Title	Guidance for Submitting a Reportable Event
Related SOP	404 Ongoing REB Review Activities
Effective Date	17 March 2017

The submission method for reportable events is as follows:

- Reportable events for studies on paper (ethics ID: xxxxx) will continue to be e-mailed to reportable.cancer@hreba.ca.
- Reportable events for studies on IRISS (ethics ID: HREBA.CC-xx-xxxxx) are to be submitted as a modification within IRISS.

When submitting a reportable event by e-mail (studies on paper):

- Include the ethics ID in the Subject.
- Attach required forms and supporting documentation.
- If the event results in changes to study materials (e.g. protocol, consent form, documents given to participants), submit updated documents as an amendment (see the guidance for amending a study).
- If the event requires immediate notification to participants for safety reasons, mark the e-mail “High Importance”.

When submitting a reportable event as a modification within IRISS:

- Complete the Modification Summary.
- Upload documentation about each event as **ONE** pdf file in the ‘Other Documents’ section. Name the document: “Reportable Event – Event Type” (e.g. Reportable Event – Local AE) and fill in the Document Date field.
- If the event results in changes to study materials (e.g. protocol, consent form, documents given to participants), upload updated documents into the applicable sections.
- If the event requires immediate notification to participants for safety reasons, Log a Comment to Administrator to indicate high importance.

Submitting a Reportable Event

Reportable events that meet the reporting criteria listed below (also see **SOP 404: Ongoing REB Review Activities)** must be reported to HREBA. **Please ensure that no identifiable health information is submitted.**

You will ONLY receive formal acknowledgements for submissions that meet reporting criteria. Only events that meet reporting criteria will be reviewed by the Chair or designee, and if necessary, the study team will be contacted for additional information.

Reportable Events include:

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

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
A summary of relevant audit findings associated with the site. 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
Details of the privacy breach 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
Summary of the complaint and site response.

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
Summary of the reportable event and any supporting documentation.

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

SOP Code	Effective Date	Summary of Changes
SOP 404.001G	01-July-2016	Original version
SOP 404.002GR	01-July-2016	Version 2 - updated hyperlinks
SOP 404.002GR	07-Nov-2016	- standardized the reporting criteria language and formatting across all events - changed all references of an REB to HREBA - changed Reporting Timelines to start when the study team becomes aware of an event - changed/added reportable events and criteria to match the SOP
SOP 404.002GR	15-Mar-2017	- added submission method directions - changed submission method for files within IRISS - removed “serious” from adverse events - added details to criteria for local and non-local AEs - added link to Guidance for Determining which Adverse Events are Reportable - updated Audit reporting criteria - updated Participant Complaints - added information on sponsor requested submissions
SOP 404.002GR	17-Mar-2017	- corrected typographical errors - removed redundant information on sponsor submissions