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OFFICIAL COLLEGE POLICY

RESEARCH INVOLVING HUMAN PARTICIPANTS (7210-41)

Vanier College. Research Involving Human Participants (7210-41). 2013.

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Division or Sector: Academic

Responsibility: Academic Dean

Approved by Academic Council May 17, 2013

Approved by the Vanier College Board of Directors October 15, 2013.

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Scope

All research involving living human participants done at Vanier College must be reviewed and approved by the Research Ethics Board (REB) before the research may begin. This definition is meant to cover research in which living humans are studied, asked to participate in any study where some legal and ethical responsibility rests with the College. It is also intended to include any research that makes use of information or databases containing specific information about human participants. Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses shall also be reviewed by the REB.

Purpose

The purpose of this policy is to ensure that those conducting research involving living human participants at Vanier, whether members of the Vanier community or others granted permission to conduct research at the College, respect the legitimate human interests of those affected by their research.

While recognizing the vital importance of research to human progress, Vanier College affirms that the welfare and integrity of the individual or particular collective must prevail over the advancement of knowledge and the researcher's use of human participants for that purpose. The College is not itself vested with any authority to decide when an individual's rights may be superseded by the need for research, but it has a responsibility to ensure that the activities it supports respect the rights of the public it serves. These guidelines also apply to the collection of data from students at any time when that data do not pertain to course content or course pedagogy. The guidelines are offered to help the researcher and the Ethics Review Board avoid any adverse effects of research involving human participants.

Compliance with Tri-Council requirements

All researchers must comply with the guidelines in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, established by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council, as well as this and other relevant Vanier policies.

Guiding Principles

The Tri-Council Policy Statement recommends that reviews be guided by the following ethical considerations:

Respect for Persons

The underlying principle is that humans cannot simply be treated as means to attain a purpose without denying their intrinsic humanity. Therefore research must be directed at achieving moral and ethical goals while institutions must ensure that in achieving these goals, the dignity of humans participating in such research is protected

Respect for Free and Informed Consent

A basic aspect of our existence as independent humans involves the right to determine what is done to us, to our persons and our right to make free and informed decisions that pertain to our lives. Ethical research therefore must ensure that all participants are afforded this opportunity as part of their fundamental rights.

Respect for Vulnerable Persons

Respect for the dignity of humans implies that particular care must be taken to respect the rights and protect the interests of vulnerable persons, those diminished faculties reduce their ability to protect themselves, make independent and informed decisions and evaluate accurately what is in their best interests. This concern must affect the procedures used to interact with such persons in research projects.

Respect for Privacy and Confidentiality

Respect for human dignity includes respect for the privacy and confidentiality. Indeed one of the major stages in human development is the acquisition of the desire for privacy and the need for confidentiality in our discourse with others. This basic fundamental need must be respected in the attitude and procedures designed to access, report, distribute and store information garnered from research participants.

Respect for Justice and Inclusiveness

This concern imposes a responsibility to ensure that the ethical review process uses fair methods, standards and procedures to evaluate research applications; that special care be taken to ensure that no group within the population be unfairly burdened by the harm research may cause or benefit unfairly from the advances research may bring.

Balancing Harms and Benefits

Human decency requires that the harm caused by any action should not exceed the benefit gained by it. Research may often impose costs or harm participants but may often produce results that directly benefit the individual or others who may be in a similar situation. Honest exposition and explanation of the likely cost or harm and the reasonably foreseeable benefits that may reasonably be expected to accrue are fundamental to seeking permission from participants for this kind of research. It also mandates that research that is directly counter to the interests of participants must never be countenanced.

Minimizing Harm

The goal of balancing harm and benefits has as its corollary the imperative to minimize harm. The design of any research project that meets high ethical standards must be to do as little harm as possible to participants and to the environment in which we live and work.

Maximizing Benefits

Most research imposes some cost on the participants although the direct benefit may accrue to others or to the society in general through the advancement of knowledge. This imposes on researchers the responsibility to maximize the benefits that may accrue from the research. One particular aspect is the psychological benefit to participants derived from understanding clearly why the research is being conducted and what the potential benefit may be for themselves and other members of their society.

The Research Ethics Committee

The Research Ethics Committee (REB) reviews applications for research activities involving human participants as described below. The REB may approve, reject, propose changes to, or terminate any proposed or ongoing research involving human participants. The REB is also expected to further the knowledge of and appreciation for research ethics at the College, serving as a source of information and advice to the Vanier College research community.

