



Ethics in Human Research

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1. Context of these guidelines

Researchers enjoy important freedoms and privileges, which include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the privilege of conducting research on human subjects with public monies, trust and support. Along with these freedoms are the responsibilities to ensure that research involving human subjects meets high scientific and ethical standards, is honest and thoughtful inquiry, involves rigorous analysis, and the application of professional standards. Peer review of research proposals, and the application of these freedoms and responsibilities, contributes to accountability, both to colleagues and to society.

At The Banff Centre, the purpose of ethics review of research involving human subjects is (a) the protection of research subjects, (b) the protection of The Banff Centre, including its members, and (c) the education of those involved in research. The following procedures have been designed to meet these three objectives. In addition, they have been designed (a) to use the resources of The Banff Centre in an efficient manner, (b) to provide an environment that facilitates dialogue on research ethics within The Banff Centre community, and (c) to institutionalize and normalize procedures that draw attention to the need to take into consideration ethical issues in training and research.

The Banff Centre endorses the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. This policy document complements and supplements the Tri-Council Policy Statement for members of The Banff Centre community.

2. Definitions

"Institution" means "The Banff Centre."

"Member" means a member of The Banff Centre community and includes all members of the academic and program staff, support staff, contract and sessional staff, Workstudies, Fellows, program participants, resident artists, and trust employees.

"Academic and Program Staff" includes both teaching and non-teaching staff, part-time or full-time, with or without definite term appointments. Academic and Program Staff also includes Adjunct (as the case may be) and other honorary appointees when carrying out their professorial duties at The Banff Centre.

"Support Staff" means persons covered by the Centre's/CUPE collective agreement and persons designated as "exempt" by virtue of their management or supervisory status.

"Program Participant" means a person registered in course or program of work.

"Workstudy or Fellow" means a person, enrolled in a program at The Banff Centre, who enjoys privileges of access to and use of Centre facilities and services for study, practice, and work. Workstudy and Fellow participants are provided an educational contract that clearly lays out the learning goals and specifies how these goals are to be achieved. Workstudy and Fellow programs are intended to provide the participant with a combination of learning opportunities and supervised, practical work related to the participant's learning objectives. Learning opportunities may be formal sessions and/or workshops or may be informal.

"Trust Employee" means persons paid from funds held in trust or administered by The Banff Centre on behalf of an outside organization.

3. Guiding Ethical Principles

3.1 Researchers contribute to human welfare by acquiring knowledge and applying it to human problems. They simultaneously consider two types of obligations in the design and conduct of research. One of these obligations is to conduct research as capably as their knowledge permits, and another is to protect the dignity and preserve the well being of human research participants.

3.2 Respect for Human Dignity

3.2.1 The cardinal principle of modern research ethics is respect for human dignity. Such respect requires that researchers protect the multiple and interdependent interests of the person - from bodily to psychological to cultural integrity - as they may be affected by the research. This principle forms the basis of the remaining ethical principles described in the following subsections.

Conflicts may sometimes arise from the application of these principles in isolation from one another. Researchers and REBs must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

3.3 Respect for Free and Informed Consent

3.3.1 Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research participant.

3.4 Respect for Vulnerable Persons

3.4.1 Respect for human dignity entails high ethical obligations towards vulnerable persons—to those whose lack of competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

3.5 Respect for Privacy and Confidentiality

3.5.1 Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying privacy, confidentiality and anonymity.

3.6 Respect for Justice and Inclusiveness

3.6.1 Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research proposals, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. On the other hand, distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

3.7 Balancing Harms and Benefits

3.7.1 The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance—that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefit analysis thus affects the welfare and rights of research participants, the informed assumption of harms and benefits, and the ethical justification for competing research paths.

This is not to say that harm may not result from research. In some areas of research such as political science, economics or modern history, there may be occasions in which research ethically results in harm to the reputations of organizations or individuals in public life.

There is often uncertainty about the magnitude and kind of benefits or harms that may result from proposed research and a resultant uncertainty about the balance of benefits and harms. This uncertainty imposes an obligation to conduct research at a high level of competency in order to maximize the potential benefits of the research.

