Procedures

Policy Name	**Ethics of Research Involving Human Participants**		
Policy #	**1102**	Category	**Research and Scholarly Activity**
Policy Sponsor	**Associate Vice-President Applied Research and Innovation**	Previous Revision Date	**March 16, 2012**
Policy Approved by	**President & CEO**	Revision Date	**June 4, 2020**
Procedures Approved by	**Provost & Vice-President, Academic**	Review Date	**June 2025**

See the related POLICY.

DEFINITIONS

Applied Research: a systematic study to gain the knowledge or understanding necessary to determine the means by which a recognized and specific need may be met.

Applied Research Project: Applied Research undertaken with an intended inquiry, examination, defined question or hypothesis, start and end dates, deliverables, and budget (if applicable).

Human participant is a person or an individual who, by virtue of his/her involvement in a data gathering situation or activity, is a primary source of data or information.

Human research refers to research that will involve a collection of human specimen, data or information from persons, through intervention or otherwise. This human research may include, but is not limited to, procedures of low degree of invasiveness such as surveys, interviews, naturalistic observations, exercise or psychometric testing, examination of patient records, as well as more invasive procedures such as blood sampling or administration of substance.

Minimal risk means the risk of harm anticipated in the proposed research is not greater or more likely than the risk normally encountered in life.

Principal Instructor/Investigator: The instructor or researcher with overall responsibility for the direction of a protocol or an Applied Research Project.

Research is a systematic investigation with the intent to facilitate a deeper and broader understanding of a phenomenon or experience, or to establish facts, principles and generalizable knowledge.

Research ethics protocol is a document submitted by an applicant (e.g., a Saskatchewan Polytechnic employee) for consideration by the Research Ethics Board. This document contains a detailed description of the rationale to conduct human research and the purpose of the study, including the procedures to be followed during the study and managing the results.

PROCEDURES

1. Responsibilities, Reporting, and Authority

1.1 The University of Saskatchewan (U of S) will act as the Research Ethics Board of Record (Board of Record) for Saskatchewan Polytechnic.

1.2 For all formal communication and any issues related to Saskatchewan Polytechnic's Human Research Ethics Review Processes, the U of S Research Ethics Board (REB) will communicate directly to the Associate Vice-President, Applied Research and Innovation.

1.3 The Research Ethics Boards (REBs) must adhere to the standards set out in the latest versions of:

a) The Tri Council Policy Statement on the Ethical Conduct for Research Involving Humans 2018 (TCPS2 2018) and subsequent revisions and updates; and

b) The Agreement on the Administration of Agency Grants and Awards by Research Institutions between NSERC, CIHR and SSHRC.

c) Any other relevant Polytechnic, U of S, provincial, federal, or international guidelines for the protection of researchers, human participants, and the public; or other legal requirements that relate to the conduct of research.

1.4 Saskatchewan Polytechnic will recommend at least one member of the Saskatchewan Polytechnic community to sit on the U of S REB.

2. Polytechnic Research with Human Participants or use of Biological Materials (including tissue and data)

2.1 Research projects subject to this policy will undergo an ethics review by either the UofS Biomedical Research Ethics Board (Bio-REB) or the Behavioural Research Ethics Board (Beh-REB).

2.2 The Human Research Ethics Review Process will be available to the Polytechnic for consideration of research to be conducted within the Polytechnic which involves human participants or biological materials (tissue and/or data).

2.3 The Principal Investigator for reviewable research shall obtain research ethics approval from the appropriate REB.

2.4 The Office of Applied Research and Innovation (OARI) requires that Polytechnic faculty, researchers and students provide OARI with a copy of all applications which are sent for review by an REB.

2.5 When the REB receives an application for review, that REB shall review the application in compliance with all the REB's normal processes and procedures, and in compliance with the requirements of all applicable guidelines and criteria.

2.6 Where the OARI has particular questions or concerns regarding an application, it shall promptly raise such matters with the REB for consideration in its review.

2.7 Certificate(s) of Ethics Approval issued as a result of the REB review will constitute appropriate documentation of research ethics approval. No subsequent research ethics review will be required by the REB of the other Party.

2.8 The Principal Investigator shall forward a copy of all correspondence with the REB and the Certificate(s) of Ethics Approval to OARI.

2.9 The Principal Investigator shall submit additional documentation as needed to maintain the research ethics application in compliance with the current requirements and procedures of the REB.

2.10 The Principal Investigator shall report any new information, including any unanticipated problem, to the REB in accordance with its Standard Operating Procedures (SOPs) and any applicable laws and regulatory requirements.

