**BRUYÈRE HEALTH RESEARCH ETHICS BOARD –**

**SERIOUS ADVERSE EVENT/**

**UNANTICIPATED PROBLEM REPORTING**

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

1. **Definitions and Use of this Form:**
	1. **Adverse Event (AE):** any unfavorable 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 unfavorable 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 centers or institutions outside the jurisdiction of the Bruyère Health 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 centers under the jurisdiction of the Bruyère Health 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 Bruyère Health REB office:** **REB@bruyere.org**

**BRUYÈRE HEALTH RESEARCH ETHICS BOARD –**

**SERIOUS ADVERSE EVENT/**

**UNANTICIPATED PROBLEM REPORTING FORM**

|  |  |
| --- | --- |
| **REB #** | **Study Sponsor** |
|  |  |
| **Study Title** | **Principal Investigator or Bruyère Health Site Investigator** |
|  |  |
| **Date of Report** | **Name of Person filling out Report** |
|  |  |
| **Brief Description of Adverse Event/Unanticipated Problem** |
|  |
| 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:
 |
| * 1. Number of Participants Enrolled at all external sites to Date:
 |
| * 1. Total Target Number of Participants:
 |
| 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):  |
| 1. **Participant Information**
 |
| Participant Study ID#:  |
| Age (years) at time of event:  |
| 1. **Event Information**
 |
| * 1. Start Date of Event:
 |
| * 1. Date Study Team became aware of Event:
 |
| 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.* |
| * 1. Describe the study team’s response to the event:

  |
| * 1. Participant outcome of the event (if known):
 |
| * 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:*  |
| * 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:*  |
| * 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
 |
|  |
| 1. PI/Site Investigator’s Comments
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|  |
| DECLARATION BY PRINCIPAL INVESTIGATOR or BRUYÈRE HEALTH SITE INVESTIGATOR |
| As the PI or Bruyère Health 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 Bruyère Health Site Investigator:**  |
| **Signature:**  | **Date:**  |