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)*:

HREB - Guidance Document - Oct 2025

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

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

Complete Study Title: This can be exactly the same as the study short title. The long title will be included in REB correspondence (ie. notice of approval). 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 or one of the teaching hospitals, the title should also 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 1.3/1.4 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***):**

	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 * **Principal Investigator's 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					

1.2 Additional Approval

1.0 * **Departmental Review:** ***Please note only ONE Department Review is required. Please ensure that this section reflects only the PRIMARY Department of the study PI.***

There are no items to display

2.0 **Internal Review** *(If the Principal Investigator is in the Department of Medicine complete the Department of Medicine Request for Internal Approval form and upload it to the "Documentation" section of this application under item 11.0 "Other Documents". Note that all fields in the form are required. The form is available at here)*:

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	Decision Received

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**

Please provide specific details.

For example, clinics or hospitals etc. where the research will be taking place.

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):*

- ☐ 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:

NOTE: If conducting research at any of the Institutions above - selection here will allow that Institution view access to the online application and is REQUIRED for operational/administrative approval.

3.0 **Multi-Institution Review**

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

◯ **Yes** ◯ **No** Clear

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.**

See REBx information here: https://www.rebexchange.ca/

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 (e.g. someone who doesn't have training in medicine and research design).

It is a requirement of the Tri-Council Policy Statement (TCPS) that research ethics boards have community members involved in the review of research proposals. Apart from this mandate, community members offer important insights essential to the ethical review of research.

These community members are drawn from the population at large and usually do not have a background in science and medicine. Accordingly, it is important that they be able to understand the nature of the research they are reviewing. This lay summary then 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**

Please see page 11.

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)*:

Please see page 12.

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.

Scientific review might include review by a granting agency or the examining committee of graduate student's work. The lack of scientific review (ie, for investigator initiated projects that were not submitted for scientific review) does not preclude ethics approval, but may prompt the REB to concern itself with the scientific merit of the project more than if such review were in place.
If the REB determines that evidence of scientific merit is required for the project, the Research Ethics Office will facilitate the review process in advance of the review of the study by the REB.

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

Parts of a clinical trial which are optional should be clearly outlined in this section (details included, not just a list). Do not simply refer the reviewer to the study Protocol. The policy of the REB will be that any optional studies will require a separate consent form to be presented to and signed by the participant.

2.1 Study Objectives and Design

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

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

This section will be reviewed in detail by REB reviewers who have scientific training but may not be experts in your specific discipline. Your description must therefore be clear, coherent, and understandable to a knowledgeable non-specialist. Provide a well-organized synthesis of your research proposal that allows reviewers to understand why the study is being conducted, what you will do, and how your methods address the research objectives.

What to Include:

Background and Justification

· Provide a brief, literature-informed explanation of the need for the study.
· Describe the gap in knowledge or limitations in current practice that your research aims to address.
· For clinical trials, outline evidence of clinical equipoise and explain the current standard of care, including why a new intervention is warranted.

Study Purpose, Questions, and Objectives

· Clearly state the overall purpose of the study.
· Identify the primary and secondary research questions or hypotheses.

Study Design and Methodology

Provide a clear overview of the study structure, including:

· The study design (e.g., randomized trial, observational study, qualitative design).
· Any comparison or control groups, and whether blinding will occur.
· **Randomization procedures**, if applicable (a commonly missing detail).
· **Study drug dosing or intervention details**, including route and schedule (another frequent omission).
· A summary of the planned analytic approach or statistical plan.

Research Procedures

Describe all procedures participants will undergo, in the order they will occur:

· Screening or eligibility processes
· Visit schedule and timelines
· Interventions, assessments, questionnaires, imaging, or sample collection
· Participant time commitment and duration of involvement
· Safety monitoring plans, if applicable

Ensure it is clear how each procedure contributes to answering the research question.

Endpoints / Outcomes

· Identify the primary and secondary endpoints or outcomes.
· Describe how each outcome will be measured and assessed.

Additional Notes

· This section should function as a **stand-alone summary**; avoid directing reviewers to the protocol to interpret key elements.
· Do not include references here—place them in the protocol.
· Ensure all interventions and procedures are summarized and justified so that reviewers can assess scientific validity and ethical acceptability.

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)**:**

In making this assessment it is important for the REB to understand clearly what procedures or activities participants will be exposed to that are OVER AND ABOVE what they would normally experience.

In clinical trials particularly this section should provide details of the procedures that are above standard of care and/or only being done for the study (details can include things like a higher frequency of procedure in the trial design).

For example:

- Interventions specific to the study, e.g. drug administration, diaries, questionnaires, etc.
-Clinic visits would normally occur yearly but for the study the visits need to occur every 3 months
- A certain test would normally only be done every 3 years, but in the study participants will have that test yearly
- Blood draws - are there additional time points where they are collected above standard of care OR is the volume of blood to be taken greater

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. This includes de-identified, anonymized, or identifiable health information.

NOTE 2: Select this option if this research 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 data, collected in another study, or for another purpose.

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?**

Specify whether the products are commercially produced or if they are being developed for this study. Please see this link on the Health Canada website.

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 behaviour.

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. Private Chatrooms or Groups.

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

1. 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.

2. 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.

3. Email Communication

2.5 Interview and/or Focus Groups

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

If interviews or focus groups will be used as part of the data collection measures, click the related box in Section 2.2 and complete this section of the form. Specify which methods will be used here (interviews, focus groups).

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 virtual). Specify who will conduct the interview or focus groups (e.g. local study team member or other). If video recordings are being captured add justification here, or confirm that recordings will be stripped of all identifiers prior to storage.

