Begin on the Study Assistant Workspace home screen. Select "Create a New Study."

4y Workspaces 🛛 🖃	Study Assistant		
	Featured Study Operations		Tasks
	Create a New Study	View All Tasks	٥
	Start a Study Submission Form		
	View My Studies		
	View My Studies Submissions		
	Track Approvals		
	Forms Pending Submission		

You are taken to the first of three sections of the application, known as the Study Shell. After the first three initial screens of this application are complete, a new study record is created in the system. Begin filling in the information.

After this point, you can exit the application at any time and it will save a Draft. Navigate through the Sections using the gray "Save and Continue to Next Section" button.

My Workspaces 🔳	Study Assistant	Study Application		🖪 Back
Section view of Application	Entire view of	the Application	Save Section	Save and Continue to Next Section
1.0 D General Information	1.0 Gene	eral Information		
	* Please ente	er the full title of your study::		
	Human Sul	oject Determination Test		

The next section of the Study Shell is where you will Setup Department(s) Access. Add or Remove Departments using the gray buttons.

My Workspaces 🔳 IRE	Number: IRB-2021-0024	Study Assistant	McLaren Initial Review Application (Version 1	🖪 Back			
Section view of Application	Entire view of the Applica	ion	Print Friendly	Save Section	Save and Continue to Next Section		
1.0 General Information 2.0 Setup Department(s)	2.0 Add departmer	its					
Access 2.1 List departments associated with this study:							
	Is Primary?         Department           Image: I	Name ral		Add Department	Remove Department		

Next, you will Grant Key Personnel access to the study. Any user added to the study will have the ability to access the study in iRIS. To add any user to any role, click the Setup Study Personnel button.

My Workspaces 🔳 IRB N PI:	lumber: IRB-2021-0024 Klaver, Andrea	Study Assistant	McLaren Initial Review Application (Version 1.0)	🖪 Back
Section view of Application	Entire view of the Applicat	tion	Print Friendly Save Section	Save and Continue to Next Section
1.0 🗋 General Information				
2.0 Setup Department(s) Access	3.0 Assign key stud	ly personnel(KSP	) access to the study	Setup Study Personnel
3.0 Grant Key Personnel access to the study	3.1 *Please add a Principa	al Investigator for the	study:	
	3.2 If applicable, please s	elect the Research Sta	aff personnel	
	A) Additional Investigators			
	B) Research Support Staff			
	3.3 *Please add a Study C	Contact		

Another screen will display in a pop-up within your window showing the study personnel list and their roles, as it is populated.

For example, let's search by Last Name. Click on the gray Find User/Search Directory button at the top right of the window.

	Setup Study Personnel X							Profile -	
- Diriciorei	User Search by Study	Last	Name: Klav	er	First Name:		Find User/Search Directo	IIV.	Er Lög ött
My Workspaces 🛛 🗷			Study: All D	vepartments		~		•,	K Back
		Searc	Search From:   IRIS Database   LDAP Directory						Continue to Next Section
Section view of Applicat		Select	Training?	Name	Department		Email		
		0	2	Klaver, Andrea	General		Andrea.Klaver@mc	laren	
1.0 🗎 General Information									
2.0 Setup Department(s) Access									etup Study Personnel
3.0 Grant Key Personnel access to the study									
		4						•	
		Selected S	Study Perso	onnel:					
		Principal In	vestigator						
			Name		Role				
		No Personne	l has been sele	ected for this group.					
		Additional I	nvestigators						
			Name		Role				
		No Personne	l has been sele	ected for this group.					
								-	
					Clear Key Study Personnel	Close Se	etup of Study Personnel		

Click the Select icon to select the user. Another screen will display in a new pop-up asking you to Select the Role the user will have on the study.

The user you add as the Principal Investigator will default to the Study Contact. You may add additional Study Contacts as needed. A Study Contact is a user on the study who will

receive study related notifications from iRIS. A Study Contact is usually also another role on the study, like a Research Coordinator. Click Save to add more Key Personnel.

