



ADVERSE EVENT REPORT

Adverse Events must be summarized on this control sheet. MEDWATCH or CIOMS reports should also be attached.

OHREB Protocol Number:	
Protocol Title:	
Principal Investigator at the Ottawa Hospital:	
Therapeutic Product name:	
Date of this Report:	
Number of Adverse Events Included in this Report:	

ID	Type	Location	Is it drug related?	Event Describe the event as concisely as possible and check app. boxes	Are changes required to:				
					*DSMB Rev?	Serious	Unexpected	Protocol	Informed consent
SAE #: Date:	<input type="checkbox"/> New <input type="checkbox"/> F/U #	<input type="checkbox"/> Local <input type="checkbox"/> External	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Possibly		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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* DSMB = Data Safety Monitoring Board

Signature of Principal Investigator

Date

PLEASE FORWARD TO:

Ottawa Hospital Research Ethics Board, 751 Parkdale Ave, Suite 106, Ottawa Hospital, Civic Campus