SHN Study No.: _____
Submission Date: _____

SCARBOROUGH HEALTH NETWORK RESEARCH ETHICS BOARD
OTHER EXTERNAL STUDIES SERIOUS ADVERSE EVENT (SAE) REPORT FORM

THIS FORM IS TO BE USED TO REPORT OTHER EXTERNAL STUDIES SERIOUS, UNEXPECTED ADVERSE REACTIONS OR EVENTS

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.

LOCAL PRINCIPAL INVESTIGATOR	
FULL PROTOCOL TITLE (Use the protocol title referenced)	
Are changes required to the Study Protocol or the Information Sheet/Consent Form as a result of this new information ☐ **YES** ☐ **NO?** If YES - I will submit changes on an Amendment Request form to the REB for review and approval.	**Signature of Local Principal Investigator:** Date:

Reactions or Events that are Not Serious, or Not Related or are Expected to the study intervention do not need to be reported to the REB.

ADVERSE REACTION OR EVENT IDENTIFICATION OR REFERENCE CODE (Reactions or events for the same study protocol approved by SHN REB but at other sites must be reported on the External SAE form)	Onset Date Indicate if Initial OR Follow Up (FU) Number	**RELATED** **R** = Related or Possibly Related **U** = Unknown or Uncertain **N** = Not Related (do not report)	**PT. OUTCOME** 1 = Death 2 = Hospitalization 3 = Medical Intervention 4 = Recovered 5= Life Threatening 6 = Other (specify)	**RESPONSE TO EVENT** 1 = none 2 = Dose Adjusted 3 = Discontinued from Study 4 = Other (specify)	Same drug different study	Same Indication Different study	**REACTION OR EVENT DESCRIPTION** *Make description very brief e.g. Syncope – hypotension due to treatment*
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					☐	☐	
					☐	☐	
					☐	☐	
					☐	☐	

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

Version: December 2018