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

Last Update	**October 17, 2018**
Intended Audience	**Principal Investigator/Researcher**
Purpose	**To provide the user with step-by-step instructions on how to complete/submit a new protocol application, including**: • Human Subjects Research Study • Determination of Human Subjects Research (including QA/QI Determination) • Establishing a prospective Data or Specimens Research Repository • Humanitarian Use Device (non-research use) • Expanded Access or Compassionate Use • Single Patient Emergency Use • Preparatory to Research Application • IRB Grant Review ONLY for preliminary approval if required by funder • Requesting Carilion Clinic RELY on another IRB of Record

Please first refer to the **User Guide:** ***Getting Started and Navigating the Study Assistant Dashboard in PRIS³M*** before continuing.

IMPORTANT: Any user creating a New Application must be selected as the PI or be added as an Research Staff Member in Section 3. If you do not add yourself to the application, you may not be able to continue accessing the application on future log ins.

IMPORTANT: All research team members must log into the PRIS³M system one time in order for their account to be created in PRIS³M, which will then make them available to be added as a study team member. If you are trying to add study team members to a study, and you cannot find someone's name, ask them to log into the system using their Carilion username and password.

Follow the steps below to submit a new application:

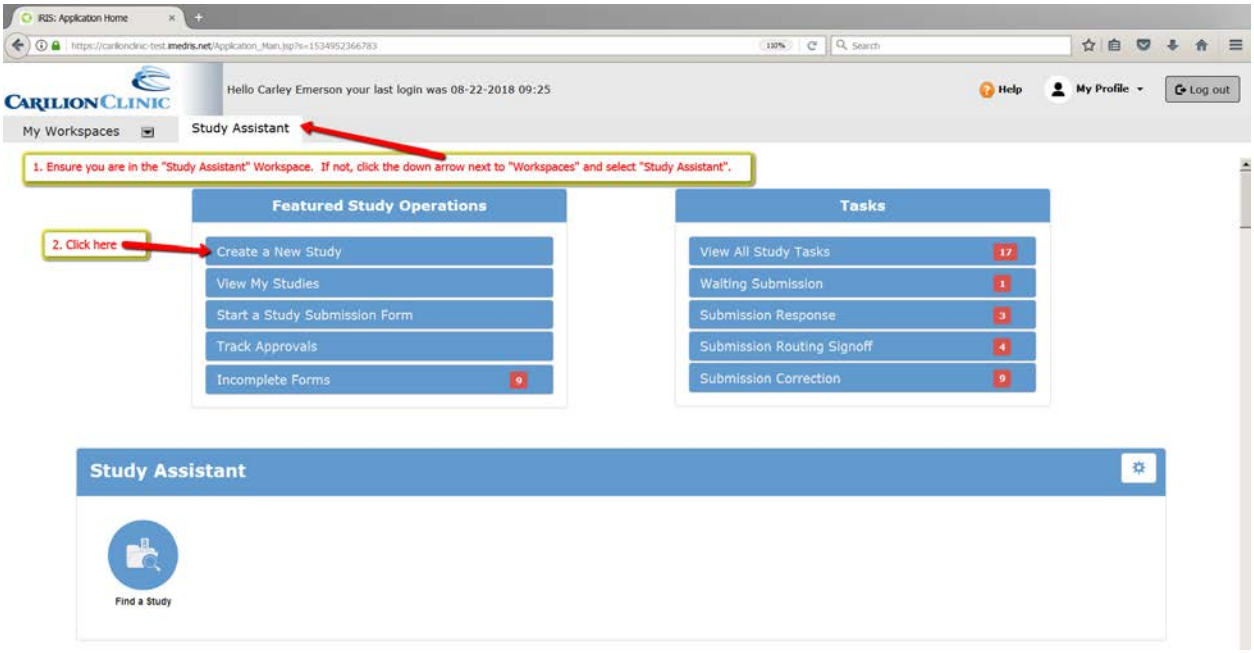
STEP 1. **Close** all open web browsers.

STEP 2. **Open** a new browser and go to: https://carilionclinic.imedris.net/

STEP 3. **Login** using your Carilion ID and password.

STEP 4. Ensure you are in the Study Assistant dashboard by hovering the pointer over "My Workspaces" on the left of the page and clicking on "Study Assistant" if necessary.

STEP 5. **Select** the "**Create a New Study**" button under Featured Study Operations on the left.

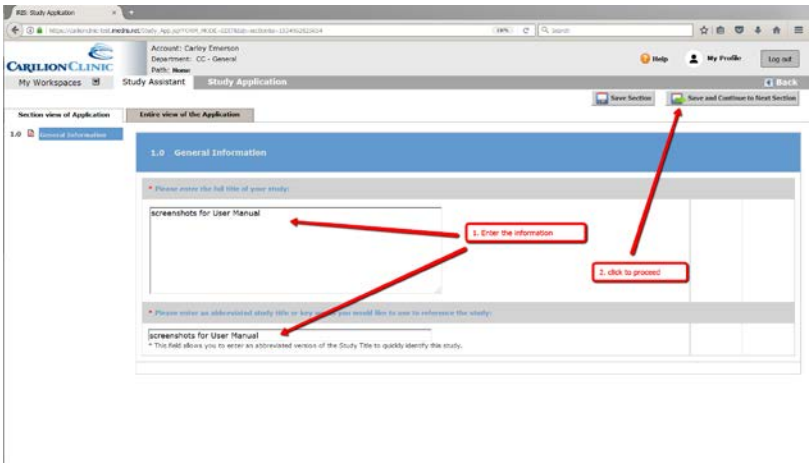


STEP 6. **Complete Section 1 – General Information**

- Enter the full study title and the Short Study Title using key words. Section 1 must be filled out completely in order for the application to be saved and generated in the system.
- Required fields are indicated with a red asterisk (*).

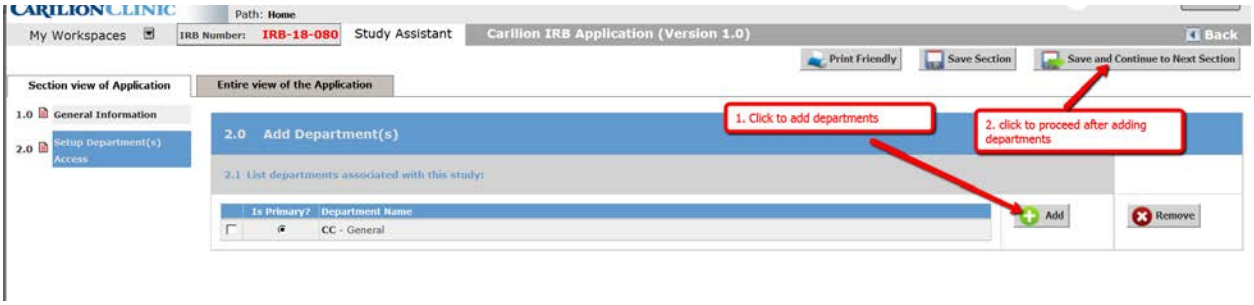
STEP 7. **Select** the "**Save and Continue to Next Screen**" button to save the application and proceed to the next section.

- The system will save the application and generate an IRB number which will appear in red in left corner of the form.



STEP 8. Complete Section 2 – Setup Department Access

- You **MUST** add the PI's department by clicking the "Add" button" and then select it as the primary department. You **MUST ALSO** add the other institutional departments of team members who will be involved with the design, conduct, or reporting of the study by clicking the "Add" button" and selecting the appropriate departments. You will be asked to list the study team on the next page.
- **Select** the "**Save and Continue to Next Screen**" button to save the application and proceed to the nextsection.



STEP 9. Complete Section 3 – Grant Key Personnel access to the study

- Add the PI, Additional Investigators (Sub-Investigators), and Research Staff Personnel (research coordinator and other research team members). 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.
- Click on the "**Add User**" button for each role to add personnel to that role.
- You will then search by last name and click **"Find"**. **Please be aware that only individuals who are employees at Carilion Clinic AND who have logged into the system at least one time will display.** If you are unable to locate someone, ask

them to sign into the system if they have not already.