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

If data will be collected using virtual platforms (e.g., Zoom) provide details about the platform and any related privacy protections. Specify where will data be stored, for how long and who will have access.

2.7 Participant Observation

1.0 Who will the observer be?

2.0 Who is being observed?

3.0 Why are they being observed?

Indicate the type of data you are hoping to collect during the participant observation.

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.

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

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 TCPS 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 TCPS 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 TCPS. 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)***?**

This question is seeking a description of the long term storage of the data. University of Alberta policy requires that data be held a minimum of 5 years prior to destruction (15 years for Health Canada regulated trials). This is often at odds with Indigenous relationships to the data, particularly biological data.
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.

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

◯ Yes ◯ No Clear

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.)?

If surveys will be used as part of the study's data collection measures click the related box in Section 2.2 and complete this section of the form.
Outline how survey data will be collected (e.g. paper or electronic). If it will be collected using an electronic capture system please provide details about the device and/or the software that will be used.
Specify if devices will be provided or if participants will be asked to download an app to their personal device.
Drug diaries or food diaries can also be described on this page.

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 local study team, and how it will be sent to the study sponsor.
If paper surveys will be entered into an electronic case report form (eCRF) provide details of the eCRF system being used. If surveys will be collected using an electronic capture device, please outline the long term storage details of the Sponsor's system, if not already outlined above.

3.0 Who will have access to the data?

Please clearly outline all parties who will have access to the data.
Specify if any identifiable data will be shared with the sponsor/ lead site or a third party vendor.

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.

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 analysis?

*Note: Secondary analysis of biological samples should be explained in Section 2.21 Secondary Use of Human Biological Materials, and not on this page.

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, when the data you're receiving is identifiable.

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).

2.14 Data Registries and Biobanks

1.0 * **Where will the databases be located? Specify if the database will be under Canadian or foreign jurisdiction.** Note that data housed on US servers fall under the US Freedom Act. At a minimum, participants should be informed of this potential breach in confidentiality.

Only fill in this page if you plan to establish a database and/or biobank. Do not complete this page if your project involves receiving data from or contributing data to an already established database/biobank.

2.0 * **Who will have access to the databases? How is that access determined?**

Describe who is responsible for the management of data in the database. In general access should be limited to only necessary personnel.

3.0 **Specify if the biobank(s) will be located under Canadian or foreign jurisdiction.**

- ☐ Canada
- ☐ Other

4.0 **Will identifying information be stored within the database or will it be coded?**

In order to protect participant confidentiality, wherever possible, identifying information should not be directly stored with any other collected data. A master list containing identifiers and the linking code should be held separately from the data variables.

5.0 **Will identifying information be forwarded to non-local registries?**

◯ Yes ◯ No Clear

6.0 **If the database is to be maintained locally, what steps have been taken to ensure the privacy and security of the database are upheld?**

Provide details regarding the privacy and security features of the database/biobank. These features must comply with University standards. Check with the Information and Privacy Office if you are not sure. Depending on the platform being used to house this data, you may need to submit for a formal Privacy and Securing Review (PSR) from the Information and Privacy Office.

7.0 Who is responsible for the database?

Indicate who is the primary responsible person for this database. Ideally, formal standard operating procedures should be developed that outline how the data is managed including requests for access to the data. These should be appended in question 11.0 of the Documents section.

8.0 Are there standard operating procedures for the database management, use and access?

◯ Yes ◯ No Clear

If YES, please attach at the Documentation Section - Other Documents

9.0 Provide information if material is linked or de-linked:

2.15 Use of Health Information

For guidance on completing an application seeking to conduct a review of records containing personally identifiable health information, please review the following guidance: https://www.ualberta.ca/research/research-support/research-ethics-office/human-research-ethics/information-and-data/health-information/chart-review.html

1.0 Estimate the number of records you will review/receive *(ie. We will review approximately 300 charts, we will receive approximately 3000 patient records from the data custodian)*

Please see page 29.

2.0 List ALL of the data source(s) that you will be using to get your data*(ie. Paper charts, e-clinician, DIMR records, NetCare, PAC system etc.)*

It is important for the REB to understand all of the sources of the data. Additionally, AHS and Covenant Health have view access to the form and will require this information for execution of the Data Disclosure Agreement (DDA).

Article 4.4.1 of the Alberta Netcare Information Exchange Protocol states that Netcare cannot be used for research purposes without the expressed consent of the individual. If you are seeking a waiver of consent, Netcare cannot be a data source.

3.0 Will the chart/record review be:

If data collection involves both retrospective AND prospective chart review, please choose both options.

- ☐ RETROSPECTIVE: The dates of the records that will be reviewed do not exceed the date of this ethics application
- ☐ PROSPECTIVE: The dates of the records to be reviewed are in the future (at a date after submission of this application)

4.0 Provide the start and end date of the records you will review*(Note: these dates do NOT refer to when the review will be performed but the actual dates on the medical records, ie., we need administrative data from January 1, 2000 to December 31, 2010):*

Start Date:

End Date:

5.0 Will individual consent be sought?

If your study involves both retrospective and prospective components, where you will be requesting a waiver of consent for the retrospective component, but will obtain consent for the prospective component, choose 'no' - then outline the request for the waiver in 5.1, AND indicate that you will obtain consent for the prospective component.

○ Yes ● No Clear

5.1 Describe why you believe it is not reasonable, feasible or practical to obtain the informed consent of the individual. *(Generally, the REB would not approve a waiver of consent for the prospective collection of data except where a robust rationale exists, ie., an inability to conduct the*

research due to resource constraints).

