SOP Title	**Quality Assurance Inspections**
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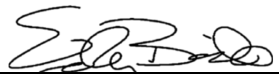
Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile, Director, Research Ethics and Compliance		28 Jan 2022
Dr. Philip Jones Chair, Health Sciences Research Ethics Board		27 Jan 2022

1. PURPOSE

This standard operating procedure (SOP) describes the processes for monitoring, evaluating and improving the effectiveness of the human research protection enterprise.

2. GENERAL POLICY STATEMENT

Quality Management programs, Quality Assurance (QA), and Quality Control (QC) activities, such as inspections of the REB and of Investigators, allow for a continuous evaluation and subsequent assurance of the human research protection enterprise.

Findings 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.

3. RESPONSIBILITY

All HSREB members, Office of Human Research Ethics (OHRE) Staff, Director, Research Ethics and Compliance, and the QA team/officer (e.g., Lawson's Quality Assurance and Education Office), if separate from the OHRE staff, are responsible for ensuring that the requirements of this SOP are met.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. REB Quality Assurance Inspections (Internal))

5.1.1. The QA Team/Officer will develop a schedule for routine QA inspections or initiate ad hoc inspections in response to complaints or other concerns;

5.1.2. QA inspections may include the REB and the REB office;

5.1.3. When the QA Officer conducts a QA inspection of the REB and the REB office inspection may including the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance,
- A review of research files, REB membership rosters, REB attendance records, and REB agendas and minutes,
- A review of workload, performance metrics, and annual reports,
- A review of stakeholder satisfaction surveys,
- An assessment of quality control procedures for compliance with the SOPs,
- A review of checklists, forms, and templates,
- Interviews with REB members, REB Office Personnel, Investigators, Sponsors, and regulators,
- A review of training/education records,
- A review of all continuous improvement activities,
- An assessment of whether any new requirements (ethical, legal, or regulatory) were incorporated into the policies and procedures,
- A review of the status of any corrective action items from previous reviews,
- A review of any deviations from ethical, legal, or regulatory requirements, or deviations from the organization's policies, and whether the deviations require remediation,
- An assessment of compliance with all applicable requirements

5.1.4. The QA Team/Officer compares the findings against established policies, SOPs and applicable ethical, legal, and regulatory requirements;

5.1.5. The QA Team/Officer prepares a written summary of the inspection, including areas requiring improvement;

5.1.6. The QA Team/Officer reports the findings to the HSREB Chair or designee, and to the HSREB and/or to the appropriate Organizational Official as required;

5.1.7. The QA Team/Officer works with the HSREB Chair or designee to implement improvements (e.g. new or revised SOPs or forms, training, education, additional resources, or modifications to existing resources).

5.2. **Investigator Quality Assurance Inspection**

5.2.1. The QA Team/Officer will develop a schedule for routine QA inspections and implement inspections in response to Investigator requests;

5.2.2. The QA Team/Officer will work with the HSREB and the organization at which the research is being conducted to determine if and when a for-cause inspection of a Investigator is warranted;

5.2.3. The HSREB may direct the QA Team/Officer to conduct for-cause inspections;

5.2.4. The QA Team/Officer or designee may request copies of the sponsor's monitoring reports for a designated research project or that a questionnaire from the HSREB is completed;

5.2.5. The criteria for selecting Investigators or research projects for inspection may include:

- The results of a previous external audit or inspection,
- The results of a Sponsor audit,
- Investigator-initiated studies (i.e., where the Investigator is also the Sponsor),
- Studies that involve a potentially high risk to participants,
- Studies that involve vulnerable populations, (in the context of research)
- Studies in which Investigator are enrolling large numbers of participants,

- Suspected noncompliance,
- Unanticipated problems involving risks to participants or others,
- Suspected or reported protocol deviations,
- Participant complaints,
- Research Staff complaints,
- Any other situation that the REB deems appropriate;

5.2.6. The QA Team/Officer or designee will notify the Investigator of the inspection and a mutually acceptable time will be scheduled. It may be necessary to schedule an inspection without first obtaining the formal consent of an Investigator (e.g., participant safety or suspected non-compliance);

5.2.7. The QA Team/Officer or designee will conduct the inspection using designated/appropriate evaluation tools;

5.2.8.8 When the QA Team/ Officer conducts an inspection of the Investigator, the inspection may include some or all of the following (as applicable):

- An assessment of the SOPs and compliance with applicable regulations and guidance,
- A review of all regulatory binders including the HSREB approval documentation, HSREB approved consent documents, signed consent documents, correspondence between the Investigator and sponsor, etc.,
- Interviews with the research staff and/or the Investigator,
- A review of test article accountability,
- A review of specimens and associated collection processes,
- A review of computer hardware and/or software associated with the research,
- A review of the consent form(s) and associated processes including eligibility requirements,
- A review of the completed case report forms (CRFs) or other data collection mechanisms,
- A review of appropriate source material (participant medical records), and
- A review of other documentation, as relevant and available;

5.2.9. The REB or the QA Team/Officer may choose to have a qualified impartial observer to monitor the consent process or to interview research participants;

5.2.10. At the conclusion of the evaluation, the QA Team/Officer or designee will discuss the findings with the Investigator;

5.2.11. The QA Team/Officer or designee will draft a report or provide a summary of the inspection including: positive findings, areas for improvement and recommendations for corrective action, and submit the report to the HSREB Chair or designee for review;

5.2.12. The Investigator will be given an opportunity to respond to the report with responses and/or corrective action plans within a time specified by the HSREB;

5.2.13. The QA Team/Officer or designee will send a copy of the final report to the Investigator and the HSREB. When applicable, the HSREB Chair or designee will provide the findings to the local Organizational Official.

5.3. **Corrective Action**

5.3.1. The QA Team/Officer may recommend corrective action based on the findings;

5.3.2. Corrective action may include a recommendation for the provision of additional resources, training, or education, the development of, or revisions to the SOPs, and changes to forms, checklists or templates;

5.3.3. The QA Team/Officer will evaluate the effectiveness of the implemented improvements and adjust processes accordingly;

5.3.4. The QA Officer will follow-up with the Investigator in a timely manner to determine if the corrective actions have been implemented by the Investigator following a Investigator audit or inspection.

5.4. **Documentation**

5.4.1. The QA Team/Officer or designee files all reports and correspondence concerning QA inspections in the appropriate QA Files.

6. REFERENCES

6.1. Health Canada, Part C, Division 5 of the Food and Drug Regulations;
6.2. Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans (TCPS2) Article 6.14;
6.3. Government of Canada, Medical Device Regulations, SOR/98-282, last amended December 16, 2011, current to February 21, 2013;
6.4. Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006;
6.5. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP);
6.6. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Parts 11, 50, 54, 56, 312 and 314.
6.7. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
901.001	Original	07/25/2014
901.002	Minor administrative revisions for clarity	05/10/2016
901.003	Minor administrative corrections	09/10/2018
901.004	Minor administrative corrections	02/21/2020
901.005	Rewritten to better align with N2 CAREB SOP.	01/28/2022