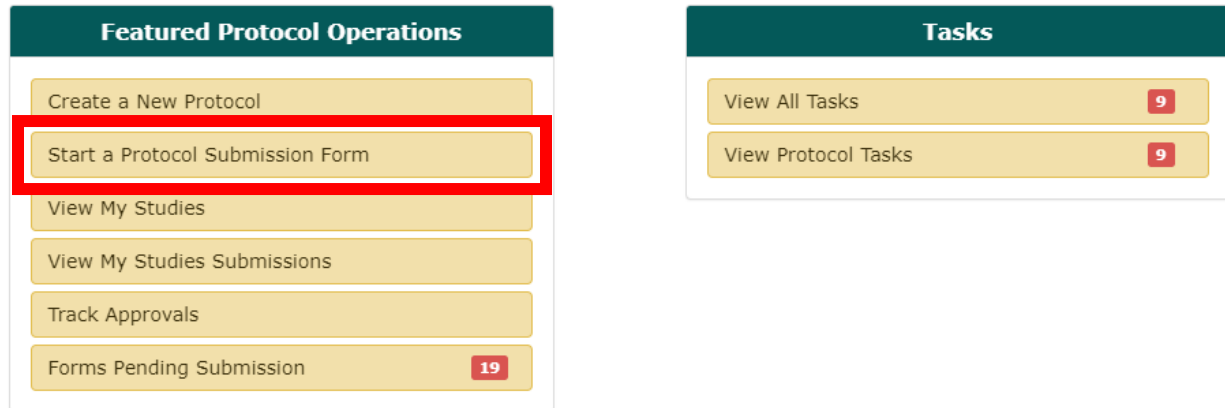


# Submitting an Unanticipated Problem Report

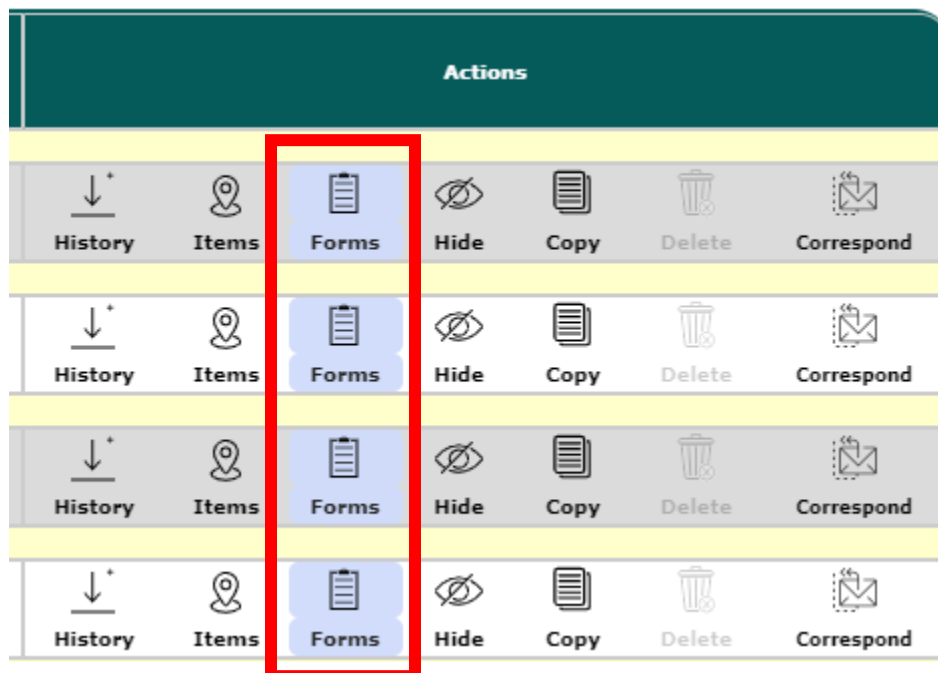
---

At any point during the life of your study you can create an **Unanticipated Problem Report** form.

To begin an **Unanticipated Problem Report** 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 an **Unanticipated Problem Report** 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 Unanticipated Problem Report** and click the  icon underneath the **Start a new Submission** column.

Submission Form List <span style="float: right;">X</span>			
	Version List	Start a new Submission	Edit incomplete Submissions
McLaren Continuing Review form			
McLaren IRB Final Report Form			
McLaren Modification form			
<b>McLaren Unanticipated Problem Report</b>			
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 indicate the type of report and other details regarding the Unanticipated Problem. You will also have the opportunity to attach any supporting documentation.

Complete the sections of the **Unanticipated Problem Report** form using the gray **Save and Continue** button in the upper right of each screen to navigate through the sections, as shown below:

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

Section view of the Form   Entire view of the Form

Instructions This form is for reporting Unanticipated Problem ...

1.0 reporting Unanticipated Problem ...

2.0 General Information

3.0 **Type of report**

### 3.0 Type of report

#### 3.1 Report

Local  
 Non Local  
 Humanitarian Use Device  
 McLaren-required Report

Please select if initial or follow-up

**NOTICE:** If you previously made a selection of initial or follow-up and now wish to change that selection, please hit the clear button before selecting your new response.

Initial  
 Follow-up

Clear

#### 3.2 Date UPIRSO occurred



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

Section view of the Form   Entire view of the Form

Instructions This form is for reporting Unanticipated Problem ...

1.0 reporting Unanticipated Problem ...

2.0 General Information

3.0 Type of report

4.0 **Location where the Unanticipated Problem occur?**

### 4.0 Location where the Unanticipated Problem occur?

#### 4.1 Where did the Unanticipated Problem Occurred?

McLaren Health Care Site  
 Off site

What McLaren Health Care Site?

