iRIS Researcher's Guide

iRIS information and FAQs available at:
https://www.einsteinmed.org/administration/institutional-review-board/education/iris.aspx .

For additional support email iris-support@einsteinmed.org or call 718-430-2237.

EINSTEIN
Albert Einstein College of Medicine

Office of Human Research Affairs

Montefiore

Logging in to the iRIS system

- https://iris.einsteinmed.org/
- Login using your MMCAD and password.
  - For more information about obtaining access to iRIS and obtaining a MMCAD go to https://www.einsteinmed.org/administration/institutional-review-board/education/iris.aspx .

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Throughout this document:
Red/italic text is used to denote important/required steps.
Black/normal text denotes instructional information.

Before beginning a new IRB application in iRIS

- All Key Personnel (KP) must obtain MMCADs
  - KP are individuals who contribute in a substantive way to the scientific development or execution of the project, or the consent process.
  - The iRIS FAQ has more information about obtaining a MMCAD (https://www.einsteinmed.org/administration/institutional-review-board/irb.aspx?id=38577)
- All KP **must** log on to iRIS and check their training history

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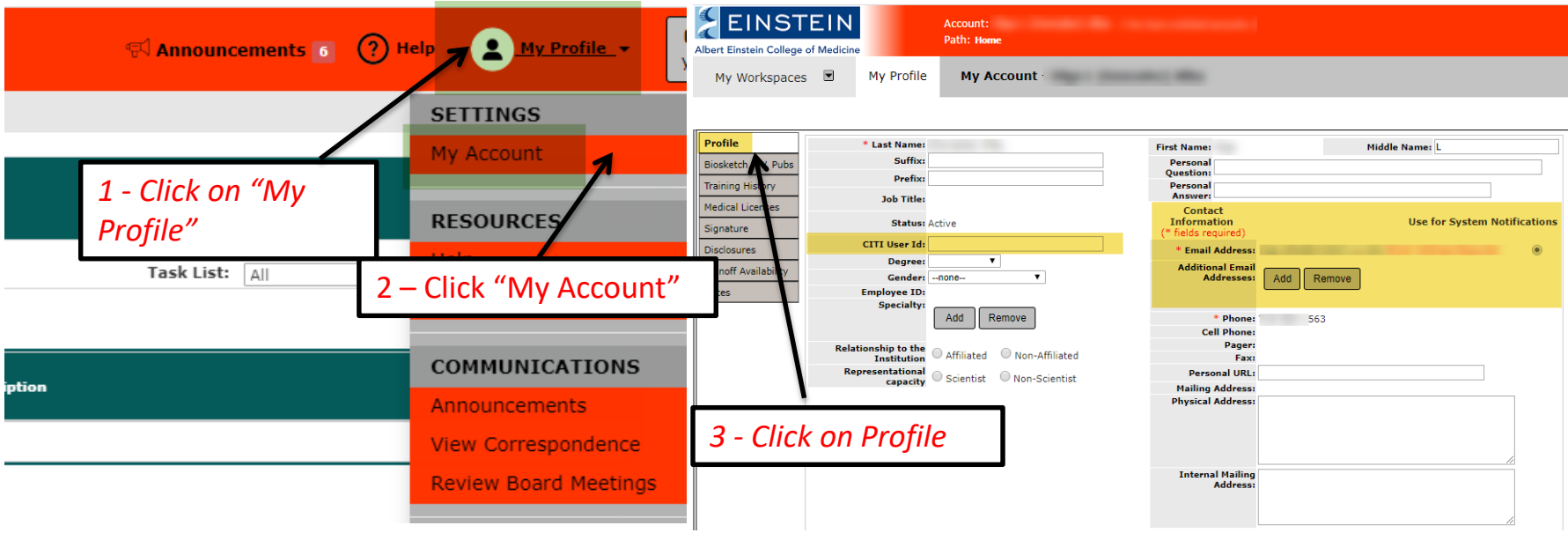
Check your iRIS e-mail address



All e-mail notifications from the iRIS system will be sent to the e-mail address listed in your profile and where "Use for System Notifications" has been selected. You are responsible for checking this e-mail account. The "preferred" e-mail address in your CITI member profile must also match any of the e-mail addresses listed in your iRIS profile. If your primary e-mail address in your iRIS profile is missing, add an e-mail address to the "Additional Email Addresses" section. Select which of the additional e-mail addresses you'd like for your iRIS notifications to be sent (notifications can only be sent to one of the selected e-mails).

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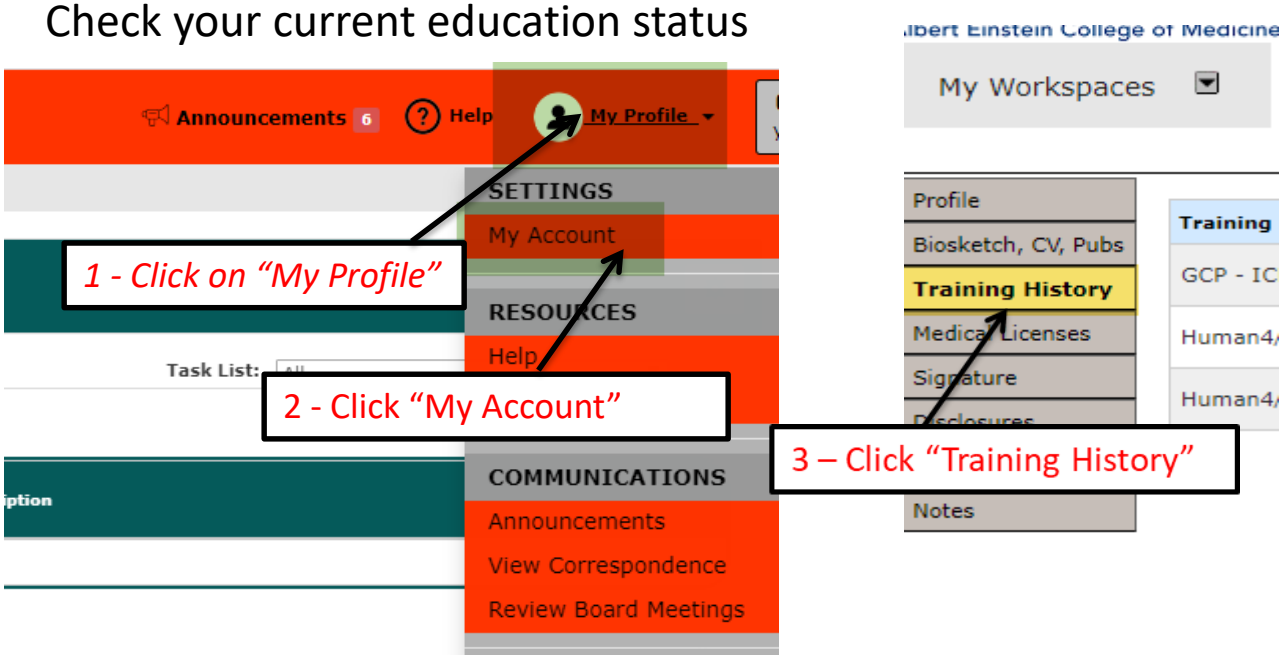
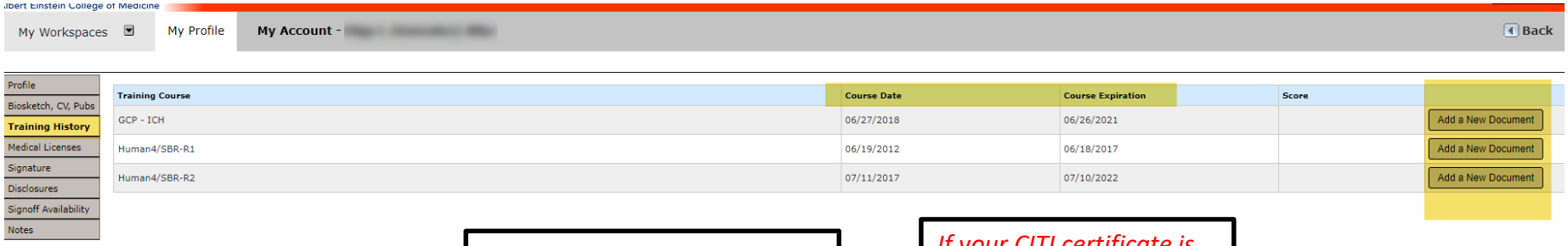
Check your current education status





*At least one **Basic** or **Refresher** course must be listed here for any KP on an IRB application.*

*All investigators and personnel directly involved in new and ongoing clinical studies that involve the testing of drugs or devices must also have a **GCP** course.*

If your CITI certificate is being requested by your PI, or study or regulatory coordinator, you can upload your certificates by clicking "Add a New Document". This option is only available after your training syncs to iRIS.

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What if my Training History is blank?

- There are several possibilities:
  - You have not yet taken the CITI exam. If this is true, follow the instructions for the CITI course here: https://www.einsteinmed.org/administration/institutional-review-board/education/human-subjects.aspx .
  - Your ***"PREFERRED"*** e-mail address in your CITI member profile does not match any of the e-mail addresses associated with your iRIS profile.
  - You are not affiliated with "*Albert Einstein College of Medicine"* in CITI.
  - You have not completed all the required coursework.
  - You have multiple CITI accounts.
  - You are missing an email address in your iRIS profile. Please go to your iRIS profile and add an e-mail address in the "Additional E-mail Address" field. Your preferred e-mail address in your CITI member profile must match the e-mail address you enter in iRIS.
  - It has been less than 24 hours since the last update to CITI training, CITI or iRIS profile information, or your initial login to iRIS . ***Note that it will take at least 24 hours for CITI training to synchronize to iRIS.***

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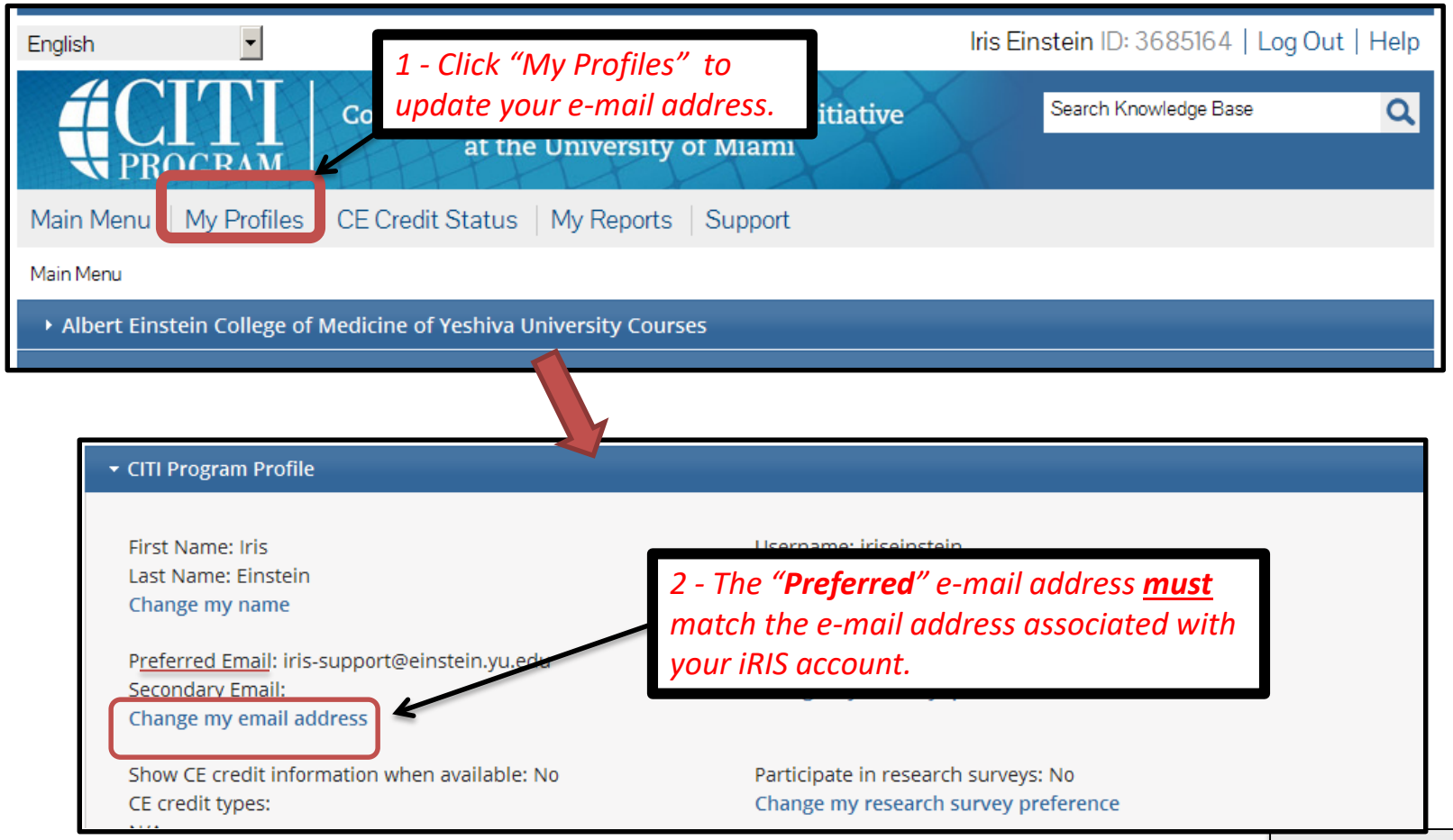
Updating Information on the CITI program website

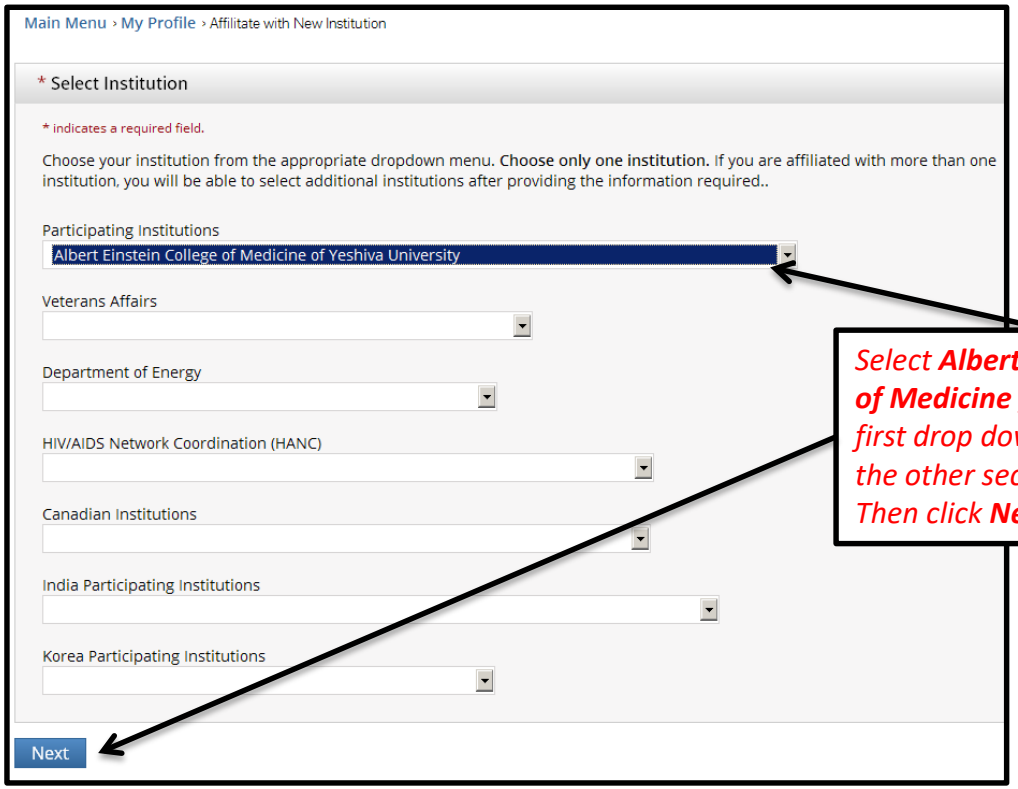
Website: http://www.citiprogram.org

Checking and Updating E-mail Address in the CITI program



- Return to Table of Contents
- Checking and updating in CITI:
  - E-mail address
  - Institutional affiliation
  - Coursework
  - Merging CITI accounts

Updating Institutional Affiliation in the CITI program

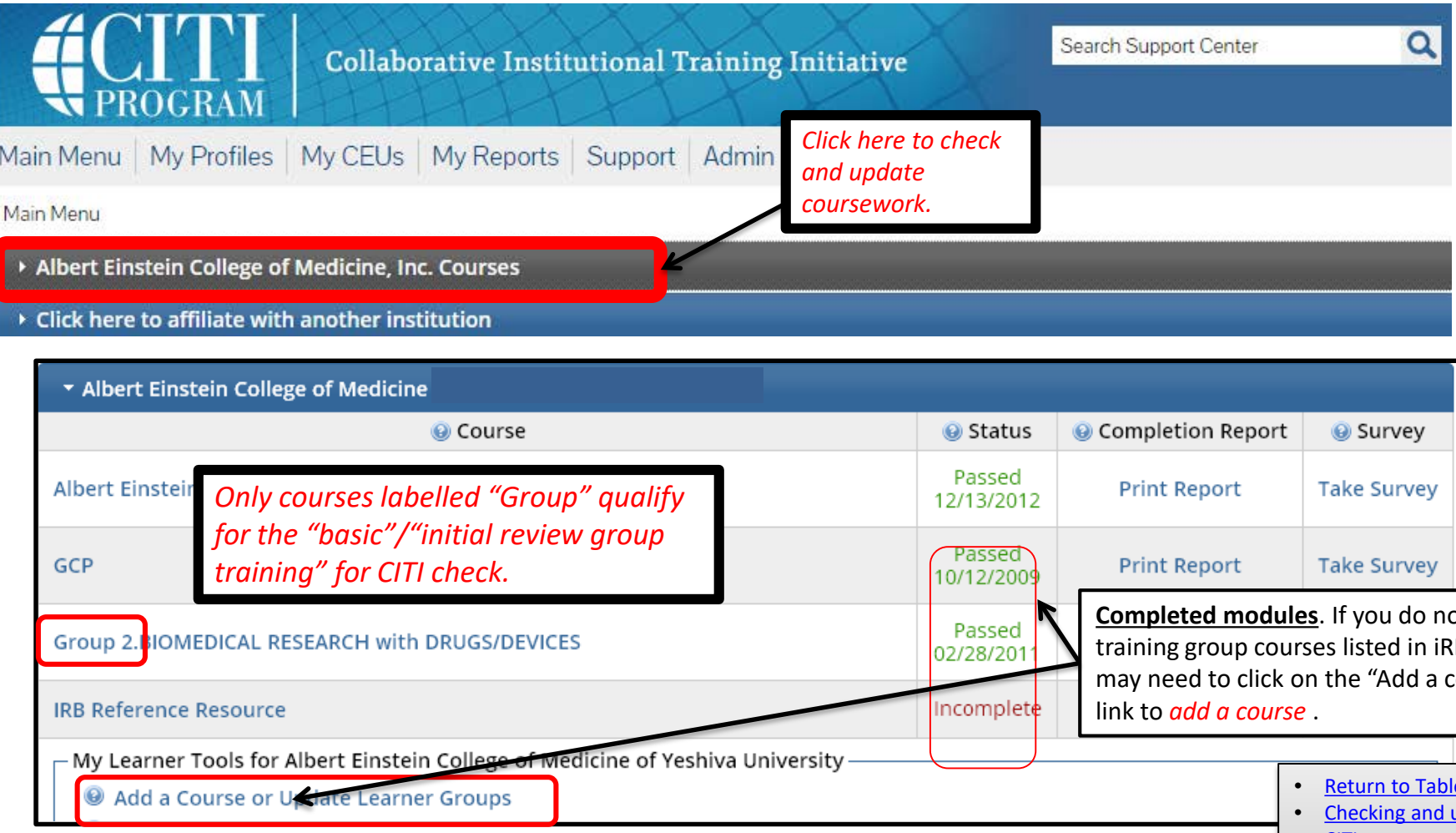


*Select **Albert Einstein College of Medicine , Inc.** from the first drop down menu. Leave the other sections blank. Then click **Next**.*

*Once you have completed registering with Einstein, check the **Main Menu** to confirm that you have completed the required modules for Einstein CITI Certification.*

- Return to Table of Contents
- Checking and updating in CITI:
  - E-mail address
  - Institutional affiliation
  - Coursework
  - Merging CITI accounts

Checking and Updating Coursework in the CITI program



- Return to Table of Contents
- Checking and updating in CITI:
  - E-mail address
  - Institutional affiliation
  - Coursework
  - Merging CITI accounts

I have two CITI accounts. How do I merge them?

- Send an e-mail to support@citiprogram.org and include the following information:
  - Your first and last name.
  - The name of your institution.
  - The username or Member ID for the account to keep.
  - The username or Member ID for the account to merge.
- For further assistance please contact the CITI Program help desk at 888.529.5929 (U.S. toll free) or +1 305.907.3100 (Outside U.S.) and choose Option 1or e-mail them at support@citiprogram.org .
  - Phone support is available 8:30 a.m. - 7:30 p.m., U.S. Eastern Time, Monday - Friday.

