# RESEARCH ETHICS BOARD – POLICIES AND PROCEDURES

## GENERAL

Briercrest College and Seminary is a community of rigorous learning that loves truth and regards obedience to the truth as the goal of study, and that values a growing understanding of and appreciation for the world in which we live and the people with whom we live. Research, defined as an undertaking designed to extend knowledge through disciplined inquiry or systematic investigation, is a natural extension of the desire to understand and to improve the world in which we live. Research is an essential component of the mission of Briercrest College and Seminary, and some of this research involves human participants.

The use of human participants in the conduct of research confers responsibilities on researchers to conduct studies in a manner that respects the inherent worth and dignity of all human beings. As an institution of higher learning, Briercrest College and Seminary shares this commitment to promote responsible research. Briercrest College and Seminary endorses the 2nd Edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*[1] (hereafter referred to as the TCPS). This document describes how Briercrest College and Seminary will apply Tri-Council policy.

This policy is intended to ensure that the highest ethical standards in the conduct of research involving human participants are maintained at Briercrest College and Seminary in compliance with the TCPS, guided by the core principles of 1. Respect for Persons, 2. Concern for Welfare, and 3. Justice.

1. Respect for Persons. This principle includes the obligations to uphold the practice of seeking informed consent, and the duty to protect those whose capacity for autonomy is compromised because of immaturity, illness, or certain psychological issues.

2. Concern for Welfare. This principle obligates researchers to protect and promote the well-being of participants, to ensure that participants are not exposed to unnecessary risks, and to minimize any risks associated with participation in a study.

3. Justice. This principle obligates researchers to treat participants fairly and equitably, so that no segment of the population is unduly burdened by or denied the benefits of a study.

[1] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010. The TCPS is available online at http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

## 1.1 RESEARCH REQUIRING RESEARCH ETHICS BOARD APPROVAL

1.1.1 In accordance with the TCPS, all research involving living human participants that is conducted by researchers, students and staff of Briercrest College and Seminary, or which is conducted within its facilities, requires approval by the Research Ethics Board (hereafter referred to as the REB) prior to commencement of the research. This includes interinstitutional collaborative research.

1.1.2 Certain classes of research are excluded from this requirement, including:

a. Research that relies exclusively on publicly available information when (1) the information is legally accessible to the public and appropriately protected by law; or, (2) the information is publicly accessible and there is no reasonable expectation of privacy.

b. Research involving the observation of people in public places where (1) it does not involve any intervention staged by the researcher or direct interaction with the individuals or groups; (2) it does not involve collecting personal information that will be disseminated through photographic, film or video footage in the research results; and (3) where individuals or groups targeted for observation have no reasonable expectation of privacy. Such research only requires ethical review if the subject is approached directly for interviews or for access to private papers.

c. Research that relies exclusively on secondary use of anonymous information.

1.1.3 Certain projects are not considered "research" by the TCPS, and so do not require REB review, including:

a. Quality assurance and quality improvement studies, program evaluation, and performance reviews or testing within normal educational requirements when used exclusively for program review, management or improvement purposes.

b. Creative practice activities through which an artist makes or interprets a work or works of art. (Research that employs creative practice to obtain responses from human participants that will be analyzed to answer a research question, or to generate research questions is, however, subject to REB review.)

1.1.4 The opinion of the REB should be sought whenever there is any doubt about whether a given project requires review.

## 1.2 RESEARCH ETHICS BOARD

*1.2.1 Structure and Composition*

1.2.1.1 The Briercrest College and Seminary REB shall consist of at least four members, of whom:

a. at least two members have expertise in relevant research disciplines, fields, and methodologies covered by the REB;

b. one member should be knowledgeable in ethics;

c. the inclusion of at least one member is knowledgeable in the law is considered advisable but not necessary. When applicable to the research project (based on the evaluation of the Chair), legal advice will be sought.

d. one member should be a community member who has no affiliation with Briercrest College and Seminary.

1.2.1.2 Members of the REB will serve in staggered 3-year terms. Members are eligible for reappointment. The REB Chair is elected by the REB following the receipt of nominations from the Board membership. The term of the Chair is two years and is renewable.

1.2.1.4 The REB will require a quorum of 100% of its members at all meetings concerned with the ethical approval of research proposals. For the review of proposals not approved for delegated review, the REB will meet face-to-face to review proposals. Ethical review of a research proposal will proceed only when attending REB members possess the range of background and expertise required to properly adjudicate the proposal. If the required range of expertise is not represented, interim members with such expertise will be appointed by the Chair or the meeting will be rescheduled to such time as regular members with such expertise can attend.

