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: <u>https://carilionclinic.imedris.net/</u>
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.

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Tasks		L
View All Study Tasks	17	
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Submission Response	3	
Submission Routing Signoff	1	
Submission Correction	9	
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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.
- $\succ \qquad \text{Required fields are indicated with a red asterisk} (*).$
- **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.

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My Workspaces 🗐	Study Assistant Study Application		E Back
		Save Section	Save and Continue to Next Section
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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 next section.

My Workspaces 🔳 🛛 IRI	3 Number: IRB-18-080 Study Assistant Carilion IRB Applicat	tion (Version 1.0)		🖬 Ba
		Reprint Friendly Sav	e Section 🛛 🔛 Save a	nd Continue to Next Sec
ection view of Application	Entire view of the Application			
General Information		1. Click to add departments	2 click to proceed all	er adding
O D Setup Department(s)	2.0 Add Department(s)		departments	er buoing
Arress	2.1 List departments associated with this study:			
				-
	S Primary 2 Department name		Add	C Remove

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 <u>AND</u> 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 <u>irb@carilionclinic.org</u> with the completion certificate <u>listing all</u> <u>the completed modules</u>. 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.

ARILIO	NCLINIC		Path: Home > study mgmt. > application		
My Works	spaces 🖻	IRB Numbe	r: IRB-18-080 Study Assista	nt Search User Directory	Back
			1. Type	e in name or partial name	Save Selected User(s)
🔒 Director	y Browse/Find:		Last Name: emerson First Name: Dy Department: All Department	(You may enter a partial name to search) ments	2. click "find"
Check for Multiple	Select User	Training	User Name	Department	Email
Π	*	- 84	Carley	General (primary)	caemerson@carilionclinic.org
		3. sele	ect the individual by clicking on the gree	n arrow verify their training is up to date by clicking on the person icon in training column	4. click "save"

> 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 **PRIS³M**, 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 **PRIS³M** 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.)

Section view of Application	Entire view of the Application	
0 📓 General Information	6.0	Application Questions Complete
Setup Department(s) Access	6.1 You have now completed the IRB Application	Please click Save & Continue to proceed to the Initial Submission Packet.
Grant Key Personnel access to the study	The Initial Submission Packet is a short form fille	d out after the IRB application has been completed and is where you will attach protocol-related documents, such as
Application Type	consent forms and recruitment materials. You wi	II also be able to conduct a final review of the IRB application.
Expanded Access For Treatment Use if APPLICATION_TYPE_SS		
0 D Application Questions Complete		

- **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.

		Print Friendly 6 Refresh Constant Fields Save Section Save and Continue to Next Section
Section view of the Form	Entire view of the Form	
1.0 Submission Packet to the Review Board	1.0	Submission Packet to the Review Board
2.0 Application	1.1 IBB Reference Number (Auto Applied	h
3.0 🗎 Informed Consent		
Study Document	IRB-18-080	
Biological Waste D	1.2 Study Title:	
	screenshots for User Manual	
	1.3 Principal Investigatori	
	Carley Emerson	
	1.4 • Lay Summary:	
	Click here to access the text editor.	Click here to provide Lay Summary

- **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.

My Workspaces S	B Number: IRB-18-080 Study	Assistant Initial Re	view Submission Packet -	(Version 1.0)		
			Print Friendly	O Refresh Constant Fields	Save Section	Save and Continue to Next S
Section view of the Form	Entire view of the Form					
1.0 D Submission Packet to the Review Board	2.0 Application					
2.0 Application	2.1 • Attach / Review your com	mleted application for this stor	(vi			
3.0 Informed Consent						
Study Document 4.0 (examples: Copy of Study, Biological Waste D	Unattach Revise/ Edit/ Attach View	Title				
		Carilion IRB Application (Ve	rsion 1.0)			

- **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.

My Workspaces 🔳	IRB Number: IRB-18-080 PI: Emerson, Carley	Study Assistant	Initial Review Subm	ission Packet - (1	Version 1.0)			🖪 Bac
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Section view of the Form	Entire view of the Form							
.0 D Submission Packet to the Review Board	3.0 Informed	Consent						
0 Application	3.1 • Attach the inform	consent(s) for this stu	dyı					
Study Document (examples: Copy of Study Biological Waste D	, GAdd a New Consen	• 🔶	click here to	upload consent docum	nents			
	Detach Version	Title	Category	Languz	ige Expiration Date	Consent Outcome Che	cked Out View Document	
	No Consent(s) have bee	en attached to this form.						
								-

