**BRUYÈRE HEALTH RESEARCH ETHICS BOARD**

**SUBMISSION FORM – GENERAL**

**INSTRUCTIONS:**

1. The REB Submission Checklist **must** accompany this submission to be considered for REB review.
2. TCPS 2 Certificates issued with the last **5 years** for all research personnel **must** accompany this submission to be considered for REB review.
3. Please refer to the **BREB Application Guidelines** when completing this application. All sections of this Application must be completed or it will not be considered for an ethical review by the Bruyère Health Research Ethics Board (REB). **Unless specifically indicated, do not refer to, or attach other documents as a means to complete a section of the REB application.**
4. A complete application and supporting documents (e.g. original study protocol if applicable, consent form(s), investigator’s brochures, recruitment and other materials) must be submitted to the REB for review. It is the responsibility of the applicant to contact the Bruyère Health REB for instructions regarding the preparation of forms and other documents, review requirements, submission deadlines, etc.
5. For Chart Review, Database Review and Secondary Use of Information studies, please use the **BREB – Chart/Database Review & Secondary Use, found on the REB website:** [**https://www.bruyere.org/en/researchethicsboard**](https://www.bruyere.org/en/researchethicsboard)

***\*If you are recruiting Bruyère Health*** ***patients (in-patients and out-patients), residents, tenants, family members, staff, students or volunteers, please complete the Impact Form, along with the appropriate director/manager signatures. Once your application is completed, please send this application, all appendices and the Impact Form (if applicable) to the REB office for review:*** [***REB@bruyere.org***](mailto:REB@bruyere.org)

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| --- | --- | --- |
| 1. **VERSION DATE** *(Please enter a new version date every time this form is re-submitted with changes)* | | |
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| 1. **FULL STUDY TITLE** *(Ensure title is consistent on all submitted documents/materials)* | | |
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| 1. **STUDY DURATION** | | |
| Expected Start Date:  Expected Completion Date: | | |
| 1. **REVIEW TYPE** | | |
| Full Review  Expedited Review (Expedited reviews are generally limited to minimal risk studies where the probability and  magnitude of possible harms is no greater than those encountered in everyday life (TCPS2 Ch. 2) and studies  that have received the prior approval of another REB). If requesting expedited review, give a brief justification. | | |
| 1. **STUDY ORIGIN** | | |
| 1. **Please check one:**   **Investigator Driven**  **Industry/External Sponsor Driven**  *(Please note that any contract or agreement with the*  *Sponsor/Funder must be submitted to your Research*  *Services Manager)* | 1. **If a Health Canada regulated clinical trial, please identify the sponsor responsible for submitting the Health Canada clinical trial application (CTA):**   Bruyère HealthRI (investigator-initiated)  External Sponsor  ***(For all regulated clinical trials, please contact the BHRI Clinical Trials Manager prior to proceeding with this application)*** | |
| 1. **FUNDING OF STUDY** | | |
| 1. Has this research been funded?  Yes  No | | |
| If yes, provide the following:  Name of the Agency/Sponsor/Grant/Award:    Name of the Contact Person for the Agency/Sponsor:    Agency/Sponsor Reference number (if applicable):    Amount of funding received: | If no, has funding been applied for?  Yes  No  If yes, provide the name of agency/Sponsor/Grant/Award:    Amount of funding applied for:    Date submitted:    *\*Please note that for regulated clinical trials, you must provide proof of funding with this application.* | |
| 1. A detailed budget is attached as an appendix.   Yes  No  If no, explain: | | |
| 1. If there is no funding or insufficient funding for this study, how will the costs of the study be met? *(Please do not leave this section blank)* | | |
| 1. **TEAM OF INVESTIGATORS** | | |
| 1. **Principal Investigator** *(This individual has the overall responsibility for the study at all research sites. If the Principal Investigator is a student or trainee, the Student/Trainee Supervisor must be affiliated with Bruyère Health and be the PI’s supervisor)* | | |
| **Last Name:** | **First Name:** | |
| **Title/Position:** | **Phone Number:** | |
| **Department/Unit:** | **Email Address:** | |
| **Division/Portfolio:** | **Signature:**  **Date:** | |
| 1. **Check if applicable:** *(Please note that for multi-site research that also involves Bruyère Health, the Bruyère Health investigator may be listed in the co-investigator section.)*   **Bruyère Health Student/Trainee Supervisor:** If the Principal Investigator is a student/trainee or has no  affiliation with Bruyère Health, identify the Bruyère Health Researcher who will serve as the study’s contact  person for the Bruyère Health REB. | | |
| **Last Name:** |  | |
| **Title/Position:** | **Phone Number:** | |
| **Department/Unit:** | **Email Address:** | |
| **Division/Portfolio:** | **Signature:**  **Date:** | |
