calerie Phase 2

Date received at DCRI Safety Surveillance

Serious Adverse Event Form

Report type: ☐ Initial
☐ Follow-up **#:** _____ **Center Number:** ___ ___ **Participant Number:** ___ ___ ___ ___ **Participant's Initials:** ___ ___ ___ (first middle last)

SAE Details:	**Participant's Details:**
SAE Term *(Medical Diagnosis)*: _____	**Date of birth:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
SAE Onset Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	**Gender:** ☐ Male ☐ Female
SAE Stop Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	

Serious Reporting Criteria: *(check all that apply)*	**Causality & Intensity:** *(check only one)*	**Outcome** *(at time of report)*: *(check only one)*
☐ Death ☐ Life-threatening ☐ Persistent or significant disability or incapacity ☐ Prolonged or required hospitalization ☐ Congenital anomaly or birth defect ☐ Other significant event requiring medical and/or surgical intervention	**Causality:** ☐ 1 None ☐ 2 Doubtful ☐ 3 Possibly ☐ 4 Probably ☐ 5 Very likely **Intensity:** ☐ 1 Mild ☐ 2 Moderate ☐ 3 Severe	☐ 1 Still present and unchanged ☐ 2 Improving ☐ 3 Resolved ☐ 4 Resolved with sequelae ☐ 5 Death → **If Death: Date of death:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Action Taken with Study Intervention: *(check all that apply)*

☐ None
☐ Intervention temporarily discontinued → **Complete and fax the Temporary Discontinuation from CR Intervention form**
☐ Medical therapy required
☐ Intervention permanently discontinued → **Complete and fax the Permanent Discontinuation from CR Intervention form**
☐ Other *(specify)*: _____

Notify DCRI Safety Surveillance of the SAE within 24 hours after your knowledge

Fax SAE form to DCRI Safety Surveillance at 1-919-668-7138 or 1-866-668-7138 within 24 hours of initial notification

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Medical History *(relevant to event)*:

Concomitant Medication *(do not list medication administered to treat this event)*:

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)

Relevant Lab Tests:

Test	Date	Value/Results	Normal Range
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		

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Please provide a brief summary of the event:	
Please describe the sequence of events including action taken, treatment given, hospital dates, etc.:	
Information Source:	
Date Investigator notified of Event: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	**Date of this report:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Person completing form: _____	**Phone number:** (___ ___ ___) ___ ___ ___ – ___ ___ ___ ___
PI name: _____	**Fax number:** (___ ___ ___) ___ ___ ___ – ___ ___ ___ ___
PI signature: _____	**Date of signature:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

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