

# How to Create an Electronic Version of a Legacy Application

- For LEGACY protocols only: You MUST submit this stand-alone MODIFICATION creating an electronic version of your protocol application BEFORE you can submit any additional Modifications or Continuing Reviews.
- If the study was initially approved as *Expedited* or *Full Board* and is currently *Open* or *Active*, investigators are required to create an electronic application. You can check your original approval letter if you are unsure of the type of approval.
- If the study was initially approved as *Exempt* or *Chart Review* investigators do not have to create an electronic application *unless there is a plan to modify the protocol*.
- If your protocol originated in iRIS and already has an electronic version of your initial application, you DO NOT need to go through this process.

Step 1. View or download the PDF version of your legacy initial application.

- a. Use the Find a Protocol widget on your home screen (Protocol Workspace) to search for and open your study.

The screenshot displays the McLaren Protocol Workspace interface. At the top, there is a navigation bar with the McLaren logo, a 'My Workspaces' dropdown menu, a 'Study' tab, and utility links for 'Help', 'Tutorial', 'My Profile', and 'Log out'. Below the navigation bar, the main content area is divided into several sections. On the left, there is a 'Featured Protocol Operations' section with a list of actions: 'Create a New Protocol', 'Start a Protocol Submission Form', 'View My Studies', 'View My Studies Submissions', 'Track Approvals', and 'Forms Pending Submission' (which has a red notification icon). To the right of this is a 'Tasks' section with two buttons: 'View All Tasks' and 'View Protocol Tasks', both featuring red notification icons. Below these sections is a 'Study' section with a 'Find a Protocol' widget, which is circled in red. At the bottom of the page, there is an 'All Tasks' section with tabs for 'Outstanding' and 'Completed', and a 'Task List' dropdown menu.

- b. Search by IRB number and then open your study by clicking on the notepad "Open" icon. (NOTE: Some text may be blurred out in this example; you WILL see the IRB Number, IRB Expiration Date, Principal Investigator, etc.)

My Workspaces ▾ Study **Find A Protocol** 1 Back

Find a Protocol Filters

Display Projects by: IRB Number ▾	IRB Number: <input type="text"/>
Protocol Alias: <input type="text"/>	Protocol Status: All ▾
Sponsor: <input type="text"/>	Protocol Classification: All ▾
Active <input type="checkbox"/> Principal Investigator: <input type="text"/>	Reference Number: <input type="text"/>
Department: <input type="text"/>	Include Studies that have not been assigned an IRB Number: <input type="checkbox"/>
IRB Expiration Date: <input type="text"/> - <input type="text"/>	

+ **Advanced Find Options**

**Application Find Options**

**Reset Find Options**

**Find ...**

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

Open	Protocol Status	IRB Number	IRB Expiration Date	Protocol Alias	Principal Investigator
	Active			Gore GREAT Registry Global Registry for Endovascular Aortic Treatment (GREAT) Outcomes Evaluation	

c. The protocol will open to the Submissions tab. Under "Initial," click "Initial Review Submission Packet."

**Submissions** Protocol Management

Current Approval Packet

Protocol Items

- Protocol Application
- Informed Consents
- Other Protocol Documents
- Contract Documents
- External IRB Request
- Initial**
  - Initial Review Submission Packet**
- Legacy McLaren IRB Final Report Form
- McLaren Continuing Review form
- McLaren Modification form
- McLaren Unanticipated Problem Report
- Protocol Violation/Exception Report

Submissions History

Protocol Correspondence

**Outstanding Submission(s)**

Track Location	Ref. Number	Request Type	Process Submission
There are no outstanding submissions.			

d. Click on the notepad "Edit/View" icon.

Compare Two Versions

**i** List of records associated with form: Initial Review Submission Packet.  
To view previous versions click on the folder icon

1 result(s) found...

