1.1 Study Identification

*All questions marked by a red asterisk * are required fields. However, because the mandatory fields have been kept to a minimum, answering only the required fields may not be sufficient for the REB to review your application.*

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

1.0 * **Short Study Title:** *(restricted to 250 characters)*:
HREB - Biomedical Panel Guidance Document – March 2022

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 can be exactly the same as the short study title. The complete study title will be included in REB correspondence (i.e. 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 complete study title should also correspond to the title on the grant or contract (but this is not a requirement). 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 complete study title is thematically similar to the grants listed.

3.0 * **Select the appropriate Research Ethics Board:**

Detailed descriptions are available at https://www.ualberta.ca/research/support/ethics-office/human-research-ethics/research-ethics-boards

HREB Biomedical

4.0 * **Is the proposed research:**
Funded (Grant, subgrant, contract, internal funds, donation or some other source of funding)

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

People listed here are responsible for this application, can edit this application, and will receive email notifications.

If the searched name does not come up when you type it in the box, the user does not have the Principal Investigator role in ARISE. Click this link for instructions on how they can Request an Additional Role. If this does not help, please contact reoffice@ualberta.ca for further assistance.

6.0 * **Type of research/study:**
Faculty/Academic Staff

7.0 **Investigator's Supervisor:**

Required for applications from undergraduate students, graduate students, post-doctoral fellows and medical residents applying to REBs 1 & 2.
Note: HREB does not accept applications from student PIs.

Name

8.0 **Study Coordinators or Research Assistants:**

People listed here can edit this application and will receive all email notifications for the study.

If the searched name does not come up when you type it in the box, the user does not have the Study Coordinator role in ARISE. Click this link for instructions on how they can Request an Additional Role. If this does not help, please contact reoffice@ualberta.ca for further assistance.

Name	Employer

There are no items to display

9.0 **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 section below instead of here.

If the searched name does not come up when you type it in the box, the user does not have the Human Research - Investigator role in ARISE. Click this link for instructions on how they can Request an Additional Role. If this does not help, please contact reoffice@ualberta.ca for further assistance.

Name	Employer
Name	VPR Research Ethics Office
Name	MH Medicine

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

Enter the name of a member of the study team who is the primary administrative contact. Should be someone who is listed as either the PI, the Co-I, or a Study Coordinator.

11.0 Study Team:

Co-investigators, supervising team, and other study team members who may not have a log in for ARISE can be listed here.

NOTE: People listed here ***cannot*** view or edit this application *and* do not receive email notifications.

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.

Department name

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 the Department of Medicine website

1.3 Study Funding Information

1.0 * Type of Funding:
Grant (external)

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. Please note that HREB will only accept clinical trial applications where the funds are held either at the U of A or at AHS/Covenant Health.

University of Alberta - Research Services Office (RSO)

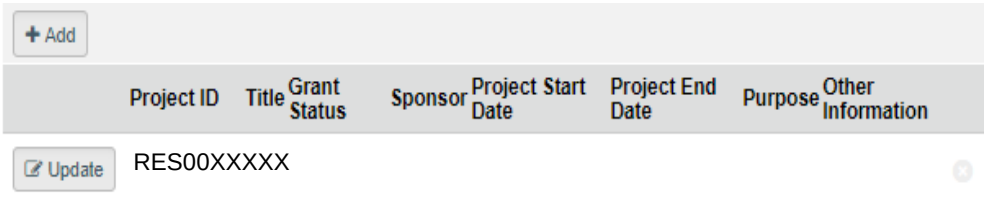
To connect your ethics application with your funding: provide all identifying information about the study funding – multiple rows allowed. For Project ID, enter a Funding ID provided by RSO/PeopleSoft Project ID(for example, RES0005638, G018903401, C19900137, etc).Enter the corresponding title for each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

It is the PI's responsibility to obtain the Project ID (RES number) from the RSO and enter it here, and to keep this information up to date.

Provide all identifying information about the study funding; multiple rows are allowed.

Enter a Funding ID number provided by the RSO for the Project ID. (eg: RES0005638, G018903401, C19900137, etc.)

Enter the corresponding title for each Project ID.



3.0 * **Funding Source**

3.1 Select all sources of funding from the list below:

CIHR - Canadian Institutes for Health Research CIHR

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.

Note: 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

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

Not applicable

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**

This includes investigator payments and recruitment incentives but excludes trainee remuneration or graduate student stipends.

personal remuneration from the funding of this study that is not accounted for in the study budget?

