|  |  |
| --- | --- |
| **Usage exclusif du BÉR pour le dossier:**  **Incomplet  Approuvé  Approuvé avec modifications  Reporté**  **Type d’évaluation :  Plénier  Délégué  Revue administrative** | **Numéro de dossier:**  **CÉR #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

|  |
| --- |
| **HÔPITAL MONTFORT’S RESEARCH ETHICS BOARD REVIEW APPLICATION FORM** |
| **INSTRUCTIONS**   1. All sections of this application must be completed before it will be considered for an ethical review by the Research Ethics Board (REB) at the facility where the research will take place (i.e., the research site facility). If a section is not applicable, please indicate “Not Applicable” and provide a brief explanation in the space provided. **Unless specifically indicated, do not refer to or attach other documents as a mean to complete a section of the REB application.** 2. The Standard Operating Procedure (SOP) 301 and Procédure de fonctionnement normalisée (PFN) 301B you must submit a complete application and all the supporting documents (e.g., original study protocol, investigator’s brochures) that must be submitted to the primary site for REB review and each site where this research will take place. It is the responsibility of the applicant to contact each research site REB (see **Appendix A** for contact information) for instructions regarding the number of copies to be submitted, and the submission deadlines, etc. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ETHICS REVIEW AND APPROVAL STATUS:**  **Institutions in the Ottawa Region where there is a REB** | | | | | | |
| Please indicate the outcome as well as the name of those other REB correspondence and the documents approved by these committees. Should the approval be pending, please ensure to forward to us a copy of all the required documents when the approval is granted. | | | | | | |
| **Application submitted to:**  **(check all that apply)** | | **Ethics Review and Approval Status:**  (Check all that apply and indicate date where applicable) | | | | |
| Date of Application Submission: | Primary Site for REB Review | Ongoing Review | Conditional  Approval  Received | Date of Final  REB Approval |
| □ | Montfort Hospital |  | □ | □ | □ |  |
| □ | University of Ottawa –  Social Sciences and Humanities |  | □ | □ | □ |  |
| □ | University of Ottawa –  Health Sciences and Sciences |  | □ | □ | □ |  |
| □ | University of Ottawa –  Heart Institute |  | □ | □ | □ |  |
| □ | The Ottawa Hospital |  | □ | □ | □ |  |
| □ | Children’s Hospital of Eastern Ontario |  | □ | □ | □ |  |
| □ | Royal Ottawa Health Care Group |  | □ | □ | □ |  |
| □ | SCO Health Service |  | □ | □ | □ |  |
| □ | The Rehabilitation Centre |  | □ | □ | □ |  |
| □ | Other (specify): |  | □ | □ | □ |  |

