HERO – New Study Human Ethics Application Form

1.1 Study Identification

1.0 * Short Study Title (restricted to 250 characters):
PlaySpaces

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

3.0 * Select the appropriate Research Ethics Board:
REB 1

4.0 * is the proposed research:
Unfunded

5.0 * Name of Principal Investigator (at the University of Alberta, Caritas, or Capital Health):
Logan Gilmour

6.0 Investigator's Supervisor (Required for graduate students, trainees, or researchers from Capital Health, Caritas who do not have a University of Alberta academic appointment):
Pierre Boulanger

7.0 * Type of study:
Instructor Course-based (where all students in a class, individually or in groups, conduct the same or similar MINIMAL risk research assignments, following project guidelines provided by instructor

8.0 Study Coordinator or Research Assistants: People listed here can edit this application and will receive all notifications for this study:
Robin Miller
Mitch Lindgren
Tyler Davidson

9.0 Co-Investigators: People listed here can edit this application but do not receive HERO notifications unless they are added to the study email list:

10.0 Study Team (co-investigators, supervising team, and other study team members): People listed here cannot edit this application and do not receive HERO notifications:

1.2 Additional Approval

1.0 * Departmental Review:
N/A

2.0 Internal Review:
N/A

1.3 Study Funding Information

1.0 * Type of Funding:
Unfunded

If OTHER, provide details:

2.0* Indicate which office administers your award (It is the PI's responsibility to provide ethics approval to any office other than the ones listed below)
N/A

3.0 *Funding Source

- 3.1 Select all sources of funding from a list:
  - N/A

- 3.2 If not available in the list above, write the Sponsor/Agency name(s) in full (you may add multiple funding sources):
  - N/A

4.0 *Indicate if this research is sponsored or monitored by any of the following:
Not Applicable

If applicable, indicate whether or not the FDA Investigational New Drug number or FDA Investigational Device Exception is required:
N/A

The researcher is responsible for ensuring that the study complies with the applicable US regulations. The REB must also meet particular review criteria and this application will likely receive full board review, regardless of level of risk.
N/A

1.4. RSO University-Managed Funding

1.0 If your funds are managed by RSO - Research Service Office: to facilitate release of your study funds, provide the following information by selecting from a list. (Not available yet)
N/A

2.0 * To connect you 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.
N/A

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?
No

If YES, explain:

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?
No

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

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

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

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

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

If YES, explain:

Important
If you answered YES to any of the questions above, you may be contacted by the REB for more information or asked to submit a Conflict of Interest Declaration.

1.6 Research Locations and Other Approval

1.0 * List the locations of the proposed research, including recruitment activities. Provide name of institution or organization, town, or province as applicable (e.g. On Campus, Alberta public elementary schools, shopping malls, doctors' offices in Lesser Slave Lake and Lac La Biche, AHS facilities in Zone 5, post-secondary students at UBC, UA, UT, McGill and Dalhousie, internet websites, etc.):
University of Alberta

2.0 * Indicate if the study will utilize or access facilities, programs, resources, staff, students, specimens, patients or their records, at any of the sites affiliated with the following (select all that apply):

Not applicable

List all facilities or institutions as applicable:

3.0 *Indicate if the proposed research has or will receive ethics approval from other Research Ethics Board or institution. Choose all that apply:
Not Applicable

If Other, list the REB or Institution:

4.0 Does this study involve pandemic or similar emergency health research?
No

If YES, are you the lead investigator for this pandemic study?
N/A

5.0 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 HERO study number, REB name or other identifying information. Attach any external REB application and approval letter in Section 7.1.11 – Other Documents.
N/A

1.7 Instructor 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 post research questions, gather data from human participants, and analyze 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 project must not involve deception, personal or sensitive topics, or physically invasive contact with the participants.

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

1.0 * Provide Course Title: Introduction to Human Computer Interaction
* Provide Course Number: CMPUT 302

2.0 * Provide a brief description of the research component in the course assignment(s), including the nature of the involvement of human participants (i.e., methods, procedures, and work that students will hand in):
We designed and implemented a novel method of conveying mixed-media information on tablet-based computers. To evaluate its effectiveness, we asked participants to read either our prototype or a standard control layout and then write a ten-question short-answer quiz to test their retention.

3.0 * What is the goal of including research assignments in the course?
To teach real-world human computer interaction and usability research techniques.

