NIAGARA COLLEGE OF APPLIED ARTS AND TECHNOLOGY

College Practices

Reviewed:
Approved: June 8, 2012
Responsibility: Executive Team

PRACTICE NUMBER: **NC900-01**

PRACTICE TITLE:

2. Niagara College requires all principal investigators, co-researchers and REB members to complete the online TCPS2 Tutorial Course on Research Ethics (CORE), found on the Interagency Advisory Panel on Research website, http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/. A printed certificate shall be submitted to the Office of Research and Innovation, also known as Niagara Research, upon completing the course. All principal investigators and researchers shall submit this certificate of completion as part of their application package for proposed research.

Scope of Research Requiring Review

3. All research involving human participants requires the review and approval of the Research Ethics Board of Niagara College prior to the start of the research. In this context, research involving human participants refers to research where humans are participating in studies where the College has the responsibility to regulate legal or ethical aspects, or where databases will be used containing specific information about the human participants. The following research requires REB review and approval according to Article 2.1[5] of the TCPS2:

    a) research involving living human participants; and

    b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

4. Research involving human biological materials, tissues, biological fluids, embryos, or fetuses is not permitted at the College at this time. The College may develop policies and procedures for the ethical review of research involving clinical trials of human biological materials when both researchers and the College wish to conduct such research. Until that time, such research is not permitted at Niagara College.

Multi-Jurisdictional Research

5. For multi-jurisdictional research, the participating REBs may choose to coordinate their review of multi-centred projects through an agreed-upon coordination method or review model. Niagara College may introduce the most appropriate alternative review model (e.g., independent ethics review by several REBs, research ethics review delegated to an external, specialized or multi-institutional REB, reciprocal REB review)6Mutiali2o9 (,)2 ((i)-2 .t (es)-5 ()-2(inpF)8v)2 (s

a) provide to their REB the rules and ethics requirements of the research site;

b) names and information of all REBs involved; and

c) "relevant information about the target populations and circumstances that might have a bearing on the research ethics review by the researchers' home REB."[8]

7. In addition, the researcher shall 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.

Research Exempt from REB Review

8. A REB review is not required when the research relies exclusively on publicly available

c) staff performance reviews; and
d) testing that occurs within normal educational requirements.

12. However, if any of the activities listed above are conducted in the context of a research framework, they may require review by the REB. In addition, a REB review is not required where the secondary use of anonymous information for which its dissemination, collection and linkage of data do not generate identifiable information.

Research Ethics Core Principles

13. Respect for human dignity has been the cardinal principle of the Tri-Council Policy Statement. This principle of research protects the multiple interests of the person from bodily to psychological to cultural integrity. It forms the basis of the ethical obligations in research involving human participants. The TCPS2 has consolidated the original eight guiding principles to three core principles (i.e., Respect for Persons, Concern for Welfare, and Justice). These three core principles are stipulated in Article 1.1[9] of the TCPS2.

14. In addition to the three core principles, research shall be inclusive in regards to the benefits of research, and shall have a fair distribution of its burdens to distinct individuals, groups or communities. There shall only be valid reasons to exclude individuals to participate in research based on their attributes (e.g., "culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age,"[10] etc.). For example, some research that is focused on a specific "religious order that is restricted to one sex."[11] Therefore researchers, hold the responsibility to justify the exclusion of participants and such justification shall answer the research question.

Respect for Persons

15. This principle encompasses the treatment of persons involved in research as participants. It recognizes the value of human beings and the respect that they should be given as individuals. This includes respecting a person's autonomy[12] and protecting those with developing or impaired autonomy. A person shall be free and capable to choose, without interference. In order to accomplish this, it is important to seek the free, informed, and ongoing consent[13] of participants.

