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Conestoga College Institute of Technology and Advanced Learning

G_9 Ethical Conduct in Research Involving Humans

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PREAMBLE

Research involving humans as participants is essential to advancing knowledge, understanding, and human welfare. Such research is a critical aspect of the work of Conestoga College Institute of Technology and Advanced Learning (CCITAL) and its academic programs. College researchers are profoundly grateful to those who volunteer to participate as subjects and make research possible. Balanced against the need for research is a moral imperative to conduct human research in an ethical manner that both respects human dignity and requires that the welfare and integrity of the individual remains paramount.

The rights and welfare of all who contribute to the advancement of learning by their participation as subjects are of prime importance to CCITAL. In addition, most external agencies require an institutional ethical standards review of the proposed research as a condition of the application for research funding. Research with humans is also constrained in various ways by Canadian laws and human rights legislation. Formal responsibility for ensuring the rights and welfare of human subjects is delegated to CCITAL Research Ethics Board which evaluates all research within a framework of Guiding Ethical Principles set out in the policy statement of the three federal granting councils (CIHR, NSERC, SSHRC)[1] also known as the Tri-Council Policy Statement (TCPS), namely:

- Respect for Human Dignity
- Respect for Free and Informed Consent
- Respect for Vulnerable Persons
- Respect for Privacy and Confidentiality
- Respect for Justice and Inclusiveness
- Balancing Harms and Benefits
- Minimizing Harm
- Maximizing Benefit

[1] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.* 1998 (with 2000, 2002 and 2005 amendments).

(Researchers are encouraged to consult the tri-council document for an expanded discussion of these principles although they should note that this discussion does not constitute a binding interpretation of them. For a complete copy of the TCPS, see: http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm)

CCITAL is confident of the high personal and professional standards of ethics observed by the members of its research community. The policy described herein is designed to support and reinforce those standards and to provide the formal mechanism for approval by the College of academic programs involving human participants.

SCOPE

The Policy on Ethical Conduct in Research Involving Humans shall apply to the involvement of human subjects in all College research projects whether funded or unfunded. In addition, the policy shall apply to research conducted by private organizations involving the use of College facilities or equipment under an agreement with the College. The College shall have only one Research Ethics Board (REB).

DEFINITIONS AND INTERPRETATION

Principal Investigator (P.I.), Locally Responsible Investigator (L.R.I.), Co-investigator (C.I.).

The Principal Investigator is the individual who assumes primary responsibility for the scientific and ethical conduct of the research study as described in the CCITAL REB signature form (link). The P.I. might be a CCITAL faculty member or professional staff member who is carrying out an research project or who is supervising a student engaged in a research project. The P.I. might also be from another educational institution or from the community.

When the P.I. is not a Conestoga College ITAL faculty or staff member, he or she is required to work with a Locally Responsible Investigator. The L.R.I. is a Conestoga College ITAL faculty or staff member who will act as a liaison to the P.I. as described in the CCITAL Institutional Approval to Conduct Research/LRI form (link).

Co-investigators are other individuals working with the P.I. to carry out the research project.

The P.I., the L.P.I. and any co-investigators are also known as researchers.

Application

The description of the project that is submitted to the College Research Ethics Board is called the application.

Minimal Risk

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 his/her everyday life that

relate to the research, then the research can be regarded as within the range of minimal risk.

Delegated Review

A process whereby applications for projects of minimal risk are reviewed by designated member(s) of the Research Ethics Board.

1. GENERAL POLICY

1.1. The policies, procedures, and standards guidelines adopted by the College are binding upon all researchers. Primary responsibility for ensuring that these policies and procedures are adhered to rests on the Principal Investigator.

1.2. All research that involves living human participants, research involving human remains, cadavers, tissues, embryos, or foetuses and biological fluids, requires review and approval by the College Research Ethics Board (REB) in accordance with this policy, before the research is started, except as stipulated below:

1.2.1. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo review by the College Research Ethics Board. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 9.6 of this Policy.

