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
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.
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 of or under control of IH which contravenes the Freedom of Information and Protection of Privacy Act (FIPPA) or other legislation.
Reportable Event	Includes anything that could significantly impact 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 Research Ethics Board (REB), by the sponsor and/or by 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 must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Reportable events include:

3.2.1 Modifications or changes 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 significantly 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 Modifications to the approved research may not be initiated without prior REB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If changes are made to eliminate immediate hazards, the researcher must notify the REB immediately.

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

3.5 The. REB has the responsibility to promptly report such events with the resulting determinations to the 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:

4.1.1 A description and explanation of the event;

4.1.2 The researcher's opinion regarding the causality;

4.1.3 The action taken in response to the event;

4.1.4 The outcome of the event;

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

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

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

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.

4.2 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 Scientific Director of Research;

4.2.1.4 Other REBs, if applicable;

4.2.1.5 Regulatory authorities, if applicable

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 Title of the research project in which the event occurred;

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 (REB number) assigned by the REB.

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 Issues of serious or non-compliance will be managed and reported according to policy RR1100 REB Management of Non-Compliance.

4.3 Scientific Director of Research Responsibilities

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

4.3.2 Investigates the report, gathers additional information, and consults with Risk Management, other internal resources/leaders, and outside agencies/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 US Federal Drug Administration (FDA) if the research is regulated by the FDA; and/or

4.3.3.4 Other agencies that are signatories to the Common Rule, if the research is conducted, funded or overseen by the DHHS.

4.3.4 Submits the notification using the appropriate form as indicated by the office to whom the report is being made, e.g. Health Canada Report Form or OHRP Incident Report Form.

4.3.5 Copies the notification to the PI and the Chair.

4.3.6 Reports the notification to the applicable IH Vice President for consideration of referral to the IH Board as appropriate.

4.3.7 The notification will also be reported in writing to the sponsor, REBs at other institutions conducting the same research project, and to applicable regulatory authorities as required.

4.4 If the research is FDA regulated, the PI is required to report to the sponsor who then reports to the FDA. If the PI is also the sponsor, then the REB requires that the sponsor/PI report to the FDA. Regardless of whether such reporting has occurred as indicated by the PI for initial determination or resolution, the REB will also report directly to the FDA.

5.0 REFERENCES

- Canadian Association of Research Ethics Boards and N2 Network of Networks. (2016). *Glossary of Terms.*
- Canadian Association of Research Ethics Boards and N2 Network of Networks. (2016). Standard Operating Procedure 404.002: *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 2014.
- Health Canada, Food and Drug Regulations, Part C, Division 5, *Drugs for Clinical Trials Involving Human Subjects*, (Schedule 1024), June 20, 2001.
- Interior Health. (2018). Research Policy Manual: *RR0900 Safety and Serious Adverse Events Reporting.*
- Island Health Authority. (2013). Research and Capacity Building Policy 511: *Reporting,* version 1.
- Office of Human Research Protections. (2011). *Compliance Oversight: Guidance on Reporting Incidents to OHRP.*
- UBC Office of Research Ethics. (2011). Standard Operating Procedure 405: *Ongoing Review and Reporting*.
- UBC Office of Research Ethics. (2011). Standard Operating Procedure 410: *Reporting*.
- US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).
- US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:
  - Part 50, Protection of Human Subjects, (21CFR50).
  - Part 56, Institutional Review Boards, (21CFR56).