# Research Ethics Board Application

Keyano College is committed to ensuring that all research affiliated with the College involving human participants meets the highest ethical standards. All research involving human participants (henceforth referred to as participants) led by College employees or students, funded or unfunded, or conducted at College facilities (whether by a College employee, student, or unaffiliated researcher) is required to be reported to and considered by the College Research Ethics Board (REB) prior to starting the research process.

The Keyano College policy, *Ethical Conduct for Research Involving Humans*, guiding this application is intended to ensure that research is conducted ethically, the rights of human participants in research are respected and protected, and research is conducted in a manner consistent with the guidelines and standards of the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html).

## Study Title

Click or tap here to enter text.

## Researchers

1. Principal Researcher Information.
	* Name: Click or tap here to enter text.
	* Position and Affiliation: Click or tap here to enter text.
	* Contact Information
	* Phone Click or tap here to enter text.
	* Email Click or tap here to enter text.
	* Mailing Address Click or tap here to enter text.
2. Identify the type of research or study.

[ ]  Faculty/staff research

[ ]  External research

[ ]  Student research

* + - If student research, identify the name of the supervisor below.

Click or tap here to enter text.

1. What qualifications are required to conduct this research? Please identify the principal researcher’s knowledge and background related to the research.

Click or tap here to enter text.

1. Co-researcher(s) contact information. Please provide email, phone, and mailing address for all persons who will have access to the raw data for data entry, analysis, and reporting purposes.

Click or tap here to enter text.

1. All researchers must complete the TCPS 2: Core 2022 certification PRIOR to receiving REB approval. Please attach a copy of successful completion for each member of the research project.

[ ]  Attached

## Project

1. Provide a lay summary of your proposed research project suitable for the general public [500-word limit].

Click or tap here to enter text.

Provide a description of your research proposal including study objectives, background, scope, methods, procedures, etc. Do not include footnotes or references.

Click or tap here to enter text.

1. Describe procedures, treatment, or activities that are above or in addition to standard practices in this study area (e.g., extra medical or health related procedures, curriculum enhancements, extra follow-up, etc.).

Click or tap here to enter text.

## Risk and Benefits Analysis

1. Provide your assessment of the risks that may be associated with this research (e.g., minimal, moderate, high). The REB uses the Tri-Council’s definition for *minimal risk research* in which the probability and scale of harm is no greater than what is encountered by the participants in those aspects of everyday life related to the research.

Click or tap here to enter text.

1. If beyond minimal risk, provide details of the risks and discomforts associated with the research (e.g., health, cognitive or emotional factors, socioeconomic status or physiological or health conditions).

Click or tap here to enter text.

1. If beyond minimal risk, describe how you will manage and minimize the risks and discomforts as well as mitigate harm.

Click or tap here to enter text.

1. If your study has the potential to identify individuals that are upset, distressed, or disturbed, or individuals warranting medical attention, describe the arrangements made to try to assist these individuals. Explain if no arrangements have been made.

Click or tap here to enter text.

1. Describe any potential benefits of the proposed research to the participants. If there are no benefits, state this explicitly.

Click or tap here to enter text.

1. Describe the scientific and/or scholarly benefits of the proposed research.

Click or tap here to enter text.

1. Describe the relationship of benefits to risk of participation in the research.

Click or tap here to enter text.

## Participants

1. Describe the population that you are studying. Identify the source of the participants and indicate any incentives for their participation.

Click or tap here to enter text.

1. Describe the inclusion criteria for participants (i.e., age range, health status, gender). Justify the inclusion criteria (e.g., safety, uniformity, research methodology, statistical requirement, etc.).

Click or tap here to enter text.

1. Describe and justify the exclusion criteria for participants.

Click or tap here to enter text.

1. Does the research specifically target Indigenous Peoples or communities?

[ ]  Yes

[ ]  No

1. Will there be direct contact with human participants for this study?

[ ]  Yes

[ ]  No

1. Will you be obtaining data from human participants (e.g., Internet survey responses from human participants)?

[ ]  Yes

[ ]  No

1. Does the project solely involve the use of pre-existing human and/or personally identifiable data and/or a review of health data (i.e., Chart review, analysis of health data held in an electronic chart/database/repository, review of administrative health data)?

[ ]  Yes

[ ]  No

1. How many participants do you hope to recruit (including controls, if applicable)? If this is a multi-site study, how many participants are expected to be enrolled by all investigators at all sites in the entire study?

