

	Office of Sponsor and Regulatory Oversight	Document #: F01-301-S01
	Serious Adverse Event Report Form	Revision #: 1
		Effective Date: 01AUG2019

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 #

REPORT TYPE: (mark one) INITIAL
 FOLLOW UP, # #

Report Information		
Date of this Report: (dd-mmm-yy)	Protocol # Enter Protocol #	CTCAE Version: Select

Patient Information			
Protocol Patient ID: (Do not use MRN) Enter Patient ID	Age (years): Numerical Value	Sex: Select Sex	Weight (kg): Numerical Value
Ethnicity: <input type="checkbox"/> Hispanic / Latino <input type="checkbox"/> Not Hispanic / Latino		Race: (check all that apply) <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White	

Serious Criteria (check all that apply)		
<input type="checkbox"/> Death	Date of death: (dd-mmm-yy) Date PI informed of death: (dd-mmm-yy)	Autopsy: <input type="checkbox"/> Done (provide report) <input type="checkbox"/> Not Done <input type="checkbox"/> Planned <input type="checkbox"/> Status Unknown
<input type="checkbox"/> Hospitalization	Admission date: (dd-mmm-yy)	Discharge date: (dd-mmm-yy)
<input type="checkbox"/> Prolonged Hospitalization	Admission date: (dd-mmm-yy)	Discharge date: (dd-mmm-yy)

	Office of Sponsor and Regulatory Oversight	Document #: F01-301-S01
	Serious Adverse Event Report Form	Revision #: 1
		Effective Date: 01AUG2019

Serious Criteria (check all that apply)
<input type="checkbox"/> Life-threatening (immediate risk of death)
<input type="checkbox"/> Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
<input type="checkbox"/> Congenital anomaly/birth defect
<input type="checkbox"/> Important Medical Event
Adverse Event of Special Interest (AESI)
<input type="checkbox"/> Reporting required per protocol

- In the section below, provide adverse event information:

Adverse Event	
Date of Event Onset:	(dd-mmm-yy)
Date PI Notified of Event:	(dd-mmm-yy)
Date PI Assessed Event As Serious	(dd-mmm-yy)
Outcome of event: Select Outcome	If resolved, provide date of resolution: (dd-mmm-yy)

- Provide CTCAE Term for Serious Adverse Event/AESI:

Event Term # #	Grade	Intervention:	Attribution to:
Click here to enter text	Select grade	Intervention # #	Select attribution
		Intervention # #	Select attribution
		Intervention # #	Select attribution
		Intervention # #	Select attribution
		Intervention # #	Select attribution
		Other: Click here to enter text.	Click here to enter text

TO ADD MORE ROWS/Event Terms and #: Click anywhere inside the table and then on the + sign on the bottom right of the table. Added rows cannot be deleted.

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

	Office of Sponsor and Regulatory Oversight	Document #: F01-301-S01
	Serious Adverse Event Report Form	Revision #: 1
		Effective Date: 01AUG2019

Study Interventions:		Actual Dose Given Prior to SAE:	Diagnosis for Use:	Route:
Intervention # ## Name: Type the name of the intervention		Enter Dose/Units	Click here to enter text	Select route Or, click here to enter text
First dose:	Last dose (prior to SAE):	Frequency:	Action Taken:	
(dd-mmm-yy)	(dd-mmm-yy)	Click here to enter frequency	Select Action	

TO ADD MORE ROWS: click anywhere inside the table and then on the plus  sign on the bottom right of the table.

- 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:

Click or tap here to enter text.

- 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:
<ul style="list-style-type: none"> ○ 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:
<ul style="list-style-type: none"> ○ <u>Initial Description of Events</u> for an Initial Report; <u>or</u> ○ <u>Follow up # Description of Events</u> for a Follow up Report.
Select report sequence as described above
Provide SAE Summary Description:
Click here to enter SAE summary description

	Office of Sponsor and Regulatory Oversight	Document #: F01-301-S01
	Serious Adverse Event Report Form	Revision #: 1
		Effective Date: 01AUG2019

- 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 #.)

Click here to enter text.

- 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
Click here to enter text.	Click here to enter text.	Click here to enter text.	(dd-mmm-yy)	(dd-mmm-yy)
Click here to enter text.	Click here to enter text.	Click here to enter text.	(dd-mmm-yy)	(dd-mmm-yy)
Click here to enter text.	Click here to enter text.	Click here to enter text.	(dd-mmm-yy)	(dd-mmm-yy)

TO ADD MORE ROWS: Click inside the table and then on the  sign on the bottom right of the table. Added rows cannot be deleted.

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

PI Information	
Principal Investigator Name: Click here to enter text.	PI Phone #: Click here to enter text.
Principal Investigator Signature:	
<div style="border: 1px solid black; height: 100px; width: 100%; display: flex; align-items: center; justify-content: center;"> X </div>	

	Office of Sponsor and Regulatory Oversight	Document #: F01-301-S01
	Serious Adverse Event Report Form	Revision #: 1
		Effective Date: 01AUG2019

Right click in the signature box above and select "Sign" to electronically sign.

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