☐ Yes ☐ No

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?**

This includes patents, trademarks, copyrights, and licensing agreements.

☐ Yes ☐ No

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

☐ Yes ☐ No

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

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

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

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

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.

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

List all health care research sites/locations:

NOTE: If conducting research at any of the Institutions above, selection here will allow that Institution access to view 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

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

2.1 Study Objectives and Design

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

It is a requirement of the Tri-Council Policy Statement (TCPS2 2018) 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.

Explain your study as if you were talking about what you do to someone completely outside of your area of expertise. ***Two or three sentences should be able to explain it.***

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

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

Your research proposal will be reviewed in detail by designated reviewers. These reviewers will have a scientific background but are unlikely to be experts in your area of research. Moreover, committee members are drawn from a wide range of scientific disciplines and will include clinicians such as physicians and associated health professionals, as well as basic scientists. As they are not likely to have expertise in your area of inquiry, it is important that your research study is presented in a manner that would be understandable to the reviewers. Simply copying over large swaths of information from the study protocol (which is intended for experts in your field) is not sufficient to permit an informed review.

Therefore, in this section, you are to provide a cogent synthesis of your research proposal under the listed headings as applicable to your project. You can assume that the reviewer will be familiar with concepts of scientific inquiry, but more general descriptions of your area of interest will be needed. Generally, this section should be written by the principal investigator who would be most knowledgeable about the condition under study.

This section should be organized under the following headings: **Purpose, Hypothesis, Justification, Objectives, Research Method, and Statistical Analysis.**

1. **Purpose**: This is the main reason that the study is being conducted (e.g. to determine efficacy, equivalence, safety, dosage levels, effectiveness) and should include the direct implications/applications of the research.

2. **Hypothesis or Aim**: This specifies the precise research questions being evaluated in the study.

3. **Justification for the study**: This includes background evidence that explains the need for the study.

For clinical trials, this information should provide evidence of clinical equipoise, which is defined as "...a genuine uncertainty on the part of the expert medical community about the comparative therapeutic merits of each arm of a clinical trial."

This would also include a clear description of the standard of care and why a new therapeutic approach is necessary (i.e. what is lacking in the current standard of care that would warrant this new treatment being explored and/or what is different between the standard of care and this new treatment).

Some studies are conducted in order to satisfy requirements for Health Canada or FDA approval. *This is not a sufficient ethical justification for the study*. Ensure that a more robust justification is provided which explains why additional studies are needed and warranted.

4. **Objectives**: This includes the specific outcomes/endpoints of the research.

5. **Research Method**: This should include a description of the target population and/or sample, sample size, sampling method (e.g. randomization), type of research design (e.g. experimental parallel group or cross-over design).

This section should include a summary of the research procedures the participants will be exposed to. Describe in a step-by-step manner the research procedures and how they differ from normal, non-research activities. Describe the period during which the procedures will be carried out, how long each procedure will last, and the frequency of the procedures. If applicable, the description should include the sampling method (e.g., random sampling), group assignment (e.g., randomization), and type of research design (e.g., ethnography). Visit by visit explanation is not necessary – simply list and explain all of the procedures in general.

Helpful Tips:

1. DO NOT simply copy and paste large sections of the Protocol without reviewing to make sure they make sense and flow. It is not helpful to paste in the 2 Primary Objectives and 8 Secondary Objectives verbatim from the Protocol and then leave out all of the study procedures. Do not "paste" in descriptions from research applications, or cite papers or books in lieu of explaining procedures.

2. Justification for the study is often overlooked. Please read notes above carefully and try to ensure reviewers can understand why this study is being conducted (i.e. not just to bring a new drug to market).

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

In keeping with a proportionate approach to research ethics review, the selection of the level of REB review shall be determined by the level of foreseeable risks to participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). 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:

- 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

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.

The TCPS requires that the REB satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research. This is most often done through scientific peer review.

The extent of the scientific review required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed (for academic merit).

Scientific review might include review by a granting agency or the examining committee of graduate student's work. The lack of scientific review (i.e. 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.

2.2 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)*

These are the most commonly selected options for clinical trial application. If your study involves access to patient charts are "part" of the research – DO NOT select chart review.

