

Effective Date: April 22, 2020**Responsible Executive:** Vice-President, Research**Amends:** Research Involving Human Participants
Approved by UNBC Senate, 20 Sept 2006**Policy #:** S-202004.04

TITLE: ETHICS REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS**Associated Terms
of Reference and
Procedures:** UNBC Research Ethics Board Terms of Reference & Procedures**1. Purpose**

- 1.1. It is the intent of the University of Northern British Columbia (UNBC, referred to as the University) to ensure that all research involving human participants conducted under the University auspice is conducted in accordance with the most current version of the Tri-Council Policy Statement for the Ethical Conduct of Research Involving Humans (the Tri-Council Policy Statement, referred to as TCPS), based on the core ethical principles of:
 - 1.1.1. Respect for Persons – a recognition of the intrinsic value of human beings and the respect and consideration they are due;
 - 1.1.2. Concern for the Welfare of Persons – a requirement of researchers and research ethics boards to aim to protect the welfare of research participants, and in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research; and
 - 1.1.3. Justice – an obligation to treat people fairly and equitably.

2. Scope

- 2.1. This policy and its related procedures apply to all research and research-related activity involving human participants, their biological material, and/or data conducted by the University faculty, staff or students; conducted under the auspices of, or in affiliation with the University; or conducted using University equipment, space or resources under the auspices of the University.

3. Responsibility of the University for Implementation

- 3.1. The responsibility for implementing and upholding the TCPS is entrusted on behalf of the University by the President to the Vice-President, Research (VPR).
- 3.2. The VPR will establish the Research Ethics Board (REB) to ensure competent independent research ethics review. The VPR is responsible for administrative and operational aspects of the REB. The VPR is responsible for determining ongoing financial and administrative resources that are necessary to enable the REB to fulfill its duties and for ensuring that these resources are provided.
- 3.3. The University delegates the authority to conduct independent ethics review of research involving human participants conducted under the aegis of the University to the REB.

4. Mandate and Authority of Research Ethics Board

- 4.1. The mandate of the University Research Ethics Board is to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted under the aegis of the University, that is, by their faculty, staff or students, regardless of where the research is conducted, or in affiliation with the University; or conducted using University equipment, space or resources under the auspices of the University, using an independent procedure for ethics review that holds the TCPS as the minimum standard. A REB review applies to the ethical acceptability of the research, ethics approval does not, in itself, constitute authorization for the research to proceed (such reasons may be administrative, regulatory or resource-based in nature).

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- 4.2. Although established by the VPR, the REB is independent in their decision-making. The University shall respect the authority delegated to the REB and may not override an REB decision to reject or approve the ethical acceptability of a research proposal.
 - 4.3. The REB is accountable to the VPR for their research ethics review processes and procedures. The REB is to establish and communicate ethics policies, procedures and maintain the Terms of Reference which accord with the current requirements of the TCPS. In the event of a conflict between the policy and the TCPS, or the Terms of Reference and the TCPS, the TCPS will prevail.
 - 4.4. The REB is to serve the research community as a consultative body and to contribute to education in research ethics.

5. Responsibility of the University Researcher

- 5.1. The University researcher is responsible for taking appropriate action to determine whether the research that the researcher, their research team or the students under their direction are proposing to undertake constitutes research involving human participants according to this policy and the TCPS.
- 5.2. Approval for a research project involving human participants within the context of this policy and the TCPS must be obtained by the University researcher from the REB before any research activity or research project involving human participants is undertaken, the University facilities or services are used, and/or any funds requiring REB certification are utilized. Failure to maintain compliance with this Policy and pertinent federal, provincial and international guidelines/legislation for the protection of Human Participants and/or failure to conduct research in the manner in which it has been approved by the REB may result in an investigation conducted by the Office of Research and may result in disciplinary action in accordance with the UNBC Integrity in Research and Scholarship Policy.