|  |
| --- |
| **RESEARCH ETHICS APPLICATION** |
| 1. **PROTOCOL TITLE:** 2. **STUDY DURATION**: Expected Start Date:   /  /     DD/MM/YYYY   Expected End Date:   /  /     DD/MM/YYYY  3. **ORIGIN OF STUDY** (check one):  a) **Investigator Driven**  b) **Corporate Sponsor**:  i) Provide name and contact information for corporate sponsor:  ii) Country |
| 1. **PRINCIPAL INVESTIGATOR**   This individual has the overall responsibility for the project at all research sites.   |  |  |  |  | | --- | --- | --- | --- | | Last Name |  | First Name |  | | Title/Position |  | Tel. | (   )    -     ext. | | Department/Unit |  | Email |  | | Institution/  Organization |  | Signature: |  | |
| 1. **RESPONSIBLE SITE INVESTIGATOR**   Please identify the Responsible Site Investigator for this site.   |  | | --- | | Do you have an affiliation with Hôpital Montfort and will you serve as the study’s contact person for the facility’s REB?  Yes  No  If **No**, have a delegate complete Section **6a**. |  |  |  |  |  | | --- | --- | --- | --- | | Last Name |  | First Name |  | | Title/Position |  | Tel. | (   )   -     ext. | | Department/Unit |  | Email |  | | Institution/  Organization |  | Signature: |  | |
| **Responsible Site Investigator Agreement**  **By signing above**, I assume full responsibility for the scientific and ethical conduct of the study at my research site as described in this REB application and supporting documentation (e.g. protocol) and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects ([TCPS2](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html" \l "5)) and any other relevant regulations or guidelines endorsed by the research site facility. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training and supervision to fulfill their role in this project.  \_\_\_\_\_ *By affixing my initials here, I certify that I meet the requirements of "qualified investigator" as defined by Health Canada*.  Not Applicable |
| 1. **CO-INVESTIGATORS**   If the Responsible Site Investigator does not have an affiliation with the research site facility, or has an affiliation, but is not available to be the contact person for the REB of the research site. Please provide the appropriate information in Section **6a and below**. If this is not needed check off “Not applicable”.  Not Applicable  **CO-INVESTIGATORS this category includes supervisors for thesis or class project**   |  |  |  |  | | --- | --- | --- | --- | | **a**) Last Name |  | First Name |  | | Title/Position |  | Tel. | (   )   -     ext. : | | Department/Unit |  | Email |  | | Institution/  Organization |  | Signature : |  | | *I have an affiliation with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (enter the name of the Research Site Facility) and will serve as the study’s contact person for facility’s REB.*  Yes  No | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | **b**) Last Name |  | First Name |  | | Title/Position |  | Tel. | (   )   -     ext. : | | Department/Unit |  | Email |  | | Institution/  Organization |  | Signature : |  | | *I have an affiliation with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (enter the name of the Research Site Facility) and will serve as the study’s contact person for facility’s REB.*   Yes  No | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | **c**) Last Name |  | First Name |  | | Title/Position |  | Tel. | (   )   -     ext. : | | Department/Unit |  | Email |  | | Institution/  Organization |  | Signature : |  | | *I have an affiliation with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (enter the name of the Research Site Facility) and will serve as the study’s contact person for facility’s REB.*   Yes  No | | | | |
| **RESEARCH COORDINATORS OR ASSISTANTS FOR THIS PROJECT**   |  |  |  |  | | --- | --- | --- | --- | | **d**) Last Name |  | First Name |  | | Title/Position |  | Tel. | (   )   -     ext : | | Department/  Unit |  | Email |  | | Institution/  Organization |  | Signature: |  | | **e**) Last Name |  | First Name |  | | Title/Position |  | Tel. | (   )   -     ext : | | Department/  Unit |  | Email |  | | Institution/  Organization |  | Signature: |  |   *As needed, cut and paste additions to this section in order to list all co-investigators.* |
| 7. IDENTIFY STUDY TYPE AND DESIGN (check as many of the following as apply) |
| |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | a) Type of Study: | | | | | | | | | |  | | Experimental Research/Clinical Trial | | | | | | | |  | | Drug Study (Select one): Phase I  Phase II  Phase III  Phase IV | | | | | | | |  | | Observational Research | | | | | | | |  | | Pilot Study | | | | | | | |  | | Sequel to previously approved project (Protocol # or title:     ) | | | | | | | |  | | Genetic Research (Genetic Addendum must be included with completed application) | | | | | | | |  | | Program Evaluation | | | | | | | |  | | Clinical Chart Review | | | | | | | |  | | Qualitative Research (e.g., Case Study, etc.) | | | | | | | |  | | Studies involving secondary use of personal health information or other confidential information. | | | | | | | |  | | Survey | | | | | | | |  | | Quality Assurance Study | within a single facility | | | | across multiple facilities | | |  | | Other (describe): | | | | | | | | b) Study Design: | | | | | | | | | |  | Controlled Experimental Study (e.g., Randomized Controlled Trial) | | | | | | | | |  | Experimental Study Employing | | |  | Single-Blind or |  | | Double-Blind (or more). | |  | Case-Control study | | | | | | | | |  | Cohort study | | | | | | | | |  | Cross-sectional Study | | | | | | | | |  | Longitudinal Study | | | | | | | | |  | Case Study | | | | | | | | |  | Other (describe): | | | | | | | | |