3.8 Minimizing Harm

3.8.1 A principle related to achieving a favorable harms-benefit balance is that of non-maleficence, or the duty to avoid, prevent or minimize harm. Research procedures which might cause serious or lasting harm to a participant must not be used unless their absence would expose the participant to a risk of even greater harm. Research participants must not be subjected to unnecessary risks of harm. Their participation must be essential to achieving scientifically and societally important aims that cannot otherwise be realized. Minimization of harm also requires that research involve the smallest number of human participants and the smallest number of tests on them that shall ensure scientifically valid data. Should adverse effects result from research procedures, the researcher has an obligation to assist the participant in reducing or eliminating those effects.

3.9 Maximizing Benefit

3.9.1 Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize benefits. The principle has particular relevance for researchers in areas such as social work, education, health care and applied psychology. Benefits of research may accrue to the research participants themselves, to other individuals or to society as a whole, or to the advancement of knowledge. In most research, the primary benefits are for society and for the advancement of knowledge.

4. Research Requiring Ethics Review

4.1 Research

For the purpose of these guidelines, research involves a systematic investigation to establish facts, principles or generalizable knowledge.

4.2 Research that Must Receive Ethics Review

4.2.1 All research that involves living human participants or involves human remains, cadavers, tissues, biological fluids, embryos or foetuses requires review and approval by a Research Ethics Board (REB) before the research is started regardless of:

- a. whether it is funded (eg, by grant, award, fellowship, contract) or is non-funded;
- b. whether funding is internal (ie, The Banff Centre) or is from an external source (including domestic and foreign public, governmental, and private sources);
- c. whether participants are drawn from The Banff Centre sources or from any other sources (eg, workplaces, residences, public places, day care centres, hospitals, universities, the military, public/private/separate schools);
- d. whether participants are paid or unpaid;
- e. whether it is conducted inside or outside Canada;
- f. whether it is conducted on The Banff Centre property or at any other location;
- g. whether it is conducted in a laboratory or in the field;
- h. whether it is conducted in person or by some other means (eg, mail, telephone, computer link);
- i. whether information is collected via direct observation, apparatus, questionnaire, interview, or review of records or other materials not normally available to the public;
- j. whether it is experimental, co-relational, qualitative, or descriptive in nature;
- k. whether it is conducted to acquire basic or applied knowledge (eg., safety and function assessments of equipment and materials, product development assessments, personnel selection, consumer preferences, and product evaluation);

- l. whether the information collected has as its focus the human participant or some aspect of the environment with which the human participant interacts;
- m. whether the research is a pilot study or a fully developed project;
- n. whether it is primarily for teaching or demonstration purposes or whether the primary purpose is the acquisition of new knowledge;
- o. whether or not it is intended for publication or other public presentation.

4.3 Research that does not require ethics review

4.3.1 Research about living persons, including persons in public life and artists, based on information contained in publicly available materials is not subject to REB review unless the subject, or a third-party, is approached directly for interviews or for access to private papers or other materials, and then only to ensure that such approaches are conducted according to professional protocols. Note that research involving the observation, assessment, or recording of public behaviour normally does require REB review. However, research involving observation of participants in, for example, political rallies, demonstrations, public meetings or similar activities does not require REB review since it can be expected that the participants are seeking public visibility and therefore observation and possible recording.

4.3.2 Quality assurance studies, performance reviews of an organization, or its employees or students within the mandate of the organization, or testing within normal educational requirements, are not subject to REB review unless they contain an element of research in addition to assessment. Researchers shall seek the advice of the REB whenever there is any ambiguity or doubt about the applicability of these guidelines to a particular project.

4.3.3 Procedures and practices exclusively used for pedagogic purposes (eg, classroom discussion, practicum observation), without a research component are not subject to REB review. Such procedures and practices do require attention to other professional standards of ethical conduct.

5. Authority, Mandate and Membership of Research Ethics Board

5.1 Authority

5.1.1 Authority for the conduct of ethics review for research involving human subjects is contained in this policy, endorsed by the Program Council and approved by the Executive Officers of The Banff Centre.

5.1.2 The Office of the Director of Research is responsible for overseeing the implementation of this policy.

5.1.3 The Director of Research is responsible for ensuring that research involving human subjects undertaken by members of The Banff Centre community is in compliance with the Tri-Council Policy Statement on Research Ethics, and with this policy.

5.1.4 In overseeing the policy on research ethics of The Banff Centre, the Director of Research will be advised by the Research Policy Committee.

