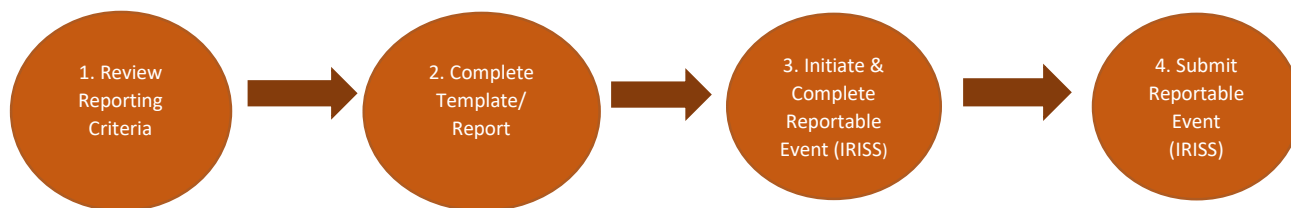


REPORTABLE EVENTS

A Reportable Event is any incident or change that happens throughout the course of research that may impact the participants or the conduct of the study.



1. REVIEW REPORTING CRITERIA

For more information on Reportable Events, including detailed descriptions of each category and reporting criteria, visit the following webpages:

- CHREB: <https://www.ucalgary.ca/research/researchers/ethics-compliance/chreb>
- CFREB: <https://www.ucalgary.ca/research/researchers/ethics-compliance/cfieb>

2. COMPLETE TEMPLATE / REPORT

For categories linked to corresponding templates, you must complete and upload the template as part of the IRISS submission.

Category	Reporting Criteria/Description	Reporting Timeline	Template
Serious Adverse Event (SAE) – Local	Adverse events experienced by research participants at the site(s) under the jurisdiction of the REB. A local SAE is reportable if the PI believes it is an unanticipated problem related to the research, and places research participants or others at a greater risk of harm.	Fatal or life-threatening SAEs should be reported within 7 calendar days of the PI becoming aware of them. All other local SAEs should be reported within 15 calendar days of the PI becoming aware of them.	CHREB CFREB
Serious Adverse Event (SAE) – Non-Local (CHREB only)	Adverse events experienced by research participants at centres/institutions outside the REB’s jurisdiction. A non-local SAE is reportable if the PI believes it is an unanticipated problem related to the research, and places research participants or others at a greater risk of harm.	Within 15 calendar days of the PI becoming aware of the non-local SAE.	CHREB
Protocol Deviation /Violation	Protocol Deviations/Violations are departures from the procedures set forth in the REB approved application. These include departures that: <ul style="list-style-type: none"> • Compromise the scientific integrity of the study, and/or • Constitute or may constitute a potential safety risk to participants enrolled in the 	Changes to eliminate immediate safety risks to the study participants should be reported within 7 calendar days. All other violations should be reported within 15 calendar days of the PI becoming aware of the deviation/violation	CHREB CFREB

	<p>protocol or others affected by the research, and/or</p> <ul style="list-style-type: none"> • Are non-compliant with applicable regulations governing human research, and/or • Are non-compliant with the requirements or determinations of the REB, or an allegation of such non-compliance, and/or • Consist of any unauthorized collection, use, or disclosure of participant personal information 		
Follow-Up Report	Follow-up report requested by the REB if/when more information becomes available, and/or if the issue remained unresolved in the initial report.		
Report	Written report or memorandum from study monitors or sponsors, such as summary or periodic safety reports or data safety monitoring board.	Within 15 calendar days of receiving the report.	
Audit	Audit, inspection, or inquiry by a university, provincial or federal agency. Only reports with information relevant to the REB should be submitted	Within 15 calendar days of receiving the audit report	
Suspension	Suspension of active and ongoing research by the sponsor, PI, REB or institution.		CHREB CFREB
Participant Complaint	Complaints made by participants or others affected by the research concerning their well-being (psychological or physical) and/or respectful and fair treatment from the researchers		CHREB CFREB

3. INITIATE & COMPLETE REPORTABLE EVENT

Any member of the Study team and Ethics Administrators can initiate a Reportable Event:

1. Login to IRISS: <https://research.ucalgary.ca/iriss>
2. Under the **Research List** tab, navigate to the study
3. Click on the ethics ID



» **My Home** Researcher Profile Help

Study / Teaching Staff

My Roles

Study / Teaching Staff

Create an application for:

Animal Care Committee

Create ACC Incident Report

Create an application for:

