REB#:

**BRUYÈRE RESEARCH ETHICS BOARD (BREB)**

**SUBMISSION FORM – GENERAL**

**Contact the REB Office:** **REB@bruyere.org**

**Visit the REB Website:** [**https://www.bruyere.org/en/researchethicsboard**](https://www.bruyere.org/en/researchethicsboard)

**INSTRUCTIONS:**

1. The REB 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 **Bruyère 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 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 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)

***\*Once your application is completed, please send the application, all appendices and the Research Study Summary to your Research Services Manager for review and to obtain the Section 25 signature. When this is completed, please send your application and all appendices to the REB office for review:*** ***REB@bruyere.org***

|  |
| --- |
| 1. **VERSION DATE** *(Please enter a new version date every time this form is re-submitted with changes)*
 |
|   |
| 1. **FULL STUDY TITLE** *(Ensure title is consistent on all submitted documents/materials)*
 |
|   |
| 1. **STUDY DURATION**
 |
|  Expected Start Date:Click or tap to enter a date.Expected Completion Date: Click or tap to enter a 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):**

 [ ] BRI (investigator-initiated) [ ]  External Sponsor  |
| 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: Click or tap to enter a date.*\*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?
 |
| 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 and be the PI’s supervisor)*
 |
| **Last Name:** | **First Name:** |
| **Title/Position:** | **Phone Number:** |
| **Department/Unit:** | **Email Address:** |
| **Division/Portfolio:** | **Signature:****Date:** Click or tap to enter a date. |
| 1. **Check if applicable:** *(Please note that for multi-site research that also involves Bruyère, the Bruyère investigator may be listed in the co-investigator section.)*

[ ]  **Bruyère Student/Trainee Supervisor:** If the Principal Investigator is a student/trainee or has no affiliation with  Bruyère, identify the Bruyère Researcher who will serve as the study’s contact person for the Bruyère REB. |
| **Last Name:** | **First Name:** |
| **Title/Position:** | **Phone Number:** |
| **Department/Unit:** | **Email Address:** |
| **Division/Portfolio:** | **Signature:****Date:** Click or tap to enter a 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, and the Bruyère 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 |
| 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)
 |
|  |
| 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 [ ]  NoIf 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:

List countries:  |
| 1. Number of research participants to be recruited at Bruyère:
 |
| 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 [ ]  NoHow was the answer 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, 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, you must obtain approval from the Privacy Office first. Contact the Privacy Office:* *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 applicableIf 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 applicableIf 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 [ ]  NoIf 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 applicableIf 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 applicableIf 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:

Click or tap here to enter text. |
| 1. Will the data collected during the course of the study be coded to remove all personal identifiers from the data?

 [ ]  Yes [ ]  No [ ]  Not applicableIf 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.  |
| 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 applicableIf 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/agreement 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/DEPARTMENT/PROGRAM APPROVAL**
 |
| This should not be completed by an administrator who is listed as the study’s Principal Investigator, Student/Trainee Supervisor, Co-Investigator, or anyone else listed on this application. *(If this section is signed by anyone listed on the application form, the application will be returned)*All applications being submitted to the Bruyère REB must be reviewed and approved by BRI **prior to REB submission**. To facilitate this review, please contact your **Research Services Manager**.All research that involves recruiting participants from within Bruyère requires the approval from the appropriate Bruyère Director and Medical Chief. To obtain this approval, the **Research Study Summary** must be provided to the Director and Medical Chief, and the applicable unit manager(s) must verify that their unit(s) is/are in agreement with this study and has the resources to support it as outlined in the Bruyère REB application. Include as many copies of this form as are needed – one per signature.  |
| **I have reviewed this application and by signing below, I certify that:**1. The study is consistent with hospital/faculty policies and mission.

[ ]  Yes [ ]  No [ ]  Not applicable 1. 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 applicable1. There are an adequate number of research participants suitable to be approached for enrolment for this study.

[ ]  Yes [ ]  No [ ]  Not applicable1. This population is not being excessively recruited for clinical research.

[ ]  Yes [ ]  No [ ]  Not applicable1. The study complies with the guidelines outlined in the most recent version of the Bruyère Research Institute “**Procedure Manual on Conducting Face-to-Face Research during a Pandemic**.”

[ ]  Yes [ ]  No [ ]  Not applicable***Note:*** *In the case where a study will affect more than one financial cost centre within a facility, separate copies of Section 25 should be completed for each cost centre. Contact the REB to identify the appropriate administrators.* |
| **Name:** **Title/Position:** **Dept/Unit & Location:** **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Date:** Click or tap to enter a date. | **Name:** **Title/Position:** **Dept/Unit & Location:** **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Date:** Click or tap to enter a date. |
| 1. **CONTINGENCY PLANNING**
 |
| 1. 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   |
| **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 |