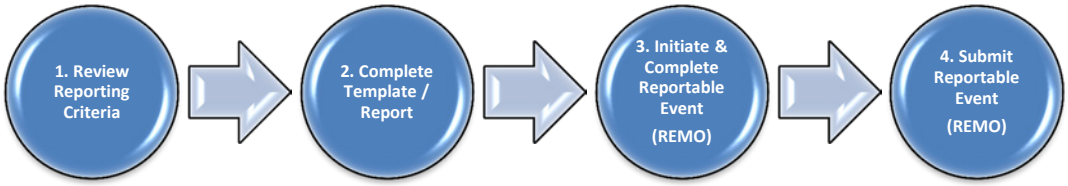
REPORTABLE EVENTS

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 Research Ethics Office webpage: https://www.ualberta.ca/research/support/ethics-office/human-research-ethics/research-ethics-boards/reb-4/reporting-requirements

2. COMPLETE TEMPLATE / REPORT

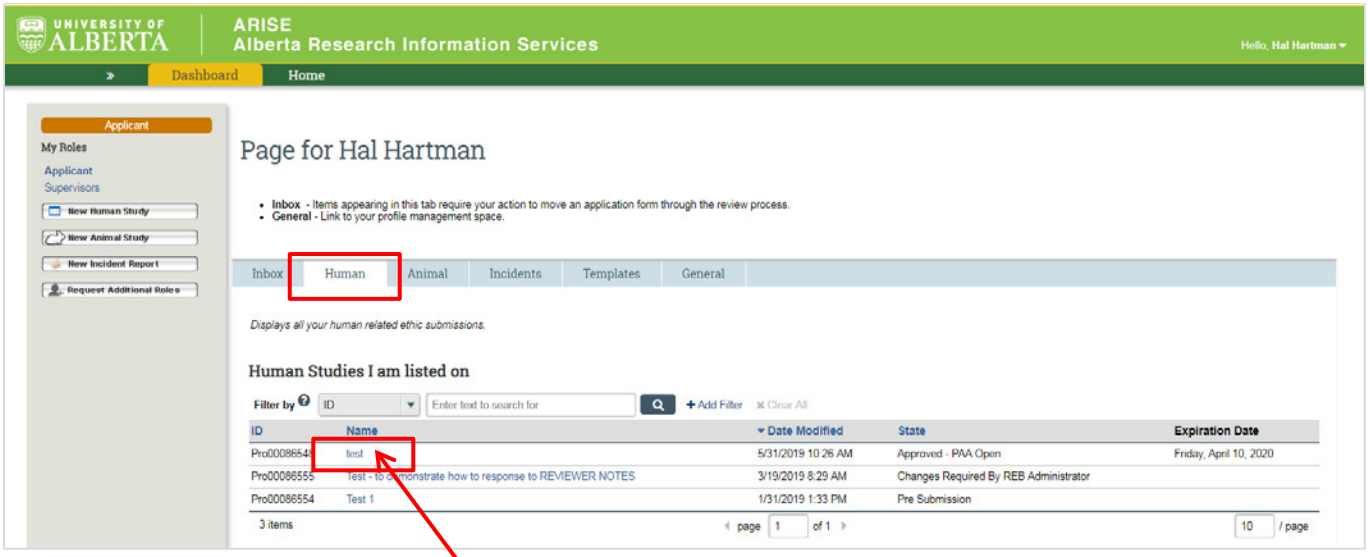
For categories linked to corresponding templates, you must complete and upload the template as part of the Reportable Event submission.

