The University of British Columbia Board of Governors	**Policy No.:** **LR9**
Long Title: Research Involving Human Participants	
Short Title: **Human Research Policy**	

Background & Purposes:

The University is committed to promoting research as a fundamental human endeavour deriving from the wish to understand and improve the collective global condition. The University recognizes that the use of Human Participants is indispensable to progress in many areas of research. All research involving Human Participants must be conducted in accordance with the highest ethical standards in ways that protect, and respect the dignity and rights of all Human Participants involved. The trust of the Human Participants and the public in the research process is built upon the consistent application of these ethical standards.

The purpose of this Policy is to create a research environment in which the University's responsibilities towards Human Participants involved in research are discharged in accordance with the highest ethical standards; to promote awareness and understanding of such standards among members or associated members of the University; to articulate clearly the Tri-Council Core Ethical Principles applicable to research in a manner consistent with the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and with international best practices; and to establish an independent research ethics review process.

1. Scope

1.1 This Policy applies to all Research Involving Human Participants.

2. Tri-Council Core Ethical Principles

2.1 Over and above the legal obligations to which all researchers and the University are bound to adhere, a fundamental imperative of Research Involving Human Participants is the respect for human dignity. The University adopts the Tri-Council Core Ethical Principles as principles that will not only guide the conduct of all Research Involving Human Participants but will also guide REBs when they are reviewing the ethical acceptability of such research.

3. Mandate and Authority of Research Ethics Boards

3.1 REBs are mandated to review and maintain, on behalf of the University, ongoing oversight of the ethical acceptability of all proposed or ongoing Research Involving Human Participants by applying the Tri-Council Core Ethical Principles to such review and oversight.

3.2 The University shall authorize such number of REBs as is determined to be appropriate from time to time by the Responsible Executive.

3.3 The Responsible Executive is responsible for determining the financial and administrative resources that are necessary to enable the REBs to fulfill their duties and shall ensure that such resources are provided.

3.4 The Responsible Executive or his or her delegate is responsible for:

3.4.1 keeping the REB Chairs informed of all ethics requirements of the Tri-Council granting agencies and of all other provincial, national and international laws, regulations, policies, standards (e.g. legal, professional, institutional), and guidelines that are relevant to research ethics review; and

3.4.2 communicating to the REB Chairs any changes in such requirements, laws, regulations, policies, standards and guidelines.

3.5 The REBs are accountable to the Responsible Executive for their research ethics review processes. However, in conducting their research ethics reviews, the REBs must operate in an impartial manner, without interference, and the decisions of the REBs with respect to any given Research project are not subject to review by the Responsible Executive or any other person except to the extent that such decisions may be appealed pursuant to the Procedures to this Policy.

4. Ethics Approval

4.1 For each Research project, there shall be one REB of record such that an Ethics Approval issued by one REB shall be recognized by all other REBs and a Research project conducted by the same researcher or researchers at more than one University site shall require Ethics Approval from only one REB.

4.2 If a researcher has made application to a REB seeking review and approval of the ethical acceptability of Research Involving Human Participants but approval is not obtained, such researcher may not withdraw his or her application and submit it to another REB with respect to the same Research Involving Human Participants unless authorized to do so by the first REB.

4.3 Unless proposed Research Involving Human Participants has first been granted Ethics Approval, a researcher must not:

4.3.1 commence or continue to carry out such research;

4.3.2 use University services or facilities, including academic space at affiliated teaching hospitals, for such research; or

4.3.3 accept or use any funds made available to such researcher for such research.

4.4 Unless Financial Services has received notification that Ethics Approval has been granted to certain Research Involving Human Participants, Financial Services must not, with respect to such Research Involving Human Participants:

4.4.1 open any research accounts; or

4.4.2 authorize spending on any research accounts.

4.5 If a REB rescinds or terminates an Ethics Approval, the REB may give notice and direction to Financial Services. Upon receipt of such notice and direction from a REB, Financial Services must freeze or close the relevant research account as appropriate.

4.6 A Research project may require a number of different approvals from various officials or committees of the University and other relevant agencies. Ethics Approval and all other required approvals with respect to such Research project must be obtained before the Research project is undertaken.

