Serious Adverse Event Form

Complete one form for each SAE. Submit all supporting source documents (with no identifying information). The source documents must be signed and dated by the investigator.

SAE report type			
☐ Initial	☐ Follow-up	☐ Final	
Participant or infant?	☐ Participant	☐ Infant	
SAE report date:	D D M M M Y Y Y Y		
Condition/Diagnosis:			
SAE Term (MedDRA Coding):			
Event Description: Include a history of the event chronologically including signs and characteristics, severity, dates and outcomes of hospitalization and any other relevant information not captured elsewhere on the form. Include relevant tests/data, treatment/procedures, medical history, treatment history.			

Serious Adverse Event Information		
Date of onset:	D D M M M Y Y Y Y	
Date when event became serious:	D D M M M Y Y Y Y	
Date SAE ended:	☐ Ongoing	D D M M M Y Y Y Y
SAE category:		
☐ Death	☐ Persistent or significant disability/incapacity	
☐ Life-threatening	☐ Other medically relevant condition judged or defined as serious	
☐ Other, please specify:	☐ New or prolonged hospitalization	
_____		
**As per the Protocol, congenital anomalies or birth defects will not be reported as an SAE*		

SAE status/clinical outcome:

- ☐ Death
- ☐ Not yet recovered
- ☐ Recovered with sequelae
- ☐ Recovered/Resolved
- ☐ Unknown

Relevant Information to SAE

Have relevant source documents been attached? ☐ Yes ☐ No

Study Medication

Date of first dose: D D M M M Y Y Y Y

Date of last dose prior to SAE: D D M M M Y Y Y Y

Action taken with study medication:

- ☐ No change
- ☐ Study medication temporarily discontinued
- ☐ Study medication permanently discontinued
- ☐ Other medication(s) started for AE/SAE: _____
- ☐ Other, please specify: _____

If the study medication was temporarily or permanently discontinued:

Study medication stopped on: D D M M M Y Y Y Y ☐ N/A

Study medication restarted on: D D M M M Y Y Y Y ☐ N/A

Did the event resolve after study medication stopped? ☐ Yes ☐ No ☐ N/A

Did event reappear after reintroducing study medication? ☐ Yes ☐ No ☐ N/A

Concomitant medications: Source documents have been attached? (Exclude those used to treat reaction) ☐ Yes ☐ No

This section to be completed by the Investigator only		
Severity/Intensity		
☐ Mild	☐ Moderate	☐ Severe
Causality		
☐ Unrelated	☐ Possibly related	☐ Related
Expectedness		
☐ Expected/Anticipated	☐ Unexpected/Unanticipated	
Gravity		
☐ Non-serious	☐ Serious	
Possible causes of the event (check all that apply):		
☐ Pre-existing/Underlying disease: _____		
☐ Study treatment: _____		
☐ Other treatment: _____		
☐ Other (e.g. accident, new or intercurrent illness): _____		

Reporting Centre	
Delegate's Name	
Delegate's Signature	
Investigator's Name:	
Signature:	
Date:	D D M M M Y Y Y Y

Coordinating Trial Centre	
Principal Investigator:	
Signature:	
Date:	D D M M M Y Y Y Y

In the occurrence of an SAE, the Sponsor is to be notified <u>within 24 hour</u>s of awareness of the event. The SAE CRF should be uploaded via the secure REDCap cloud electronic data management system along with all de-identified source documents, with an email to <u>laskeith@ucalgary.ca</u> and <u>alexandra.garven@ucalgary.ca</u> to confirm receipt of the SAE electronic CRF.