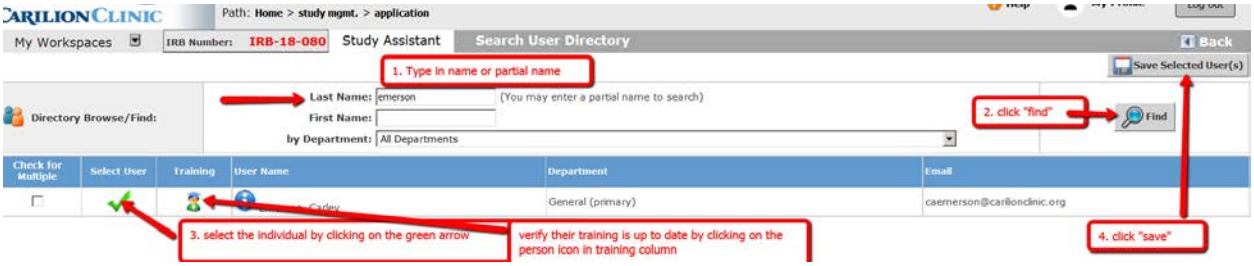
- Before adding the individual, please click on the graduate icon under "Training" next to their name. Verify that the selected individual has completed the appropriate CITI training modules and that their training is up to date. Note: this requirement is only applicable for new human subjects research studies and biorepository studies). If an individual does not have the appropriate training, but is added to the study team anyway, the PI will be prevented from submitting the application due to outstanding training. It is the policy of the IRB to only accept applications in which all team members have completed training.

  Note: If you wish to add someone to the research team who has completed training through another institution or using a different email address, you must email the IRB at irb@carilionclinic.org with the completion certificate listing all the completed modules. The IRB will review the modules and determine if this training is sufficient, and if so, will add the training to the individual's profile in the system. A certificate that does not list the modules WILL NOT be accepted.

- Once you verify their CITI training, click the green arrow next to the person's name for them to be added to the study team.

- Verify in Section 3 that they were added to the study team, and select their role on the study.

- You must complete this process for each member of the study team.



IMPORTANT: It is IRB policy to not begin conducting a review of a submission until all team members have completed required CITI Human Subjects Research training. If training for one or more research team members is not up to date or the correct modules have not been completed, the IRB will receive the application but will not begin the review unless those individuals are removed from the study or they provide evidence of completion. If the individual does complete their training after they have been added to the team but before you have tried to submit to the IRB, you will need to verify that the system received the update from CITI (updates are sent from CITI to the system every day) and before submiting the application.

IMPORTANT: Research Team members who are not employees at Carilion should not be added to the study team in **PRIS^{3}M**, as their role will be reviewed by their own IRB. If you would like to request that their IRB rely on Carilion's IRB review, please first contact the Carilion IRB to discuss. If their IRB agrees to rely on Carilion's IRB, and the research team member will have contact with Carilion patients/participants or identifiable data, **AND** will need access to the **PRIS^{3}M** system, the PI will need to submit a ticket in Edison to request a Carilion ID for each team member so that they can gain access to the system. Once their ID is created, they will

need to log into the system. Only AFTER they log in to the system one time will they be able to be selected as a member of the research team. Their CITI training will need to be manually added to their profile by an IRB staff member if they have did not affiliate with Carilion in CITI. Please send their completion certificate with a complete listing of course modules completed to an IRB staff member. If their IRB will rely on Carilion's IRB review, but they will not have contact with Carilion patients/participants or identifiable data, **AND** they won't need access to the PRISM system, you should upload a list of study personnel from the external sites and their training certificates in the submission packet supplemental document section. Additional documentation will likely be needed from the external IRB agreeing to rely on Carilion's IRB and documentation of their local review requirements, including training as required by their home institution.

STEP 10. Complete Section 4– Application Type

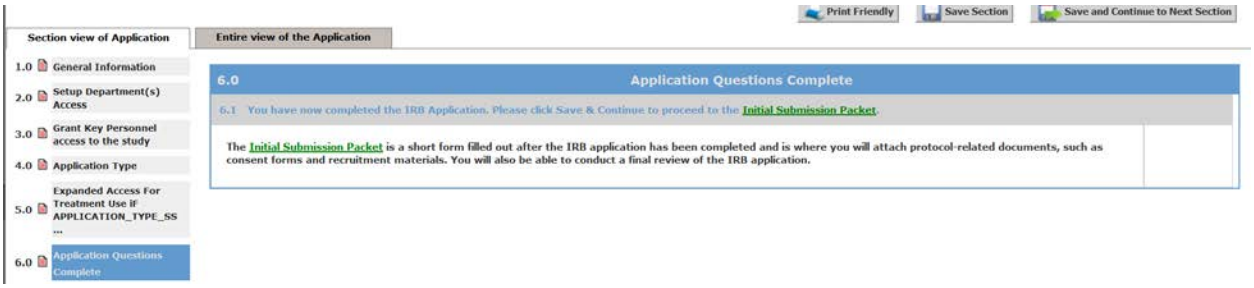
- **Select the application type**

STEP 11. **Navigate** through and complete the remaining application sections

- Proceed by clicking the "**Save and Continue to Next Screen**" button to save the application and proceed to the next section.
- The rest of the questions will branch depending on the specifics of your study.
- When "**Save and Continue to Next Screen**" is selected, the system automatically saves the form.
- You can select "**Save Section**" at any time. If needed, you can come back later and finish the form.
- If you spend a lot of time responding to one question in the application, it is recommended to copy your response, then click "**Save Section**" before proceeding to the next question on that page. If the system has timed out when you were preparing this response, you will be able to get back to the page, but you may lose information entered onto that page before you clicked "**Save Section**".
- If you step away from your computer for any amount of time, it is recommended you save what you have entered and when you come back, close out the browser and log in again. Then navigate back to that page. This may prevent you from losing work due to the system timing out when inactive.
- Select "**Back**" to close the SmartForm and return to your Study Assistant Dashboard.
- **WARNING:** If the "**Back**" button is selected, the system will not automatically save the information entered on that page of the form. Be sure to select "**Save Section**" before the "**Back**" button is selected.

STEP 12. Once the application is completed, you will be taken to the last section of the application letting you know that the IRB application has been completed.

- Click **"Save and Continue"** to be taken to the Initial Submission packet where you will upload study documents. (Think of the submission packet as a large folder where you can put all your study related documents for storage. The IRB application is a separate component of the entire submission.)



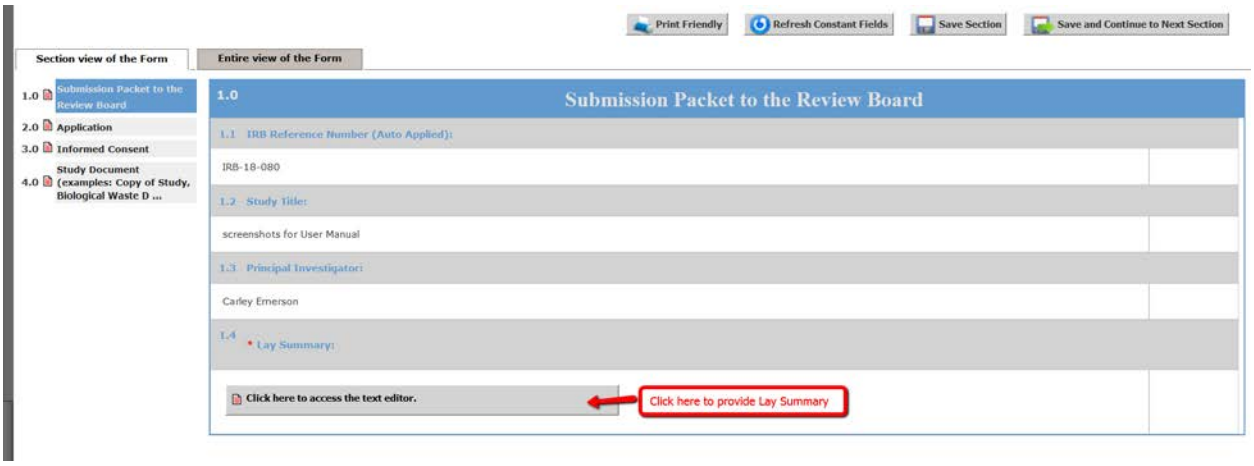
STEP 13: You will first be taken to the page where you will begin to create your Submission Packet.