6. Research Not Requiring Ethics Review

- 6.1. All research conducted under the aegis of the University involving human participants, except in those excluded categories stipulated in the most current version of the TCPS, requires approval of the REB before the research begins. REB review is not required for the initial exploratory/developmental phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal, however, REB review is required before engaging in the actual research.
- 6.2. In situations where researchers believe they are conducting research in an excluded category, they may consult with the Chair of the REB, or delegate, to confirm that this is the case.

7. Ethics Review Agreements

- 7.1. 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 may enter into agreements to accept reviews undertaken by an external REB, or it may conduct the research ethics review on behalf of other institutional partners.
- 7.2. Prior to entering into an Ethics Review Agreement with another institution, the university shall take into account the manner in which the other institution's research ethics board conducts research ethics reviews; and consult with the Chair of the University REB.
- 7.3. An Ethics Review Agreement may be limited to a specific research project.

UNBC Research Ethics Board Terms of Reference & Procedures

Policy Authority: Vice-President, Research

Parent Policy: Ethics Review of Research Involving Human Participants

1. RESEARCH ETHICS BOARD

The University of Northern British Columbia (UNBC) Research Ethics Board (REB), oversees research involving human participants conducted under the auspices of the University, to ensure that all University research involving human participants is conducted in accordance with the most current version of the Tri-Council Policy Statement for the Ethical Conduct of Research Involving Humans (the Tri-Council Policy Statement, referred to as TCPS).

2. PURPOSE

The purpose of the terms of reference and procedures is to outline the structure and appropriate process to ensure that the conduct of research involving human participants, performed under the auspices of the University, follows the highest ethical standards as defined in the Policy.

3. DEFINITIONS

- 3.1. **Closure / Conclusion of a Research Project** for research ethics depends on several research project specific factors, including stipulations associated with funding and journal requirements. Normally the research ethics completion date can be when all meaningful contact with the participants is completed (after transcripts have been reviewed, community collaborations completed, any activities that would affect research outcomes are finished) and any activities that would affect research outcomes have ceased. The researcher is still bound to follow the research data management plan as expressed in their ethics application, however the researcher does not have to continue to renew their ethics status.
- 3.2. **Ethics Approval** refers to the research ethics approval granted in accordance with the Policy and its Procedures by the REB for proposed Research Involving Human Participants.
- 3.3. **Human Participants** are those individuals whose data or responses to interventions, stimuli or questions by the researcher are relevant to answering the research question.
- 3.4. **Minimal Risk** refers to research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by a participant in those aspects of their everyday life that relate to the research.
- 3.5. **Policy** refers to the University policy on the Ethics Review of Research Involving Human Participants.
- 3.6. **Procedures** refers to the Procedures in force with respect to this Policy.
- 3.7. **Reconsideration** refers to the process by which a researcher and the REB attempt to resolve any disagreements, through deliberation and consultation, about the decision rendered by the REB.
- 3.8. **Research Ethics Appeals Process** refers to the process that allows a researcher to request a review of an REB decision when, after reconsideration, the REB has refused ethics approval of the research.
- 3.9. **Research Ethics Board (REB)** refers to a body of researchers, community members and others with specific expertise (e.g., in ethics, in relevant disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within an institution's jurisdiction or Under its Auspices.
- 3.10. **Research Involving Human Participants** means an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation involving Human Participants and includes: (a) research involving living human participants; or (b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells, whether derived from living or deceased individuals.
- 3.11. **Unanticipated Problem** refers to any incident, experience, or outcome that meets all of the following criteria:
 - 3.11.1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the REB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;

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- 3.11.2. Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
 - 3.11.3. Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
 - 3.12. **Under the Auspices** means with the protection or support of someone or something, especially an organization such as a University.
 - 3.13. **University** means University of Northern British Columbia.

4. REPORTING RELATIONSHIP

- 4.1. The REB will submit an annual report in February for the activities of the previous calendar year (January through December) to the VPR for information for the Board of Governors.
- 4.2. The report shall include the number of proposals reviewed/rejected and the submitting Faculties, a generic description of ethics issues/concerns that have been addressed in the past year and any necessary changes to the REB Terms of Reference and Procedures.

