

ARISE Alberta Research Information செல்லம்











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1.1 Study Identification

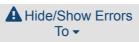
All questions marked by a red asterisk * are required fields. However, because the mandatory fields have been kept to a minimum, answering only the required fields may not be sufficient for the REB to review your application.

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

*	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.					
		•	form will indicate which sections will branch (or open up) by: aning "complete section 1.7".			
			questions will open up additional questions directly below, be shown by a darkened circular button.			
	Use the	Book	marks 🔲 to jump to specific sections.			
*	Select the		priate Research Ethics Board (Detailed descriptions are available at here):			
	Name		Description			
			·			
		n arch Board	REB3: All NON-invasive health research involving patients, health information, Al- (Edmonton Region) or Covenant Health facilities and researchers except cancer-			
	O Resea	n arch Board n Panel	REB3: All NON-invasive health research involving patients, health information, AH (Edmonton Region) or Covenant Health facilities and researchers except cancer-related research, which should be reviewed by the HREBA-CC (click here for mor information)			
	Research Ethics Health HREE Biome	n arch Board n Panel	REB3: All NON-invasive health research involving patients, health information, Al- (Edmonton Region) or Covenant Health facilities and researchers except cancer- related research, which should be reviewed by the HREBA-CC (click here for mor information) All invasive health research involving patients, health information, AHS (Edmontor 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 HREE Biome Research 1 Research Ethics 2	n arch Board n Panel Bedical	REB3: All NON-invasive health research involving patients, health information, AH (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) All invasive health research involving patients, health information, AHS (Edmontor 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 primarily involving in-person interviews, focus groups, ethnographies, or community engagement and instructor-led course-based research assignments.			
	Research Health HREE Biome Research Ethics Research Ethics Research Clear	n arch Board n Panel Bedical Broard Broard	REB3: All NON-invasive health research involving patients, health information, AH (Edmonton Region) or Covenant Health facilities and researchers except cancerrelated research, which should be reviewed by the HREBA-CC (click here for more information) All invasive health research involving patients, health information, AHS (Edmontor 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 primarily involving in-person interviews, focus groups, ethnographies, or community engagement and instructor-led course-based research assignments. Research primarily concerning privacy, data-sharing, confidentiality, questionnaires survey methods and internet research.			
*	Research Health HREE Biome Research Ethics Research Ethics Clear Is the pro-	arch edical arch Board arch Board arch Board	REB3: All NON-invasive health research involving patients, health information, AH (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) All invasive health research involving patients, health information, AHS (Edmontor 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 primarily involving in-person interviews, focus groups, ethnographies, or community engagement and instructor-led course-based research assignments. Research primarily concerning privacy, data-sharing, confidentiality, questionnaire survey methods and internet research.			
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* T	la / . 4 l			
Type of rese	earcn/study: Academic Staff			
	lealth Services			
O Covenar	t Health			
			ts in a class, individually or in group ents, following project guidelines pr	
O Graduate	e Student			
O Medical	Resident			
O Post-doo	toral Fellow			
O Undergra	aduate student			
O Universit	y of Lethbridge			
External	Researcher (exte	ernal to U of A, Al	HS and Covenant Health)	
Clear				
tudents, pos		ws and medical	cations from undergraduate stud residents to REBs 1 & 2. HREB o	
			•••	
Study Coordi eceive all em	nators or Rese	arch Assistants or the study:	: People listed here can edit this ap	plication and will
Study Coordi eceive all em	nators or Rese ail notifications f	arch Assistants: or the study:		plication and will
Study Coordi receive all em	i nators or Rese ail notifications f	arch Assistants: or the study: Emplo	: People listed here can edit this ap	plication and will
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Name There are no notestigators was tead of here incipal Investigational Role Name There are no notestigational Role Name There are no notestigational Role Study Team:	items to display tors: People liste who do not wish e). ed name does no stigator role in Ri e. items to display	Emplo ed here can edit to receive email, ot come up when EMO. Click the fo	People listed here can edit this applyer his application and will receive emashould be added to the study email you type it in the box, the user doe ollowing link for instructions on how pyer m, and other study team members) receive email notifications.	nil notifications (Co- list team below s not have the to Request an









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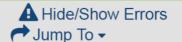