- You should review the study information on this page to ensure there are no spelling errors in the study title and the correct Principal Investigator is displayed.

- If this information is not correct, you will need to navigate back to the IRB application to make the changes.

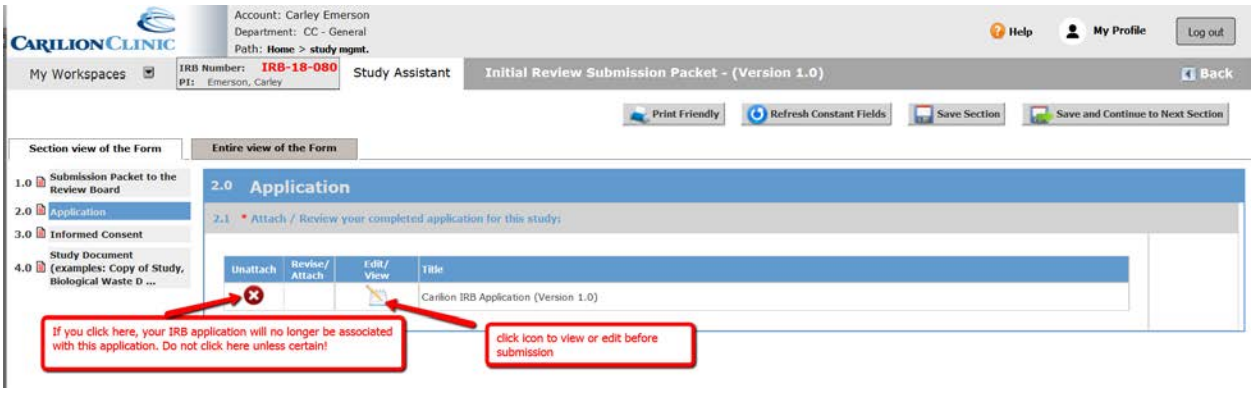
- If all information is correct, you will provide a brief lay summary of the study. This should be a paragraph or two in simple language.

- Click "Save and Continue" once your lay summary is complete.



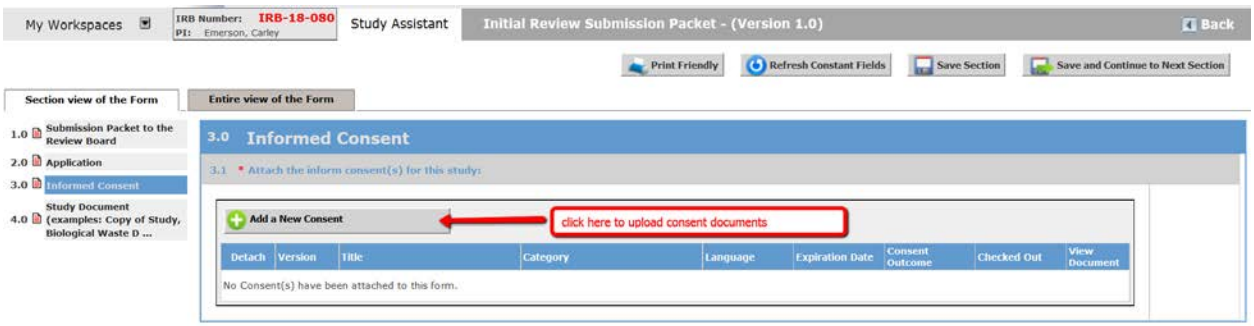
STEP 14. You will then be taken to the Application summary page. You can complete your final review and edits of your IRB application from this page.

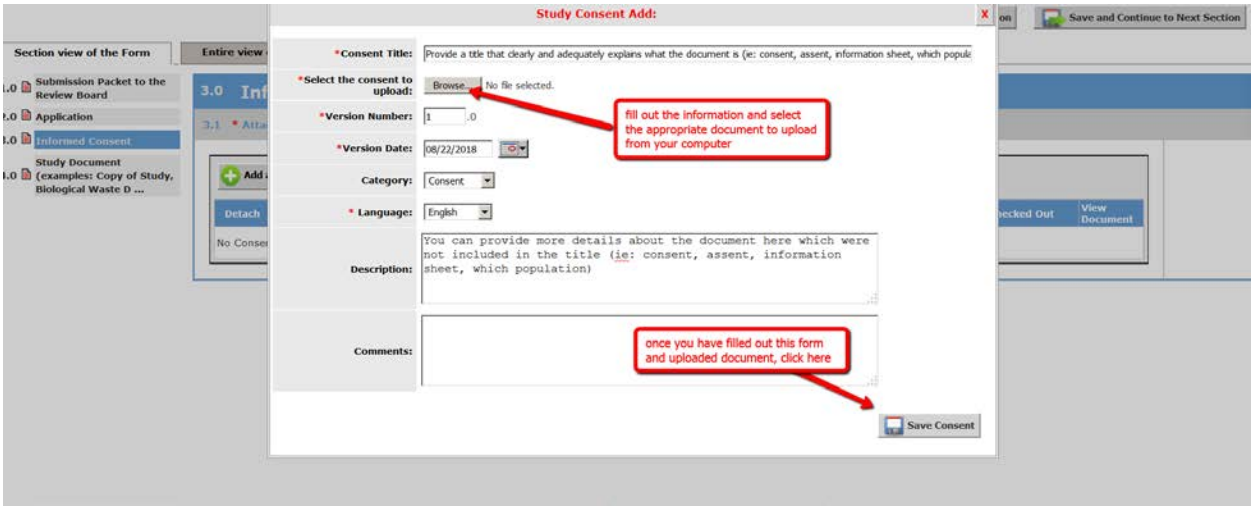
- If you do not wish to review further or make any edits, click "Save and Continue to Next Section" in top right of page.

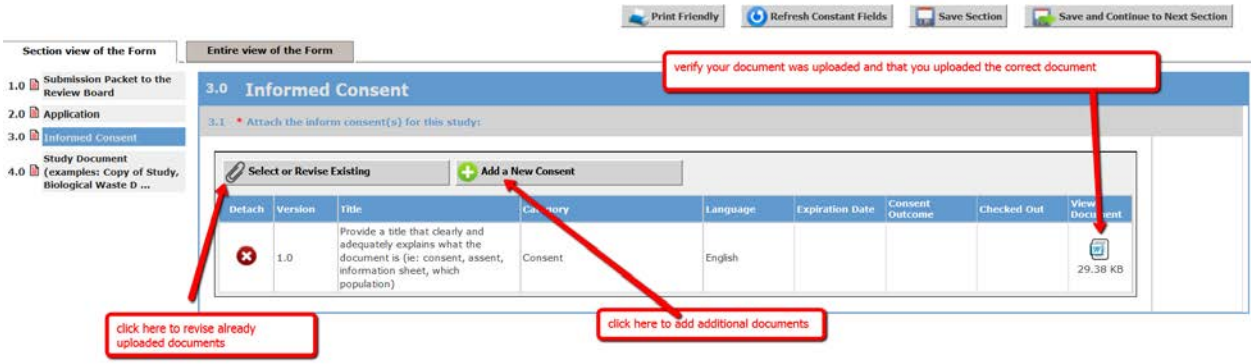


STEP 15. You will now be able to upload your consent and assent documents from your computer, as applicable to your study.

- Click "Save and Continue to Next Section" in top right of page when finished.
- You will be asked on the next page to upload other supporting documents.

