Research Ethics for Human Participants – Process

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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.

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Who Does This Procedure Apply 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

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

- 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

1 Introduction

When conducting research that involves human participants, BCIT researchers must comply not only with the requirements of BCIT 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 the Second Edition of their Policy Statement on the Ethical Conduct for Research Involving Humans ("TCPS 2" [2]).

If there should be any instance where BCIT's policy 6500 or the procedures in this document vary from the TCPS 2, the Institute and the researcher should comply with whichever standard is higher.

2 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 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.

3 Scope of Research Requiring Review

Research is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
All research associated with BCIT that involves living human participants (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 begins.

Research involving human remains, cadavers, tissues, biological fluids, embryos, or fetuses must 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 participant 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.

[2] 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.

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., by 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; and
- The research is sponsored by BCIT or uses BCIT employees or students.

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/

Multicentred research associated with BCIT and/or conducted by staff or students of BCIT outside the Institute's jurisdiction or outside Canada must nevertheless 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.

4 BCIT Research Ethics Board Terms of Reference

4.1 Responsibilities

The BCIT REB reports to the BCIT Board of Governors and is administratively responsible to the Vice-President Education, Research and International 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, Research and International;
- Preparing an annual report summarizing the activities of the REB, for submission to the BCIT Vice-President Education, 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 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."

4.2 Composition of the REB

The REB normally consists of seven (7) 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 not the institution's legal counsel or risk manager. A person knowledgeable in law is required for biomedical research;
- at least one has no affiliation with BCIT;
- at least one has a primary area of interest in a non-technological area.
- To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB.

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

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

4.3 Quorum and Decision-Making

A quorum consists of four (4) REB members if the total REB membership is eight (8) or fewer persons or five (5) if the total REB membership is nine (9) or ten (10) persons. Furthermore, the REB members forming the quorum are to 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 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.

4.4 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 are not 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.

4.5 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.

4.6 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.

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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, 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 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

All applicants must send their application first to their academic advisor, dean, or manager for review and endorsement prior to submission to the BCIT REB.

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

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

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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 and in hard copy 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 a panel of two members of the REB, selected by the Chair. The applicant will normally 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

In cases of research proposals that present greater than minimal risk, the researcher must demonstrate scholarly review of the design of the project. The peer review is to make certain that it 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*

[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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- *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 the 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 outlined by the applicant 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 the submission of 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 will be asked to include monitoring mechanisms by which participants 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 "Request for continuation or Amendment of an Approved Project" (Form 3) 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.

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1.5 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) 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.

2 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 endeavour 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.

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 requests for changes 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 are ratified 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 responses to questions from the REB provided by researchers

2.3 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

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is 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 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 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 Education, Research and International.

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 Education, 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 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-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 re look 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).

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

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

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

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unanticipated problems and adverse events will be reported to the full REB at its next scheduled meeting.

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 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. Participant, authorized third party 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 Form 2 and Form 5 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, for example, political rallies, demonstrations, or public meetings.

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

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adequate opportunities to discuss and contemplate their participation. The REB may approve research without requiring that he researcher obtain the participant's consent in accordance with TCPS-2, 3.1-3.5 where the REB is satisfied and documents that all of the following apply:

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.

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

a. ***Recruitment:*** Subject to applicable legal requirements, individuals who lack the capacity to consent are not legally competent therefore shall be asked to become research participants only when:

   I. The research question can only be addressed with participants within the identified group; and

   II. The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or

   III. Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

b. ***Conditions:*** For research involving participants who lack the capacity to consent, the REB must ensure that, as a minimum, the following conditions are met:

   I. The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;

   II. The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;

   III. The authorized third party is not the researcher or any other member of the research team;

   IV. 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 not for benefit of other persons in the same category then research must expose the participant to minimal risk and burden and protect the participants welfare throughout the research; and

   V. When authorization for participation was granted by an authorized third party, and

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a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent; and

VI. When an authorized third party has consented and the participant has some ability to understand the significance of the research the wishes of the participant will be honoured.

3.6 Research in Emergency Health Situations

Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall 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; and

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; 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 participant; and

d. The prospective participant 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 participant is known to exist.

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

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. The following documents are available:

- Form 1 - Application for Ethical Review
- Form 2 - Guidelines for Completing Applications for Ethical Review of Activities involving Human Participants
- Form 3 - Application for Continuing Review or Amendment of an Approved Project
- Form 4 – Adverse/Unanticipated Event Report
- Form 5 - Guidelines for Creating an Informed Consent Document
- Form 6 - Checklist and Suggestion for Applications
- Form 7 - Checklist for Submissions
- Form 8 - REB Protocol Review Form
- Form 9 - Statement on Minimal Risk
- Form 10 - Delegated Review Protocol

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Amendment History

1. Created 2007 Mar 27
2. Revision 1 2011 May 04

Appendix – Further Information on Full and Delegated Review Processes

1 Full Review

The REB normally meets 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 accommodates reasonable requests from researchers to participate in discussions about their proposals, but the researcher(s) may not be present when the REB is making its decision. Minutes are kept for these meetings and inserted into the appropriate case files. Minutes of REB meetings include information about REB decisions and any dissents and reasons for them.

The REB keeps an "open file" in a secure location determined by the Chair of the REB, for researchers applying for ethical approval. The file is 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 are 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 are "closed" and kept for a period of at least seven 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 are 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
- Written informed consent forms and any updates
- Participant recruitment procedures (e.g., advertisements)
- Investigator's brochure (if one exists)
- Available safety information
- Information about payments and compensation available to participants
- Investigator's current curriculum vitae and/or other documents on qualifications
- Any other documents that the REB may need to fulfill its responsibilities

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

2 Delegated Review

Delegated 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 by the REB chair that the proposal is of minimal risk. The Chair must report requests for Delegated Review and results of such reviews to other members of the REB for approval at the next scheduled REB meeting or an appropriate time.

The researcher may request an expedited or a full review; however, the decision on whether a Delegated Review will be granted resides with the REB Chair. If the researcher requests a Delegated 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.

A Delegated Review is conducted 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 the following criteria:

a. Research which obviously involves no more than minimal risk (as defined in the TCPS as: "research in which the probability and magnitude of possible harms implied by participation in the research is not greater than those encountered by participants in those aspects of their everyday life that relate to the research"). The researcher is responsible to the REB for demonstrating that any risk exposure to the research participants will be minimal.