5.1.4.1 The Research Policy Committee is composed of a minimum of three members, including the Director of Research (Chair), two senior staff members drawn from any two of the Program Divisions, including Fine Arts, Performing Arts, Leadership Development and Mountain Culture, and other members who are appointed from time to time by the President.

5.1.4.2 The Research Policy Committee shall report to the Executive Officers on an annual basis.

5.1.5 A Research Ethics Board (REB) will be established for the review of proposals to conduct research involving human subjects.

5.2 Mandate

5.2.1 The Banff Centre Research Ethics Board has the mandate to approve, reject, propose modifications to, or terminate any proposed or ongoing research which is subject to REB review. A decision of the REB to allow research on ethical grounds is final. A decision of the REB to disallow research on ethical grounds unless reversed by that REB on reconsideration pursuant to The Banff Centre Standards, may be reversed only through the appeal process described in this policy.

5.2.2 The REB shall suspend any ongoing research under its purview that it deems to pose an unacceptable risk of harm to participants.

5.2.3 Research that has not been submitted to and approved by the REB as required pursuant to this policy cannot be undertaken. Non-compliance with this provision may constitute misconduct under The Banff Centre Policy on Integrity in Scholarly Activity.

5.3 Membership

5.3.1 The Research Ethics Board shall consist of at least five members, including both men and women.

5.3.1.1 Chair, appointed by the President, in consultation with the Vice-President Programming and the Director of Research.

5.3.1.2 At least two members shall have broad expertise in research methodology.

5.3.1.3 At least one member shall be knowledgeable in ethics.

5.3.1.4 At least one member shall have no other formal affiliation with The Banff Centre, and shall be from the community served by The Banff Centre.

5.3.1.5 At the discretion of the REB Chair, temporary members may be appointed on an ad hoc basis, or outside advice and opinions solicited, when special expertise regarding participant populations, research disciplines, methodologies or other matters is required to reach a competent decision.

5.3.1.6 All REB members shall be competent to judge the ethical acceptability of proposals and shall be knowledgeable about The Banff Centre Standards and about the specific procedures of the REB of which they are a member.

6. Review Process

6.1 Proportionate Approach to Ethics Review

6.1.1 The Research Ethics Board adopts a proportionate approach to ethics review based on the general principle that the more invasive the research, the greater will be the care in assessing the research

6.2 Level of Risk

6.2.1 The actual review process followed by the REB varies according to the level of risk posed to research subjects. The level of risk can be identified as minimal risk, or greater than minimal risk.

6.3 Minimal Risk

6.3.1 Consistent with the Tri-Council Guidelines, minimal risk occurs when 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.

6.4 Determination of minimal risk

6.4.1 The determination of minimal risk may be accomplished in one of two ways.

6.4.1.1 The Chair of the REB reviews the proposal and assesses whether greater than minimal risk will be incurred by subjects.

6.4.1.2 The Chair of the REB sends the proposal to three reviewers, who are ad hoc reviewers of the REB, for an initial assessment of the research proposal. If these reviewers identify factors within the research proposal leading to greater than minimal risk, then the Chair must have the proposal reviewed using the regular, and not the expedited, review procedures.

6.5 Regular Review Process

6.5.1 The Research Ethics Board will meet on a regular basis in face-to-face meetings. The meeting schedule will be developed by the Chair of the REB and will be circulated to members of the REB, and posted on the REB webpage for the information of members of the Banff Centre community.

6.5.2 Fifty percent plus one of the members of the REB constitutes a quorum. This quorum should be broadly representative of the character of the full REB.

6.5.3 Research which involves greater than minimal risk will be reviewed by the REB in a face-to-face meeting.

6.5.3 When research proposals involve more than minimal risk, scholarly merit will be reviewed.

6.5.3.1 Evaluation of scholarly merit involves a global assessment of the degree to which the research might further the understanding of the phenomenon being studied. The primary test for scholarly merit is the application of scientific and scholarly standards, regardless of personal biases or preferences.

6.5.3.2 A review of scholarly merit may be conducted at the same time as the ethics review or by a separate committee of qualified peers.

6.5.3.3 When a scholarly review is conducted during the ethics review, the REB must include one member, on an ad hoc basis, with the necessary expertise to carry out a peer review of the research question.

6.6 Record Keeping

6.6.1 Minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document the REB's decisions and any dissents, and the reasons for them. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes must be accessible to authorized representatives of The Banff Centre, researchers and funding agencies.

