CAPILANO UNIVERSITY	Policy No.	Replaces	Policy
	S2002-01	**EC2002-01**	**Senate**
	Policy Name		
	Research Ethics Policy: Research With Human Subjects		
Approved by	Responsibility		Category
Senate	**Senate**		
Date Issued	Date Revised	Review Date	Related Policies, Reference
January 2002	**February 2012**	**February 2017**	

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SECTION A: PURPOSE

The purpose of this policy is to ensure that research at Capilano University involving human participants is conducted to the highest ethical standards within all disciplines, protects the interest of human participants, and describes the institutional standards and procedures governing research. Capilano University recognizes the importance of research while committed to upholding the values of respect, welfare, and dignity for humans. This policy is in compliance with the standards specified by the Tri-Council Policy Statement on Ethical Research Involving Humans which is comprised of the Canadian Institute Health Research (CIHR), Natural Sciences and Engineering Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). All of the Articles in this document are in reference to the Tri-Council Policy Statement (TCPS, 2010).

SECTION B: GOVERNING PRINCIPLES

In carrying out its responsibilities, researchers and the Research Ethics Board (REB) will act at times guided by the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, or future standards that may come to stand its place. As noted in the Tri-Council statement, **Respect for human dignity** is the underlying ethical principle in conducting research involving humans. Research must be "conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due" (p. 8). The Tri-Council Policy guidelines express respect for human dignity through three core principles: **Respect for Persons, Concern for Welfare**, and **Justice.**

1. Respect for Persons

In accordance with the Tri-Council Policy Statement (Article 1.1), the principle of Respect for Persons "recognizes the intrinsic value of human beings and the respect and consideration that they are due" (p. 8). Research with humans should not treat individuals as merely a means to accomplishing the research objectives. Research involving humans must give priority to the welfare and integrity of the participant(s). Participants include those who are directly involved, and those who are indirectly involved through use of their data or biological materials.

Respect for persons presumes that individuals have autonomy and can make voluntary and informed decisions to participate in research. Respecting the individual's ability and right to freely give or refuse their consent to participate involves providing complete information about the purpose of the research, what is involved in the research, and about its risks and possible benefits. In making their decisions, participants must not be coerced or influenced within an imbalance of power in the relationship between researcher and participant, and participants with developing, impaired or diminished autonomy must be protected.

2. Concern for Welfare

As participation in research has the potential to affect the welfare of an individual or group, it is vital to ensure that participants are not exposed to unnecessary risks to their physical, mental, spiritual, social and economic welfare, and that their rights to privacy and confidentiality be ensured. Such risks must be eliminated or minimized, and the benefits of the research must be maximized balanced against these risks.

3. Justice

"Justice refers to the obligation to treat all people fairly and equitably" (p. 10). Thus, the risk of harm from research and the benefits of the knowledge obtained from research should not be unfairly allocated to specific individuals or groups while neglecting or discriminating against others. Criteria for including and excluding individuals or groups as participants should be justified by the research question; groups should not be excluded from participating in research "arbitrarily or for reasons unrelated to the research question" (p.11). An imbalance of power that may exist between researcher and participant can be a threat to this principle.

SECTION C: DEFINITIONS

Research

For the purpose of this policy, research is defined as an undertaking intended to extend knowledge through a discipline based inquiry or any systematic investigation that is quantitative or qualitative in nature to establish facts, principles, or generalizable knowledge which involves humans as research participants.

Researcher

A researcher is defined as any person who undertakes to conduct research as defined above. This includes employees and students as well as persons from the community seeking approval of Capilano University for research.

Principal Investigator

The principal investigator is the researcher who has primary responsibility for a given research project. In the case of course-based research involving human participants (which is described in Section D.8), the faculty member advising a student engaged in a research project (including a minor or major project) shall function as the principal investigator for the purposes of complying with REB requirements.

Human Research Participants

A human participant is any person who is exclusively a source of primary data in regards to the research conducted. This term may refer to a living human participant or groups of individuals about whom a researcher obtains: (1) data through direct or indirect interaction with the individual or group, or (2) identifiable private information. In addition, this term refers to research involving human biological materials derived from living and deceased individuals.

Minimal Risk

The current Tri-Council Policy Statement defines minimal risk as follows: "the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research" (p.23).

Informed Consent

The ethical requirements for consent in research are twofold: (1) individuals who participate in research should do so voluntarily, understanding the purpose of the research, and its risks and potential benefits as fully and as reasonably as possible and (2) those individuals who lack capacity to decide for themselves should nevertheless have the opportunity to participate in research that may be of benefit to themselves or others but an authorized third party, acting on the behalf of the individuals, should decide on whether participation is appropriate. In both cases, the principal investigator is responsible for ensuring that the consent process is followed and is responsible for the actions of any member of the research team involved in the consent process.

Conflict of Interest

Tri-Council Policy Statement defines conflict of interest as "The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another." (p. 190).

Confidentiality

The Tri-Council Policy Statement defines confidentiality as "The ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss or theft." (p. 190).

SECTION D: PROCEDURES AND GUIDELINES

D.1 Research Requiring Review

The Tri-Council Policy states (see Article 2.1) that all research involving humans requires ethics review prior to commencement of the research, notwithstanding the exceptions noted below. In accordance, research conducted under the auspices of Capilano University is subject to REB review including, but not limited to research: (1) that is conducted at Capilano University; (2) research where the principle investigator's affiliation is with Capilano; (3) research where the researchers' affiliation with Capilano had been specified in reports, publications, or contracts; and (4) research undertaken with Capilano's students, faculty, resources or facilities.

REB review is ongoing throughout the duration of the research. Post REB approval of the initial research, any changes to the research project requires notification and approval of the REB for the research to continue.

All research that involves human participants requires review and approval by the Research Ethics Board (REB) of Capilano University, before the research is started, except as stipulated. Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection human biological materials.

D.2 Proportionate Approach to Ethical Review

The REB will take a proportionate approach to the research ethics review such that the level of risk (i.e., the magnitude and probability of harm) determines the level of review. A full board review is required when the level of risk is moderate to high, while minimal risk research is generally eligible for delegated review. "Minimal risk" research is research in which the "probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research" (p. 23). Whether the review is delegated or a full board review, a proportionate approach involves consideration of foreseeable risks, the potential benefits and the ethical implications of the research (Article 2.9).