[Click here to access the text editor.](#)



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

Section view of the Form   Entire view of the Form

Instructions This form is for reporting Unanticipated Problem ...

1.0 reporting Unanticipated Problem ...

2.0 General Information

3.0 Type of report

4.0 Location where the Unanticipated Problem occur?

5.0 **Unanticipated Problem Type**

### 5.0 Unanticipated Problem Type

#### 5.1 Select ALL that apply:

Treatment  
 Unanticipated drug reaction  
 Device malfunction  
 Consent  
 Hospitalization/prolonged hospitalization  
 Persistent or significant disability /harm  
 Death  
 Breach of Privacy/Confidentiality  
 Other

#### 5.2 Unanticipated Problem Description

Include the following details in the narrative, as applicable:  
-Description of what happened;  
-Dates when the event occurred;



[Print Friendly](#)   [Refresh Constant Fields](#)   [Save Section](#)   [Save and Continue to Next Section](#)

**Section view of the Form**

- 1.0 Instructions This form is for reporting Unanticipated Problem ...
- 2.0 General Information
- 3.0 Type of report
- 4.0 Location where the Unanticipated Problem occur?
- 5.0 Unanticipated Problem Type
- 6.0 Criteria for Determination of Unanticipated Problem - Initial Report

**Entire view of the Form**

**6.0 Criteria for Determination of Unanticipated Problem - Initial Report**  
All three criteria above must be met for an event to be considered an unanticipated problem. If there is a possibility that an event meets the criteria, the event should be reported to the IRB via this form.

**6.1 Expectedness**

Is the event unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.

Yes    No

**6.2 Relatedness**

Is the event related or possibly related to participation in the research? (Possibly related means there is a reasonable possibility that the incident, experience, or outcomes may have been caused by the drug, device, or procedure involved in the research).



[Print Friendly](#)   [Refresh Constant Fields](#)   [Save Section](#)   [Save and Continue to Next Section](#)

**Section view of the Form**

- 1.0 Instructions This form is for reporting Unanticipated Problem ...
- 2.0 General Information
- 3.0 Type of report
- 4.0 Location where the Unanticipated Problem occur?
- 5.0 Unanticipated Problem Type
- 6.0 Criteria for Determination of Unanticipated Problem - Initial Report
- 7.0 Action(s) taken and Medical Treatment Related to the Unanticipated Problem

**Entire view of the Form**

**7.0 Action(s) taken and Medical Treatment Related to the Unanticipated Problem**

**7.1 Describe the medical treatment (already provided or planned) for the participant related to this Unanticipated Problem.**

No action taken  
 Dose adjustment or other alteration of the intervention  
 Temporary discontinuation of study drug/device/procedure  
 Permanent discontinuation of study drug/device/procedure  
 Other - Please explain:

Please explain:

[Click here to access the text editor.](#)



[Print Friendly](#)   [Refresh Constant Fields](#)   [Save Section](#)   [Save and Continue to Next Section](#)

**Section view of the Form**

- 1.0 Instructions This form is for reporting Unanticipated Problem ...
- 2.0 General Information
- 3.0 Type of report
- 4.0 Location where the Unanticipated Problem occur?
- 5.0 Unanticipated Problem Type
- 6.0 Criteria for Determination of Unanticipated Problem - Initial Report
- 7.0 Action(s) taken and Medical Treatment Related to the Unanticipated Problem
- 8.0 Attachments

**Entire view of the Form**

**8.0 Attachments**

**8.1 Add your attachments here**

Add a New Document

Add Multiple Documents

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

When you have completed all sections of the Unanticipated Problem Report form, you will be presented with a screen notifying you that the form is complete, as shown below:

The screenshot shows the 'Form has been Completed!' message at the top of the form. On the left is a table of contents with sections 1.0 through 8.0. At the top right are 'Print Friendly' and 'Signoff and Submit' buttons. In the center of the form area are 'Exit Form' and 'Signoff and Submit' buttons. The 'Signoff and Submit' buttons are highlighted with red boxes.

Section view of the Form	Entire view of the Form
1.0 Instructions This form is for reporting Unanticipated Problem ...	Form has been Completed!
2.0 General Information	
3.0 Type of report	
4.0 Location where the Unanticipated Problem occur?	
5.0 Unanticipated Problem Type	
6.0 Criteria for Determination of Unanticipated Problem - Initia ...	
7.0 Action(s) taken and Medical Treatment Related to the Unantic ...	
8.0 Attachments	

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

The pop-up window shown below will appear. Click **OK** to proceed:

The pop-up window contains the following text:

**You are required to signoff on the submission.**

You will now be redirected to the signoff screen to apply your electronic signature.

You can monitor the submission progress with the Submission Status - In Progress.

OK (8)

The **Unanticipated Problem Report** form is now available for review.



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

If you are *NOT* the PI: The PI will be notified that there is an **Unanticipated Problem Report** awaiting their electronic signoff in iRIS. When you reach the end of the **Unanticipated Problem Report** form, select either of the **Notify PI to Signoff** buttons.

At any time while working through the **Unanticipated Problem Report** 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.

When you return to iRIS to complete your **Unanticipated Problem Report** 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 **Unanticipated Problem Report** 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 Unanticipated Problem Report**.

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 Unanticipated Problem Report form.

Submission Form List			
	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 Unanticipated Problem Report form to complete and submit, click on the icon underneath the Edit/View column.

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

1 result(s) found...

	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	10/25/2021 09:03:04 AM	Andrea Klaver	10/25/2021 09:03:12 AM