			Study Consent Add:	×on	Save and Continue to Next Section
Section view of the Form	Entire view	•Consent Title:	Provide a title that clearly and adequately explains what the document is (ie: consent, assent, information sheet, which populate		
1.0 Submission Packet to the Review Board	3.0 Inf	*Select the consent to upload:	Browse., No fie selected.		
t.0 🗎 Application	3.1 Atta	*Version Number:	1 .0 fill out the information and select		
1.0 Informed Consent		*Version Date:	08/22/2018 To +		
I.0 (examples: Copy of Study, Biological Waste D	C Add	Category:	Consent 💌		
	Detach	* Language:	English	Hes	ked Out View Document
	No Conser	Description:	You can provide more details about the document here which were not included in the title (ie: consent, assent, information sheet, which population)		
		Comments:	once you have filled out this form and uploaded document, click here		
			Save Conser	t	

	Entire view	of the For	m		unthe your decume	ot was unloaded and	that you uple	aded the correct do	cument
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tion	3.1	3.1 * Attack the inform consent(s) for this study:							
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Study Document (examples: Copy of Study, Biological Waste D	1 Sele	ct or Revis	e Existing 🛟 Add a	New Consent					
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	0	1.0	Provide a title that clearly and adequately explains what the document is (ie: consent, assent, information sheet, which	Consent	English				29.38 KB

- **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.

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Section view of the Form	4.0 Study Document (exa	mples: Copy of Study, Bio	ogical Waste Disposal P	lan, Decontamii	nation template)
0 Application	4.1 Attach any study documents to include	e with the initial review submission packet:			
Informed Consent	Examples would include Drug Brochure	es, Spousor Information, etc.			
Add other suppor checklist, case / documents.clear	Add a New Document Petad Version Title No G nument(s) have been attached to this rting documents, such as recruitment materials, eport forms, full protocol, grant application, etc. tem as It is baleded from where It's uploaded, rty labeled. Also assign a category to the docum	forn forn eligibility The title will o be sure the nent for easy	Study Document Add: RooseNo file selected. 0 8/22/2018 ROOSENO PORENO PORENO		×
Clear labeling of IRB review and a	documents here is important for ease of access ipproval.	later on and for Comments:			
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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"

		👟 Print Friendly	O Refresh Constant Fields	Save Section	Save and Continue to Next Section
Section view of the Form	Entire view of the Form				
1.0 Submission Packet to the Review Board	5.0 Signoff				
2.0 Application	5.1 Please add the department chair or division chief for signoff.				
3.0 🗋 Informed Consent					
Study Document 4.0 (examples: Copy of Study, Biological Waste D	Add Selected User				
5.0 🗟 signatt					

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

My Workspaces 🔳	IRB Number: IRB-18-092 PI: Researcher, IRB	Study Assistant	Initial Review Submission Packet - (Version 1.0)		🚺 Back
Section view of the Form	Entire view of the Form			Rint Friendly	Signoff and Submit
1.0 Submission Packet to the Review Board			Form has been Completed!		
2.0 Application			Instruction of Form has Been Completed Screen		
3.0 Informed Consent					
4.0 Study Documents					
			Exit Form	to subm	it

- > 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.

Section view of the Form	Entire view of the Form	Print Friendly 🔬 Notify PI to Signoff
1.0 Submission Packet to the Review Board		Form has been Completed!
2.0 Application	I	nstruction of Form has Been Completed Screen
3.0 D Informed Consent		
Study Document 4.0 (examples: Copy of Study, Biological Waste D		click on either button to let the PI know the application is ready for signoff. The PI will receive an
5.0 🖻 signoff		
		Exit Form
	click here to create a PDF of your entire submission that you will be able to save to your computer for your files	Create PDF Packet

CARILIONCLINIC Department: CC- Ge Path: Home	neral				7 Help	A My Profile	Log out
My Workspaces II PI: Emerson, Carley	Study Assistant						Back
Study Status: Draft IRB Number : IRB	18-081 Study Title	testing sig	noff with	this role as study team mer	nber and C	BE as PL8.23.18	
Protocol Items	The Principal investigator has I	been notified to com	plete the si	utmission			
Study Application				ок			
Other Study Documents +			Outstand	ing Suhmission(s)			
		Track Location	Ref Number	Request Type			Process Submission
Carilion Clinic - Conclusion Form		Waiting for PI	000169	Click on the hyperlink to ed	t/view the s ssion Pack	ubmission. et	Retract Submission
Carilion Clinic - Continuing Review Form		Signon					
Carilion Clinic - Promptly Reportable Information Form							
Carilion Clinic - Research Change / Update Form							
Initial							
Initial							
Initial Review Submission Packet							

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

Study Status: Draft TRB Number : IRB-18-081 Study Title Submissions Study Management	testing signoff with this role as study team member and CBE as PL8.23.18 can view more details about submission history by clicking the Submissions History	
Study Application	Submissions History Study Correspondence	
Informed Consent		
Other Study Documents	Outstanding Submission(s)	
	Track Ref Location Number Request Type	Process Submission
Carilion Clinic - Conclusion Form	Click on the hyperlink to edit/view the submission.	Retract Submission
Carilion Clinic - Continuing Review Form	signoff	1
Carilion Clinic - Promptly Reportable Information Form	Click here if you need to with	draw
Carilion Clinic - Research Change / Update Form	the submission. The submissi only be withdrawn until the II	on can RB
Initial	begins processing. Once proc begins, it cannot be withdraw	essing m. You
Initial	will need to contact the IRB to request withdraw	0
Initial Review Submission Packet		