Click or tap here to enter text.

1. Justification for sample size?

Click or tap here to enter text.

## Recruitment

1. Describe how you will identify potential participants (please be specific)?

Click or tap here to enter text.

1. Once you have identified a list of potentially eligible participants, indicate how the potential participants’ names will be passed on to the researchers AND how the potential participants will be approached about the research.

Click or tap here to enter text.

1. How will people obtain details about the research to make a decision about participating?

Click or tap here to enter text.

1. If appropriate, provide the locations where recruitment will occur.

Click or tap here to enter text.

1. Will potential participants be recruited through pre-existing relationships with researchers (e.g., Will an instructor recruit student from their classes? Will an employer recruit employees?)

[ ]  Yes

[ ]  No

* + If yes, identify the relationship between the researchers and participants that could compromise the freedom to decline (e.g., professor-student). How will you ensure that there is no undue pressure on the potential participants to agree to the study?

Click or tap here to enter text.

1. Outline any other means by which participants could be identified, should additional participants be needed (e.g., responses to advertising, pre-existing records, community organization referrals).

Click or tap here to enter text.

## Informed Consent

Researchers must ensure that participants understand that their participation is voluntary. Participants must freely agree to any specific disclosure that may be required and be fully aware of (and consent to) any risks that may be involved.

1. Describe who will provide informed consent for this study. Provide a sample document of how you plan to obtain participants’ informed consent (e.g., copy of email, word document, Google Form).

Click or tap here to enter text.

1. How is participant consent to be indicated and documented?

Click or tap here to enter text.

1. Describe the circumstances and limitations of data withdrawal from the study, including the last point at which it can be done.
2. Will this study involve any groups(s) where non-participants are present? For example, classroom research might involve groups which include participants and non-participants.

[ ]  Yes

[ ]  No

* + If yes, how will you ensure that non-participants are not included in the study? How will you ensure that data from non-participants are not used in the study?

Click or tap here to enter text.

* + If yes, during the recruitment process, how will you guard against peer pressure influencing an individual’s decision to participate or not?

Click or tap here to enter text.

* + If yes, how will you provide appropriate activities for non­participants?

Click or tap here to enter text.

* + If yes, how will you address discomfort or disadvantage, if any, arising outof non­participation?

Click or tap here to enter text.

1. Explain if consent obtained at the beginning of the study will be sufficient, or if it will be necessary to obtain consent at different times, for different stages of the study, or for different types of data.

Click or tap here to enter text.

1. At what stage, if any, can a participant withdraw their material?

Click or tap here to enter text.

## Confidentiality and Anonymity

Confidentiality ensures that the identity of participants is known only to the researcher(s) and in reporting, participants are not identifiable.

1. How will you ensure confidentiality of the information collected? Describe the collection process and plan for storage of information.

Click or tap here to enter text.

1. How will you ensure participants remain anonymous (is so desired)?

Click or tap here to enter text.

1. If appropriate, describe how consent will be obtained from participants for exceptions to confidentiality or anonymity.

Click or tap here to enter text.

1. If data are to be taken from existing sources, discuss the implications of pre-existing (implicit or explicit) guarantees of confidentiality or anonymity.

Click or tap here to enter text.

## Methodology & Data Management

1. If you or your participant’s audio­ or video­records, photographs, or other materials artistically represent participants or others, what steps will you take to protect the dignity of those that may be represented or identified?

Click or tap here to enter text.

1. Who will have access to this data? For example, in cases where you will be sharing sounds, images, or materials for verification or feedback, what steps will you take to protect the dignity of those who may be represented or identified?

Click or tap here to enter text.

1. When publicly reporting data or disseminating results of your study (e.g., presentation, reports, articles, books, curriculum material, performances, etc.) that include the sounds, images, or materials created by participants you have collected, what steps will you take to protect the dignity of those who may be represented or identified?

Click or tap here to enter text.

1. What opportunities are provided to participants to choose to be identified as the author/creator of the materials created in situations where it makes sense to do so?

Click or tap here to enter text.

1. If necessary, what arrangements will you make to return original materials to participants?

Click or tap here to enter text.

1. For interviews, focus groups, surveys, and questionnaires: Are any of the questions potentially of a sensitive nature?

[ ]  Yes

[ ]  No

* + - If yes, provide details.

Click or tap here to enter text.

1. If any data were released, could it reasonably place participants at risk of criminal or civil lawsuits?

[ ]  Yes

[ ]  No

* + - If yes, provide the justification for including such information in the study.

