## ETHICS SUBMISSION CHECKLIST

# INSTRUCTIONS:

**STEP 1:**

Send your entire ethics submission, along with the **Research Study Summary** to your Research Services Manager for review and to obtain the Bruyère Health RI Senior Director of Research Operations Signature. We will not review your submission until this signature has been obtained.

**STEP 2:**

Complete this form and include it with your study submission. 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** | **PRINCIPAL INVESTIGATOR** |
|  |  |
| **BOARD OF RECORD**  | **RESEARCH SERVICES MANAGER** |
|  |  |
| **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. |  |  |  |
| **1.** | **BREB Application:** If Bruyère Health REB is not the board of record (BOR), you may submit the original REB Application (IRIS, etc.) along with the approved protocol, informed consent forms, and all appendices. | [ ]  | [ ]  | [ ]  |
| **2.** | **Original protocol**: if applicable. | [ ]  | [ ]  | [ ]  |
| **3.** | **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. | [ ]  | [ ]  | [ ]  |
| **4.** | **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. | [ ]  | [ ]  | [ ]  |
| **5.** | **Bruyère Health RI Senior Director of Research Operations Signature** (section 25 of the BREB – General and section 20 of the BREB – Chart/Database Review & Secondary Use), and Department Head Signature (if applicable):Please send full ethics submission to your **Research Services Manager** for review and to obtain Section 20 or 25 signature **prior** to applying to the REB. We will not review your study without this signature. | [ ]  | [ ]  | [ ]  |
| **6.** | 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> | [ ]  | [ ]  | [ ]  |
| **7.** | **Informed Consent Form(s) (ICF) WITH version dates:** Please see our website for ICF templates.  | [ ]  | [ ]  | [ ]  |
| **8.** | **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. | [ ]  | [ ]  | [ ]  |
| **9.** | **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.  | [ ]  | [ ]  | [ ]  |
| **10.** | **Itemized Budget.** Please submit as a separate, individual attachment. | [ ]  | [ ]  | [ ]  |
| **11.** | **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.  | [ ]  | [ ]  | [ ]  |
| **12.** | **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. | [ ]  | [ ]  | [ ]  |
| **13.** | **Investigator’s Brochure 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. | [ ]  | [ ]  | [ ]  |