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

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

**PROTOCOL DEVIATION REPORTING FORM**

**INSTRUCTIONS**

1. Submit this form via email with the original signature of the Local Principal Investigator (PI), along with all applicable documents, to the WWREB Administrative Coordinator at [wwreb@grhosp.on.ca](mailto:shelley.croth@grhosp.on.ca)
2. Indicate the number associated with your submission (if this is the first, second, third, etc. protocol deviation for this study)

**SECTION 1: Study Information**

Local PI:

Study title:

WWREB Study #:

Expiry date of WWREB approval:

Sponsor/funder:

Hospital/site name:

**SECTION 2: Protocol Deviation Report Information**

Study Protocol Deviation number (1, 2, 3, etc.):

Date of Protocol Deviation:

Date Deviation Reported to WWREB:

Date Deviation Reported to Sponsor (if applicable):

Participant Study ID # (if applicable):

This report pertains to a single study participant only:  Yes  No

If No, how many participants are affected: Click or tap here to enter text.

**SECTION 3: Protocol Deviation Details**

Describe the protocol deviation in detail, including an explanation for the reason for its occurrence**.**

Describe in detail how the event was handled and any corrective actions for this event, including a description of the participant’s outcome.

Provide a detailed plan to prevent similar deviations in the future.

**SECTION 4: Impact Assessment**

Does the Protocol Deviation impact the research participants’ rights, safety, or well-being?  Yes  No

Does the Protocol Deviation affect the scientific integrity of the study?  Yes  No

Does the Protocol Deviation require change(s) to the study protocol?  Yes  No

Does the Protocol Deviation require change(s) to the consent form(s)?  Yes  No

Was/were study participant(s) informed of the deviation?  Yes  No

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

Did this Protocol Deviation result in a Serious Adverse Event (SAE) / Unanticipated Problem?  Yes  No

If yes, please submit the SAE Reporting form.

**SECTION 5: Local Principal Investigator Attestation**

As the Local Principal Investigator, I have reviewed the protocol deviation and attest to the accuracy of this report.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name Signature Date