User Guide: *How to Submit a New Application in PRIS3M*

Purpose: To provide the user with step-by-step instructions on how to complete/submit a new protocol application.

Last Update: February 2025

Important steps prior to application:

- ❑Refer to **User Guide: *Getting Started and Navigating the Study Assistant Dashboard in PRIS3M*** before continuing.
- ❑Any user creating a New Application **must** be selected as the Principal Investigator (PI) or be added as a team member in Section 3 of application.
- ❑Team members must log into PRIS3M one time to create their account before they can be added to studies. If you can't find someone's name when adding team members, have that person log in with their Carilion credentials.

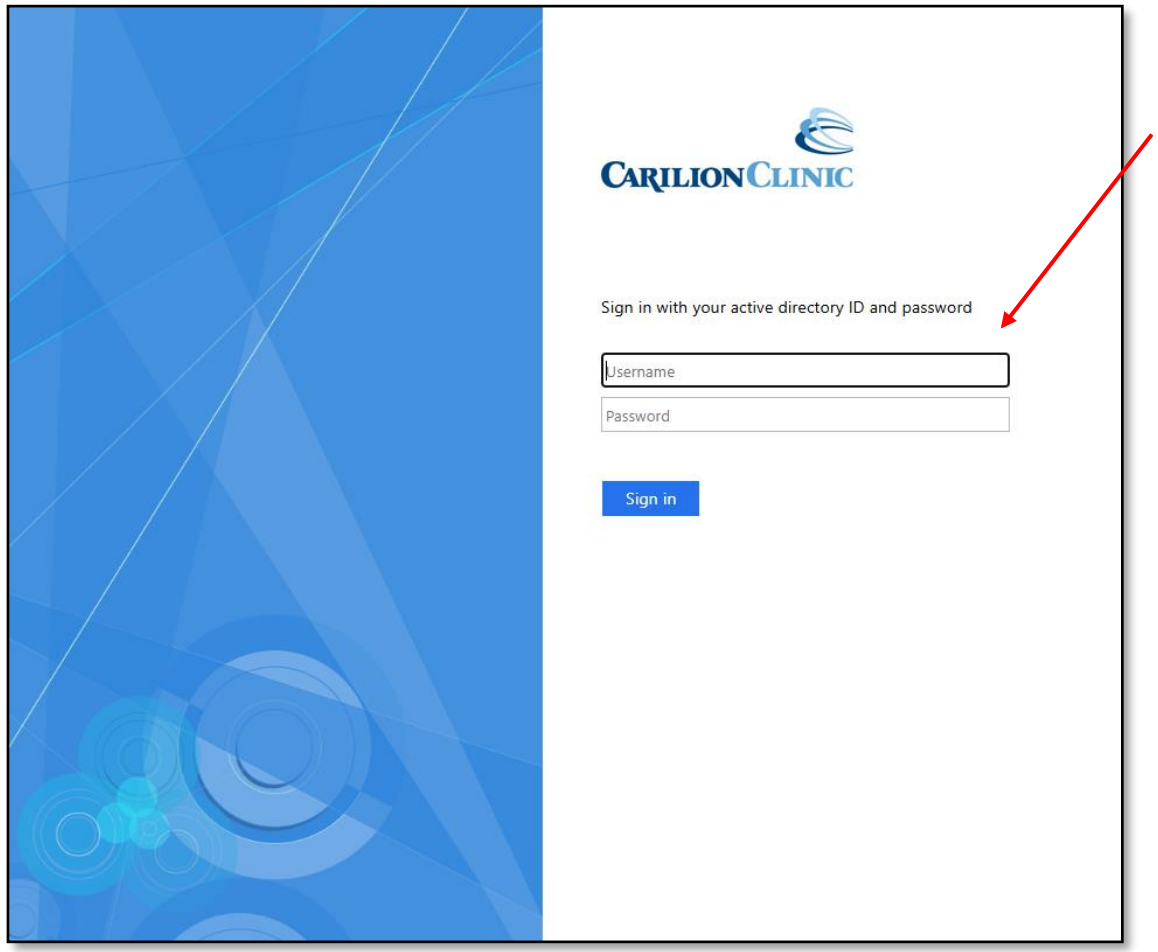
Carilion Clinic **PRIS3M**: Partnership in Research Integrity and Subject Safety Submission Module

For the best experience, use one of the following **recommended browsers**:

Platform	Browser
Microsoft Windows (in recommended order)	Chrome, Firefox, or Edge
Apple Mac	Chrome, or Firefox

Allow pop-ups for this site: Certain actions within the PRIS3M application will not function if the pop-up blocker is enabled.

Navigate to https://carilionclinic.imedris.net/



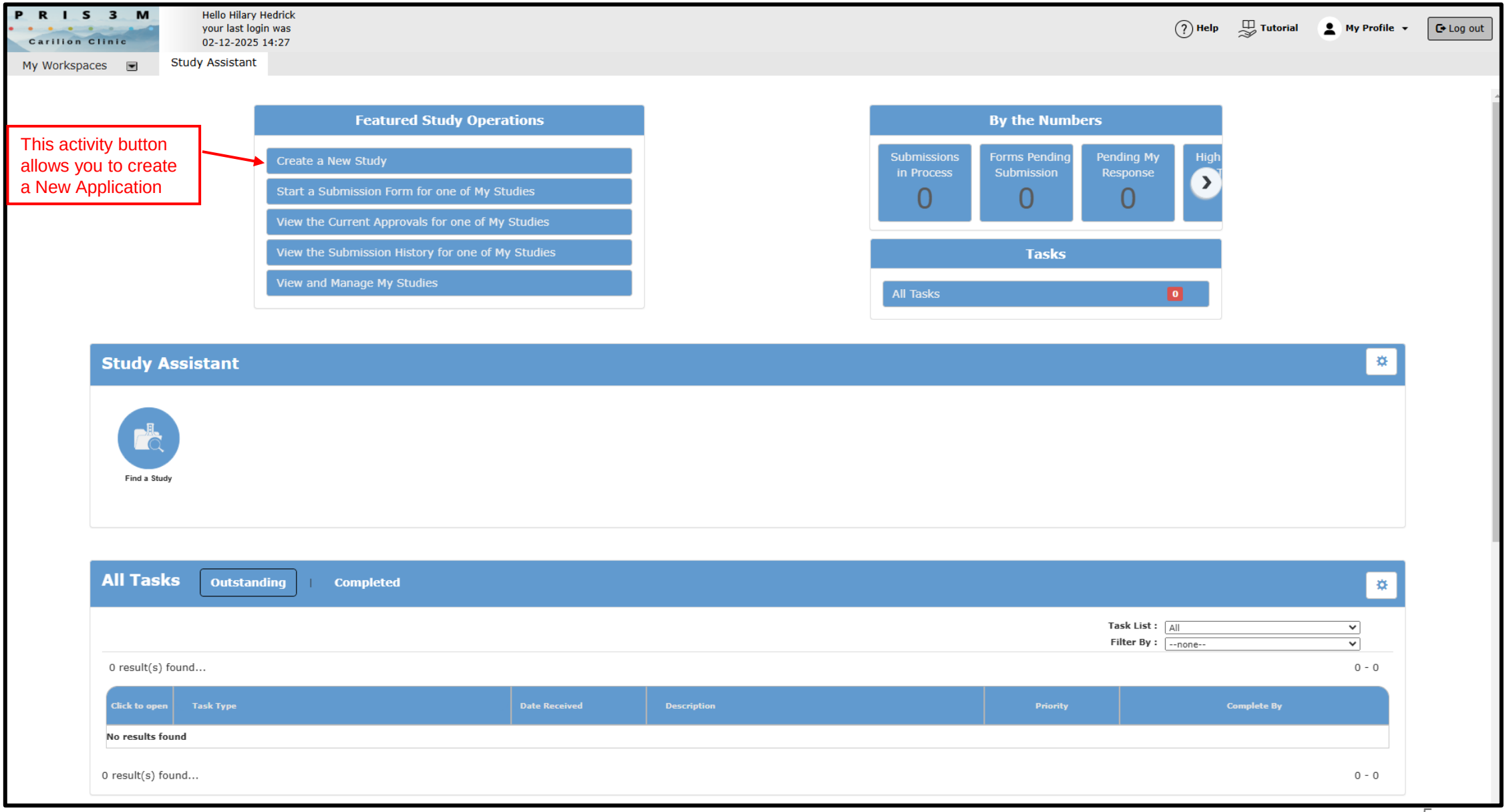
Enter your **Carilion Clinic ID** and **password** to access the PRIS3M system.