5. RESPONSIBILITIES OF THE RESEARCHER:

- 5.1. A researcher who plans to conduct Research Involving Human Participants is required to:
 - 5.1.1. be familiar with all University policies relating to research, including without limitation Ethics Review of Research Involving Human Participants, UNBC Research Ethics Board Terms of Reference & Procedures and the most current version of the TCPS;
 - 5.1.2. submit an ethics application accompanied by any supplementary materials necessary for ethics review and approval prior to recruiting any human participants (with the exceptions noted in the TCPS), accessing data, or collecting human biological materials;
 - 5.1.3. consult with the REB Chair or designate if there is any doubt as to whether a research project constitutes Research Involving Human Participants, to obtain a determination as to whether such research project requires research ethics review;
 - 5.1.4. 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 the REB for as long as required by the research;
 - b. the TCPS Core Ethical Principles;
 - c. the most current version of the TCPS;
 - d. 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 regulation), policies, standards (including professional and institutional standards) and guidelines, where applicable to a particular area of research or to the funding of such research;
 - 5.1.5. promptly report to the REB the occurrence of any Unanticipated Problem during the course of the implementation of the approved research project, or that has other ethical implications that may affect the welfare of such Human Participants;
 - 5.1.6. promptly submit an amendment to the REB for any proposed changes to the research project and obtain the approval of the REB before implementing the changes, except when necessary to eliminate immediate hazards to Human Participants, or to implement minor logistical changes that do not increase risk to Human Participants;
 - a. in the event of eliminating immediate hazards, submit changes made to the research project to the REB as soon as practicable;
 - b. in the event of minor logistical changes, summarize changes made and include with the annual renewal of a longer term research project or with the research project closure documentation;
 - 5.1.7. notify the REB when the research project has concluded.
- 5.2. The University is committed to ensuring that research conducted under its auspices is done with the highest ethical standards. As part of this commitment, the REB, with support of the VPR, have set completion of the TCPS online tutorial, presently called "Course on Research Ethics" (CORE), as mandatory for all research personnel who are part of a research project that is to be conducted as Research Involving Human Participants. The CORE Tutorial is free and can be completed in about two hours, a dated CORE certificate (or certificate of the most current version of the TCPS tutorial) is

issued upon completion. The tutorial provides an essential orientation to Canadian human research ethics guidelines.

- 5.2.1. The CORE tutorial must be completed before submitting one's application to the REB for ethics review. All students (graduate and undergraduate) must submit the tutorial certificate of completion with their application for ethics review.
- 5.2.2. Students involved in course-based research must submit the certificate of completion with the application provided to their instructor.
- 5.2.3. All other research project personnel (e.g. faculty and staff) do not need to attach the certificate of completion to the application; however, copies should be retained and be made available upon request.
- 5.3. Supervisors of Student Research:
 - 5.3.1. In supervised research, the term "researcher" includes both the supervisor and the individual(s) being supervised. All student research must be supervised by a faculty member who accepts responsibility for overseeing the ethical conduct of the student's research.
 - 5.3.2. In the case of undergraduate or graduate course-based Minimal Risk research projects, the instructor may apply, for the specific course and semester, to the REB for delegated authority to review student course-based research. Applications should be made well in advance (four weeks are suggested) of the semester start to ensure timely review, revisions and approval prior to the course syllabus distribution.
 - 5.3.3. Faculty supervisors should act as a resource for the student when preparing the ethics application, providing guidance and reviewing the application prior to submission. Faculty supervisors must:
 - a. Ensure that their students have the training and competence necessary to execute the proposed research in an ethical manner;
 - b. Ensure the proposed research has been reviewed and accepted by the advisory committee (where applicable) and is of scientific merit;
 - c. Assist students with the preparation of their application for REB review;
 - d. Ensure that the application is clearly written, scientifically valid, and provides the appropriate protections for human research participants;
 - e. Review and approve the student's application prior to submission to the REB.
 - 5.3.4. Following ethics approval, the supervisor is responsible for ensuring that the conditions of the research project are properly executed.
- 5.4. Student Researchers:
 - 5.4.1. Graduate and undergraduate students wishing to conduct Research Involving Human Participants must obtain the appropriate ethics review and approval of their proposed research, as previously reviewed and cleared by their advisory committee (where applicable) and supervisor before the research may begin. Research projects will be supervised by a faculty member who shares in accepting responsibility for the ethical conduct of the research.
 - 5.4.2. In the case of undergraduate or graduate course-based Minimal Risk research projects, approval may be granted by the course instructor as delegated by the REB specifically for the course and semester [see 5.3.2].
 - 5.4.3. When submitting their first ethics application (whether individually or within a course), all students (both graduate and undergraduate) are also required to submit a certificate of completion of the TCPS online tutorial "Course on Research Ethics" (CORE). The CORE is designed to familiarize researchers with the ethical principles associated with the conduct of Research Involving Human Participants. Although a student's research must be supervised by a faculty member, such supervision does not in any way diminish the obligation of the student to comply with the Policy, the TCPS or other regulations that govern the ethical conduct of Research Involving Human Participants.
 - 5.4.4. It is the joint responsibility of the student and faculty supervisor to ensure that the research project receives and maintains the appropriate ethics approval.

