

**RESEARCH ETHICS BOARD (REB)  
INTERNAL SERIOUS ADVERSE EVENT (SAE) REPORTING FORM**

<b>NYGH REB #:</b>		<b>NYGH Principal Investigator (PI) Name:</b>			<b>Person Completing Form Name:</b>		<b>Phone Number:</b>				
					<b>Role:</b>		<b>E-mail:</b>				
<b>PROTOCOL TITLE:</b>				<b>Drug/Device/Intervention:</b>		<b>Sponsor:</b>			<b>Does study have a DSMB:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Date first member of study team aware of the SAE (dd-mm-yyyy)</b>	<b>Subject Code</b>	<b>Onset Date &amp; Resolution Date of SAE</b>	<b>Type</b>	<b>Name or Medical Term of SAE</b>	<b>Patient Outcome</b> 1 = Death 2 = Hospitalization 3 = Medical Intervention 4 = Recovered 5 = Other (specify)	<b>Response to Event</b> 1 = None 2 = Dose Adjusted 3 = Discont'd from Study 4 = Other (specify)	<b>Unexpected event</b>	<b>Relationship to Study Intervention</b>			
								<b>Related/ Probably Related</b>	<b>Possibly Related</b>	<b>Unlikely Related</b>	<b>Unrelated</b>
		<b>Date:</b>	<input type="checkbox"/> Initial <input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Study action recommended (if Yes go to * below)</b> <input type="checkbox"/> Yes <input type="checkbox"/> No						<b>Does this SAE meet the criteria for submission to Health Canada? (See REB Guidelines for Reporting an Internal SAE for submission requirements.)</b>					
						<input type="checkbox"/> Yes (The PI/Co-I attests that the SAE has been/will be submitted to Health Canada as required.)					
<b>* PI/Co-I recommends changes to:</b>						<input type="checkbox"/> No (The PI/Co-I attests that the SAE does not require submission to Health Canada.)					
<b>Protocol</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>Consent</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>IB</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		<b>Other changes</b> <input type="checkbox"/> Yes - Specify: <input type="checkbox"/> No							

**Summary of Serious Adverse Event:**

My signature below attests that I as a Principal Investigator (PI) or Co-Investigator (Co-I) have reviewed the SAE and its safety implications, assessed the relationship of the SAE to the study intervention and attest to the accuracy of this form.

\_\_\_\_\_  
Printed name of PI/Co-I

\_\_\_\_\_  
Signature of PI/Co-I

\_\_\_\_\_  
Date (dd/mmm/yyyy)