**RESEARCH ETHICS BOARD APPLICATION**

REB#: Click or tap here to enter text.

***\*Once your application is completed, please send application and all appendices to the REB office for preliminary review.***

***\*Please note that ONLY electronic copies of your ethics submission will be accepted.***

***\*Please submit the Study Information Sheet with this submission.***

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| ***SECTION 1 – GENERAL ADMINISTRATIVE INFORMATION*** |  |
| **Full Study Title:**  Click or tap here to enter text. | |
| **1.1 Responsible Site Principal Investigator** *(This individual has overall responsibility for the study at this site)* | |
| **Last Name:**  Click or tap here to enter text. | **First Name:**  Click or tap here to enter text. |
| **Title/Position:**  Click or tap here to enter text. | **Phone Number:**  Click or tap here to enter text. |
| **Department/Unit:**  Click or tap here to enter text. | **Email Address:**  Click or tap here to enter text. |
| **Responsible Site Investigator Agreement:** *By signing below, I assume full responsibility for the scientific and ethical conduct of the study at my research site as described in the REB application and supporting documentation and agree to conduct this study in compliance with the Tri-Council Policy Statement (TCPS2): Ethical Conduct for Research Involving Human Subjects, the International council for Harmonisation Good Clinical Practice Guidelines (ICH-GCP) where applicable, the Ontario PHIPA legislation and all applicable regulatory requirements (e.g. Health Canada) where applicable. I certify that all researchers and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training and supervision to fulfill their role in this project.*  **Investigator Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| **1.2 Co-Investigators** (*Please list only one co-investigator on this form who can be contacted in absence of the site investigator. Please be sure to list all co-investigators on the study delegation log. It is the responsibility of the site investigator to ensure the delegation log is up-to-date and that all co-investigators have evidence of appropriate training on file.)* | |
| **Last Name:**  Click or tap here to enter text. | **First Name:**  Click or tap here to enter text. |
| **Title/Position:**  Click or tap here to enter text. | **Phone Number:**  Click or tap here to enter text. |
| **Department/Unit:**  Click or tap here to enter text. | **Email Address:**  Click or tap here to enter text. |
| **Co-Investigator Signature:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **1.3 Main Study Coordinator/Contact for this Project** | |
| **Last Name:**  Click or tap here to enter text. | **First Name:**  Click or tap here to enter text. |
| **Title/Position:**  Click or tap here to enter text. | **Phone Number:**  Click or tap here to enter text. |
| **Department/Unit:**  Click or tap here to enter text. | **Email Address:**  Click or tap here to enter text. |
| **1.4 Funding Source** | |
| Industry (Pharmaceutical/Device Company/Biotech Company) Specify Name: Click or tap here to enter text.  Government Funding Agency (e.g.CIHR, NIH) Specify: Click or tap here to enter text.  Government (e.g. Ministry of Health, Department of Defense) Specify: Click or tap here to enter text.  Charitable Organization (e.g. Heart & Stroke) Specify: Click or tap here to enter text.  Internal Funds/Discretionary Account Describe: Click or tap here to enter text. | |
| **1.5 Status of Funding** *(Note: The REB retains the right to hold an application for REB review until confirmation of funding is obtained)* | |
| Funding Obtained  Applied for Funding – Provide Expected Date of Decision: Click or tap to enter a date.  No Funding Required (briefly explain): Click or tap here to enter text. | |
| ***SECTION 2 – STUDY INFORMATION*** |  |
| **2.1 Origin of the Study** | |
| Investigator-Initiated (Local IMHR/ROMHC affiliated Investigator)  Investigator-Initiated by another Academic Centre  Name of Investigator: Click or tap here to enter text.  Academic Center: Click or tap here to enter text.  Corporate/Industry Sponsored  Name of Sponsor: Click or tap here to enter text. | |
| **2.2 Ethics Review Status** | |
| **Is the Royal’s REB the primary site for REB review?**  Yes  No, the primary site for REB review is:  The OHSN-REB (TOH/UoHI/OHRI)  Children’s Hospital of Eastern Ontario (CHEO)  The Montfort Hospital  University of Ottawa Social Science & Humanities  SCO Health Service  The Rehabilitation Centre  Other (specify): Click or tap here to enter text. | |
| **If the primary review site is one other than the Royal’s REB, please indicate the status of the approval from that site:**  Not Applicable  Approved (approval letter is included with this application)  Submitted, currently under review  Conditionally approved | |
| **2.3 Scientific Review** | |
| **Has the attached protocol undergone an independent scientific review?**  Yes, please describe (name of committee/individuals involved in the review): Click or tap here to enter text.  No | |
| **2.4 Study Duration** | |
| **Expected Start Date:** Click or tap to enter a date. | **Expected End Date:** Click or tap to enter a date. |
| **2.5 Training Program Information** | |
| **Is this research part of an academic training program?**  No – proceed to next section  Yes:  Post-Doctoral  PhD  Masters  Undergraduate  Resident/Clinical Fellow | |
| **Name(s) of Student(s):** Click or tap here to enter text. | |
| **Name of Supervisor:**  Click or tap here to enter text. | **Institution:**  Click or tap here to enter text. |
| **Department/Division**:  Click or tap here to enter text. | **Program:**  Click or tap here to enter text. |
| **Phone Number:**  Click or tap here to enter text. | **Email Address:**  Click or tap here to enter text. |
| **2.6 Budget** | |
| An itemized budget is attached (include all study costs, e.g. database, participant reimbursement, study payments, monitoring expenses, etc.)  A budget is not required for this study. Provide brief explanation below:  Click or tap here to enter text. | |