*1.2.2 Authority, Mandate and Accountability*

1.2.2.1 Consistent with the TCPS, the Education Team of Briercrest College and Seminary has mandated the REB as an autonomous entity to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within, or by members of the institution, using the considerations set forth in the TCPS as the minimum standard. Such decisions will be based on ethical considerations.

1.2.2.2 The REB is responsible to the Education Team of Briercrest College and Seminary for:

a. developing policies regarding ethical issues relating to the use of human participants in research and experimental protocols

b. reviewing all protocols requiring the participation of human participants for ethical approval

c. reviewing biannually all policies regarding ethical issues relating to the use of human participants in research projects to ensure that the policies remain current

d. preparing an annual report

1.2.2.3 Meetings of the REB will be held once a year (additional meetings may be called by the Chair). The REB shall normally meet face-to-face to review proposed research that is not assigned to delegated review. Videoconferencing, teleconferencing and use of other technologies may be regarded as necessary for meetings when REB members are geographically dispersed and there is no other way of holding an effective REB meeting or when exceptional or exigent circumstances significantly disrupt or limit the feasibility of face-to-face REB meetings.

### *1.2.3 Conflict of Interest*

1.2.3.1 Conflicts of Interest by REB Members

If the REB is reviewing research in which a member of the REB has a personal interest in the research under review (for example, a student's thesis or MRRP for which an REB member is also serving as the student's advisor), conflict of interest principles require that the member not be present when the REB is discussing or making its decision. The REB member may disclose and explain the conflict of interest and offer evidence to the REB provided the conflict is fully explained to the REB, and the proposer of the research has the right to hear the evidence and to offer a rebuttal. In such cases where an REB member is excused due to conflict of interest, the Chair will ensure that the remaining composition of the REB still possesses the range of background and expertise required to properly adjudicate the proposal, and if necessary, appoint an interim member.

1.2.3.2 Conflicts of Interest Involving the Chair

In such cases where a conflict of interest is perceived to exist, the Chair of the REB shall appoint an interim member to replace that member in conflict of interest. If the Chair is in a position of conflict of interest, the Vice-President (Academic) shall appoint an interim Chair.

1.2.3.3 Conflicts of Interest Involving Researchers

The REB should assess the likelihood that the researcher's judgment may be influenced, or appear to be influenced, by private or personal interests, and assess the seriousness of any harm that is likely to result from such influence or from the mere appearance of undue influence. Competing interests may arise from family relationships, financial partnerships, or other economic interests. When a significant real or apparent conflict of interest is brought to its attention, the REB shall require the researcher to disclose this conflict to the prospective participants during the free and informed consent process. To identify and address conflicts properly, the REB shall be provided with details on the research project,

budgets, commercial interests, consultative relationships, and any per capita payments for clinical trials. REB management of conflicts of interest requires a proportionate approach. Where the conflict is so pervasive that it is not enough merely to disclose it to the research participants, the sponsors of research, institutions, relevant professional bodies, or the public at large, the REB may require the researcher to abandon one of the interests in conflict. However, in other cases, the REB might conclude that the identified conflict of interest does not warrant specific actions. When significant conflicts of interest are identified, the continuing ethics review process by the REB should be employed to manage them. When a conflict of interest is unavoidable, the continuing review process should be made more stringent to ensure that conflicts are managed appropriately.

1.2.3.4 Institutional Conflicts of Interest

The REB must act independently from Briercrest College and Seminary. Therefore, Briercrest College and Seminary respects the autonomy of the REB and will act to ensure that the REB has the appropriate independence to fulfill its primary duties. In order to mitigate against situations where Briercrest College and Seminary might have a strong interest in seeing a project approved before all ethical questions are resolved, the REB must maintain an arms-length relationship with Briercrest College and Seminary and avoid and manage real or apparent conflicts of interest.

## 2.1 PROCEDURAL GUIDELINES FOR REVIEW OF A RESEARCH PROPOSAL

2.1.1 Researchers themselves are first responsible for determining the advisability of requesting an ethics evaluation for research. Whenever there is uncertainty with regard to the relevance of such an evaluation, they must consult the Chair of the REB. The REB shall function impartially and provide a fair hearing to all those involved. An application for an ethics review by the REB requires the submission of the form, "Application for Review by Research Ethics Board for Research With Human Participants."

