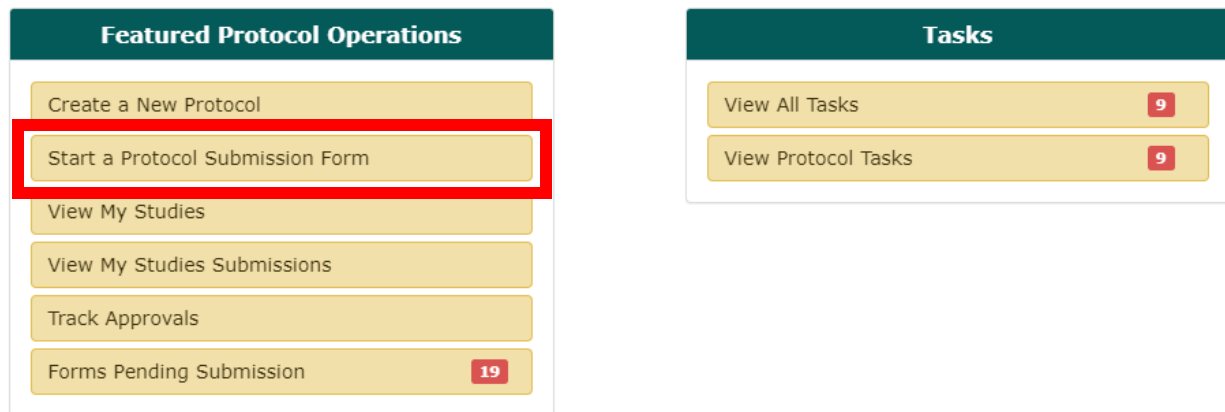


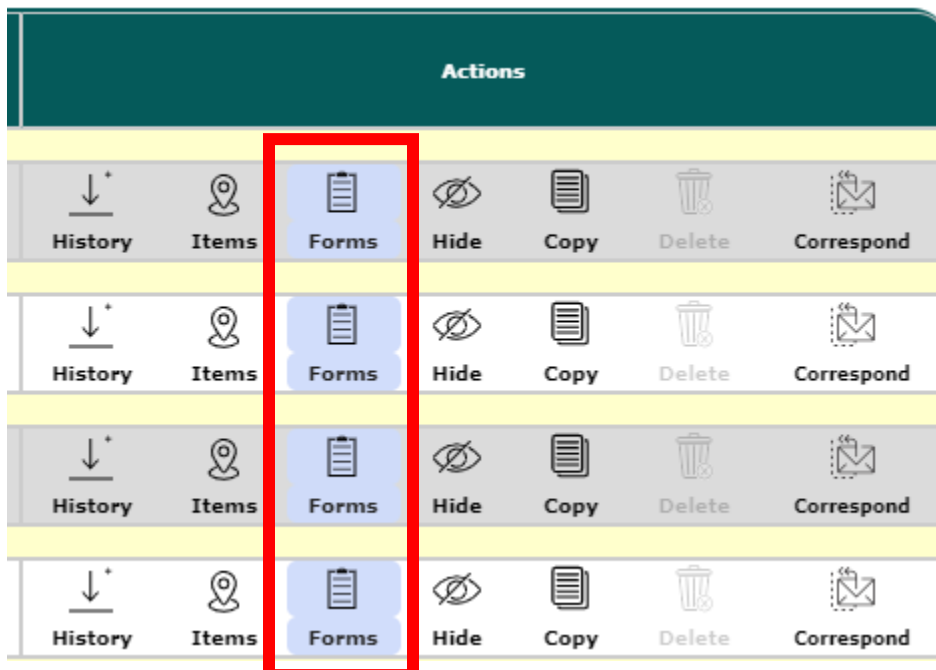
Submitting a Modification

At any point during the life of your study you can create a Modification form to submit changes for approval. Certain changes to a study require you to submit the change to the IRB before that change can be applied to the study. Changing key study personnel, the study population, recruitment, and/or enrollment goal, and a change in Conflict of Interest (COI) are just some of the items that must be submitted in the form.


To begin a Modification form, select the yellow **Start a Protocol Submission Form** button on your iRIS home screen.













You will be automatically directed to your **All Studies** section tab. The **Forms** icons next to each of your studies will flash light blue for a few seconds. Click on the **Forms** icon next to the study you would like to submit a Modification form for.



A new screen will display in a pop-up within your window showing the different types of forms you may submit in iRIS for your study.

Find the **McLaren Modification Form** and click the  icon underneath the **Start a new Submission** column.

Submission Form List X			
	Version List	Start a new Submission	Edit Incomplete Submissions
McLaren Continuing Review form			
McLaren IRB Final Report Form			
McLaren Modification form			
McLaren Unanticipated Problem Report			
Protocol Violation/Exception Report			

Within this form, you will be presented with progressive questions. Based on the answers you provide to the questions you see on the screen, you will be able to request changes to certain areas of your study.

