RR1100 – MANAGEMENT OF NON-COMPLIANCE

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

1.0 PURPOSE

To describe the responsibilities of the Interior Health (IH) Research Ethics Board (REB) for responding to reports of Non-Compliance and the actions that the REB may take as a result of its review of reports of Non-Compliance.

2.0 DEFINITIONS

TERM	DEFINITION
Compliance:	Adherence to all study-related requirements, including IH policies, Good Clinical Practice (GCP), and applicable legislation and regulatory requirements.
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.

3.0 POLICY

3.1 IH pledges to promote and uphold the highest ethical standards in the conduct of human research.

3.2 Researchers are required to comply with all of the applicable guidelines and regulations governing the conduct of human research, as well as with the required conditions of approval of the REB.

3.3 The rights and welfare of research participants could be at risk if there were serious or repeated Non-Compliance on the part of a researcher or any member of the research team. It is, therefore, the duty of the REB to accept any reports and to act on all credible allegations of Non-Compliance.

3.4 The Chair or Designee is responsible for the initial review of allegations of Non-Compliance.

3.5 If intentional, serious or continuing Non-Compliance is established, the REB is responsible for determining the relevant corrective actions.

3.6 The REB is responsible for reporting any incidents of serious or continuing Non-Compliance to the Chief Nursing & Allied Health Officer and Professional Practice Leader (CNO). The CNO may in turn report to the Vice President, Human Resources (VP HR who has the authority to notify the regulatory authorities (as applicable) and the sponsor.

4.0 PROCEDURES

4.1 Reports of Non-Compliance

4.1.1 Reports of Non-Compliance in human participant research may come from many sources including but not limited to:

4.1.1.1 A researcher, as a self-report;

4.1.1.2 A member of the research team;

4.1.1.3 A research participant;

4.1.1.4 A sponsor representative;

4.1.1.5 A quality assurance or Compliance officer;

4.1.1.6 An IH employee; or

4.1.1.7 A person not directly related to the research.

4.1.2 Persons raising such concerns are encouraged to express them in writing, however the REB will receive and document oral reports of Non-Compliance.

4.1.3 Evidence of serious or repeated Non-Compliance may also arise from human protection related Quality Assurance inspections, sponsor audits or inspections, or regulatory agency audits.

4.2 Evaluating Allegations of Non-Compliance

4.2.1 When an allegation of Non-Compliance is referred to the REB, the REB Coordinator will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the Chair or Designee.

4.2.2 The Chair or Designee manages all allegations and reports of Non-Compliance.

4.2.3 The Chair or Designee will conduct an initial review of all allegations to determine the veracity of the allegations.

4.2.4 The Chair or Designee will obtain as much information as possible from the individual reporting the incident.

4.2.5 The Chair or Designee will obtain as much information as possible, or verification from other sources by one or more of the following means:

4.2.5.1 Contacting the researcher or member of the research team directly;
4.2.5.2 Consulting with other relevant IH personnel;
4.2.5.3 Collecting and reviewing relevant documentation; and
4.2.5.4 Interviewing knowledgeable sources.

4.2.6 If the Chair or Designee determines that there is evidence of Non-Compliance, he/she will then assess whether the Non-Compliance was intentional, serious, and/or repeated.

4.2.7 If the Chair or Designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

4.3 Managing Non-Compliance

4.3.1 The REB will attempt to resolve any instances of Non-Compliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research.

4.3.2 If the Chair or Designee determines the Non-Compliance was not serious or repeated, and if the research staff recognized the Non-Compliance and took appropriate corrective actions, no further action may be required.

4.3.3 If the Chair or Designee determines that the Non-Compliance was not serious or repeated, but the research staff did not recognize the Non-Compliance or take appropriate corrective actions, the Chair or Designee may discuss the matter directly with the researcher, recommend corrective action, request a quality assurance inspection, and/or refer the matter to the REB at the next scheduled REB meeting.

4.3.4 If it appears that a researcher was intentionally Non-Compliant, the Chair or Designee may suspend the conduct of the research immediately and refer the matter to the next scheduled REB meeting. The Chair or Designee will inform the CNO. See also policy *RR1200 Suspensions and Terminations of Research Ethics Board Approval*.