2.1.2 The REB shall follow a research ethics review process proportionate to the level of risk presented by the research under review. The Chair of the REB decides on the level of review to be utilized. A reduced level of scrutiny of a research project with minimal risks does not imply a lower level of adherence to the core principles. Rather, the intention is to reduce unnecessary impediments and facilitate the progress of ethical research. Two levels of ethics review may apply:

a. Full REB review: Ethics review by the full REB should be the default requirement for research involving human participants.

b. Delegated REB review: The REB delegates ethics review to an individual or individuals. Delegates may be selected from among the REB membership or at the faculty or department level. The REB shall require that the actions and decisions of the delegated reviewer(s) be well documented and formally reported to the full REB in a timely and

appropriate manner, thus permitting the REB to maintain oversight over the decisions made on its behalf so as to protect the interests of participants. Accountability requires that, regardless of the review strategy, the REB continues to be responsible for the ethics of all research involving human participants within its jurisdiction.

1) Examples of categories that may be delegated for ethics review include:

a) research that is confidently expected to involve minimal risk;

b) minimal-risk changes to approved research;

c) annual renewals of approved minimal risk research;

d) annual renewals of more than minimal risk research where the research will no longer involve new interventions to current research participants, does not involve the recruitment of new research participants, and the remaining research activities are limited to data analysis;

e) evidence that conditions or other requirements laid down by the REB in an initial review have been met.

If ethical approval is granted to the proposal on the basis of the review, approval will be granted without a formal meeting of the REB. The researcher will be notified and research can begin.

2.1.3 The standard of minimal risk is defined as follows: if potential participants 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 participant in those aspects of her or his everyday life that relate to the research then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective participants. There is a similar threshold regarding undue or excessive offers of benefit. As an offer of payment in relation to research participation exceeds the normal range of benefits open to the research subject, it is increasingly likely to amount to an undue incentive for participation.

2.1.4 Applications for review involving human participants may be:

a. approved without questions or request for modification;

b. approved subject to clarification and/or modifications;

c. deferred, pending receipt of additional information or major revisions; or

d. rejected.

The REB will strive to reach consensus of all members in respect to its decisions concerning applications for review. In the event that consensus cannot be reached, the decision of the majority of the REB shall prevail. The REB may request that any given researcher attend one of its meetings before it renders a decision. Conversely, any researcher may request an audience with the REB by contacting the Chair of the REB. In the case where the REB is considering a negative decision, the researcher shall be informed of the reasons and given the opportunity to reply before the REB makes a final decision. However, at no time may a researcher participate in the decision-making process concerning the review of his or her research.

2.1.5 Where researchers do not receive ethics approval upon initial review, or receive approval with conditions that they find compromise the feasibility or integrity of the proposed research, applicants have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research project. Applicants who are dissatisfied with the decision concerning their application, must first try to resolve the matter by contacting the REB Chair. When an applicant and the Chair cannot reach agreement, the REB will convene and the matter will be discussed with the applicant. When an applicant and the REB cannot reach agreement, the decision of the REB may be appealed by the applicant to the Education Team. In keeping with Section 1.2.1.1, the Education Team will strive to conduct the appeal in a manner that does not violate the autonomous status of the REB. The Education Team shall establish or appoint an ad hoc appeal committee that reflects a range of expertise and knowledge similar to that of the REB, and that meets the procedural requirements of this policy. The appeal committee shall have the authority to review negative decisions made by the REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision shall be final.

2.1.6 Multi-Jurisdictional Research

Contemporary research often involves collaborative partnerships among researchers from multiple institutions or countries. It may call upon the participation of a number of local populations and involve multiple institutions and/or multiple Research Ethics Boards. In such cases, approval of a project by Briercrest College and Seminary's REB is not a sufficient condition for a project to proceed. It is incumbent upon the researcher to determine whether there is a requirement for ethical approval by another body (e.g., a hospital REB).

Multi-jurisdictional research may include:

a. a research project conducted at more than one institution or organization either by the same or different researchers;

b. a research project conducted jointly by researchers affiliated with different institutions or organizations; and

c. a research project being conducted by a researcher who changes affiliation from one institution or organization to another.

Where research involves a number of different institutions and researchers, Briercrest College and Seminary retains accountability for the research within its institution. In order to minimize unnecessary duplication of review, the research ethics board needs to be advised as to whether the same protocol has been reviewed by another research ethics board, including reviews conducted outside of Canada.

