NIAGARA COLLEGE OF APPLIED ARTS AND TECHNOLOGY

College Practices

Reviewed:
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Responsibility: Executive Team

PRACTICE NUMBER: **NC900-01**

PRACTICE TITLE: **Research Involving Human Participants**

A. Background and Definitions

This practice applies to all research involving human participants conducted by faculty, staff, and students, regardless of where the research is conducted. It also applies to research conducted on Niagara College premises by researchers who are not members of the Niagara College community. If there are any questions about the applicability of this practice to a particular research project, the advice of the Research Ethics Board (REB), through its Chair, shall be sought.

B. Purpose

The principle behind this practice is to ensure that the rights of human participants[1] in research[2] are respected and protected, as well as to ensure that research is conducted ethically, according to the guidelines and standards of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* or TCPS2.[3] This practice shall serve as a framework for the ethical conduct of research. It is not intended to introduce or amend any changes to any other Government of Canada policies, such as the TCPS2. Furthermore, it will guide the REB and principal investigators[4] (also referred to as researchers) to view and understand the perspective of human participants when participating in research.

C. Practice Statements

Compliance with the Tri-Council Policy Statement (TCPS2)

1. All research conducted by Niagara College staff, faculty or students that involves human participants shall comply with the standards stipulated in the TCPS2 and those in this practice. In addition, all research involving human participants shall be subject to review by the Niagara College REB. The TCPS2 shall be consulted for guidance by the REB members and principal investigators. The TCPS2 is found at http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/.

[1]TCPS2 defines human participants as "those individuals whose data, or responses to interventions, stimuli or question by the researcher, are relevant to answering the research question," p.16.
[2]TCPS2 defines research as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation," p. 15.
[3]Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010.
[4]The TCPS2 defines principal investigator as "the leader of a research team who is responsible for the conduct of the research and for the actions of any member of the research team," p. 194.

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)[6] for research that will involve multiple REBs or institutions. However, it shall "remain responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction or under its auspices irrespective of where the research is conducted."[7]

6. If the research is being conducted at more than one centre or site, there may be more than one REB involved. All REBs with jurisdiction over the research project must approve the planned research. When conducting research in Canada outside the REBs jurisdiction or abroad, researchers shall:

[5]Article 2.1 of the TCPS2, Research Requiring Review, p. 15.
[6] See pp. 99-100 of the TCPS2 for further details of each model.
[7]Article 8.1 of the TCPS2, Adoption of Alternate Review Models – An Institutional Responsibility, p.98.

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 information that is legally accessible to the public and appropriately protected by law, and when the information is publicly accessible and there is no reasonable expectation of privacy. This may include, but is not limited to:

    a) research involving public policy issues, the writing of modern history, or literary or artistic criticism; and

    b) research about a living person involved in the public arena, or about an artist, if such research is exclusively based on publicly available information, documents, records, works, performances, archival materials, or third-party interviews.

9. If the participant is to be approached directly for interviews or for access to private papers, then a REB review is required to ensure that such approaches are conducted following ethical research protocols.

Observation of People

10. A REB review is also not required when research involving the observation of people in public places does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups. As a result, the individuals or groups targeted for observation should not have reasonable expectation of privacy and any dissemination of research results do not allow identification of specific individuals.

Other Activities

11. Any activity that refers to the performance of employees or students of the organization that are required within the mandate of the organization, according to its terms and conditions of employment, shall not be subject to a REB review. These activities may include, but are not limited to:

    a) quality assurance and improvement studies;
    b) assessing the performance of the College;

[8]Article 8.4 of the TCPS2, Ethics Review of Research Conducted Outside the Institution, p. 103.

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]TCPS2 defines consent as "an indication of agreement by an individual to become a participant in a research project," p. 190. The TCPS2 refers to consent as being voluntary or "free, informed and ongoing consent," p. 27.

a) the purpose of the research;
b) its potential risks and benefits to the participant and others; and
c) what it is involved in the research.

