Research Ethics Board
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Bruyère Research Ethics Board

BRUYÈRE CONTINUING CARE REB (BREB)
SUBMISSION GUIDELINES

All research projects involving Bruyère Continuing Care and Bruyère Research Institute physicians, staff, students or patients must obtain ethical approval from the Research Ethics Board (REB) before research involving human participants can begin. The REB and the investigators are responsible for ensuring that research conducted under the auspices of Bruyère meets current ethical standards, including the requirement for prior review of all research involving human participants. Heads of departments/divisions and programs are responsible for ensuring that all such research is submitted for ethics review.

Note that information contained in Sections 2, 4, 6 a) and b), 9, and the study's approval status may be released to the general public through annual reports or other forms of information released by the research site facility or its affiliated institute(s), or upon reasonable request.

The Tri-Council Policy Statement 2 (TCPS 2) defines research as "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation." The term "disciplined inquiry" refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.

Further, the TCPS 2 describes "human participants" as "those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question."

TYPES OF REVIEW

Full Board Review: An ethical review of the application will be undertaken by the full REB at a convened meeting unless the study fulfills the criteria for an expedited review.

The REB generally meets once per month. The schedule of meeting dates and deadlines for submission are found at the Bruyère research ethics website at: www.bruyere.org

Expedited Review: The decision whether a study qualifies for expedited review rests with the REB Chair. Expedited reviews may be submitted at any time. Studies that qualify for expedited review are those that:

a) are determined to be minimal risk and non-invasive (e.g. retrospective chart reviews, non-intrusive questionnaires or surveys, non-invasive assessments, use of existing samples), or

b) involve only current standard of care treatments, or

c) have had prior approval from another Research Ethics Board that is compliant with the Tri-Council Policy Statement 2, as amended from time to time. All case relevant

documentation (submission materials from the other REB and its approval letter(s) must be provided.

THE SUBMISSION FORM – INSTRUCTIONS

The REB Submission Form (BREB) may be found on the Research Ethics Board website at: www.bruyere.org. The fully completed BREB Form must be submitted electronically. Paper copies are not accepted. If you are unsure about any aspect of these instructions, contact the Bruyère REB at REB@bruyere.org or at 613-562-6262 ext. 4003.

The REB Checklist **must** accompany all ethics submissions to be considered for REB review. The checklist can be found on the Research Ethics Board website at: www.bruyere.org

TCPS 2 Certificates for all research personnel **must** accompany this submission to be considered for REB review. The TCPS 2 tutorial can be found at: https://tcps2core.ca/welcome

If this is a multi-centre study, check with the other institutional REB(s) to confirm their review and submission requirements.

Answer all of the questions in each section. If a question does not apply, indicate "Not Applicable." Do not refer to, or attach, other documents in response to questions except where indicated. The following are further explanatory notes regarding some items on the BREB Form. The numbering corresponds to the items on the Form.

1. SUBMISSION VERSION DATE

Include the date of submission as the Submission Version Date. Each revised iteration of the Form should show an updated Version Date.

2. STUDY TITLE

Include the full title of the study. The title must match that of the study protocol, if any. Correspondence between the investigators and the REB office will cite this title for identification purposes.

3. STUDY DURATION

State the expected start and end dates. As applicable, update these dates on all revised REB applications or amendments to REB approved submissions and protocols.

4. REVIEW TYPE

Indicate whether you are requesting a full or an expedited review and give a brief justification if requesting expedited review. The final determination will be made by the REB Chair.

5. ORIGIN AND FUNDING OF STUDY

Indicate whether the study originated from the Investigator(s) (Investigator Driven), or has originated from an industry sponsor who is funding the study. If the originator of the study is a corporate sponsor, provide the company's contact information and country.

6. TEAM OF INVESTIGATORS

In this section, identify the Investigators for the study and provide the contact information requested.

a) The Principal Investigator (PI) is the individual who has overall responsibility for the project at all research sites.

b) The Responsible Site Investigator (RSI) must be affiliated with Bruyère, has responsibility for the research activities at Bruyère, and also serves as the study's contact person for the REB. There must always be at least one RSI for each approved study. If the PI is also the RSI, check Not Applicable.

   Where the Principal Investigator or a Co-Investigator of the study is a student or trainee, the RSI should be the student's supervisor. If this is not possible, contact the REB for direction.