Please see the next page.

6.0 How will the data be received?

If you are conducting a secondary review of health data please remember to upload the following to the Documentation Section:

1. *Your data collection sheets or a listing of the variables that you wish to collect.*
2. *If you are collecting health data using AHS or Covenant Health resources, you will be required to upload a formal research proposal/protocol to the Documentation Section*

2.15 Use of Health Information

1.0 Estimate the number of records you will review/receive *(ie. We will review approximately 300 charts, we will receive approximately 3000 patient records from the data custodian)*

This section is no longer just for individual chart reviews. This section must be completed if you will be accessing health records as part of the study, even if it is not the main methodology. Completion of this section allows the REB to evaluate the use of health information in accordance with the Health Information Act. ONLY complete this section with respect to the use of health information that would fall under the Alberta Health Information Act (i.e., do not describe data collected in other provinces here).

DO NOT complete this section to describe a request for waiver of consent for screening purposes. Waiver of consent for screening is handled in section 4.3 (questions 1.2 and 1.2.1).

For this question, please provide an estimation of the number of charts that will be reviewed. For clinical trials, this would presumably be the number of anticipated local participants.

5.1 Describe why you believe it is not reasonable, feasible or practical to obtain the informed consent of the individual. *(Generally, the REB would not approve a waiver of consent for the prospective collection of data except where a robust rationale exists, ie., an inability to conduct the*

The Health Information Act charges the REB with determining whether it is reasonable, feasible or practical to obtain consent for access to an individual's health information.

Researchers should consider the following when outlining their rationale:

- Sample size. Is the sample size too large to contact all individuals or is it small enough that contacting individuals is feasible?

- The dates on the medical records. Many individuals may be lost to follow up from older medical files whereas it may be possible to contact individuals who recently received medical care.

- The impact of contact for consent. Depending on the nature of the medical condition under study, will contact from the research team cause undue stress to the individual?
- Consent may introduce bias. Where the population is small and requiring consent may put the scientific integrity at risk.

2.16 Clinical Trial

1.0 Protocol

1.1 Protocol Number (if applicable):

This field will auto-populate in your approval letter. Ensure it is correct and contains the protocol number of the most up to date protocol.

1.2 Clinical trials must be registered before participant recruitment can begin. Provide registry and registration number, e.g. clinicaltrials.gov:

2.0 Is this an investigator-initiated or sponsored clinical trial?

The two options under this question are intended to be either/or. Is the protocol local investigator initiated OR was it written externally (e.g. industry sponsor, collaborative group, etc)

*** Is this study authored and initiated by a researcher from the University of Alberta, Alberta Health Services and/or Covenant Health?**

◯ Yes ◯ No Clear

*** Is this study authored or sponsored by any outside entity including, but not limited to, a pharmaceutical company or clinical research organization?**

◯ Yes ◯ No Clear

3.0 *Does the study involve any of the following?

Answer	Description
◯ Yes ◯ No Clear	A drug, device, biologics, vaccine or natural health product not marketed in Canada?
◯ Yes ◯ No Clear	A comparative bioavailability trial?
◯ Yes ◯ No Clear	Use of a marketed drug, device, biologics, vaccine, or natural health product outside the parameters of its officially “approved use” by Health Canada?

If you have answered yes to any of the questions above, a Health Canada Clinical Trial Application (CTA) may be required. The investigator MUST coordinate with the University of Alberta - Quality Management in Clinical Research for all Health Canada clinical trials, as the University will be the named Sponsor of the trial. Please contact lori.anderson@ualberta.ca for assistance.

4.0 Trial Phase:

- ☐ Phase I clinical trials test a new biomedical intervention in a small group of people (eg. 20-80) for the first time to evaluate safety (e.g. to determine a safe dosage range and to identify side effects)
- ☐ Phase II clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety
- ☐ Phase III investigates efficacy of biomedical or behavioral intervention in large groups of human participants (several hundred to several thousand) by comparing the intervention to other standard or experimental interventions and monitor adverse effects
- ☐ Phase IV studies are conducted after intervention has been marketed. Studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about adverse effects associated with widespread use

5.0 Describe the provisions made to break the code of a double-blind study in an emergency situation, and indicate who has the code (if applicable):

6.0 Provide justification for using placebo or no-treatment arm (if applicable): *(i.e. why/how is it OK to give a participant an inactive substance instead of a treatment)*

Please see the next page.

7.0 Describe the clinical criteria for withdrawing an individual participant from the study due to safety or toxicity concerns (if applicable):

The response to this question can come directly from the protocol.

Many applicants provide information on stopping rules for the study as a whole here, however that question is asked on 2.17 (3.0).

This question refers to withdrawal of an INDIVIDUAL participant based on safety concerns.

8.0 * Expected Length/Duration of Clinical Trial *(in months)*:

12

If this is a multi-site study "Duration of Clinical Trial" is referring to the expected # of months for study as a whole, not just the local site.

2.16 Clinical Trial

6.0 Provide justification for using placebo or no-treatment arm (if applicable): *(i.e. why/how is it OK to give a participant an inactive substance instead of a treatment)*

In assessing the value of a treatment during a clinical trial, placebo controls (or, in the case of a trial of a procedure, sham procedures) are commonly used. Such controls are scientifically rigorous but they must be ethically justifiable. Assignment of a study participant to a placebo or a sham procedure must not cause that participant hardship or harm and must not deprive the participant of therapy to which they would otherwise be entitled to as part of the standard of care for their condition. For purposes of this document “standard of care” does not necessarily imply regulatory approval but rather represents that care that the community of practice (including licensing colleges or bodies) would deem acceptable for patients with the condition being studied.