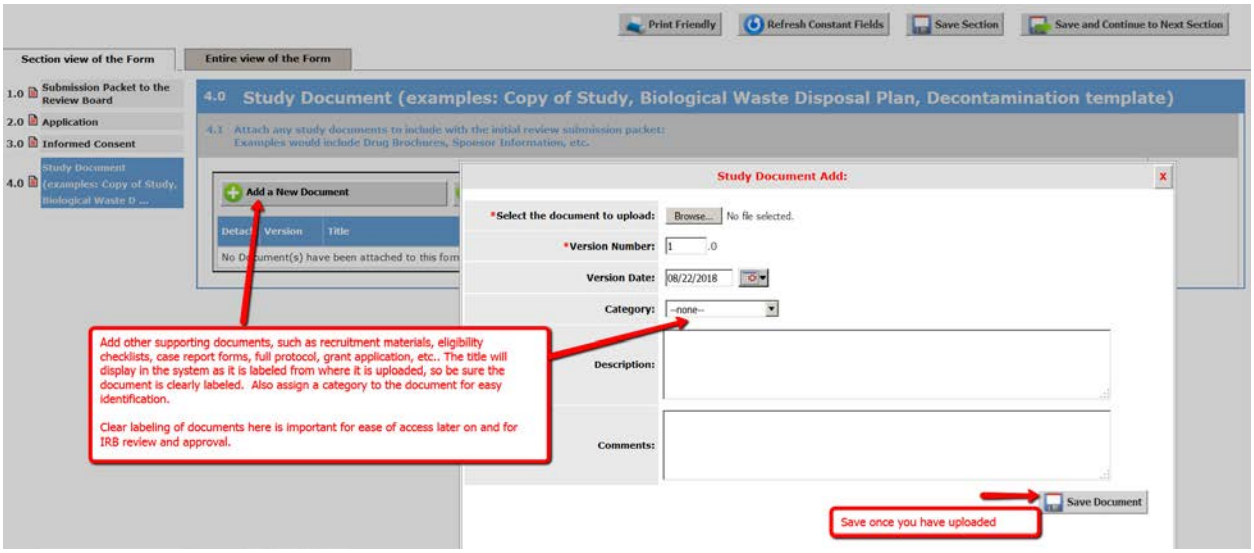






STEP 16. Upload supplemental documents such as full protocol, CRFs, eligibility checklist, questionnaires/surveys, CITI training certificates, etc.

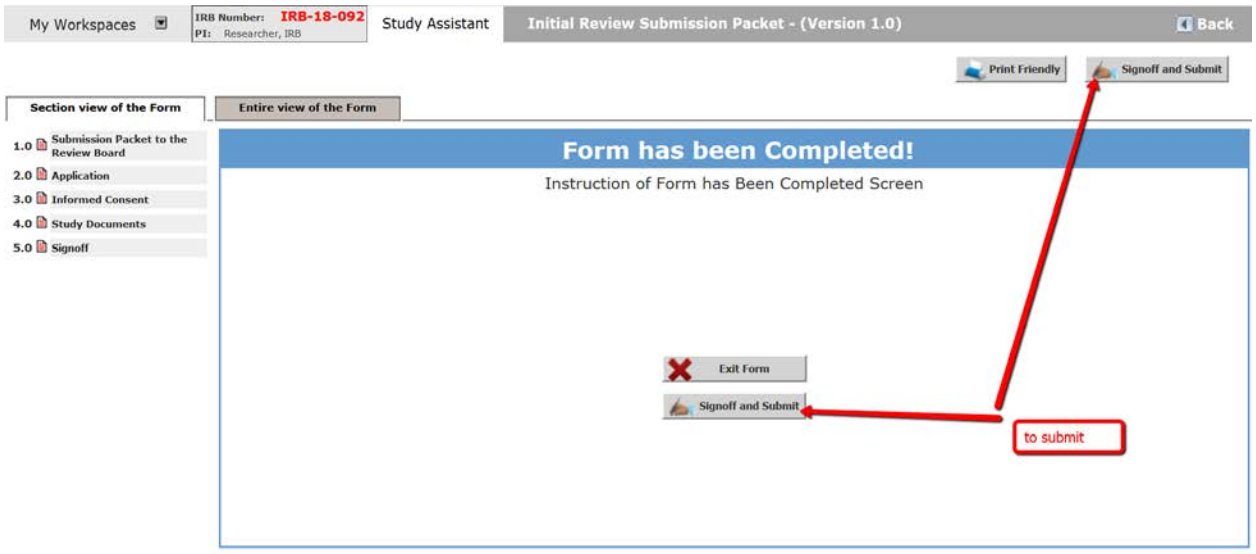
- Click "Save and Continue to Next Section" in top right of page when finished uploading all documents and verifying they are correctly and clearly labeled.



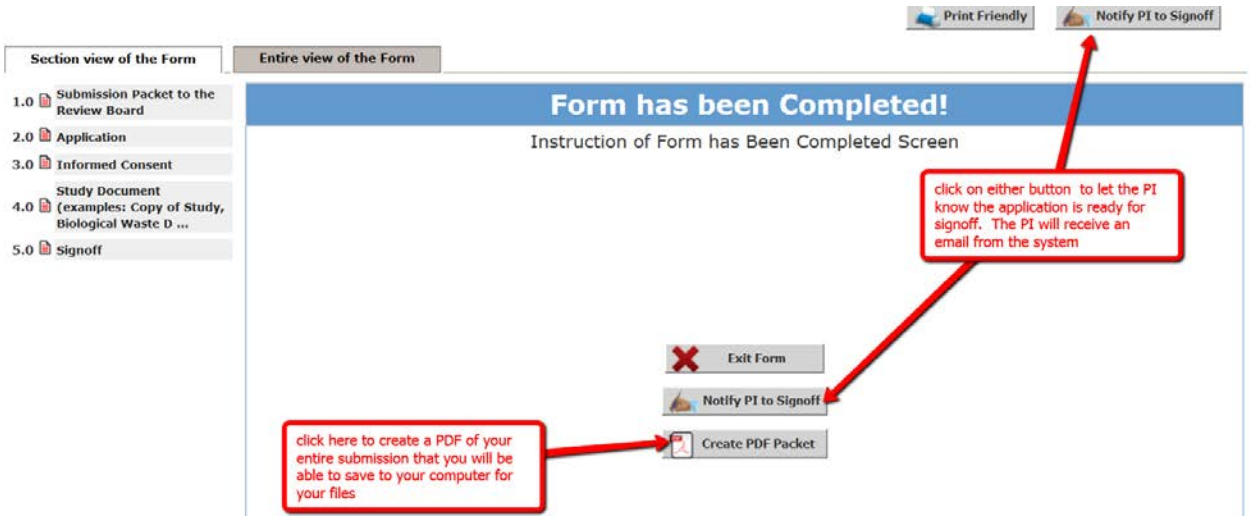
STEP 17. Add the Designated Department Approval based on the department of the PI.

