

	Office of Sponsor and Regulatory Oversight	Document #: <b>FI01-301-S01</b>
	<b>Instructions for the Serious Adverse Event Form</b>	Revision #: <b>1</b>
		Effective Date: <b>01AUG2019</b>

**General information:**

The CCR OSRO SAE report form is accessed on the CCR website. Open “CCR Clinical Operations” Home Page at the following link <https://ccrod.cancer.gov/confluence/display/CCRCRO/Home>. Click on option #12 “CCR IND/IDE management” and in the new page click on “CCR SAE report form”. Open the CCR OSRO SAE report form and save the document in a secure location on the computer being used to complete the SAE report form.

The completed SAE report form should be emailed to [OSROSafety@mail.nih.gov](mailto:OSROSafety@mail.nih.gov). When sending the completed SAE report form (initial and follow up), please include the following information in the email subject line:

- Protocol number
- Protocol-specific patient ID number
- Serious adverse event CTCAE term
- Type of report: SAE initial report or follow-up report (with follow up number).

**NOTE:** When providing copies of medical records, redact all personal identifiers, label copies with the Protocol # and Protocol Patient ID #. Any patient Personally Identifiable Information (PII) shown on supporting documentation must be redacted prior to submission. There should be no names, addresses, identifying numbers (social security, hospital, medical record) on submitted documents. Review the documentation to ensure no other personally identifiable information is legible.

**Initial report:**

**Report type:** Indicate if this an initial report or a follow up report by putting an X in the appropriate box. With the initial SAE report provide the baseline H&P and baseline laboratory test results (at time of enrollment), concomitant medications, and diagnostic test reports (lab tests and imaging performed as part of the SAE evaluation).

Follow up reports are for any new information or updates related to a previous report. Select the follow up number from the drop-down list. This is a sequential number starting with “1” for the first follow up report submitted and then “2” for the second follow up report submitted and so on. This will be the same number as “follow up #” added under “Description of SAE”.

**Report information:** The “Date of this report” should be the date that the SAE report is being emailed to OSRO Safety. Enter the CCR protocol number in the field “Protocol #” and enter the CTCAE version number specified in the protocol in the field “CTCAE version”.

**Patient information:** Enter the protocol specific patient identification number. **Do not use the Medical Record Number (MRN).** Enter age, sex and weight in kilograms. For “Ethnicity”, check one box. For “Race” check all that apply. If there is additional race information available to include, document in the “Description of the SAE”.

**Serious Criteria:** check all that apply.

- Death: Provide the date of death from the drop-down calendar. Provide the date from the drop-down calendar on which the PI was informed of the death. To answer the question “was an autopsy

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performed?” check the appropriate box Done, Not Done, Planned, or Status Unknown. If an autopsy was performed, please request a copy of the autopsy report. If the autopsy report is not available, document contact attempts made to obtain the report and the reason the report will not be provided.

- Hospitalization: Provide the dates the patient was admitted to hospital and discharged from hospital. If the patient is currently in the hospital, leave the discharge date blank. In a follow up report enter the discharge date, outcome and resolution date. Provide a copy of the discharge summary when it becomes available. If during the hospitalization, another SAE occurs, the new SAE should be reported on a separate SAE report form.
- Prolonged Hospitalization: Provide the dates on which the patient was admitted to hospital and discharged from hospital. If the patient is currently in the hospital, leave the discharge date blank. In a follow up report enter the discharge date, outcome and resolution date. Provide a copy of the discharge summary when it becomes available.
- Congenital anomaly / birth defect: Check the box if the patient gave birth to an infant with a congenital anomaly or birth defect.
- Important Medical Event: These events may not result in death, be life threatening, or require hospitalization but may be considered serious, when based upon appropriate medical judgment. They may jeopardize the patient and may require medical or surgical intervention to prevent one of the other outcomes listed.

### Adverse Event of Special Interest (AESI)

If reporting an AESI, check the box on the SAE report form, “Reporting required by protocol”, under Adverse Events of Special Interest (AESI). Complete the form. If the AESI met serious criteria, then check the criteria as indicated under “Serious Criteria”.

### Event information:

1. **Date of Event Onset:** is the date the PI considers the event to have met one of the serious criteria.
2. **Date PI Notified of Event:** is the date the PI was informed of the event.
3. **Date PI Assessed Event as Serious:** date the PI determined the event met one of the serious criteria.
4. **Outcome of event and date of resolution:** If at the time of initial report, the event is ongoing, a follow up report must be submitted to provide final outcome and resolution date.

For “recovered/resolved” or “recovered/resolved with sequelae,” provide the date of resolution: Select the resolution date from the drop-down calendar. Note that SAEs will be followed until resolution. For “recovered/resolved with sequelae,” indicate the sequelae in the event description (for example, if the event is “stroke,” the sequelae may be “numbness in left arm”).

Some events may not resolve and should be followed until stabilization (until the PI does not expect any further improvement or worsening. Document the date of stabilization as the “resolution date” and outcome as “resolved with sequelae” and note the sequelae.

