Research Ethics Board

Standard Operating Procedure

Document Number	**REB.SOP.902**
Title	External Inspections or Audits
Effective Date	September 23, 2021
Next Review	2026
Next Administrative Review	2023

1. **Purpose**
   This standard operating procedure (SOP) describes the procedures to be followedbefore, during and following an external inspection or audit.

2. **Definitions**
   See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. **Scope**
   This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

4. **Responsibilities**
   All REB members, REB Office Personnel and Researchers are responsible for ensuringthat the requirements of this SOP are met.

5. **Procedures and/or Specific Policies**
   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 REB; therefore, the REB must have policies in place for dealing with external audits or inspections. The Researcher is responsible for notifying the REB of any planned audits or inspections of research projects overseen by the REB.

   5.1. Preparing for an Inspection or Audit

5.1.1. The REB Chair or designee will confirm with the Sponsor and/or the Researcher(or inspector/auditor, as applicable) regarding the agreed dates and times of theinspection/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 REB Chair or designee will notify the REB members and the REB OfficePersonnel of the inspection/audit;

5.1.3. The REB Chair or designee will review the inspection/audit procedures with theREB members and REB Office Personnel and conduct a thorough review of therequired documentation;

5.1.4. The REB Chair or designee will arrange for access to the appropriate documents for the inspector/auditor;

5.1.5. The REB Chair or designee will confirm that the REB members and REB OfficePersonnel are available for interviews or to assist the inspector/auditor;

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

5.2. Participating in an Inspection or Audit

5.2.1. The REB Chair or designee will meet with the inspector/auditor as scheduled. Prior to being granted access to the research-specific REB documentation, theinspector/auditor must exhibit proof of authority or authorization to conduct theinspection/audit;

5.2.2. The REB Chair or designee will record the name, contact information and title ofthe inspector/auditor, and retain any written notices of inspection/audit for the REB files;

5.2.3. The REB Chair or designee will provide a brief orientation to the inspector/auditorof REB procedures;

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

5.2.5. The REB Chair or designee will always accompany the inspector/auditor while in confidential areas of the REB office and/or the organization;

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

5.2.7. The REB Chair or designee will request meetings with the inspector/auditor at theend of each day, as needed, to discuss any observations. If questions are askedor 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;

5.2.8. 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;

5.2.9. The REB Chair or designee will record any observations of the inspector/auditorand any discussion and ascertain when/if a written response

is required.

5.3. Follow-up after an Inspection or Audit

5.3.1. The REB Chair or designee will request a copy of the report from theResearcher;

5.3.2. 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. Theresponse to the inspector/auditor should be coordinated through the appropriate channels (e.g., the sponsor via the Researcher);

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

5.3.4. The REB Chair or designee will file the original inspection/audit and responsedocuments in the appropriate files (e.g., quality assurance).

6. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved June 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.902	Original	September 2021

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