SHN Study No.: _____
Submission Date: _____

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

THIS FORM IS TO BE USED TO REPORT EXTERNAL SERIOUS, UNEXPECTED ADVERSE REACTIONS OR EVENTS FROM THE SAME STUDY
(ALL OTHER EXTERNAL REPORTING MUST BE REPORTED ON OTHER EXTERNAL STUDIES 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.

LOCAL PRINCIPAL INVESTIGATOR	
FULL PROTOCOL TITLE	

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, expected, or Not Related to the study intervention do not need to be reported to the REB.

ADVERSE REACTION OR EVENT IDENTIFICATION OR REFERENCE CODE AND DATE OF SUBMISSION	**Onset Date (1) and Date of Resolution of SAE (2)**	**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)	**REACTION OR EVENT DESCRIPTION** *Make description very brief e.g. Syncope – hypotension due to treatment* Any additional documentation should be appended in the same order as listed on this form
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