SOP 004_01

Title	Research Ethics Board: Submissions and Ongoing Communication
SOP Code	SOP 004_01
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the required communication (submission, follow-up, etc.) between the Sponsor-Investigator or Qualified Investigator (QI)/Investigator and the Research Ethics Board (REB)/Independent Ethics Committee (IEC) during the course of clinical studies.

2.0 SCOPE

This procedure applies to Erie Shores Health Care (ESHC) research site performing studies governed by the Clinical Trial Regulations and Medical Device Regulations of Canada, the United States, and other jurisdictions.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Qualified Investigator (QI)/Investigator is responsible for ensuring that all required information is forwarded to the REB/IEC in a timely manner.

The study must not be initiated until the written REB/IEC approval is received.

Tasks required for the submission may be delegated, but the responsibility rests with the Sponsor-Investigator or QI/Investigator to ensure compliance with the REB/IEC policies and procedures.

The REB/IEC may be asked by investigators, sponsors, or regulatory authorities, to provide copies of its written procedures and membership lists.

4.0 PROCEDURE

4.1 Research Ethics Board Attestation Form

4.1.1 Complete and sign a Research Ethics Board Attestation (REBA) form OR receive an equivalent document from the REB/IEC, for each Clinical Trial Application and Investigational Testing Authorization.

4.1.2 Retain this form/document in the study essential documentation file.

4.1.3 Revise/receive updated document/s, as required throughout the course of the study. File as above.

4.1.4 Do not submit this form/document to Health Canada, unless specifically requested to do so.

4.2 Initial REB/IEC Submission

4.2.1 Determine any local REB/IEC submission or document requirements (e.g., electronic template or web-based application) requirements.

4.2.2 Prepare a submission checklist and submission letter template (recommended).

4.2.3 Submit the following documents, as applicable (unless otherwise requested by local REB/IEC):
• Original Protocol (version number/date)
• Protocol Summary
• Protocol Amendment/s (version number/date)
• Original Informed Consent Form (version number/date)
• Revised Informed Consent Form (version number/date)
• Other written participant Information (describe)
• Investigator Brochure (or equivalent) (version number/date)
• Other Safety Information (describe)
• Investigator/s Curriculum Vitae
• Recruitment Plan
• Advertising (specify)
• Other locally required documents (describe)

4.2.4 File a copy of the submission, and all related correspondence with the study-related essential documents.

4.2.5 Do not begin study until REB/IEC written approval is received.

4.3 REB/IEC Response to Submission

4.3.1 Ensure that the response letter includes the following information:
• Clinical study identification, protocol title and number,
• Name and version number/date of all documents reviewed,
• Date of review by the Board,
• Statement of *full board* or *delegated review*,
• Decision/opinion/approval of the clinical study, including required modifications, if applicable,
• Procedures for appealing the decision/opinion of the committee (if not provided separately in REB/IEC policy/procedure),
• Any other information, if applicable,
• Date of required renewal of approval, or statement of the length of time for which the approval is effective, and
• Signature of the Chair of the REB/IEC and date of the response

4.4 Changes Requested by the REB/IEC

4.4.1 The REB/IEC may request changes to the protocol, ICF, or any other materials planned for participant recruitment or participant information.

4.4.2 Forward REB/IEC-requested revisions to the Sponsor or Sponsor-Investigator for review (if applicable).

4.4.3 Sponsor-Investigator or QI/Investigator: Revise documents, as required. Ensure that all revised documents contain a new version number and date.

4.4.4 Document and file re-submissions in the same manner as initial submissions.

4.4.5 Do not begin study until REB/IEC written approval is received.

4.5 Protocol and/or Informed Consent Form Amendments

4.5.1 Submit significant amendments to the study protocol or participant ICF during the course of a clinical study to the REB/IEC, prior to implementation. Examples of significant changes include, but are not limited to:
• procedural changes that might increase participant risk,
• change in sample size,
• dropping of a control or treatment arm,
• change in study drug exposure, and
• any other change that could influence the scientific validity of the study results.

4.5.2 Submit logistical or administrative changes (e.g., change of phone number, auditor, correction of minor typographical errors, etc.) to the REB/IEC for information only.

4.5.3 Submit administrative information promptly, rather than with the annual re-approval (unless requested otherwise by the local REB/IEC).