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| ***SECTION 3 – STUDY DESIGN*** |  |
| **3.1 Study Type** | |
| **Interventional (check all that apply)**  Pilot Trial  Open-Label  Single-Blind  Double-Blind (or more)  Randomized Control (RCT) | **Observational/No Intervention (check all that apply)**  Case Control  Cohort  Cross-sectional  Decision Rule Research  Longitudinal  Qualitative (surveys, interviews, etc.)  Registry  Involves biological specimen collection  Involves imaging/radiologic procedure  Positron Emitting Radiopharmaceutical – for basic  clinical research studies under Health Canada  Division 3. |
| **NOTE:** *The definition of a* ***REGULATED*** *(Health Canada approval required) research study:*   * *All clinical trials from phase I to phase III for new Investigational products (drug, natural health product, biologic) as well as any unlicensed medical devices (class 2 and up)* * *Marketed products (drug, natural health products, biologic) being researched outside of their approved indication (i.e. new age group, new disease entity or new dosage range)* * *Exception\* - Phase IV trials do not require approval from health Canada however sponsors are mandated to conduct the trial according to section C.05.10, Good Clinical Practice, and keep the required records as indicated in C.05.12.* | |
| **3.2 Noting the definition for regulated research (above) this study is:** | |
| **Non-Regulated** (e.g. behaviour modification such as diet, exercise, psychotherapy, educational research, radiologic procedures, preventative care, process of care, genetic research)  **Specify:**  Cognitive Behavioural Therapy  Educational Research  Imaging Research\*  Preventative Care  Genetic Research\*  Other (specify): Click or tap here to enter text.  \*Using positron emitting radiopharmaceuticals that have a predefined safety profile for basic clinical research is non-regulated – a CTA is not required.  \*For any genetic research, you are required to submit the **Genetic Addendum** with this submission. | **Regulated** (e.g. using a drug, vaccine, biologic, medical device, natural health product, radiopharmaceutical)  **Specify:**  Drugs, biologics, radiopharmaceuticals  Phase I  Phase II  Phase III  Phase IV    Natural or non-prescription health products  Medical Devices  Class I  Class II  Class III  Class IV |
| **3.3 Regulatory Oversight – applicable to regulated trials under section 3.2 above** | |
| a) An application (CTA) been submitted to Health Canada for approval?  Yes  No | |
| b) The sponsor responsible for submitted the clinical trial application (CTA) is:  IMHR (investigator-initiated, regulated trial)  External Sponsor (provide name): Click or tap here to enter text. | |
| c) The Health Canada Approval letter is:  Attached  Pending and will be provided upon receipt | |
| **NOTE:** *The REB retains the right to hold final approval until receipt of regulatory approvals. A study regulated by Health Canada may not commence until regulatory and REB approval(s) are obtained.* | |

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| ***SECTION 4 – CLINICAL TRIAL REGISTRATION*** | **Section 4 – Not Applicable** |
| **NOTE: *You must complete this section if you identified the study as a clinical trial (interventional) in Section 3 a.*** *TCPS2 requires that all clinical trials (interventional) be registered on a public registry. The International Committee of Medical Journal Editors (ICMJE) has indicated that clinical trials will not be published without the registration of that trial prior to participant enrollment. In June 2007, the ICMJE adopted the WHO’s definition of a clinical trial: “Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.” This definition includes drugs, procedures, devices, behavioural treatments, process of care changes and the like. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration. Health related interventions include any intervention used to modify a biomedical or health-related outcome. Health outcomes include any biomedical or health related measure obtained in patients or participants, including pharmacokinetic measures and adverse events.* | |
| **Given the definition noted above, does this study require trial registration?**  Yes – Provide the registration site (e.g. clinicaltrials.gov): Click or tap here to enter text.  Enter the clinical trial registration number: Click or tap here to enter text.  No – Justify the reason registration is not required (maximum 1 paragraph):  Click or tap here to enter text. | |