Ethically acceptable responses to the section include:

1. The investigational agent is novel and no standard of care alternative exists. Patients with the condition generally do not receive active therapy.

2. The investigational agent is novel and is added on to the standard of care therapy. Participants assigned to placebo will still be receiving standard of care therapy.

3. The agent is novel and there are no Health Canada approved therapies for the condition although there may be evidence based or guideline directed therapies considered as standard of care by the community of practitioners. In such circumstances placebo assignment may be problematic. Justification for placebo use will require careful evaluation of the risks to the potential participant, justification of the risk burden that the participant is to endure and must ultimately be considered to fit within the spectrum of what is considered appropriate and ethical clinical care.

2.17 Data Safety and Monitoring for Clinical Trials

1.0 * **Check one that most accurately reflects the plan for data safety and monitoring for this study:**

- ◯ The study will be monitored only by the study investigators.
- ◯ The study will be monitored by at least one individual who is not associated with the study, but not by a formally constituted Data and Safety Monitoring Board (DSMB).
- ◯ A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.

Clear

2.0 * **Describe data monitoring procedures while research is going on. Include details of planned interim analysis, Data Safety Monitoring Board, or other monitoring systems:**

"Data and Safety Monitoring Board" is also known as "Data Monitoring Committee" (DMC). Typically, investigational drug studies create such a board to independently review study data for safety.
Information here could include details related to the composition of the DSMB and/or the independent monitor. The REB reviewers question use of an individual (instead of a DSMB) to monitor for safety. How unencumbered is the assigned individual from the company? Is the monitor in conflict of interest due to his/her relationship with sponsor? Details can be provided here.

3.0 * **Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns:**

This question asks when the study AS A WHOLE may be stopped due to safety concerns.

2.18 Collection of Human Biological Materials

1.0 * **Indicate the human biological material(s) that will be collected** *(for example, blood, urine, CSF, liver tissue, etc.)*:

Please ensure that this section matches the protocol AND any procedures you have listed in 2.1 (2.0 & 3.0). Include any biosamples that may be collected for research screening (e.g. pregnancy testing).

2.0 * **Specify all intended uses of collected specimen:**

Specify the intended research uses of collected specimen, including any optional specimen collection (ie: optional collection for genetic analysis, or future unspecified research).
For 3.0 below:
- "immediate use" is meant to include use at the end of the study (ie: for batch processing) as defined in the Protocol.
- "Collection of sample for banking (future use)" is meant to indicate future, not currently specified research which is not defined in the current protocol.

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

- ☐ Collection of sample for immediate use
- ☐ Collection of sample for banking (future use)
- ☐ Genetic analysis
- ☐ Other

4.0 **Explain how and by whom the specimen will be collected**

5.0 **Explain HOW the specimen will be stored:**

Answer should address security and privacy considerations of storage.

6.0 Explain WHERE the specimens will be stored *(e.g. incluc out of the province)*:

7.0

Explain HOW LONG the specimens will be stored:

The reasons for duration of sample storage should be clear. Response here needs to account for main protocol sample retention and also any biobanking/ unspecified future use retention plans as applicable.

2.19 Investigational Drugs, Devices, Biologics, Vaccines or Natural Health Products

1.0 **List all the investigational drugs, biologics, vaccine, natural health products, or devices used in the study. Enter the Health Canada No Objection Letter (NOL) control number and date of approval if available for the initial application and subsequent NOLs for amendments. Upload the NOL letter in the Documentation Section of your application.**

+ Add

Name	Manufacturer	Type	Health Canada Approval Status	NOL Control Number	Date

There are no items to display

2.21 Secondary Use of Human Biological Materials

1.0 Outline where will you be getting the human biological materials from?

This page should reflect sample use which involves analysis of blood/tissue/specimens that were originally collected for another purpose but are now being used to answer your research question.

2.0 How/under what authority were these human biological materials originally collected? *(i.e. clinical specimens now being used for research, collected under a previous research protocol)*

3.0 If specimens were originally collected under a research protocol, please outline how the proposed use of the samples is consistent with the parameters or restrictions of use described at the time of initial collection *(i.e. consent for future use was outlined in original consent form or ethics approval documentation)*

4.0 Are the human biological materials you will be receiving/using:

- (●) Identifiable (i.e. you will receive identifiers with specimen or will be linking specimens with clinical records to pull additional information)
- ( ) Non-identifiable (i.e. you will not receive any identifiable health information linked to the specimens, nor would you ever be able to identify who the specimen came from)

Clear

4.1 Will you be seeking consent for the secondary use of identifiable human biological materials/specimens?:

- ( ) Yes: Consent is generally required for the secondary use of identifiable human biological materials – UNLESS the researcher satisfies the REB as to the following 6 conditions (a) – (f) per Article 12.3A of TCPS2)
- (●) No

Clear

4.2 If no, please state how your research meets the criteria per Article 12.3A of TCPS2 for a waiver of consent:

2.22 Stem Cell Research

1.0 **A stem cell oversight committee (SCOC) was created by CIHR in 2003. SCOC reviews all research involving human pluripotent stem cells that have been derived from an embryonic source and/or will be transferred into humans or non-human animals to ensure compliance with Chapter 12, Section F, of the TCPS 2. Referring to these guidelines, does this research require SCOC approval:**

◯ Yes ◯ No Clear

If yes, please upload the SCOC approval in the Document section

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.**

Please see page 41.

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 outlined above for participants and others (e.g. reporting side effects, rescue medication, early withdrawal from the study).

