

## How to Complete a Request to Use External IRB Application in iRIS

1. Select Create a New Protocol in iRIS

My Workspaces  Study

Featured Protocol Operations

- Create a New Protocol
- Start a Submission Form for one of My Studies
- View the Current Approvals for one of My Studies
- View the Submission History for one of My Studies
- View and Manage My Studies

2. In Section 3.0 Setup Key Study Personnel (KSP) List

Section view of Application

Entire view of the Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study

**3.0 Assign key study personnel (KSP) access to the study**
Click Here to Setup Protocol Personnel

3.1 \* Please add a Principal Investigator for the study:

Name	Role	Training Record
Michael Flores	● Principal Investigator	<a href="#">View Training Record</a>

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Name	Role	Training Record
Mott, Donna	● Co-Investigator	<a href="#">View Training Record</a>

B) Research Support Staff

Name	Role	Training Record
Ivery, Patricia	● Regulatory Specialist	<a href="#">View Training Record</a>
Wilson, Jacki	● Clinical Trials Coordinator	<a href="#">View Training Record</a>

\* It is critical to finalize KSP list before moving on with the application and submitting application to the IRB.

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### 3. In Section 5.0 Select “Request to Use External IRB Application”

<p>Section view of Application</p> <ul style="list-style-type: none"> <li>1.0 General Information</li> <li>2.0 Setup Department(s) Access</li> <li>3.0 Grant Key Personnel access to the study</li> <li>4.0 IRIS Application: General Information</li> <li>5.0 Type of Application</li> </ul>	<p>Entire view of the Application</p> <div style="background-color: #004a7c; color: white; padding: 5px;"><b>5.0 Type of Application</b></div> <div style="background-color: #fff9c4; padding: 5px;"><b>5.1 What type of Study will you be conducting?</b></div> <p> <input type="radio"/> Request for Determination of Human Subject Research  <input type="radio"/> Entering a new study application for review by McLaren Health Care IRB  <input type="radio"/> * IRB review non-research activity where the IRB has regulatory authority and oversight  <input checked="" type="radio"/> Request to Use an External IRB         </p>
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### 4. In Section 6.21 Complete Principal Investigator Information

<p>Section view of Application</p> <ul style="list-style-type: none"> <li>1.0 General Information</li> <li>2.0 Setup Department(s) Access</li> <li>3.0 Grant Key Personnel access to the study</li> <li>4.0 IRIS Application: General Information</li> <li>5.0 Type of Application</li> <li>6.0 External IRB Request</li> </ul>	<p>Entire view of the Application</p> <div style="background-color: #fff9c4; padding: 5px;"><b>6.21 Principal Investigator training information: ALL research personnel are required to complete researcher training prior to engaging in any research-related activities.</b></div> <p><b>CITI Human Subject Research Training</b></p> <p>01/25/2024</p> <p><b>CITI COI</b></p> <p>01/25/2024</p> <p><b>CITI GCP (You only need to enter a GCP training date if your study requires compliance with ICH GCP E6 and you have completed CITI GCP training).</b></p> <p>01/25/2024</p> <p>Have you completed GCP training with an organization other than CITI?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p><small>If yes, attach certificate instead rather than entering a date. ( For information on qualifying GCP training organization, please visit our webpage <a href="https://www.mclaren.org/main/required-training-citi">https://www.mclaren.org/main/required-training-citi</a>)</small></p> <p><b>Other Training (title &amp; date completed)</b></p> <p>N/A</p>
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### 5. In Section 6.28 Fill in Key Study Personnel Information