Definitions

Minimal Risk

A situation in which the probability and magnitude of possible harms associated with the research are no greater than those that would be encountered by the subject in those aspects of his or her everyday life. This evaluation should be made from the perspective of the research subject (TCPS section 1: C1).

In the assessment of the acceptable threshold of minimal risk, special ethical consideration must be given towards individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project.

Vulnerable Persons

Persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority (TCPS i.5). In the course of research, such individuals are entitled to caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination.

PROCEDURE FOR ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

An Application to Conduct Research Form, completed and signed by the researcher, must be submitted to the Research Office. If the research involves human participants, the Research Office must forward the application to the REB requesting a review of the research plan. The Chair of the REB must make a preliminary determination of the level of risk to human participants involved in participating in the research. On the basis of this initial review the Chair of the REB will decide the nature of the ethical review the application should undergo. The guiding principle is that the depth of the review should be proportional to the degree of risk the research imposes on its participants. If the Chair of the REB determines that the risk is minimal, a delegated review may be recommended. Otherwise a full review will be instituted.

Delegated review

In a delegated review a sub-committee of the REB comprised of three members including the Chair will decide whether the research application should be accepted as submitted, or accepted with minor modifications; in this latter case it is returned to the applicant with a request for changes. This committee may also decide that the application should undergo a Full Review. The applicant must be informed of the decision no later than 14 days after the submission of the application. All approvals of applications under delegated review must be reported at the next meeting of the full REB. An application cannot be rejected without a Full Review and an applicant always has the right to request such a review.

Full Review

If the Chair of the REB determines that a delegated review is not appropriate; or if the applicant chooses full review, the application must be distributed to members of REB and taken up at next available meeting. The REB may meet with the applicant to discuss the proposal, to seek additional supporting information if necessary and to permit the applicant to ask and answer questions. The applicant will not be present when decision is made.

Scholarly Review

The TCPS recommends that:

a. 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.
b. The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.
c. 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.
d. Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms-benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, in extremis, through action in the courts for libel.

The REB may ask for scholarly peer review by either accepting the granting agency assessment; establishing a peer review committee; undertake the review itself if expertise exists on the committee.

If the research proposal is acceptable, the chair signs the form on behalf of the committee; if it is acceptable with modifications then the proposal is returned to applicant with suggestions for modifications; if the proposal is unacceptable, the Chair must inform the applicant in writing stating reasons for the decision; the applicant has the right to ask that decision be reconsidered.

Reconsideration of REB decisions (by REB)

If requested by the applicant, the REB must reconsider a negative decision on the research proposal and must invite the applicant to discuss the application before a second decision is rendered. This provides an opportunity for the applicant to be heard, to hear at first hand explanations of the reasons for the rejection, and to advance arguments in response to these explanations. The resulting decision, with the reasons for the decision, must be communicated to the applicant in writing, preferably within 5 working days of the meeting. The applicant has the right to appeal a negative decision to the Research Ethics Appeal Board (REAB).

Appeal of REB decisions by REAB

An applicant who wishes to appeal a negative decision of the REB after a reconsideration must do so within 30 days after receiving the written decision of the REB. The appeal must be sent in writing, with relevant supporting documentation included, to the Coordinator of the Research Office, who will forward the appeal request and supporting documents to the Chair of the REAB. The applicant has the right to appear in person before the REAB to discuss the case but may not be present when the decision is made.

The Research Ethics Appeal Board may sustain, modify or reverse a decision of the REB. The decision of the Research Ethics Appeal Board is final, and will be communicated in writing promptly to the applicant.

The membership of the Research Ethics Appeal Board shall be similar to that of the Research Ethics Board, and should operate under the same reporting and administrative practices as the REB. Current members of the REB shall not be eligible for membership on the REAB. [Niagara direct quote]

On-going Research Ethics Review

The principle of proportionality implies that, while all research projects should undergo on-going review, the regularity and rigor of such on-going review should reflect the level of risk posed to participants; the researcher (or principal researcher where there is more than one) should propose, and REB should establish, terms for ongoing review when first approval is given. The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year).

Any significant change in the research procedures or in research design must be reported promptly to the REB. Serious incidents must be reported immediately to the REB. Researchers must accompany any request for modification of research procedures or design with clear explanations for the reasons. The REB and researcher must collaborate to ensure that modifications meet ethical standards. Modifications must be reviewed and approved by 2 members of REB including Chair; the full REB must be notified at next meeting.

Annual reports on the research project must be filed with the Research Officer. When the research is supported by outside funding agencies their reporting requirements must be followed. However the researcher must inform the REB upon finalizing the research.

