MacEwan UNIVERSITY | RESEARCH ETHICS BOARD

SOP 402.01

Title	Initial Review – Criteria for REB Approval
SOP Code	402.01
Effective Date	September 2023

Site Approvals

Name and Title (typed or printed)	Signature	Date
Dr. Craig Kuziemsky Associate Vice-President, Research	*Original signed*	October 2020
Dr. Craig Kuziemsky, AVPR	*Original signed*	September 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 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 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 institution 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 by a designated Institutional 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 risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk;

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

5.1.5 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;

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

5.1.7 When some or all of the participants may be in vulnerable circumstances that could impact the ability to provide free and informed consent, additional safeguards have been included in the research, and in the REB review process to protect the rights and welfare of these participants;

5.1.8 The amount and method of compensation to participants is appropriate to ensure that there is no coercion or undue influence and is appropriately outlined through the informed consent process;

5.1.9 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;

5.1.10 The informed consent form will accurately explain the research and contain the required elements of consent;

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

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

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

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.

5.2.3 For studies considered to be above minimal risk, the REB will evaluate the methodology to determine if it is appropriate with respect to the discipline, and capable of answering the research question.

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
403.00	October 8 2020	Original version
403.01	September 2023	Reviewed, no revisions needed