

**Research Ethics Board**

Application Procedure

All submissions to the Red River College Polytechnic Research Ethics Board will be submitted electronically to reb@rrc.ca

The Red River College Polytechnic REB follows the ethical guidelines governing research involving human subjects as outlined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS-2 (2018) <https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html>

Starting **October 1, 2020,** all researchers listed as principle investigators and submitting to the RRC Polytech REB, including student researchers, will be required to submit proof of completion of the TCPS 2: CORE Tutorial which introduces the researcher to the principles of the Tri-Council Policy statement <https://tcps2core.ca/welcome> A certificate is provided at the end of the tutorial that does not expire. Protocols will not be reviewed without proof of completion of the TCPS-2 CORE tutorial.

# Application Guidelines

1. The Research Protocol Submission Form is to be competed in detail, attaching additional pages as required, by all applicants. Incomplete applications will be returned to the applicant. The Board may request additional information as required.
2. Please also complete the checklist at the end of the Protocol Submission Form.
3. Applicants may submit their application at any time. Meetings of the RRC Polytech REB are scheduled monthly as per the dates posted on the RRC Polytech REB webpage <https://www.rrc.ca/numbers/ethics-board/>
4. As per the TCPS, all protocols by default may undergo review by the entire panel at the next scheduled REB. If a protocol is deemed minimal risk, it *may* be selected for a delegated review (two board members and the chair) and will be reviewed outside of the board meeting schedule within 10 business days of submission. High or medium risk protocols must be submitted a minimum of seven business days prior to a scheduled RRC Polytech REB meeting (for 2020-2021 – expect all protocols will be reviewed at REB meetings).
5. Protocols that have been pre-approved by Research Ethics Boards at another Canadian post-secondary institution following TCPS policies, in lieu of completing this form, may submit their approved forms and approval certificates from the original institution of approval. In most cases, the RRC Polytech REB chair or a delegate will review pre-approved protocols within 10 business days of submission. Please also complete the Addendum for Pre-Approved Protocols found on the RRC Polytech REB website: <https://www.rrc.ca/numbers/ethics-board/>
6. Protocols are approved for one year. After one year, applicants will be required to submit a request for renewal form or a study closure form. The RRC Polytech REB must approve any changes to the study protocol, including emergent design studies, prior to implementation using the Amendment Request Form. All adverse events must be reported using the Adverse Events Form.
7. Appeals:

Researchers must apply in writing to the President to appeal a negative REB decision. Appeals must be in writing and a copy of the appeal letter should also be sent to the REB Chair. RRC Polytech shall use a duly constituted Appeal Committee to review decisions of the REB. The appeal committee will be appointed by the President and consist of at least five members, none of whom is a member of the REB. Appeal committees shall have the same constitution as the REB. The appeal committee shall consist of both men and women, of whom:

* at least two members have expertise in the area of research covered by the appeal committee;
* at least one member is knowledgeable in the area of ethics;
* in the case of biomedical research at least one member must be knowledgeable in the area of biomedical research law;
* at least one community member with no affiliation to the institution;
* at least one member whose primary area of interest is in a nonscientific area.

Non-compliance with the substance of the TCPS is a reason for refusing to grant an appeal. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the TCPS. The decision of the Appeal Committee shall be binding.

Protocol #

(Assigned by REB Admin.)



# Research Protocol Submission Form

# Research Ethics Board

## Request for Approval of Proposed Research

|  |  |
| --- | --- |
| **Principal Researcher(s):**  |  |
|  **Position:** |  |
|  **Affiliation:**  |  |
|  **Address:**  |  |
|  **Phone:**  |  |
|  **Email:**  |  |
| **Research Project Title:** |  |
| **Project location:**  |  |
| **Start date:** |  |
| **Planned period of research:**  |  |
| **Expected date of termination:** |  |
| **Funding source (if any):**  |  |
| **Funding source grant# (for Tri-council funded RRC Polytech projects)** |  |
| **Study Sponsor (if any – please provide name and contact information and nature of sponsorship)** |  |

**Please list names and affiliations of other persons involved in conducting the research.**

|  |  |  |
| --- | --- | --- |
| **Name** | **Affiliation** | **Email** |
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**NOTE:** Please add additional rows to the table if there are more persons involved in conducting the research.

