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

SHN Study No.: _____
Submission Date: _____

This form is to be used to report **INTERNAL** Adverse Events **ONLY**
Use **one** form for each adverse event or patient
Initial and Follow-up Reports may be combined if appropriate

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	
Name of Sponsor	Name of Person Completing Form:
# patients enrolled at SRH to date	# of patients enrolled study wide to date

PATIENT ID OR REFERENCE #		INITIAL REPORT (**X** if YES)		FOLLOW UP REPORT #	
SEX M☐ F☐	**AGE**	**DATE(S) OF EVENT**			
Name or Medical Term of SAE:					

OUTCOME OF REACTION OR EVENT?	Death	
	Life threatening	
	Hospitalization – initial or prolonged	
	Disability	
	Congenital Deformity	
	Other (Describe in Synopsis section)	
UNEXPECTED OR EXPECTED?	**UNEXPECTED** – not identified in Investigator's Brochure, Product Monograph or Protocol or occurring with more than expected frequency	

ACTION TAKEN Indicate all that apply	Hospitalization – initial or prolonged	
	Study treatment altered (e.g. drug dose changed)	
	Study treatment stopped (e.g. drug stopped or device removed)	
	Study blind broken	
	Other (Describe under Description SAE/AE)	

If noted in ACTION TAKEN that the study treatment was stopped …..		
Is the subject still being followed up according to the study protocol?	YES	
	NO	
If NO, is the subject's clinical status being monitored	YES	
	NO	
	Not Applicable	
	Follow up not normally part of care	

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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OUTCOME Check all that apply	Complete resolution	
	Ongoing/Unresolved	
	Partial Recovery	
	Disability or impairment (Permanent)	
	Disability or impairment (May improve with time)	
	Death	
	Other (Describe under Description SAE/AE)	

In the opinion of the Local Principal Investigator, is this reaction or event related to the study drug, device or procedure? Please explain below rationale if event is not related.	YES – Definitely Related	
	YES – Probably or Possibly Related	
	Uncertain or Unknown	
	NO – Not Related	

In the opinion of the Local Principal Investigator, does the reaction or event warrant….	Closure of the Study?	**YES** ☐ **NO** ☐
	Changes to Study procedures and/or protocol?	**YES** ☐ **NO** ☐
	Revisions to the Information/Consent documents?	**YES** ☐ **NO** ☐

SYNOPSIS OF ADVERSE REACTION OR EVENT

Please provide a description of the serious adverse event below. Describe the symptoms of the event and the diagnosis if relevant. E.g. to simply indicate 'syncope' is not sufficient. If known, you must also include a diagnosis or reason for the event e.g. Syncope due to treatment-induced hypotension.
In addition to this Synopsis, you may attach other reporting forms or documentation as required by sponsors and regulatory authorities. Attachments must be legible and of good print quality.

_____ _____ _____
Printed Name of Principal Investigator Signature of Principal Investigator Date

The signature attests that the Principal Investigator has reviewed the SAE and its safety implications and the accuracy of the form.

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