6. RESPONSIBILITY OF THE RESEARCH ETHICS BOARD

- 6.1. Provide impartial, fair and reasoned review of the ethical acceptability of proposed and ongoing research in an efficient and timely manner on behalf of the University;
- 6.2. Ensure that REB decisions are communicated clearly to the researchers in writing including all approvals and refusals of, all proposed modifications to, and any requirements they may impose on proposed or ongoing Research Involving Human Participants;

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- 6.3. Ensure that the potential benefits of the proposed research are sufficient to warrant human participant involvement;
 - 6.4. Provide continuing research ethics review of research that it has approved on an annual basis at a minimum;
 - 6.5. Provide prompt reconsideration of decisions as requested by the researcher in writing, for which the REB may require from the researcher additional information;
 - 6.6. Prepare and maintain comprehensive records, including all documentation related to the projects submitted to the REB for review, attendance at all REB meetings, and accurate minutes reflecting REB decisions. Where the REB denies approval for a research project, the minutes shall clearly document the reasons for the decision.

7. MEETINGS AND REVIEW

- 7.1. Principle of proportionate review:
 - 7.1.1. REB review engages the degree of scrutiny for an application requiring ethics approval that is proportional to the risk posed to research participants. The participant vulnerability and research risk matrix completed in the application is assessed to determine between above-minimal and minimal risk protocols. Regardless of the degree of scrutiny, the ethical requirements for approval are identical.
 - 7.1.2. The REB may ask that the researcher provide the full documentation of scholarly reviews already completed. The REB does not normally conduct scholarly review.
 - 7.1.3. Minimal risk applications will be reviewed through the delegated review process on a rolling basis [see 7.5].
 - 7.1.4. Above minimal risk application will be reviewed at full board meetings.
 - 7.1.5. The Chair of the REB may request further information and/or attendance by the applicant to the REB meeting.
- 7.2. Meeting Schedule and Notice:
 - 7.2.1. The REB will schedule full board meetings monthly from September through June for the review of above-minimal risk applications received before the posted submission deadline. During the months of July and August, review of above minimal risk applications will be done on an "ad hoc" basis.
 - 7.2.2. Additional meetings will be held whenever deemed necessary by the REB Chair.
 - 7.2.3. Seven days' notice shall be given for all meetings except that a meeting may be held at any time without due notice if quorum is met.
 - 7.2.4. The REB shall schedule its meetings to ensure a timely flow of reviews such that research is not unduly impeded;
- 7.3. Meeting Decisions:
 - 7.3.1. Business involving decisions related to research protocols shall be by consensus as declared by the Chair. In the event that a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort should be made to reach consensus. Consultation with the researcher, external advice, peer review or further reflection by the REB may be helpful.
 - 7.3.2. If decisions related to research protocols are made by majority vote, the views of the minority will be communicated to the researcher.
 - 7.3.3. Decisions requiring full review are only to be adopted when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary, as determined by the Chair, to provide an adequate research ethics review of the proposals under consideration.
 - 7.3.4. Decisions made without quorum are not valid or binding.
- 7.4. Quorum is met when the minimum requirements of membership representation are present, as defined in the TCPS. The REB quorum shall consist of at least five members, including both men and women, of whom at least:
 - 7.4.1. two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
 - 7.4.2. one member is knowledgeable in ethics;
 - 7.4.3. one member is from the community, with no affiliation to the institution;
 - 7.4.4. the presence of a member knowledgeable in the relevant law is only mandatory when reviewing biomedical research.
- 7.5. Minimal Risk Applications Delegated Review Process:

