Ethical Practice for Research Involving Human Participants

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Objectives

This procedure applies directly to Policy 6500, Research Ethics for Human Participants[1].

This procedure describes the process that BCIT researchers and associated BCIT employees are required to follow when submitting applications to the Research Ethics Board (REB) to conduct research involving human participants. This procedure further describes the role of the REB and the review process.

This procedure may be updated from time to time to accommodate future approved amendments to the Tri-Council Policy, or new BCIT research activities.

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[1] BCIT Policy 6500, Research Ethics for Human Participants is available on the BCIT website.

Who This Procedure Applies To

This procedure applies to the following:

- BCIT administrators, faculty, staff, and students who engage in (or assist with) any research activities carried out under the auspices of BCIT, that involve human participants
- Any researchers from outside BCIT who intend to use BCIT employees or students as participants, or other individuals recruited by BCIT as human participants, in their research activities
- BCIT senior managers and administrators who engage in research or are responsible for employees or students engaged in research activities involving human participants
- Members of the BCIT Research Ethics Board, and any BCIT researchers involved in research activities that are funded by major granting agencies

Compliance

When conducting research that involves human participants, BCIT researchers must comply not only with the requirements of BCIT Policy 6500 and this procedure, but also with the standards established by the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC), known as the Tri-Council, and published in the Second Edition of their Policy Statement on the Ethical Conduct for Research Involving Humans ("TCPS 2" [2]).

In any instance where BCIT's policy 6500 or the procedures in this document vary from the TCPS 2, the Institute and the researcher are expected to comply with the higher standard.

Role of the Research Ethics Board (REB)

The role of the Research Ethics Board (REB), as mandated by BCIT Policy 6500, is to develop procedures and guidelines for ethical review of research that falls within the jurisdiction of the REB, and to review applications submitted by researchers. The REB is authorized to accept, reject, propose modifications to, or terminate any proposed or ongoing BCIT research that is subject to REB review. The complete terms of reference of the REB are given in this procedure's appendix.

Scope of Research Requiring Review

Review and written approval by the REB are required before the research begins, for any of the following situations:

1. All research associated with BCIT that involves living human participants.

2. Research involving human biological materials, including tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva and other body fluids, and materials related to human reproduction.
   - *Exception:* REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, *so long as the*

[2] The Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans" is available on The Government of Canada's website for the Panel on Research Ethics.

process of data linkage or recording or dissemination of results does not generate identifiable information.

3. Multicentred research associated with BCIT and/or conducted by staff or students of BCIT outside the Institute's jurisdiction or outside Canada. In such cases, the research must be reviewed by BCIT's REB as well as the REB(s) of any partner institution. Where BCIT or TCPS standards differ from that of the other institution or the other jurisdiction, BCIT requires its researcher to comply with the higher standards.

4. Research about a living individual involved in the public arena, or about an artist, only if the participant is approached directly for interviews or for access to private papers, and then only to ensure that professional protocols guide such approaches. (Review is not required regarding publicly-available information about such a person.)

5. Research that employs creative practice to obtain responses from participants, which will be analyzed to answer a research question.

For greater clarity, note that the above requirements for REB review of research projects remain, regardless of any of the following circumstances—whether:

- The research is funded or not;
- The funding is internal or external;
- The participants are from inside or outside the institution;
- The participants are paid or unpaid;
- The research is conducted inside or outside Canada;
- The research is conducted inside or outside the institution;
- The research is conducted by staff or by students;
- The research is conducted in person or remotely (e.g., online, mail, electronic mail, fax, or telephone);
- The information is collected directly from participants or from existing records not in the public domain;
- The research is to be published or not;
- The focus of the research is the participant;
- The research is observational, experimental, correlational, or descriptive;
- A similar project has been approved elsewhere or not;
- The research is a pilot study or a fully developed project;
- The research is to acquire basic or applied knowledge;
- The research is primarily for teaching or training purposes or whether the primary purpose is the acquisition of knowledge; or
- The research is sponsored by BCIT or uses BCIT employees or students.

Additional Situations

Faculty, Administrators and Staff Research

All faculty, administrator, and staff research must be submitted to the REB.

Student Research
If a study is a teaching exercise (i.e., part of a diploma or undergraduate degree level course), and entailing no more than minimal risk, it may be reviewed by a school/departmental level committee on behalf of the REB and in compliance with the TCPS. The school/departmental ethics committee, as needed, must report results of such reviews to the REB at the end of the academic year.