4.0 If there is a possibility that the research will involve participants who might not be capable of providing informed consent, provide details:
N/A

5.0 Will any of the research study specifically target the involvement of Aboriginal People?
No

1.8 Student Policy Education

1.0 * Explain how you will prepare your students to comply with Tri-Council Policy Statement (TCPS2) guidelines and the University Human Research Ethics Policy in completing the course assignment(s). Attach any relevant materials to section 7.1 Documentation section of this form.

N/A

2.1 Study Objectives and Design

1.0 Date that you expect to start working with human participants:
April 19th, 2012

2.0 Date that you expect to finish working with human participants, in other words, you will no longer be in contact with the research participants, including data verification and reporting back to the group or community:
April 21st, 2012

3.0 * Provide a lay summary of your proposed research suitable for the general public (restricted to 300 words). If the PI is not affiliated with the University of Alberta, Alberta Health Services or Covenant Health, please include institutional affiliation:
Our research compares a novel mixed-media interface to a traditional static document to determine the efficacy of the new interface in facilitating learning.

4.0 * Provide a description of your research proposal (study objectives, background, scope, methods, procedures, etc) (restricted to approx. 1,000 words):
Our goal is to modernize multi-modal media. We will be exploring novel methods of integrating interactive content into information presentation. For example, we could create an eBook/app hybrid which would use content-aware interactions to help users connect concepts in their minds. A textbook with geographical information, for instance, might allow the users to view pictures of important locations by selecting them on a map. In contrast with simply placing the pictures in a sidebar, which gives little information about their relevance, the map could help users build a strong mental correlation between the locations and the content of the pictures. This is a fairly simple example, but by taking a scientific approach to learning methodology and measuring knowledge retention, we could build powerful methods to help users understand complex data more efficiently and accurately.

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

6.0 If the proposed research is above minimal risk and is not funded via a competitive peer review grant or industry-sponsored clinical trial, the REB will require evidence of scientific review. Provide information about the review process and its results if appropriate:
N/A

7.0 For clinical research only, describe any sub-studies associated with this application.
N/A

3.1 Risk Assessment

1.0 * After reviewing the Minimal Risk Criteria provided in User Help, provide your assessment of the risk classification for this study:
Minimal Risk

2.0 * Select all that might apply (choose Yes, No or Possibly for each):
Description of Potential Physical Risks and Discomforts

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

Potential Psychological, Emotional, Social and Other Risks and Discomforts

- Participants might feel psychologically or emotionally stressed, demeaned, embarrassed, worried, anxious, scared or distressed, e.g. description of painful or traumatic events: No
- Participants might feel psychological or mental fatigue, e.g. intense concentration required: No
- Participants might experience cultural or social risk, e.g. loss of privacy or status or damage to reputation: No
- Participants might be exposed to economic or legal risk, for instance non-anonymized workplace surveys: No
- The risks will be greater than those encountered by the participants in everyday life: No

3.0 * Provide details of the risks and discomforts associated with the research, for instance, health cognitive or emotional factors, socio-economic status or physiological or health conditions:
None

4.0 * Describe how you will manage and minimize risks and discomforts, as well as mitigate harm:
Our study involves very little risk of any sort, as all that is required is for participants to read a short document and then answer a brief quiz on it. Participants have the option to cease participation at any time.

5.0 * If your study has the potential to identify individuals that are upset, distressed, or disturbed, or individuals warranting medical attention, describe the arrangements made to try to assist these individuals. Explain if no arrangements have been made:
N/A

3.2 Benefits Analysis

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

2.0 * Describe the scientific and/or scholarly benefits of the proposed research:
Our research will help identify the potential learning advantages of novel mixed-media interfaces compared to traditional static interfaces.

3.0 Benefits/Risks Analysis - describe the relationship of benefits to risk of participation in the research:
Our study has neither risks nor benefits to the participants.

4.1 Participant Information

1.0 * Who are you studying? Describe the population that will be included in this study:
General population

2.0 * Describe the inclusion criteria for participants (e.g. age range, health status, gender, etc.) Justify the inclusion criteria (e.g. safety, uniformity, research methodology, statistical requirement, etc.)
Anyone over the age of 18 (and therefore legally able to give consent) may be included in our study.