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- 7.5.1. Minimal risk applications submitted to the REB will have the risk matrix assessed upon receipt. Applications deemed by the Chair to be above minimal risk will be escalated to the next scheduled full board meeting. Researchers will be made aware of the decision immediately.
 - 7.5.2. Confirmed minimal risk applications will normally be forwarded to two ethics review members, who will review the application.
 - a. Reviewers are to provide, as needed, a series of concise points that are to be addressed by the researcher(s) prior to the application receiving ethics approval.
 - b. All application related information is to be treated confidentially, with secure transmission of materials, storage and disposition as appropriate.
 - 7.5.3. Any ethics review member who disagrees with the initial designation of an application as minimal risk shall return the application to the REB to discuss the option of escalating it to full board review with the Chair and the Chair's determination is final.
 - 7.5.4. The REB Chair or designate will review all minimal risk reviews along with the application and reviewer comments to ensure that decisions are consistent, recorded accurately and communicated clearly to researchers in writing.
 - 7.5.5. A summary of all delegated reviews will be appended to the minutes of regular full board meetings.
 - 7.6. Harmonized Review of Multi-Jurisdictional Applications
 - 7.6.1. Both minimal risk and above minimal risk applications that involve multiple partners from the Research Ethics BC (REBC) network are able to be reviewed by all participating partner boards through one application submitted through the Provincial Research Ethics Platform (PREP).
 - 7.6.2. The University is a founding partner of REBC and is able to act as Board of Record as well as Partner Board for reviews involving University researchers.
 - 7.6.3. Review procedures are updated on the REBC website for application information.
 - 7.7. Ongoing Research and Continuing Ethics Review:
 - 7.7.1. Ongoing research is subject to continuing ethics review that is based on a proportionate approach to risk assessment. The REB will make the final determination as to the nature and frequency of continuing research ethics review of approved research projects. Review on an annual basis will be required at a minimum through a status report and formal request for continuing approval submitted to the REB.
 - 7.7.2. Substantive changes made to ongoing research may require a new application be submitted for review as the cumulative ethical ramifications are too extensive to be reviewed through the amendment process.

8. MEMBERSHIP

- 8.1. The membership of the REB is designed to ensure competent independent research ethics review. Annually, the REB determines the need for expertise in relevant research disciplines in order to ensure competent independent research ethics review. Members shall be appointed by the VPR on the recommendation of the Chair of the Research Ethics Board. The REB may consult with Faculty Deans, Department Chairs and the Office of Research in maintaining appropriate REB membership.
- 8.2. Initial appointments shall be for a single year, with re-appointments of three year terms. Terms will be staggered to ensure continuity and may be renewed. There is no limit on reappointments.
- 8.3. Meeting attendance is required by members, those absent for more than 50% of the face-to-face meetings over the course of one year will have the Chair review whether that member should continue to serve on the REB in a report to the VPR.
- 8.4. Unexpected circumstances and/or regional campus duties may prevent individual members from attending the REB meeting in person. In these exceptional cases, input from members by the use of technology is acceptable.
- 8.5. The complement of the REB will be determined by the ongoing needs of the University, but should include:
 - 8.5.1. Four tenure track faculty members all of whom are active in research with human participants;
 - 8.5.2. At least one member knowledgeable in ethics;
 - 8.5.3. At least one member is a community member with no affiliation with the University, and who is recruited from the communities served by the University;
 - 8.5.4. At least two members with broad expertise in the methods or in the areas of research that are covered by the REB;
- 8.6. Other members who may serve on the REB include:
 - 8.6.1. Ad hoc members for special purpose reviews [see 8.11];