16. Individuals are generally presumed to have the capacity and the right to make free and informed decisions. Respect for persons translates in practice into the dialogue, process, rights, duties and requirements for free and informed consent by the research participant. This ensures that the participant has a complete understanding of the following:

[9]Article 1.1 of the TCPS2, Core Principles, provides details and an explanation for each core principle, pp. 8 – 11.
[10]Article 4.1 of the TCPS2, Fairness and Equity Research Participation, Appropriate Inclusion, p. 48.
[11] Article 4.1 of the TCPS2, Fairness and Equity Research Participation, Appropriate Inclusion, p. 48.
[12]TCPS2 defines autonomy as "the ability to deliberate about a decision and to act based on that deliberation," p. 8.
[13]

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PRACTICE TITLE: Research Involving Human Participants

23. It is important to know the vulnerability of individuals due to their limited capacity or access to their rights, opportunities, and power. It is the responsibility of the REB and researchers to make sure vulnerable persons, including children, elderly, and institutionalized persons, are entitled to special protection against exploitation, discrimination, or abuse.

24. Treating people fairly and equitably does not necessarily mean treating people exactly the same, thus special procedures may be required to protect these persons. Therefore, the ethics review process and research shall have fair methods, standards, and procedures.

Research Ethics Board

25. The responsibility of the Niagara College Research Ethics Board is to ensure that any research involving human participants will comply with this research practice and with the guidelines stated in the TCPS2. Any research involving human participants at Niagara College must be reviewed and approved by the College's REB. Ultimately, the Research Ethics Board is responsible for ensuring that the physical safety and personal integrity of all human participants in research are protected and respected. In addition, the REB shall ensure that researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information.

REB Authority and Mandate

26. The Research Ethics Board reviews applications for research activities involving human participants as described in this practice. The REB has the authority to review and make decisions on any proposed or ongoing research. The REB also serves the Niagara College research community as a consultative body, thus contributing to education in research ethics.

27. The Research Ethics Board is mandated by the President of the College to accept, reject, propose modifications to, or terminate any proposed or ongoing research that is subject to REB review and is conducted within, or by members of, the College (e.g., faculty, students or staff), regardless where the research is conducted. In addition, the President shall ensure that appropriate financial and administrative independence is provided to the REB to enable it to fulfill its mandate.

REB Membership

28. The REB shall consist of at least five members, including both men and women, of whom:

    a) at least two members have broad experience in the areas of research covered by the REB at the College;

    b) at least one member is knowledgeable in ethics;

REB Terms of Appointment

32. Members normally serve for a two-year term and may be re-appointed. The term of appointment of REB members should be balanced to ensure both continuity and appropriate diversity of membership. The Chair shall be elected by the REB on a two-year appointment.

REB Recruitment

a) enhance the operation of the REB;
b) facilitate the discussion of arising issues;
c) review, understand, and/or improve relevant policies; and
d) ensure the proper training of REB members.

REB Quorum

38. A quorum for the REB is 50% plus one of the members present. Decisions requiring a full review shall be adopted only if the members in attendance have sufficient background and expertise to conduct the review(s) Membership (2020)

Full REB Review

48. Research ethics review by the full REB should be the default requirement for research involving humans. If the applicant elects a full review or if the Chair determines that a delegated review is not appropriate, the application will be copied and distributed to the members of the REB for consideration at the next scheduled REB meeting. A full REB review must take place in a face-to-face REB meeting. The applicant may be present to discuss the proposed research and answer questions the REB may have about the research, but may not be present when the REB is making its decision.

Delegated REB Review of Minimal-Risk Research

49. Research that involves minimal risks, minimal-risk changes to approved research, and annual renewals of minimal-risk research that has been approved, are examples of research that may be delegated. A subcommittee (i.e., the REB Chair and one other member) of delegated reviewers shall be selected from amongst the REB membership.

50. If the Chair of the REB determines that the proposed research will involve a minimal risk to the research participants, and if the principal investigator has not indicated a preference for a full review, the sub-committee shall determine whether the proposed research shall be:

    a) acceptable as submitted,
    b) acceptable with minor modifications, or
    c) required to undergo a full ethical review.

51. Approvals of the delegated reviews must be reported to the REB by the next scheduled meeting. In addition, an application cannot be rejected without full REB review and validation before communicating the decision to the researcher.

Scholarly Review

52. The REB has the responsibility to "review the ethical implications of the methods and design of the research."[19] Scholarly reviews are different amongst various fields of research. This includes the stage at which a scholarly review may occur. Researchers shall demonstrate to their REB when and how scholarly reviews have been or will be undertaken for their research. In addition, the REB may request the full documentation of the scholarly reviews already completed.