5. Ethics Review Agreements with Other Institutions or Organizations

5.1 In order to facilitate collaborative research projects involving researchers, data or participants from more than one institution, and in order to avoid a duplication of efforts with respect to research ethics reviews, the University through its authorized signatories may enter into Ethics Review Agreements.

5.2 An Ethics Review Agreement may be limited to a specific type of Research.

5.3 Prior to entering into an Ethics Review Agreement with another institution, the University shall:

5.3.1 take into account the manner in which the other institution's research ethics board conducts research ethics reviews; and

5.3.2 consult with the Chairs of the REBs.

6. Institutional Conflicts of Interest in Relation to Research

6.1 The University has many diverse objectives. From time to time these objectives may appear to be, or may actually be in conflict with one another. For example, the University has an interest in enhancing its investment returns, fundraising activities and operational efficiencies in order to achieve its mission and to serve the people of British Columbia, Canada and the world. However, regardless of any other interest it may have, the University has an overriding interest in ensuring that Research activities are undertaken with integrity and in a manner that is consistent with the Tri-Council Core Ethical Principles. To the extent that there is a conflict between this overriding interest and any other interest the University may have, any decisions made by the REBs shall be consistent with this overriding interest.

6.2 In addition, academic freedom is one of the University's core values. As a result, no person at the University may interfere with Research unless the Research is contrary to applicable legal

requirements or University policies. Furthermore, the University's administrative structure is organized in such a manner as to create separation between Research activities and the financial and other operations of the University. Due to the University's limited ability to interfere with Research and the University's organizational separation, the risk of the University's operational interests influencing or compromising the Tri-Council Core Ethical Principles is minimized.

6.3 In the unlikely event that a conflict arises between the Tri-Council Core Ethical Principles and the University's other objectives that cannot be adequately managed by the structural separation described in Section 6.2, the Responsible Executive will be charged with the responsibility of reviewing the matter and reporting to the President of the University and any external agencies as may be appropriate. Any person who has a concern that such a conflict may exist is encouraged to bring it to the attention of the Responsible Executive. All concerns submitted pursuant to this Section 6.3 will be taken seriously. The anonymity of the person raising a concern will be maintained, and the University will protect personal information of all parties involved as required under the *Freedom of Information and Protection of Privacy Act*. The University will not tolerate any retaliation, directly or indirectly, against anyone who, in good faith, raises a concern pursuant to this Section 6.3, gives evidence or otherwise participates in a process under this Policy.

7. Definitions

7.1 "Anonymous", when used to describe information, data or materials, means information, data or materials that has never had personal identifiers associated with it (e.g. anonymous surveys) where the nature of the information, data or materials is such that it would be extremely unlikely that the persons having access to the information, data or materials could determine the identities of individuals by combining such information, data or materials with information, data or materials that are publicly available or that would otherwise be expected to be in their possession. For the purposes of this Policy, genetic material shall not be considered Anonymous unless a REB determines otherwise.

7.2 "Tri-Council Core Ethical Principles" means the following principles:

7.2.1 Respect for Persons: This principle requires the recognition of the intrinsic value of human beings and the respect and consideration that they are due, whether they are involved in research directly as subjects, or whether they are involved solely by virtue of their data or Human Biological Materials being used in research. This principle also incorporates the requirement that all Human Participants give their free, informed and ongoing consent as a prerequisite for participation in research.

7.2.2 Concern for Welfare: This principle requires that the welfare of Human Participants in research be protected and promoted, and the recognition that the welfare of a person is the quality of that person's total experience of life, which consists of the impact caused, among other things, by factors such as his or her physical, mental and spiritual health, as well as his or her physical, economic and social circumstances.

7.2.3 Justice: This principle requires that all Human Participants in research be treated fairly and equitably so that individuals or groups are not inappropriately included in or

excluded from participation in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender, age, developmental stage, reproductive capacity, capacity to consent, or presumed vulnerability. Instead, the question of participation should be based on inclusion and exclusion criteria that are required in order to carry out the research project. Also, the principle of justice requires that researchers consider ways to ensure the equitable distribution of any benefits of participation in research (e.g. amelioration of a health condition for an individual as a result of experimental therapy; the establishment of health care or beneficial services in a community which has been involved in research).

