fraserhealth	**RESEARCH ETHICS BOARD** **STANDARD OPERATING PROCEDURES**	
	SOP Number	403
	Initial Review - Criteria for REB Approval	
	Date of Issue **Date of Revision**	2012 06 28 2018 03 30 2022 07 13

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).

Directive: Fraser Health Policy "The Ethical Conduct of Research and Other Studies Involving Human Participants"

References: 2019 10 08 CAREB SOP 403.003, Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, The International Conference on Harmonization Guidelines for Good Clinical Practice, US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.111

Responsibility: 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.

Procedure

All research involving human participants must meet certain criteria before REB approval may be granted. The approval criteria are based on the guiding ethical principles of the Tri-Council Policy Statement and applicable regulations and guidelines. 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 protocol, the REB should be prepared to make a determination as to the approvability of the research.

In addition to REB approval, the requirements of Fraser Health and any other institutions where the research will be conducted must also be met before the research can begin (e.g. department approvals, the provisions of the Fraser Health Research Policy, etc.).

1.0 Minimal Criteria for Approval of Research

In order for a research study to receive REB approval, the REB must find that:

1.1 The Researcher has the qualifications to conduct the research as attested to by the department/division/program head;

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

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

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

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

1.6 Risks to participants are minimized by:

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

1.7 Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that will generated;

1.8 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 the scientific and ethical reasons for including vulnerable populations, if applicable;

1.9 There are sound scientific and ethical reasons for excluding classes of persons who might benefit from research;

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;

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;

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;

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

1.14 The informed consent process will be appropriately documented in accordance with the relevant regulations;

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;

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

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;

1.18 There will be adequate provisions for the timely publication and dissemination of the research results;

1.19 The resources required for successful completion of the study are committed (e.g., funding, space, personnel, etc.);

1.20 If applicable, evidence that 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 requires registration and is not yet registered, the researcher shall provide the REB with the registration number upon registration.

2.0 Additional Criteria

2.1 The REB may require verification of information submitted by a Researcher. The need to verify any information will be determined by the REB at a convened meeting. The purpose of the verification will be to provide necessary protection to participants when deemed appropriate by the REB;

2.2 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;

2.3 Additional criteria for research involving Indigenous peoples in Canada, or research on materials related to human reproduction, or genetic research, or

children, or prisoners, or pregnant women shall be applied when applicable in accordance with governing principles and/or Regulations.

3.0 US Federally Funded Research

3.1 For research that is subject to the provisions of 45 CFR 46 or 21 CFR 56, the REB shall consider the listed criteria in the application regulations to the extent that they differ from or vary the criteria noted in 1.0 and 2.0 above;

3.2 REB members are provided with an REB reviewer form to ensure that these criteria are considered in the review process. For U.S. regulated studies, considerations of the eight (8) required elements is discussed and documented in the meeting minutes:

- Risks to subjects are minimized by use of sound research design and that wherever appropriate procedures that are already being performed for diagnostic reasons are being used in the research,
- Risks to subjects are reasonable in relation to anticipated benefits,
- Selection of subjects is equitable,
- Informed consent will be appropriately sought,
- Informed consent will be appropriately documented,
- There are adequate provisions for monitoring,
- There are adequate privacy protections,
- Vulnerable persons are protected through the use of additional safeguards.

4.0 Length of Approval Period

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

4.2 The REB may require review more often than annually as deemed appropriate by the REB;

4.3 In instances where the research project has been continually renewed or modified over several years, the REB may require a new application be submitted.