| Principal 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 2: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization – Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004, and the Food and Drug Act of Health Canada and its applicable regulations, and any other relevant regulations or guidelines endorsed by Bruyère Health, and the Bruyère Health Research Institute. I certify that all researchers and other personnel involved in this study at this institution are appropriately qualified and experienced, or will undergo appropriate training and supervision to fulfill their role in this study.  By checking here, I certify that I meet the requirements of a “Qualified Investigator” as defined by Health Canada.    Not applicable ***(if this is not a regulated clinical trial, please check this box)*** | | |
| 1. **Co-Investigators** (duplicate this section as necessary) | | |
| **Name:**  **Title/Position:**  **Department/Institution:**  **Email Address:** | | **Name:**  **Title/Position:**  **Department/Institution:**  **Email Address:** |
| **Name:**  **Title/Position:**  **Department/Institution:**  **Email Address:** | | **Name:**  **Title/Position:**  **Department/Institution:**  **Email Address:** |
| 1. **Study Staff** (List all significant study personnel, including email addresses and phone numbers) | | |
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| 1. **STUDY TYPE AND DESIGN** | | |
| 1. Study Type (check all that apply):   Experimental (Drug, Device or NHP)  **Drugs, biologics, radiopharmaceuticals:**  Phase I  Phase II  Phase III  Phase IV  **Medical Devices**  Class I  Class II  Class III  Class IV  **Natural or non-prescription health products**    Observational (No clinical intervention involved)  Pilot Study  Qualitative (Interviews, focus groups, etc.)  Chart Review (For studies that are only chart  reviews, please use the ***Chart Review/Database***  ***Review/Secondary Use BREB form***)  Genetic Research (***Genetic Addendum*** must be  included with application)  Survey Research  Other (describe): | 1. Study Design (check all that apply):   Controlled Experimental Study (e.g. Randomized  Controlled Trial)  Case-Control Study  Cohort Study  Cross-Sectional Study  Longitudinal Study  Case Study  Quality Assurance Study  Within a single facility  Across multiple facilities  Other (describe): | |
| 1. **RESEARCH STUDIES REQUIRING HEALTH CANADA OR FDA APPROVAL**  Not Applicable (skip to s. 10) | | |
| Drug/Device/Natural Health Product Trial  Health Canada No Objection Letter is attached.  Health Canada No Objection Letter will be forwarded to the REB office as soon as it is available. This is  mandatory to final approval. | | |
| **NOTE:** TCPS2 requires that all interventional clinical trials be registered with 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. The ICMJE adheres to 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 includes drugs, procedures, devices, behavioural treatments, etc.  Please indicate, according to the definition above, if your study requires clinical trial registration:  Yes Please provide the registration site (e.g. clinicaltrials.gov):  Clinical trial registration number:  *(Please note that this number needs to be added to all informed consent forms)*  No Please justify why this is not necessary | | |
| 1. **STUDY SUMMARY** | | |
| This summary must be suitable for lay audience (approximately 200 words). Briefly outline the study purpose and give an overview of research procedures involving participants. Do not refer the reader to sections of an attached protocol. | | |
| 1. **PURPOSE AND OBJECTIVES** *(please provide a brief description)* | | |
| 1. Justify the need for this study. Clearly outline its background and rationale. | | |
| 1. What are the objectives of the study and, if applicable, the hypotheses to be tested. | | |
| 1. What is the clinical relevance of the study, if any.   No clinical relevance | | |
| 1. **DESCRIPTION OF METHODS AND PROCEDURES** | | |
| 1. Describe the study design and methods. | | |
| 1. Describe the nature, frequency, and duration of research participation required by the study. | | |
| 1. Data Collection Methods (How will data be collected, for example, by clinical testing, physiological monitoring, survey, interview, focus group or other. Photos, audio-recording, and video-recording require explicit written consent). | | |
| 1. What are the Primary Outcome Measures? (Describe the measures that will be used in this study and appropriateness of these measures for this study). | | |
| 1. Collection of Biological Samples (Describe the collection of any biological materials, including tissue or fluids. If samples will be retained, explain how, and for how long. If samples are to be destroyed, when will this be done?). | | |
| 1. Does this study involve any deception, or withholding information from study participants?   Yes  No  If yes, justify these techniques. Also, describe the plan for de-briefing and opportunities for the participants to withdraw their data. Any variation from these rules must be justified. | | |
| 1. Analysis Plan (Provide the plan for the statistical analyses of the study’s results). | | |
| 1. **SAMPLE SIZE AND RESEARCH SITES** | | |
| 1. Total number of research participants recruited at all study sites globally: | | |
| 1. Total number of sites:   Recruitment sites (please list all places/departments you are planning to recruit in):  List countries: | | |
| 1. Number of research participants to be recruited at Bruyère Health: | | |
| 1. How was the sample size determined? Justify the number of participants to be recruited. | | |
