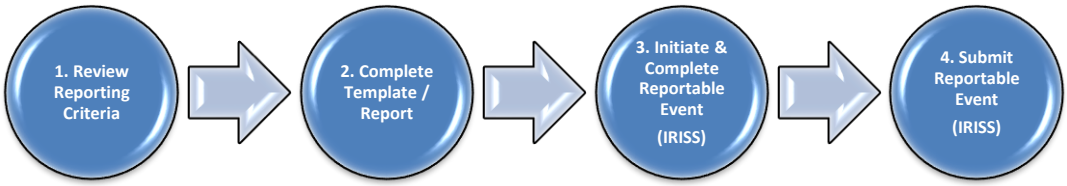
REPORTABLE EVENTS

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 webpage:

- HREBA.CC: http://hreba.ca/hreba-cancer-committee/submitting-a-reportable-event/

2. COMPLETE TEMPLATE / REPORT

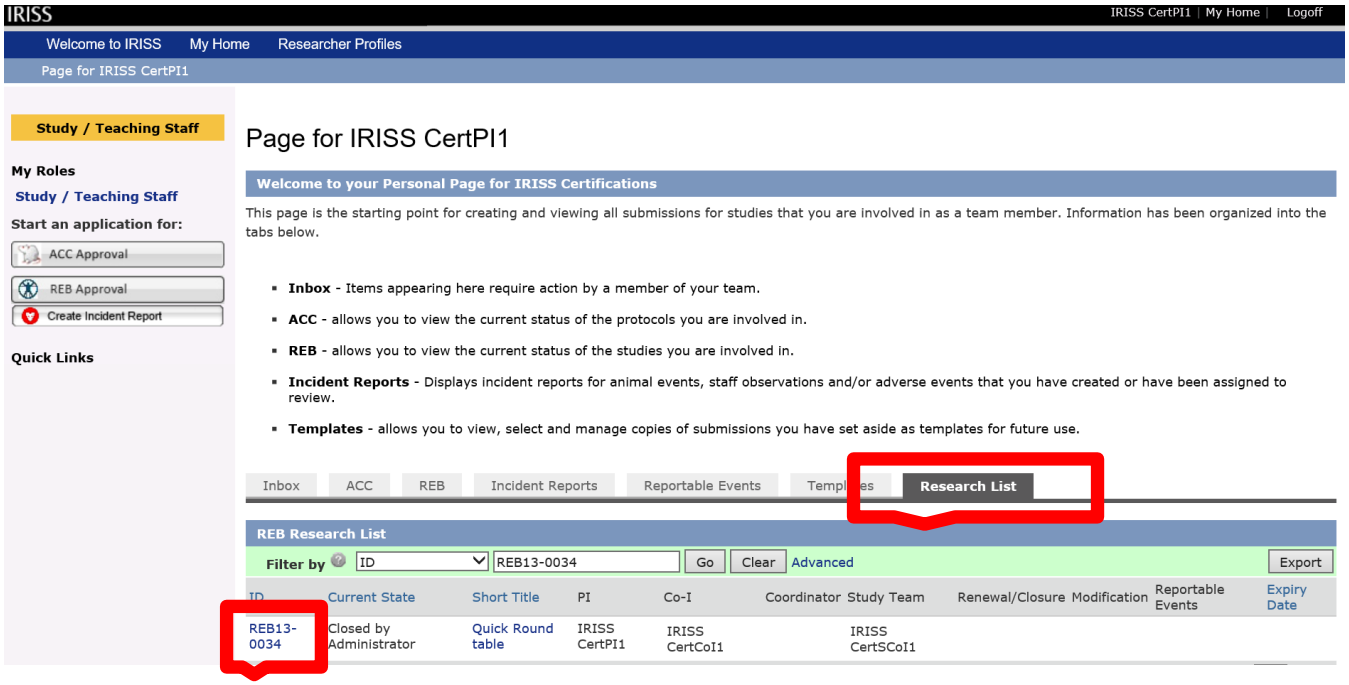
For categories linked to corresponding templates, you must complete and upload the template as part of the IRISS submission.