For example, if the study drug causes an infusion reaction minimizing the potential would be if the protocol mandated Benadryl be given pre-infusion and managing the harm would be details related to what will be done if the participant experiences an Infusion Reaction.
For example, if a study drug has the potential to cause optic neuritis – eye examination by an Ophthalmologist will be schedule at times throughout the study.
For example, if a study drug as the potential to cause cardiac side effects, ECG testing will be part of study visits.

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.

Please see the next page.

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 to the study participant.

3.1 Risk Assessment

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

Please outline all risks related to your study interventions and procedures.
The risks identified here should correspond with your selections under Q2.0 above.

Clinical risks should be listed as bullet points. The HREB requires numeric (usually percentage) quantification of risks wherever possible. Quantification should include information about the seriousness and consequences of the different types of adverse events that have been observed, as well as the probability of these events occurring. Quantification of these harms should emphasize the incremental risk with the experimental intervention as compared to placebo or no treatment, wherever possible. Expected outcomes related to risks is required. For example, is the adverse event likely to be self limited, will require additional therapy or surgery or lead to permanent disability or death.

The HREB prefers researchers to list risks in descending order of frequency and/or to group them according to category of risk (e.g. by magnitude, severity, organ system, etc.). For example:

- Very Common (50% -75%)
- Common (20% - 50%)
- Less Common (5% to 20%)
- Uncommon (1% to 5%)
- Rare (Less than 1%)

If available, provide some idea of the number of people who have taken part in trial to date (ie. to date 2000 people have taken part in studies with the drug).

Where no percentages are available, specific discussion about risks encountered in case series/case reports, preclinical studies or studies involving similar drugs or procedures is required. If absolutely no relevant data about harms of the experimental procedures are available (e.g. a Phase 1 trial), Investigators are required to make their best effort to honestly inform participants about possible risks of participating in the research, even if they cannot be quantified. This quantification can be in the form of "for thirty participants, five experienced a particular side effect". This information must always be included in the consent form. Risks of allergy and of death should be discussed.

It is generally acceptable to provide a qualitative description of the risks associated with standard blood drawing (venipuncture). For example, the consent form should state that the side effects of blood draw include pain and/or discomfort, bruising, fainting and/or light-headedness, and the rare possibility of infection.

Information on risks in the application and the consent form must be consistent with the information provided in the protocol and the Investigator's Brochure/Product Monograph if applicable, however, shall not be a cut and paste from the consent form.

Unanticipated side effects: The consent form must include an explanation that unanticipated side effects, including severe or irreversible ones, could occur if a novel combination of drugs is being tested, even if the individual drugs are not expected to have these side effects.

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, unforeseen side-effects of a medication or natural health product, discovery of a clinically actionable finding during genetic analysis), as well as unavoidable single incidents (e.g., a translator not available for a day, or a failure to follow correct research procedure for one participant on one occasion). They may be minor or serious in magnitude, with short- or long-term implications.

Describe the arrangements or referral the researcher will make. Explain if no arrangements have been made. The REB will require evidence that the researcher has made arrangements to support participants in dealing with any issues described above. Simply stating that you will refer them back to a GP (who did not order the testing to begin with) will not be acceptable.

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.

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 is undertaken to answer a scientific question and while it may benefit society or add to scientific knowledge in the future, its primary intent is not solely to benefit the consenting participant.
The consent form and the application should specify the known benefits to the prospective participants. If there are no direct benefits to the participants from participating in the research, this must be stated explicitly.
If any specific therapeutic 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.
Please note that study procedures such as more frequent testing or more frequent follow-up are not benefits, but rather risk mitigation strategies.
Incentives (i.e., money, prize draws, 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 protocol.

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

Explain how the potential benefits of the study outweigh the possible risks to individual participants
Researchers must ensure that participants are not exposed to unnecessary risks. Researchers 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 (TCPS), participants or authorized third parties, make the final judgment about the acceptability of this balance to them.
This section is vital to the ethical review of your protocol. If the discussion is inadequate or the section not completed it will not be possible for the REB to review your protocol.

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

1.2 Would you like to include information about this study on the Be The Cure searchable database?

○ Yes ○ No Clear

This response should be 'yes' if you are: a) recruiting patients, caregivers, physicians, nurses, staff, or other participants, OR b) accessing participants' health information from, **Alberta Health Services, Covenant Health or another data custodian, as outlined in the Health Information Act.**

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.

If you study involves the recruitment of healthy control participants, please ensure that this group is also reflected here.

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

Generally will be taken directly from the research protocol.

3.0 Describe and justify the exclusion criteria for participants:

Generally will be taken directly from the research protocol.

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?

A control group is defined as a group or condition in a research study that serves as a baseline for comparison with an experimental group or intervention (e.g. placebo control, standard of care comparison group).

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

5.0 Justification for sample size:

If no formal sample calculations are available, this question should address how the research has arrived at the determination that enrolling the number of people stated above, will be able to achieve an answer to the research question.

4.3 Recruitment of Participants (Health)

Use questions 1.1, 1.2 and 1.3 to clearly articulate how potential participants will be identified and then approached about participation. Include the following elements:
1) What records you will use to find potential participants (ie. pre-screening for basic eligibility) (question 1.1);
2) Who will review these records (i.e., clinical care physician, research coordinator, PI) (question 1.1);
3) Who will make the initial contact with the prospective participant(s) to see if they are interested in hearing more about the research (questions 1.2 and 1.3);
4) How/When the prospective participant will be initially contacted (question 1.3).
Sufficient detail in this section is critical to the REB review of your application. If appropriate information is not included and/or not enough detail is provided, the committee will not be able to review your application.