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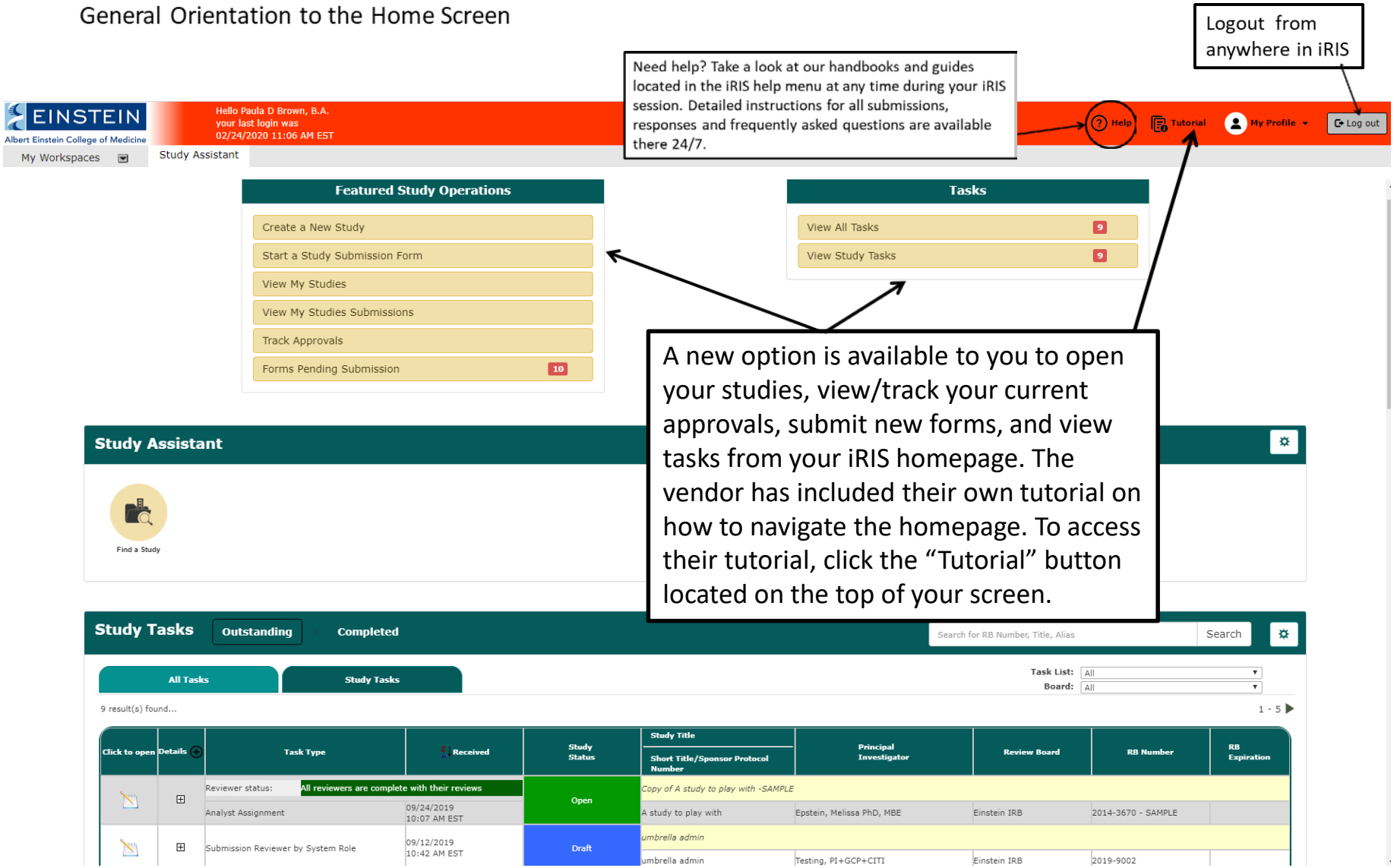
General Orientation to the Home Screen



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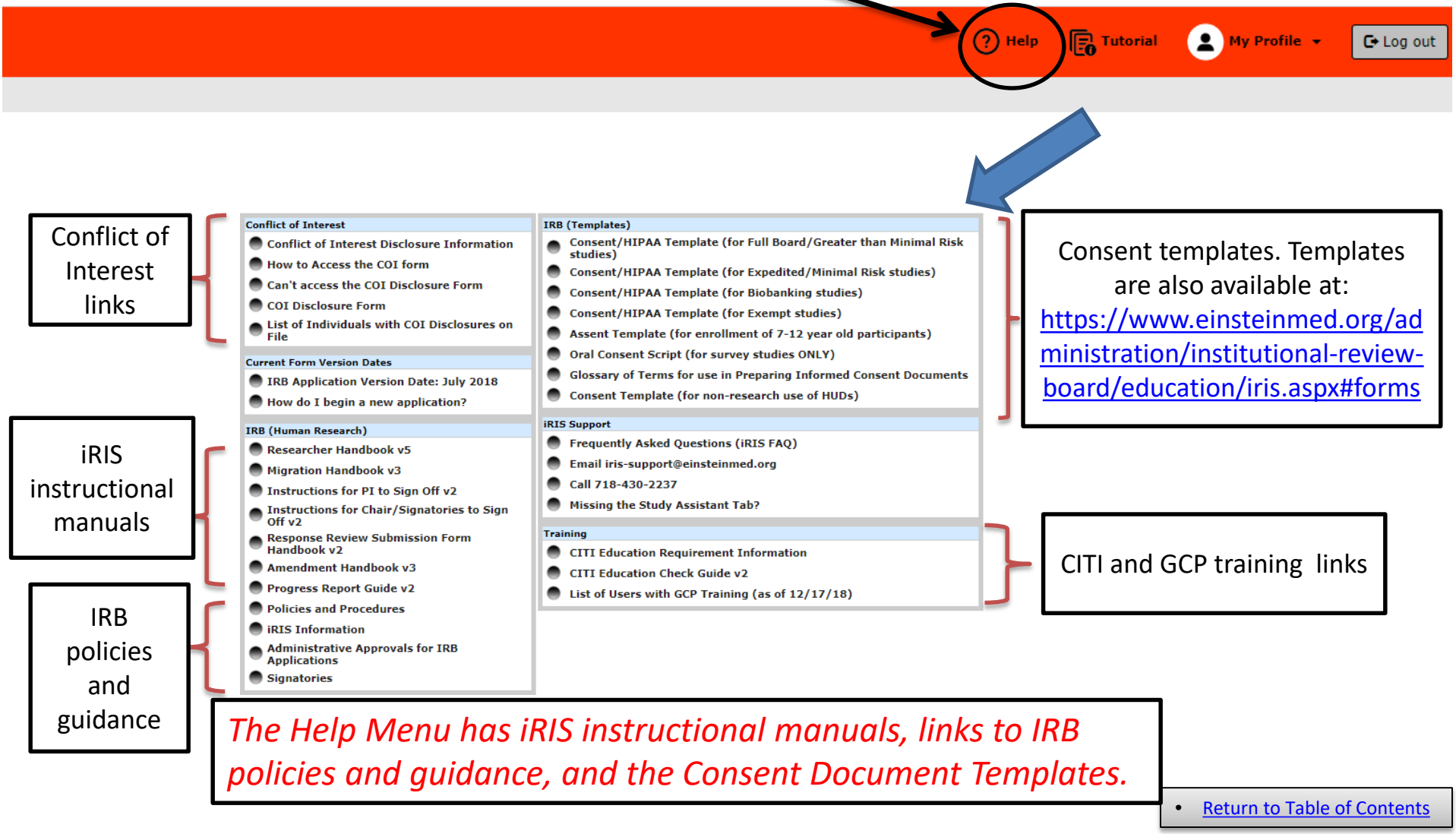
The iRIS Help Menu



Conflict of Interest links

iRIS instructional manuals

IRB policies and guidance

Consent templates. Templates are also available at: https://www.einsteinmed.org/administration/institutional-review-board/education/iris.aspx#forms

CITI and GCP training links

The Help Menu has iRIS instructional manuals, links to IRB policies and guidance, and the Consent Document Templates.

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Panels on the Home Screen

- **Study Assistant** – Depending on the type of system access granted to the user. Users with global/departmental study access can find the "Find a Study" button here.
- **All Tasks** – Shows both outstanding and completed tasks. The user can opt to see a brief description of the task details via the "All Tasks" tab or view the study details via the "Study Tasks" tab. Requests for signoff, responses to stipulations, and to address denied submissions will be seen here.
- **Studies Submission Status** – Shows the status for both study submissions that are in progress and study submissions that have been completed. The "Actions" column allows the user to view the steps/history of the submission without the user having to open the study. The user is provided with the date each step was created, completed, and the duration of each step. If a submission was returned with stipulations, the duration is also calculated for each round.
- **All Studies** – This panel replaces the "My Studies" option. Users can search for studies via IRB number, Title, or Alias. When "Study Status" is selected, the user can choose to filter studies based on a specific study status. Under the "Actions" column, users can view the history of all submissions for the specified study (this includes pending and completed submissions, outcome letters, submission details). The following options are under the "Actions" column:
  - The "items" option allows the user to select the submitted items (documents) and create a PDF packet.
  - The "forms" option allows the user to view the versions of a form, begin a new form, or complete an existing form.
  - The "hide" option allows the user to hide the study from the panel. If you ever need to see the hidden study click the widget icon in the right corner of the panel section to select "Show Hidden".
  - The "copy" option allows the user to copy the study.
  - The "delete" option allows the user who initially created the study to delete the study.
  - Lastly, the "Corr" option allows the user to view all study correspondence.

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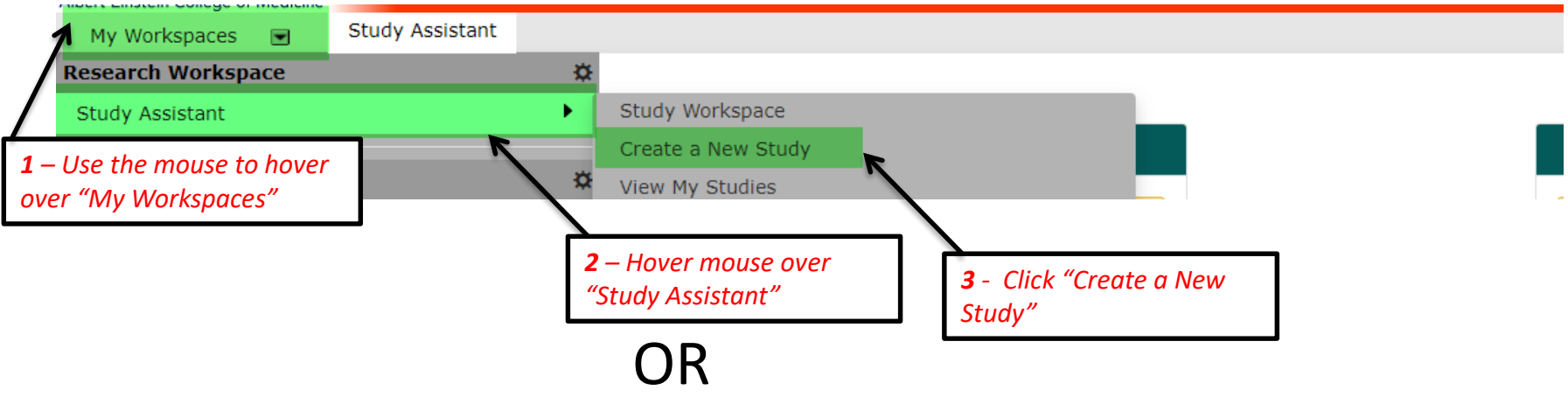
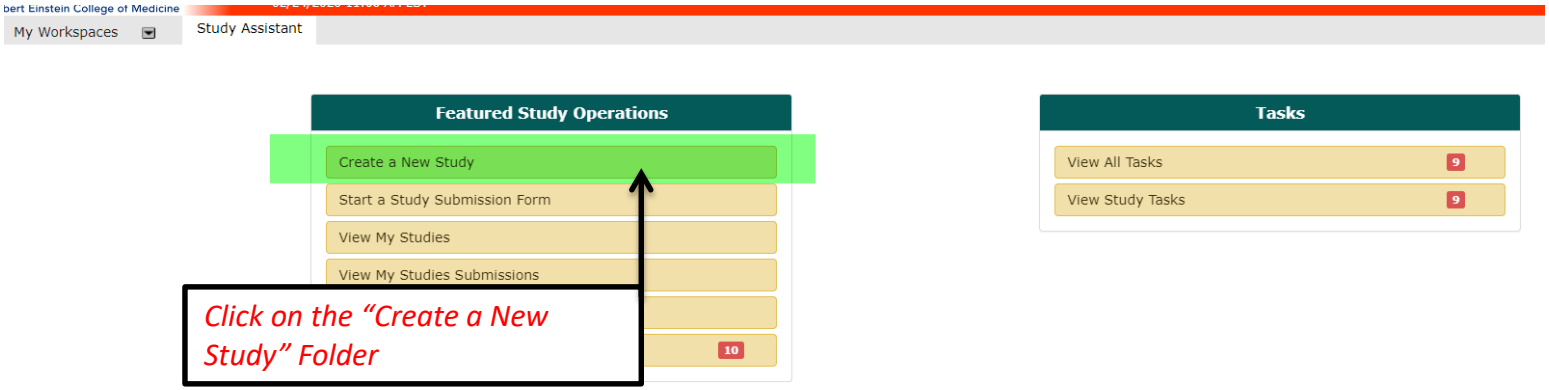
Start a New Study



OR



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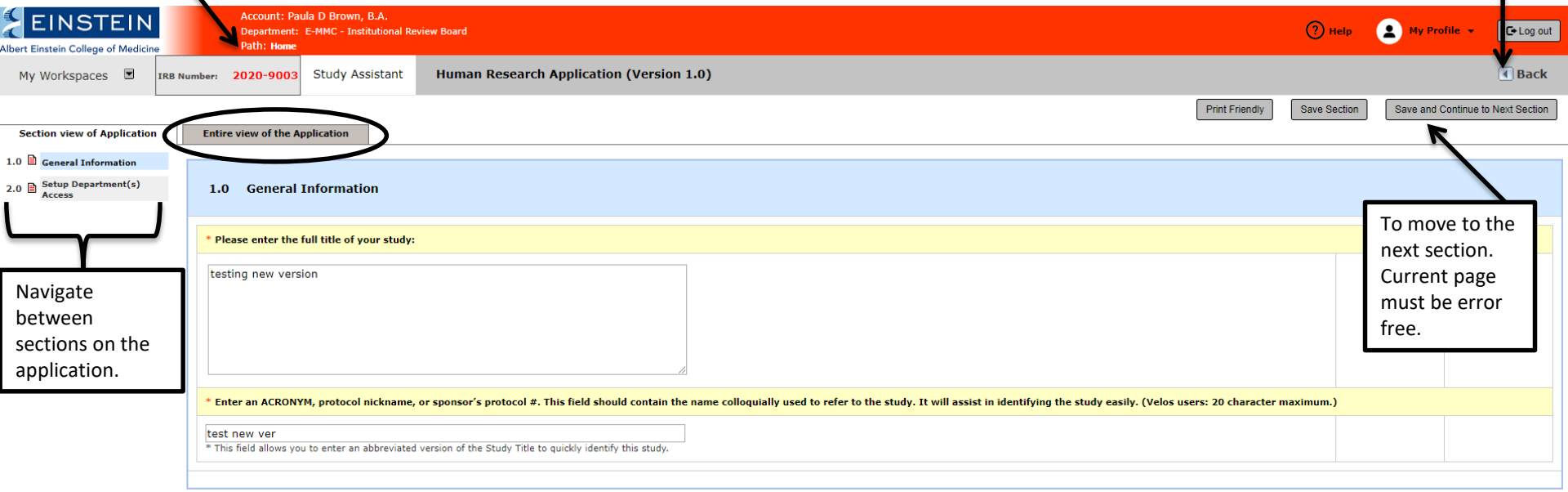
General Navigation within a Study Application

Navigation within iRIS.

Returns to last level in iRIS. DON'T use this to move between application sections.



Navigate between sections on the application.

To move to the next section. Current page must be error free.

Your application will have unique section numbers depending on the content of your application. The section numbers in the Handbook may not correspond to the section numbers in your application.

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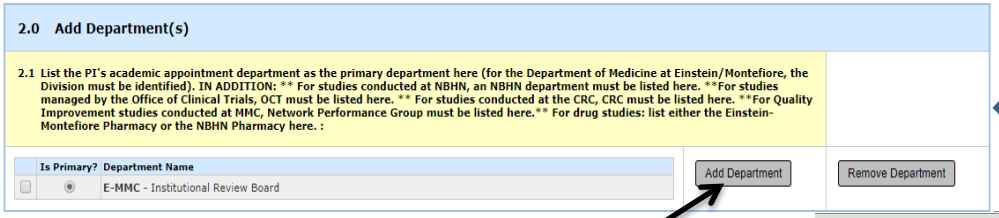
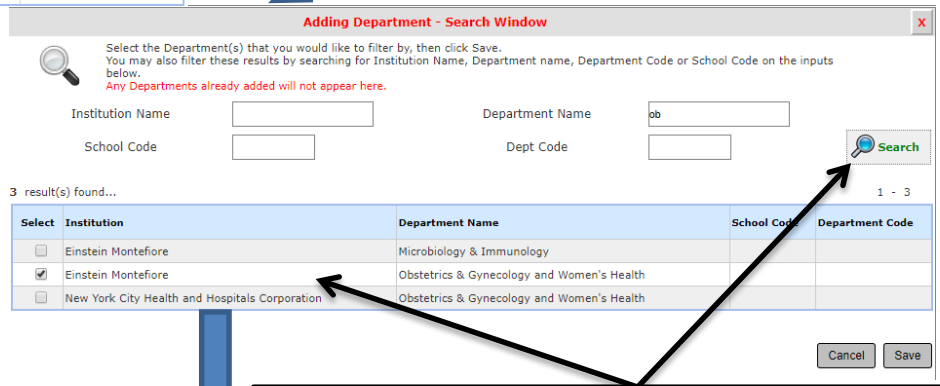
Set up Department Access

This department MUST match the PI's primary department. If it does NOT match change the department as follows:



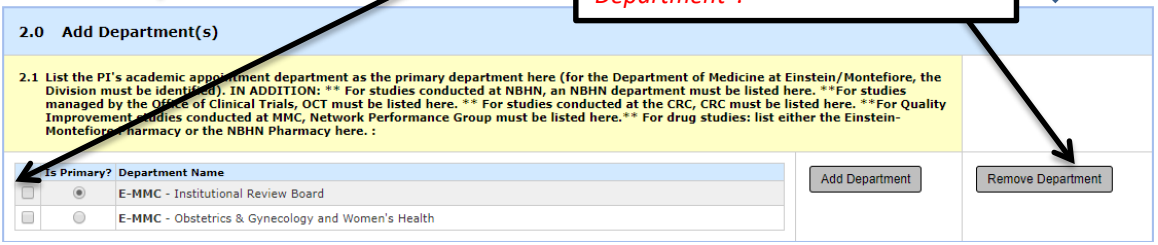
1 *- ADD Department*



2- Search for the Department, then select the Department Name in the checkbox and click on "Save". You may need to scroll down to find the "save" button.

3 *- Select Primary Department*

4 *- To REMOVE a department: select department and then click "Remove Department".*



**** When you are finished adding/removing the departments, click "Save and Continue to next section".***

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Requirements for all KP

- Meet human subjects education requirements (https://www.einsteinmed.org/administration/institutional-review-board/education/human-subjects.aspx).
  - **Drug/Device studies**: Make sure all Key Personnel have satisfied the GCP requirement (https://www.einsteinmed.org/administration/institutional-review-board/education/gcp.aspx) .
  - Check your current education status or check the education status of all KP on the study by clicking on these links or by going to the CITI Education Check Guide in the iRIS Help Menu.
- **PI, Additional Investigators and Key Personnel (KP)** (sections3.1 and 3.2A): Must have a current (updated within the past 180 days) Conflict of Interest (COI) Disclosure Form with the Conflict of Interest Office (see https://www.einsteinmed.org/administration/conflict-of-interest/disclosure-form/ for further guidance).
- *What happens if these requirements are not met?*
  - *The Migration Completion Form (MCF) may be submitted in iRIS, but the IRB will NOT receive the submission. Check your study status (page 62) on a regular basis to see if the submission is delayed due to COI check or CITI education check.*

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Assigning Key Personnel (KP)

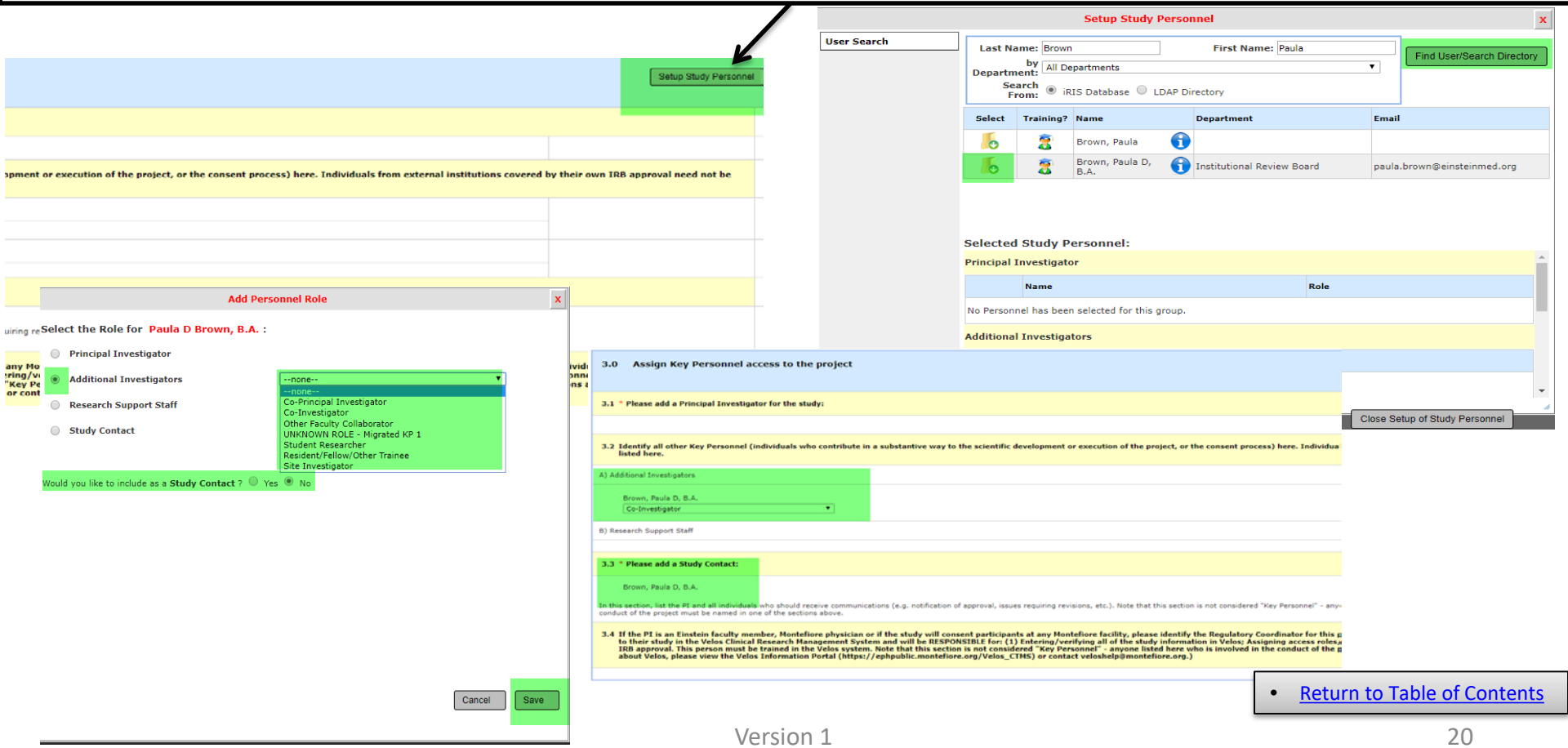
A PI must be assigned to all studies. Only faculty may serve as PIs. All other internal KP (individuals who contribute in a substantive way to the scientific development or execution of the project, or the consent process) must also be added on this page. See the "External Researchers & Sites" page for guidance on external KP.