   For clinical studies regulated by Health Canada that require the Site Principal Investigator to be a "Qualified Investigator" (a physician or, where applicable, a dentist, and a member in good standing of a professional medical or dental regulatory body) the Responsible Site Investigator must certify that he or she meets this requirement by initialing the "Responsible Site Investigator Agreement" that appears in Section 6b.

c) The Co-Investigator(s), with the Principal Investigator, are typically those investigator(s) who i) originated or made a significant contribution to the study, ii) obtained funding and/or iii) will be an author of any publications arising from the research project.

   All Co-Investigators and their contact information should be listed in Section 6. When a student is listed as a Co-Investigator, his/her student status should be identified under "Title/Position."

Note: Signatures are required for all investigators listed in Section 6. All investigators are responsible to carry out the study in accordance with the REB Submission, once approved. The signatures of the Principal Investigator, Research Site Investigator and all Co-Investigator(s) attest to their agreement to carry out the study in accordance with the Submission.

7. STUDY TYPE AND DESIGN

a) **Type of Study:** The purpose of this checklist section is to orient the REB reviewer to the type of study. The list is not intended to be exhaustive. Check off the most appropriate items.

b) **Study Design:** The purpose of this checklist section is to provide the REB reviewer with some information about the experimental design of the study. The list is not intended to be exhaustive. Check off the most appropriate items.

8. RESEARCH PROJECTS REQUIRING HEALTH CANADA OR FDA APPROVAL

Clinical trials of Investigational drugs including Biologics and natural health products, as well as approved drugs or medical devices being tested for a new indication (e.g., age group, new disease entity), new dosage or new method of administration may require Health Canada approval. It is the responsibility of the study sponsor and research team

to ensure that all Health Canada regulatory requirements are met, including requirements relating to Health Canada prior clearance of proposed trials.

Applicable studies involving regulated investigational products must apply for authorization for research use from Health Canada under certain circumstances. For drug trials, a "Clinical Trial Application" form must be submitted to Health Canada. Provide a copy of the authorization or "No Objection" letter from Health Canada as soon as it becomes available. In general, final REB approval for the study will not be granted until the "No Objection" letter has been provided. There are similar rules for other kinds of Health Canada regulated investigational products. For certain medical device studies, however, Health Canada requires REB approval first.

If results are to be submitted for US Food and Drug Administration (FDA) approval, provide the IND number showing research approval from the FDA.

There is no representation that Bruyère REB approval of a regulated clinical trial, or other study means that the study complies with applicable laws and regulations in any jurisdiction. Investigators must be satisfied that they have met all required laws and regulations, and if in doubt, should consult their own legal advisors.

9. STUDY SUMMARY

The study summary is intended to provide a brief overview of the study, including a brief description of the purpose, study population and study interventions. This summary should be written using lay language (as should all sections of this Form), and should not normally exceed 200 words.

10. PURPOSE AND OBJECTIVES

a) Justification: In this subsection, justify the need for this study, and clearly outline your objectives so that the appropriateness of the study's design and methodology can be evaluated. Also, describe the potential clinical relevance of the study and its expected findings.

b) Objectives: Outline the main objectives for this study. If this is a pilot study, indicate how the outcomes of this study will contribute to the main study.

c) Clinical Relevance: To properly evaluate the balance between the risks to the research subject and the benefit to society, describe the clinical relevance of this study.

11. DESCRIPTION OF METHODS AND PROCEDURES

a) **Study Design and Methods:** In this subsection, provide a description of the study design and methods including the method chosen to assign subjects to groups, if any. Study procedures and interventions should be sufficiently described so that the reviewer does not need to obtain information from secondary sources (e.g. funding grants, investigator's brochures). For better comprehension, flow diagrams and point form presentations are encouraged.

b) Describe the nature, frequency, and duration of research participation required by the study: Describe what research participants will be asked to do, how many sessions or visits will be involved and how much time will be required for each study session or visit.

c) **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.

d) **Primary Outcome Measures:** Describe the measures that will be used in this study and the appropriateness of these measures for this study. If data will be obtained from interviews, questionnaires or standardized data collection instruments, attach copies of and any interview scripts to be used in the study. If the study will recruit subjects from different linguistic groups, attach all translated copies and state whether the translations have been validated using an appropriate methodology.

e) **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?

f) **Does this study involve any deception, or withholding information from study participants?** If yes, describe and justify the use of deception. Describe also your plan for debriefing participants and obtaining their consent to the use of their data. Note that, generally, participants must be advised of the purpose and rationale for the use of deception or partial withholding of information and must have the option to withdraw their data after learning of the use of deception. Any variation from these rules be justified.

g) **Plan for the Analysis of Results:** Provide the plan for the statistical analyses of the study's results. Although it may be necessary to change the statistical plan after the data are collected, include the actual statistical tests that are currently being considered for the analyses. For qualitative data, briefly describe the analysis method(s) planned.