<p>Section view of Application</p> <ul style="list-style-type: none"> <li>1.0 General Information</li> <li>2.0 Setup Department(s) Access</li> <li>3.0 Grant Key Personnel access to the study</li> <li>4.0 IRIS Application: General Information</li> <li>5.0 Type of Application</li> <li>6.0 External IRB Request</li> </ul>	<p>Entire view of the Application</p> <div style="background-color: #fff9c4; padding: 5px;"><b>6.28 Other Study Personnel</b></div> <p>Individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data.</p> <p><i>ALL research personnel are required to complete researcher training prior to engaging in any research-related activities.</i></p> <p><b>Entry 1</b></p> <p>Click here to add another entry</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;"><b>Name</b></td> <td>Donna Mott</td> </tr> <tr> <td><b>Title</b></td> <td>Co-Sub: (Co-Sub-Investigator)</td> </tr> <tr> <td><b>Study Role(s):</b></td> <td> <input checked="" type="checkbox"/> Study-related Procedures  <input checked="" type="checkbox"/> Obtaining Consent  <input type="checkbox"/> Regulatory Activities  <input type="checkbox"/> Submitting Forms (Such as CRFs/DCFs, IRB Submissions)  <input type="checkbox"/> Administrative/No Subject Contact  <input type="checkbox"/> Supervising Research Activities         </td> </tr> <tr> <td><b>CITI Human Subject Research Training</b></td> <td>01/25/2024</td> </tr> <tr> <td><b>CITI COI (Investigators and Academic Advisors)</b></td> <td>01/25/2024</td> </tr> <tr> <td><b>CITI GCP (You only need to enter a GCP training date if your study requires compliance with ICH GCP E6 and you have completed CITI GCP training).</b></td> <td>01/25/2024</td> </tr> <tr> <td><b>Have you completed GCP training with an organization other than CITI?</b></td> <td><input type="radio"/> Yes <input checked="" type="radio"/> No</td> </tr> <tr> <td><b>Other Training</b></td> <td> <p>Title: None</p> <p>Date completed:</p> </td> </tr> </table>	<b>Name</b>	Donna Mott	<b>Title</b>	Co-Sub: (Co-Sub-Investigator)	<b>Study Role(s):</b>	<input checked="" type="checkbox"/> Study-related Procedures <input checked="" type="checkbox"/> Obtaining Consent <input type="checkbox"/> Regulatory Activities <input type="checkbox"/> Submitting Forms (Such as CRFs/DCFs, IRB Submissions) <input type="checkbox"/> Administrative/No Subject Contact <input type="checkbox"/> Supervising Research Activities	<b>CITI Human Subject Research Training</b>	01/25/2024	<b>CITI COI (Investigators and Academic Advisors)</b>	01/25/2024	<b>CITI GCP (You only need to enter a GCP training date if your study requires compliance with ICH GCP E6 and you have completed CITI GCP training).</b>	01/25/2024	<b>Have you completed GCP training with an organization other than CITI?</b>	<input type="radio"/> Yes <input checked="" type="radio"/> No	<b>Other Training</b>	<p>Title: None</p> <p>Date completed:</p>
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<b>Other Training</b>	<p>Title: None</p> <p>Date completed:</p>																

\* Critical that all KSP has verified CURRENT CITI Training

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### 6. In Section 6.31 – 6.34 Complete IND/IDE/HDE Information

Section view of Application	Entire view of the Application
1.0 General Information	6.31 Does the study involve an IND application? <input type="radio"/> Yes <input checked="" type="radio"/> No
2.0 Setup Department(s) Access	
3.0 Grant Key Personnel access to the study	6.32 Does the study involve an IDE application? <input type="radio"/> Yes <input checked="" type="radio"/> No
4.0 iRIS Application: General Information	
5.0 Type of Application	6.33 Does the study involve a HDE? <input type="radio"/> Yes <input checked="" type="radio"/> No
6.0 External IRB Request	6.34 Name of the organization or individual who holds the IND/IDE/HDE, or, write <u>Not applicable</u> : <input type="text"/>

\* Do not put Sponsor (if study has Sponsor)

### 7. In Section 6.36 - Complete Funding/Sponsor Information

**6.36 Funding Source:**  
Please select one of the following funding sources.

- None\*
- Federal\*\*
- Industry\*\*
- Departmental\*\*\*
- MHC foundation\*\*\*\*
- Other \*\*\*\*

Please select the Sponsor(s).