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| ***SECTION 5 – UNITED STATES REGULATIONS REQUIREMENTS*** |  |
| **NOTE:** *The United States Food and Drug Administration (FDA) Code of Federal Regulations (CFR) title 21, food & Drugs, or the United States Common Rule, CFR title 45, Part 46, (United States Department of Health and Human Services, Office of Human Research Protection) do apply to studies conducted in Canada. To determine if these regulations apply, please complete the following:* | |
| 1. The study is sponsored by, or is using a product from a U.S. based company?  Yes  No | |
| 1. The investigator has received an award/grant from, or the research is supported by the United States Federal Government (i.e. Department of Health and Human Services/NIH)?  Yes  No | |

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| ***SECTION 6 – INTERNATIONAL SITE(S)*** |  |
| **Will there be sites participating in this study in Countries outside of Canada?**  No  Yes – Please list the countries: Click or tap here to enter text. | |

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| ***SECTION 7 – QUALITATIVE RESEARCH*** | **Section 7 Not Applicable** |
| 1. **The qualitative research that is being proposed is (check all that apply):**   Focus Groups  Interviews  Observational (e.g. naturalistic, field, etc.)  Questionnaires/Surveys  Other (specify): Click or tap here to enter text. | |
| 1. **How will the surveys/questionnaires/interviews/focus groups be administered?** (check all that apply)   Paper  Electronic or online  In-person/via telephone/Email  Other (specify): Click or tap here to enter text. | |
| 1. **Have the surveys/questionnaires been validated?**   Yes  No | |
| *Please attach surveys, questionnaires, interview scripts etc. that will be used in this study*. | |

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| ***SECTION 8 – BIOLOGICAL SPECIMEN COLLECTION***  **(blood/tissue, biomarker, biobanking, genetic testing) – excludes specimens taken as part of normal care.** | **Section 8 – Not Applicable** |
| 1. **What type of specimen(s) will be collected from the study participants?**   Click or tap here to enter text. | |
| 1. **How will the specimens be collected?** (check all that apply)   Previously acquired clinical specimens (e.g. leftover or archived specimens)  Prospectively collected for the study (e.g. not yet collected)  Other (specify details): Click or tap here to enter text. | |
| 1. **Does the investigator/sponsor/collaborating centre plan to put a material transfer agreement (MTA) or similar agreement in place with each participating centre to ensure secure transfer and storage of the specimens?**   Not Applicable – specimens will not be transferred  Yes  No – Explain and justify: Click or tap here to enter text. | |
| 1. **Select the purpose(s) for which the specimens will be collected.** (check all that apply)   For the purpose of this study (study specific samples)  For genetic testing (e.g. gene identification, DNA screening, gene mapping)  Stored or retained or banked for future testing | |

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| ***SECTION 9 – IMAGING/RADIOPHARMACEUTICAL*** | **Section 9 Not Applicable** |
| **NOTE:** *This section* ***ONLY*** *applies to radiopharmaceuticals that have a* ***predefined safety profile in humans****. Basic clinical research studies using radiopharmaceuticals aim to advance scientific knowledge and are not intended to fulfill any immediate diagnostic or therapeutic purposes. If you are conducting a study using a positron-emitting-radiopharmaceutical (PER) that is first-in-humans or a study that does not meet the basic research criteria as outlined in Health Canada Division 3, the study is considered interventional and must be submitted to Health Canada as a Clinical Trial Application (CTA), per Part C, Division 5 of the Food and Drug Regulations. For these studies, please complete section XXXX of this application.* | |
| 1. **The imaging techniques used in this study include (check all that apply):**   MRI  fMRI  PET Scan\*  For PET scans, please complete the following:   1. The total radiation dose incurred annually by a study participant from study drugs, contaminants or impurities and from the use of other procedures for the purpose of this study are not more than 50 mSv.  Yes  No 2. The study shall not involve more than 30 participants.  Yes  No | |
| *Health Canada will issue the Authorization for the sale of the drug for PERs upon receipt of REB approval. Please submit a copy of the Authorization to the REB upon receipt from Health Canada.* | |

