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)*:

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

The online application form is a "smartform" - questions/sections appear (or open up) depending on how previous questions were answered.

This sample form will indicate which sections will branch (or open up) by: "[>> 1.7]" meaning "complete section 1.7".

Some yes/no questions will open up additional questions directly below, and these will be shown by a darkened circular button.

Use the Bookmarks to jump to specific sections.

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 (click here for more information)
○	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 (click here for more information)
○	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	Research primarily concerning privacy, data-sharing, confidentiality, questionnaires, survey methods and internet research.

Clear

4.0 * **Is the proposed research:**

○ Funded (Grant, subgrant, contract, internal funds, donation or some other source of funding) [>> 1.3]

○ Unfunded

Clear

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

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

- ○ Faculty/Academic Staff
- ○ Alberta Health Services
- ○ Covenant Health
- ○ 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) [>> 1.7]
- ○ Graduate Student
- ○ Medical Resident
- ○ Post-doctoral Fellow
- ○ Undergraduate student
- ○ University of Lethbridge
- ○ External Researcher (external to U of A, AHS and Covenant Health)

Clear

7.0 **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):**

8.0 **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	

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 email list 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 REMO. Click the following link for instructions on how to Request an Additional Role.

Name	Employer
There are no items to display	

10.0 **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 http://www.reo.ualberta.ca/Forms-Cabinet/Forms-Human.aspx)*:

- Pediatrics
- AHS Pharmacy
- Medicine
- University of Lethbridge (Division)
- MacEwen University (Division)
- Dentistry

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)*

[If RSO, answer question below]

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

Clear

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

+ Add

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

There are no items to display

3.0 * **Funding Source**

3.1 Select all sources of funding from the list below:

There are no items to display

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

There are no items to display

+ Add

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

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

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

1.4 Conflict of Interest

1.0 * **Are any of the investigators or their immediate family receiving any personal remuneration (including investigator payments and recruitment incentives but excluding trainee remuneration or graduate student stipends) from the funding of this study that is not accounted for in the study budget?**
○ Yes ○ No Clear

2.0 * **Do any of investigators or their immediate family have any proprietary interests in the product under study or the outcome of the research including patents, trademarks, copyrights, and licensing agreements?**
○ Yes ○ No Clear

3.0 * **Is there any compensation for this study that is affected by the study outcome?**
○ Yes ○ No Clear

4.0 * **Do any of the investigators or their immediate family have equity interest in the sponsoring company? (This does not include Mutual Funds)**
○ Yes ○ No Clear

5.0 * **Do any of the investigators or their immediate family receive payments of other sorts, from this sponsor (i.e. grants, compensation in the form of equipment or supplies, retainers for ongoing consultation and honoraria)?**
○ Yes ○ No Clear

6.0 * **Are any of the investigators or their immediate family, members of the sponsor's Board of Directors, Scientific Advisory Panel or comparable body?**
○ Yes ○ No Clear

7.0 * **Do you have any other relationship, financial or non-financial, that, if not disclosed, could be construed as a conflict of interest?**
○ Yes ○ No Clear

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

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

1.5 Research Locations and Other Approvals

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

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
- ☐ Capital Care Institutions and Facilities
- ☐ Covenant Health Institutions and Facilities
- ☐ Not applicable

List all health care research sites/locations:

3.0 **Multi-Institution Review**

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

[If yes, answer question below]

● **Yes** ○ **No** Clear

3.2 Select the REB that applies below: (*The University of Alberta has entered into formal reciprocity agreements with the REBs listed below. Because of this agreement, if you have already received approval from one of the REBs specified below. Please upload the other REBs* ***application***, ***approval*** and ***approved consent forms*** *to the Documentation Section (11.0). In doing this your study may be eligible for a delegated review instead of requiring full board review.*)

- ☐ University of Calgary Conjoint Health REB (CHREB)
- ☐ University of British Columbia affiliated REB (UBC)
- ☐ University of Saskatchewan REB
- ☐ Other

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.**

1.6 Instructor-led Course-based Application

Frequently, undergraduate courses incorporate class projects and other activities for the purposes of developing research skills. These projects may be carried out by individual students, small groups or as a single class project.

Examples of course-based research activities include:

- *Having students conduct interviews, administer standard tests, or distribute questionnaires to develop interview or questionnaire design skills, or*
- *Conduct "mini" research projects where students pose research questions, gather data from human participants, and analyse data for presentation*

Regardless of the activities, course-based student research assignments must be no more than minimal risk and the participants must be drawn from the general population and be capable of giving free and informed consent. In addition, the student projects must not involve deception, personal or sensitive topics, or physically invasive contact with the participants.

NOTE: All instructor-led course-based student research ethics application will be reviewed by Board 1. Please ensure you have selected Board 1 in the first page of this application.