6.7 Outcomes of the Regular Review Process

6.7.1 Where the Chair is of the opinion that a consensus of the REB exists in favour of granting ethical approval, such approval will be granted in writing, and the research can be initiated.

6.7.2 Where the Chair is of the opinion that a consensus of the REB reveals ethical problems such that ethical approval cannot be granted, the Chair will communicate the problems in writing to the applicant. The Chair will then meet with the researcher(s) to determine if the protocol can be modified to satisfy the concerns of the REB.

6.7.3 Where the researcher believes the protocol cannot be modified to resolve ethical issues s/he has the right to meet with the REB to discuss the ethical concerns.

6.7.4 Where the Chair is of the opinion that a consensus exists against granting ethical approval, and attempts to address the ethical problems are unsuccessful, the REB may disallow or suspend research on ethical grounds. This decision shall be provided in writing to the researcher(s).

6.7.5 Researchers have the right to request, and the REB has the obligation to provide, reconsideration of a negative decision.

6.8 Expedited Review Process

6.8.1 The Chair of the REB will review submitted proposal to assess whether they can be reviewed through an expedited process. Proposals qualifying for an expedited review include those that:

- have been previously approved but require minor revisions;
- involve a replication of a previously approved protocol;
- have been approved by a REB at another institution;
- do not create risks greater than the minimum threshold; and/or
- do not include biomedical elements.

6.8.1.1 If the proposal is a resubmission for review because of minor revisions to the protocol, involves a replication of a previously approved protocol, and/or has been approved by another REB the Chair may approve the application in writing based on his or her review.

6.8.1.2 If a proposal is new or involves significant revisions, does not create risks greater than the minimum threshold and does not include biomedical elements, it is sent to three reviewers who are members of the REB and who serve as ad hoc reviewers for the REB. At least one of the three reviewers must have scholarly expertise in the discipline of the proposal.

6.8.1.3 The reviewers provide a written assessment of the level of risk and any other ethical issues arising from the review.

6.8.1.4 On the basis of the three reviews, the Chair of the REB identifies needed changes to the proposal, assesses the risk level and determines whether the proposal receives expedited clearance or must be submitted for review by the full REB in a face-to-face meeting.

6.8.1.5 If the proposal receives clearance at this stage, the researcher is notified in writing and research can begin.

6.8.1.6 If the Chair believes more than minimal risk is involved and/or biomedical procedures are being used, then the proposal is to be reviewed by the REB in a face-to-face meeting.

6.9 Outcomes of the Expedited Review Process

6.9.1 Where the Chair is of the opinion that a consensus exists in favour of granting ethical approval, such approval may be granted by the Chair without a formal meeting of the REB. The decision is communicated in writing to the researcher(s).

6.9.2 Where the Chair is of the opinion a consensus of the reviewers identifies ethical problems that prevent ethics approval, the Chair will first communicate in writing with the applicant to see if the ethical problems can be addressed satisfactorily. If the ethical problems cannot be satisfactorily addressed the Chair will request, in writing, that the researcher submit the proposal for a full ethics review.

6.9.3 Where the Chair instructs the researcher to submit the proposal for a full review, and the researcher declines to do so and wishes to appeal the refusal, the REB shall hear that appeal in a face-to-face meeting.

6.9.4 Where a research protocol is reviewed through the expedited review process, the Chair must report on the outcome of the review at the next regular meeting of the REB.

6.10 Educational role of REB

6.10.1 It is the responsibility of the REB to ensure the members of the REB have appropriate opportunities to increase their level of knowledge and understanding of ethical conduct in research involving human subjects.

6.10.1.1 The REB shall hold general meetings, retreats and educational workshops in which members can (1) take advantage of educational opportunities that may benefit the overall operation of the REB, (2) discuss any general issues arising out of the REB's activities, or (3) revise policies.

6.10.1.2 The REB shall be responsible for developing an educational program for the research community at The Banff Centre to increase awareness and understanding of ethical conduct in research involving human subjects.

7. Reconsideration and Appeal Process

7.1 If the REB decides against granting ethical approval of a proposal or project, the applicant has the right to request reconsideration, and to appear and to be heard in a meeting with the REB.

7.2 An appeal of a decision of a REB can be made to the Research Ethics Appeal Board.

7.2.1 The grounds for an appeal must be on the basis of an error in process.

7.2.2 The decisions of the Research Ethics Appeal Board are final and binding in all respects for any appeal taken by an affected person or group against the decision of a REB.