In order to facilitate coordination of the ethics review of a multi-jurisdictional study, the researcher shall where appropriate, distinguish between core elements of the research which cannot be altered without invalidating the pooling of data from the participating institutions – and those elements that can be altered to comply with Briercrest College and Seminary's local requirements. The REB will communicate any concerns that they may have with other REBs reviewing the same project.

2.1.7 Undergraduate courses which include class projects and activities designed to develop research skills require the filing of a separate "Application for Review by Research Ethics Board for Course-Based Research" form.

2.1.8 Relationship between Ethics Review and Scholarly Review

As part of ethics review, the REB shall review the ethical implications of the methods and design of the research. The primary test to be used by the REB in evaluating a research project should be ethical probity and, where appropriate, relevant disciplinary scholarly standards. Traditions for scholarly review vary among disciplines or fields of research, including the stage at which scholarly review occurs, and this needs to be taken into account by the REB. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed. The REB should normally avoid duplicating previous professional peer-review assessments unless there is a good and defined reason to do so. Researchers have a role to play in demonstrating to their REB whether, when and how appropriate scholarly review has been or will be undertaken for their research. The REB may request that the researcher provides them with the full documentation of reviews already completed. If, based on criteria outlined in the TCPS, the project is deemed to be high or medium risk by any one of the reviewers, the Chair, or the researcher(s), the project is sent for scholarly review and for consideration by the entire REB in a face-to-face meeting. Scholarly reviews as part of an ethics review will proceed as per Article 2.7 of the TCPS. A scholarly review consists of an ad hoc committee assembled by the REB, consisting of experts in the proposed project's subject matter, that functions in the place of the REB in granting or denying approval for research projects.

2.1.9 Monitoring

Research at Briercrest College and Seminary is subject to ongoing review, proportionate to the risk involved in the research. Briercrest College and Seminary expects that all researchers will conduct their

own monitoring of their research studies. Researchers are required to advise the REB annually concerning the status of their research by means of the form "Annual Renewal of Research Ethics Board Approval For Research with Human Participants," and to advise the REB as soon as the research has been completed. The REB must be promptly notified of any substantial changes to the research plan, research protocol or changes to the consent form/process. The annual renewal form must be received within one month of the "anniversary" of the original REB approval. If this form is not received within that time frame, REB approval of the project is automatically revoked, and the research must submit a new application for approval.

## 3.1 PRINCIPLES OF REVIEW

3.1.1 Risks and Benefits

The REB will determine whether the risks of the research are reasonable in relation to the anticipated benefits (if any) to the human subjects and the importance of the knowledge that may reasonably be expected to result. Foreseeable harms should not outweigh anticipated benefits.

3.1.1.1 Risks

Research participants must not be subject to unnecessary risks of harm, and their participation in research must be essential to achieving scientific and societally important aims. The REB is concerned about risks to:

a. The subjects involved

b. Clearly identifiable third parties

c. The researcher personally and any staff involved

The REB is concerned about risks of:

a. Physical harm

b. Psychological or emotional harm

c. Injury to reputation or privacy

d. Breach of any relevant law

3.1.1.2 Benefits

In all research involving human participants, there is a duty not only to benefit others, but to maximize the net benefits of the research. Benefits include:

a. Specific advantages to participants to third parties or to society or a segment thereof

b. Any general increase in human knowledge

c. Increased knowledge of the researcher

3.1.1.3 Risk Assessment

The REB must determine that risks to participants in all research are minimized by the use of procedures that are consistent with sound research design and which will not expose the subjects to unnecessary risks. In keeping with this principle, the REB will examine the research plan, including the research design and methodology, and including the risk that the research is so poorly designed or is so lacking in statistical power that meaningful results cannot be obtained. The REB will also consider the professional qualifications and resources of the research team in its assessment of risk.

### *3.1.2 Informed Consent*

Informed consent is a process whereby a choice is made by a competent person on the basis of adequate information concerning the nature and foreseeable consequences of the research and all available alternatives, without controlling influences such as force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion.

