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1.1 Study Identification

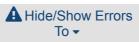
All questions marked by a red asterisk * are required fields. However, because the mandatory fields have been kept to a minimum, answering only the required fields may not be sufficient for the REB to review your application.

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

70000	anovor <u>am referant queedone</u>	that will reasonably help to describe your study or proposed research.				
1.0	* Short Study Title (restrict	cted to 250 characters):				
2.0	* Complete Study Title (c	can be exactly the same as short title):				
		ion form is a "smartform" - questions/sections appear (or g 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".					
		ions will open up additional questions directly below, and by a darkened circular button.				
		▲				
3.0	* Select the appropriate Research Ethics Board (Detailed descriptions are available at http://www.reo.ualberta.ca/Human-Research-Ethics/Research-Ethics-Boards.aspx):					
	Board Desc Name	ription				
	Research (Edmo	: All NON-invasive health research involving patients, health information, AHS onton Region) or Covenant Health facilities and researchers except cancerd research, which should be reviewed by the HREBA-CC (click here for more nation)				
	HREB Region	rasive health research involving patients, health information, AHS (Edmonton n) or Covenant Health facilities and researchers except cancer-related rch, which should be reviewed by the HREBA-CC (click here for more nation)				
	Research Ethics Board comm	arch primarily involving in-person interviews, focus groups, ethnographies, or unity engagement and instructor-led course-based research assignments.				
		arch primarily concerning privacy, data-sharing, confidentiality, questionnaires, y methods and internet research.				
4.0	* Is the proposed research					
	O Unfunded Unfunded	rant, contract, internal funds, donation or some other source of funding) [>> 1				
	<u>Clear</u>					
5.01	* Name of local Principal	Investigator:				

Type of research	/study:			
O Faculty/Acade	•			
O Alberta Health	Services			
O Covenant Hea	lth			
	rse-based (where all st MAL risk research ass			
O Graduate Stud	lent			
O Medical Reside	ent			
O Post-doctoral F	ellow			
Undergraduate	e student			
O External Research	archer (external to U of	f A, AHS and Co	ovenant Health)	
Clear				
		•••		
	s or Research Assist tifications for the study:		ted here can edit this	application and will
	tifications for the study:		ted here can edit this	application and will
receive all email not	tifications for the study:	•••	ted here can edit this	application and will
Name There are no items Co-Investigators: Investigators who do instead of here). If your searched nai	tifications for the study:	mployer edit this applica mail, should be when you type in	tion and will receive endeded to the study ended in the box, the user of	email notifications (Co mail list team below does not have the
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Name There are no items Co-Investigators: Fine the investigators who do not each of here). If your searched nail Principal Investigators Additional Role.	Er to display People listed here can to not wish to receive en the does not come up wor role in REMO. Click to	edit this applica mail, should be when you type in the following lini	tion and will receive endeded to the study ended in the box, the user of	email notifications (Co mail list team below does not have the
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Name There are no items Co-Investigators: Investigators who do nated of here). If your searched nate of the principal Investigator Additional Role. Name There are no items Study Team: (co-in	Er to display People listed here can o not wish to receive er me does not come up vor role in REMO. Click to to display	edit this applica mail, should be when you type in the following linit	tion and will receive endeded to the study ended in the box, the user of for instructions on himself.	email notifications (Co mail list team below does not have the ow to Request an
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1.2 Additional Approval

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

•••

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

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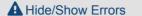
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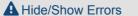
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1.3 Study Funding Information

* T	ype of Funding: Grant (external)
	Contract (eg. Commercial, Industry, For-profit funding, etc)
	idicate which office administers your award. (It is the PI's responsibility to provide ethics approvalification to any office other than the ones listed below)
C	University of Alberta - Research Services Office (RSO) [>> 1.4]
C	Alberta Health Services (NACTRC)
C	Covenant Health (including Institute for Reconstructive Sciences in Medicine-IRSM)
) Other
) Other
* F	Other Clear unding Source Select all sources of funding from the list below:
* F	Clear unding Source Select all sources of funding from the list below:
* F 3.1 Th 3.2 Sp of th	unding Source Select all sources of funding from the list below: nere are no items to display If your source of funding is not available in the list above, click "Add" below and write the
* F 3.11 3.22 Spp of t	unding Source Select all sources of funding from the list below: Pere are no items to display If your source of funding is not available in the list above, click "Add" below and write the consor/Agency name(s) in the free text box that pops up. (Nore: You may reflect multiple sources funding by continuing to click "Add" to add each additional source of funding). There are no items to display
* F 3.11 3.22 Spp of t	unding Source Select all sources of funding from the list below: nere are no items to display If your source of funding is not available in the list above, click "Add" below and write the onsor/Agency name(s) in the free text box that pops up. (Nore: You may reflect multiple sources funding by continuing to click "Add" to add each additional source of funding). There are no items to display Add Indicate if this research sponsored or monitored by any of the following:
* F 3.11 Th 3.22 Spp of t 1 * III	unding Source Select all sources of funding from the list below: There are no items to display If your source of funding is not available in the list above, click "Add" below and write the onsor/Agency name(s) in the free text box that pops up. (Nore: You may reflect multiple sources funding by continuing to click "Add" to add each additional source of funding). There are no items to display Add Add Indicate if this research sponsored or monitored by any of the following:
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* F 3.11 3.22 Spp of ##	unding Source Select all sources of funding from the list below: """ """ """ """ """ """ """
* F 3.1 3.2 Sp of t + III	unding Source Select all sources of funding from the list below: Incre are no items to display If your source of funding is not available in the list above, click "Add" below and write the onsor/Agency name(s) in the free text box that pops up. (Nore: You may reflect multiple sources funding by continuing to click "Add" to add each additional source of funding). There are no items to display Add 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)
* F 3.1 3.22 Spp of f 1 * II	unding Source Select all sources of funding from the list below: If your source of funding is not available in the list above, click "Add" below and write the onsor/Agency name(s) in the free text box that pops up. (Nore: You may reflect multiple sources funding by continuing to click "Add" to add each additional source of funding). There are no items to display - Add -