4.3.5 The REB will review the information at the next full Board meeting and determine the corrective actions.

4.3.6 Corrective actions are based upon the nature and the degree of the Non-Compliance. In evaluating the Non-Compliance, the REB may consider one or more of the following actions:

4.3.6.1 Request modification of the protocol;

4.3.6.2 Request modification of the informed consent document;

4.3.6.3 Request that additional information be provided to past participants;

4.3.6.4 Require that current participants be notified;

4.3.6.5 Require that current participants re-consent to participation;

4.3.6.6 Modify the continuing review schedule;

4.3.6.7 Require onsite observation of the consent process;

4.3.6.8 Suspend the new enrollment of participants;

4.3.6.9 Suspend REB approval of the research;

4.3.6.10 Suspend researcher involvement in the research;

4.3.6.11 Terminate REB approval of the research;

4.3.6.12 Notify IH entities (e.g. Privacy, Policy and Risk Management)

4.3.6.13 Ensure that all other regulatory reporting requirements are met, as required;

4.3.6.14 Any other action deemed appropriate by the REB.

4.4 REB Response to Reports of Non-Compliance

4.4.1 The Chair or Designee will notify the researcher in writing that an allegation of Non-Compliance has been made.

4.4.2 The Chair or Designee will notify the researcher in writing of the results of the REB review of incidents of Non-Compliance and any remedial actions required.

4.4.3 The Chair or Designee will report any serious or continuing Non-Compliance to the VP HR via the CNO. The VP HR has the authority to report to the regulatory authorities (as applicable) and the sponsor. The VP HR may consider referring the matter to the IH Board as appropriate.

4.4.4 The REB may submit an allegation of research misconduct to the CNO for referral to the VP HR as appropriate.

4.4.5 The REB will request a time-sensitive response in writing from the researcher, including the corrective action plan.

4.4.6 Depending upon the nature and seriousness of the Non-Compliance, the researcher's response may be reviewed using a delegated REB review procedure or the review may be referred to the REB for a decision from the full Board.

4.4.7 The Chair or Designee will follow-up to assess any corrective measures implemented by the researcher.

4.4.8 The REB is responsible for reporting Non-Compliance to funders, the sponsor, REBs at other institutions conducting the same research project, and to applicable regulatory agencies as required.

4.4.8.1 If the Non-Compliance is related to research funded by the Canadian Institutes of Health Research (CIHR), the natural

Sciences and Engineering Research Council (NSERC), or the Social Sciences and Humanities Research Council (SSHRC), the VP HR will advise the relevant funding agency in writing of any allegations related to activities funded by the agency that may involve significant financial, health and safety, or other risks.

4.4.8.2 If the Non-Compliance is determined to be serious and/or continuing, and is related to a research project funded and supported by the US Federal Government or regulated by the US Food and Drug Administration, the VP will notify the applicable regulatory authorities with a written report.

4.5 Documenting Non-Compliance

4.5.1 The Chair or Designee will document the findings of reports of Non-Compliance. The report will include the allegations, the information obtained during the initial assessment, whether allegations of Non-Compliance were verified, the REB's decision and actions taken, and the researcher's response.

4.5.2 For those incidents of Non-Compliance referred to the full Board, the REB Coordinator will document the following in the REB meeting minutes: a description of the incident and findings, verification of the Non-Compliance, the REB's decision, the remedial action required by the REB, the researcher's response and actions implemented and plans for further follow up.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 903.003: *Non-Compliance*

2. 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 2022.

3. Health Canada, Food and Drug Regulations, Part C, Division 5, *Drugs for Clinical Trials Involving Human Subjects*, January 5, 2022. Retrieved from Food and Drug Regulations (justice.gc.ca).

4. Interior Health. (2022). Research Policy Manual: RA0900 Reportable Events.

5. Interior Health. (2022). Research Policy Manual: RR1200 Suspension and Terminations of REB Approval.

6. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonized Guideline, Integrated Addendum to ICH E6(R1); *Guideline for Good Clinical Practice*, E6(R2), November 9, 2016.

7. Panel on Research Ethics (2021) TCPS2 Interpretations: Roles and Responsibilities. Retrieved from https://ethics.gc.ca/eng/policy-politique_interpretations_roles.html

8. Panel on Research Ethics (2021) *Tri-Agency Framework: Responsible Conduct of Research*

9. UBC Office of Research Ethics. (2018). Standard Operating Procedure 903: *Non-Compliance*.

10. US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46) Section 46.115.

11. US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1: Part 56, Institutional Review Boards, (21CFR56) Section 56.108.