|  |
| --- |
| **8. PROJECTS REQUIRING HEALTH CANADA APPROVAL**  Not Applicable |
| |  |  |  | | --- | --- | --- | |  | **Medical Device Research,** please indicate the status of the Health Canada application or the approval: | | |  |  | **Health Canada Application/Approval** is appended to the submission | |  |  | **The investigator will require a conditional approval letter from the REB in order to obtain a “No Objection Letter” from Health Canada. Conditional approval letters will be provided if the REB approval is the only impediment to the issuing of a Health Canada license.**  **Please forward the “No Objection Letter” to the REB office as soon as it is available.** This is mandatory prior to final REB approval. | |  | **Drug Trial**, please attach a letter from sponsor indicating Health Canada application/approval. This is mandatory prior to final REB approval. | | |  |  | **Health Canada Application/Approval** is attached is appended to the submission | |
| **9. PROJECTS UNDER UNITED STATES OF AMERICA (USA) REGULATIONS**  Not applicable |

|  |  |  |
| --- | --- | --- |
| |  | | --- | | Is the product /instrument under study and/or the data gathered at Montfort will be used to seek FDA approval?  **Yes**  **No** | | Are you receiving funds from a governmental agency in the USA (ex NIH) to realize this project?  Yes No | |

|  |
| --- |
| **10. REGISTRATION OF CLINICAL TRIALS** |
| The [Article 11.10](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter11-chapitre11.html" \l "c:~:text=in%20accordance%20with-,Article%2011.10,-%2C%20researchers%20are%20responsible) of the latest version of the TCPS 2 requires that all types of clinical trials be registered. Please provide the evidence of registration (e.g., registration number) with the registry [www.clinicaltrials.gov](http://www.clinicaltrials.gov) :   |  | | --- | | **NOTE**: The clinical trials shall be registered **before recruitment** of the first trial participant. | |
| **11. STUDY** **SUMMARY/ABSTRACT**  This summary must be suitable for lay audience (approximately 200 words).  Please note that this is not a substitute for the full protocol, and do not refer the reader to sections of an attached protocol. |

|  |
| --- |
|  |

|  |
| --- |
| **12. PURPOSE AND OBJECTIVES** |
| a) Based on the current literature, justify the need for this study and clearly outline the rationale as well as the hypothesis to be tested: |
| b) Objectives of the project: |
| c) Project relevance: |
| **13. DESCRIPTION OF METHODS AND PROCEDURES** |

|  |
| --- |
| a) Study Design and Methodology: |
| b) Primary Outcome Measures: |
| c) Plan for the Analyses of the Results: |

