1.1 Study Identification

Please answer all relevant questions that will reasonably help to describe your study or proposed research.

1.0 * **Short Study Title** (restricted to 100 characters)**:**

The short study title can be a quick reference, working title or acronym. The short title will be what you see in your "inbox" view of your applications.

2.0 * **Complete Study Title** (can be exactly the same as short title)**:**

This can be exactly the same as the short study title in Q1 (above). The complete title will be included in REB correspondence (i.e. approval letters, etc). The title given in the application form must correspond to the title on the consent form and other study documents. If the study is supported by research grant or contract funding that is being administered by the University, the title should correspond to the title on the grant or contract. If the research project is supported by multiple grants with different titles, ensure that all of the grants are clearly listed in Section 1.3 of the application and the title is thematically similar to the grants listed.

3.0 * **Select the appropriate Research Ethics Board (**Detailed descriptions are available at here**):**

Select the appropriate board which best suits your project.

	Board Name	Description
○	Health Research Ethics Board - Health Panel	REB3: All NON-invasive health research involving patients, health information, AHS (Edmonton Region) or Covenant Health facilities and researchers except cancer-related research, which should be reviewed by the HREBA-CC
○	HREB Biomedical	All invasive health research involving patients, health information, AHS (Edmonton Region) or Covenant Health facilities and researchers except cancer-related research, which should be reviewed by the HREBA-CC
○	Research Ethics Board 1	Research primarily involving in-person interviews, focus groups, ethnographies, or community engagement and instructor-led course-based research assignments.
○	Research Ethics Board 2	All interventional type research (behavioural, educational, social or performance interventions) and research where the primary ethical consideration relates to privacy or confidentiality (ie. surveys, questionnaires, secondary use of data).

Clear

4.0 * **Is the proposed research:**

○ Funded (Grant, subgrant, contract, internal funds, donation or some other source of funding)

○ Unfunded

Clear

5.0 * **Name of local Principal Investigator:**

6.0 * **Type of research/study:**

- ◯ Faculty/Staff
- ◯ Instructor Course-based (where all students in a class, individually or in groups, conduct the same or similar MINIMAL risk research assignments, following project guidelines provided by instructor)
- ◯ Graduate Student
- ◯ Medical Resident
- ◯ Post-doctoral Fellow
- ◯ Undergraduate student

Clear

7.0 * **Institutional Affiliation:**

- ◯ Alberta Health Services
- ◯ Athabasca University
- ◯ Concordia University of Edmonton
- ◯ Covenant Health
- ◯ Grant MacEwan University
- ◯ Norquest College
- ◯ St. Stephen's College
- ◯ University of Alberta
- ◯ University of Lethbridge
- ◯ Other External Institution

Clear

8.0 **Investigator's Supervisor**(required for applications from undergraduate students, graduate students, post-doctoral fellows and medical residents to REBs 1 & 2. HREB does not accept applications from student PIs):

9.0 **Study Coordinators or Research Assistants:** People listed here can edit this application and will receive all email notifications for the study:

Name	Employer
There are no items to display	

10.0 **Co-Investigators:** People listed here can edit this application and will receive email notifications (Co-investigators who do not wish to receive email, should be added to the study team below instead of here).
If your searched name does not come up when you type it in the box, the user does not have the Principal Investigator role in the online system. Click the following link for instructions on how to Request an Additional Role.

Name	Employer
There are no items to display	

11.0 **Primary Admin Contact** (a member of study team)**:**

12.0 **Study Team:** (co-investigators, supervising team, and other study team members) - People listed here cannot view or edit this application and do not receive email notifications.

+ Add

Last Name	First Name	Organization	Role/Area of Responsibility	Phone	Email
There are no items to display					

1.3 Study Funding Information

1.0 * **Type of Funding:**

- ☐ Grant (external)
- ☐ Contract (eg. Commercial, Industry, For-profit funding, etc)
- ☐ Internal Funds (eg. Start-up funds, TLEF, Operational, etc)
- ☐ Service Agreement (Funder pays for specific services, e.g. animal testing)
- ☐ Other

2.0 * **Indicate which office administers your award.** *(It is the PI's responsibility to provide ethics approval notification to any office other than the ones listed below)*

- ◉ University of Alberta - Research Services Office (RSO)
- ○ Alberta Health Services (NACTRC)
- ○ Covenant Health (including Institute for Reconstructive Sciences in Medicine-IRSM)
- ○ University of Lethbridge
- ○ Other

Clear

To connect your ethics application with your funding: provide all identifying information about the study funding – multiple rows allowed. For Project ID, enter a Funding ID provided by RSO/PeopleSoft Project ID *(for example, RES0005638, G018903401, C19900137, etc).***Enter the corresponding title for each Project ID.**

+ Add

Project ID	Title	Grant Status	Sponsor	Project Start Date	Project End Date	Purpose	Other Information

There are no items to display

3.0 * **Funding Source**

3.1 Select all sources of funding from the list below:

There are no items to display

3.2 If your source of funding is not available in the list above, click "Add" below and write the Sponsor/Agency name(s) in the free text box that pops up. *(Nore: You may reflect multiple sources of funding by continuing to click "Add" to add each additional source of funding).*

There are no items to display

+ Add

4.0 * **Indicate if this research sponsored or monitored by any of the following:**

- [ ] US Department of Health and Human Services (DHHS)
- [ ] US National Institutes of Health (NIH)
- [ ] US National Cancer Institute (NCI)
- [ ] US Food and Drug Administration (FDA)
- [ ] US Office of Human Research Protection (OHRP)
- [ ] Not applicable
- [ ] Other

The researcher is responsible for ensuring that the study complies with the applicable US regulations. The REB must also comply with US Regulations.

1.4 Conflict of Interest

1.0 * **Are any of the investigators or their immediate family receiving any personal remuneration (including investigator payments and recruitment incentives but excluding trainee remuneration or graduate student stipends) from the funding of this study that is not accounted for in the study budget?**

◯ Yes ◯ No Clear

2.0 * **Do any of investigators or their immediate family have any proprietary interests in the product under study or the outcome of the research including patents, trademarks, copyrights, and licensing agreements?**

◯ Yes ◯ No Clear

3.0 * **Is there any compensation for this study that is affected by the study outcome?**

◯ Yes ◯ No Clear

4.0 * **Do any of the investigators or their immediate family have equity interest in the sponsoring company? (This does not include Mutual Funds)**

◯ Yes ◯ No Clear

5.0 * **Do any of the investigators or their immediate family receive payments of other sorts, from this sponsor (i.e. grants, compensation in the form of equipment or supplies, retainers for ongoing consultation and honoraria)?**

◯ Yes ◯ No Clear

6.0 * **Are any of the investigators or their immediate family, members of the sponsor's Board of Directors, Scientific Advisory Panel or comparable body?**

◯ Yes ◯ No Clear

7.0 * **Do you have any other relationship, financial or non-financial, that, if not disclosed, could be construed as a conflict of interest?**

◯ Yes ◯ No Clear

Please explain if the answer to any of the above questions is Yes:

Important

If you answered YES to any of the questions above, you may be asked for more information.

1.5 Research Locations and Other Approvals

1.0 * **List the locations of the proposed research, including recruitment activities. Provide name of institution, facility or organization, town, or province as applicable**

Provide specific details. For example, the institution(s), campus(es), school(s), etc., where the research will be taking place.

Clarify if the local research team or a member of the local research team will be travelling to conduct research activities (i.e., travelling internationally, travelling to a remote site, etc.). NOTE: The University of Alberta Field Research Office may need to be contacted before conducting the research.