By default, only the PI receives system notifications and can access the study. Any other person who needs to receive notifications or access to the study must be listed as a Study Contact.

***** Study contacts do not need to be listed as key personnel.***

Click "Setup Study Personnel" to begin locating and adding personnel. Be sure to only search for personnel listed in the "iRIS Database". The "LDAP Directory" option may consist of inactive accounts as this option gives you all users listed in Montefiore's active directory.

Select the personnel's role during this step also. You will be given the option to add the user as "Study Contact" without having to search for the same user multiple times. Click "Save" when you are done adding all your personnel. The personnel will then show in the key personnel section of the application.



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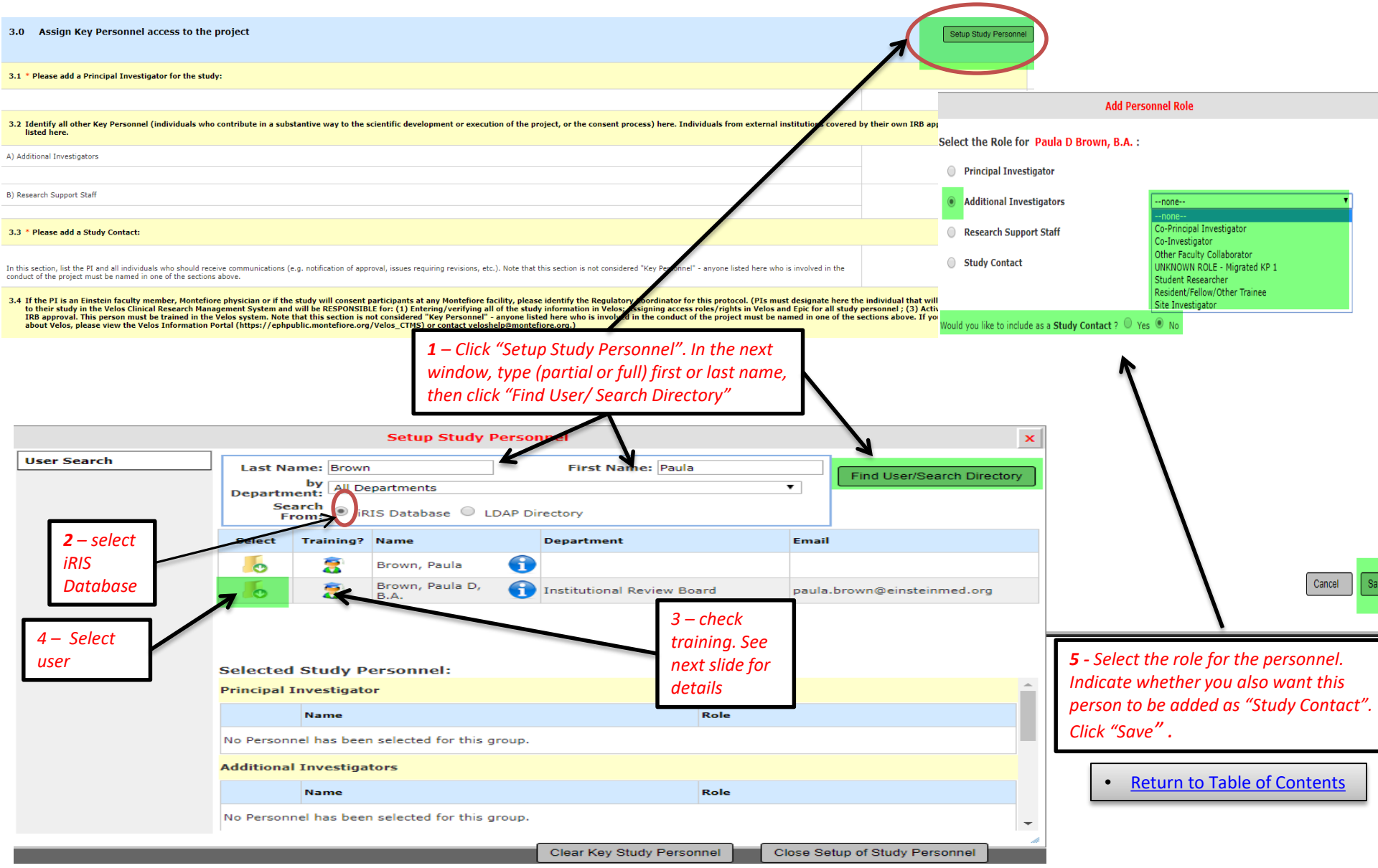
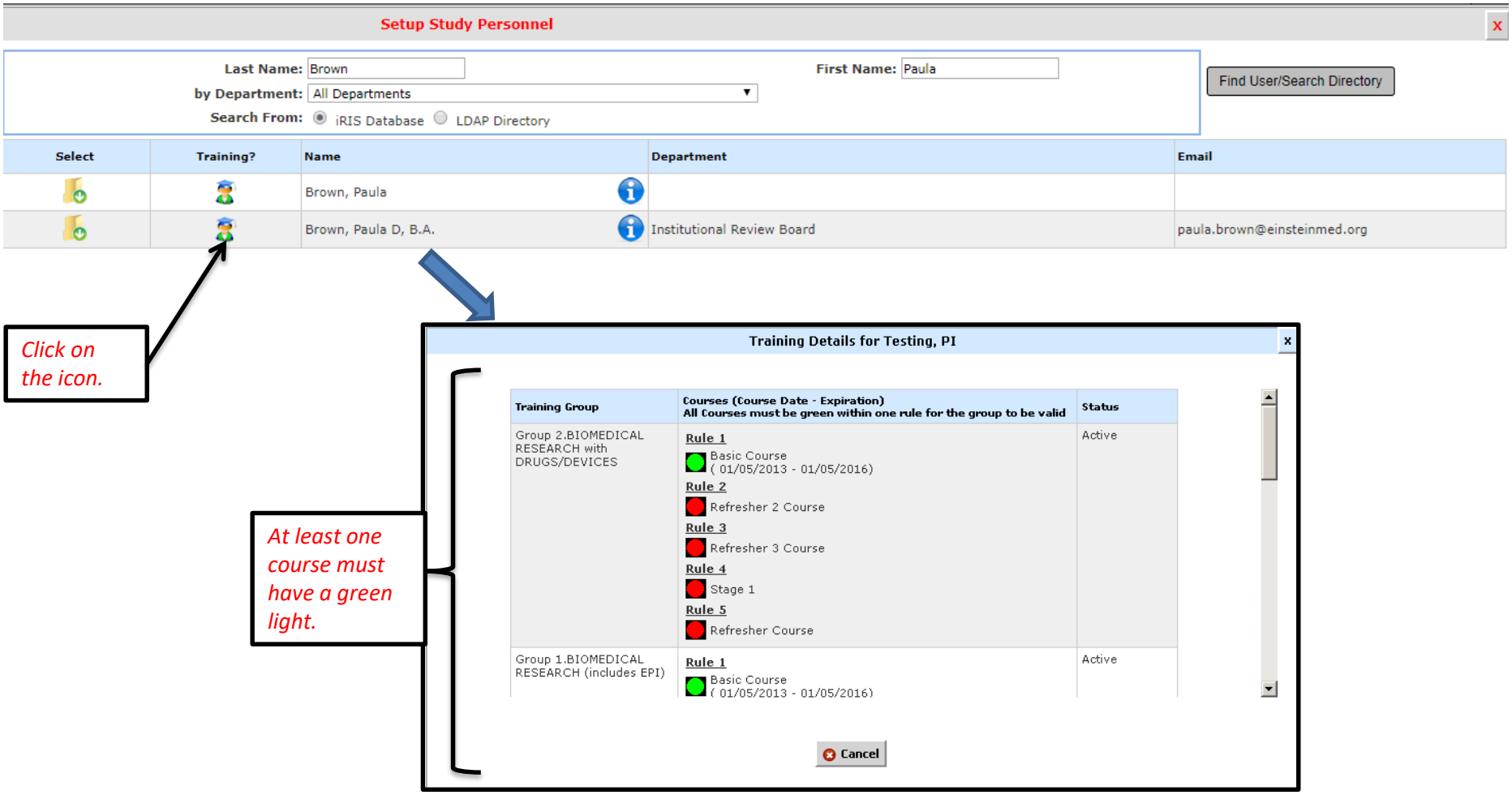
Adding a User



- Return to Table of Contents

Check education training status of users



- Return to Table of Contents
- Return to Adding a User

External Researchers & Sites

- **Generally**, collaborators from external institutions do not need to be listed in iRIS.
- **Exception**: the external institution does NOT have its own IRB but is "engaged" in the research.
  - Contact the Einstein IRB at 718-430-2237 for guidance.
  - If the Einstein IRB serves as the IRB of record for the collaborators, they will need to satisfy Einstein IRB educational and COI requirements. In addition, a legal agreement (IIA or IAA depending on the circumstances) is required.

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Conflict of Interest Disclosure Requirements

- *The IRB will NOT begin its review until the Conflict of Interest Committee completes its review.*
- In order to ensure prompt review by the COI committee, you must complete the following steps:
  - Verify that any additional PIs or Additional Investigators have current (filed within the past 180 days) COI disclosures on file. Please contact the COI department at coi@einsteinmed.org for a list of individuals with COI disclosures on file.

  - The IRB recommends that you send the following information by e-mail to all investigators who do not have a current COI disclosure on file:

    PI Name:

    Protocol Title:

    Please complete or update your Conflict of Interest disclosure form. COI disclosure forms must be filed or updated electronically.

    Contact COI at coi@einsteinmed.org for the link to the COI disclosure form.

    If you can't access the disclosure form or can't login to the COI website, e-mail coi@einsteinmed.org .

    *NOTE: THE IRB WILL **NOT** RECEIVE THIS SUBMISSION UNTIL ALL INVESTIGATORS HAVE A CURRENT CONFLICT OF INTEREST DISCLOSURE ON FILE.*

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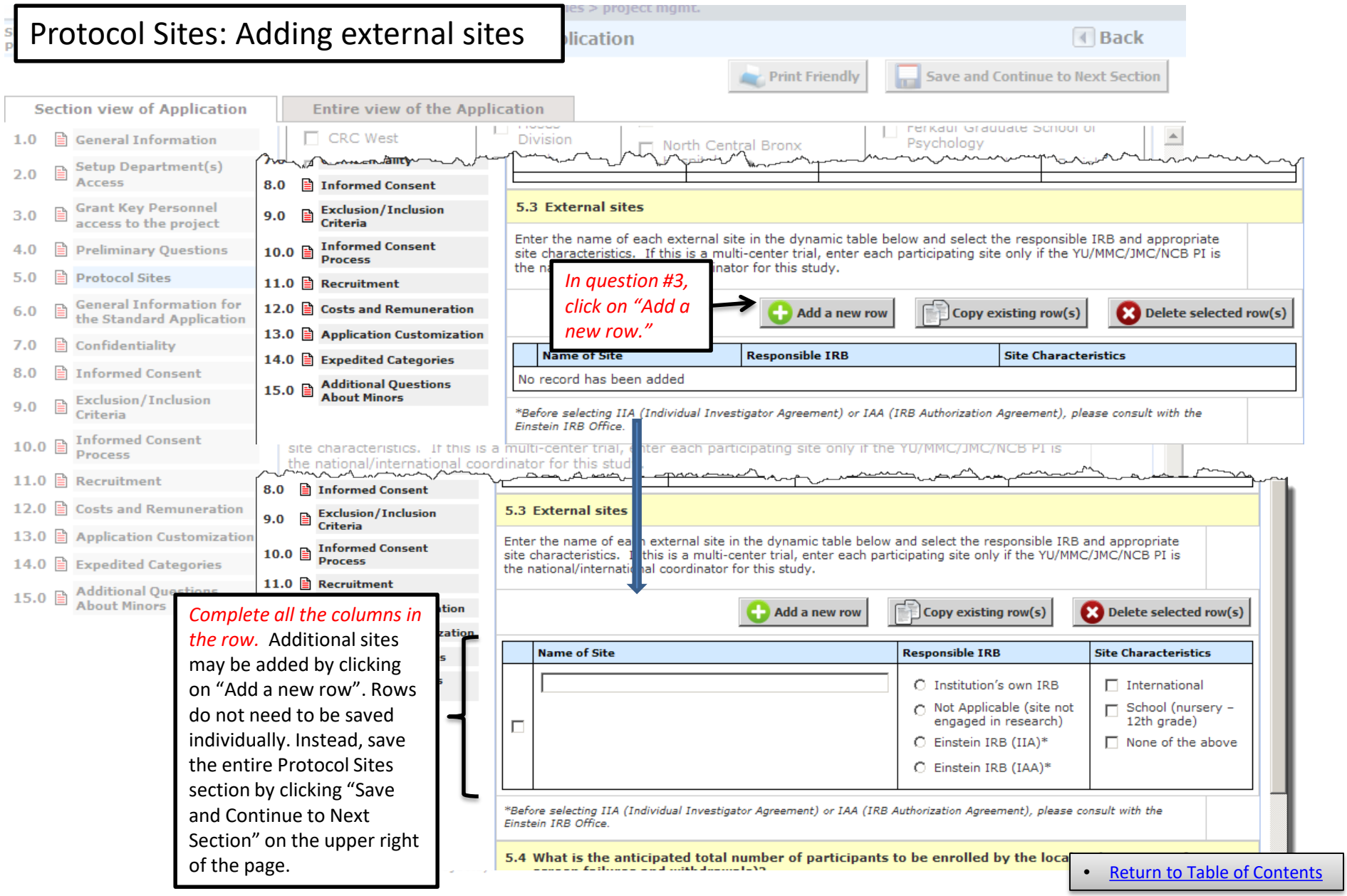
Protocol Sites: Adding external sites



In question #3, click on "Add a new row."

Complete all the columns in the row. Additional sites may be added by clicking on "Add a new row". Rows do not need to be saved individually. Instead, save the entire Protocol Sites section by clicking "Save and Continue to Next Section" on the upper right of the page.

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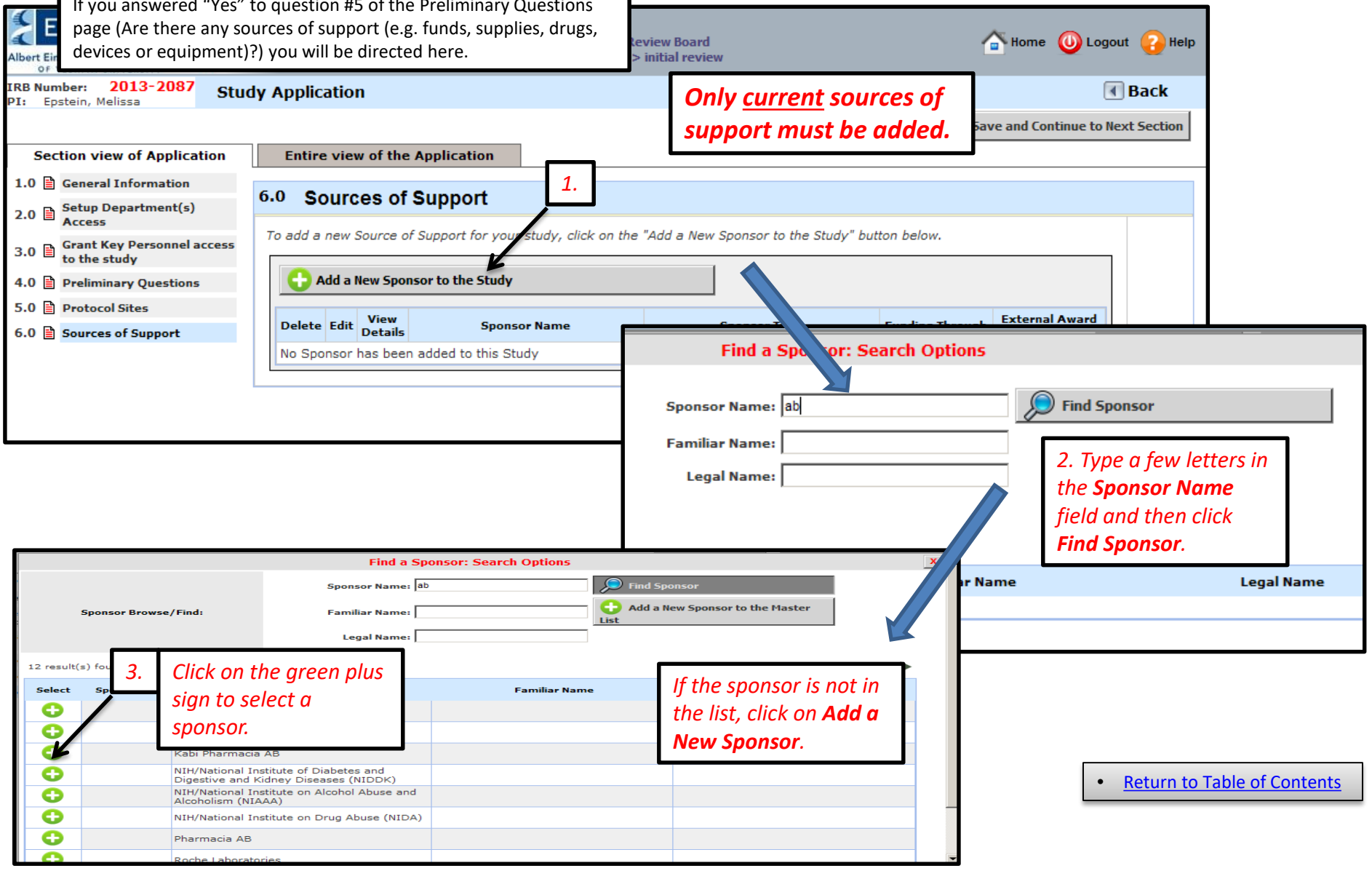
Sources of Support

If you answered "Yes" to question #5 of the Preliminary Questions page (Are there any sources of support (e.g. funds, supplies, drugs, devices or equipment)?) you will be directed here.



