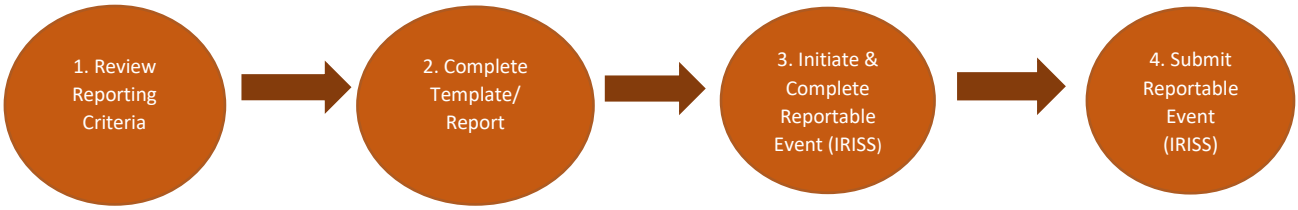
REPORTABLE EVENTS

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/cfreb

2. COMPLETE TEMPLATE / REPORT

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

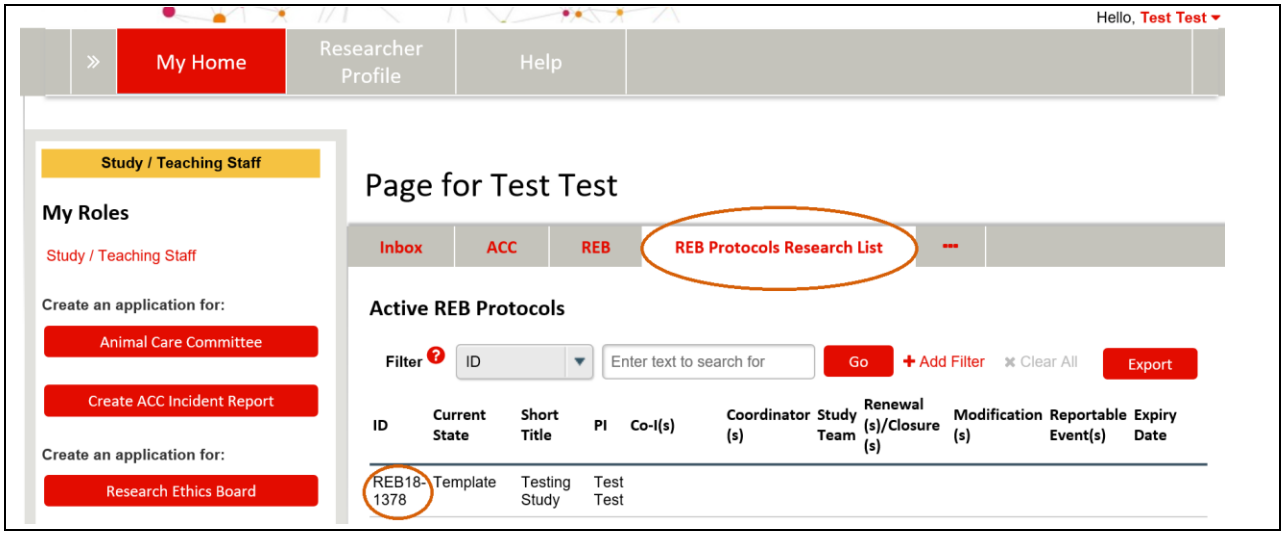
Category	Reporting Criteria/Description	Reporting Timeline	Template
Serious Adverse Event (SAE) – Local	Adverse events experienced by research participants at the site(s) under the jurisdiction of the REB. A local SAE is reportable if the PI believes it is an unanticipated problem related to the research, 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: • Compromise the scientific integrity of the study, and/or • Constitute or may constitute a potential safety risk to participants enrolled in the protocol or others affected by the research,	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