1.0 Recruitment

* **1.1 How you will identify potential participants? Please be specific.** *(i.e. Will you be screening clinical lists, accessing electronic health records (e-clinician), asking staff from a particular area to let you know when a patient meets criteria, will you be sitting in the emergency department waiting room, etc?)*

Please see page 48.

1.2 If you are using patient/clinical records to identify potential participants for research purposes, will someone from the data custodian/clinical care team seek prior consent of the participant to allow the researcher to look at their records?

◯ Yes ● No Clear

Please see our Screening Patient Records to Determine Eligibility guidance in our Forms Cabinet.

1.2.1 Justify why prior consent to look at clinical records is not reasonable, feasible or practical to obtain *(Under the Health Information Act, a researcher cannot access a patient's personally identifiable health information (i.e. name or health records) for the purpose of contacting them directly without prior consent from that patient which must be obtained by the custodian of those patient records. The first contact with that patient MUST be made through an individual already involved in the clinical care of the patient, who will then determine the individual's willingness to be approached by the researcher regarding research participation and obtain their consent for the same. The requirement to obtain consent for the disclosure of contact information to a researcher before the researcher contacts the patient is found in section 55 of the HIA)***:**

If you are requesting a waiver of consent:

To be granted, the researcher must justify in the ethics application (Section 4.3) why obtaining consent is unreasonable, impractical, or not feasible. The REB may consider a researcher's request to waive this consent requirement for the purposes of screening to determine eligibility criteria is met if the researcher makes a ROBUST justification as to why it would not be reasonable, feasible or practical to obtain this consent. In these cases, the researcher would only be looking for minimal data elements to determine if basic inclusion/exclusion criteria are met to justify even approaching someone about their interest in learning more about the study.

1.3 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.

Once written/electronic consent is obtained or a waiver of consent is granted by the REB any member of the research team (e.g., PI, Study Coordinator) named in the ARISE application and provisioned access to medical records by the data custodian (e.g., via Connect Care) may perform this screening of patient records to determine eligibility.
Only someone in the patient's clinical care team (the patients clinical care provider or an employee of the data custodian (ie. "AHS intermediary")) may approach the patient to:
Inform them about the study.
Ask if they wish to be contacted by the research team.

1.4 Outline any other means by which participants could be identified*(e.g. response to advertising such as flyers, posters, ads in newspapers, websites, email, list serves, physicial or community*

organization referrals):

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 before they are implemented.
Please be mindful to ONLY submit those industry provided advertising materials that your site will be using. It is onerous to review a large package of advertising materials that the site has no plans to ever use.

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):*

The REB must be provided with a clear description of any pre-existing relationships between the research team and participants.

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

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.

If there is a pre-existing relationship such as physician and patient, the REB will expect that someone NOT involved in the prior clinical care relationship obtain the informed consent of the participant. So while it will be OK for the physician to explain the study and answer any questions his/her patient/potential research participant may have, someone else should actually be left to obtain the written consent for that patient.

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

4.3 Recruitment of Participants (Health)

* **1.1 How you will identify potential participants? Please be specific.** *(i.e. Will you be screening clinical lists, accessing electronic health records (e-clinician), asking staff from a particular area to let you know when a patient meets criteria, will you be sitting in the emergency department waiting room, etc?*)

This question allows the REB to determine if the proposed method for identifying potential participants complies with the Health Information Act.

Accessing Records to Determine Eligibility (Pre-Screening):

Accessing patient records to determine study eligibility is considered a disclosure of health information under Alberta's Health Information Act (HIA). Therefore, consent is required to access patient records for research purposes (i.e., you cannot just look because you have access as a care provider).

Acceptable Approaches re: consent to determine eligibility:

- Written or electronic consent
    - Access may be granted when the patient provides written or electronic consent specifically authorizing the use of their health information for eligibility screening.
- Waiver of Consent
    - Researchers may apply for an REB-approved waiver of consent to access patient records without obtaining individual consent. To be granted, the researcher must justify in the ethics application (Section 4.3) why obtaining consent is unreasonable, impractical, or not feasible. The REB must approve this request.
- Verbal consent is not sufficient:
    - Verbal consent does not meet the requirements of the HIA to authorize access to patient records for pre-screening. Researchers must obtain written/electronic consent or an REB-approved waiver.

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)*

As a general rule, informed consent should be sought from all research participants. Your response here should specify if the individual participant will consent for themselves, or if there will be an alteration to consent (e.g. in cases where the participant lacks capacity).
Refer to TCPS Guidance for acceptable consent alterations.

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 52.

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)

Please see page 52.

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

- ☐ Signed consent form
- ☐ 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:

A written (documented) signed consent form will be the gold standard to enroll a participant in a research study. Modifications to this method of consent documentation must be clearly articulated here.
E-consent processes should be described here. If e-consent will be used select 'Signed consent form' in Q2.0 above. Refer to HREB Forms cabinet for local guidance about a e-consent process. If e-consent will be used to provide consent for access to medical records, then describe the process for ensuring two-factor authentication.

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.).*

Please see page 52.

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.

The TCPS 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.
Those 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)

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?

Please see page 53.

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 unethical to exclude participants who may require additional assistance in this regards (ie. we will only enroll English speaking participants). Describe what measures are in place to ensure that the study is as inclusive as it can possibly be.

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.

