**BRUYÈRE RESEARCH ETHICS BOARD –**

**SERIOUS ADVERSE EVENT/**

**UNANTICIPATED PROBLEM REPORTING**

*See* **‘Bruyère Research Ethics Board Guidelines for Reporting Serious Adverse Events / Unanticipated Problems’**

1. **Definitions and Use of this Form:**
   1. **Adverse Event (AE):** any unfavourable or unintended occurrence in the health or well-being of a research participant

who is administered an investigational product (drug, natural health product, or device) or who undergoes any other research procedure(s), and which does not necessarily have a causal relationship with the investigational

product or any research procedure(s). An AE can therefore be any unfavourable and unintended event, occurrence,

sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an

investigational product or other research procedure.

* 1. **Serious Adverse Event/Experience (SAE) or Reaction:** any Adverse Event that:

1. results in death
2. is life-threatening
3. requires inpatient hospitalization or prolongation of existing hospitalization
4. results in persistent or significant disability/incapacity
5. results in a congenital anomaly/birth defect; or
6. based upon appropriate medical judgment, is an important medical event that may jeopardize the health of the research participant or may require medical intervention to prevent one of the outcomes listed above.
   1. **Unanticipated Problem**: any incident, experience, or outcome (an event) that is:
7. A Serious Adverse Event; or
8. any other event, incident, experience, or outcome, meeting the conditions below, that in the opinion of the investigator or sponsor, places research participants or others at a greater risk of physical or psychological harm than was previously anticipated, or have implications for the conduct of the study or the integrity of the research data;

*and that meets all the following criteria:*

1. The event is **unexpected** (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents (e.g. the BREB-approved research Protocol and Informed Consent document(s), Investigator’s Brochure, Product Monograph); and/or the nature of the research participant population being studied; ***and***
2. The event is related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the event, experience, or outcome may have been caused by the investigational product(s) or procedures involved in the research); ***and***
3. The event suggests that the research **places research participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

There are two categories of **Unanticipated Problems**, namely:

* ***External Unanticipated Problem***: an Unanticipated Problem experienced by a research participant enrolled by investigator(s) at centres or institutions outside the jurisdiction of the Bruyère REB as REB of Record.
* ***Local Unanticipated Problem***: An adverse event experienced by a research participant enrolled by the investigator(s) at one or more centres under the jurisdiction of the Bruyère REB as REB of Record.

*Please see* ***Guidelines*** *for reporting requirements to the REB.*

|  |  |  |
| --- | --- | --- |
| **Initial Assessment of Serious Adverse Event/Unanticipated Problem** | YES | NO |
| Is this adverse event/unanticipated problem *unexpected*? |  |  |
| Is there a reasonable possibility\* that this adverse event/unanticipated problem may be *related* to the research? *(\* A reasonable possibility means that a causal relationship cannot be ruled out.)* |  |  |

**For Local Unanticipated Problems, if you answered “NO” to any of the above questions, report to the REB is not required.**

**For External Unanticipated Problems, report is required only if, in addition, the unanticipated problem is serious (see definition), and:**

* + - **requires a change to the Protocol and/or Consent Form(s); or**
    - **requires immediate notification to research participants to ensure safety.**

