IWK Research Ethics
Standard Operating Procedures

Document # **RE 9.901**	Title: **Audits and Inspections**	Effective Date: **November 19, 2024**
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POLICY

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.

PROCEDURES

Preparing for an Inspection or Audit

Upon being informed of an upcoming audit or inspection, the REO Manager will talk 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.

Upon confirmation of the audit/inspection date and time the Manager will:

- Notify the REB Chair and REB members of the audit/inspection
- Review audit/inspection procedures with appropriate REO staff and conduct a thorough review of relevant documentation
  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

Participating in an Audit/Inspection

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

No individual 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.
The REO Manager or designate will ensure that the required personnel are present at the exit interview and that all audit/inspection observations are understood.

Follow-up After an Audit/Inspection
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. When applicable, the REB shall address any deficiencies noted; describe the intended corrective actions and the timeframe for implementation. A response letter and action plan will be forwarded to the audit inspector.

Note: US regulations will be applied as applicable.

REFERENCES

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), 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

Forms/Records:

Form #	Form/Record Name
SOP 901	Audits and Inspections

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 9, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 19, 2024	Added note regarding compliance with US regulations where applicable & update to responsibility (RIA)