Consistent with TCPS 2 and ICH-GCP, participants may withdraw at any time without penalty, and do not need to do so in writing. The consent form and protocol should describe what happens upon withdrawal, including options for continued safety follow-up and study-related access to medical records, and the handling of data and samples already collected. At the time of withdrawal, the investigator (or delegate) must document the participant's choices in the study records. A separate signed "graded withdrawal" consent form is NOT required unless (a) explicitly mandated by the approved protocol/sponsor, or (b) a specific legal requirement applies in the jurisdiction of conduct.

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.

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

1.1 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)**

The REB may approve research that involves an alteration to the requirements for consent set out in TCPS 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 fulfil 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 TCPS Article 3.7.
If you are conducting a chart review and have requested a waiver of consent for access to medical records, do not complete this question here, as you should have already provided your rationale for the waiver request in section 2.15 (5.1) of this application.
Do NOT complete this question if you are seeking a waiver of consent to prescreen medical records for eligibility. This waiver request is provided in section 4.3 (2.1) of this application.

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)

A deferred consent process can be described here, when applicable.
Click on 'guidance document' above to access HREB Forms cabinet for local guidance about a Deferred Consent process.
Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the following apply:
a) a serious threat to the prospective participant requires immediate intervention;
b) either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care;
c) either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant;
d) the prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project;
e) third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and no relevant prior directive by the participant is known to exist.
f) When a previously incapacitated participant regains decision-making capacity, or when an authorized third party is found, consent shall be sought promptly for continuation in the project, and for subsequent examinations or tests related to the research project.

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. (TCPS, Chapter 3, C.)
Capacity to consent to research is not a static determination; it may vary over time, and upon the complexity and circumstances of the decision being made. It is the responsibility of the Principal Investigator (PI) to determine and monitor participants' capacity to consent and to describe this to the REB in the context of the proposed study.
Researchers should describe the population with whom they are doing research, and how they will assess capacity. This may include cognitive tests designed for determining a persons' capacity, e.g. the mini mental. The application should outline how the PI and study team will continue to monitor a participant's consent to participate when their capacity is diminishing or fluctuating.
The ability to consent to research is not based upon on a participant's age or whether they have reached the legal age of majority. Generally, the threshold for recognition of maturity by the Courts is at least sixteen years and none have recognized any individual younger than fourteen years. In accordance with the TCPS2, the capacity to consent to research is premised upon an individual's ability to understand the nature of the research and the consequences of participation in the research project.
The researcher should describe to the REB how the study team will determine the capacity to consent to the research for those proposed participants who are under the age of majority. Factors to consider in making the decision to seek consent from children should include the following: the level of risk the research may pose to participants, provincial legislation and other applicable legal and regulatory requirements related to the legal age of consent, and the characteristics of the intended research participants. In Alberta, this usually requires the attestation of a parent or healthcare provider or someone with significant knowledge of the child, such as a teacher.

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

Where consent was obtained from a legally authorized third party, and the participant regains capacity, the researcher must obtain their consent to continue to participate in the research. The REB may require that Investigators re-consent participants after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., participants with progressive neurological disorders).

Research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, must meet at a minimum the following conditions in order to be considered for REB approval:

a) the researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;

b) the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;

c) the authorized third party is not the researcher or any other member of the research team;

d) the researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and

e) when authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation. (TCPS2 3.9). See the Research Ethics Office website for a regained capacity consent template.

4.6 Expense Reimbursements and Incentives

1.0 Participant Expense Reimbursements:

1.1 An expense reimbursement is defined as: *A payment to a research participant for expenses incurred as part of participation in a study (e.g., travel, parking, meals). This payment requires supporting receipts and is* ***not taxable****.*

Describe the expense for which participants will be reimbursed (Example response. Participants will be reimbursed up to $20 per visit for parking, participants will receive mileage reimbursement at $0.50/km, up to a maximum of $100 per participant). Reimbursements will be issued by the University of Alberta via cheque within 30 days. Receipts will be required.

Include specific details of the reimbursement of receipted expenses related to study costs such as 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.

Ensure that a clear discussion of reimbursement and payments is in the consent form, including a schedule for pro-rating the reimbursement, if applicable. 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 amounts, only stating that reimbursement will be provided.
If the participant will not be remunerated for participation or reimbursed for expenses, this should be clearly stated in the consent form.

2.0 Participant Compensation / Incentives:

2.1 Participant Compensation/Incentives is defined as:
Compensation: *A fixed payment to participants for their time and effort in research generally referred to as a per visit stipend or per visit payment amount;*

Incentive: *A financial or non-financial benefit offered to participants to encourage research participation (i.e. gift card, prize draw, etc.)*

Will participants receive any compensation or incentives for participating in this research (i.e. gift card, per visit stipend, entered into a prize draw)? If yes, provide details of the value, including the likelihood (odds) of winning for prize draws and lotteries.

Please ensure that any incentives offered to participants are compliant with the University of Alberta Policy on Gifts.

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.

Note that Social Insurance Number (SIN) typically should not be collected unless required for taxation purposes. Refer to AHS/UofA financial policies for taxation amounts.

2.3 Justify the value of compensation/incentives.
Explain why the amount is appropriate and not coercive or an undue influence for this participant

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.

TCPS 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".

3.0 Personal Information for Payments (Reimbursement, Compensation, or Incentives)

3.1 Will you collect personal information from participants in order to provide reimbursement or compensation (e.g. name, address, email, banking information)?

● Yes ○ No Clear

If yes, the following needs to be described both in the consent form and in the application:

- What information will be collected
- How it will be stored(e.g. encrypted server, secure drive)
- Who will have access(study team, institutional finance office, AHS, Covenant Health, payment vendor)
- How it will be securely transferred for payment processing

Note:
If compensation may exceed $500 per calendar year, CRA requires a T4A tax slip to be issued. This must also be clearly disclosed in the consent form.
Detailed tax processing procedures should be discussed with your respective financial office (office that you hold your accounts with) and do not need to be included in the REB application.