For further information, reference may be made to the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

7.3 "Ethics Approval" means the research ethics approval granted by a REB in accordance with this Policy.

7.4 "Ethics Review Agreement" means an agreement between the University and another research institution or organization that authorizes an alternative model or models for ethics review of Research Involving Human Participants. Such agreements may or may not be reciprocal in nature.

7.5 "Human Biological Materials" means human tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials and stem cells.

7.6 "Human Participants" means individuals whose data, or responses to interventions, stimuli or questions by a researcher are gathered or utilized for the purposes of a Research project.

7.7 "REB" means a research ethics board authorized by the University.

7.8 "Research" means any disciplined inquiry or systematic investigation (including pilot studies) intended to extend knowledge or to establish facts or principles that is:

7.8.1 conducted by members or associated members of the University acting in their University capacity, including but not limited to faculty, emeritus faculty, staff, sessional instructors, clinical professors, administrators, students, visiting or adjunct scholars, fellows, paid or unpaid associates and any other person associated with research at the University;

7.8.2 conducted with the authorization of the University using resources (including but not limited to space that is under the administration of the University and academic space at affiliated teaching hospitals) that have been provided by the University but that are not generally available to the public; or

7.8.3 in need of research ethics review by the University pursuant to the terms of an affiliation agreement with another agency;

but does not include:

7.8.4 quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes. For greater certainty, where data is collected for purposes set out in the preceding sentence but later proposed to be used for research purposes, such use may be considered Secondary Use of information not originally intended for research, which would require research ethics review in accordance with this Policy.

7.9 "Research Ethics Appeal Committee" means the committee which the Responsible Executive may from time to time create for the purpose of hearing appeals of decisions made by the REBs.

7.10 "Research Involving Human Participants" means Research involving

7.10.1 Human Participants; or

7.10.2 Human Biological Materials;
but does not include:

7.10.3 Research that relies exclusively on publicly available information when such information: (i) is made accessible to the public through legislation and regulation, and is therefore appropriately protected by law, or (ii) is disseminated in the public domain (e.g. through print or electronic publications), may contain identifiable information, and for which there is no reasonable expectation of privacy;

7.10.4 Research involving the observation of individuals or groups in public places so long as: (i) the research does not involve any intervention staged by the researcher or any direct interaction between the researchers and the individuals or groups; (ii) the individuals or groups being observed have no reasonable expectation of privacy; and (iii) the dissemination of research results from such observation does not allow identification of specific individuals; and

7.10.5 Research that relies exclusively on Secondary Use of Anonymous information or Anonymous materials, so long as the process of data linkage or recording or dissemination of the Research results does not generate information about an identifiable individual.

7.11 "Responsible Executive" means:

7.11.1 individual(s) assigned by the President, from time to time, to be responsible for this Policy and any associated Procedures; and

7.11.2 any sub-delegate of such assigned responsible individual(s) except to the extent that the power to delegate is specifically excluded in this Policy or in the appointment by the President, and provided that the assigned responsible individual(s) shall not be limited in sub-delegation of the duties hereunder but shall remain responsible for oversight and remain answerable to the President.

7.12 “Secondary Use” means the use in Research of information or Human Biological Materials originally collected for a purpose other than the purpose of the current Research.

7.13 “University” means The University of British Columbia.

PROCEDURES ASSOCIATED WITH THE HUMAN RESEARCH POLICY

Pursuant to the Regulatory Framework Policy, the President may approve Procedures or the amendment or repeal of Procedures. Such approvals must be reported at the next meeting of the UBC Board of Governors or as soon thereafter as practicable.

Capitalized terms used in these Procedures that are not otherwise defined herein shall have the meanings given to such terms in the accompanying Policy, being the Human Research Policy.