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1.4 RSO Managed Funding

* 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 Project Title

Speed Code

Other Information

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1.5 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 O No Clear
3.0	* Is there any compensation for this study that is affected by the study outcome? O Yes O 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) O Yes O 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 O 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? O Yes O 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:
-	ortant I answered YES to any of the questions above, you may be asked for more information.







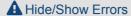


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1.6 Research Locations and Other Approvals

	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?
yes, answe		Yes No Clear
estion belo	ovv]	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.
		approación and approvariente in the bounnemation dection - Other bounnema.









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1.7 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.

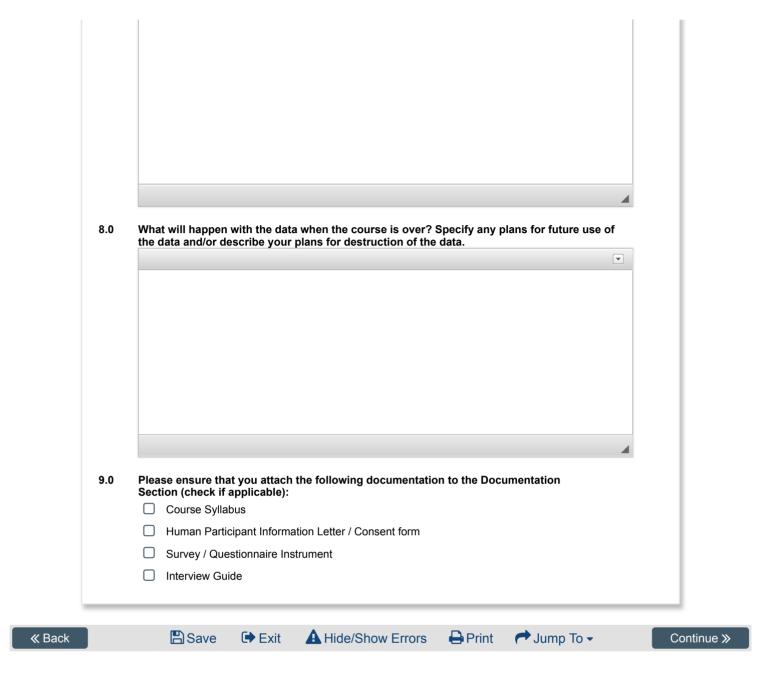
Examples of course-based research activities include:

- 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.

* Provide Course Title:			
* Provide Course Numb	per:		
Provide a brief descri	ption of the course (<u>includi</u> bjectives of the course).	ing how this research assig	nment helps
			•
	ption of the research assig	nment(s)/what students will	be doing (i.e.
Provide a brief descri	the methods, procedures, na	iture of the involvement of hu	man participants
include details related to	dents will hand in):		
* Provide a brief descri include details related to and/or the work that stud	dents will hand in):		•
include details related to	dents will hand in):		•
include details related to	dents will hand in):		v
include details related to	dents will hand in):		•
include details related to	dents will hand in):		•
include details related to	dents will hand in):		•



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).



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2.1 Study Objectives and Design

Provide planned start and end date of human participant research.				
Start Date:				
End Date:				
* Provide a lay summary of your proposed research which would be understandable to general				
public				
v				
* Provide a full description of your research proposal outlining the following:				
PurposeHypothesis				
PurposeHypothesisJustification				
 Purpose Hypothesis Justification Objectives Research Method/Procedures 				
 Purpose Hypothesis Justification Objectives 				
 Purpose Hypothesis Justification Objectives Research Method/Procedures Plan for Data Analysis 				
 Purpose Hypothesis Justification Objectives Research Method/Procedures 				
 Purpose Hypothesis Justification Objectives Research Method/Procedures Plan for Data Analysis 				
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 Purpose Hypothesis Justification Objectives Research Method/Procedures Plan for Data Analysis 				

4
Describe procedures, treatment, or activities that are above or in addition to standard practices this study area (eg. extra medical or health-related procedures, curriculum enhancements, extra follow up, etc):
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.
For clinical trials, describe any sub-studies associated with this Protocol.