Category	Reporting Criteria/Description	Reporting Timeline	Template
Local Adverse Event (AE)	Local AEs are adverse events experienced by research participants enrolled by the Principal Investigator(s) (PI) at the site(s) under the jurisdiction of the REB. A local AE is reportable if in the opinion of the PI it is an unanticipated problem.	Within 15 calendar days of the study team becoming aware of the event; or 7 days if the AE was life threatening or resulted in the death of the participant.	HREBA.CC
Non-Local Adverse Event (AE)	Non-local AEs are adverse events experienced by research participants enrolled at other site(s) outside the jurisdiction of the REB. They can be received from the sponsor in the form of individual adverse event reports, periodic safety updates, or safety summary reports. A non-local AE is reportable if it is an unanticipated problem AND requires a) a change to the research and/or b) a change to the informed consent form and/or c) immediate notification to participants for safety reasons.	Within 15 calendar days of the study team becoming aware of the event.	HREBA.CC
Protocol Deviation	A protocol deviation that, in the opinion of the PI: a) jeopardizes the safety of research participants or b) jeopardizes the research efficacy/data integrity or c) results in a sponsor-approved waiver to the participant eligibility criteria or d) is a change in the approved process for obtaining consent or e) led to a serious AE (SAE).	Within 15 calendar days of the study team becoming aware of the event, or 7 calendar days if the deviation led to a death/life threatening AE.	HREBA.CC
Suspension/ Termination	Premature suspension or termination of the research, or a part of the research, by the sponsor, PI, or institution.	Within 15 calendar days of the study team becoming aware of the event.	
Audit	Any audit, inspection, or inquiry findings by a university, provincial or federal agency that may adversely affect research participants or the conduct of the research. Include all relevant findings in your submission, do not attach the entire report.	Within 15 calendar days of the study team becoming aware of the event.	
Privacy Breach	Any unauthorized collection, use, or disclosure of participant personal information. Include details of the breach in your submission.	Within 15 calendar days of the study team becoming aware of the event.	
Participant Complaint	Any complaint where the participant reports concerns about their rights as a research participant or about ethical issues related to the research. Include a summary of the complaint and the site's response in your submission.	Within 15 calendar days of the study team becoming aware of the event.	
DSMB/Interim Analysis Report	Results of any interim analysis or data safety monitoring board assessments.	Within 15 calendar days of the study team becoming aware of the event.	
Other	Includes: a) any documentation that indicates a change to the risks/benefits of the research and/or b) a change in Health Canada or FDA safety labelling or withdrawal of the investigational product and/or c) any event that could significantly impact the conduct of the research at the site.	Within 15 calendar days of the study team becoming aware of the event.	

