TITLE	**902: External Inspections or Audits**
SCOPE	The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	March 2022

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 DEFINITIONS

See Glossary of Terms.

3.0 RESPONSIBILITIES

HREB members, Research Ethics Office (REO) Personnel 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 HREB; therefore, the HREB must have policies in place for dealing with external audits or inspections. The Researcher is responsible for notifying the HREB of any planned audits or inspections of research projects overseen by the HREB.

5.1 Preparing for an Inspection or Audit

5.1.1 The Ethics Director or designee, in consultation with the HREB Chair, will confirm with the Sponsor and/or the Researcher (or inspector/auditor, as applicable) the agreed upon 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 Ethics Director or designee will notify the HREB members and the REO Personnel of the inspection/audit.

5.1.3 The Ethics Director or designee will review the inspection/audit procedures with the HREB Chair, HREB members and REO Personnel and conduct a thorough review of the required documentation.

5.1.4 The Ethics Director or designee will arrange for access to the appropriate documents for the inspector/auditor.

5.1.5 The Ethics Director or designee will confirm that the HREB Chair, HREB members and REO Personnel are available for interviews or to assist the inspector/auditor.

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

5.1.7 The Ethics Director or designee will advise the inspector/auditor of any requirements regarding privacy and confidentiality (e.g. Access to Information and Protection Act (2015), Personal Health Information Act). The inspector/auditor will sign an Oath of Confidentiality before the inspection may begin.

5.2 Participating in an Inspection or Audit

5.2.1 The Ethics Director or designee will meet with the inspector/auditor as scheduled. Prior to being granted access to the research-specific HREB documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit.

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

5.2.3 The Ethics Director or designee will provide a brief orientation to the inspector/auditor of HREB procedures.

5.2.4 The Ethics Director 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 Ethics Director or designee will accompany the inspector/auditor at all times while in confidential areas of the HREB office.

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

5.2.7 The Ethics Director 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 Ethics Director 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 Ethics Director or designee will ensure that the required personnel are present at the exit interview and that observations are understood before the inspector/auditor leaves the facility.

5.2.9 The Ethics Director 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 Ethics Director or designee will request a copy of the report from the inspector/auditor.

5.3.2 The Ethics Director or designee, in consultation with the HREB Chair and any other designated individuals, will review any findings relevant to the HREB and prepare a written response to each item or observation, including any clarification or corrective action that will be taken.

5.3.3 The Ethics Director or designee, in consultation with the HREB Chair and any other designated individuals, will institute any corrective actions, as applicable, and revise the HREB SOPs as needed.

5.3.4 The Ethics Director or designee will file the original inspection/audit and response documents in the appropriate HREB files.

6.0 REFERENCES

Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6(R2), Notice - Interim Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Canada.ca

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46): 2018 Requirements (2018 Common Rule) | HHS.gov

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=