|  |
| --- |
| **14. JUSTIFICATION OF THE SAMPLE SIZE AND RESEARCH SITES** |
| 1. Total number of research participants being recruited at all Centers globally: |
| b) Total number of sites      **and** list countries     **.** |
| c) Please indicate the number of research participants to be recruited at each COREB research site below:   |  |  | | --- | --- | | University of Ottawa – Social Sciences and Humanities |  | | University of Ottawa – Health Sciences and Sciences |  | | University of Ottawa – Heart Institute |  | | Ottawa Hospital |  | | Children’s Hospital of Eastern Ontario |  | | Montfort Hospital |  | | The Rehabilitation Centre |  | | SCO Health Service |  | | Royal Ottawa Health Care Group |  | | Other (Specify) |  | |
| d) Is the enrollment of individuals into multiple studies likely to be an issue in this participant population?  Yes  No  If “**yes**”, also indicate how this will be addressed.  Please include the sample size for your project. |
| 1. For quantitative studies, include sample size power calculations. |
| 1. For qualitative studies indicate approximate sample size and rationale. |
| **15. DESCRIPTION OF STUDY POPULATION** |
| a)Inclusion criteria (who is being recruited and what are the criteria for their selection) |
| b) Exclusion criteria (identify which research participants will be excluded from research and justify) |
| c) Which linguistic groups will be recruited?  French-speaking:  English-speaking:  Other (specify):   |  | | --- | | Please note that all documentation (e.g., advertisements, telephone scripts, information/consent forms, de-briefing summaries, etc.) should be translated into the language of each linguistic group being recruited for the study and submitted for review after the primary version (English or French) is approved. | |
| 1. Does this research require the approval of communities or organizations where participants are being recruited?  Yes  No  |  | | --- | | The [chapter 9](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html) of the TCPS2 identify the principles and guidelines on research involving Aboriginal peoples in Canada, including First Nations, Inuit and Métis peoples. This chapter is designed to serve as a framework and to provide guidance to researchers. Researchers have to respect these rules on the ethical conduct of research involving Aboriginal peoples. Researchers are advised to consult reference documents that apply to their research undertaking. |   Please note that some communities have promulgated their own guidelines and have their own REB, thus the researchers should ask the community if they should respect other standards.  If **yes**, please explain.  Please describe the process that will be used to obtain consent for their participation: |
| 1. If the study population includes individual’s incapable of giving consent, please justify the need to do so. |
| **16. IDENTIFICATION AND RECRUITMENT OF RESEARCH PARTICIPANTS** |
| 1. Describe how the research study will be publicized for recruitment purposes. If the initial contact is by letter, telephone, e-mail, website and/or advertisement, attach applicable copies of the text to be used. For studies recruiting participants from different linguistic groups, please forward the translated texts.   Consult the REB policy PFN **110** [C](https://savoirmontfort.ca/wp-content/uploads/2021/05/PFN110-Contexte-linguistique-CER-Montfort-Mai2021-1.pdf)*[ontexte linguistique](https://savoirmontfort.ca/wp-content/uploads/2021/05/PFN110-Contexte-linguistique-CER-Montfort-Mai2021-1.pdf)* which complies with the **COM 005** the linguistic policy of Hôpital Montfort since both are identifying French as a defining trait of the institution.  Texts are attached:  Yes  No  Not applicable  Translated texts will follow:  Yes  No  Not applicable |
| 1. If the identification of prospective participants will involve using information from their personal health information record, describe how the participant’s agreement to be contacted by the researcher(s) will be obtained by members of his/her health care team or by the custodian of his/her health information record.  Not applicable |
| c) Once identified, how will prospective research participants be recruited? |
| 1. How will the researcher ensure that there are no breaches of a prospective participant’s privacy during the recruitment process? |
| e) Does the study include participants in a control group?  Yes  No  **If yes**, are the identification and/or recruitment consent processes different from those described above?  Yes  No  **If yes**, provide details. |
| 1. Will research participants receive financial compensation?  Yes  No   **If yes**, please explain the purpose of the compensation (e.g., reimbursement for expenses, gifts for participation, compensation for time spent in the study, etc.). |
| 1. Commission fees that are to be paid to health professionals or research staff for the successful recruitment of research participants are prohibited. Nonetheless, reimbursement for time spent is permitted, if fees are to be paid, please provide details below.   Yes  No  Not applicable |
| **17 A) USE AND PROTECTION OF RESEARCH DATA** INCLUDING BIOLOGICAL DATA |
| |  | | --- | | **Consent for secondary analysis has already been obtained  Yes  No** | | According to the TCPS2 requirements listed in [*article 5.5A*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#5a) or [Article 12.3A](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter12-chapitre12.html#3a) **(a) to (f)**and the Personal Health Information and Protection Act (PHIPA) must be met for the REB to approve the use of the data without a consent form or if the form has been altered.  Please explain how the requirements have been met. | |
| |  |  | | --- | --- | | **Identify the types of information and coding that have been used** (TCPS2 [chapter 5)](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html)**:** | | |  | *Directly identifying information –* the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).  *Indirectly identifying information –*the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic). | |  | *Coded information* – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants’ code names with their actual name so data can be re-linked if necessary). | |  | *Anonymized information –* the information is irrevocably stripped of direct identifiers; a code is not kept allowing future re-linkage. | |  | *Anonymous information –* the information never had identifiers associated with it (e.g., anonymous surveys). | |
| |  | | --- | | **Are multiple sources of data being used?  Yes  No** | | **If yes**, please tell us.   1. the sources of the data and submit the process to access the data: 2. Will data be linked?  Yes  No   **If yes**, explain why is it necessary to link the data?   1. And how will data be linked? | |
| **17 B) CREATING A DATA BANK FRAMEWORK is required when the data is kept BEHOND THE DURATION OF THE INITIAL PROJECT OR BEING MADE AVAILABLE TO OTHER RESEARCH TEAMS** |
| |  | | --- | | **NOTE**: [Additional information](https://savoirmontfort.ca/en/research-2/research-ethics/ressources/banque-de-donnees/) on the use of data bank and the creation of a research data bank. |  1. Provide the name of the bank. |
| 1. Name of the person or persons maintaining or managing the bank |
| 1. Please submit the bank’s management framework protocol or the contract agreement   The following link will give you more information about the ethics guidelines to follow when creating the framework to create and manage a data bank: [Management framework](https://savoirmontfort.ca/en/research-2/research-ethics/ressources/banque-de-donnees/) |
| **18. PROCEDURES FOR SEEKING INFORMED CONSENT** (PFN 701) |

