William Osler Health System
Going Beyond

Research Ethics Board
William Osler Health System
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PLANNED PROTOCOL DEVIATION FORM

The WOHS Research Ethics Board serves as the Board of Record for Headwaters Health Care Centre and Central West Local Health Integration Network (LHIN).

Sites included in this review **(PLEASE CHECK ALL THAT APPLY)**:

☐ William Osler Health System ☐ Headwaters Health Care Centre ☐ Central West LHIN

Use this form if you are carrying out *temporary* changes to approved study procedures as a result of a publicly declared emergency. Please consider the impact of the publicly declared emergency on the whole conduct of your study to avoid multiple submissions of this form

This form must be submitted to the REB within 5 days of implementing the planned change

I. STUDY INFORMATION	
Name of Principal Investigator	
Study Full Title:	
Sponsor:	
REB#	
Is this study regulated by the FDA?	Yes ☐ No ☐
Is this study regulated by Health Canada	Yes ☐ No ☐

II. TYPE OF PLANNED PROTOCOL DEVIATION	
☐	Change the location of visits
☐	Changes to study intervention visit activities (i.e., removal of study procedures)
☐	Changes to visits (cancel/reschedule outside of approved window)
☐	Changes to post-intervention follow-up activities
☐	Changes to the nature of the study visits (i.e., in-person to telephone visit)
☐	Other planned protocol deviation

III. DESCRIPTION OF PLANNED CHANGE

Describe the currently approved procedure/protocol	
Describe the nature of the change (i.e., where visits will be moving to) **if changes are to the dosing window, explain how long the dosing window will be extended*	
Describe if the change will result in any other impacts (i.e., participant compensation, data analysis, study budget, etc.)	
Describe if the change will result in any impact on patient safety	
Describe the plan to notify patients of the proposed change (i.e., phone, email, letter) **Note: email contact is only permitted if explicit permission to use email has been obtained by the participant*	
Date planned deviation was implemented (DD/MMM/YY)	
Date planned deviation was notified to study Sponsor (DD/MM/YY)	
Planned change impacted on the following study participants:	Study Subject Number(s):
Was the planned change a result of a Serious Adverse Event (SAE)/ Unanticipated Problem?	☐ No ☐ Yes If Yes, please explain:
Are any of the following study documents affected by this change? **Note: Provide tracked and clean copies with this form*	☐ Informed Consent Form ☐ Protocol ☐ Data Collection Form ☐ Other:

This signature attests that the PI is aware of the deviation and its safety implications and has assessed the impact of the deviation on the study procedures:

Principal Investigator:_____ _____ _____

Print Name *Signature* *Date (DD/MMM/YY)*