3.0 Describe and justify the exclusion criteria for participants
We will only exclude those who are not capable of legally giving consent to participate

4.0 * Are there any direct recruitment activities for this study?
No

5.0 Participants

How many participants do you hope to recruit (including controls, if applicable?)
10

Of these how many are controls, if applicable (Possible answer: Half, Random, Unknown, or an estimate in numbers, etc).
Half

If this is a multi-site study, how many participants (including controls, if applicable) do you anticipate will be enrolled in the entire study?
N/A

6.0 Justification for sample size:
In a discussion with Professor Pierre Boulanger, he indicated that 10 was an acceptable sample size for a project of this scope at the undergraduate level, as the primary goal is not obtaining accurate statistics but rather understanding the research process.

7.0 Does the research specifically target aboriginal groups or communities?
No

4.2 Chart Reviews

1.0 Estimate the number of records you will access and provide the start and end dates of the data pull (e.g. we will review approximately 300 charts from December 2005 to November 2009).
N/A

2.0 How will you receive the data?
N/A

3.0 If a member of the study team is pulling the data, does the individual normally have access to the records, e.g. for clinical purposes?
N/A

4.0 Will individual patient consent be sought or is a waiver of consent required? If requesting a waiver of consent, describe why it is not reasonable, feasible or practical to obtain consent
N/A

4.3 Recruit Potential Participants

1.0 Recruitment

.1 How will potential participants be identified? Outline how you will identify the people who will be approached for participation or screened for eligibility.
We will approach people we know personally who might consent to taking part in the study.

.2 How will people obtain details about the research in order to make a decision about participating? Select all that apply:
- Researchers will contact potential participants

.3 If appropriate, provide the locations where recruitment will occur (e.g. schools, shopping malls, clinics, etc.)
N/A

2 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

2.2 If yes, identify the relationship between the researchers and participants that could compromise the freedom to decline (e.g. professor-student). How will you ensure that there is no undue pressure on the potential participants to agree to the study?
Friends and family members. We will ensure that none of our friends or family members feel unduly compelled to participate.

3.0 Outline any other means by which participants could be identified (e.g. response to advertising such as flyers, posters, ads in newspapers, websites, email, list serves; pre-existing records or existing registries; physician or community organization referrals; longitudinal study, etc.):
N/A

4.0 Will your study involve any of the following (select all that apply)?
None

.4 Third Party or Intermediary Contact Methods

1.0 If contact will be made through an intermediary (including snowball sampling), select one of the following:
N/A

2, 0 Explain why the intermediary is appropriate and describe what steps will be taken to ensure participation is voluntary;
N/A

4.5 Informed Consent Determination

1.0 * Describe who will provide informed consent for this study:
All participants will be competent to give informed consent

2.0 How is consent to be indicated and documented?
Explicit oral consent

Except for “Signed consent form” use only, explain how the study information will be communicated and participant consent will be documented. Provide details for EACH of the options selected above:
In person with researches. Documentation will occur implicitly within our research data. That a response is included in our data means that the participant gave explicit oral consent to the evaluator.

3.0 Authorized Representative, Third Party Consent, Assent
N/A

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

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

Provide details, if applicable, attach a copy of the assent form(s) in the Documentation section.
N/A

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

4.0 What assistance will be provided to participants, or those consenting on their behalf, which have special needs (e.g. non-English speakers, visually impaired, etc)?
Evaluators will do everything in their power to accommodate any special needs.

5.0 * If at any time a participant wishes to withdraw or not participate in certain aspects of the research, describe the procedures and the last point at which it can be done:
Participants may withdraw at any time and have their quiz answers discarded, if those answers have recorded.

6.0 Describe the circumstances and limitations of data withdrawal from the study, including the last point at which it can be done:
There are no limitations. Any participant who wishes to withdraw will have all associated data deleted.

7.0 Will this study involve an entire group where non-participants are present? For example, classroom research might involve groups which include participants and non-participants
No

4.6 Reimbursements and Incentives

1.0 If you are providing expense reimbursements, describe in detail the expenses for which participants will be reimbursed, the value of the reimbursements and the 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).
N/A

2.0 If you will be collecting personal information to reimburse or pay participants, describe the information to be collected and how privacy will be maintained.
N/A

3.0 Will participants receive any incentives for participating in this research? Select all that apply:
No

Provide details of the value, including the likelihood (odds) of winning for prize draws and lotteries:
N/A

4.0 Excluding prize draws, what is the maximum value of the incentives offered to an individual throughout the research?
N/A

5.0 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.
N/A

4.7 Group Research Documentation

1.0 * How will you ensure that non-participants are not included in the study? How will you ensure that data from non-participants were not used in the study?
During the recruitment process, how will you guard against peer pressure influencing an individual's decision to participate or not?
Participants directly input their responses into a Google document via Google Docs forms in the presence of evaluators. This ensures that non-participants will not be included. Potential participants will be approached by evaluators one-on-one to prevent any influence of peer pressure.