D.3 Full Review

When the proposal poses more than minimal risk, the REB will assess the harms and benefits of the proposed research project, assess whether the research design is capable of answering the research questions, and ensure that the research procedures and materials conform to established ethical standards.

D.4 Expedited/Delegated Review

Where a proposal poses only minimal risk, or has received ethics approval from another institutions REB, the Chair (or another designated member) of the REB will review the proposal and its conformity to established research ethics standards and practices (Article 6.12). Course-based/course-related research will be eligible for delegated review (see D.8)

D.5 Review Procedure for On-going Research

Ongoing research shall have a continuing ethics review. In the research proposal submitted for REB review, the researcher shall also describe the continuing review process planned for the project which would normally consist of an annual status report to the REB and prompt notification to the REB when the project concludes. For research that is above minimal risk, the REB should receive reports at intervals on the progress of the research project.

D.6 Application for Ethics Review

The researcher is responsible for submitting the research proposal to the REB for review prior to initiating the research. It is the responsibility of the researcher to ensure that the research is carried out professionally and ethically, including the need to consider the principles of free and informed consent (Article 3.1), privacy and confidentiality (Article 5.2), conflict of interest (consult Tri-Council Policy Statement Chapter 7), and the needs of specific populations of research participants (consult Tri-Council Policy Statement Section Chapter 8). This also entails following the approved protocol and abiding by the decision of the REB.

A faculty member enrolled in a graduate program in another institution or otherwise conducting research approved by an REB at another institution shall submit a copy of the approval form from that institution prior to engaging in the project or upon becoming affiliated with Capilano University if the research is to be conducted under the auspices of Capilano University. If so, then approval from Capilano University's REB is required.

A researcher presenting a proposal for multi-centered research, research which involves Capilano University, and sites overseen by other REBs, must identify the research as such and provide Capilano University's REB with contact information for all REBs with potential oversight. The researcher may consider providing the REBs with detailed information regarding the core elements of the research, which cannot be altered without invalidating the pooling of data from the participating institutions, and those elements which can be altered to comply with local requirements without invalidating the research project. Capilano University's REB may coordinate their review of such projects with other REBs, including sharing information and concerns with the other REBs during the review process.

Research to be performed outside of Canada shall undergo prospective ethics review both by Capilano University's REB and by the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the county or jurisdiction where the research is to be done.

In addition to REB review, researchers who work with Aboriginal peoples need to consult the Tri-Council Policy Statement for guidance on such research. As well, researchers working with Aboriginal peoples should consult the protocols established in the governing councils of the local Aboriginal community in which they plan to work.

To undergo REB review, researchers will:

- submit the full research proposal that describes in sufficient detail the purpose of the research, the overall methodology, informed consent, copies of questionnaires or other research instruments, and a statement regarding approval from other REBs
- complete the online "Application for Ethics Review" (*UNDER DEVELOPMENT*)
- any additional materials or information that may be requested by the REB

D.7 Research Exempt from Ethics Review

Research involving publically available data does not require REB review when that information is (1) legally accessible and protected by law and (2) publicly accessible with no reasonable expectation of privacy (Article 2.2.). Examples include film, digital or audio recordings; online archival materials or published third-party interviews to which the public is given uncontrolled access on the Internet; documents accessible to the public; artistic installations, exhibitions, or literary events freely open to the public; or publications accessible in public libraries.

Research involving observations of people in public places where there is no expectation of privacy; dissemination of results would not identify individuals, and does not involve any intervention staged by the research nor was there direct interaction between the researcher and participants (Article 2.3).

Research about a living individual involved in the public arena, based exclusively on publicly available information such as documents, records, works, or performances is not required to undergo ethics review. Such research only requires ethics review if the individual is approached directly for interviews or access to private documents.

Program evaluations, performance reviews, testing, and quality assurance studies are exempt. These activities constitute assessments within an organization and are not subject to REB review except in cases where research is proposed that differs from the original intent of the data collection. For example, student grades or employee reviews would not constitute research as outlined in this policy (Article 2.5).

Any research not affiliated with or supported by Capilano University, conducted by University employees on their own time, outside of their role at the University, not using University students or resources.

When in doubt about the applicability of this section of the policy to their research, researchers should consult with the REB.

D.8 Ethical Review of Course-based Research

According to the Tri-Council Policy Statement, course-based and course-related research is defined as follows: "Activities assigned to students within the context of a course that meets the definition of research but are not conducted for a research purpose. The intent of these activities is usually to give the students experience in the conduct of research (e.g., surveying other students outside of class, observing people at a concert, etc) and to provide material for a course-based project" (p. 190).

Although the intent of the many course-based/course-related research projects is not for publication or public dissemination, there may nevertheless be potential risks to human participants that require ethical review. However, course-based research intended solely for pedagogical purposes can be delegated to non-REB members for review such as a designated faculty member in the Department under which the course falls.

In delegating research ethics review, the REB should be assured that all designated reviewers have the appropriate experience, expertise, training and resources required to review the ethical acceptability of all aspects of the proposed course-based/course-related research to be in accordance with the Tri-Council Policy Statement (Article 6.12). The designated faculty member is required to complete the TCPS online tutorial and provide evidence of the certificate of completion.

As an alternate, in very small Departments, or Departments in which research with human participants is rare, or in which a Department thinks there is not adequate expertise in the field of research ethics, there may be on a semi-permanent basis collaboration with another Department where there is expertise in research ethics. An additional alternative is that the Department could request review and approval for the course-based/course-related research from the REB.

Once approved, the course would then be designated as a "Research Ethics Approved Course" and this designation will remain with the course as long as the course description and the general method of teaching the course does not change significantly. Course-based/course-related research for designated review should:

- Provide a copy of the course outline
- Demonstrate that the research is confidently expected to involve minimal risk

- Demonstrate that the instructor holds primary responsibility the research and for students' adherence to the ethical standards outlined by this policy and the TCPS.
- Provide a general description of the type(s) of research activities that are likely to be part of the course.
- Provide the means by which the students of the course are made familiar with appropriate ethical standards.
- Provide a general description of how the student research activity will be monitored.
- Provide evidence that informed consent from participants will be obtained.
- The decisions and actions of the delegated review will be summarized in a report to the REB Chair (Article 6.12)

SECTION E: FREE AND INFORMED CONSENT

Research governed by this policy may begin only if (1) prospective participants, or authorized third parties, have been given the opportunity to give free and informed consent about participation; (2) their free and informed consent has been given and is maintained throughout their participation in the research and; (3) the participants, or authorized third parties are informed that consent can be withdrawn at any time without consequences, if withdrawal of data is not possible, participants should be informed of this prior to data collection (Article 3.1).

