SOP Title	External Inspection or Audit
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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Dr. Joseph Gilbert Chair, Health Sciences Research Ethics Board		05/11/2016

1. PURPOSE

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

2. GENERAL POLICY STATEMENT

Health Canada has the authority to inspect Investigator sites conducting clinical trials that fall under Division 5 of the Food and Drug Act, to assess compliance with relevant regulations and guidelines.

The US Food and Drug Administration (FDA) has the authority to audit Investigator sites involved in studies conducted under the US Investigational New Drug Application (IND), to assess compliance with relevant regulations and guidelines. The US Office for Human Research Protection (OHRP) has the authority to audit Canadian Research Ethics Boards (REBs) that oversee studies that are federally (US) funded.

Sponsors, funding entities, or others authorized by regulations or agreements with the institutions may have the authority to audit or inspect study-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 and inspections.

3. RESPONSIBILITY

This SOP applies to all Office of Human Research Ethics (OHRE) staff, Health Sciences Research Ethics (HSREB) Chair, vice-chair(s), HSREB members and the Non Medical Research Ethics Board (NMREB) Chair and NMREB members. All named above are responsible for participating as required, in the external inspections/audit that involves Western University's OHRE.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1 Preparing for an Inspection or Audit

5.1.1 The Director, Research Ethics or designee will confirm with the inspector/auditor 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 both HSREB Chair, vice-chair(s), HSREB members, NMREB Chair, NMREB members and the OHRE staff of the inspection/audit;

5.1.3 The Director, Research Ethics or designee will review the inspection/audit procedures with the applicable individuals/groups listed in 5.1.2 and conduct a thorough review of the required documentation;

5.1.4 The Director, Research Ethics or designee will arrange for access to the online system for the inspector/auditor;

5.1.5 The Director, Research Ethics or designee will confirm that the individuals/groups listed in 5.1.2 are available for interviews or to assist the inspector/auditor;

5.1.6 The Director, Research Ethics or designee will arrange 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 HSREB Chair, vice-chair(s) and/or the NMREB Chair and the Director, Research Ethics will meet with the inspector/auditor as scheduled. Prior to being granted access to the study-specific OHRE documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit;

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 OHRE files;

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

5.2.4 The Director, Research Ethics or designee will provide access to the study-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 OHRE;

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 individuals/groups listed in 5.1.2 must make every reasonable effort to be available and to accommodate the requests of the inspector/auditor;

5.2.7 The HSREB Chair and/or NMREB Chair and the Director, Research Ethics will request meetings with the inspector/auditor at the end of each day to discuss any observations. If questions are asked or observations are made during the daily meetings, the HSREB Chair and/or NMREB Chair or designee will research the issues and provide the inspector/auditor with clarification at the beginning of the next day;

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 observations of the inspector/auditor and any discussion and ascertain with/if a written response is required.

5.3 **Follow-up after an Inspection or Audit**

5.3.1 The HSREB Chair and/or NMREB Chair will request a copy of the report for the Investigator;

5.3.2 The HSREB Chair and/or NMREB Chair, Director, Research Ethics and the Ethics Officer (EO) will review any findings relevant to the OHRE 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 Investigator);

5.3.3 The HSREB Chair and/or NMREB Chair, Director, Research Ethics and the Ethics Officer (EO) will institute any correction actions as applicable and revise the OHRE 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. REFERENCES

6.1. Health Canada, Division 5 of the Food and Drug Act;
6.2. Summary Report of the Inspections of Clinical Trials, Health Canada Report;
6.3. Health Products and Food Branch Inspectorate (HPFBI) Inspection Strategy;
6.4. US Food and Drug Administration (FDA) Code of Federal Regulations (CRF) Title 21 Part 312 Subpart D.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyy
902.001	Original	05/29/2014
902.002	Minor administrative revisions for clarity	05/10/2016