2.0 How will you provide appropriate activities for non-participants?
N/A

3.0 How will you address discomfort or disadvantage, if any, arising out of non-participation?
N/A

4.8 Aboriginal People

1.0 * If you will be obtaining consent from Elders, leaders, or other community representatives, provide details:
N/A

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

3.0 Provide details if:
N/A

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

5.0 Provide information how final results of the study will be shared with the participating community (e.g. via band office, special presentation, deposit in community school, etc)?
6.0 Is there a research agreement with the community?
N/A

Provide details about the agreement or why an agreement is not in place, not required, etc.
N/A

5.1 Research Methods and Procedures

1.0 * This study will involve the following (select all that apply)
The list only includes categories that trigger additional page(s) for an online application. For any other methods or procedures, please indicate and describe in your research proposal in the Study Summary, or provide in an attachment:

- Surveys and Questionnaires (including internet surveys)
- Sound or Image Data (other than audio or video-recorded interviews)

2.0 Is this study a Clinical trial (Any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes?
None

3.0 If you are using any tests in this study diagnostically, indicate the member(s) of the study team who will administer the measure/instruments:
N/A

4.0 If any test results could be interpreted diagnostically, how will these be reported back to the participants?
N/A

5.2 Clinical Trial

1.0 Protocol

1.1 Protocol Number, if applicable (if you don't know what this is, you don't have one and that's okay):
N/A

1.2 Protocol Date:
N/A

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

2.0 Is this an investigator-initiated clinical trial?

- No

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

- No

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

- No

3.0 *Does the study involve any of the following?

Answer Yes or No

- A drug, device, biologics, vaccine or natural health product not marketed in Canada? No
- A comparative bioavailability trial? No
- Use of a marketed drug, device, biologics, vaccine, or natural health product outside the parameters of it's officially "approved use" by Health Canada? No

If you have answered yes to any of the questions above, a Health Canada Clinical Trial Application (CTA) may be required. The investigator MUST coordinate with NACTRC for all Health Canada clinical trials. Please contact NACTRC at 407-3809 for assistance.

4.0 Trial Phase:
N/A

5.0 If applicable, describe the provisions made to break the code of a double-blind study in an emergency situation, and indicate who has the code:
N/A

6.0 If applicable, provide justification for using placebo or no-treatment arm:
N/A

7.0 If applicable, describe the clinical criteria for withdrawing an individual subject from the study due to safety or toxicity concerns:
N/A

5.3 Information for Ethics Review Fee (industry sponsored studies only)

N/A

5.4 Data Safety and Monitoring for Clinical Trials

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

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

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

5.5 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:
N/A

2.0 Provide a rationale for withholding information:
N/A

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:
N/A

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:
N/A

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

5.6 Sound or Image (other than audio- or video-recorded interviews) or Material Created by Participants

1.0 Explain if consent obtained at the beginning of the study will be sufficient, or if it will be necessary to obtain consent at different times, for different stages of the study, or for different types of data:
N/A

2.0 At what stage, if any, can a participant withdraw his/her material?
N/A

3.0 If you or your participant's audio- or video-records, photographs, or other materials artistically represent participants or others, what steps will you take to protect the dignity of those that may be represented or identified?
N/A

4.0 Who will have access to this data? For example, in cases where you will be sharing sounds, images, or materials for verification or feedback, what steps will you take to protect the dignity of those who may be represented or identified?
N/A

5.0 When publicly reporting data or disseminating results of your study (e.g. presentation, reports, articles, books, curriculum material, performances, etc) that include the sounds, images, or materials created by participants you have collected, what steps will you take to protect the dignity of those who may be represented or identified?
N/A

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

7.0 If necessary, what arrangements will you make to return original materials to participants?
N/A

5.7 Interviews, Focus Groups, Surveys and Questionnaires

1.0 Are any of the questions potentially of a sensitive nature?
No

If YES, provide details:
N/A

2.0 If any data were released, could it reasonably place participants at risk of criminal or civil law suits?
No

If YES, provide the justification for including such information in the study:
N/A

3.0 Will you be using audio/video recording equipment and/or other capture of sound or images for the study?
No

If YES, provide details:
N/A

5.8 Internet-based Research

Internet-based Research

1.1 Will your interaction with humans occur in private spaces (e.g. member's only chat rooms, social networking sites, email discussions, etc.)?
N/A

1.2 Will these interactions occur in public space(s) where you will post questions initiating and/or maintaining interaction with participants?
N/A

2.0 *Describe how permission to use the site(s) will be obtained, if applicable
N/A

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?
Security is guaranteed by the University of Alberta Google Apps agreement.