1.0

* **Provide Course Title:**

* **Provide Course Number:**

* **Provide a brief description of the course (including how this research assignment helps students to meet the objectives of the course).**

2.0 * **Provide a brief description of the research assignment(s)/what students will be doing** *(i.e. include details related to the methods, procedures, nature of the involvement of human participants and/or the work that students will hand in)*:

3.0 **Will any of the research study specifically focus on First Nations, Inuit or Metis Peoples?**

○ Yes ○ No Clear [Yes >> 2.8]

4.0 **Explain how you will prepare your students to comply with Tri-Council Policy Statement (TCPS2) guidelines and the University Human Research Ethics Policy in completing the course assignments(s).**

5.0 **Explain the oversight you will have over the students while conducting the course assignment.**

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

7.0 **Describe how any data collected 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, documents must be kept in a locked filing cabinet and computer files are encrypted, etc.)**

8.0 **What will happen with the data when the course is over? Specify any plans for future use of the data and/or describe your plans for destruction of the data.**

9.0 **Please ensure that you attach the following documentation to the Documentation Section (check if applicable):**

- ☐ Course Syllabus
- ☐ Human Participant Information Letter / Consent form
- ☐ Survey / Questionnaire Instrument
- ☐ Interview Guide

For Instructor-led course-based applications, no other sections of the application need to be completed (aside from section 2.8 and Documentation section, as required).

2.1 Study Objectives and Design

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

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

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

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)*:

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.**

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

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 [>> 2.3]
- ☐ Internet-based Interaction with Participants (excluding internet surveys or data collection over internet without human interaction) [>> 2.4]
- ☐ Interviews and/or Focus Groups [>> 2.5]
- ☐ Materials created by participants (eg. artwork, writing samples, photo, voice, etc.) [>> 2.6]
- ☐ Participant Observation [>> 2.7]
- ☐ Research focusing on First Nations, Inuit and Metis Peoples [>> 2.8]
- ☐ Surveys and Questionnaires (including internet surveys) [>> 2.9]
- ☐ Use of Partial Disclosure and/or Use of Deception [>> 2.11]
- ☐ Use of Participant Subject Pool (i.e. Psychology Research Participation Program, Alberta School of Business Research Panel, Department of Linguistics) [>> 2.12]
- ☐ Data Registries and/or Biobanking (collection of samples to put in a Biobank/Sample Repository) [>> 2.14]
- ☐ Clinical Trial [>> 2.16, 2.17]
- ☐ Collection of Human Biological Materials (ie. blood, tissue etc.) [>> 2.13, 2.18]
- ☐ Drugs, Medical Devices, Biologics or Vaccines and/or Natural Health Products [>> 2.19]
- ☐ Radiation: Any test or procedure that may involve exposure to radiation (including screening chest x-ray) [>> 2.20]
- ☐ Stem Cell Research (attach CIHR Oversight Committee Approval in Documentation section) [>> 2.22]
- ☐ Use of Health Information - *See NOTE 1 below* [>> 2.15]
- ☐ Secondary Use of Human Biological Materials - *See NOTE 2 below* [>> 2.21]
- ☐ Secondary Use of Information (Use of data previously collected for another purpose) - *See NOTE 3 below* [>> 2.10]
- ☐ None of the above

NOTE 1: Select this if you are directly collecting health information as part of your protocol OR will be conducting a chart/record review/reviewing health data secondarily. This includes anonymized or identifiable health information.

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

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

2.3 Food, Nutrition, and Nutraceuticals Information

1.0 Product Source

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

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

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

2.2 If YES, please describe the safety and monitoring processes planned *(particularly if the source does not fall under any regulatory bodies/sanctions of the Canadian government):*

3.0 Dietary Levels

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

● Yes ○ No Clear

3.2 If YES, please justify the level in terms of potential risks associated with over-consumption of the ingredient:

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:

3.0 * 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?

4.0 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:

5.0 * 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?

2.5 *Interview and/or Focus Groups*

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

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

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

2.6 Material Created by Participants

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

2.0 **Who will have access to this data?**

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

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

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

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

● Yes ○ No Clear

If YES, provide details:

2.7 *Participant Observation*

1.0 **Who will the observer be?**

2.0 **Who is being observed?**

3.0 **Why are they being observed?**

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

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:

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:**

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

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

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

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)***?**

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.)?**

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)?**

3.0 **Who will have access to the data?**

2.10 Secondary Analysis

1.0 Outline what data you are analyzing for this research

2.0 How was the original data collected?

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).

Please remember to upload the following to the Documentation Section:

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

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

2.11 Use of Deception or Partial Disclosure

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

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

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

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

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

2.12 Use of Participant Subject Pool

1.0 What subject pool will you use to recruit participants?

2.0 Amount of time the study will take:

3.0 Will Participant Receive:

Course credit

● Yes ○ No Clear

Provide Details

Payment

● Yes ○ No Clear

Provide Details

4.0 Provide a brief description of the alternate task:

If there is no alternate task, explain why:

5.0 Will participants be debriefed?

○ Yes ○ No Clear

if YES please attach the debriefing document in the Documentation Section

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

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.

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

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

- [ ] Canada
- [x] Other

If Other, provide details:

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

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?**

7.0 **Who is responsible for the database?**

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 Chart/Medical Record Reviews

Guidance

1.0 Estimate the number of records you will access *(ie. we will review approximately 300 charts, we will review 300 patient records)*

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.)*

3.0 Will the chart/record review be:

- ☐ 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?

