

Title	Guidance for Submitting a Reportable Event
Related SOP	404 Ongoing REB Review Activities
Effective Date	01 October 2018

Reportable events are to be submitted using the reportable event feature within IRISS. When submitting reportable events:

- 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/modification (see the guidance for amending a study).
- If the event requires immediate notification to participants for safety reasons “Log Comment to REB Admin” – Jacqueline Senych, 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.**

Once reviewed, 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.

Please note:

- 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](#).
- Serious adverse events (SAEs) are always considered to place research participants at greater risk of harm (criteria # 3); however, AEs which are not serious may also meet this criteria (e.g. events of medical importance, etc.).
- If the Principal Investigator determines that HREBA should be informed of a local AE which is not an unanticipated problem (e.g. the relation is unknown, it is a sponsor requirement, etc.), it should be submitted with justification as to why research ethics review is required.
- 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 (using “Log Comment to REB Admin” – Jacqueline Senych); 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 data 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.

Note that on August 31, 2018 Health Information Act mandatory breach reporting requirements came into effect ([details](#)). Where there is risk of harm to an individual, health custodians are required to notify the a) minister of health, b) information and privacy commissioner, and c) individual(s) affected by the privacy breach.

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. If the report requires site action, a completed [Additional Reportable Events Form](#) must also be uploaded.

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.

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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - corrected typographical errors - removed redundant information on sponsor submissions
SOP 404.002GR	28-Jun-2017	<ul style="list-style-type: none"> - updated submission method section with new reportable event feature in IRISS
SOP 404.002GR	11-Aug-2017	<ul style="list-style-type: none"> - updated links to online forms - Additional Reportable Events Form introduced
SOP 404.002GR	01-Feb-2018	<ul style="list-style-type: none"> - changed the name of the person to indicate in IRISS notifications when there is a risk to participant safety (administrator = Jacqueline Senych) - Clarified that serious adverse events (SAEs) are not limited to the examples listed in the text. - added Additional Reportable Events Form to DSMB - minor formatting inconsistencies updated
SOP 404.002GR	13-Feb-2018	<ul style="list-style-type: none"> - corrected grammatical error
SOP 404.002GR	05-Jul-2018	<ul style="list-style-type: none"> - added information about Health Information Act mandatory breach reporting requirements in Privacy Breaches section
SOP 404.002GR	16-Aug-2018	<ul style="list-style-type: none"> - provided clarification on criteria #3 of local AEs, and added details on the submission of local AEs which don't meet criteria - minor grammatical corrections
SOP 404.002GR	01-Oct-2018	<ul style="list-style-type: none"> - Removed reference to paper, as all files now being processed exclusively through IRISS