**RESEARCH ETHICS BOARD – SERIOUS ADVERSE EVENT/UNANTICIPATED PROBLEM REPORT**

**DEFINITIONS**

**ADVERSE EVENT (AE):**

Any negative or unintended occurrence in the health or well-being of a research participant who is administered an investigational product (drug, device, or natural health product), or who undergoes a research procedure, and the event does not necessarily have a causal relationship with the investigational product or procedure.

**SERIOUS ADVERSE EVENT (SAE) OR REACTION:**

Any adverse event that:

* Results in death
* Is life-threatening
* Requires hospitalization, or an extended stay of existing hospitalization
* Results in significant birth defect/anomaly
* A medically significant event that jeopardizes the health of the research participant in order to prevent one of the above-mentioned outcomes.

**UNANTICIPATED PROBLEM**

An event, incident, or experience that is categorized as the following:

* A serious adverse event, or
* An event, incidence, outcome, or experience that generates a greater risk of either physical or psychological harm to the participant than what was initially anticipated, and may result in negative implications for the conduct of the study and the integrity of the research data;

**AND** meets **all** of the following criteria:

* The event, incident or experience is **unexpected** in light of the research procedures described in the study Protocol, consent forms, and all other related study documents;
* The event is either related or possibly related to the research activities;
* The event that occurred indicates that the research activities bring a greater risk of physical, psychological, economic or social harm to research participants than initially anticipated.

LOCAL UNANTICIPATED PROBLEM

An unexpected adverse event/problem that occurs at one of the locations or institutions in which the ROHCG REB serves as the board of record.

**EXTERNAL UNANTICIPATED PROBLEM**

An unexpected adverse event/problem that occurs at a location or institution outside of the ROHCG REB’s jurisdiction as the board of record.

|  |  |
| --- | --- |
| **REB NUMBER:** Click here to enter text.**PROTOCOL TITLE:** Click here to enter text. | **DATE:** Click here to enter a date.**PRINCIPAL INVESTIGATOR:** Click here to enter text. |
| **RECRUITMENT:**[ ]  Actively Enrolling [ ]  Closed to Enrollment | [ ]  On Hold [ ]  Active Study Participants |

**PLEASE ANSWER THE FOLLOWING:**

|  |  |
| --- | --- |
| Is the adverse event/problem **UNEXPECTED**? | ☐ Yes ☐ No |
| Is there a reasonable possibility that this adverse event/problem has, or may have, a **causal relationship** to the research?  | ☐ Yes ☐ No |

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 above), and:

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

**SECTION ONE: PARTICIPANT INFORMATION**

1.1 Participant Study ID#: Click here to enter text.

**SECTION TWO: EVENT INFORMATION**

2.1 Date of unexpected adverse event/problem: Click here to enter a date.

2.2 Date PI became aware of the unexpected adverse event/problem: Click here to enter a date.

2.3 Relatedness of the unexpected adverse event/problem:

 [ ]  Related / Probably Related

 [ ]  Possibly Related

 [ ]  Unlikely to be related

2.4 Description of the unexpected adverse event/problem: Click here to enter text.

2.5 Describe why the event is considered an adverse event/problem (please attach the

 sponsor’s serious adverse event (SAE) form (if applicable) to this report: Click here to enter text.

2.6 Seriousness of the unexpected adverse event/problem:

[ ]  Resulted in death

[ ]  Life threatening

[ ]  Required hospitalization or extended existing hospitalization

[ ]  Resulted in significant disability/incapacity

 [ ]  Caused congenital malformation/birth defect

 [ ]  Caused mental/emotional stress or outburst

 [ ]  A breach of confidentiality (If a privacy breach has occurred, the Privacy Office must be notified

 immediately)

**SECTION THREE: OUTCOME AND FOLLOW-UP**

3.1 What was the response by the study team to the unexpected adverse event/problem?

 Click here to enter text.

3.2 Describe the participant’s response to the unexpected adverse event/problem:

 Click here to enter text.

3.3 Did the participant remain in the study?

 [ ]  Participant remained in the study

 [ ]  Participant withdrew from the study

 [ ]  Participant was withdrawn from the study by the PI or site PI

3.4 As a result, does this require changes to the study Protocol or consent form(s)?

 ☐ Yes ☐ No

 If yes, please submit an amendment to the REB for review.

3.5 Will other study participants be notified of the unexpected adverse event/problem?

 ☐ Yes ☐ No

 If no, please explain: Click here to enter text.

3.6 Will this unexpected adverse event/problem reported to a family physician, emergency

 physician, or other medical personnel?

 ☐ Yes ☐ No

 If no, please explain: Click 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 here to enter text.

3.8 Is there an Independent Data Safety Monitoring Board (DSMB) for this study?

 ☐ Yes ☐ No

 If yes, ensure all DSMB Meeting Summaries are submitted to the REB.

* 1. Please describe what measures will be taken to avoid recurrence of the adverse

 event/unanticipated problem:

 Click here to enter text.

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*As the PI or Site Investigator, I confirm that the above information is true and accurate.*

*I confirm that this study has been conducted in compliance with TCPS2, ICH Good Clinical Practice Guidelines (ICH-GCP) and all applicable regulations and institutional policies and procedures.*

**Qualified/Principal Investigator Name (typed):** Click here to enter text.

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 **Qualified/Principal Investigator Signature** **Date of Signature:** Click here to enter a date.

***You must keep a copy of this completed form for your study file***