12. SAMPLE SIZE AND RESEARCH SITES

a) Include the total number of the subjects being recruited at all sites.

b) Specify the number of sites and list countries of all sites.

c) Indicate the number of research participants being recruited at Bruyère sites.

d) Investigators should ensure that individuals to be recruited at Bruyère sites have not been excessively recruited for multiple research projects. Describe how the answer to this question was determined. If the patient population has been recruited for several studies, describe how the issue of over-recruitment will be addressed

e) For quantitative studies, include sample size power calculations. You may refer to the protocol for this information. For qualitative studies indicate approximate sample size and rationale.

13. DESCRIPTION OF POPULATION

In sections a) and b), outline the inclusion and exclusion criteria that will be used to select subjects. In addition, include the methodology that will be used to discern whether a prospective subject meets the criteria. If participants are to be excluded because of cognitive impairments, describe the assessment procedure that will be used to identify

the presence and severity of cognitive impairments and whether a prospective participant is capable of giving valid consent.

In section c), specify whether there will be any restrictions on the linguistic groups that will be recruited. For studies where language fluency may have an influence on the results, the criteria used (i.e. language of formal education etc.) to determine language fluency should also be included.

14. IDENTIFICATION AND RECRUITMENT OF RESEARCH PARTICIPANTS

a) Describe how the research study will be publicized for recruitment purposes. If the initial contact is by letter, e-mail, web-site and/or advertisement, attach applicable copies of the text to be used. The REB must review all study-related materials that will be seen by, or given to subjects, including research advertisements or letters. The specific dollar amount of compensation paid to subjects should not be listed in the advertisement.

   For studies recruiting participants from different linguistic groups, attach translated texts for approval. Projects may not recruit a linguistic group until the respective texts are approved.

b) If recruiting participants at Bruyère, identify what units/ programs/ departments/ etc. you will be recruiting from, and which staff or clinical team members of the units in question you have engaged in this project. At minimum, the unit manager and physician lead must be involved in the planning of the project to ensure feasibility of logistics.

c) If the identification of prospective subjects will involve using information obtained from their personal health information record, members of the participant's health care team are generally required to obtain the patient's verbal or written approval before identifying prospective patients to the study's research staff so that confidentiality is not broken. In this section, describe how the patient's agreement to be contacted by the researcher(s) will be obtained by members of his/her health care team. It is important to ensure that the role of the members of the participant's health care team is limited to seeking agreement to be contacted by the project's research staff and does not involve any active recruitment activities or undue encouragement. In addition, the investigator should ensure that the patient perceives research staff as separate from their health care team.

d) In this section, specify the methodology to be used for recruitment once prospective participants have been identified. Given that it is important for REB reviewers to determine whether any coercion is present in the recruitment process, provide scripts that will be used in the recruitment process

e) Describe how the privacy of the individual will be protected during the recruitment process. Unless there is a justifiable exception, the subject's decision whether to participate in a study should be treated as confidential. If circumstances may prevent the participant's decision from remaining confidential, then the participant should be informed of such an eventuality.

f) If control groups will be used, indicate whether the recruitment process will differ among these groups. Explain any differences in the recruitment processes.

g) Given that the decision to participate in human research should be voluntary, informed and without coercion or undue influence, indicate whether incentives will be offered. If incentives will be used, justify that they are reasonable in the circumstances. Describe how the amount of payment will be calculated if the participant withdraws partway through the study. In general, payment should be prorated by the amount of time spent in study activities.

h) Finder fees include monetary or other substantial rewards that are paid to members of the study's research staff or health care staff specifically for the successful recruitment of subjects and are paid as a bonus to regular salary or fees. Finder's fees are prohibited. If you are uncertain as to whether your disbursements to health professionals or research staff will be considered to be "finder's fees," provide details.

