Title	Quality Assurance
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N2/CAREB SOP CODE	Adapted from SOP 901.002 and SOP 902.002
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Status	Name and Title	Date
Author of Harmonized Template	SOPs, Institutional REBs	2019-04-01
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1 PURPOSE

This standard operating procedure (SOP) describes the procedures to be followed before, during and after an external inspection or audit.

2 SCOPE

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

3 RESPONSIBILITIES

All REB members, designated REB staff, and Researchers are responsible for ensuring that the requirements of this SOP are met.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

Quality Management programs, Quality Assurance (QA) and Quality Control (QC) activities, such as inspections of the REB and of Researchers, aim to ensure the protection of the human participants in research studies.

Findings of these activities are measured against established policies and procedures and all of the applicable ethical, legal, and regulatory requirements. When areas for improvement are identified, corrective action is taken including training, education, and the revision of SOPs.

5.1 Quality Assurance Inspections by the Institution, MSSS, and OHRP

The Board of Directors of the institution may request an inspection of REB activities. Appropriate measures should be taken to avoid conflict of interest on the part of investigators. Thus, neither the Research Centre nor the Research Director's Office may conduct the investigation.

The Quebec Minister of Health and Social Services (*Ministère de la Santé et des Services sociaux*, MSSS) may appoint a group or individual to conduct quality control visits of designated REBs at any time, in accordance with article 21 of the *Civil Code of Quebec*.[1] These investigators are obliged to respect confidentiality and show discretion.[2]

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 supported by the U.S. federal government.

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1 *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, *Gouvernement du Québec, Ministère de la Santé et des Services sociaux*, June 1998, hereafter "PAM", p. 24.

2 *Ibid*.

5.2 Inspections/Audits Related to Research Studies

Sponsors, funding entities, or others authorized by regulations (e.g. Health Canada) 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. The Researcher is responsible for notifying the REB of any planned audits or inspections of research projects overseen by the REB.

5.3 Annual REB Report

5.3.1 Every year, the REB submits a report of all REB activities to its governing body.[3] To preserve REB independence, the report does not have to be approved by the governing body, but merely acknowledged;

5.3.2 The REB also submits an annual report of REB activities to the MSSS[4];

5.3.3 The report, drafted in accordance with MSSS requirements,[5] may contain the following:

- Roster of REB members, including qualifications and roles within the REB,
- Number of REB meetings held in the year,
- List of research applications received,
- Continuing reviews throughout the year,
- Any other item that the REB wishes to bring to the attention of the MSSS.

5.4 Preparing for an Inspection or Audit

5.4.1 The REB Chair or designee will verify the purpose of the inspection/audit, the applicable project(s) undergoing inspection/audit and the inspection/audit plan and procedures;

5.4.2 The REB Chair or designee will notify the REB Support Staff of the inspection/audit;

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

5.4.4 The REB Chair or designee will confirm that the REB members and REB Support Staff are available for interviews or to assist the inspector/auditor.

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[3] *Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le Ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil, Gazette officielle du Québec*, Part I, vol. 35, 1998, hereafter "Avis"; Civil Code of Québec (CCQ), c. CCQ-1991, art. 21; Modèle de règles de fonctionnement d'un comité d'éthique de la recherche, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter "Modèle", s. 15.1.

[4] PAM, p. 24; Modèle, s. 15.1.

[5] PAM, p. 24; Modèle, s. 15.2.

5.5 Participating in an Inspection or Audit

5.5.1 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;

5.5.2 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;

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

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

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

5.5.6 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 Support Staff and REB members must make every reasonable effort to be available and to accommodate the requests of the inspector/auditor;

5.5.7 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;

5.5.8 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;

5.5.9 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.

5.6 Follow-up after an Inspection or Audit

5.6.1 The REB Chair or designee will request a copy of the inspection/audit report;

5.6.2 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;

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

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

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 701.001	2020-03-20	Original version (MUHC Board of Directors acknowledged 2020-03-20; approved 2021-03-22)

8 APPENDICES