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| ***SECTION 10 – INTERVENTIONAL/CLINICAL TRIALS*** | **Section 10 Not Applicable** |
| 1. **Intervention** | |
| **Health-related intervention(s) (e.g. behavioural treatments, dietary interventions, etc.)**  **Please specify the intervention:** Click or tap here to enter text.  **Clinical Trial Using:**  Investigational Drug(s)  Investigational Biologic(s)  Investigational Natural Health Product(s)  Investigational Medical Device(s)  Investigational (no previous safety profile) Radiopharmaceutical(s)  **Name/list the specific intervention (e.g. drug name/device type):** Click or tap here to enter text.  **This study is a:**  Phase I  Phase II  Phase III  Phase IV  **Which of the following will be used in this study (check all that apply) or  Not Applicable**  Placebo  Sham Procedure(s)  A “no treatment” arm  Washout  Withholding Treatment  Blinding (single or double)    **If using one or more of the methods above, please provide justification for each:**  Click or tap here to enter text.  **IF this study will be “double-blind”, describe the provisions made to break the code in an emergency situation or**  **Not Applicable.**  Click or tap here to enter text. | |

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| ***SECTION 11 – DRUGS/BIOLOGICS (INCLUDING VACCINES)/GENETIC THERAPIES/RADIOPHARMACEUTICALS* (no previous safety profile)** | **Section 11 Not Applicable** |
| **11.1 Product Status** | |
| New Drug/Investigational  Approved (e.g. has Drug Identification Number (DIN)), but will be used outside of the conditions approved by Health Canada**. Describe how the product(s) is/are being used outside of current approval (e.g. different dose, different population, etc.) :** Click or tap here to enter text.  Approved (e.g. has Drug Identification Number (DIN)) and will be used within the marketing approval in a Phase IV study. | |
| **11.2 Product Information** | |
| **Please indicate which of the following document(s) are included in this application:**  Investigator Brochure (IB) attached  Product Monograph (attached) | |
| **11.3 Clinical Trial Application Information** | |
| **Please indicate the status of the Sponsor’s Clinical Trial Application (CTA) made to Health Canada**  No Objection Letter (NOL) is attached  No Objection Letter (NOL) is pending and will be submitted when available  Phase IV study and CTA to Health Canada is not required and an NOL will not be issued | |

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| ***SECTION 12 – NATURAL HEALTH PRODUCTS/NON-PRESCRIPTION/DISINFECTANT DRUGS* (as per Health Canada NNHPD)** | **Section 12 Not Applicable** |
| **12.1 Product Status** | |
| New Product/Investigational  Approved (e.g. has Natural Product Number, NPN or Homeopathic Medicine Number, DIN-HM), but will be used outside of the conditions approved by Health Canada**. Describe how the product(s) is/are being used outside of current approval (e.g. different dose, different population, etc.) :** Click or tap here to enter text.  Approved (e.g. has Natural Product Number, NPN or Homeopathic Medicine Number, DIN-HM) and will be used within the marketing approval in a Phase IV study. | |
| **12.2 Product Information** | |
| **Please indicate which of the following document(s) are included in this application:**  Investigator Brochure (IB) attached  Product Monograph (attached) | |
| **12.3 Clinical Trial Application Information** | |
| **Please indicate the status of the Sponsor’s Clinical Trial Application (CTA) made to Health Canada**  Notice of Authorization (NOA) is attached  Notice of Authorization (NOA) is pending and will be submitted when available  Phase IV study and CTA to Health Canada is not required and an NOA will not be issued | |

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| ***SECTION 13 – MEDICAL DEVICES*** | **Section 13 Not Applicable** |
| **13.1 DEVICE CLASSIFICATION** | |
| Class I – a lowest risk medical device (e.g. tongue depressors, bandages), no application to Health Canada is required  Class II – low risk devices (e.g. pregnancy tests, surgical gloves, epidural catheters)  Class III – moderate risk devices (e.g. orthopaedic devices, glucose monitors, diagnostic ultrasound systems)  Class IV – highest risk devices (e.g. pacemakers, angioplasty catheters)  **Name all of the components, parts and/or accessories as per the product label for devices covered under the ITA with Health Canada:** Click or tap here to enter text. | |
| **13.2 Device Status** | |
| Licensed (e.g. has Medical Device License (MDL)), but is being used outside of current Health Canada authorization **Describe how the device component, parts and/or accessories is/are being used in the study outside of the parameters of the conditions of use approved by Health Canada:** Click or tap here to enter text.  New, un-licensed device  **Does this device contain a drug?**  Yes, drug contained in this device is: Click or tap here to enter text.  No | |
| **13.3 Clinical Trial Application Information** | |
| **Please indicate the status of the Investigational Testing Authorization (ITA) made to Health Canada**  Investigational Testing Authorization (ITA) is attached  Investigational Testing Authorization (ITA) is pending  Investigational Testing Authorization (ITA) is not required as per Health Canada guidelines | |