	Show Rev	Edit/View	Details	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
<input type="checkbox"/>				008425				04/22/2015 12:00:00 AM EDT	Administrator	04/22/2015 12:00:00 AM	Administrator	04/22/2015 12:00:00 AM

e. Click "Click to view the Document." Your PDF will open in a separate window. This is your INITIAL APPLICATION that was submitted in the old software system, NOT taking into account any Modifications that were done in the old software system. See below for instructions of how to find this form.

Print Friendly

Section view of the Form Entire view of the Form

1.0 Legacy Initial Review Submission Packet

1.0 Legacy Initial Review Submission Packet

1.1 Please select the button below to view components of your Study.

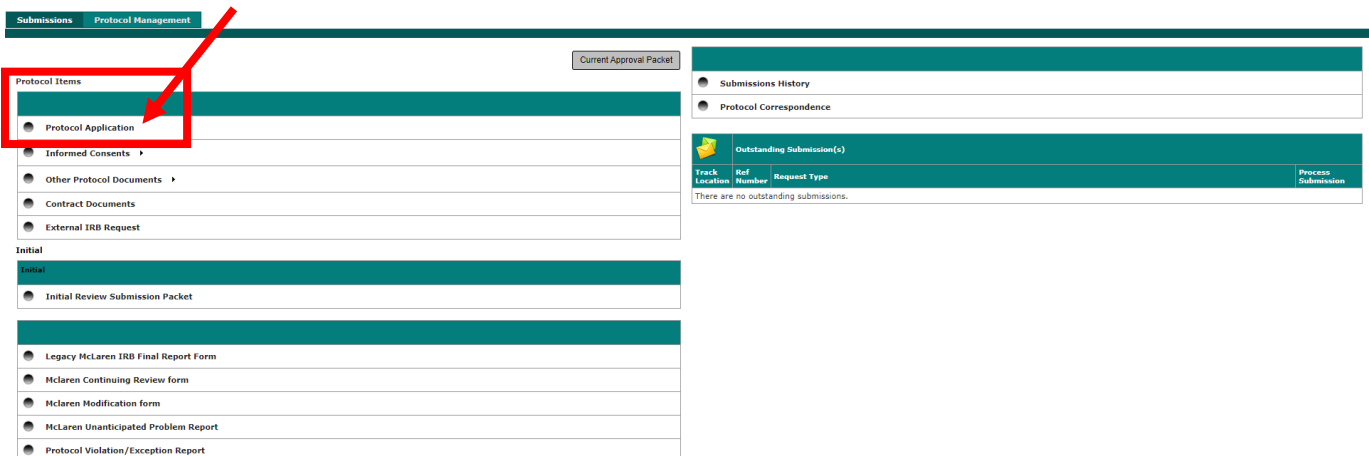
Click to view the Document

**\*\* A NOTE ON CREATING YOUR LEGACY INITIAL APPLICATION: If you also had Modifications done in the old software system, you will need to include those, too. \*\***

- ✓ To find them, click on the Submission History link under the Submissions tab.
- ✓ Then, click the Completed Submissions tab.
- ✓ Open the most recent submission (Modification or Continuing Review) that was done in the old software system and **use that application form to create your legacy initial application.**
  - Typically, these will be dated before December 2020.
- ✓ These forms will have the most updated protocol information for the study. We suggest creating your legacy initial application in this manner **if you had Modifications done in the old software system.**
- ✓ Once you have populated all the information within the legacy initial application in this manner, you can further update the application for any submissions (Modification or Continuing Review) that were done in iRIS (December 2020 to present).

