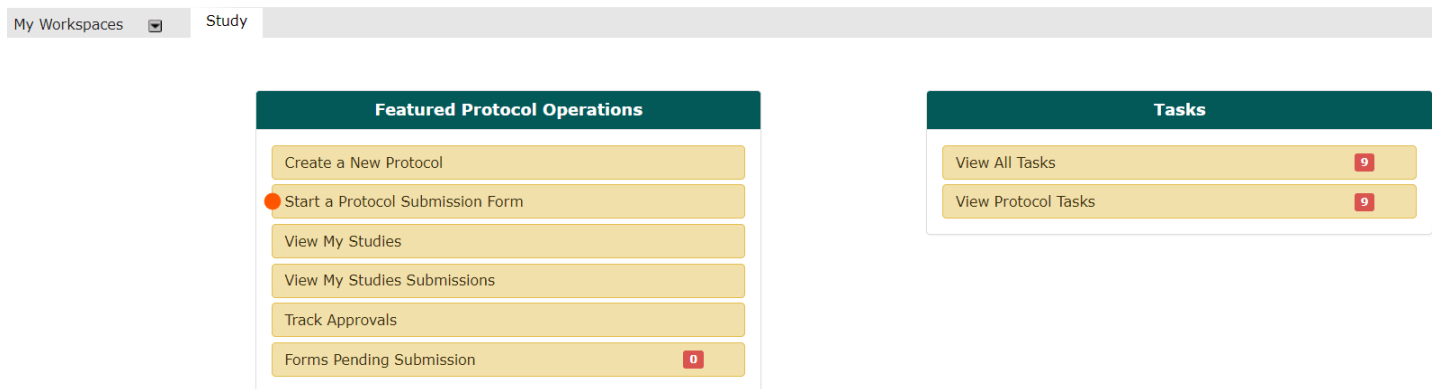
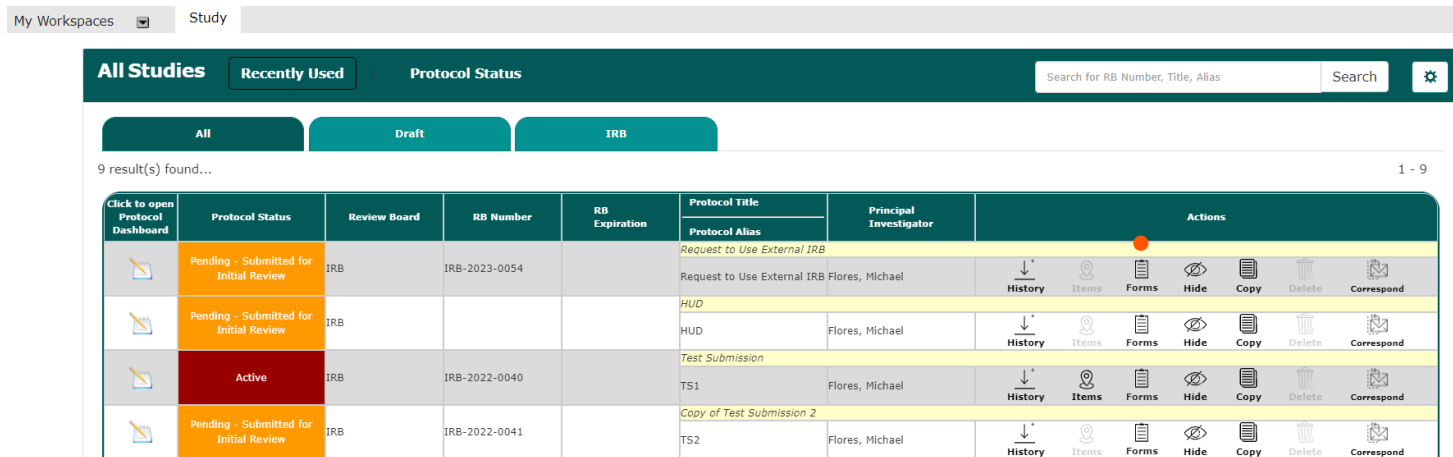