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| 1. In my judgment this project involves:
 |[ ]  minimal risk |
|  |[ ]  more than minimal risk |

The definition of minimal risk is “. . . that the risks of harm anticipated in the proposed research are not greater nor more likely, considering probability and magnitude, than those ordinarily encountered in life, including those encountered during the performance of routine physical or psychological examinations or tests.”

1. I confirm that all individuals named as co-investigators on this protocol are aware they have been listed in this submission.

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|[ ]  Yes |

1. Is this a student project? (e.g., is the research being conducted as partial fulfillment toward a degree?

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| --- |
|[ ]  Yes |
|[ ]  No |

 If yes, please provide the name of your faculty advisor.

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| --- | --- | --- |
| Name | Institution | Email |
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**Please complete the questions on the following pages in the expanding response boxes. Ensure that you have text in every response box even if the response is N/A (not applicable). All Appendix documents mentioned within should be included as a single separate file in the order they are mentioned within this protocol.**

**Describe the Proposed Study:**

1. Please Provide a concise summary of the project which describes:
	1. The study purpose.
	2. The study methodology (qualitative or quantitative and specific study design).
	3. The study procedures describing a timeline of research activities (when and how data will be collected, who will collect the data, intervention protocols, etc.)
	4. Make reference to and attach any relevant supplementary documents as Appendixes (Appendix A, Appendix B… etc.).

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1. Please provide a list of study instruments including all surveys, questionnaires, and interview questions.
	1. Write a brief description of what each instrument or survey is asking from participants.
	2. If you have included a demographic form, please briefly describe what demographics you are gathering and why collecting that demographic information about your sample will help answer your research question.
	3. If you are asking about personal health related information, please briefly describe why collecting this data is relevant for answering your research question.
	4. All instruments should be attached as Appendixes to this protocol.

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**Study Participants**

1. Describe your study population. Include in your description:
	1. Inclusion and exclusion criteria for participation
	2. How your participants will be recruited.
	3. How many participants you expect to recruit.
	4. Expected time commitment for the participants.
	5. Attach as Appendixes any relevant recruitment scripts or emails, or posters that will be used in your recruitment processes.

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1. Will the subjects in your study be AWARE that they are subjects?

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|[ ]  Yes |
|[ ]  No |

*If no, please elaborate:*

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1. Will any information about the subjects be obtained from sources other than the subjects (e.g. grades for courses, information from student records, medical records etc.)?

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|[ ]  Yes |
|[ ]  No |

*If yes, please elaborate:*

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1. Will participants receive any incentives or compensation for participating (e.g. honorariums, course credit, reimbursements etc.)?

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|[ ]  Yes |
|[ ]  No |

*If yes, please describe and justify the compensation that the participants will receive:*

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1. Are you or any members of your research team in a position of conflict of interest (e.g. power differential, financial, etc.) with participants (e.g. students, clients), family members, organizations, sponsors, or other groups with respect to this research?

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|[ ]  Yes |
|[ ]  No |

*If yes, please clarify this relationship and how procedures will be managed to reduce the conflict of interest:*

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1. Does the study involve participation of individuals who may be marginalized or vulnerable in the context of the research?

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|[ ]  Yes |
|[ ]  No |

*If yes, please describe how you will ensure that the participants do not feel pressured to participate:*

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1. Will your research involve individuals from Indigenous populations (First Nations, Inuit, or Metis)? Answer yes to this question only if you can say yes to any of a, b, or c:

	1. Your primary recruitment is exploring the experiences and/or opinions of individuals identifying as Indigenous or will take place on Indigenous lands.
	2. Your analysis intends to make comparisons between participants identified as having Indigenous heritage and those who do not.
	3. Your interpretation of your findings will consider Indigenous culture, history, language, and/or Indigenous knowledge in its conclusions.

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|[ ]  Yes |
|[ ]  No |

*If yes, please refer to Chapter 9 in the TCPS-2 and describe how in the planning of your research you have engaged with and/or sought involvement from Indigenous communities and/or organizations and addressed the core ethical principles of respect for persons, concern for welfare, and justice and their unique application to Indigenous populations. Please also attach any relevant supporting documentation or agreements to this protocol.*

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**Informed Consent Procedures:**

1. Describe how informed consent will be obtained from participants:
	1. Please review consent forms checklist available at the end of this form, and provide copies of all consent forms as Appendixes to this application.

