**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

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| --- | --- |
| **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:

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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:

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|       |

1. **ACTION TAKEN**

Check **all** that apply.

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| --- | --- |
| 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:

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1. **SIGNATURE**

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