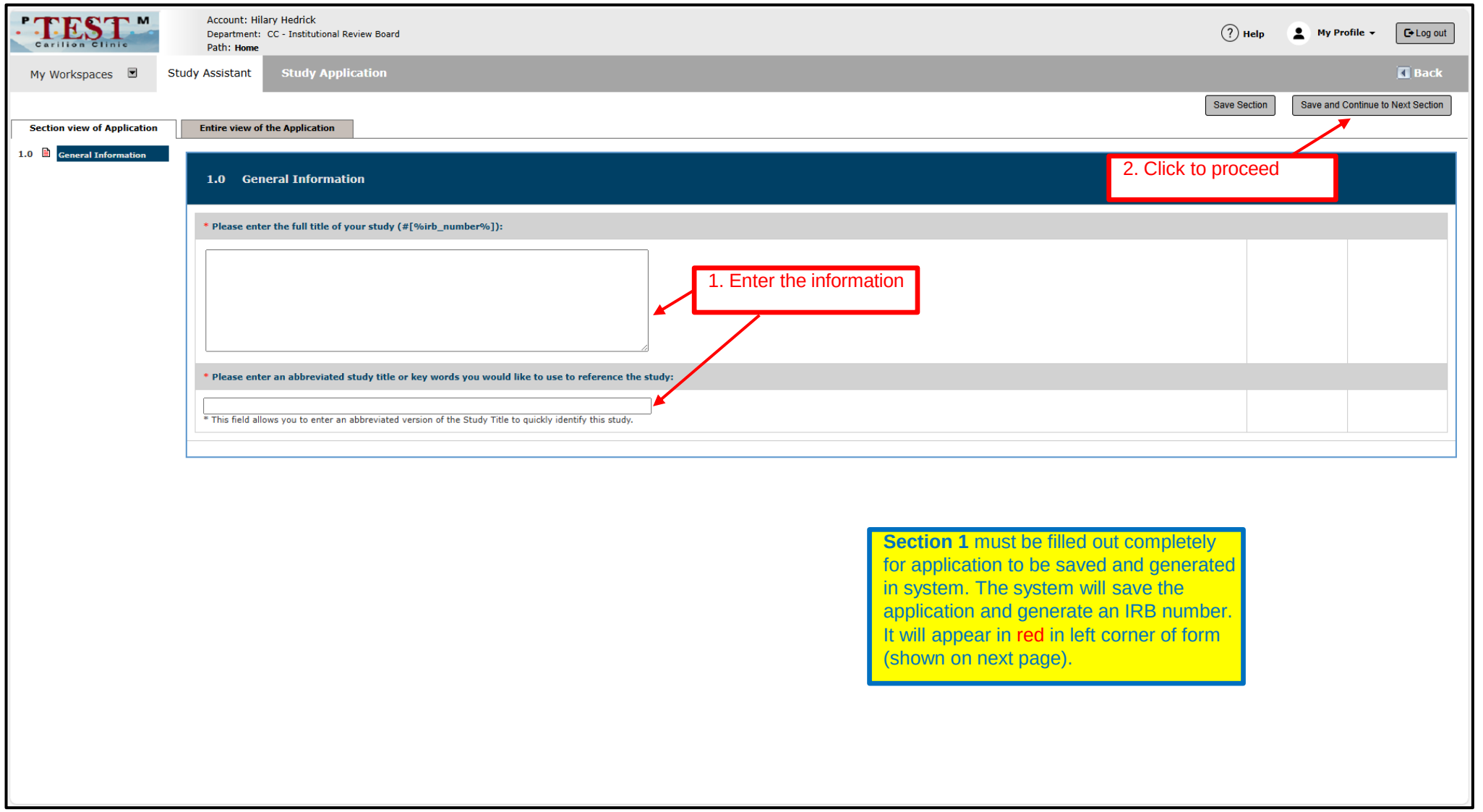
Troubleshooting: If you cannot login due to incorrect credentials or missing access: Review USER GUIDE-Getting Access to PRIS3M.

If you are still unable to log in:

- Contact the IRB office directly at irb@carilionclinic.org
- Submit Help ticket at https://is.gd/PRIS3M_IRB_Help_Form

Study Assistant Dashboard

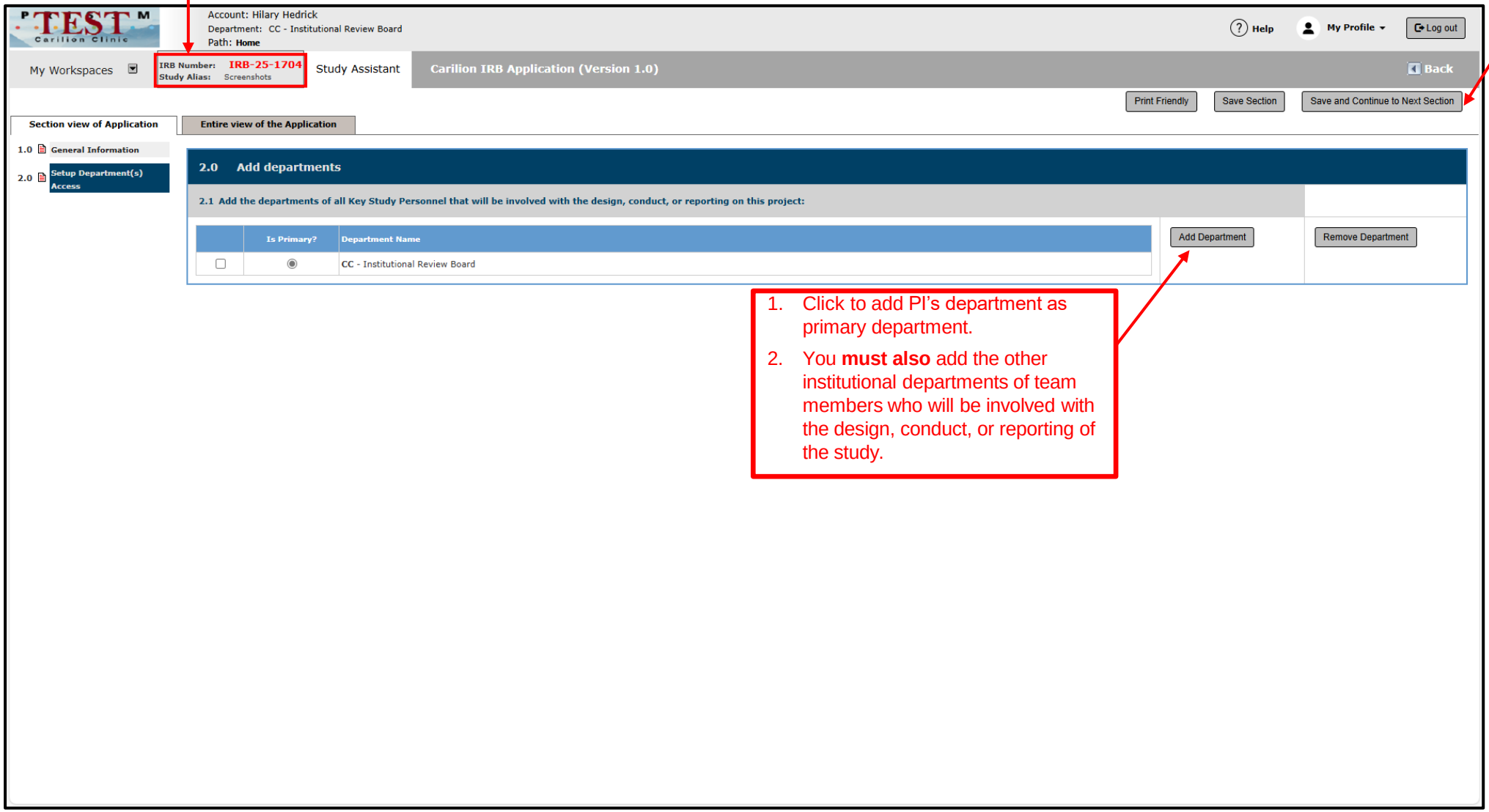




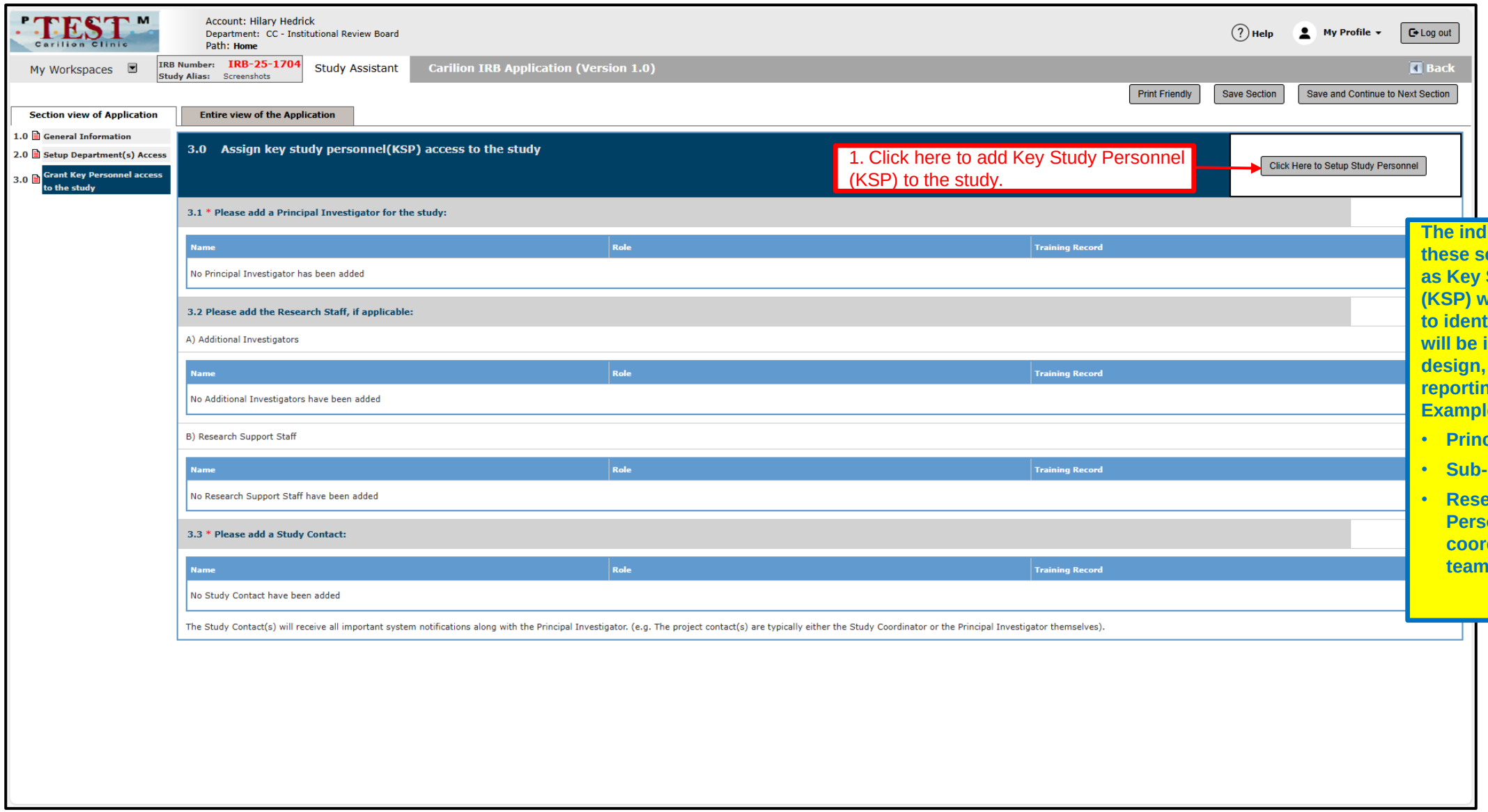
Section 1 must be filled out completely for application to be saved and generated in system. The system will save the application and generate an IRB number. It will appear in red in left corner of form (shown on next page).

