NIAGARA UNIVERSITY	*Responsible Office or Department:*	Academic Affairs
	Effective Date:	07/01/2018

Institutional Review Board and Tri-Council Policy

PURPOSE:

To ensure compliance with governing regulations for human subject research

SCOPE:

All students and faculty who are engaged with human subject research.

MAIN PROVISIONS:

Research involving human subjects conducted by faculty members and students under the auspices of Niagara University must be reviewed and approved by the Niagara University Institutional Review Board (IRB) prior to its commencement. The IRB is charged with developing policies and guidelines in compliance with 45 CFR 46.101 for research involving human subjects conducted in the United States and either the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2014), or the Tri-Agency Framework: Responsible Conduct for Research (2016) for research conducted in Canada. The IRB is a University-wide Academic Board that reports to the Provost.

Regulation: The Belmont Report

In 1974, the signing of the National Research Act required every US institution involved in biomedical or behavioral research with human subjects to establish an Institutional Review Board (IRB) "in order to protect the rights of the human subjects of research." This resulted in the emergence of IRBs in hospitals, universities, and other research institutions across the country. IRBs are essentially non-governmental committees responsible for federal regulatory oversight. The Act also created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was charged with the task of articulating ethical conduct within the context of human subjects research. The Commission's work resulted in The Belmont Report, which identifies three basic ethical principles for human subjects research. Accordingly, they form the basis for the IRB review process:

- *Respect for Persons. Individuals should be treated as autonomous agents, and therefore researchers should respect their decisions. People with diminished autonomy (e.g., children, prisoners) are entitled to protection*. This principle led to the requirement of obtaining informed consent. According to The Belmont Report, "Respect for persons requires that subjects, to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them." To do so, subjects

must be given sufficient information about the research using language they understand, and their decision to give or withhold consent must be free of coercion or undue influence

- Beneficence. *Do not harm. Maximize possible benefits and minimize possible harm*. This principle led to the requirement of assessing and disclosing the risks and benefits of the research. Risks can be conceptualized in terms of probability and magnitude, and characterized in terms of psychological, physical, legal, social, and economic harm. Benefits are less rigorously conceptualized and characterized.

- Justice. *The burdens and benefits of research should be equitably distributed*. This principle led to the requirement of articulating selection procedures as well as any exclusion criteria. For example, selection procedures should not burden one group over another (e.g., Black men over White men), and research should not exploit a characteristic of one group (e.g., illiteracy) for the sake of convenience.

45 CFR 46 (Protection of Human Subjects)

Based on The Belmont Report and issued by the US Department of Health and Human Services (HHS), 45 CFR 46 is the primary federal regulation that governs research on human subjects as well as the activity of the IRB. Known as "The Common Code," Subpart A outlines the Department's basic policy on the protection of human subjects. Among other things, it:

- Defines research that is exempt from IRB review (46.101)
- Defines the authority and duties of the IRB (46.101, 103, 107-110, 113-115)
- Defines key regulatory terms, such as "research" and "human subject" (46.102)
- Defines the criteria for reviewing an IRB application (46.111)
- Defines the general requirements for informed consent (46.116-117) Subparts B, C, and D address research involving vulnerable subjects, including pregnant women and fetuses, prisoners, and children.

CANADA Tri-Council/Tri-Agency Policy Statement

Parallel to the American 45 CFR 46, the Tri-Council Policy Statement is the governing document for research involving humans in Canada. On February 1, 2010, the IRB of Niagara University formally adopted the Tri-Council Policy Statement for all IRB applications involving Canada. In order to remain current, the most recent version (2014) has been adopted.

In addition, NU recognizes the role of the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) (herein identified as the Agencies) to institutions that receive Agency funding. In any instance of receiving such funding, the University shall promote the responsible conduct of research (RCR) as defined by those agencies, including the responsibilities and corresponding policies for researchers, institutions, and the Agencies, that together help support and promote a positive research environment, as administered by the Secretariat on Responsible Conduct of Research (SRCR) and the Panel on

Responsible Conduct of Research (PRCR) as identified in the TriAgency Framework: Responsible Conduct for Research (2016).

PROCEDURES:

Research involving human subjects conducted by faculty members and students under the auspices of Niagara University must be reviewed and approved by the Niagara University Institutional Review Board (IRB) prior to its commencement.

ADDITIONAL INFORMATION:

None

POLICY HISTORY:

- Originated: 2/2/2010
- Current Effective Date: 07/01/2018
- Next Review Date: **12/1/2026**
- Revision/Renewal Log:
    - Reviewed 12/01/2023, no revisions necessary
    - Replaces “Niagara University Institutional Review Board and Tri-Council Policy Statement”, effective 07-01-2018
    - Revised 3/30/2017
    - Revised 7/1/2018