Click or tap here to enter text.

1. Will you be using audio/video recording equipment and/or other capture of sound or images for the study?

[ ]  Yes

[ ]  No

* + - If yes, provide details.

Click or tap here to enter text.

1. Will the researcher or study team be able to identify any of the participants at any stage of the study?

[ ]  Yes

[ ]  No

1. Will participants be recruited, or their data be collected from Alberta Health Services or Covenant Health, or a data custodian as defined in the Alberta Health Information Act?

[ ]  Yes

[ ]  No

1. Describe the primary/raw data being collected. Directly identifying information identifies a specific individual through direct identifiers like a name, social insurance number or personal health number. In contrast, indirect identifiers can, in combination, lead to identification (e.g., uncommon ethnicity, extreme age, unusual occupation, and other specific details).

Click or tap here to enter text.

1. If this study involves secondary use of data, list all original sources.

Click or tap here to enter text.

1. Describe how the data will be analyzed to answer the research question (e.g., statistical tests, content analysis, etc.).

Click or tap here to enter text.

1. In research where total anonymity and confidentiality is sought but cannot be guaranteed (e.g., where participants talk in a group) how will confidentiality be achieved?

Click or tap here to enter text.

1. Identify the personal identifiers you will be collecting at any time during the study, including recruitment, and provide a comprehensive rationale to explain why it is necessary to collect this information?

Click or tap here to enter text.

1. If identifying information will be removed at some point, when and how will this be done?

Click or tap here to enter text.

1. Specify what identifiable information will be retained once data collection is complete and explain why retention is necessary. Include the retention of master lists that link participant identifiers with de­identified data.

Click or tap here to enter text.

1. If applicable, describe your plans to link the data in this study with data associated with other studies (e.g., within a data repository) or with data belonging to another organization.

Click or tap here to enter text.

1. How will confidentiality of the data be maintained? Describe how the identity of participants will be protected both during and after research.

Click or tap here to enter text.

1. How will the principal investigator ensure that all study personnel are aware of their responsibilities concerning participants' privacy and the confidentiality of their information?

Click or tap here to enter text.

1. Will identifiable data be transferred or made available to persons or agencies outside the research team?

[ ]  Yes

[ ]  No

* + - If yes, describe in detail what identifiable information will be released, to whom, why they need access, and under what conditions? What safeguards will be used to protect the identity of subjects and the privacy of their data.

Click or tap here to enter text.

* + - Provide details if identifiable data will be leaving the institution, province, or country (e.g., member of research team is at another institution or country, etc.)

Click or tap here to enter text.

1. Describe below or provide a copy of your data management plan. Please cover the following topics:
	* Data collection: data types, files formats, naming, and version control
	* Documentation: ensure data can be read and interpreted
	* Data storage and backup throughout the research
	* Data preservation strategy for long-term access
	* Provisions for sharing and reuse
	* Data management responsibilities and resources
	* Ethical and legal compliance

Click or tap here to enter text.

1. Specify any plans for future use of the data. If the data will become part of a data repository or if this study involves the creation of a research database or registry for future research use, please provide details.

Click or tap here to enter text.

1. If you plan to destroy your data, describe when and how this will be done? Indicate your plans for the destruction of the identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs.

Click or tap here to enter text.

1. How will you ensure that the provisions of this policy are adhered to? For example, how will you or a co-researcher monitor each part of the research project to ensure the provisions of this policy are adhered to?

Click or tap here to enter text.

## Statement of Agreement

1. I have read the Keyano College Guidelines for Human Research Ethics and agree to abide by all obligations with respect to this project.

Initials of Principal Researcher: Click or tap here to enter text.

1. I agree to provide an annual status report due each June as well as an end of study report.

Initials of Principal Researcher: Click or tap here to enter text.

## Attachment Checklist

Refer to the checklist below to ensure you have provided all necessary documentation with your application. Please label all attached documents with the name of the document and principal researcher’s last name.

[ ]  TCPS 2: CORE certificate(s)

[ ]  Informed Consent Form(s)/Information Documents

[ ]  Research Instruments (e.g., Surveys, Cover Letters, Tests, Interview Scripts, etc.)

[ ]  Data Management Plan

[ ]  Other (e.g., Confidentiality Agreement, Study Budget, Course Outline, etc.)

## Contact

Research Ethics Board Email: REB@keyano.ca