	and/or • 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

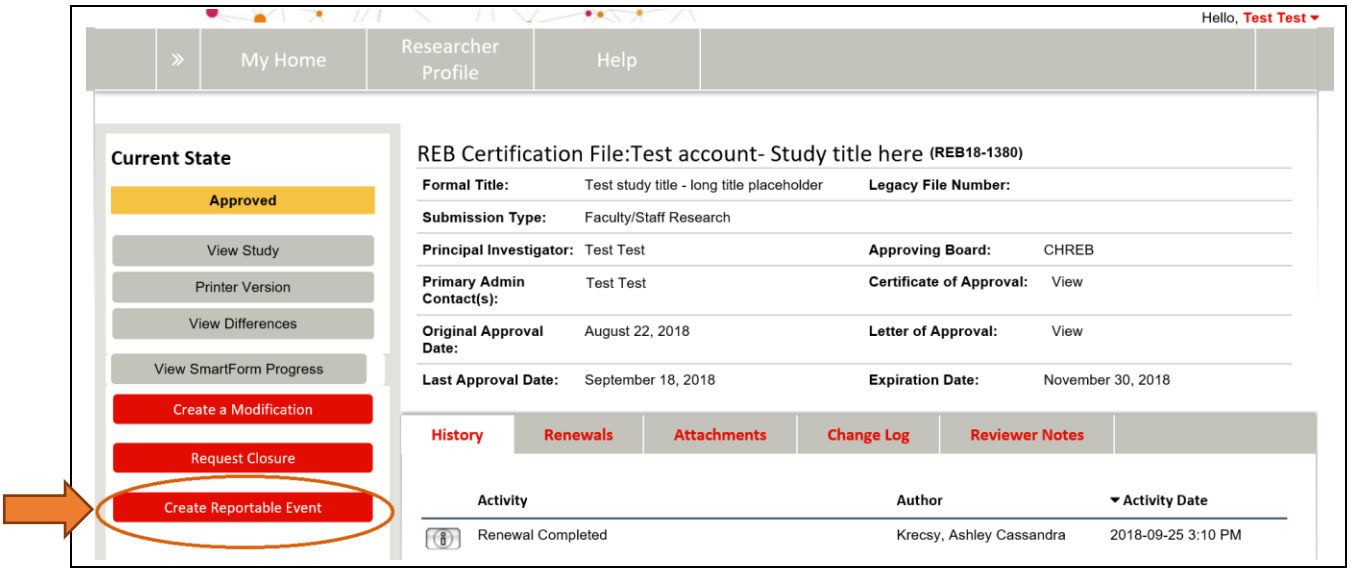
3. INITIATE & COMPLETE REPORTABLE EVENT

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

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

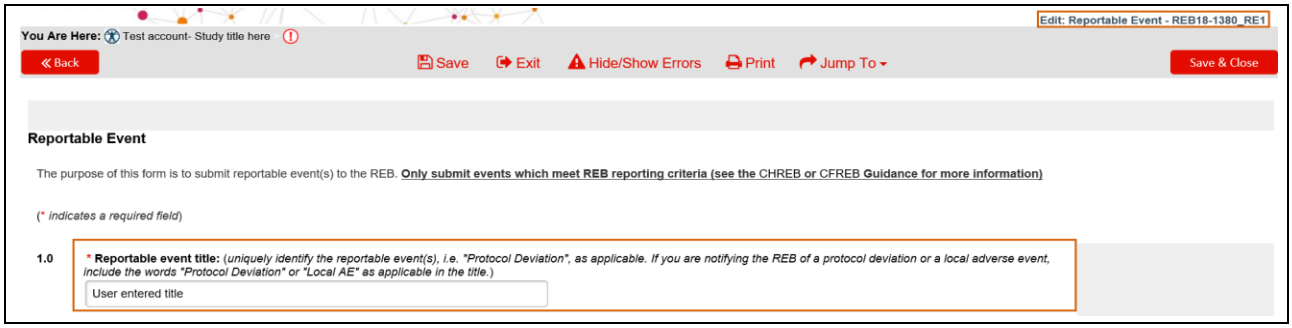


4. Click on Create Reportable Event



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. Enter a meaningful title that will allow you to quickly identify the Reportable Event. The Reportable Event ID is generated (top right corner) when saved.