Student research deemed to be beyond minimal risk must be reviewed by the REB.

Individual departments are expected to support and train students so that their research projects are ethical, and those that exceed minimal risk may be efficiently reviewed by the REB. Departments should screen student applications for ethical review prior to submission to the REB. The REB may return applications to the department if they do not conform to the requirements of the TCPS.

Exemptions from Ethics review

Research that does not require ethics review includes the following:

1. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials, or third-party interviews.

2. Publicly available information when it is: (a) legally accessible to the public and appropriately protected by law, and (b) publicly accessible and there is no reasonable expectation of privacy. For example, research involving password-protected information on public sites (e.g., Facebook) is not exempt from review because there is an expectation of privacy by members.

3. Quality assurance studies, performance reviews, or testing within normal educational requirements.

If in Doubt
Researchers in doubt about whether their work requires REB review should consult with the Chair or a member of the REB for guidance. Contact information for the Chair is provided on the REB web site. http://www.bcit.ca/appliedresearch/ethics/

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1. Submission Requirements

1.1 General Submission Requirements

REB approval must be obtained before the research work begins. Bearing in mind that ethics review may take considerable time and that no grant funding may be spent towards the research prior to REB approval, researchers should plan to make their application for ethics approval well in advance of the anticipated start date of the project. Applications for review should be submitted to the REB using the appropriate forms and by following the instructions on those forms. Prospective applicants may approach the REB Chair or any REB member for assistance.

It is not generally necessary for research proposals to be submitted to the REB before an application is made to a funding agency. However, once funding is approved, the project must then be submitted to the REB for ethics review before research work begins.

1.2 Application Procedure – Full Review and Delegated Review

Applicants must send their application first to their academic advisor, dean, or manager for review and endorsement prior to submission to the BCIT REB. In cases where dean or manager approval may violate existing policy (e.g., Academic Freedom), the applicant will provide a written

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explanation for missing signatures.

Application for ethics review should normally be made using BCIT's "Request for Ethical Review" form[3].

In cases where applicants have already prepared similar applications for ethics review of the same project to another institution, they may wish to submit the completed form for the other institution to BCIT. The REB Chair will decide on a case-by-case basis whether the REB will accept an application made on a different form. If the non-BCIT application form is not accepted, the applicant must resubmit, using BCIT's form.

Applications should be complete (i.e. with all approval signatures in place and all necessary attachments included), and the documentation submitted electronically to the REB Administrator and/or the REB Chair.

Full review will take place when the research is deemed to involve greater than minimal risk[4], or when the applicant requests full review. Full reviews must take place at a face-to-face meeting of the REB; they cannot be conducted by REB meetings held over the telephone, or through email. Full reviews must also satisfy the requirement for peer review (see Part 1.3 of this Procedure section). Conducting a full review involves distributing the application to all the members of the REB at least two weeks prior to the REB meeting where the application is to be considered. The applicant may be invited to attend the REB meeting to discuss the proposed research and answer questions, but may not be present when the REB is making its decision.

Delegated review may take place if the REB Chair decides that the proposed research involves minimal risk to the research participants, and if the applicant has not requested a full review. Delegated Review is performed by the REB Chair or by one or more qualified REB members as designated by the REB Chair or designee. The applicant will be notified in writing on whether the project is deemed to be of minimal risk, within approximately five working days after submitting the application, and will receive the decision of the Delegated Review panel within approximately a further 10 working days.

The Delegated Review panel will determine whether the proposed research is (a) acceptable as submitted, (b) acceptable with minor modifications, in which case it will be returned to the applicant with a request that it be modified and re-submitted, or (c) that the proposed research must undergo a full ethical review.

Approvals of expedited research proposals are reported to the full REB at its next scheduled meeting, after which a certificate of approval is issued.

1.3 Scholarly (Peer) Review

In cases of greater than minimal risk

[3] Available at: the BCIT Applied Research / Ethics website.
http://www.bcit.ca/appliedresearch/ethics/

[4] "Minimal risk" 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.