- Surveys and Questionnaires (including internet surveys)
- Clinical Trial
- Collection of Human Biological Materials (i.e. blood, tissue etc.)
- Drugs, Medical Devices, Biologics or Vaccines and/or Natural Health products
- Radiation: Any test or procedure that may involve exposure to radiation (including screening chest x-ray)

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 visit data collection measures, click the survey box in Section 2.2 and complete this section of the form.

Outline how survey data will be collected (paper survey forms 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.

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 sent to the study sponsor and/or stored. If paper surveys will be entered into an eCRF - provide details of the eCRF system being used. If surveys have been 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.

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?

Please clearly outline how you will ensure the security of data gathered at that site.

2.16 Clinical Trial

1.0 Protocol

1.1 Protocol Number (if applicable):

This field will auto-populate 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:

Can also include EudraCT numbers. IND numbers are the US FDA Registration numbers and are NOT what is being asked in this question.

2.0 Is this an investigator-initiated clinical trial?

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

☐ **Yes** ☐ No

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

☐ **Yes** ☐ No

3.0 *** Does the study involve any of the following?**

Answer	Description
☐ Yes ☐ No	A drug, device, biologics, vaccine or natural health product not marketed in Canada?
☐ Yes ☐ No	A comparative bioavailability trial?
☐ Yes ☐ No	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.

A CTA may be required if you are using a drug, biological or natural health product "off label". Off label is generally understood to mean:

- in a patient population not indicated.
- being used per a different route of administration.
- being used for a therapeutic indication that is not listed in the Product Monograph.
- different dosage than what is listed in the Product Monograph.

If any of the above conditions apply, the REB will request an opinion from Health Canada as to whether a CTA is required before approval will be considered.

It is the HREB's right to request confirmation from Health Canada about approvals.

4.0 **Trial Phase:**

There are no items to display

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 patient 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.

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

The response to this question should come directly from the protocol and refers to withdrawal of an INDIVIDUAL participant based on safety concerns.

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.

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:
A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.

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 (3.0 and 4.0).

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.

3.0 * **This study will involve the following** *(select all that apply)***:**
Collection of sample for immediate use

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. include information if the specimens will be sent out of the province)***:**

7.0 **Explain HOW LONG the specimens will be stored:**

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.**

Name	Manufacturer	Type	Health Canada Approval Status	NOL Control Number	Date

There are no items to display

Ensure that the NOL that you provide for the study is dated AFTER the protocol version date that you are submitting, or you will be asked for an updated NOL.

2.20 Radiation Safety

1.0 **Will your research involve any of the following?** *(Check all that apply)*
There are no items to display

2.0 **Research involving exposure of participants 0-17 years of age to any amount ionizing radiation, regardless of how little, must be approved by the AHS Regional Radiation Safety Committee (RSC). Will your research involve exposure to participants aged 0-17 years to any amount of ionizing radiation?**

☐ Yes ☐ No

The HREB strongly encourages researchers to check with Radiation Safety before application to the HREB if the protocol proposes to expose participants 0-17 year to any amount of ionizing radiation. If the intervention is not clinically indicated, it may not be suitable for approval.

3.0 **If this application is for the amendment of a pre-existing clinical study, have procedures which involve exposing subjects to ionizing radiation been**

added to the research that was not identified in the original study protocol?

Note: If you answered YES to any of the above, the system will forward your project information to the AHS Regional Radiation Safety Committee for review. You will be notified of any issues pertaining to RSC approval which may include adding a radiation risk statement to the patient information sheet/consent form or the rewording of an existing risk statement. Protocol amendment is rarely necessary.

For further information, contact the RSC by email at radnsfty@ualberta.ca.

Gail Schaffler, MRT (R)
Research Technologist

Dr. Derek Emery
Professor and Chair
Department of Radiology and Diagnostic Imaging
The University of Alberta

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)

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

Description of Possible Physical Risks and Discomforts	
Yes	Participants might feel physical fatigue, e.g. sleep deprivation
No	Participants might feel physical stress, e.g. cardiovascular stress tests
Possibly	Participants might sustain injury, infection, and intervention side- effects or complications
Yes	The physical risks will be greater than those encountered by the participants in everyday life

Possible Psychological, Emotional, Social and Other Risks and Discomforts	
No	Participants might feel psychologically or emotionally stressed, demeaned, embarrassed, worried, anxious, scared or distressed, e.g. description of painful or traumatic events
No	Participants might feel psychological or mental fatigue, e.g intense concentration required

No	Participants might experience cultural or social risk, e.g. loss of privacy or status or damage to reputation
No	Participants might be exposed to economic or legal risk, for instance non- anonymized workplace surveys
No	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.**

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 (i.e. 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.

