

Policy Name	RESEARCH INVOLVING HUMAN SUBJECTS		
Policy #	905	Category	900 RESEARCH
Steward	VP, External Relations, International & Research	Date Approved	February 1, 2024
Next Review Date		Date Reviewed or Revised	

POLICY

The College shall regulate and monitor all research involving humans conducted at the institution. The College will do so through the University of Regina’s Research Ethics Board (REB) or an Internal Review Team. This policy will establish principles and guidelines for maintaining quality and ethical standards in conducting research at the College on human subjects, consistent with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans.

The purpose of this policy is to govern the standards regarding the ethical conduct of research involving human subjects at the College.

PRINCIPLES

- Research involving human participants at the College will at a minimum be conducted in accordance with the most current version of the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans.
- The purpose of this process is to ensure that all research with human subjects is conducted in a fair and ethical manner and conforms to legal requirements and the standards outlined in the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans (TCPS2, 2022) all projects will be assessed by one of two processes..
- All research projects involving human subjects with greater than minimal risk must be approved by the University of Regina REB
- Greater than minimal risk applications are those including, but not limited to, those that may pose greater than minimal risk to participants (i.e., physiological, psychological, social, legal, or other) as defined by the TCPS 2 , i.e. 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;

- Involve recruitment of persons who may be vulnerable as research participants in the context of a specific study, and/or cannot legally give free and informed consent;
 - include ethically sensitive issues, topics and/or procedures; and
 - represent applications to certain granting agencies that stipulate full REB review.
- Projects of minimal risk will be reviewed by an Internal Review Committee (IRC) made up of a minimum of three staff members:
 - An Indigenous representative;
 - A member of the counselling staff and;
 - An administrator (coordinator or chair).
- Research involving humans must be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. Respect for human dignity is expressed through three core principles: Respect for Persons, Concern for Welfare, and Justice.

SCOPE

This policy applies to all staff, students/learners and volunteers involved in applied research as part of a curriculum exercise or as a standalone project that includes human subjects in the research. This includes research involving human subjects that takes place outside of the College and research by researchers outside the College community that access College resources (equipment, personnel, or learners) for any part of their research.

This policy does *not* apply to Institutional Research, the ongoing collection of data used to facilitate the management of the College as part of its normal operations and related directly to the normal administering, evaluating, or improving of an operation, program, service or activity within the College.

DEFINITIONS

Captive Populations and Dependent Populations: individuals or groups where a power differential could operate to their disadvantage as subjects (for example, students, minors, prisoners, employees, military personnel, minority groups, incapacitated people and the socially-deprived). The review will be especially careful to ensure that consent is not obtained by subtle pressures on the captive or dependent subjects.

Deception: a situation in which essential information is withheld from research subjects and/or they are intentionally misled about procedures and purposes.

- Deception is not permitted when there is risk of harm to the subject or when it is not possible to advise subjects subsequently as to the reasons why the deception was necessary;
- Deception should only be used when:
 - Significant scientific advance could result; and
 - No other methodology would suffice.

Methodological requirements of a study may make the use of concealment or deception necessary. Before conducting such a study, the investigator has a special responsibility to determine whether the use of such techniques is justified by the study's prospective scientific, educational, or applied value and determine whether alternative procedures are available that do not use concealment or deception. The researcher must also ensure the participants are provided with sufficient explanation as soon as possible.

After the data are collected, the investigator provides the participant with information about the nature of the study and attempts to remove any misconceptions that may have arisen. Where scientific or humane values justify delaying or withholding this information, the investigator incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participant.

Human Subject and Research Involving Humans: any person who is a source of raw or unformulated research data and who is not acting as, or assisting, the principal investigator.

- These terms refer to living individuals and also to groups of living individuals (for example, social, ethnic, religious, or economic groups). Also included is human remains, cadavers, tissues, biological fluids, embryos, or fetuses.
- Research involving human subjects means the collection or analysis of information or data that are obtained from or about human subjects. This includes physical, biological, sociological, or psychological tests and procedures involving individuals or groups, and also the study of records obtained as a result of such studies, or from archival or public records, in which it is possible to identify living individuals.
- Research or study of published writings or public utterances of human subjects are not considered within the context of this regulation. Also excluded is the distribution of a questionnaire by an instructor to the class, concerning the instructor's teaching performance, the course content, or for program evaluation.
- If a researcher is uncertain whether a contemplated research does or does not require approval under this regulation, the researcher should consult with the Applied Research Lead who may refer it to the internal review committee

Informed Consent: The principles of informed consent can be found in the Tri-Council Statement for Research Involving Human Subjects, Part 2, Section 1. In general, research is viewed as a partnership between the researcher and the research participants. A morally valid choice concerning research participation is made:

- by a competent individual;
- on the basis of adequate information regarding the nature and foreseeable consequences of the research (as these are known at the time the request is made) and all available alternatives; and
- without controlling influences such as 'force, fraud, deceit, duress, over-reaching, or other ulterior forms of constraint or coercion' (from the National Council of Bioethics in Human Research).

Additional useful definitions of some of these and other terms can be found in the Glossary of the Tri- Council Policy Statement, 2022 (pages 191-202).