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In cases of research proposals that present greater than minimal risk, the researcher must demonstrate scholarly review of the project's design. The peer review is to make certain that the project design is capable of addressing the question(s) being asked in the research. Prior to submission to the BCIT REB, sufficient peer review must consist of any one of the following:

- Successful funding of a grant proposal by a funding agency (given confirmation that the granting agency's peer review process prior to awarding the grant meets the requirements of the REB)
- Ad hoc independent external peer review conducted by an expert reviewer appointed by and reporting directly to the REB
- For dissertations or academic research, documentation of scholarly review approval of the research plan by an academic panel such as a dissertation committee

In cases of minimal risk

The extent of review for scholarly standards, that is required for biomedical research involving minimal risk, will vary according to the specific research being carried out. (That is, some biomedical research proposals, even though they may be deemed to involve minimal risk, may nevertheless be required to undergo peer review, depending on the nature of the research). The decision whether a minimal risk biomedical research proposal requires peer review rests with the REB Chair.

Research in the humanities and social sciences, which poses, at most, minimal risk, is not normally required by the REB to be peer reviewed. However, it is highly recommended that all research proposals be reviewed by supervisor and peers for quality of design.

Certain types of research, particularly in the social sciences and the humanities, may legitimately (through exposure) have a negative effect on public figures in politics, business, labour, the arts, or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. Such research should be carried out according to the professional standards of the relevant field of research. The benefits and risks to those who are researched are considered along with the potential benefit of the research to the society.

Principle of Proportionate Review
The REB will use a proportionate approach based on the general principle that the more risk and invasive the procedures involved in the research, the more diligent the assessment of the perceived risks and benefits inherent in the study procedures must be.

1.4 Continuing Ethics Review

The REB'S approval of a research project covers only the procedures the applicant outlines in his/her original application. Any changes in the procedures affecting interaction with human participants are reported to the REB on an approved amendment form. Significant changes require submitting a revised application for ethics approval.

- Ongoing research is subject to continuing ethics review. The Chair of the REB must be promptly notified of any substantial change to the research plan or research protocol. Researchers are required to include monitoring mechanisms by which participants in the research may contact the REB Chair. The REB will take problems or complaints seriously,

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and researchers may need to modify their studies in view of such complaints.

- Ethics certificates are normally issued for one year, except in cases where the REB deems that the certificate should be for less than one year. If the project continues after one year, the researcher must submit a completed "Request for continuation or Amendment of an Approved Project" to the REB. If no substantial change has been made to the research plan or research protocol, the Chair of the REB may issue a one-year extension. If in the opinion of the REB Chair, the research plan or research protocol has been substantially changed, re-submission and review by the REB is required.
- The researcher promptly notifies the REB when the project concludes by completing an End of Study form.

1.5 Conflict of Interest

Conflicts of interest (COI) (real, potential or perceived) arise when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her professional judgment, objectivity, and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict. Researchers and research staff should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the research process. If a COI cannot be avoided, procedures should be in place to manage and/or to mitigate the conflict.

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), the member must declare their interest and remain neutral or not be present while the REB is discussing or making its decision. The REB Chair or designee will determine whether the circumstances should be defined as a COI, and the member will follow the REB's decision regarding any actions required to mitigate his/her real or perceived COI. In the event that the REB Chair declares a COI, the Vice-Chair or alternate REB member will assume the REB Chair's responsibilities for the specific project(s).

All research protocols submitted for approval will include information on funding (if any) and a budget, as appropriate, for the research. Where funding is provided for the research, the REB should review the funding arrangements to be sure that no conflict of interest exists which would affect the human participants being recruited for the research.

If there is an intent to commercialize the results of the research (and at BCIT, there is often such an intent), then this intent must be disclosed to the human participants. The REB may approve the research and may require a management plan, which may include changes at the Researcher's or sponsor's expense, to eliminate or mitigate the conflict. After review by the REB and others at BCIT, if applicable, the REB may reject research that involves a COI that cannot be appropriately managed.

2. Decisions of the REB

The REB will determine the ethical acceptability of the research proposal, based on the information provided to it, and on additional expert advice obtained, if any. The REB will convey its decision in writing to the applicant and, where appropriate, to the granting agency. In the case of a negative decision, the Chair will be available to the applicant on a reasonable basis to help in developing a proposal that will meet the ethical standards required by the REB. In the event that such efforts fail and approval is not granted, the applicant will be informed of the REB's decision in writing.

