



Research Ethics for Human Subjects Procedures

Procedure No. 6500
Policy No.: 6500
Category: Research
Department Responsible: Research and International
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Who Should Know about These Procedures?

BCIT faculty, staff and students who engage in (or assist with) any research activities carried out under the auspices of BCIT, that involve human subjects;

Any researchers from outside BCIT who intend to use BCIT employees or students as subjects, or other individuals recruited by BCIT as human subjects, in their research activities;

BCIT senior managers and administrators who are responsible for employees or students engaged in research activities involving human subjects;

Members of the BCIT Research Ethics Board; and any BCIT researchers involved in research activities that are funded by major granting agencies.

Guidelines and Forms

The guidelines and required forms for submission to the REB are provided on BCIT's web site to assist researchers make applications to the REB. Currently, the following documents are available:

- Form 1 - Application for Ethical Review
- Form 2 - Guidelines for Completing Applications for Ethical Review of Activities involving Human Subjects
- Form 3 - Application for Continuing Review or Amendment of an Approved Project
- Form 5 - Guidelines for Creating an Informed Consent Document
- Form 6 - Checklist and Suggestion for Applications
- Form 7 - Checklist for Submissions

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- Form 8 - REB Protocol Review Form
- Form 9 - Statement on Minimal Risk
- Form 10 - Expedited Review Protocol
- Adverse Event Report

Forms are available from the following web site:

<http://www.bcit.ca/appliedresearch/downloads/ethics.shtml>

1. General

This document sets out procedures which are to be followed to implement BCIT's Policy #6500 "Research Ethics for Human Subjects"¹.

When conducting research that involves human subjects, BCIT researchers must comply not only with the requirements of BCIT's Policy #6500, 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 set forth in their Policy Statement on the Ethical Conduct for Research Involving Humans ("TCPS"²).

If there should be any instance where BCIT's policy #6500 or the procedures in this document vary from the TCPS, the Institute and the researcher should comply with whichever standard is higher.

2. Research Ethics Board (REB)

The role of the Research Ethics Board ("REB"), as mandated by BCIT's Policy # 6500, is to develop procedures and guidelines for ethical review of research that falls within the jurisdiction of the REB, and to conduct reviews of applications that are 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.

¹ BCIT's Policy #6500 "Research Ethics for Human Subjects" is available at:
<http://www.bcit.ca/files/pdf/policies/6500.pdf>.

² Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans" is available at <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

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2.1 Scope of Research Requiring Review

All research associated with BCIT that involves living human subjects (i.e. research where humans are participating in, or are the subject of, studies over which BCIT has the responsibility to regulate legal or ethical aspects) requires review and written approval by the REB in accordance with these procedures, before the research is started.

Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses shall also be reviewed by the REB.

Research that does not require ethics review includes 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. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols.

In addition, quality assurance studies, performance reviews or testing within normal educational requirements do not require REB review.

For greater clarity, note that REB review of research projects is required in all the following circumstances:

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



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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.

Multicentred research associated with BCIT and/or conducted by staff or students of BCIT outside the Institute's jurisdiction or outside Canada must undergo ethics review by BCIT's REB and by the REB(s), where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the institutions(s), country or jurisdiction where the research is to be done. If local practice or standards in the other jurisdiction vary from those of BCIT or the TCPS, the Institute requires its researchers to comply with whichever expectation is higher.

3. BCIT Research Ethics Board Terms of Reference

3.1 Responsibilities

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

- Developing procedures and guidelines relating to the use of human subjects in research activities done under the auspices of BCIT;
- Conducting ethical reviews of all protocols in projects that involve use of human subjects, 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 subjects 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 Research and International;
- Preparing an annual report summarizing the activities of the REB, for submission to the BCIT Vice-President Research and International, 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 subjects.

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."

3.2 Composition of the REB

The REB shall normally consist of seven (7) members, including both men and women, of whom:

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- at least two members have expertise in the areas of research covered by the REB at BCIT;
- at least one member is knowledgeable in the area of ethics;
- for biomedical research, at least one member is knowledgeable in the relevant law;
- at least one member has no affiliation with BCIT;
- at least one member has a primary area of interest in a non-technological area.