15. PROCEDURES FOR SEEKING INFORMED CONSENT

Indicate whether the study will obtain informed consent from the study participants and complete the sections as indicated. When completing Sections 15b-h, note that the consent process (oral or written) is required to meet the standards of the Tri-Council Policy Statement 2. Refer to Appendix A of these Guidelines for the elements that should be included in the consent form and consent process. For clinical trials regulated by Health Canada or FDA, a written informed consent is required.

c) Research subjects should give free and informed consent to participate in the study. Signing an information/consent form is the usual method to document that a subject has made an informed decision to enroll in a study. It is important then that the information/consent form is written at a level that can be understood by the population being recruited for the study, and that each research subject actually understands the content of the information/consent form. In addition to providing the reading level in this section, describe the methodology used to make this determination. More information about calculating the reading level of text, and a simple calculator, is found at: http://www.readabilityformulas.com/smog-readability-formula.php. Other online tools may be available.

   Where it is not possible to determine the reading level of the population being sampled, Grade 8 can be used as the "default" reading level. When a Grade 8 reading level of an information/consent form is considered to be inadequate to provide participants with an understandable description of the study, investigators may develop other methodologies to ensure that research subjects understand the information/consent form and that the information is readily available to the research participant for future reference as needed.

Note 1: Articles 2.1(c), and 2.3 of the Tri-Council Policy Statement II, permit the REB to approve a study that does not obtain informed consent or uses an altered consent procedure when all of the following conditions are met:

i. the research involves no more than minimal risk to the subjects;

ii. the waiver or alteration of consent is unlikely to adversely affect the rights and welfare of the subjects;

iii. the research could not practicably be carried out without the waiver or alteration of consent (e.g. naturalistic observation of individuals at public meetings and rallies);

iv. whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and

v. the waived or altered consent does not involve a therapeutic intervention.

If requesting a waiver of consent, describe how the study meets all the conditions outlined above.

d) Attach the information/consent form or oral script that will be used. In the case of oral consent, the investigator should make provisions for the participant to receive, or if online, to print off, a copy of the script.

e) Describe in a step-by-step manner how informed consent will be sought. In addition, describe how the subject's comprehension and informed consent will be verified. If there are special circumstances (e.g. special needs, variable capacity to give consent), describe the special procedures that will be followed to protect subject interests and promote valid consent. Attach copies of the materials (e.g. scripts, texts) that will be used in these circumstances. In the case of oral consent, include a description of how and where the oral consent for each subject will be documented.

f) A dual relationship should <u>not</u> exist between the person obtaining consent and the research subject. For example, it would generally be inappropriate for a care provider to recruit and to obtain consent from one of his/her patients to participate in a research project. If a dual relationship is unavoidable, justify and outline the safeguards that will be used to protect the interests of the individual being recruited.

g) Personal health information to be used for research purposes should be accessed only with the consent of the research participant. If personal health information will be accessed without consent, justify. As required by the Personal Health Information Protection Act (PHIPA), 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.

h) For studies that require more than one contact with research participants, describe the methodology that will be used to ensure that the participant continues to have decision-making capacity and that consent from the participant remains current.

i) Research involving emergency health situations can only be conducted if it addresses the emergency needs of the individual involved, and then only in accordance with the criteria established in advance of such research by the REB. As outlined in Section 3.8 of the TCPS 2, a REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if <u>all</u> of the following apply:

   i) a serious threat to the prospective subject requires immediate intervention; and

   ii) either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and

   iii) either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject; and

   iv) the prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research; and

   v) third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

vi) no relevant prior directive by the subject is known to exist.

In order to justify the need to proceed without consent, describe in this section how all of the required conditions outlined above will be met. Also include the procedure for obtaining consent once the research participant has regained the capacity or when an authorized third party is found.

16. CAPACITY TO GIVE CONSENT

a) If a study will be recruiting from a population where some individuals may lack the capacity to give consent, justify the inclusion of these individuals in the study. The TCPS 2 describes decision-making capacity as "the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate. This ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought." According to the TCPS 2, individuals who are not able to give informed consent may be enrolled in a study only when:

   i) the research question can only be addressed using individuals within the identified population(s);

   ii) the research does not expose them to more than minimal risk without the potential for direct benefits for them;

   iii) free and informed consent is obtained from their authorized legal representative(s).

b) Describe the methodology that will be used to determine an individual's capacity to give informed consent. It is the responsibility of the research investigator to determine the capacity of an individual to consent to participate in the study at the time consent is obtained, and that capacity is maintained throughout study participation.

c) When prospective participants include individuals who lack the capacity to give consent, describe: i) who will be providing consent on behalf of the incapable individual, ii) how free and informed consent will be sought from the participant's legal representative and iii) how the participants' interests will be protected. The legally authorized third party may not be the researcher or any other member of the research team.

