## ETHICS SUBMISSION CHECKLIST

# INSTRUCTIONS:

**DO I NEED TO COMPLETE THE IMPACT FORM?**

Regardless of who the REB of Record is, 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

**SUBMIT TO THE REB:**

Complete this Form and include it with your study submission, along with the **Impact Form** (if applicable). For studies that require full board review, submissions must be received by the REB on **the 1st of each month** to be considered for review during the next month’s REB meeting. For studies not requiring full-board review, you may submit them to the REB office at any time.

# Please email all submission documents to REB@bruyere.org

**Questions?** Please direct inquiries to the Research Ethics Manager: Kristi Wilde (REB@bruyere.org)

# Please visit <https://www.bruyere.org/en/researchethicsboard> for the most recent forms, guidelines and information.

|  |
| --- |
| **STUDY TITLE** |
|  |
| **REB OF RECORD**  | **BRUYÈRE HEALTH PRINCIPAL INVESTIGATOR** |
|  |  |
| **Please identify if patients, residents or care partners are involved in the following study elements:** |
| [ ] Advisory Role[ ]  Study Design[ ]  Study Analysis[ ]  Other Please identify: |
|  **REQUIRED DOCUMENTS/ITEMS** | **Included** | **Pending** | **N/A** |
| **1.** | **Version dates on all documents.** Documents without version dates will be returned. | [ ]  **PRINCIPAL INVESTIGATOR** | [ ]  | [ ]  |
| **2.** | **BREB Application:** If Bruyère Health REB is not the board of record (BOR), you may submit the original REB Application along with the approved protocol, informed consent forms, and all appendices. | [ ]  | [ ]  | [ ]  |
| **3.** | **Original protocol**: if applicable. | [ ]  | [ ]  | [ ]  |
| **4.** | **Approval letter from the BOR, and other REB’s (if applicable):** If we are not the BOR, we require the original approval letter from the BOR. Your study will not be reviewed by the REB until received. | [ ]  | [ ]  | [ ]  |
| **5.** | **Signatures for: Principal Investigator(s).** If you are submitting an ethics form from another REB that does not include signatures, you may download our BREB form, and use the signature pages. | [ ]  | [ ]  | [ ]  |
| **6.** | **Impact Form** (if applicable) | [ ]  | [ ]  | [ ]  |
| **7.** | TCPS 2 Certificates **(issued within the past 5 years):** This is requiredfor all Canadian investigators and research personnel (even if we are not the BOR). For those renewing, and using the same TCPS2 login information, please send a copy of the original certificate, along with a screenshot of the last page of the tutorial. Link to tutorial: <https://tcps2core.ca/login> | [ ]  | [ ]  | [ ]  |
| **8.** | **Informed Consent Form(s) (ICF) WITH version dates:** Please see our website for ICF templates.  | [ ]  | [ ]  | [ ]  |
| **9.** | **Participant Documents/Appendices:** This includes documents that will be given to, read to, or seen by participants. (E.g. Non-standardized/validated questionnaires/surveys, information sheet(s), diary, advertisement, interview guide, focus group guide, telephone, in person, or email recruitment materials and scripts, etc.). All appendices must be submitted as separate, individual attachments. | [ ]  | [ ]  | [ ]  |
| **10.** | **Other-language participant documents if recruiting other-language speaking individuals:** [ ]  **Option #1:** You may wait for REB feedback on the English  documents, then have them translated (please include a  translation certificate). [ ]  **Option #2:** If you are unsure of whether or not you will  be recruiting other-language participants, you may  obtain study approval, having submitted only English  documents, and specifying in your ethics application that  you will submit an addendum if, at a later date, you will  be recruiting other-language participants.  | [ ]  | [ ]  | [ ]  |
| **11.** | **Itemized Budget.** Please submit as a separate, individual attachment. | [ ]  | [ ]  | [ ]  |
| **12.** | **Access to Health Records/Patient Charts:**If you require access to HR/EMR at Bruyère Health, you will require approval from the Privacy Office prior to data collection. We suggest applying to the Privacy Office simultaneous with submitting your REB application. For inquiries, or a copy of the form, please contact the Privacy Office at: chartaccess@bruyere.org.  | [ ]  | [ ]  | [ ]  |
| **13.** | **No Objection Letter (NOL) / Investigational Testing Authorization (ITA) / Notice of Authorization (NOA):**Applicable for all studies requiring submission to Health Canada. Approval will not be issued until these are submitted. | [ ]  | [ ]  | [ ]  |
| **14.** | **Investigator’s Brochure and/or Product Monograph:**Applicable for all studies involving a drug or device. | [ ]  | [ ]  | [ ]  |
| **15.** | **Pledges of Confidentiality**: This is required for PI’s, co-investigators and research staff, even if we are not the BOR. | [ ]  | [ ]  | [ ]  |