IRB number has now been generated

3. Click to proceed after adding departments



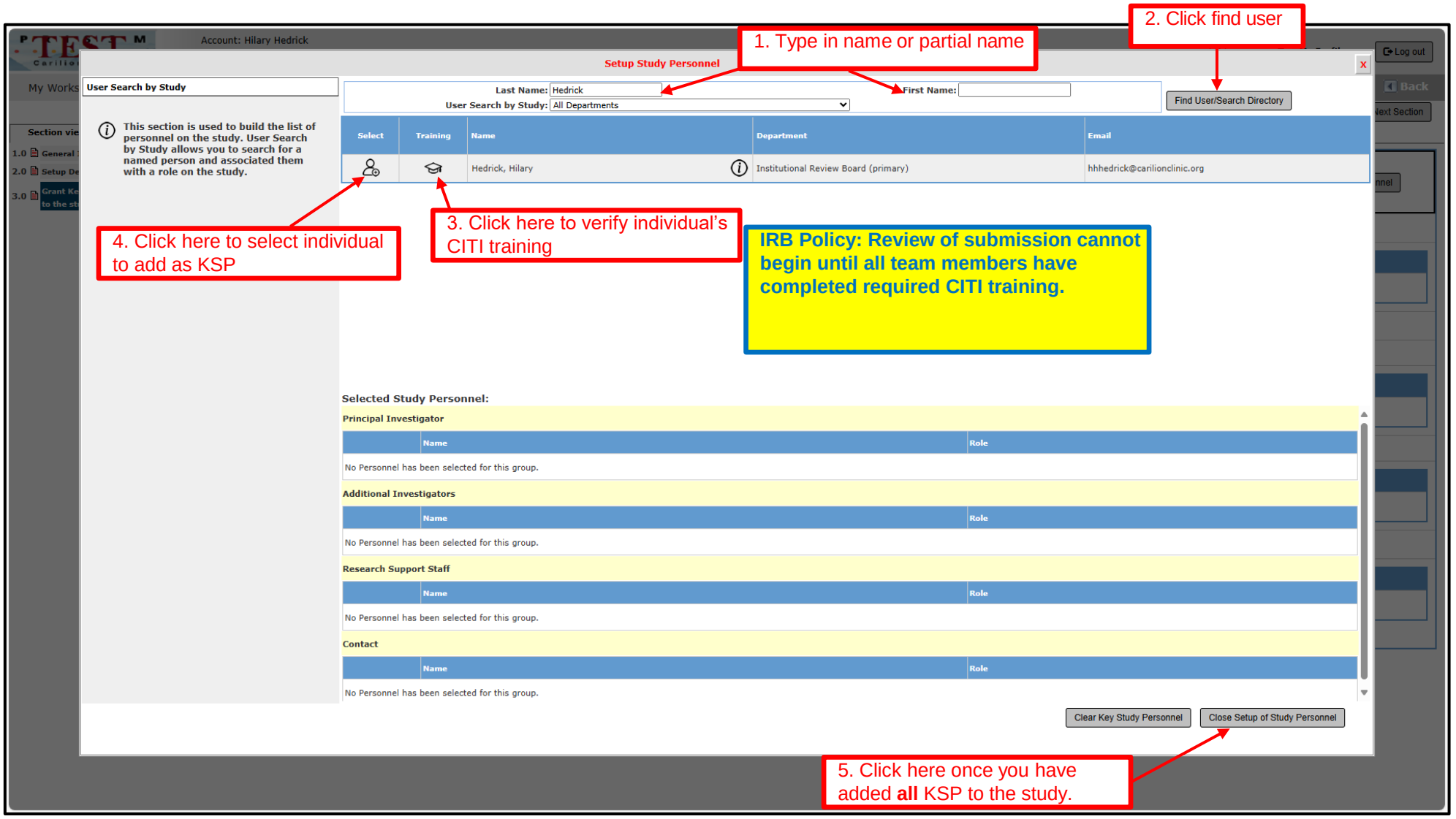
1. Click to add PI's department as primary department.
2. You **must also** add the other institutional departments of team members who will be involved with the design, conduct, or reporting of the study.



The individuals added in these sections are defined as Key Study Personnel (KSP) who will have access to identifiable data and who will be involved with the design, conduct, or reporting of the study. Examples include:

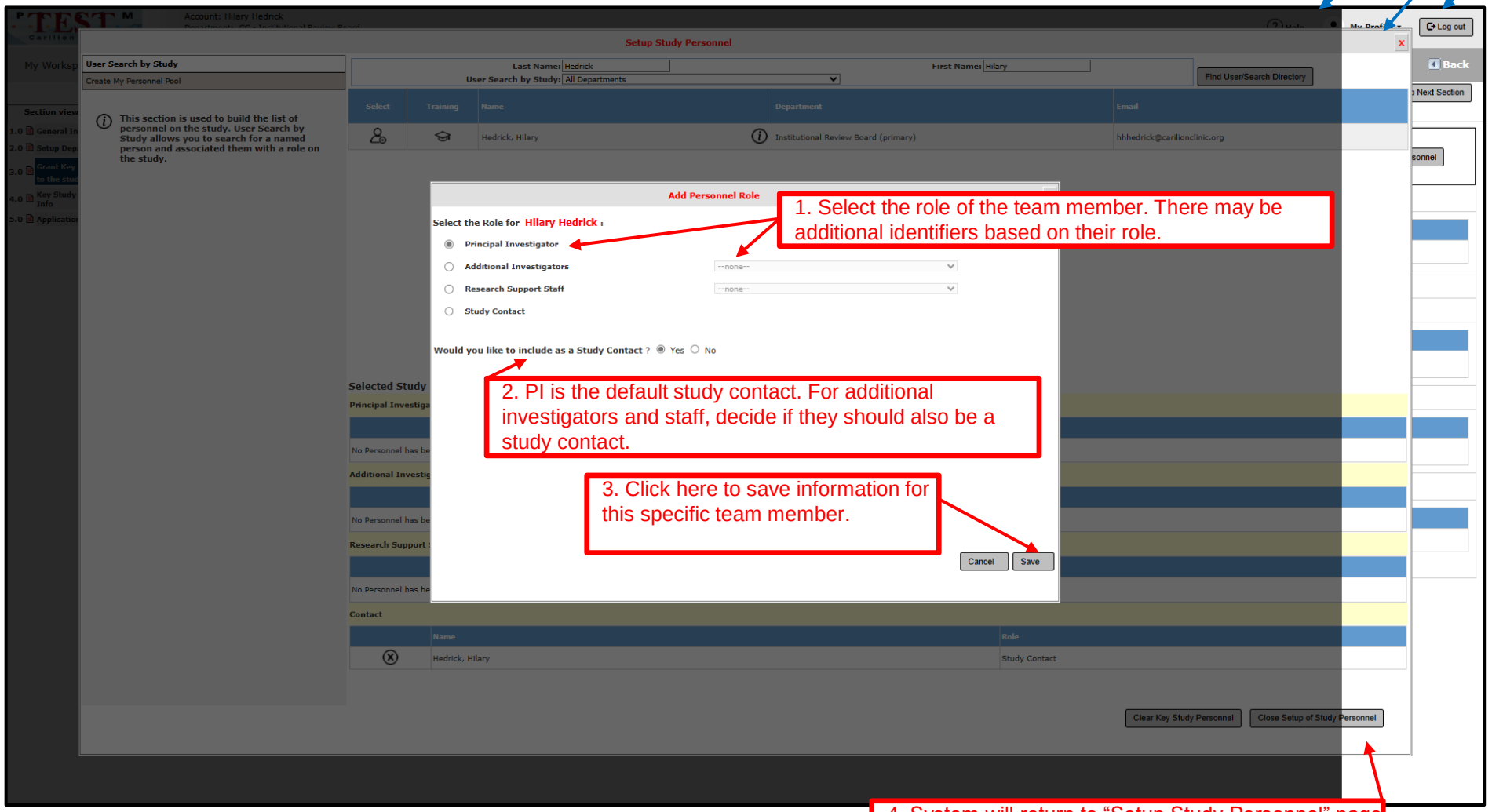
- **Principal Investigator**
- **Sub-Investigators**
- **Research Staff Personnel (research coordinator and other team members)**

This screen will pop up to manually enter KSP. You must complete this process for each member of the study team.



This pop-up window will cue you to select the role for each team member.

Note the different pop-up screens from the application dashboard. The system will automatically do this for KSP.