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- 8.6.2. Alternate members appointed by the VPR in consultation with the REB and the Chair to serve as replacements for regular members when they are unable to attend [see 8.12];
 - 8.6.3. For biomedical research or other research involving special legal risks, at least one member knowledgeable in the relevant law (but the member should not be the University's legal counsel or risk manager);
 - 8.6.4. Research Ethics and Administration Officer, where the officer has the requisite experience, expertise and knowledge comparable to what is expected of REB members, may be appointed to serve as a non-voting member on the REB;
 - 8.6.5. A representative from an Indigenous group or organization, to provide assessment and interpretation of issues specific to research involving and/or affecting Indigenous participants and/or communities.
 - 8.7. Each member shall be appointed to formally fulfill the requirements of only one of the above categories.
 - 8.8. REB Chair is the REB member responsible for ensuring that the REB review process conforms to the requirements of the TCPS. Their role is to provide leadership and to facilitate the REB review process, based on institutional policies and procedures and the TCPS. The Chair should monitor the REB's decisions for consistency and ensure that these decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or their designate. The position is to be provided the necessary resources and adequate administrative support to enable the REB Chair to fulfil the responsibilities of their position.
 - 8.8.1. REB Chair Selection: The Chair shall be appointed by the VPR based on the recommendation of the REB normally from among the appointed members and shall serve, normally, for a term of three years, once renewable. The Chair shall hold a tenured position with the University and upon the end of the Chair's three-year term(s), they would normally serve for an additional six months in the capacity as "former Chair".
 - 8.8.2. The Chair shall not serve in the positions of community member, member with expertise in the area of ethics, or member knowledgeable in relevant law.
 - 8.9. REB Vice-Chair: Also holds responsibility for ensuring that the REB review process conforms to the requirements of the TCPS. Their role is to fulfil the role of the Chair when the Chair is either not available, or there is a conflict of interest declared by the Chair. Ideally, the Vice-Chair will move into the Chair position when the Chair either leaves the REB or completes their term(s).
 - 8.9.1. REB Vice-Chair Selection: The Vice-Chair shall be appointed by the VPR based on the recommendation of the REB, normally from among the appointed members and shall serve, normally, for a term of three years, once renewable. Preferably, the Vice-Chair will hold a tenured position with the University, however it is not necessary.
 - 8.9.2. The Vice-Chair shall not serve in the positions of community member.
 - 8.10. Senior Administrators or Members of the Board of Governors shall not serve on the REB, nor directly or indirectly influence the REB decision-making process.
 - 8.11. Ad Hoc Advisors: Individuals consulted by the REB in the event that the REB membership lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. A research project that requires particular community or participant representation or specific disciplinary or methodological expertise not available from its members should have such consultation sought, as needed. Ad Hoc Advisors would be consulted for a specific research ethics review and for the duration of that review. Ad Hoc Advisors are not to be counted in the quorum for the REB, nor allowed to vote on REB decisions.
 - 8.12. Alternate Members: Each REB member is asked to propose the name of another faculty member who could be, if need be, recommended for nomination by the VPR in the case that the regular member is unable to carry on their duties. Alternate members are usually selected considering past experience with ethics review, and are to substitute similar expertise of the incapacitated/absent regular member. Alternate Members are to be counted in the quorum for the REB and are to vote on REB decisions.
 - 8.13. Observers: At the Chair's discretion, observers may be admitted to REB meetings, provided that they sign a confidentiality agreement and they do not have a conflict of interest with the specific meeting agenda. Observers may participate in discussions, are not to be counted in the quorum, nor allowed to vote on REB decisions.
 - 8.14. Conflicts of Interest: Any REB member who has a personal/professional interest or a real or perceived conflict of interest with a research proposal under review (as principal or co-investigator, supervisor, committee member, student, funder) may be asked by the Chair to leave the meeting while the REB deliberates its decision, if not asked to leave the meeting, the member in conflict shall not be allowed to participate in the vote on the REB decision.
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9. ADMINISTRATIVE SUPPORT

- 9.1. Administrative Office is the Office of Research.
- 9.2. The REB will be provided human resources, office space and support services from the Office of Research.
- 9.3. Minutes of all REB meetings, including all decisions, dissents, and the reasons for them shall be prepared and maintained by the support personnel for the REB. Minutes of all REB meetings are accessible to authorized representatives of the institution, researchers and funding agencies.