Delete	Edit	View Details	Sponsor Name	Sponsor Type
			Inari Medical, Inc.	04 - Industry Sponsored

**6.37 Funding Contact Name**

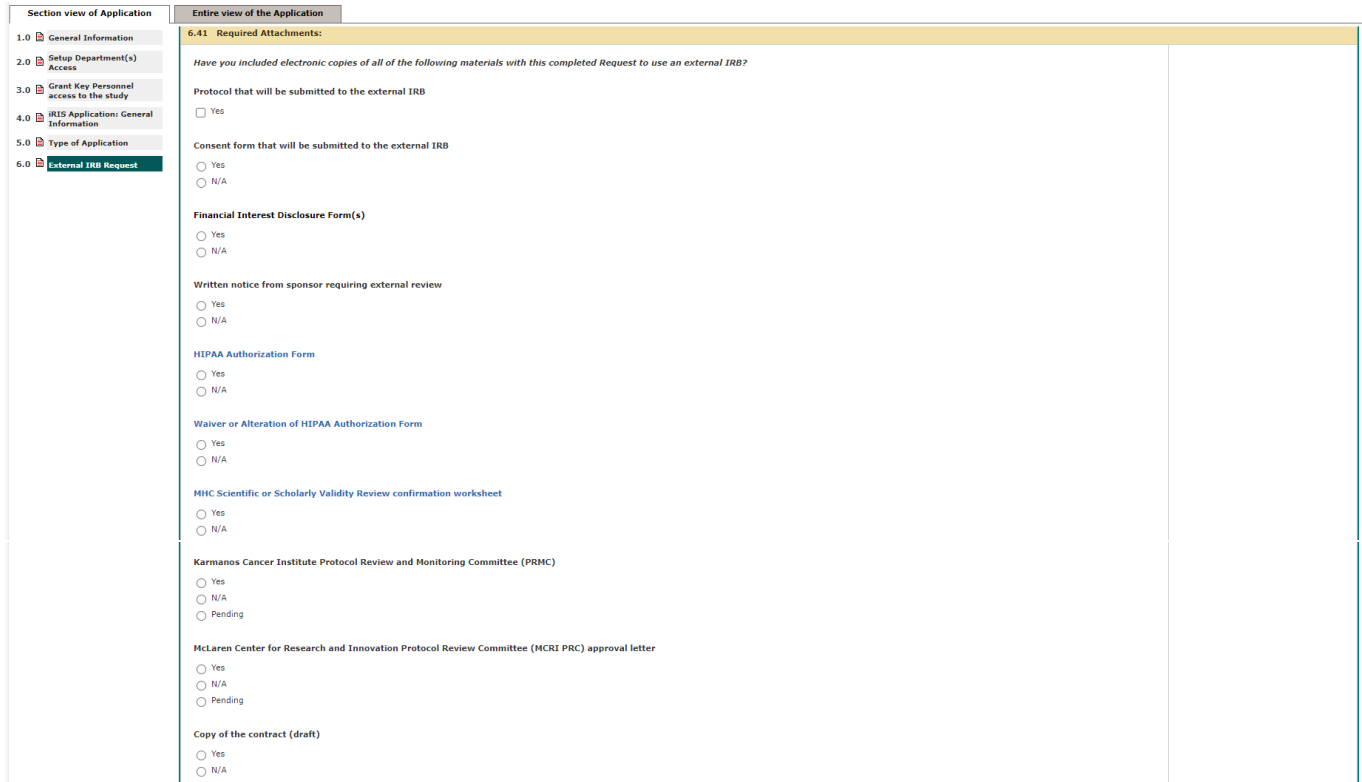
Please select the Sponsor(s).

