a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

SOP 902

TITLE	**902: External Inspections or Audits**
SCOPE	All research submitted to the University of British Columbia's Research Ethics Boards
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Office of Research Ethics, all Research Ethics Board (REB) Chairs and members, all REB Office Personnel and all Researchers
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	May 2011; April 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the procedures to be followed before, during and following an external inspection or audit.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 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. For external audits involving Health Canada, the following must be notified immediately:

- Vice-President, Research & Innovation
- Relevant REB Chair
- Hospital Administration, if applicable
- Health Records, if applicable.

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

These audits or inspections may involve the REB; therefore, the REB must have policies in place for dealing with external audits or inspections. Quality assurance and quality control of the daily operations of the REB ensure that they effectively support the REB's mandate. The Researcher is responsible for notifying the REB of any planned audits or inspections of research projects overseen by the REB.

3.1 Preparing for an Inspection or Audit

3.1.1 The Sponsor and/or the Researcher (or inspector/auditor, as applicable) will confirm with the REB Chair or designee 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;

3.1.2 The REB Chair or designee may notify the REB members and the REB Office Personnel of the inspection/audit;

3.1.3 The REB Chair or designee may review the inspection/audit procedures with the REB members and REB Office Personnel and conduct a thorough review of the required documentation;

3.1.4 The REB Chair or designee will be responsible for the preparation of such information from REB files prior to the audit as may be required;

3.1.5 The REB Chair or designee will arrange for access to the appropriate documents for the inspector/auditor[1];

3.1.6 The REB Chair or designee will confirm that the REB members and REB Office Personnel are available for interviews or to assist the inspector/auditor;

3.1.7 The REB Chair or designee will ensure that 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.

3.2 Participating in an Inspection or Audit

3.2.1 The REB Chair 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;

3.2.2 The REB Chair 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;

3.2.3 The REB Chair or designee will provide a brief orientation to the inspector/auditor of REB procedures;

3.2.4 The REB Chair or designee will provide access to the REB records of the research-specific documents requested by the inspector/auditor and maintain a list of the documents reviewed;

3.2.5 No entity other than those listed on the consent forms may have access to any document that includes participant identifiers;

3.2.6 The REB Chair or designee will accompany the inspector/auditor at all times while in confidential areas of the REB office;

3.2.7 Documents may be copied and taken off-site only by individuals authorized by writing by the Director, Office of Research Ethics, or Vice-President, Research & Innovation, to do so;

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

3.2.9 The REB Chair 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 REB Chair or designee will research the issues and provide the inspector/auditor with clarification as soon as possible once the information is available;

3.2.10 The REB Chair 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;

3.2.11 The REB Chair or designee will record any observations of the inspector/auditor and any discussion and ascertain when/if a written response is required.

3.3 Follow-up after an Inspection or Audit

3.3.1 The REB Chair or designee will request a copy of the report from the Researcher;

3.3.2 Reports of the audit, either verbal or written, in relation to the operation of the REB should be presented to the Vice-President, Research & Innovation, the Director, Office of Research Ethics, and the applicable REB Chair(s) and addressed as soon as reasonably possible;

3.3.3 The REB Chair 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);

3.3.4 The REB Chair or designee and any other designated individuals will institute any corrective actions as applicable and revise the REB SOPs as needed;

3.3.5 The REB Chair or designee will file the original inspection/audit and response documents in the appropriate files (e.g. quality assurance).

4.0 REFERENCES

1. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.115(b)):* https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.115
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.115(b)): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115