|  |
| --- |
| 1. Is the informed consent being obtained by the participants of the research or their agents (e.g., parents, tutors/prosecutors)  Yes  No   **If yes,** please complete the sections **18 b) to m).**  **If no,** select “Not applicable” in sections **18 b) to h)** |
| 1. What is the reading comprehension grade level of the information and consent form? Please include a description of the methodology used to make this determination.  |  | | --- | | **Please consult the REB Website where tools are available to evaluate the readability level.**  Click the following link to access Microsoft Office’s Help Page on how to « [Test Your Document’s Readability](https://support.microsoft.com/en-us/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2) » for the Flesch Reading Ease and Flesch-Kincaid Grade Level Systems. | |
| c) Is the information/consent form written at the reading level of the population being sampled?  Yes  No  **If « No »** is selected please, describe the methodology used to ensure that research participants have a sufficient level of understanding to be able to give their “informed” consent”. |
| 1. If the informed consent will be **obtained in writing**, please attach a copy.   If **consent will be oral** (in-person, via telephone or during video call), append a copy of the script that will be used to document the consent process and will be given to the research participant for his/her information.  The information/consent form or oral script is attached:  Yes  No Not applicable  For templates of Information/Consent Forms please [visit our Web site](https://savoirmontfort.ca/en/research/research-ethics/ressources/formulaires-et-gabarits/) |
| 1. Describe the consent process (e.g., who will obtain consent and how will the research staff ensurethat “informed” consent has been obtained?). In the case of oral consent, include a description of how and where the consent for each participant will be documented. Not applicable |
| 1. Is there a relationship (e.g., physician-patient, employer-employee, and professor-student) between the participants and the person obtaining consent? Yes  No Not applicable   **If yes**, explain the nature of the relationship and describe the steps that will be taken to minimize the potential risk of coercion, real or perceived. |
| 1. Will personal health information be accessed without first obtaining consent?  Yes  No  Not applicable   **If yes,** provide justification. As required by the Personal Health Information Protection Act, also attach a copy of the agreement between the health care custodian and the study’s investigator(s) that outlines the terms and obligations imposed upon the investigators when using personal health information for research purposes without obtaining the patient’s consent. |
| 1. For studies that involve more than one contact with participants, describe the methodology that will be used to ensure that the participant’s consent is maintained.  Not applicable |
| 1. For studies where informed consent is not obtained, justify under the requirements specified in articles [2.1](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#1:~:text=are%20defined%20in-,Article%202.1,-.%20Some%20research%20is), 2.3 and 2.8 of *TCPS2*.  Not applicable |
| 1. If any deception or partial disclosure is involved in the design of this study (consult TCPS2, chapter 3 [Articles 3.7A and its application](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#d:~:text=Note%20that-,Article%203.7A,-does%20not%20address)) You must describe:  * The rationale or justification for the planned deception or partial disclosure, * The reason(s) for using this strategy, * The approach proposed for debriefing participants and the reason for not having participants affirming their informed consent for the research (attach a copy of document(s) that will be used). |
| 1. Is it likely that information generated could influence the will of participants to pursue their involvement during the course of this study?  Yes  No   **If yes**,ongoing consent is required, describe how it will be obtained. |
| l) Will the data collected potentially be used for other purposes in the future (secondary analyses)?  Yes  No  Not applicable  **If yes,** participants must be informed of this possibility in the consent form or in the instructions that will be handed out with the research tools/questionnaires in order to obtain their consent and indicate that any secondary use of the data will be authorized by an REB. |
| 1. Fortuitous or unanticipated discoveries are made during research and are outside the scope of the research (Glossary, TCPS2). Do you anticipate that your project can produce incidental findings.  Yes  No   **If yes**, justify the procedure that will be used to manage an incidental findings (see art. [3.3](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#3)). |