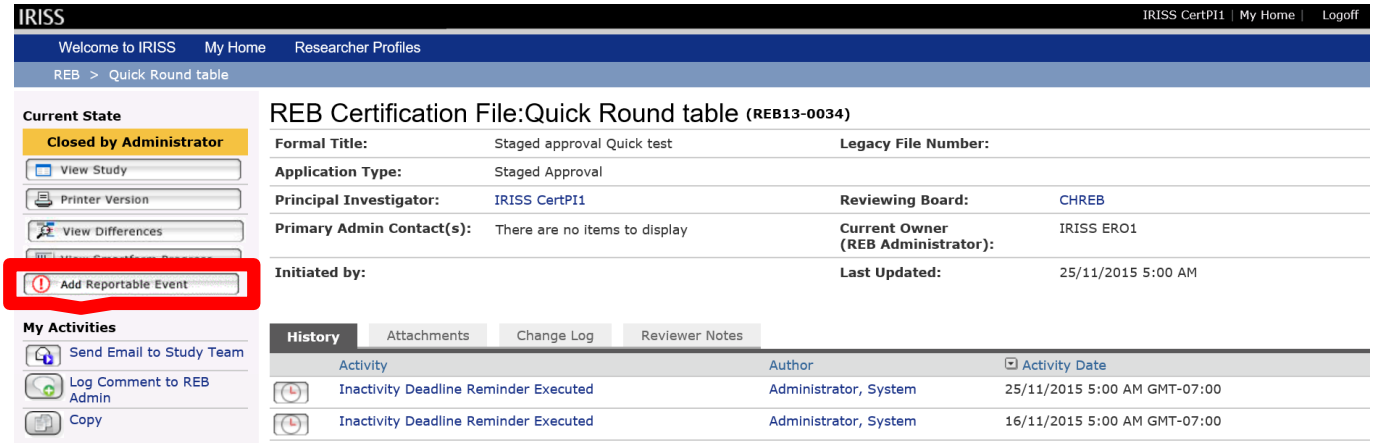
3. INITIATE & COMPLETE REPORTABLE EVENT

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

1. Login to IRISS: http://iriss.ucalgary.ca or https://iriss.ucalgary.ca/IRISSPROD/login/
2. Under the Research List tab, navigate to the study