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5. **Reported term:** the “Serious Adverse Event term” must be the primary event that met serious criteria and is a valid CTCAE term according to the CTCAE version designated in the protocol. A specific diagnosis or syndrome should be provided rather than a list of signs and symptoms when possible (for example “lung infection” instead of “dyspnea” and “hypoxia”). Use the most accurate medical terminology when providing the SAE term, which can be updated when more information or a final diagnosis becomes available.

Provide the medical diagnosis or syndrome and not a list of symptoms. Grade of the event according to CTCAE grading: [https://ctep.cancer.gov/protocolDevelopment/electronic\\_applications/ctc.htm](https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm)

The Form contains a default table for reporting one event term. To report additional terms, click anywhere inside the table and then click on the  sign located at the bottom right corner of the table to add an additional blank table/row. If more than one term is reported, the study team will be queried to confirm serious criteria, onset date, and resolution for each term.

When only signs and symptoms are identified, as a diagnosis has not yet been made, then provide this information in the initial report. Once a diagnosis is made, submit a follow up report with the diagnosis listed and document in the description of the SAE that the reported term has been changed to the diagnosis and the signs and symptoms (that are part of the diagnosis) are no longer the SAE reported terms.

6. **Grade:** Select 1, 2, 3, 4, or 5 from the drop-down list to indicate the severity of the SAE according to the CTCAE clinical description for that CTCAE term.
7. **Intervention #:** Select the number of each intervention.
8. **Attribution** (related or unrelated): provide assessment for each study agent based on the current information available.
- Related: There is a reasonable possibility that the study product caused the adverse event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the adverse event.
  - Unrelated: There is not a reasonable possibility that the administration of the study intervention caused the event.

If the attribution for a study intervention is “unrelated” then the alternate etiology must be documented under “other” with a text description. For example, for a SAE of “back pain” which was unrelated to the study intervention, document under “Other” that the “back pain was related to a fall”.

Alternate etiology should be documented under “Other” with text description.

**Study Interventions information:** 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:** List the name and then number each of the study interventions (investigational and FDA approved, if applicable) and include administration information, “First dose”, “Last dose prior to SAE”, “Actual dose given prior to SAE”, “Frequency” (or regimen) and “Action taken” for each.

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**Diagnosis for use:** Enter the diagnosis under study or the indication for the intervention as listed in the protocol. If the intervention is being given as treatment for the cancer diagnosis under study in the protocol, then list the cancer diagnosis. If the intervention is, for example, chemotherapy for purposes of lymphodepletion prior to administering the cancer treatment, then document “lymphodepletion” as the indication for the chemotherapy.

If the answer to the question, “Has this patient previously experienced an AE or SAE in this clinical trial which required a modification or interruption in study intervention dosing?” is yes, provide the details of the dosing schedule change and the event that prompted the change.

**Description of SAE:**

**Description of event:** a chronological medical 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

Using the drop-down list, select Initial Description of Events for an initial report or select Follow up [#] Description of Events for a follow up report. Select the correct number for the Follow up Report in case of multiple follow up reports for the same SAE.

**Diagnostic Testing:** List any diagnostic tests performed as part of the SAE evaluation which could include imaging and laboratory tests. Attach a copy of all diagnostic reports. Label the reports with Protocol number and Protocol Patient ID number. All patient Personally Identifiable Information (PII) must be redacted from the diagnostic reports.

**Relevant concomitant medications** or therapies: note start dates and if administration is ongoing. Complete the provided table for concomitant medications or attach a separate list of medications. Mark the check box on the Form to indicate that a list is attached. If an attached list is provided, it must contain the information requested on the Form.

**Reporter Information Section:** The individual completing the Form will provide his/her name, credential/title, CCR branch, email address and phone number.

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**PI Signature:** It is required that the PI provide a signature on the SAE report form. Note: For the PI to digitally sign the SAE report, save the report to the computer which has the PI's PIV card inserted.

If the PI is not available to sign the Form, then the Form should be signed by the "covering" PI. If no PI is available to sign the report, provide the SAE report immediately and follow with the SAE report with PI signature within 24 hours. Once the SAE report form is signed the report can no longer be modified.

**Follow up report:**

Follow up reports are for any new information or updates related to a previous report. Select the follow up number from the drop-down list.

**Submit** a follow up report to provide final outcome and if resolved, provide the resolution date, if at the time of initial report, the event was ongoing.

**Summarize** the new information relevant to the course and outcome of the SAE.

**Changes to SAE event term** should be entered in the form and details provided in the description of the SAE. If the initial report provided signs and symptoms and subsequently those signs and symptoms were determined to represent a specific diagnosis, then provide the diagnosis as the event term. In the description, indicate that the signs and symptoms should be replaced with the unifying diagnosis.

The **grade of the event and attributions** may also be changed based on supporting evidence from further evaluation since the initial report was submitted.