17. For some research, participation is requested from individuals incapable of exercising autonomy due to their youth, cognitive impairment or illness. Additional measures are necessary to protect those participants. This may generally include seeking consent from an authorized third party.[14]

Concern for Welfare

18. The TCPS2 states that welfare of participants consists on how individuals, either as distinct persons or as a group, may be impacted by various circumstances such as their physical, economic and social status. This could also include their mental and spiritual health. For example, housing, employment, security, family life, community membership and social participation are determinants of welfare.

19. The privacy and control of information about the person is another contributing factor to welfare. This may include protecting the access, control, and dissemination of personal information and materials. Concern for welfare is fundamental to the principle of respect for human dignity. In addition, the treatment of human biological materials, according to the free, informed and ongoing consent of the person who was the source of the information or materials may be another contributing factor to welfare.

20. The principal investigator and the REB shall protect the welfare of participants and promote the welfare in view of any foreseeable risk. Participants must be provided with enough information to be able to assess the risks and potential benefits associated with the research with which they will be involved as participants.

21. Moreover, the analysis and balance of harms and benefits are critical to the ethics of research involving human participants. Therefore, foreseeable harms should not outweigh anticipated benefits of the research. The balance must respect human dignity and impose strict ethical obligations on the validity, design, and conduct of research. It is the duty of those conducting research involving human participants to avoid, prevent or minimize harm to others. Research participants must be fully aware of any potential for harm, at any stage of the research, to both individual participants and to groups of participants.

Justice

22. According to this principle, humans shall be treated fairly and equitably, that is treating all people with respect and concern. This includes not segmenting a group or population to be burdened by the harms of research or denied the benefits of the knowledge generated from it.

[14]TCPS2 defines an authorized third party as "any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to consent to participate or to continue to participate in a particular research project," p. 27.

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;

c) one is a community member with no affiliation with the College; and

d) one is a lawyer, who is not the College legal counsel and knowledgeable in the relevant law. For biomedical research, it is mandatory that the REB member should be knowledgeable in the relevant law.

29. A senior administrator shall not serve as a member of the REB or indirectly influence the REB decision-making process. A trained student REB member may be added if the REB is mainly reviewing student research.

Chair

30. The responsibility of the REB Chair is to ensure that the REB review process conforms to the requirements of the TCPS2 and those of the College. The Chair shall also provide overall leadership for the REB and to facilitate the REB review process. In addition, the Chair shall be responsible for:

a) calling and chairing regular meetings of the REB and other meetings as required;

b) maintaining and coordinating communication with REB members and the Office of Research and Innovation, also known as Niagara Research;

c) communicating decisions to the research applicant;

d) assisting in determining delegated reviews of proposed research;

e) recommending experts to the REB where appropriate;

f) ensuring that appropriate documentation of REB meetings and decisions are kept and submitted to the Office of Research and Innovation;

g) monitoring and ensuring the REB's decisions are consistent;

h) ensuring that REB's decisions are recorded accurately; and

i) ensuring that the REB's decisions are communicated clearly to researchers, in writing, within 10 to 14 working days of the scheduled reviewed date of the proposed research, by him/her or by his/her designate.

REB Substitute Members

31. When possible, substitute members shall be nominated so that the REB can continue to function when regular members are unable to attend due to illness, conflict of interest, or other unexpected circumstances. Substitute members shall have the appropriate training, expertise, and knowledge and not alter the REB membership composition.

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

33. Niagara Research shall send out a membership advertisement to recruit qualified individuals to be part of the Research Ethics Board. Interested individuals shall submit their curriculum vitae and cover letter to Niagara Research, highlighting their expertise, qualifications, as well as any education and relevant participation on research ethics training. Candidate qualifications will be reviewed by a panel appointed by the College President. The College President will appoint members based on the panel's recommendations.

REB Renewal

34. At the end of their term, REB members will have the opportunity to be reappointed. Members will have to submit a letter to Niagara Research highlighting their interest in continuing with the REB membership and their expertise, qualifications, and recent participation on research ethics training. Letters shall be reviewed by the panel appointed by the College President. The College President will appoint members based on the panel's recommendations.

REB Removal

35. If a member cannot fulfill his/her responsibilities as an REB member, his/her term will be terminated. Some circumstances that will lead to termination include, but are not limited to, excessive absences to meetings and inability to attend related research ethics training. Circumstances that may lead to removal shall be reviewed by the panel appointed by the College President. The College President will make the recommendation for removal based on the panel's recommendations.

REB Meetings and Attendance

36. In order to fulfill REB responsibilities, the REB shall have regular face-to-face meetings at a minimum of bimonthly, unless there is a need to meet at an earlier date, or there are no proposals on the agenda. The REB should determine and post a schedule of their meeting dates by August of every year. The schedule of REB meetings shall be made available to all College researchers.

37. Attendance at regular REB is necessary to ensure effective communication and decision making. Under unexpected circumstances, such as emergencies, member participation through technology is acceptable. Additionally, the REB should hold general meetings, retreats, and workshops to:

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) required.

Ad Hoc Advisors

39. Ad hoc advisors will only be consulted in the event that the REB lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal because that expertise is not available from the REB. Ad hoc advisors are not allowed to vote. In addition, as per Items 29 and 75 of this practice, a senior administrator may not directly or indirectly influence the REB decision-making process.

Recording and Keeping REB Documents

40. All records and documents of meetings and research applications must be maintained in the REB committee files. The files are maintained in the Office of Research and Innovation. Minutes are accessible to authorized personnel of the College, researchers and funding agencies.

41. It is the responsibility of the REB to prepare and maintain comprehensive records. This includes the following:

    a) all documentation related to the projects submitted to the REB for review;
    b) attendance at all REB meetings; and
    c) accurate minutes reflecting all REB decisions.

42. REB minutes shall include roll call, conflicts of interest and their handling, dissents and reasons for dissents, clear references such as date of decisions and title of project, documentary basis for decision, and plan for continuing ethics review and timelines. In addition, Niagara Research will maintain general records of the REB, such as copies of curriculum vitae and documentation of the members' participation on research ethics training.

REB Education and Training

43. Education and training opportunities shall be provided to members of the REB to enable them to fulfill their duties throughout their term. The training shall be at a minimum in the following areas:

a) core principles and understanding of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans or TCPS2;

b) basic ethics standards;

c) applicable institutional policies; and

d) legal or regulatory requirements.

Procedures for the Ethical Review of Research Involving Human Participants

44. For research involving human participants, a Niagara College application package for "Research Involving Human Participants"[15] shall be completed and signed by the principal investigator and submitted to the Office of Research and Innovation. The REB must satisfy itself that the design of the research involves a "minimal risk."[16]

45. No research is permitted to begin until the REB review process has been completed. Ongoing research is also subject to an ethics review, based on the proportionate approach to assessment which includes the level of risks, the potential benefits, and the implications of the proposed research.[17]

Initial Research Ethics Review

46. For any research involving human participants, the REB shall ensure that the research, including research for pilot studies, shall be submitted for review and approval to the REB prior the start of recruitment of participants, access or collection of data. The REB has the responsibility to ensure that the research projects, including those of pilot studies, involve minimal risks, based on the TCPS2 guidelines for the proportionate approach. However, a REB review is not required for communication with organizations for purposes of establishing partnerships and collaboration prior to the research design plan.

Determining the Level of Research Ethics Board Review

47. The Research Ethics Board will review the proposed research and determine the level of the ethical review ("full" or "delegated" review) based on the proportionate approach. This is determined by the level of anticipated risks to participants; therefore, the more invasive the research, the greater should the care of assessing that research be. According to Article 6.12[18] of the TCPS2, a full or delegated research ethics review may apply.

[15] The Niagara College application package for "Research Involving Human Participants" may be downloaded from the Niagara Research website or requested directly via email from research@niagaracollege.ca.

[16] TCPS2 defines minimal risk as "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research," p.23.

[17] For further explanation of the proportionate approach to assessment, refer to the TCPS2 Ethics Framework, p. 11 and to Article 2.9, pp. 24-25 of the TCPS2.

[18] Refer to Article 6.12, pp. 77 – 79, for further explanation of the two levels of research ethics review.

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.

58. The REB shall endeavour to reach consensus on decisions, and may wish to request external advice if it lacks expertise in the area of research being proposed. If a consensus cannot be reached, a decision shall be made by majority vote. In case of a tie vote, the Chair will break the tie.

Communicating Decisions

59. All decisions must be recorded and communicated in writing, either by print or electronically, with reasons for the decision by the Chair or by his/her selected designate. The applicant will be notified in writing of the decision within 10 to 14 working days of the scheduled reviewed date of the proposed research.

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.

61. 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 must be clearly documented and reviewed by the REB prior to the start of the research. Original consent forms must be kept in a secured locked file or by a password protected electronic file by the department responsible for the research.

Requests of Research Changes to Approved Decisions

62. Researchers shall submit to the REB request for substantive changes to an approved research proposal. The request shall include an explanation of the reasons for the request. Depending on the level of risk to participants, the changes may receive delegated or full review. The REB shall decide on the ethical acceptability of the proposed changes and may determine that the changes are substantial, which may require a new REB review.

Reconsideration of Negative Decisions

63. The REB and researchers shall endeavour to resolve disagreements on decisions through reconsideration, discussions, or advice. A researcher has the right to have a negative REB decision reconsidered by the REB. Therefore, the researcher shall have the opportunity to reply prior to the REB making a final decision. The reconsideration is guided by the principles of natural and procedural justice, including a reasonable opportunity to be heard, an explanation of the reasons for opinions and decisions, the opportunity for rebuttal, fair and impartial judgement, and consideration in a timely manner.

64. The REB's negative decision may require only modifications in the research plan or methodology to be overturned. The REB shall consult with the researcher to assist him or her in planning research that meets ethical requirements. Once the research plan has been modified to comply with the REB requests, and reviewed by the Chair of the REB and one other member, the Chair will issue approval and notify the members of the REB. If the modifications do not meet REB requests, the applicant will be invited to the next REB meeting for assistance in amending the application.

65. Additionally, the researcher will be invited to be present to discuss the application with the REB prior to making a final decision. The researcher has the responsibility to justify the grounds on which they request reconsideration. The decision of the REB will be made in writing to the applicant, with reasons for the decision. If the decision of the REB, on reconsideration, remains negative, the applicant may appeal the decision to the Research Ethics Appeal Board (REAB).

Appeal of REB Decisions

66. After the researcher and REB have exhausted the reconsideration process, and the REB has issued a final decision, the researcher may initiate an appeal. The researcher must initiate the appeal within 30 days of the receipt of the written decision. The appeal must be made in writing to the Chair of the Research Ethics Appeal Board, and include all supporting documents.

67. 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 promptly to the applicant. A decision of the REB to disallow research on ethical grounds, unless reversed on reconsideration by the REB, may only be reversed through the appeal process.

REAB Membership

68. The REAB shall hear any appeals arising from negative decisions of the Research Ethics Board. Such appeals may only be initiated by the research applicant. Appeals may be made in writing and follow the procedure outlined in this practice. Researchers from Niagara College that wish to appeal a decision shall send their appeal in writing electronically to Niagara Research. Niagara Research will forward all materials to the Chair of the REAB.

69. 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. The REAB reports to the President of the College. The REB shall be comprised of at least five members, appointed by the President of the College, including both men and women, of whom:

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

    b) one member is knowledgeable in ethics;

    c) one is a lawyer, who is not the College legal counsel; and

    d) one is a community member with no affiliation with the College.

70. Current members of the REB shall not be eligible for membership on the REAB. Members normally serve a two-year term, and may be re-appointed. Current members of the REB may not serve on the REAB. Niagara College may have a formal agreement with an alternate college to use each other's REB as their appeal boards.