Research Ethics Board

Page for Test Test

Inbox ACC REB **REB Protocols Research List** ⋮

Active REB Protocols

Filter ? ID ▾ Enter text to search for Go + Add Filter ✕ Clear All Export

ID	Current State	Short Title	PI	Co-I(s)	Coordinator (s)	Study Team	Renewal (s)/Closure (s)	Modification (s)	Reportable Event(s)	Expiry Date
REB18-1378	Template	Testing Study	Test	Test						

4. Click 'Create Reportable Event'.

Create Reportable Event

» **My Home** Researcher Profile Help

Hello, Test Test ▾

Current State

Approved

View Study

Printer Version

View Differences

View SmartForm Progress

Create a Modification

Request Closure

Create Reportable Event

REB Certification File: Test account- Study title here (REB18-1380)

Formal Title: Test study title - long title placeholder **Legacy File Number:**

Submission Type: Faculty/Staff Research

Principal Investigator: Test Test **Approving Board:** CHREB

Primary Admin Contact(s): Test Test **Certificate of Approval:** View

Original Approval Date: August 22, 2018 **Letter of Approval:** View

Last Approval Date: September 18, 2018 **Expiration Date:** November 30, 2018

History Renewals Attachments Change Log Reviewer Notes

Activity	Author	Activity Date
Renewal Completed	Krecsy, Ashley Cassandra	2018-09-25 3:10 PM

Important! Each Reportable Event requires a document to be uploaded before the Principal Investigator can submit. Refer to the guidance website for more information.

5. By pressing 'Save or Continue' you will create a new REB reportable event. You will be able to access this reportable event through your personal page. As you complete this form, you can save your work, exit and come back at any time.

Getting Started – Reportable Event

By completing the information on the next page and clicking 'Save and Close' you will create a new REB Reportable Event. You will be able to access this Reportable Event through your Personal Page. As you complete this form, you can save your work, exit and come back at any time.

✕ Exit

Save

Continue ➔



6. Enter a meaningful title that will allow you to quickly identify the Reportable Event.

Validate Compare

Getting Started – Reportable Event

Reportable Event Information

Editing: REB21-1529_RE2

Go to forms menu Print Help

Reportable Event

The purpose of this form is to submit reportable event(s) to the REB. **Only submit events which meet REB reporting criteria (see the CHREB or CFREB Guidance for more information)**

(* indicates a required field)

1.0 * **Reportable event title:** (uniquely identify the reportable event(s), i.e. "Protocol Deviation", as applicable. If you are notifying the REB of a protocol deviation or a local adverse event, include the words "Protocol Deviation" or "Local AE" as applicable in the title.)

2.0

7. Select applicable categories.

Validate Compare

Getting Started – Reportable Event

Reportable Event Information

(* indicates a required field)

Go to forms menu Print Help

1.0 * **Reportable event title:** (uniquely identify the reportable event(s), i.e. "Protocol Deviation", as applicable. If you are notifying the REB of a protocol deviation or a local adverse event, include the words "Protocol Deviation" or "Local AE" as applicable in the title.)

2.0 * **Identify the categories that represent the reportable event:** (select all that apply)

Category	Reporting Criteria / Description	Reporting Timeline	Template
<input type="checkbox"/> Serious Adverse Event (SAE) - Local	Local SAEs are adverse events experienced by research participants at the site(s) under the jurisdiction of the REB. A local SAE is reportable if the PI believes it is an unanticipated problem related to the research, and places research participants or others at a greater risk of harm.	Fatal or life-threatening SAEs should be reported within 7 calendar days of the PI becoming aware of them. All other local SAEs should be reported within 15 calendar days of the PI becoming aware of them.	CHREB CFREB
<input type="checkbox"/> Serious Adverse Events (SAE) - Non-Local	Non-local SAEs are adverse events experienced by research participants at centers/institutions outside the REB's jurisdiction. A non-local SAE is reportable if the PI believes it is an unanticipated problem related to the research, and places research participants or others at a greater risk of harm.	Within 15 calendar days of the PI becoming aware of the non-local SAE.	CHREB
<input type="checkbox"/> Protocol Deviation/Violation	Protocol Deviations/Violations are departures from the procedures set forth in the REB approved application. These include departures that: <ul style="list-style-type: none">Compromise the scientific integrity of the study, and/orConstitute or may constitute a potential safety risk to participants enrolled in the protocol or others affected by the research, and/orAre non-compliant with applicable regulations governing human research, and/orAre non-compliant with the requirements or determinations of the REB, or an allegation of such non-compliance, and/orConsist of any unauthorized collection, use, or disclosure of participant personal information.	Changes to eliminate immediate safety risks to the study participants should be reported within 7 calendar days, all other violations should be reported within 15 calendar days of the PI becoming aware of the deviation/violation.	CHREB CFREB
<input type="checkbox"/> Follow-Up Report	Follow-up report requested by the REB if/when more information becomes available, and/or if the issue remained unresolved in the initial report.	As required	
<input type="checkbox"/> Report	Written report or memorandum from study monitors or sponsors, such as summary or periodic safety reports or data safety monitoring board (DSMB).	Within 15 calendar days of receiving the report	
<input type="checkbox"/> Audit	Audit, inspection, or inquiry by a university, provincial or federal agency. Only reports with information relevant to the REB are to be submitted.	Within 15 calendar days of receiving the audit report	
<input type="checkbox"/> Suspension	Suspension of active and ongoing research by the sponsor, PI, REB or institution.		CHREB CFREB
<input type="checkbox"/> Participant Complaint	Complaints made by participants or others affected by the research concerning their well-being (psychological or physical) and/or respectful and fair treatment from the researchers		CHREB CFREB