6. Select applicable categories.

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

	Category	Reporting Criteria / Description	Reporting Timeline	Template
☐	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
☐	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
☐	Protocol Deviation/Violation	Protocol Deviations/Violations are departures from the procedures set forth in the REB approved application. These include departures that: ▪ Compromise the scientific integrity of the study, and/or ▪ Constitute or may constitute a potential safety risk to participants enrolled in the protocol or others affected by the research, and/or ▪ 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.	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
☐	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	
☐	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	
☐	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	
☐	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

7. Upload completed template or report

3.0

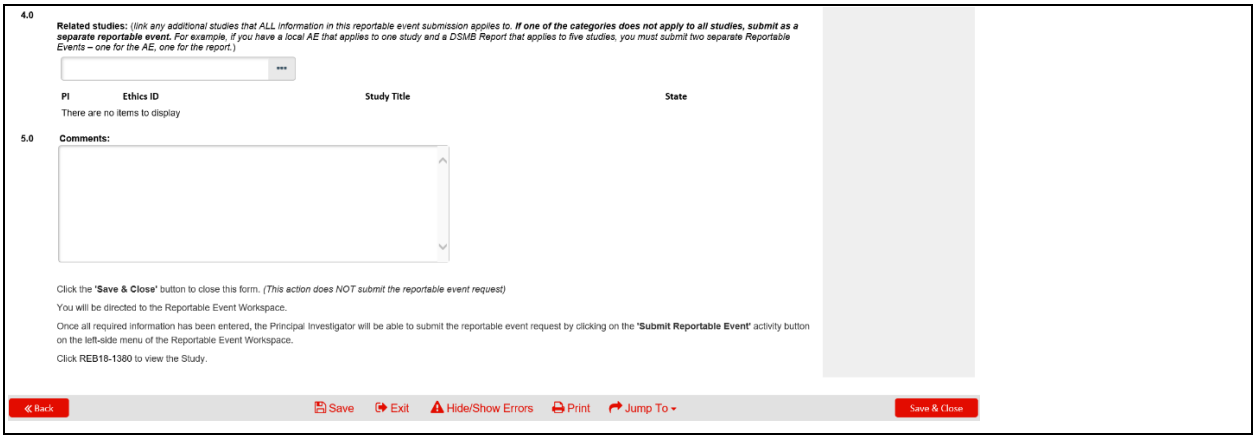
Attach completed template and/or relevant supporting documentation: (*The Principal Investigator will NOT be able to submit this reportable event without uploaded documentation.*)

+ Add

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

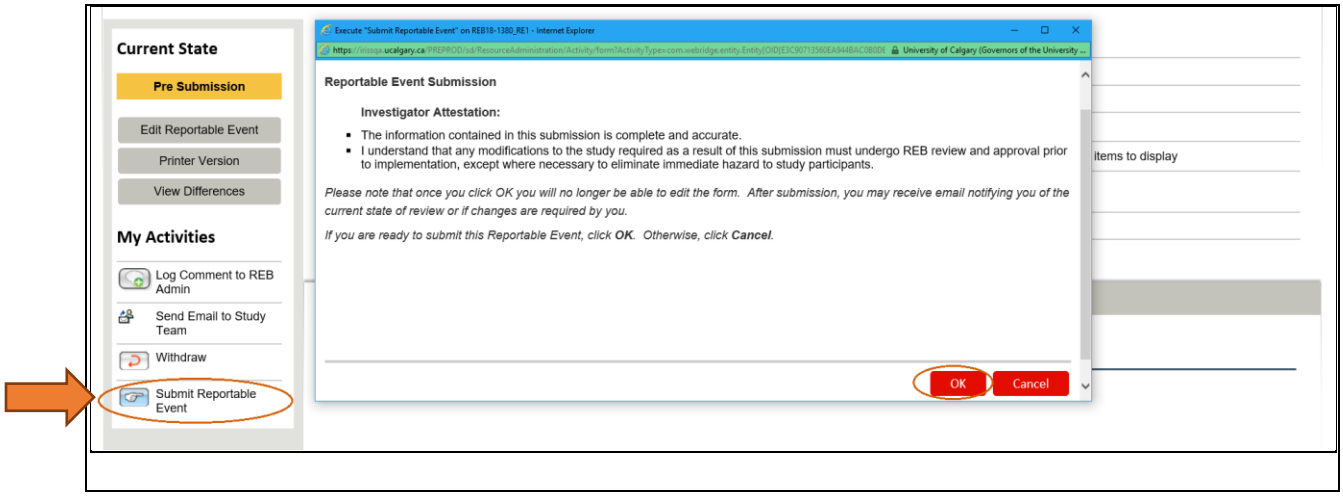
OPTIONAL:

- **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. SUBMIT REPORTABLE EVENT

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



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 but only submitted by the Principal Investigator.

➢**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, 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.