SOP Title	Internal Quality Assurance Inspections
Number.Version	901.005
Effective Date	02/21/2020

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile, Director, Research Ethics and Compliance		Oct 1, 2021
Dr. Philip Jones Chair, Health Sciences Research Ethics Board		Oct 1, 2021

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 under the Lawson Quality Assurance Education Program which allows 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 Sponsor-Investigator or Qualified Investigator (SI/QI) 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 SI/Q.

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 Lawson Quality Assurance and Education Program;

5.1.3. Studies may also be identified for routine audit by the Research Ethics Board (REB) 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 REB 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 REB deems appropriate.

5.1.5. The SI/QI and key stakeholders are informed, at a minimum of four weeks, once a study is selected for an IQAA;

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

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

- Original study protocol, informed consent form(s), participant handouts, advertisements, and Investigator Brochure(s)/Product Monograph(s); and all subsequent amendments to each,
- Correspondence files between the study team and Health Canada,
- Correspondence files between the study team and the REB,
- Standard operating procedures (SOPs),
- Training Records,
- Task delegation log,
- Informed consent procedures including signed informed consent documents;
- Research participant study files including completed case report forms (CRFs) and source documents (medical records); or
- Interviews of the research staff and/or investigator;

5.1.8. At the conclusion of the IQAA, observations will be discussed with the SI/QI 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 SI/QI and key stakeholders. When applicable, the Lawson Quality Assurance Education Program manager will provide the observations to the Institutional Official and/or the REB;

5.1.10. In response to the audit report, the SI/QI 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 REB and/or Office of Human Research Ethics (OHRE) processes will be provided in a written summary to the REB Chair and director.

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

5.2.1. The Lawson Quality Assurance Education Program 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. The Lawson Quality Assurance Education Program team will review the CAPA plan to confirm all observations have been appropriately addressed;

5.2.4. The Lawson Quality Assurance Education Program 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 UWO 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 REB study files, REB membership lists, REB meeting attendance records, and REB 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 REB Chair, Vice Chair(s), REB members, OHRE staff;

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

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

5.4. **Program Compliance**

5.4.1. Investigator non-compliance with the program is reported to the Lawson Quality Assurance and Education Program Manager for required actions. Occurrences of non-compliance will be escalated to the institutional official as deemed appropriate by the Lawson Quality Assurance Education Program Manager.

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 2010 (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	5.1.4 inclusion of misconduct/fraud	