Complete the sections of the Modification form using the gray **Save and Continue** button in the upper right of each screen to navigate through the sections.

Section view of the Form Entire view of the Form

1.0 Modification/Amendment

1.0 Modification

1.1 This Modification is related to COVID-19.

Yes No

1.2 Examples of changes that require an update to the study application:

- Change in Study Protocol - (Administrative/Editorial, Study Overview/Inclusion/Exclusion Criteria, Study Design, New/changed Research Participant Enrollment & Participation, Change or Addition of Vulnerable Participant Populations, New/modified Potential Benefits to Participants, Change in Data Collection Methods, Change in Radiation Risks, Change in Drugs, Change in Devices, Change in Gene Therapy)
- Recruiting/Advertising Materials
- Revisions/additions to the Consent, Assent and/or Information Sheet

For Amendment questions please contact IRB at hrrp@mclaren.org or call 248-484-4950



Section view of the Form Entire view of the Form

1.0 Modification/Amendment
2.0 IRB Fees
3.0 General Information

2.0 IRB Fees

2.1 The IRB charges an administrative review fee for proposed research applications (<https://www.mclaren.org/uploads/Public/Documents/Corporate/irbrates.pdf>).

Please check the appropriate box below:

Review Fee Submitted to the IRB -- Check Number:
 Request for Invoice
 Review Fees Waived for this study at the time of Initial Review
 Not applicable to this submission



Section view of the Form Entire view of the Form

1.0 Modification/Amendment
2.0 IRB Fees
3.0 General Information

3.0 General Information

3.1 Form completed by:
Andrea Klaver

3.2 Date Submitted:
07/30/2021

3.3 Protocol Number:
IRB-2021-0207

3.4 Protocol Title
Test 063021

3.5 Principal Investigator:
Andrea Klaver



Section view of the Form Entire view of the Form

1.0 Modification/Amendment
2.0 IRB Fees
3.0 General Information
4.0 Modification Submission Type

4.0 Modification Submission Type

4.1 Please select one.

Humanitarian Use Device (HUD) Study
 Modification Request Form When Using an External IRB as an IRB of Record
 All other studies



The image shows two screenshots of a web form. The top screenshot is for section 5.0, 'Current Study Status'. It features a sidebar with menu items 1.0 through 5.0, where 5.0 is selected. The main content area has a heading '5.0 Current Study Status' and a sub-heading '5.1 A) Select one descriptor below that applies to the study:'. Below this are several radio button options, with the third option selected. At the top right, there are four buttons: 'Print Friendly', 'Refresh Constant Fields', 'Save Section', and 'Save and Continue to Next Section'. The bottom screenshot is for section 6.0, 'Modification Details'. The sidebar now shows 6.0 selected. The main content area has a heading '6.0 Modification Details' and a sub-heading '6.1 Select all the proposed changes that apply:'. Below this is a note: 'NOTE: IF CHANGES IMPACT INFORMATION IN THE ORIGINAL APPLICATION, YOU MUST GO TO THE APPROPRIATE SECTION(S) AND ENTER YOUR UPDATES'. This is followed by a list of checkboxes for various changes, with the first checked option being 'Change in Key Study Personnel'. At the bottom, there is a text box with the instruction 'Describe each change and explain the rationale for each change. ("See attached" response is not acceptable)' and the text 'Removing outgoing Resident and Adding incoming Resident.'.

In **Section 6.0 Modification Details**, you will have the opportunity to select which type(s) of Modifications you would like to make to your study.

This section asks you to briefly describe the proposed changes in a free text box.

Further down the screen in this section, you are also asked if there are changes to the consent form, and if the Modification will affect the risks and/or benefits to subjects.

In this example, I would like to add and remove key study personnel.

Section 7.0 Changes in Key Study Personnel gives you the opportunity to amend the list of approved key study personnel through addition or removal.

Click on the Setup Key Study Personnel Request button.

Print Friendly Refresh Constant Fields Save Section **Save and Continue to Next Section**

Section view of the Form Entire view of the Form

1.0 Modification/Amendment
2.0 IRB Fees
3.0 General Information
4.0 Modification Submission Type
5.0 Current Study Status
6.0 Modification Details
7.0 **Changes in Key Study Personnel**

7.0 Changes in Key Study Personnel

7.1 Please complete this section if you are making changes to research personnel.

Assign key study personnel(KSP) Request to the study

Setup Key Study Personnel Request

If applicable, please add the new Principal Investigator for the study:

--	--	--

If applicable, please select the new Research Staff personnel:

A) Additional Investigators

--	--	--

B) Research Staff

--	--	--


If applicable, please add any new Study Contact:

--	--	--

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

If applicable, please select any existing Personnel you wish to remove:

--	--	--

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 list of Key Study Personnel. Select the User and their Role (in a 2nd pop-up; not pictured). To undo an addition, click the  icon.