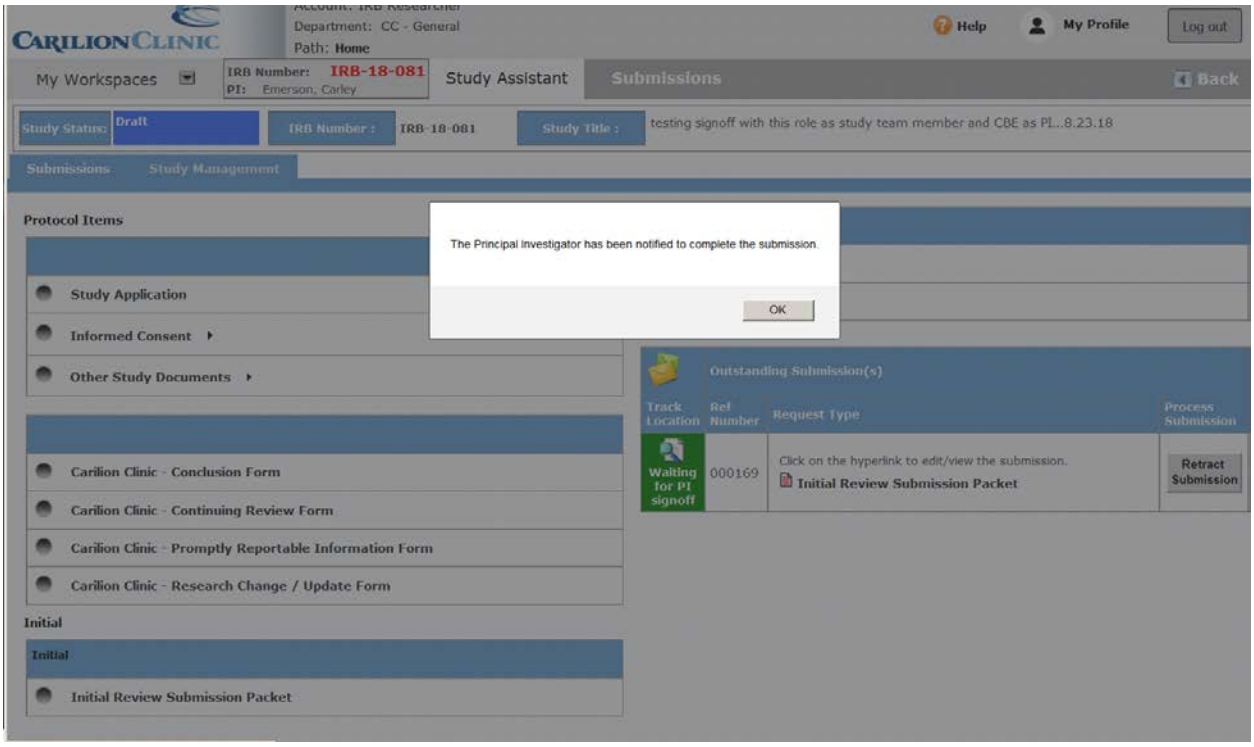
- You can find the name of the individual responsible for signing off for the PI's department by clicking on orange Help bubble to the right of the question.
- **IMPORTANT:** If the PI is not affiliated with a department, select the PI's supervisor as the signoff person. Please note that individual will need to log into the system one time before their name will be able to be selected. You will not be able to proceed with the submission until you add the signoff person.
- Click "Save and Continue to Next Section"

STEP 18. On the **"Form has been Completed"** page, if you are the PI, you may submit the study to the IRB.

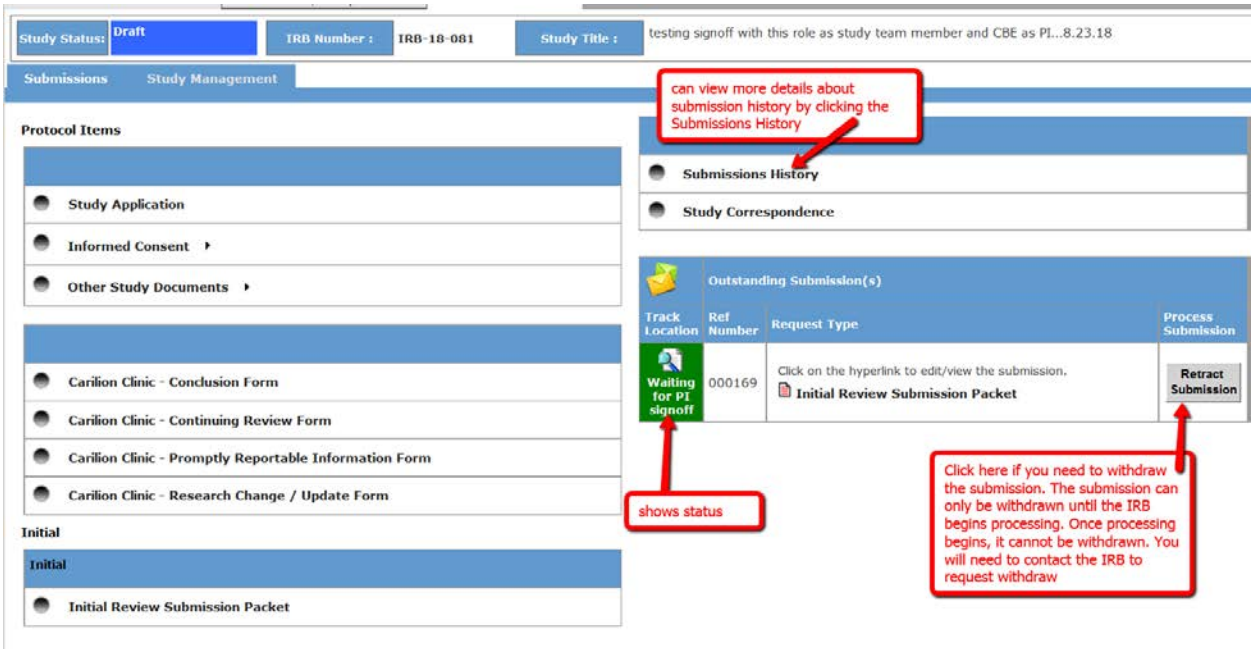


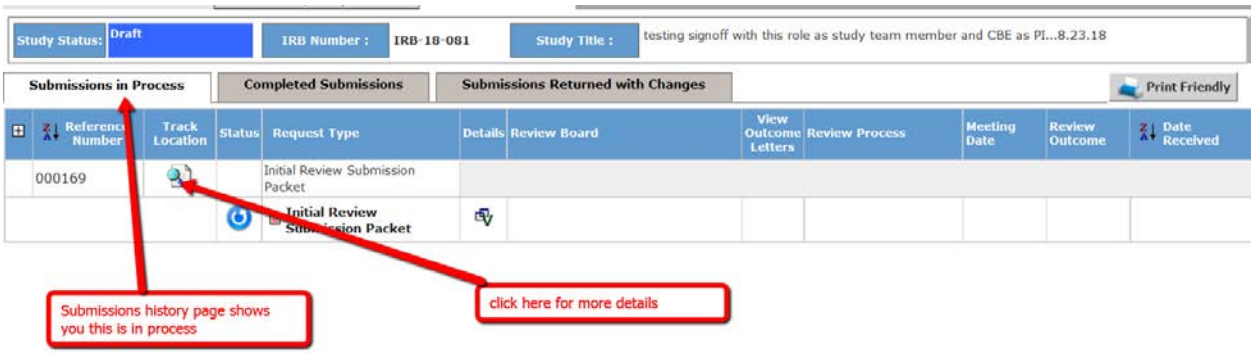
- **If you are not the PI,** you must notify the PI to signoff.
- **The application is NOT sent through the next steps in the workflow until the "Submit" activity on the workspace is run by the PI.**
- **IMPORTANT**: THE PI MUST SUBMIT THE APPLICATION.

