

Ethical Conduct for Research Involving Humans Policy

Questions regarding this policy should be directed to the Policy Administrator.

Effective Date:	August 27, 2018	Cross Reference:	<p>Internal</p> <ul style="list-style-type: none"> • Academic Freedom Policy • College Involvement in Commercialization Policy • Copyright – Fair Dealing Policy • Intellectual Property and Ownership Policy • Integrity in Research Activity Policy • Research Activities Policy • Research or Teaching Involving Animals Policy <p>External</p> <ul style="list-style-type: none"> • CIHR Best Practices for Protecting Privacy in Health Research (http://www.cihr-irsc.gc.ca/e/29072.html) • CIHR Guidelines for Health Research Involving Aboriginal People (http://www.cihr-irsc.gc.ca/e/29134.html) • Good Clinical Practice: Consolidated Guideline (http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/e6-eng.pdf) • Personal Information Protection and Electronic Documents Act (http://laws-lois.justice.gc.ca/eng/acts/P-8.6/) • Post-Secondary Learning Act (http://www.qp.alberta.ca/documents/Acts/p19p5.pdf) • Tri-Agency Framework: Responsible Conduct of Research (http://www.rcr.ethics.gc.ca/eng/resources-ressources/news-nouvelles/2016-12-23/) • Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS2 2014 (http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf)
Policy Owner:	Vice President Academic	Appendices:	
Policy Administrator:	Director, Quality Assurance and Research Services		
Approver:	Executive Committee		

Review Schedule:	Every 3 years		
------------------	---------------	--	--

1. Policy Statement

- 1.1. The Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2) establishes the procedures and standards for the ethics review of research involving human participants conducted at Keyano College (hereinafter referred to as the “College”) or on behalf of the College.
- 1.2. The Research Ethics Board (REB) and its associated committees govern the ethical conduct of research on human participants at the College.
- 1.3. All research projects involving human participants undertaken by members of the College or conducted at the College – including all faculty, staff and students as well as contractors, consultants, clients, and volunteers – shall fall within the jurisdiction of the REB, irrespective of the source of financial support (if any) and irrespective of the location of the project, in the latter case, so long as the researcher represents the work as College research.
- 1.4. Projects conducted by researchers from outside the College community who access College resources (either equipment or personnel) also fall within the jurisdiction of the College’s REB.
- 1.5. All research that involves living human participants requires review and approval by the REB before the research is started.

2. Background

- 2.1. This document, “Ethical Conduct for Research Involving Humans Policy”, sets out the policy and regulations governing research involving human participants conducted at the College or on behalf of the College. The development of this policy was informed by documents from the Tri-Council Agencies, as well as a review of existing policies and procedures from Canadian colleges and universities with a focus on similar institutions.

3. Policy Objective

- 3.1. The purpose of this policy is to ensure that the highest ethical standards in the conduct of research involving human participants are maintained at the College in compliance with the TCPS2.
- 3.2. This policy outlines the College’s position on research involving human participants conducted at the College or on behalf of the College and identifies the rights and responsibilities of faculty, staff, and students as well as contractors, consultants, clients, and volunteers with respect to research involving humans.

4. Scope

- 4.1. This policy applies to all faculty, staff, and students as well as contractors, consultants, clients, and volunteers who are engaged in research involving human participants at the College or on behalf of the College.

5. Definitions

- 5.1. **Human research** refers to any project that involves the collection of specimens, data or information from persons, through intervention or otherwise. Included are procedures that have a low degree of invasiveness (e.g., surveys, interviews, naturalistic observations, exercise or psychometric testing, and examination of patient records), as well as more invasive procedures (e.g., blood sampling and administration of a substance).
- 5.2. **Participant** refers to any person who, by virtue of his/her involvement in a data- gathering situation or activity, is a source of primary data or information.
- 5.3. **Research** refers to any activity which involves a systematic investigation to establish facts, principles, or generalizable knowledge. Any undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation shall be considered research.
- 5.4. **Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2)** refers to the joint research ethics policy statement of the federal research agencies – Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC) and Social Sciences and Humanities Research Council of Canada (SSHRC).

6. Guiding Principles

- 6.1. **Respect for human dignity** – This is an underlying value of the TCPS2 for human dignity requires that research involving humans be conducted in ways that are sensitive to the inherent worth of all human beings and the respect and consideration that they are due. Respect for human dignity manifests through three complementary and interdependent core principles: Respect for Persons, Concern for Welfare, and Justice.
- 6.2. **Respect for persons** – This recognizes the intrinsic value of human beings and the respect and consideration they are due. It encompasses the treatment of persons involved in research directly as participants and those who are participants because their data or human biological materials are used in research. Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy. An important mechanism for respecting participants' autonomy in research is the requirement to seek their free, informed and ongoing consent.
- 6.3. **Concern for welfare** – The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances. Concern for Welfare means that researchers and REBs should aim to protect the welfare of participants and inform them of foreseeable risks associated with the research.
- 6.4. **Justice** – Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

7. Roles & Responsibilities

STAKEHOLDER	RESPONSIBILITIES
Executive Committee	<ul style="list-style-type: none"> Approve and formally support this policy.
Vice President Academic	<ul style="list-style-type: none"> Review and formally support this policy.
Deans' Council	<ul style="list-style-type: none"> Develop and maintain this policy. Take proactive steps to reinforce compliance with this policy by all stakeholders.
Managers, Supervisors, or Representatives	<ul style="list-style-type: none"> Explain the terms of this policy to faculty, staff, and students as well as contractors, consultants, clients, and volunteers and assist users to understand the requirements of this policy. Ensure that all stakeholders follow the requirements of this policy.
Procurement and Managers	<ul style="list-style-type: none"> Follow the guidelines provided in this policy when performing due diligence and assessment of the risks related to intellectual property for any new contracts with third parties. Ensure that responsibilities and obligations of each party to the contractual relationship are outlined in the contract executed between the College and the contractor/sub-contractor.
Human Resources	<ul style="list-style-type: none"> Ensure each new employee has read and signed off understood this policy upon the first 7 days of employment with the College. Support all employees in the understanding of the requirements of this policy.
All users (faculty, staff, students, and third parties)	<ul style="list-style-type: none"> Comply with the requirements of this policy as applicable to them at all times. Report all non-compliance instances with this policy (observed or suspected) to the Vice President Academic as soon as possible.

8. Policy Management

Policy Title:	Ethical Conduct for Research Involving Humans Policy
Approval Date:	July 15, 2018
Effective Date:	August 27, 2018
Historical Review Dates:	February, 2020
Next Review Date:	February, 2023
Related Legislation:	<ul style="list-style-type: none"> CIHR Best Practices for Protecting Privacy in Health Research CIHR Guidelines for Health Research Involving Aboriginal People Good Clinical Practice: Consolidated Guideline Personal Information Protection and Electronic Documents Act Post-Secondary Learning Act Tri-Agency Framework: Responsible Conduct of Research Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2014)
Supersedes Policies:	N/A
Monitoring/Frequency:	<ul style="list-style-type: none"> Monitoring of compliance activities will be reviewed at a minimum, once a year.

	<ul style="list-style-type: none">• Education and training sessions will periodically take place throughout the year.
Policy Owner:	Vice President Academic
Policy Administrator:	Director, Quality Assurance and Research Services
Policy Coordinator:	Executive Assistant, Academic