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

REPORTING TIMELINES TO OHSN-REB	
Type of Event ***must be considered related or possibly related to study intervention/drug*	**Reporting Timeline* to the REB** **within the study team's awareness of the event/report*
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 *Examples:* • *SU-ADR Listings* • *CIOMS*	15 days

Other Unanticipated Problem
Examples:
• *Updated Safety Information:*
  o *DSMB/C Report*
  o *Interim Analysis Results*
• *Pregnant Partner*
• *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*
• *Information that is published from another research project that shows that an arm of the research study is of no therapeutic value*
• *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*
	15 days

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

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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: • 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 heath of patient, user or other person or could do so were it to recur. Medical Device Regulations Subsection 81 (k)(v)-	72 hours • 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**
N/A	September 29, 2023	No revisions required to appendix 1 with version N2 CAREB SOP 404.004.
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