1.2.2. Quality assurance studies, performance reviews or testing within normal educational requirements are not subject to College Research Ethics Board review.

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

1.3. Nothing in this policy should be interpreted as relieving a researcher of any obligations he/she has acquired as a result of his/her membership in a professional association; however, adherence to a professional code of ethics does not in itself satisfy the obligation to observe the procedures set out here, where they normally would apply.

1.4. The College Research Ethics Board created to implement this policy has the discretion to introduce flexibility in applying the standards guidelines, where exceptional circumstances or common sense dictates, provided that the basic principles underlying the policy are not compromised.

2. COLLEGE RESEARCH ETHICS BOARD (REB)

2.1. The College Research Ethics Board shall constitute a standing committee of the Research Board.

2.2. Membership

2.2.1. The College Research Ethics Board shall consist of at least five members including both men and women of whom:

2.2.1.1. At least two members who have broad expertise in the methods or in the areas of research that are covered by the REB at the College;

2.2.1.2. At least one member is knowledgeable in ethics;

2.2.1.3. One is a lawyer, who is not the College legal counsel. For biomedical research, the member should be knowledgeable in the relevant law;

2.2.1.4. At least one member has no affiliation with the institution but is recruited from the community served by the institution.

2.2.2. Members of the REB under 2.2.1.1., 2.2.1.2., and 2.2.1.3 should contain a majority of those whose main responsibilities are in research or teaching. As the size of the REB increases beyond the minimum of five members, the number of community representatives should also increase.

2.2.3. The role of the member knowledgeable in the applicable law is to alert the REBs to legal issues and their implications, not to provide formal legal opinions nor to serve as legal counsel for the REB.

2.2.4. In the event that the REB is reviewing an application that requires a particular community of research representation, or an application that requires specific expertise not available from its regular members, the REB Chair should nominate appropriate ad hoc members for the duration of the review. Should this occur regularly, the membership of the REB should be modified.

2.2.5. The Chair of the REB shall be elected by the members of the REB from among the College members of the REB (2.2.1.1). The term is three years, renewable once. The Chair shall sign the Certification of Ethical Acceptability of Research Involving Human Participants. The Vice Chair of the REB shall be elected by the members of the REB from among the College members of the REB (2.2.1.1). The term is one year and is renewable. The duties of the Vice Chair shall be to, in the absence of the Chair, sign the Certification of Ethical Acceptability of Research Involving Human Participants and chair the full board meeting of the REB. The position of Vice Chair is not a prerequisite for the position of the Chair, nor is it intended as a long-term replacement for the Chair. In such a circumstance, an Acting Chair must be appointed.

2.2.6. The Chair of the REB shall be free to ask experts outside the REB to provide advice to the REB on particular applications.

2.2.7. The Research Ethics Coordinator (REC) shall be the Secretary and a non-voting member of the REB. The REC shall report to the Director, Applied Research.

2.2.8. Membership in the REB will be for a three-year term, but members may be re-appointed to a maximum of two consecutive terms.

2.2.9. As faculty vacancies arise, the Chair of the Research Board will ask Executive Deans of the Schools to nominate faculty members to the REB.

2.2.10. As community vacancies arise, the REB members and/or the Vice-President, Applied Research will nominate members.

3. AUTHORITY OF THE REB, FUNCTIONS AND RESPONSIBILITIES:

3.1. The REB shall approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted within, or by members of, the institution, using the considerations set forth in the TCPS Policy as the minimum standard. Conestoga will provide the appropriate financial and administrative independence to the REB to fulfill its primary duties. Conestoga may not override negative REB decisions reached on grounds of ethics without a formal appeal mechanism as set out in this Policy. The REB will review only applications submitted with a duly executed Institutional Approval to Conduct Research form. Conestoga may refuse to allow certain research within its jurisdiction.

3.2. REB approval is required for all research whether the research is funded or unfunded.

3.3. The approval of the REB under 3.1 shall constitute ethics approval of the College where required by a funding agency or sponsor.

