**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
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.

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Print Name Signature Date