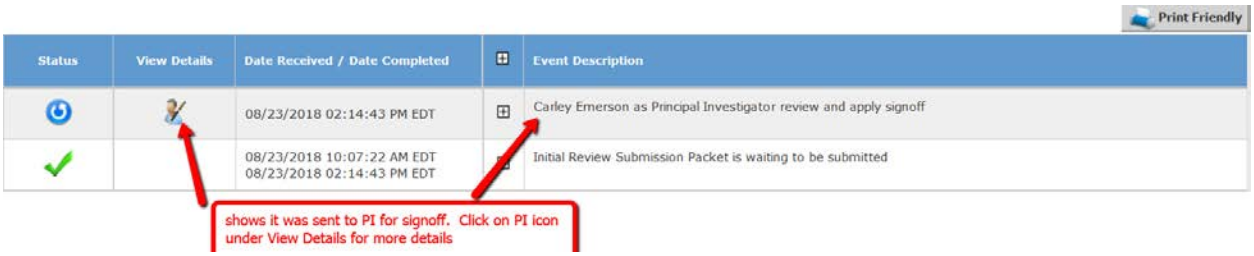


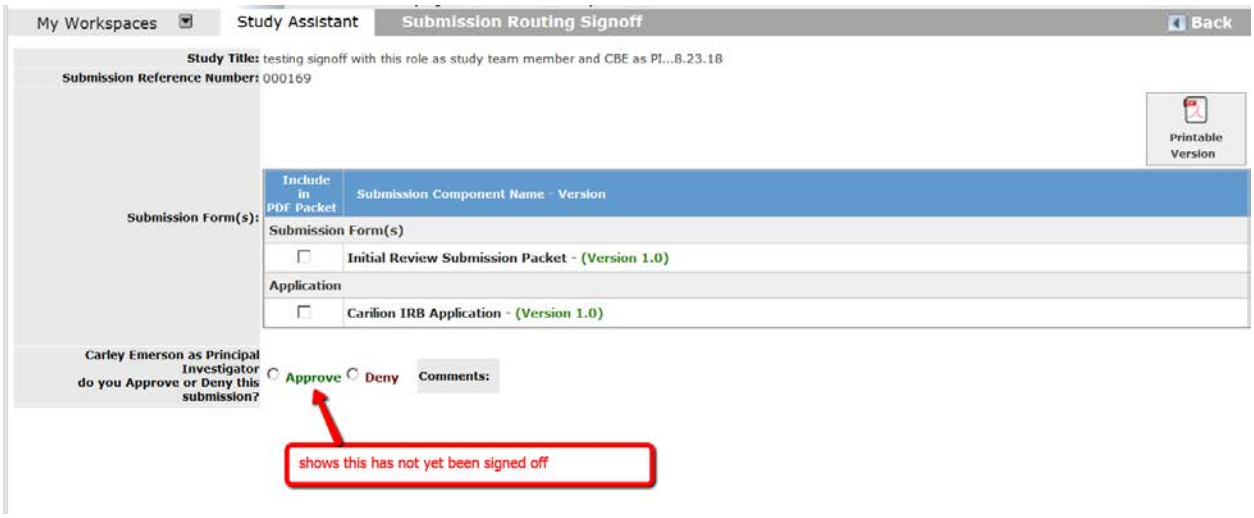


STEP 19: **Verify** that the application packet was submitted **OR** that the PI was notified to submit by viewing the **Submissions History**.









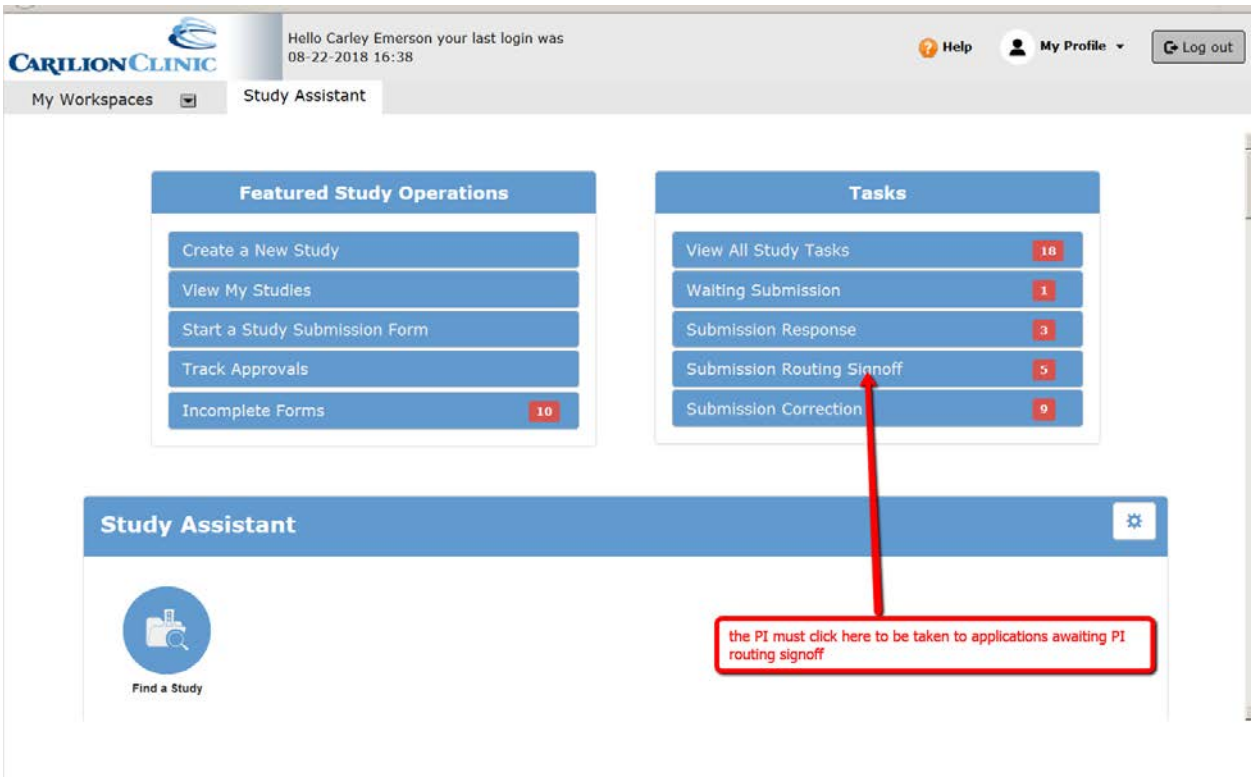
STEP 20: Dependent on the type of application, the application packet may be routed to a Department level signoff, then to Compliance/R&D for review before proceeding to the IRB.

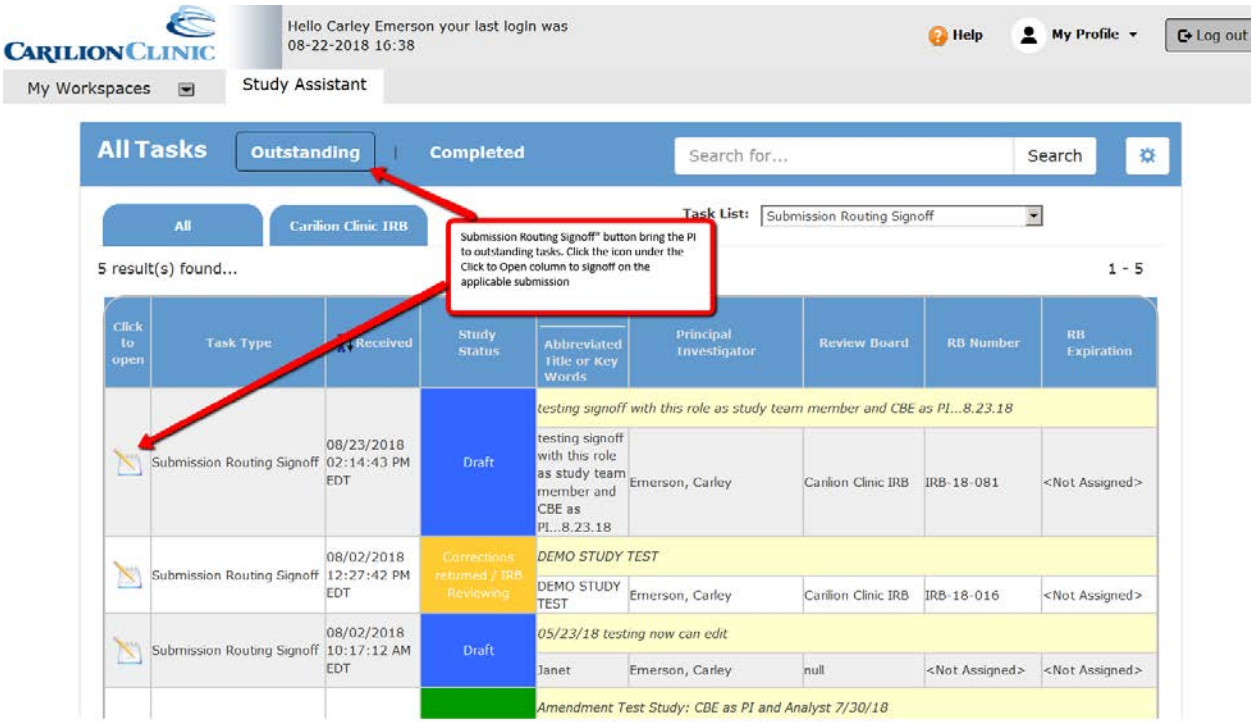
- You can view the Submissions History to determine the status of the application.

