NORTH YORK GENERAL
Making a World of Difference

PROTOCOL DEVIATION FORM

Please submit a typed signed hard copy of this form to the REB office

Date of this submission (dd/mmm/yyyy):	
NYGH REB #:	Multi -Site Study? YES ☐ NO ☐
Study Title:	
Name of NYGH Investigator:	
Funding Agency:	
Industry-Sponsored/Supported?* YES ☐ NO ☐ N/A ☐	
Date of Protocol Deviation (dd/mmm/yyyy):	
Date Protocol Deviation Reported to REB (dd/mmm/yyyy):	
Date Protocol Deviation Reported to Sponsor (dd/mmm/yyyy):	
Does this report pertain to a single study subject? YES ☐ NO ☐	

1. Type of Protocol Deviation (Check all that apply)	
Change in study procedure(s) initiated to eliminate immediate hazards to research participants	☐
Enrolment of a research participant who did not meet all protocol inclusion/ exclusion criteria, whether agreed to or not by the study Sponsor	☐
Over-enrolment (exceeding the target number of participants approved by the REB)	☐
Deviation in the consent process (i.e., failure to obtain informed consent, use of an invalid consent form, missing date of consent, missing signature)	☐
Performance of a study procedure not approved by the REB	☐
Failure to perform a required study procedure that, in the opinion of the Principal Investigator, may affect participant safety or data integrity	☐
Study procedure (i.e., study visit) performed outside of the required timeframe that, in the opinion of the Principal Investigator, may affect participant safety **or** data integrity	☐
Study drug/intervention errors (i.e., incorrect study drug/intervention, incorrect dosage of the study drug)	☐
Breach of confidentiality whereby a research participant's personal health information (PHI) is revealed to a person without a need to know, or by data exposure (i.e., digital device security breach, documents containing PHI are left unsecured)	☐
Other	☐

2. **Explain Protocol Deviation in Brief:**

3. Did (or could) the protocol deviation adversely affect the rights, safety, welfare or well-being of research participants or others?	☐
If YES, explain:	
4. Did this Protocol Deviation result in a Serious Adverse Event (SAE) / Unanticipated Problem?	☐
If YES, submit the 'Local SAE / Unanticipated Problem Reporting Form'	
5. Did (or could) this deviation compromise scientific integrity of the study?	☐
6. Does the Protocol Deviation require change(s) to the study protocol?	☐
If YES, submit the changes using the 'Amendment Form'	
7. Does the Protocol Deviation require change(s) to the consent form(s)?	☐
If YES, submit the changes using the 'Amendment Form'	

8. Describe the steps taken to correct /address the problems resulting from the protocol deviation:

9. Describe steps proposed to mitigate risk of similar deviation in future:

10. Statement of North York General Hospital (NYGH) Principal Investigator (PI)

(A NYGH Sub/Co-Investigator may sign in absence of PI if delegated by PI on the Task Delegation Log)

I attest that I as the Principal Investigator (PI) , I have reviewed the protocol deviation and its safety implications, assessed the relationship of the protocol deviation to the research study and attest to the accuracy of this report.

I warrant that this study will continue to be conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS), the Ontario Personal Health Information Protection Act (PHIPA) 2004 and other relevant laws, regulations or guidelines, [e.g., Health Canada Part C, Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations, Medical Devices Regulations, and ICH/GCP Consolidated Guideline E6].

Name of Investigator Signature of Investigator Date (dd/mmm/yyyy)

Research Ethics Office Use Only:

NYGH REB # :

Study Title:

Date Submitted : **Date Reviewed:**

Review Type: ☐ Expedited Review ☐ Full Board Review

Decision:

☐ Further review is NOT required by the REB

☐ REB Response letter with questions about protocol deviation

☐ Changes required by the REB (Description of Changes Required)

Final Decision by REB Chair/REB:
☐ Approved for continuation
☐ Approved conditional on changes
☐ Study Suspended pending further review

COMMENTS:

_____ _____
Chair, Research Ethics Board/ Designate Date (dd/mm/yyyy)