Research at many different sites will require review and approval by the REB of all participating sites. The researcher should distinguish between core elements of the research (those that cannot be altered without invalidating the combined data from the participating institutions or centres) and those elements that may be altered to comply with local requirements without invalidating the research project. The participating REBs may choose to coordinate their review of multi-centred projects through an agreed on coordination method.

Research Not Requiring REB Review

Some research is exempt from REB review where protections are available by other means. This policy allows the following exemptions:

- Research that relies exclusively on publicly available information;
- Research involving the observation of people in public places;
- Research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;

Activities Not Requiring REB Review

The following distinguishes research requiring REB review from non-research activities that have traditionally employed methods and techniques similar to those employed in research. Such activities are not considered “research” as defined in this Policy, and do not require REB review.

- Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes;

- Creative practice activities (a process through which an artist makes or interprets a work or works of art).
- "Research" projects with minimal risk, conducted by students as part of their course activities, where the activity's primary purpose is as a teaching/training exercise. Teachers of such courses should ensure that students adhere to ethical standards of practice as described in this policy. The teacher should consult the Teacher Guidelines, available on the Vanier College Website (http://www.vaniercollege.qc.ca/idr/research/vanier-college-research-ethics-board-reb/teacher-guidelines/). For additional information the teacher can contact the Research Ethics Board via the Coordinator of the Institutional Development and Research Office.

A. Conflict of Interest

Trust and integrity lie at the core of research activity and real or perceived conflicts of interests among researchers, research participants or members of review committees cannot be permitted to undermine that trust. All members involved in the research community have an obligation to disclose any conflict of interest that may arise during the process of proposing, reviewing, participating in or leading research activities at the College. A member of the REB or the REAB must withdraw from consideration of any issue before their committee in which the member has a personal interest.

B. Free and Informed Consent [adopted with permission from the Niagara College Policy]

Free and informed consent must be voluntarily given, without manipulation, undue influence, or coercion. There shall not be incentives offered that are so large as to become an undue influence and undermine the voluntary nature of their participation. Researchers must take care to avoid problems of informed consent based on a special relationship between researcher and participant, so that such relationship does not unduly influence the participant's free and informed consent.

Participants may withdraw their consent at any time during the research program, and such withdrawal shall not result in penalty or harm or loss of promised benefits that are not inherently dependent on completion of their participation.

Free and informed consent should normally be provided in writing, following section 6.5 of this practice document. If written consent is not culturally acceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent must be documented for review by the REB.

The REB may approve a consent procedure that does not include, or alters some or all of the elements of informed consent as noted above, or waives the informed consent, provided that the REB documents that:

a) The research involves no more than minimal risk to the participants;
b) the waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
c) the research could not practicably be carried out without the waiver or alteration;
d) whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and

e) the waiver or altered consent does not involve a therapeutic intervention.

In studies that include randomized consent or blinding in clinical trials, neither the research participants nor those responsible for their care know which treatment the participants are receiving before the project begins. Such research is not regarded as a waiver or alteration of the requirements for consent if the participants are informed of the probability of being randomly assigned to one part of the study or another.

Where any research participants express significant concern about the nature of the informed consent or the use of the research, the researcher should report the concerns to the REB.

REB review is normally required for research involving naturalistic observation, except for observation of participants in public meetings, demonstrations, political rallies or like activities where participants are expected to be seeking or are aware of public visibility. Naturalistic observation is used to study behaviour in a natural environment. If the naturalistic observation does not allow for the identification of the participants, and is not staged, then the research will normally be considered as of minimal risk. However, naturalistic observation still raises the concerns of privacy and the dignity of those being observed. Accordingly, REB review is required and free and informed consent should be obtained from the participants following this practice.

Procedures for Free and Informed Consent

When a proposal has been approved, the principal researcher (head of research team) must ensure that all participants are fully informed about the nature of the research, their roles, any risks involved and the perceived benefits of the research. They must consent in writing to participate by signing the relevant form. If written consent is not appropriate, either due to cultural norms or in situations where such written consent may pose risks to the participants that they may be unwilling to accept, the methods used to achieve free and informed consent must be documented and reviewed by the Chair of the REB before the research may begin. The department responsible for the research must keep completed original consent forms. In situations where the demands of privacy and confidentiality require greater security than is likely to be possible within a department, such documents must be entrusted to the Research Office for safekeeping. The guidance of the Research Office should be sought if there is any doubt as to the correct course of action.

