SOP Title	**Internal Quality Assurance Audits**
Number.Version	901.001
Effective Date	02/25/2025

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile, Director, Research Ethics and Compliance	Erika Basile	Mar 3, 2025
Dr. Isha DeCoito Chair, Non-Medical Research Ethics Board	Isha DeCoito	Mar 4, 2025

1. PURPOSE

This standard operating procedure (SOP) describes the processes to be followed prior to, during, and following audits or regulatory inspections.

2. GENERAL POLICY STATEMENT

Internal quality assurance audits (IQAA) are conducted by either the University of Western Ontario's ("Western") Quality and Research Compliance team. These reviews allow for continuing evaluation and oversight, assuring human research participant protection. The program is compliant with established policies and procedures; and applicable ethical, legal, and regulatory requirements.

3. RESPONSIBILITY

The Researcher is responsible for ensuring that the study site and all team members are prepared to receive audits or regulatory inspections, as required.

Some parts of audit/inspection preparation may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the Researcher.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Internal Quality Assurance Audits (IQAA)

5.1.1. IQAA may be directed, random, or by request in preparation for external audits or regulatory inspections;

5.1.2. Studies may be identified for routine audit by the Western Quality and Research Compliance team;

5.1.3. Studies may also be identified for routine audit by the Non-Medical Research Ethics Board (NMREB) during initial review based on the following criteria;

- Involve a greater than minimal risk to participants,
- Involve vulnerable populations (in the context of research),
- Large numbers of participants are to be enrolled, or
- Any other situation the REB deems appropriate.

5.1.4. Studies may be identified for directed audit by the NMREB during continuing review based on the following criteria:

- Suspected noncompliance or misconduct/fraud,
- Reported unanticipated problems involving risks to participants or others,
- Reported protocol deviations,
- Results of previous external audit or inspection,
- Reported complaint(s), or
- Any other situation the NMREB deems appropriate.

5.1.5. The Researcher and key stakeholders are informed, at a minimum of two weeks, once a study is selected for an IQAA;

5.1.6. The audit team and Researcher schedule a mutually acceptable time to conduct the introductory meeting to review the program processes (e.g., audit procedures, and determine study personnel required during the audit);

5.1.7. The IQAA may include, and is not limited to, a review of the following:

- NMREB application, study protocol, informed consent form(s), participant handouts, advertisements, and all subsequent amendments to each,
- Correspondence files between the study team,
- Correspondence files between the study team and the NMREB,
- Standard operating procedures (SOPs),
- Training Records,
- Task delegation log,
- Informed consent procedures including signed informed consent documents,
- Research participant study files including data collection forms and source documents (e.g., questionnaires), or
- Interviews of the research staff and/or the Researchers and their team.

5.1.8. At the conclusion of the IQAA, observations will be discussed with the Researcher in a post-audit meeting;

5.1.9. A written audit report, including recommended or required corrective actions and preventative actions based on the observations, is provided to the Researcher and key stakeholders. When applicable, either Western's Quality and Research Compliance team will provide the observations to the Institutional Official(s) and/or the NMREB;

5.1.10. In response to the audit report, the Researcher must submit a Corrective Action and Preventative Action (CAPA) Plan detailing how the observations will be addressed;

5.1.11. When applicable, observations related to the NMREB and/or Office of Human Research Ethics (OHRE) processes will be provided in a written summary to the REB Chair and Director, Research Ethics and Compliance.

5.2. **Corrective Action and Preventative Action (CAPA) Plan**

5.2.1. Western's Quality and Research Compliance team will recommend or require corrective actions and preventative actions based on the observations;

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

5.2.3. Western's Quality and Research Compliance team will review the CAPA plan to confirm all observations have been appropriately addressed;

5.2.4. Western's Quality and Research Compliance team may conduct a follow-up visit to evaluate the effectiveness of the CAPA plan and adjust processes accordingly.

5.3. **Office of Human Research Ethics (OHRE) Quality Assurance (QA) Reviews**

5.3.1. Quality assurance reviews of the OHRE processes may be conducted in relation to an IQAA as identified in Section 5.1; or in response to complaints, concerns, or other circumstances applicable to the Western Board of Record;

5.3.2. The QA review may include, and is not limited to, the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance;
- A review of NMREB study files, NMREB membership lists, NMREB meeting attendance records, and NMREB agendas and minutes;
- An assessment of quality control procedures for compliance with the SOPs;
- A review of checklists, forms and templates; and/or
- Interviews with the NMREB Chair, Vice Chair(s), NMREB members, OHRE staff;

5.3.3. A written summary of the QA review, including the observations and areas requiring improvement, is provided to the NMREB Chair and Director, Research Ethics and Compliance;

5.3.4. The NMREB Chair or Director, Research Ethics and Compliance works with the OHRE staff and NMREB members (if necessary) to implement improvements (e.g., new or revised SOPs/forms, training, education).

5.4. **Program Compliance**

5.4.1. Researacher non-compliance with the program is reported to Western's Quality and Research Compliance team for required actions. Occurrences of non-compliance will be escalated to the institutional official as deemed appropriate by the Director,

Research Ethics and Compliance, the NMREB Chair or designee, Western's Quality and Research Compliance Manager.

6. REFERENCES

6.1. Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans (TCPS2) Article 6.14;
6.2. Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006;
6.3. 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	02/25/2025