

SCARBOROUGH HEALTH NETWORK RESEARCH ETHICS BOARD PROTOCOL DEVIATION FORM

Please note, as of January 1st 2019, all researchers are required to have TCPS2 Certification. If you have not already done so, please provide your certificate.

SHN PROTOCOL NUMBER		
LOCAL PRINCIPAL INVESTIGATOR		
PROJECT TITLE		
Signature of Principal Investigator:		Date:
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		dd/mm/yr

1	Date of Protocol Deviation	dd/mm/yr
b	Date deviation reported to sponsor <input type="checkbox"/> N/A	dd/mm/yr
c	This report pertains to a single study subject	YES
		NO
d	This report pertains to more than one study subject	YES
		NO

2	The Protocol deviation was administrative	YES
a		NO
b	Summary of the deviation	

3	The Protocol deviation was clinically significant	YES
a		NO
b	Were study subject(s) adversely affected by the deviation? If yes, explain and submit a serious internal adverse event form	YES
		NO
c	Were study subject(s) informed of the deviation? If no, explain	YES
		NO
d	Does this deviation require a protocol amendment?	YES
		NO

Submit signed original: Research Office, Scarborough Health Network, 3050 Lawrence Avenue East, Room 1.245, 1st Floor, Scarborough, Ontario, M1P 2V5



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e	Provide description of the deviation. Attach any relevant supporting documentation including the report filed with the study sponsor (if applicable)
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