E.1 Requirement for Free and Informed Consent

Voluntariness of consent must be demonstrated because it respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes. In considering voluntariness of consent, researchers and the REB should be cognizant of situations where undue influence, coercion or the offer of incentives many undermine the voluntariness of a participant's consent to participate in research (Article 3.1).

Evidence of free and informed consent by the participant, or authorized third parties, should ordinarily be obtained in writing. When written consent is culturally unacceptable, or when there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.

E.2 Informed Consent

The key to informed consent is that the prospective participants understand the information being conveyed to them by the researchers. At the commencement of any process researchers shall provide prospective participants, or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent the researcher must ensure that prospective participants are given adequate opportunity to discuss and contemplate their

participation. With the exceptions noted above, the information provided to participants by the researcher, or their qualified designated representatives, shall generally include the following for informed consent and be in accordance with Article 3.2:

- Information that the individual is being invited to participate in a research project
- A statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of the research procedures, information about any payments, including incentives for participation, reimbursement for participation-related expenses and
- Plain language of all reasonably foreseeable risks and potential benefits both to the participants and in general, that may arise from research participation, as well as the likely consequences of non-action, particularly research related to treatment, or when invasive methodologies are involved, or when there is a potential for physical or psychological harm.
- An assurance to prospective participants, or authorized third parties, that they are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, will be given continuing and meaningful opportunities for deciding whether or not to continue to participate, and will be given information on the right to request withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal.
- The possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or research sponsors. Researchers should separate, to the greatest extent possible, their role as researcher from their roles as teachers, advisors, consultants, supervisors, employers or the like. If a researcher is acting in dual roles, this must always be disclosed to the participant.

E.3 Capacity

Research may involve individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate. Many participants who lack the legal capacity to make decisions may still be able to express their wishes in a meaningful way, even if such expression may not fulfill all of the requirements for consent. Prospective participants may be capable of verbally or physically assenting to, or dissenting from, participation in research. According to Article 3.10, those who may be capable of assent or dissent include:

- Those whose capacity is the process of development, such as children whose capacity for judgment and self-direction is maturing;
- Those who were once capable of making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating; and
- Those whose capacity remains only partially developed, such s those living with permanent cognitive impairment.

Research may involve individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met in accordance with Article 3.9:

- The researcher involves participants who lack the capacity to consent on their own behalf to the to the greatest extent possible in the decision-making process
- The researcher seeks and maintains consent from authorized third parties in accordance with the best interest of the persons concerned. When authorization for participation was granted by a third party and a participant acquires or regains capacity during the course of the research, the researcher shall promptly see the participant's consent as a condition of continuing participation.
- The authorized third party is not the researcher or any member of the research team.
- The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the research.

E.4 Alteration of Consent in Minimal Risk Research

In accordance with Article 3.7, the REB may approve a consent procedure that does not include, or alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the REB finds and documents that:

- The research involves no more than minimal risk to the participants
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants
- It would be impossible or impractical to carry out the research and to answer the research question properly if the prior consent of the participant was obtained
- Whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information at which point they will have the opportunity to refuse consent in accordance with Article 3.1
- The waivered or altered consent does not involve a therapeutic intervention

E.5 Research Involving Partial Disclosure or Deception

Some types of research can be carried out only if the participants do not know the true purpose of the research in advance. In some research that uses partial disclosure or deception, participants may not know that they are part of a research project until it is over, or they may be asked to perform a task and told about only one of several elements the researchers are observing. Research employing deception can involve a number of techniques, such as giving the participants false information about themselves, events, social conditions and/or the purpose of the research. For such techniques to fall within the exception to the general requirement of full disclosure for consent the research must meet the requirements of **Alteration of Consent in Minimal Risk Research** noted above and be in accordance with Article 3.7 of the TCPS.

- At completion of research conducted with partial disclosure or deception the researchers:
- Debrief participants as soon as is feasible. Debriefing is an important mechanism in maintaining the participant's trust in the research community. The debriefing should be proportionate to the sensitivity of the issue. In some cases, such as research with children, it may be more appropriate to debrief the parents, guardians or authorized third parties rather the participants themselves. In other cases, it may more appropriate to debrief the entire family or community.
- Debrief while alert and sensitive to participant's needs, feelings, reactions and concerns
- Following the debriefing, participants must nevertheless be able to indicate their consent or refusal at the conclusion of the project. In cases where participants express concerns about their participation in a project, the researcher may give participants the option of removing their data from the project. Where the terms of the research proposal do not permit the participants to withdraw their data, in the absence of the consent of the participant, the identity of the participants shall be protected at all times during and following completion of the project. Participants who have concerns should be given the contact information for the REB.
- Report to the REB concerns about the project raised by participants at the time of the debriefing.

SECTION F: PRIVACY AND CONFIDENTIALITY

F.1 Privacy

Article 5.0

Privacy refers to an individual's right to be free from intrusion or interference by others. Individuals have privacy interests in relation to their bodies, personal information, expressed thought and opinions, personal communications with others, and spaces they occupy. An important aspect of privacy is the right to control information about oneself. Privacy is respected and an individual has the opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection,

use and/or disclosure of information. Privacy may be violated if the information provided by a participant may reasonably be expected to identify an individual.
For the purposes of this Policy, researchers and the REB shall consider whether information proposed for use in research is identifiable. The following categories provide guidance for assessing the extent to which information could be used to identify the individual:

- Directly identifying information ~ the information identifies a specific individual through direct identifiers (e.g, name, social insurance number, student number)
- Indirectly identifying information ~ the information can reasonably be expected to identify an individual through a combination of identifiers (e.g., date of birth, place of residence or unique personal characteristic).
- Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals
- Anonymized information ~ the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage and the risk of re-identification of the individuals is low or very low
- Anonymous information ~ the information never had identifiers associated with it and the risk of identification is low or very low

Ethical concerns regarding privacy decrease as it becomes more difficult to associate information with a particular individual. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual or group.