   According to the TCPS 2, there is no strict age limit for decision-making capacity. Children will often have capacity depending upon the complexity and consequences of the study information needed to be understood. However, it is fair to assume that children 16 years of age or older likely have capacity to consent to most studies. Unless very young, children who lack capacity should generally give their assent to participation and an Assent Form should typically be prepared and submitted for review. A child's wish not to participate should generally be accepted unless research participation has a reasonable prospect of significant benefit to the child. If unsure, researchers should contact the REB for direction.

d) The capacity to give consent may fluctuate over time. Describe the methods to be used to regularly assess the capacity to consent and the steps to obtain consent in the case when an incapable participant regains capacity during the study.

e) When consent is being obtained from a legally authorized third party under current statutes and regulations, it is also important to ensure that the incapable individual assents to participating in the study, unless there is a significant likelihood of benefit. This means that the incapable participant must appear willing to participate in the study's interventions and does not display "dissent" behaviors to suggest that participation is against his or her own preferences. For these cases, describe how "assent" and "dissent" on the part of the incapable individual will be assessed for the duration of the study and how "dissenting" participants will be precluded or withdrawn from the study.

17. RISKS AND BENEFITS

a) Whenever possible, proposed research should be designed so as to offer at least the possibility of benefit to participants. Studies that involve significant risk without a balance of significant benefit may be unethical.

   Document the risks associated with the study. If the likelihood of adverse events is known, document them.

b) Describe the possible benefits of the study to individual participants. If no benefits are anticipated, say so.

18. USE OF PATIENTS AS RESEARCH PARTICIPANTS

a) For research studies involving the recruitment of patients (people who have an illness or condition relevant to the study), describe the usual standard of care for this population and how the usual standard of care will be affected. This should include any additional laboratory samples, questionnaires, interviews, assessment protocols, and any other activities undertaken to benefit the research study but not normally used as part of clinical care. If changes in the standard of care will vary according to the group to which patients are assigned, document the changes in usual care for each group. These changes in care should also be described in the information/consent form.

b) If any standard therapies, diagnostic procedures or information will be withheld from research subjects for the purpose of the study, explain in detail and justify it in terms of the risks and potential benefits. The fact that usual care will be withheld must be described in the information/consent form and reviewed with the patient.

c) If a placebo control group is to be used, justify the choice of a placebo, as opposed to other possible controls. Article 11.2 of the TCPS 2 describes criteria for the use of a placebo control group as follows:

   a. A new therapy or intervention should generally be tested against an established effective therapy.

   b. As with all of choices of control, a placebo control is ethically acceptable in a randomized controlled clinical trial only if:

      - its use is scientifically and methodologically sound in establishing the efficacy or safety of the test therapy or intervention; and
      - it does not compromise the safety or health of participants; and
      - the researcher articulates to the REB a compelling scientific justification for the use of a placebo control.

c. For clinical trials involving a placebo control, the researcher and the REB shall ensure the general principles of consent are respected and that participants or their authorized third parties are specifically informed:

- about any therapy that will be withdrawn or withheld for purposes of the research; and
- of the anticipated consequences of withdrawing or withholding the therapy.

d) If participation in this study will affect the individual's future care, or available options for future care, describe. These effects on future care should also be described in the information/consent form.

e) If the management of the research subject's condition will be prolonged or delayed because of the research, describe how usual care will be affected and justify in detail why this is appropriate. The usual care for the patient's condition and the possible effects on the management of a patient's condition should be described in the information/consent form.

f) List any restrictions on medications/treatments or lifestyle, such as diet, exercise, smoking, exposure to sun or driving. Specify the duration of restrictions and the reasons why the restrictions are necessary. All restrictions must be described in the information/consent form and reviewed with the study participant at the time consent is obtained.

g) Describe the conditions under which the Responsible Site Investigator will withdraw a research subject from the study. These could be safety thresholds for individual participants or other circumstances. Although this applies primarily to research that can have a direct effect on the research subject's physical health, studies that are investigating psychological variables should also consider whether rules relating to the withdrawal of participants are needed.

h) Describe the study stopping rules – circumstances under which the study may or will be stopped. For example, statistical thresholds for safety data, adverse events, or other factors.