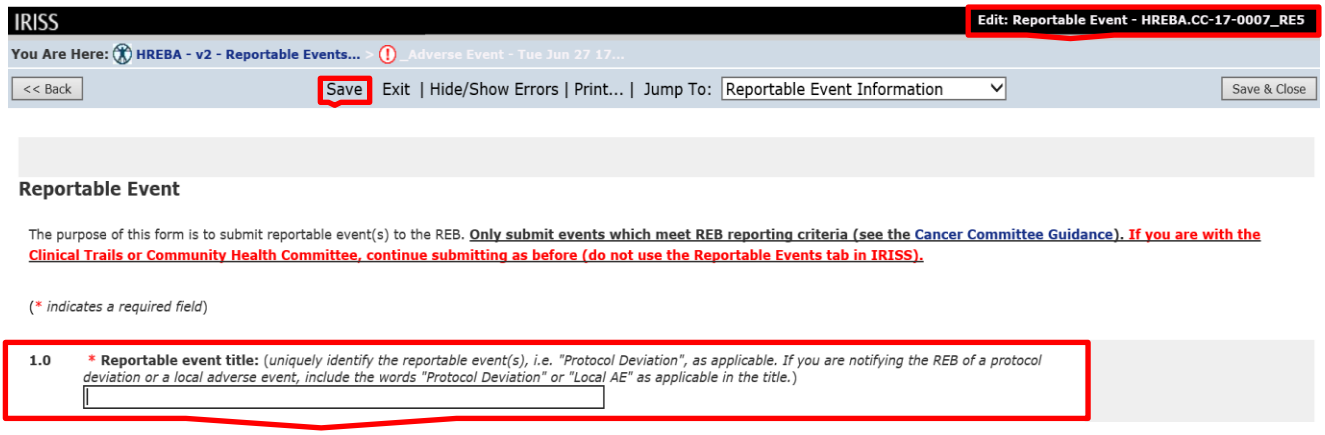


3. Click on the ethics ID
4. Click on 

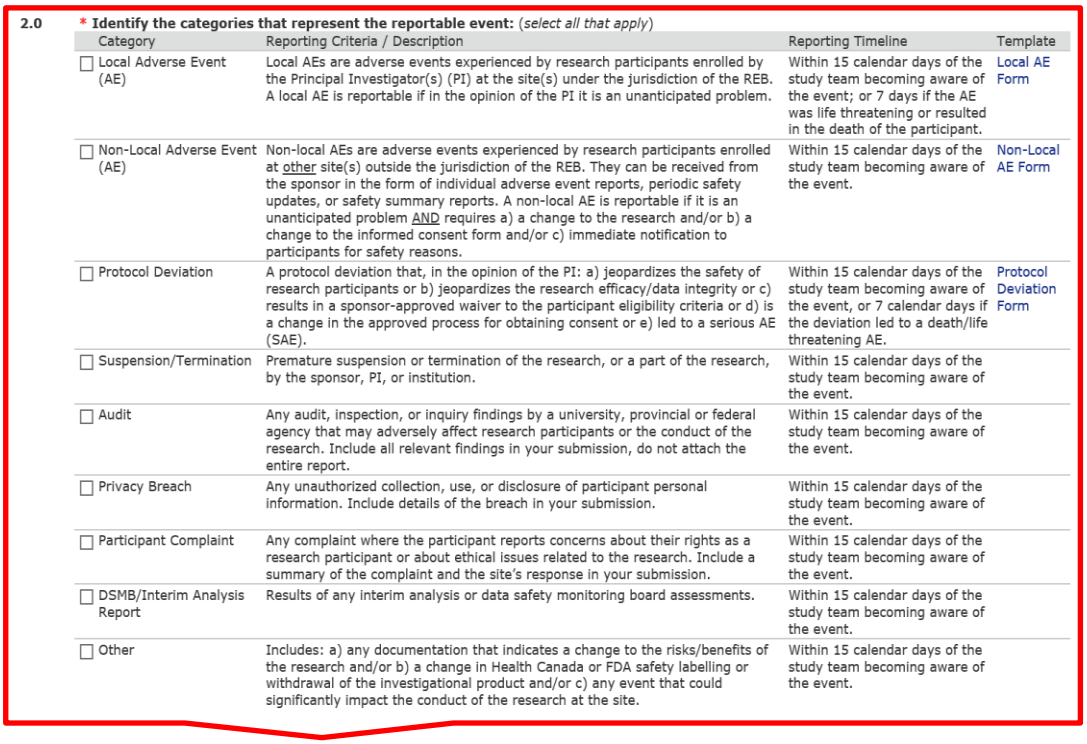


Important! Each **Reportable Event** requires a document to be uploaded before the Principal Investigator can submit. Refer to the guidance website for more information.

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.