3.4. The REB shall review applications submitted for research projects in order to ensure that such projects, in their involvement of human participants, will meet the ethical standards adopted by the College.

3.5. The REB shall meet regularly to discharge their responsibilities. The REB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions.

3.6. While review by the full REB shall be the normal practice, in the following situations, a delegated review may be carried out on behalf of the full REB by one or more members who are designated by the Chair:

i. where, in the opinion of the Chair, the research involves only minimal risk;

ii. annual reviews of approved projects in which there has been little or no change in the ongoing research.

3.7 If a delegated review mechanism is undertaken, such approvals shall be reported in appropriate ways to the full REB, permitting the REB to maintain surveillance over the decisions made on its behalf. Principles of accountability require that, regardless of the review strategy, the REB continue to be responsible for the ethics of all research involving human participants that is carried out within the institution.

3.8 Decisions requiring a full review should be adopted only if the members in attendance have the sufficient background and expertise to conduct the review(s) required.

3.9 As part of its review, the REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research. The REB shall assume that this is so for:

i. a project that has received support from an internal or external sponsor that utilizes peer review;

ii. a student research project that has been approved by a faculty member and/or departmental chair.

For other projects, the REB shall arrange for peer review of the research but shall not, itself, act as a peer review committee (see also 7)

3.10 As part of the approval, the REB shall require a project to be monitored in such a manner as it deems appropriate. Monitoring will require, at a minimum, an annual statement from the Principal Investigator that the protocol remains unchanged from that originally approved.

3.11 In the event that a minority within the REB membership considers a research project to be unethical, even though it is acceptable to a majority of members, an effort should be made to reach consensus. Consultation with the researcher, external advice, and/or further reflection by the REB may be helpful. If disagreement persists, a decision will be made according to 3.12.

3.12 If the REB can not reach consensus, despite its best efforts, a majority vote shall decide the issue. A quorum for this vote shall be 50% plus one of the members present. In such instances, the position of those disagreeing may be communicated to the researcher. The Chair should monitor the REB's decisions for consistency, ensure that these decisions are recorded properly, and ensure that researchers are given written communication of the REB's decisions (with reasons for negative decisions) as soon as possible.

3.13 The REB will clarify and interpret the policies, procedures, and standards guidelines where necessary and may recommend changes to the Research Board and provide information to faculty as appropriate.

3.14 Except as they are expressly set out here, the College Research Ethics Board shall develop its own procedures.

3.15 If a 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.

4. REQUEST FOR REVIEW

4.1. The Principal Investigator shall initiate a request for approval of a College research project involving human participants (1.2) by submitting the completed application and all relevant attachments (5.1) to the Office of Applied Research. The P.I. submits the Institutional Approval to Conduct Research form (link) to show that the research project has received prior approval of appropriate College administration. It shall be the responsibility of the P.I. to submit this material sufficiently in advance of the start of the project or the granting agency deadline, as appropriate, to permit the REB to carry out the review and to allow time for any requested revisions to the protocol to be made.

5. APPLICATION and RESEARCH PROTOCOL

5.1. The application form (entitled ***Application to Involve Human Participants in Research***) available from the Office of Applied Research, will include:

5.1.1. the name, department, and contact information of the Principal Investigator, Locally Responsible Investigator, and all Co-Investigators, title and commencement date of the project;

5.1.2. a summary of the proposed project, its purpose and methodology, including copies of any instruments to be used;

5.1.3. a description of the participant group, and how participants will be enlisted, along with notice of any institutions that will serve as participant sources;

5.1.4. A detailed description of the procedures in which the participant will take part;

5.1.5. An assessment of the anticipated risks and benefits involved in the project;

5.1.6. A statement of information to be afforded the participant, and of the method of providing it, with sample written forms, if any; if the participant will not receive complete and accurate information, a statement demonstrating compliance with the special standards set out in Section 9;

5.1.7. A statement of the competence of the participant to give consent, and of the method of obtaining consent, including the consent form, if any;

5.1.8. A description of the methods to be adopted to protect the right of the participant to privacy, anonymity, and confidentiality of data;

5.1.9. A description of the feedback to be given to the participant.

5.2. The full and detailed plan for the research project as outlined in 5.1 is known as the research protocol.

6. REVIEW BY THE COLLEGE RESEARCH ETHICS BOARD

6.1. The REB shall adopt a proportionate approach to ethics assessment based on the general principle that the more invasive the research, the greater should be the care in assessing the research.

