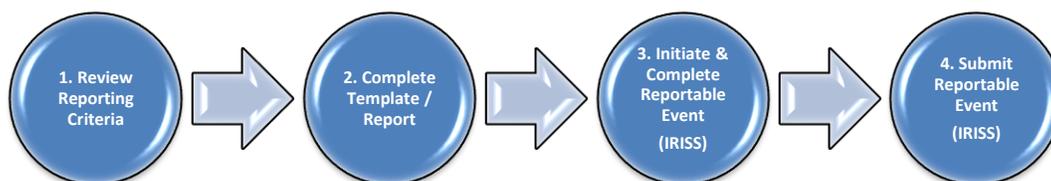


REPORTABLE EVENTS

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

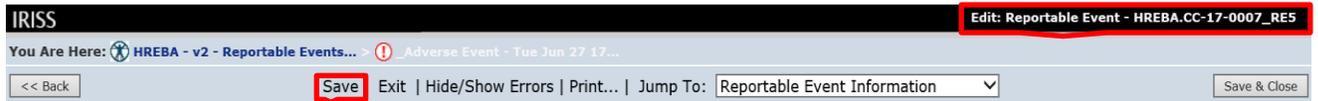
The screenshot shows the IRISS web interface. The top navigation bar includes 'Welcome to IRISS', 'My Home', and 'Researcher Profiles'. The main content area is titled 'Page for IRISS CertP11'. On the left sidebar, there are sections for 'My Roles' (Study / Teaching Staff), 'Start an application for:' (ACC Approval, REB Approval, Create Incident Report), and 'Quick Links'. The main area has a 'Welcome to your Personal Page for IRISS Certifications' message and a list of items: Inbox, ACC, REB, Incident Reports, Reportable Events, Templates, and **Research List** (highlighted with a red box). Below this is the 'REB Research List' table with a search filter set to 'ID' and 'REB13-0034'. The table has columns for ID, Current State, Short Title, PI, Co-I, Coordinator, Study Team, Renewal/Closure Modification, Reportable Events, and Expiry Date. One row is visible with ID 'REB13-0034', Current State 'Closed by Administrator', and Short Title 'Quick Round table' (highlighted with a red box).

3. Click on the ethics ID
4. Click on  Add Reportable Event

The screenshot shows the 'REB Certification File: Quick Round table (REB13-0034)' page. The top navigation bar is the same as the previous screenshot. The main content area shows details for the certification file. On the left sidebar, there is a 'Current State' section with a yellow banner 'Closed by Administrator' and buttons for 'View Study', 'Printer Version', 'View Differences', and **Add Reportable Event** (highlighted with a red box). Below this is a 'My Activities' section with buttons for 'Send Email to Study Team', 'Log Comment to REB Admin', and 'Copy'. The main content area has a 'History' tab selected, showing a table of activities. The table has columns for Activity, Author, and Activity Date. Two rows are visible: 'Inactivity Deadline Reminder Executed' by 'Administrator, System' on '25/11/2015 5:00 AM GMT-07:00' and 'Inactivity Deadline Reminder Executed' by 'Administrator, System' on '16/11/2015 5:00 AM GMT-07:00'.

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.



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 Cancer Committee Guidance). If you are with the Clinical Trails or Community Health Committee, continue submitting as before (do not use the Reportable Events tab in IRISS).**

(* 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.)

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 |
|---|---|--|-------------------------|
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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. | |
| <input type="checkbox"/> 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. | |
| <input type="checkbox"/> 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. | |
| <input type="checkbox"/> 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. | |
| <input type="checkbox"/> 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. | |
| <input type="checkbox"/> 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

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.)

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

Note: If there is no template for the selected categories attach a letter detailing the reportable event.

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.

4.0 **Related studies:** (link any studies that ALL information in this reportable event submission applies to. **If one of the categories does not apply to all studies, submit as a separate reportable event.** For example, if you have a local AE that applies to one study and a DSMB Report that applies to five studies, you must submit two separate Reportable Events – one for the AE, one for the report.)

| 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 HREBA.CC-17-0007 to view the Study.

<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Reportable Event Information ▼
Save & Close

4. SUBMIT REPORTABLE EVENT

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

The screenshot shows the IRISS web interface. At the top, there's a navigation bar with 'Welcome to IRISS', 'My Home', and 'Researcher Profiles'. Below that, a breadcrumb trail reads 'REB > survey testing > Reportable Event'. The main content area is titled 'Submit Reportable Event' and includes a section for 'Investigator Attestation' with the following text:

- 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.

Below the list, there is a note: "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." and another instruction: "If you are ready to submit this Reportable Event, click OK. Otherwise, click Cancel." At the bottom right of the dialog box, there are 'OK' and 'Cancel' buttons. In the left sidebar, under 'My Activities', the 'Submit Reportable Event' button is highlighted with a red box.

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