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Frequently Asked Questions about the Application

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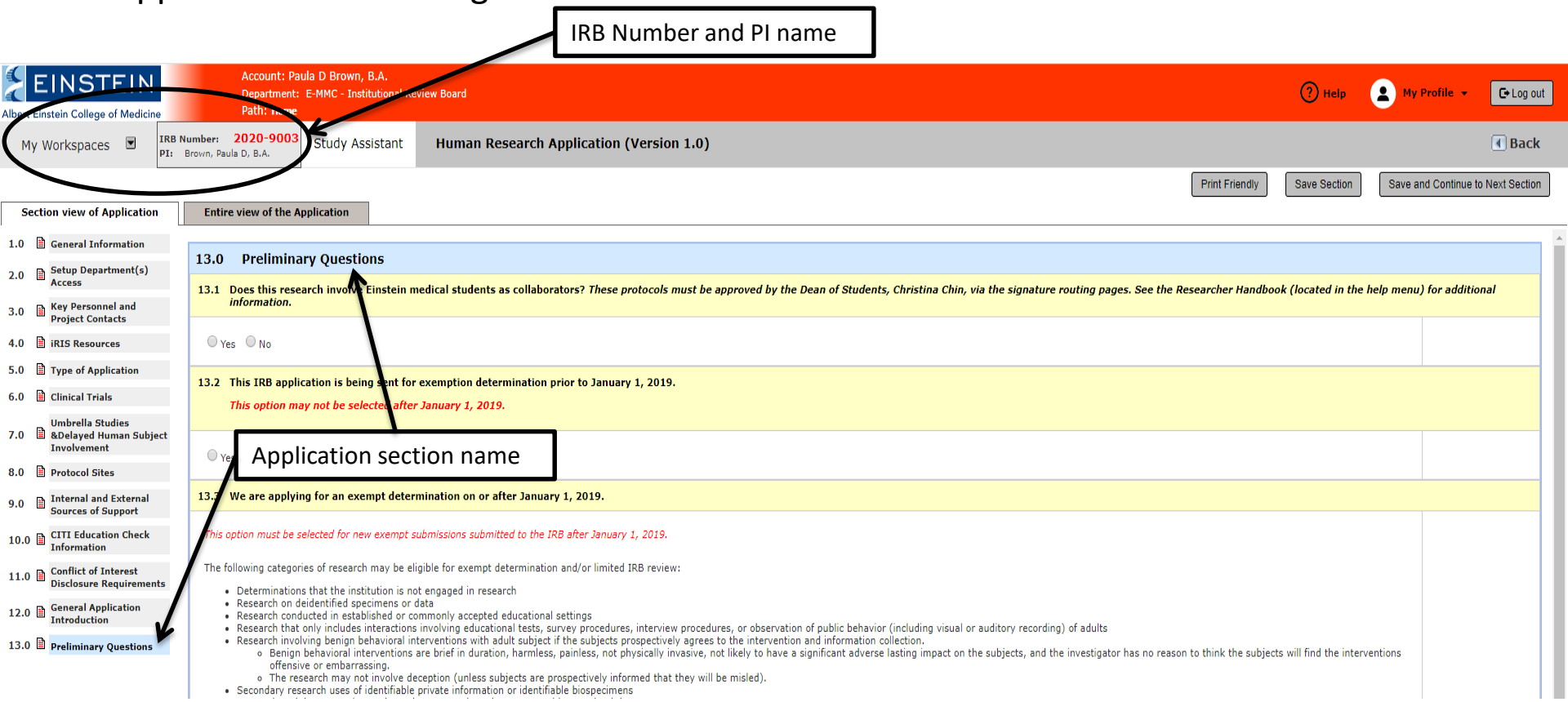
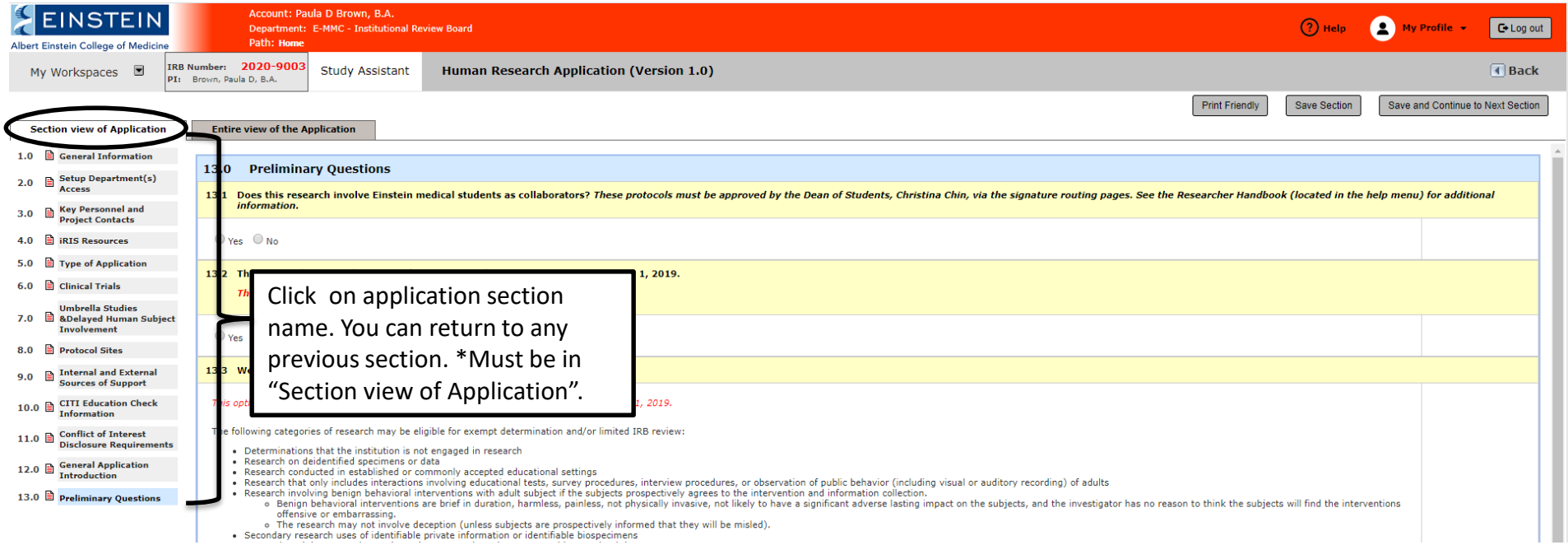
- Go to Initial Review Submission Packet

Where am I? How can I tell which study I'm working on? How can I tell which section of the application I'm working on?



- Return to Table of Contents
- Return to Frequently Asked Questions
- Go to Initial Review Submission Packet

How do I move between sections of the application? Can I go back to a section I already completed?



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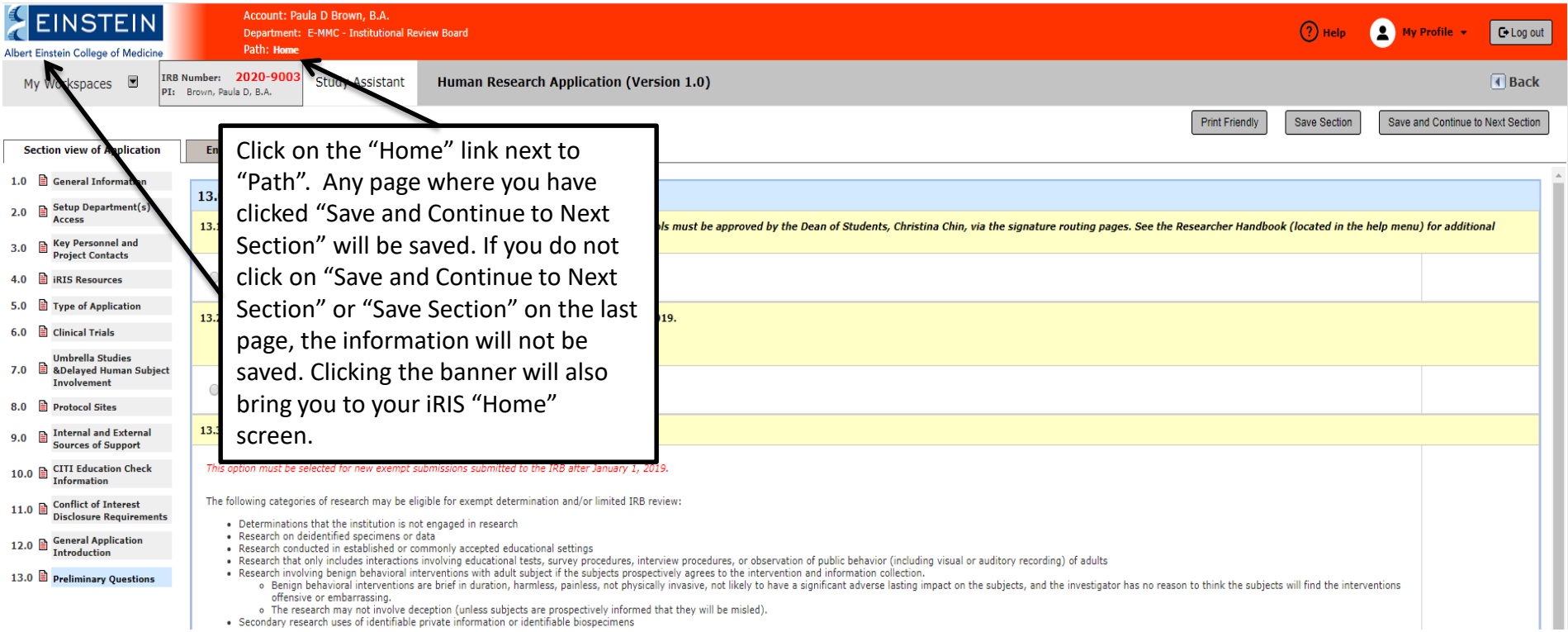
- Return to Frequently Asked Questions
- Go to Initial Review Submission Packet

How do I stop working on the application?



Click on the "Home" link next to "Path". Any page where you have clicked "Save and Continue to Next Section" will be saved. If you do not click on "Save and Continue to Next Section" or "Save Section" on the last page, the information will not be saved. Clicking the banner will also bring you to your iRIS "Home" screen.

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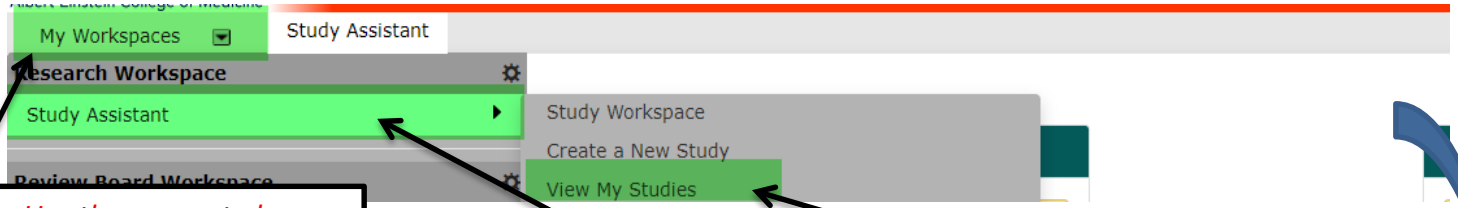
- Return to Frequently Asked Questions
- Go to Initial Review Submission Packet

Opening a draft of a study that has NOT been submitted to the IRB
Page 1

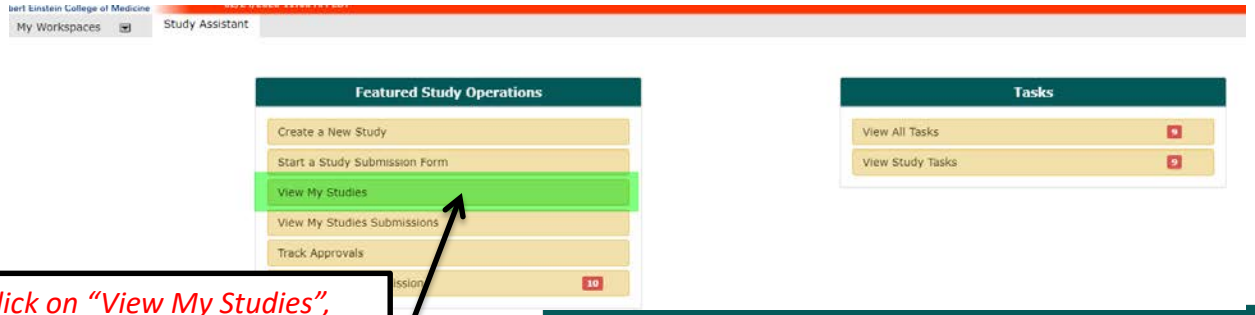


***1** – Use the mouse to hover over "My Workspaces"*

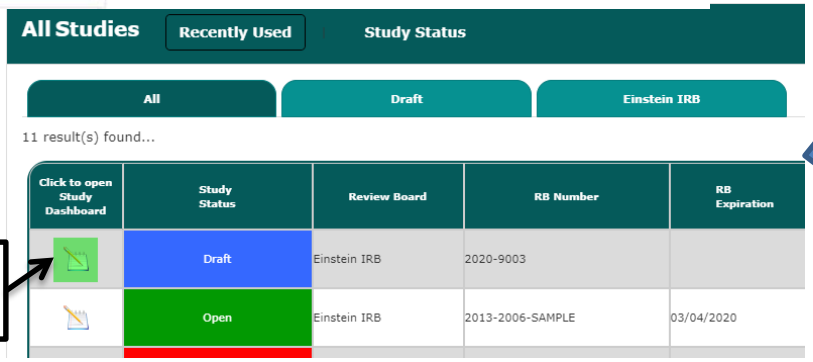
***2** – Hover mouse over "Study Assistant"*

***3** - Click "View My Studies"*

OR



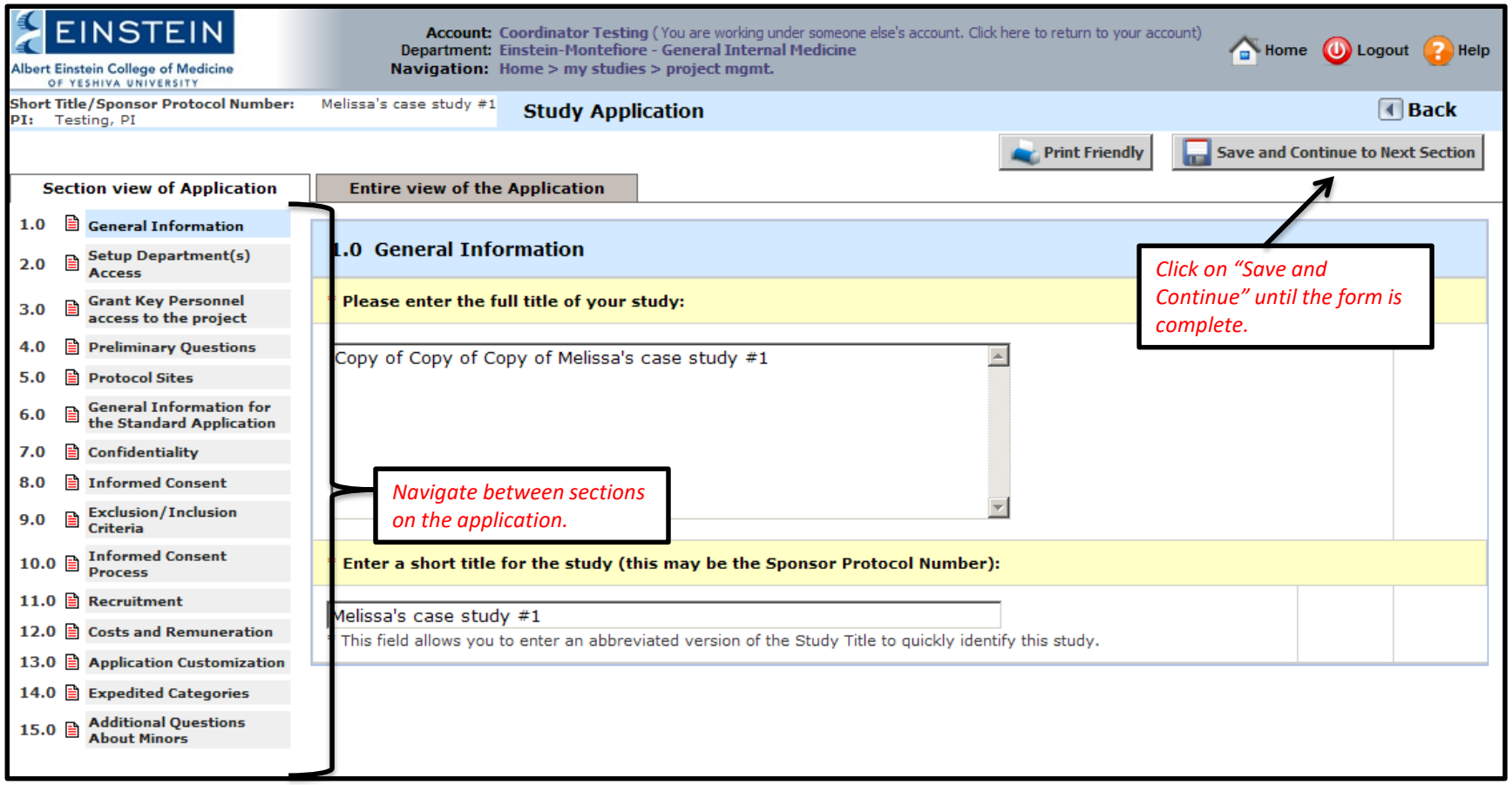
Click on "View My Studies", the system will bring you down to the "All Studies" Panel. Or you can scroll down the page to go to "All Studies".



3 – Click the notepad icon to open the study.

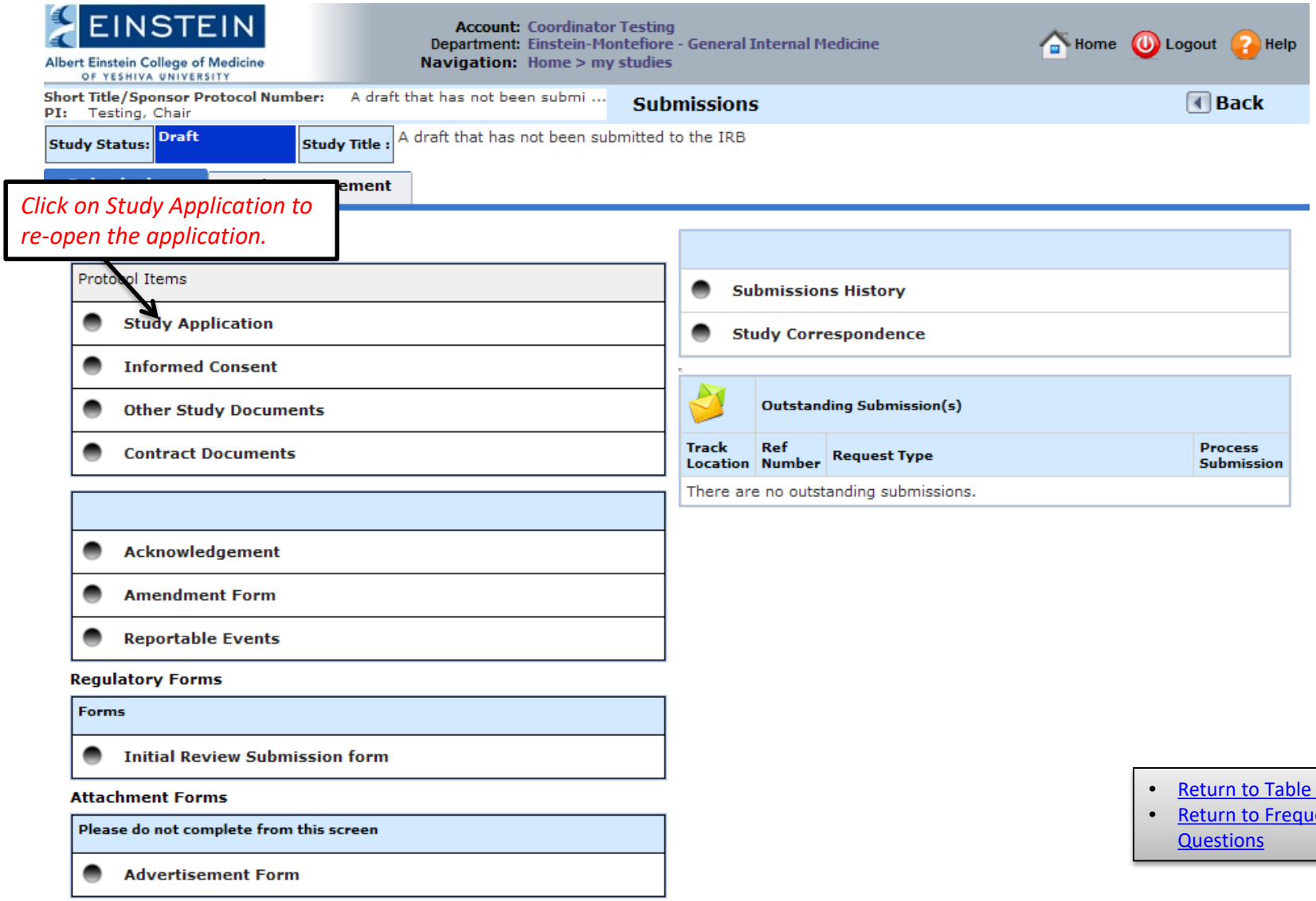
- Return to Table of Contents
- Return to Frequently Asked Questions

If you have **NOT** completed the application, the Study Application screen will open.



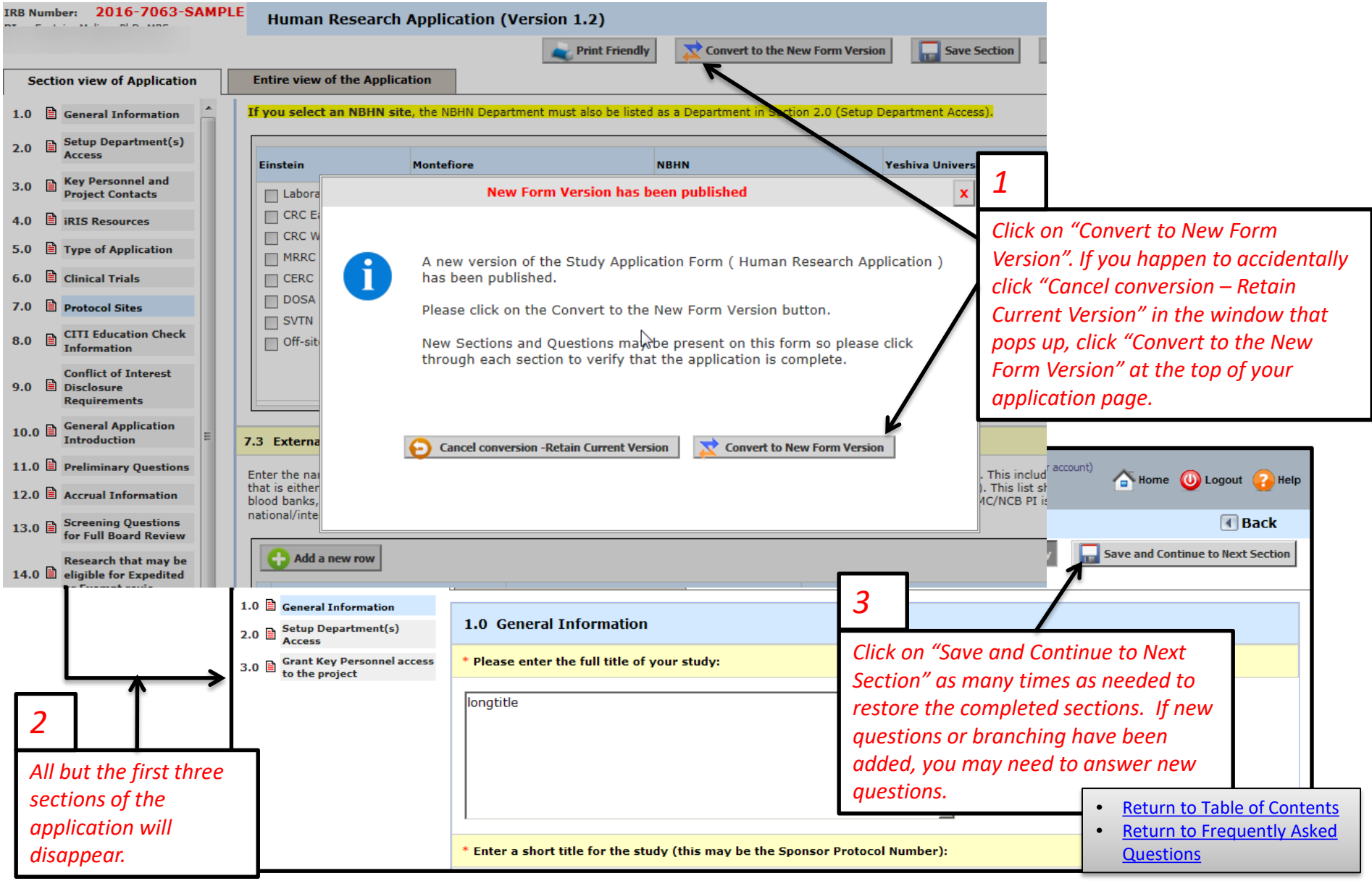
- Return to Table of Contents
- Return to Frequently Asked Questions

If you've **completed** the application, the Project Management Screen will open.