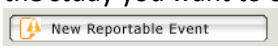
Category	Reporting Criteria/Description	Reporting Timeline	Template
Serious Adverse Event (SAE) – Local	Local SAEs are adverse events experienced by research participants at the site(s) under the jurisdiction of the REB. A local SAE is reportable if the PI believes it is an unanticipated problem related 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.	HREB
Serious Adverse Event (SAE) – Non-Local (*REB4 only*)	Non-local SAEs are 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 (unexpected, related or possibly related to participation in the research and places research participants or others at a greater risk of harm) **AND** requires a change to the protocol and/or informed consent form or immediate notifications to participants for safety reasons.	Within 15 calendar days of the PI becoming aware of the non-local SAE.	See SOP
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.	HREB
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	Report any local audit, inspection, or inquiry by a university, provincial or federal agency to the REB. A copy of the audit findings must also be submitted.	Report that audit will be conducted once it is scheduled. Submit the audit report within 15 calendar days of receipt.	
Suspension	Suspension of active and ongoing research by the sponsor, PI, REB or institution.	Report as information is received.	
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.		

3. INITIATE & COMPLETE REPORTABLE EVENT

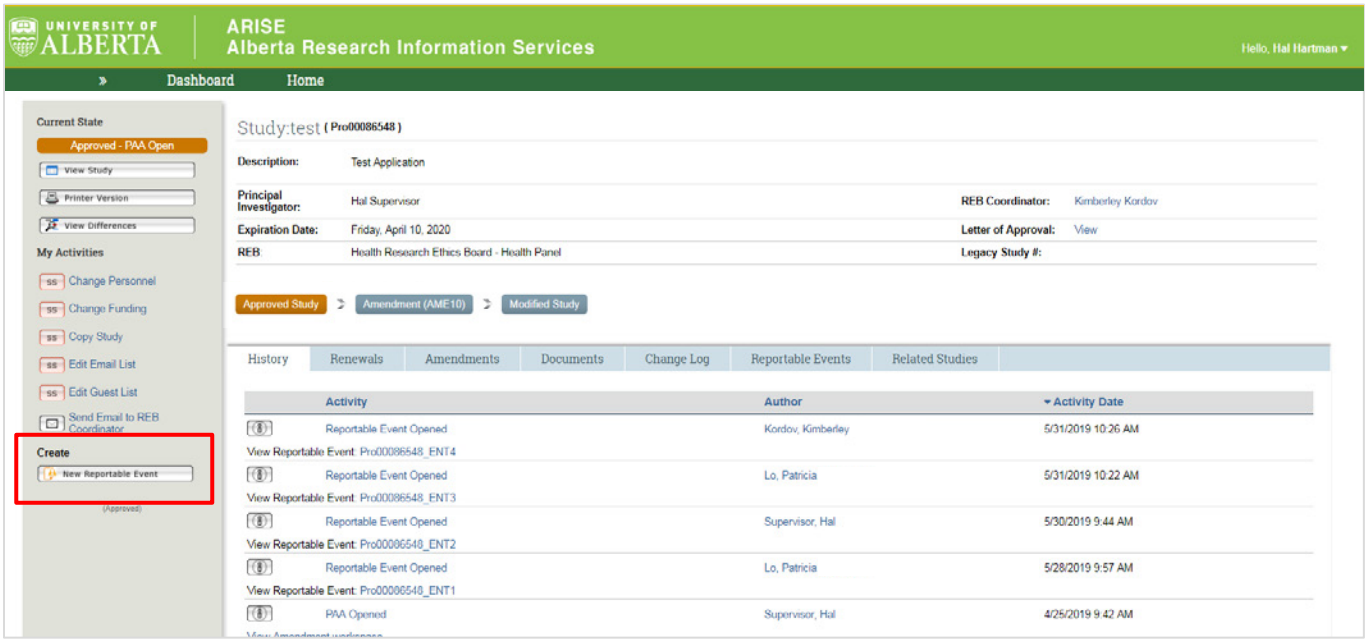
Any member of the Study Team and Ethics Administrators can initiate a **Reportable Event**:

1. Login to the on-line system: https://arise.ualberta.ca
2. Under the Human tab, navigate to the study.

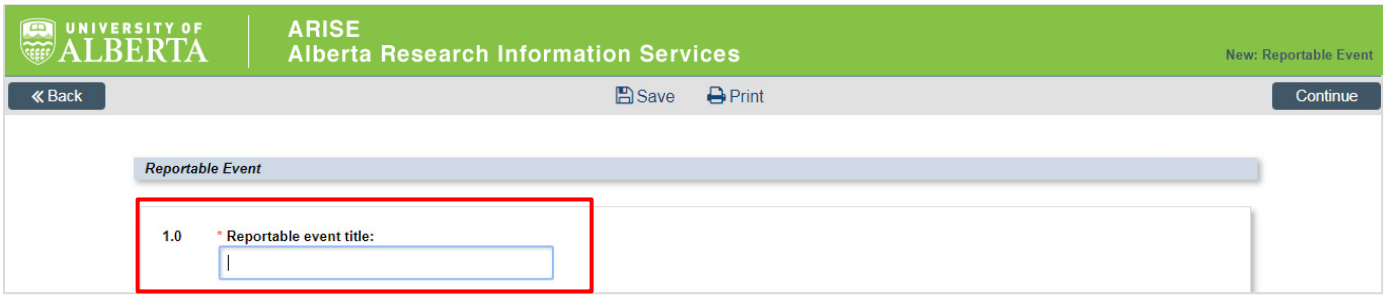


3. Click on the study you want to open.
4. Click on 

.



5. Enter a meaningful title that will allow you to quickly identify the **Reportable Event**. The title you enter will be auto-populated onto the acknowledgement letter. The **Reportable Event ID** is generated (top right corner) when saved. We recommend the "type of reportable event" followed by a participant ID if it is related to a particular participant (ie: SAE Participant 001; or DSMB letter Nov 2018).



6. Select applicable category. You are able to select multiple categories for one submission. However, consider submitting categories of events (ie: DSMB Reports 2018-Mar 2019) rather than combining unrelated events (ie: SAE Participant 001, DSMB and Sponsor Memo).

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

Category	Reporting Criteria/Description	Reporting Timeline	Template
☐ Serious Adverse Event (SAE) – Local	Serious adverse events (as defined in ICH) experienced by a research participants at the local site(s) under the jurisdiction of the REB. A local SAE is reportable if the PI believes it is an unanticipated problem (unexpected, related or possibly related to participation in 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	Local SAE Report(0.01)
☐ Serious Adverse Event (SAE) – Non-Local	Non-local SAEs are 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 (unexpected, related or possibly related to participation in the research and places research participants or others at a greater risk of harm) AND requires a change to the protocol and/or informed consent form or immediate notifications to participants for safety reasons.	Within 15 calendar days of the PI becoming aware of the non-local SAE	
☐ Protocol Deviation/Violations	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	Protocol-Violation Form(0.01)
☐ 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.		
☐ 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		

7. Upload completed template or report, if applicable. Otherwise, upload supporting documentation (ie: site Note to File or Memo). Click + Add to upload your file, or drag and drop the file.

3.0 **Attach completed template and/or relevant supporting documentation:** *(if applicable.)*

