Title	Initial Review – Criteria for REB Approval
SOP Code	403.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager	M Sidhu	12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023

1.0 PURPOSE

This standard operating procedure (SOP) describes the minimum requirements that research proposals involving human participants must meet to be approved by the Research Ethics Board (REB), independent of the review pathway (i.e., Full Board or delegated review).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB members are responsible for determining whether the research meets the criteria for approval.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

All research involving human participants must meet specific criteria before REB approval may be granted. Initial REB approval of the research is based on assessment of a complete submission to the REB. The REB and/or REB Office Personnel may consult the Researcher for additional information as necessary.

Following an initial review of the research, the REB should be prepared to determine the approvability of the research.

Applicable only to Clinical Trials Ontario (CTO), initial approval of the study is reflected in the Provincial Initial Application (PIA) approval. However, for centres that wish to start the research project at their site, must obtain approval using a Centre Initial Application (CIA).

Before assigning a new study, CTO will screen the research ethics application to ensure it adheres to the CTO mandate and agreements.

In addition to REB approval, the requirements of the organization where the research will be conducted must also be met before the research can begin (e.g., department approvals, adequate resources, etc.).

5.1 Minimal Criteria for Approval of Research

For the research to receive REB approval, the REB will consider the following:

5.1.1 That the Researcher has the qualifications to conduct the research;

5.1.2 Any potential conflicts of interest are declared and managed appropriately to prevent any compromises to the safety or well-being of the participants or the integrity of the data;

5.1.3 There is a state of clinical equipoise when there is a comparison of two or more treatment arms;

5.1.4 The research will generate knowledge that could be generalized and lead to improvements in health or well-being;

5.1.5 The methodology is scientifically sound and capable of answering the research question;

5.1.6 The risks to participants are minimized by:

- Using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
- By using procedures already being performed on the participants for diagnostic or treatment purposes whenever appropriate.

5.1.7 The risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated.

5.1.8 The selection of participants is equitable. In making this assessment, the REB will consider the research's purpose and setting. The REB will consider the scientific and ethical reasons for including vulnerable populations, if applicable.

5.1.9 There are sound scientific and ethical reasons for excluding classes of persons who might benefit from the research.

5.1.10 When some or all of the participants, such as children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self-determination who may be vulnerable to coercion or undue influence, in the context of research, additional safeguards have been included in the research, and in the REB review process to protect the rights and welfare of these participants.

5.1.11 The amount and method of payment to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding payment to participants including method, amounts and schedule is provided to participants when applicable.

5.1.12 Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by applicable regulations and guidelines.

5.1.13 The informed consent form will accurately explain the research and contain the required elements of consent.

5.1.14 The informed consent process will be appropriately documented in accordance with the relevant regulations.

5.1.15 There will be provisions for on-going data and safety monitoring procedures

that are appropriate to the size, complexity, phase, and level of risk of the research. The REB may recommend the use of a Data and Safety Monitoring Board (DSMB) to enhance participant protection.

5.1.16 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

5.1.17 There will be adequate provisions for continued access to the agent or device or adequate replacement of the test agent after the research is complete, when appropriate.

5.1.18 There will be adequate provisions for the timely publication and dissemination of the research results.

5.1.19 If applicable, evidence that the research has been or will be registered via an internationally recognized clinical trial registry.

5.2 Additional Criteria

5.2.1 Studies proposing to access or collect personal information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether appropriate privacy legislation is adhered to.

5.2.2 Additional criteria for research involving Indigenous peoples in Canada or research on materials related to human reproduction, genetic research, children, prisoners, or pregnant women shall be applied when applicable per governing principles and/or Regulations.

5.2.3 **In CTO applications, after a PIA has been approved, each participating centre must submit a CIA. Often, a provincial applicant (PA) will submit a PIA and CIA for approval. CIAs can only be submitted after the approval of the PIA. A centre cannot begin their trial until their CIA has been approved.**

At the CIA level, centre-specific changes from the PIA should be noted such as: potential conflicts of interest are declared and managed appropriately to prevent any compromises to the safety or well-being of the participants or the integrity of the data;

The recruitment methods respect the privacy of individual participants and conform to the privacy regulations;

The informed consent process will be appropriately documented as required by applicable regulations and guidelines;

There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

NOTE: Participating centres will adopt the expiry date of the overall study, regardless of when the CIA is approved.

To present consistent information to all study participants in Ontario, each centre must adopt the approved provincial consent forms included in the PIA. The version date of the centre's consent form must match that of the approved provincial version. NOTE: only 1 version date must be visible on the centre-specific consent form.

5.3 Length of Approval Period

5.3.1 The REB shall review research at periods appropriate to the degree of risk and at least annually.

5.3.2 The REB may require review more often than annually when there is a high degree of risk to participants relative to the population.

5.3.3 The REB may consider reviewing the research more often than annually, as required by the continuing review procedure.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes

SOP403.001	15-Sept-2014	Original version
SOP403.002	08-Mar-2016	No revisions needed
SOP403.003	08-Oct-2019	5.1.1: deletion of ' The application has been signed by the Researcher and, if applicable, by a designated Organizational Official, indicating'; 5.1.10: addition of ….who may be vulnerable 'in the context of research'; 5.1.19: First sentence changed to 'If applicable, **evidence that** the research has been or will be registered via an internationally recognized clinical trial registry; deletion of 'and a registration number has been/will be submitted to the REB. If the research is not yet registered, the researcher shall provide the REB with the registration number upon registration.'; 5.2.2: replaced the word Aboriginal with Indigenous
SOP403.004	15-May-2023	No revisions needed
SOP403.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text