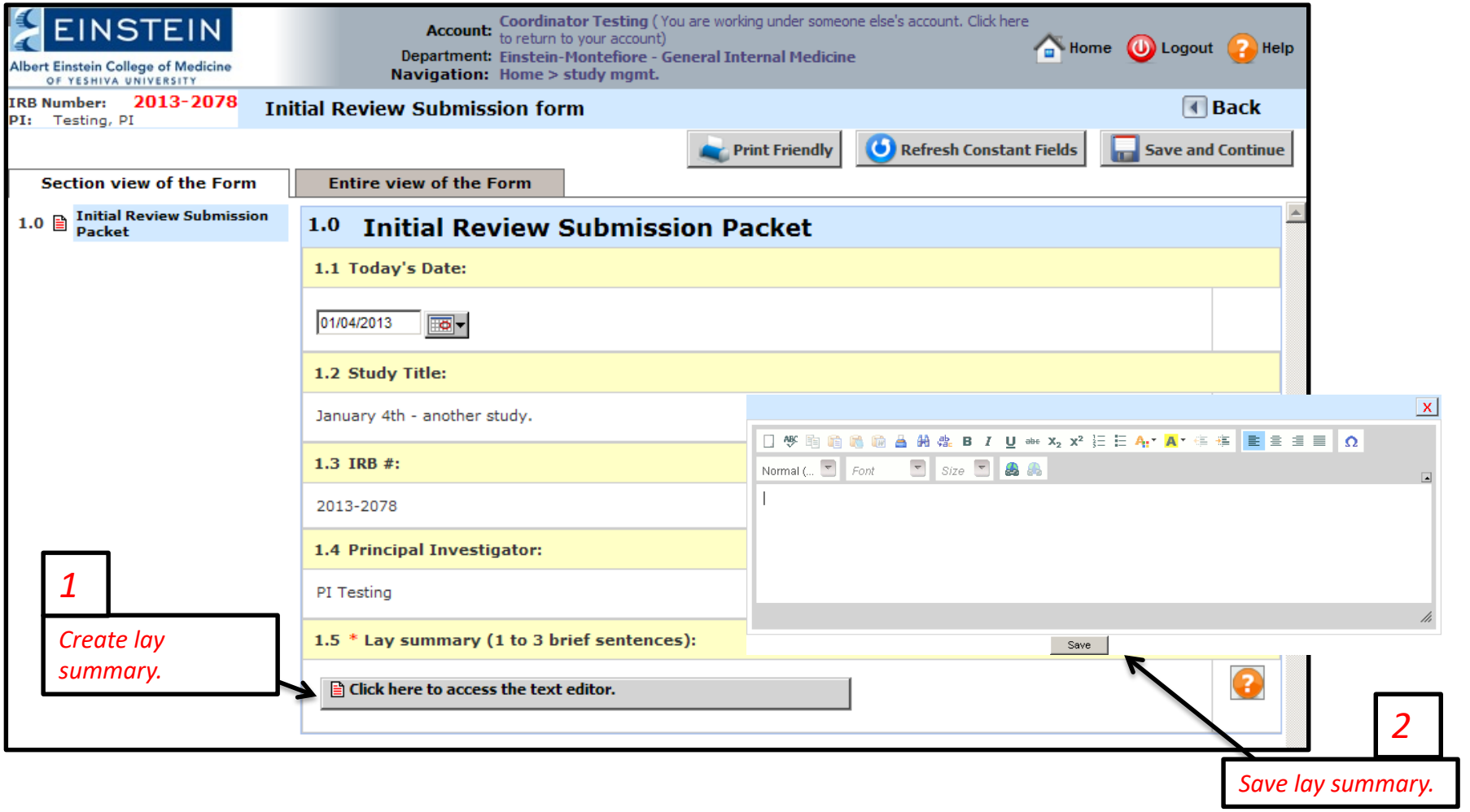
- Return to Table of Contents
- Return to Frequently Asked Questions

I have a message that there is a ***new version of the application***. What do I do?



Initial Review Submission Packet – Section 1

The submission packet contains the new protocol application, the protocol and any other documents you wish to include in the submission. Below is the first page of the submission packet.



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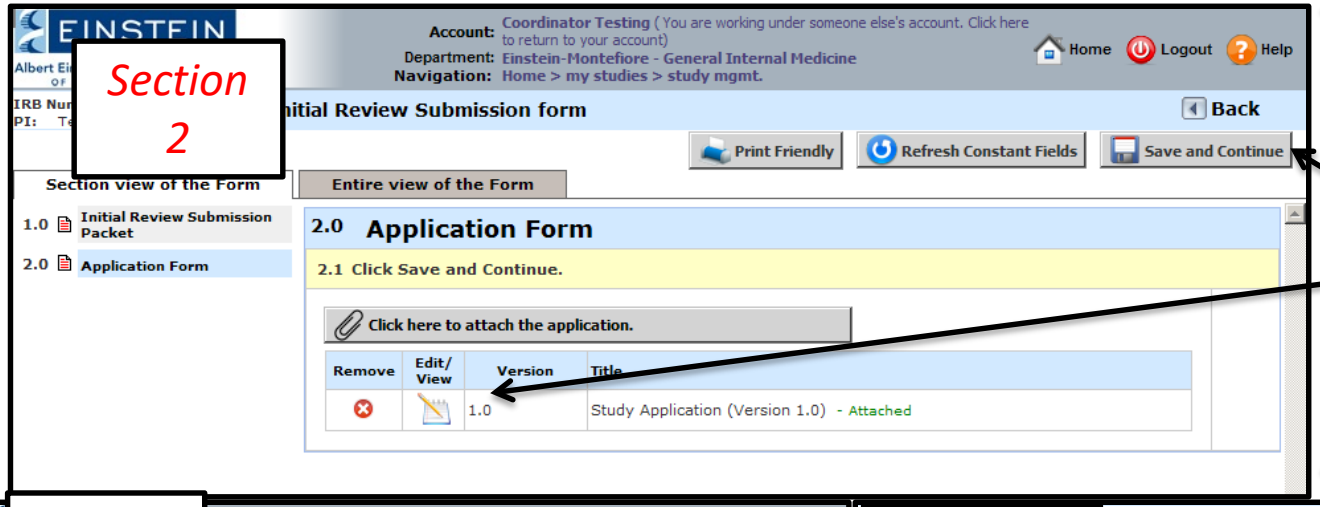
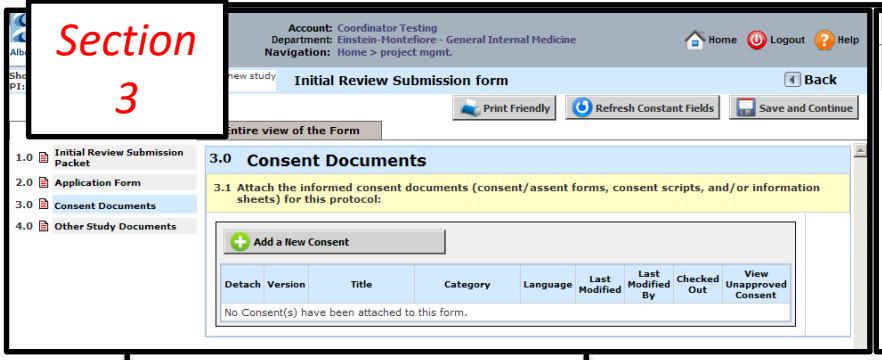
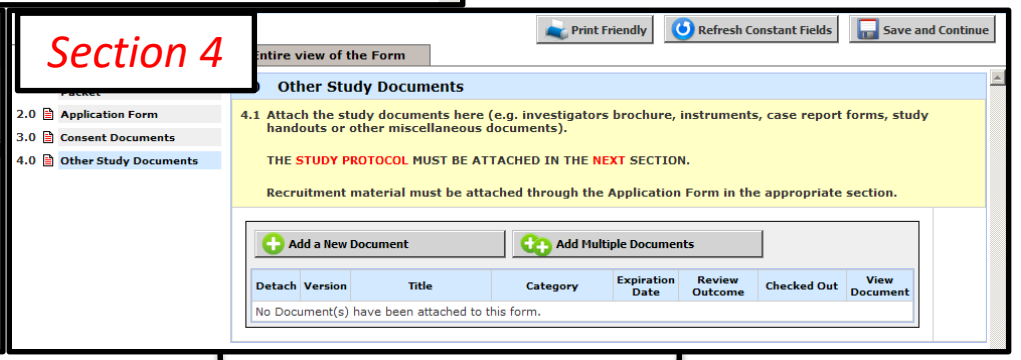
Initial Review Submission Packet – Sections 2-4

The next five sections allow you to edit the application form and attach the consent document, protocol and any other supporting materials. On the first section you add the lay summary. The final page provides instructions for signature routing.



Click on "Save and Continue" if you do not need to edit the application. Click on the notebook icon below Edit/View if you need to edit the application before submission.





Add Consent Documents here. If the study does not involve written/oral consent, just press "Save and Continue".

Add Other Study Documents here. **Note: Recruitment Materials must be added within the application form. The protocol must be attached in the next section.**

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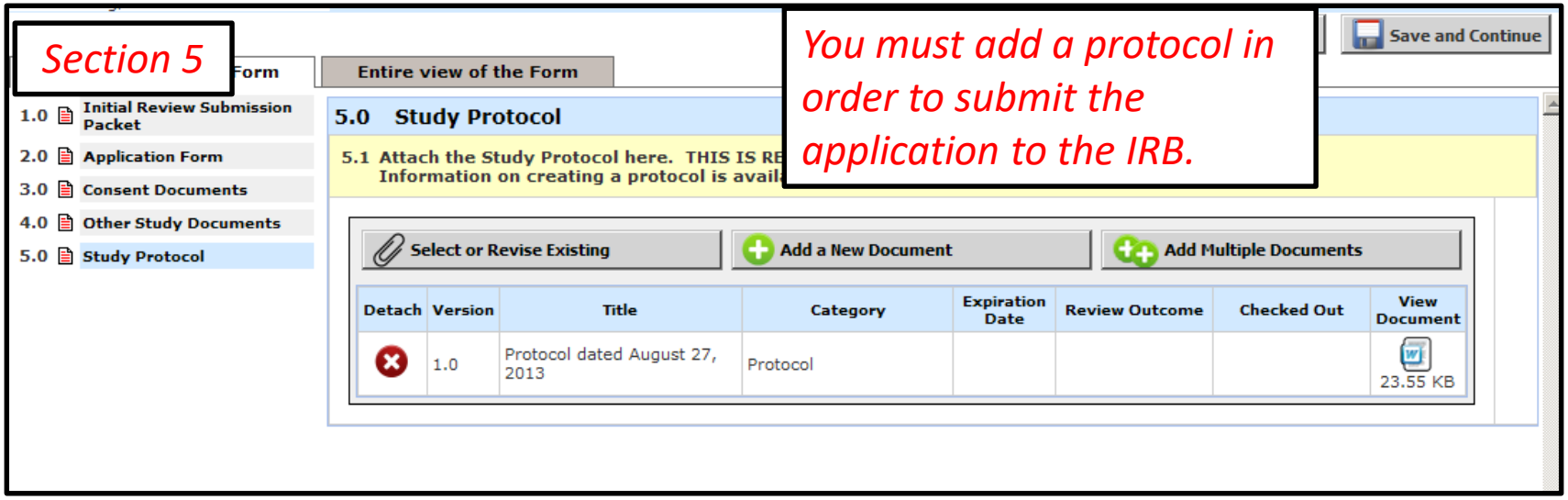
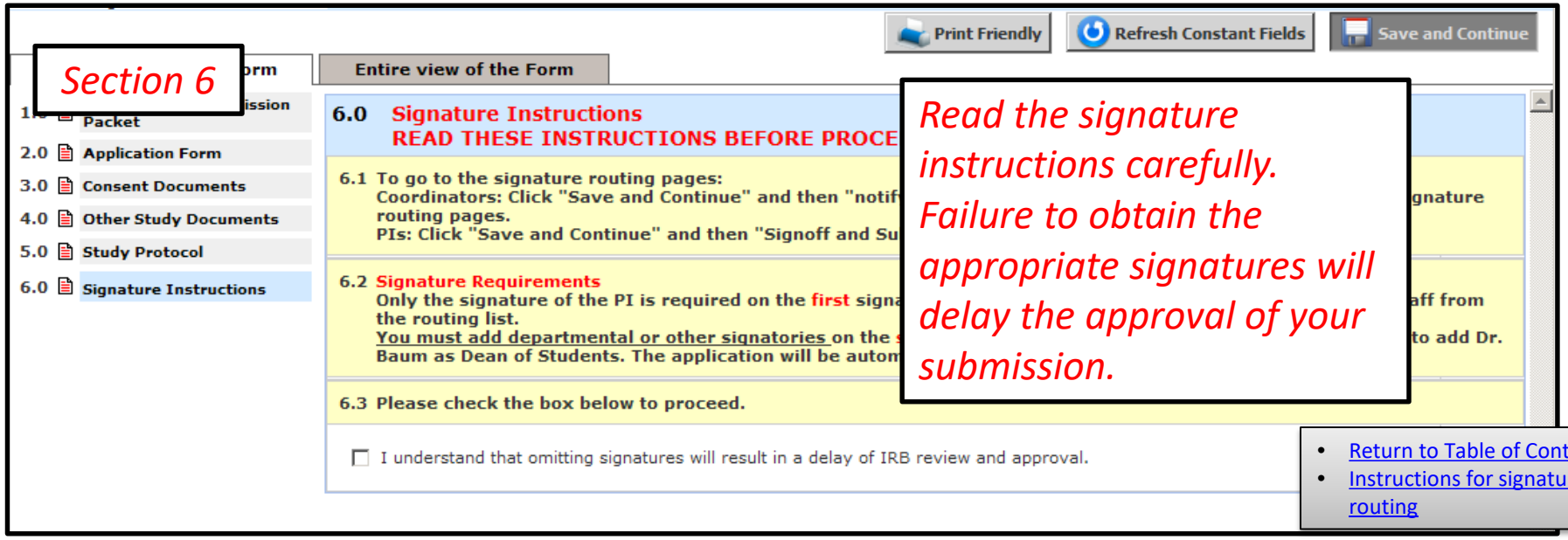
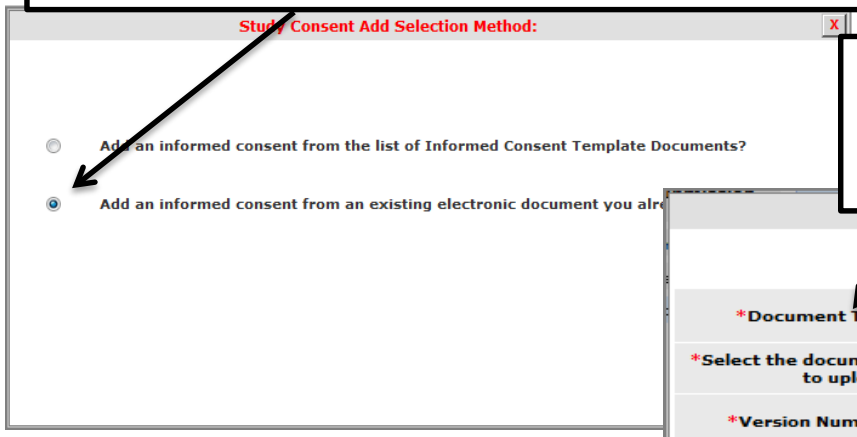
Initial Review Submission Packet – Sections 5-6



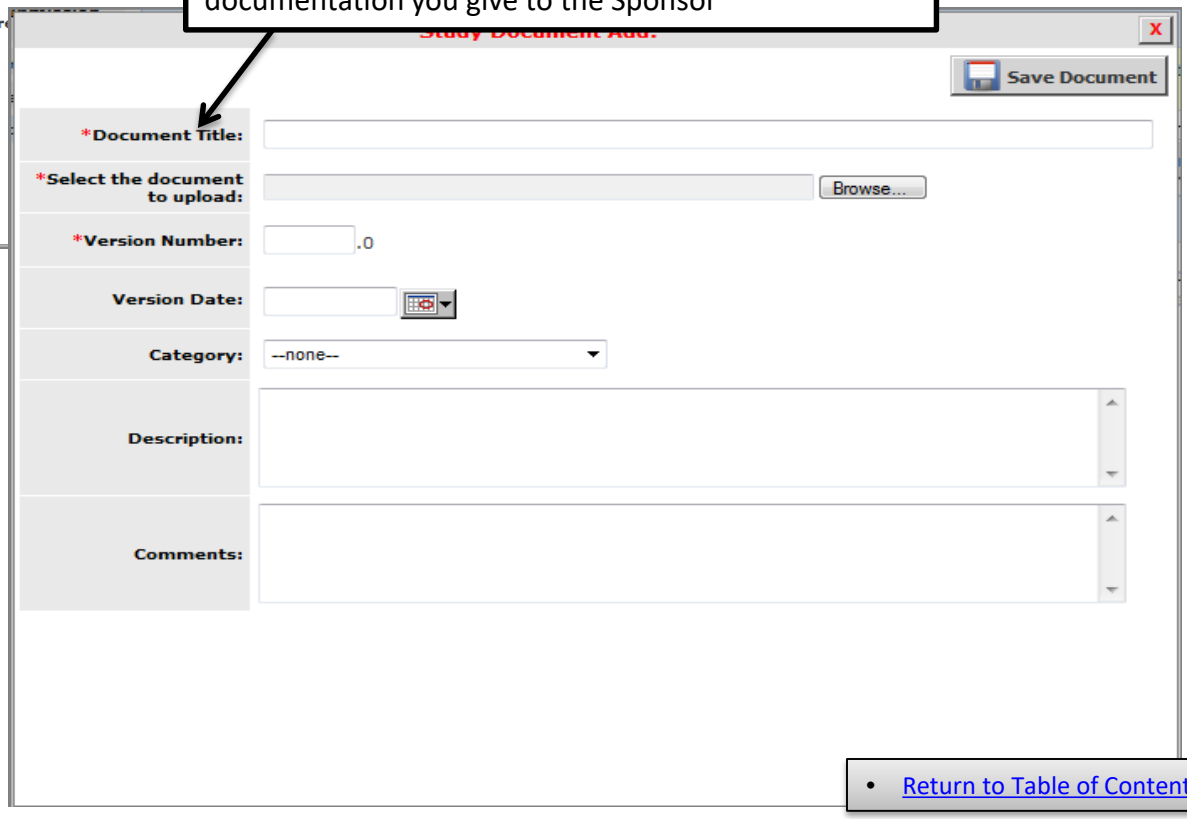


Additional guidance on adding consents and other study documents

For consent documents, choose the 2nd option. For guidance on the new Einstein Consent and HIPAA Templates go to the iRIS Frequently Asked Questions (FAQ) section of the Einstein IRB website (https://www.einsteinmed.org/administration/institutional-review-board/).