| 1. Is the enrollment of individuals into multiple studies likely to be an issue in this participant population?   Yes  No   1. How was the answer determined? individuals into multiple studies likely to be an issue in determined? | | |
| 1. **DESCRIPTION OF STUDY POPULATION** | | |
| 1. Inclusion Criteria – Who is being recruited and what are the criteria for their selection? | | |
| 1. Exclusion Criteria – Who is being excluded from the study participation. Explain if needed. (There is no need to list the opposite of what is listed in the inclusion criteria) | | |
| 1. What linguistic groups will be recruited?   French-speaking  English-speaking  Other (specify):  **Note:** 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 REB review prior to use. | | |
| 1. **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, email, website and/or advertisement, attach copies. For studies recruiting participants from different linguistic groups, forward the translated texts for REB approval prior to use.   Translated texts will follow:  Yes No  Not applicable | | |
| 1. If recruiting participants at Bruyère Health, identify the units/programs/departments, etc., you will be recruiting from, and which members of the units in question you have engaged in this study. | | |
| 1. If the identification of prospective participants will involve using information from their personal health information record, how will the participant’s agreement to be contacted by the researcher(s) be obtained?   Not applicable    Please identify what personal health information will be collected, used or disclosed from patient-participant records:  None, participant ID only  Full name  Age  Partial initials  Full initials  Partial date of birth  Sex/Gender  Address  First 3 digits of postal code  Admission date  Full Postal code  Medical record number  OHIP #  Full face photograph  Telephone number  Email address  Discharge date  Other: Click or tap here to enter text.  ***Please note:*** *Prior to accessing patient charts/health records at Bruyère Health, you must obtain approval from the Bruyère Health Privacy Office first. Contact the Privacy Office:* [*chartaccess@bruyere.org*](mailto:chartaccess@bruyere.org) | | |
| 1. Once identified, explain how prospective research participants be approached for recruitment, and how the researcher will ensure that there are no breaches of a prospective participant’s privacy during this process. | | |
| 1. 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 incentives, compensation or reimbursement?   Yes No  If yes, give the amount and purpose of any payments or compensation (e.g. reimbursement for expenses, gifts/incentives for participation, etc.). | | |
| 1. Commission fees paid to health professionals or research staff for the successful recruitment of research participants is prohibited. However, reimbursement for time spent recruiting is permitted. If fees are to be paid to caregivers for the recruitment of participants, provide details below.   Not applicable | | |
| 1. **PROCEDURES FOR SEEKING INFORMED CONSENT** | | |
| 1. Are you requesting any alterations to the consent requirements? (e.g. a waiver of all or partial consent requirements)   Yes No  If yes, describe and justify: | | |
| 1. Will “written” informed consent be obtained from the study participants (or their legal representative)?   Yes No If yes, attach a copy of the form(s). If no, describe and justify the consent process. | | |
| 1. What is the reading comprehension grade level of the information/consent form?   Describe how this was determined and justify in light of the expected reading level of the participant population. | | |
| 1. If consent will be verbal (in-person, telephone or other virtual means), include a copy of the consent script or virtual text that will be used during the consent process.   Will participants be given a copy of the consent text for their information?  Yes No  For a description of elements required by the TCPS2 to be included in the consent form(s) and consent process, see Appendix A of the Guidelines.  The information/consent form or verbal script is attached.  Yes No  Not applicable | | |
| 1. Describe the consent process (e.g. who will obtain consent and how will the research staff ensure that informed consent has been obtained?). In the case of verbal consent, include a description of how and where such consent for each participant will be documented. | | |
| 1. Is there a relationship (e.g. physician-patient, employer-employee, 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 of undue influence, real or perceived. | | |
| 1. Will personal health information be accessed without first obtaining consent?   Yes No  If yes, provide justification: | | |
| 1. For studies that involve more than one contact with participants, describe how you will ensure ongoing consent and decision-making capacity.   Not applicable | | |
| 1. Does the research study involve emergency situations where consent cannot be obtained?   Yes No  If yes, provide justification for proceeding without consent, referencing the provisions of [TCPS2 Art. 3.8](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html), and describe plans to seek consent to use the data if the individual later becomes able to provide consent or the individual’s legal representative is found (see the Guidelines for all of the conditions that must be met): | | |
| 1. **CAPACITY TO GIVE CONSENT** | | |