C Mel arou		Ad	id Personnel Role	1	< X	Profile z Chi os out
	User Search by S	Select the Role for Andrea Klaver :				
My Workspaces 🔳	Create My Personne				7Search Directory	K Back
Section view of Applicat		Principal Investigator			a	Continue to Next Section
1.0 General Information					rea.Klaver@mclaren	
2.0 Setup Department(s) Access		O Additional Investigators	none	~		etup Study Personnel
3.0 🗎 Grant Key Personnel		Research Support Staff	none	$\checkmark$		
access to the study		Study Contact			,	
		O Department Administrator	none	$\checkmark$	<u>^</u>	
		Would you like to include as a Study Contact	? 🖲 Yes 🔿 No			
					Personnel	
	The Stu			Cancel Save	e typically	

Next, you will be asked to enter General Information about your study submission. This includes whether medical residents, medical students, nursing students, etc. are participating in the study. Continue filling in the information.

My Workspaces 🔳	IRB Number: IRB-2021-0024 PI: Klaver, Andrea	Study Assistant	McLaren Initial Review Application (Version 1	🖪 Back			
Section view of Application	Entire view of the Applica	tion	Print Friendly	Save Section	Save and Continue to Next Section		
1.0 General Information 2.0 Setup Department(s)	4.0 iRIS Application	: General Informa	ation				
3.0 Grant Key Personnel access to the study	4.1 Form completed by: Andrea Klaver						
4.0 Information	<b>4.2 Date of Submission</b>						
	4.3 Required Reporting Information						
	1. Select from one of the McLaren Center for Rese	following groups that earch Innovation	your study falls under.				
	<ul> <li>Karmanos Cancer Cente</li> <li>Graduate Medical Educa</li> </ul>	r MHC Community Based tion Department (GME) r	l sites required research project				

Indicate your Request for Determination of Human Subject Research in the next section.

My Workspaces 🔳 IRB PI:	Number: IRB-2021-0024 Klaver, Andrea	Study Assistant	McLaren Initial Review Application (Version 1	🖪 Back		
Section view of Application	Entire view of the Applica	tion	Print Friendly	Save Section	Save and Continue to Next Section	
1.0       Image: General Information         2.0       Image: Setup Department(s) Access	5.0 Type of Applica	tion ill you be conducting?				
3.0 Grant Key Personnel access to the study	<ul> <li>Request for Determinat</li> </ul>	on of Human Subject Re	search			
<ul> <li>4.0 Application: General Information</li> <li>5.0 Type of Application</li> </ul>	<ul> <li>Entering a new study a</li> <li>* IRB review non-resea</li> <li>Request to Use an External</li> </ul>	oplication for review by M rch activity where the IR mal IRB	IcLaren Health Care IRB B has regulatory authority and oversight			

Information to complete in this section includes:

- INVESTIGATOR INFORMATION: Indicate Principal Investigator (PI) by selecting one of the boxes below.
- RESIDENT/FELLOW/STUDENT SUB-INVESTIGATOR (if applicable): The individual acting in role of co-investigator under the supervision of the PI.
- ACADEMIC ADVISOR (if applicable): Required for students who are McLaren employed and NOT a part of McLaren's GME program. This person is required to sign this form along with the PI.
- MORE SECTIONS: Project Information, Study Sites, Study Title, Primary Objective, and Secondary Objective (if applicable), Summary, Subject Population, Common Rule Determination, Explanation why you believe your activity does not require IRB review, etc.