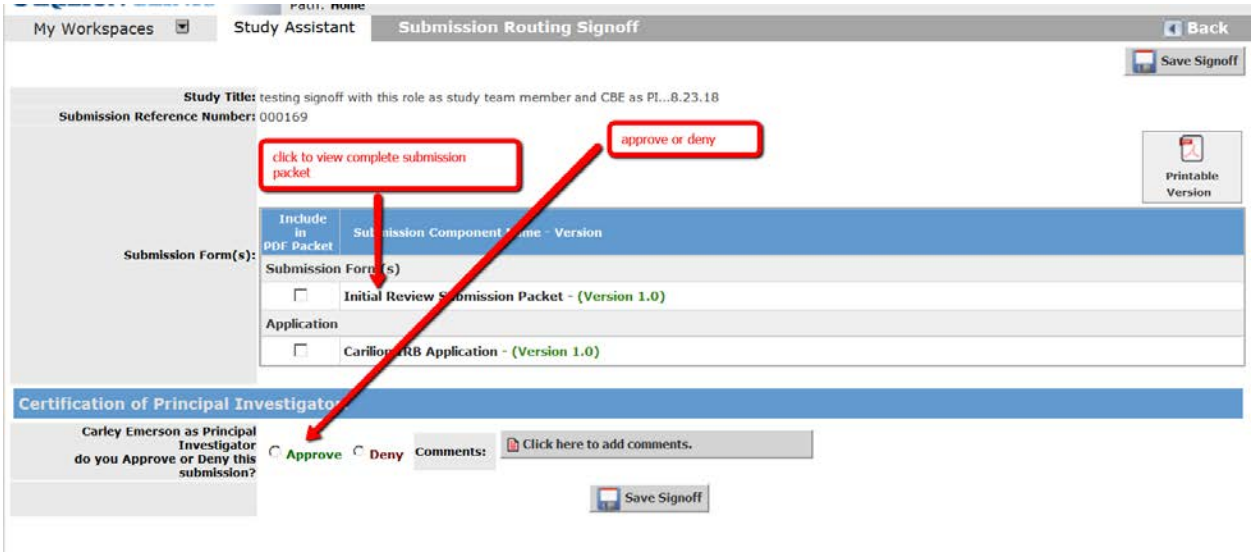
Instructions for Signoff by PI when notified there is a signoff waiting:

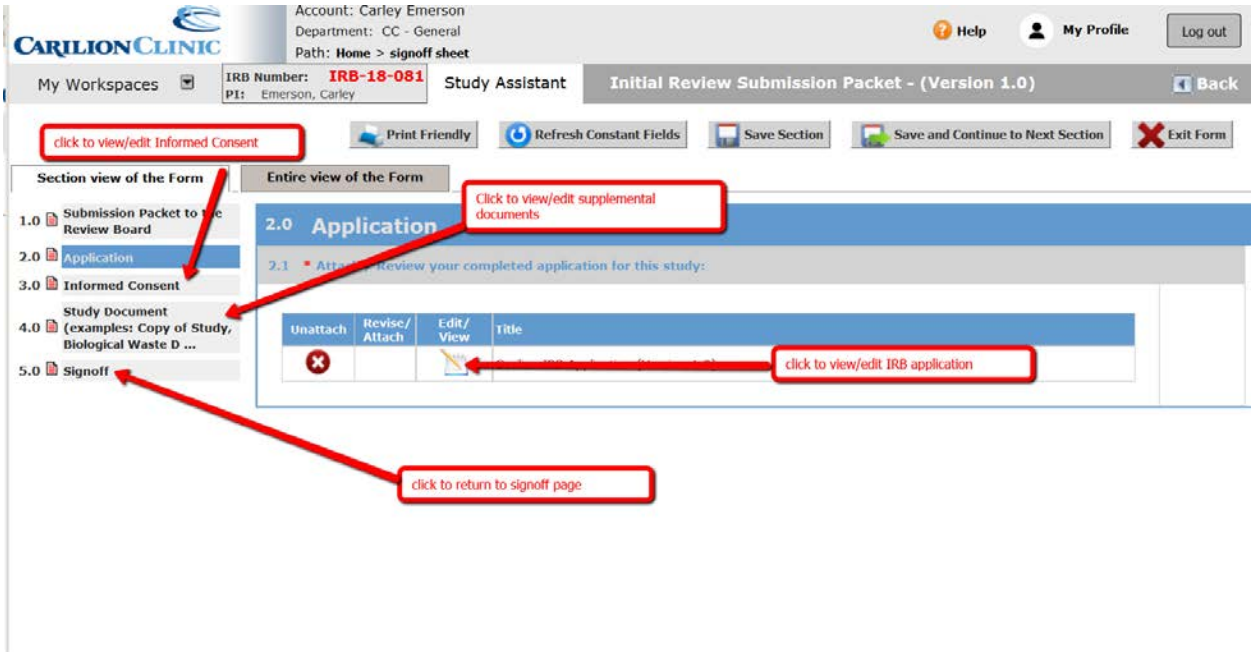
Note: There is a separate User Guide for PI Signoff that provide more details than what is provided here.

1. When the PI logs into the system after receiving an email that there is a submission routed for their signoff
   a. the PI will be able to easily access the study from their dashboard using the "Submission Routing Signoff" button
   b. select the applicable study by clicking on the "Click to Open" icon
   c. click Initial Submission Review Packet to review and/or edit all documents
   d. approve or Deny once ready to proceed
   e. save Signoff