Modification - How to Add/Remove Key Study Personnel

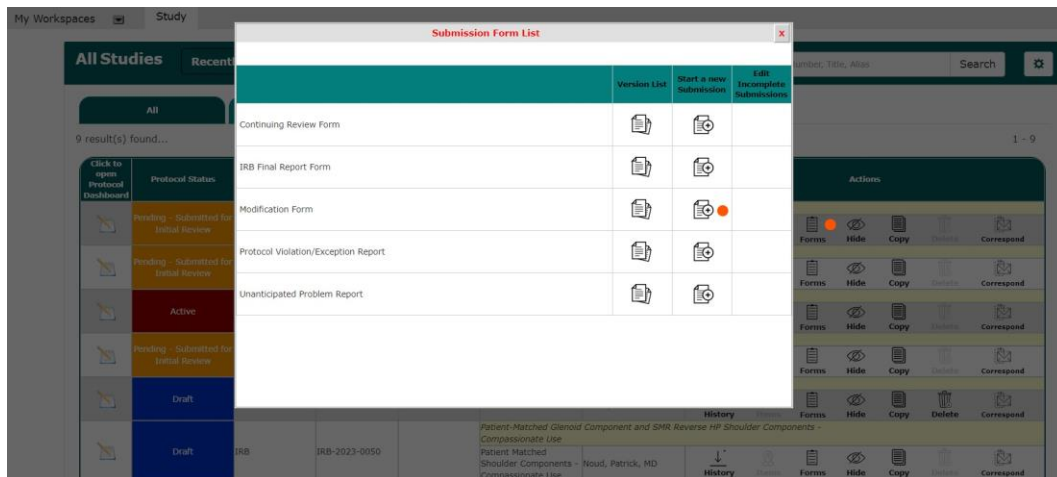
Step 1: After you login, iRIS will direct you to the Study Workspace. Under featured protocol operation, select “Start a Protocol Submission Form” to find the study protocol number for which you wish submit a Modification



Step 2: The “Start a Protocol Submission Form” command will direct you to the “All Studies” table (shown below), which lists all the studies associated with a particular PI. Locate the desired study IRB protocol number. Navigate to the right side of this row to the column titled “Actions”. Select the “Forms” icon.



Step 3: Once you select the Forms icon, a pop-up box will display the submission form list. From the submission form list select the Modification form.



Step 4: Begin filling out the preliminary Modification form information. *The Section view of the Form window allows you to view the previous sections and toggle up or down if you need to check your work. The ‘Save and Continue to Next Section’ button allows you to move on to the next section.*

There are two questions under section 4.1 that will need to be answered to direct you to the correct Modification form you want to submit. Continue working through the sections of the form until you get to the Modification Details section.

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

4.0 Modification Submission Type

4.1 Important Notice: Data from our old IRB system has now been migrated into IRIS. All the data is in the format of PDFs. If your original study application was approved in the old IRB system, you must create an electronic version of this application in IRIS, in order to make updates to your original application. Unfortunately, the IRB cannot do this on your behalf.

If you have already created an electronic version of your application, you may ignore the remaining instructions.

Creation of an electronic application must be completed before January 30, 2023. This electronic version should be created using your last IRB approved application in the *old software* and all IRB approved modifications (including IRB approved modifications done within the Continuing Review form) in IRIS. ONLY a MODIFICATION form can be used to create an electronic version. Instructions on how to create an electronic version can be found under the IRIS Quick Guide section on our website at: <https://www.mclaren.org/main/iris-research>

Remember you must create an electronic version before you submit a MODIFICATION or CONTINUING REVIEW application. Do not start a MODIFICATION or CONTINUING REVIEW until you receive written notice from the IRB that the electronic application is approved.

Note: The IRB analyst will do a quality check of the electronic version of the application to make sure it is consistent with your last IRB-approved application in the old system and any modification(s) approved in IRIS. Any discrepancies, errors, missing information will cause the application to be returned for corrections.

● Have you already created an electronic version of your application?

- No, this modification is to create the electronic version
- Not applicable, the original application was approved in IRIS
- Yes, an electronic version was already approved by IRB
- No

● Please select one.

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

Step 5: Once you reach the Modification Details section, select “Change in Key Study Personnel”.

