# 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**<br>☐ **Initial** ☐ **Follow-up** ☐ **Final** |
| **SAE report date:** D D M M M Y Y Y Y |
| **Condition/Diagnosis:** |

| **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 of last study dose:** | 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
☐ Life-threatening
☐ Other, please specify: _____

☐ Persistent or significant disability/incapacity
☐ Other medically relevant condition judged or defined as serious
☐ 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

**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.

## 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

**Is there a reasonable possibility that the SAE is related to the study medication?** ☐ Yes ☐ No

**Action taken with study medication:**

- ☐ No change
- ☐ Study medication temporarily discontinued
- ☐ Study medication permanently discontinued
- ☐ New medication(s) started: _____
- ☐ Other, please specify: _____

**Was the study medication temporarily interrupted?** ☐ No ☐ Yes, please complete below

Study medication stopped on: D D M M M Y Y Y Y

Study medication restarted on: D D M M M Y Y Y Y

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** | | |
|---|---|---|
| **Intensity** | | |
| ☐ Mild | ☐ Moderate | ☐ Severe |
| **Causality** | | |
| ☐ Unrelated | ☐ Possibly related | ☐ Related |
| **Grading** | | |
| ☐ Expected/Anticipated | ☐ Unexpected/Unanticipated | |
| **Possible causes of the event (check all that apply):** | | |
| ☐ Pre-existing/Underlying disease: _____ | | |
| ☐ Study treatment: _____ | | |
| ☐ Other treatment: _____ | | |
| ☐ Protocol-related procedure: _____ | | |
| ☐ Other (e.g. accident, new or intercurrent illness): _____ | | |

| **Reporting Centre** | |
|---|---|
| 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 within 24 hours 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 laskeith@ucalgary.ca to confirm receipt of the SAE electronic CRF.**