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| ***SECTION 14 – STUDY DETAILS*** | |  | |
| **14.1 Study Summary (this is not a substitute for a study protocol) – approximately 200 words** | | | |
| **NOTE:** *This brief summary/abstract must be suitable for a lay audience. This is not a substitute for the full protocol. Do not refer to section of an attached protocol.* | | | |
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| **14.2 Purpose and Objectives** | | | |
| **a) Based on current literature, briefly justify the need for this study and clearly outline the rationale as well as the hypothesis to be tested.** | | | |
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| **b) List (in point form) the objectives of this project.** | | | |
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| **c) Briefly describe the clinical relevance (overall anticipated public/scientific benefit) of the project. (max. ¼ page)** | | | |
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| **14.3 Methods & Procedures** | | | |
| **a) Describe the design and methodology (e.g. pre/post design, pilot, study visits, procedures, study intervention). (max ½ page)** | | | |
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| **b) Describe the primary outcome measures/goals of the study. (max ¼ page)** | | | |
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| **c) List all criteria for withdrawal of a participant from the study. (max ¼ page) or  Not Applicable** | | | |
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| **d) Does this study involve deception or intentional lack of disclosure?**  Yes, explain (max ¼ page)  No | | | |
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| **e) Will participants be withdrawn from or denied usual therapy for any condition in order to participate in the study?** (This would include medications that are prohibited or restricted in order to be eligible for the study or that my be prohibited or restricted during the course of the study)  Yes, explain (max ¼ page)  No | | | |
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| **f) Will participants be subject to other restriction (e.g. lifestyle) during the study?**  Yes, explain (max ¼ page)  No | | | |
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| **g) Describe how incidental findings will be managed and under what circumstances they would be disclosed to participants. (max ¼ page)** | | | |
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| **14.4 Participants & Controls** | | | |
| **a) List the inclusion and exclusion criteria (numbered)** | | | |
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| **b) Are any of the eligibility criteria based on ethnicity, gender or language?**  **Yes, justify (max ¼ page)**  **No** | | | |
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| **c) Indicate the rationale for control group(s). (max ¼ page) or  Not Applicable** | | | |
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| **14.5 Sample Size** | | | |
| **a) Total participants that will be enrolled in the study:**  Click or tap here to enter text. | | **b) Total Participants to be enrolled in the study at this site:** Click or tap here to enter text. | |
| **c) Time period for enrollment:**  **Start Date:** Click or tap to enter a date.  **End Date:** Click or tap to enter a date. | | | |
| **NOTE:** *It is important to provide sample size justification in the study protocol. Please ensure this is included in the protocol submitted with this application.* | | | |
| **14.6 Participant Population(s)** | | | |
| **a) This study will target the following population(s)** (check all that apply) | | | |
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| Patients | Healthy Volunteers | | Students\* |
| Staff\* | People Institutionalized\* | | Prisoners/In Detention\* |
| People in poverty/economically  disadvantaged\* | People who lack capacity to  consent\* | | People unable to read/write\* |
| Children\* | Cognitively impaired individuals\* | | Pregnant Women\* |
| Elderly | Aboriginal people and/or ethno-  cultural minorities\* | |  |
| **b) For special participant populations identified with an \* above, please provide justification of the inclusion of the population in this study.** (max ½ page) | | | |
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| **14.7 Study Interventions & Study Procedures or  Not Applicable** | | | |
| **a) What procedures will be done in the study that are not considered part of the diagnostic therapeutic “routine” or standard of care? Attach a copy of all non-standardized instruments. (e.g. questionnaires, rating scales, etc.) – (max ¼ page)** | | | |
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| **b) Indicate the additional risks associated with the study as compared to usual standard of care. (max ½ page)** | | | |
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| **c) Indicate the duration of study visits and extra time commitment (length of visits, number and frequency of test sessions) for study participants. (max ½ page)** | | | |
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| **14.8 Data Analysis** | | | |
| **Briefly explain what methods will be used to analyze study data. (max ¼ page)** | | | |
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| ***SECTION 15 – RECRUITMENT*** | |  | |
| **NOTE:** *According to the Personal Health Information Protection Act (PHIPA), researchers must communicate their research proposal in writing and answer a series of privacy related questions as requested by the Act (it is the law!). The REB considers the recruitment, consent and privacy and confidentiality sections of this application to be the investigator’s privacy plan, a requirement of PHIPA. The REB will review and approve this plan. Any subsequent changes to the privacy plan require submission to the REB as an amendment. Non-compliance with any part of your privacy plan is a privacy breach and may result in disciplinary actions, notification to the applicable regulatory professional body and/or to the Information & Privacy Commissioner of Ontario (PIC).* | | | |
| **15.1 Participant Identification & Selection** | | | |