Course-Based Research REB Review

53. Course-based research may be delegated if its activities are intended solely for pedagogical purposes. For example, the objectives of these activities are to provide students exposure to research methods in their field of study. In contrast, faculty engaged in course-based research for the purpose of research shall undergo regular REB procedures.

[19] Article 2.7 of the TCPS2, Relationship between Research Ethics Review and Scholarly Review, p. 20.

54. For course-based research, REB review authority may be delegated to selected reviewers that are not members of the REB or to the REB subcommittee for delegated reviews. Course-based research reviewers shall have the experience, expertise, training and resources required to review the ethical acceptability of research within the proposed field of research, according to this practice, and the guidelines of the TCPS2.

Continuing Research Ethics Review

55. On-going research is subject to an ethics review at the level consistent with the level of risk in the research. As part of the research proposal submitted for REB review, the principal investigator shall propose a process for on-going review of the research. For minimal-risk research, at minimum, multi-year research will require an annual status report, and projects lasting less than one year will require an end-of-study report. Where there is more than minimal risk, a more stringent review process may be required. In addition, funded programs of research shall also follow the reporting requirements of the funding agency.

Reporting Unanticipated Issues

56. The REB must be notified, as soon as possible, of any adverse or unanticipated issue or event that may have ethical implications or increase the level of risk to participants during the research. The reporting of the unanticipated issue shall include a description of the issues or incident, as well as details of how the researcher dealt with the situation. The REB may require researchers to adjust their procedures to prevent recurrence.

REB Decision Making

57. All REB submissions shall have an impartial and fair hearing. Researchers may request or can be invited to attend an REB meeting to provide further information about their proposal. However, the researcher shall not be present when the REB is making a decision.

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Approved Decisions

60. After receiving an approved decision by the REB, the researcher must be certain that all participants are informed of the nature of the research and details about their participation. This includes understanding the risks and benefits of the research, as well as providing their consent to participate, in writing, by signing an informed consent form for research participants.

the research applicant by him/herself or by his/her designate.

d) an assurance that prospective participants are under no obligation to participate and are free to withdraw at any time, without prejudice to pre-existing entitlements; will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

e) information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;

f) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;

g) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;

h) the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;

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Consent Withdrawal

83. Participants may withdraw their consent at any time during the research program without offering any reasons, 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.

Withdrawal of Data and Human Biological Materials

84. If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials. For research projects in which the withdrawal of human biological materials is not possible, the identity of the participants must be protected at all times.

Modification of Consent

85. Free and informed consent should normally be provided in writing. 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 alter some or all of the elements of the informed consent or waives the informed consent only for minimal risk research. The REB must ensure that all of the following apply:[24]

    a)

87. In some circumstances, a person may have some ability to understand the importance and implications of the research. Although some individuals lack the legal capacity and are required to have an authorized third party, they may still be able to express their wishes, either by verbally or physically disagreeing to participate in research. The researcher shall respect the wishes of these individuals in regards to their participation.

Individuals who Lack the Capacity to Consent

88. Individuals who lack the legal capacity to consent to participate in a proposed research shall only be asked to become research participants when:[26]

    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; and

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

89. 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 subjects 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

Participant Ability to Understand the Research

92. 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. 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.
93. Researchers must ensure that they comply with all applicable federal and provincial legislative requirements and with the legislative requirements of the jurisdiction in which participation takes place. 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; and

    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.

94. 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, the research must terminate for that participant.

Consent During Individual Medical Emergencies

95. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or of his or her authorized third party, if all of the following apply:[29]

    a) a serious threat to the prospective participant requires immediate intervention;

    b) no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison to the standard of care;

    c) either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant;

[29] Derived directly from Article 3.8 of the TCPS2, p. 39.

d) the prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research;

e) third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts; and

(f) no relevant prior directive by the participant is known to exist.

96. If a previously incapacitated participant regains capacity, or when an authorized third party is found, the free and informed consent of the participant or authorized third party shall be sought promptly for the participant's continuation in the project and for subsequent examinations or tests related to the study to be conducted.

