1. **Instructions**

Send the following to OSRO Safety immediately:

- Completed SAE report form with PI signature
- List of concomitant medications
- Baseline H&P and baseline lab results (at time of enrollment) for initial report
- Diagnostic test result reports (lab tests and imaging performed as part of SAE evaluation)
- If SAE was "hospitalization" or "prolonged hospitalization", provide Discharge Summary

NOTE: When providing copies of medical records, redact all personal identifiers, label copies with the Protocol # and Protocol Patient ID #

2. **REPORT TYPE**: (mark one) ○ INITIAL
○ FOLLOW UP, # #

3.

Report Information		
Date of this Report:	Protocol #	CTCAE Version: Select

Patient Information			
Protocol Patient ID: (Do not use MRN)	Age (years):	Gender (choose one): ☐ Female ☐ Intersex ☐ Male ☐ Transgender ☐ Prefer not to disclose	Weight (kg):
Ethnicity: ○ Hispanic / Latino ○ Not Hispanic / Latino	Race: (check all that apply) ☐ American Indian or Alaskan Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White		

4.

Serious Criteria (check at least one or all that apply)		
☐ Death	Date of death: Date PI informed of death:	Autopsy: Done (provide report) Not Done Planned Status Unknown
☐ Hospitalization	Admission date:	Discharge date:
☐ Prolonged Hospitalization	Admission date:	Discharge date:

Serious Criteria (check all that apply)
☐ Life-threatening (immediate risk of death)
☐ Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
☐ Congenital anomaly/birth defect
☐ Important Medical Event

5. **Adverse Event of Special Interest (AESI)**

☐ Reporting required per protocol

6. • In the section below, provide adverse event information:

Adverse Event	
Date of Event Onset:	
Date PI Notified of Event:	
Date PI Assessed Event As Serious	
Outcome of event: Select	If resolved, provide date of resolution:

7. • In the section below, list all **Study Interventions** that are part of the IND, and **commercial products** being used to test the research hypothesis:

Study Interventions:		**Actual Dose Given Prior to SAE:**	**Diagnosis for Use:**	**Route:**
Intervention # Select **Name**:		Enter Dose/Units		
First dose:	**Last dose** (prior to SAE)**:**	**Frequency:**	**Action Taken:**	
			Select Action Select	
Study Interventions:		**Actual Dose Given Prior to SAE:**	**Diagnosis for Use:**	**Route:**
Intervention # Select **Name**:		Enter Dose/Units		
First dose:	**Last dose** (prior to SAE)**:**	**Frequency:**	**Action Taken:**	
			Select Action Select	
Study Interventions:		**Actual Dose Given Prior to SAE:**	**Diagnosis for Use:**	**Route:**
Intervention # Select **Name**:		Enter Dose/Units		
First dose:	**Last dose** (prior to SAE)**:**	**Frequency:**	**Action Taken:**	
			Select Action Select	

Click button below to add another Study Interventions page.

Add Page

Event Term Table

8. • Provide CTCAE Term for Serious Adverse Event/AESI:

Event Term # #	Grade	Intervention:	Attribution:
	Select		Select
			Select
			Select
			Select
			Select
		Alternate Etiology:	
Event Term # #	**Grade**	**Intervention:**	**Attribution:**
	Select		Select
			Select
			Select
			Select
			Select
		Alternate Etiology:	
Event Term # #	**Grade**	**Intervention:**	**Attribution:**
	Select		Select
			Select
			Select
			Select
			Select
		Alternate Etiology:	
Event Term # #	**Grade**	**Intervention:**	**Attribution:**
	Select		Select
			Select
			Select
			Select
			Select
		Alternate Etiology:	

Click the button below to add another Event Terms page

Add Page

9. Has this patient previously experienced an AE or SAE in this clinical trial which required a modification or interruption in study intervention dosing?

◯ Yes ◯ No

If Yes, provide details:

10. • In the section below, provide specified information:

Description of SAE
IMPORTANT - The chronological summary of the clinical course of the SAE must include the following: ○ Clinical evaluations, assessments and diagnostic tests performed to evaluate the SAE ○ Relevant past medical, oncological, and other contributing history (e.g., allergies, smoking, alcohol use, etc.) ○ Events or comorbidities that confound or contributed to the SAE ○ Treatment(s) for the SAE ○ Alternate etiologies- must provide if event judged not related to study intervention(s) ○ PI overall assessment of the SAE
Select from the 'Description of Events' drop-down pick list: ○ Initial Description of Events for an Initial Report; or ○ Follow up # Description of Events for a Follow up Report.
Select report sequence as described above Select
Provide SAE Summary Description: (see next page)

Description of SAE

11. • What diagnostic testing was performed as part of the evaluation of this SAE?

List below. Provide a copy of Diagnostic Report(s). (Redact all Personal Identifiers, and label diagnostic report(s) with Protocol # and Protocol Patient ID #.)

12. In the section below, list all **Concomitant Medications** or provide a list of concomitant medications:
☐ Mark box if this section was left blank intentionally – list of concomitant medications provided

Drug name	Daily dose and route	Indication	Treatment start date	Treatment stop date

13.

Reporter Information	
Last name, First name	
Credential/Title	
CCR Branch	
Email address	
Phone number	

14.

PI Information	
Principal Investigator Name:	**PI Phone #:**

Principal Investigator Signature:

NOTE: the form will not be able to be modified after signature.

Click the button below to check that form is complete before saving.

Check Form