19. CONFIDENTIALITY

a) Indicate in this section: i) the source of any records containing personal information that will be used in this study, ii) the legal requirements for access (e.g. signed consent to comply with the Personal Health Information Protection Act), and iii) whether the access requirements will be met before accessing the records. For studies that do not involve accessing personal ***health*** information, accessing other personal information may involve seeking the approval of data stewards or information custodians, including registries and government departments. Describe the policies or statutes/regulations that govern the access to these sources of information and whether the access requirements have been met and approval has been received.

b) For categories of identifiability, note that anonymized information (including biological materials) is that which is irrevocably stripped of direct identifiers, a code is not kept to allow future relinkage, and the risk of re-identification of individuals from remaining indirect identifiers is low. Anonymous information (including biological materials) is information originally collected without identifiers and the risk of re-identification of individuals is very low. De-identified information includes that which is anonymized and anonymous.

c) For studies accessing and storing personal and/or health information, all data collected that contains personal identifiers (e.g. name, OHIP number, chart number, address, initials, social insurance number) is confidential and must be protected against breaches in security/privacy. Describe the procedures that will be used to maintain confidentiality for all media (e.g. paper, digital files, audio-tapes, video-tapes, online cloud storage) that will be used to store information.

d) At the earliest opportunity, all personal information and other data should be securely encoded to remove all personal identifiers and the code-list containing personal identifiers required by the research project should be securely stored with restricted access. In this section, describe in detail how and when the data will be so encoded. Whenever possible, secondary identifiers such as initials, date of birth, postal code, admission dates to hospital, dates of events specific to the research subject (e.g. date of stroke, date of admission to hospital, chart number) that can indirectly identify a research participant should be stored as part of the code-list and not part of the coded data.

e) If data containing personal identifiers will not be encoded at the earliest opportunity, justify in this section.

f) Describe where data will be stored and the security measures (eg. encryption, password protection, locked file cabinet) 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? In what country will the server housing the survey data be located.

g) If data containing personal identifiers will be transferred to another facility, justify. Describe the methods used to maintain confidentiality of this information at the receiving facility. Include documentation demonstrating that the receiving facility has agreed to store and to destroy data containing personal identifiers according to the study's protocol described in this application.

h) Indicate whether data, including code list(s), will be retained, and if so, how long? If it will be destroyed, describe how.

i) Describe the proposed services of a translator or transcriber in handling and protecting personal information. Indicate whether a confidentiality agreement will be used.

j) 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. * If long term storage of specimens is planned, you must complete the "Genetic Addendum."

20. MONITORING

a) Monitoring refers to activities performed by groups, such as the study sponsor, to protect the interests of the research subjects and to ensure compliance with the approved research protocol. These groups may include the project's research staff, the study sponsor (e.g. site visits to check for GCP compliance, interim analysis of results by a data and safety monitoring board), steering committees and external/internal auditing committees endorsed by the research site facility.

Monitoring allows researchers and others to know whether new and unknown risks have developed for the research subjects and whether the approved research

protocol is being followed. In this section, outline your monitoring plan for this study. If applicable, include a description of how research subjects will be informed of new risks that are identified during the course of the study.

If there is a data safety monitoring board in place, it is important for the REB to know the degree to which the board is independent of the sponsor.

21. PUBLICATION AND DISSEMINATION OF RESULTS

a) Outline how the results will be communicated to the scientific community, research subjects and other stakeholders. It is also recommended that research staff document whether each research subject was given the opportunity to request a summary and whether he/she accepted or declined.

b) Specify whether the approval of the sponsor(s) is required before the publication and/or dissemination of the results of the study. Agreements regarding the publication of research should not prevent the publication of results or the communication of information important to subject safety as determined by the either the Principal Investigator, Responsible Site Investigator, Co-investigators, the REB, or any other parties monitoring the research study.

c) Specify in which languages the summary of the study will be available.

d) Specify if you will be providing research participants with a summary of results once the study is finished. If yes, this must be clearly stated in the consent form. If no, please provide an explanation why not.

