  

# TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)

## LOCAL UNANTICIPATED PROBLEM OR SERIOUS ADVERSE EVENT REPORT FORM

*This form can be downloaded at:* [*http://www.grhosp.on.ca/research/tri-hospital-research-ethics-board*](%20http:/www.grhosp.on.ca/research/tri-hospital-research-ethics-board%20)

**Handwritten submissions are NOT acceptable**

**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:**

* the event described is a local event
* the event described is both serious and unexpected and related or possibly related to participation in the study,
* the report identifies all previous safety reports concerning similar adverse experiences,
* the report analyzes the significance of the current adverse experience in light of the previous reports, and
* the report outlines any proposed protocol changes, informed consent form changes or other corrective actions to be taken in response to the unanticipated problem. (THREB SOP4.5 [http://www.grhosp.on.ca/research/tri-hospital-research-ethics-board](%20http:/www.grhosp.on.ca/research/tri-hospital-research-ethics-board%20) )

THREB #:

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*

Please send completed form to: Shelley Croth, THREB, Building-Forty-Green Rm K415,

Grand River Hospital, 835 King St. W., Kitchener, ON N2G 1G3