F.2 Confidentiality

Article 5.0

The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. The ethical duty of confidentiality includes to protect information from unauthorized access, use or disclosure, modification, loss or theft. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and participant, and to the integrity of the research project.

In accordance with Article 5.2, researchers shall describe measures for meeting confidentiality obligations and explain any foreseeable disclosure requirements:

- In application materials submitted to the REB; and
- During the consent process with prospective participants

F.3 Safeguarding Information

Article 5.3

Researchers shall provide details to the REB regarding their proposed measures for safeguarding information for the full cycle of information: its collection, use, dissemination, retention and/or disposal. Factors relevant to the REB's assessment of the adequacy of the researchers' proposed measures for safeguarding information include:

- The type of information to be collected
- The purpose for which the information will be used, and the purpose of any secondary use of identifiable information
- Limits on the use, disclosure and retention of the information;
- Risks to participants should he security of the data be breached, including risks of re-identification of individuals
- Appropriate security safeguards for the full cycle of information
- Any recording of observations (e.g, photographs, videos, sound recordings) in the research that may allow identification of particular participants;
- Any anticipated uses of personal information from the research;
- Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records, and;
- Provisions for confidentiality of data resulting from the research.

F.4 Consent and Secondary Use of Identifiable Information for Research Purposes

Article 5.5

Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose. Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

- Identifiable information is essential to the research;
- The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
- The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
- The researchers comply with any known preferences previously expressed by individuals about any use of their information;
- It is impossible or impracticable to seek consent from individuals to whom the information relates; and

- The researchers have obtained any other necessary permission for secondary use of information for research purposes.
- If a researcher satisfies all the conditions in Article 5.5 (a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.

SECTION G: FAIRNESS AND EQUITY IN RESEARCH PARTICIPATION

The principle of Justice holds that particular individuals, groups or communities should neither bear an unfair share of the direct burdens of participating in research, nor should they be unfairly excluded from the potential benefits of research participation. Issues of fair and equitable treatment arise in deciding whether and how to include individuals, groups or communities in research, and the basis for the exclusion of some.

G.1 Appropriate Inclusion

Article 4.1

Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals form the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for exclusion.

G.2 Inappropriate Exclusion

Article 4.2; 4.3

Women should not be inappropriately excluded from research solely on the basis of gender or sex; or their reproductive capacity, or because they are pregnant or breastfeeding.

Article 4.4

Children shall not be inappropriately excluded from research solely on the basis of their developmental stage. The inclusion of children in research is subject to Article 4.6.

Article 4.5

Elderly people should not be inappropriately excluded from research solely on the basis of their age.

Article 4.6

Subject to applicable legal requirements, individuals who lack the capacity to consent to participate in research shall not be inappropriately excluded from research. Where a researcher seeks to involve

individuals in research who do not have capacity to consent for themselves, the researcher shall, in addition to fulfilling the conditions in Article 3.10, satisfy the REB that:

- The research question can be addressed only with the participants within the identified group; and
- The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or
- Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of research and to which the participants belong.

SECTION H: RESEARCH INVOLVING THE FIRST NATIONS, INUIT AND METIS PEOPLE OF CANADA

As noted in the Tri-Council Policy Statement, "research involving Aboriginal peoples in Canada has been defined and carried out primarily by non-Aboriginal researchers. The approaches used have not generally reflected Aboriginal world views, and the research has not necessarily benefited Aboriginal peoples or communities. As a result, Aboriginal peoples continue to regards research, particularly research originating outside their communities, with a certain apprehension or mistrust" (p. 105).

The ethical guidelines presented in this section are intended to be a "framework for the ethical conduct of research.... It is not intended to override or replace ethical guidelines offered by Aboriginal peoples themselves. Its purpose is to ensure, to the extent possible, that research involving Aboriginal peoples is premised on respectful relationships. It also encourages collaboration and engagement between researchers and participants" (p. 105).

H.1 Requirement of Community Engagement in Aboriginal Research

Article 9.1

Where research is likely to affect the welfare of an Aboriginal community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required to include, but are not limited to:

- Research conducted on First Nations, Inuit or Métis lands;
- Recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
- Research that seeks input from participants regarding a community's cultural heritage, artifacts, traditional knowledge, or unique characteristics
- Research in which Aboriginal identity or membership in an Aboriginal community is used as variable for the purpose of analysis of the research data; and

- Interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture.

Article 9.2

The nature and extent of community engagement is a project shall be determined jointly by the researcher and the relevant community, and shall be appropriate to community characteristics and the nature of the research.

H.2 Respect for First Nations, Inuit and Métis Governing Authorities

Article 9.3

Where a proposed research project is to be conducted on lands under the jurisdiction of a First Nations, Inuit and Métis authority, researchers shall seek the engagement of formal leaders of the community. Research ethics review by Capilano University's REB and any responsible community body recognized by the First Nations, Inuit and Métis authority is required in advance of recruiting and securing consent of individuals.

H.3 Engagement with Organizations and Communities of Interest

Article 9.4

For the purpose of community engagement and collaboration in research undertakings, researchers and the REB shall recognize Aboriginal organizations, including First Nations, Inuit and Métis representative bodies, and service organizations and communities of interest, as communities. They shall also recognize these groups through representation of their members on ethical review and oversight of projects, where appropriate.

H.4 Complex Authority Structures

Article 9.5

Where alternatives to securing the agreement of formal leadership are proposed for research on First Nations, Inuit and Métis lands or organizational communities, researchers should engage community processes and document measures taken, to enable the REB to review the proposal wit due consideration to complex community authority structures.

H.5 Recognizing Diverse Interest with Communities

Article 9.6

In engaging territorial or organizational communities, researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors – including individuals and subgroups

who may not have a voice in the formal leadership. Groups or individuals whose circumstances make them vulnerable may need or desire special measures to ensure their safety in the context of a specific project. Those who have been excluded in the past may need special measures to ensure their inclusion in research.

H.6 Critical Inquiry

Article 9.7

Research involving Aboriginal peoples that critically examines the conduct of public institutions, First Nations, Inuit and Métis governments, institutions or organizations or persons exercising authority over First Nations, Inuit and Métis individuals may be conducted ethically, notwithstanding the usual requirement of engaging community leaders.