2.11 Copies of the applications submitted to the REB will be stored in OARI.

3. Research Subject to REB Review and Approval

3.1 All research at Saskatchewan Polytechnic or under the aegis of Saskatchewan Polytechnic involving human participants needs prior REB review and approval and applies to the following:

3.1.1 All types of research conducted with human participants when research data are derived from, but not exclusively limited to:

- information collected through intervention or interaction with living individual(s);
- identifiable private information about individuals;
- information collected through naturalistic observation of humans, except as stipulated in Section 4 of these Procedures;
- human organs, remains, tissues or body fluids, cadavers, embryos or fetuses;
- written or recorded information derived from individually identifiable human participants.

3.1.2 In addition, ethics review is required for the following categories of research that may be overlooked:

- pilot studies and feasibility studies, even those involving only one human participant;
- projects that involve the secondary use of data on human participants gathered in earlier projects;
- research conducted by administrative and academic units that involves the collection of survey replies or the use of records as it correlates to survey replies from human participants (e.g., students, staff and/or faculty members);
- all independent student projects conducted in partial fulfillment of certificate, diploma or degree requirements. Research projects conducted as part of formal course requirements may, in certain circumstances, require REB review and approval. It is incumbent upon the Saskatchewan Polytechnic course instructor to check the applicability of this requirement with the REB chair;
- research involving naturalistic observations requires an REB review and approval with some exceptions (see 4.1.3)

4. Research Not Subject to REB Review

4.1 Prior review and approval from the REB will not be required for the following types of research:

4.1.1 A limited type of research most often found within the humanities, fine arts, and in some historical research which involves:

(a) a public database where aggregated data that cannot be associated with any individual are obtained; or
(b) information already in the public domain (i.e., autobiographies, biographies, or public archives)

4.1.2 Archival analysis of records by Saskatchewan Polytechnic Programs normally engaged in the collection, maintenance and analysis of such records.

4.1.3 Naturalistic observation of participants in, for example, political rallies, demonstrations or public meetings where the participants are seeking public visibility.

4.1.4 Class research projects which involve human participants and which are conducted by students on other members of the class as an exercise to learn how to conduct research.

4.1.5 Evaluations of courses or training programs that are designed to provide feedback.

4.1.6 Preliminary and informal interviews or casual conversations that are carried out to help clarify the design of a research project.

4.1.7 Information gathering procedures in support of the general administration of Sask Polytech where the preliminary purposes are:

(a) to diagnose problems, identify appropriate solutions, provide advice for operation management, or assess performance; or
(b) to collect data primarily designed to affect the operations of Saskatchewan Polytechnic through affirming satisfaction with the status quo or leading to quality improvement

4.1.8 Information gathering procedures to collect institutional level data for administrative purposes.

4.1.9 Research undertaken as a teaching exercise and entailing minimal risk shall be reviewed by the program head or designate, and if they deem it appropriate they will forward it to the REB. In general, for such research involving teaching exercises, interviews, surveys or naturalistic observations where no personal or confidential information is used or disclosed will not require REB approval.

5. In the Case of Doubt

5.1 For research/scholarly work where the researcher is in doubt whether the REB review and approval is required, it is the responsibility of the researcher to consult with OARI and if needed OARI will direct the researcher to obtain a written opinion of the chair of the REB as to whether or not the research must be subjected to prior ethics review and approval.

6. Responsibilities of Researchers

6.1 Whenever research involving human participants is to be performed at Saskatchewan Polytechnic or under the auspices of Saskatchewan Polytechnic or by any Saskatchewan Polytechnic researcher, the researcher is responsible for meeting the following requirements:

6.1.1 Reading and becoming thoroughly familiar with applicable policies and ethical guidelines.

6.1.2 The researcher shall carefully monitor and assure the validity and appropriateness of the research submitted to the REB.

6.1.3 Determining if the proposed research requires ethics review. If there is any uncertainty about whether the research requires ethics review and approval, the researcher shall consult the REB for advice and decision.

6.1.4 Notifying the REB of the proposed research by submitting a completed Human Research Ethics Protocol accompanied by any supplementary materials necessary for full ethics review, and providing any additional information requested by the REB in a timely fashion.

6.1.5 Not involving human participants in the proposed research until the REB has informed the researcher of approval in writing for the use of human participants in the research.

6.1.6 Abiding by all decisions of the REB, including following all modifications required for the REB approval and not undertaking the research if it has not been approved.