3.1.2.1 Informed Consent Letter and Form

Researchers must explain on the application form the process to be used to inform prospective participants adequately in regard to details about the study as well as the procedure to be used to obtain consent. A copy of the document to be used in this process must be appended to the application for ethics review. Normally participants who are being asked to participate in other than a study involving use of a questionnaire, must be asked to provide their consent in writing. Two copies of the information-consent letter must be signed. The researcher retains one and the other is provided to the participant for his or her records. It is understood that all participants will provide free and informed consent, voluntarily given, without manipulation, undue influence or coercion. A number of important details/elements must appear in the Information Letter in order to ensure that the participants have been adequately informed. An acceptable information letter normally would include:

a. name of faculty investigator (and student investigator(s), where applicable).

b departmental affiliation(s) with local telephone extension and/or e-mail address for each.

c. a statement indicating that the project is research, and explaining the purpose for conducting the study. This should include several sentences outlining the rationale for the study.

d. description in lay language of all procedures. For studies involving questionnaires or interviews, the information/cover letter should provide examples of the types of questions to be asked or themes to be explored. When the Information Letter is longer than one page, the participant and investigator must initial each page.

e. description of all known or anticipated benefits to accrue to the person or to society from the conduct of the project. If none are expected to accrue, this should be stated.

f. description of all known and/or reasonably anticipated risks to participants.

g. details of time commitment required for participation in the study.

h. details about any plan to re-contact participants for follow-up sessions, or for subsequent participation in related projects.

i. procedures to ensure confidentiality of data and anonymity of participants.

j. details concerning compensation (financial or otherwise) of participants.

k. information on length of retention of data and arrangements for ensuring security of the data.

l. details on participants' right to withdraw consent to participate at any time without fear of reprisal.

m. details on what to do/say to communicate a decision to withdraw from the study.

n. for studies involving questionnaires or interviews, a statement should be included which advises that participants may decline answering any question(s) they prefer not to answer.

o. statement that encourages participants to contact the researcher(s) in the event they have any question pertaining to their involvement in the study. A contact number for the researcher(s) is provided.

p. statement that the project has been reviewed by, and received ethics clearance through, the REB. Participants also must be advised that they may contact the REB Chair with any concerns or questions about their participation. A contact number for the REB must be provided.

q. the possibility of commercialization of research findings, and the presence of any apparent, actual, or potential conflict of interest on the part of the researchers, their institutions, or sponsors.

3.2.1.2 Voluntariness

For consent to be voluntary, free and genuine, an individual must have the opportunity to choose between consent and refusal, without undue interference, fear, constraint, compulsion or undue inducement. Undue influence includes physical duress; fraudulent misrepresentation, or promises of companionship, love or affection; economic incentives; emphasis on benefits over risks or burdens; or appeals to emotional weaknesses, loyalty to professional caregivers, or family solidarity. Particular care must be taken in cases where the prospective research participants are students, or employees, or are dependent upon family or other caregivers, or where the prospective participants are in long-term care facilities. Payments or incentives to participate must be reasonable and must not place undue pressure on research participants either to join or remain within a research project. Generally, participants may be reimbursed for out-of-pocket expenses, and lost wages and inconvenience, provided that these are at an appropriate (not inducing) rate.

3.2.1.3 Special Research Circumstances and Vulnerable Populations

Special research circumstances include the following:

a. research involving children

b. research involving those who are not legally competent to consent

c. research involving mentally incompetent persons

d. research involving "captive" groups such as employees, students, legal wards and the therapeutically dependent

Individuals who are not legally competent to consent to research or who are included in the definition of special research circumstances, shall only be asked to become research participants when:

a. the research question can only be addressed using individuals within the identified groups;

b. the research does not involve more than minimal risk without the potential for direct benefits for them;

c. the written consent of the personal having legal authority to give that consent is obtained, and

d. if a legally incompetent individual is capable of understanding the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation, and the potential participant 's dissent will preclude his or her participation, regardless of the authorization of the person having legal authority.

Research involving children and young people should only be conducted where:

a. the research question posed is important to the health and well-being of the children

b. the participation of children is indispensable to the purpose of the research

c. the study method is appropriate for children and young people; and

d. the circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person

Researchers should consider that those who are not competent to consent for themselves should not be automatically excluded from research which could potentially benefit them as individuals or the group that they represent. An incompetent participant's withdrawal of consent must be respected, whether or not the participant was competent at the time of the withdrawal.

An authorized legal representative cannot consent to research that is not in the best interests of the person they represent. In general, a potential research participant's next-of-kin cannot give a legally valid consent, unless they have been specifically authorized to take that role.

There are no clear legal guidelines about children's abilities to consent to, or refuse, participation in a research project. Guided by some of the relevant literature on this issue,[2] the following guidelines will be followed:

a. for minors with no language comprehension and no decisional capacity

1) The parent or legal guardian will be provided with an information sheet describing the study and an authorization form to be signed.

b. for minors with some language comprehension and no or some decisional capacity

1) The parent or legal guardian will be provided with an information sheet describing the study and an authorization form to be signed.

