RA0900 – REPORTABLE EVENTS

1.0 PURPOSE

To provide direction for the responsibility of reporting protocol deviations, unanticipated issues, non-compliance, or other new information for research projects previously approved by the Interior Health (IH) Research Ethics Board (REB).

2.0 DEFINITIONS

TERM	DEFINITION
Non-Compliance	Failure to follow applicable guidelines and regulations governing human participant research; failure to follow the protocol approved by the REB, or failure to follow stipulations imposed by the REB as a condition of approval.
Privacy Breach	The unauthorized access, collection, use, or disclosure of personal information in the custody or control of an individual or IH.
Protocol Deviations	Any unplanned or unforeseen change to a REB approved protocol or protocol procedures. Deviations are different from amendments in that they generally apply to a single occurrence or participant and are not intended at the time to modify the entire protocol.
Reportable Event	Anything that could affect the conduct of the research or alter the REB's approval or favourable opinion to continue the research.
Suspension	A temporary or permanent halt to all research activities pending future action by the REB, the sponsor and/or the researcher.
Termination	A permanent halt by the REB, the sponsor, or the researcher to all or some research activities.
Unanticipated Issues	Issues that: occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the researcher in the research proposal submitted for research ethics review.

3.0 POLICY

3.1 The researcher is responsible for reporting to the REB any new information generated throughout the course of the research, including any unanticipated issues or serious or continuing non-compliance that might affect the rights, safety and well-being of research participants.

3.2 The REB will review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants,

and/or is required by the protocol and/or by the Board of Record. Reportable events include:

3.2.1 Amendments to the previously approved research;

3.2.2 Reports of unanticipated issues involving risks to participants or others;

3.2.3 Reports of any serious or continuing non-compliance;

3.2.4 Reports of any changes affecting the conduct of the research or increasing the risk to research participants;

3.2.5 Protocol deviations from the previously approved research;

3.2.6 Reports of any privacy breaches;

3.2.7 Summary reports of any audits and inspections; or

3.2.8 Any other new information that may affect adversely the safety of the research participants or the conduct of the research;

3.3 Amendments to the approved research may not be initiated without REB review and approval except where necessary to eliminate apparent immediate hazards to human participants. The researcher must notify the REB immediately if changes are made to eliminate immediate hazards.

3.4 The REB will make determinations about the reported event and direct appropriate follow up with the researcher(s).

3.5 The REB is responsible for promptly reporting such events with the resulting determinations to institutional officials and regulatory authorities as applicable.

4.0 PROCEDURES

4.1 Researcher Responsibilities

4.1.1 The researcher is responsible for reporting to the REB within 14 days, any reportable event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare. Serious events, where there is potential or real harm to participants must be reported to the REB at the earliest opportunity and no later than 7 days from the time of the event.

4.1.2 For all reportable events, the researcher should include the following information in the report:

4.1.2.1 A description of the event and an explanation of the circumstances that led to the event and the resulting problems;

4.1.2.2 The researcher's opinion regarding the causality;

4.1.2.3 The action taken in response to the event;

4.1.2.4 The outcome of the event;

4.1.2.5 Any change in the risk or the possibility of risk for participants;

4.1.2.6 The researcher's opinion regarding the implications for continuation of the project;

4.1.2.7 The researcher's opinion regarding the need for any changes to the protocol, research procedures or consent documents.

4.1.2.8 A description of what measures have been but in place to ensure that a similar event does not occur in the future, or a description of the plan which will be implemented to ensure that a similar event does not occur in the future.

4.1.2.9 The report should be signed by the Principal Investigator or Qualified Investigator at the research site where the event occurred.

4.1.3 The researcher is also responsible for reporting any unanticipated issue, protocol deviation, or non-compliance that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare to the sponsor and applicable regulatory authorities.

4.1.4 If the research is regulated by the US Food and Drug Administration (FDA), the researcher is required to report to the sponsor who then reports to the FDA. If the researcher is also the sponsor, then the REB requires that the sponsor-researcher report to the FDA. Regardless of whether such reporting has occurred as indicated by the researcher for initial determination or resolution, the REB will also report to the FDA via the Chief Nursing Officer and Professional Practice Lead (CNO) and the Vice President (VP), Clinical Operations North (CON).

4.1.5 All other events must be reported to the REB within 30 days of their discovery. This includes Protocol Deviations, Privacy Breaches, or any other reportable event which has been deemed as not posing any new or additional risks to participants or others.

4.2 REB Responsibilities

4.2.1. The REB is responsible for reporting determinations of reportable events involving risks to participants or others, to the following entities within 15 days of the REB's determination:

4.2.1.1 Researcher;

4.2.1.2 Research Department Navigator, who will contact the IH Administrators that provided Operational Approval;

4.2.1.3 CNO, who in turn reports to the VP CON;

4.2.1.4 Other REBs, if applicable;

4.2.1.5 Regulatory authorities, if applicable, CNO and the VP CON;

4.2.2 The following information will be included in the REB report:

4.2.2.1 Name of the institution where the research is being conducted;

4.2.2.2 Full title of the research project;

4.2.2.3 Name of the researcher who is the Principal Investigator and his/her primary institutional affiliation;

4.2.2.4 Unique file identifier assigned to the project;

4.2.2.5 A detailed description of the unanticipated issue, non-compliance, or reasons for suspension or termination;

4.2.2.6 Actions the REB is taking or plans to take to address a protocol deviation or unanticipated issue may include: revise the protocol, revise the informed consent document(s), inform enrolled participants, increase monitoring of participants, suspend participant enrollment, or terminate the research project;

4.2.3 The REB will manage and report issues of serious or non-compliance according to policy RR1100 REB Management of Non-Compliance.

4.3 VP Clinical Operations North

4.3.1 Receives the REB report and reviews with the CNO, REB Chair and REB Coordinator.

4.3.2 Investigates the report, gathers additional information, and consults with Risk Management, other internal resources and leaders, and outside agencies and regulators as required.

4.3.3 Notifies external agencies of unanticipated issues involving risk to participants or others, serious or continuing non-compliance, or suspension or termination of approved research by the REB, based on jurisdiction, as follows:

4.3.3.1 Health Canada

4.3.3.2 The Office of Human Research Protections (OHRP) if the research is conducted, funded or overseen by the Department of Human and Health Services (DHHS);

4.3.3.3 The FDA, if the research is regulated by the FDA; and/or

4.3.3.4 Other current authorized external regulatory bodies.

4.3.4 Submits the notification per the requirements of the office to whom the report is being made, e.g. OHRP Incident Report Form.

4.3.5 Copies the notification to the PI and the REB Chair.

4.3.6 Refers to the IH Board of Directors as appropriate.

5.0 REFERENCES

- Canadian Association of Research Ethics Boards and N2 Network of Networks. (2019). Standard Operating Procedure 404.003: *Ongoing REB Review Activities.*
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018.
- Health Canada, Food and Drug Regulations, Part C, Division 5, *Drugs for Clinical Trials Involving Human Subjects, Section 5.14 Serious Unexpected Adverse Drug Reaction Reporting*.
- Interior Health. (2019). Research Policy Manual: *RR0900 Safety and Serious Adverse Events Reporting.*
- Office of Human Research Protections. (2011). *Compliance Oversight: Guidance on Reporting Incidents to OHRP.*
- UBC Office of Research Ethics. (2018). Standard Operating Procedure 404: *Ongoing REB Review Activities*
- UBC Office of Research Ethics. (2018). Standard Operating Procedure 408: *Reportable Events and Reporting*.
- US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:
  - Part 56, Institutional Review Boards, (21CFR56).