2.0 * **Indicate if the study will use or access facilities, programmes, resources, staff, students, specimens, patients or their records, at any of the sites affiliated with the following** (select all that apply):

The selection here will allow that institution view-access to the ethics application and is REQUIRED for operational/ administrative approval at that institution.

- ☐ Alberta Health Services Institutions and Facilities
- ☐ Covenant Health Institutions and Facilities
- ☐ Capital Care Institutions and Facilities
- ☐ Lethbridge School Division Zone 6
- ☐ Not applicable

List all health care research sites/locations:

3.0 **Multi-Institution Review**

* **3.1 Has this study already received approval from another REB?**

◯ **Yes** ◯ **No** Clear

Minimal risk ethics applications may be eligible for a streamlined REB review. Additional information is available here on our website.

If partnering with researchers at UCalgary or UBC, researchers are encouraged to use REB Exchange (REBX). Please see REBX information on their website. Contact the UAlberta REB Office via email at ethics@ualberta.ca with any questions.

4.0 **If this application is closely linked to research previously approved by one of the University of Alberta REBs or has already received ethics approval from an external ethics review board**(s)**, provide the study number, REB name or other identifying information. Attach any external REB application and approval letter in the Documentation Section – Other Documents.**

2.1 Study Objectives and Design

1.0 * **Provide a lay summary of your proposed research which would be understandable to general public**

Your response here MUST be written at a grade 6-8 reading level. Explain your study as if you were talking about what you do to a member of the general public. For guidance on ensuring that your reponse is written at a reading level of grade 8 or below, please see: https://hemingwayapp.com/

It is a requirement of the Tri-Council Policy Statement (TCPS2) that research ethics boards (REB) have community/committee reviewers involved in the review of research proposals. Community/committee reviewers offer important insights essential to the ethical review of research and can be from diverse backgrounds. Accordingly, it is important that they be able to understand the nature of the research they are reviewing. This lay summary should explain in non-technical and non-scientific terms the nature of the research being proposed.

2.0 * **Provide a full description of your research proposal outlining the following:**

- **Purpose**
- **Hypothesis**
- **Justification**
- **Objectives**
- **Research Method/Procedures**
- **Plan for Data Analysis**

Click this triangle to expand a tool bar. This can facilitate the text formatting, such as adding bullets or pasting content from a Microsoft Word

Please use the headings listed above. NOTE: Not all heading may be applicable to your research. For example, some social science research studies may not have a hypothesis.

Your research proposal here will be reviewed in detail by a REB reviewer. The REB reviewers will have a scientific background but may not be an expert in your field. Therefore, in this section, you are to provide a clear and descriptive outline of your research proposal that would be understandable to the reviewers. For example, explain the flow of events, explain the setting of data collection (i.e. online, in person, etc), explain your research population, explain estimated time commitments of participation. NOTE: Details on your recruitment plans will be captured in a later section (Section 4.4) and therefore a brief overview on recruitment should be sufficient in this section.

Helpful Tips:

Define all acronyms upon first use.

References/citations do not need to be listed here if they are included in a protocol or proposal document within section 6.0 of the Documentation section.

For multi-site studies: In this section, first clearly outline what the local researcher's role in the study will be. For example; "The University of Alberta researcher's role in this multi-site project is restricted to <insert role>". Some example roles could be data/sample analysis, development of survey/questionnaire, manuscript preparation, local recruitment/enrolment, etc. Clearly outlining your role will help the REB determine the research activities under the University of Alberta Ethics purview.

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

This question does not apply to majority of REB1 and REB2 studies. Response can be left blank.

4.0 If the proposed research is above minimal risk and is not funded via a competitive peer review grant or industry-sponsored clinical trial, the REB will require evidence of scientific review. Provide information about the review process and its results if appropriate.

This question does not apply to majority of REB1 and REB2 studies. Response can be left blank.

5.0 For clinical trials, describe any sub-studies associated with this Protocol.

This question does not apply to majority of REB1 and REB2 studies. Response can be left blank.

The methods listed below have additional branching out Sections that will populate as a result of your choices. Please select all methods listed below as they apply to your research and complete all applicable Sections that populate.

2.2 Research Methods and Procedures

Some research methods prompt specific ethical issues. The methods listed below have additional questions associated with them in this application. If your research does not involve any of the methods listed below, ensure that your proposed research is adequately described in Section 2.1: Study Objectives and Design or attach documents in the Documentation Section if necessary.

1.0 * **This study will involve the following**(select all that apply)

- ☐ Food, Nutrition and Nutraceuticals
- ☐ Internet-based Interaction with Participants (excluding internet surveys or data collection over internet without human interaction)
- ☐ Interviews and/or Focus Groups
- ☐ Materials created by participants (eg. artwork, writing samples, photo, voice, etc.)
- ☐ Participant Observation
- ☐ Research focusing on First Nations, Inuit and Metis Peoples
- ☐ Surveys and Questionnaires (including internet surveys)
- ☐ Use of Partial Disclosure and/or Use of Deception
- ☐ Use of Participant Subject Pool (i.e. Psychology Research Participation Program, Alberta School of Business Research Panel, Department of Linguistics)
- ☐ Data Registries and/or Biobanking (collection of samples to put in a Biobank/Sample Repository)
- ☐ Clinical Trial
- ☐ Collection of Human Biological Materials (ie. blood, tissue etc.)
- ☐ Drugs, Medical Devices, Biologics or Vaccines and/or Natural Health Products
- ☐ Stem Cell Research (attach CIHR Oversight Committee Approval in Documentation section)
- ☐ Use of Health Information - See NOTE 1 below
- ☐ Secondary Use of Human Biological Materials - See NOTE 2 below
- ☐ Secondary Use of Information (Use of data previously collected for another purpose) - See NOTE 3 below
- ☐ None of the above

NOTE 1: Select this if you are directly collecting health information as part of your protocol OR will be conducting a chart/record

review/reviewing health data secondarily. This includes anonymized or identifiable health information.

NOTE 2: Select this option if this research ONLY involves analysis of blood/tissue/specimens originally collected for another purpose but now being used to answer your research question. If you are enrolling people into the study to prospectively collect specimens to analyze you SHOULD NOT select this box.

NOTE 3: This section is intended to reflect the secondary use of non-health data. Do NOT select this if you are using data that originally came from health sources, i.e., anonymized administrative data.

2.3 Food, Nutrition, and Nutraceuticals Information

1.0 Product Source

*** 1.1 What is the source of any dietary products that participants will consume?**

*** 1.2 Describe how you know that the products were produced within acceptable standards for food safety?**

Please see this website for guidelines.

2.0 Safety Monitoring

*** 2.1 Is there any current recommendation that the use of the products identified requires any additional safety testing or monitoring?**

◯ Yes ◯ No Clear

3.0 Dietary Levels

*** 3.1 Does the level of dietary ingredients exceed any Canadian nationally recommended levels?**

◯ Yes ◯ No Clear

4.0 Nutritional/Dietary counseling or advice

4.1 If any nutritional or dietary advice or counseling will be offered to participants in conjunction with this study, what is the nature of the advice? *(i.e., does it follow any specific published dietary recommendations?)*

4.2 What are the qualifications of the person(s) who will be providing the advice (either in paper or leaflet format, or in personal counseling or lectures)?

2.4 Internet-based Interaction with Human Participants

1.0 Internet-based Research

1.1 Will your interaction with participants occur in private internet spaces (eg. members only chat rooms, social networking sites, email discussions, etc)?

◯ Yes ◯ No Clear

1.2 Will these interactions occur in public space(s) where you will post questions initiating and/or maintaining interaction with participants?