Privacy and Confidentiality

97. Researchers shall comply with all applicable privacy legislation of the jurisdiction in which the research takes place. Wherever possible, participants must be guaranteed privacy[30] and anonymity, and their responses must be treated with confidentiality[31]. If anonymity and confidentiality cannot be assured or guaranteed, potential participants must be made aware of the limitations and possible consequences before they are asked for their consent to participate.

Safeguarding Information

98. The ethical duty of confidentiality by researchers and REB members includes safeguarding information. This entails the collection, use, dissemination, retention and/or disposal of the information for its full life cycle. In addition, the following, as stipulated in the TCPS2, must apply for the proposed measures to safeguard information:[32]

a) type of information to be collected and how it will be used;

b) purpose of any secondary use of identifiable information;

c) limits on the use, disclosure and retention of the information;

d) risks to participants if the security of the data be breached, including risks of re-identification of individuals;

e) any documentation in the research that may identify particular participants;

f) any anticipated uses of personal information from the research; and

g) any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records.

[30]The TCPS2 refers to privacy as "an individual's right to be free from intrusion or interference by others," p. 55.
[31]The TCPS2 refers to "confidentiality" as the "obligation of an individual or organization to safeguard trusted information," p. 56.
[32]The measures to safeguard information were derived directly from Article 5.3 of the TCPS2, pp. 60 -61.

99. Researchers "shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements."[33] This will be established during the consent process and in the application materials submitted to the REB.

Obtaining REB Approval

100. REB approval is not required for access to publicly available information or materials, including archival documents and records of public interviews or performances. Researchers who plan to interview a participant to secure identifiable personal information must obtain REB approval for the consent and the interview procedures used, and shall ensure the free and informed consent of the participant, as required within this practice. An interview may be face-to-face, by telephone, electronic media, or through individualized questionnaires.

Secondary Use of Identifiable Information

101. As stipulated in Article 5.5 of the TCPS2,[34] researchers may forego obtaining the consent of participants for the secondary use of identifiable information only when the REB has determined that:

    a) the identifiable information is essential to the research;

    b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;

    c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;

    d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;

    e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and

    f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

102. The 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. Where the secondary use of the data will not include access to any personal identifiers, an REB review may not be required.

[33] Article 5.2 of the TCPS2, Ethical Duty of Confidentiality, p. 59.
[34] Derived from Article 5.5 of the TCPS2, The Consent and Secondary Use of Identifiable Information for Research Purposes, p. 62.

Research in Emergency Health Situations

103. Publicly declared emergencies are due to unexpected circumstances (e.g., public health outbreaks, natural disasters, etc.). 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 establishe). 1l ( )-10 (ne)4Eadc (jeSan)-4 (t)3 (c (. 1l ((u)-4f s)-1 (ha53.9 (es)-5( )]TJ (ed)-4 (i))-
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107. In addition, the extent of community engagement shall be determined by both the community and the researcher, based on the characteristics and nature of the research. When appropriate, researchers shall seek engagement with the formal leaders of the community (e.g., research conducted on lands under the jurisdiction of an authority).

108. Both researchers and REB members shall consult the TCPS2 for further guidance on the ethical conduct of research involving Aboriginal peoples (e.g., engagement with organizations and communities of interest, complex authority structures, recognizing diverse interests with communities, critical inquiry, etc.).[37]

Qualitative Research

109. Qualitative research, including pilot studies, requires REB review and approval. Researchers shall present their research design, as well as explain their consent process and plan to document consent, prior to recruiting participants or accessing their data. If participants choose to disclose their identity through the dissemination process, such as having their names on publications, the researcher shall record each participant's consent for disclosing information. Researchers hold the responsibility to communicate to the REB any changes to the data collection process that may present any real, perceived, or potential risks or ethical implications.

110. If the research requires observation in a natural or virtual setting environment, the principal investigator may request to be exempt from the consent process only when individuals have a "reasonable or limited expectation of privacy."

113. The College may develop further policies and procedures for the ethical review of research involving clinical trials, as both researchers and the College wish to conduct such research. REB members and researchers shall consult the TCPS2 for further guidance to the ethical practice for research involving clinical trials.

D. Related Documents and Links

Tri-Council Policy Statement (TCPS2):
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

Interagency Advisory Panel on Research:
http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/