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1. Does the study involve recruitment of participants who are not legally or practically able to give informed consent to participate in your study?

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|[ ]  Yes |
|[ ]  No |

*If yes, please describe who will provide consent on behalf of the participants, how you will gain assent from the participant (generally required from participants under the age of 18), or how you will recognize the participants’ change in willingness to participate in the research activities:*

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1. If study conditions dictate that informed consent will not be sought, please indicate the alternative consent procedures.

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1. How will participants be informed of their right to withdraw from the study?
	1. Describe the process for participants wishing to withdraw.
	2. What will happen to the data of participants wishing to withdraw?
	3. Identify if there is a point in the research processes after which withdraw of a participant’s information will no longer be possible.

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**Privacy and Confidentiality**

**All data collected for research purposes may be subject to privacy legislation and should be managed according to all applicable legislation. Please indicate your agreement with this statement:**

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|[ ]  I am aware that all research data management practices must comply with privacy legislation.  |

**Are you collecting data that falls under the Personal Health Information Act (PHIA)? E.g., if you ask about medical history, health service usage, or collect data on anxiety, depression, or other diagnosable psychological constructs, this would be considered PHIA data. PHIA data requires the highest level of data protection (e.g., encryption, password protection when sharing between team members).**

**Data management and breaches of data management are one of the most critical zones for protecting the privacy and confidentiality of participants. Prior to completing this section of the form, please review TCPS-2 Chapter 5 for complete definitions of the types of information researchers collect from participants.**

1. Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, student number, personal health number).
2. Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
3. Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants’ code names with their actual name so data can be re-linked if necessary).
4. Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
5. Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.
6. Please list all the forms of data that participants will be contributing to your research (e.g. paper surveys, electronic surveys, videos, audio recordings, transcripts, journals, emails to and from participants, course assignments, artwork, etc.) and label the data type with level of identifiability as noted in a. to e. above.

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1. Describe for each form of data mentioned in #14:
	1. How you will store the information or data collected and what measures will be taken to ensure it remains confidential (e.g., password protection, paper copies locked in a filing cabinet, encryption, de-identify data, code the data, use of pseudonyms)?
2. Who will have access to the data?
3. Describe how you will transfer the data (as applicable) to other research team members, transcriptionists, statisticians, etc. and ensure that the data will remain protected and confidential?
4. If any of the data is an electronic survey, identify privacy and confidentiality as indicated by the developer of the survey program (e.g. Qualtrics, Survey Monkey, etc.)
5. How long do you plan to keep the data at the end of the project and how will it be deleted/destroyed? (deletion from devices, shredding of paper surveys).
6. Do you plan to make the data public (open access) in any format, where will it be posted, and how will the data be prepared for those purposes? Note: Open data may be required if your project has Tri-council funding (CIHR, SSHRC, NSERC).

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1. If participants are identified directly by name or other means, do you plan to recruit them for future studies? (Please note, a separate ethics application may be required for this recruitment).

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|[ ]  Yes |
|[ ]  No |

*If yes, please elaborate.*

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1. Are there conditions where the privacy and confidentiality of your participants cannot be guaranteed? (e.g. focus groups, group intervention or activities where participants come face to face with each other)

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|[ ]  Yes |
|[ ]  No |

*If yes, please explain the processes that will be used to help limit risks to confidentiality for these participants.*

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1. Will participants be given the option to waive their anonymity*?*

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|[ ]  Yes |
|[ ]  No |

*If yes, please elaborate with rationale and ensure that you have acknowledged this waiver specifically in your consent processes:*

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1. If an unauthorized person was to gain access to any potentially identifiable participant data, are there any negative consequences that could arise for the individual participants or the community they belong to?

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**Risks and Benefits**

1. Identify any direct and indirect benefits to study participants and/or their community related to their involvement in this research study.

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1. What potential risks do study participants, the research team, or third parties, face with respect to the research activities? These risks may be physical, psychological (stress, re-traumatization), economic, legal, political or social (e.g. stigma). How will possible risks be reduced within the study procedures?