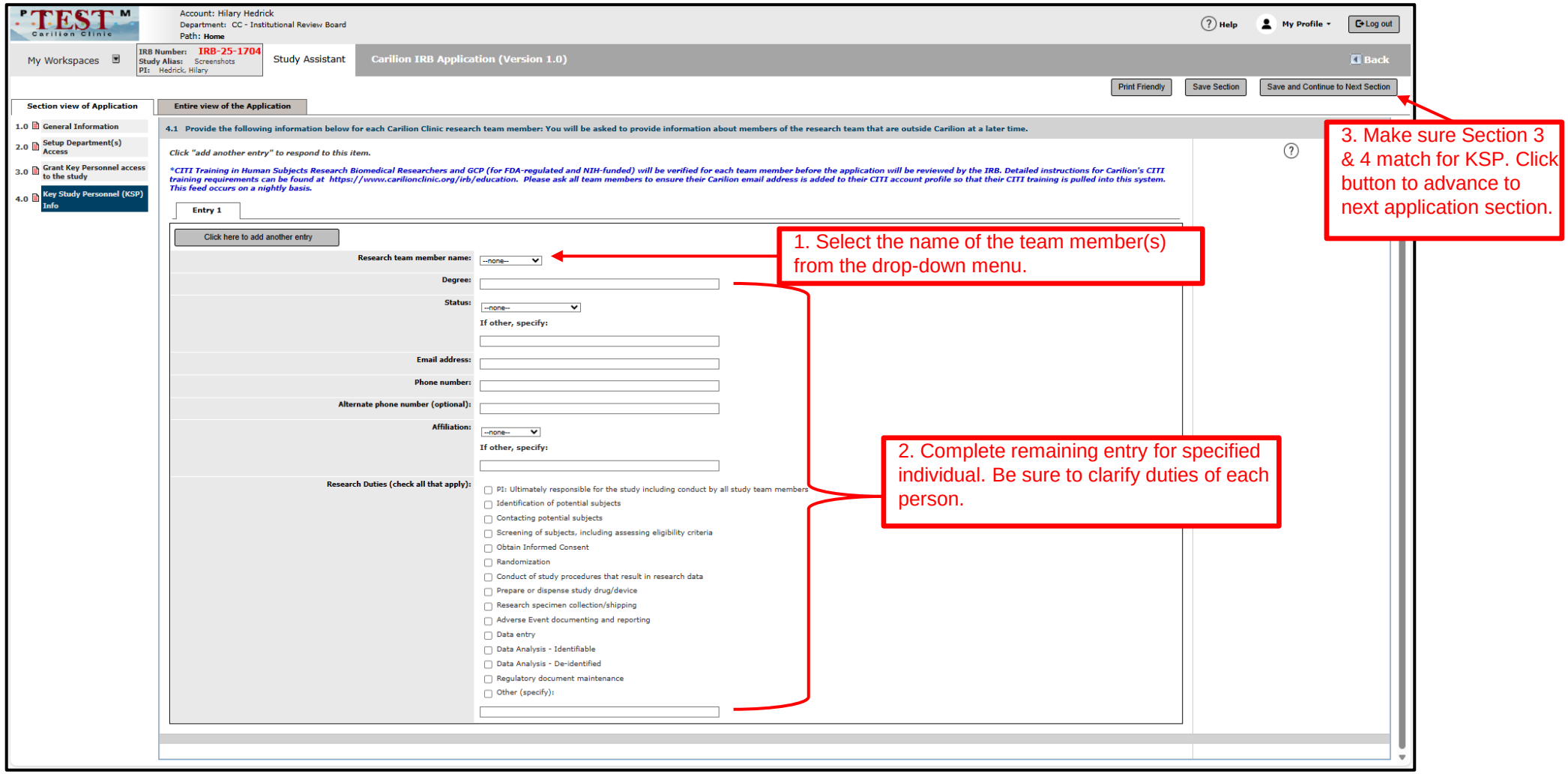
1. Select the role of the team member. There may be additional identifiers based on their role.

2. PI is the default study contact. For additional investigators and staff, decide if they should also be a study contact.

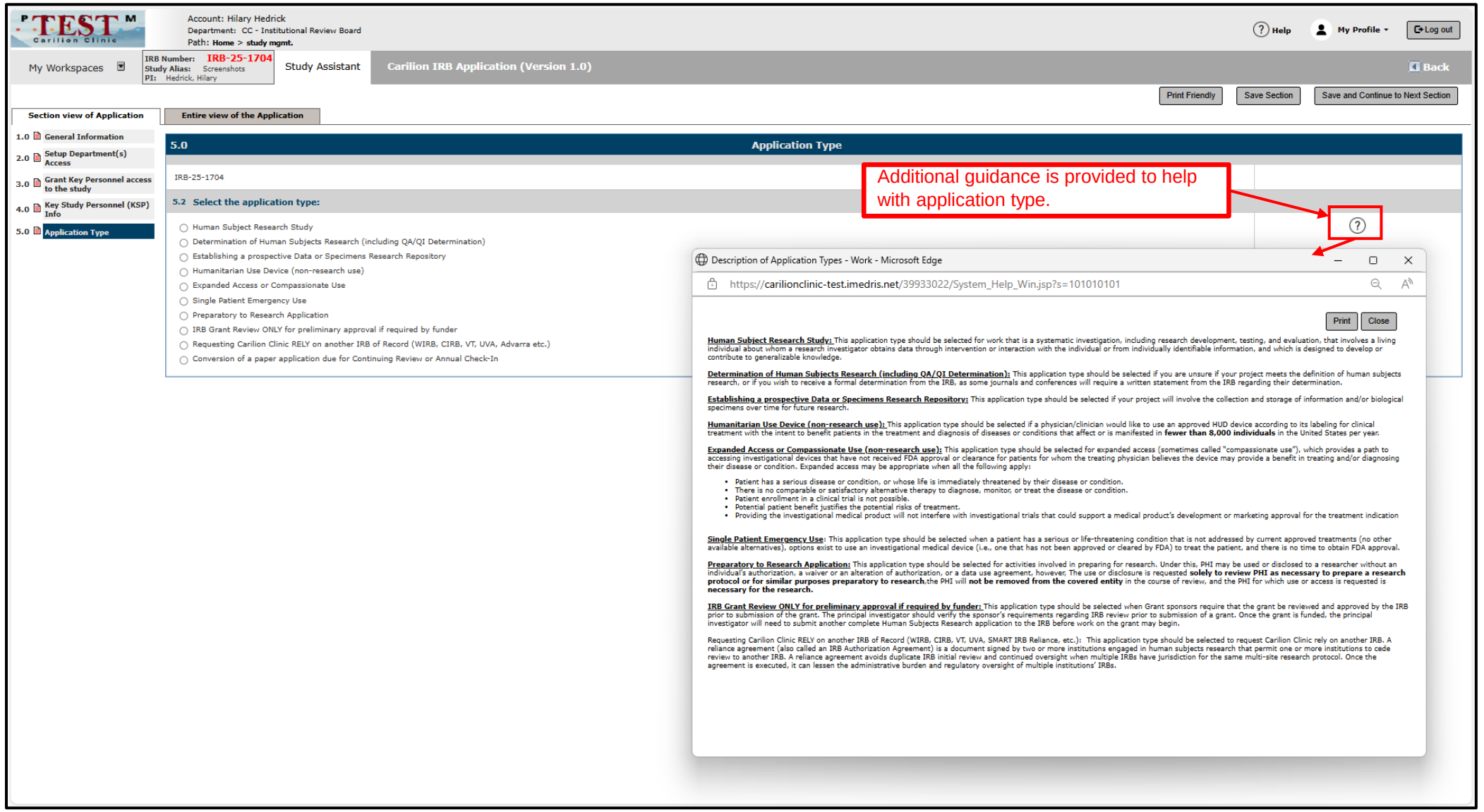
3. Click here to save information for this specific team member.

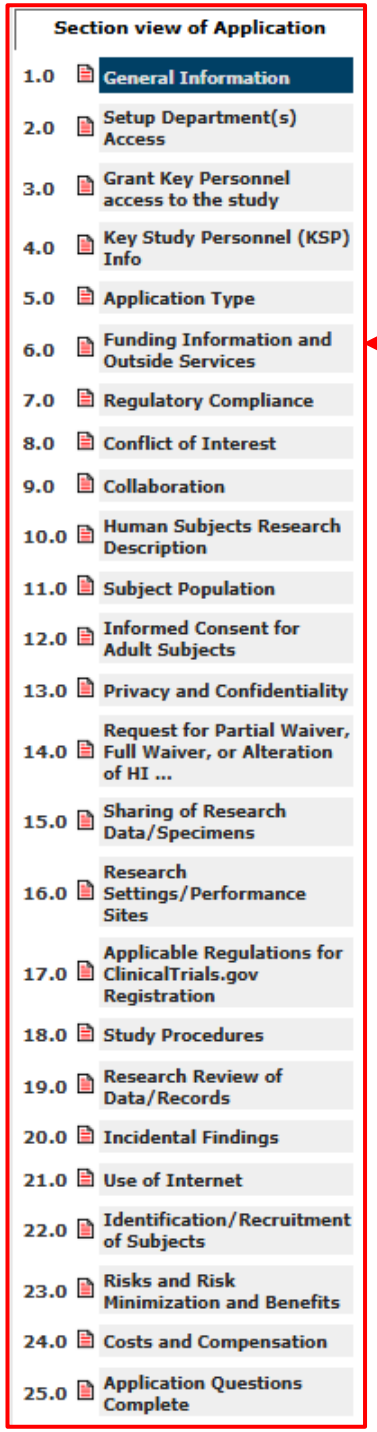
4. System will return to “Setup Study Personnel” page (pg. 9) to enter more team members. Choose “close setup of study personnel” if all are entered.

Section 4—You will complete a new entry for each team member.



Section 5: Identify the type of application for submission.