Researchers shall provide to prospective participants, or to authorized third parties, full and frank disclosure of all information relevant to their free and informed consent. Throughout this process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation.

Researchers shall provide at a minimum the following information:
a) Information that the person is being invited to participate in a research project;
b) comprehensible statement of the research purpose, the identity of the researcher and College, the expected duration and nature of participation, and a description of the research procedures;
c) a comprehensible description of reasonably foreseeable risks and benefits that may arise from participation in the research, as well as any consequences of non-action, particularly related to research involving treatment, or where invasive methods are involved, or where there is a potential for physical or psychological harm;

d) assurance that the prospective participants are free not to participate, and are able to withdraw at any time without prejudice;
e) assurance that the participants have ongoing opportunities to decide whether or not to continue to participate during the course of the research;
f) the potential of commercialization of research findings, and the presence of any apparent, actual, or potential conflict of interest on the part of the researchers, sponsors, or institutions.
g) the name, and contact information for a person who may be contacted for information on the nature of the research, or in the case of concerns, complaints, or consequences.

Additional information may be required, depending on the nature of the research project, including:

a) Assurance that new information will be provided to the participants in a timely manner whenever such information is relevant to the participant's decision to continue or withdraw from the research;
b) information on the resources available outside the research team to contact regarding possible ethical issues in the research;
c) an indication as to who will have access to the information collected on the identity of participants, descriptions of how confidentiality will be protected, and the anticipated uses of the data;
d) an explanation of the responsibilities of the participant;
e) information on the circumstances under which the researcher may terminate the individual's participation in the research;
f) information on any costs, payments, reimbursement for expenses, or compensation for injury;
g) in the case of randomized trials, the probability of participant assignment to each of the options;
h) the ways in which research results will be published, and how the participants will be informed of the results of the research.

Written consent must normally be obtained and properly filed.

The competence of the potential participants to provide free and informed consent is an important factor in the validity of the consent. Competence refers to the ability to understand the information presented about the research, to appreciate the potential consequences of a decision, and to provide free and informed consent to participate in a specific research project. Competence is not an all or nothing condition. The prospective participants do not need to have the capacity to make every kind of decision, only the informed decision about participation in the specific research.

Researchers must ensure that they comply with all applicable federal and provincial legislative requirements and the legislative requirements of the jurisdiction in which participation takes place.

Individuals who are not legally competent to participate in the proposed research shall only be asked to become research participants when:

a) The research question can only be addressed using the identified group(s);
b) free and informed consent is sought from their authorized representatives, such as parents or legal guardians;
c) the research does not expose them to more than minimal risk without the potential for direct benefits to them.

For research involving individuals who are not competent, the REB shall ensure that, as a minimum, the following conditions are met:

a) The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the participant's best interests will be protected;
b) the authorized third party is not the researcher or any other member of the research team;
c) the continued free and informed consent of the authorized third party is required in order for the continuation of the participation of the legally incompetent person in the research project, as long as the person remains incompetent;
d) if the incompetent participant becomes competent during the research project, his or her informed consent will be sought as a condition of continuing participation.

If the free and informed consent has been obtained from an authorized third party, and the legally incompetent participant understands the nature and consequences of the research, the researcher must seek to determine the wishes of the participant. If the potential participant does not agree, their participation in the research project cannot begin.

C. Privacy and Confidentiality

Researchers must ensure that they comply with all legislation governing the privacy of individuals that apply in the jurisdictions where the research is being performed. They must submit and gain approval from the REB of any interview procedures designed to elicit identifiable personal information from research participants, whether the interview is in person, on the telephone, electronic media or by means of individualized questionnaires.

In evaluating this aspect of research proposals the REB must consider: (Niagara RIHS p. 12)

a) The type of data to be collected;
b) purpose of collection;
c) limits on use, disclosure and retention of data;
d) safeguards for security and confidentiality;
e) modes of observation or access to information that allows identification of particular participants;
f) anticipated secondary use of identifiable data from research;
g) anticipated linkage of data gathered in the research with other data about participants;
h) provisions for confidentiality of data resulting from the research.

The primary researcher has the exclusive right to use the data collected in any study for the approved period of time that is required for the completion of the approved research. Following this period, the researcher is encouraged to make such data available to other researchers. Secondary use of the data will not normally include access to any personal identifiers. REB approval is required for any secondary use of the data.

ACKNOWLEDGEMENTS

We would like to express our gratitude to Red River College and Niagara College for their generous assistance and for having given us permission to use part of their policies in the creation of our own policy.