

## Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax : 613-761-4311  
http://www.ohri.ca/ohreb

### ADVERSE EVENT REPORT

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

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

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"/>
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, 725 Parkdale Avenue, Civic Box 411, LOEB Building, Ottawa, ON K1Y 4E9