H.7 Respect for Community Customs and Codes of Practice

Article 9.8

Researchers have an obligation to become informed about, and to respect, the relevant customs and codes of research practice that apply in the particular community or communities affected by their research. Inconsistencies between community custom and Capilano University's Ethics Policy should be identified and address in advance of initiating the research, or as they arise.

H.8 Institutional Research Ethics Review Required

Article 9.9

Research ethics review by community REB or other responsible bodies at the research site will not be a substitute for review by Capilano University's REB.

H.9 Requirement to Advise the REB on a Plan for Community Engagement

Article 9.10

When proposing research expected to involve First Nations, Inuit and Métis participants, researchers shall advise the REB at Capilano University as to how they have engaged, or intend to engage, the relevant community. Alternatively, researchers may seek REB approval for an exception to the requirement of community engagement, on the basis of an acceptable rationale.

H.10 Research Agreements

Article 9.11

Where a community has formally engaged with a researcher or research team through a designated representative, the terms and undertakings of both the researcher and the community should be set out in a research agreement before participants are recruited.

H.11 Collaborative Research

Article 9.12

As part of the community engagement process, researchers and communities should consider applying a collaborative and participatory approach as appropriate to the nature of the research, and the level of ongoing engagement desired by the community.

H.12 Mutual Benefits in Research

Article 9.13

Where the form of community engagement and the nature of the research make it possible, research should be relevant to community needs and priorities. The research should benefit the participating community (e.g., training, local hiring, recognition of contributors, return of results), as well as extend the boundaries of knowledge.

H.13 Strengthening Research Capacity

Article 9.14

Research projects should support capacity building through enhancement of the skills of community personnel in research methods, project management, and ethical review and oversight.

H.14 Recognition of the Role of Elders and Other Knowledge Holders

Article 9.15

Researchers should engage the community in identifying Elders or other recognized knowledge holders to participate in the design and execution of the research, and the interpretation of findings in the context of cultural norms and traditional knowledge. Community advice should also be sought to determine appropriate recognition for the unique advisory role fulfilled by these persons.

H.15 Privacy and Confidentiality

Article 9.16

Researchers and community partners shall address privacy and confidentiality for communities and individuals early on in the community engagement process. The extent to which limited or full disclosure of personal information related to the research is to be disclosed to community partners shall be addressed in research agreements where these exist. Researchers shall not disclose personal information to community partners without the participants consent.

H.16 Interpretation and Dissemination of Research Results

Article 9.17

Researchers should afford community representatives engaged in collaborative research an opportunity to participate in the interpretation of the data and the review of research findings before completion of the final report, and before finalizing all relevant publications resulting from the research.

H.17 Intellectual Property Related to Research

Article 9.18

In collaborative research, intellectual property rights should be discussed by researchers, communities and Capilano University. The assignment of rights, or grant of licenses and interests in material that may flow from the research, should be specified in a research agreement (as appropriate) before the research is conducted.

H.18 Collection of Human Biological Materials Involving Aboriginal Peoples

Article 9.19

As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and associated data to be collected, stored and used in the course of the research.

H.19 Secondary Use of Information or Human Biological Materials Identifiable as Originating from Aboriginal Communities or Peoples

Article 9.20

Secondary use of data and human biological material identifiable as originating from an Aboriginal community or peoples is subject to REB review.

Researchers shall engage the community from which that data or human biological materials and associated identifiable information originate, prior to initiating secondary use where:

- Secondary use has not been addressed in a research agreement and has been authorized by the participants in their original individual consent; or
- There is no research agreement; and
- The data are not publicly available or legally accessible

Article 9.21

Where research relies only on publicly available information, or on legally accessible information, community engagement is not required. Where the information can be identified as originating from a specific community or a segment of the Aboriginal community at large, seeking culturally informed advice may assist in identifying risks and potential benefits for the source community.

Article 9.22

REB review is required where the researcher seeks data linkage of two or more anonymous datasets or data associated with human biological materials and there is a reasonable prospect that this could generate information identifiable as originating from a specific Aboriginal community or a segment of the Aboriginal community at large.

SECTION I: CLINICAL TRIALS

According to the Tri-Council Policy statement, a clinical trial is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.

I.1 Clinical Trials include, but are not restricted to, drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products, process of care changes, preventive care, manual therapies and psychotherapies

Article 11.1

In the design and review of a such clinical trials noted above, researchers and the REB shall consider the type of trial (e.g., pharmaceutical, natural product, medical device, psychotherapy), its phase (if appropriate) and the corresponding particular ethical issues associated with it, in light of the core principles of the Tri-council Policy Statement and those outlined in this Capilano University's Ethics Policy. In a proposal submission for research ethics review, the researcher shall:

- Clearly specify the type of trial proposed (and, where relevant, its phase)
- Identify foreseeable risks and potential benefits to participants

- Demonstrate how this information will be clearly communicated to participants in the informed consent process

The REB reviewing clinical trials need to be familiar with the ethical issues raised by the different types of clinical trials. If the REB does not have members with the appropriate expertise to review a particular trial, then it shall seek out someone with the necessary expertise to consult as an ad hoc advisor (see Section L.3).

I.2 Clinical Trials: Placebo-Controlled Trials

A clinical trial in which one or more interventions are compared with a placebo control group raises specific ethical issues. Where there is an established effective treatment, use of placebo may deprive participants of needed therapy. It is the responsibility of the researcher to provide justification to the REB for the choice of placebo control group, as opposed to the other possible choices of control group (e.g., active control or wait-list control). The following Articles set out the criteria for placebo control group.

Article 11.2

- A new therapy or intervention should generally be tested against an established effective therapy.
- As with all alternative choices of control, a placebo control is ethically acceptable in a randomized clinical trial only if:
  - Its use is scientifically and methodologically sound in establishing the efficacy or safety of the test therapy or intervention; and
  - It does not compromise the safety or health of participants; and
  - The researcher articulates to the REB compelling scientific justification for the use of the placebo control
- For clinical trials involving placebo control, the researcher and the REB shall ensure the general principals of consent are respected and that participants or their authorized third parties are specifically informed:
  - About any therapy that will be withdrawn or withheld for purposes of the research; and
  - Of the anticipated consequences of withdrawing or withholding the therapy.
  -

I.3 Assessing Safety and Minimizing Risk

Articles 11.4, 11.5, 11.6, 11.7, 11.8 and 11.9

Participants enrolled in clinical trials are commonly exposed to investigational therapies, interventions, drugs or devices, each of which carries specific and possibly unknown risk. Because of the nature of clinical interventions, the potential harms can be physical, psychological or social and may cause lasting, irreparable damage.

