|  |  |
| --- | --- |
|  | **Subject:**  Research Study Summary |
| **Document Type:**  Form | **Last review/ revision date:**  February 22, 2024 |
| **Issued by:**  Office of Research Services | **Applies to:**  Bruyère Health Research Institute |

|  |
| --- |
| **INSTRUCTIONS:** This form must be completed for all research studies that require:   * Approval by any department at Bruyère Health to conduct the research study. * Sign-off by Bruyère Health Research Institute for their research ethics submission. |
| *We recognize that information in this form is subject to change. All changes to project plans must be done in consultation with the clinical departments at Bruyère Health (as applicable) and must be updated in the project’s ethics application (BREB and associated documents) and the Access to Health Records form (as applicable).* ***In the event of discrepancies between this form and the REB and Access to Health Records forms, the REB and Access to Health Records forms will be taken as correct.*** |

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION 1: Study Contact** | | | |
| Date of form completion | Click here to enter text. | Email | Click here to enter text. |
| Study Contact Person | Click here to enter text. | Phone | Click here to enter text. |

|  |  |
| --- | --- |
| **SECTION 2: General Study Information** | |
| Full Study Name |  |
| Protocol # (if applicable) | Click here to enter text. |
| Study Acronym (use by team) | Click here to enter text. |
| Financial study acronym (on financial records) | Click here to enter text. |
| Study Status | Potential proposal  New ethics application  Existing project with major changes  Existing project adding additional Bruyère Health clinical units/departments |
| REB # (if known/applicable) | Click here to enter text. |
| Bruyère Research Institute Responsible Investigator | Click here to enter text. |
| All Principal Investigators & Bruyère Health co-Investigators | Click here to enter text. |
| Funder | Click here to enter text. |
| Total Amount of Study Funding | Click here to enter text. |
| Indicate Study Partners & Funding Partners | Click here to enter text. |
| Briefly describe the study’s primary objective | Click here to enter text. |
| Briefly describe the study’s design | Click here to enter text. |
| Is this study a clinical trial?  *Reminder*: *All clinical trials must be registered on a public registry, as per policy BRI 09. BRI recommends clinicaltrials.gov.* | YES  NO  ***Definition****: a clinical trial is a research study involving human participants that evaluates the safety and/or effects of one or more interventions on health outcomes. An observational study in which there is no pre-planned intervention is not considered to be a clinical trial. Interventions include, but are not limited to, drugs, vaccines, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products (NHPs), process-of-care changes, preventive care, manual therapies, and psychotherapies.*  *(source:*[*https://cihr-irsc.gc.ca/e/52810.html*](https://cihr-irsc.gc.ca/e/52810.html)*)* |

|  |  |  |
| --- | --- | --- |
| **SECTION 3: Study Summary** | | |
| Lay Study Summary from the REB Application (250 words) | Click here to enter text. | | |
| What is the impact and benefit of this research? How will findings help improve care and health systems? | Click here to enter text. | | |
| If applicable, how will this study impact the future care of patients, residents, and families at Bruyère Health? | Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| **SECTION 4: Participants and Recruitment** | | |
| Reminder: Bruyère Health Research Institute has several different internal and external ways to promote recruitment for research studies and sharing findings. These include social media, newsletters, posters in hallways, InfoNet, Participate in Research website, among other options. Contact Jasmine Rooke at [JRooke@bruyere.org](mailto:JRooke@bruyere.org) to discuss options. | | |
| (if no participants are involved, skip to SECTION 5) | | |
| Indicate the date when recruitment is anticipated to end | Click here to enter text. | |
| List the study recruitment inclusion and exclusion criteria. | Click here to enter text. | |
| Where will the research study occur?  (indicate site and unit, e.g., EBH – level 2: outpatient stroke) | Click here to enter text. | |
| Who are the participants? | In-patients  Out-patients  Residents  Tenants  Unit staff | Physicians  Students  Community members  Other:  N/A |
| How many study participants will be recruited and over what period of time? | Click here to enter text. | |
| If this research involves a clinical unit, what are the activities and time commitment required of the participants and how will this fit into the unit workflow? | Click here to enter text. | |
| Are unit staff being asked to help with the study? | Yes  No  N/A | |
| If yes, describe what unit staff are being asked to do, what the time commitment will be, when will this be done (during work hours, after hours) and describe any compensation the clinical unit will receive. | Click here to enter text. | |

|  |  |
| --- | --- |
| **SECTION 5: Data and/or Biological Sample Sharing or Transfer** | |
| Reminder: A research agreement is *always required* before data and/or biological samples are transferred between BHRI/BHRI personnel and external sites/non-BHRI personnel, even if the data and samples are de-identified. If data is leaving Bruyère Health/RI, we initiative the DSA. If BHRI is receiving data, the disclosing institution generally initiates. | |
| Type of Transfer (select all that apply) | |
| BHRI is receiving data from another institution | BHRI is receiving biological samples from another institution |
| BHRI is sending/sharing data to another institution  data includes information from Bruyère Health medical records  data does **not** include information from Bruyère Health medical records | BHRI is sending biological samples to another institution |
| BHRI is not receiving or sending data | BHRI is not receiving or sending biological samples |
| Nature of Data/Biological Samples Transfer | |
| Please provide a description of the type of data and/or biological samples being transferred: | |
| Click here to enter text. | |
| Please provide a description of:   * The intended transfer method for the data and/or biological samples (e.g., Citrix, Sync, REDCap, encrypted USB, courier) * The anticipated frequency of the transfer(s) (i.e., one-time, periodic, etc.) | |
| Click here to enter text. | |

|  |  |
| --- | --- |
| **SECTION 6: Face-to-Face Research Approval** | |
| Does the research study follow the most current version of the Procedure Manual on Conducting Face-to-Face Participant Research? | Yes  No  N/A |
| If no, explain why not and what additional approvals have been sought. | Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| **SECTION 7: Unit/Department Approval** | | |
| Reminder: All new studies must obtain Departmental Sign-off on Section 25 of the Research Ethics Application. Directors will generally ask if the applicable manager is in support of the research being undertaken. Provide that information here. | | |
| If working with a clinical unit or department at Bruyère Health on this project, indicate the individual(s) with whom you are working. | Click here to enter text. | |
| Has the unit manager reviewed this form, and are they in support of this research study? | Yes  No  N/A | Provide their name(s):  Click here to enter text. |

|  |
| --- |
| **SECTION 8: 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 relevant information, please email Alex Cornett at [ACornett@bruyere.org](mailto:ACornett@bruyere.org). |