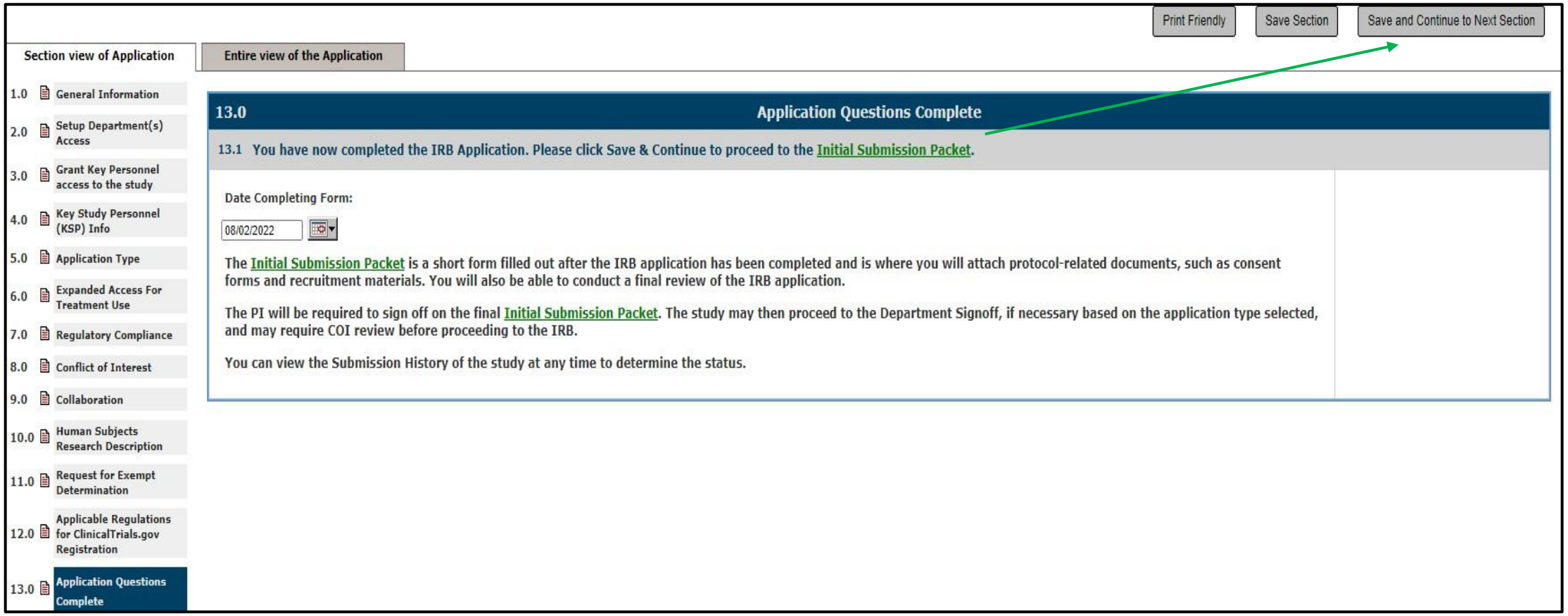




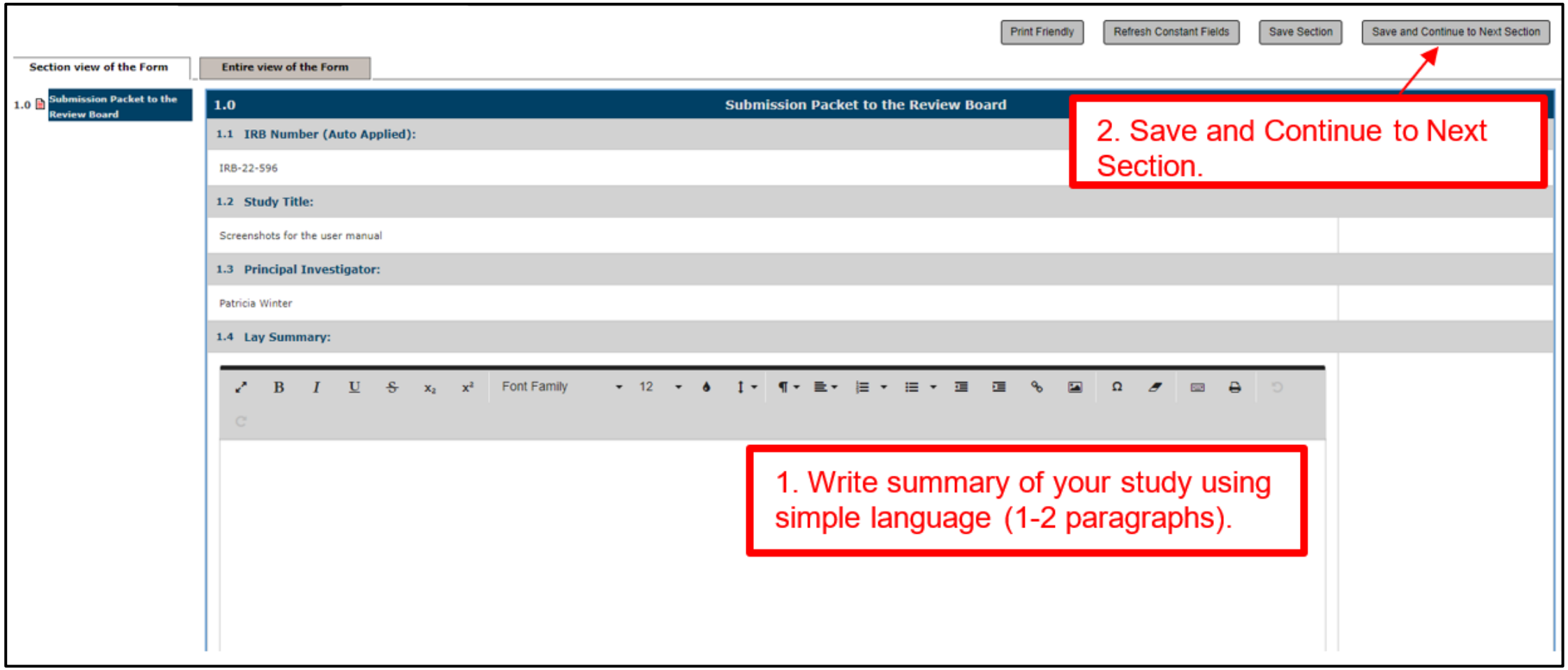
Navigate through & complete application sections

- Depending on the type of application for submission, there are Sections 6-Section 25 [category preview]
- Questions will branch depending on specifics of <u>your</u> study
- “Save Section” allows you to come back and finish section. It is recommended you hit this button frequently.
- “Save and Continue to Next Section” saves the entire form and advances to next section of application.

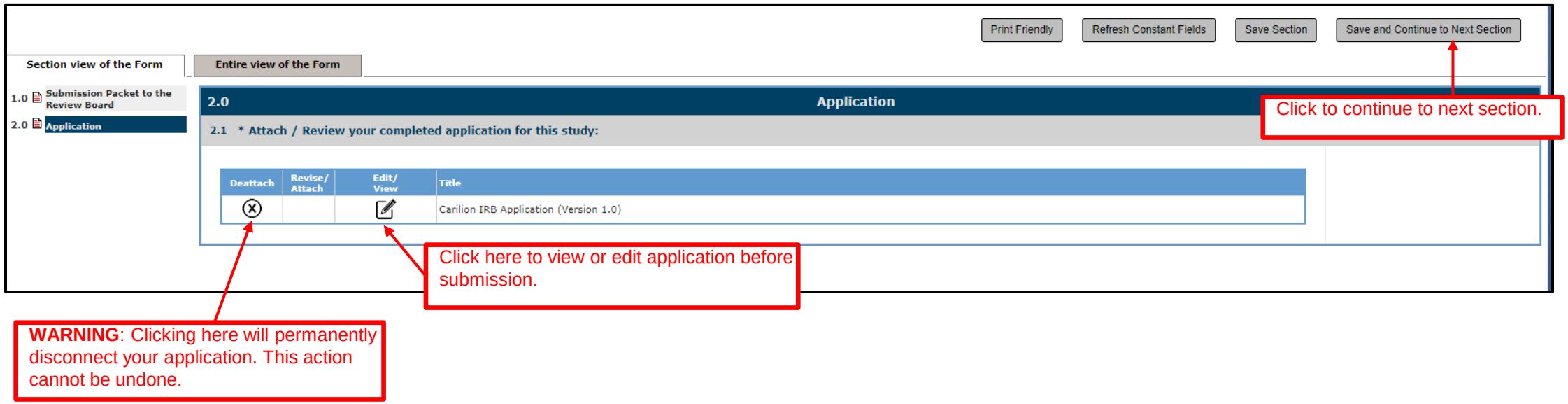
After completing each section of application, click “**Save and Continue to Next Section**” to access the Initial Submission packet. This is where you’ll upload all your study-related documents. The submission packet is like a central storage folder for all study materials.