|  |
| --- |
| **18 A) PROCEDURES FOR ALTERING THE CONSENT REQUIREMENTS (**[**Articles 3.7A**](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#7a) **of TCPS2)** |
| |  | | --- | | The REB may approve research that involves an alteration to the requirements for consent set out in [Articles 3.1](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#1) to [3.5](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#5) |   Please demonstrate that your request proposing an alteration(s) to the regular consent process meets all the elements listed below:   1. the research project involves no more than minimal risk to the participants. |
| 1. the alteration(s) to consent requirements is(are) unlikely to adversely affect the welfare of participants. |
| 1. it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required. |
| 1. the precise nature and extent of any proposed alteration(s) proposed alteration is defined. |
| **19. COMPETENCY TO GIVE CONSENT (PFN 701)** |
| 1. Does the research study include the participation of people who may not be capable of giving informed consent?  Yes   No   **If yes**, justify and explain why they have been included in the research and how consent will be obtained and from whom.  Describe what plans are in place to regularly assess capacity to consent and obtain consent if the individual later becomes capable of providing consent. |
| 1. For studies involving the participation of people for whom decision-making authority can be questioned, please describe the methods that will be used in order to assess the ability of the participant to consent. |
| 1. For the participants incapable of consenting, please explain how and from whom the consent will be obtained. Also, explain how you will make sure that the consent obtained from a third party will be valid for the duration of the study provided that the participant remains unable in this regard. |
| 1. For studies involving the participation of people for whom decision-making authority can be questioned, please specify the methodology used to periodically assess the participant's ability to consent and how you will proceed if it becomes possible to obtain the consent of the participant. |
| 1. For studies involving the participation of people for whom decision-making authority can be questioned, please specify the measures taken to ensure that participants demonstrating behaviors of dissent will be excluded when recruiting or withdrew from the study. |
| f)Does the research study involve emergency situations where consent cannot be obtained?  Yes  No  If yes, please provide justification for proceeding without consent, and describe plans to seek consent to use the data if the individual later becomes able to provide consent. |
| **20. RISKS, BENEFITS AND USUAL STANDARD OF CARE** |
| 1. Identify if participants enrolled in this project will be exposed to the following kind of risk   psychological  physical  social  other  Please submit a plan to manage/minimize each identified risk will be managed:   |  | | --- | | **NOTE:** If the risk is serious, please provide a security protocol with measures to effectively address the materialization of the risks. | |
| 1. For research studies involving patients, document the usual standards of care for this population in the research site facility and describe how the usual standards of care will be affected for patients participating in this study. If changes in the standards of care should vary according to the group to which patients will be assigned, document the changes in the usual care for each group.  Not applicable |
| 1. For research studies that do not involve patients and where research participants will be recruited from other sources (e.g., general public), indicate the frequency, duration and nature of contacts with research participants that are required by the study.  Not applicable |
| 1. Document the risks associated with the study. When the research participant is a patient, document the risks as compared to the usual care that the patient would receive. If the risks vary according to the group to which patients are assigned, document the risks for each group. |
| 1. Will participation in this study affect alternatives for the future care of the participant? |
| 1. Will the management of the participant’s condition be prolonged or delayed because of the research?  Yes  No  Not applicable   **If yes**, describe any risks associated with prolongation or delay (e.g., washout period, withholding of treatment or absence of treatment). |