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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.

	s 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]
	Secondary Use of Information (analyzing data previously collected for another purpose) [>> 2
	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]
	Biohazardous Substances [>> 2.13]
	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]
	Chart Review/Review of Health Data (ie. paper charts, electronic health records or administrative health data) - See NOTE 1 below [>> 2.15]
	Secondary Use of Human Biological Materials - See NOTE 2 below [>> 2.21]
	None of the above
char you a addi	E 1: Select this ONLY if your application SOLELY involves a review of paper ts/electronic health records/administrative health data to answer the research question. If are enrolling people into a study and need to collect data from their health records in tion to other interventions, then you SHOULD NOT select this box.
origii you i	E 2: Select this option if this research ONLY involves analysis of blood/tissue/specimens nally collected for another purpose but now being used to answer your research question. If are enrolling people into the study to prospectively collect specimens to analyze you bull NOT select this box.









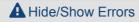


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2.3 Food, Nutrition, and Nutraceuticals Information

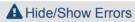
	* 1.1 What is the source of any dietary products that participants will consume?					
	* 1.2 Describe how you know that the products were produced within acceptable standards for food safety?					
0	Safety Monitoring * 2.1 Is there any current recommendation that the use of the products identified requires 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					
	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):					
0	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): Dietary Levels					
0	does not fall under any regulatory bodies/sanctions of the Canadian government): Dietary Levels					
0	does not fall under any regulatory bodies/sanctions of the Canadian government): Dietary Levels * 3.1 Does the level of dietary ingredients exceed any Canadian nationally recommended levels?					

4.1 If any nutritional or dietary advice or counseling will be offered to participants in conjunctio 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
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)?

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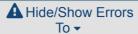




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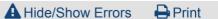


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2.4 Internet-based Interaction with Human Participants

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 O No Clear
	1.2 Will these interactions occur in public space(s) where you will post questions initiating and/or maintaining interaction with participants? O Yes O 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?











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2.5 Interview and/or Focus Groups

4.0	Will you can dust interviews focus maynes on heth? Provide detail
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)?
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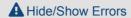
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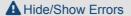


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2.6 Material Created by Participants

who will ha	ve access to this data?
articles, boo	cly reporting data or disseminating results of your study (eg. presentation, reports, oks, curriculum material, performances, etc) that include the materials created by is, what steps will you take to protect those who may be represented or identified - both and non-participants?
What oppor	tunities are provided to participants to choose to be identified as the author/creator o
the material	s created in situations where it makes sense to do so?
	y, what arrangements will you make to return original materials to participants?
if necessary	
Will you be the study?	using audio/video recording equipment and/or other capture of sound or images for
Will you be	No <u>Clear</u>









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2.7 Participant Observation

Who will the observer be?
Who is being observed?
Why are they being abouted?
Why are they being observed?
When and where will participants be observed (i.e. during class, during their workday)?
Then and this of the participance so escent ou (not during class), during their mentady).
Will others be present who are not being observed (i.e. non-participants)?
Will others be present who are not being observed (i.e. non-participants)? ■ Yes ○ No Clear
Yes No Clear
Yes No Clear
Yes No Clear Provide details:
Provide details: What data will be collected? Video and/or audio recordings
Provide details: What data will be collected? Video and/or audio recordings Photographs
Provide details: What data will be collected? Video and/or audio recordings Photographs Field notes
Provide details: What data will be collected? Video and/or audio recordings Photographs Field notes Other
Provide details: What data will be collected? Video and/or audio recordings Photographs Field notes
Provide details: What data will be collected? Video and/or audio recordings Photographs Field notes Other
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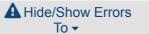


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2.8 First Nations, Inuit and Metis People

If leaded	ers of the group will be involved in the identification of potential participants, provid :
	e details if: rty or private information belonging to the group as a whole is studied or used;
• the re	search is designed to analyze or describe characteristics of the group, or duals are selected to speak on behalf of, or otherwise represent the group
* Provi	de information regarding consent, agreements regarding access, ownership and sh
	e information about how final results of the study will be shared with the participation inity (eg. via band office, special presentation, deposit in community school, etc)?
	e a research agreement with the community?











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2.9 Surveys and Questionnaires (including Online)

here will the data be stored once it's collected (i.e. will it be store ovider servers, will it be downloaded to the PI's computer, other)	
The will have access to the data?	
no will have decess to the data.	

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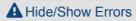
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2.10 Secondary Analysis

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
5.0	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).
	provide justification for a waiver of consent for ALL criteria (a-e).
5 4	and the standard the fall of the December of t
	se remember to upload the following to the Documentation Section:
•	riginal data collection instrument(s), or an outline of the information you are analyzing.
	riginal consent/info (if applicable - if individuals have previously agreed for their data to be used rure research/for research purposes).