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1. During the course of the research, is it possible that unintended findings or revelations may emerge as a result of the data collection and trust relationships built during the research process? Unintended findings or revelations might include, but are not limited to, identification of abuse to a vulnerable population, diagnosis of a threating disease, identification of suicide risk, or admission of intention to commit a crime.

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|[ ]  Yes |
|[ ]  No |

*If yes, what provisions have you made in order to address these possible unintended findings or revelations, and at what point in the research will a participant be informed of these processes?*

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**Deception**

1. Will deception be involved in this study? Deception refers to any condition under which the participant will not be told the complete rationale for the purposes of the research. Need for deception might arise when knowledge of the true study purpose may influence participant behavior or responses. This may include situations where the participant is told an alternate purpose for the study. If relevant, the explanation given below must be sufficient to justify the deception and the possible need for waiver of informed consent.

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1. If deception is used, debriefing of participants at the conclusion of the study is mandatory. Please describe how participants will be debriefed about the deception procedures.

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**Feedback and Debriefing**

1. Will a summary of the study results be provided to participants? What procedures will be used in order to ensure participants can receive such a summary? Every effort should be made to provide a non-technical summary of results to participants if they desire or (if no contact information is collected) they should be made aware in the consent form that they could contact the researchers if they wish such a summary.

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1. How do you plan to disseminate your research findings?

	1. List all forms of dissemination anticipated.
	2. How will participant confidentiality be maintained? (e.g. aggregated data or pseudonyms)
	3. Please make your dissemination plans clear in your consent form.

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**Attestation:**

* I have reviewed the protocol contents and confirm that the information provided in this application is complete and correct.
* I agree to abide by the ethical guidelines and policies of the REB, including the Tri-Council Policy Statement and the Red River College Polytechnic Policy on the Ethics of Research Involving Humans.
* I will ensure the study does not commence until the final certificate of approval has been issued by the REB.
* I will ensure the study does not commence until approval has been granted by the appropriate organization, if applicable (i.e. chief and council, school board).
* I will ensure that study personnel are qualified, appropriately trained and will adhere to the REB-approved application.
* I will notify the REB of any protocol changes and report adverse events/experiences as soon as possible.
* I will submit a request for annual approval to the REB prior to the expiry date indicated on the approval certificate.
* I will submit a Study Closure Form to the REB when all study activity is completed at the local site.

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| **Signature of the Principal Researcher:**  |  | **Date:** |
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| **Signature of Faculty Advisor** **(for student submissions only)** |  | **Date:** |
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**Review your submission according to this checklist:**

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|  | **Checklist** |
|[ ]  All contact information requested is completed and accurate.  |
|[ ]  All questions within the application form contain a response even if the response is “not applicable.” Please do not leave any question blank.  |
|[ ]  Appendix documents are alphabetized in the order mentioned within the protocol and will be included in a single MS Word or PDF document. Appendix documents include: 1. All recruitment scripts and materials
2. All study instruments and interview questions
3. All consent forms
4. All supplemental material mentioned within the body of this application.
 |
|[ ]  Submission of the TCP2 Core Tutorial Certificate of the Principal researcher(s) is included with submission.  |
|[ ]  Checklist for informed Consent: [ ]  States the individual is being invited to participate in a research project;[ ]  Statements reflecting: the research purpose in plain language, the identity of the researcher, the identity of any funders or sponsors, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;[ ]  A plain language description of all reasonably foreseeable risks and potential benefits that may arise from research participation;[ ]  An assurance that prospective participants:1. are under no obligation to participate and are free to withdraw at any time without prejudice to pre-existing entitlements;
2. will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation;
3. will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

[ ]  As applicable, information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;[ ]  Statements reflecting how the research will be disseminated and whether participants will be identified directly or indirectly;[ ]  The contact information of the research team member assigned to explain scientific or scholarly aspects of the research to participants;[ ]  The contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;[ ]  Statements reflecting: what information will be collected about participants and for what purposes; who will have access to information collected about the identity of participants; a description of how confidentiality will be protected; a description of the anticipated uses of data; and, as applicable, information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;[ ]  Information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury, as applicable;[ ]  A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; |
|[ ]  Copy of this checklist.  |