HREBA | Health Research Ethics Board of Alberta Clinical Trials Committee

Guidance for Submitting a Reportable Event

Title	Guidance for Submitting a Reportable Event
Effective Date	11 August 2017

The Clinical Trials Committee (CTC) has adopted the procedure for submitting reportable events developed by the Network of Networks (N2) and the Canadian Association of Research Ethics Boards (CAREB).

The following points outline the new process and provide links to the various forms.

Submitting a Reportable Event

- Reportable events for studies on paper (ethics ID: xxxxx) are to be e-mailed to sae.clinicaltrails@hreba.ca
- Reportable events for studies on IRISS (ethics ID: HREBA.CC-xx-xxxx) are to be submitted using the reportable event feature within IRISS.
- Submissions that do not meet reporting criteria will not reviewed / acknowledged

When submitting reportable events:

- Attach required forms and supporting documentation.
- Ensure that no identifiable health information is submitted
- If the event results in changes to study materials (e.g. protocol, consent form, documents given to participants), submit updated documents as an amendment/modification
- If the event requires immediate notification to participants for safety reasons:
    - for studies on paper, mark the e-mail “High Importance”
    - for studies within IRISS, Log a Comment to Administrator to indicate high importance
- For studies on paper, include the ethics ID in the subject of the e-mail.

Reportable Events include:

- Local Adverse Events
- Non-Local Adverse Events
- Protocol Deviations
- Audits
- Privacy Breaches
- Participant Complaints
- DSMB / Interim Analysis Reports
- Other

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Local Adverse Events (AEs)

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 Research Ethics Board (REB).

Reporting Criteria

Any local adverse event that in the opinion of the Principal Investigator meets the definition of an **unanticipated problem**:

1. is unexpected (in terms of nature, severity, or frequency) given the approved research procedures, Investigator Brochure, and research population being studied; **AND**
2. related or possibly related to participation in the research (study intervention or research procedures); **AND**
3. *suggests that the research places research participants or others at a greater risk of harm (physical, psychological, economic, or social) than was previously known or recognized.

* *Any adverse events that are serious (SAEs) meet criteria 3.*

Further details on how to determine if an adverse event is an unanticipated problem are found in the Guidance for Determining which Adverse Events are Reportable.

Once a local AE is acknowledged by HREBA, subsequent follow-up reports related to the AE should be submitted when available. If a follow-up report indicates the event was found not to meet reporting criteria, a final submission regarding the AE is to be made.

Report Format

Completed Local AE Reporting Form and any supporting documentation.

Reporting Timelines

Within 15 calendar days of the study team becoming aware of the event. If the AE was life threatening or resulted in death of the participant, HREBA must be notified within 48 hours of event discovery (by e-mail for studies on paper, by a comment to administrator for studies on IRISS); a completed form must follow within 7 calendar days.

Non-Local Adverse Events (AEs)

Non-local AEs are adverse events experienced by research participants enrolled by researchers 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.

Reporting Criteria

Any non-local adverse event, periodic safety update, or safety summary report that in the opinion of the Principal Investigator meets the definition of an unanticipated problem (see above); **AND** requires:

- *a change to the research; **AND/OR**
- a change to the informed consent form; **AND/OR**
- immediate notification to participants for safety reasons.

**Non-Local AEs which result in a change to the Investigator Brochure but no changes to the protocol do not meet this criteria.*

Report Format

Completed Non-Local AE Reporting Form and any supporting documentation for the event.

Reporting Timelines

Within 15 calendar days of the study team becoming aware of the event.

Protocol Deviations

Reporting Criteria

Any deviation from previously approved research, that in the opinion of the Principal Investigator:

- jeopardizes the safety of research participants; OR
- jeopardizes the research efficacy or date integrity; OR
- resulted in a sponsor-approved waiver to the participant eligibility criteria; OR
- is a change in the approved process for obtaining consent; OR
- led to an SAE

Report Format

Completed Protocol Deviation Reporting Form and any supporting documentation.

Reporting Timelines

Within 15 calendar days of the study team becoming aware of the deviation. If the deviation resulted in death and/or a life threatening AE, the completed Protocol Deviation form must be submitted within 7 calendar days of event discovery, and the AE must be reported as per the local AE procedures above.

Audits

Reporting Criteria
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.

Report Format
Completed Additional Reportable Events Form and any supporting documentation. Do not attach the entire audit report.

Reporting Timelines
Within 15 calendar days of the study team receiving the audit report.

Privacy Breaches

Reporting Criteria
Any unauthorized collection, use, or disclosure of participant personal information (i.e. individually identifying health information), including, but not limited to:

- the collection, use, and disclosure of personal information:
  - not in compliance with local legislation or regulations
  - that was not authorized under the research and approved in the plan submitted to HREBA
- when personal information is stolen, lost, or subject to unauthorized use or disclosure
- when personal information is subjected to unauthorized copying, modifications, or disposal

Report Format
Completed Additional Reportable Events Form and any supporting documentation.

Reporting Timelines
Within 15 calendar days of the study team becoming aware of the breach. If applicable also notify the privacy office at the institution where the research is being conducted.

Participant Complaints

Reporting Criteria
Any complaint where the participant reports concerns about their rights as a research participant or about ethical issues related to the research.

Report Format
Completed Additional Reportable Events Form and any supporting documentation.

Reporting Timelines
Within 15 calendar days of the study team becoming aware of the complaint.

DSMB / Interim Analysis Reports

Reporting Criteria
Any Data Safety Monitoring Board or Interim Analysis Report.

Report Format
Submission of the report.

Reporting Timelines
Within 15 calendar days of receipt of the report.

Other

Reporting Criteria

- Any documentation from the sponsor that indicates a change to the risks or potential benefits of the research
- A change in Health Canada or FDA safety labeling or withdrawal from marketing of the drug, device, health product, genetic therapy, or biologic used in the research
- Any event that could significantly impact the conduct of the research at the site (e.g. concerns of non-compliance with regulations, changes to the research initiated without prior REB approval to eliminate an apparent immediate hazard to a research participant, etc.)

Report Format
Completed Additional Reportable Events Form and any supporting documentation.

Reporting Timelines
Within 15 calendar days of the study team receiving the documentation / becoming aware of the event.

Effective Date	Summary of Changes
11-Aug-2017	Original version