



REB Received Stamp

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

SAEs must be summarized on this summary form. Actual reports should be attached.

Typewritten submissions are preferred. Email to santost@stjoe.on.ca or fax 416-530-6054.

(Version Date: October 27, 2004)

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	
PI Initial & Date of Submission (dd-mmm-yy)	SAE Serial#/IND Report #	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)	Check All Applicable		
								Alters risk-benefit ratio	Event frequency/severity greater than expected	Changes to Protocol/Consent
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Signature of Principal Investigator

Date

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REB #:	Principal Investigator:	Person Completing Form (Include Fax number to receive acknowledgement) Name: _____ Fax Number: _____		
PROTOCOL TITLE or #:		Drug / Device / Intervention:	Sponsor:	DSMB <input type="checkbox"/> Yes <input type="checkbox"/> No

PI Initial & Date of Submission (dd-mmm-yy)	SAE Serial#/IND Report #	Onset Date & Resolution Date of SAE	Type		Name or Medical Term of SAE	Patient Outcome 1 = Death 2 = Hospitalization 3 = Medical Intervention 4 = Recovered 5 = Other (specify)	Study Action 1 = None 2 = Dose Adjusted 3 = Discont'd from Study 4 = Other (specify)	Check All Applicable		
								Alters risk-benefit ratio	Event frequency/severity greater than expected	Changes to Protocol/Consent
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Date: Date:	<input type="checkbox"/> Initial	<input type="checkbox"/> F/Up <input type="checkbox"/> Final				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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