4.5.4 Follow all other submission and approval requirements, as for the original submission.

4.6 Annual Re-approval Submission

4.6.1 Provide study progress reports to the REB/IEC on an annual basis (or more frequently, according to the REB/IEC procedures).

4.6.2 Prepare and submit a study follow-up report, which may include the following items:
• Clinical study identification (if applicable), protocol title and number,

• Previous approval date,
• Updated number of participants recruited/enrolled/treated/terminated, withdrawals and reasons for withdrawal,
• All changes of personnel on the clinical research team,
• All administrative changes to the protocol/ICF (unless already submitted),
• All deviations/violations of the protocol (unless already submitted),
• All serious adverse reactions and mandatory problem reports during the review period (unless already submitted),
• Any information recently reported or obtained particularly regarding risks associated with the research, and
• An updated Investigator Brochure or Product Monograph, if applicable.

4.6.3 Obtain re-approval **BEFORE** the previous approval expires.

4.7 Communication with the REB/IEC during the Study

4.7.1 Promptly report the following information to the REB/IEC, as per REB policy:

• Any significant protocol change or deviation (e.g., deliberate action required to avert an immediate hazard to a participant, or post facto discovery of dosing error). See Section 5.8, Reportable Protocol Deviations.
• Any serious adverse reaction or mandatory problem report, involving a participating participant enrolled at the institutional site,
• For multicentre studies, any serious, unexpected, adverse reaction or mandatory problem report, involving a participant at any site. (This information is to be forwarded by the Sponsor or Sponsor-Investigator),
• Updates to the Investigator Brochure or Product Monograph, if required, or
• Any new information that may have an impact on the safety or conduct of the study, safety of the participant, or his/her willingness to continue participating in the study. Such new information should also be reflected in an amended ICF.

4.7.2 Document and file all communications with the REB during the course of the study.

4.7.3 Inform Sponsor or Sponsor-Investigator, as/if required.

4.8 Reportable Protocol Deviations

4.8.1 The term protocol deviation is not well defined by regulations or guidelines. Deviations are identified as any unplanned or unforeseen change to a REB approved protocol or protocol procedures. Deviations are different from amendments in that they generally apply to a single occurrence or participant and are not intended to modify the entire protocols.

4.8.2 The definition of a reportable deviation may vary across local REBs, however, generally include an unanticipated deviation or divergence from the approved research protocols, consent document(s) or study addenda that jeopardizes participant safety, study efficacy, or data integrity.

4.8.3 If a reportable protocol deviation occurs (as required by Sponsors and/or REBs):

- The Sponsor-Investigator, QI/Investigator or designated person, should document and explain the reportable deviation(s);
- Deviations should not be implemented without prior agreement from the Sponsor or Sponsor-Investigator and approval from the REB (as required) unless to eliminate an immediate hazard to trial participants or when the change is administrative or logistical in nature.
- If a deviation has been implemented in order to eliminate an immediate hazard, the Sponsor-Investigator or QI/Investigator must report the deviation or change, the reasons for it, and if appropriate, the proposed protocol amendment(s) to the REB, the Sponsor, and regulatory authorities (as required) as soon as possible following the event.
- If the Sponsor allows minor changes to the protocol, confirmation of this should be provided in writing by the Sponsor. The documentation of the waiver should be filed in the study files and available to the REB for review upon request.

4.9 Suspension or Early Termination of a Clinical Study

4.9.1 Promptly notify the REB/IEC if the site's participation in a trial is suspended or prematurely terminated. Include an explanation in the correspondence.

4.10 Completion of a Clinical Study

4.10.1 Provide the REB/IEC with a summary report of the trial's outcome.

4.10.2 Submit a final study report to the REB/IEC, including the following:

- Total number of participants: recruited, completed, withdrawn and reasons for withdrawal,
- Study results, if known, and
- Any other information required by the institution.

5.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Government of Canada, Medical Device Regulations, SOR/98-282, last amended December 16, 2011, current to February 4, 2015.

Government of Canada, Natural Health Products Regulations, Part 4 Clinical Trials Involving Human Subjects, SOR/2003-196, June 5, 2003; last amended June 1, 2008, current to February 4, 2015.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada,

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014.

Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006.

Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, Annexe 11, Computerised Systems.

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

- Part 11, Electronic Records; Electronic Signatures, (21CFR11).
- Part 50, Protection of Human Subjects, (21CFR50).
- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).