



REB Received Stamp

ST. JOSEPH'S HEALTH CENTRE REB INTERNAL SERIOUS ADVERSE EVENT REPORTING FORM

This form is to be used for events in SJHC study subjects only. Please use the External SAE Summary form for all events in subjects outside SJHC. Typed submissions are preferred. Email to santost@stjoe.on.ca or fax 416-530-6054.

(Version Date: 27Oct04)

REB Study#:		Principal Investigator:			Person Completing Form Name:		Fax Number:				
PROTOCOL TITLE or #:				Drug / Device / Intervention:		Sponsor:		DSMB <input type="checkbox"/> Yes <input type="checkbox"/> No			
Date of Submission (dd-mmm-yy)	Subject Code	Onset Date & Resolution Date of SAE	Type		Name or Medical Term of SAE	Patient Outcome 1 = Fatal 2 = Hospitalization 3 = Medical Intervention 4 = Recovered 5 = Ongoing 6 = Other (specify)	Study Action 1 = None 2 = Dose Adjusted 3 = Discont'd from Study 4 = Other (specify)	Relationship to Study Intervention			
			<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				Definitely/ Probably Related	Possibly Related	Unlikely/ Unrelated	Changes to IB/ protocol/ consent?
		Date: Date:	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Summary of Serious Adverse Event:

This signature attests that the PI has reviewed the SAE and its safety implications, has assessed the causality of the SAE and attests to the accuracy of the form.

Signature of Principal Investigator

Date

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Signature of Principal Investigator

Date

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