| 1. Does the research study include research participants who may not be capable of giving informed consent?   Yes No  If yes, justify according to the conditions outlined in the Guidelines:  *\*Please note that participants initially determined to be incapable must later give their own consent if they regain capacity. Likewise, if participants initially determined to be capable later loses capacity, an appropriate substitute decision maker must give consent to continue in the study.* | | |
| 1. For those participants who are not capable of providing informed consent, describe how consent will be obtained and from whom. If assent is to be obtained from minor participants, attach an Assent Form.   Not applicable | | |
| 1. **RISKS AND BENEFITS** | | |
| 1. Describe the risks associated with the study, including physical, psychological/emotional, social/legal/economic, and privacy. | | |
| 1. Describe any possible benefits to the research participants because of their participation in the research study. *(**Please note that receiving incentives, reimbursements or compensation is not considered a benefit)*   Not applicable | | |
| 1. **USE OF PATIENTS AS RESEARCH PARTICIPANTS** | | |
| 1. For research studies involving patients (people who have an illness or conditions relevant to the study), describe how the usual standard of care for such patients will be affected, and how the risks may be affected by the presence of such illness or condition.   Not applicable (If not applicable, skip to section 20)  If changes in the standard of care will vary according to the group to which patients are assigned, describe the changes in the usual care for each group. | | |
| 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 any such standard therapies, and risks and possible benefits to participants. In the case of risks to the research participant that go beyond those of usual care, provide the justification for exposing research participants to additional risks. | | |
| 1. Are placebos being used:   Yes  No  If yes, explain and provide justification – see Guidelines. | | |
| 1. Will participation in this study affect alternatives for the future care of the patient-participants?   Yes  No  Not applicable  If yes, describe. | | |
| 1. Will the management of any patient-participant’s condition be prolonged or delayed as a result of the research?   Yes  No  Not applicable  If yes, describe any risks associated with treatment prolongation or delay (e.g. washout period, withholding of treatment, or absence of treatment). | | |
| 1. Are there any restrictions being placed on the study’s participants? For example, dietary restrictions (eating or drinking), medications, recreational drugs, nicotine, becoming pregnant, exercise, etc.   Yes  No  If yes, explain: | | |
| 1. Outline the criteria for the early withdrawal of research participant(s) by the study team. | | |
| 1. Under what circumstances will the study be stopped? | | |
| 1. **CONFIDENTIALITY** | | |
| 1. Describe any medical or other records containing personal information to be accessed for the study.   Not applicable    Describe the health information custodian’s requirements for access, and how the requirements have been met  and access has been approved. | | |
| 1. To what extent will the participants’ personal information be identifiable:   Directly identifying information (individual may be readily identified from data)  Indirectly identifying information (individual may reasonably be identified through a combination of indirect  identifiers)  Coded information (there is a code linking study data with personal identifiers and stored apart from the data;  information is not otherwise identifiable)  Anonymized or anonymous information (individuals may not be identified from data)  Explain if needed. | | |
| 1. Describe the process for collection, use and storage of participants’ personal information: | | |
| 1. Will the data collected during the course of the study be coded to remove all personal identifiers from the data?   Yes  No  Not applicable  If yes, describe how and when this will be done. | | |
| 1. If data containing personal identifiers will not be anonymized or coded at the earliest opportunity, justify:   Not applicable | | |
| 1. Describe where data will be stored and the security measures (e.g. encryption, password protection, locked file cabinet, etc.) to be used to maintain confidentiality of identifiable data, including the storage mediums to be used. For online data, describe the platform or sites to be used.   Will participant IP addresses be recorded, and are there any other special limits to privacy?  Yes  No    Indicate the country in which the server housing the data is located. | | |
| 1. If data containing personal identifiers, or de-identified data, will be transferred to another facility, justify and describe the confidentiality measures to be used at the receiving facility. Please submit a copy of any Data/Materials Transfer or similar Agreement related to such transfer when available. (Please note the transfer of information should also be described in the information/consent form) | | |
| 1. Indicate whether data, including code list(s), will be retained, and if so, how long? If it will be destroyed, describe how. | | |
| 1. Describe the proposed services of a translator or transcriber in handling and protecting personal information.   Indicate whether a confidentiality agreement will be used. | | |