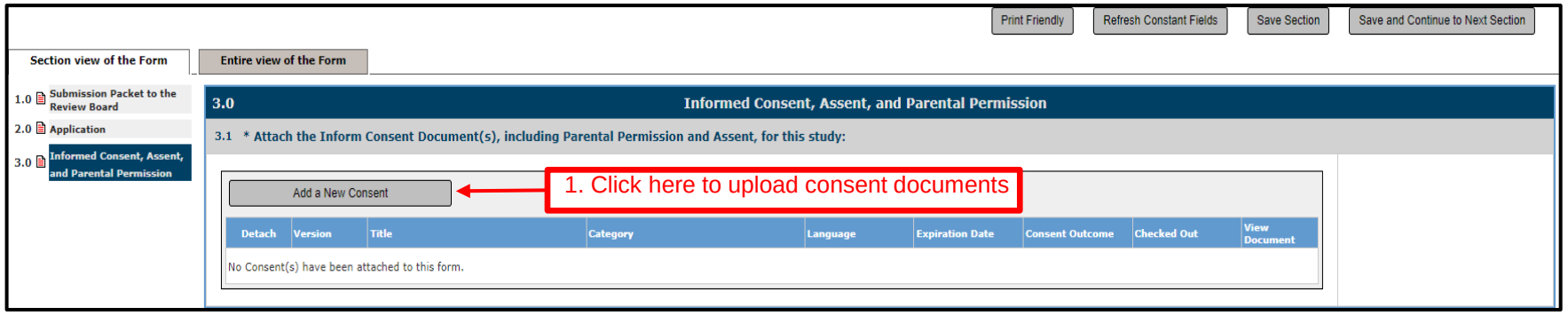
Submission Packet Study Dashboard



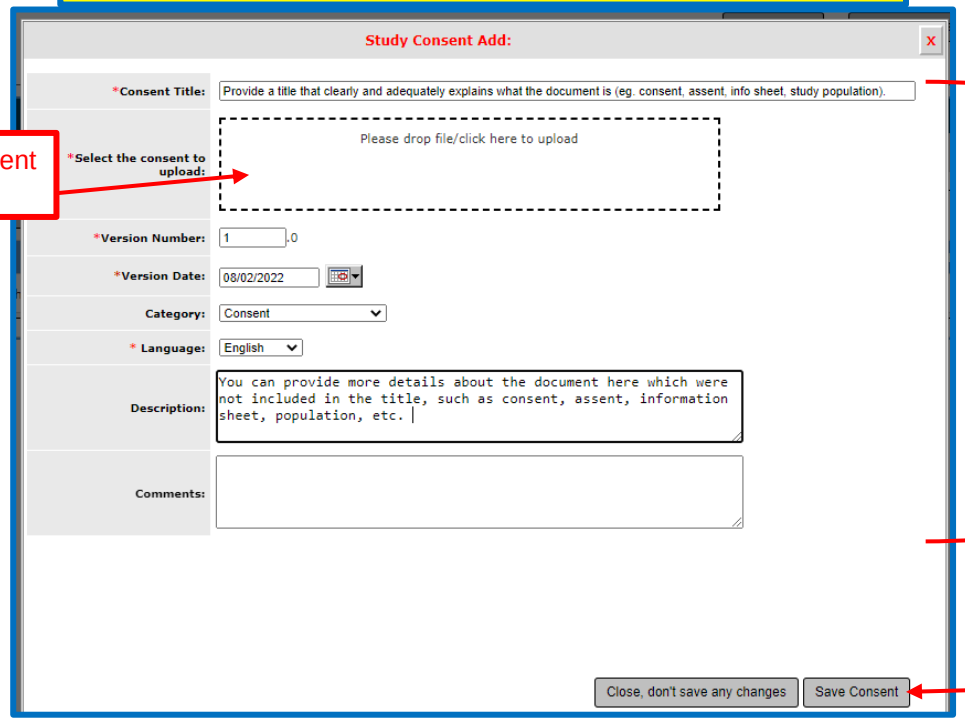
Next, you will be taken to the Application summary page. You can complete your final review and edits of your IRB application from this page.



Upload your required consent and assent documents, as applicable to your study.



This screen will open after "Add a New Consent" button is clicked.

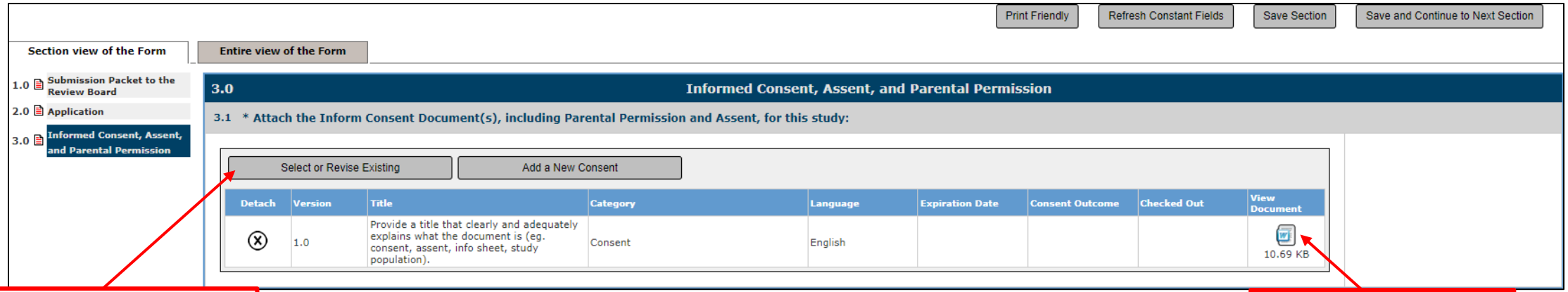


Click here to upload consent Word document.

Fill out each required section of the "Study Consent Add" entries that are marked with an asterisk(*).

After completing form and uploading document, click here.

Double-check uploaded consent document

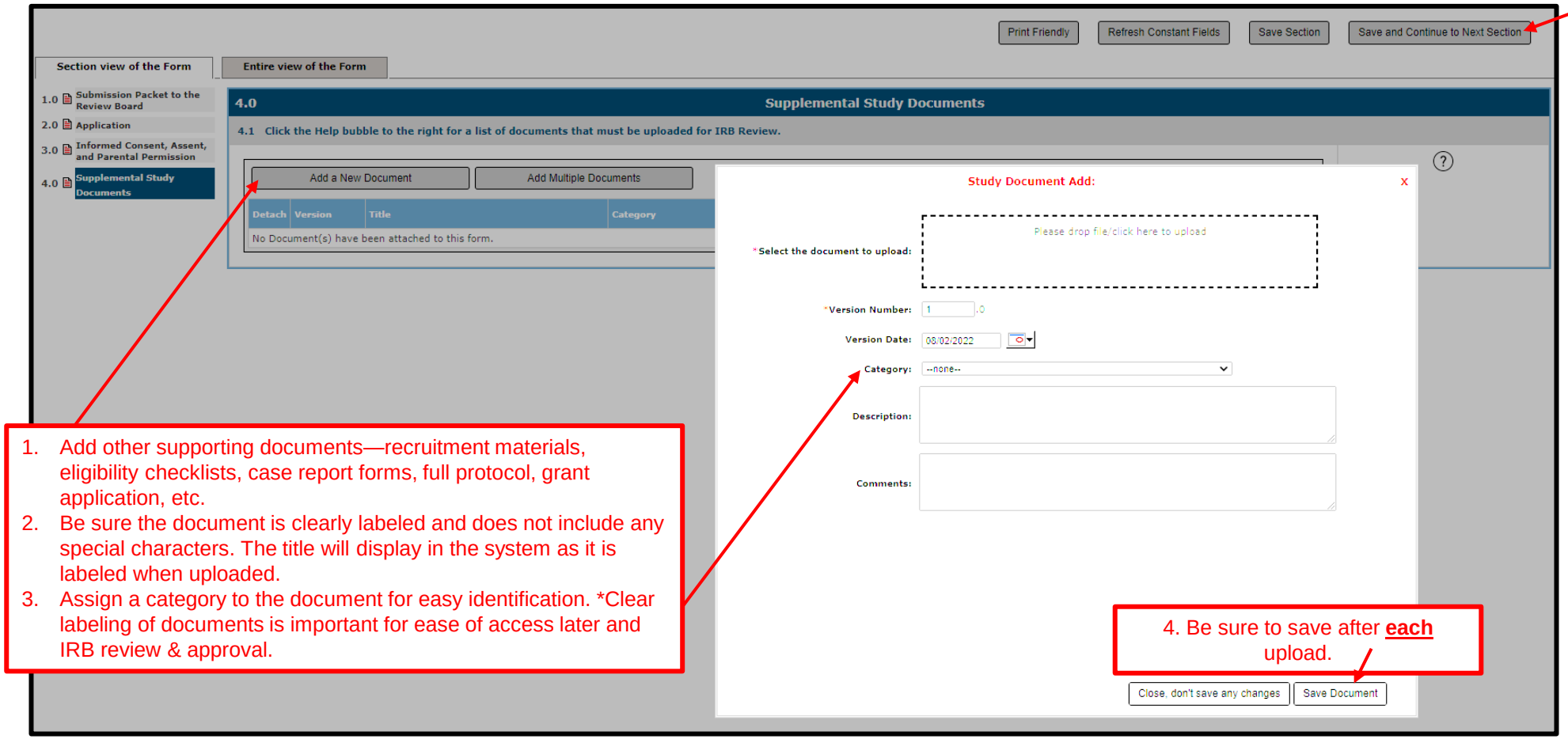


Click here to revised and/or add additional comments to previously uploaded document.

Verify that the correct document was uploaded by clicking icon.