For both consents and study documents, carefully consider the *Document Title*. It will be used for your reference, the IRB's reference, and in any documentation you give to the Sponsor



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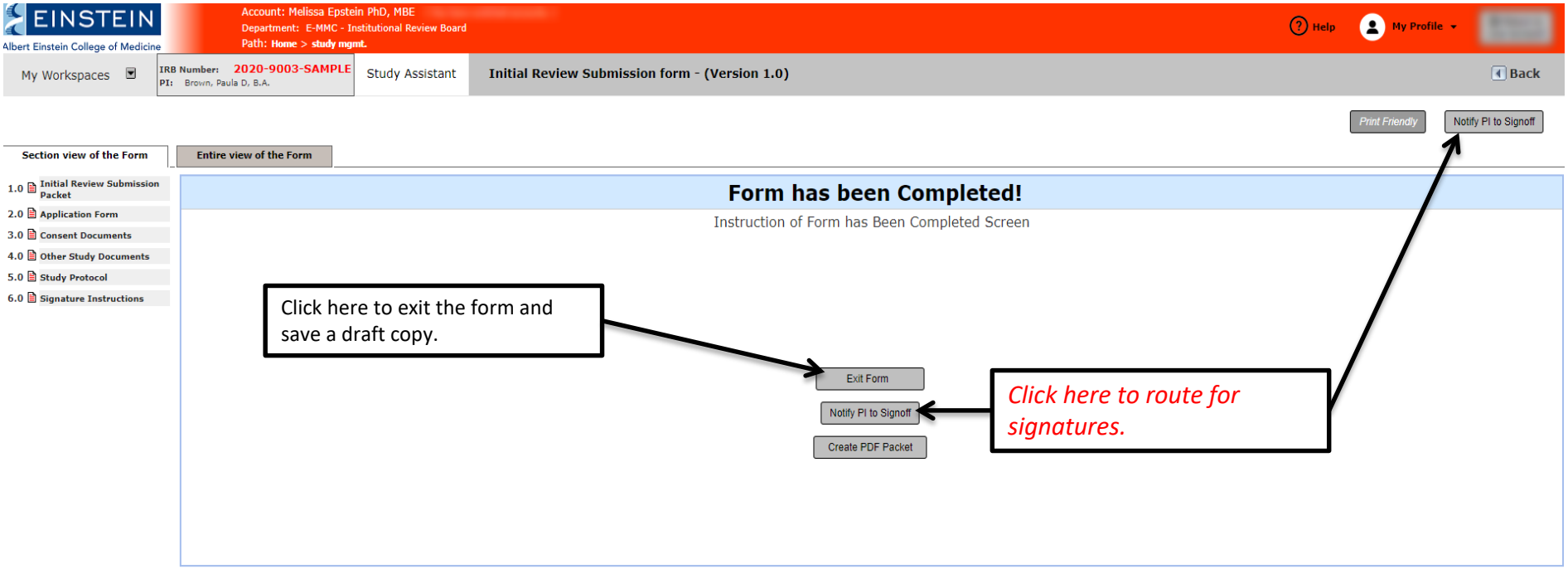
Form Completed!



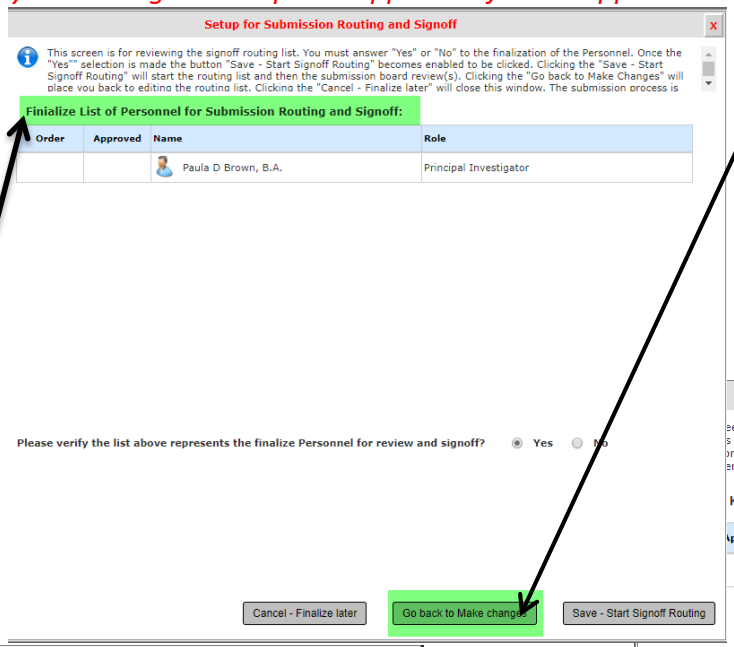
- Instructions for signature routing.
- Return to Table of Contents

Routing Submission for Signoff

The next three pages allow you to assign the required approvals for the application.

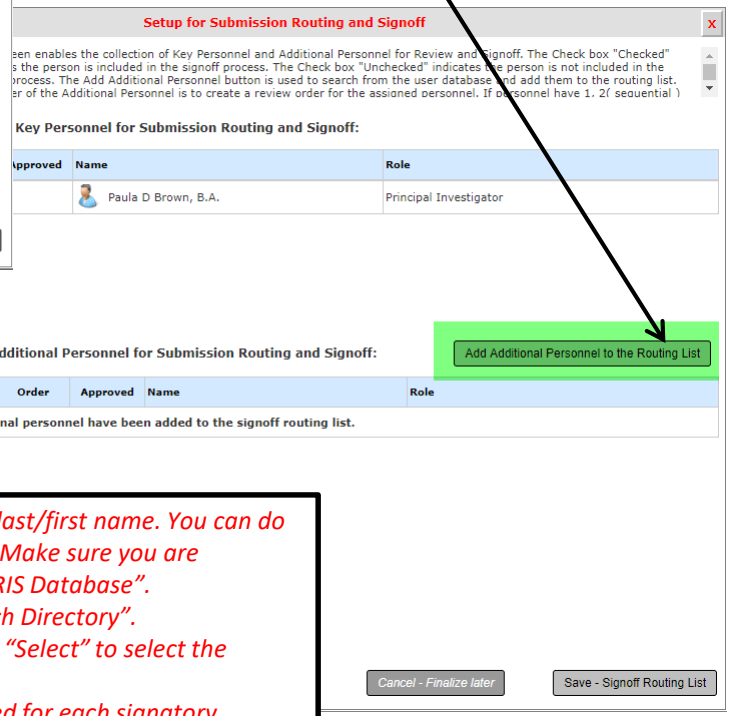
1

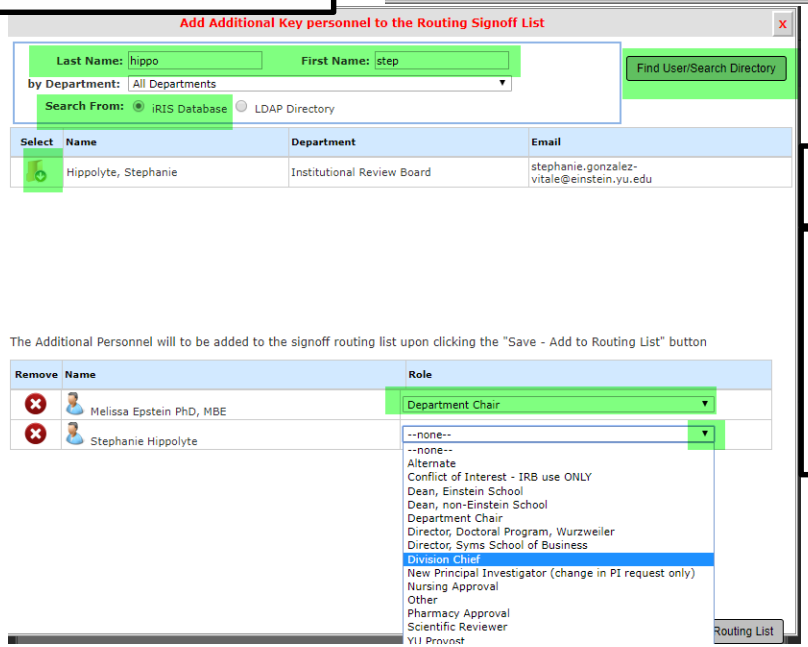
- *Among the KSP, only the PI is required to approve the submission.*
- *By default, the PI will appear under "Finalize List of Personnel for Submission Routing and Signoff:".*
- *Additional signatories are required for initial submissions and may be required for other types of submissions i.e., amendments to change PI.*



2

- *Add the PI's department chair and other required signatories by using the "Go back to Make changes" button.*
- *Click the "Add Additional Personnel to the Routing List" button.*





3

- *Enter the Signatory's last/first name. You can do a full or partial entry. Make sure you are searching from the "iRIS Database".*
- *Click "Find User/Search Directory".*
- *Click the Folder under "Select" to select the signatory.*
- *A **role** must be selected for each signatory.*

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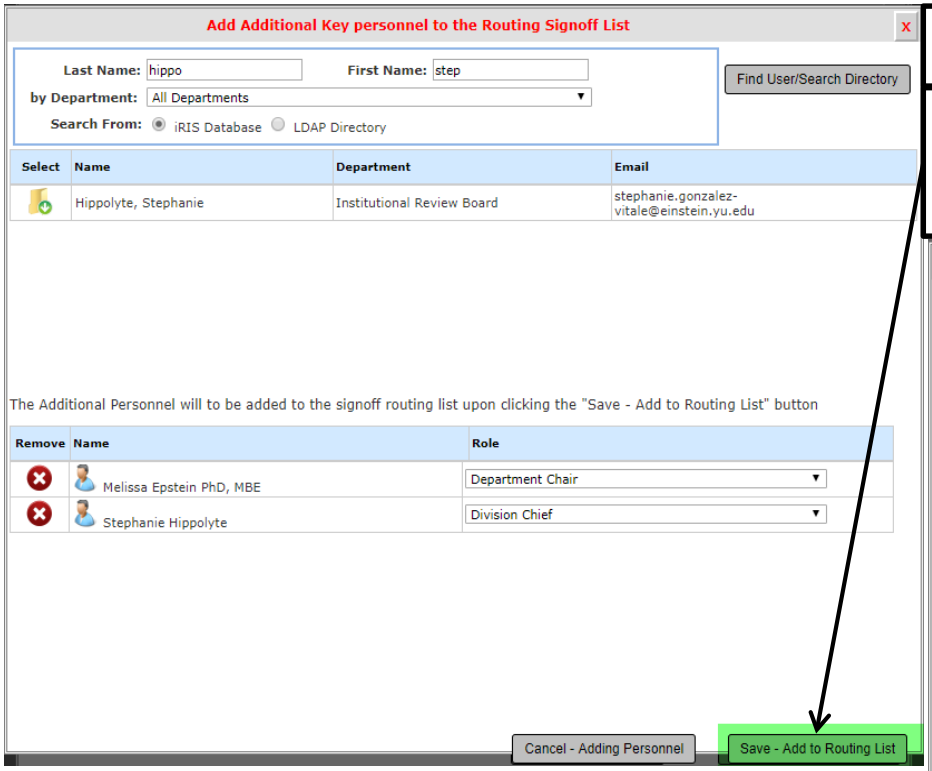
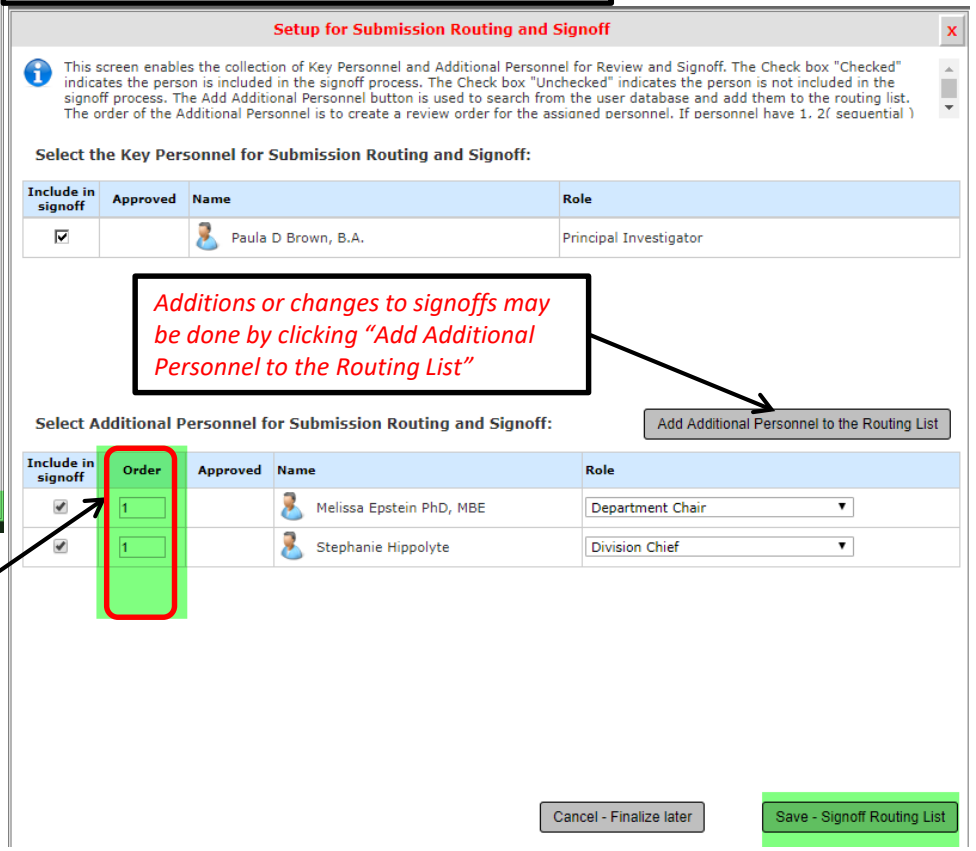
Routing Submission for Signoff - Continued



4

- *Once all signatories have been added, click "Save – Add to Routing List".*



5

- *If you would like all signatories to be notified simultaneously (recommended), set each order to 1.*
- *When you are done, with specifying the routing order, click "Save – Signoff Routing List".*

List of required approvals: https://www.einsteinmed.org/administration/institutional-review-board/approvals.aspx
List of authorized signatories: https://www.einsteinmed.org/administration/institutional-review-board/authorized-list.aspx

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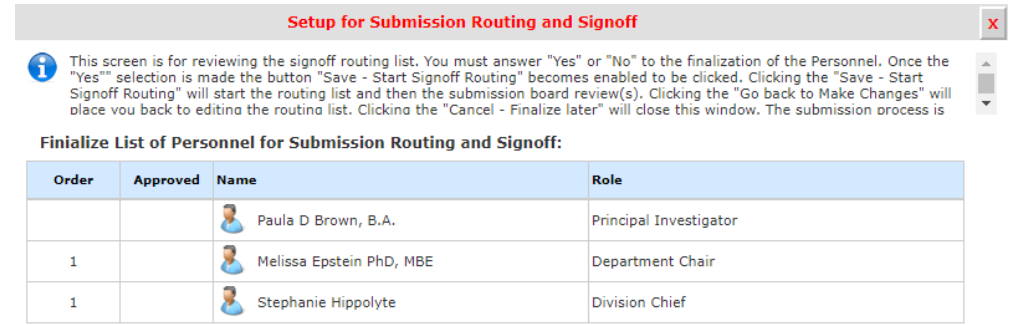
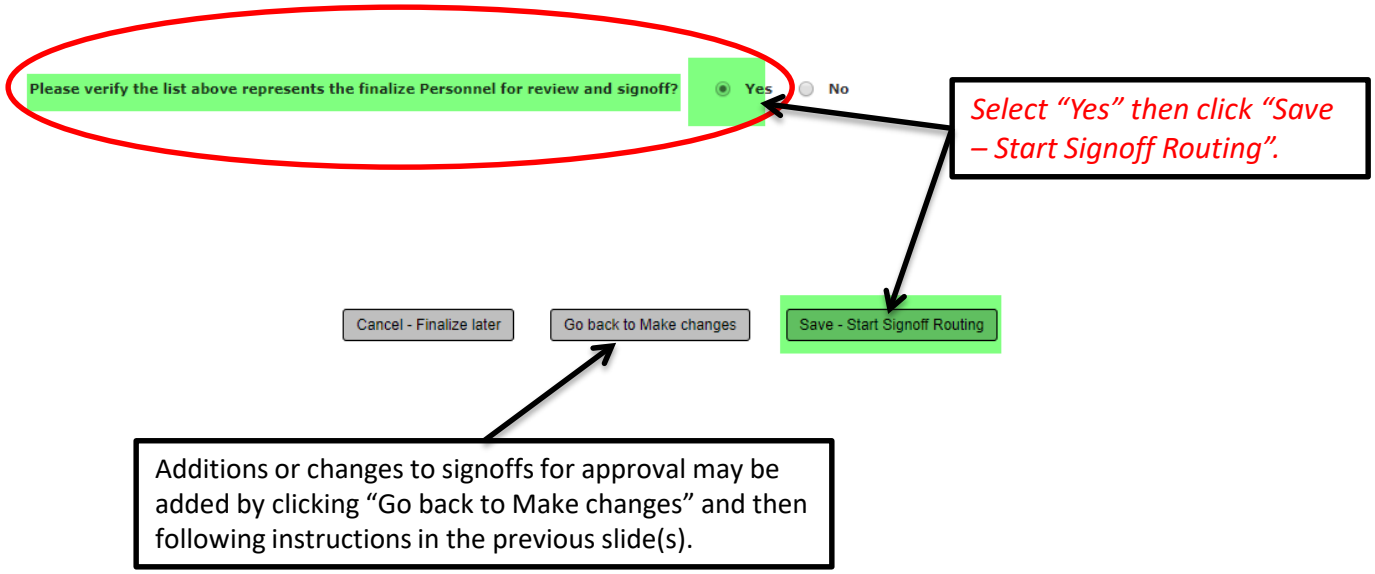
Finalizing Routing for Submission Signoff



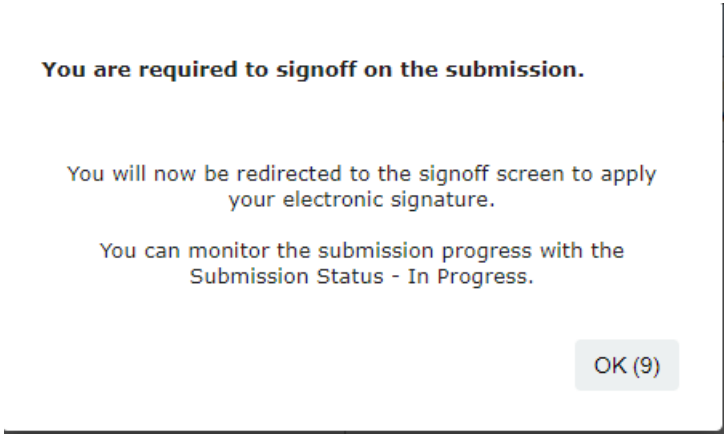


- Return to Table of Contents

The submission has now been sent for signatures!
Now you must wait for the submission to be signed and for the IRB to review.

Upon finalizing the routing and sending the submission for signoff, you will receive a pop-up message which displays the following:

If you are the PI and have routed the submission for signoff, you will receive a pop-up message which displays the following:



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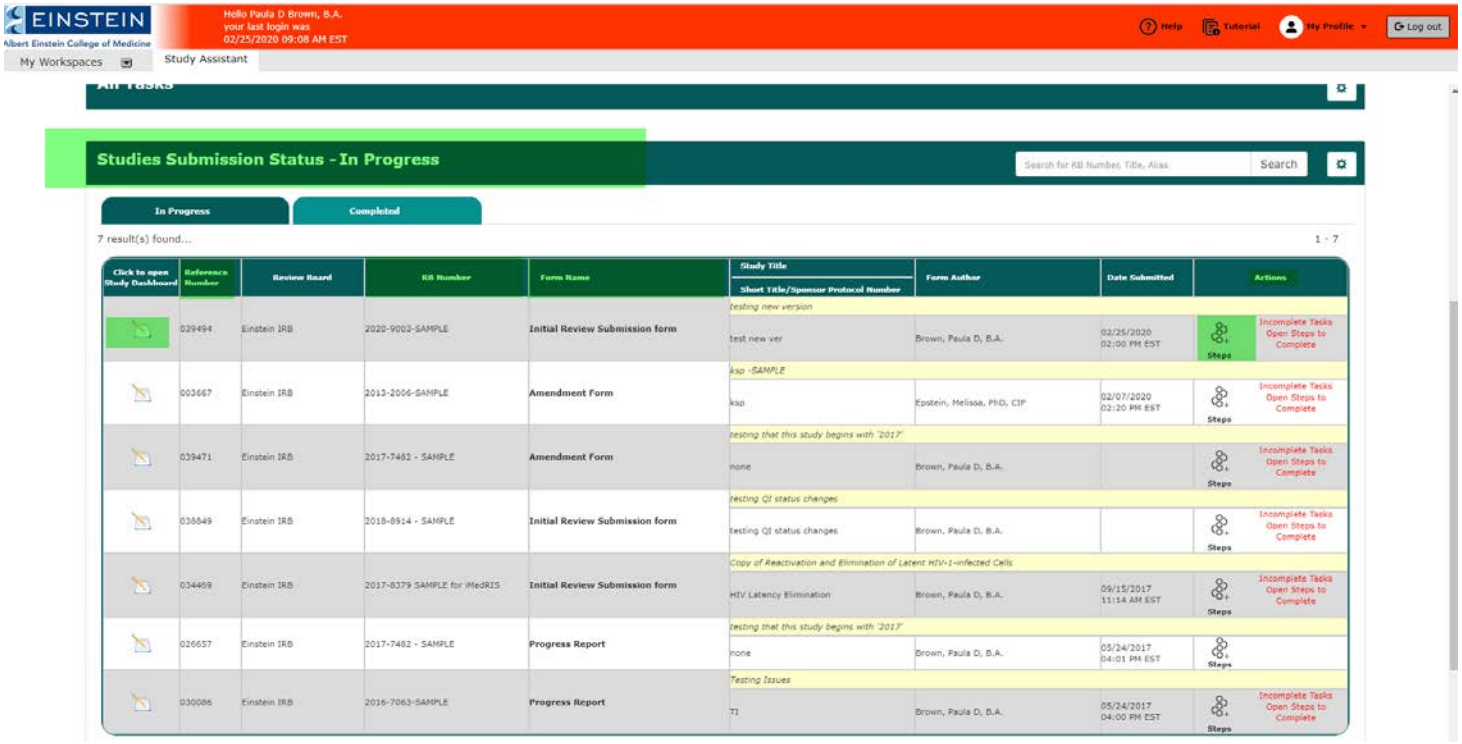
How to View Submission Status

- Once you've submitted for signoff you are automatically re-directed to your iRIS homepage.

- To view the status, go to the "Studies Submission Status – In Progress" Panel:
  - Option 1: Click the notepad icon to open the entire study
    - I. Under track location click the magnifying glass icon.
    - II. Click the "+" symbol under "Task Status" next to "Pre-Submission".
    - III. The "Task Status" column tells you whether the task has been received or completed and the "Task Action/Details" tells you the type of task that is pending or has taken place.
  - Option 2: Click "Steps +" under the "Actions" column in the "Studies Submission Status – In Progress" Panel (on your iRIS homepage):
    - I. Click the "+" symbol under "Task Status" next to "Pre-Submission".
    - II. To collapse the history, click "Steps -". You can then choose another submission to view without having to enter a new IRB number.
    - III. The IRB number, submission reference number, and form name are all available via this view.