7.3 The Research Ethics Appeal Board of the University of Calgary serves as the Research Ethics Appeal Board of The Banff Centre.

8. Conflict of Interest

8.1 If an 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 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.

9. Review Procedures for Ongoing Research

9.1 Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment.

9.2 As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.

9.3 Continuing review shall consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.

10. Review of Research in Other Jurisdictions or Countries, and Multi-centred Research

10.1 Research to be performed outside Canada shall undergo prospective ethics review by (a) by the REB of The Banff Centre; and (b) by the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

10.2 Where research involves collaboration with researchers from other research institutions, the researcher shall advise the REB of ethics reviews of the project at other institutions.

10.2.1 The REB may initiate communication with the REB at the other institution regarding the ethics review of the protocol.

11. Researchers' Procedural Responsibilities

11.1 Submission of Proposals and Projects

11.1.1 It is the responsibility of the researcher(s) to obtain ethical approval for any active project, funded or not, involving human subjects and to submit that project with complete documentation to the REB.

11.1.2 In particular, researchers must be aware that ethical review may in the ordinary course take three weeks to complete. Cases involving significant ethical problems may take substantially longer. It is the researchers' responsibility to ensure that there is adequate lead time available for ethical review in relation to other deadlines.

11.1.3 In supervised research, the term "the researcher" must be defined as including both the supervisor and the individual(s) being supervised.

11.2 Sponsored Projects

11.2.1 Applications for ethics certification may be made before or concurrently with the submission of proposals to Research Services.

11.2.2 The Office of Research will advise applicants on the need for ethics certification and on The Banff Centre and sponsor requirements and procedures. However, it remains the responsibility of the applicant to provide the REB with complete documentation in adequate time.

11.2.3 Official Banff Centre endorsement does not certify ethics acceptability unless a proper certification has been issued by the appropriate REB Chair. Official endorsement will be rescinded if an applicant fails to obtain ethics certification. Sponsors may be informed that ethics certification of an application is pending.

11.2.4 Project funds will not be accepted and/or released to the project principals until ethics certification is issued and a copy is on file in the Office of Research.

12. Guidelines – Risks and Benefits

12.1 Researchers' Responsibilities

12.1.1 The researcher must assess all possible risks involved in and benefits expected from the research.

12.1.2 The researcher must be prepared to document all risks and benefits involved.

12.1.3 The researcher must be prepared to demonstrate that there is no reasonable alternative methodology that would avoid or reduce possible risks.

12.1.4 Where appropriate in light of the risks involved, the researcher may be required to demonstrate successful prior first-hand experience with the methodology proposed and the absence of detriment to the subjects involved.

12.1.5 The researcher proposing to use a new methodology must undertake wide consultation and preliminary work, and must be prepared to make the results available to the REB.

12.2 Risks

12.2.1 Risks that go beyond the threshold of minimal risk, including both identifiable and unforeseen risks must be considered.

12.2.2 The researcher must be concerned with risks to:

- the subjects involved;
- clearly identifiable third parties;
- the researcher personally and any staff involved; and
- broader cultural, ethnic and national interests.

12.2.3 The researcher must be concerned with at least the following types of risk:

- physical harm;
- psychological harm;
- injury to reputation or privacy; and
- breach of any relevant law.

12.2.4 The researcher must assess not only the likelihood of a given risk, but also the duration and likely reversibility of its impact should it materialize.

12.3 Benefits

12.3.1 'Benefits' include specific advantages to subjects, to third parties or to society or a segment thereof, and any general increase in human knowledge.

12.3.2 'Benefits' include advantages or increases in knowledge both consciously sought by the researcher and likely to arise as byproducts of the research.

12.4 Balancing Risks and Benefits

12.4.1 It is always the responsibility of the researcher, and of the REB, to ensure that the projected benefits outweigh the possible risks.

12.4.2 The more incalculable the risks or the less tangible the benefits, the more cautious must be the researcher and the REB.

12.4.3 The REB must ensure that the research design and proposed implementation procedures are consistent with sound research standards and, where appropriate, with sound standards of professional conduct and practice, in order to be satisfied that there is no unnecessary exposure to risk.

12.4.4 The REB must always be conscious of the importance of academic freedom for the researcher, particularly where risks are minimal or are the subject of informed consent, or will devolve upon the researcher personally.