| **15.1.1 - What recruitment materials will be used? (check all that apply)** | | | |
| None | | Brochures, flyers, posters | |
| Recruitment Database | | Newspaper ad | |
| Telephone call scripts | | Website | |
| Social Media | | Other (describe): Click or tap here to enter text. | |
| *Please ensure all posters, scripts, information cards etc. that will be provided to participants are attached to this application for review by the REB.* | | | |
| **15.1.2 - If special populations were selected in section 14.6, describe the strategies for minimizing coercion or undue influence for the special populations included in the study, or,  Not Applicable** | | | |
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| **15.1.3 - Which of the following criteria apply to this research?** (select all that apply) | | | |
| The research conducted on First Nations, Inuit or Metis lands  Recruitment criteria that include Aboriginal identity as a factor for the entire study or for subgroup in the study  Research that seeks input from participants regarding an Aboriginal community’s cultural heritage, artifacts,  traditional knowledge or unique characteristics  Research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the  purpose of analysis of the research data  Interpretation of results that will refer to Aboriginal communities, peoples, language, history or culture  None of the above – proceed to 15.1.4 | | | |
| **15.1.4 - Is there any plan to engage the relevant community or communities?**  No  Yes | | | |
| **If yes, attach the following as applicable**:  a) preliminary or formal research agreement between the researcher and the responsible body a the research site  b) a written decision/documentation of an oral decision taken in a group setting to approve the research/decline  c) a written summary of advice received from a culturally informed advisory group or ad hoc committee  **If no, provide the rationale below (max ¼ page)** | | | |
| **15.1.5 - What tools will be used to identify potential participants for recruitment into the study?** | | | |
| Permanent Health Record/Clinical Chart  Existing Database (specify)  i) Does the Principal Investigator maintain the database?  Yes  No  ii) If no, identify the entity that maintains the database: Click or tap here to enter text.  Has access/use for research purposes been granted?  Yes  No  Yes pending REB approval  **Note:** *The creation and maintenance of a database for research purposes is a research activity that may require a separate REB application. Consult the REB for further information*.  Advertisements, including web based recruitment tools (attach)  i) Indicate where these will be posted: Click or tap here to enter text.  Other (specify): Click or tap here to enter text. | | | |
| **15.1.6 - Who will identify potential study participants?** | | | |
| Investigator/study personnel  Other healthcare professional (e.g. non-study personnel)  Self-referral (e.g. response to advertisement or online recruitment tools) | | | |
| **15.2 Research Contact** | | | |
| **15.2.1 - How will the potential participant’s permission to be contacted for research purposes be obtained?** (check all that apply) | | | |
| Institutional “Permission to Contact” Registry  Individual from the participant’s circle of care  Not Applicable – potential participant self-refers in response to ad/survey/social media  Other (describe): Click or tap here to enter text. | | | |
| **15.2.2 - How will initial contact be made?** (check all that apply) | | | |
| In person  Telephone  Letter  Email  Other (specify): Click or tap here to enter text. | | | |
| **15.3 Social Media Use or  Not Applicable** | | | |
| **15.3.1 - If a website or social media scripts are being used for recruitment purposes, confirm the use of social media is for advertisement only; explain rationale as an effective form of advertisement, and demographics of target audience (max ½ page)** | | | |
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| ***SECTION 16 – INFORMED CONSENT INFORMATION*** |  |
| **16.1 - Is a waiver of the requirement to obtain informed consent being requested for this study?** | |
| No  Yes, provide justification below: | |
|  | |
| **16.2 – Informed Consent will be obtained from the study participants or their legal representatives?** | |
| Yes  No | |
| **NOTE:** *All consent forms must be submitted with this application. Please ensure that all pages are numbered and each consent form has an appropriate**version/date in the footer of the document.* | |
| **16.3 – Describe the consent process. (e.g. who will obtain consent)** (max ¼ page) | |
|  | |
| **16.4 – Is there a relationship (e.g. physician/patient) between the subjects and the person obtaining consent?** | |
| No  Yes – explain the nature of the relationship and steps that will be taken to minimize potential coercion. | |
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| **16.5 – For studies that involve more than one visit with participants, how will ongoing consent be confirmed, or,  Not Applicable** | |
|  | |
| **16.6 – Does the research study include research participant who may not be capable of giving consent?** | |
| Yes  No | |
| **16.7 – For those who are not capable of giving informed consent, describe how consent will be obtained.** | |
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| ***SECTION 17 – COMPENSATION*** |  |
| **17.1 - Will study participants receive any incentive to participate in the study through compensation/payment?** (e.g. money for time, gifts or gift cards, etc.) | |
| No  Yes, please provide the payment details (amount, payment schedule justification) below. (max ¼ page) | |
| **17.2 - Does the budget allow for reimbursement of study participants for additional costs that may occur due to their participation in the study such as travel, parking and meals?** | |
| No, justify below  Yes, please describe below | |
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| ***SECTION 18 – SAFETY*** |  |
| **18.1 Study Related Risks & Benefits** | |
| **18.1.1 - List the known short-term risks or discomforts associated with study participation, including approximate rates of occurrence, severity and reversibility, if applicable.** | |
|  | |