** iRIS now calculates how long a submission has been at each step. This could be useful to determine why a submission has not yet gotten to the IRB for review, and who the submission is with and for how long (if signoffs are still required). The duration is listed under the "Total Time" column.



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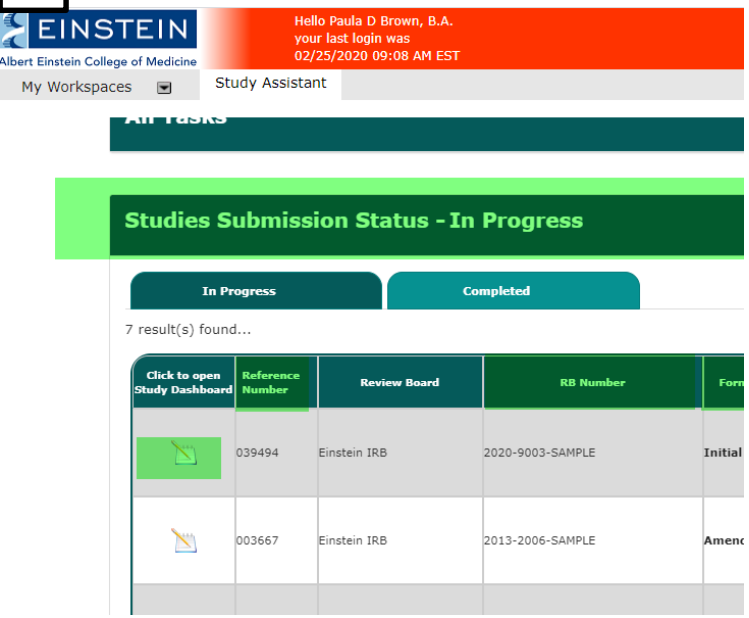
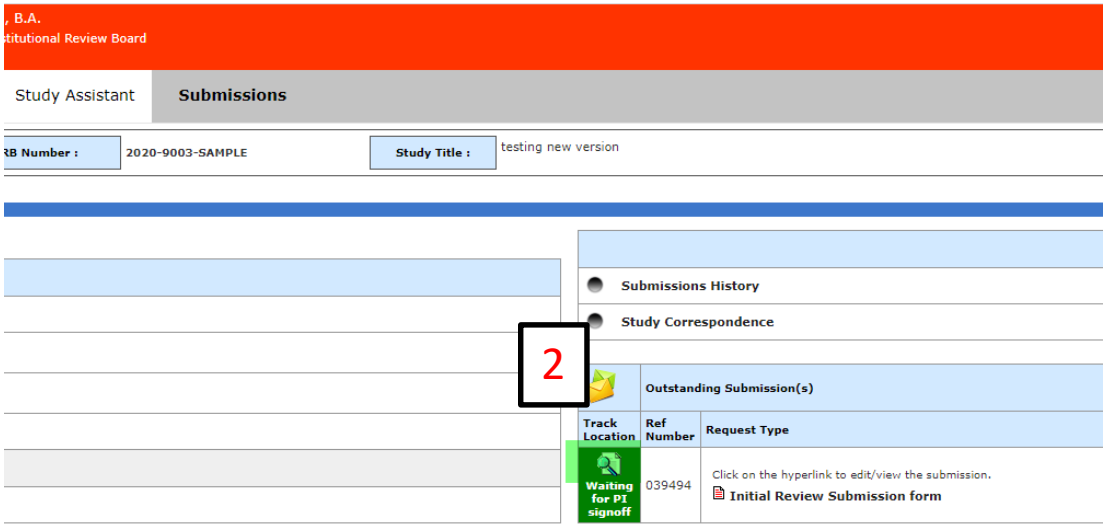
How to View Submission Status – Continued (Option 1 details on slide 44)

1





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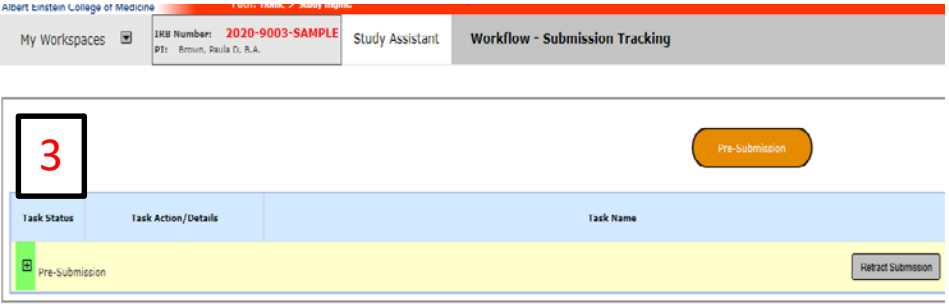
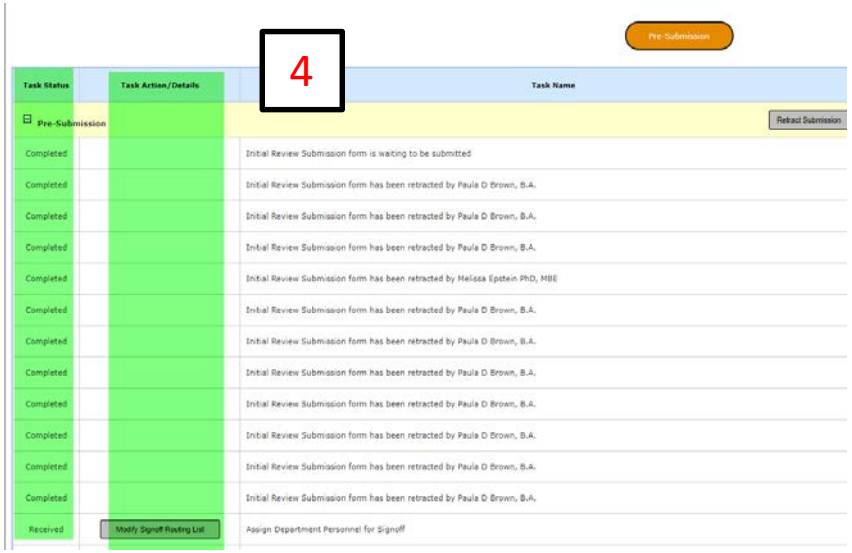


3



4

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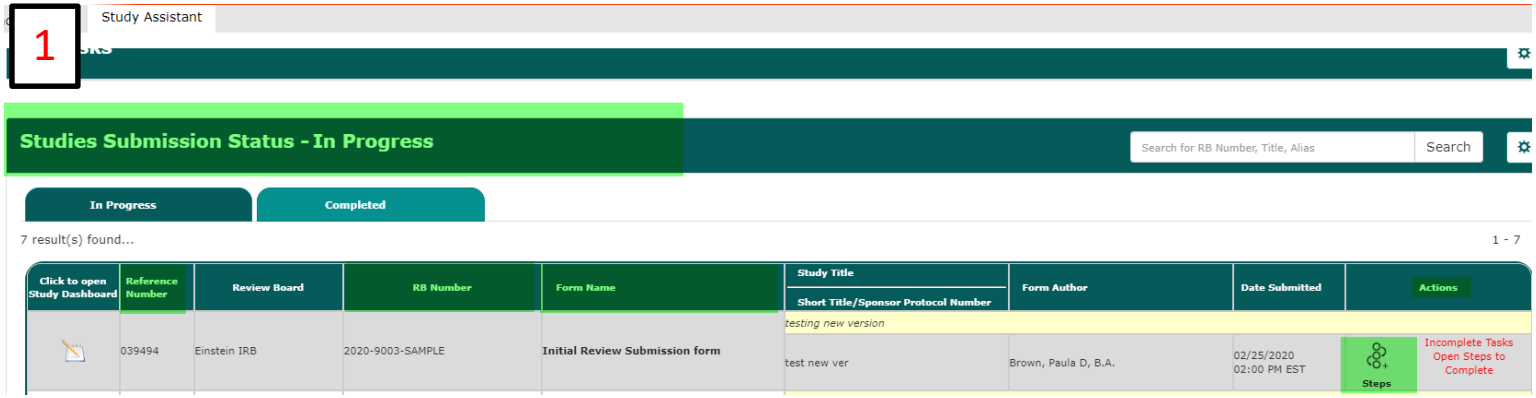
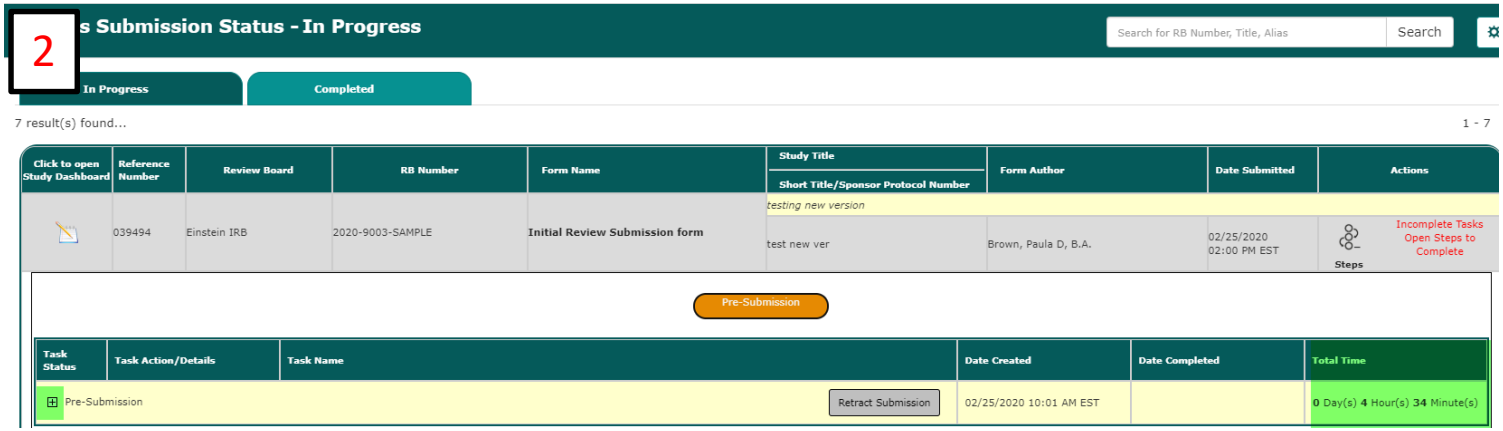
How to View Submission Status – Continued (Option 2 details on slide 44)

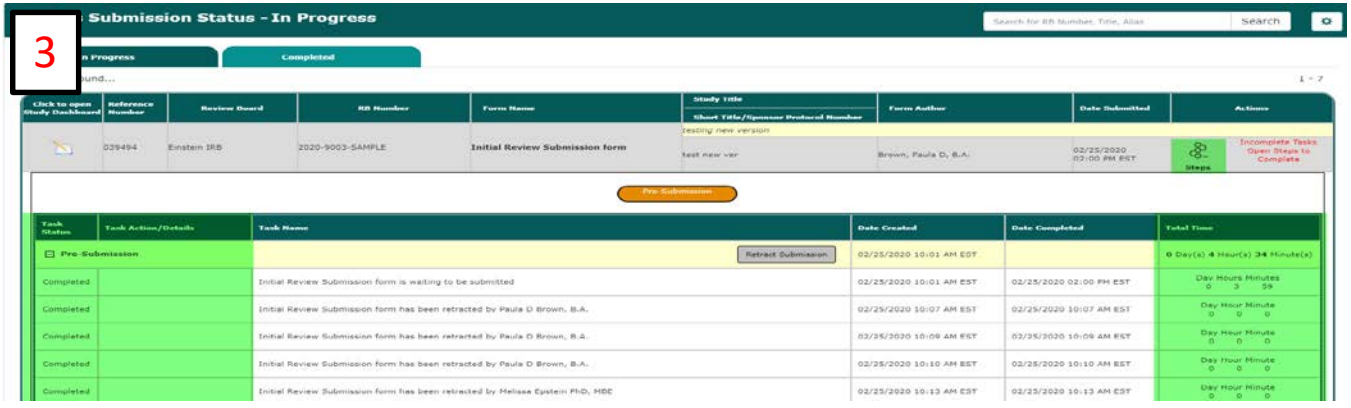
1



2



3



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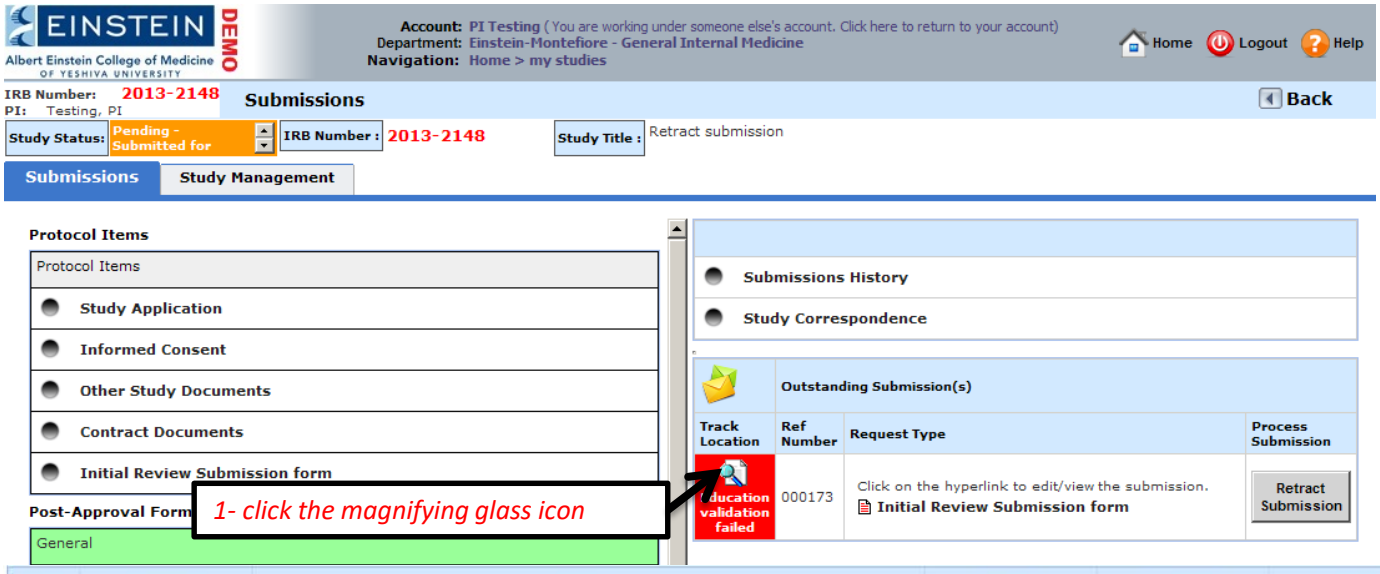
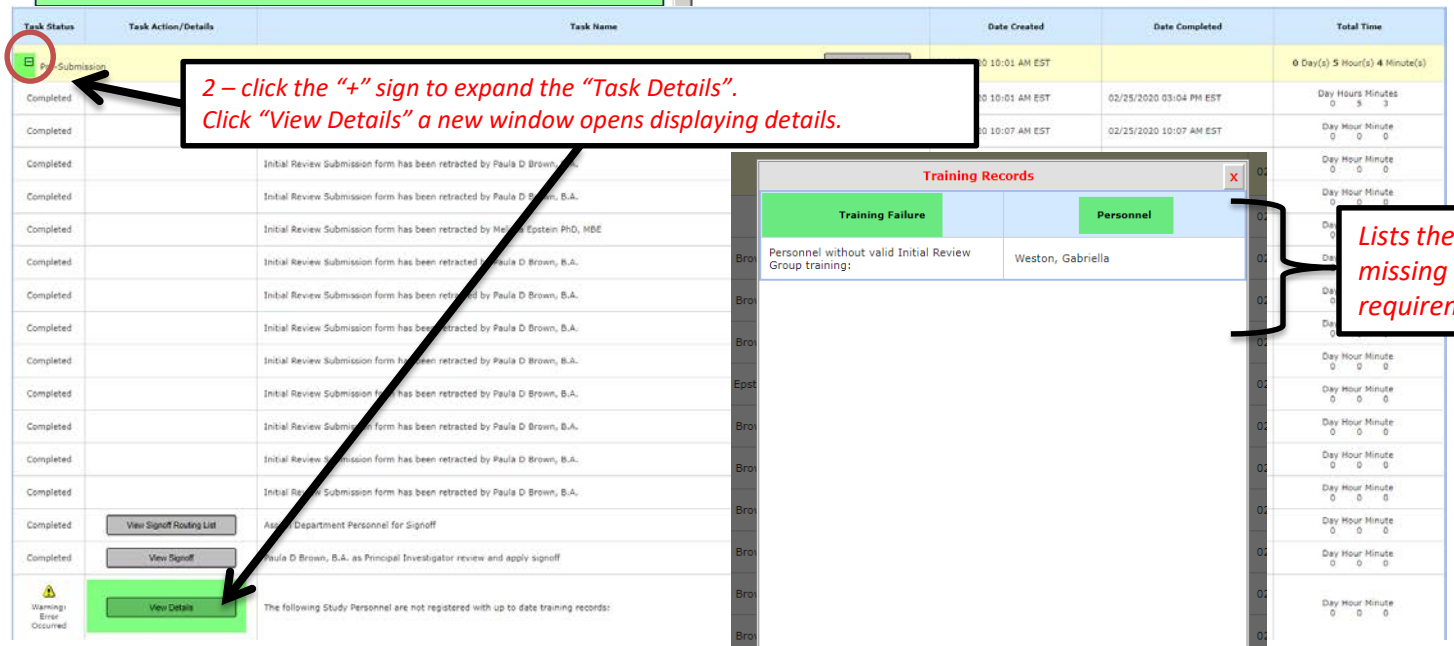
Training Validation Failed - Identifying KSP with missing education requirements





Lists the personnel that are missing education requirements.

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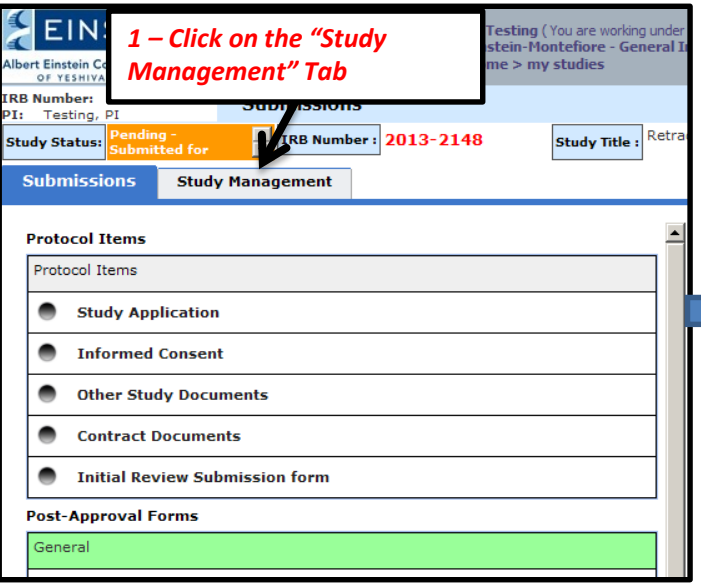
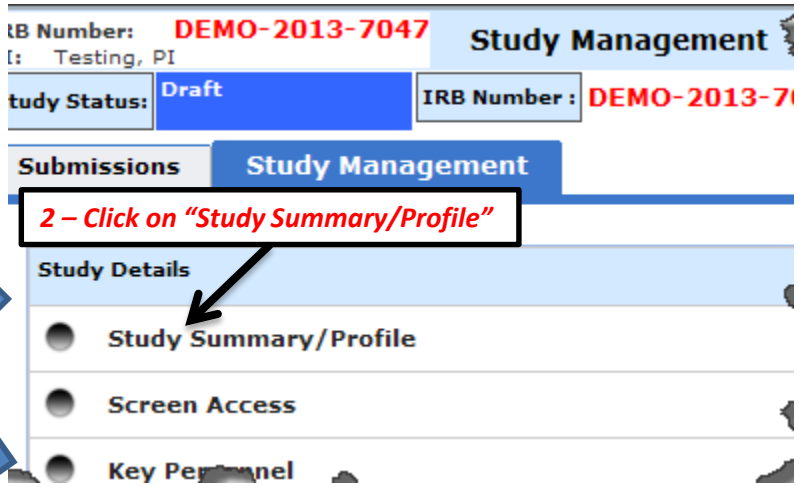
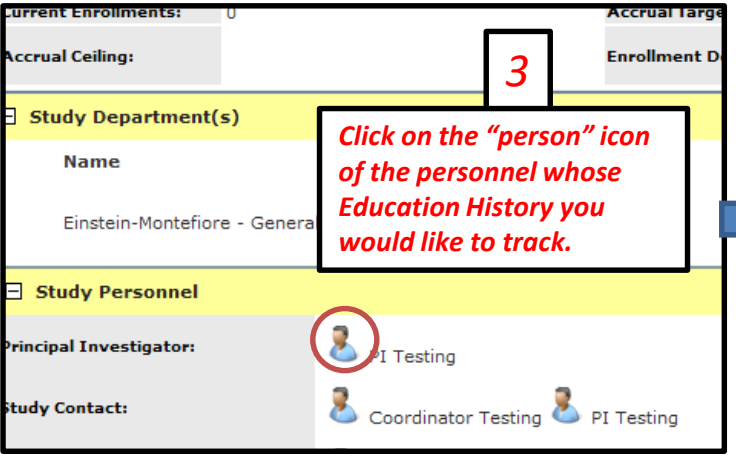
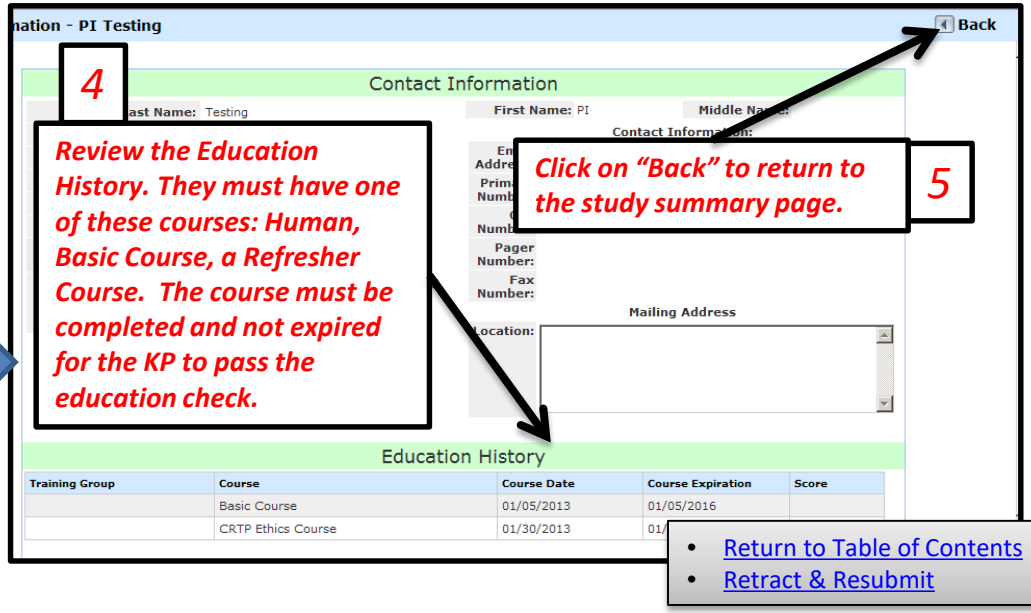
Checking the education status for all KP