13. Guidelines – Free and Informed Consent

13.1 Nature of Free and Informed Consent

13.1.1 The objective of obtaining free and informed consent is to ensure adherence to the ethical principle of respect for persons. The elements of consent that must be considered are capacity, comprehension, and voluntariness.

13.1.1.1 Free and informed consent must always be provided in advance of the subject participating in the research project.

13.1.1.2 Subjects must maintain their free and informed consent throughout the duration of their participation in the research. Free and informed consent may be withdrawn at any time, without penalty by the subject.

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

13.1.2 The subject or surrogate who is to give informed consent must be given sufficient time and opportunity to consider the information provided, including the opportunity to consult with an advocate or other knowledgeable person, depending on the discipline in question or to the risks involved.

13.1.3 The researcher must provide any person who is to give informed consent with at least the following information:

- that research is involved;
- that they may withdraw from the research, without penalty, at any time;
- the identity of the researcher;
- a description of the topic being researched;
- a precise description of the subject's involvement;

- a description of the research procedures;
- a description of the possible benefits involved;
- a description of the risks or discomforts involved;
- a description of the likely consequences of non-participation if the research is therapeutic;
- where a possible benefit is to be conferred on the subject, a description of any reasonably available alternative means for delivering substantially the same benefit to the subject;
- an assurance that exemplary care will be taken to safeguard the subject;
- a description of the extent to which privacy and confidentiality will be protected;
- 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;
- a description of how the data will be stored and/or when it will be destroyed; and
- a contact name, telephone number, and address of an individual in the office of the Director of Research.

13.1.4 When more than minimal risk is involved, the researcher must provide a description of the available mechanisms of compensation, if any, should a risk materialize.

13.1.5 The researcher must ensure that prospective subjects understand that their consent may be withdrawn without penalty.

13.2 Format of Consent

13.2.1 Consent in any format must demonstrate that there has been compliance with the foregoing requirements.

13.2.2 Written consent shall be dated and signed by the subject. While there is no prescribed form, specimen forms are attached and may be used, with appropriate modifications, whenever feasible.

13.2.3 All consents shall be in writing for projects or proposals involving greater than minimal risk and/or biomedical procedures unless a REB specifically authorizes in advance the use of another format in a particular case.

13.2.4 Subject to 13.2.3 above, consent may be tape-recorded or oral.

13.2.5 Where consent is tape-recorded, the recording shall clearly identify the subject, the researcher and the date. It is the researcher's responsibility to propose arrangements for preserving the tape in order to prevent alteration or erasure.

13.2.6 Where consent is oral, the researcher must make a record of it in an appropriate log or book dated and signed by the researcher.

13.2.7 Where appropriate to the discipline in question or to the risks involved, a neutral witness should be identified as being present when the consent is given.

13.3 Special Research Circumstances

13.3.1 'Special Research Circumstances' include the following:

- therapeutic research in emergency circumstances;
- research capable of impacting physically on a foetus;
- research capable of impacting physically or psychologically on pregnant women;
- research involving human in-vitro fertilization;
- research involving children and mentally incompetent persons;

- research involving prisoners; and
- research involving 'captive groups' such as employees, students, legal wards and the therapeutically dependent.

13.3.2 In all cases involving 'Special Research Circumstances', the researcher must consult with the REB to obtain details of any specific additional requirements for informed consent.

13.3.3 In all cases involving 'Special Research Circumstances', informed consent must be in writing, save that the REB may authorize other formats in cases involving 'captive groups'.

13.3.4 In cases involving children or mentally incompetent persons, the written consent must be signed by a person having legal authority to give that consent.

13.3.5 In cases involving 'captive groups', informed consent shall be obtained from each individual subject, save that the REB may grant a total or partial exemption from this requirement when it is satisfied:

- that it is impracticable to require that such individual consents be sought;
- that the risks to the subjects involved are minimal; and,
- that 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.

13.4 Where free and informed consent is not required

13.4.1 The requirement for free and informed consent may be waived if:

- the research involves no more than minimal risk to subjects;
- the waiver is unlikely to adversely affect the rights and welfare of the subjects;
- the research could not be practically carried out without the waiver;
- wherever possible and appropriate subjects will be provided with additional pertinent information after participation; and
- the waived consent does not involve a therapeutic intervention.