| 1. Are there any standard therapies, diagnostic procedures, or information to be withheld from participants for the purpose of the study?  Yes  No  Not applicable   **If yes**, describe the risks and benefits to the participants. In the case of risks to the research participant that go beyond those of usual care, please provide the justification for exposing the research participants to these additional risks. |
| 1. Are there any restrictions being placed on the study’s participants?  Yes  No   **If yes,** please explain. |
| 1. Are placebos being used?  Yes  No   **If yes**, please explain and provide justification according to the TCPS2 [chapter 11](https://ethique.gc.ca/fra/tcps2-eptc2_2022_chapter11-chapitre11.html). |
| 1. Does this study involve any deception of, (partial disclosure, withholding information) from study participants?  Yes  No   **If yes**, please provide the justification for employing these techniques. |
| 1. Outline the criteria for the early withdrawal of research participants. |
| 1. Describe any possible benefits to the research participants as a result of their participation in the research study. |
| **21. CONFIDENTIALITY AND PARTICIPANT’S RIGHTS** |
| 1. List the types of records containing personal and health information that you will accessed and whether the requirements have been met and ~~access has been~~ approved by the custodian.  * Please submit proof that you will comply with the requirements of the information custodian and obtained permission to access the data (paper or electronic). |
| 1. List the personal information or health information that will be collected for the purpose of this study and why they are required. The use of:  * full name * partial date of birth and death: * sex/gender * full postal code: * first 3 digits of postal code: * health card number: * Medical chart number (including specimen sample number): * social security number * telephone number: * email address/internet protocol address (IP) * information from Medical History needed: * Other: (please specify) |
| 1. Describe how and when the data will be encoded to remove all personal identifiers from the data collected during the study. |
| 1. If data containing personal identifiers will not be encoded at the earliest opportunity, please justify.  Not applicable |
| 1. Please indicate where the code-list will be stored and when it will be destroyed. Please note that the Health Records Departments of some facilities offer a service to store code-lists over long periods of time (e.g., 15 years). |
| 1. Please justify, why data containing personal identifiers will be transferred to another facility and how the confidentiality of this data will be ensured at the receiving facility. The transfer of information to another facility should also be described in the information/consent form. |
| 1. Please indicate the period in which the data will be saved, how it will be deleted, and measures taken to ensure the confidentiality of the stored research data. |
| 1. If your study involves the collection of human biological samples (e.g., Blood, tissue, urine, etc.), please indicate if the personal identifiers will be removed from the samples, where the samples will be stored, for what period of time and how you plan to destroy the samples. |
| 1. Please indicate what personal identifiers and health information  * will be collected and RETAIN LOCALLY/on-site for the purposes of this study (e.g., recruitment tools, contact with participants, shadow files, recruitment, or screening logs)? * will be transferred OUTSIDE the local institution using one of the following secure methods.   + Data transfer agreement   + Secure network   + Other, please specify |
| **22. MONITORING** |
| a) Is there a plan to monitor the study (e.g. internal audits or sponsor-initiated site visits)?  Yes  No  **If yes**, describe briefly and append the plan as an appendix. |
| 1. For sponsor-initiated research (e.g., drug trials, medical devices) is there a data safety monitoring board in place?  Yes  No  Not applicable     **If yes**, describe the composition of the board’s members. Are the board’s members independent of the study and/or sponsor? |
| c) Are there interim analyses planned?  Yes  No  **Is yes**, describe briefly. |
| d) Describe the stopping rules for the study. |
| **23. PUBLICATION AND DISSEMINATION OF RESULTS** |

