

REB Received Stamp

MSH REB EXTERNAL SERIOUS ADVERSE EVENT SUMMARY REPORTING FORM

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

Handwritten submissions are NOT acceptable.

(Version Date: November 11, 2003)

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"/>
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		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

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