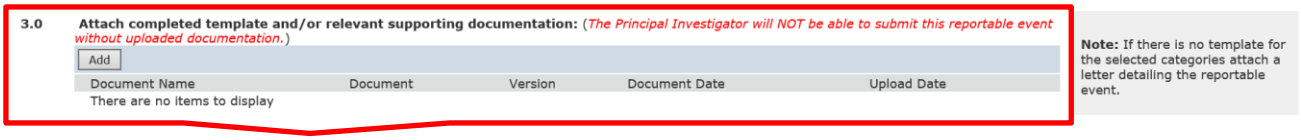
6. Select applicable categories



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

Category	Reporting Criteria / Description	Reporting Timeline	Template
☐ Local Adverse Event (AE)	Local AEs are adverse events experienced by research participants enrolled by the Principal Investigator(s) (PI) at the site(s) under the jurisdiction of the REB. A local AE is reportable if in the opinion of the PI it is an unanticipated problem.	Within 15 calendar days of the study team becoming aware of the event; or 7 days if the AE was life threatening or resulted in the death of the participant.	Local AE Form
☐ Non-Local Adverse Event (AE)	Non-local AEs are adverse events experienced by research participants enrolled at other site(s) outside the jurisdiction of the REB. They can be received from the sponsor in the form of individual adverse event reports, periodic safety updates, or safety summary reports. A non-local AE is reportable if it is an unanticipated problem AND requires a) a change to the research and/or b) a change to the informed consent form and/or c) immediate notification to participants for safety reasons.	Within 15 calendar days of the study team becoming aware of the event.	Non-Local AE Form
☐ Protocol Deviation	A protocol deviation that, in the opinion of the PI: a) jeopardizes the safety of research participants or b) jeopardizes the research efficacy/data integrity or c) results in a sponsor-approved waiver to the participant eligibility criteria or d) is a change in the approved process for obtaining consent or e) led to a serious AE (SAE).	Within 15 calendar days of the study team becoming aware of the event, or 7 calendar days if the deviation led to a death/life threatening AE.	Protocol Deviation Form
☐ Suspension/Termination	Premature suspension or termination of the research, or a part of the research, by the sponsor, PI, or institution.	Within 15 calendar days of the study team becoming aware of the event.	
☐ Audit	Any audit, inspection, or inquiry findings by a university, provincial or federal agency that may adversely affect research participants or the conduct of the research. Include all relevant findings in your submission, do not attach the entire report.	Within 15 calendar days of the study team becoming aware of the event.	
☐ Privacy Breach	Any unauthorized collection, use, or disclosure of participant personal information. Include details of the breach in your submission.	Within 15 calendar days of the study team becoming aware of the event.	
☐ Participant Complaint	Any complaint where the participant reports concerns about their rights as a research participant or about ethical issues related to the research. Include a summary of the complaint and the site's response in your submission.	Within 15 calendar days of the study team becoming aware of the event.	
☐ DSMB/Interim Analysis Report	Results of any interim analysis or data safety monitoring board assessments.	Within 15 calendar days of the study team becoming aware of the event.	
☐ Other	Includes: a) any documentation that indicates a change to the risks/benefits of the research and/or b) a change in Health Canada or FDA safety labelling or withdrawal of the investigational product and/or c) any event that could significantly impact the conduct of the research at the site.	Within 15 calendar days of the study team becoming aware of the event.	

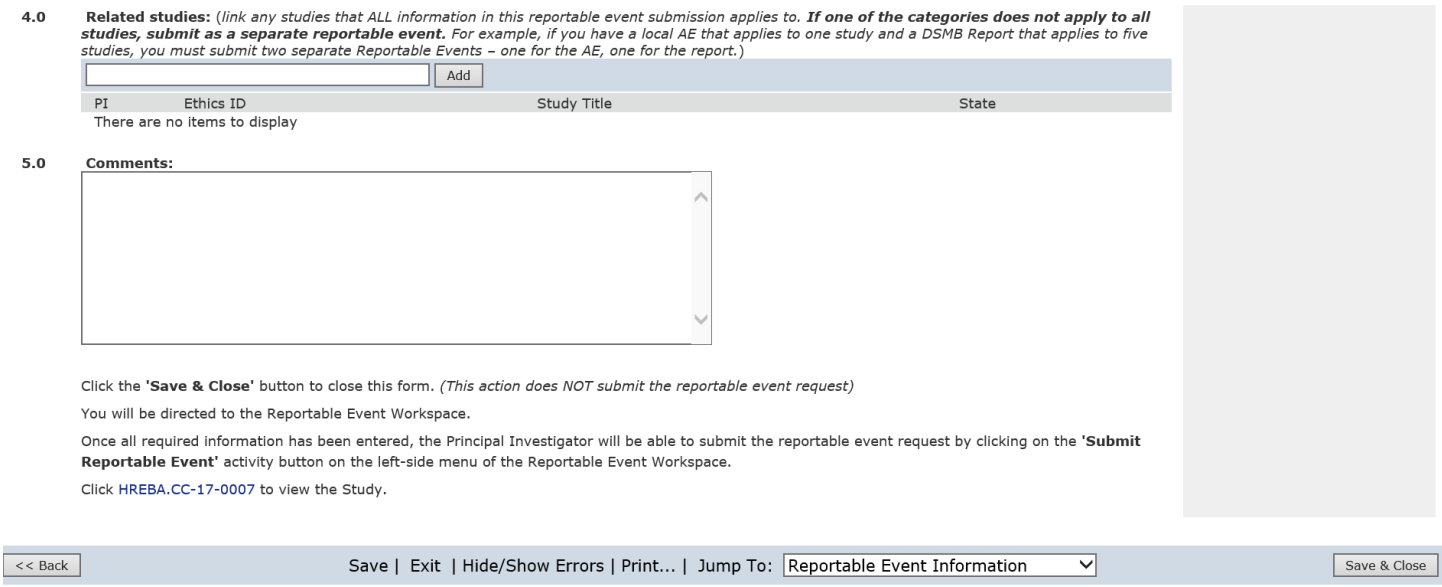
7. Upload completed template or report



Important! The Principal Investigator cannot submit the **Reportable Event** without uploaded supporting documentation.

