Title	External Inspections or Audits
SOP Code	902.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures to be followed before, during and following an external inspection or audit.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members, Research Ethics staff and Researchers are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Health Canada has the authority to inspect Researcher sites conducting clinical trials that fall under the *Regulations* to assess compliance with relevant regulations and guidelines.

The US Food and Drug Administration (FDA) has the authority to audit Researcher sites involved in studies conducted under a US Investigated New Drug Application (IND) or Investigational Device Exemption (IDE) to assess compliance with relevant regulations and guidelines. The US Office for Human Research Protection (OHRP) has the authority to audit Canadian REBs that oversee studies that are supported by the US federal government.

Sponsors, funding entities, or others authorized by regulations or agreements with the organizations may have the authority to audit or inspect research-related documents and procedures.

These audits or inspections may involve the REB; therefore, the REB must have policies in place for dealing with external audits or inspections. The Researcher is responsible for promptly notifying Research Ethics of any planned audits or inspections of research projects overseen by the REB.

5.1 Preparing for an Inspection or Audit

5.1.1 The Director, Research Ethics or designee will confirm with the Sponsor and/or the Researcher (or inspector/auditor, as applicable) regarding the agreed dates and times of the inspection/audit, and verify the purpose of the inspection/audit, the applicable project(s) undergoing inspection/audit and the inspection/audit plan and procedures;

5.1.2 The Director, Research Ethics or designee will notify the REB members, the Research Ethics staff and Legal Counsel of the inspection/audit;

5.1.3 The Director, Research Ethics or designee will review the inspection/audit procedures with the REB members and conduct a thorough review of the required documentation;

5.1.4 The Director, Research Ethics or designee will arrange for access to the appropriate documents for the inspector/auditor in accordance with the University's policies, applicable law and any applicable agreements.

5.1.5 The Director, Research Ethics or designee will confirm that the REB members and Research Ethics staff are available for interviews or to assist the inspector/auditor;

5.1.6 The Director, Research Ethics or designee will arrange for a suitable work area (e.g. private and with sufficient space, with access to a computer and in close proximity to a photocopier and telephone) for the inspector/auditor.

5.2 Participating in an Inspection or Audit

5.2.1 The Director, Research Ethics or designee will meet with the inspector/auditor as scheduled. Prior to being granted access to the research-specific REB documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit and may be required to execute a confidentiality agreement;

5.2.2 The Director, Research Ethics or designee will record the name, contact information and title of the inspector/auditor and retain any written notices of inspection/audit for the REB files;

5.2.3 The Director, Research Ethics or designee will provide a brief orientation to the inspector/auditor of REB procedures;

5.2.4 The Director, Research Ethics or designee will provide access to the research-specific documents requested by the inspector/auditor and maintain a list of the documents reviewed;

5.2.5 The Director, Research Ethics or designee will accompany the inspector/auditor at all times while in confidential areas of the Research Ethics office and/or the University;

5.2.6 The Director, Research Ethics or designee will ensure that the inspector/auditor's questions are answered by the most appropriate personnel. The Director, Research Ethics or designee, Research Ethics staff and REB members must make every reasonable effort to be available and to accommodate the requests of the inspector/auditor;

5.2.7 The Director, Research Ethics or designee will request meetings with the inspector/auditor at the end of each day, as needed, to discuss any observations. If questions are asked or observations are made during the daily meetings, the Director, Research Ethics or designee will research the issues and provide the inspector/auditor with clarification as soon as possible once the information is available;

5.2.8 The Director, Research Ethics or designee will ensure that the required personnel are present at the exit interview and that observations are understood before the inspector/auditors leave the facility;

5.2.9 The Director, Research Ethics or designee will record any observations of the inspector/auditor and any discussion and ascertain when/if a written response is required.

5.3 Follow-up after an Inspection or Audit

5.3.1 The Director, Research Ethics or designee will request a copy of the report from the Researcher;

5.3.2 The Director, Research Ethics or designee and any other designated individuals will review any findings relevant to the REB and prepare a written response to each item or observation, including any clarification or corrective action that will be taken. The response to the inspector/auditor should be coordinated through the appropriate channels (e.g., the sponsor via the Researcher);

5.3.3 The Director, Research Ethics or designee and any other designated individuals will institute any correction actions as applicable and revise the REB SOPs as needed;

5.3.4 The Director, Research Ethics or designee will file the original inspection/audit and response documents in the appropriate files (e.g., quality assurance).

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP902.001	15-Sept-2014	Original version
SOP902.002	08-Mar-2016	No revisions needed
SOP902.003	08-Oct-2019	No revisions needed
SOP902.004	15-May-2023	No revisions needed