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:
N/A

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?
Identifying information, if available, will not be disclosed.

5.9 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.
N/A

5.10 Food, Nutrition, and Nutraceuticals Information

1.0 Product Source

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

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

2.0 Safety Monitoring

* 2.1 Is there any current recommendation that the use of the products identified requires any additional safety testing or monitoring?
- No

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):
N/A

3.0 Dietary Levels

* 3.1 Does the level of dietary ingredients exceed any Canadian nationally recommended levels?
- N/A

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

4.0 Nutritional/Dietary counseling or advice

4.1 If any nutritional or dietary advice or counseling will be offered to participants in conjunction with this study, what is the nature of the advice? (i.e., does it follow any specific published dietary recommendations?)
N/A

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)?
N/A

5.11 Health and Biological Specimen Collection

1.0 * Indicate health or biological specimen(s) that will be collected (for example, body tissues or fluids, be specific):
N/A

2.0 * This study will involve the following (select all that apply):
N/A

If OTHER, provide details:

3.0 Explain how the specimen will be collected:
N/A

1.0 Explain HOW the specimen will be stored, and for how long:
Explain HOW LONG the specimens will be stored
N/A

2.0 Explain WHERE the specimens will be stored (e.g. include information of the specimens will be sent out of the province):
N/A

3.0 Specify all intended uses of collected specimen:
N/A

5.12 Registries and Databases (including 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 Patriot Act. At a minimum, participants should be informed of this potential breach in confidentiality.
N/A

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

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

If other provide details
N/A

4.0 Will identifying information be sorted within the database or will it be coded?
N/A

5.0 Will identifying information be forwarded to non-local registries?
N/A

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?
N/A

7.0 Who is responsible for the database?
N/A

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

If yes, please attach at Section 7.11 – Other Documents
N/A

9.0 Provide information if material is linked or de-linked:
N/A

5.13 Biohazard Safety

1.0 Amendment or Renewal: If this application if for the amendment or renewal of a pre-existing clinical study: have new biohazards and/or manipulations been added to the research that was not identified in the original study protocol?
N/A

If you selected NO, this amendment or renewal is exempt from requiring further review by the EHS Biosafety Division and the original biohazard approval remains valid. You do not need to respond to any of the question below.
N/A

If you selected YES, this amendment or renewal is considered new research – please respond to question 2.0 below.
N/A

2.0 Will your research involve the use of one or more of the following? Provide a response for each item.
N/A

Answer Yes or No

- Risk group 2, 3 or 4 viruses, bacteria, fungi, parasites or eukaryotic cell lines: No
- Environmental specimens suspected to contain risk group 2, 3 or 4 microbes: No
- Large-scale single volume culture in excess of 10 litres for any microbe or eukaryotic cell line: No
- Microbial toxins: No
- Human clinical specimens, including blood or other body fluids, or primary culture of human cells: No
- Xenotransplant studies involving vertebrate donors and/or recipients: No
- Genetic therapy studies involving vertebrate donors and/or recipients: No
- Genetic manipulation involving virulence genes from risk group 2, 3 or 4 microbes, mammalian oncogenes, mammalian cytokine or interleukin genes, or microcide resistance genes: No

If you answered YES to any of the above, you will need to apply for Biohazards Approval. Send a copy of your grant application or experimental plan detailing the planned use of these biohazards to:
Biosafety Division
Environmental Health and Safety
EHS_RSR@ehs.ualberta.ca

In a cover letter, be sure to include the Principal Investigator's name and department, and the name of the funding source, if applicable

5.14 Radiation Safety

1.0 Will your research involve:

- Screening chest x-ray only, in adults only? Your study subjects will be exposed to a very small amount of radiation and the benefit far outweighs the risk. Usually no specific radiation risk statement is required in the patient information sheet.
  No

- Bone Densitometry only, in adults only? Your study subjects will be exposed to a very small amount of radiation. The patient information sheet should include a short radiation risk statement, an example of which appears below:
  No

"If you take part in this research, you will be exposed to a very small amount of radiation. The risk from this amount of radiation has been categorized by the Radiation Safety Committee as 'very low'."