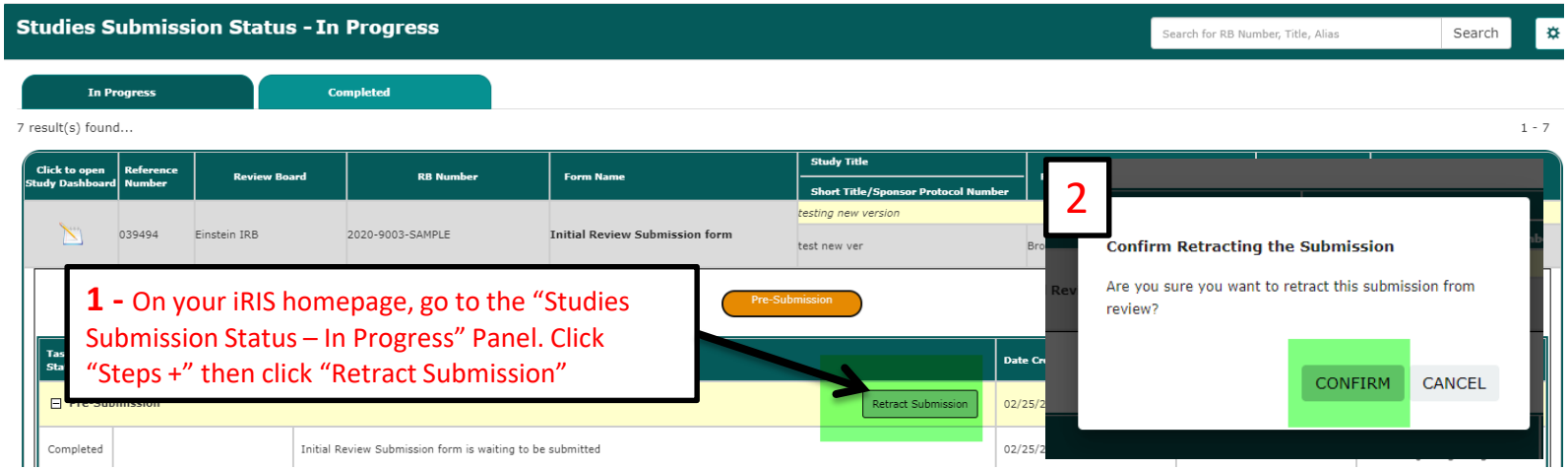


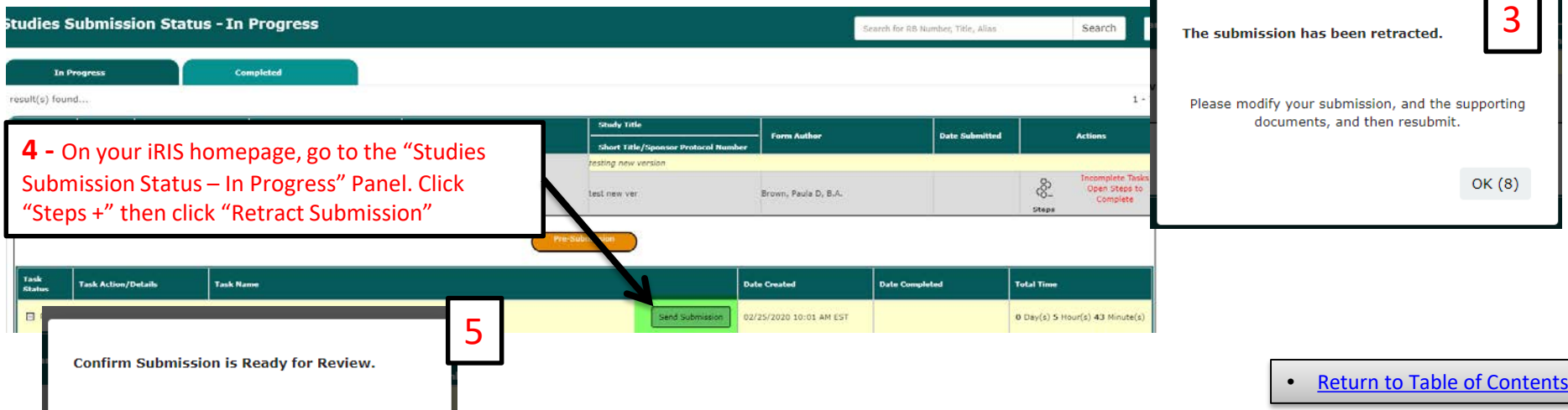




Retracting & Resubmitting the Study to Clear Education Validation

Once ALL KP have completed their required training and checked their status on iRIS, the submission must be retracted and resubmitted. Note that CITI information is automatically updated in iRIS overnight, so it may take up to 24 hours for the update to occur.





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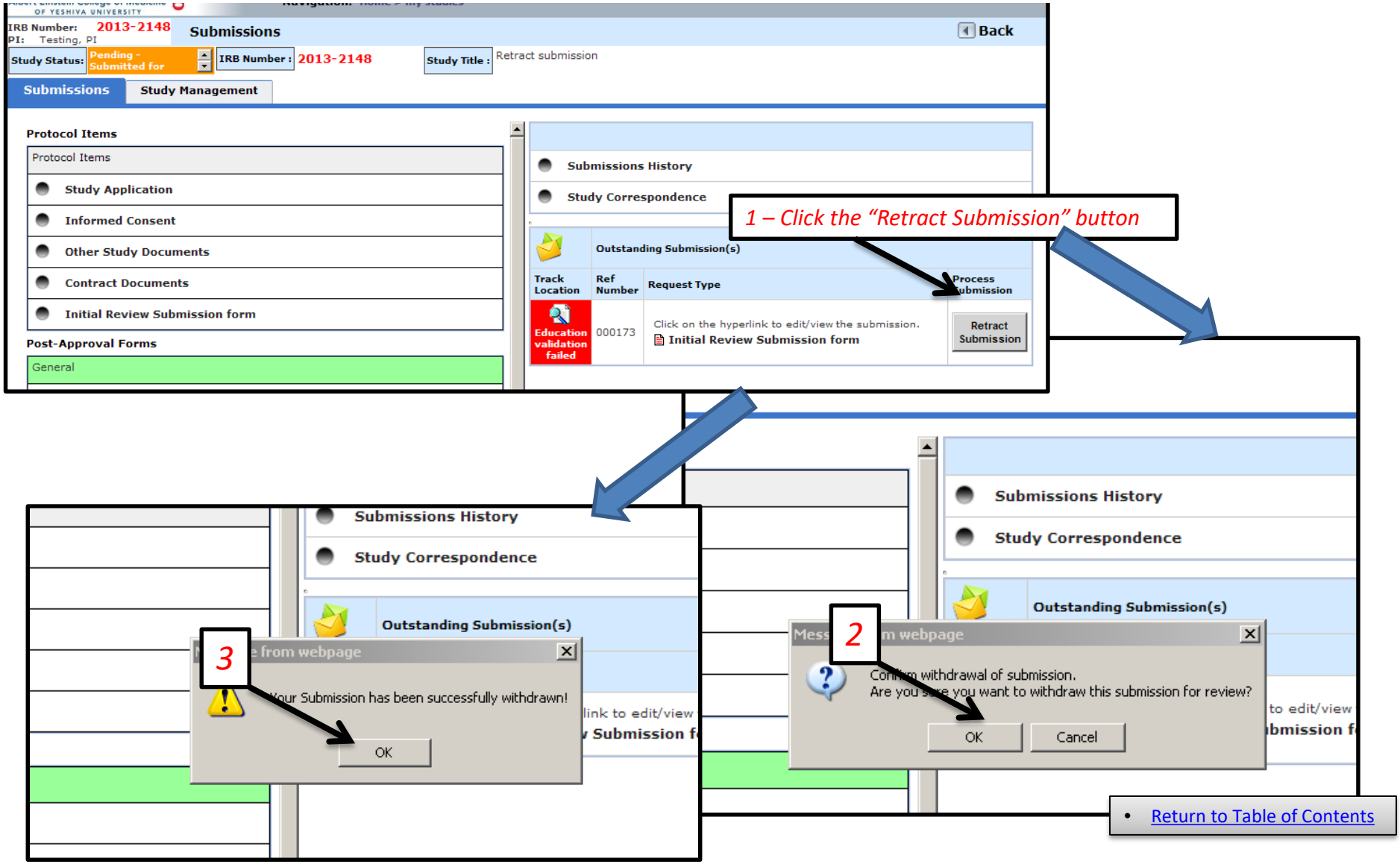
Retracting the study when you have opted to open the entire study either via the “All Studies” panel or the Studies Submission Status – In Progress” panel .



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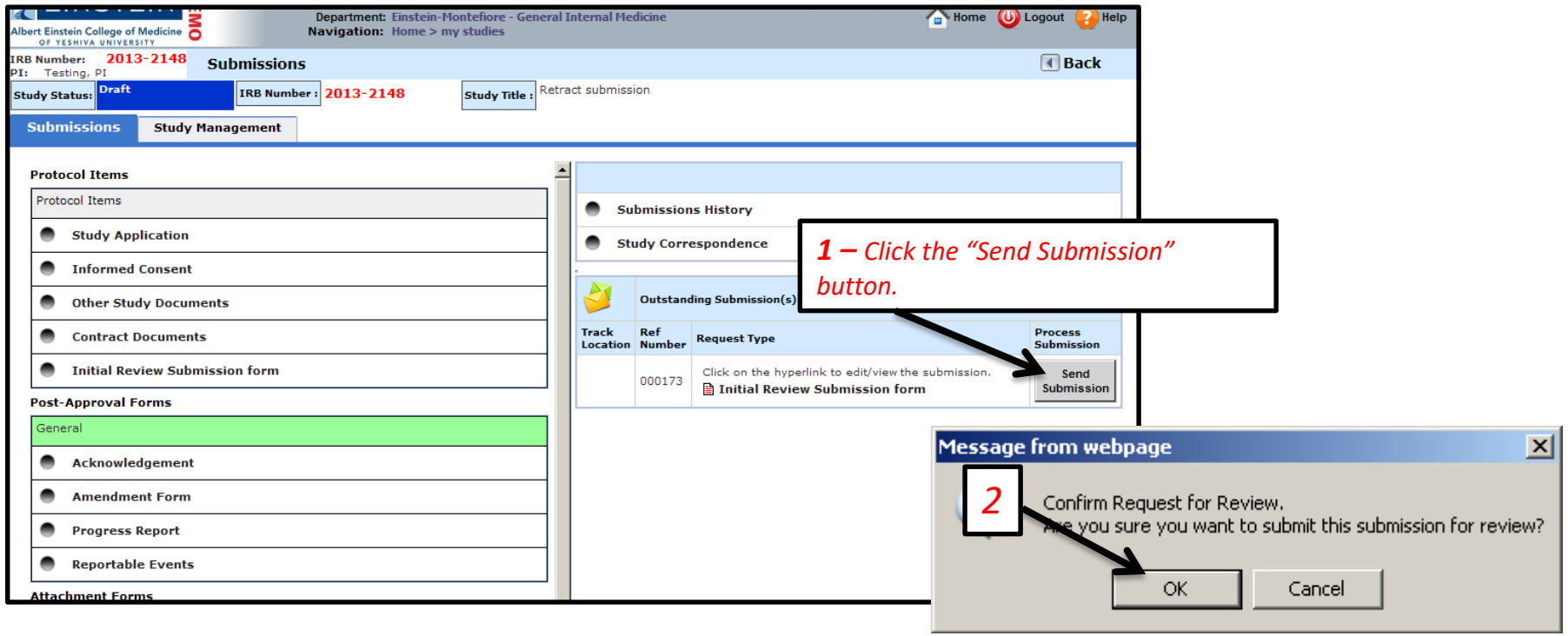
Resubmitting the study



3 - *Signatures must be re-assigned (follow instructions in slides 40-42).*

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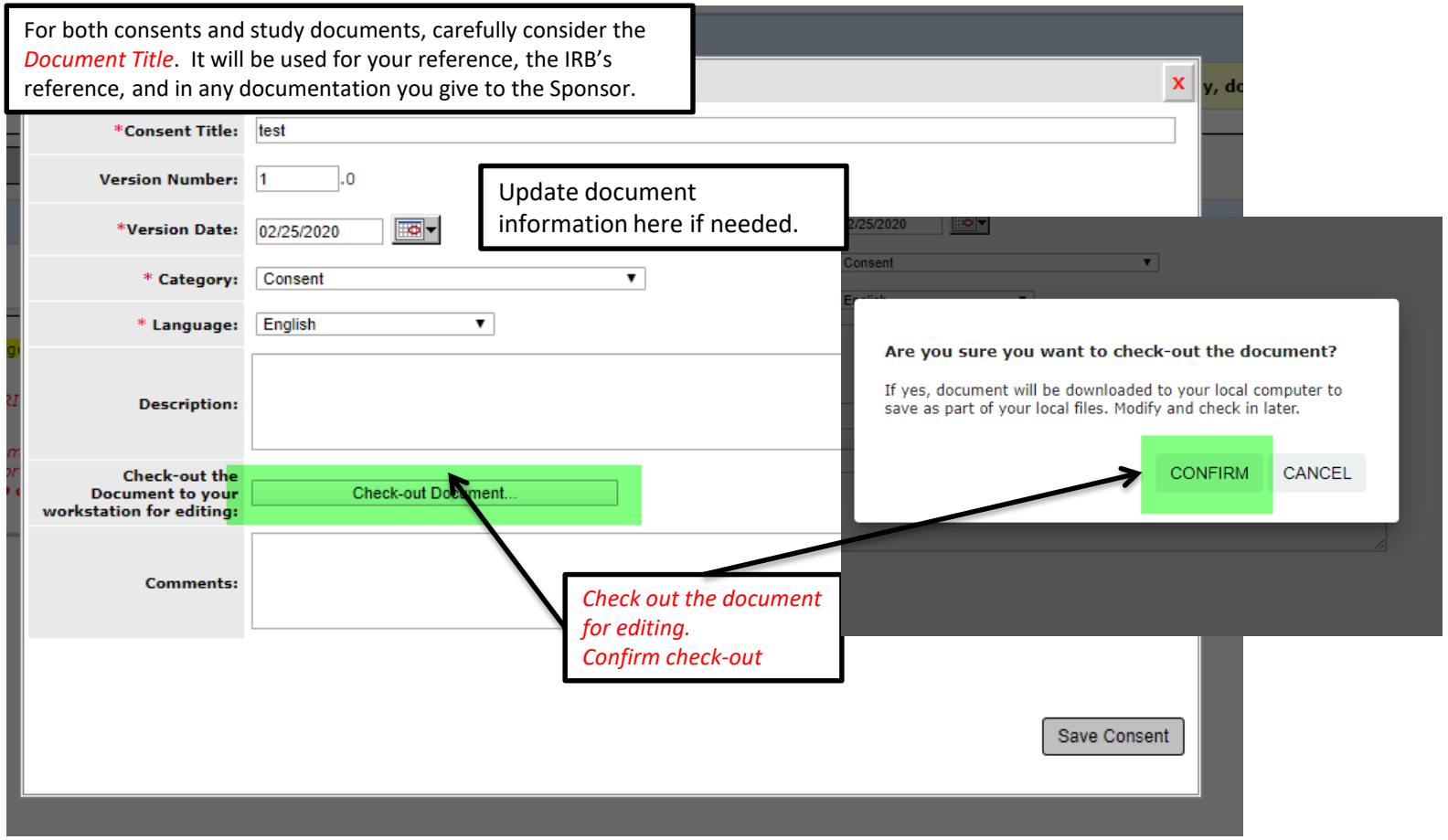
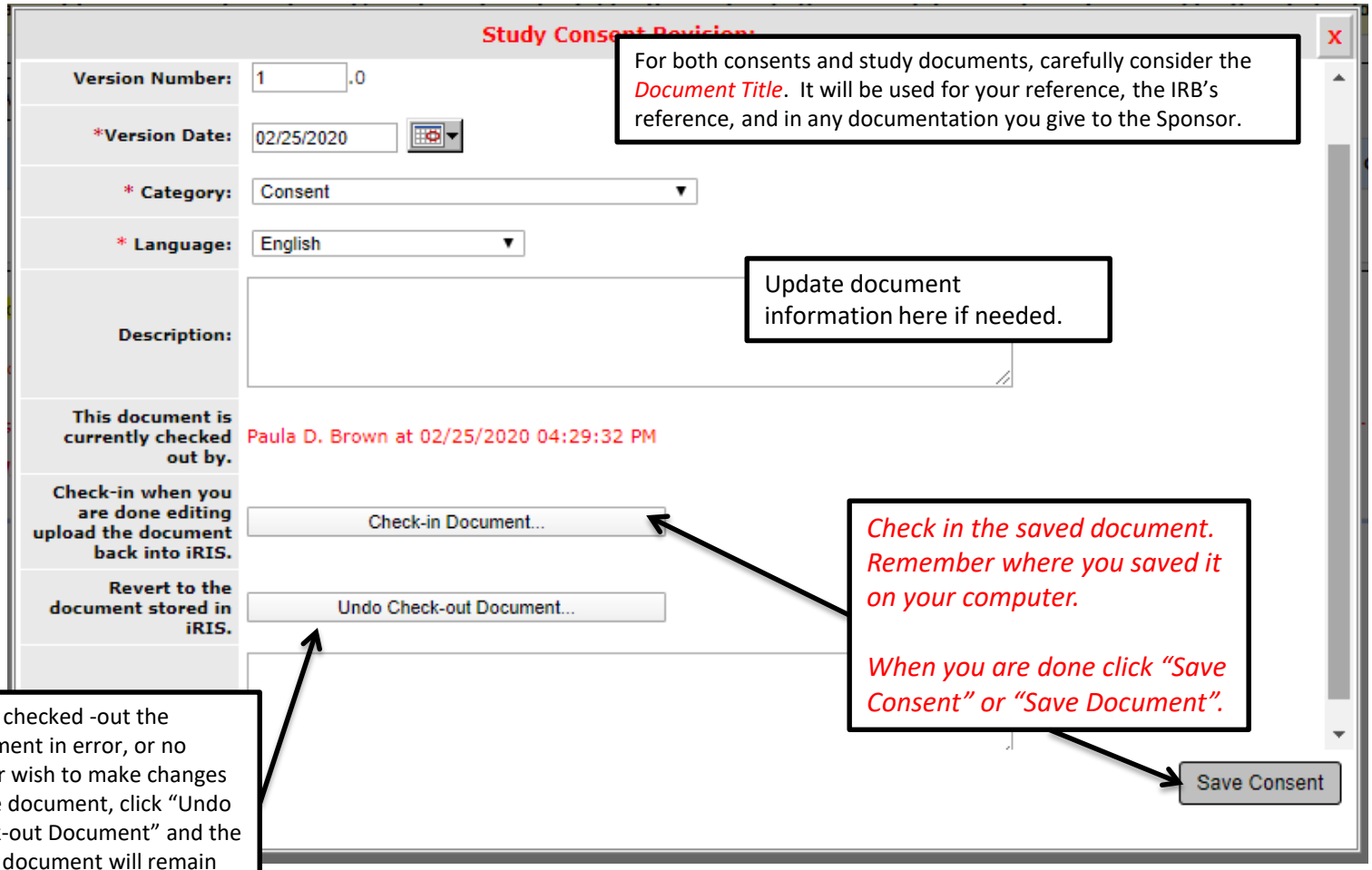
How to check out a document for editing



- Return to Table of Contents
- Return to Frequently Asked Questions

How to “check-in” a document after editing OR Undo the “check-out”



For both consents and study documents, carefully consider the *Document Title*. It will be used for your reference, the IRB’s reference, and in any documentation you give to the Sponsor.

Update document information here if needed.

Check in the saved document. Remember where you saved it on your computer.

When you are done click “Save Consent” or “Save Document”.

If you checked -out the document in error, or no longer wish to make changes to the document, click “Undo Check-out Document” and the initial document will remain attached.

- Return to Table of Contents
- Return to Frequently Asked Questions