

N2/CAREB SOP 404 OHSN-REB ADDENDUM, APPENDIX 1
SUMMARY OF REPORTING TIMELINES IN CALENDAR DAYS

REPORTING TIMELINES TO OHSN-REB	
Type of Event	Reporting Timeline* to the REB
<i>**must be considered related or possibly related to study intervention/drug</i>	<i>*within the study team's awareness of the event/report</i>
**Local (internal) Serious Adverse Event/ Unanticipated Problem that is fatal or life threatening	3 days
**Local (internal) Serious Adverse Event/ Unanticipated Problem (non-fatal, non-life threatening)	7 days
** Non-Local (external) Serious Adverse Event/ Unanticipated Problem that requires change(s) to study documents and/or notification to participants	7 days
Periodic Safety Update Reports or Safety Summary Reports <i>Examples:</i>	15 days
• <i>SU-ADR Listings</i> • <i>CIOMS</i>	
Other Unanticipated Problem <i>Examples:</i>	15 days
• <i>Updated Safety Information:</i> ○ <i>DSMB/C Report</i> ○ <i>Interim Analysis Results</i> • <i>Pregnant Partner</i> • <i>Sponsor Safety Notice, Action Letter or Alert that would cause the sponsor to modify the Investigator's Brochure, the research, or the consent form, or would prompt other action by the REB to ensure protection of research participants</i> • <i>Information that is published from another research project that shows that an arm of the research study is of no therapeutic value</i> • <i>A change in Health Canada or FDA safety labelling therapy or withdrawal from marketing of a drug, device, health product, genetic therapy or biologic used in research</i>	

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- Any unanticipated problem or other event that could significantly impact the conduct of the research at the site (e.g.: concern of non-compliance)

Major Protocol Deviation	15 days
Privacy Breach	Within 24 hours Note , for TOH/OHRI, it is within 24 hours of TOH Privacy Office confirming incident is a privacy breach
Relevant Audit or Inspection Findings	15 days
Research Participant Complaint	Within 24 hours

REPORTING TIMELINES TO SPONSOR

Type of Event	Reporting Timeline* to Sponsor
<i>**must be considered related or possibly related to study intervention/drug</i>	<i>*within the study team awareness of the event/report</i>
**Local (internal) Serious Adverse Event/ Unanticipated Problem	24 hours <i>(if OHRI is sponsor, report to clinicalresearchadmin@ohri.ca)</i>
**Individual Non-Local (external) Serious Adverse Event/ Unanticipated Problem that requires change(s) to study documents and/or notification to participants	24 hours <i>(if OHRI is sponsor, report to clinicalresearchadmin@ohri.ca)</i>

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REPORTING TIMELINES TO HEALTH CANADA

**If study involves Drug(s)
& Investigator/OHRI/UOHI is the Study Sponsor**

Reporting Timeline* to Health Canada

**within the study team awareness
of the event/report*

Serious Unexpected–Adverse Drug Reaction (SU-ADR)

15 days

SU-ADR that is fatal or life threatening

7 days
with follow-up within 8 days

**If study involves Natural Health Product or Radiopharmaceutical(s)
& Investigator/OHRI/UOHI is Study Sponsor**

Reporting Timeline* to Health Canada

**within the study team awareness
of the event/report*

Serious Adverse Drug Reaction, expected or unexpected

15 days

SADR that is fatal or life threatening

7 days
with follow-up within 8 days

**If study involves an
Investigational Medical Device**

Reporting Timeline* to Health Canada

**within the study team awareness
of the event/report*

Mandatory Problem Reporting timeline for Investigator's who are the sponsor and/or manufacturer/importer

Serious Adverse Event that has led to death or a serious deterioration in the state of health of a patient, user or other person

10 days

SAE that has not led to the death or serious deterioration in the health of a patient, user or other person, but could do so were it to recur. Please review

[Health Canada Medical Device Regulations Sections 59 to 61.1.](#)

30 days

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Mandatory Problem Reporting timeline for local Investigator's participating in a device trial

Mandatory problem reporting for serious adverse event related to the device that:

72 hours

- is related to failure of the device, deterioration in effectiveness or inadequacy in labelling or direction in use
 - led to death or serious deterioration of health of patient, user or other person or could do so were it to recur. [Medical Device Regulations Subsection 81 \(k\)\(v\)-](#)
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- Must submit to Manufacture and Importer as well as Health Canada

Note: The REB guidelines for reporting serious adverse events / adverse drug reactions/ unanticipated problems apply when the OHSN-REB is the Board of Record for the research study. If OHSN-REB is not the Board of Record for the research study, the researcher will refer to the serious adverse event /unanticipated problem reporting requirements as stated in the Board of Record Agreement for the research study.

Revision History		
Version Number	Effective Date	Summary of Changes
Version 2	January 12, 2022	Added note into 'Privacy Breach' line item; updated reporting timeline for participant complaints from 15 days to 24 hours.
Version 1	October 1, 2019	Initial Version