**Step 2. Create your electronic initial application.**

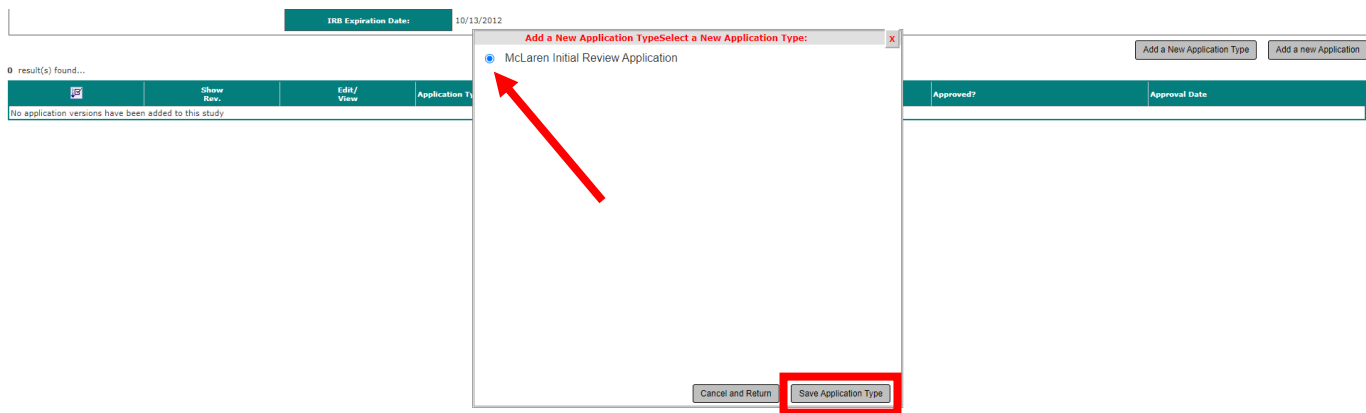
- a. Follow steps a. and b. from Step 1 above to open your study to the Submissions tab.
- b. Under "Protocol Items," click on "Protocol Application."



c. Click on the “Add a New Application Type” gray button.



d. Select “McLaren Initial Review Application.” This should be the only option. Then, click on the “Save Application Type” gray button.



e. To complete your initial application, you will need:

- ✓ Your PDF version of your legacy initial application from Step 1 (including any Modifications that had been done in the old software system, if any)
- ✓ All Modifications that have been submitted in iRIS
- ✓ Any Continuing Reviews with Modifications that have been submitted in iRIS

This is so that you may create an accurate picture of your protocol at this point in time, including all legacy information and any changes made to the protocol since that time.

- ✓ Please COMPLETE ALL SECTIONS of the application, and feel free to copy and paste narrative text from your legacy PDF if nothing has changed! Many (not all) sections from the old electronic software application are the same in iRIS.

f. SOME NOTES as you COMPLETE ALL SECTIONS of your initial application...

- ✓ Please remember to use the gray “Save and Continue to Next Section” button.

- ✓ Section 3.0 (Grant Key Personnel access to the study): DO NOT make any changes to this section at this point. Make notes on key personnel you'd like to add or remove to bring the section up to date, but do not make any changes. **Key personnel changes will need to be made on a separate Modification after this one.**
- ✓ Section 4.0 (iRIS Application: General Information): The "Date of Submission" is the date you are completing this form.
- ✓ Section 5.0 (Type of Application): Please select "Entering a new study application for review by McLaren Health Care IRB."
  - \*\*If your submission was originally Emergency Use, Expanded Access/Compassionate Use, or HUD, please select "IRB review non-research activity where the IRB has regulatory authority and oversight" and the corresponding submission type.
- ✓ Section 7.0 (Personnel Information): As in Section 3.0, please make NO CHANGES to key personnel. Please enter information in this section EXACTLY as it appears in Section 3.0.
- ✓ Section 8.0 (Review Fees): Please enter information in this section as you normally would for a Modification.

g. After you have completed all sections of the application, you will see your Initial Review Application (Version 1.0):

1 result(s) found...

	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Modified by	Date Modified
<input type="checkbox"/>			McLaren Initial Review Application (Version 1.0)	No		Andrea Klaver	06-30-2022 14:30	Andrea Klaver	06-30-2022 14:46

**Step 3. Create a Modification to submit your Version 1.0 Initial Application.**

- a. Follow steps a. and b. from Step 1 above to open your study to the Submissions tab.
- b. Click on "McLaren Modification Form."