New Information About Risks
When previously unknown/undisclosed risks of research become available, researchers are required to inform all relevant participants and their legal representatives (if appropriate) of this information within an appropriate timeframe. The timeframe depends on the nature of the study and the consequences of the risk. This may involve the following:

Informing the participants(s) verbally of additional risks or changes in procedures and ensuring that the communication of this information is documented in the study notes; informing the participants in writing of the additional risks via an addendum or amendment to the consent form. Note that in situations where the new information may affect the participants' willingness to remain in a study, the participant should be informed of these changes in writing (e.g. revised informed consent form or addendum; (ICH-GCP 4.8.2.), and informing the participants who have completed their study treatment if the newly identified risks could still affect them (e.g. irreversible or delayed adverse effects).

Any new or revised information given orally or in writing, including changes to the consent form (or consent addenda), information letters, or telephone scripts must be submitted to the REB for approval before use.

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 Opthalmologist 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

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), 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.

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:**

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.

3.2 Benefits Analysis

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

Research benefits can be direct, e.g. a health condition improves, or indirect, e.g. the research benefits a group in which the participant belongs. As stated in the TCPS2, "researchers should be sensitive to the expectations and opinions of participants regarding potential benefits of the research." (TCPS 2, Chapter 4, Equitable Distribution of Research Benefits, p. 53.)

This being said, research is undertaken to answer a scientific question and while it may benefit society in the future, its primary intent is not to benefit the consenting participant.
The consent form and the application should specify the benefits to the prospective participants. If there are no direct benefits to the participants from participating in the research, this must be stated explicitly. 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.

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.**

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

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

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

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:**

4.0 **Participants**

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

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

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

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)

1.0 Recruitment

1.1 How will you 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.?*)

Recruitment: General Instructions:
Use these 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. prescreening 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 (Question 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.

Section 1.1
This section allows the REB to determine if the proposed method for identifying potential participants complies with the Health Information Act. If you are using existing clinical records to identify who may be eligible to be in the study (ie. pre-screening) clearly disclose what records you will be reviewing and who will be doing the pre-screening. For example: the Principal Investigator is a doctor in a specialized clinic and, therefore, has access to patient records within the clinic.

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)***:**

Ideally, prospective participants in clinical studies are approached for the purpose of recruitment by someone who is within their circle of clinical care.

The Health Information Act states that 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 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 a potential patient who meets basic inclusion/exclusion criteria is identified - this section should outline how that patient will be approached to see if they want to hear more about the research.

The first contact with a patient who has been identified as meeting basic inclusion/exclusion criteria 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. This requirement is found in section 55 of the HIA and CANNOT be waived by the REB.

Please remember that if contact information is being obtained using data under the control of a data custodian (ie. Medical Records, Databases, or Registries) researchers should ensure that the data custodian would approve of the proposed screening method outlined in these sections (ie. approval by the REB for the proposed screening methods outlined in these sections - will not guarantee approval by the data custodian).

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, physical 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). Industry sponsored participant materials should not have industry logos if they are to be used locally.

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

***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 who will obtain consent to participate in the study, and what is the relationship between the person obtaining consent and the participant.

The person obtaining consent must be sufficiently familiar with the study, the disease being treated (if applicable), and the process of informed consent.

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.

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

The REB will look for wording which explicitly states that an individual not directly involved in the clinical care of the patient (e.g. the study coordinator, or an MD not directly caring for the participant) will conduct the informed consent process. In cases where the investigator and the care provider are the same person, he/she can make himself/herself available to answer questions before/after the consent process has been conducted by a third party.

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, childcare, lost wages, etc.

4.5 Informed Consent Determination

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

Free and informed consent lies at the heart of ethical research involving human participants. The Tri-Council Policy Statement 2 (TCPS 2) defines consent to mean "free, informed and ongoing." (TCPS 2 Chapter 2 p. 27) Individuals are generally presumed to have the capacity to make free and informed decisions about participating in research when properly informed of the purpose of the research and its risks and benefits. As a general rule, informed consent should be sought from all research participants.

There are exceptions to this which are outlined below by following the link to the TCPS2.