My Workspaces 🔳 IRB r	Number: IRB-2021-0024 Klaver, Andrea	Study Assistant	McLaren Initial Review Application (Version 1.0)	🖬 Back
Section view of Application	Entire view of the Application	١	Print Friendly Save Section	Save and Continue to Next Section
1.0 🗎 General Information	6.0 Request for Deter	mination of Hun	nan Subject Research	
2.0 Setup Department(s) Access	6.1 All research involving hu	ıman subjects at Mc	Laren Health Care subsidiary hospitals must be reviewed by the McLaren Health C	are Institutional Review
3.0 Grant Key Personnel access to the study	Board (MHC IRB). For the limited to, your protocol, interview questions, etc.	he IRB to make a de , data collection inst	termination, you will need to complete this application and attach supporting doc trument, list of all variables and/or information to be used, recorded, and/or anal	uments such as, but not yzed, and any surveys,
4.0 IRIS Application: General Information				
5.0 Type of Application	** Missing documents will delay	y the determination pr	rocess **	
6.0 Provide the formation for the formation for the formation of Human Subject Provide the formation for the formation f	6.2 INVESTIGATOR INFORM	ATION: Indicate Prin	ncipal Investigator by selecting one of the boxes below.	
Rescal UI	<ul> <li>PRINCIPAL INVESTIGATOR research activities.</li> <li>* FACULTY/ADVISOR PRINC is the sub-investigator(s). T research projects conducter governing the protection of</li> </ul>	(PI)- The individual th CIPAL INVESTIGATOR ( The IRB holds this pers d by student/resident/ human subjects of res	IRB holds ultimately responsible for the design, conduct and evaluation of human subject (PI)- The individual acting as the PI over research project where the student/resident/fellov son responsible for reviewing the application and accepting responsibility for assuring fellow sub-investigators adhere to the federal and state regulations and institutional policie search.	v v
	Name:			

Note regarding signatures:

- 1. If you are the PI of this study: You will be required to electronically signoff when you reach the end of this Submission.
- For Medical Residents and Fellows that are part of MHC Graduate Medical Education Program: You are required to route this application to the PI of the study and your Ph.D. Advisor for signature (sign-off) prior to submitting to the IRB.
- **3.** If you are other research personnel on this the study: At the end of this Submission, you will be allowed to route this Study to notify the individual(s) such as the Principal Investigator, Ph.D. Advisor, Academic Advisor etc. that there is a submission awaiting their signature.

My Workspaces IRB N PI:	umber: IRB-2021-0024 Study Assistant	McLaren Initial Review Application (Version 1.0)	🗹 Back								
Section view of Application	Entire view of the Application	Print Friendly Save Section	Save and Continue to Next Section								
1.0          General Information          2.0          Setup Department(s)         Access	7.0 Confirmation of Scientific or Sci 7.1 A research plan must be scientifically sou	holarly Review of Validity and and minimizes risk to the subjects and can reasonably be expected to answer the	proposed question. Scientific								
3.0 Grant Key Personnel access to the study	or scholarly review can be performed by approval of a human research study. See participant safety as needed, that role wi	or scholarly review can be performed by the members of the IRB reviewing the study and is based on the criteria required by federal regulations for IRB approval of a human research study. See Policy MHC-RP0109 Criteria for IRB approval. Although the IRB can review issues of scientific design and participant safety as needed, that role will be a secondary one.									
4.0 iRIS Application: General Information	This application should be used for scient below.	tific reviews that are not required to go through the McLaren Protocol Review Commit	tee (PRC). See instructions								
5.0 🗎 Type of Application											
6.0 B Request for Determination of Human Subject Research	Instructions: • All Prospective Interventional Studies	scientific reviews will be done by the convened MHC Protocol Review Committee (PRC). Send									
7.0 Confirmation of Scientific or Scholarly Review of Validity	<ul> <li>Already have PRC approval: Skip this for</li> </ul>										
	<ul> <li>For Non-Interventional Studies         If you are a researchers not associated with             review and sign off: The Reviewer must be     </li> </ul>	h the Graduate Medical Education program, complete this form. Route this form for appropriate someone other than the $\mbox{PI}.$									
	If you are affiliated with the Graduate Medi the Program Director is the PI on the study Director is the PI or if there is no Assistant	ical Education program, complete this form. Route form for appropriate review and sign off: If y then review/ginature is done by the Assistant Program Director. If the Assistant Program Program Director, the review/signature is done by Chief Medical Officer (CMO).									

In this section, it is noted that the **Scientific Reviewer's** signature confirms the soundness of the research design and the ability of the research to achieve its aims.

The Scientific Reviewer must be someone other than the PI.

For Medical Resident and Fellows that are part of MHC Graduate Medical Education Program, the Scientific Reviewer must be:

- Program Director
- Assistant Program Director (if Program Director is the PI)
- Chief Medical Officer (if Assistant Program Director is the PI or if no Assistant Program Director)

Medical Residents and Fellows that are part of MHC Graduate Medical Education Program must also obtain signature of Ph.D. Advisor.

