**IMPACT FORM – FOR RESEARCH**

**Version date: January 29, 2025**

**PURPOSE**

This Form is for the purpose of ensuring that units/departments at Bruyère Health are aware of research occurring on their unit/department and/or with the support of their personnel, and that their team has the capacity to support the research. Confirmation of support from impacted units/departments is an organizational & Bruyère Health REB requirement. **Regardless of the REB of Record**, this Form is required if research recruitment will occur on/in any Bruyère Health units/departments as described below.

This Form replaces the BREB Departmental Approval and the Research Study Summary Form. All hospital-based REBs in Ottawa require this type of sign-off. This Form has been created in collaboration with stroke rehab leadership to ensure the information provided meets the needs of clinical teams. This Form will be incorporated into the Research Administration System being implemented at Bruyère Health RI. This Form is also required for research under CTO or harmonization agreements when Bruyère Health clinical/departmental approval is required.

**INSTRUCTIONS & USE OF THIS FORM:**

This Form is only to be used for research studies where Bruyère Health patients (inpatients or outpatients), residents, tenants, family members, caregivers, staff, or volunteers are being recruited for research or if a member of a Bruyère Health unit/department are being asked to perform any of the following tasks.

**Check all that apply:**

|  |  |
| --- | --- |
| 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 (please list all additional required activities/tasks): \_\_\_\_\_\_\_\_\_\_ |

**Complete all the sections. Incomplete forms will be returned.**

**The information in this form must align with the Bruyère Health Research Ethics Board (REB) application documents. Updates to this form are only required if there are significant changes to the unit/department’s involvement that require re-approval.**

**WHO NEEDS TO SIGN THIS FORM?**

1. Clinical Directors are required to sign this form if research is impacting or taking place on a unit which they are responsible for. Clinical Managers should be involved in the discussion prior to obtaining their Director’s sign-off.
2. If the study involves more than one Director’s area of responsibility, the signatures of all Directors involved must be obtained. If different things are required from different departments, separate forms may be used.
3. If the study involves physicians, the relevant Physician Department Head(s) must sign this form.

|  |  |
| --- | --- |
| **REB #** | **DATE OF THIS REQUEST** |
|  |  |
| **STUDY TITLE** | **PRINCIPAL INVESTIGATOR/BRUYÈRE HEALTH INVESTIGATOR** |
|  |  |
| **ESTIMATED START AND END DATE OF STUDY**  Note: Departmental involvement may not be required for this entire length of time. | **ACCESS TO HEALTH RECORDS/PATIENT CHARTS IS REQUIRED *(Privacy Approval must be obtained prior to accessing any health records/charts)*** |
| **Start Date:**  **End Date:** | Yes  No |
| **GIVE A BRIEF SUMMARY OF THE RESEARCH STUDY & STATE THE STUDY OBJECTIVES** (point form) | |
|  | |
| **What units/departments are you recruiting from?** *(Please list all applicable departments and/or units)* | |
|  | |
| **Who are the participants? Check all that apply.** | |
| In-patients  Out-patients  Residents  Tenants  Unit/Departmental staff | Physicians  Students  Volunteers  Family/Community members  Other: |
| **If staff are involved in this study (as participants or to assist with the study), will their involvement take place during their work hours?**  Yes  No | |
| **What time commitment is anticipated for staff? (# hours, days of the week, particular times of day, etc.)** | |
|  | |
| **Based on the boxes checked on page 1, briefly describe the operational “ask” from the unit/department** (point form) | |
|  | |
| **How many study participants will be recruited and over what period of time? Provide a start & end-date for unit/departmental involvement if you can.** | |
|  | |
| **WHAT TYPE OF STUDY IS THIS?** | |
| **Observational**  **Qualitative (interviews, focus groups, etc.)**  **Chart Review**  **Survey**  **Pilot study**  **Genetic research** | **Experimental**  **Physical intervention (e.g. movement intervention)**  **Drugs, biologics, radiopharmaceuticals**  **Medical Devices**  **Natural or non-prescription health products**  **Other (describe): \_\_\_\_\_\_** |
| **Is this study a Health Canada regulated** **clinical trial?**   Yes  No  If a Health Canada regulated trial, this Impact Form must be signed by the Office of Research Services Clinical Trials Manager.  **If yes, indicate which type of trial:**  Health Canada regulated – drug  Health Canada regulated – device  Health Canada regulated – natural health product | |
| **SIGNATURE SECTION (Duplicate this section as necessary)** | |
| By signing below, I confirm:   * the Principal Investigator (lead researcher at Bruyère Health named above) has notified me of which areas of the hospital/residence/department/unit will be impacted and where data collection will take place. * I have reviewed the information provided in this form and give my approval for this research to proceed. * the resources requested of my department/unit as outlined in this document are appropriate. * if applicable, there are an adequate number of potential research participants suitable to be approached for enrolment in this study, and there isn’t a risk of over-recruiting this study population in my unit/department. | |
| **Name:**  **Title/Position:**  **Dept/Unit & Location:**  **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  If you are a clinical director, have you reviewed this study with the applicable clinical managers?  Yes  No  **Date:** Click or tap to enter a date. | **Name:**  **Title/Position:**  **Dept/Unit & Location:**  **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  If you are a clinical director, have you reviewed this study with the applicable clinical managers?  Yes  No  **Date:** Click or tap to enter a date. |
| **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. |
| **SIGNATURE SECTION – TO BE COMPLETED BY** **ORS CLINICAL TRIALS ONLY (complete if required)** | |
| I have reviewed the necessary documents for this study and confirm it is ready for REB review/Registration. | |
| **Name:** Marie McNamara-Kilian  **Title/Position:** Clinical Trials Manager, Office of Research Services | **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date:** Click or tap to enter a date. |