**RESEARCH ETHICS BOARD**

**LOCAL SERIOUS ADVERSE EVENT REPORT FORM**

**Instructions:**

* Use one (1) form for each local serious adverse event (note: non-local serious adverse events should be reported separately. See Instructions for Reporting of Local and Non-Local Adverse Events Guidelines).
* Email one (1) copy of the Local Serious Adverse Event Report form and any supporting documents to the WRH Research Ethics Board at [research.ethics@wrh.on.ca](mailto:research.ethics@wrh.on.ca)

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Title:** |  | | |
| **Principal Investigator:** |  | **WRH Principal/Local Investigator:** |  |
| **Report Type:** | Initial Report  Follow-Up Report | **WRH REB Reference #:** |  |
| **Most recent Data Safety Monitoring Board (DSMB) or Sponsor-generated analysis of SAEs to date (if applicable):** | | Attached  To follow  N/A – this is a single-centre study | |

1. **TYPE OF EVENT** (Check all that apply)

|  |  |
| --- | --- |
| Death |  |
| Life-threatening |  |
| Hospitalization – initial or prolonged |  |
| Disability |  |
| Congenital deformity |  |
| Medically important event |  |
| Other SAE *(specify in event description below*) |  |

1. **PARTICIPANT INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARTICIPANT ID:** | **SEX:** |  | **DATE(S) OF THE EVENT:** |
| **AGE:** |  |

1. **DESCRIPTION OF THE EVENT**

Provide a description of the serious adverse event below. Please include the following information:

* Medical term of the event;
* Description of the symptoms or event (including seriousness) AND the probable cause for the event;
* Participant’s current medical status
* If a Serious Adverse Drug Reaction Reporting Form for Hospitals was submitted to Health Canada, please attach a copy to this application

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1. **CAUSALITY**
2. In the opinion of the Local Principal Investigator, what is the relationship of the event to the study intervention? Check **one** only.

Unrelated

Unlikely related

Possibly related

Probably related

Definitely related

Unknown

1. Does the opinion of the Local Principal Investigator differ from the opinion of the Sponsor regarding the relationship of the event to the study intervention?

Yes  No

If ‘Yes’, the Local Principal Investigator must provide a comment below to help clarify any contrary opinion:

|  |
| --- |
|  |

1. **If both the Local Principal Investigator and the Sponsor state UNKNOWN** **regarding causal relationship to study intervention**, the Local Principal Investigator must provide a description of the reasoning:

|  |
| --- |
|  |

1. **ACTION TAKEN**

Check **all** that apply.

|  |  |
| --- | --- |
| Hospitalization – initial or prolonged |  |
| Study treatment altered (e.g. drug dose changed) |  |
| Study treatment stopped (e.g. drug stopped or device removed) |  |
| Study blind broken |  |
| Other (specify): |  |

1. **OUTCOME**

Check **all** that apply.

|  |  |
| --- | --- |
| Ongoing/Unresolved |  |
| Complete resolution |  |
| Partial recovery |  |
| Disability or impairment (permanent) |  |
| Disability or impairment (may improve with time) |  |
| Death |  |
| Other (specify): |  |

1. Did the participant remain in the study on protocol?

Yes  No

If ‘No’, is the participant’s clinical status being monitored?

Yes  No

1. In the opinion of the Local Principal Investigator, does the event alter the risk/benefit ratio?

Yes  No

1. In the opinion of the Local Principal Investigator, does the event warrant:
2. Continuation of the study?

☐ Yes ☐ No

1. Changes to study procedures and Protocol?

☐ Yes ☐ No

1. Changes to Information/Consent documents?

☐ Yes ☐ No

If ‘Yes’ to 9a, b, or c, please describe suggested changes:

|  |
| --- |
|  |

1. **SIGNATURE**

|  |  |  |
| --- | --- | --- |
| **Signatory Name** | **Signature** | **Date** |
| Local Principal Investigator |  | Date: |