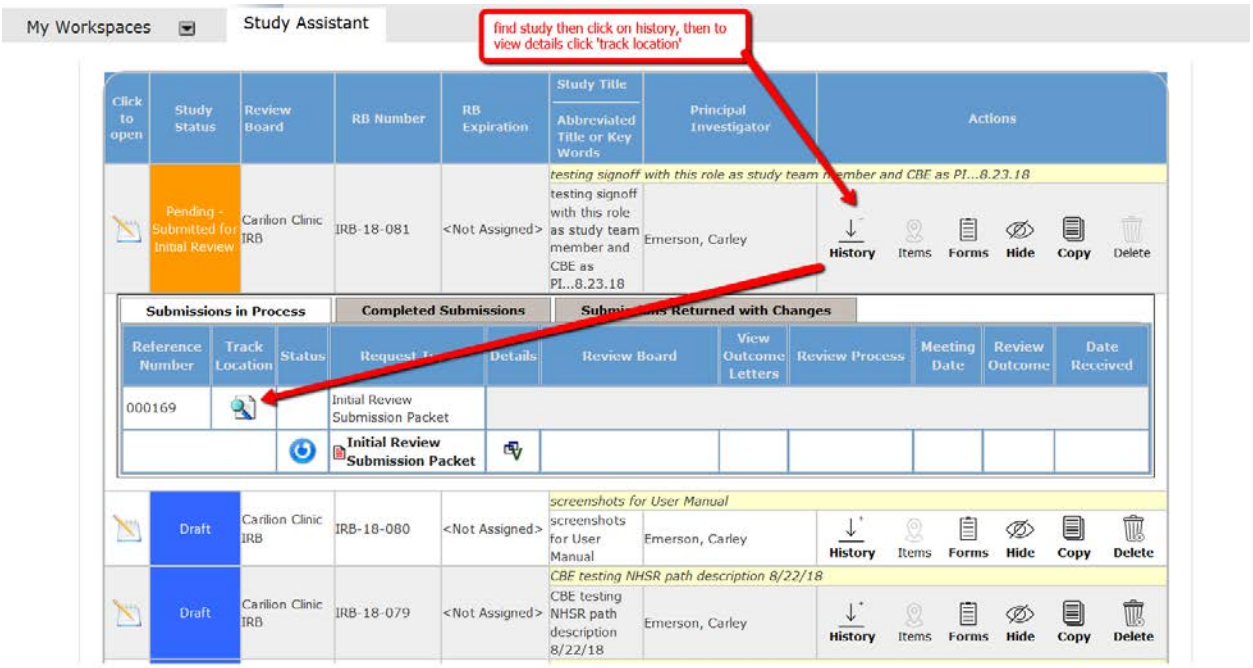


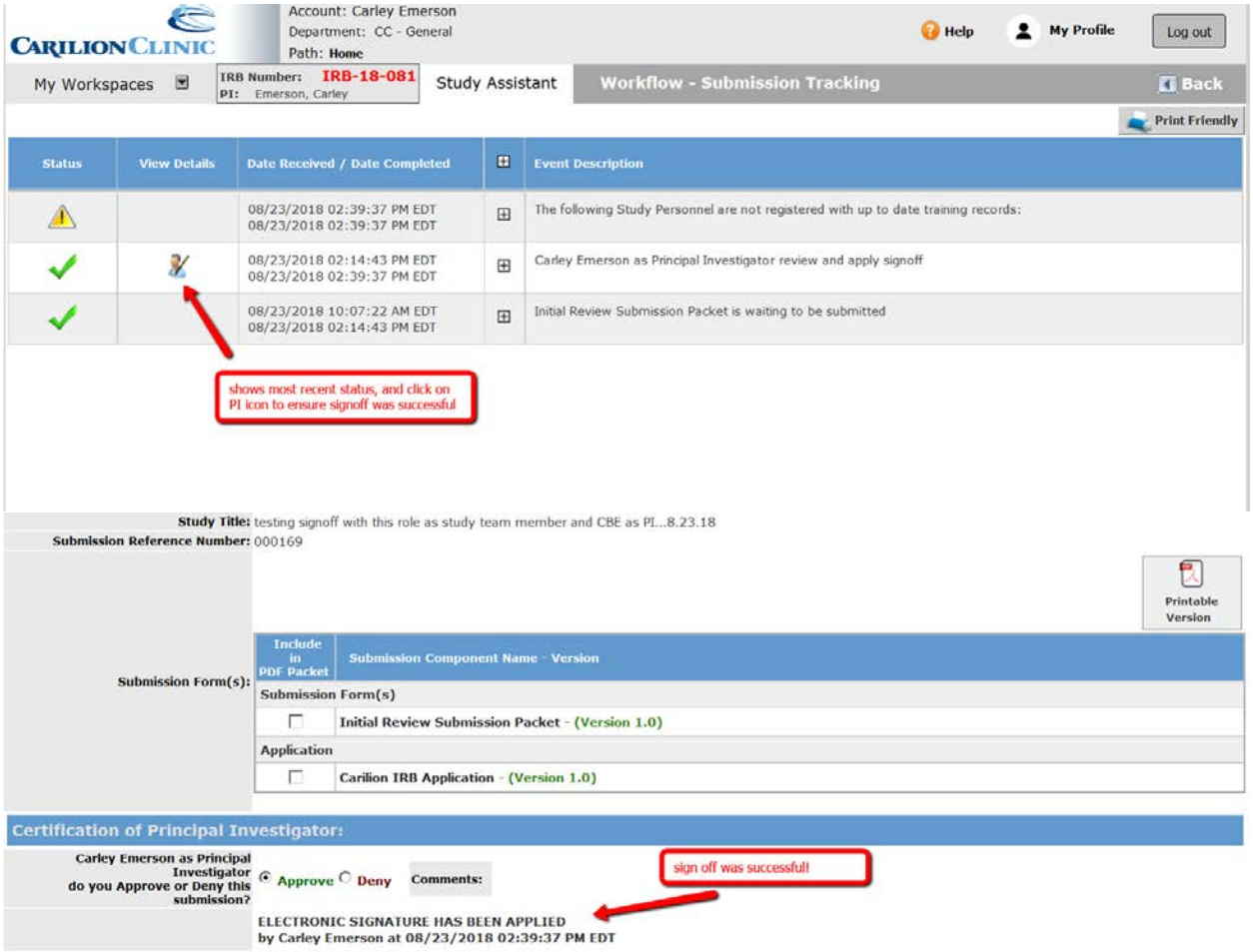

CARILION CLINIC
Hello Carley Emerson your last login was
08-22-2018 16:38
Help
My Profile
Log out
My Workspaces
Study Assistant
All Tasks
Outstanding
Completed
Search for...
Search
All
Carilion Clinic IRB
Task List:
Submission Routing Signoff
Submission Routing Signoff" button bring the PI to outstanding tasks. Click the icon under the Click to Open column to signoff on the applicable submission
5 result(s) found...
1 - 5
Click to open
Task Type
Received
Study Status
Abbreviated Title or Key Words
Principal Investigator
Review Board
RB Number
RB Expiration
testing signoff with this role as study team member and CBE as PI...8.23.18
Submission Routing Signoff
08/23/2018 02:14:43 PM EDT
Draft
testing signoff with this role as study team member and CBE as PI...8.23.18
Emerson, Carley
Carilion Clinic IRB
IRB-18-081
<Not Assigned>
Submission Routing Signoff
08/02/2018 12:27:42 PM EDT
Corrections returned / IRB Reviewing
DEMO STUDY TEST
DEMO STUDY TEST
Emerson, Carley
Carilion Clinic IRB
IRB-18-016
<Not Assigned>
Submission Routing Signoff
08/02/2018 10:17:12 AM EDT
Draft
05/23/18 testing now can edit
Janet
Emerson, Carley
null
<Not Assigned>
<Not Assigned>
Amendment Test Study: CBE as PI and Analyst 7/30/18


My Workspaces
Study Assistant
Submission Routing Signoff
Back
Save Signoff
Study Title: testing signoff with this role as study team member and CBE as PI...8.23.18
Submission Reference Number: 000169
click to view complete submission packet
approve or deny
Printable Version
Submission Form(s):
Include in PDF Packet
Submission Component Name - Version
Submission Form(s)
Initial Review Submission Packet - (Version 1.0)
Application
Carilion IRB Application - (Version 1.0)
Certification of Principal Investigator
Carley Emerson as Principal Investigator do you Approve or Deny this submission?
Approve
Deny
Comments:
Click here to add comments.
Save Signoff



The PI will receive an email confirmation from the system that the signoff was successful, or can click on View My Studies button, find the study, and determine that the status is no longer being reflected as draft. The study will now be with department signoff. The history of the study can also be viewed under **Submissions History** to verify PI signoff was successful.




CARILION CLINIC
Account: Carley Emerson
Department: CC - General
Path: Home
Help
My Profile
Log out
My Workspaces
IRB Number: IRB-18-081
PI: Emerson, Carley
Study Assistant
Workflow - Submission Tracking
Back
Print Friendly
Status
View Details
Date Received / Date Completed
Event Description
08/23/2018 02:39:37 PM EDT
08/23/2018 02:39:37 PM EDT
The following Study Personnel are not registered with up to date training records:
08/23/2018 02:14:43 PM EDT
08/23/2018 02:39:37 PM EDT
Carley Emerson as Principal Investigator review and apply signoff
08/23/2018 10:07:22 AM EDT
08/23/2018 02:14:43 PM EDT
Initial Review Submission Packet is waiting to be submitted
shows most recent status, and click on PI icon to ensure signoff was successful
Study Title: testing signoff with this role as study team member and CBE as PI...8.23.18
Submission Reference Number: 000169
Printable Version
Submission Form(s):
Include in PDF Packet
Submission Component Name - Version
Submission Form(s)
Initial Review Submission Packet - (Version 1.0)
Application
Carilion IRB Application - (Version 1.0)
Certification of Principal Investigator:
Carley Emerson as Principal Investigator do you Approve or Deny this submission?
Approve
Deny
Comments:
sign off was successful!
ELECTRONIC SIGNATURE HAS BEEN APPLIED
by Carley Emerson at 08/23/2018 02:39:37 PM EDT