RA1200 – EXTERNAL AUDITS FOR REB-APPROVED RESEARCH

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 provide direction for the procedures before, during and following an external Audit of Interior Health (IH) Research Ethics Board (REB) approved clinical trials.

2.0 DEFINITIONS

TERM	DEFINITION
Audit:	*A systematic and independent examination of human participant research-related activities and documents of the Research Ethics Board to monitor for compliance with applicable regulations and policies.*
Auditor:	*External regulatory agency such as Health Canada or the US Office for Human Research Protections (OHRP), Accreditation Canada, IH Internal Audit Department or other individuals authorized to conduct the Audit.*
Audit Report:	*A written evaluation by the Auditor of the Audit results.*

3.0 POLICY

3.1 Health Canada has the authority to Audit clinical trials approved by the REB to assess compliance with relevant regulations and guidelines, as such research falls under the *Food and Drug Regulations*.

3.2 OHRP and other current authorized external regulatory bodies have the authority to Audit research approved by Canadian REBs to assess compliance with relevant regulations and guidelines.

3.3 Sponsors, funding entities, or others authorized by regulations or agreements with IH may have the authority to inspect research-related REB documents and procedures related to the research being Audited.

4.0 PROCEDURES

4.1 Preparation for an Audit

4.1.1 The Auditor will work with the REB Chair or Designee to schedule dates and times of the Audit. The Auditor will communicate in writing the purpose of the Audit, the research undergoing the Audit, and the plan for the Audit.

4.1.2 The REB Chair or Designee will notify the REB members and the Corporate Director, Internal Audit of the Audit.

4.1.3 The REB Chair or Designee will initiate work with the IH Privacy Office to create an Information Sharing Agreement between IH and the Auditor.

4.1.4 The Auditor will sign a Confidentiality Agreement and an External User Access Agreement if s/he requires access to IH systems.

4.1.5 For Audits involving Health Canada, federal granting agencies, the FDA, or current authorized external regulatory bodies, the REB Chair or Designee will notify the following:

4.1.5.1 Chief Nursing and Allied Health Officer and Professional Practice Leader (CNO), who will in turn notify the Senior Executive Team;

4.1.5.2 Corporate Director of Research;

4.1.5.3 IH Internal Audit;

4.1.5.4 IH Research Department Navigator, who in turn will notify the Administrative Contact(s) for the research; and

4.1.5.5 Other IH Departments, Programs and Services, as applicable (e.g. Health Information Management; Quality and Patient Safety; Privacy, Policy and Risk Management).

4.1.6 The REB Chair or Designee will review the Audit plan with the REB members and review the required documentation. The REB Chair or Designee will prepare the REB files prior to the Audit.

4.1.7 The REB Chair or Designee will arrange for document access for the Auditor.

4.1.8 The REB Chair or Designee will confirm that the REB members are available to assist the Auditor.

4.1.9 The REB Chair or Designee will arrange for a suitable work area (e.g. private and with sufficient space, with access to necessary equipment) for the Auditor.

4.2 Participating in an Audit

4.2.1 The REB Chair or Designee will meet with the Auditor as scheduled and ask to see proof of authority.

4.2.2 The REB Chair or Designee will record the name, contact information and title of the Auditor and retain any written notices of Audit for the REB files.

4.2.3 The REB Chair or Designee will introduce the Auditor to personnel who will be involved with the Audit; and will orient the Auditor on REB policies and Standard Operating Procedures.

4.2.4 The REB Chair or Designee will provide access to the research-specific documents requested by the Auditor. Only those personnel or agency representatives listed on the consent forms may access documents that include information that could identify research participants.

4.2.5 The REB Chair or Designee will accompany the Auditor at all times while in confidential areas of the organization.

4.2.6 The REB Chair or Designee will facilitate having the most appropriate personnel answer the Auditor's questions. The REB Chair or Designee and REB members will make reasonable efforts to accommodate the requests of the Auditor.

4.2.7 The REB Chair or Designee will request meetings with the Auditor at the end of each day, as needed. The REB Chair or Designee will review issues identified and will clarify the issues as soon as possible.

4.2.8 The REB Chair or Designee will ensure that the required personnel are present at the exit interview, which takes place at the conclusion of the Auditor being onsite.

4.2.9 The REB Chair or Designee will record any Auditor's unresolved questions and any discussion and ascertain when/if a written response is required.

4.3 Follow-up after an Audit

4.3.1 The REB Chair or Designee will present verbal and written reports of the Audit to the CNO.

4.3.2 The REB Chair or Designee will prepare a written response to the Auditor's Report, including clarifications or corrective actions. The REB Chair or Designee will share the written response with the CNO and the REB members.

4.3.3 The REB Chair or Designee and any other designated individuals will institute any correction actions as applicable and revise the REB policies and Standard Operating Procedures as required.

4.3.4 The REB Chair or Designee will file the original Audit Report and response documents in the appropriate files.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 network of Networks (2023). *Glossary of Terms*.

2. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 902.003: *External Inspections or Audits*.

3. Health Canada, Food and Drug Regulations, Part C, Division 5, *Drugs for Clinical Trials Involving Human Subjects* GUI-0100, March 14, 2023 version 2.

4. 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.

5. UBC Office of Research Ethics. (2018). Standard Operating Procedure 902: *External Inspections or Audits.*

6. Personal correspondence for Regulatory Affairs and Quality Officer, Clinical Trials BC dated November 19, 2020 confirming which external regulatory bodies may conduct an REB audit.

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