The REB, at its discretion and in the interest of ensuring diversity, may appoint up to three (3) additional members, to bring the total REB membership to ten (10).

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" shall be taken to mean the Vice-Chair, when the latter is acting on behalf of the Chair.

Appointments of members, Chair and Vice Chair are reported to the Vice President Research and International.

3.3 Quorum and Decision-Making

A quorum shall consist of four (4) REB members if the total REB membership is eight (8) or less, or five (5) if the total REB membership is nine (9) or ten (10). Furthermore, the REB members forming the quorum shall include one who is the Chair or Vice-Chair, at least one who has expertise in the areas of research covered by the REB at BCIT, at least one who is knowledgeable in the requirements of the TCPS, at least one who is unaffiliated with BCIT, and for biomedical research, at least one who is knowledgeable in the relevant law.

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

3.4 Input from Advisors and the Researcher

The REB may find it desirable, on occasion, to call on specialists to provide expert advice. The responsibility for selecting such advisors will rest with the Chair. Advisors will not be voting members of the REB but may participate in the REB's deliberations.

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.

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3.5 Meetings

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

3.6 Records

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, must be maintained in accordance with BCIT's Records Management System. Minutes of the REB meetings shall be accessible to authorized personnel of BCIT, researchers, and funding agencies.

4. Submission Requirements

4.1 General Submission Requirements

REB approval must be obtained before the research work begins. Bearing in mind that ethics review may take considerable time, researchers should plan to make 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 that form. Prospective applicants may approach the REB Chair or any REB member for assistance in selecting the appropriate forms for submission.

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 the research work can begin.

4.2 Application Procedure - Full Review and Expedited Review

Application for ethics review should normally be made using BCIT's "Request for Ethical Review" form³.

In some cases, when applicants have already prepared similar applications for ethics review of the same project to another institution, they may wish to submit the form of the other institution to BCIT. In such cases, 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 submit using BCIT's form.

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

³ Available at: http://www.bcit.ca/files/appliedresearch/doc/reb_ethical_review_request.doc

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Full review will take place when the research is deemed to involve more than minimal risk⁴, 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 Section 4.3). 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.

Expedited review may take place if the REB Chair decides that the proposed research involves minimal risk to the research subjects, and if the applicant has not requested a full review. Expedited review is performed by a panel of two members of the REB selected by the Chair. The applicant will normally be notified in writing whether the project is deemed to be of minimal risk within approximately 5 working days after submitting the application, and will receive the decision of the expedited review panel within approximately a further 10 working days.

The expedited 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. In the latter case, it should be noted that an application undergoing expedited review cannot be rejected without a consideration by the full REB.

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

4.2 Scholarly (Peer) Review

In case of research proposals that present more than minimal risk, the design of the project must be peer reviewed to assure that it is capable of addressing the question(s) being asked in the research. Sufficient peer review may be considered to be any one of the following:

- Successful approval by the REB (if research is in the REB's field of expertise).
- Successful funding of a grant proposal by a funding agency (it will be presumed 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, approval of the research plan by an academic panel such as a dissertation committee.

⁴ "minimal risk" means that the probable level of harm that subjects will meet as a result of participating in the project is reasonably expected to be no greater than the harm they would normally encounter in those aspects of their everyday life that relate to the research.

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The extent of the review for scholarly standards that is required for biomedical research that involves minimal risk will vary according to the research being carried out (i.e. biomedical research proposals, even though they may be deemed to involve minimal risk, may be required to undergo peer review). The decision whether a minimal risk biomedical research proposal requires peer review shall rest with the REB Chair.

Research in the humanities and the social sciences, which poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed.

Certain types of research, particularly in the social sciences and the humanities, may legitimately 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. The safeguard for those in the public arena is through public debate and discourse and, in extremis, through action in the courts for libel.

4.3 Principle of Proportionate Review

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

4.4 Continuing Ethics Review

The REB'S approval of a research project covers only the procedures outlined by the applicant in his/her original application. Any changes in the procedures affecting interaction with human subjects should be reported to the REB on an approved amendment form. Significant changes will require the submission of a revised application for ethics approval.