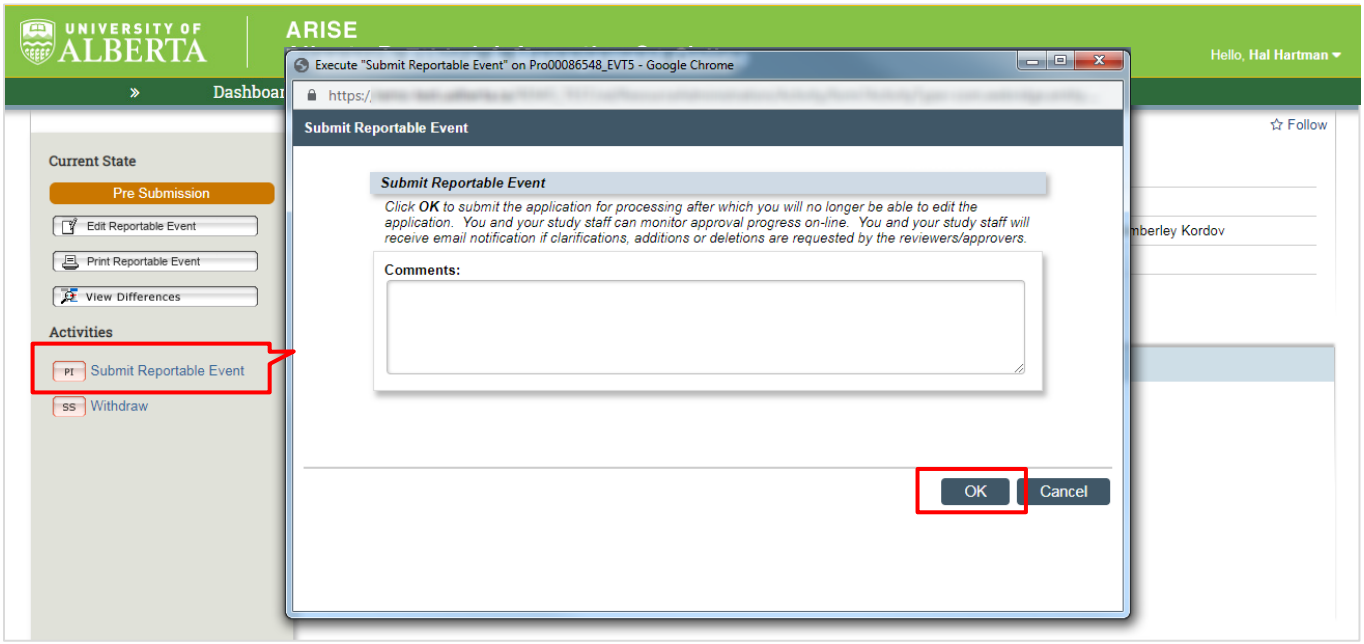
+ Add

Document Name	Version	Date	Description
There are no items to display			

8. Comments: Enter any additional information you would like to communicate to the REB. Then click the **Continue** button to save and exit the form.

4. SUBMIT REPORTABLE EVENT

Submit the prepared **Reportable Event** to the REB by clicking "Submit Reportable Event" on the left. Enter any comment to the REB in the pop-up, and click OK.



Notes:

a. If you would like to Withdraw your Reportable Event from review, you can click the Withdraw button (shown above).
b. After submitting the reportable event, the REB Administrator who manages your study will receive the event for review. The event may be forwarded to the REB Chair for review. Should the REB have any questions pertaining to the event, the Study Team will be notified.

FREQUENTLY ASKED QUESTIONS

- Q: When can a **Reportable Event** be created?
- A: **Reportable Events** can be created any time after ethics approval. This includes studies that are Completed or Closed by the REB Administrator.

- Q: I have a renewal or amendment open; can I create and submit a **Reportable Event** at the same time?
- A: Yes, **Reportable Events** can be created and submitted when an amendment, renewal, or closure is in process.

- Q: Can I create and submit multiple **Reportable Events** at the same time?
- A: Yes, multiple **Reportable Events** can be created and submitted at any time. Reportable Events can be acknowledged by REB in any order submitted.

- Q: An REB Administrator started a **Reportable Event**, is that permitted?
- A: Yes, **Reportable Events** can be created by an REB Administrator but they can only submitted by the Study Team. After a reportable event is created, the REB Administrator will send the study team an email within the system to notify them to review and submit the reportable event.

- Q: What happens if a **Reportable Event** is submitted that doesn't meet the REB reporting standard?
- A: The REB Administrator will send communication back to the Study Team (Changes requested) asking them to Withdraw the Reportable Event.

- Q: How do I find the **Reportable Events** I created?
- A: Look under the Reportable Events tab of the study.