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2.11 Use of Deception or Partial Disclosure

* Describe the information that will be withheld from, or the misinformation that will be provided to, the participants:
Provide a rationale for withholding information:
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:
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:
Indicate how participants may follow-up with researchers to ask questions or obtain information about the study:







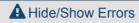


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2.12 Use of Participant Subject Pool

Amount of time the study will take: Will Participant Receive: Course credit Yes No Clear Provide Details Payment Yes No Clear Provide Details Provide Details Provide a brief description of the alternate task:	0	What aukinet and will you use to requisit portion and?
Will Participant Receive: Course credit	•	What subject pool will you use to recruit participants?
Will Participant Receive: Course credit		
Will Participant Receive: Course credit		
Will Participant Receive: Course credit		
Will Participant Receive: Course credit		
Will Participant Receive: Course credit Yes No Clear Provide Details Payment Yes No Clear Provide Details Provide Details		Amount of time the study will take:
Course credit Yes No Clear Provide Details Payment Yes No Clear Provide Details Provide Details Provide a brief description of the alternate task:		Amount of time the study will take.
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Course credit Yes No Clear Provide Details Payment Yes No Clear Provide Details Provide Details		
Provide Details Payment Yes No Clear Provide Details Provide Details Provide a brief description of the alternate task:		Will Participant Receive:
Payment		Course credit
Payment		Yes No Clear
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Provide Details Provide a brief description of the alternate task:		Frovide Details
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Provide Details Provide a brief description of the alternate task:		
Provide Details Provide a brief description of the alternate task:		Payment
Provide a brief description of the alternate task:		Yes No Clear
Provide a brief description of the alternate task:		Provide Details
If there is no alternate task, explain why:		Provide a brief description of the alternate task:
If there is no alternate task, explain why:		
If there is no alternate task, explain why:		
If there is no alternate task, explain why:		
If there is no alternate task, explain why:		
		If there is no alternate task, explain why:
Will participants be debriefed? O Yes O 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:	.,
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2.13 Biohazard Safety

Α	nswer		Description
(Yes O	No <u>Clear</u>	Risk group 2, 3 or 4 viruses, bacteria, fungi, parasites or eukaryotic cell lines
(Yes O	No Clear	Environmental specimens suspected to contain risk group 2, 3 or 4 microbes
(Yes O	No <u>Clear</u>	Large-scale single volume culture in excess of 10 litres for any microbe or eukaryotic cell line
(Yes O	No Clear	Microbial toxins
(Yes O	No Clear	Human clinical specimens, including blood or other body fluids, or primary culture of human cells
(Yes O	No Clear	Xenotransplant studies involving vertebrate donors and/or recipients
(Yes O	No Clear	Genetic therapy studies involving vertebrate donors and/or recipients
(Yes O	No Clear	Genetic manipulation involving virulence genes from risk group 2, 3 or 4 microbes, mammalian oncogenes, mammalian cytokine or interleukin genes, or microcide resistance genes
(Yes O	No <u>Clear</u>	Genetic manipulations involving the use of recombinant vector systems based on lentivirus, adenovirus, retrovirus or herpesvirus backbones

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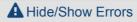


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2.14 Data Registries and Biobanks

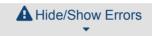
* Who will have access to the databases? How is that access determined? Specify if the biobank(s) will be located under Canadian or foreign jurisdiction. Canada Other If Other, provide details: Will identifying information be stored within the database or will it be coded? Will identifying information be forwarded to non-local registries? Yes ○ No Clear If the database is to be maintained locally, what steps have been taken to ensure the privacy ar security of the database are upheld?	participants should be informed of this potential breach in confidentiality.
Specify if the biobank(s) will be located under Canadian or foreign jurisdiction. □ Canada ☑ Other If Other, provide details: Will identifying information be stored within the database or will it be coded? Will identifying information be forwarded to non-local registries? ○ Yes ○ No Clear If the database is to be maintained locally, what steps have been taken to ensure the privacy are	
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Will identifying information be forwarded to non-local registries? Yes No Clear If the database is to be maintained locally, what steps have been taken to ensure the privacy ar	If Other, provide details:
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Will identifying information be forwarded to non-local registries? Yes No Clear If the database is to be maintained locally, what steps have been taken to ensure the privacy ar	MENT CALL SECTION AND ADDRESS OF THE SECTION
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Yes No Clear If the database is to be maintained locally, what steps have been taken to ensure the privacy ar	
O Yes O No Clear If the database is to be maintained locally, what steps have been taken to ensure the privacy ar	
Yes No Clear If the database is to be maintained locally, what steps have been taken to ensure the privacy ar	
Yes No Clear If the database is to be maintained locally, what steps have been taken to ensure the privacy ar	Will identifying information be forwarded to non-local registries?
If the database is to be maintained locally, what steps have been taken to ensure the privacy ar security of the database are upheld?	
If the database is to be maintained locally, what steps have been taken to ensure the privacy as security of the database are upheld?	
	If the database is to be maintained locally, what steps have been taken to ensure the privacy and security of the database are upheld?