+ Add a New Contact(s) to the Protocol								
Delete	Edit	View Details	Sponsor Name	Division	Contact Name	Title	Primary Phone	Email
			Inari Medical, Inc.		Smith, John			jsmith@email.com

## How to Complete a Request to Use External IRB Application in iRIS

### 8. In Section 6.41 Attach Required Documents

- PRMC approval letter is only for KCI submissions (current letters only)
- PRC approval letter is only for non-Oncology submissions (current letters only)
- AAHRPP Checklist Contract is only required for Industry Sponsored Studies

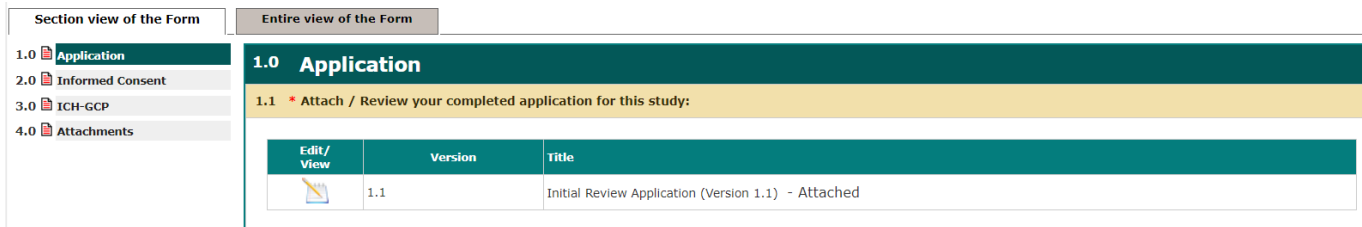


The screenshot shows the 'Entire view of the Application' for Section 6.41. The left sidebar lists sections 1.0 through 6.0, with 6.0 'External IRB Request' selected. The main content area contains the following questions and options:

- 6.41 Required Attachments:** Have you included electronic copies of all of the following materials with this completed Request to use an external IRB?
  - Protocol that will be submitted to the external IRB:  Yes
  - Consent form that will be submitted to the external IRB:  Yes,  N/A
  - Financial Interest Disclosure Form(s):  Yes,  N/A
  - Written notice from sponsor requiring external review:  Yes,  N/A
  - HIPAA Authorization Form:  Yes,  N/A
  - Waiver or Alteration of HIPAA Authorization Form:  Yes,  N/A
  - MHC Scientific or Scholarly Validity Review confirmation worksheet:  Yes,  N/A
  - Karmanos Cancer Institute Protocol Review and Monitoring Committee (PRMC):  Yes,  N/A,  Pending
  - McLaren Center for Research and Innovation Protocol Review Committee (MCRI PRC) approval letter:  Yes,  N/A,  Pending
  - Copy of the contract (draft):  Yes,  N/A

### 9. Submission Packet


- Section 1.0 will contain the completed application.
- Section 2.0 the ICF will already be attached here.
- Section 3.0 complete the questions as applicable.
- Section 4.0 the attachments will already be attached here.



The screenshot shows the 'Entire view of the Form' for Section 1.0. The left sidebar lists sections 1.0 through 4.0, with 1.0 'Application' selected. The main content area contains the following information:

**1.0 Application**

1.1 \* Attach / Review your completed application for this study:

Edit/View	Version	Title
	1.1	Initial Review Application (Version 1.1) - Attached

## How to Complete a Request to Use External IRB Application in iRIS

**3.0 ICH-GCP**

Good Clinical Practice (GCP) guidance is an international "ethical and scientific quality standard" for designing, conducting, recording, and reporting clinical trials in human subjects that was developed by the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). The GCP guidance developed by ICH is based on FDA regulations for the protection of human subjects and defines the roles and responsibilities of IRBs, investigators, monitors, and sponsors.

Sponsors or funding agencies like the NIH may require researchers who conduct clinical research to demonstrate knowledge of ICH good clinical practices. Typically, a drug study's sponsor indicates in the protocol and/or clinical trial agreement whether the study is subject to ICH-GCP guidelines.

The failure to follow GCP can expose research sponsors, clinical investigators and institutions to serious concerns about potential legal liability, not only from study participants, but from future health consumers (e.g., class action suits).