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1.2 Additional Approval

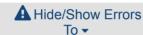
* Departmental Review: Please note only ONE Department Review is required. Please ensure that this section reflects only the PRIMARY Department of the study Pl.
There are no items to display
2.0 Internal Review (If the Principal Investigator is in the Department of Medicine complete the Department of 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)

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- Dentistry





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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)
RSO, answer	University of Alberta - Research Services Office (RSO)
estion below]	Alberta Health Services (NACTRC)
	O Covenant Health (including Institute for Reconstructive Sciences in Medicine-IRSM)
	Other
	<u>Clear</u>
	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.
	Project Project
	Project Project Project Other ID Status Project Project End Purpose Information Date Date
	There are no items to display
3.0	* Funding Source
	3.1 Select all sources of funding from the list below:

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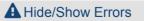


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1.4 Conflict of Interest

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? O Yes O 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? 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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1.5 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, ans		Yes No Clear
question b	elow]	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.























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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.

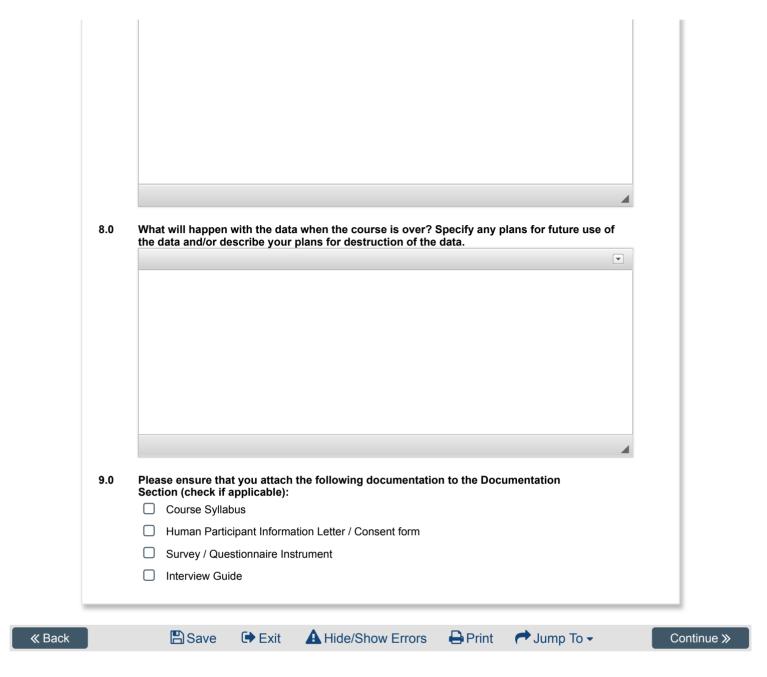
Examples of course-based research activities include:

- 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.

Provide Course Number:				
Provide a brief description tudents to meet the objecti	of the course (includ	ing how this research	assignment helps	
students to meet the objecti	ves of the course).			T
Provide a brief description	of the research assig	nment(s)/what stude	nts will be doing (i.e.	
nclude details related to the n	nethods, procedures, na	ature of the involvemen	t of human participant	s
and/or the work that students	wiii riariu iri):			-



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

					v
* Provid	de a full descrip	tion of your resear	ch proposal outlii	ning the following:	
• F • H • C	Purpose Hypothesis Justification Objectives Research Metho	d/Procedures	ch proposal outlii	ning the following:	
• F • H • C	Purpose Hypothesis Justification Objectives	d/Procedures	ch proposal outlii	ning the following:	
• F • H • C	Purpose Hypothesis Justification Objectives Research Metho	d/Procedures	ch proposal outlii	ning the following:	•
• F • H • C	Purpose Hypothesis Justification Objectives Research Metho	d/Procedures	ch proposal outlii	ning the following:	•
• F • H • C	Purpose Hypothesis Justification Objectives Research Metho	d/Procedures	ch proposal outlii	ning the following:	•
• F • H • C	Purpose Hypothesis Justification Objectives Research Metho	d/Procedures	ch proposal outlii	ning the following:	v
• F • H • C	Purpose Hypothesis Justification Objectives Research Metho	d/Procedures	ch proposal outlii	ning the following:	~

up, etc):					
grant or	pposed research is ab industry-sponsored c information about the	linical trial, the	REB will require	evidence of scientif	
For clini	cal trials, describe an	y sub-studies as	ssociated with th	is 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.