6.2. Minutes of all meetings of the College Research Ethics Board clearly documenting the REBs decisions and any dissents, and the reasons for

them, shall be prepared and maintained by the REB. 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 institution, researchers and funding agencies.

6.3. The College Research Ethics Board shall meet face-to-face to review an application that is not assigned to delegated review. The REB review shall be based upon fully detailed research applications, or, where applicable, Renewal/completion reports. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but not be present when the REB is making its decision. When the REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

6.4. The College Research Ethics Board shall provide to researchers appropriately documented opinions and decisions.

6.5. Where a project involves researchers at other institutions, the REB shall coordinate as required with the Research Ethics Boards at those institutions. Research to be performed outside the jurisdiction or country of the institution that employs the researcher shall undergo prospective ethics review both (a) by the REB within the researcher's institution; 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.

6.6. Researchers shall have the right to request, and the REB shall have an obligation to provide, reconsideration of decisions by the College Research Ethics Board affecting their applications.

6.7. Where the Principal Investigator and the College Research Ethics Board cannot reach agreement through discussion and reconsideration, and the P.I. wishes to appeal the decision of the REB, he/she shall so notify the Chair of the College Research Ethics Board and the Chair of the Research Board (see 8).

6.8. Where a Principal Investigator contemplates substantially altering any element of a research protocol for which an application was approved, either before or after commencement of the project, the researcher will submit a Change Request form and consult with the Chair of the REB about the alteration. It is within the discretion of the Chair to refer the matter for the opinion of the REB, or to approve it on his/her own authority. It is recognized that the P.I. must exercise professional discretion in determining whether a contemplated alteration is substantial; however, any change that imports deception or risk, or reduced protection of the participant's anonymity, or the confidentiality of data collected, is deemed to be substantial for the purposes of this policy and in such a case the proposed change will be referred to the College's Research Ethics Board (see also 3.10).

7. PEER REVIEW

7.1. Where the REB requires a separate peer review of the research which would involve human subjects (3.9) the REB will seek a written

assessment of the scholarly merit of the project from at least one expert in the discipline in question who is arms-length from the project under review. The project researchers shall be given an opportunity to suggest appropriate reviewers (see also 3.9).

7.2. The project researchers are encouraged to provide any relevant information to the REB.

8. APPEALS COMMITTEE

8.1. In cases when a researcher wishes to appeal a negative decision of the REB following reconsideration, the institution shall permit review of an REB decision by an Appeals Committee, provided that the Appeal Committee follow the membership and procedures as outlined in this Policy, and in conformity with Article 1.3 of the TCPS. No ad hoc appeal committees are permitted.

8.2. Written appeals must be made within 30 days of receipt of the written decision of the REB to the Chair of the Research Board. The appeal letter must contain all supporting documentation and be signed by the Principal Investigator.

8.3. The role of the Chair of the Research Board in the appeal process will be that of an administrator. The Chair will be responsible for convening the appeals committee and ensuring that the appeals committee meets the requirements as set out in 8.1

8.4. The Chair of the Research Board shall transmit to the Appeals Committee the full documentation on the application under appeal.

8.5. The Appeals Committee, by majority vote, may confirm or modify the decision of the College Research Ethics Board and may impose its own conditions for approval of the project, or for its continuation.

8.6. The decision of the Appeals Committee is final and will be communicated promptly in writing to the applicant.

8.7. The deliberations of the Committee will be held in camera.

8.8. Current members of the REB shall not be eligible for membership on the Appeals Committee.

9. FREE AND INFORMED CONSENT

9.1. Research governed by this policy may begin only if (1) prospective participants, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and information consent has been given and is maintained through their participation in the research. Articles 9.3, 9.6 and 14 provide exceptions to article 9.1

9.2. Evidence of free and informed consent by the subject or authorized party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.