6.1.7 Obtaining free and informed consent from all participants involved in research.

6.1.8 Ensuring that students and research staff are carefully trained and supervised in the conduct of research.

6.1.9 Maintaining the confidentiality of data obtained from participants in the manner required by the REB and relevant organizations.

6.1.10 Protecting the privacy of any individuals whose personal information has been obtained as part of any research activities as required under the *Local Authority Freedom of Information and Protection of Privacy Act* and the *Health Information Protection Act* and any other relevant legislation and policies.

6.1.11 Promptly reporting to the REB any injuries to human participants, any unanticipated problems which involve risks or unusual costs to the participants, or other adverse events resulting from the research. Initial reports may be verbal; subsequent reports shall be in the manner required by the REB, in most cases in writing.

6.1.12 Promptly reporting to the REB any proposed changes in the research which would result in a significantly different involvement of human participants and obtaining the approval of the REB prior to the changes being made, except where necessary to eliminate apparent and immediate hazards to participants.

6.1.13 Promptly reporting to the REB any proposed involvement of human participants in research which previously had no plans, or only indefinite plans, for participant involvement and obtaining the approval of the REB prior to the involvement of any participants.

6.1.14 Promptly reporting to the REB any serious or continuing non-compliance with the requirements of this policy or of the procedures stipulated by the REB by any individual associated with the research.

6.1.15 Providing details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.

6.1.16 Disclosing to the participant(s) any material incidental findings discovered in the course of research.

7. Free and Informed Consent of Participants

7.1 The researcher is responsible for obtaining free and informed consent from all prospective participants, or authorized third parties, in accordance with the standards and guidelines established by the REB, prior to commencing research activities. Free and informed consent must be maintained throughout participation in the research. Free and informed consent must be given voluntarily, without manipulation, undue influence or coercion.

7.2 In research that involves randomization and blinding in clinical trials free and informed consent is still required.

8. Research Involving First Nations, Inuit and Métis Peoples of Canada

8.1 Research involving First Nations, Inuit and Métis People of Canada requires review by the REB. The REB will review the research based on the standards and guidelines established in the TCPS2 2018 and any other guideline laid out by the REB.

8.2 The guidelines of the REB are not intended to override or replace ethical guidelines offered by Indigenous peoples themselves. Its purpose is to ensure, to the extent possible, that research involving Indigenous peoples is premised on respectful relationships.

8.3 Research ethics review by community REBs or other responsible bodies at the research site will not be a substitute for research ethics review by institutional REBs, and will not exempt Saskatchewan Polytechnic researchers from seeking institutional REB approval.

9. Qualitative Review

9.1 Qualitative research projects are subject to review and approval by the REB, following the standards set out in the TCPS2 2018 and any other guidelines laid out by the REB.

9.2 Researchers shall submit their research proposals, including proposals for pilot studies, for REB approval of its ethical acceptability prior to the start of recruitment of participants, or access to data.

9.3 Subject to the exceptions in TCPS2 2018, REB approval is not required for the initial exploratory phase (often involving contact with individuals or communities) intended to discuss the feasibility of the research, establish partnerships, or the design of a research proposal.

10. Research in Emergency Health Situations

10.1 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 advance of the research by the REB.

10.2 The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or of their authorized third party if ALL of the following apply:

- a serious threat to the prospective participant requires immediate intervention;
- either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care;
- either the risk of harm is not greater than that involved in standard efficacious care, or it is not clearly justified by the direct benefits to the participant;
- the prospective participant is unconscious or lacks capacity to understand risks, methods

and purposes of the research;
- third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; or
- no relevant prior directive by the participant is known to exist.

10.3 When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

11. Other Duties Related to the Support of the REB in Carrying Out its Mandate

11.1 The Saskatchewan Polytechnic deans and associate vice-presidents will provide support to the Saskatchewan Polytechnic member who sits on the REB with respect to:
- educational activities;
- committed time to serve on the REB;
- advising their faculty members about the need to comply with the TCPS.

11.2 Individual departments are expected to support and train faculty and students so that their research projects are ethical and those that exceed minimal risk may be efficiently reviewed by the REB.

11.3 Program heads (or designates) must screen student applications for ethical review prior to submission to the REB where such review is required.

12. Interpretation

12.1 Questions of interpretation or application of this policy or its procedures shall be referred to the Associate Vice-President Applied Research and Innovation or designate, who will interpret and apply the policy and procedures in congruence with the interpretations of the TCPS2 2018.