10. RECONSIDERATION OF REB DECISIONS

- 10.1. Researchers have the right to request and the REB has the obligation to provide, reconsideration of a decision.
- 10.2. Initial reconsideration may simply consist of informal discussions between the researcher and the REB Chair. If the matter is resolved through this process, the resolution will be documented, and reflected in the application materials as appropriate.
- 10.3. If informal discussions do not lead to a resolution, the researcher may request a formal reconsideration. The researcher must provide a written request for reconsideration to the Chair of the REB, outlining the concerns they have with the initial REB review. The researcher has the right to be heard in a meeting with the REB to discuss the issues identified.
- 10.4. When requesting a formal reconsideration, the onus is on the researcher to justify the grounds on which the reconsideration is requested and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision not supported by the TCPS.

11. APPEAL PROCESS

- 11.1. If after having fully exhausted the reconsideration process, the researcher continues to be dissatisfied with the REB decision, the researcher may utilize the Research Ethics Appeal Process and appeal the decision of the REB to the Appeal Board at the University of Victoria.
- 11.2. The University of Victoria (UVic) has agreed to provide appeal services for UNBC's REB process that is consistent with the TCPS.
- 11.3. An appeal may be launched for procedural or substantive reasons. Procedural error includes real or reasonably apprehended bias, including bias based on validity, method, theory of the method, theoretical grounds of the work or scope, or undeclared conflict-of-interest on the part of one or more members of the UNBC REB.
- 11.4. The researcher making the appeal (the *Appellant*) will provide the Executive Assistant in the UNBC Office of Research (the *UNBC Representative*) with a written description of the alleged procedural error that is the basis of the appeal (the *Submission*). The appellant must also sign a waiver in favour of each of the UNBC and UVic, in the prescribed form, to protect the institutions from any liability or legal claim related to the review.
- 11.5. As soon as is practicable, the UNBC Representative will send the appellant's submission to the Chair of UNBC's REB.
- 11.6. Within thirty (30) working days of receipt of the appellant's submission, the Chair of the UNBC's REB will file with the UNBC Representative a written response to the allegation. As soon as is practicable, the UNBC Representative will send a copy of the Chair's response to the appellant. The Appellant will have the opportunity to provide a written reply to that response within thirty (30) working days of receipt of the response.
- 11.7. Once the file, comprising the original application for ethics approval and the documents referenced above, is complete, the UNBC Representative will forward the file to the Associate Vice President Research, UVic, with a cover letter requesting an Appeal Board review.
- 11.8. The procedures to be followed by UVic's Appeal Board will be those of the University of Victoria and may be modified, as required, by UVic's Human Research Ethics Coordinator. The appellant and the Chair of the UNBC REB have the right to meet with the UVic REB regarding the appeal. In reviewing the appeal, the UVic REB will determine if there has been a procedural error that materially and adversely influenced the decision of the UNBC REB, normally within thirty (30) working days of receipt of the file, and will transmit its decision and reasons to the parties.
- 11.9. If the UVic REB determines that there has been such a procedural error, it will direct the UNBC REB to reconsider the application, employing any changes in procedure outlined by the UVic REB within its decision and reasons.

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- 11.10. Normally, within ten (10) working days of the decision of the UVic REB, the written results of the appeal and reasons will be forwarded to the appellant and the Chair of the UNBC REB. The results will be binding on the appellant and UNBC and not subject to further appeal.
- 11.11. Should any costs be associated with the appeal (e.g. travel of the appellant, lawyer's fees, etc.), the appellant and UNBC will each bear their own costs.