|  |
| --- |
| 1. If this study is funded, will the investigator(s) require the approval of the sponsor(s) before publication or dissemination of the results?  Yes  No  Not applicable   **If yes,** please explain. |
| b) Please describe the plan for publication and other dissemination of the study’s results. |
| c) Will a summary of the results be available in multiple languages?  English  Yes  No  French  Yes  No  Other  Yes  No  **If yes**, specify**.** |

|  |
| --- |
| **24. BUDGET** |

|  |
| --- |
| 1. Has this research been funded? Yes  No |
| b) If **yes**, provide the:  Name of the Agency/Sponsor:  Name of the Contact Person for the Agency/Sponsor:  Address:  Telephone:  E-mail Address:  Agency/Sponsor Protocol number (if applicable):  **Amount of funding received:** $ |
| c) **If no**, has funding been applied for:  Yes  No  **If yes**, please provide the name of the Agency/Sponsor:  Amount of funding applied for:        Date submitted:   /  /    (DD/MM/YYYY) |
| d) A detailed budget is attached as an appendix. Yes  No |
| e) If there is no funding or insufficient funding for this project, how will the cost of the study be financed? |

|  |
| --- |
| **25. CONTRACTS** |

|  |
| --- |
| 1. Please list and attach copies of all contracts/agreements with the corporate sponsor(s), public funding agencies or other parties (e.g., copyright holders) that are related to this study. These contracts/agreements may include but are not limited to clinical trial agreements, material transfer agreements involving human material and licensing agreements for the use of copyrighted materials.     All contracts have been forwarded to the relevant departments at the research site.  Yes  No  Not applicable  If no, please explain. |
| 1. Please indicate who will cover the costs of treatment not covered by the provincial health plan in case of injury directly resulting from participation in a research study (e.g. sponsor, research facility or university). |

|  |
| --- |
| **26. POTENTIAL CONFLICTS OF INTEREST** (SOP 105B et PFN 105BB) |
| 1. Please indicate whether the Principal Investigator, the Responsible Site Investigator or any Co-Investigators or other research staff involved in this research study or any member of their immediate family:   i) function as an advisor, employee, officer, director, or consultant for the study sponsor?  Yes  No  ii) have direct or indirect financial interest in the sponsoring corporation (e.g., stocks) drug, device or technology employed (e.g., patents) in this research study?  Yes  No  iii) will receive an honorarium or other financial benefits from the sponsor (apart from fees  for service or regular salary)?  Yes  No  iv) are receiving incentives to recruit research participants for this study?  Yes  No  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. |

|  |
| --- |
| b) Does this study comply with the current “conflict of interest” policies of the research site facility?  Yes  No  Not applicable  If **no or not applicable**, please explain. |

|  |
| --- |
| **27. CONTINGENCY PLANNING IN CASE OF EMERGENCY** (SOP 501) |
| According to the current procedure SOP 501.001 when an emergency situation has been declared, a contingency plan to anticipate the steps that need to be taken, should be implemented, please describe the specific steps that could be taken if a suspension of activities at the hospital research site is necessary. If the health of the research participants may be adversely affected by the suspension of the project, please outline the steps that will be taken to mitigate those risks and protect the interests of the research participants. |