



TITLE	101: Authority and Purpose
SCOPE	The activities of the Research Ethics Boards operating under the direct authority of the University of British Columbia
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Research Ethics, all Research Ethics Board (REB) Chairs and members, and all REB Office Personnel
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	May 2011, March 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to:

1. State the institutional authority under which the REB is established and empowered
2. Define the purpose of the REB.
3. State the principles governing the REB to assure that the rights and welfare of participants are protected.
4. State the authority of the REB.
5. Define the relationship of the REB to other committees and to Officials within the University system.

2.0 DEFINITIONS

See Glossary of Terms

3.0 PROCEDURE

The REB will maintain and follow all written policies and procedures consistent with federal and provincial regulations, good clinical practice and ethics guidelines when reviewing proposed research.

3.1 Statement of Institutional Authority

The UBC Research Ethics Boards are established and empowered under the authority of the Board of Governors through the Vice-President, Research & Innovation involving humans as participants or human biological material be reviewed and approved by a UBC REB prior to initiation of any research related activities, including recruitment and screening activities.

3.2 Purpose of the REBs

- The REB's purpose is to protect the rights and welfare of human participants participating in research conducted at UBC.
- The UBC REBs review and oversee such research to assure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection.
- These include but are not limited to [Health Canada's Food and Drugs Act](#),²the [International Conference on Harmonization Good Clinical Practice: Consolidated Guidelines](#),³ the [Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects](#),⁴ [The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#),⁵ UBC Policy 89 and where applicable,⁶ U.S. Federal Regulations.

3.3 Governing Principles

The REB is guided by the ethical principles regarding all research involving humans as set forth in the Core Principles⁷ of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans as follows:

- Respect for Persons:
 - Recognize the intrinsic value of human beings and the respect and consideration they are due;
 - Incorporate moral obligations to respect autonomy and to protect and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare:
 - Aim to protect the welfare of participants, and in some circumstances to promote that welfare in view of any foreseeable risks;
 - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation and that participants are not exposed to unnecessary risks.
- Justice:
 - Obligation to treat people fairly with equal respect and concern;
 - Vulnerable or marginalized people may need to be afforded special attention in order to be treated justly in research.

3.4 REB Authority

3.4.1 UBC's REBs are established to review all research involving human participants that is conducted by UBC faculty, staff or students, or anyone conducting research under the auspices of the University of British Columbia;

3.4.2 The REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare and privacy of research participants;

Specifically, the REB has the authority to:

- approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction;
- conduct continuing ethical review as it deems necessary to protect the rights and welfare and privacy of research participants;

Continuing review activities include, but are not limited to:

- Review of regular progress reports;
- Review of changes in the design or conduct of the study prior to implementation;
- Review of unanticipated problems and serious adverse events;
- Monitoring to determine that a study is being conducted as approved;
- Observation of the informed consent process; and
- Any other review procedure deemed to be necessary to protect the rights and welfare of human participants;
- suspend or terminate approval of a study;
- place restrictions on a study.

4.0 SPECIFIC POLICIES

4.1 Federally Funded Research

If the study is part of funded grant by a sponsoring agency, the human protocol must be reviewed by the REB prior to expenditure of any grant funds.⁸

4.2 U.S. Federally Funded or U.S. FDA Regulated Research

If a study is funded or supported by the U.S. Federal Government or is a clinical investigation regulated by the U.S. Food and Drug Administration, the provisions of those regulations, to the extent applicable to the REB and to the study will apply. The provisions of those regulations are specifically not extended to review of any other research reviewed by UBC's REBs.

4.3. Relationship of the REB to Institutional, Hospital and Health Agency officials and other committees

- 4.3.1** Research that has been reviewed and approved by the REB may be subject to review and disapproval by the officials or committees of the University or its affiliated hospitals or Provincial Health Agencies. Those officials or committees may not approve research if it has been disapproved by the REB;
- 4.3.2** The REBs function independently of the University or any associated Hospital or Provincial Health Authority. They are, however, accountable to the University and its affiliated Hospitals and Health Authorities for their research ethics review processes;
- 4.3.3** The REBs function independently of, but in coordination with, each of the University of British Columbia affiliated REBs. The REBs use common application forms created for the University of British Columbia, and a common on-line system for work-flow, data entry and data storage (the RISE system).

4.4 Board of Record Agreement

Each research project reviewed by a UBC REB should have a single REB of record. The UBC REB that initially reviews a project normally becomes the REB of Record for the project. Once established as the Board of Record, that REB handles all subsequent ethical supervision of that project.

The purpose of implementing one Board of Record is to avoid the requirement for multiple formal reviews of the same research project. The need to identify one of several possible REBs to be the Board of Record arises when the same Principal Investigator is conducting research at more than one institution under the auspices of UBC.

Although there is one Board of Record, in order to ensure that institutional specific requirements are being met, the Chair and the Manager of each UBC REB for the Institutions involved in the research have the ability in the RISE system to view the studies approved by the REB of Record and the authority to direct questions or concerns to the REB Chair of the REB of Record for resolution.

4.5 Use of Policies and Procedures

The REBs will maintain and follow all written policies and procedures consistent with federal and provincial regulations, good clinical practice and ethics guidelines when reviewing proposed research.

4.6 Authorization

The Vice-President Research & Innovation, reporting through to the President and the Board of Governors, has authorized the UBC REBs to review research involving human participants conducted by faculty, staff and students under the auspices of the University of British Columbia.

4.7 Number of REBs

The Board of Governors has authorized six (6) REBs to review research involving humans which is conducted under the auspices of UBC by faculty, staff and students of the University. The University consists of the undergraduate and graduate schools of the University of British Columbia, Point Grey, Robson Street and Okanagan campuses.

5.0 REFERENCES

1. *UBC Policy 89*, section 7.8:
<http://universitycounsel.ubc.ca/files/2012/06/policy89.pdf>
2. *Health Canada Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects* (Schedule 1024):
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/links.html>
3. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997:
http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/e6-eng.pdf
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/efficacy/guidance-document-good-clinical-practice-integrated-addendum-e6-r1-topic-e6-r2.html>
<http://www.ich.org/products/guidelines.html>
4. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*:
<http://www.wma.net/en/30publications/10policies/b3/>
5. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*:
<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
6. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46)*:
<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 50 (21 CFR 50):
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=50>
7. *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/#toc01-1b>
8. *Agreement on the Administration of Agency Grants and Awards by Research Institutions*, section 3.4(a)(iv):
<http://science.gc.ca/default.asp?lang=En&n=56B87BE5-1>