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2.1 Decisions of the Chair

The Chair of the REB may make the following decisions, if in doing so, it would facilitate the deliberations of REB and assist researchers in completing their submission process:

- Decisions related to whether an application entails minimal risk, and therefore, whether the submission may undergo delegated review
- Decisions related to an applicant's compliance with REB requests for changes to an application
- Decisions related to amendments for previously approved applications
- Decisions related to the continuation of an approval if requested by an applicant

All decisions made by the Chair are reported to and reviewed by the REB at the next regularly scheduled meeting.

2.2 Acceptability of materials provided by Applicants

The REB Chair has the authority to determine the sufficiency and acceptability of any and all researcher responses to REB questions.

2.3 Reconsideration by the REB

Researchers have the right to request, and the REB has an obligation to reconsider, decisions affecting a research project. When the REB is asked to reconsider a negative decision, it is guided by the principles of natural and procedural justice, including giving the applicant a reasonable opportunity to be heard. The REB will explain the reasons for opinions and decisions, and provide opportunity for rebuttal, fair and impartial judgment, and consideration in a timely manner. The applicant will be invited to be present to discuss the application with the REB prior to decision making. The REB's decision will be made in writing to the applicant, with reasons for the decision, and will be issued in a timely manner.

If the REB decision, on reconsideration, remains negative, the applicant may appeal the decision to the Vice-President Academic.

BCIT may not override negative REB decisions without following the formal appeal mechanism in Section 2.4 — Appeal.

2.4 Appeal

To appeal a negative REB decision, researchers must apply in writing to the Vice-President Academic (the "Vice-President"). A copy of the appeal letter should also be sent to the REB Chair. The Vice-President will submit the appeal request to a Research Ethics Appeal Committee (REAC).

Royal Roads University's Research Ethics Board is the Research Ethics Appeal Committee (REAC) for BCIT. The decisions of the REAC are final and binding in all respects for any appeal lodged against a decision of BCIT's REB.

Appeals may be heard only on the basis of a procedural error that materially and adversely influenced the decision of the REB, including real or reasonably apprehended bias, including bias resulting from philosophical differences on the nature of knowledge, or undeclared conflict-of-

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interest on the part of one or more members of the REB. Accordingly, the Research Ethics Appeal Committee will first determine whether a procedural error, bias, or a conflict of interest (as described above) occurred, and if so, report back to the Vice President on its finding. Based on the recommendations of the REAC, BCIT's REB will amend its procedures regarding the proposal in question, and then look again at the proposal and make a final determination.

2.5 Reports

Certificates of Ethical Approval, signed by the Chair of the BCIT REB will be issued to the Principal Investigator(s). Copies of the Certificates of Ethical Approval will be forwarded to Finance and the Operations Manager for Applied Research in order to authorize the release of project funding.

Decisions on minor amendments to Delegated Reviews will be reported to and reviewed by the REB at the next scheduled meeting.

The REB will make an annual report to BCIT's Vice-President Academic, and the BCIT Board of Governors.

The REB will also notify Finance and the Operations Manager for Applied Research of any change in status or withdrawal of REB approval. Should REB approval be withdrawn, Finance will no longer allow any new funds to be released towards the project until the REB approval is reinstated.

2.6 Unanticipated Problems/Adverse Event Reports

The REB must be notified immediately of any unanticipated problems or adverse event that occurs during the research. This includes completion of an unanticipated/adverse event report on the appropriate forms and in accordance with the guidelines provided by the REB. Appropriate institute and other governing officials must be notified as appropriate to the specific research. The chair or other assigned REB members may choose to act immediately on the report. All unanticipated problems and adverse events will be reported to the full REB at its next scheduled meeting.

2.7 Other Reportable Events

The Researcher is responsible for reporting to the REB unanticipated problems, events, or findings that could significantly impact the overall conduct of the research or alter the balance of risk versus benefit, such as any of the following:

- Any new information (e.g., sponsor's safety notice or action letter) that would cause the sponsor to modify the research or the consent form, or that would prompt other action by the REB to ensure protection of research participants.
- Any increase in the risks or decrease in the potential benefits of the research.
- A change in Health Canada or FDA safety labeling or withdrawal from marketing of a drug, device, health product, genetic therapy or biologic used in research.
- DSMB reports.
- Interim analysis results.
- A change to the research that was initiated without prior REB review to eliminate an apparent immediate hazard to a research participant.
- Deviations from previously approved research.
- Privacy Breaches: The Researcher must report to the REB any unauthorized collection, use, or disclosure of personal information (PI).