* 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 [>> 2.12 School of Business Research Panel, Department of Linguistics) Data Registries and/or Biobanking (collection of samples to put in a Biobank/Sample [>> 2.14]	2]
Repository)	
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) [>>	2.2
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.	





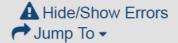














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2.3 Food, Nutrition, and Nutraceuticals Information

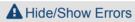
* 1.1 What is the source of any dietary products that participants will consume?
* 1.2 Describe how you know that the products were produced within acceptable standards for food safety?
Safety Monitoring
* 2.1 Is there any current recommendation that the use of the products identified requires any additional 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):
Dietary Levels
Dietary Levels
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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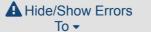


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2.4 Internet-based Interaction with Human Participants

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)?
	O 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?
	○ Yes ○ No <u>Clear</u>
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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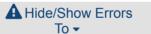
2.5 Interview and/or Focus Groups

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)?
2.0	Tion will participation take place (e.g. in porcent, via priorie, cinail, exype).
3.0	How will the data be collected (e.g. audio recording, video recording, field notes)?

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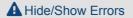


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2.6 Material Created by Participants

Who will have ac	ccess to this data?
articles, books, o participants, who	eporting data or disseminating results of your study (eg. presentation, reports, curriculum material, performances, etc) that include the materials created by at steps will you take to protect those who may be represented or identified - bot non-participants?
What opportunit	ies are provided to participants to choose to be identified as the author/creator o
ine materials ore	
The materials of	
	at arrangements will you make to return original materials to participants?
If necessary, who	at arrangements will you make to return original materials to participants? g audio/video recording equipment and/or other capture of sound or images for
If necessary, who	at arrangements will you make to return original materials to participants? g audio/video recording equipment and/or other capture of sound or images for Clear
f necessary, who Vill you be using the study? Yes No	at arrangements will you make to return original materials to participants? g audio/video recording equipment and/or other capture of sound or images for Clear











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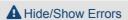


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2.7 Participant Observation

Who will the observer be?	
Who is being observed?	
Who are they being about 42	
Why are they being observed?	
When and where will participants be observed (i.e. during class, during their workday)?	
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	
Provide details: What data will be collected?	
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	
Provide details: What data will be collected? Video and/or audio recordings Photographs Field notes Other	











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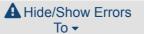


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2.8 First Nations, Inuit and Metis People

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?
	O Yes O No Clear









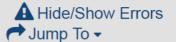


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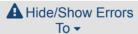
2.9 Surveys and Questionnaires (including Online)

	Il the data be stored once it's servers, will it be downloade	be stored on the survey soft r, other)?	ware
Who will	have access to the data?		

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2.10 Secondary Analysis

	How was the original data collected?				
	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).				
	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				
	Will you be obtaining consent from participants for the secondary use of identifiable information O 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).				
as	e remember to upload the following to the Documentation Section:				
) Dr	iginal data collection instrument(s), or an outline of the information you are analyzing.				
	iginal consent/info (if applicable - if individuals have previously agreed for their data to be used				
r					









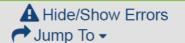


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2.11 Use of Deception or Partial Disclosure

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:
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:







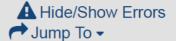














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2.12 Use of Participant Subject Pool

)	Amount of time the study will take:
)	Will Participant Receive:
	Course credit
	Yes No Clear
	Provide Details
	Payment
	Yes O No Clear
	Provide Details
	Drovide a brief description of the alternate tooks
)	Provide a brief description of the alternate task:
)	Provide a brief description of the alternate task:
)	Provide a brief description of the alternate task:
)	Provide a brief description of the alternate task:
)	Provide a brief description of the alternate task: If there is no alternate task, explain why:
)	
)	
)	

		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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2.14 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
	✓ 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?