Enrollment of Children/Adolescents in Research
There is no legal age of majority in Alberta in regard to consent to participate in research. Depending on the nature of the research, a participant may have the capacity to consent well before the age of 18. The common law has two well accepted doctrines that are applicable to the consent of minors. The first is the "emancipated minor" doctrine, and the second is the "mature minor" doctrine.

The emancipated minor doctrine, which is commonly applied by the REB, provides that persons under the age of majority who are "emancipated" in the sense of living on their own, earning their own income, etc. are generally capable of consent, because they are "emancipated from parental control and guidance."

The mature minor doctrine is a common law rule that takes the varying abilities of young people into account, and recognizes that some minors are able to make decisions for themselves. Generally, at common law, if a minor has reached a level of intellectual and emotional maturity such that he or she is capable of understanding and appreciating the nature and consequences of a particular treatment / decision, together with its alternatives they can be considered capable of consenting. Put another way, if it can be determined that a minor in fact understands the proposed interventions, can properly weigh the risks and benefits of various procedures, understands other courses of action and their implications, and it is not prohibited from consenting by legislation, a minor may give a legally valid consent.

There is some debate concerning whether the mature minor doctrine applies in instances where treatment is not beneficial or therapeutic, but increasingly the "rights of minors" to decide are being recognized, except in the most extreme cases, e.g. life and death situations.

The ability to consent to research is not based upon on a participant's age or whether they have reached the age of majority. In accordance with the TCPS2 and in keeping with Article 15.1 above, 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 Panel on Research Ethics (PRE) stresses that no two research studies or research participants are the same. Therefore, the researcher plays an important role in determining whether a particular research participant is capable of consenting on their own behalf or whether an authorized third party should be used. (Panel on Research Ethics.) Within the same research project, there may be some minors who are capable of consenting and others who are not. As per Article 15.1 above, the researcher should describe to the REB how the study team will determine capacity to consent to the research for those proposed participants who are under the age of majority. The PRE advises that 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 legal age of consent, and the characteristics of the intended research participants. (Panel on Research Ethics).

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 Articles 3.1 to 3.5 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 Article 3.7B.

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 justify the waiver or alteration and explain how the study meets ALL of the criteria outlined in Article 3.8 of TCPS2 (a-f)**.**

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.

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

There are no items to display

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.

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

☐ Yes ☐ **No**

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

Capacity is the ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information. (TCPS2, Chapter 3, C.) The TCPS2 states that a participant may have developing or diminished capacity, i.e. a minor or person with a cognitive impairment, but still be able to decide whether to participate in certain types of research (ibid). If a potential research participant has the capacity to consent, consent must be sought from them before research with them commences. If a person does not have the capacity to consent, they should still be involved in the consent process where possible and appropriate and given the opportunity to assent. If a person who lacks the capacity to consent declines to participate in research, his or her dissent must be respected and the person may not be included in the research, see Article 15.5 for further discussion on assent and dissent.

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. This should include details of obtaining consent from a legally authorized third party, in the event that the participant can no longer consent to participate in the research. If a 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). Researchers are encouraged to contact the REB for advice on specific situations involving people with fluctuating or diminishing capacity to consent.

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

◆**Yes** ☐ No

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

Where a legally authorized third party has consented on behalf of an individual who lacks legal capacity, but that individual has some ability to understand the significance of the research, the researcher should determine the wishes of that individual with respect to participation. If this person "assents" to the research, they are agreeing with or concurring with the consent of their authorized third party. While the individual's assent would not be sufficient to permit them to participate in the absence of consent by an authorized third party, their expression of dissent or signs suggesting they do not wish to participate must be respected and precludes their participation. 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)

Determination of assent is generally done through a face-to-face interview with the prospective participant and the principal investigator/person obtaining consent. This interview must convey the main information contained in the consent form using concepts and terms that are developmentally and cognitively appropriate. If the prospective participant is able to read, an assent form should be prepared in a language that is appropriate to the participant.

The following elements should be included in the assent form:

1. a description of the purpose, procedures and the potential risks, discomforts, and hoped for benefits of participation, including possible benefits to others. The REB recognizes that it will often be appropriate to give this information summarily and with less precision than is normally found in a consent form. Nevertheless, the information should not be so scant that a participant is surprised by aspects or consequences of their participation;
2. a statement of the amount of time that participation in the study will take;
3. a statement that the participant's confidentiality will be respected, e.g. that the participant's involvement will be kept private;
4. a statement that participation is voluntary, that the participant may refuse to participate at any time without giving reasons, e.g. no one connected with the study will be angry if a decision to leave the study is made after giving assent, and that all other health care will remain available. Statements that prospective participant has had the opportunity to ask questions, is encouraged to discuss his or her participation with relatives or friends, and that all questions have been answered.
5. a statement that questions are encouraged and may be asked at any time.