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:

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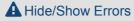


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- Data custodian will provide the data to the study team without identifiers; - Data custodian will provide the data to the study team with identifiers;

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2.15 Chart/Medical Record Reviews

List ALL of the data source(s) that you DIMR records, NetCare, PAC system etc.)	will be using to get your data (ie. Paper charts, e-clinician,
ethics application	e records that will be reviewed do not exceed the date of this ecords to be reviewed are in the future (at a date after
submission of this application) Provide the start and end date of the re	cords you will review (Note: these dates do NOT refer to actual dates on the medical records, ie., we need
Start Date:	
End Date:	

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

- Your data collection sheets or a listing of the variables that you wish to collect.
 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

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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-init	tiated clinical trial?					
	Health Services and/or C	nd initiated by a researcher from the University of Alberta, Alberta ovenant Health?					
	Yes No Clear						
		r sponsored by any outside entity including, but not limited to, a or clinical research organization?					
	O 103 O 140 Olean						
3.0	*Does the study involve a	any of the following?					
	Answer	Description					
	O Yes O No Clear	A drug, device, biologics, vaccine or natural health product not marketed in Canada?					
	O Yes O No Clear	A comparative bioavailability trial?					
	O Yes O 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?					
	may be required. The investin Clinical Research for all	o any of the questions above, a Health Canada Clinical Trial Application (CTA) stigator MUST coordinate with the University of Alberta - Quality Management Health Canada clinical trials, as the University will be the named Sponsor of anderson@ualberta.ca for assistance.					
4.0	Trial Phase:						
4.0	Phase I clinical trials	test a new biomedical intervention in a small group of people (eg. 20-80) for ate 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						
	or experimental interv	hundred to several thousand) by comparing the intervention to other standard ventions and monitor adverse effects					
	monitor the effectiver	conducted after intervention has been marketed. Studies are designed to ness of the approved intervention in the general population and to collect verse effects associated with widespread use					
5.0		made to break the code of a double-blind study in an emergency no has the code (if applicable):					

	fication for using placebo or an inactive substance instead		(if applicable): (i.e. why	//how is it Ok
		- ,		
Describe the	clinical criteria for withdraw erns (if applicable):	ving an individual s	subject from the study	due to safet
	orno (n' appricable).			

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2.17 Data Safety and Monitoring for Clinical Trials

0	The study will be monitored only by the study investigators.
0	The study will be monitored by at least one individual who is not associated with the study, but no by a formally constituted Data and Safety Monitoring Board (DSMB).
0	A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.
	Clear
* D	escribe data monitoring procedures while research is going on. Include details of planned
	escribe data monitoring procedures while research is going on. Include details of planned erim analysis, Data Safety Monitoring Board, or other monitoring systems:
inte	
inte	erim analysis, Data Safety Monitoring Board, or other monitoring systems:

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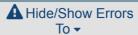
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2.18 Collection of Human Biological Materials

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
4.0	Explain flow and by whom the specimen will be conected
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:



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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

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2.20 Radiation Safety

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)
rega (RS ioni	earch involving exposure of participants 0-17 years of age to any amount ionizing radiation, ardless of how little, must be approved by the AHS Regional Radiation Safety Committee C). Will your research involve exposure to participants aged 0-17 years to any amount of zing radiation? Yes No Clear
Plea	ase describe
If th	is application is for the amendment of a pre-existing clinical study, have procedures which olve exposing subjects to ionizing radiation been added to the research that was not identified ne original study protocol?
If the invoint to	is application is for the amendment of a pre-existing clinical study, have procedures which olve exposing subjects to ionizing radiation been added to the research that was not identified ne original study protocol?
If the invoint to O	is application is for the amendment of a pre-existing clinical study, have procedures which olve exposing subjects to ionizing radiation been added to the research that was not identified ne original study protocol? Yes No
If the invoint to O	is application is for the amendment of a pre-existing clinical study, have procedures which olve exposing subjects to ionizing radiation been added to the research that was not identified ne original study protocol? Yes No Not Applicable (this application is for a new study)
If the invoint to O	is application is for the amendment of a pre-existing clinical study, have procedures which olve exposing subjects to ionizing radiation been added to the research that was not identified ne original study protocol? Yes No
If the invoint of the	is application is for the amendment of a pre-existing clinical study, have procedures which olve exposing subjects to ionizing radiation been added to the research that was not identified ne original study protocol? Yes No Not Applicable (this application is for a new study)
If the inverse in the	is application is for the amendment of a pre-existing clinical study, have procedures which blve exposing subjects to ionizing radiation been added to the research that was not identified ne original study protocol? Yes No Not Applicable (this application is for a new study) Clear e: If you answered YES to any of the above, the system will forward your project information to the S Regional Radiation Safety Committee for review. You will be notified of any issues pertaining to RSG roval which may include adding a radiation risk statement to the patient information sheet/consent
If the invoint to OOO OOO OOO OOOO OOOOOOOOOOOOOOOOO	is application is for the amendment of a pre-existing clinical study, have procedures which believe exposing subjects to ionizing radiation been added to the research that was not identified ne original study protocol? Yes No Not Applicable (this application is for a new study) Clear E: If you answered YES to any of the above, the system will forward your project information to the Se Regional Radiation Safety Committee for review. You will be notified of any issues pertaining to RSC roval which may include adding a radiation risk statement to the patient information sheet/consent to or the rewording of an existing risk statement. Protocol amendment is rarely necessary.