Upload all required supplemental documents (as applicable):

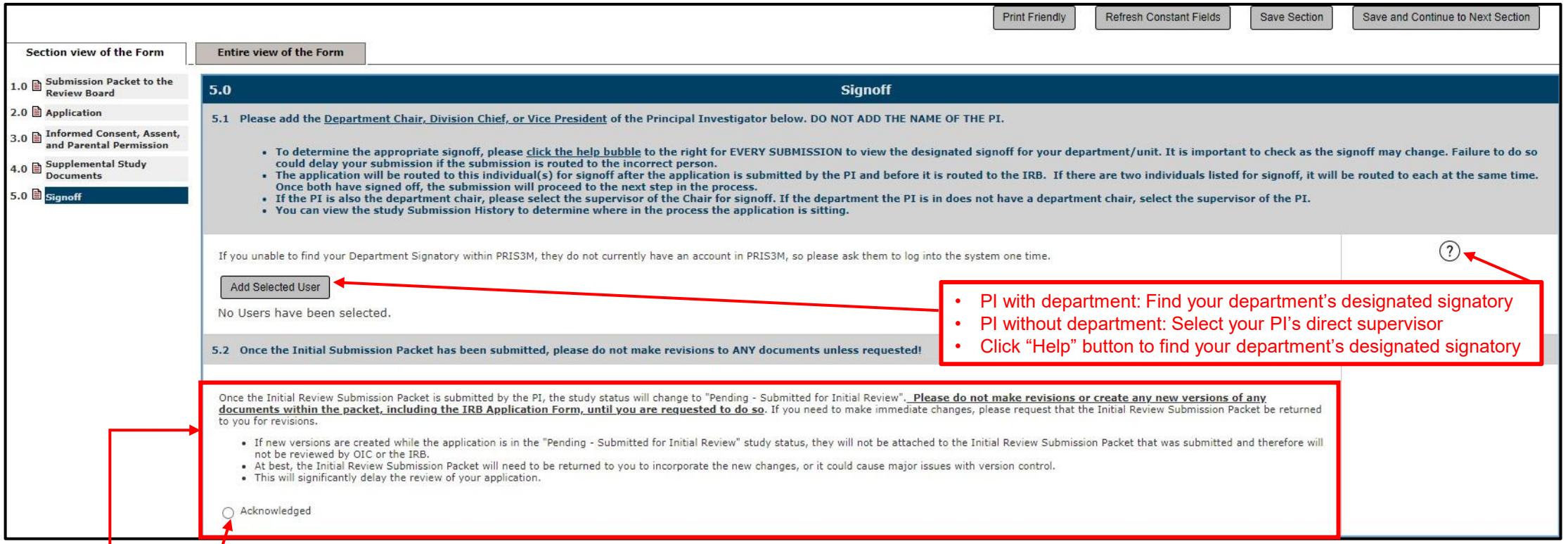
5. Click here when **all** documents are uploaded and have been verified and clearly labeled.



1. Add other supporting documents—recruitment materials, eligibility checklists, case report forms, full protocol, grant application, etc.
2. Be sure the document is clearly labeled and does not include any special characters. The title will display in the system as it is labeled when uploaded.
3. Assign a category to the document for easy identification. *Clear labeling of documents is important for ease of access later and IRB review & approval.

4. Be sure to save after **each** upload.

Select your Department Approval Signatory



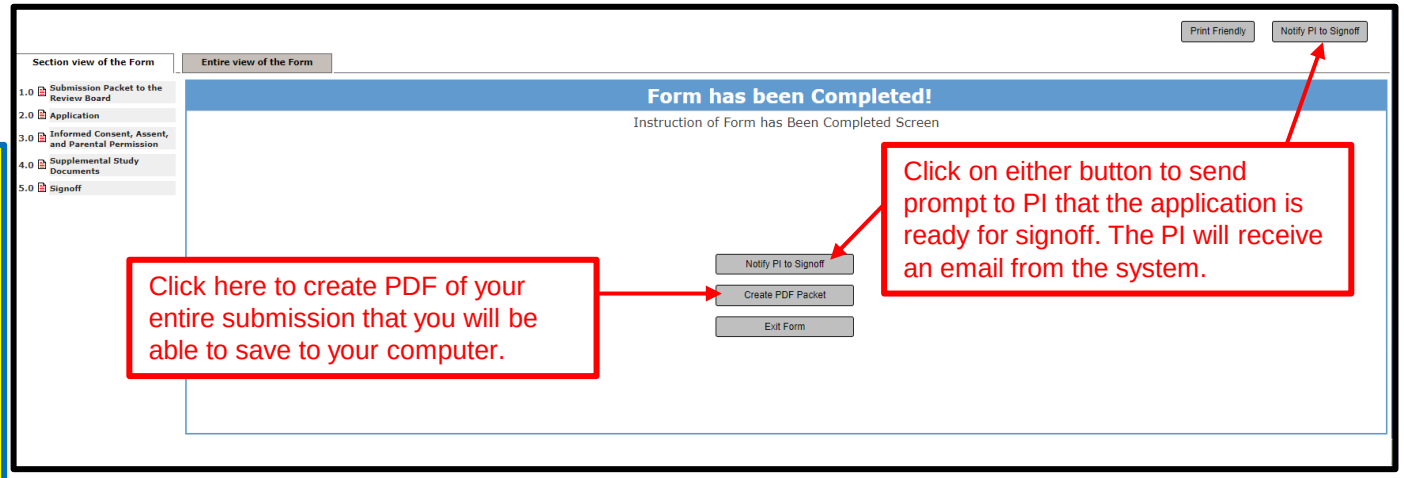
- PI with department: Find your department's designated signatory
- PI without department: Select your PI's direct supervisor
- Click "Help" button to find your department's designated signatory

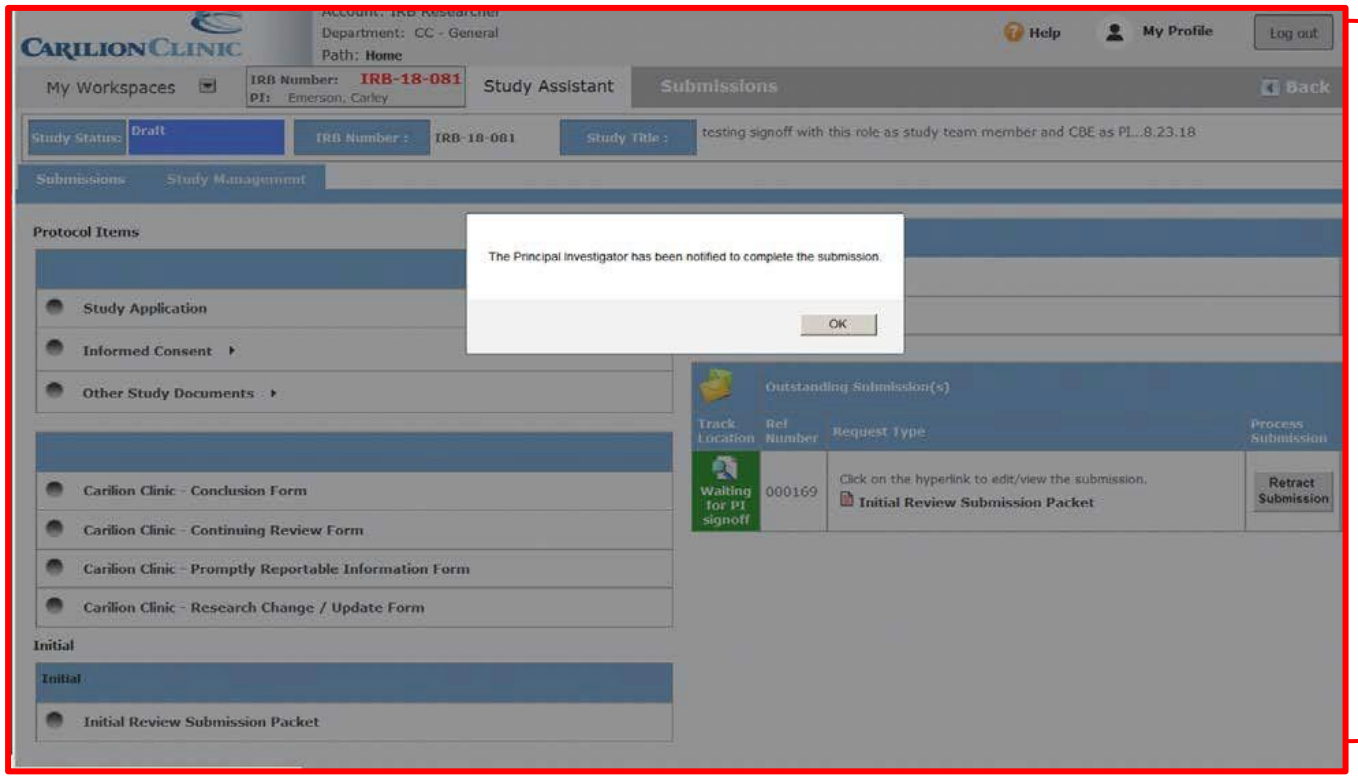
- Review and click "Acknowledge"

For Team Members:

1. Notify your PI that the study application is ready for submission
2. The PI must log in and click submit the application to begin the review process