1. Researcher Responsibilities

1.1 A researcher who plans to conduct Research Involving Human Participants is required to:

1.1.1 be familiar with all University policies relating to research, including without limitation the Human Research Policy, these Procedures, and the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

1.1.2 bring to the attention of the Head of such researcher's department, or where the researcher is in a non-departmentalized faculty, the Dean or the Dean's designate, any research project proposed by such researcher, or proposed by a student working under the direction of such researcher;

1.1.3 if the research project referred to in Section 1.1.2 constitutes Research Involving Human Participants, submit a proposal for such research project to the appropriate REB for review and approval of its ethical acceptability prior to the start of recruitment of Human Participants, access to data, or collection of Human Biological Materials, and include in such proposal such details as are reasonably required by the appropriate REB in order to enable such REB to discharge its duties as set out in Section 3.1 of the Human Research Policy;

1.1.4 if there is any doubt as to whether such research project constitutes Research Involving Human Participants, consult the appropriate REB to obtain a determination as to whether such research project requires research ethics review;

1.1.5 conduct all REB-approved Research Involving Human Participants in accordance with:

(a) any determinations respecting such research made by the REB that has continuing oversight of such research and comply with and maintain in good standing any Ethics Approval issued by such REB for as long as is required by such REB;

(b) the Tri-Council Core Ethical Principles;

(c) the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

(d) the University's policies and procedures governing security and privacy, and all other applicable policies and procedures of the University; and

(e) other relevant legal obligations (including provincial, national and international laws and regulations), policies, standards (including professional and institutional standards) and guidelines, where applicable to a particular area of research or to the funding of such research;

1.1.6 promptly report to the relevant REB the occurrence of any unanticipated issue or event during the course of the implementation of the approved research project that may result in an increased level of risk to Human Participants involved in the research project, or that has other ethical implications that may affect the welfare of such Human Participants;

1.1.7 promptly submit to the REB that has continuing oversight of the research project any proposed changes to the research project and notify such REB when the research project concludes; and

1.1.8 ensure that any proposed changes to an approved research project are approved by the REB that has continuing oversight of such research project prior to implementation of the changes, except when such changes are required to be made in order to eliminate immediate hazards to Human Participants involved in such research project or to implement minor logistical changes.

2. Composition of REBs

2.1 The Responsible Executive shall make appointments to the REBs.

2.2 Any REB constituted by the Responsible Executive under Section 4 of the Human Research Policy will consist of at least 5 members, including both men and women, of whom:

2.2.1 at least 2 members shall have broad expertise in the methods or in the areas of research that are covered by the relevant REB;

2.2.2 at least one member shall be knowledgeable in ethics;

2.2.3 at least one member shall be knowledgeable in law; and

2.2.4 at least one member shall have no affiliation with the University, but shall be recruited from the community served by the University.

2.3 Members of REBs shall normally serve in one capacity only for each of the membership categories listed in Section 2.2.

2.4 Terms of appointment of individual members shall be established at the time such appointments are made and should be staggered to allow for continuity of the research ethics review process.

2.5 A REB member shall disclose to the REB in question the nature of any real, potential or perceived conflict of interest such member may have with respect to any Research project being reviewed by such REB. If the REB member chooses to recuse himself or herself from all discussion or decisions regarding such Research project or group of Research projects, such recusal shall be recorded in the minutes of the REB proceedings. If the REB member does not recuse himself or herself, the conflict of interest disclosure shall be recorded in the minutes of the REB proceedings and the REB Chair and remaining REB members shall reach agreement on an appropriate course of action by majority vote. If the REB Chair is the individual disclosing a real, potential or perceived conflict of interest, the Associate Chair shall perform the duties of REB Chair during all discussion or decisions regarding such conflict of interest, or if the Associate Chair is conflicted, unable to act, or not present, such non-conflicted REB member as may be selected by the majority of the non-conflicted REB members, shall perform the duties of REB Chair during all discussion or decisions regarding such conflict of interest.

3. REB Chairs

3.1 The Responsible Executive will appoint a Chair to each REB and may also appoint to each REB one or more Associate Chair(s).

3.2 The Chair of each REB is responsible for ensuring that the research ethics review process adhered to by his or her REB conforms to the requirements of the Tri-Council Core Ethical Principles and all other relevant requirements, laws, regulations, policies, standards and guidelines that are relevant to research ethics review.