◯ Yes ◯ No Clear

2.0 Describe how permission to use the site(s) will be obtained, if applicable:

Please see the next page.

3.0 If you do not plan to identify yourself and your position as a researcher to the participants, from the onset of the research study, explain why you are not doing so, at what point you will disclose that you are a researcher, provide details of debriefing procedures, if any, and if participants will be given a way to opt out, if applicable:

4.0 * How will you protect the privacy and confidentiality of participants who may be identified by email addresses, IP addresses, and other identifying information that may be captured by the system during your interactions with these participants?

2.4 Internet-based Interaction with Human Participants

2.0 Describe how permission to use the site(s) will be obtained, if applicable:

The intent of this section is to capture research that involves internet-based interaction with human participants, such as observing individuals interacting online or using the internet as an environment to study human behavior. The following types of research should be described in this section:

1. Social Media Platforms: Platforms like Facebook, X, Instagram, and LinkedIn where there is direct interaction with human participants.
2. Online Forums and Communities: Websites like Reddit, Quora, and various specialized forums allow people to engage in discussions, share ideas, and answer questions.
3. Online Games: Multiplayer online games like Fortnite, World of Warcraft, and others create spaces where people can interact in real-time through gaming.
4. E-commerce: People interact with sellers or other buyers on platforms like Amazon, eBay, or Etsy, often involving messaging, feedback, or transaction processes.
5. Private Chatrooms or Groups.

The following types of research should not be described in this section:

6. Video Conferencing: Tools such as Zoom, Microsoft Teams, and Google Meet enable face-to-face communication over the internet through video calls, webinars, and virtual meetings.
7. Chatbots or AI Assistants: Interactions where users communicate with automated systems or AI-driven programs like virtual assistants (e.g., Siri, Alexa, or ChatGPT) for assistance, customer service, or entertainment.
8. Email Communication

2.5 Interview and/or Focus Groups

1.0 Will you conduct interviews, focus groups, or both? Provide detail.

- Specify which methods will be used here (interviews, focus groups, sharing circles).
- Specify the estimated time commitment, number and frequency of interviews/focus groups/sharing circles.
- Specify the estimated number of participants within each focus group/sharing circle.

2.0 How will participation take place (e.g. in-person, via phone, email, Skype)?

- Outline how data will be collected (e.g. in person, telephone, or video conferencing platform).
- Specify who will conduct the interview or focus groups (e.g. local study team member or other).
- If video conferencing platform recordings are being collected, name the platform which will be used.

Note: The participants should be given the option to turn off their cameras if using video conferencing, unless the researchers have a justified reason for data collection via the video recordings.

3.0 How will the data be collected (e.g. audio recording, video recording, field notes)?

- Be clear if you are collecting field notes, audio, video or a combination. Name the type of device that is used to collect the recordings.

NOTE: If collecting video data, explain why it is necessary to take a video recording. Capturing an audio recording rather than a video recording would reduce risks to participants' privacy/confidentiality.

- If virtual platform recordings are being collected, the recordings should be downloaded to a locally secure device and not stored on a cloud-based platform.

2.6 Material Created by Participants

1.0 Provide a summary of the materials created by participants that will be included in this research project:

Please see the next page.

2.0 Who will have access to this data?

3.0 When publicly reporting data or disseminating results of your study (eg. presentation, reports, articles, books, curriculum material, performances, etc) that include the materials created by participants, what steps will you take to protect those who may be represented or identified - both participants and non-participants?

4.0 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?

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

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

◯ Yes ◯ No Clear

2.6 Material Created by Participants

1.0 Provide a summary of the materials created by participants that will be included in this research project:

This methodology should reflect materials created by participants to be analyzed as data for this research study. These are not materials that existed already, instead they were generated specifically for this project. Common examples include artwork, writing samples, photos provided by participants (i.e. Photo-voice methodology), music or audio created by participants, other intellectual property created by participants etc.

NOTE: This section DOES NOT apply to the following scenarios:
- Audio/video recordings are part the data collected via interviews/focus groups/sharing circles or other observational methodologies.
- Open-ended responses within a survey/questionnaire.

Participant observation may be used to study actions or behaviours in a variety of settings such as in publicly accessible spaces (e.g., a stadium, library, museum, beach, park), in virtual settings (e.g., online groups), or in private or controlled spaces (e.g., private clubs or organizations).

2.7 Participant Observation

1.0 Who will the observer be?

2.0 Who is being observed?

3.0 Why are they being observed?

Address if the dissemination of research (e.g., through publications, photographs, audio recordings, or video footage of groups or particular individuals) will allow the identification of individuals observed in public places especially if the public place may be predicted to be associated with potential stigma.

4.0 When and where will participants be observed (i.e. during class, during their workday)?

Be sure to address if the participants within that setting may have an expectation of privacy. For example some religious ceremonies may take place in a public location but the persons attending may expect privacy in that setting.

5.0 Will others be present who are not being observed (i.e. non-participants)?

● Yes ○ No Clear

Provide details:

6.0 What data will be collected?

- ☐ Video and/or audio recordings
- ☐ Photographs
- ☐ Field notes

☑ Other

Provide details:

If your data collection method for the participant observation is not reflected from the list above, select "Other" and add details here.

NOTE: The selections here should reflect data collected for the participant observation methodology only.

2.8 First Nations, Inuit and Metis People

1.0 * **If you will be obtaining consent from Elders, leaders, or other community representatives, provide details:**

Article 9.1 of the TCPS2 provides criteria for when community consultation or engagement should occur. Where these criteria are met, the onus is on the researcher to demonstrate to the REB that efforts have been taken to engage with the community that will be involved with this project BEFORE the submission of this ethics application. This question is not asking whether or not you will consent Elders, leaders, etc., as research participants but rather, it is here that you will demonstrate that you have engaged in appropriate community consultation. Here you should describe who you have consulted with and what that process looked like. Many Indigenous communities have formal processes for engaging with them. When there is no specific community, the researcher should consult Chapter 9 of the TCPS2 and demonstrate to the REB how they have effectively incorporated Indigenous representation and voice into the project.

2.0 **If leaders of the group will be involved in the identification of potential participants, provide details:**

It is often the case that Elders will be involved in the identification and recruitment of potential participants. Where it may seem that there is a power differential in this methodology, it may be culturally appropriate and acceptable to the specific community. Recruitment procedures are often a part of the engagement process and should be described here.

3.0 **Provide details if:**

- property or private information belonging to the group as a whole is studied or used;
- the research is designed to analyze or describe characteristics of the group, or
- individuals are selected to speak on behalf of, or otherwise represent the group

The bulleted criteria above are taken from Article 9.1 TCPS2. These are some of the criteria that determine if the project is Indigenous focused and therefore requires community consultation/engagement. Describe how any aspect of your project meets these criteria and how this contributes to the overall study objective/purpose.

4.0 * **Provide information regarding consent, agreements regarding access, ownership and sharing of research data with communities:**

Through the consultation and engagement process, parameters are set regarding ownership, control, access and possession (OCAP) of the data that is provided and generated in the research process. These general principles should be applied to all Indigenous research. Describe here what provisions have been made to ensure that these principles are being upheld. How is the data being shared with the community being studied? Describe how consent is being obtained where there may be deviation from normal consent processes.

5.0 **Provide information about how final results of the study will be shared with the participating community** *(eg. via band office, special presentation, deposit in community school, etc)***?**

Describe how the data may be jointly shared with the community during requisite data retention periods and ultimately returned to the community once these retention periods have passed.

