TITLE	**901: Monitoring HREB Approved Research**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the processes for monitoring health research to ensure compliance with applicable legislation, policies, regulations and guidance in the conduct of research.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All Researchers, HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 PROCEDURE

The HREB is responsible for monitoring approved health research based on applicable legislation, regulations and policy. Designated REO Personnel will conduct the compliance oversight activities, including routine, as well as, for-cause inspections of HREB approved research.

Monitoring inspections allow for continuous evaluation and subsequent assurance of ethical research conduct. Findings are measured against established policies and procedures and applicable ethical, legal and regulatory requirements. When areas for improvement are identified, corrective action will be recommended. In the event of non-compliance, further measures will be implemented as outlined in SOP 903.

The Ethics Director or designee, in collaboration with the HREB, will develop a schedule for routine monitoring of research that has been approved by the HREB, and may also implement inspections in response to Researcher requests.

The Ethics Director or designee, in collaboration with the HREB, will determine when a for-cause inspection of a Researcher is warranted.

4.1 Monitoring HREB Approved Research

4.1.1 The criteria for selecting Researchers or research projects for inspection may include:

- Random selection,
- The results of a previous external audit or inspection,
- The results of a questionnaire requested by the HREB or designee,
- The results of a sponsor's monitoring report (for clinical trials),
- The results of a sponsor audit,
- Researcher-initiated studies where the Researcher is also the sponsor,
- Studies that involve a potentially high risk to participants,
- Studies that involve vulnerable populations,
- Studies in which Researchers are enrolling large numbers of participants,
- Suspected non-compliance,
- Unanticipated problems involving risks to participants or others,
- Suspected or reported protocol deviations,
- Research terminated by the HREB due to failure by the investigator to submit the study for continuing review or failure to respond to a request for information from the HREB,
- Studies reporting a large number of serious adverse events and/or protocol deviations,
- Participant complaints,
- Research Staff complaints,
- Any other situation that the REB deems appropriate.

4.1.2 The Researcher will be notified of the inspection via email, and a mutually acceptable time will be scheduled. It may be necessary to conduct an inspection without notifying the Researcher in advance (e.g. risk to participant safety).

4.1.3 A pre-inspection interview may be conducted with the Researcher and/or research personnel to review the study processes.

4.1.4 The inspection will be conducted using monitoring tools, such as checklists.

4.1.5 The inspection will include a review of the following (**as applicable):**

- compliance with SOPs and applicable regulations and guidance,
- computer hardware and/or software associated with the research,
- consent form(s) and associated processes including eligibility requirements,
- HREB approval documentation,
- completed data collection/case report forms (CRFs)
- participant interviews with research staff and/or the Researcher,
- test article accountability,
- specimens and associated collection processes,
- source material (participant medical records), and
- other relevant documentation.

4.1.6 A qualified impartial observer may be chosen to monitor the consent process or to interview research participants, on behalf of the HREB.

4.1.7 At the conclusion of the inspection, the findings may be discussed with the Researcher.

4.1.8 Following the inspection, the HREB will be provided with a summary of the inspection, including all significant observations and findings, as well as corresponding regulatory references.

4.1.9 An initial report will be sent to the researcher, which will include areas for improvement and recommendations, or requirements for corrective actions, if applicable.

4.1.10 The Researcher will be given an opportunity to respond to the report with responses and/or corrective action plans within a time specified by the HREB. The HREB will review the response and determine its acceptability and whether additional action is required.

4.1.11 A copy of the final report will be sent to the Researcher and the HREB. When applicable, the HREB or designee will provide the findings to the Researcher's organizational official.

4.2 Corrective Action

4.2.1 The HREB may recommend corrective action based on the findings. This may include, but is not limited to, 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. If the audit results in findings of non-compliance, SOP 903 will be followed.

4.2.2 The designated REO Personnel will follow up with the Researcher in a timely manner to determine if the corrective actions have been implemented following the inspection.

4.3 Documentation

4.3.1 Inspection reports will be stored in the applicable study file, as well as in the HREB Monitoring file.

5.0 REFERENCES

Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6(R2), Notice - Interim Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Canada.ca

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46): 2018 Requirements (2018 Common Rule) | HHS.gov

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart