Institutional Review Board Policy and Procedures

Mission

The Institutional Review Board (IRB) is Niagara University's research ethics board (REB). The IRB is responsible for developing policies and guidelines in compliance with the Department of Health and Human Services, Office for Human Research Protections' Code of Federal Regulations 45 CFR 46.101 for research involving human subjects conducted in the United States and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2010) in Canada.

The IRB Mission involves ensuring that all research conducted at Niagara University that involves human subjects comports with American and Canadian Core Principles, which include Respect for Persons, Concern for subjects' Welfare, and Justice. The IRB thus tasked with reviewing all human subject research project applications with respect the human subjects' rights and related ethical considerations.

Faculty members and students who wish to conduct research under the auspices of Niagara University that involves human subjects **must have their research proposals reviewed and approved by the Niagara University Institutional Review Board (IRB)** prior to its commencement.

Governance and Support

As an Academic Board, the IRB reports to the Provost. The Office for Academic Affairs will provide support staff in the form of one Graduate Assistant enrolled in at Niagara University. The Graduate Assistant will receive compensation during the academic year through the graduate assistantship (GA) program, at a value determined by the Provost in consultation with the IRB Chair, and through the summer months through a stipend of $2000.00. The Office for Academic Affairs will also provide support for the IRB by funding Member certification requirements necessary.

The IRB will be officiated by a Chair and Vice Chair who will both report to the Provost. The Chair and Vice Chair will officiate together as they deem most beneficial to Committee governance. The Vice Chair will temporarily officiate in the Chair's stead when the Chair is away or unable to do so. Their rights and responsibilities are not limited to those specifically expressed in this document. However, they include the authority to represent IRB Committee before the Academic Senate should they wish to present reports or request support from the Senate, in person, if so desired by either party.

The IRB will select a Chair and Vice Chair to serve for at least 3 years, and each service year will begin in the fall, extend through the summer, and end with the beginning of the next academic year (i.e., the fall semester). If multiple candidates wish to serve as either Chair or Vice Chair, or if there is disagreement with a candidate's fitness to serve as either Chair or Vice Chair, current IRB members will vote to determine through majority vote who shall be Chair and Vice Chair. The IRB committee members may also remove a Chair or Vice Chair by majority vote, to the Provost Office, if they deem that officer derelict in duty.

Committee Membership

The IRB will consist of a minimum of 15 tenured and tenure-tracked faculty Committee Members. Because of the nature and amount of committee work, there is a presumption for more and more diverse membership. Therefore, there is no statutory maximum number of members, and if possible, membership will include a minimum of two representatives from each college.

New IRB Members serve 3-year terms. There will be no term limit to serving on the IRB, and Members in good standing are welcome to continue their memberships indefinitely. Members are responsible for informing the IRB chair when they will be on sabbatical and when they will return. When Members wish to relinquish their membership, they will inform the Chair of their intent.

When the IRB needs new Members, the IRB Chair will contact the Chair for the Committee on Committees and request a call for volunteers. The Chair of the Committee on Committees will

forward their selections to the IRB Committee Chair for final approval. This comports with the NULTA Collective Bargaining Agreement regarding the shared governance role of the Committee on Committees in helping to select faculty members to serve on university committees.

Training Requirements for IRB Members

Under the United States Department of Health and Human Services (DHHS) Human Subjects Protection Regulations §45 C.F.R.46.103 (The Common Rule), every institution engaged in human subject research supported or conducted by the NIH-sponsored institution, must obtain an assurance of compliance approved by the Institutional Review Board (IRB).

All members serving on the IRB should therefore complete National Institute of Health (NIH) training available at **https://phrp.nihtraining.com/users/login.php .** IRB Members will notify and send their certifications of completion to the IRB Chair of the IRB who will then keep certification record on file.

For compliance with accreditation requirements of our Ontario programs, the IRB must have at least one member of the IRB must be from an Ontario program, and have completed the TCPS -2 Tutorial available at http://pre.ethics.gc.ca/eng/education/tutorial-didacticiel/
This will ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2010) in Canada.

The Chair may ask any Member who does not complete their respective training in a timely fashion to resign from the IRB.

Ethical Standards for Research with Human Subjects

Criteria for IRB Research Approval

As per the Office of Human Research Protections' Code of Federal Regulations 46.111, the IRB shall determine that all of the following requirements are satisfied before approving research applications:

1. Risks to subjects are minimized and do no unnecessarily expose subjects to risk;
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge reasonably expected to result. In evaluating risks and benefits, the IRB should consider those risks and benefits that may result from the research;
3. Selection of subjects is equitable. The IRB should take into account the purposes of the research and the setting in which it will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. When some or all of the subjects are vulnerable persons such as these, potentially subject to undue coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects;
4. Informed consent will be appropriately documented;
5. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

General Requirements for Informed Consent

As per the Office of Human Research Protections' Code of Federal Regulations 46.116, an investigator shall seek consent and provide the prospective subject or the representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether verbal or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Basic elements of informed consent include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomfort to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate precautions, or alternative procedures and/or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and the time period for destroying data and/or records;
6. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' right, and whom to contact in the event of a research-related injury to the subject; and
7. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled to receive, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Application Submissions and Review

All researchers intending to do research involving human subjects must have their research approved by the IRB **before they begin**. This will also help the Graduate Assistant under the IRB Chair and Vice Chair's guidance to maintain an accurate database of all research involving human subjects and data conducted at Niagara University. This database will assist with the procurement of internal and external funding opportunities for researchers as well as assist in ensuring efficient resource are management. Therefore, all researchers planning to conduct research involving human subjects should be submit their proposals to the IRB for approval **before** conducting their research.

Previously Conducted Research

The IRB cannot grant approval for research that researchers have already conducted without IRB approval. If a researcher has already collected data from an IRB-approved project and wishes to use those data for different purposes, the researcher must submit a new IRB application. See the applicable section below. If researchers wish to use data previously collected as part of a course requirement for new and publishable research, they must apply for IRB approval. Researchers should submit their applications early enough to give the IRB sufficient time to properly review them before research is to be conducted. See the applicable section below.

Course-based Research Projects

Course-based research projects may include undergraduate or graduate student-initiated projects, theses, or course assignments. These projects must be designed and conducted with the same ethical standards as are faculty research projects and must therefore be approved by the IRB. Therefore, it is the responsibility of the instructor to submit to the IRB a copy of the assignment as part of the application for approval. This will alleviate the need for individual students to submit separate proposals.

However, if students or instructors wish to use these projects in whole or part for **publication or dissemination outside the classroom**, each student-researcher must submit a separate application. As with faculty research, the IRB cannot grant approval for any course-based research that any researcher has already conducted.

International Research

Any researcher intending to conduct or fund research outside the U.S. or Canada is responsible for understanding and abiding by other nations' legal and ethical requirements, which may be more stringent than they are in the U.S or Canada. In this regard, Niagara University recognizes two helpful tutorials. One is the TCPS -2 Tutorial "Introductory Tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans", which is available at **http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/** . The other is the NIH-supported "Protection of Human Research Subjects: Computer-Based Training for Researchers" which is available at **ohsr.od.nih.gov/cbt/**.

Quality Assurance Projects

Quality Assurance and quality improvement (QA/QI) studies, program evaluation activities, and performance reviews, or testing within normal educational conditions and requirements, when used for the sole purpose of assessment, management, or improvement do not constitute research **need not be submitted for review**. However, projects that fall within the category of QA/QI or program evaluation for which the instructor wishes to publish the results do necessitate IRB review.

Cooperative Research Projects

As per 46.113 of the Office for Human Research Protections' Code of Federal Regulations, cooperative research projects are those projects covered by this policy involving more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy, and researchers should therefore get approval from each institution's IRB. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a

joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Submission Guidelines and Procedures

The IRB accepts submissions on a rolling basis throughout the year. Researchers must complete and submit the required application online and upload supplementary documents as required **through the IRB portal system** available at **http://www.niagara.edu/irb/**. **The IRB only accepts electronic submissions**, and this includes all revised applications. The IRB will **not accept hardcopy submissions or resubmission**.

Researchers submitting IRB applications are responsible for producing and filing applications in compliance with all of the guidelines posted on the IRB website at **http://www.niagara.edu/irb-application/**. It is the responsibility of the applicant to ensure that he or she has permitted a sufficient amount of time for a judicious review to occur. Researchers should therefore submit their applications well in advance of your intended start date to give the IRB sufficient time to review applications. There is no statutorily required time limit to completing a given review. The duration of a given review will depend on how many rounds of revision are required. The IRB will make a good-faith effort to review each application within (2 – 3 weeks) of having received a properly submitted application. Missing information or supportive documentation will delay this time-line. The IRB's Graduate Assistant will maintain all records, of application dates and reviews in the IRB database overseen by the IRB Chair and Vice Chair.

Research in Schools and Institutions

Research in schools or agencies must have administrative consent/permission prior to recruitment. This will often require that a separate review by the school district, agency, or institution ethical IRB (or REB). Projects that fall under this domain may not receive final approval from the University without first receiving approval from the partnering district/agency. Researchers may receive conditional approval, which they may submit along with the application should that agency or institution require conditional university IRB approval. Please be sure to contact the school district/agency directly to determine protocol. It is the responsibility of the

researcher seeking IRB approval from Niagara University to forward an approved copy along with the conditional acceptance from the University to the chairperson for the IRB when the researcher submits an NU IRB application at **IRBproposal@niagara.eduz**.

Responses & Revisions

Should the research require some level of applicant response or revision concerning IRB comments, please include a cover letter responding to each question/comment provided by the IRB and bolded changes within the revised submission. Responses and revisions must be submitted through the IRB portal.

Research Renewal Review

In some cases, the IRB will approve research with an expiration date. In those cases, researchers will need to either complete their research before the expiration dates or they will need to apply for renewal. Researchers with projects approved with expiration dates who want to continue beyond their expiration dates must submit a review for continuance.

Amended Research Studies

Any change to the original submission that potentially alters the risk to participants (increases or decreases), requires an amendment submitted to the IRB Chair. Some examples of amendments include:

- Sampling/Recruitment population, criteria, methods or materials
- Researcher/Personnel – if principal investigator or faculty supervisor changes
- Change in the location of the research – that may require additional permission or review (e.g. new school board or agency)
- The length of study or intervention if risk level changes
- Privacy issues and/or the nature or depth of the information being collected (e.g. adding data in combination with existing information could potentially identify participants)
- Data management plan – modes of collection, change in storage, retention or destruction – physical and electronic safeguards
- Informed consent forms (unless only minor wording), procedures or information

- Change to funding sources, compensation to respondents
- Newly arisen conflicts of interests
- Change(s) of other institutional administration approval, (i.e., the REB from the other institution/District/Agency)

Approval Suspension or Termination

As per the Office for Human Research Protections' Code of Federal Regulations 46.113 the IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. The IRB will promptly report to the investigator, appropriate institutional officials, and the department or agency head any suspension or termination of approval shall include a statement of the reasons for the IRB's action.

Adverse Effects

Researchers must report adverse or unanticipated events that occur to participants in the course of the research to the IRB Committee as soon as possible. Researchers are ethically required to report these events to the IRB Chair through the IRB portal.