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:


2. COMPLETE TEMPLATE / REPORT

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Reporting Criteria/Description</th>
<th>Reporting Timeline</th>
<th>Template</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Adverse Event (AE)</td>
<td>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.</td>
<td>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.</td>
<td>HREBA.CC</td>
</tr>
<tr>
<td>Non-Local Adverse Event (AE)</td>
<td>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.</td>
<td>Within 15 calendar days of the study team becoming aware of the event.</td>
<td>HREBA.CC</td>
</tr>
<tr>
<td>Protocol Deviation</td>
<td>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).</td>
<td>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.</td>
<td>HREBA.CC</td>
</tr>
<tr>
<td>Suspension/Termination</td>
<td>Premature suspension or termination of the research, or a part of the research, by the sponsor, PI, or institution.</td>
<td>Within 15 calendar days of the study team becoming aware of the event.</td>
<td></td>
</tr>
<tr>
<td>Audit</td>
<td>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.</td>
<td>Within 15 calendar days of the study team becoming aware of the event.</td>
<td></td>
</tr>
<tr>
<td>Privacy Breach</td>
<td>Any unauthorized collection, use, or disclosure of participant personal information. Include details of the breach in your submission.</td>
<td>Within 15 calendar days of the study team becoming aware of the event.</td>
<td></td>
</tr>
<tr>
<td>Participant Complaint</td>
<td>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.</td>
<td>Within 15 calendar days of the study team becoming aware of the event.</td>
<td></td>
</tr>
<tr>
<td>DSMB/Interim Analysis Report</td>
<td>Results of any interim analysis or data safety monitoring board assessments.</td>
<td>Within 15 calendar days of the study team becoming aware of the event.</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>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.</td>
<td>Within 15 calendar days of the study team becoming aware of the event.</td>
<td></td>
</tr>
</tbody>
</table>
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](http://iriss.ucalgary.ca) or [https://iriss.ucalgary.ca/IRISSPROD/login/](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 [Add 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

7. Upload completed template or report

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**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 DSHB AE that applies to five studies, you must submit two separate Reportable Events – one for the AE, one for the report.)

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.

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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