13.5 Subjects who are not legally competent

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

- the research question can only be addressed using individuals within the identified group(s); and
- free and informed consent will be sought from their authorized representative(s); and
- the research does not expose them to more than minimal risk without the potential for direct benefits for them.

13.5.2 For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met;

- 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;
- the authorized third party may not be the research or any other member of the research team;
- the continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally competent subject in research, so long as the subject remains incompetent;

- 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.

13.5.3 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.

13.6 Research in Emergency Health Situations

13.6.1 In view of the mandate of The Banff Centre, research in emergency health situations is not permitted by members of The Banff Centre community.

14. Guidelines – Deception

14.1 Definition of Deception

14.1. 'Deception' involves any research procedure which does not include, or which alters, some or all of the elements of informed consent as described in section 9. Typically this involves either the deliberate withholding of relevant information or the deliberate giving of false information as part of the methodology of research.

14.2 Exceptions to Full and Informed Consent

14.2.1 An REB may approve an incomplete and/or deceptive consent procedure if, after rigorous scrutiny, all of the following conditions are satisfied:

14.2.1.1 The research involves minimal risk to the participants, and minimal levels of risk are documented.

14.2.1.2 Participant rights and welfare are not adversely affected by the procedure.

14.2.1.3 The research could not practically be carried out without the deception. Researchers must:

- justify their use of the procedure, identifying the manner(s) in which the benefits of the deception outweigh the potential costs;
- demonstrate the inappropriateness of alternative research methods;
- document precedents for using the proposed methodology in their application.

14.2.1.4 Participants must be fully debriefed immediately following their involvement. This debriefing must include all pertinent information in which the exact nature of the deception and its necessity are clearly and fully articulated. A detailed written debriefing scenario, that fully explains the manipulation and its need to the participant, must be submitted as part of the application. Researchers must also provide an explanation of how potential negative effects will be handled.

14.2.1.5 Participants must be given the opportunity to withdraw from the study if, after debriefing, they feel they would not have participated had they known about the deception.

14.2.1.6 The proposal does not involve a therapeutic intervention.

15. Guidelines – Privacy and Confidentiality

15.1 Privacy

15.1.1 'Privacy' involves the right to decide the extent to which personal data that is not already in the public domain may be disseminated.

15.1.2 'Personal data' includes all information relating to a physical or mental condition; personal attitudes, values, concerns, habits or circumstances; social relationships.

15.1.3 Privacy must be looked at from the cultural perspective of the subject, not the researcher.

15.1.4 It is a requirement of informed consent that a subject be informed both of any anticipated acquisition of personal data by observation or study in a private setting and of the extent to which privacy will be protected.

15.2 Confidentiality

15.2.1 'Confidentiality' involves the preservation of a subject's anonymity and the respecting of guarantees of privacy or confidentiality given to others whose data are to be used.

15.2.2 Confidentiality must be preserved when handling the data during the research, when using the data in teaching or for scholarly presentations, and in publication.

15.2.3 The research design must include procedures appropriate to securing the degree of confidentiality guaranteed.

15.2.4 Confidentiality is assumed to be guaranteed in the absence of a clear statement to the contrary.

15.2.5 It is a requirement of informed consent that any anticipated breach of confidentiality be clearly explained by the researcher to the subject.

15.2.6 Appropriate care must be taken to guard against unintended breaches of confidentiality. In particular, where an unintended breach can be anticipated due to the nature or size of a subject population, association or combination of information, the researcher should deal with this risk accordingly.

15.2.7 Where the researcher either uses existing data maintained in computerized form or in data banks or institutional records, or proposes to place data in any such system, the researcher must keep in mind that the format may make it impossible to get prior consent for the use of such data.

15.2.8 The researcher must always be concerned about risks to third parties arising from the use of confidential material.

15.2.9 Researchers are responsible for ensuring the confidentiality of data on human subjects by maintaining such data in secure storage and by limiting access to data to authorized individuals.

15.2.10 Upon completion of data analysis, researchers are responsible for ensuring the confidentiality of data on human subjects by destroying, or having suitably destroyed, papers, documents, tapes, questionnaires, etc., collected on these subjects. If any of the research records are to be held for future analysis, secure storage must be provided.

16. Approval

16.1 This policy was approved by the Program Council of The Banff Centre on (July 31, 2006), and by the Executive Officers of The Banff Centre on (August 15, 2006).