○ 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).*

6.0 How will the data be received?

- A member of the study team will extract data from original sources;
- Data custodian will provide the data to the study team without identifiers;
- Data custodian will provide the data to the study team with identifiers;
- Other

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*

2.16 Clinical Trial

1.0 Protocol

1.1 Protocol Number (if applicable):

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 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 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 patient an inactive substance instead of a treatment)*

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

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:**

3.0 * **Summarize any pre-specified criteria for stopping or changing the study protocol 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.)*:

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

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:**

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:**

« Back

Save Exit Hide/Show Errors To Print Jump

Continue »

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

2.20 Radiation Safety

1.0 **Will your research involve any of the following?** *(Check all that apply)*

- [ ] Screening chest X-ray (in adults)
- [ ] X-rays of the shoulder, elbow, forearm, wrist, hand, knee, ankle or foot
- [ ] X-rays of the skull, facial bones, neck, spine, thorax, abdomen, pelvis or hip
- [ ] Mammography
- [ ] Computed Tomography (CT)
- [ ] Radioisotope Scan (includes MIBI, bone scan, GFR measurement, PET, etc.)
- [ ] Fluoroscopic Procedure (includes angiography, cardiac catheterization, EP lab)
- [ ] Bone Densitometry (in adults) (DEXA, DXA, BMD)

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

Clear

Please describe

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?**

- ( ) Yes
- ( ) No
- ( ) Not Applicable (this application is for a new study)

Clear

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

2.21 Secondary Use of Human Biological Materials

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

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

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:**

- Yes
- No
- Possibly

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.**

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

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.

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?**

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:**

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

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

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 [If No skip to 5.1]

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 [Yes >> 4.3. No >> 4.4]

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

○ Yes ○ No Clear [Yes >> 4.8]

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):*

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

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:

4.3 Recruitment of Participants (Health)

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?)*

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

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)***:**

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.

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):*

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):*

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

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 [>> 4.6]
- [ ] Payment or incentives, e.g. honorarium or gifts for participating in this study [>> 4.6]
- [ ] None of the above

4.4 Recruitment of Participants (non-Health)

1.0 Recruitment

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

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

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)*

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

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 [>> 4.6]
- ☐ Payment or incentives, e.g. honorarium or gifts for participating in this study [>> 4.6]
- ☐ None of the above

4.5 Informed Consent Determination

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

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)**

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)**.**

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:

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.).*

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.

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

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

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.**

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)*

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 [If Yes >> 4.7]

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)*

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

2.0 Incentives:

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

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

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.

4.7 Group Research Documentation

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

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

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

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

4.8 Be The Cure Questions

1.0 * **What is the lay title of your study?**

2.0 * **In lay language, describe the summary/purpose of your study (750 characters or less).**

3.0 **What are the eligible ages of participants?**

* Lower Age Limit:

* Upper Age Limit:

4.0 * **What is the eligible sex of participants?**

- [ ] Male
- [ ] Female
- [ ] Intersex
- [ ] Any

5.0 * **In lay language, outline the inclusion criteria.**

6.0 * **In lay language, outline the exclusion criteria.**

7.0 * **Does this study accept healthy participants?**

Yes No Clear

8.0 * **What will be the recruitment status of this study once ethics approval is obtained?**

- Not currently recruiting participants;
- Currently recruiting participants;
- Closed to recruitment

9.0 **If there are external links that participants can access for this study, please provide:**

+ Add

Site Name	Link

There are no items to display

10.0 * **Add keywords (in lay language, seperated by comma) associated with this study.**

11.0 **Who can potential study participants contact for more information about the study?**

+ Add

Name	Title	Phone	Email

There are no items to display

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 [If No skip to 5.4]

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:**

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?**

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:**

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

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:**

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:**

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.**

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?**

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 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 subjects and the privacy of their data.

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)*

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)*

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:**

Documentation

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

Sample templates are available by clicking HERE.

1.0 Recruitment Materials:

+ Add

Document Name	Version	Date	Description
There are no items to display			

2.0 Letter of Initial Contact:

+ Add

Document Name	Version	Date	Description
There are no items to display			

3.0 Informed Consent / Information Document(s):

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

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

+ Add

Document Name	Version	Date	Description
There are no items to display			

4.0 Assent Forms:

+ Add

Document Name	Version	Date	Description
There are no items to display			

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

+ Add

Document Name	Version	Date	Description
There are no items to display			

6.0 Protocol/Research Proposal:

+ Add

Document Name	Version	Date	Description
There are no items to display			

7.0 Investigator Brochures/Product Monographs:

+ Add

Document Name	Version	Date	Description
There are no items to display			

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

+ Add

Document Name	Version	Date	Description
There are no items to display			

9.0 **Confidentiality Agreement:**

+ Add

Document Name	Version	Date	Description
There are no items to display			

10.0 **Conflict of Interest:**

+ Add

Document Name	Version	Date	Description
There are no items to display			

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

+ Add

Document Name	Version	Date	Description
There are no items to display			