**If a report is required, please fill out the form below and submit**

**to the REB office:** [**REB@bruyere.org**](mailto:REB@bruyere.org)

**SERIOUS ADVERSE EVENT/**

**UNANTICIPATED PROBLEM REPORTING FORM**

|  |  |  |
| --- | --- | --- |
| **REB #** | | **Sponsor** |
| Click or tap here to enter text. | | Click or tap here to enter text. |
| **Study Title** | | **Site Investigator or Principal Investigator at Bruyère** |
| Click or tap here to enter text. | | Click or tap here to enter text. |
| **Date of Report** | | **Name of Person filling out Report** |
| Click or tap here to enter text. | | Click or tap here to enter text. |
| **Brief Description of Adverse Event/Unanticipated Problem** | | |
| Click or tap here to enter text. | | |
| 1. **Study Information** | | |
| * 1. Study Status (check all that apply:   Actively Enrolling  Closed to Enrollment  On Hold  Active Study Participants | | |
| * 1. Number of Participants Enrolled at the Network site(s) to Date:   Click or tap here to enter text. | | |
| * 1. Number of Participants Enrolled at all external sites to Date:   Click or tap here to enter text. | | |
| * 1. Total Target Number of Participants:   Click or tap here to enter text. | | |
| 1. **Report Information** | | |
| * 1. Type of Report:   Initial  Follow-up | | |
| * 1. If this is a follow-up report, please indicate the REB submission date(s) of previous   report(s):  Click or tap here to enter text. | | |
| 1. **Participant Information** | | |
| Participant Study ID#: Click or tap here to enter text. | | |
| Age (years) at time of event: Click or tap here to enter text. | | |
| 1. **Event Information** | | |
| * 1. Start Date of Event: Click or tap here to enter text. | | |
| * 1. Date Study Team became aware of Event: Click or tap here to enter text. | | |
| 4.3 Describe the Adverse Event(AE)/Unanticipated Problem:  *(Include why it is considered an unanticipated problem; concomitant illness; past medical history; medications;*  *relevant test results, etc.) \*Attach the completed sponsor’s serious adverse event (SAE) form (if applicable). Include*  *also, whether the event reaction was mild, moderate or severe.*  Click or tap here to enter text. | | |
| * 1. Describe the study team’s response to the event:   Click or tap here to enter text. | | |
| * 1. Participant outcome of the event (if known):   Click or tap here to enter text. | | |
| * 1. The Participant:   has withdrawn from the study  has been withdrawn from the study by the PI or site PI  has chosen to remain in the study | | |
| 1. **Seriousness (outcome) of the Adverse Event (AE)/Unanticipated Problem** | | |
| Check all that apply:  Resulted in death  Life Threatening  Required In-patient hospitalization or prolonged existing hospitalization  Resulted in persistent or significant disability/incapacity  Caused congenital malformation/birth defect  Caused mental/emotional stress or outburst  A breach of confidentiality  Based upon appropriate medical judgment, is an important medical event that may  jeopardize the health of the research participant, or may require medical  intervention to prevent one of the outcomes listed above. | | |
| 1. **Relatedness of the Adverse Event (AE)/Unanticipated Problem** | | |
| Check one:  Related / Probably Related  Possibly Related  Unlikely to be related | | |
| 1. **Safety Monitoring** | | |
| Is there an Independent Data Safety Monitoring Board/Independent Safety Monitoring Board for this study?  Yes  No  *If yes, ensure all DSMB/IDMC Meeting Summaries and decisions are submitted to the REB.* | | |
| 1. Impact Assessment | | |
| 8.1 Does the Adverse Event (AE)/Unanticipated Problem *require change(s) to the study protocol*?  Yes  No  *If yes, submit the changes using the Amendment Form.* | | |
| 8.2 Does the Adverse Event (AE/Unanticipated Problem *require change(s) to the informed consent form(s)?*  Yes  No  *If yes, submit the changes using the Amendment Form.* | | |
| 8.3 Should other study participants be *notified* of this Adverse Event (AE)/Unanticipated Problem?  Yes  No  *If no, please explain:*  Click or tap here to enter text. | | |
| * 1. Is this a reportable Serious Unexpected-Adverse Drug Reaction (SU-ADR) to Health Canada, the FDA or other   regulatory agency?  Yes  No  *If yes, please describe:*  Click or tap here to enter text. | | |
| * 1. Was this Adverse Event (AE) / Unanticipated Problem reported to a family physician, emergency physician, or   other medical personnel?  Yes  No | | |
| 1. Measures Proposed or Taken to Avoid Recurrence of the Event/Problem | | |
| Click or tap here to enter text. | | |
| 1. Site Investigator’s Comments | | |
| Click or tap here to enter text. | | |
| DECLARATION BY SITE INVESTIGATOR | | |
| As the PI or Site Investigator, I have reviewed and confirm the accuracy of the information included in this report. I confirm further that this study will continue to be conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans 2 ([TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/)), all applicable privacy legislation and other regulatory requirements. | | |
| **Name of PI or Site Investigator:** Click or tap here to enter text. | | |
| **Signature:** | **Date:** Click or tap here to enter text. | |