Meetings and Decisions

71. Meetings are called by the Chair, who is elected by the REAB for a two-year term. A quorum is determined to be 50% plus one of the membership, provided that there is sufficient background and range of expertise present to conduct the appeal review(s) required. The REAB will make every attempt to reach consensus in its decision making. All decisions must be made in writing with reasons for the decision and communicated to

the research applicant by him/herself or by his/her designate. The REAB decision is final, and it may carry on, amend, or reverse a decision of the REB. All files are maintained in the Office of Research and Innovation.

Conflict of Interest

72. Researchers hold a relationship of trust with research participants, sponsors, professional bodies and society. Trust relationships must not be put at risk by a conflict of interest. Researchers, REB members, and REAB members must disclose any actual, perceived, or potential conflict of interest to the REB.

73. Researchers, institutions and the REB have the responsibility to identify and address conflicts of interests, whether they are "real, potential, or perceived to discharge professional and institutional obligations, maintain public confidence and trust, and ensure accountability."[20] The REB has the authority to decide how conflicts of interest shall be managed. This includes developing a process that will identify the steps taken to manage the conflict. All researchers and REB members have the responsibility to review the Niagara College practice on Research Integrity and the guidelines stipulated in the TCPS2 to avoid or prevent being in a position of conflict of interest, as well as to understand how to minimize or manage the conflict.[21]

Institutional Conflict of Interest

74. Niagara College shall identify, eliminate, minimize or manage conflicts of interest that affect research. This includes for researchers, administrators, REB members, faculty, and all other parties involved to act in a transparent manner while identifying and addressing conflicts of interests. In addition, any institutional conflict of interest that may affect research shall be reported to the REB.

REB Member Conflict of Interest

75. A member of the REB or REAB shall not be part of any discussion or decision regarding a research project in which the member has a personal or financial conflict of interest (e.g., review of a member's research project). If the absence of the member will alter a quorum, a substitute member may be present to maintain the quorum. Senior administrators shall not serve on the REB, or directly or indirectly influence the REB decision-making process.

Researchers and Conflicts of Interest

76. Researchers shall include any potential, actual or perceived conflict of interest in their research proposal. Researcher conflicts of interest may include dual or multiple roles (e.g., acting as researcher and advisor), as well as any financial conflicts of interests. It is the responsibility of the REB to determine how to manage the conflicts of interest.

[20] TCPS2, Chapter 7, Conflicts of Interest. p.89.
[21] Refer to Chapter 7, Conflict of Interest of the TCPS2, pp. 89-97.

Consent Process

77. There are three general principles to the consent process.[22] These are:

    a) consent shall be given voluntarily;

    b) consent can be withdrawn at any time; and

    c) if a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

78. Research may begin only if prospective participants, or authorized third parties, have been provided with the opportunity to give free and informed consent about participation, and their free and informed consent has been given. The inclusion of a participant's data or human biological materials in the research is contingent on their free and informed consent being maintained throughout their participation in the research.

79. Participants must have freely agreed to serve in the research study on the basis of well-understood information about the objectives of the research and the nature of their participation. Additionally, they must be fully informed of any and all known risks associated with the research, as well as possible benefits of their participation. They must have the opportunity and ample time to evaluate the relative weight of any known risks and benefits.

Informed Consent

80. 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 in order to make an informed decision to participate in a research project.

81. Throughout this process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation by giving them enough time and the opportunity to ask questions. Researchers shall provide at a minimum the following information, which was directly derived from the Tri-Council Policy Statement:[23]

    a) information that the individual is being invited to participate in a research project;

    b) a statement of the research purpose in plain language, the identity of the researcher(s), the identity of the funder(s) or sponsor(s), the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;

    c) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;

[22] For further explanation for each principle of the consent process, refer to Article 3.1 of the TCPS2, p. 28.
[23] Derived directly from Article 3.2 of the TCPS2, Consent Shall Be Informed, pp. 30 – 31.

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;

i) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants; a description of how confidentiality will be protected; a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;

j) information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;

k) a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and

l) in clinical trials, information on stopping rules and when researchers may remove participants from trial.