Study Status:	Draft	IRB Number :	IRB-18-081	Study Title :	testing signoff	with this role as study team men	ber and CBE as	PI8.23.18	
Submissions	in Process	Completed Submissio	ns Subm	issions Returned wi	th Changes				👟 Print Friendly
Referer Number	er Location	Status Request Type	Detail	s Review Board		View Outcome Review Process Letters	Meeting Date	Review Outcome	A Date Received
000169	21	Initial Review Submis Packet	ssion						
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Submiss you this	sions history pages is in process	ge shows	c	ick here for more de	tails				
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Status	Detw Details	Date Received / Date C	ompiered	Carley Emerson	as Principal Inves	stinator review and apply signoff			
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×		08/23/2018 10:07:22 08/23/2018 02:14:43	PM EDT	Initial Review Su	Dmission Packet	is waiting to be submitted			
		shows it was sent to PI fr under View Details for m	or signoff. Click o ore details	n PI icon					
My Works	spaces 🔳	Study Assistant	Submission	Routing Signo	10 as 01 - 0 - 73 - 10				Back
Submiss	sion Reference N	umber: 000169	no role uo orday re	an menor and eac	63 F10.4.5.4.0				Printable Version
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		Application	Review Submiss	ion Packet - (Versio	n 1.0)				
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Carlı do yo	ey Emerson as P Inve: ou Approve or Do subn	rincipal stigator my this nission?	Comments:						
		shows this ha	s not yet been sig	ned off	ב				

- **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

workspaces			
	Featured Study Operations	Tasks	
1	Create a New Study	View All Study Tasks	18
1	View My Studies	Waiting Submission	1
	Start a Study Submission Form	Submission Response	3
	Track Approvals	Submission Routing Signoff	5
I	Incomplete Forms	Submission Correction	
Study	Assistant		*

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5 m	sult(All Carrii s) found	ion Clinic IRB	Submission Ro to outstandin Click to Open applicable sut	outing Signoff" butt tasks. Click the ico column to signoff o mission	Task List: S on bring the PI on under the in the	ubmission Routing Sign	off	•
c o	ick o ren	Task Type	Received	Study Status	Abbreviated Title or Key Words	Principal Investigator	Review Board	RB Number	RB Expiration
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My Workspaces	•	Study Assistant	Submission Routing Signoff	🚺 Bac
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	Study	Title: testing signoff with	this role as study team member and CBE as PI8.23.18	
Submission Referen	nce Nun	nber: 000169		
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		Include		
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Submissi	aon For	Submission Forn	(s)	
		🗖 Initia	Review Symmission Packet - (Version 1.0)	
		Application		
		Carili	op RB Application - (Version 1.0)	
ertification of Pri	incipa	Investigato		
Carley Emersor	n as Prin	cinal		
do you Approve	Investig	ator C Approve C L	comments: Click here to add comments.	
ao tou Approve	submis	sion?		
			Save Signoff	

CARILIONCLINIC	Account: Carley Emerson Department: CC - General Path: Home > signoff sheet		🕜 Help	My Profile	Log out
My Workspaces 🔳 📕	RB Number: IRB-18-081 I: Emerson, Carley Study Assistan	nt Initial Review Submission	Packet - (Version 1	0)	🖪 Back
click to view/edit Informed Con	sent Print Friendly O Re	fresh Constant Fields	Save and Continue	to Next Section	Exit Form
Section view of the Form	Entire view of the Form	edit supplemental			
1.0 Review Board	2.0 Application				
3.0 Informed Consent	2.1 • Attack Review your completed ap	plication for this study:			
Study Document 4.0 (examples: Copy of Study, Biological Waste D	Unattach Revise/ Edit/ Title				
5.0 Signoff	8	click to v	view/edit IRB application		
	<hr/>				
	click to return to signoff	page			

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.

	s 💌	Study Assi	stant	find stud view det	ly then click on ails click 'track l	history, then to ocation						
C					Study Title		-					
Click to open	Study Status	Review Board	RB Number	RB Expiration	Abbreviated Title or Key Words	- Principal Investigator						
8	Pending - Submitted fr Initial Review	Canlion Clinic IRB	IRB-18-081	<not assigned=""></not>	testing signofi testing signoff with this role as study team member and CBE as PI8.23.18	f with this role as study i ¹ Emerson, Carley	team member a ↓ History	Items	Forms	23.18 Ø Hide	Сору	Delet
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