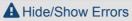


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2.21 Secondary Use of Human Biological Materials

	Outline where will you be getting the human biological materials from?
	How/under what authority were these human biological materials originally collected? (i.e. clinic specimens now being used for research, collected under a previous research protocol)
	f 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
t	he time of initial collection (i.e. consent for future use was outlined in original consent form or ethics approval documentation)
t	he time of initial collection (i.e. consent for future use was outlined in original consent form or ethics approval documentation) Are the human biological materials you will be receiving/using:
t	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)
t	he time of initial collection (i.e. consent for future use was outlined in original consent form or ethics approval documentation) 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
t t	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 specimen
t t	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 specimen or would you ever be able to identify who the specimen came from) Clear 1.1 Will you be seeking consent for the secondary use of identifiable human biological
t t	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 specimen or would you ever be able to identify who the specimen came from) Clear 1.1 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 material UNLESS the researcher satisfies the REB as to the following 6 conditions (a) – (f) per Article











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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:

O Yes O No Clear

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

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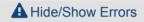
3.1 Risk Assessment

		re to the research (TCPS2)
O		n Minimal Risk
	<u>Clear</u>	
		might apply:
Des	cription of Po	ssible Physical Risks and Discomforts
	•	Participants might feel physical fatigue, e.g. sleep deprivation
sibly	•	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
Pos	sible Psychol	ogical, 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
		of all the risks and discomforts associated with the research for which you r POSSIBLY above.
) * De:	scribe how y	you will manage and minimize risks and discomforts, as well as mitigate harm:

	Yes No		,	make. Explain if no arrangements have
0		any tests in this study o		icate the member(s) of the study team
	Test Name	Test Administrator	Organization	Administrator's Qualification
	There are no i	tems to display		
0		related procedures/tests o the participants and if		eted diagnostically, will these be hom?













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3.2 Benefits Analysis

	ny potential benefits of the proposed research to the participants. If there are te this explicitly:
* Describe th	e scientific and/or scholarly benefits of the proposed research:
If this resear	ch involves risk to participants explain how the benefits outweigh the risks.

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4.1 Participant Information

0	* Will you be recruiting hur people online surveys to con	man participants (i.e. enrolling people into the study, sending nplete)?			
	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 database?	de information about this study on the Be The Cure searchable			
	O Yes O No Clear	[Yes >> 4.8]			

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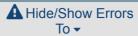


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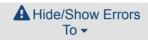
4.2 Additional Participant Information

enroilir	ng healthy contro	no do wonj.				
						•
* Desc etc.):	ribe and justify	the inclusion	criteria for p	articipants (e.	.g. age range, l	health status, gende
010.).						▼
Doscri	ibe and justify t	the exclusion (critoria for na	articinants:		
Descri	be and justiny t	ile exclusion e	interia for pe	ii ticipanto.		▼

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:











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4.3 Recruitment of Participants (Health)

Yes No Clear

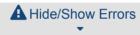
* 1.1 How you will identify potential participants? Please be specific. (i.e. Will you be screening
clinical lists, accessing electronic health records (e-clinician), asking staff from a particular area to let know when a patient meets criteria, will you be sitting in the emergency department waiting 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 practice 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 record 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 contact 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 approached about the research.
1.4 Outline any other means by which participants could be identified(e.g. response to advertise such as flyers, posters, ads in newspapers, websites, email, list serves, physicial or community organization referrals):

Other examples may be employees, acquaintances, own children or family members, etc)?

	2.3 How will you ensure that there is no undue pressure on the potential participants to agree to
	the study?
	Will your study involve any of the following (select all that apply)?
n	Reimbursement for any expenses incurred by the participants, e.g. parking costs, child care, lost
.0	The Religious efficial for any expenses incurred by the participants, e.g. parking costs, child care, lost
.0	wages, etc [>> 4.6]
.0	
0	wages, etc [>> 4.6]











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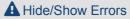
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4.4 Recruitment of Participants (non-Health)

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
2.0	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











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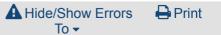
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4.5 Informed Consent Determination