In accordance with the core principles of the Tri-Council Policy Statement and Capilano University's Ethics Policy, it is the responsibility of the researchers and the REB to ensure that:

- Foreseeable risks to participants are minimized and appropriately evaluated alongside potential benefits
- Participants are clearly informed as the nature of foreseeable risks and potential benefits
- The plan for monitoring participant safety is clearly stated and accurately reported
- Any new information that may impact on the welfare of participants, or their decision to remain involved in a trial, be shared appropriately.

I.4 Financial Conflicts of Interest

Article 11.10

Researchers and the REB should be aware of and consider the possibility of financial conflicts of interest. Financial considerations shall not affect standards of participant's safety or the scientific validity and transparency of trial procedures.

Related to this is that the REB shall ensure that clinical budgets are reviewed to ensure that conflicts of interest are identified and minimized, or otherwise managed (Article 11.11).

I.5 Analysis and Dissemination of Clinical Trial Outcomes

Article 11.12

With respect to research findings:

- Capilano University and the REB will take reasonable measures to ensure that sponsors, researchers publish or otherwise disseminate the analysis data and interpretation of clinical trial results in a timely manner without undue restriction; and
- Any prohibition or undue limitation on the publication of dissemination of scientific findings from clinical trials is ethically unacceptable.

SECTION J: HUMAN BIOLOGICAL MATERIALS INCLUDING MATERIALS RELATED TO HUMAN

REPRODUCTION

The Tri-Council Policy Statement notes that "the sources of these materials can be from patients following diagnostic or therapeutic procedures, autopsy specimens, donations of organs or tissue from living or dead humans, body wastes or abandoned tissue. Ethical considerations raised by research involving human biological materials centre on acceptable access to, and use of, the materials, potential privacy

concerns arising from handling of information derived from such materials, and the special status some individuals and groups accord to the human body and its parts" (p. 169).

J.1 Human Biological Materials Including Materials Related to Human Reproduction

Article 12.1

Research involving collection and use of human biological materials requires REB review and:

- Consent of the participant who will donate biological materials; or
- Consent of an authorized third party on behalf of the participant who lacks capacity, taking into account any research directive that applies to the participant; or
- Consent of a deceased participant through a donation decision made prior to death , or by an authorized third party

Article 12.2

To seek consent for use of human biological materials in research, researchers shall provide of prospective participants or authorized third parties, issues regarding Section E, informed consent, as well as the following details:

- The type and amount of biological materials to be taken
- The manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition
- The intended use of the biological materials, including any commercial use
- The measures employed to protect the privacy of and minimize risks to participants
- The length of time the biological materials will be kept, who they will be preserved, location of storage (e.g., in Canada, outside of Canada), and process for disposal, if applicable
- Any anticipated linkage of biological materials with information about the participant; and
- The researchers' plan for handling results and findings, including clinically relevant information and incidental findings.

J.2 Consent and Secondary use of Identifiable Human Biological Materials

Capilano University's Ethics Policy does not require that researchers seek consent from individuals for the secondary use of non-identifiable human biological materials. In the case of the secondary use of identifiable human biological materials, researchers must obtain consent in accordance with applicable laws, unless the researcher satisfies all the requirements noted below.

Article 12.3

Researchers who have not obtained consent from participants for the secondary use of identifiable human biological materials shall only use such material for these purposes if the REB is satisfied that:

- Identifiable human biological materials are essential to the research;
- The use of identifiable human biological materials without the participant's consent is unlikely to adversely affect the welfare of individuals from whom the materials were collected;
- The researchers will take appropriate measures to protect the privacy of individuals and to safeguard any use of their biological materials
- It is impossible or impractical to seek consent from individuals from whom the materials were collected; and
- The researchers have obtained any other necessary permission for secondary use of human biological materials for research purposes.

J.3 Storage and Banking for Human Biological Materials

Article 12.5

Capilano University and researchers that maintain biobanks:

- Shall ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely, and in accordance with applicable standards
- Shall establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorized handling.

J.4 Research Involving Materials Related to Human Reproduction

Employing the definitions from the Tri-Council Policy Statement, the following definitions apply:
"Embryo means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being.

Fetus means a human organism during the period of its development beginning on the 57 day following fertilization or creation, excluding any time during which its development has been suspended, and ending with birth.

Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus.

Human reproductive materials means a sperm, ovum or other human cell, or human gene, and includes any part of them" (p.176 – 177).

Article 12.6

In addition to requirements that apply to all research involving human biological materials, the following guidelines apply to research involving materials related to reproduction:

- Research using materials related to human reproduction in the context of an anticipated or ongoing pregnancy shall not be undertaken if he knowledge sought can reasonably be obtained by alternative means
- Materials related to human reproduction for research shall not be obtained through commercial transaction, including exchange for services.

Article 12.7

Research on in vitro embryos already created and intended for implantation to achieve pregnancy is acceptable if:

- The research is intended to benefit the embryo;
- Research interventions will not compromise the care of the woman, or the subsequent fetus;
- Researchers closely monitor the safety and comfort of the woman and the safety of the embryo, and
- Consent was provided by the gamete donors.

Article 12.8

Research involving embryos that have been created for reproductive or other purposes permitted under the *Assisted Reproduction Act* , but are no longer required for these purposes, may be ethically acceptable if:

- The ova and sperm from which they are formed were obtained in accordance with Article 12.7;
- Consent was provided by the gamete donors;
- Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and
- Research involving embryos will take place only during the first 14 days after their formation by combination of the gametes, excluding any time during which embryonic development has been suspended.

CAPILANO UNIVERSITY	Policy No.	Replaces	Policy
	S2002-01	**EC2002-01**	**Senate**
	Policy Name		
	Research Ethics Policy: Research With Human Subjects		
Approved by	Responsibility		Category
Senate	**Senate**		
Date Issued	Date Revised	Review Date	Related Policies, Reference
January 2002	**February 2012**	**February 2017**	

Article 12.9

Research involving a fetus or fetal tissue:

- Requires the consent of the woman; and
- Should not compromise the woman's ability to decide to continue with her pregnancy

Article 12.10

Researchers who intend to conduct research to derive or use pluripotent stem cells shall follow the *Guidelines for Human Pluripotent Stem Cell Research*, as amended time to time and published by the Canadian Institutes of Health Research.