| **18.1.2 - Describe the risks related to study procedures that are not considered part of the diagnostic, therapeutic “routine” or standard of care.** | |
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| **18.1.3 - For studies involving placebo, sham procedures, washout, withholding treatment or no-treatment arm interventions, list any risks related to withdrawal or absence of treatment Or  Not Applicable** – proceed to 18.1.4 | |
|  | |
| **a) Describe the provisions to minimize risks to participants.** | |
|  | |
| **b) Describe if, and when the withdrawal or absence of treatment will be disclosed to the participant.** | |
|  | |
| **18.1.4 - Are there any known reproductive risk associated with participation in the study?  No  Yes,**  **Summarize below** | |
|  | |
| **18.1.5 - Does participation in this study affect alternatives for future care of eligibility for future research?**  **No**  **Yes, Explain below (max ½ page)** | |
|  | |
| **18.1.6 - will participants receive any direct benefits from participating in this study?  No  Yes, describe** | |
|  | |
| **18.2 Safety Oversight** | |
| **18.2.1 - Describe the safety monitoring plan for this study.** | |
|  | |
| **18.2.2 - Are there any plans to perform an interim analysis?  Yes, describe  No, justify** | |
|  | |
| **18.2.3 - Is there a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Committee (DSMC)?** | |
| **Yes –** please attach a copy of the DSMB Charter/Terms of Reference  **No** | |
| **Note:** *For interventional trials where DSMB oversight is applicable, please ensure all DSMB reports are submitted to the REB for review and inclusion in the REB file.* | |
| **18.2.4 - Who will conduct the onsite monitoring of the study at the center(s)?** | |
| Sponsor (provide sponsor name): Click or tap here to enter text.  Outside Agency (e.g. CRO), provide name: Click or tap here to enter text.  Other (specify): Click or tap here to enter text.  Not Applicable | |
| **18.2.5 - If applicable, describe the criteria for stopping the study due to safety concerns or other reasons, or,**  **Not Applicable** | |
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| ***SECTION 19 – PRIVACY & CONFIDENTIALITY*** | |  | |
| **NOTE:** *Investigators must comply with the duties set out for researchers in the Personal Health Information Protection Act (PHIPA), with the privacy and confidentiality and consent guidelines outlined in TCPS2. It is a requirement of PHIPA that a complete information access log be kept for each study and for the duration of the study to identify all personnel who have access to personal health information for research purposes. The REB may require access to this log as part of the monitoring process. This log must be kept as part of the recruitment and study conduct processes.* | | | |
| **19.1 Data Collection** | | | |
| **19.1.1 - What (if any) personal information will be collected, used, or disclosed from the records during the course of the proposed research study?** | | | |
| None, participant ID only | Full Name | | Full Initials |
| Partial Initials | Partial Date of Birth | | Age |
| Sex/Gender | Full Postal Code | | First 3 digits of postal code |
| Admission Date | Discharge Date | | Medical Record Number (MRN) |
| OHIP/Provincial Insurance # | Address | | Telephone Number |
| Email Address | Full Face Photograph | | Voice/Audio Recording |
| Other: Click or tap here to enter text. | Other: Click or tap here to enter text. | | Other: Click or tap here to enter text. |
| **19.1.2 - Provide justification for each personal identifier that is being collected.** | | | |
|  | | | |
| **19.1.3 - Attach a copy of the demographic pages of the data collection form or tool(s).** | | | |
| Attached  Not Applicable | | | |
| **19.1.4 - Will there be a code linking identifiers to the study participants?** | | | |
| Yes – a code will be assigned and will only be linked on the secure master list.  No | | | |
| **19.1.5 - If study data will be sent or received by the site, indicate how this will occur.** | | | |
| Fax  Electronic (online) data capture system  Private Courier  Regular Mail  Email  Not Applicable | | | |
| **19.1.6 - Is a Data Transfer Agreement (DTA) in place with each participating site to ensure secure transfer and storage of the study data?** | | | |
| Not Applicable  Yes  No – please justify below | | | |
|  | | | |
| **19.1.7 – Who will have access to study data?** (max ¼ page) | | | |
|  | | | |
| **19.1.8 – Identify all potential sources of information.** | | | |
| Permanent Health Record/clinical Chart  Existing Database (detail): Click or tap here to enter text.  Directly from the participant  From other institutions, (specify): Click or tap here to enter text.  Other (specify): Click or tap here to enter text. | | | |
| **19.2 Data Security, Retention & Storage** | | | |
| **19.2.1 – Indicate how data will be stored during the study.** | | | |
| Computerized files (specify):  Server  Desktop  Laptop  Hard Copy  Audio Recordings/Video Recordings  USB Key or similar portable device  E-Reader, Tablet or similar hand-held computer  Other: Click or tap here to enter text. | | | |
| **19.2.2 – Indicate which measures will be taken to protect the confidentiality and security of the data, including any physical and technical safeguards.** | | | |
| Data stored on mobile devices will be encrypted | | Data will be password protected | |
| Data will be stored on institution’s secure network | | Hard copy records will be stored in locked cabinet | |
| Access to records and data will be limited to authorized personnel | | Study data will be de-identified or coded | |
| Study data will be anonymized (identifiers removed) | | Study data will be anonymous (identifiers will not be collected) | |
| **If audio/video recordings will be used:**  Recordings will be destroyed after use  Recordings will not capture date and time | | Recordings will be coded | |
| Other (specify): Click or tap here to enter text. | | | |
| **19.2.3 – Indicate how long the study data will be retained.** | | | |
| 10 Years, as this study is not regulated by Health Canada  15 Years, this study is regulated by Health Canada under a Clinical Trial Application or is a U.S. FDA Trial | | | |