Note: If you have checked either of these boxes, a separate application to the Radiation Safety Committee (RSC) for approval is not usually required.

2.0 Will your research involve exposure of subjects aged 0-17 years to any amount of ionizing radiation?
No

Regardless of how little radiation is involved, this requires separate application to the Radiation Safety Committee (RSC) for approval. Please complete section 3.0 and contact the committee as indicated below.

3.0 Will your research involve any of the following at screening, baseline or follow-up? (Check all that apply)
- X-rays of the shoulder, elbow, forearm, wrist, hand, knee, ankle or foot: No
- X-rays of the skull, facial bones, neck, spine, thorax, abdomen, pelvis or hip: No
- Mammography: No
- Computed Tomography (CT): No
- Radioisotope Scan (includes MIBI, bone scan, GFR measurement, PET, etc.): No
- Fluoroscopic Procedure (includes angiography, cardiac catheterization, EP lab): No
- Bone Mineral Densitometry using x-rays (DEXA, DXA, BMD): No

Note: if you checked any box in section 3.0, you need to apply for RSC approval.

To apply for RSC approval, e-mail a copy of the complete research protocol, including patient information sheet, to: radnsfty@ualberta.ca

In most cases, RSC approval will be issued in 1-2 days, unless otherwise notified. Some rewording of the patient information sheet is often required. Protocol amendment is rarely necessary.

For further information, contact the RSC at:

Dr. R. Lambert
Chair, Alberta Health Services/University of Alberta Regional Radiation Safety Committee
2A2.18 WMC, UAH Site
Ph. 407-8223, Fax 407-3853, E-mail: radnsfty@ualberta.ca.

6.1 Data Collection

1.0 * Will the study team be able to identify any of the participants at any stage of the study?
Yes

2.0 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?
No

3.0 Primary/raw data collected will be (check all that apply):

- Anonymous
- Confidential

4.0 If this study involves secondary use of data, list all original sources:
N/A

5.0 In research where total anonymity and confidentiality is sought but cannot be guaranteed (e.g. where participants talk in a group) how will confidentiality be achieved?
N/A

6.2 Data Identifiers

1.0 * Personal Identifiers: will you be collecting any of the following (check all that apply):

- Surname and First Name
- Initials
- Address
- Full Postal Code
- First 3 digits of postal code
- Telephone Number
- Fax Number
- Social Insurance Number
- Email Address
- Full Face Photograph or Other Recording
- Student ID Number
- Employee ID Number
- Full Date of Birth
- Year of Birth
- Age at time of data collection
- Vehicle Identifiers
- Professional Certificate/License Number
- Other

We will collect **none of the above.**

If OTHER, please describe:

2.0 Will you be collecting – at any time of the study, including recruitment of participants – any of the following (check all that apply):

- Health Care Number
- Healthcare Provider
- Hospital Discharge Date
- Other Date (e.g. Date of Service)
- Medical Device Identifier
- Medical Record Number
- Other

We will collect **none of the above.**

If OTHER, please describe:

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

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

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

6.0 If applicable, describe your plans to link the data in this study with data associated with other studies (e.g. within a data repository) or with belonging to another organization:
N/A

6.3 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
Responses are not associated with any personally identifying information.

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?
All study personnel have been informed of privacy and confidentiality responsibilities.

3.0 External Data Access

3.01* * Will Identifiable data be transferred or made available to persons or agencies outside the research team?
No

3.02If YES, describe in detail what identifiable information will be released, to whom, why they need access, and under what conditions? What safeguards will be used to protect the identity of participants and the privacy of their data?
N/A

3.03Provide details if identifiable data will be leaving the institution, province, or country etc.
N/A

6.4 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.
Digital files on Google Docs

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.
No plans for future use of data.

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:
Data will be deleted from Google Docs five years hence.

7.1 Documentation

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

1.0 Recruitment Materials:

2.0 Letter of Initial Contact:

3.0 Informed Consent/Information Document(s)

3.01What is the reading level of the Information Letter:
3.02Informed Consent Form(s)/Information Document(s):

4.0 Assent Forms

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

6.0 Protocol:

7.0 Investigator Brochures/Product Monographs (Clinical Applications only):

8.0 Health Canada No Objection Letter (NOL):

9.0 Confidentiality Agreement:

10.0 Conflict of Interest:

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