Please consult Article 9.17 and Article 9.18 for additional considerations on the interpretation and dissemination of research results.

6.0 **Is there a research agreement with the community?**

◯ Yes ◯ No

As per Article 9.11 of the TCPS2, Where a community has formally engaged with a researcher or research team through a designated representative, the terms and undertakings of both the researcher and the community should be set out in a research agreement before participants are recruited. If there is no formal research agreement in place, please describe the process for community engagement/consultation. Any records or evidence of this consultation (i.e., email correspondence) should be appended in the documents section Q11.0

2.9 Surveys and Questionnaires (including Online)

1.0 How will the survey/questionnaire data be collected (i.e. collected in person, or if collected online, what survey program/software will be used etc.)?

Outline how survey data will be collected (e.g. paper or electronic) and returned. If it will be collected using an electronic survey program/software please provide details about the platform and/or the software that will be used.

2.0 Where will the data be stored once it's collected (i.e. will it be stored on the survey software provider servers, will it be downloaded to the PI's computer, other)?

- Provide details on how the survey data will be stored by the research team.
- If paper surveys will be entered into an electronic software/platform, provide details of the program/software being used.
- For any survey program/software which are hosted on servers external to the University, it's recommended to remove data from the survey program/software after data collection is complete.

3.0 Who will have access to the data?

Please clearly outline all parties who will have access to the data.

4.0 If you are using a third party research tool, website survey software, transaction log tools, screen capturing software, or masked survey sites, how will you ensure the security of data gathered at that site?

Provide details about the online tool/software privacy and security, and data storage/data retention policies. Consider any technical safeguards of the survey platform/software (i.e. protection behind University firewall, encryption, etc.) or any study-specific practices (i.e., limited collection of identifiable participant data on the survey platform, restricted access to the data on the platform, etc.)

2.10 Secondary Analysis

1.0 Outline what data you are analyzing for this research

What data that was previously collected are you now proposing to use for secondary use of the information? Provide an outline of the information you are analyzing.

2.0 How was the original data collected?

Explain if data was originally collected from another research project, through a survey, interviews, if it is data from an existing database, etc.

3.0 Estimate how many records you will analyze, if applicable (i.e. approximately 300 surveys collected from 2012, 5000 student records from 1999-2009 at University of Alberta).

4.0 How will you receive the data for analysis?

- ☐ Data is anonymous
- ☐ Anonymized by the data holder/custodian (study team never has access to identifying data)
- ☐ Study team will be provided identifying data

5.0 Will you be obtaining consent from participants for the secondary use of identifiable information?

○ Yes ● No Clear

5.1 If you are asking for a waiver of participant consent, please refer to Article 5.5A of TCPS2 and provide justification for a Waiver of Consent for ALL criteria (a-e).

Note: This question is not asking if consent was obtained for the original data collection, but if consent will be obtained for THIS new secondary analysis of the previously collected data. This question need only be completed if the data you are receiving from the data custodian is identifiable.
Click the link within question 5.1 above to access Article 5.5A of the TCPS2. You need to justify to the REB using all bullets (A-F) if you are asking for a waiver of consent.

Please remember to upload the following to the Documentation Section:

1) Original data collection instrument(s), or an outline of the information you are analyzing.

2) Original consent/info (if applicable - if individuals have previously agreed for their data to be used in future research/for research purposes).

2.11 Use of Deception or Partial Disclosure

1.0 * **Describe the information that will be withheld from, or the misinformation that will be provided to, the participants:**

In some research, a certain level of deception or partial disclosure of information is necessary in order for the research to be successful. Article 3.7A of the TCPS2 sets strict conditions for scenarios where deception or partial disclosure is permitted:
- the research involves no more than minimal risk to the participants;
- the use of deception or partial disclosure is unlikely to adversely affect the welfare of participants;
- it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
- the precise nature and extent of any proposed deception or partial disclosure is defined; AND
- there is a plan to provide a debriefing that may also offer participants the possibility of refusing consent and/or withdrawing data. If debriefing is not planned, this must be justified to the REB in accordance with Article 3.8B of the TCPS2.

2.0 **Provide a rationale for withholding information:**

3.0 **Indicate how and when participants will be informed of the concealment and/or deception. Describe the plans for debriefing the participants. Indicate when the participants will be debriefed, and describe the nature and extent of debriefing:**

4.0 **Describe the procedure for giving the participants a second opportunity to consent to participate after debriefing. Explain if debriefing and re-consent are not viable:**

At the time of debriefing, participants should, whenever possible, practicable and appropriate, be able to indicate their consent/assent or their refusal for the continued use of their data (Article 3.7B of the TCPS2).

5.0 **Indicate how participants may follow-up with researchers to ask questions or obtain information about the study:**

The debriefing document/script should be uploaded for REB review in the Documentation Section.
The following elements should be included in the debriefing script:
- The researcher's name and institutional contact information.
- PI's institutional logo.
- Explanation of the nature of deception/partial disclosure and its necessity.
- UofA REB Office contact information and the Ethics ID # (i.e. Pro00xxxxxx).
- Details regarding participants' freedom to withdraw from the study and/or withdraw their data following learning about the use of deception.

This section is only for STUDENT participant pools. Recruitment via other participants pools (i.e. MTurk, Qualtrics Pool etc) will be captured in Section 4.4 of the application.

2.12 Use of Participant Subject Pool

1.0 What participant pool will you use to recruit participants?

Name
☐ REES (Resource Economics and Environmental Sociology)
☐ Other
☐ Business
☐ Psychology
☐ Educational Psychology
☐ Linguistics

2.0 Amount of time the study will take:

3.0 Will Participant Receive:

Course credit

◯ Yes ◯ No Clear

Payment

◯ Yes ◯ No Clear

4.0 Provide a brief description of the alternate task:

Where students do not wish to participate in research studies for course credits, they should be offered a comparable alternative to receive the course credit (per TCPS2 Article 3.1). The time commitment required to complete alternative tasks should be equivalent to the time required to complete study activities.

The alternate task should only be offered as a choice to participants at the time of consent and never offered as a consequence of early withdrawal from the research task(s).

If there is no alternate task, explain why:

5.0 Will participants be debriefed?

◯ Yes ◯ No Clear

if YES please attach the debriefing document in the Documentation Section

6.0 Explain the procedure students will follow if they choose to withdraw participation and/or data, and any limitation to withdrawal:

Ensure your practices allow for allotment of the course credit incentive to be made to participants who withdraw mid-way through participation.
The participant should not suffer any disadvantage or reprisal for withdrawing participation, nor should any allotment of course credit due before the point of withdrawal be withheld. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a schedule of incentives is used, student participants shall be awarded the incentive earned in proportion to the extent of their participation (per TCPS2 Article 3.1).

3.1 Risk Assessment

1.0 * **Provide your assessment of the risks that may be associated with this research:**

- ◯ Minimal Risk - research in which the probability and magnitude of possible harms implied by participation is no greater than those encountered by participants in those aspects of their everyday life that relate to the research (TCPS2)
- ◯ Greater than Minimal Risk

Clear

2.0 * **Select all that might apply:**

Description of Possible Physical Risks and Discomforts	
	Participants might feel physical fatigue, e.g. sleep deprivation
	Participants might feel physical stress, e.g. cardiovascular stress tests
	Participants might sustain injury, infection, and intervention side-effects or complications
	The physical risks will be greater than those encountered by the participants in everyday life

Possible Psychological, Emotional, Social and Other Risks and Discomforts	
	Participants might feel psychologically or emotionally stressed, demeaned, embarrassed, worried, anxious, scared or distressed, e.g. description of painful or traumatic events
	Participants might feel psychological or mental fatigue, e.g intense concentration required
	Participants might experience cultural or social risk, e.g. loss of privacy or status or damage to reputation
	Participants might be exposed to economic or legal risk, for instance non-anonymized workplace surveys
	The risks will be greater than those encountered by the participants in everyday life

3.0 * **Provide details of all the risks and discomforts associated with the research for which you indicated YES or POSSIBLY above.**

In this question, please describe all study risks. Risks outlined in this section should correspond with your responses to question 2.0 above. Risks described in question 3.0 should also correspond with risks stated in the information letter/consent form.

