Research Ethics Board Standard Operating Policies and Procedures

Audits and Inspections of REB Operations

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ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

This Standard Operating Procedure (SOP) describes the procedures to be followed before, during and following an inspection or audit of Women's College Hospital (WCH) Research Ethics Board (REB) operations.

Certain regulatory, accreditation and qualification agencies have the authority to audit or inspect the operations of the REB to assess compliance with research ethics regulatory standards and policy requirements.

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 a 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 WCH 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 or inspections.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to Investigators and their staff, all WCH REB members including the Chair and Vice-Chair, and to all WCHREB office personnel.

The Investigator is responsible for notifying WCH REB of any planned audits or inspections of studies overseen by WCH REB.

The WCH REB Chair, WCH REB members and WCH Research Ethics Office (REO) personnel are responsible for participating as required, in the external inspections/audits that involve WCH REB.

4.0 PROCEDURES:

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Audits and Inspections of REB Operations

4.1. Preparing for an Inspection or Audit

4.1.1. When the WCH REB is informed of an upcoming external audit or inspection involving Health Canada, the federal granting agencies, the FDA or OHRP, the REO must immediately notify the Vice-President, Research and Director, Research Operations at WCH.

4.1.2. Upon being informed of an upcoming audit or inspection, the REO will confer with the audit/inspection agency regarding the scheduled audit/inspection date, and verify the purpose of the audit/inspection, the applicable project(s) undergoing audit/inspection, and the audit/inspection plan and procedures (including follow-up requirements and procedures for non-compliance);

4.1.3. Upon confirmation of the audit/inspection date and time the REO will:

- notify the WCH REB Chair, WCH REB members and all relevant physicians and staff members of the audit/inspection
- review audit/inspection procedures with appropriate REO staff and conduct a thorough review of relevant documentation
- ensure that original relevant documents are available and that the information is complete and up-to-date
- prepare the logistics for the audit/inspection visit including but not limited to:
    - ensure access to a photocopier, telephone, and internet connection
    - reserve work space
    - ensure availability of appropriate personnel for interviews

4.2. Participating in an audit/inspection

4.2.1. Prior to being granted access to WCH REB documentation, auditors/inspectors must present identification and proof of their authority or authorization to conduct an audit/inspection and access REB documents.

4.2.2. No entity other than those listed on the relevant consent forms may have access to any document that includes participant identifiers. The REO will be responsible for the preparation of such information from relevant files prior to the audit/inspection as required.

4.2.3. The Manager or designate will ensure that the required personnel are present at the exit interview and that all audit/inspection observations are understood

4.2.4. The Manager or designate will record any observations of the inspector/auditor and determine whether a written response is required.

4.3. Follow-up after an Audit/Inspection

4.3.1. Written reports listing the observations/deviations noted during the audit/inspection will be addressed by the REB Chair and REO staff as soon as possible following the audit/inspection.

4.3.2. Reports of the audit/inspection shall be shared with the Vice-President, Research, the Director, Research Operations and the Medical Advisory Committee at WCH as soon as possible.

4.3.3. When applicable, the REB shall address any deficiencies noted, describe the intended corrective actions and the timeframe for implementation, and submit to the Medical Advisory Committee for approval. Following approval, a response letter and action plan will be forwarded to the audit/inspector.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Article 6.17
2. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 4.8.10
3. Health Canada, Division 5 of the Food and Drug Act
4. Summary Report of the Inspections of Clinical Trials. Health Canada Report
5. Health Products and Food Branch Inspectorate (HPFBI) Inspection Strategy
6. US Food and Drug Administration (FDA) Code of Federal Regulation (CFR) Title 21 Part 312 Subpart D
7. Holland Bloorview Research Ethics Board Standard Operating Procedure 901 Audits and Inspections
8. OCREB Standard Operating Procedure, External Inspections or Audits. 902.002. version June 25, 2010