Voluntary Consent

82. Free and informed consent must be given voluntarily, 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. The researcher has the responsibility to justify the intended use of incentives. 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.

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) 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, clinical or diagnostic intervention.

Capacity of Individuals

86. Some individuals may permanently or temporarily lack the capacity to decide for themselves to participate in a research project. The REB must ensure special measurements and safeguards will be taken to protect individuals from any potential or perceived harms and risks.[25]

[24]Derived directly from Article 3.7 of the TCPS2, Alteration of Consent in Minimal Risk Research, p. 37.
[25]Article 3.9 of the TCPS2 lists the minimum conditions that must be met involving individuals who lack the capacity to make an informed decision to participate in a research project, p. 41.

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 the probability of being randomly assigned to one part of the study or another.

Reporting Concerns and Incidental Findings

90. Where any research participant expresses significant concern about the nature of the informed consent or the use of the research, the researcher should report the concerns to the REB. Researchers also have the duty to "disclose to the participant any material incidental findings[27] discovered in the course of research."[28]

Activities Exempt from Consent

91. 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. REB review is required and free and informed consent shall be obtained from the participants following this practice.

[26]Derived directly from Article 4.6 of the TCPS2, Research Involving Participants Who Lack the Capacity to Consent for Themselves, p. 51.
[27]TCPS2 defines "incidental findings" as "unanticipated discoveries made in the course of research but that are outside the scope of the research," p. 34.
[28]Article 3.4 of the TCPS2, Incidental Findings, p. 34

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 established in advanced of such research by the REB.

104. REB review shall follow modified procedures and practices during emergencies. A preparedness plan for an emergency research ethics review shall be developed in collaboration with researchers, institutions, and the REB. These plans shall take place once an emergency has been declared and must be stopped after the end of the publicly declared emergency. The REB and researchers shall consult the TCPS2 for further guidance regarding research in emergency situations.

Research Involving the First Nations, Inuit and Métis Peoples of Canada

105. Researchers and REB members shall apply all the principles and values stated in the TCPS2 when conducting research involving Aboriginal people of Canada and respect all other Government of Canada policies. Research involving Aboriginal people shall acknowledge their unique status and affirm the "respect for community customs and codes of research practice in researcher-community relations."[35]

106. Furthermore, the REB and researchers hold the responsibility to interpret the ethics framework in an Aboriginal context. Where research will involve an Aboriginal community or communities, the researcher has the responsibility to engage with the relevant community. Engagement is required, but not limited, under the following conditions:[36]

    a) research conducted on First Nations, Inuit or Métis lands;

    b) recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;

    c) research that seeks input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics;

    d) research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data; and

    e) interpretation of research results that will refer to Aboriginal communities, people, language, history or culture.

[35] Chapter 9, Research Involving the First Nations, Inuit and Métis Peoples of Canada, p. 106.
[36] Derived directly from Article 9.1 of the TCPS2, Requirement of Community Engagement in Aboriginal Research, p. 110.

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."[38] The REB may approve the exemption of consent after the researcher has provided a reasonable explanation for this request, and only if the REB is satisfied that there will be no breaches of privacy such as the possible identification of individuals.

Clinical Trials

111. For all clinical trials, the researchers and the REB hold the responsibility to consider any potential risks associated with the type of clinical trial (e.g., pharmaceutical, natural health product, medical device, psychotherapy, etc.) during the design and review of the clinical trial. Prior to the recruitment of participants, clinical trials must be registered in a "recognized and easily web-accessible public registry."[39]

112. All risks to participants shall be appropriately minimized and be justified by the potential benefits to be gained. In addition, researchers shall provide the REB with a plan to monitor the safety of participants and the collection, analysis, and reporting of data. Any new findings that may threaten the welfare of participants must be reported to the REB and corresponding regulatory agencies.

[37]See Article 9.3 - 9.22 of the TCPS2, pp. 114-119.
[38]Article 10.3 of the TCPS2, p. 141
[39]Article 11.3 of the TCPS2, p. 156

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/