**WATERLOO-WELLINGTON RESEARCH ETHICS BOARD (WWREB)**

**Formerly known as Tri-Hospital Research Ethics Board (THREB)**

**LOCAL UNANTICIPATED PROBLEM OR SERIOUS ADVERSE EVENT REPORT FORM**

**INSTRUCTIONS**

1. Please email completed form with original signature of the Local Principal Investigator to: WWREB Administrative Coordinator, wwreb@grhosp.on.ca
2. Handwritten applications will not be accepted; please submit as a MS Word document
3. **Individual serious adverse events should only be reported when a determination has been made that the event meets all of the criteria for an unanticipated problem and the report includes all of the following information:**
	1. the event described is a local event
	2. the event described is both serious and unexpected and related or possibly related to participation in the study
	3. the report identifies all previous safety reports concerning similar adverse experiences
	4. the report analyzes the significance of the current adverse experience in light of the previous reports
	5. the report outlines any proposed protocol changes, informed consent form changes or other corrective actions to be taken in response to the unanticipated problem. (WWREB SOP4.5 <https://www.grhosp.on.ca/research/wwreb>)

**STUDY INFORMATION**

WWREB #:

Research Study, Full Title:

Local Responsible Investigator and Contact Information:

Sub-Investigator(s) or Research Coordinator(s):

1. Describe the event with a brief history:

2. a. Is it local? [ ] Yes [ ] No

b. Is it serious? [ ] Yes [ ] No

 c. Is it unexpected? [ ] Yes [ ] No

 d. Is it related or possibly related to the study? [ ] Yes [ ] No

**(NOTE: If you answered “No” to any of the above questions, there is no need to submit this report.)**

3. Identify any previous safety reports concerning similar adverse experiences:

4. Describe the significance of the current adverse experience in light of any previous reports:

5. Outline any proposed protocol changes, consent form changes, or other corrective actions to be taken:

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*Signature of Local Responsible Investigator* *Date*