8. Upload completed template or report.

3.0

Attach completed template and/or relevant supporting documentation: (The Principal Investigator will NOT be able to submit this reportable event without uploaded documentation.)

+ Add

Document Name	Document	Version	Document Date	Upload Date
There are no items to display				

Note: Most categories have a corresponding template, upload the completed template along with any supporting documentation.



OPTIONAL:

- **Related Studies:** Link studies to the Reportable Event when all categories selected apply. When processed, it will be acknowledged for all studies.
- **Comments:** Any additional information you would like to communicate to the REB.

4.0

Related studies: Link any additional studies that ALL information in this reportable event submission applies to. If any of the documents do not apply to all studies, submit a separate reportable event for that document.

PI	Ethics ID	Study Title	State
There are no items to display			

5.0

Comments:

Click the 'Save & Close' button to close this form. (This action does NOT submit the reportable event request)

You will be directed to the Reportable Event Workspace.

Once all required information has been entered, the Principal Investigator will be able to submit the reportable event request by clicking on the 'Submit Reportable Event' activity button on the left-side menu of the Reportable Event Workspace.

Click REB18-1101 to view the Study.

Exit

Save

Finish

9. Click the 'Save & Close' button to close this form. (This action does NOT submit the reportable event request).
10. You will be directed to the Reportable Event Workspace.
11. Once all required information has been entered, the Principal Investigator will be able to submit the reportable event request by clicking on the 'Submit Reportable Event' activity button on the left-side menu of the Reportable Event Workspace.



4. SUBMIT REPORTABLE EVENT

The Principal Investigator can submit the prepared Reportable Event to the REB.

Current State

Pre Submission

Edit Reportable Event

Printer Version

View Differences

My Activities

Log Comment to REB Admin

Send Email to Study Team

Withdraw

Submit Reportable Event

Reportable Event Submission

Investigator Attestation:

- The information contained in this submission is complete and accurate.
- I understand that any modifications to the study required as a result of this submission must undergo REB review and approval prior to implementation, except where necessary to eliminate immediate hazard to study participants.

Please note that once you click OK you will no longer be able to edit the form. After submission, you may receive email notifying you of the current state of review or if changes are required by you.

If you are ready to submit this Reportable Event, click OK. Otherwise, click Cancel.

OK Cancel

FAQs

- **Q:** When can a **Reportable Event** be created?
- **A:** **Reportable Events** can be created any time post ethics approval. This includes studies that are Completed or Closed by Administrator.
- **Q:** I have a renewal or modification open; can I create and submit a Reportable Event at the same time?
- **A:** Yes, **Reportable Events** can be created and submitted when a modification, renewal or closure is in process.
- **Q:** An ethics administrator started a **Reportable Event**, is that permitted?
- **A:** Yes, **Reportable Events** can be created by an ethics administrator. However, they can only be submitted by any member on the study team.
- **Q:** I submitted a **Reportable Event** that doesn't meet the REB reporting standard, what happens?
- **A:** It will be closed by an ethics administrator and you will receive an email notification indicating the submission did not meet the REB reporting standard.
- **Q:** Can I create and submit multiple **Reportable Events** at the same time?
- **A:** Yes, there is no restriction on the number **Reportable Events** that can be created and submitted.