22. BUDGET

a) Research Ethics Boards are interested in ensuring that the research study has sufficient support to be completed and that expenses do not reveal an unacceptable conflict by the investigator(s) or sponsor.

b) In addition to completing the summary in this section of the application, attach as a separate appendix, a detailed itemized budget listing expenses for the study. The REB will consider aspects such as investigator payments, reimbursement for subjects, and whether there are adequate funds to cover study treatments and procedures.

c) If funding has not been obtained, describe how the costs of the research study will be covered. Complete all applicable sections.

23. CONTRACTS

a) All contracts/agreements with the corporate sponsor(s), public funding agencies or other parties (e.g. copyright holders) related to this study must have appropriate approval from the relevant institutional authority. These contracts/agreements may include, but are not limited to: clinical trial agreements, material transfer agreements involving human material, licensing agreements for the use of copyrighted materials, etc.

b) Indicate who will cover the costs of treatment not covered by the provincial health plan in case of injury directly resulting from participation in the research study (i.e. sponsor, institution-specific, other).

Contact the REB of each research site for additional details regarding submission of contracts.

24. POTENTIAL CONFLICTS OF INTEREST

The term “conflict of interest” refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a researcher’s professional judgment and obligation to protect research participants and the scientific integrity of the study.

a) As specified in the application form, indicate if the Principal Investigator, Responsible Site Investigator or any Co-Investigators involved in this research study or any member of their immediate family have a conflict of interest.

25. DIVISION/DEPARTMENT/PROGRAM APPROVAL

Hospital and university administrators share responsibility for research activities within their division, department or program. The purpose of this signature section is to ensure that appropriate administrators at research sites are aware of: a) the research activities undertaken in their division, department or program and b) the impact of these activities on the resources of their division, department or program and the patients they serve.

This form should be completed and signed by the administrator who has signing authority for the financial cost centre(s) affected by the research study. This section should not be completed by an administrator who is listed as the Principal Investigator, the Responsible Site Investigator or a Co-Investigator.

Contact the REB to identify the appropriate administrators, if needed.

26. CONTINGENCY PLANNING

All researchers are being asked to develop contingency plans in the event of an epidemic, pandemic or similar emergency situation.

At the time that a pandemic is declared, and in keeping with current infection control best practices, Bruyère may prevent access to all of its sites for anyone who is not directly involved in the care of in-patients or residents. Consequently, project research staff and research subjects may not have access to our hospital sites.

Given that the suspension of research activities at Bruyère may have adverse effects on research subjects and the integrity of a research study, outline the contingency plans for the research project in this section.

If it is the opinion of the Responsible Site Investigator that the suspension of the research project has the potential to cause significant adverse effects for the project’s research subjects, the contingency plan must incorporate appropriate steps to mitigate these risks for research subjects. Alternatively, if it is in the best interests of research subjects to continue with the research study, the contingency plan should include the relocation of the research project to a temporary off-site location. The off-site location should not expose research subjects to an increased risk without the approval of the REB.

27. IMPROVING THE CLARITY AND USABILITY OF THIS FORM

We are interested in your feedback about the use of this Form. If you have any comments or suggestions to make this form more user-friendly, please email us at **REB@bruyere.org** or include them in this section.

APPENDIX A: SECTION D1 OF THE TRI-COUNCIL POLICY STATEMENT STANDARDS FOR INFORMING POTENTIAL SUBJECTS

"D. Informing Potential Subjects

D1. General Conditions

Article 2.4

Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective subjects with the following:

a. Information that the individual is being invited to participate in a research project;
b. A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;
c. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;
d. An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and
e. The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

Under the normal process of obtaining written consent, the prospective subject should be given a copy of the consent form and any relevant written information. The consent of the participants shall not be conditional upon, or include any statement to the effect that, by consenting, subjects waive any legal rights.

In light of (b) and (c), REBs may require researchers to provide prospective subjects with additional information, such as that detailed in Table 1, below.

Article 2.4 indicates the requirement to give prospective subjects the information they need to give free and informed consent on whether to be involved in the research project. In a research team, the principal researcher is ultimately responsible for the actions of those acting with delegated authority.

