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THE UNIVERSITY OF BRITISH COLUMBIA

SOP 403

TITLE	**403: Initial Review – Criteria for REB Approval**
SCOPE	All research submitted to the University of British Columbia's Research Ethics Boards
RESPONSIBILITIES	The Vice-President Research & Innovation, delegated to the Director, Office of Research Ethics, all Research Ethics Board (REB) Chairs and members and all REB Office Personnel. The REB members are responsible for determining whether the research meets the criteria for approval.
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	May 2011, March 2010, April 2009, July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the minimal requirements that research proposals involving human participation 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), for conduct at or under the auspices of the University of British Columbia.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

All research proposals that intend to enroll human participants must meet certain 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. The criteria are based on the guiding ethical principles of the Tri-Council Policy Statement 2[1] and are specified below.

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, certain other criteria that are unique to the Institution, such as the provisions of UBC Policy 89[2], department approvals, etc. must also be met before the research may begin.

3.1 Minimal Criteria for Approval of Research

In order for the research to receive REB approval, the REB will take the following into consideration[3]:

3.1.1 The research application has been submitted via the RISe system and electronically signed by the Researcher, as well as the applicable Department/Division Head, indicating that the Researcher has the qualifications to conduct the research[4];

3.1.2 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];

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

3.1.4 The risks to participants are minimized by[8]:

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

3.1.5 The risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated[9];

3.1.6 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 the scientific and ethical reasons for including vulnerable populations, if applicable[10];

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

3.1.8 When some or all of the participants are likely to be in vulnerable circumstances, additional safeguards have been included in the research, and in the REB review process to protect the rights and welfare of these participants[11];

3.1.9 Recruitment methods which respect the privacy of individual participants must be followed. Except under unusual circumstances, only members of the patient's healthcare team may approach the patient regarding potential participation in a research study[12];

3.1.10 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;

3.1.11 Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by appropriate local, provincial or national guidelines or regulations[13];

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

3.1.13 Informed consent will be appropriately documented as required by local, provincial and federal regulations;

3.1.14 Any waiver or alteration of the informed consent process will be properly justified and documented;

3.1.15 Where applicable, 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[14];

3.1.16 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data[15];

3.1.17 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;

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

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

3.1.20 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 requires registration and is not yet registered, the researcher shall provide the REB with the registration number upon registration.

3.2 Additional Criteria

3.2.1 The REB may require verification of information submitted by an investigator. 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. Sources of external verification are detailed in SOP 404 and criteria for considering external verification are detailed in SOP 405;

3.2.2 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;

3.2.3 Additional criteria for research involving specific populations shall be applied when applicable in accordance with governing principles and/or Regulations.

3.3 Cooperative Research Arrangements

3.3.1 The Vice-President, Research & Innovation may enter into joint review arrangements, rely upon the review of another qualified REB, or make similar arrangements to avoid duplication of effort as allowed. Where necessary, the Institutional FWA will be appropriately modified, and REB Authorization Agreements will be entered into.

3.4 U.S. Federally Funded Research

3.4.1 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 applicable regulations, to the extent that they differ from or vary the criteria noted in 3.1 and 3.2 above;

3.4.2 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, consideration 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.

3.5 Length of Approval Period

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

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

3.5.3 In instances where the research project has been continually renewed and modified over several years, the REB may request a new application be submitted.

4.0 REFERENCES

1. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 1, Part B: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/

2. *UBC Policy 89*: http://universitycounsel.ubc.ca/files/2012/06/policy89.pdf

3. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111):* https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111

4. *International Conference on Harmonization – Good Clinical Practice (ICH-GCP 4.1.1)*: http://ichgcp.net/4-investigator

5. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 7.4: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/#toc07-1d

6. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 1, Part B: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/

7. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 2.7:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.6

8. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 1, Part B:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(1)):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(1)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111

9. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 1, Part B:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(2)):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(2)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111

10. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 4.1:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/#ch4_en_a4.1
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(3)):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(3)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111

11. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 3.9:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.9
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 4.6:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/#ch4_en_a4.6
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Articles 8.3 & 8.4:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter8-chapitre8/#ch8_en_a8.3
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (b)):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (b)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111

12. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 5, Part A:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1a
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(7)):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(7)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111

13. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Articles 3.1 & 3.2:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1a
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 3.9:

http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.9
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(4) & (5)):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(4) & (5)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111

14. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 3.3:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1a
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(6)):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.111 (a)(6)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111

15. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 5, Part A:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1a
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111 (a)(7)):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111
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