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- Audit or Inspection Findings: The Researcher must report to the REB a summary of any relevant audit or inspection findings following a Health Canada inspection, an FDA or other regulatory audit, an internal QA audit or other audits at the site.
- Research participant complaint when the participant reports concerns about their rights as a research participant or about ethical issues related to the research.

3. Free and Informed Consent

3.1 Requirement for Free and Informed Consent

With limited exceptions set forth in Sections 3.1 (b), 3.3, and 3.6, below, research governed by Policy 6500 may begin only if prospective participants or authorized third parties have given their free and informed consent, and their consent is maintained throughout their participation in the research.

a. Participant or authorized third party consent, or documentation by the researcher of other appropriate means of consent is required.

b. The REB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

   i. The research involves no more than minimal risk to the participants;

   ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;

   iii. The research could not practicably be carried out without the waiver or alteration;

   iv. Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation and be given the opportunity to refuse consent; and

   v. The waived or altered consent does not involve a therapeutic intervention or other clinical or diagnostic interventions.

c. In studies including randomization and blinding in clinical trials, neither the research participants nor those responsible for their care know which treatment the participants are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if participants are informed of the probability of being randomly assigned to one arm of the study or another.

d. Applicants should refer to BCIT's appropriate forms, and contact the Chair for further guidance.

3.2 Consent must be voluntary

Free and informed consent must be voluntarily given, without manipulation, undue influence, or coercion. Consent can be withdrawn at any time. If consent is withdrawn, the participant can request that their data or human biological materials also be withdrawn.

3.3 Naturalistic observation

REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in public places where there is no expectation of privacy are exempt from REB review where:

(a) It does not involve any intervention staged by the Researcher, or direct interaction with

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the individuals or groups,

(b) Individuals or groups targeted for observation have no reasonable expectation of privacy, and

(c) Any dissemination of research results does not allow identification of specific individuals.

3.4 Informing Potential Participants

Researchers must provide to 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 opportunities to discuss and contemplate their participation. The REB may approve research without requiring that the researcher obtain the participant's consent in specific circumstances (*see Waiver below*). Informed consent consists of the following in accordance with TCPS2, Articles 3.1–3.5, and where the REB is satisfied that all of the following are documented:

a. Information that the individual is being invited to participate in a research project;
b. A comprehensible statement of the research purpose, the identity of the researcher, the identity of the funder, the expected duration and nature and responsibilities of the participant, and a description of research procedures;
c. A plain language description of all reasonably foreseeable risk and potential benefits, both to the participants and in general, that may arise from research participation;
d. An assurance that prospective participants: are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements; will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;
e. Information concerning 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 the research sponsors.

In some types of research, and for some groups or individuals where written signed consent may be felt by the participants as mistrust on the part of the researcher, the REB may approve the process of oral consent, a verbal agreement or a handshake. Where consent is not documented in a signed consent form, researchers may use a range of consent procedures (e.g., oral consent, field notes, implied consent through the return of a completed questionnaire). The procedures used to seek consent must be documented by the researcher and approved by the REB.

If a research participant is unable to read, an impartial witness must be present during the entire informed consent discussion. The research participant gives verbal consent after the informed consent document and any other written information is read and explained to the research participant. The impartial witness and the research participant (if capable) give their signatures on the informed consent document, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by, the research participant, and that the research participant gave informed consent freely. The REB requires that the applicant submit the translated informed consent materials for review and approval prior to

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use in enrolling non-English-speaking participants. The REB may require that the researcher include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the REB approved English materials.

3.5 Waiver or Alteration of Informed Consent

The REB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, provided that the REB finds and documents that:

- The regulatory and ethics guidance framework supports the waiver;
- The research involves no more than minimal risk to the participants;
- The waivered or altered consent does not involve a therapeutic intervention;
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration;
- The information is used in a matter that will ensure its confidentiality;
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

3.6 Research Involving Participants Who Lack the Capacity to Consent for Themselves

For research involving individuals who lack capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB must ensure that at a minimum the following conditions are met:

- The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;
- The researcher seeks and maintains consent from authorized third parties;
- The authorized third party is not the researcher or any other 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 the potential for direct benefit to the participant, the researcher must demonstrate how the research will expose the participant to only a minimal risk and how the participant's welfare will be protected during participation in the research.