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| ***SECTION 20* – *POTENTIAL CONFLICTS OF INTEREST*** |  |
| **20.1 – Please indicate whether the Principal Investigator, Responsible Site Investigator or any Co-Investigators or other research staff involved in this research study or any member of their immediate family:** | |
| **a) function as an advisor, employee, officer, director or consultant for the study sponsor?**  Yes  No  Not Applicable | |
| **b) have direct or indirect financial interest in the drug, device or technology employed in this research study?**  Yes  No  Not Applicable | |
| **c) receive an honorarium or other financial benefits from the sponsor, or company providing the drug, device, etc.**  Yes  No  Not Applicable | |
| **d) are receiving incentives to recruit research participants for this study?**  Yes  No | |
| **20.2 – If the answer is yes to any of the above questions, append a letter detailing these activities. Please include a description of all conflicts of interest (actual, apparent, perceived or potential) relating to this project.** | |

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| ***SECTION 21* – *DIVISION/DEPARTMENT PROGRAM APPROVAL*** |  |
| ***NOTE:*** *This should not be completed by an administrator who is listed as the study’s Principal Investigator, Site Investigator or Co-Investigator.* | |
| **\*The Clinical Director/Department Head must complete and sign this section** | |
| **I have reviewed this application and by signing below, I certify that:** | |
| a) the study is consistent with hospital/faculty policies and mission  Yes  No  Not Applicable | |
| b) the study resources (budget, space, and support staff) and/or the resources of my division, department or program  are adequate to support the study  Yes  No  Not Applicable | |
| c) there are an adequate number of research participants suitable to be approached for enrollment for this study  Yes  No  Not Applicable | |
| d) this population is being excessively recruited for clinical research  Yes  No  Not Applicable | |
| **Name:** Click or tap here to enter text. | **Contact Number:** Click or tap here to enter text. |
| **Title/Position:** Click or tap here to enter text. | **Department/Unit:** Click or tap here to enter text. |
| **Signature:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| ***22 – CONTINGENCY PLANNING*** |  |
| Outline the contingency plans for this project if the research hospital site becomes close to all but essential personnel during an epidemic, pandemic or civil disaster. Describe the specific steps that will be taken to suspend the project at the site. If the health of the participants may be adversely affected by the suspension of the project, outline the steps that will be taken to protect the interests of the participants. | |
|  | |