- Ongoing research shall be 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 will be asked to include monitoring mechanisms by which subjects participating in the research may contact the Chair of the REB. Problems or complaints will be taken seriously by the REB and researchers may be asked 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 "Annual Renewal and Amendment Form" 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 shall promptly notify the REB when the project concludes.

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4.5 Conflict of Interest

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 declare their interest and remain neutral or not be present while the REB is discussing or making its decision. In cases of disagreement over conflicts of interest, both the REB member in potential conflict and the researcher may present evidence and offer a rebuttal concerning the nature of the conflict of interest. The other members of the REB will make a final decision regarding the conflict and how to proceed.

All research protocols submitted for approval will include information on funding (if any) for the research. Where funding is provided for the research, the REB should review the funding arrangements to ensure that no conflict of interest exists which would affect the human subjects 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 subjects.

5. Decisions of the REB

The REB will come to a conclusion regarding the ethical acceptability of the research proposal on the basis of the information provided to it and additional expert advice obtained, if any. The decision of the REB will be conveyed in writing to the applicant and, where appropriate, to the granting agency. In the case of a negative decision, the Chair will make himself or herself available to the applicant on a reasonable basis to endeavor to develop 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.

5.1 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 expedited review.
- Decisions related to an applicant's compliance with observations made by the REB in response 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 will be ratified by the REB at the next regularly scheduled meeting.



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5.2 Reconsideration by the REB

Researchers have the right to request, and the REB has an obligation to provide reconsideration of decisions affecting a research project. When the REB is asked to reconsider a negative decision, it shall be guided by the principles of natural and procedural justice, including giving the applicant a reasonable opportunity to be heard. The REB will provide an explanation of the reasons for opinions and decisions and the opportunity for rebuttal, fair and impartial judgement 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 decision of the REB will be made in writing to the applicant, with reasons for the decision, and will be issued in a timely manner.

If the decision of the REB, on reconsideration, remains negative, the applicant may appeal the decision to the Vice-President Research and International.

BCIT may not override negative REB decisions without following the formal appeal mechanism in Section 5.3.

5.3 Appeal

To appeal a negative REB decision, researchers must apply in writing to the Vice-President Research and International (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 will be the Research Ethics Appeal Committee (REAC) for BCIT. The decisions of the REAC shall be final and binding in all respects for any appeal lodged against a decision of BCIT's REB.

Appeals may only be heard 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-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 accordingly, and then make a final determination on the research proposal.

5.4 Reports

Certificates of Ethical Approval, signed by the Chair of the BCIT REB will be issued to the Principal Investigator(s).

Any decisions by way of expedited review to approve minor amendments will be reported to and ratified by the REB at the next scheduled meeting.



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An annual activity report from the REB will be made to the Vice-President Research and International of BCIT, and the BCIT Board of Governors.

5.5 Adverse Event Reports

The REB must be notified immediately of any adverse event that occurs during the research. This shall include completion of an adverse event report on the appropriate forms and in accordance with the guidelines provided by the REB.

6. Free and Informed Consent

6.1 Requirement for Free and Informed Consent

With limited exceptions set forth in Sections 6.1(b) 6.3 and 6.6 below, research governed by Policy #6500 may begin only if prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and their free and informed consent has been given and is maintained throughout their participation in the research.

- a. Evidence of free and informed consent by the subject or authorized third party should normally be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.
- 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 subjects;
 - ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;
 - iii. The research could not practicably be carried out without the waiver or alteration;
 - iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
 - v. The waived or altered consent does not involve a therapeutic intervention.
- c. In studies including randomization and blinding in clinical trials, neither the research subjects nor those responsible for their care know which treatment the subjects are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if subjects are informed of the probability of being randomly assigned to one arm of the study or another.

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- d. Applicants should refer to BCIT's Form 2 and Form 5 (see Appendix 1, Section 4) for further guidance.

6.2 Consent must be voluntary

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

6.3 Naturalistic observation

REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.