If an authorized third party has consented on behalf of a person who lacks legal capacity but that person has some ability to understand the significance of the research, the researcher ascertains the wishes of that individual with respect to participation.

Assent from a participant is not sufficient to permit them to participate in a research project in the absence of consent by an authorized third party; however, their expression of dissent must be respected.

Prospective participants who may be capable of verbally or physically assenting to, or dissenting from, participation in research include:

- Those whose capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing;
- Those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating; and

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- Those whose capacity remains only partially developed, such as those living with permanent cognitive impairment.

If assent for research is required, the researcher must submit to the REB the proposed procedures for obtaining consent from the capable substitute decision maker and assent from the research participant. The researcher must submit an assent form or summary of the assent process to the REB for approval as per the organization's guidelines. When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the researcher will seek the participant's consent as a condition of continuing participation. If an individual signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that the individual loses capacity or upon their death, an authorized third party may be guided by these directives during the consent process.

3.7 Other Vulnerable Groups

The REB will determine appropriate protections for individuals and groups who might be inappropriately excluded from research on the basis of attributes such as culture, language, sex, race, ethnicity, age and disability, and who require additional protections. For these individuals and groups the REB will take into account the risks and benefits of the research, and will consider protections afforded by organizational policies, and provincial and federal law.

In addition, when the REB regularly reviews research involving a vulnerable population, it will consider including one or more researchers who are knowledgeable and experienced in working with these participants this population.

Potentially vulnerable groups may include, but are not limited to:

- Children
- The elderly
- Individuals with mental illness
- Pregnant women
- Individuals with limited language skills
- Aboriginal individuals and communities
- Prisoners

If research involves prisoners, children, pregnant women, fetuses and/or neonates, and is funded or supported by the US Federal Government, the REB will apply the requirements of 45 CFR 46, including as appropriate, Sub-Parts, B, C and D.

3.8 Consent for Research in Emergency Health Situations

Subject to all applicable legal and regulatory requirements, research involving medical emergencies may be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or authorized third parties, if all of the following apply:

a. A serious threat to the prospective participant requires immediate intervention;

b. Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care;

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c. Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant;

d. The prospective participant is unconscious or lacks capacity to understand risks, methods, and purposes of the research;

e. Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

f. No relevant prior directive by the participant is known to exist.

When a previously incapacitated participant regains capacity, or when an authorized third party is found, consent must be sought promptly for continuation in the project, and for subsequent examinations or tests related to the research project.

3.9 Consent and Secondary Use of Identifiable Information and/or Human Biological Materials for Research Purposes

The REB allows the secondary use of identifiable information and/or human biological materials for research purposes without obtaining consent from research participants if the researcher is able to satisfy the following conditions:

- Identifiable information/materials is essential to the research;
- The use of identifiable information/materials without the participant's 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/materials;
- The researchers will comply with any known preferences previously expressed by individuals about any use of their information/materials;
- It is impossible or impractical to seek consent from individuals to whom the information relates/materials were collected; and
- The researchers have obtained any other necessary permission for secondary use of information/materials for research purposes.

In cases where the REB has approved secondary use of identifiable information/materials without the requirement to seek consent, if the researcher proposes to contact individuals for additional information and/or materials, the researcher must obtain REB approval prior for contact.

3.10 Incidental Findings

Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research. The researcher's plan to identify and to disclose incidental findings must be included in the application to the REB, as a part of the proposed research project plan.

Appendix 1 BCIT Research Ethics Board Terms of Reference

1. Responsibilities

The BCIT REB reports to the BCIT Board of Governors and is administratively responsible to the Vice-President Academic for:

- Developing procedures and guidelines relating to the use of human participants in research activities done under the auspices of BCIT;
- Conducting ethical reviews of all protocols in projects that involve use of human participants, to grant or deny approval within the authority of the REB;
- Reviewing annually all BCIT policies regarding ethical issues relating to the use of human participants in research, to ensure that policies remain current with the TCPS and the relevant issues affecting BCIT;
- Dealing with matters concerning research on humans referred to the REB by the President of BCIT, or by the Vice-President Academic;
- Preparing an annual report summarizing the activities of the REB, for submission to the BCIT Vice-President Academic, Education Council, and the BCIT Board of Governors;
- Participating in continuing education activities for the Institute community in matters relating to ethics and the use of human participants.