Setup Protocol Personnel




User Search

Remove Personnel List Create My Personnel Pool

Last Name: Klaver First Name: **Find User/Search Directory**

by Department: All Departments

Search From: iRIS Database LDAP Directory


Select	Training?	Name	Department	Email
		Klaver, Andrea	 General	Andrea.Klaver@m

Selected Protocol Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
 Klaver, Andrea	Co-Investigator

Clear Key Protocol Personnel Close Setup of Protocol Personnel

To remove Key Study Personnel, navigate to the **Remove Key Personnel** section by clicking on the link on the left side of the window.

Setup Protocol Personnel

User Search
Remove Personnel List
Create My Personnel Pool

Save Selections

<input checked="" type="checkbox"/>	Name	Role on the Protocol
<input type="checkbox"/>	Andrea Klaver	Principal Investigator
<input type="checkbox"/>	Andrea Klaver	Study Contact
<input type="checkbox"/>	Andrea Klaver	Study Author

Selected Protocol Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
<input checked="" type="checkbox"/> Klaver, Andrea	Co-Investigator

Clear Key Protocol Personnel Close Setup of Protocol Personnel

In the top section, find the Key Study Personnel and their Role on the Protocol that you would like to remove. Check the box to the left of their name/Role.

Their name/Role will be moved down to the **Remove Personnel List** section of the window.

Click **Save Selections** and **Close Setup of Protocol Personnel** to apply your changes.

Setup Protocol Personnel

User Search
Remove Personnel List
Create My Personnel Pool

Save Selections

<input checked="" type="checkbox"/>	Name	Role on the Protocol
<input type="checkbox"/>	Andrea Klaver	Principal Investigator
<input type="checkbox"/>	Andrea Klaver	Study Author

Selected Protocol Personnel:

Contact

Name	Role
No Personnel has been selected for this group.	

Remove Personnel List

Name	Role
<input checked="" type="checkbox"/> Klaver, Andrea	Study Contact

Clear Key Protocol Personnel Close Setup of Protocol Personnel

After you **Save Selections**, you will be taken back to **Section 7.0 Changes in Key Study Personnel** of the Modification form. You should now see any added personnel and any existing personnel for removal, along with their Roles.

Section view of the Form

Entire view of the Form

1.0 Modification/Amendment

2.0 IRB Fees

3.0 General Information

4.0 Modification Submission Type

5.0 Current Study Status

6.0 Modification Details

7.0 **Changes in Key Study Personnel**

8.0 Application Revision

9.0 Items to be included in Approval Letter

10.0 Attachments

11.0 Submission

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section Signoff and Submit

If applicable, please select the new Research Staff personnel:

A) Additional Investigators

Richards, Markeda
Co-Investigator

Ivery, Patricia
Co-Investigator

B) Research Staff

If applicable, please add any new Study Contact:

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

If applicable, please select any existing Personnel you wish to remove:

Klaver, Andrea Study Contact

Entry 1 Entry 2

Click here to add another entry Click Here to Delete this entry

Name Richards, Markeda

COI date 08/02/2021

Below the personnel changes, you will be prompted to enter Conflict of Interest (COI) information for Key Study Personnel to be added in the Modification (Investigators only).

Use the drop-down menu to select the name of the new personnel. Use the calendar to select the date. To ensure there is an entry for each new personnel to be added, select the **Click here to add another entry** button.

Continue completing the sections of the Modification form using the gray **Save and Continue** button in the upper right of each screen as before.

Print Friendly Refresh Constant Fields Save Section **Save and Continue to Next Section**

Section view of the Form

Entire view of the Form

1.0 Modification/Amendment

2.0 IRB Fees

3.0 General Information

4.0 Modification Submission Type

5.0 Current Study Status

6.0 Modification Details

7.0 Changes in Key Study Personnel

8.0 Application Revision

9.0 **Items to be included in Approval Letter**

9.0 **Items to be included in Approval Letter**

9.1 List all the items to be included in the approval letter (e.g. investigator brochure, protocol document, informed consent form, advertisement/recruitment material(s), etc. below. If the version or date of any of the items is important, please include those numbers or dates to have them on the approval letter.



Section view of the Form Entire view of the Form

1.0 Modification/Amendment
 2.0 IRB Fees
 3.0 General Information
 4.0 Modification Submission Type
 5.0 Current Study Status
 6.0 Modification Details
 7.0 Changes in Key Study Personnel
 8.0 Application Revision
 9.0 Items to be included in Approval Letter
 10.0 Attachments

10.0 Attachments

10.1 Upload any supporting documents in this Attachments section. Attach Informed Consent Form(s) in the Informed Consent section.