9.3. 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:

9.3.1. The research involves no more than minimal risks to the participant.

9.3.2. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects.

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

9.3.4. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation, and

9.3.5. The waived or altered consent does not involve a therapeutic intervention.

9.4. In studies including randomization and blinding in clinical trials, neither the research subjects not 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.

9.5. Voluntariness

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

9.6. Naturalistic Observation

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

9.7. Informing Potential Participants

9.7.1. Researchers shall provide, to prospective participants or authorize third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in 9.3, at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective participants with the following:

9.7.1.1. A researcher will identify himself/herself (and the Principal Investigator if that researcher is not the P.I.) to the subjects. He/she will identify his/her association with the College, and his/her status as faculty member, student or technician, and indicate to the prospective

participant that they are being invited to participate in a research project;

9.7.1.2. A comprehensible statement of the research purpose and its usefulness, the nature of the research, the expected duration;

9.7.1.3. The nature of their participation and a description of the research procedures in which she/he will personally be asked to participate;

9.7.1.4. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequence of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical, psychological, or social harm;

9.7.1.5. An assurance that prospective participants 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;

9.7.1.6. The methods for protection of confidentiality and anonymity that will be observed by the P.I. and his/her colleagues in respect of the individual's participation as well as the legal limitations to anonymity and confidentiality (see 15); and

9.7.1.7. The possibility of commercialization or publication of research findings, and the presence of any apparent or actual or potential conflicts of interest on the part of researchers, their institutions or sponsors.

9.8. Where appropriate the participant should also be informed of:

9.8.1. The anticipated benefits of participation to himself/herself;

9.8.2. the social benefits that are anticipated, and to whom they accrue;

9.8.3. the anticipated risks to a larger social group or a third party;

9.8.4. the extent to which risks in the project have been pre-tested, and whether the project that the individual will participate in differs from pre-tested practice;

9.8.5. the possibility that the data from this research project may be stored and used for a different purpose in future without obtaining a new consent from the participant, if this is the case;

9.8.6. the availability of the results of the research project from the Principal Investigator when they are published;

9.8.7. the availability of further information from the Principal Investigator;

9.8.8. the name of the chair of the College Research Ethics Board to whom comments on the project may be directed.

9.9. Where the participant is a child or a legally incompetent person, full information must be provided to the legal guardian. The Principal Investigator must also demonstrate that the participant himself/herself will receive a simple explanation of the elements set out in 9.7.1.2, 9.7.1.3, 9.7.1.5, at a minimum. In any event, in the case of legally incompetent participants, dissent is to be considered as a refusal to participate even if a third party has consented on behalf of the participant.

9.10. Except where the Principal Investigator justifies an alternative method, the information set out in 9.7 and 9.8 will be presented to the participant in writing, as part of the consent form. 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

v. the waived or altered consent does not involve a therapeutic intervention.

9.11. Where the Principal Investigator justifies presenting the information set out in 9.2 and 9.3 to the subject orally, the person who presents the information will refer to a printed copy of the information.

9.12. The researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation.

10. DECEPTION OF PARTICIPANT

10.1. Where it is necessary to withhold or to misrepresent significant facts in informing the participant, such deception must be expressly justified by the Principal Investigator in his/her application. In particular, the application must demonstrate:

10.1.1. that the deception is indispensable to the effectiveness of the project;

10.1.2. that the deception must extend to all the elements as proposed;

10.1.3. that all alternative investigative methods are significantly less satisfactory;

10.1.4. that the deception will not invalidate any aspects of informed consent that would influence participants' willingness to participate (e.g. length of the study, procedures to be followed);

10.1.5. that the participant will be fully informed of all elements of the project that were withheld or misrepresented to him/her, by a member of the research team in person, as soon as possible after his/her participation in the research project has been completed.