For example, if you will be asking participants to complete a questionnaire that asks about the state of participants' mental health, you need to describe in this section the risks associated with the completion of this questionnaire.

4.0 * **Describe how you will manage and minimize risks and discomforts, as well as mitigate harm:**

Minimize Harms: Include an explanation of any strategies put in place to minimize and/or manage the risks for participants you have outlined in question 3.0 above.

For example, if the study team will provide a mental health resource list, describe the resources that will be provided.

5.0 **Is there a possibility that your research procedures will lead to unexpected findings, adverse reactions, or similar results that may require follow-up** (i.e. individuals disclose that they are upset or distressed during an interview/questionnaire, unanticipated findings on MRI, etc.)**?**

● Yes ○ No Clear

Describe the arrangements or referral the researcher will make. Explain if no arrangements have been made.

Over the course of the implementation of the approved research project, issues may arise that the researcher did not anticipate when originally submitting the research for ethics review. Unanticipated issues include unexpected reactions by participants to a research intervention (e.g., unintended stimulation of traumatic memories, etc.,). They may be minor or serious in magnitude, with short- or long-term implications.
Describe the arrangements or referrals the researcher will make. Explain if no arrangements will be made and justify why. The REB will require evidence that the researcher has made arrangements to support participants in dealing with the issues described above.

The researcher has a duty of care to the participant and must ensure that such unanticipated findings are handled in a manner that is respectful to the well-being of the study participant.

6.0 **If you are using any tests in this study diagnostically, indicate the member(s) of the study team who will administer the measures/instruments:**

+ Add

Test Name	Test Administrator	Organization	Administrator's Qualification

There are no items to display

7.0 **If any research related procedures/tests could be interpreted diagnostically, will these be reported back to the participants and if so, how and by whom?**

Indicate how you plan on communicating results of the tests you have listed above question 6.0 to the study participant.

3.2 Benefits Analysis

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

Research benefits can be direct or indirect (e.g. the research benefits a group in which the participant belongs). This being said, research is undertaken to answer a scientific question and while it may benefit society in the future, its primary intent is not to benefit the consenting participant. Scholarly and global benefits should be described in question 2.0 below.

The consent form and your response to question 1.0 should specify the benefits to the prospective participants. If there are no direct benefits to the participants from participating in the research, this must be stated explicitly in question 1.0 (and in the consent form). If any specific benefits cannot be assured but may be hoped for by the participant, state explicitly that the participant may or may not benefit from participation in the study.

Incentives (i.e. money, prize draws, course credits, etc.) are not a study benefit. Please do not mention incentives in this section.

2.0 * Describe the scientific and/or scholarly benefits of the proposed research:

This section MUST be completed and shall be an appropriate discussion of why you believe the study should be done. Without this information, the REB will not be able to properly review your application.

3.0 If this research involves risk to participants explain how the benefits outweigh the risks.

REB review is based on a core principle of Concern For Welfare for participants. Researchers and REBs should aim to protect the welfare of participants, and, in some circumstances, to promote that welfare given any foreseeable risks associated with the research. They are to provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation in the research. To do so, researchers and REBs must ensure that participants are not exposed to unnecessary risks. Researchers and REBs must attempt to minimize the risks associated with answering any given research question. They should attempt to achieve the most favourable balance of risks and potential benefits in a research proposal. Then, in keeping with the principle of Respect for Persons, participants or authorized third parties, make the final judgment about the acceptability of this balance to them.

4.1 Participant Information

1.0 * **Will you be recruiting human participants** *(i.e. enrolling people into the study, sending people online surveys to complete)***?**

● Yes ○ No Clear

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

○ Yes ○ No Clear

4.2 Additional Participant Information

1.0 **Describe the participants that will be included in this study. Outline ALL participants** (i.e. if you are enrolling healthy controls as well):

Provide an overview of the participant population(s) that you will recruit.

2.0 * **Describe and justify the inclusion criteria for participants** (e.g. age range, health status, gender, etc.):

You might respond to this question with bullet points where each line item would list the inclusion criteria with its associated justification.

Helpful Tips:

• If recruiting from a student participant pool (i.e. Psychology, Business), note that participants may not be of the age of 18 however the TCPS does not rely on the concept of "age of majority" to determine whether people have the necessary capacity to consent to research. In the case of post-secondary students recruited as research participants, the relevant criterion is not their age, but rather whether these students have the capacity to consent on their own behalf in the context of the particular study (see Article 3.10 of the TCPS2).

• When you are recruiting several groups of participants, please describe the full inclusion criteria for each group under a separate subheading.

3.0 **Describe and justify the exclusion criteria for participants:**

You might respond to this question with bullet points where each line item would list the exclusion criteria with its associated justification.

4.0 Participants

4.1 How many participants do you hope to recruit (including controls, if applicable?)

4.2 Of these, how many are controls, if applicable?

4.3 If this is a multi-site study, how many participants do you anticipate will be enrolled in the entire study?

A study with multi-site recruitment will involve more than one institution carrying out recruitment and enrollment of study participants.

5.0 Justification for sample size:

If no formal sample calculations are available, address how the research has arrived at the determination that enrolling the number of people stated in question 4.1 (and if applicable question 4.2) will allow your team to address your research question.

4.4 Recruitment of Participants (non-Health)

1.0 Recruitment

1.1 How will you identify potential participants? Outline all of the means you will use to identify who may be eligible to be in the study(i.e. response to advertising such as flyers, posters, ads in newspapers, websites, email, list serves, community organization referrals, etc.)

Clearly articulate how potential participants will be identified. Are you identifying individuals from publicly available sources, i.e., the internet? Will you identify individuals from confidential sources, i.e., memberships in particular groups or organizations that are not publicly available?

1.2 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 will the potential participants be approached about the research.

- With as much description as possible, outline how potential participants are approached. For closed membership groups, it may be that an administrator of that group forwards the recruitment materials to potential participants on behalf of the study team.
- Where there is direct participant recruitment, describe in detail how that encounter occurs, including details about where, how and who is making the first contact. Address any potential for undue influence.
- If there is more than one recruitment method be sure to describe each of these, i.e., word-of-mouth, poster, email or in-person.
- All methods of advertising the study to participants should be listed here (ie. social media, presentations at community group meetings, radio ads).
- All advertising materials must be submitted to the REB and approved before they are used. Any changes to these materials and/or methods of recruitment must be approved via an amendment before they are implemented.
- Explain if recruitment reminders/repeated invitations will be sent to potential participants. NOTE: The REB will only approve a maximum of 3 reminder notices.

2.0 Pre-Existing Relationships

2.1 Will potential participants be recruited through pre-existing relationships with researchers(e.g. Will an instructor recruit students from his classes, or a physician recruit patients from her practice? Other examples may be employees, acquaintances, own children or family members, etc.)?