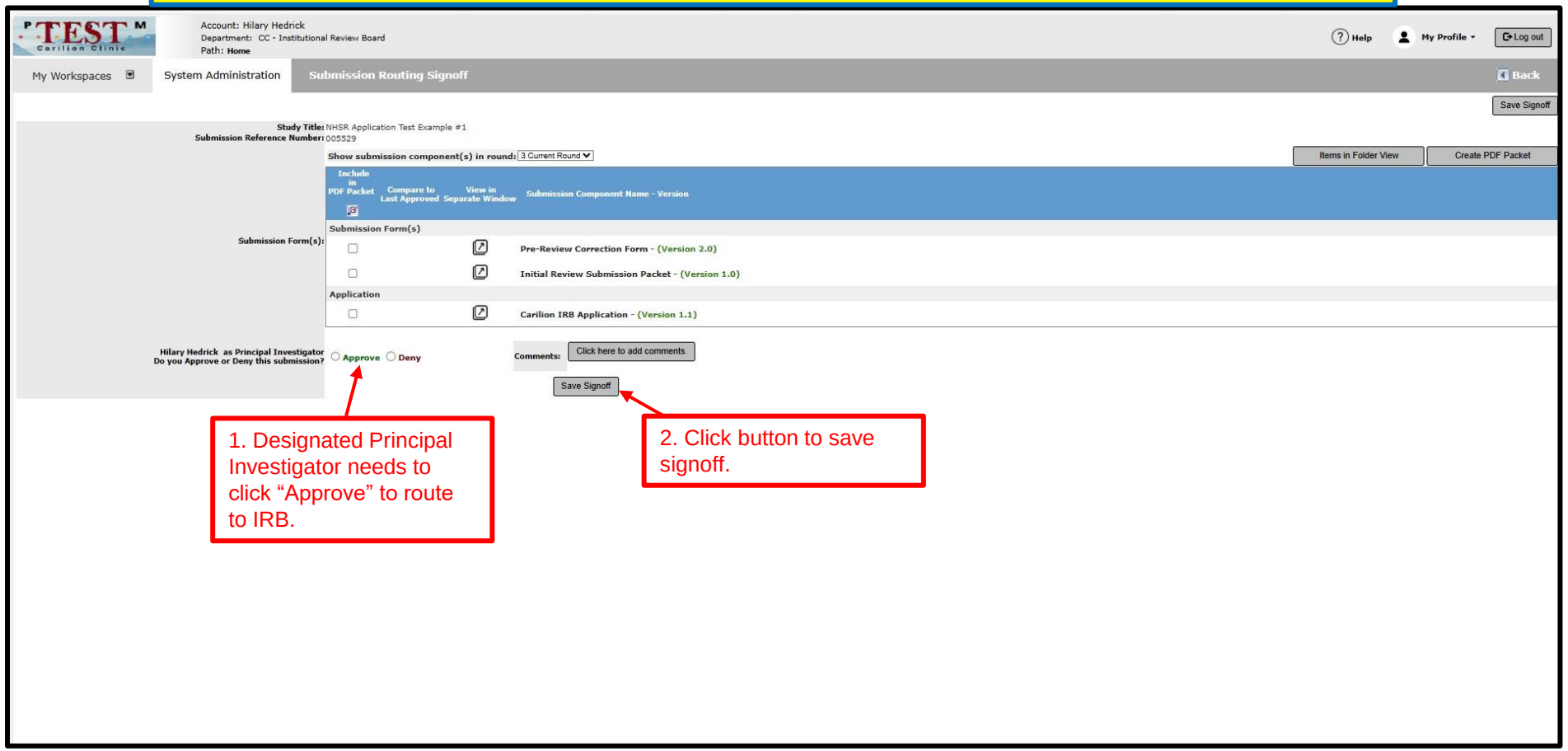
Important to note: Only the PI can submit the application to begin the review process.





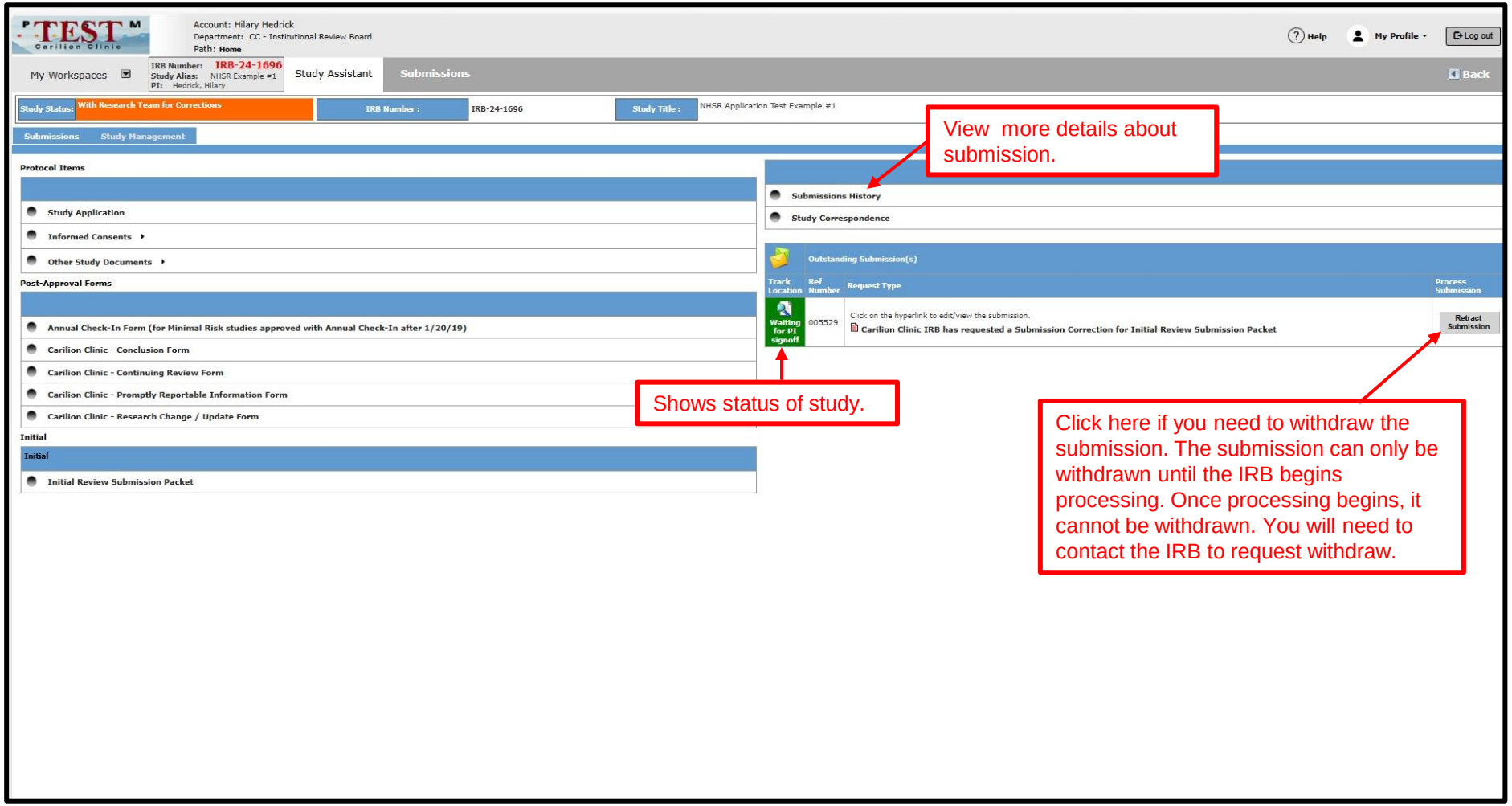
Screenshot of confirmation screen that PI has been notified.

For Principal Investigators (PIs):
Click “Signoff and Submit” to send your study to IRB review

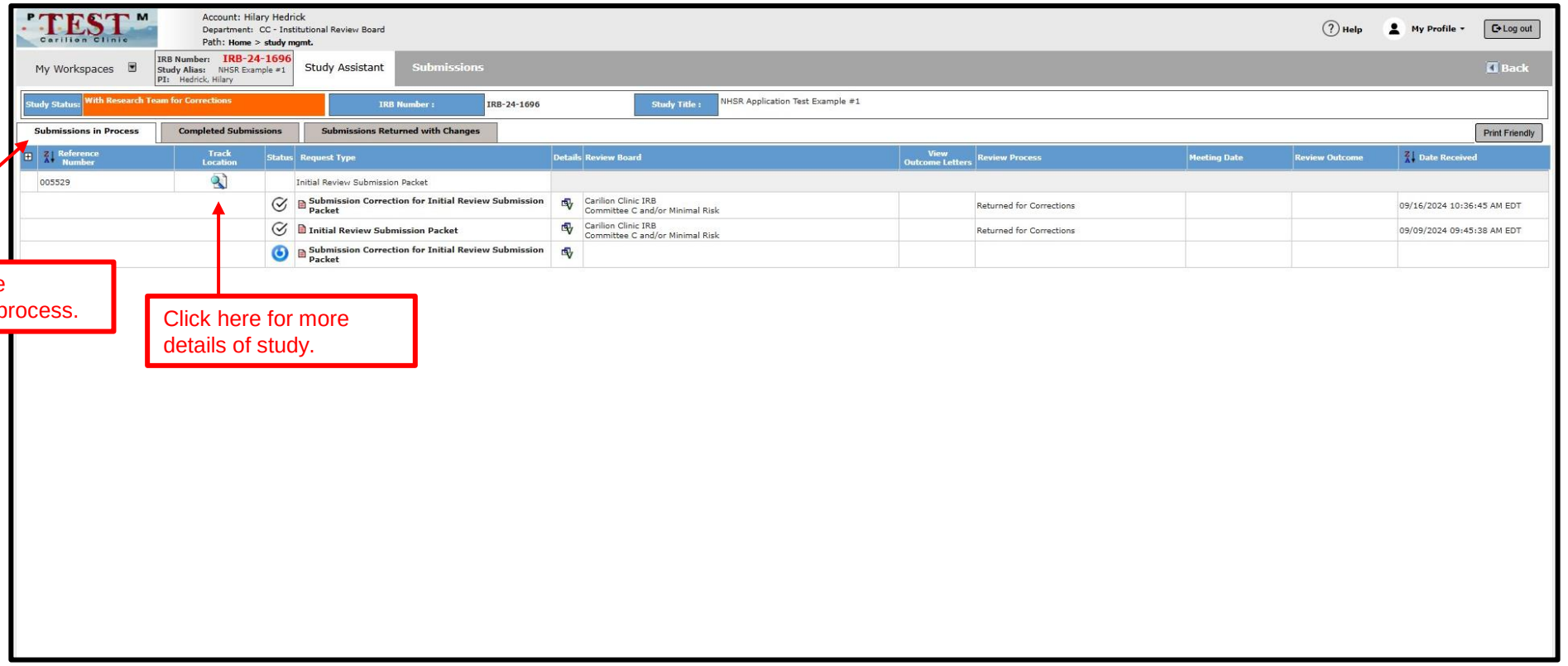


Study Dashboard

You can view the **Submissions History** to determine the status of application.



This page can be found under the **Submissions History** tab.



Need more help? Contact the HRPO team to assist.

Email IRB@carilionclinic.org