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

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 HREB Health Panel applications, this section is often already answered in Section 2.10 (Secondary analysis of Data) or 2.15 (Chart Review of Health Data).

This question is not applicable in trials where you are enrolling people and prospectively collecting data.

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. It is often not applicable to HREB applications.

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 (ie. why do you need to collect these variables).
The REB will often cross check this section with the variables listed in the CRF or data collection forms. Make sure they are harmonized.
RE: 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 HREB Email Guidance on the REO website.

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

Identifiers (such as name, contact information, date of birth, Personal Health Number) should not be kept together (physically or electronically) with the non-identifiable or coded data at any time. Participant names should not be on surveys, patient labels should not be kept on data collection forms/CRF, master lists should not be kept at the front of CRF binders, participant ID number should not be put onto the consent forms.

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:

This section can be used to detail what you will be keeping and WHY it is important to retain that data (ie. source verification, need to go back to participants with updated safety information, agreement to participate in future research).

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 of participants so full details need to outlined here. Details can include who is doing the linkage and what 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.**

This section relates to specifics of confidentiality for the participant both during and after collection of the data (examples - data collection in the field, transportation of the data between sites, anonymization of data). It should include details on both physical (above) and electronic safeguards (ie. encryption, master lists). Include who will have access and how that will be managed securely.
If data is being shared between multiple sites - this section can be used to describe how the data transfer will occur (even if no identifiers will be transferred which is outlined below).

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?**

Response to this question can address:

Have research personnel taken Health Information Act privacy training either through the data custodian (ie. AHS, Covenant) or have they taken the University of Alberta Privacy training? Have staff taken Collaborative Institutional Training Initiative (CITI) training and/or International Council for Harmonization of Good Clinical Practice (ICH GCP) training?

Are there signed confidentiality agreements in place between the researcher and any contract staff?

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 are: Any third party vendors that will have access to identifiers, electronic platforms for data collection (surveys, diaries), third party reimbursement or travel vendors.
-If you are sharing any data with external sites that are outside the local institution that should be described here.
-You do not need to outline clinical trial monitoring activities 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.)*

5.4 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. Specify any data storage platforms that will be used (e.g. Dataverse, redcap, research data storage services RDSS, health research data repository HRDR. It is an expectation that any electronic data that contains any identifiers will be encrypted.

Please note that it may be wise to not provide too narrow of a location for records (e.g. room #), as PI 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.

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)*

Specify how long your data will be kept.
Data retention requirements vary based on the type of research you are doing, and where the research is being conducted. Current retention guidelines include:
Health Canada - Part C Div 5 Food and Drug Regulations - 15 years for Drug, Biological and Natural Health Product Directorates (Medical Device does not specify this, check with Sponsor for requirements)
If subject to General Data Protection Regulation GDPR (European Union) requirements data may need to be retained for a minimum 25 years.
AHS and Covenant Health - If a study is funded - 7 years, if not funded 5 years after completion
University of Alberta - 5 years after study completion
In light of the Tri-Agency policy for data to be placed into an open access repository for future use, researchers should carefully consider what will happen with the data at the end of the study.
Ensure that what is written here is harmonized with the consent document.

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 expect that data WILL be destroyed. It is up to the researcher to outline if and when data will be destroyed at the end of the study.

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

Once documents are uploaded and submitted they can't be deleted. If a document is uploaded in error (and therefore NOT requiring REB review) you can re-name it "Disregard".

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:

a) Section 4.3 or 4.4 in the application form should include corresponding explanations of the materials uploaded here. E.g. When, where, how will the materials be used and distributed?
b)Recruitment materials uploaded here should be in line with Local Recruitment Guidance which is posted to REB website Forms Cabinet
c) Study sponsor global recruitment efforts often fall outside local REB jurisdiction/ authority and don't need to be submitted for local review and approval.

+ 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):

Consent forms should be written at a Grade 6-9 level of understanding. Please use a readability index, such as hemingwayapp.com, to confirm the level.

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

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

Make sure that the version date of the document title is accurate and matches the version within the footer on each page.

+ Add

Document Name	Version	Date	Description

There are no items to display

4.0 Assent Forms:

Assent form reading level should be tailored to the expected audience ages. It is acceptable to have multiple assent form versions in order to target a broader range of child ages and reading comprehension levels (i.e. younger child and adolescent forms).
For child participants who can provide assent but aren't able to read and sign an assent form you should provide a verbal script to document the assent conversation.

+ 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:

The HREB requires that a formal protocol be attached to all submissions to clearly define the scope of research, and to ensure that proper operational approvals can be obtained (where applicable).

+ Add

Document Name	Version	Date	Description

There are no items to display

7.0 Investigator Brochures/Product Monographs:

Note, the most recent Investigator Brochure version should be uploaded for review. IBs are usually updated annually to comply with regulations.
Investigator Brochure/ Product Monograph attachments (or equivalent) should be included for all drugs, natural health products, and/ or devices that are being used as part of the research study.

+ Add

Document Name	Version	Date	Description

There are no items to display

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

The Health Canada approval letter should correspond to the protocol version & date.

+ Add Drag and drop files to upload

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

Note that a budget is required for any funded studies.
Data collection forms or Case Report Forms (CRFs) should be provided to list all data to be collected from health records.

+ Add

Document Name	Version	Date	Description

There are no items to display