3.3 The role of each REB Chair is to:

3.3.1 provide leadership for the relevant REB;

3.3.2 facilitate the research ethics review process, based on University policies and procedures and the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

3.3.3 oversee decisions of the relevant REB for consistency;

3.3.4 ensure that REB decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or his or her designate; and

3.3.5 ensure appropriate quorum requirements are met for each Research project being reviewed.

4. Responsibilities of REBs

4.1 REBs shall conduct initial reviews of the ethical acceptability of all proposed Research Involving Human Participants and continuing reviews of all previously approved Research Involving Human Participants of which they have ongoing oversight, and may, where applicable, approve, reject, propose modifications to, terminate or suspend such research.

4.2 In discharging their responsibilities described in Section 4.1 above, REBs shall:

4.2.1 have regular meetings and shall normally meet face to face;

4.2.2 function impartially, provide a fair hearing to the researchers involved, and provide reasoned opinions and decisions;

4.2.3 make the final determination as to the nature and frequency of continuing research ethics review of approved research projects;

4.2.4 communicate to researchers in writing all approvals and refusals of, all proposed modifications to, and any requirements they may impose on proposed or ongoing Research Involving Human Participants; and

4.2.5 prepare and maintain comprehensive records, including all documentation related to the research projects submitted to REBs for review, attendance at all REB meetings, and accurate minutes reflecting REB decisions, as well as any dissents and the reasons for them. Where a REB denies approval for a Research project, the minutes shall clearly document the reasons for this decision. Providing reasons for REB decisions is optional when approval is granted.

5. Reconsideration of REB Decisions

5.1 A researcher may request reconsideration of a decision made by a REB. The relevant REB will reconsider its decision upon receipt of a written request, and the researcher may submit additional information and/or attend the REB meeting in person to present information.

6. Appeal of REB Decisions

6.1 If, after the completion of the relevant REB's reconsideration, a researcher is still not satisfied with the decision made by a REB, such researcher may make a written request to the Responsible Executive to appeal such decision.

6.2 The Responsible Executive shall appoint individuals to a Research Ethics Appeal Committee which shall hear such appeal.

6.3 The composition of the Research Ethics Appeal Committee, as well as its terms of membership and quorum requirements, must satisfy the REB requirements in Section 2 of these Procedures.

6.4 No person can serve as a member of the Research Ethics Appeal Committee with respect to a review of a decision made by a REB if such person was a member of the REB that made or reconsidered such decision.

6.5 The Research Ethics Appeal Committee shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented decisions and reasons for such decisions.

6.6 Both the appealing researcher and a representative of the REB whose decision is being appealed shall be granted the opportunity to address the Research Ethics Appeal Committee, but neither shall be present when the Research Ethics Appeal Committee deliberates and makes a decision.

6.7 When reviewing decisions made by a REB with respect to a Research project, the Research Ethics Appeal Committee may approve, reject or request modifications to such Research project.

6.8 The decision made by the Research Ethics Appeal Committee on behalf of the University shall be final and should be communicated in writing to the relevant researcher and to the REB whose decision was appealed.

EXPLANATORY NOTES REGARDING THE HUMAN RESEARCH POLICY AND ASSOCIATED PROCEDURES

Issued July 2019 by the Office of the University Counsel

The OUC has prepared these Explanatory Notes to provide context and background regarding the Human Research Policy. These Explanatory Notes do not replace or supersede the content of the Human Research Policy and its Procedures.

Policy Long Title:	Research Involving Human Participants
Policy Short Title:	Human Research Policy
Policy Number:	LR9
Responsible Executive:	Vice-President, Research and Innovation
Responsible Board Committee:	Learning & Research Committee
Related Policies:	GA2 - Regulatory Framework Policy LR2 - Research Policy
History:	• The Human Research Policy was first approved by the Board of Governors in March 2002; • The Procedures to the Human Research Policy were first approved by the Board of Governors in May 2009; • The Human Research Policy and Procedures were revised in June 2012; • The Human Research Policy was updated in July 2019 to reflect a new policy identification system; it is currently identified as the Human Research Policy, its long title is Research Involving Human Participants, and its number is LR9. The previous identification number for this policy was #89.
Related Legislation:	*Freedom of Information and Protection of Privacy Act* R.S.B.C. 1996, c. 165