<u>At the end of the Submission</u>, you will be prompted to select individuals to route this Submission to for review (i.e. Ph.D. Advisor (if applicable)).

When you are finished filling out the form sections, iRIS will transition you into the Initial Review Submission Form/Packet. You will have transitioned to the next section when the screen appears that is shown below. An informative message between completing the Study Application and moving onto the Submission Packet has been added for clarity.

My Workspaces 🔳	IRB Number: IRB-2021-0024 PI: Klaver, Andrea	Study Assistant	Initial Review Submission Packet - (Version 1.0)	🚺 Back
Section view of the Form	Entire view of the Form  1.0 Application  1.1 * Attach / Revise/ Editory  Unattach Revise/ Editory  Comparison	Yo The System hi Packet Please complete any supi	Print Friendy Save Section but have completed the Application. and your application has been attached. It he Initial Review Submission and your application has been attached. It he Initial Review Submission Packet and attach porting documents with your submission. OK (9)	Save and Continue to Next Section

The Submission Packet functions the same way as the Study Application, regarding navigating and completing sections by adding information into the fields within each section. Complete this form by completing each section, attaching the necessary documentation, and clicking the Save and Continue button to proceed.

The Study Application will be attached to the Submission Form, along with any supporting study documents. Because the Study Application has already been completed and you transitioned to the Initial Review Submission Form, the Study Application will auto-attach.

NcLaren	Account: Andrea Klaver Department: MHC - Genera Path: Home > study mgmt.	ıl			? Help	My Profile -	C+ Log out
My Workspaces 🔳	IRB Number: IRB-2021-0024 PI: Klaver, Andrea	Study Assistant	Initial Review Submissi	ion Packet - (Version	1.0)		🖪 Back
				Print Friendly	Save Section	Save and Continue to	Next Section
Section view of the Form	Entire view of the Form						
1.0 🗎 Application	<sup>1.0</sup> Application						
	1.1 * Attach / Review your	completed application	n for this study:				
	Unattach Revise/ Edit, Attach View	/ Title					
	8	McLaren Initial Re	view Application (Version 1.0)				

Upload all study documents in this section. A numbered list has been included in this section for your convenience.

My Workspaces 🔳	IRB Number: IRB-2021-0024 PI: Klaver, Andrea	Study Assistant	Initial Review Submission Packet - (Versio	n 1.0)	🖪 Back
	Further class of the Form	1	Print Friendly	Save Section	Save and Continue to Next Section
Section view of the Form 1.0 Application 2.0 Attachments	2.0 Attachments     2.1 Please upload study d     For Human Subject Resea     1. Protocol document if avail     2. Handouts	ocuments. rch Determination Requ able	uest attach the following documents:		
	<ol> <li>Surveys</li> <li>Questionnaires</li> <li>Supporting Documents</li> </ol>				

		Add a	New Document	Add Multiple Doc	uments			
Ī	Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	No Docu	ument(s) h	nave been attached to this form	n.				

Once the Study Application and Submission Packet are complete and the required documents are attached, the form is ready to send to the IRB. You will be presented with a screen notifying you that the form is complete, as shown below.

My Workspaces 🔳	IRB Number: IRB-2021-0024 PI: Klaver, Andrea	Study Assistant	Initial Review Submission Packet - (Version 1.0)		🖪 Back
				Print Friendly	Signoff and Submit
Section view of the Form	Entire view of the Form				
1.0 Application			Form has been Completed!		
			Project Access and Assignments		
			Exit Form Signoff and Submit		

If you are the PI of this study: You will be directed to electronically signoff when you reach the end of the Submission. Select the Signoff and Submit button.

For Medical Residents and Fellows that are part of MHC Graduate Medical Education Program: You are required to route this application to the PI of the study and your Ph.D. Advisor for signature (sign-off) prior to submitting to the IRB. (If you are NOT the PI on this study, the buttons on this page will be "Exit Form" and "Notify PI to Signoff." Select the Notify PI to Signoff button.)