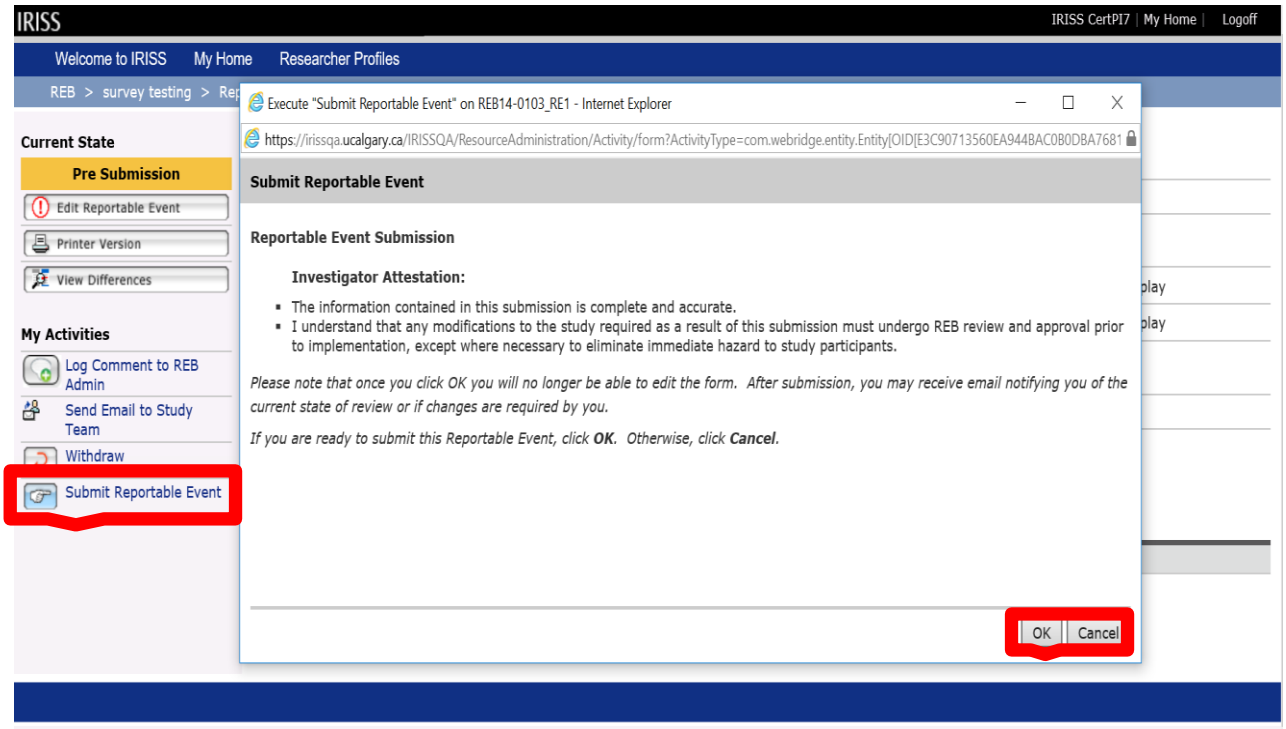
OPTIONAL:

- **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. SUBMIT REPORTABLE EVENT

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



5. FREQUENTLY ASKED QUESTIONS

- 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 restrictions on the number **Reportable Events** that can be created and submitted.

Questions?

General Inquiries: info@hreba.ca
Technical ''how to" Inquiries: iriss.support@ucalgary.ca