Submissions Protocol Management

Current Approval Packet

Protocol Items

- Protocol Application
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- Other Protocol Documents
- Contract Documents
- External IRB Request

Initial

- Initial Review Submission Packet
- Legacy McLaren IRB Final Report Form
- McLaren Continuing Review form
- McLaren Modification form**
- McLaren Unanticipated Problem Report
- Protocol Violation/Exception Report

Submissions History

Protocol Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

c. Here, you will see all the Modifications that were created in the previous electronic system and migrated to iRIS. Click on the gray "Add a New Form" button.

List of records associated with form: McLaren Modification form.  
To view previous versions click on the folder icon

Copy Form Add a New Form Compare Two Versions Delete Selected Form(s)

3 result(s) found...

ISV	Show Rev	Edit/View	Details	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Modified By	Date Modified
<input type="checkbox"/>							05/23/2018 12:00:00 AM EDT	Administrator	05/23/2018 12:00:00 AM	Administrator	05/23/2018 12:00:00 AM
<input type="checkbox"/>							08/26/2016 12:00:00 AM EDT	Administrator	08/26/2016 12:00:00 AM	Administrator	08/26/2016 12:00:00 AM
<input type="checkbox"/>							06/14/2016 12:00:00 AM EDT	Administrator	06/14/2016 12:00:00 AM	Administrator	06/14/2016 12:00:00 AM

d. SOME NOTES as you complete your Modification...

- ✓ Please remember to use the gray "Save and Continue to Next Section" button.
- ✓ Section 2.0 (IRB Fees): Please select "Not applicable to this submission."
- ✓ Section 3.0 (Information): The "Date Submitted" is the date you are completing this form.
- ✓ Section 4.0 (Modification Submission Type): This section shows language pertaining to this process, creating an electronic version of a legacy application. **Please read these instructions carefully.** As this Modification is being submitted to create an electronic initial application, please select "No, this modification is to create the electronic version."

- ✓ Section 6.0 (Modification Details): Please ONLY select "Other:" In the free text box, enter "Creating an electronic version from PDF version of the IRB application."

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

8.0 Application Revision

8.1 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.

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

A new window will pop up where you will have the option to select the electronic application you just created, Version 1.0. Select the radio button next to this application and then click the gray "Save Attachment" button.

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  
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Click here to attach the application.

No Application has been associated with this submission.

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

Attaching Protocol Application

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

Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
<input type="radio"/>			McLaren Initial Review Application (Version 1.0)	No	

You will then see that Section 8.0 has been updated with Version 1.0 of your electronic application attached to the Modification submission.

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  
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8.1 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.

Unattach	Revoke/Attach	Edit/View	Title
			McLaren Initial Review Application (Version 1.0)

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

- ✓ Section 9.0 (Items to be included in Approval Letter): Please leave Section 9.0 blank.

- ✓ Section 10.0 (Attachments): Please do not add any attachments to this Modification.

- e. Your form has been completed! Please remember to notify your PI to signoff by selecting the gray "Notify PI to Signoff" button.

After an IRB Analyst has performed 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, the PI and all Study Contacts will receive an **Acknowledgement Letter via iRIS**. (Any discrepancies, errors, or missing information will cause the application to be returned for corrections.)

The screenshot displays the iRIS application interface. On the left, a sidebar lists sections from 1.0 to 11.0, with 10.0 'Attachments' selected. The main content area features a green header with the text 'Form has been Completed!'. Below this header, three buttons are visible: 'Exit Form', 'Notify PI to Signoff' (highlighted with a red box), and 'Create PDF Packet'. In the top right corner, there are two additional buttons: 'Print Friendly' and 'Notify PI to Signoff'.