● Yes ○ No Clear

2.2 If YES, identify the relationship between the researchers and participants that could compromise the freedom to decline(e.g. clinician/patient, professor/student)

A central premise of consent to participate in research is that it should be given voluntarily, free of undue influence or coercion. Undue influence may arise when a person in a position of authority or a person in a dependency relationship is involved in the consent process, e.g. employers and employees, physician and patient, or professor and student.

2.3 How will you ensure that there is no undue pressure on the potential participants to agree to the study?

The REB will look for wording which explicitly states that an individual without direct authority over the potential participant (e.g. a research assistant instead of a course instructor) will conduct the informed consent process.

3.0 Will your study involve any of the following? *(select all that apply)*

- ☐ Reimbursement for any expenses incurred by the participants, e.g. parking costs, child care, lost wages, etc
- ☐ Payment or incentives, e.g. honorarium or gifts for participating in this study
- ☐ None of the above

4.5 Informed Consent Determination

1.0 Describe who will provide informed consent for this study(i.e. the participant, parent of child participant, substitute decision maker, no one will give consent – requesting a waiver)

Please see page 39.

1.1 Waiver of Consent Requested
If you are asking for a waiver of participant consent, please justify the waiver or alteration and explain how the study meets all of the criteria for the waiver. Refer to Article 3.7 of TCPS2 **and provide justification for requesting a Waiver of Consent for ALL criteria (a-e)**

Please see page 39.

1.2 Waiver of Consent in Individual Medical Emergency
If you are asking for a waiver or alteration of participant consent in individual medical emergencies, please review our guidance document**. Justify the waiver or alteration and explain how the study meets all of the criteria outlined in** Article 3.8 of TCPS2 (a-f)

This question is not applicable for REB 1/2 applications; please do not respond to this question.

2.0 How will consent be obtained/documented? Select all that apply

- ☐ Signed consent form (including where signatures are collected electronically)
- ☐ Verbal consent
- ☐ Implied by overt action (i.e. completion of questionnaire)
- ☐ Other (i.e. inaction/non-objection)

If you are not using a signed consent form, explain how the study information will be provided to the participant and how consent will be obtained/documented. Provide details for EACH of the

options selected above:

If you are not collecting signatures to document consent, then you will need to explain your consent practices.
- Verbal consent: Explain how the study information is provided to participants (i.e. Setting/context of the verbal consent discussion? An information letter should be provided to participants in advance). Explain how you will retain documentation of the verbal consent (i.e. Via researcher notes? Via an audio recording? etc.). NOTE: A verbal consent script should be uploaded for REB review within the Documentation section of this application.
- Implied consent by an overt action: Explain how the study information is provided to participants (i.e. embedded at the start of an electronic survey? Other?). Explain what action will participants be told will be used to document implied consent (i.e. completion and submission of survey implies consent? Other action?)
If you are obtaining electronic consent, please see the electronic consent guidelines on our website and describe that process here as well.

3.0 Will every participant have the capacity to give fully informed consent on his/her own behalf?

○ Yes ● No Clear

3.1 Explain why participants lack capacity to give informed consent (e.g. age, mental or physical condition, etc.).

Capacity is the ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information. (TCPS2, Chapter 3, C.) In this question, researchers should describe the population with whom they are doing research, and how they will assess capacity.

3.2 Will participants who lack capacity to give full informed consent be asked to give assent?

● Yes ○ No Clear

Provide details. IF applicable, attach a copy of assent form(s) in the Documentation section.

Please see page 39.

3.3 In cases where participants (re)gain capacity to give informed consent during the study, how will they be asked to provide consent on their own behalf?

4.0 What assistance will be provided to participants or those consenting on their behalf, who may require additional assistance? (e.g. non-English speakers, visually impaired, etc.)

It is generally considered to be unethical to state that you will exclude participants who may require additional assistance in this regard (i.e., we will only enroll English-speaking participants).

5.0 * If at any time a PARTICIPANT wishes to withdraw from the study or from certain parts of the study, describe when and how this can be done.

As per the TPCS2, participants should be able to withdraw without consequence. In this question please outline how participants can inform the study team that they wish to withdraw from the study.

6.0 Describe the circumstances and limitations of DATA withdrawal from the study, including the last point at which participant DATA can be withdrawn (i.e. 2 weeks after transcription of interview notes)

Depending on the study design, data may be kept or may be deleted if a participant withdraws from the study. What you state here must be harmonized with what is conveyed in the consent form.

As per the TCPS2, if there are situations where data withdrawal is not possible, this should be clearly outlined in the consent form (i.e., focus groups, anonymous survey, etc.,).

If data withdrawal is possible, please provide the time frame following data collection in which participants can request the withdrawal of their data (e.g., data can be withdrawn up to 2 weeks following the end of data collection).

7.0 **Will this study involve any group(s) where non-participants are present? For example, classroom research might involve groups which include participants and non-participants.**

◯ Yes ◯ No Clear

4.5 Informed Consent Determination

1.0 Describe who will provide informed consent for this study *(i.e. the participant, parent of child participant, substitute decision maker, no one will give consent - requesting a waiver)*

Free and informed consent is essential to ethical research involving human participants. The TCPS2 defines consent as "free, informed and ongoing." (TCPS2 Chapter 3).
The REB is looking for the researchers to identify who will be providing informed consent. (i.e. the participant themself will provide consent, parents of the child/youth participant will provide consent in addition to the child/ youth's assent, etc.).
If you will recruit participants under the age of 18 in this study there a special considerations for how consent will be obtained. While the TCPS does not specify an age of consent for children, it does propose that seeking consent from individuals under the age of 18 should be based on their capacity to understand the significance of the research and the implications of the risks and benefits to themselves. At the University of Alberta, children 15 years of age and older are generally mature enough to provide consent to participate in research independently of their parents provided that they possess the capacity to understand the research study. Given this, parental consent should be obtained from participants who are 14 years of age and those who are 15-17 years of age who do not possess decision-making capacity.
If your study involves the recruitment of individuals under the age of 18 years of age, under question 1.0, please outline how you will determine whether adolescents 15-17 years of age possess decision-making capacity.

1.1 Waiver of Consent Requested
If you are asking for a waiver of participant consent, please justify the waiver or alteration and explain how the study meets all of the criteria for the waiver. Refer to Article 3.7 of TCPS2 and provide justification for requesting a Waiver of Consent for ALL criteria (a-e)

A waiver of informed consent means there is no process for consenting participants and no consent documentation. When a waiver of consent is granted, participants are not provided with information about the study or given a choice of whether their data can be used in the research study.
The REB may approve research that involves an alteration to the requirements for consent set out in the TCPS2 Chapter 3 if the REB is satisfied, and documents, that all of the following apply:
a) the research involves no more than minimal risk to the participants;
b) the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
c) it is impossible or impracticable (see Glossary) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required; Note that "inconvenience" does not fulfill this criterion;
d) in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined;
e) and the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.
If a waiver of consent is required for your study, please ensure that when outlining your justification for a waiver of consent you have addressed all criteria outlined above (i.e. criteria in a-e in Article 3.7 of the TCPS2).

3.2 Will participants who lack capacity to give full informed consent be asked to give
● Yes ○ No Clear

Provide details. IF applicable, attach a copy of assent form(s) in the Documentation section.