6.4 Informing Potential Subjects

Researchers shall provide to prospective subjects, 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 subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective subjects with the following:

- 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 expected duration and nature of participation, and a description of research procedures;
- c. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;
- d. An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and
- e. The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

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6.5 Legally Incompetent Subjects

Recruitment: Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

- i. The research question can only be addressed using individuals within the identified group(s); and
 - ii. Free and informed consent will be sought from their authorized representative(s); and
 - iii. The research does not expose them to more than minimal risk without the potential for direct benefits for them.
- b. Conditions: For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:
- i. The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the subjects' best interests will be protected.
 - ii. The authorized third party may not be the researcher or any other member of the research team.
 - iii. The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent.
 - iv. When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.
- c. Consideration of the wishes of legally incompetent subjects: Where free and informed consent has been obtained from an authorized third party and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.

6.6 Research in Emergency Health Situations

Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of 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 health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if ALL of the following apply:

- a. A serious threat to the prospective subject requires immediate intervention; and
- b. Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and
- 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 subject; and



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

If a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

Appendix I – Further Information on Procedures

1. Normal Review Process

The REB shall normally meet face to face in order to review submitted research proposals. In case of controversial research proposals, the REB may meet face to face with researchers in order to consider the ethical solutions proposed by researchers for problems arising in their studies. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but not be present when the REB is making its decision. Minutes will be kept for these meetings and inserted into the appropriate case files. Minutes of REB meetings shall include information about REB decisions and any dissents and reasons for them.

The REB shall keep an “open file” in a secure location determined by the Chair of the REB, for researchers applying for ethical approval. The file shall be opened by the Chair when sufficient information has been submitted by the researcher to start the review process. The original application, descriptions of research and methodology, correspondence, relevant documents, ethical certificates, revised materials, and any comments from the public or other information relevant to the research project shall be kept in the file. It is the responsibility of the researcher to address all the recommendations made by the REB in order to keep the file complete and up-to-date at all times. When the research project is finished, and the researcher(s) notifies the REB, these files shall be “closed” and kept for a period of at least five years by the REB as records demonstrating compliance with the TCPS. The files remain the property of BCIT and cannot be removed from their secure location by the researchers. These files shall be subject to audit by authorized representatives of BCIT (research administrators), members of Appeal Boards, and funding agencies.

The REB file on applications for ethical review should contain the following documents:

- Application form
- Trial protocol and amendments

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- Written informed consent forms and any updates
- Subject recruitment procedures (e.g. advertisements)
- Investigator's brochure (if one exists)
- Available safety information
- Information about payments and compensation available to subjects
- Investigator's current curriculum vitae and/or other document on qualifications
- Any other documents that the REB may need to fulfill its responsibilities

All research receiving ethical approval, whether through the normal or expedited process, as well as that receiving departmental level review shall require a proper file showing compliance with the TCPS. Insufficient information in the file is grounds for refusing or delaying ethical approval.

2. Expedited Review

Expedited review does not require face-to-face meetings of the REB members. It is usually completed within two weeks of submission of a completed application form and a decision that the proposal is of minimal risk. The Chair must report requests for expedited review and results of such reviews to other members of the REB at an appropriate time.

The researcher may request an expedited or a full review, however, the decision on whether an expedited review will be granted resides with the REB Chair. If the researcher requests an expedited review the REB Chair may reject it and refer the application to the REB for a full review. If the researcher requests a full review, then the REB Chair may not override such a request.

Expedited review is review by two members of the REB (one of which may be the Chair) rather than the full REB. It is available only in cases which fulfill one or other of the following criteria:

- a. Research which obviously involves no more than minimal risk (as defined in the TCPS: "if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk"). Given the heterogeneous nature of subjects, a "reasonable person's" definition of "minimal risk" as is often employed in the courts concerning subjective harms will also be acceptable to the REB. (An acceptable definition of minimal risk has been developed by the REB and is available in the application material). The researcher is responsible for an acknowledgement of minimal risk to the REB.
- b. Research projects which have already received approval by the BCIT REB, have complied fully with any requirements, have an up to date file, and the applicant is



British Columbia Institute of Technology

Research Ethics for Human Subjects Procedures

Procedure No.	6500
Policy No.:	6500
Category:	Research
Department Responsible:	Research and International
Most Recent Revision:	2007 March 27

simply renewing the ethical approval certificate without significant changes to the ongoing research process.

3. Acceptability of Materials provided by Applicants

The REB Chair has the authority to determine the sufficiency and acceptability of any and all responses provided by researchers.