The assent form should be as brief as reasonably possible, e.g. for children under 12 it should not exceed 2 pages. Merely technical information, such as the name of the sponsor, disclosure of an investigator's financial interest, advice that legal rights are not limited by participating etc. can typically be omitted. The participant must receive a copy of the assent form and have had adequate time to review it and to discuss it with relatives or friends and the principal investigator (or delegate) prior to assenting. See assent templates on the Research Ethics Office website.

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?

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.

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

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

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

Notification of withdrawal can be given verbally by the participant to any member of the research team and the study team shall not require a written request from the participant to withdraw from the study. In addition, a participant lost to follow-up is considered by the HREB to have voluntarily left the study and shall be treated in the same manner as a participant who has actively given notice of their desire to leave the study. Practically, a participant who does not respond to two telephone calls and a registered letter can reasonably be considered lost to follow-up and withdrawn from a study. Other definitions may be defined in a study's protocol and would be subject to HREB approval.

Once a participant has withdrawn from the study, it is assumed that the following will occur:

a) All study related activities shall cease except those required for the safety of the participant. This includes, but is not limited to, the further collection of health information and activities such as future determination of vital status.
b) Upon withdrawal from the main study, the participant is considered withdrawn from all other aspects of the study including, but not limited to: all optional sub-studies, all analyses of "left-over" samples and all subsequent use of their data not related to the study prime objectives.

The study team may provide the participant with a series of options that may allow participation in the study in a more limited manner (graded withdrawal). This could include provisions for future contact, future use of data for secondary purposes and for continued participation in sub-studies. All options for such limited participation shall be by written informed consent and the possibility of such graded options for study withdrawal shall be made clear in the original consent document. Under no circumstances shall a participant be required to sign a document stating their desire to fully withdraw from a study. The consent for limited study participation after withdrawal from a study is considered voluntary and as such may be withdrawn at any time as described above. For further discussion, refer to the HREB Guidance Withdrawal Policy and Template.

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)*

The HREB consent template states that if a participant withdraws from the study, data collected up until the withdrawal will be kept for the study, but no new data will be collected. As such, this should be stated here and/or in any case the consent MUST be harmonized with what is written here.

Per the HREB Withdrawal Guidance, if a participant withdraws consent, all remaining biological samples are to be destroyed by the researcher/Sponsor, unless the participant explicitly consents for them to be retained.

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**

4.6 Expense Reimbursements and Incentives

1.0 Expense Reimbursements:

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

Include specific details of the reimbursement of expenses related to transportation and parking and when these will be paid. The timing of the reimbursement should be appropriate to the length of time the study is to continue i.e. if a study is 2 years long, consider reimbursement of expenses every 6 months and not at the end of the study.

Ensure that a clear discussion of reimbursement and payments is in the consent form, including a schedule for pro-rating the reimbursement, if applicable. However, do NOT include reimbursements or payments on recruitment materials.

If the participant will not be remunerated for participation or reimbursed for expenses, this should be clearly stated in the consent form.

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

2.0 Incentives:

2.1 Will participants receive any incentives for participating in this research *(i.e. gift card, cash payment, prize draw)***? If yes, provide details of the value, including the likelihood (odds) of winning for prize draws and lotteries.**
https://www.ualberta.ca/research/research-support/research-ethics-office/human-research-ethics/recruitment/use-of-incentives-in-research.html

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.

2.3 IF incentives are offered to participants, they should not be so large or attractive as to constitute coercion. Justify the value of the incentives you

are offering relative to your study population.

Voluntary consent must be free of undue influence in the form of inappropriate inducements. The amount or kind of payment should not be such that the participant will base his/her decision to participate on the potential material rewards.

TCPS2 states, "In considering the possibility of undue influence in research involving financial or other incentives, researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and capacity of participants, the customs and practices of the community and the magnitude and probability of harms".