**If you are other research personnel on this the study:** At the end of the Submission, you will be allowed to route this Study to notify the individual(s) such as the Principal Investigator, Ph.D. Advisor, Academic Advisor etc. that there is a submission awaiting their signature.

If your role on the study does not allow submission of forms, you will only have the Exit Form button. Exit the form and the PI and other Study Contact will be notified that a submission is waiting to be sent to the IRB.

Prior to initiating the signoff tasks, iRIS will ask you to define your Routing Signoff List.

Include the PI of the study, your Ph.D. Advisor, and a Scientific Reviewer [could be Program Director; Assistant Program Director (if Program Director is the PI); or Chief Medical Officer (if Assistant Program Director is the PI or if no Assistant Program Director)].

			Setup for Submission Routing and	Signoff		x
This so indicat signof The or	creen enable tes the pers f process. T rder of the A	es the collecti on is included he Add Additi Additional Per	on of Key Personnel and Additional Personi I in the signoff process. The Check box "Un onal Personnel button is used to search fro sonnel is to create a review order for the a	nel for Revie ichecked" in m the user o ssigned ners	w and Signoff. The Check box "Checked" dicates the person is not included in the database and add them to the routing list. sonnel If personnel have 1 2( sequential )	•
Select th	e Key Per	sonnel for	Submission Routing and Signoff:			
Include in signoff	Approved	Name		Role		
		🚴 Andre	a Klaver	Principal Ir	nvestigator	
Select Ac Include in signoff	dditional F Order	Personnel f	or Submission Routing and Signoff: Name	Role	Add Additional Personnel to the Routing List	t
Select Ad Include in signoff No addition	dditional F Order nal personi	Personnel f Approved nel have bee	or Submission Routing and Signoff: Name en added to the signoff routing list.	Role	Add Additional Personnel to the Routing List	t

A screen will display in a pop-up within your window showing the Routing Signoff List, their Role, and their Order, as it is populated by you. (As the PI signature is required, that user will be pre-selected, and you will NOT be able to de-select the PI from the signoff process.)

To generate your Routing Signoff List, select the Add Additional Personnel to the Routing List button.

Another screen will display in a new pop-up where you can search for and find users in the iRIS Directory to add to your Routing Signoff List (below). Select the user and their Role.

	Add Additiona	I Key personnel to t	he Routing Signof	if List		x
La	st Name: Richards	First Name: Marke	eda 🗸 🗸		Find User/Search Dir	rectory
Sear	r <b>ch From: ()</b> iRIS Database () LDAP D	irectory				
Select	ame	Department		Email		
6	chards, Markeda	General		Markeda.Richar	ds@mclaren.org	
The Addit	tional Personnel will to be added to Name	the signoff routing list	upon clicking the "S	Save - Add to Ri	outing List" button	
8	시 Markeda Richards		PhD Advisor		~	

Continue adding users to your Routing Signoff List in the same manner.

Add Additional Key personnel to the Routing Signoff List x										
Last Name: Waris by All Departments	First Name: Mahjabeen	~		Find User/Search Directory						
Search From: IRIS Database C LDAP	Directory									
Select I me	Department	E	mail							
aris, Mahjabeen	General	M	lahjabeen.Waris	@mclaren.org						
'he Additional Personnel will to be added t	to the signoff routing list upon a	clicking the "Sa	ve - Add to Ro	uting List" button						
he Additional Personnel will to be added t Remove Name	to the signoff routing list upon a Role	clicking the "Sa Advisor	ve - Add to Ro	uting List" button						

## \*\* Please note! The following step is not required! Ordering your signoffs is optional. \*\*

After you have saved your Routing Signoff List, iRIS allows you to list the users in the order you'd like them to receive the routing for signoff *if you wish to do so*.

The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2 (sequential) respectively, the first personnel applies signoff before the second personnel receives it. If personnel have 1, 1 (parallel) respectively, the first and second personnel receive it at the same time.

If a personnel denies the signoff, then the submission must be revised and resubmitted with the routing starting from the beginning.

You have two options at this point:

1. Order your signoffs: iRIS will send signoff notifications in the order you choose. Signoff notifications will not be sent to the next user until the previous user has signed off. See screenshot below.

