University of Windsor
Office of Research Ethics

SOP 403.001

Title	Initial Review – Criteria for REB Approval
SOP Code	403.001
Board Review/Approval Date	03/16/2023

Site Approvals

Name and Title	Signature	Date dd/mm/yyyy
Dr. Scott G. Martyn, Chair		03/03/2023
Harmony Peach, Manager ORE		02/01/2023

1.0 PURPOSE

This standard operating procedure (SOP) describes the minimum requirements that research proposals involving human participants must meet in order 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 policies and guidelines.

3.0 RESPONSIBILITIES

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

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 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 initial review of the research, the REB should be prepared to make a determination as to the approvability of the research.

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

In order for the research to receive REB approval, the REB will take the following into consideration:

5.1.1 The application has been authorized by the Researcher and, if applicable, by a designated Organizational Official, indicating that the Researcher has the authority to conduct the research;

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

5.1.3 The research will generate knowledge that could lead to improvements in health or well-being of individuals or society;

5.1.4 The methodology is appropriate with respect to the discipline and capable of answering the research question;

5.1.5 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;

5.1.6 The risks to participants (if any) are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated;

5.1.7 The selection of participants is equitable. In making this assessment, the REB will take into account the purpose of the research and the research setting. The REB will consider vulnerability of participant populations with respect to ethical reasons for their inclusion, as appropriate;

5.1.8 There are sound methodological and ethical reasons for excluding classes of persons who might benefit from the research;

5.1.9 When some or all of the participants may be in situations or circumstances that make them vulnerable in the context of the research, additional safeguards have been included in the research, and in the REB review process, to protect the rights and welfare of these participants;

5.1.10 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;

5.1.11 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 policies and guidelines;

5.1.12 The informed consent process will ensure the research and the required elements of consent are accurately explained to participants;

5.1.13 The informed consent process will be appropriately documented in accordance with the relevant policy;

5.1.14 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

5.1.15 There will be adequate provisions for the timely publication or dissemination of the research results, unless there is an ethically acceptable reason for withholding publication or dissemination (e.g., Indigenous community control);

5.1.16 If applicable, the research has been or will be registered via an internationally recognized clinical trial registry 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 Additional Criteria

5.2.1 Studies proposing access to, or collection of, 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, or genetic research shall be applied when applicable in accordance with policies and/or Regulations.

5.3 Length of Approval Period

5.3.1 The REB shall establish the length of approval in relation to the degree of risk to participants, up to a maximum of one year;

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP403.001		Original version