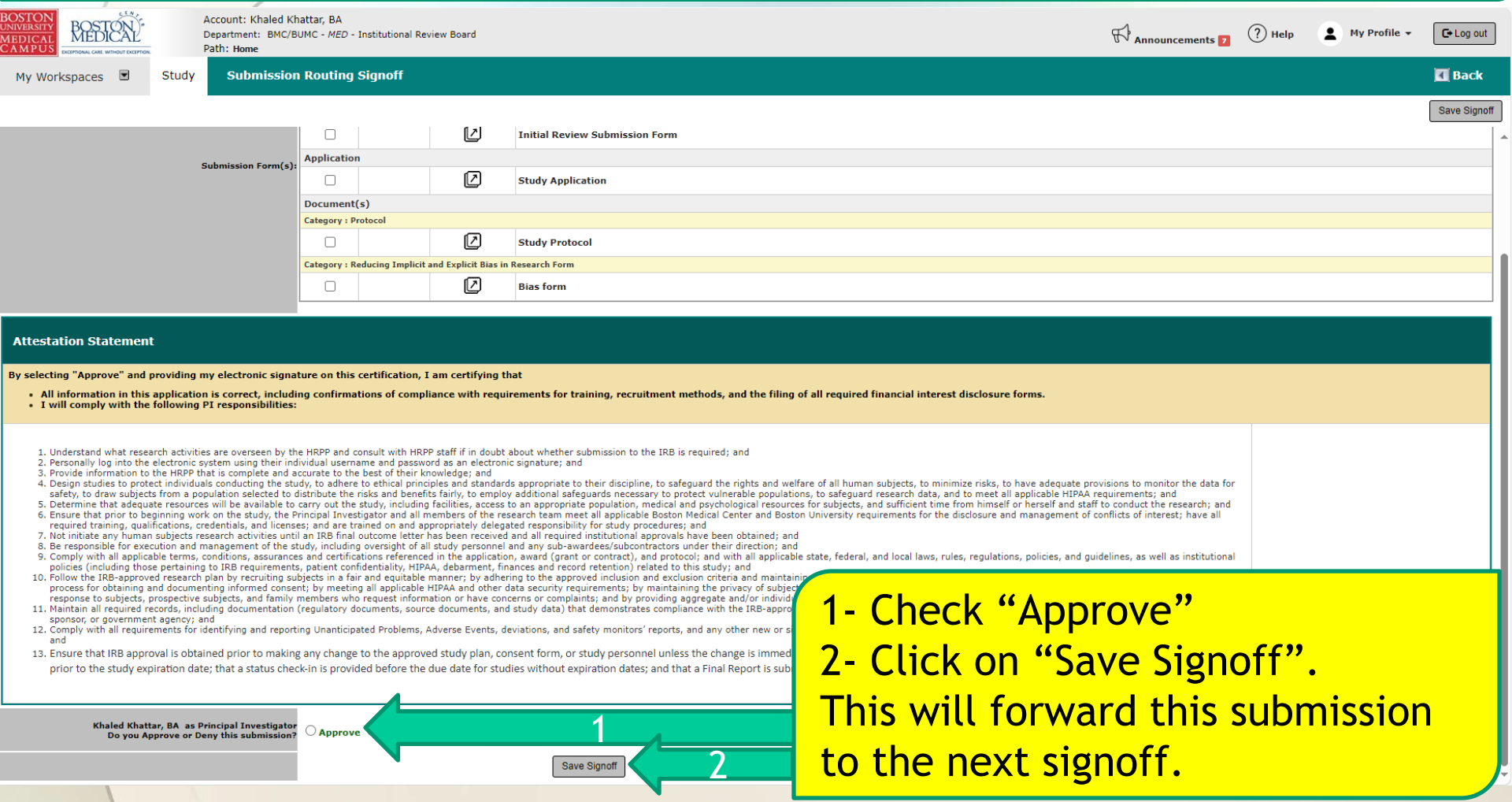
If you have clicked in the previous screen on “Save – Signoff Routing List”, the system will bring you to this screen.



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.



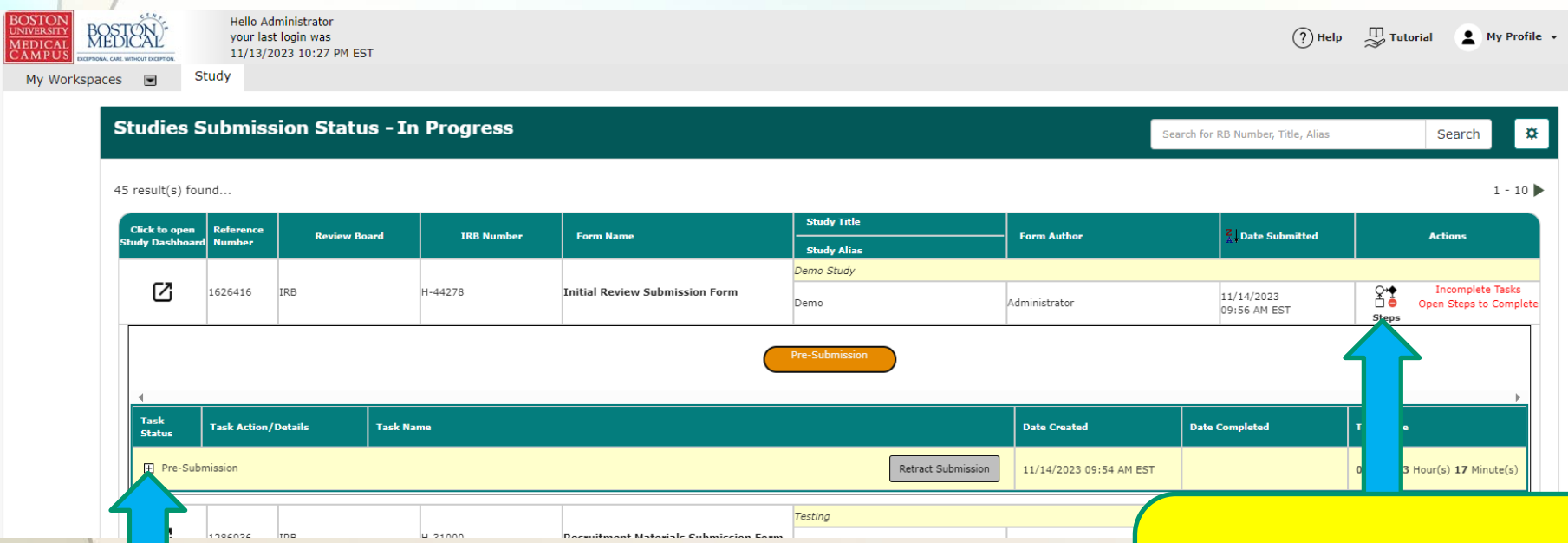
You are still in the PI's "Submission Routing Signoff" page.



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 check on a submission status anytime after submission, go to your Home page and scroll down to this section.



1. Click on the “Steps” icon to expand it

2. Click on the “+” icon to display all the steps taken by this submission

Questions

If you need help with the INSPIR System, feel free to call me between 7:30 AM and 3:30 PM.

Khaled Khattar

IRB INSPIR Application Administrator

Phone: 617-638-7203, Email: kkhattar@bu.edu