			Setup for Submission R	touting and Sig	jnoff		x
This indication	screen enab ates the pers off process. 1	les the collectior son is included i The Add Additior	n of Key Personnel and Addi n the signoff process. The C nal Personnel button is used	tional Personnel fo heck box "Unchec to search from th	or Review and Signoff. ked" indicates the pers a user database and a	The Check box "Checked" son is not included in the dd them to the routing list.	The 🗸
Select t Include in signoff	the Key Pe Approved	ersonnel for S Name	ubmission Routing and	Signoff:			
R		Andrea Kl	aver	Princ	ipal Investigator		
		-					
Select /	Additional	Personnel fo	r Submission Routing a	nd Signoff:	Add Additional	Personnel to the Routing	List
Select / Include in signoff	Additional Order	Personnel fo	r Submission Routing a me	nd Signoff:	Add Additional	Personnel to the Routing	List
Select / Include in signoff	Additional Order	Personnel fo Approved Na	r Submission Routing a me Markeda Richards	ind Signoff:	Add Additional Role PhD Advisor	Personnel to the Routing	List
Select / Include in signoff	Additional Order	Personnel fo Approved Na	r Submission Routing a me Markeda Richards Mahjabeen Waris	ind Signoff:	Add Additional Role PhD Advisor Eaculty/Advisor PI	Personnel to the Routing	List
Select / Include in signoff	Additional Order 1 2	Personnel fo Approved Na 2	r Submission Routing a me Markeda Richards Mahjabeen Waris	Ind Signoff:	Add Additional Role PhD Advisor Faculty/Advisor PI	Personnel to the Routing	List
Select / Include in signoff	Additional Order 1 2	Personnel fo Approved Na 2	r Submission Routing a me Markeda Richards Mahjabeen Waris	nd Signoff:	Add Additional Role PhD Advisor Eaculty/Advisor PI	Personnel to the Routing	List
Select / Include in signoff	Additional Order 1 2	Personnel fo Approved Na 2	r Submission Routing a me Markeda Richards Mahjabeen Waris	Ind Signoff:	Add Additional Role PhD Advisor Faculty/Advisor PI	Personnel to the Routing	List

2. Do not order your signoffs: If you do not want any signoff notifications withheld (i.e. you would like all signoff notifications sent out simultaneously), do not order your signoffs. Make sure that the number in each Order box is "1." See screenshot below.

			Setup for Submission Routin	g and Signoff		)
The resp resp be i	e order of the A pectively, the f pectively, the f revised and re	Additional Per first personne first and seco submitted wil	sonnel is to create a review order for applies signoff before the second p nd personnel receive it at the same th the routing starting from the begi	or the assigned person personnel receives it. I time. If a personnel d inning.	nel. If person If personnel ha enies the sign	nel have 1, 2( sequential ) ave 1, 1( parallel ) off, then the submission must
Select	the Key Per	sonnel for	Submission Routing and Sign	off:		
Include i signoff	n Approved	Name		Role		
◄		🧏 Andre	a Klaver	Principal Inve	estigator	
				ſ		
Select Include ii	Additional I	Personnel f	or Submission Routing and Si	gnoff:	Add Additiona	al Personnel to the Routing List
Select Include in signoff	Additional I n Order	Personnel f	For Submission Routing and Si	i <b>gnoff:</b> Role PhD Advi	Add Additiona	al Personnel to the Routing List
Select Include in signoff	Additional I Order 1 1	Personnel f	For Submission Routing and Single States Sta	ignoff: [ Role PhD Advi Faculty/A	Add Additiona sor	al Personnel to the Routing List

When you have verified your Routing Signoff List and Order, select the Save – Start Signoff Routing button (below). This will initiate the process of notifying the users that they have been assigned a signature task. System-generated emails will be sent.