Are there standard operating procedures for the database management, use and access? O Yes O No Clear
If YES, please attach at the Documentation Section - Other Documents
Provide information if material is linked or de-linked:

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	hart/Medical Record Reviews				
ance					
0	Estimate the number of records you will access (ie. we will review approximately 300 charts, we will review 300 patient records)				
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.)				
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				
)	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:				
	Clart Date.				
	End Date:				

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:

- 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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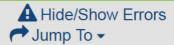
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2.16 Clinical Trial

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-ini	tiated clinical trial?			
	* Is this study authored and initiated by a researcher from the University of Alberta, Alberta Health Services and/or Covenant Health? O Yes O No Clear				
	* Is this study authored or sponsored by any outside entity including, but not limited to, a pharmaceutical company or clinical research organization? O Yes O No Clear				
3.0	*Does the study involve any of the following?				
3.0	Answer	Description 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 i.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		made to break the code of a double-blind study in an emergency no has the code (if applicable):			

Provide justification for using placebo or no-treatment arm (if applicable): (i.e. why/how is it O give a patient an inactive substance instead of a treatment)
Describe the clinical criteria for withdrawing an individual subject from the study due to safe toxicity concerns (if applicable):

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2.17 Data Safety and Monitoring for Clinical Trials

C	The study will be monitored only by the study investigators.
C	The study will be monitored by at least one individual who is not associated with the study, but n by a formally constituted Data and Safety Monitoring Board (DSMB).
C	A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.
	Clear
	escribe data monitoring procedures while research is going on. Include details of planned
	erim analysis, Data Safety Monitoring Board, or other monitoring systems:
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int * s	erim analysis, Data Safety Monitoring Board, or other monitoring systems:
int * s	erim analysis, Data Safety Monitoring Board, or other monitoring systems:

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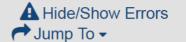


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2.18 Collection of Human Biological Materials

liver tissue, etc.):
* Specify all intended uses of collected specimen:
* 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
Explain how and by whom the specimen will be collected
Explain HOW the specimen will be stored:
Explain HOW the specimen will be stored.
Explain WHERE the specimens will be stored (e.g. include information if the specimens will be sout of the province):





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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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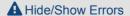


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2.20 Radiation Safety

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
	Mammography
	Computed Tomography (CT)
	, , , ,
	Bone Densitometry (in adults) (DEXA, DXA, BMD)
rega (RS	earch involving exposure of participants 0-17 years of age to any amount ionizing radiation, ordless 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 O No Clear
Plea	ise describe
If the invo	is application is for the amendment of a pre-existing clinical study, have procedures which slve exposing subjects to ionizing radiation been added to the research that was not identified
If the invointh	is application is for the amendment of a pre-existing clinical study, have procedures which
If the invoin the	is application is for the amendment of a pre-existing clinical study, have procedures which live exposing subjects to ionizing radiation been added to the research that was not identified the original study protocol?
If the invoint the 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 be original study protocol?
If the invoint the 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 the original study protocol? Yes
If the invoint the OOO	is application is for the amendment of a pre-existing clinical study, have procedures which live exposing subjects to ionizing radiation been added to the research that was not identified the original study protocol? Yes No Not Applicable (this application is for a new study)
If the invoint the OOO	is application is for the amendment of a pre-existing clinical study, have procedures which live exposing subjects to ionizing radiation been added to the research that was not identified the original study protocol? Yes No Not Applicable (this application is for a new study) Clear See If you answered YES to any of the above, the system will forward your project information to the Regional Radiation Safety Committee for review. You will be notified of any issues pertaining to RSG toval which may include adding a radiation risk statement to the patient information sheet/consent
If the invoint the OOO	is application is for the amendment of a pre-existing clinical study, have procedures which live exposing subjects to ionizing radiation been added to the research that was not identified the original study protocol? Yes No Not Applicable (this application is for a new study) Clear If you answered YES to any of the above, the system will forward your project information to the Regional Radiation Safety Committee for review. You will be notified of any issues pertaining to RSC oval which may include adding a radiation risk statement to the patient information sheet/consent or the rewording of an existing risk statement. Protocol amendment is rarely necessary.