10.2. No project application will be approved where deception underplays the risk to participants or in itself creates a substantial risk to the participant's self-esteem and dignity.

11. CONSENT OF PARTICIPANT

11.1. A person must voluntarily give express consent (free of coercion, constraint, inducement, manipulation, or undue influence) to take part in any College research project as a human participant with information in his/her possession adequate to evaluate the anticipated risks and benefits inherent in his/her participation in the project. Their free and informed consent must be maintained throughout their participation.

11.2. A person is legally incompetent when he/she cannot be legally bound by his/her own action, as with a person under 18 years of age, or a person of limited mental capacity because of senility or disorder. In cases where the participant is legally incompetent, consent must be obtained from the legal guardian, except where the College Research Ethics Board, in its discretion, allows otherwise (see 1.4). In cases of legally incompetent participants, dissent is to be considered as a refusal to participate even if a third party has consented on behalf of the participant. Unless the researcher has justified oral consent in his/her application, consent shall be given in writing.

11.3. It is preferable that the information and consent forms be integrated; where this is not possible, the following elements of information must appear on the consent form;

11.3.1. the name of the College and name of the Principal Investigator and Locally Responsible Investigator (if applicable);

11.3.2. a brief but explicit description of the procedures in which the individual personally will participate;

11.3.3. an explanation that the participant is free to withdraw from the research project at any time, without penalty or explanation, even after he/she has given consent and the project has commenced;

11.3.4. a comprehensive description of reasonably foreseeable harms and benefits, both to the participants and in general.

11.4. When appropriate, it is recommended that the consent form contain a general statement indicating that the participant understands that the nature of the research may make it impossible for him/her to be informed completely of the nature and purpose of the procedures to be followed, but that he/she will be fully informed when his/her participation has been completed.

11.5. Remuneration for participation as a subject in a College research project, if any, will be based on the time required of the participant and the

inconvenience caused him/her and will not be sufficient to induce the individual to disregard any risks inherent in his/her participation.

11.6. Where the participant group is a captive population such as populations of correctional institutions or hospitals, provision must be made in the protocol for receiving the consent of the institutional authority and of the individual participant and/or his/her legal guardian.

11.7. Where the research subject may be an entire community, especially a community with a culture distinct from that of the mainstream, the Principal Investigator must demonstrate in his/her protocol effective measures to obtain consent and approval of the project by recognized spokespersons for the community, as well as the consent of individual participants.

12. COMPETENCE:

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

i. the research question can only be addressed using individuals within the identified groups(s); and

ii. free and informed consent will be sought from their authorized representative(s); and

iii. the research does not expose them to more than minimal risk without the potential for direct benefits for them.

For research involving incompetent individuals, the REB shall ensure that, as a minimum the conditions laid out in Article 2.6 of the TCPS are met.

13. RISKS AND BENEFITS

13.1. It is the responsibility of the Principal Investigator to demonstrate in his/her application, where appropriate:

13.1.1. that a careful analysis of the direct and indirect risks to human participants of the proposed research, however remote, has been made, particularly where the participant population displays vulnerability by reason of factors such as age or mental capacity;

13.1.2. that consideration has been given to the risk of damage or offense to third parties who may identify with subject individuals and groups for racial, cultural or sexual reasons, and to public sensitivity at large;

13.1.3. that whenever the methodology proposed creates foreseeable risk, the Principal Investigator or the person authorized by him/her to carry out the research has had previous experience with application of the methodology.

13.2. The REB reviewing the application has the duty to decide:

13.2.1. whether the Principal Investigator has explored the risk area sufficiently in his/her protocol;

13.2.2. whether the benefits to the participant himself/herself and the importance of the knowledge to be gained for society outweigh the risks inherent in the project;

13.2.3. whether risks have been minimized and provision made to remedy any harm;

13.2.4. whether the consent the participant will give encompasses all foreseeable risk factors.

13.2.5. Procedures involving physiological intrusions of clear medical concern will be performed by a medically authorized person.