The policies and practices followed by the REB will be consistent with the current approved Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans," and as described in standard operating procedures (SOPs) created by the Canadian Association of Research Ethics Boards (CAREB) and Network of Networks (N2).

2. Composition of the REB

The REB will include at least five members, including both men and women, of whom:

- at least two have expertise in the areas of research covered by the REB at BCIT;
- at least one is knowledgeable in the area of ethics;
- at least one is knowledgeable in the relevant law but is not the institution's legal counsel or risk manager. A person knowledgeable in law is required for biomedical research;
- at least one is a community member with no affiliation to BCIT (including family members);
- at least one has a primary area of interest in a non-scientific discipline
- none are Institute senior administrators—to ensure the independence of REB decision making.

A member may not fulfill more than two representative capacities or disciplines, and members will include men and women, a majority of whom are Canadian citizens or permanent residents, and who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed research. The REB membership should contain a majority whose main responsibilities are in the areas of research and teaching. New members are elected by the existing REB members for a two-year term, and they may be re-elected for subsequent two-year terms. Terms of appointments of REB members should be staggered to ensure both continuity and appropriate diversity of membership. The Chair is elected from among the REB members, by the REB members, for a two-year term, and may be re-elected for subsequent terms.

The REB may, at its discretion, elect a Vice-Chair to act on behalf of the Chair, in the Chair's absence. In this procedure document, the term "Chair" means the Vice-Chair, when the latter is acting on behalf of the Chair.

The REB Chair or designee may ask an alternate REB member to attend an REB meeting to draw on his/her expertise in an area that may be relevant to that meeting's deliberations, or to establish a quorum for that meeting in the absence of the regular REB member. Only alternate REB members of comparable qualifications may substitute for an REB member (a non-scientific member may not substitute for a scientific member).

Appointments of members, Chair, and Vice-Chair are reported to the Vice-President Academic.

3. Quorum and Decision-Making

A quorum consists of a simple majority of Research Ethics Board (REB) members (50% + 1), who collectively have sufficient expertise in the scientific, methodological, and clinical areas of the research under review, and are knowledgeable about relevant ethical and legal matters. The quorum includes at least one community member and a member whose primary experience and expertise are in a non-scientific discipline. A quorum includes REB members participating by telephone or video conference. A quorum also includes alternate REB members substituting for regular REB members in the same membership category.

The REB will endeavour to make decisions through consensus. If consensus cannot be reached on a given issue, the decision will be made by majority vote, to be recorded in the minutes of the REB meeting. The vote details will be made available to the researcher if requested.

4. Input from Advisors and the Researcher

At his/her discretion, the REB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB. The ad-hoc advisor may be asked to participate in the REB meeting to lend expertise to the discussions. The ad-hoc advisor may not contribute directly to the REB's decision, and the advisor's presence or absence may not be used in establishing a quorum.

Observers may be invited or permitted to attend REB meetings, subject to the agreement of the REB and execution of a confidentiality agreement. Where the REB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed input if it is relevant and significant to the discussion. Observers may not participate when the REB discusses its decision, reaches consensus or votes on the application. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the REB meeting.

The REB may request representation in person from a researcher prior to decision-making. In such cases the researcher will leave the REB meeting after providing his or her input.

5. Meeting Scheduling

The REB normally meets face-to-face every other month during the academic year at BCIT. Additional meetings may be held as deemed necessary by the REB.

6. Record-Keeping

All records and documents of meetings (including minutes of REB meetings), research applications, decisions and the reasons for them, as well as dissents and the reasons for them, are maintained in accordance with BCIT's Records Management System. Minutes of the REB meetings are accessible to authorized personnel of BCIT, researchers, and funding agencies.

Forms Associated With This Procedure

The guidelines and required forms for submission to the REB are provided on BCIT's Applied Research website to assist researchers in making applications to the REB. Please contact the REB Chair or Administrator for information on completing and submitting the forms.

Amendment History

1. Created 2007 Mar 27
2. Revision 1 2011 May 04
3. Revision 2 2018 Mar 20