PROCEDURES

1. Review of Research

- 1.1 Research at greater than minimal risk involving human participants requires an external review and approval by the University of Regina REB before the research commences. Minimal Risk projects may be approved internally. The risk level is determined in the Principles above.
- 1.2 For higher than minimal risk projects, the University of Regina REB requires that a Behavioural or Biomedical Ethics Application be completed.
- 1.3 The opinion of the internal Review Team shall be sought whenever the researcher is in doubt about the applicability of the Policy to a particular research project.
- 1.4 Projects deemed at minimal risk will be reviewed by the Internal Review committee (IRC) for ethics compliance.

2. Proportionate Ethics Review

- 2.1 All research proposals and activities that involve human subjects will be reviewed through a Proportionate Ethics Review process which is based on the ethical principle that, while all research involving human subjects must be reviewed adequately to ensure protection for the subjects, the greater the potential for risk or harm to the subjects, the greater the scrutiny required in reviewing the research.

3. Authority of REB and Internal Review Team

- 3.1 For above minimal risk projects, the mandate of the University of Regina REB is to approve, reject, propose modifications to, or terminate research involving human subjects, which is conducted under the aegis of the College, using the standards outlined in TCPS2 (2022).
- 3.2 For minimal risk projects, the Internal Review Committee will approve, reject, propose modifications to, recommend submission to the U of R REB or terminate research involving human subjects, which is conducted under the aegis of the College, using the standards outlined in TCPS2 (2022).
- 3.3 Ethics approval may be withdrawn for ongoing research in case of any issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare. Thus the authority of the University of Regina REB or Internal Review Committee extends to requiring modifications and terminations of research.

4. Responsibilities of the Internal Review Team

- 4.1 The Internal Review Committee are responsible for making reasonable decisions consistent with the standards laid out in TCPS 2 (2022).

- 4.2 The Internal Review Committee shall function impartially, provide a fair hearing to relevant parties, and provide justification with appropriately documented opinions and decisions.
- 4.3 The Internal Review Committee has the responsibility to review ongoing research. This review should be proportionate to the level of risk posed by the research.
- 4.4 The Internal Review Committee shall adhere to the "conflict of interest" guidelines as outlined in article 7 of the Tri-Council Policy Statement and conflict of interest policy. See the University of Regina Conflict of Interest and Conflict of Commitment policy.
- 4.5 The Internal Review Committee shall conduct an inquiry and, if necessary, an investigation of every allegation of research ethics misconduct.

5. Ethical Obligations of Researchers

- 5.1 Researchers must follow best research practices when engaging in all research activities and knowledge dissemination. Furthermore, researchers must comply with applicable law, ethical and professional standards, College policies and contractual obligations.
- 5.2 Approval for research involving human subjects within the context of this policy shall be obtained by the researcher from the University of Regina REB in accordance with its procedures before any research activity is undertaken and before any College facilities or services are used.
- 5.3 Proposed modifications to a research project must be submitted to the original REB for approval, such as changes to applicants(s), design, procedures, instruments, sampling that substantively alter the research. Modifications must be approved by the original REB prior to implementation.
- 5.4 Ethical approval is granted for one year. Ethical approval is required for as long as the researcher is engaged with participants. If a researcher intends to interact with human participants beyond one year of receiving REB approval, they must request an extension to their approval. Extension requests must be submitted to the original REB prior to the anniversary date of ethics approval being granted and approval will be extended in one-year increments. If a researcher allows their ethical approval to lapse before they have finished engaging with human subjects, then they will be considered in breach of College policy and all research activities must cease immediately. To reinstate ethics approval, the researcher must submit a new ethics application to the University of Regina REB. No further research can be conducted until approval is restored.
- 5.5 Research with Indigenous peoples requires a higher level of scrutiny in accordance with TCP2 (2022) guidelines. Including Indigenous people in the REB decision either as panel members or as advisors is paramount. Research projects on Indigenous people should also ideally include Indigenous researchers as contributing members of the project from inception to knowledge dissemination.

- 5.6 Research on minors requires a higher level of compliance in research. Informed consent of the parent or guardians of the child must be obtained before using minors in research. Where a child is a ward of the state or of an agency, such as the Ministry of Social Services, informed consent of the agency director, as well as of the person having custody, must be obtained. Children must be individually given the opportunity to refuse to participate or to withdraw.
- 5.7 It is the responsibility of the researcher to provide research participants with all of the information necessary to make an informed decision to participate in a research study. In cases where there are considerations related to participants' language or literacy skills, the researcher must use plain language throughout the informed consent forms and related materials. Prospective participants must be given adequate time to review information materials about the project and should be permitted to pose questions to the research team before deciding whether or not to participate.
- 5.8 Where a researcher does not comply with the stipulations set out by the REB or internal review team, this may be considered academic misconduct and will be investigated appropriately.

LEGISLATIVE AND COLLECTIVE AGREEMENT REFERENCES

N/A

LINKS TO OTHER RELATED POLICIES, DOCUMENTS, AND WEBSITES

- Policy 901 Research
- Policy 901 Research Administration
- Policy 903 Integrity in Research & Scholarship
- Policy 904 Intellectual Property
- Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans (TCPS2, 2022): https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html
- U of R REB Research application forms: <https://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/ethicsforms.html>
- This policy was developed from similar policies from Algonquin College, Camosun College, Selkirk College, and Bow Valley College.