participant, substitute decision maker, no one will give consent – requesting a waiver)				
1.1	Waiver of Consent Requested			
If yo	ou are asking for a waiver of participant consent, please justify the waiver or alteration a lain how the study meets all of the criteria for the waiver. Refer to Article 3.7 of TCPS2 an vide 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 t				
	rgencies, please justify the waiver or alteration and explain how the study meets ALL of			
crite	rgencies, please justify the waiver or alteration and explain how the study meets ALL of			
crite	ergencies, please justify the waiver or alteration and explain how the study meets ALL of eria outlined in Article 3.8 of TCPS2 (a-f).			
crite	ergencies, please justify the waiver or alteration and explain how the study meets ALL of eria outlined in Article 3.8 of TCPS2 (a-f).			
crite	rigencies, please justify the waiver or alteration and explain how the study meets ALL of eria outlined in Article 3.8 of TCPS2 (a-f). will consent be obtained/documented? Select all that apply Signed consent form			
crite	rigencies, please justify the waiver or alteration and explain how the study meets ALL of eria outlined in Article 3.8 of TCPS2 (a-f). will consent be obtained/documented? Select all that apply Signed consent form Verbal consent			
How If you the	will consent be obtained/documented? Select all that apply Signed consent form Verbal consent Implied by overt action (i.e. completion of questionnaire)			
How If you the	regencies, please justify the waiver or alteration and explain how the study meets ALL of the pria outlined in Article 3.8 of TCPS2 (a-f). If 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) Outlined in Article 3.8 of TCPS2 (a-f).			
How If you the	regencies, please justify the waiver or alteration and explain how the study meets ALL of the pria outlined in Article 3.8 of TCPS2 (a-f). If 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) Outlined in Article 3.8 of TCPS2 (a-f).			

	2 Will participants who lack capacity to give full informed consent be asked to give assent? Yes No Clear rovide details. IF applicable, attach a copy of assent form(s) in the Documentation section.
	3 In cases where participants (re)gain capacity to give informed consent during the study, he ill they be asked to provide consent on their own behalf?
	hat assistance will be provided to participants or those consenting on their behalf, who may equire additional assistance? (e.g. non-English speakers, visually impaired, etc.)
	If at any time a PARTICIPANT wishes to withdraw from the study or from certain parts of the udy, describe when and how this can be done.
st	
st	escribe the circumstances and limitations of DATA withdrawal from the study, including the









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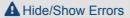


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4.6 Expense Reimbursements and Incentives

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.
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/support/ethics-office/human-research-ethics/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.
constitute coercion. Justify the value of the incentives you are offering relative to your study











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4.7 Group Research Documentation

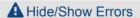
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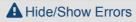


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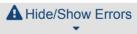
4.8 Be The Cure Questions

)	* What is the lay title of your study?
)	* In lay language, describe the summary/purpose of your study (750 characters or less).
)	What are the eligible ages of participants?
,	what are the engine ages of participants?
	* Lower Age Limit:
	* Harran Arra Lisatio
	* Upper Age Limit:
	* Mile of the file of the control of the district of the
)	* What is the eligible sex of participants? Male
	☐ Female
	☐ Intersex
	Any
)	* In lay language, outline the inclusion criteria.
)	* In lay language, outline the exclusion criteria.

	dy accept healthy part	icipants?		
O Yes O No	Clear			
* What will be t	he recruitment status	of this study once ethics	approval is obtained?	
			urrently recruiting participants; ntly recruiting participants;	
			d to recruitment	
If there are external links that participants can access for this study, please provide:				
+ Add				
Site Name			Link	
There are no ite	ems to display		ZIIIK	
* Add keywords	s (in lay language, sep	erated by comma) assoc	ciated with this study.	
Who can poten	tial study participants	contact for more inform	ation about the study?	
+ Add				
	Title	Phone	Email	
Name	tems to display			











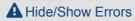


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5.1 Data Collection

0	* Will the researcher or study team be able to identify any of the participants at any stage of the
	study?
	Yes O No Clear [If No skip to 5.4]
)	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 o 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
)	If this study involves secondary use of data, list all original sources:
)	In research where total anonymity and confidentiality is sought but cannot be guaranteed (eg.
)	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?
)	
)	
)	
)	











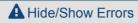


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5.2 Data Identifiers

Initials	
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 Will you be collecting - at any time of the study, including recruitme 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	
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 Employee ID Number Full Date of Birth Year of Birth Age at time of data collection Vehicle Identifiers Professional Certificate/License Number Other Will you be collecting - at any time of the study, including recruitme 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	
 □ 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 Will you be collecting - at any time of the study, including recruitme 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 	
 □ 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 Will you be collecting - at any time of the study, including recruitment 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 	
 □ 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 Will you be collecting - at any time of the study, including recruitment 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 	
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 Will you be collecting - at any time of the study, including recruitme 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	
 □ 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 Will you be collecting - at any time of the study, including recruitment 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 	
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 Will you be collecting - at any time of the study, including recruitme 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	
 □ Employee ID Number □ Full Date of Birth □ Year of Birth □ Age at time of data collection □ Vehicle Identifiers □ Professional Certificate/License Number □ Other Will you be collecting - at any time of the study, including recruitment 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 	
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Year of Birth Age at time of data collection Vehicle Identifiers Professional Certificate/License Number Other Will you be collecting - at any time of the study, including recruitme 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	
Age at time of data collection Vehicle Identifiers Professional Certificate/License Number Other Will you be collecting - at any time of the study, including recruitment 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	
 □ Vehicle Identifiers □ Professional Certificate/License Number □ Other Will you be collecting - at any time of the study, including recruitment 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 	
 □ Professional Certificate/License Number □ Other Will you be collecting - at any time of the study, including recruitment 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 	
Will you be collecting - at any time of the study, including recruitment 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	
Will you be collecting - at any time of the study, including recruitment 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	
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	
Healthcare Provider Hospital Discharge Date Other Date (eg Date of Service) Medical Device Identifier Medical Record Number	nt of participants - any of th
 ☐ Hospital Discharge Date ☐ Other Date (eg Date of Service) ☐ Medical Device Identifier ☐ Medical Record Number 	
 Other Date (eg Date of Service) Medical Device Identifier Medical Record Number 	
Medical Device IdentifierMedical Record Number	
Medical Record Number	
Other	
* If you are collecting any of the above, provide a comprehensive range of the collect this information:	itionale to explain why it is