The TCPS2 states that a participant may have developing or diminished capacity, i.e. a minor or person with a cognitive impairment, but still be able to decide whether to participate in certain types of research (ibid). If a potential research participant has the capacity to consent, consent must be sought from them before research with them commences. If a person does not have the capacity to consent, they should still be involved in the consent process where possible and appropriate and given the opportunity to assent. If a person who lacks the capacity to consent declines to participate in research, his or her dissent must be respected and the person may not be included in the research, see Article 15.5 for further discussion on assent and dissent.
hose who may be capable of assent or dissent include:
a) those whose capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing;
b) those who once were capable of making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating; and
c) those whose capacity remains only partially developed, such as those living with permanent cognitive impairment. (TCPS2 3.10)
Determination of assent is generally done through a face-to-face interview with the prospective participant and the principal investigator/person obtaining consent. This interview must convey the main information contained in the consent form using concepts and terms that are developmentally and cognitively appropriate.

4.6 Expense Reimbursements and Incentives

1.0 Expense Reimbursements:

1.1 Describe in detail the expenses for which participants will be reimbursed, the value of the reimbursements per item as well as the total maximum reimbursement and the reimbursement process *(e.g. participants will receive a cash reimbursement for parking at the rate of $12.00 per visit for up to three visits for a total value of $36.00)*

Please see page 42.

1.2 If you will be collecting personal information to reimburse or pay participants, describe the information to be collected and how privacy will be maintained.

2.0 Incentives:

2.1 Will participants receive any incentives for participating in this research *(i.e. gift card, cash payment, prize draw)***? If yes, provide details of the value, including the likelihood (odds) of winning for prize draws and lotteries.** *The Use of Incentives In Research*

Please ensure that any incentives offered to participants are compliant with the University of Alberta Policy on Gifts. If there will be a draw for a prize (i.e., gift card) please outline the odds of winning the draw based on the expected sample size.

2.2 What is the maximum value of the incentives offered to an individual throughout the research?

The REB will weigh the amount of remuneration offered against the amount of time and inconvenience to the participant on a case-by-case basis. It is considered unacceptable to have payment depend on completion of the project. However, reimbursement may be pro-rated based on the time a participant was enrolled in the study.

2.3 If incentives are offered to participants, they should not be so large or attractive as to constitute undue influence. Justify the value of the incentives you are offering relative to your

study population.

Voluntary consent must be free of undue influence in the form of inappropriate inducements. The amount or kind of payment should not be such that the participant will base his/her decision to participate on the potential material rewards. Article 3.1 of the TCPS2. states, "In considering the possibility of undue influence in research involving financial or other incentives, researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and capacity of participants, the customs and practices of the community and the magnitude and probability of harms".

4.6 Expense Reimbursements and Incentives

1.0 Expense Reimbursements:

1.1 Describe in detail the expenses for which participants will be reimbursed, the value of the reimbursements per item as well as the total maximum reimbursement and the reimbursement process *(e.g. participants will receive a cash reimbursement for parking at the rate of $12.00 per visit for up to three visits for a total value of $36.00)*

Include specific details of the reimbursement of expenses related to transportation and parking and when these will be paid. The timing of the reimbursement should be appropriate to the length of time the study is to continue (i.e. if a study is 2 years long, consider reimbursement of expenses every 6 months and not at the end of the study). It is acceptable to indicate that one will be reimbursed or that there is an incentive on the recruitment materials, but this should not be overly emphasized. Where possible, refrain from listing specific amounts, only stating that reimbursement will be provided. Be sure that what is stated in this section matches what is indicated in the consent form and the recruitment materials. Ensure that a clear discussion of reimbursement and payments is in the consent form, including a schedule for pro-rating the reimbursement, if applicable. If the participant will not be remunerated for participation or reimbursed for expenses, this should be clearly stated in the consent form.

4.7 Group Research Documentation

1.0 * **How will you ensure that non-participants and/or their data are excluded in from the study?**

In settings, i.e., observational studies, where not everyone has provided their consent to be in the study, describe what measures will be taken to ensure that non-participants are not recorded or data collected from them.

2.0 **During the recruitment process, how will you guard against peer pressure influencing an individual's decision to participate or not?**

If research is taking place in a classroom setting where some students may consent to participate and others may not, please review the content within STUDENTS AS RESEARCH PARTICIPANTS on our website.

3.0 **Outline alternate activities for non-participants, if applicable**

This is most likely to occur in the classroom setting, but there may be other applications as well. For example, if the research activities are taking place during regular classroom time, describe what meaningful activities are planned for those students who are not taking part in the research but are missing valuable classroom time.

4.0 **How will you address discomfort or disadvantage, if any, for non-participants?**

This question relates to the prior question. Non-participation in the research could be viewed as potentially disadvantageous. Describe how this will be addressed. For example, in the example above, ensuring that non-participants are provided with meaningful and educationally appropriate activities.

5.1 Data Collection

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

◯ Yes ◯ No Clear

Please select "Yes" here if you will collect identifiers (i.e. names, email addresses, student IDs, etc) at any point in the research. For example if you will collect emails for scheduling purposes or for distributing incentives, then you should select "Yes"

2.0 **Primary/raw data collected will be** *(check all that apply)*:

- ☐ **Anonymous** - the information **NEVER** had identifiers associated with it (eg anonymous surveys) and risk of identification of individuals is low or very low
- ☐ **Directly identifying information** - the information identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number, etc.)
- ☐ **Indirectly identifying information** - the information can reasonably be expected to identify an individual through a combination of indirect identifers (eg date of birth, place of residence, photo or unique personal characteristics, etc)
- ☐ **All personal identifying information removed (anonymized)**
- ☐ **Made Public and cited** (including cases where participants have elected to be identified and/or allowed use of images, photos, etc.)
- ☐ None of the above

3.0 **If this study involves secondary use of data, list all original sources:**

In REB2 applications, this section is often already answered in Section 2.10 (Secondary Analysis). If you are conducting a secondary data analysis, the original data sources should be identical to those stated in Section 2.10 of the application.

4.0 **In research where total anonymity and confidentiality is sought but cannot be guaranteed** *(eg. where participants talk in a group)* **how will confidentiality be achieved?**

This question is specific to focus group research or classroom-based research where not everyone in the room is part of the research.
Researchers can consider adopting language in the consent and at the onset of group activities to explain the limitations on confidentiality and anonymity. For example, researchers can explain that focus group attendees are asked not to discuss what was said or who attended. However, anonymity and confidentiality in focus groups cannot be guaranteed by the research team.

5.2 Data Identifiers

1.0 * **Personal Identifiers:** will you be collecting - at any time during the study, including recruitment - any of the following *(check all that apply)*:

- ☐ Surname and First Name
- ☐ Initials
- ☐ Address
- ☐ Full Postal Code
- ☐ First 3 digits of postal code
- ☐ Telephone Number
- ☐ Fax Number
- ☐ Social Insurance Number
- ☐ Email Address
- ☐ Full Face Photograph or Other Recording
- ☐ Student ID Number
- ☐ Employee ID Number
- ☐ Full Date of Birth
- ☐ Year of Birth
- ☐ Age at time of data collection
- ☐ Vehicle Identifiers
- ☐ Professional Certificate/License Number
- ☐ Other

2.0 **Will you be collecting - at any time of the study, including recruitment of participants - any of the following** *(check all that apply)*:

- ☐ Health Care Number
- ☐ Healthcare Provider
- ☐ Hospital Discharge Date
- ☐ Other Date (eg Date of Service)
- ☐ Medical Device Identifier
- ☐ Medical Record Number
- ☐ Other

3.0 * **If you are collecting any of the above, provide a comprehensive rationale to explain why it is necessary to collect this information:**

It is the role of the REB to assess that a researcher is ONLY collecting identifiers that are required to complete the analysis for the research you are conducting. Any of the identifiers in question 1.0 and 2.0 should be detailed here as to how the collection will be used in the analysis of the research (i.e., explain why do you need to collect these variables).