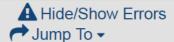


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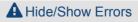
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2.21 Secondary Use of Human Biological Materials

Outline where will you be getting the human biological materials from?
How/under what authority were these human biological materials originally collected? (i.e. clinical specimens now being used for research, collected under a previous research protocol)
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 a the 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
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)
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
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
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













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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:

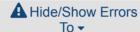
O Yes O No Clear

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

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3.1 Risk Assessment

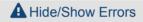
	 participation is no greater than those encountered by participants in those aspects o life that relate to the research (TCPS2) 	Tulen everyda
	O Greater than Minimal Risk	
	<u>Clear</u>	
.0	* Select all that might apply:	
	Description of Possible Physical Risks and Discomforts	
S	Participants might feel physical fatigue, e.g. sleep deprivation	
ssibly	Participants might feel physical stress, e.g. cardiovascular stress tests	
	Participants might sustain injury, infection, and intervention side-effects or co	mplications
	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, e worried, anxious, scared or distressed, e.g. description of painful or traumation	
	Participants might feel psychological or mental fatigue, e.g intense concentra	tion required
	Participants might experience cultural or social risk, e.g. loss of privacy or state to reputation	itus or damage
	Participants might be exposed to economic or legal risk, for instance non-and workplace surveys	onymized
	The risks will be greater than those encountered by the participants in everyo	lay life
	* Provide details of all the risks and discomforts associated with the research for windicated YES or POSSIBLY above.	hich you
.0	* Describe how you will manage and minimize risks and discomforts, as well as mit	igate harm:

	Pescribe the arbeen made.		he researcher will	make. Explain if no arrangements have
.0		g any tests in this study ister the measures/instr		cate the member(s) of the study team
	Test Name	Test Administrator	Organization	Administrator's Qualification
	There are no i	tems to display		
)	If any research			ted diagnostically, will these be nom?
0	If any research	related procedures/test		
0	If any research	related procedures/test		

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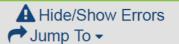














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3.2 Benefits Analysis

bene	cribe any potential benefits of the proposed research to the participants. If there are no fits, state this explicitly:
* Des	cribe the scientific and/or scholarly benefits of the proposed research:
If this	research involves risk to participants explain how the benefits outweigh the risks.

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4.1 Participant Information

1.0	* Will you be recruiting hum people online surveys to com	nan participants (i.e. enrolling people into the study, sending plete)? [If No skip to 5.1]
		uited or their data be collected from Alberta Health Services custodian as defined in the Alberta Health Information Act? [Yes >> 4.3. No >> 4.4]
	1.2 Would you like to includ database?	le information about this study on the Be The Cure searchable
	O Yes O No Clear	[Yes >> 4.8]

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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

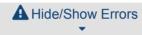
*AAH
* 1.1 How you will identify potential participants? Please be specific. (i.e. Will you be screening clinical lists, accessing electronic health records (e-clinician), asking staff from a particular area to let y know when a patient meets criteria, will you be sitting in the emergency department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

	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)?
J.U	Reimbursement for any expenses incurred by the participants, e.g. parking costs, child care, lost
5.0	wages, etc [>> 4.6]
5.0	magas, sta
5.0	Payment or incentives, e.g. honorarium or gifts for participating in this study [>> 4.6]
J.0	

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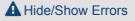


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4.4 Recruitment of Participants (non-Health)

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
	 2.1 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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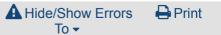
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4.5 Informed Consent Determination

If yo	Vaiver of Consent Requested use asking for a waiver of participant consent, please justify the waiver or alteration as ain how the study meets all of the criteria for the waiver. Refer to Article 3.7 of TCPS2 and ide justification for requesting a Waiver of Consent for ALL criteria (a-e)
If yo	Vaiver of Consent in Individual Medical Emergency u are asking for a waiver or alteration of participant consent in individual medical rgencies, please justify the waiver or alteration and explain how the study meets ALL of ria outlined in Article 3.8 of TCPS2 (a-f).
Crite	ria outlinea in Article 3.8 of TCPS2 (a-i).
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 yo	u are not using a signed consent form, explain how the study information will be provid
	participant and how consent will be obtained/documented. Provide details for EACH of tons selected above:

	2 Will participants who lack capacity to give full informed consent be asked to give assent? Yes No Clear Tovide 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 ll 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 quire additional assistance? (e.g. non-English speakers, visually impaired, etc.)
	f 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.	







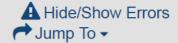














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4.6 Expense Reimbursements and Incentives

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. 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.