explair	ify what <u>identifiable</u> information will be RETAINED once data collection is complete, ar n why retention is necessary. Include the retention of master lists that link participant iers with de-identified data:
	icable, describe your plans to link the data in this study with data associated with othe s (e.g within a data repository) or with data belonging to another organization:
studies	











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5.3 Data Confidentiality and Privacy

0	* How will confidentiality of the data be maintained? Describe how the identity of participants will be protected both during and after research.
	protocous sour during und unto roccurs
0	How will the principal investigator oncurs that all study personnel are aware of their
U	How will the principal investigator ensure that all study personnel are aware of their responsibilities concerning participants' privacy and the confidentiality of their information?
)	
,	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.)









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5.4 Data Storage, Retention, and Disposal

ex	pecify the physical location and how it will be secured to protect confidentiality and privacy ample, study documents must be kept in a locked filing cabinet and computer files are encrypted, rite N/A if not applicable to your research)
co the <u>res</u>	Iniversity policy requires that you keep your data for a minimum of 5 years following impletion of the study but there is no limit on data retention. Specify any plans for future us a data. If the data will become part of a data repository or if this study involves the creation search database or registry for future research use, please provide details. (Write N/A if not plicable to your research)
the	you plan to destroy your data, describe when and how this will be done? Indicate your plan e destruction of the identifiers at the earliest opportunity consistent with the conduct of the search and/or clinical needs:
Te:	search and/or chinical needs.













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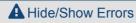


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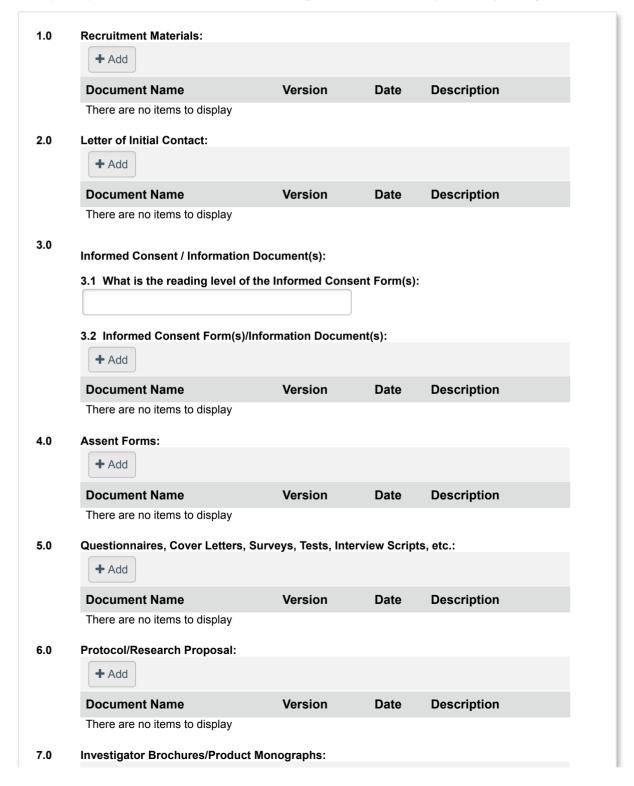


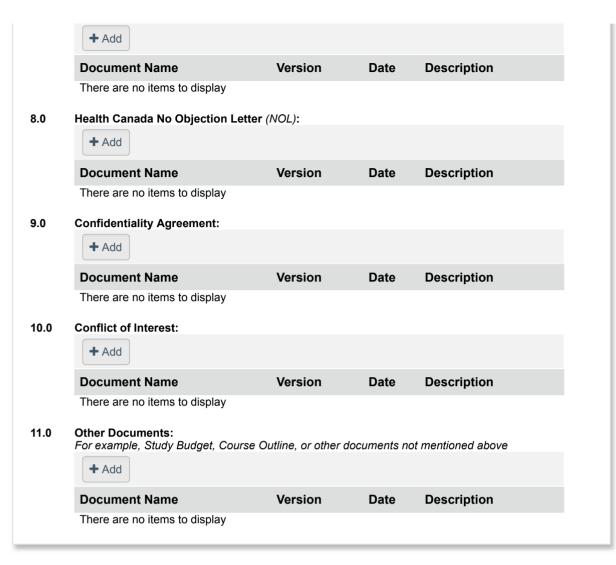
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Documentation

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 in the REMO Home Page in the Forms and Templates, or by clicking HERE.

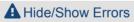
















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