**3.2 Does your study require adherence to ICH GCP E6 guidelines?**

Yes  
 No  
 I am not sure

\* If you select "No," do not continue with remainder of questions/request for documents.  
 \* If you are not sure, please call the IRB office at 248-484-4950 or email [hrpp@mclaren.org](mailto:hrpp@mclaren.org)

**3.3 Have you and all key study personnel completed the required ICH GCP training?**

Yes  No

**3.4 Email a copy of your CV to [hrpp@mclaren.org](mailto:hrpp@mclaren.org)**

Completed  
 Previously done in a past submission

**3.5 If the Sponsor or Funding Agency of the research requires investigator compliance with ICH-GCP E6, the Investigator must attest that they will comply. Please attach signed attestation statement to this application in the next section called Attachments.**

## 10. Signoffs

My Workspaces  IRB **Submission Routing Signoff** Back

Protocol Title: Phase III Prospective Randomized Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed By Concurrent Mediastinal Chemoradiation For Locally Advanced Non-Small Cell Lung Cancer  
 Submission Reference Number: 007829

Printable Version

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version
<b>Submission Form(s)</b>			
<input type="checkbox"/>			Initial Review Submission Packet - (Version 1.0)
<b>Application</b>			
<input type="checkbox"/>			Initial Review Application - (Version 1.0)
<b>Consent Form(s)</b>			
<input type="checkbox"/>			HIPAA Authorization (English) - (Version 1.0)
<input type="checkbox"/>			Main consent form (English) - (Version 1.0)
<b>Document(s)</b>			
<input type="checkbox"/>			GCP_ [redacted] _042823_MSU - (Version 1.0)
<input type="checkbox"/>			NRG-LU008_ [redacted] _Admin_ Approv_091923 - (Version 1.0)
<input type="checkbox"/>			33711_ [redacted] _Protocol_v033023 - (Version 1.0)

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

ELECTRONIC SIGNATURE HAS BEEN APPLIED

## How to Complete a Request to Use External IRB Application in iRIS

### 11. Tracking

My Workspaces Study

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

11 result(s) found... 1 - 10 ▶

Click to open Protocol Dashboard	Reference Number	Review Board	RB Number	Form Name	Protocol Title	Form Author	Date Submitted	Actions
					Protocol Alias			
	007695	IRB	IRB-2023-0182	Initial Review Submission Packet	Chart Review - Exempt (new patch 12/08) CR-E 12.08	Flores, Michael	01/22/2024 11:57 AM EST	
Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time			
	Pre-Submission		01/22/2024 11:55 AM EST	01/22/2024 11:57 AM EST	0 Day(s) 0 Hour(s) 2 Minute(s)			
	IRB	Submission Components <span style="border: 1px solid gray; padding: 2px;">View Details</span>	Review Process Exempt	Review Outcome	Outcome Letters	01/22/2024 11:57 AM EST	01/22/2024 11:58 AM EST	0 Day(s) 0 Hour(s) 1 Minute(s)

### 12. Responding to stipulations

**All Tasks**
Outstanding
Completed
⚙️

All Tasks
Protocol Tasks
Task List : All
Filter By : --none--

13 result(s) found... 1 - 13

	Click to open	Task Type	Date Received	Description	Priority	Complete By
<input type="checkbox"/>		Submission Routing Signoff	01/23/2024 04:13 PM EST	Michael Flores as Principal Investigator review and apply signoff	No Priority	
<input type="checkbox"/>		Analyst Assignment	01/17/2024 09:47 AM EST	Michael Flores has been assigned as the analyst	No Priority	
<input type="checkbox"/>		Analyst Assignment	11/16/2023 09:53 AM EST	Michael Flores has been assigned as the analyst	No Priority	
<input type="checkbox"/>		Waiting Submission	10/27/2023 04:11 PM EST	Initial Review Submission Packet is waiting to be submitted	No Priority	

### 13. Response time

If there are any stipulations from the IRB Analyst or IRB Reviewer and you are not sure how to answer, please contact us. This will cut down on the turnaround time to complete the application.

## How to Complete a Request to Use External IRB Application in iRIS

### 14. Support

The IRB analyst are available for support to get your submission completed. You can reach us via Microsoft Teams, Outlook or call directly. Teams is recommended as we can assist in real time and take you through your issue step by step within your application.