13.2.6. No methodology will be approved whose object is long-term behavioral change to the participant, unless such change is directly beneficial to that individual.

13.2.7. The REB reviewing the application will observe caution in approving any methodology that stimulates negative behaviour, such as anger, aggression, and racial antagonism.

14. RESEARCH IN EMERGENCY HEALTH SITUATIONS

14.1. Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if ALL of the following apply:

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

14.1.2. 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

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

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

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

14.1.6. 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, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

15. PRIVACY OF PARTICIPANTS

15.1. The College recognizes and supports the freedom of persons and communities to reveal or withhold all information about themselves not

already in the public domain by deliberate, fully informed decisions, and with the assurance that the participant's anonymity will be protected and all records of his/her participation in a College research project will be kept confidential. Such assurance is subject to the constraints of Canadian Law (see 16.5).

15.2. The Principal Investigator in his/her protocol must account for differing sensibilities among participant groups in the matter of invasion of privacy especially if the participant group is a particularly vulnerable one, or if the background of the group is radically different from that of the researcher.

15.3. The REB reviewing the application will closely examine the proposed use of institutional records in a project. The REB will consider the potential invasion of the privacy of the individuals whose records are to be used, and the advisability of obtaining consent from those individuals as well as from the institutional authorities.

15.4. Consideration must be taken of the privacy of third parties where the participant will be asked to disclose information or opinions about such third parties.

15.5. Mechanical methods of observations, such as TV cameras, microphones, tape recorders, and one-way mirrors, may be used only with the consent (obtained prior to participation or post debriefing) of the participant and/or his/her legal guardian. Where a participant has been recorded, the participant must be given the opportunity to call for erasure of the recording when his/her participation is complete. Any disclosure of a mechanical recording to persons who are not involved in carrying out the project (for instance, as an audio-visual demonstration) must be expressly consented to by the participant.

15.6. Use of student records will be consistent with the College Policy on the Freedom of Information and Protection of Privacy Act/Confidentiality.

15.7. Location of a College research project on private property must be disclosed in the application and approved in advance by the property owner. Shopping malls and stores are private property.

15.8. A College researcher who is given access to a government or community institution or agency has a responsibility not to make public exposure of conditions or practices with which he/she disagrees without first reporting them to the responsible authority and giving reasonable time for an investigation to be made and a decision reached.

16. ANONYMITY OF PARTICIPANTS AND CONFIDENTIALITY OF DATA

16.1. Except where the participant or legal guardian has expressly consented otherwise in writing, the participant's anonymity will be strictly protected and all data collected will remain absolutely confidential. Where the participant has given written consent to disclosure, information may be disclosed only within the strict limits of the terms of the consent.

16.2. It is the responsibility of the Principal Investigator to describe positive measures to be taken to preserve the anonymity of the research participant, both in the published results of the project, and in the records retained by the College and the P.I.

16.3. Where confidential data will be stored for possible re-use, the method of recording and storing the data must be strictly designed to confer anonymity on the participant.

16.4. All research assistants and persons having access to confidential data must be briefed by the Principal Investigator on the duty to observe the rules of anonymity and confidentiality set by this Policy.

16.5. There are certain circumstances which will limit the assurance of confidentiality to a participant:

i. In certain circumstances, a researcher may acquire information on illegal activities or information relevant to a criminal investigation. A researcher who acquires such information may be called as a witness in court proceedings and can be compelled to make full disclosure of such information received.

ii. A researcher has a positive duty to report suspected child abuse.

iii. A researcher has a positive duty to report a positive HIV test.

RELATED POLICIES

- Applied Research Policy
- College Approval to Submit Research Applications/Proposals to External Sponsors
- Conflict of Interest in Research
- Integrity in Research
- Research Administration & Policy Development
- Research in the Yukon, Northwest Territories and Nunavut
- Research Intellectual Property Rights
- Research Involving Biohazards and Radioactive Materials
- Student Rights in the Conduct of Research
- Use of Animals in Research, Teaching and Testing

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