SECTION K: HUMAN GENETIC RESEARCH

As outlined in the Tri-Council Policy Statement, "Genetic information has implications beyond the individual because it may reveal information about biological relatives and others with whom the individual shares genetic ancestry. The participation of an individual in genetic research may therefore have ramifications for these other persons, communities or groups. In some cases, researchers specifically seek to conduct genetic research with members of families, communities or groups that requires particular attention to the social and cultural contexts in which participants live. Research with families, communities or groups may raise special considerations regarding recruitment of participants, consent processes, privacy and confidentiality.

K.1 Human Genetic Research

Article 13.1

Guidance regarding a proportionate approach to research ethics review, consent, privacy, confidentiality, research with human biological materials and other ethical guidance described in earlier sections of this Policy apply equally to human genetic research .

K.2 Plans for Managing Information Revealed Through Genetic Research

Article 13.2

Researchers conducting genetic research shall:

- In their proposal, develop a plan for managing information that may be revealed through their genetic research;
- Submit their plan to the REB; and

- Advise prospective participants of the plan for managing information revealed through the research.

Article 13.3

Where researchers plan to share findings with individuals, researchers shall provide participants with an opportunity to:

- Make informed choices about whether they wish to receive information about themselves; and
- Express preferences about whether information will be shared with biological relatives, or others with whom the participants have a family, community or group relationship.

Article 13.4

Where researchers plan to share results of genetic research with participants, the research proposal should make genetic counselling available at the time, where appropriate.

K.3 Genetic Research Involving Families

Article 13.5

Researchers who seek to recruit members of a family to participate in genetic research shall:

- ensure recruitment processes respect privacy and other personal interests of family members; and
- seek consent from individual family members.

K.4 Genetic Research Involving Communities and Groups

Article 13.6

Where researchers intend to recruit participants for genetic research based on their membership in specific communities or groups, it may be appropriate for researchers to discuss the research with community or group members, and/or their leaders, in addition to seeking consent from individual participants. In these cases, researchers shall provide details to the REB about their proposed methods for engaging in discussion.

K.5 Genetic Material Banks

Article 13.7

Researchers who propose research involving the collection and banking of genetic material shall indicate in their research proposal, and in the information they provide to prospective participants, how they plan

to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings and withdrawal by participants as well as future contact of participants, families, communities and groups.

Researchers who propose research involving the secondary use of previously collected and banked genetic material shall, likewise, indicate in their research proposal how they plan to address associated ethical issues.

SECTION L: GOVERNANCE OF RESEARCH ETHICS REVIEW

L.1 Establishment of Research Ethics Board (REB)

In accordance with Article 6.1, Capilano University shall establish a REB to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices, that is, by their faculty, staff or students, regardless of where the research is conducted, in accordance with the Tri-Council Policy Statement.

Capilano University does agree to provide the REB with necessary and sufficient ongoing financial and administrative resources to fulfill their duties. The REB is independent in its decision making and is accountable to the President's Office (Article 6.2).

Capilano University shall grant the REB the mandate to review the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. This mandate shall be more fully articulated in L.2 below and shall apply to research conducted under the auspices or within the jurisdiction of the institution (Article 6.3).

L.2 Mandate of the REB

Ensuring that ethical principles are applied to research involving human participants is the responsibility of the Research Ethics Board. The REB has two primary roles; to be educative and to review research proposals. In the educative role, the REB serves the Capilano University research community as a consultative body and thus, contributes to the education in research ethics. In its review role, the REB has the responsibility to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted within, or by members of Capilano University including faculty, staff and students, using the considerations set forth in the Tri-Council Policy Statement (TCPS-2, 2010) as the minimum standard.

L.3 Membership of the REB

The membership of the REB is designed to ensure competent independent research ethics review. Provisions respecting its size, composition, terms of appointment and quorum are set out below in accordance with Article 6.4.

The REB shall consist of at least 6 members, including both women and men, of whom:

- at least three are faculty members, each of whom is from a different Faculty within Capilano University, who have expertise in relevant research disciplines, fields and methodologies covered by the REB
- at least one member is knowledgeable in ethics
- at least one member is knowledgeable in the relevant law (but that member should not be the Capilano University's legal counsel or risk manager).
- at least one member has no affiliation with Capilano University and is recruited from the community served by the institution.

It is advisable that each member be appointed to formally fulfill the requirements of only one of the above categories. To ensure the independence of the REB decision making, institutional senior administration shall not serve on the REB.

- The Chair is responsible for ensuring that the REB review process conforms to the requirements of the Tri-Council policy statement. The Chair is a voting member whose vote becomes the deciding vote in the event of a tie.
- The institution should consider the nomination of substitute REB members such that the REB may continue to function when regular members are unable to attend due to illness or other unforeseen eventualities. The appointment of substitute members should not alter the REB membership composition and these members should have the appropriate knowledge, expertise and training to contribute to the research ethics review process.
- The REB should have provisions for consulting ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. Ad hoc members are consulted for a specific research ethics review and for the duration of that review. Ad hoc advisors should not be counted in the quorum for an REB, nor be allowed to vote on REB decisions.

L.4 Terms of Appointment

Articles 6.6, 6.8

The three representatives from the different Faculties at Capilano University will be selected, one of whom will be elected by the REB, to serve as the Chair. In addition, the REB will select a Vice-Chair who will assume the duties of the Chair when the Chair is absent. The member knowledgeable in ethics, the member knowledgeable in the law and the community member will be appointed by the President.

- All members of the REB shall attend a workshop or orientation to reinforce the principles and practices of ethical review. All members of the REB are required to complete the on-line tutorial, TCPS 2: CORE that can be accessed at http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/
- Regular attendance by REB members at meetings is required. Frequent unexplained absences will be construed as a notice of resignation.
- Members of the REB will normally serve for two-year terms. An annual, staggered system of nomination and selection will be employed to ensure continuity in fulfilling the required tasks of the REB. Members can be re-nominated and selected for consecutive terms. Normally, no more than three consecutive terms will be served. Terms will begin and end using the academic year or as occasioned by unexpected vacancies.
- When it is anticipated that the REB will require new members, the Chair of the REB will inform the community at Capilano University of the need for new members and the expertise to be filled on the REB. After receiving the nominations, the Chair will review with the REB and then present a list of individuals who meet the relevant expertise requirements to the Vice President of Academic, who in turn, recommends a list to the President. The President or President's delegate then appoints the new member of the REB.