- Protocol amendments, IB, DSMB reports
- Conflict of Interest Disclosures
- adverse event/deviations
- Audit report (Do not include internal reviews/audits by the McLaren Office of Research Compliance)

List all items to be included in the approval letter(e.g. Investigator Brochure, protocol document, informed consent form, advertisements/recruitment material(s),etc)below. If the version or date of any of the items is important, please include those numbers or dates to have them on the approval letter.

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

Section view of the Form Entire view of the Form

1.0 Modification/Amendment
 2.0 IRB Fees
 3.0 General Information
 4.0 Modification Submission Type
 5.0 Current Study Status
 6.0 Modification Details
 7.0 Changes in Key Study Personnel
 8.0 Application Revision
 9.0 Items to be included in Approval Letter
 10.0 Attachments
 11.0 Submission

11.0 Submission

11.1 Is this an Investigator-Initiated Study (IIS)?

Yes No

If yes, does this form require routing to other individuals for sign off before proceeding with IRB submission? (Ph.D. Advisor, Clinical Faculty Advisor, Program Director, Assistant Program Director)

Yes No

When you have completed all sections of the Modification form, you will be presented with a screen notifying you that the form is complete, as shown below.

Section view of the Form Entire view of the Form

1.0 Modification/Amendment
 2.0 IRB Fees
 3.0 General Information
 4.0 Modification Submission Type
 5.0 Current Study Status
 6.0 Modification Details
 7.0 Changes in Key Study Personnel
 8.0 Application Revision
 9.0 Items to be included in Approval Letter
 10.0 Attachments
 11.0 Submission

Form has been Completed!

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

The Modification form and the Initial Study Application are available for review.

Approve the submission and save your signoff by clicking the **Save Signoff** button.

Protocol Title: Test 063021
Submission Reference Number: 001261

Save Signoff

Printable Version

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version
<input checked="" type="checkbox"/>			
<input type="checkbox"/>			McLaren Modification form - (Version 1.0)
<input type="checkbox"/>			McLaren Initial Review Application - (Version 1.1)

Submission Form(s):

Andrea Klaver as Principal Investigator
Do you Approve or Deny this submission? Approve Deny

Comments:

Save Signoff

If you are NOT the PI: The PI will be notified that there is a Modification awaiting their electronic signoff in iRIS. When you reach the end of the Modification form, select the **Notify PI to Signoff** button.

Print Friendly

Notify PI to Signoff

Section view of the Form

Entire view of the Form

Form has been Completed!

Exit Form

Notify PI to Signoff

Create PDF Packet

- 1.0 Modification/Amendment
- 2.0 IRB Fees
- 3.0 General Information
- 4.0 Modification Submission Type
- 5.0 Current Study Status
- 6.0 Modification Details
- 7.0 Changes in Key Study Personnel
- 8.0 Application Revision
- 9.0 Items to be included in Approval Letter
- 10.0 Attachments
- 11.0 Submission

At any time while working through the Modification form submission, you may select the gray **Save Section** button that appears on most screens in the upper right corner. This will save your progress if you need to leave the form and continue another time.

Print Friendly



Refresh Constant Fields

Save Section












Save and Continue to Next Section


When you return to iRIS to complete your Modification form submission, begin the process the same way as before: select the yellow **Start a Protocol Submission Form** button on your iRIS home screen and click on the **Forms** icon next to the study you would like to continue your Modification form for.





When the pop-up opens within your window showing the different types of forms you may submit in iRIS for your study, find the **McLaren Modification Form**.

Instead of clicking the  icon underneath the **Start a new Submission** column, click the  icon underneath the **Edit Incomplete Submissions** column.

You will be taken back into your Modification form.

Submission Form List X			
	Version List	Start a new Submission	Edit Incomplete Submissions
McLaren Continuing Review form			
McLaren IRB Final Report Form			
McLaren Modification form			
McLaren Unanticipated Problem Report			
Protocol Violation/Exception Report			

To open your Modification form to complete and submit, click on the  icon underneath the **Edit/View** column.

Protocol Status:	Approved	IRB Number :	IRB-2021-0207	Protocol Title :	Test 063021						
						Copy Form	Add a New Form	Compare Two Versions	Delete Selected Form(s)		
	List of records associated with form: McLaren Modification form. To view previous versions click on the folder icon  .										
1 result(s) found...											
<input type="checkbox"/>	Show Rev	Edit/View	Details	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
<input type="checkbox"/>								Andrea Klaver	07/30/2021 03:58:34 PM	Andrea Klaver	07/30/2021 03:58:34 PM