NOTE: This screen shot is for a submission for a study where MHC is the IRB of Record

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

6.0 Modification Details

6.1 Select all the proposed changes that apply:

NOTE: IF CHANGES IMPACT INFORMATION IN THE ORIGINAL APPLICATION, YOU MUST GO TO THE APPROPRIATE SECTION(S) AND ENTER YOUR UPDATES

- Protocol document Amendment/Revision (Attach a tracked changed copy, along with the sponsor's Summary of Changes if applicable, in the Attachments section)
- Change(s) to Consent Form (Attach a tracked changed copy of the revised consent form in the Attachments section)
- Changes to the consent process
- Consent Form Addendum (Attach copy in the Attachments section)
- Change to the HIPAA Authorization, Waiver, or Alteration Documents (Attach a tracked changed copy of the revised form in the Attachments section)
- IB Update (Attach copy, along with the sponsor's Summary of Changes, in the Attachments section) Enrollment Status Change
- Enrollment Status Change
- Change in Population, Recruitment, and/or Enrollment Goal
- Change in Key Study Personnel (NOTE: If you are making changes in Personnel (i.e. personnel added or removed) please review Potential COI page and update, if applicable.)
- Change in Conflict of Interest (COI)
- Change in Study Purpose
- Change in Procedures
- Advertisement/Recruitment tool(s) (Attach copy in the Attachments section)
- Funding change or change in billing contact information
- Other:

NOTE: This screen shot is for a submission for a study where MHC is *not* the IRB of Record (External IRB Study)

5.0 Modification Request form when using an external IRB as an IRB Of record

5.1 This form is to be used by investigators requesting changes to research personnel, conflicts of interest, and/or McLaren sites/departments when using an external IRB as an IRB of Record. (Please see SOP: MHC_RPD128_Relying on an External IRB as an IRB of Record)

If this modification request is approved, the Corporate HRPP will provide a letter. The letter must be included with your submission to the external IRB of Record.

5.2 Study Status: Select one descriptor that applies to the status of the study.

- Study involves only the review/use of data, documents, records, or specimens (i.e. no subject enrollment; Active for data collection).
- Study is open to enrollment.
- Closed to enrollment: In data collection only.
- Closed to enrollment: In data analysis only.
- Not begun.
- On Hold. Please explain:
- Humanitarian Use Devise
- Other: Specify

5.3 Modifications Requested: Select all that apply.

NOTE: IF CHANGES IMPACT INFORMATION IN THE ORIGINAL APPLICATION, YOU MUST GO TO THE APPROPRIATE SECTION(S) AND ENTER YOUR UPDATES.

- Change in Study Personnel (Note: If you are making changes to personnel, please review the potential conflict of interest page and complete).
- Change in Conflict of Interest (COI)
- Change in Study Sites/Departments
- Change in HIPAA (HIPAA Authorization and/or Request for HIPAA Waiver/Alteration)
- *Other important Information (i.e. Local context changes to ICF)

Step 6: Once you get to the section to make **Changes in Key Study Personnel**, you will see a table that allows you to complete the task. You have the option to add or remove Study Personnel (can do multiple personnel in one submission). Select Setup Key Study Personnel Request.

6.0 Changes in Key Study Personnel

6.1 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

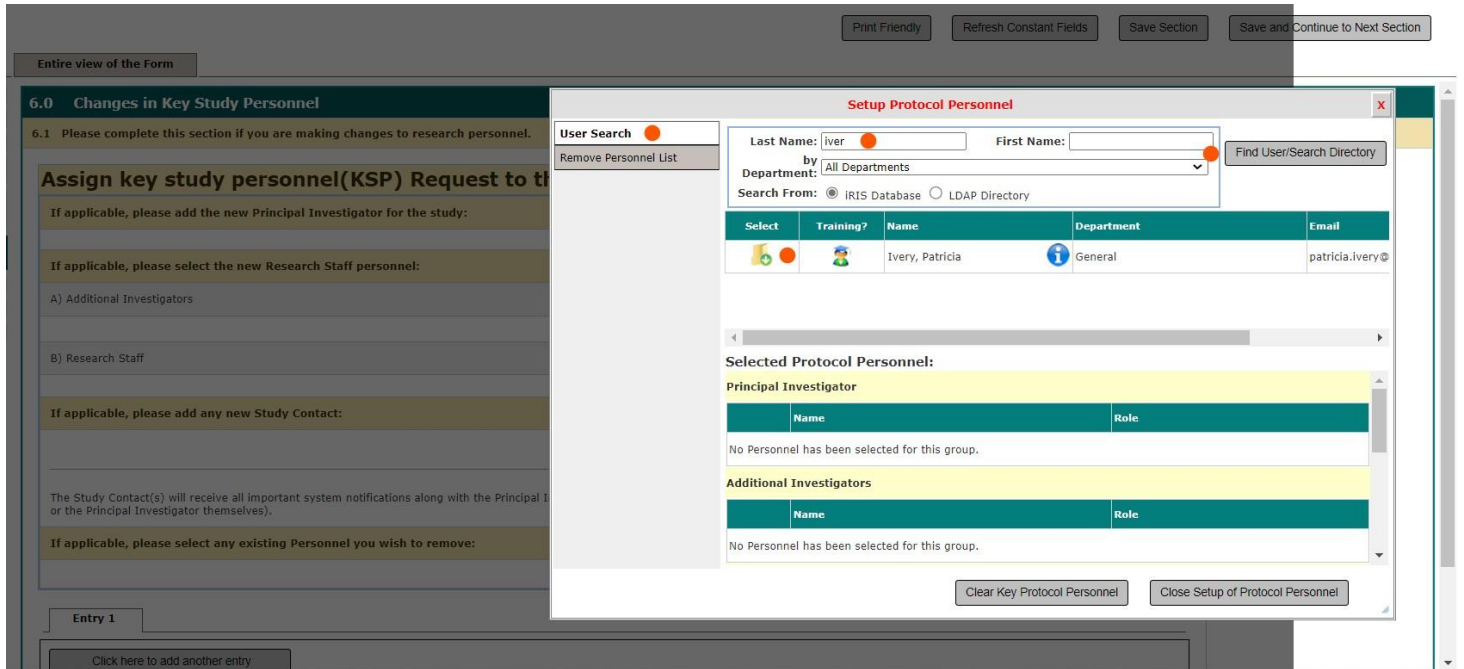
If applicable, please add any new Study Contact:

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).

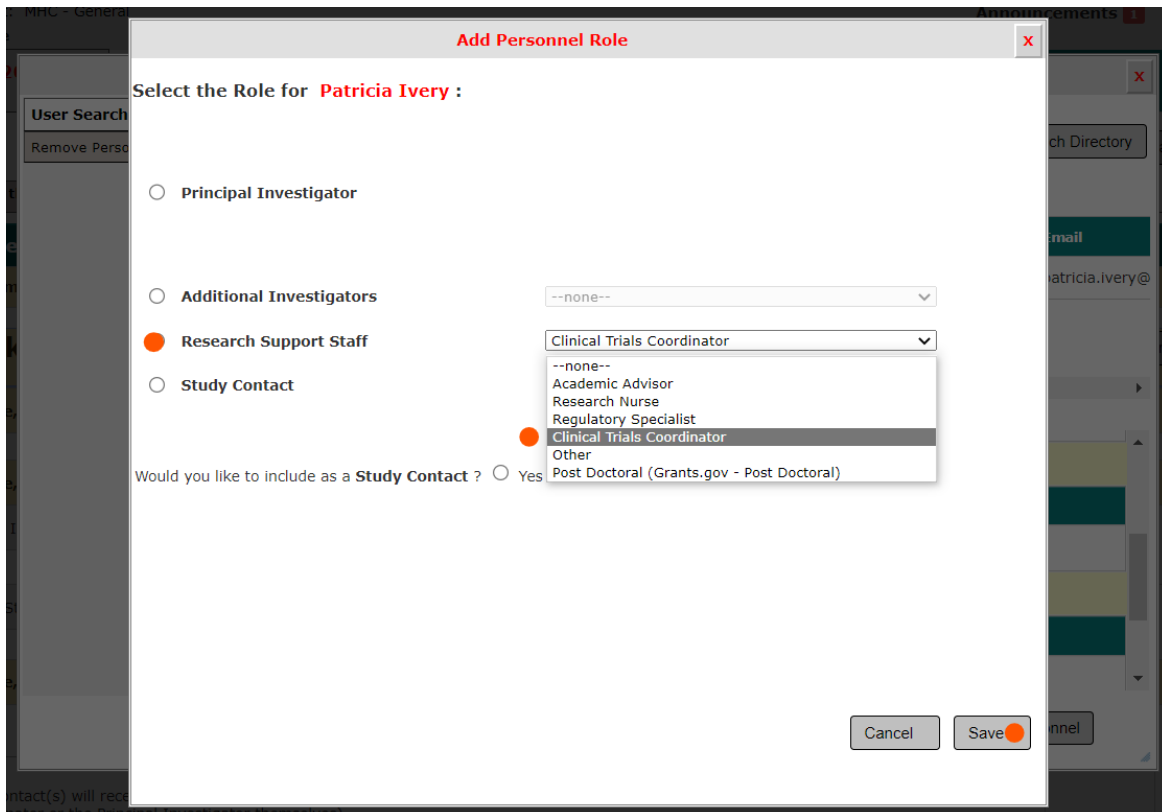
If applicable, please select any existing Personnel you wish to remove:

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

Step 7: Adding Key Study Personnel - Below is how the table (pop-up) looks like when you are “adding” KSP. Use the search fields to type in Last/First name (can be either one or both), then select Find User/Search Directory. The table below will display the user(s) that fit the name in the search fields. By selecting the green arrow facing down, this will allow you to request that user to be on the study.