L.5 Meetings and Attendance

Article 6.10

The REB shall meet regularly to discharge its responsibilities and shall normally meet face to face to review proposed research that is not assigned to delegated review. A schedule of when the REB will sit to review research proposals will be communicated to the faculty, staff and students of Capilano University. The REB may request informal meetings with each other prior to the formal review process in order to expedite and facilitate the review process. Such informal meetings cannot, however, substitute for the formal review process.

The REB may hold general meetings, retreats, and educational workshops for members for education, discussion of issues, or revision of policies. The REB will also promote and communicate the policy of Research Ethics with Human Participants to, and provide educational opportunities, the faculty, staff and students at Capilano University.

L.6 Conflicts of Interest

Article 7.3

If the REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making its decision. It is expected that all REB members must disclose actual, perceived or potential conflicts of interest. The REB member may offer evidence to the REB provided the conflict is fully explained to the REB and the researcher has the right to hear the evidence and to offer a rebuttal.

Disclosure of the conflict of interest will comply with Capilano University's Conflict of Interest Policy.

L.7 Record Keeping

Article 6.17

Minutes of all REB meetings shall be prepared and maintained by the *Teaching and Learning Centre* on behalf of the REB. The minutes shall clearly document attendance at the meetings, the REB's decisions, any dissents and the reasons for them. REB decisions should be supported by clear references (e.g., date of decision, title of the project), documentary basis for decision (e.g., documents or progress reports received and reviewed), the plan for continuing ethics review and timelines, reasons for decisions, and any conditions or limitations attached to the proposal. Providing reasons for REB decisions is optional when ethics approval is granted.

Capilano University and its REB shall prepare and maintain adequate documentation of REB activities including the following:

- Copies of all research proposals reviewed, certificates of approval, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to research participants
- Records of continuing review activities
- Copies of all correspondence between the REB and research investigators
- A list of REB members and contact information
- Written procedures for the REB

Records required by this policy shall be retained for at least 7 years, and records relating to research which is conducted shall be retained for at least 7 years after the completion of the research. All minutes shall be accessible for inspection and copying by authorized representatives of Capilano University, researchers, sponsors, funding agencies, Government, Departments, or Agencies at reasonable times and in a reasonable manner.

L.8 Decision-Making

The REB shall meet on a regular basis to review proposed research that is not delegated to expedited review. The REB review shall be based upon fully detailed research proposals or, where applicable, progress reports. The REB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but researchers shall not be present when the REB is making its decisions. When an REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

Final decisions in full review of projects that are based on a majority quorum (where the Committee at first meeting will decide its own quorum) will be adopted only if the members attending the meeting possess the range and background outlined in Section L.3 of this policy.

The REB shall notify research investigators and Capilano University in writing of its decision to:

- Approve the proposed research activity as submitted; or
- Require minor modifications to the proposed research activity. The resubmitted proposal would be reviewed by the Chair or Vice-Chair of the REB; or
- Require significant modifications or additional information or major revisions. The resubmitted proposal would be reviewed by the REB; or
- Disapprove the proposed research activity.

A subcommittee consisting of the Chair and Vice-Chair of the REB will conduct the expedited reviews, will follow the same format as the full REB in recording minutes and communicating results and will send a copy of the minutes and decisions/recommendations made to the REB.

L.9 Reconsideration

Article 6.18

Where researchers do not receive ethics approval, or receive approval conditional on revisions that they find compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the REB. The REB is to be guided by principles of natural and procedural justice in their decision-making. Such principles include providing a reasonable opportunity to be heard, an explanation for the reasons for opinions or decisions, and the opportunity for rebuttal, fair and impartial judgment, and reasoned and written grounds for the decisions. The researcher may seek advice from the *Teaching and Learning Centre* for assistance to improve the researcher's request for ethical review.

L.10 Appeals

Article 6.19

In cases where the researchers and the REB cannot reach agreement through reconsideration, Capilano University will permit review of the REB's decision. Capilano University shall enter into an agreement with an institution, whose Human Research Ethics Board, shall function as the Appeal Board for the purposes outlined in this policy. In return for providing the Appeal Board, Capilano University's REB may be made available to hear appeals of the applications rejected by the REB of the other institution.

Researchers wishing to appeal a decision of the REB to reject a research proposal or to rescind approval of on-going research previously approved by the REB, shall within 30 days, provide the President's Office with the following:

- The application as submitted to Capilano University's REB
- A statement of ground for appeal, and
- The ground for rejection of the application or rescindment of the approval issued by Capilano University's

Provided that the grounds of the appeal are consistent with this policy, and the memorandum of understanding establishing Capilano University's Appeal Board, the President's Office shall submit the materials to the Appeal Board within 10 working days of receipt of the materials described above.

Where the appeal concerns on-going research, the REB may direct that the research be suspended during the reconsideration dialogue and appeal process.

All appeal decisions of the Appeal Board shall be final and binding upon Capilano University and the researcher. Written documentation of the Appeal Board's decision will remain on record with Capilano University's REB.

L.11 Review Procedure for Ongoing Research

The REB shall maintain a continuing interest in the research after the project has undergone ethical approval and ongoing research is subject to continuing ethics review. An ongoing status report on the research must be submitted to the REB by the researcher annually, or as required by the REB. The rigour of the continuing review will be in accordance with a proportionate approach to ethics assessment. If a change in the research procedure is contemplated, the researchers will immediately submit an amended proposal to the REB for review.

In addition to the above requirement, the REB may work with the researcher to develop an appropriate plan for continuing review and the reporting structure for the termination of the project. A report, in the

format specified by the REB must be submitted by the researcher to the REB within 60 days of request for review. Some examples of continuing review plans include:

- Formal review of the process of free and informed consent
- Establishment of a safety monitoring committee
- Periodic review by a third party of the documents generated by the study
- Review of reports of adverse events

L.12 Breach of Policy

Capilano University reserves the right to immediately halt any research involving human participants that has been started without the required approval from, or which does not comply with the institution's REB.