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

2.0 **Primary/raw data collected will be** *(check all that apply)***:**
There are no items to display

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 2.9 (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** *(e.g. where participants talk in a group)*, **how will confidentiality be achieved?**

This question is often 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 Biomedical Panel 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)***:**

Other

If OTHER, please describe:

2.0 Will you be collecting - at any time of the study, including recruitment of participants - any of the following *(check all that apply)***:**
There are no items to display

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

It is the role of the REB to assess that a researcher is ONLY collecting identifiers that are required to complete the analysis for the research you are conducting. Any of the identifiers in question 1.0 and 2.0 should be detailed here as to how the collection will be used in the analysis of the research (i.e. 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, PHN) should not be kept together (physically or electronically) with the non-identifiable or coded data at any time (i.e. names should not be on surveys, patient labels should not be kept on data collection forms/CRF etc., master lists should not be kept at the front of CRF binders, participant ID number should not be put onto the consent form).

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

5.0 * Specify what identifiable information will be RETAINED once data collection is complete and explain why retention is necessary. Include the retention of master lists that link participant identifiers with de-identified data:

Researchers often perceive that the REB believes identifiers should be destroyed at the earliest opportunity - but this is not the case. This section can be used to detail what you will be keeping and WHY it is important to retain that data (i.e. 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 so need careful consideration and full details outlined here.
Details can include who is doing the linking 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 (i.e. encryption, master lists).

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 include:

Have research personnel taken Health Information Act privacy training either through the data custodian (i.e. AHS, Covenant) or have they taken the University of Alberta Privacy training? Have staff taken CITI training and/or 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?**

☐ **Yes** ☐ **No**

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 subjects and the privacy of

their data.

3.3 **Provide details if identifiable data will be leaving the institution, province, or country** *(e.g. 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.

Ensure that what is here is harmonized with the consent document. Additionally, closing reports that you submit will be checked against what is written here.

It is an expectation that any data that contains any identifiers will be Encrypted. Resources:
https://www.ualberta.ca/chief-information-security-officer/encryption/index.html
https://www.ualberta.ca/medicine/programs/medit/policies/encryption-policy

Please note that it may be wise to not provide too narrow of a location for records, 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)*

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 under the *Food and Drug Regulations* and *Natural Health Products Regulations* (Medical Device does not specify this, check with Sponsor for requirements)

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:

An 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.

Documentation

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

Sample forms and templates are available on the REO website in the Forms cabinet, here.

1.0 Recruitment Materials:

Document Name	Version	Date	Description
There are no items to display			

2.0 Letter of Initial Contact:

Document Name	Version	Date	Description
There are no items to display			

Letter of initial contact to participant, which will come from the data custodian.

3.0 Informed Consent / Information Document(s):

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

- Use HREB templates
- Upload CLEAN and TRACKED CHANGE version each time changes are made.
- Ensure version footers are consistent on all pages.
- Ensure Ethics ID is in footer.

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

Document Name	Version	Date	Description
	0.01		

4.0 Assent Forms:

Document Name	Version	Date	Description

There are no items to display

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

Document Name	Version	Date	Description

There are no items to display

- Upload ALL instruments to be used by participants for review at same time as initial submission.

6.0 Protocol/Research Proposal:

Document Name	Version	Date	Description

There are no items to display

- All applications to HREB require a formal protocol be uploaded.
- Cannot be password protected.

7.0 Investigator Brochures/Product Monographs:

Document Name	Version	Date	Description

There are no items to display

- Cannot be password protected.
- Must be the most recent version.

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

Document Name	Version	Date	Description

There are no items to display

- Date of NOL cannot precede protocol date.
- Studies can be SUBMITTED without an NOL but cannot be APPROVED until this is received.

9.0 Confidentiality Agreement:

Document Name	Version	Date	Description

There are no items to display

10.0 Conflict of Interest:

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

Document Name	Version	Date	Description
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- Budget (final or draft) must be submitted within initial submission) clinical trials Article 11.11 TCPS2).
- Training certificates for Key Personnel for NIH Funded studies.
- eCRFs.

Final Page

You have completed your ethics application! Click "Continue" to go to your study workspace.

This action will NOT SUBMIT the application for review.

Only the Study Investigator can submit an application to the REB by selecting the "SUBMIT STUDY" button in My Activities for this Study ID: Pro000XXXXX.

If in doubt, check it out.

Our contact information is on our website at https://www.ualberta.ca/research/research-support/research-ethics-office/contact.html

Email or call us if you have any questions.