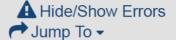








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4.7 Group Research Documentation

During the individual	recruitment process, how will you guard against peer pressure influencing an s decision to participate or not?
Outline alt	ernate activities for non-participants, if applicable
How will y	ou address discomfort or disadvantage, if any, for non-participants?



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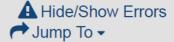














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4.8 Be The Cure Questions

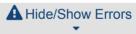
* What is the lay title of your study?
* In lay language, describe the summary/purpose of your study (750 characters or less).
in lay language, describe the summary/purpose of your study (750 characters of less).
What are the eligible ages of participants?
* Lower Age Limit:
Lower Age Limit.
* Upper Age Limit:
* 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.

* Dogo this study	account lacalting mant	iaimanta?	
O Yes O No G	accept healthy part	icipants ?	
* What will be the	recruitment status		s approval is obtained? currently recruiting participants;
		- Curre	ently recruiting participants;
If there are extern	al links that narticin		ed to recruitment s study, please provide:
+ Add	ai iiiks tilat particip	dina can access for the	s study, picuse provide.
→ Add			
Site Name			Link
There are no item	s to display		
* Add keywords (i	n lay language, sep	erated by comma) asso	ciated with this study.
		-	
Who can potentia	l study participants	contact for more inform	nation about the study?
+ Add			•
17.00			
Name	Title	Phone	Email
There are no iter			

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5.1 Data Collection

.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 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
.0	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. where participants talk in a group) how will confidentiality be achieved?



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5.2 Data Identifiers

	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
Will follo	you be collecting - at any time of the study, including recruitment of participants - any of the wing (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
	rou are collecting any of the above, provide a comprehensive rationale to explain why it is essary to collect this information:
	•

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:			
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:				
studies				

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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 <u>identifiable</u> 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.)







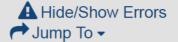














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5.4 Data Storage, Retention, and Disposal

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:













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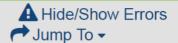


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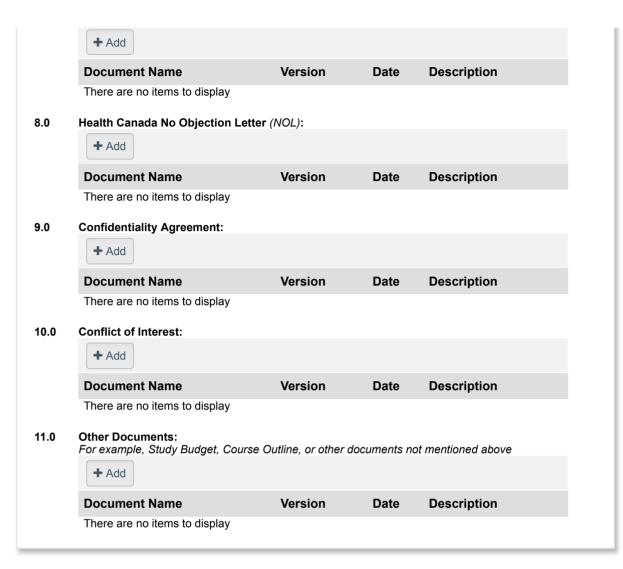
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Documentation

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 by clicking HERE.

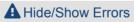
)	Recruitment Materials:						
	+ Add						
	Document Name	Version	Date	Description			
	There are no items to display						
	Letter of Initial Contact:						
	+ Add						
	Document Name	Version	Date	Description			
	There are no items to display						
	Informed Concept / Informatio	n Dooument(e)					
	Informed Consent / Information						
	3.1 What is the reading level of	of the Informed Conse	ent Form(s)	1			
	3.2 Informed Consent Form(s)	/Information Docume	ent(s):				
	+ Add						
	Document Name	Version	Date	Description			
	There are no items to display						
	Assent Forms:						
	+ Add						
	Document Name	Version	Date	Description			
	There are no items to display						
	Questionnaires, Cover Letters	, Surveys, Tests, Inte	rview Scrip	ts, etc.:			
	+ Add						
	Document Name	Version	Date	Description			
	There are no items to display						
	Protocol/Research Proposal:						
	+ Add						
	Document Name	Version	Date	Description			
	There are no items to display						
)	Investigator Brochures/Produc	ct Monographs:					















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