2) The authorization form will include a statement to the effect that the research has been explained to the minor in a manner appropriate for his/her level of understanding.

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[2] Canadian Psychological Association. (2000). *Canadian code of ethics for psychologists (3rd edition)*. Ottowa: Author. Downie, J. (2000). Information/consent/authorization for minors' participation in research. *Health Law Review, 8 (2)*, 10-12. Henkelman, J. J, & Everall, R. D. (2001). Informed consent with children: Ethical and practical implications. *Canadian Journal of Cousnelling, 35*, 109-121.

c. for minors with good language comprehension and sufficient decisional capacity

1) The minor and the parent or legal guardian will both be provided with an information sheet describing the study.

2) The minor will be provided with a consent form to be signed.

3) the parent or legal guardian will be provided with an authorization form to be signed.

d. regardless of parental consent, minors who protest or refuse to participate (including nonverbal indicators) may discontinue their participation at any time

In cases involving "captive groups" informed consent shall be obtained from each individual subject. The research ethics board may grant a total or partial exemption from this requirement, provided that:

a. it is impracticable to require that such individual consents be sought;

b. the risks to the subjects involved are minimal; and

c. informed consent is given by one or more proper persons with responsibility for 'the captive group' in the knowledge that informed consent is not being sought from some or all individual subjects within that group; and

d. the research does not involve a therapeutic intervention.

### *3.1.3 Anonymity of Participants and Confidentiality of Data*

Any information provided by an individual participant as a result of her or his participation in a study will be considered confidential and will not be released unless otherwise contracted with the participant or required by law. It is the responsibility of the researcher to ensure that, once collected, data are securely stored in a locked area, and are accessible only to authorized personnel. Researchers will employ data encryption to ensure the security of data stored electronically. Participants must be aware of the arrangements in place to ensure confidentiality of data, the length of time the data will be retained and the purpose(s) for which the data will be used. They also must be advised of any plan to allow access to the aggregated, anonymous data by persons other than members of the research team. When no longer required, data must be destroyed in a manner which protects the participants' identities.

### *3.1.4 Deception*

Free and Informed Consent requires that subjects be fully informed about the purpose of the study before being asked to agree to participate. In some fields of research, in particular in social /

behavioural research, studies cannot be conducted without deception, concealment or covert observation. Such research may be approved by the REB, provided that at a minimum:

a. The research involves no more than minimal risk;

b. The use of deception is unlikely to adversely affect the rights and welfare of the participants;

c. The research could not be carried out without the use of deception, concealment or covert observation;

d. Wherever possible, the participants are provided with full debriefing subsequent to their participation;

e. The research does not involve a therapeutic intervention.

In addition, the researcher should provide the REB with information specifically detailing the precise extent of the deception, concealment or covert observation. In cases where deception is utilized, researchers should be especially careful to ensure that participants are informed that they have the right to withdraw data obtained from them during the research without their knowledge or consent.

## 3.2 RESEARCH INVOLVING ABORIGINAL PEOPLES OF CANADA

The Aboriginal and treaty rights of Aboriginal peoples of Canada, including the Indian, Inuit and Métis peoples of Canada, were recognized and affirmed in the Constitution Act, 1982. This affirmation implies an ethical duty for those involved in research to acknowledge and support the desire of Aboriginal Peoples to maintain their collective identities and the continuity of their cultures. Researchers must conform to the principles and Articles found in Chapter 9 of the TCPS in conducting research of this kind.

## 3.3 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 participant 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 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 subject is known to exist. When a previously incapacitated participant 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. Because their incapacity to exercise free and informed consent makes them vulnerable, prospective participants for emergency research are owed special ethical obligations and protection commensurate with the harms involved. Their interests, rights, and welfare should be protected by additional safeguards which should include, where feasible and appropriate, one or more of the following:

    a. Additional scientific, medical or REB consultation;

    b. Procedures to identify potential participants in advance to obtain free and informed consent prior to the occurrence of the emergency situation;

    c. Consultation with former and potential participants;

    d. Special monitoring procedures to be followed by safety and monitoring boards; and

    e. Careful review by the REB of the relative harms and benefits of participation.

## ACKNOWLEDGEMENTS

In preparation of this document, the members of the Research Ethics Board of Briercrest College and Seminary wish to acknowledge their reliance on the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. We also wish to acknowledge our reliance on the research ethics policies of McMaster University, Redeemer University College, the University of Regina, and the University of Saskatchewan.