Research subjects, whether inside or outside Canada, may have cultural values different from those of the researcher. Thus, as Articles 2.4(a-c) indicate, researchers must clearly explain the nature and goals of the research and other essential information, in a manner appropriate for the prospective subjects" cultural settings. With some cross-cultural research

projects, it may not be possible to offer an adequate translation of the researcher's understanding to prospective subjects. REBs should proceed cautiously in such cases and require stringent protection for the interests of subjects, such as appointing an individual to act in an independent advocacy role. On the other hand, REBs should not assume an unnecessarily protective role that suggests that those who do not share the culture of the researchers, particularly those in foreign countries, are incapable of making rational decisions in their own interest.

Articles 2.2 and 2.4(d) help to ensure that a prospective subject's choice to participate is voluntary. Pre-existing entitlements to care, education and other services shall not be prejudiced by the decision on whether to participate. Accordingly, a physician should ensure that continued clinical care is not linked to research participation, and teachers should not recruit prospective subjects from their classes, or students under their supervision, without REB approval. Nothing in this section should be interpreted as meaning that normal classroom assessments of course work require REB approval. Article 2.4(d) also requires that researchers specifically ascertain continuing consent from subjects on the basis of new information.

Table 1

Additional information that may be required for some projects:

1. An assurance that new information will be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw from participation;
2. The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;
3. Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research;
4. An indication of who will have access to information collected on the identity of subjects, descriptions of how confidentiality will be protected, and anticipated uses of data;
5. An explanation of the responsibilities of the subject;
6. Information on the circumstances under which the researcher may terminate the subject's participation in the research;
7. Information on any costs, payments, reimbursement for expenses, or compensation for injury;
8. In the case of randomized trials, the probability of assignment to each option;
9. For research on biomedical procedures, including health care interventions: information about (a) foregoing alternative procedures that might be advantageous to the subject, (b) which aspects of the research involve the use of procedures that are not generally recognized or accepted; and, (c) particularly in trials of therapeutic interventions, the care provided if the potential subject decides not to consent to participation in the study;
10. The ways in which the research results will be published, and how the subjects will be informed of the results of the research.

Article 2.4(e) reminds researchers of relevant ethical duties that govern potential or actual conflicts of interest, as they relate to the free and informed consent of subjects. To preserve and not abuse the trust on which many professional relations reside, researchers should separate their role as researcher from their roles as therapists, caregivers, teachers, advisors, consultants, supervisors, students, employers and the like. If a researcher is acting in dual roles, this fact must always be disclosed to the subject. Researchers should disassociate their role as researcher from other roles, in the recruitment process and throughout the project. Conflict of interest matters are further elaborated below in Section 4.

Table 1 also indicates other information that researchers may be required to provide in some areas of research for the purpose of obtaining free and informed consent. Item 2 refers to the qualified designated representative who is usually someone on the research team. When the research poses more than minimal risk, it may be advisable to have a person who is independent of the research team in this role. Item 3 acknowledges that some institutions may decide either to name an ombudsman for research subjects, or designate, with the agreement of the researcher, a resource person to handle queries, receive complaints, and transmit them to the REB. Item 7 is intended to prevent the development of a payment structure for research participation that might place undue pressure on research subjects either to join or remain within a research project. It does not imply that subjects should be paid for their participation in research. In research projects where subjects will be compensated, REBs should be sensitive to the possibility of undue inducement for participation, such as payments that would lead subjects to undertake actions that they would not ordinarily accept. REBs should pay attention to issues such as the economic circumstances of those in the pool of prospective subjects, and to the magnitude and probability of harms.

Item 10 in Table 1 indicates that subjects have the right to know whether they will be identified directly or indirectly in publications resulting from the research.

Rushing the process of free and informed consent, or treating it as a perfunctory routine, violates the principle of respect for persons, and may cause difficulty for potential subjects. The time required for the process of free and informed consent can be expected to depend on such factors as the magnitude and probability of harms, the setting where the information is given (e.g., hospital or home) and the subject's situation (e.g., level of anxiety, maturity or seriousness of disease).

In some circumstances, witnessing the signatures on the consent form may be felt to be appropriate. In law, the role of a witness is only to attest that the person actually signed the form; a witness is not responsible for certifying such factors as the signature being obtained under defined conditions or that the signers were competent. However, a court might subsequently seek the opinions of the witness on such issues" [1].

[1] http://www.pre.ethics.gc.ca/english/policystatement/section2.cfm