The REB will cross-check the variables mentioned here with the variables listed in the data collection tools uploaded to the documentation section.

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

Identifiers (such as names) should not be kept together (physically or electronically) with non-identifiable or coded data at any time (i.e., names should not be on surveys, participants names should not be kept on data collection forms, etc., and participant ID numbers should not be put onto the consent form).

This section can be used to detail how you will be keeping master lists and data separate.

5.0 * 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 de-identified data:

The REB does not required that identifiers be destroyed at the earliest opportunity. Researchers need to outline what identifiers they will retain and why it is important to retain these identifiers (i.e., source verification, need to go back to participants with updated safety information, agreement to participate in future research, etc.,).

Signed Consent Forms, which include participant names/signatures, should be securely stored for a minimum of 5 years, as per University policy.

6.0 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:

This question relates to whether you will be linking the data collected in this study to another source. This can increase the likelihood of identifiability the need to do this requires careful consideration and full details should be provided in this section. Details should include who is responsible for linking data with another source and what data is being linked.

5.3 Data Confidentiality and Privacy

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

Please see the next page.

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

Consider the following probing questions:
- Have research personnel taken any ethics courses/training modules (i.e. TCPS2 Core Training)?
- Will signed confidentiality agreements be used between the researcher and any contract staff (i.e. transcriptionists, research assistants, etc.)?
- Will there be other practices in place to ensure proper oversight and supervision of the research team regarding concepts of privacy and confidentiality?

3.0 **External Data Access**

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

Note: If you are conducting research recruiting patients or using data within an AHS facility, please note that AHS de-identification standards consider any FULL date as an identifier (i.e. full DOB, full date of admission, discharge or treatment). As such, please review your data collection forms and if any full date forms part of the data you are collecting and sending to a collaborator and/or sponsor you must indicate YES here AND your consent form must inform participants that their data will be sent off site.)

● **Yes** ○ **No** Clear

3.2 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 participants and the privacy of their data.

Examples:
- Any third party vendors that will have access to identifiers, electronic platforms for data collection that will have access to identifiers, third party reimbursement or travel vendors that will have access to identifiers.
-If you are sharing any data with external sites that are outside the local institution that should be described here.

3.3 Provide details if identifiable data will be leaving the institution, province, or country *(eg. member of research team is located in another institution or country, etc.)*

5.3 Data Confidentiality and Privacy

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

Confidentiality means protecting data from disclosure to unauthorized access, disclosure, modification, loss or theft. Address practices that will be adopted both during and after collection of the data that will respect the confidentiality of the participant (i.e., practices on data transfer/transportation between research sites, restricted access to the data, anonymization of data, disseminating aggregate data only, etc.). The description here should include details on both physical (i.e. storage of identifiers separately from coded data) and electronic safeguards (i.e., encryption, master lists).

As email is an unsecured method of communication, non-encrypted emails containing directly or indirectly identifying information will not be allowed. If you are using encrypted email, describe the software being used to encrypt. Email scripts must be included with the application. Please refer to the REB Email Guidance on the REO website.

NOTE: Some REB1/2 research studies may wish to provide the option to participants to choose to be directly identified in publications/dissemination activities. This is ethically acceptable so long as it is in compliance with the participants expressed wishes (i.e. via the consent process).

5.4 Data Storage, Retention, and Disposal

1.0 * **Describe how research data will be stored, e.g. digital files, hard copies, audio recordings, other. Specify the physical location and how it will be secured to protect confidentiality and privacy.** (For example, study documents must be kept in a locked filing cabinet and computer files are encrypted, etc. Write N/A if not applicable to your research)

Please see the next page.

2.0 * **University policy requires that you keep your data for a minimum of 5 years following completion of the study but there is no limit on data retention. 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.** (Write N/A if not applicable to your research)

Please see the next page.

3.0 **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:**

The REB does not require that the data be destroyed. It is up to the researcher to outline if and when data will be destroyed after following the applicable data retention timeline (as outlined in question 2.0 above).

If the identifiers will be destroyed but de-identified data will be retained, please clearly outline this here.

5.4 Data Storage, Retention, and Disposal

1.0 * **Describe how research data will be stored, e.g. digital files, hard copies, audio recordings, other. Specify the physical location and how it will be secured to protect confidentiality and privacy.** (For example, study documents must be kept in a locked filing cabinet and computer files are encrypted, etc. Write N/A if not applicable to your research)

The REB is looking for details related to physical, administrative and electronic safeguards that will be in place after study completion. As well as an indication of who is responsible for the data storage.

It is an expectation that any data that contains any identifiers will be encrypted. Please see this website for more information.

Please do not provide too narrow of a location for data storage, as the Principal Investigator may move both within the University and/or to another Institution at some point. Providing too many details here may limit future use of data or require that amendments be submitted post-approval. Rather an attestation of who will retain responsibility for the data storage may be more appropriate, i.e., the PI will maintain the data within their office.

Ensure that what is here is harmonized with the consent document.

Please note that the information you provide in your closing report (submitted when the study is completed) will be checked against what is written here.

2.0 * **University policy requires that you keep your data for a minimum of 5 years following completion of the study but there is no limit on data retention. 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.** (Write N/A if not applicable to your research)

Data retention requirements vary based on the type of research you are doing, and where the research is being conducted. Consider the following factors when determining your data retention requirements:
- University of Alberta: University of Alberta Policies and Procedures Online (UAPPOL) requires retention of data for a minimum of 5 years after study completion
- Indigenous Data Governance: If the research involves Indigenous communities, be aware of policies relating to Indigenous data sovereignty, i.e. The First Nations principles of Ownership, Control, Access, and Possession (OCAP). Ideally, a data management plan should be co-developed with the Indigenous communities and/or stakeholders that your research involves.

Researchers should carefully consider what will happen with the data at the end of the study including any obligations (for example, obligations from the study's funder and/or from the intended journal) to publish the data in an open access repository for future use.

Ensure that what is written here is harmonized with the consent document.

Documentation

Add documents in this section according to the headers. Use Item 11.0 "Other Documents" for any material not specifically mentioned below.

Sample templates are available by clicking HERE.

1.0 Recruitment Materials:

+ Add

Document Name	Version	Date	Description
There are no items to display			

2.0 Letter of Initial Contact:

+ Add

Document Name	Version	Date	Description
There are no items to display			

3.0 Informed Consent / Information Document(s):

3.1 What is the reading level of the Informed Consent Form(s):

3.2 Informed Consent Form(s)/Information Document(s):

+ Add

Document Name	Version	Date	Description
chat.txt(0.02) •••	0.02	9/19/2023 9:23 AM	

4.0 Assent Forms:

+ Add

Document Name	Version	Date	Description
There are no items to display			

5.0 Questionnaires, Cover Letters, Surveys, Tests, Interview Scripts, etc.:

+ Add

Document Name	Version	Date	Description

There are no items to display

6.0 Protocol/Research Proposal:

+ Add

Document Name	Version	Date	Description

There are no items to display

7.0 Investigator Brochures/Product Monographs:

+ Add

Document Name	Version	Date	Description

There are no items to display

8.0 Health Canada No Objection Letter *(NOL)*:

+ Add

Document Name	Version	Date	Description

There are no items to display

9.0 Confidentiality Agreement:

+ Add

Document Name	Version	Date	Description

There are no items to display

10.0 Conflict of Interest:

+ Add

Document Name	Version	Date	Description

There are no items to display

11.0 Other Documents:
For example, Study Budget, Course Outline, or other documents not mentioned above

+ Add

Document Name	Version	Date	Description

There are no items to display