When you select the green arrow, another pop-up window will appear where you can assign the new user a role on the study. Select the role then Save.



The table will register the user requested and their role will appear in the request. You can do another request to add or complete your request by selecting the Close Setup of Protocol Personnel button.

Setup Protocol Personnel X

User Search

Remove Personnel List

Create My Personnel Pool

by

All Departments

Department:

All Departments

Search From:

iRIS Database
 LDAP Directory

Select	Training?	Name	Department	Email
		Ivery, Patricia	General	patricia.ivery@

Selected Protocol Personnel:

Research Support Staff

	Name	Role
	Ivery, Patricia	Clinical Trials Coordinator

Contact

	Name	Role
No Personnel has been selected for this group.		

After you select Close Setup of Protocol Personnel button, the table in the Modification form is updated to reflect the request that was made.

Note: IF added KSP does not automatically generate on the Entry table after you select the Close Setup of Protocol Personnel button, click the Save Section button on the top right of the screen, so iRIS can register that request and update the table and the name(s) on the drop-down selection.

6.0 Changes in Key Study Personnel

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

Assign key study personnel(KSP) Request to the study

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

Ivery, Patricia

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:

Step 8: Removing Key Study Personnel - The table below looks like the one for adding KSP, however this time you select "Remove Personnel List", and the table displays current study personnel. Select the user(s) you want to remove then select "Close Setup of Protocol Personnel."

Entire view of the Form

6.0 Changes in Key Study Personnel

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

Assign key study personnel(KSP) Request to the study

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 or the Principal Investigator themselves).

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

Entry 1

Setup Protocol Personnel

User Search

Remove Personnel List

Name	Role on the Protocol
<input type="checkbox"/> Michael Flores	Principal Investigator
<input type="checkbox"/> Donna Mott	Study Contact
<input type="checkbox"/> Jiacheng Li	Study Contact
<input type="checkbox"/> Jill George	Study Contact
<input type="checkbox"/> Michael Flores	Study Contact
<input type="checkbox"/> Dr. Patrick Noud, MD	Study Contact
<input type="checkbox"/> Michael Flores	Study Author
<input type="checkbox"/> Donna Mott	Regulatory Specialist

Selected Protocol Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

How to Do Modification in iRIS -Add/Remove KSP_version 4/27/23

6

Step 9: After you select Close Setup of Protocol Personnel button, the table in the Modification form is updated to reflect the request that was made and the name(s) will appear under the header “If applicable, please select any existing Personnel you wish to remove:”

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:		
<small>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).</small>		
If applicable, please select any existing Personnel you wish to remove:		
●		

Step 10: Edit/Update Initial Application - This tool will allow you to update the original application before submitting to the IRB. Once you update the original application a new version will be created. Please follow this step anytime you update the original application. In this example you are going to add information for each KSP added to the original application or remove information for personnel that is taken off the study.

*** NOTE:** At the bottom of this document, there are instructions to guide the PI in submitting a Modification within a Continuing Review form.

Section view of the Form

- 1.0 Modification/Amendment
- 2.0 IRB Fees
- 3.0 General Information
- 4.0 Modification Submission Type
- 5.0 Modification Request form when using an external IRB as an I ...
- 6.0 Changes in Key Study Personnel
- 7.0 Application Revision

Entire view of the Form

7.0 Application Revision

7.1 Please click on the button below and select the Application to complete your edits/changes. Once complete, you can attach the revisions to this Submission Form.

Click here to attach the application.

No Application has been associated with this submission.

When you click on the button “Click here to attach the application” there will be a pop-box that allows you to Add Revision to the last approved Initial Review Application (currently Version 1.0). After you click on the Add Revision icon, another pop-up will display to Confirm action.