| 1. If your study involves collection of any biological specimens (e.g. blood, tissue, urine, etc.) indicate whether specimens are de-identified, where specimens will be stored, for how long, and how they will be destroyed. *(Please note that if long-term storage of specimens is planned, you must complete the Genetic Addendum)*   Not applicable | | |
| 1. **MONITORING** | | |
| 1. Is there a plan to monitor the study (e.g. internal audits or sponsor-initiated site visits)?   Yes  No  Not applicable  If yes, briefly describe and attach the written plan if there is one.    *(Please contact the* ***BHRI Clinical Trials Manager*** *for assistance, if required)* | | |
| 1. For industry/sponsor-initiated research (e.g. drug trials, medical devices), is there a data safety monitoring board, or a Data Monitoring Committee, or something similar in place?   Yes  No  Not applicable | | |
| 1. **PUBLICATION AND DISSEMINATION OF RESULTS** | | |
| 1. Describe the plan for publication and other dissemination of the study’s results. | | |
| 1. Will the investigator(s) require the approval of the sponsor or funder before publication or dissemination of the results?   Yes  No  Not applicable  If yes, explain: | | |
| 1. Will a summary of the results be available in multiple languages?   English  Yes  No  French  Yes  No  Other  Yes  No If yes, specify: | | |
| 1. Will you be offering to send participants a summary of results once the study is finished?   Yes  No  If yes, this option must appear in the consent form(s)  If no, explain: | | |
| 1. **CONTRACTS** | | |
| 1. Have all study contracts been approved by the relevant departments at the research site? These contracts/agreements may include, but are not limited to, clinical trial agreements, data sharing agreements, service agreements, material transfer agreements involving human material, and licencing agreements for the use of copyrighted materials.   Yes  No  Not applicable  If no, explain:    *(**Please contact your Research Services Manager for assistance)* | | |
| 1. 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)? | | |
| 1. **POTENTIAL CONFLICTS OF INTEREST** | | |
| 1. Will the Principal Investigator, Student/Trainee Supervisor, or any Co-Investigators or other research staff involved in this research study, or any member of their immediate family: 2. Function as an advisor, employee, officer, director or consultant for the study sponsor?   Yes  No   1. 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   1. Receive an honorarium or other financial benefits from the sponsor (apart from fee for service or regular   salary)?  Yes  No   1. Receive incentives to recruit research participants for this study   Yes  No  **If the answer is yes to any of the above questions, please complete the Conflict of Interest Declaration.** | | |
| 1. **DIVISION/DEPARTMENTAL SIGN-OFF** | | |
| You are required to submit an **Impact Form** if you are recruiting Bruyère Health patients (inpatients or outpatients), residents, tenants, family members, caregivers, staff, or volunteers OR if a member of a Bruyère Health unit/department are being asked to perform any of the following tasks:   * Share recruitment information (email, poster or brochure) with potential participants (Bruyère Health staff or volunteers only) * Assist with scheduling participant sessions/travel * Identify potential participants * Accompany patient on transport to other areas * Obtain consent to contact & share with research team * Sample collection/preparation of requisitions * Education & training of clinical staff * Additional documentation added to patient record for study purposes * Perform procedure(s) * Staff involvement in use of study equipment or new procedure/process * Assist researcher/research staff with procedure(s) * Change of practice for Bruyère Health staff * Collect and document data (on form other than standard healthcare documents) * Monitor vital signs * Administer medication * Other   **Once the Impact Form is signed by the appropriate unit/department, please include it with your ethics submission to the REB.** | | |
| 1. **CONTINGENCY PLANNING** | | |
| Outline the contingency plans for this study if the research hospital site becomes closed to all but essential personnel during an epidemic, pandemic or civil disaster. In the contingency plan, describe the specific steps that will be taken to suspend the study at the hospital research site. If the health of the research participants may be adversely affected by the suspension of the study, outline the steps that will be taken to protect the interest of the research participants. | | |
| 1. **IMPROVING THE CLARITY AND USABILITY OF THIS FORM** | | |
| If you have any suggestions to make this form clearer, easier to use, or to ensure that it captures all ethically relevant information, please email the REB office at: [REB@bruyere.org](mailto:REB@bruyere.org) | | |
| **Notice with Respect to the Collection of Personal Information** | | |
| The personal information requested on this form is collected in accordance with ***“Freedom of Information and Protection of Privacy Act”*** (FIPPA). The information provided will not be used for any purposes other than those stated upon this form unless you provide consent. Should you have any questions concerning your personal information, please email the REB office at: [REB@bruyere.org](mailto:REB@bruyere.org) | | |