		Setup for Submission	n Routing an	d Signoff		x
This s made then t	creen is for r the button " he submissio	eviewing the signoff routing list. You must answ Save - Start Signoff Routing" becomes enabled n board review(s). Clicking the "Go back to Mal	ver "Yes" or "No to be clicked. O ke Changes" wi	" to the finalization of the Personnel. licking the "Save - Start Signoff Routi II place you back to editing the routing	Once the "Yes"" selection is ing" will start the routing list an g list. Clicking the "Cancel -	nd 📕
Finialize	List of Pe	rsonnel for Submission Routing and Sig	noff:			
Order	Approved	Name	Role			
		Andrea Klaver	Principa	l Investigator		
1		👃 Markeda Richards	PhD Ad	visor		
2		🤶 Mahjabeen Waris	Faculty/	Advisor PI		
Please veri	ify the list a	bove represents the finalize Personnel for	review and si	gnoff? 💿 Yes 🔿 No		
		Cancel - Fin	alize later	Go back to Make changes	Save - Start Signoff Routin	20

Users also receive a corresponding Submission Routing Signoff task on their homepage.

All	Ta	sks Ou	tstanding Completed		*
	A	ll Tasks	Study Tasks	Task I	ist: All v
2 r	esult(	s) found			1 - 2
		Click to open	Task Type	Z Date Received	Description
(			Submission Routing Signoff	01/20/2021 12:53 PM EST	Andrea Klaver as Principal Investigator review and apply signoff

When the user opens the task to complete the signoff, this screen will appear:

My Workspaces	Study	Assistant	Submis	sion Routing S	ignoff	🖪 Back
						Save Signoff
Submission Reference	tudy Title e Number	Human Subje 000940	ct Determinatio	on Test		
						Printable Version
6. hui iniu	. Farm(	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version	
Submission	i Form(	Submission	Form(s)			
					Initial Review Submission Packet - (Version 1.0)	
		Application				
					McLaren Initial Review Application - (Version 1.0)	
Andrea Klaver as Principal In Do you Approve or Deny this sui	vestigato bmission	r ? • Approve	Deny	Comment I appro	here to add comments.	

The Submission Packet and the Study Application are available for review.

The user may add comments by clicking the Click here to add comments button.

The user may Approve or Deny the submission and save their sign off by clicking the Save Signoff button.

You can track the status of your study submission on your iRIS home screen (Study Assistant Workspace) under the Studies Submission Status – In Progress section header.

tudies S	Subm	nission S	itatu	s - In Pr	ogress				Search	for RB Number, Ti	tle, Alias		Search 🔅
In Pro	gress			Completed									
result(s) four	nd												1 - 1
Click to open	Study	Reference			DR Number	Form Name	Study Title		Earner Austhan		ZDate		8-11
Dashboar	rd	Number	Ke	Review Board RB Number Form Name Fo				<sup>X.+</sup> Submi	tted	Actions			
2		000940	IRB		IRB-2021-0024	Initial Review Submission Packet	Human Subject Determin	nation Test	Klaver, Andrea		01/20/202 12:45 PM I	1 EST Steps	Incomplete Tasks Open Steps to Complete
Task	Task A	ction/Details		Task Name		Pre-Subm	ission	Date Crea	ited	Date Completed		Total Time	
Pre-Sub	mission						Retract Submission	01/20/20	21 12:44 PM EST			0 Day(s) 0 Ho	ur(s) 10 Minute(s)
Completed				Initial Review	Submission Packet is wai	ting to be submitted		01/20/20	21 12:44 PM EST	01/20/2021 12:4	20/2021 12:45 PM EST Day Hc 0		our Minute 0 0
Received	Modi	ify Signoff Routin	g List	Assign Depart	ment Personnel for Signo	ff		01/20/20	21 12:45 PM EST	01/20/2021 12:4	15 PM EST	Day H 0	our Minute 0 0
Received		Pending Signoff		Andrea Klaver	as Principal Investigator	review and apply signoff		01/20/20	21 12:53 PM EST			Day H 0	our Minute 0 1
Received		Pending Signoff		Andrea Klaver	as Principal Investigator	review and apply signoff		01/20/20	21 12:53 PM EST			Day H 0	our Minute 0 1

To modify your Routing Signoff List, you may select the Modify Signoff Routing List button. This button only appears PRIOR to IRB submission (Pre-Submission) while signoffs are still pending.

Once the signoffs have all been completed, this button will change to the View Signoff Routing List button (read-only).