Entire view of the Form

7.0 Application Revision

7.1 Please click on the button below and select the Application to complete your edits/changes. Once complete, you can attach the revisions to this Submission Form.

Click here to attach the application.

No Application has been associated with this submission.

Attaching Protocol Application

Select the application that you would like to attach and then click Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted			Initial Review Application (Version 1.0)	No	 Add Revision

Confirm the adding a revision.

Are you sure you want to create a revision?

Step 11: To account for the added KSP, toggle down to the Personnel Information section of the Initial Review Application. There is a table where you can add entries for each added personnel and their respective information. Once you complete each added KSP information, click on the Save Section button then the Back button to return to the Modification Submission Form.

[Print Friendly](#) [Save Section](#) [Save and Continue to Next Section](#) [Back](#)

Entire view of the Application

Study Coordinator(s)
The MHC IRB defines a "study coordinator" as an individual who assists the investigator in the conduct of research.

● Entry 1

Click here to add another entry

Name of Study Coordinator	Patricia Ivery
Degree (MD/PhD)	xxxxx
Title	Clinical Trials Coordinator
Email	xxxxx
Phone	xxxxx
Fax	
Research Group	xxxxx
Pager Number	
Mailing Address	xxxxx
Study Role: Select all that apply.	<input checked="" type="checkbox"/> Study-related Procedures <input type="checkbox"/> Obtaining Consent <input checked="" type="checkbox"/> Regulatory Activities

Step 12: If you are removing KSP, locate the panel of the person you are removing from the study and select the Click Here to Delete this entry button. Be sure you are on the right Entry before you delete. Save Section and select the Back button to return to the Modification form.

Entire view of the Application

Study Coordinator(s)
The MHC IRB defines a "study coordinator" as an individual who assists the investigator in the conduct of research.

● Entry 1 Entry 2 Entry 3 Entry 4

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

Name of Study Coordinator	Patricia Ivery
Degree (MD/PHD)	xxxxx
Title	Clinical Trials Coordinator
Email	xxxxx
Phone	xxxxx
Fax	
Research Group	xxxxx
Pager Number	
Mailing Address	xxxxx
Study Role: Select all that apply.	<input checked="" type="checkbox"/> Study-related Procedures <input type="checkbox"/> Obtaining Consent <input checked="" type="checkbox"/> Regulatory Activities

Important Note: You are not to make any changes to section 3.0 of the original application

Step 13: You are now back in the Modification Submission form, and you will notice that after you revised the Initial Review Application, it is now Version 1.1 on the table.

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 Modification Request form when using an external IRB as an I ...
- 6.0 Changes in Key Study Personnel
- 7.0 **Application Revision**

7.0 Application Revision

7.1 Please click on the button below and select the Application to complete your edits/changes. Once complete, you can attach the revisions to this Submission Form.

Unattach	Revise/Attach	Edit/View	Title
			Initial Review Application (Version 1.1)

Step 14: You will Save and Continue to the next section and complete applicable questions. Once you are complete, you will see this screen where you can Signoff and Submit.

Print Friendly **Signoff and Submit**

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 Modification Request form when using an external IRB as an I ...
- 6.0 Changes in Key Study Personnel
- 7.0 Application Revision
- 8.0 Attachments
- 9.0 Submission

Form has been Completed!

Step 15: After you click Signoff and Submit, iRIS will direct you to this page where you can approve the Submission and record your electronic signature. iRIS will automatically route the submission to the PI. The submission will not be submitted to the IRB until the PI has signed off.

Save Signoff

Protocol Title: Request to Use External IRB
Submission Reference Number: 010662

Printable Version

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

Michael Flores as Principal Investigator
Do you Approve or Deny this submission? Approve Deny

Comments:

Step 16: After you submitted the Modification Submission form, you can track the progress of your submission. In the Study Workspace, there is a table called Studies Submission Status – In Progress.

My Workspaces ▾ Study

Featured Protocol Operations

- Create a New Protocol
- Start a Protocol Submission Form
- View My Studies
- View My Studies Submissions
- Track Approvals
- Forms Pending Submission 0

Tasks

- View All Tasks 9
- View Protocol Tasks 9

This is how the table looks like after iRIS toggles you down to the Studies Submission Status table.

My Workspaces ▾ Study

Studies Submission Status - In Progress Search for RB Number, Title, Alias Search ⚙️

In Progress Completed

8 result(s) found... 1 - 8

Click to open Protocol Dashboard	Reference Number	Review Board	RB Number	Form Name	Protocol Title	Form Author	Date Submitted	Actions
					Protocol Alias			
	010662	IRB	IRB-2023-0054	Modification Form	Request to Use External IRB	Flores, Michael	03/16/2023 02:43 PM EDT	
Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time			
● ▾ Pre-Submission	Retract Submission		03/16/2023 02:40 PM EDT	03/16/2023 02:43 PM EDT	0 Day(s) 0 Hour(s) 3 Minute(s)			
Completed		Modification Form is waiting to be submitted	03/16/2023 02:40 PM EDT	03/16/2023 02:42 PM EDT	Day Hour Minute 0 0 1			
Completed	View Signoff	Michael Flores as Principal Investigator review and apply signoff	03/16/2023 02:42 PM EDT	03/16/2023 02:43 PM EDT	Day Hour Minute 0 0 1			
● ▾ IRB			03/16/2023 02:43 PM EDT		0 Day(s) 0 Hour(s) 0 Minute(s)			
Received		IRB received the submission	03/16/2023 02:43 PM EDT		Day Hour Minute 0 0 0			

Please note the any Key Study Personnel changes submitted via the process above are not effective until IRB Review of the modification is complete.

Completing a Modification within the Continuing Review Form

The process of completing a modification within the Continuing Review application is like a solo Modification submission. Below are a couple of screen shots that will guide you.

Step 1: Follow steps 1-3 in the Modification guide. When you get to number three, select Continuing Review and begin filling out the form.

Step 2: On the Study Progress Status section of the Continuing Review, you have the options to select what type of changes you are requesting. If any of the ones below are selected, Save and Continue to Next Section.

Section view of the Form

- 1.0 IRIS Study Continuation Report
- 2.0 General Information
- 3.0 Submission Type
- 4.0 Current Study Status
- 5.0 Enrollment and Subject Status
- 6.0 Status of Chart Reviews Data/Specimen Collection
- 7.0 Informed Consent Form
- 8.0 Study Progress Status

Entire view of the Form

8.2 Are you submitting changes with this continuing review?

Yes No

NOTE: IF THE CHANGES IMPACT INFORMATION IN THE ORIGINAL APPLICATION, GO TO THE APPROPRIATE SECTION(S) AND ENTER YOUR UPDATES

- Protocol document amendment/revision (attach a tracked changes copy, along with the sponsor's Summary of Changes, if applicable, in the Attachments section).
- Change(s) to Consent Form (Attach a tracked changes copy of the revised consent form in the Informed Consent section)
- Change(s) to Consent Process
- Consent Form Addendum (Attach copy in the Informed Consent section)
- Change to the HIPAA Authorization, Waiver, or Alteration Documents (Attach a tracked changes copy of the revised form in the Attachments section)
- IB Update (Attach copy, along with the sponsor's Summary of Changes, in the Attachments section)
- Enrollment Status Change
- Change in Population, Recruitment, and/or Enrollment Goal
- Change in Study Personnel (NOTE: If you are making changes in Personnel (i.e. personnel added or removed) please review Potential COI page and update, if applicable.)
- Change in Conflict of Interest (COI)
- Change in Study Purpose
- Change in Procedures
- Advertisement/Recruitment tool(s) (Attach copy in the Attachments section)
- Funding change or change in billing contact information
- Other:

Step 3: IRIS will direct you to the next section, Revisions to the Application. The tool to change/edit the Initial Review Application and add/remove KSP will both be in this section. Both tools work the same way as in the Modification Submission form.

Section view of the Form

- 1.0 IRIS Study Continuation Report
- 2.0 General Information
- 3.0 Submission Type
- 4.0 Current Study Status
- 5.0 Enrollment and Subject Status
- 6.0 Status of Chart Reviews Data/Specimen Collection
- 7.0 Informed Consent Form
- 8.0 Study Progress Status
- 9.0 Revisions to the Application

Entire view of the Form

9.0 Revisions to the Application

9.1 Click the bar below to make revisions to the application form:
(Note: you are seeing this section because you indicated that there are changes that affect the application.)

[Click here to attach the application.](#)

No Application has been associated with this submission.

9.2 Changes in Key Study Personnel
(Note: you are seeing this section because you indicated personnel changes.)

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

Assign key study personnel(KSP) Request to the study

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:

--	--	--

Please note the any Key Study Personnel changes submitted via the process above are not effective until IRB Review of the modification is complete.