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	Instructions for the Serious Adverse Event Report Form	Revision #: 2
		Effective Date: 08FEB2021

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1. General Information

The Serious Adverse Event Report form (F01-301-S01) is accessed on the CCR website under the [Clinical Research Operations Home Page](#). 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 NCIOSROSafety@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

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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.

2. Report Type

Indicate if this an initial report or a follow-up report by selecting the appropriate option.

- 2.1. **Initial SAE Reports:** 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).
- 2.2. **Follow-up Reports:** Used 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” (see Section [10](#)). See Section [15](#) for more information on Follow-up Reports.


3. Background Information

- 3.1. **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 select the CTCAE version number specified in the protocol from the drop-down list in the field “CTCAE version.”
- 3.2. **Patient information:** Enter the protocol specific patient identification number. **Do not use the Medical Record Number (MRN).** Enter age, gender 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 “Description of SAE” (see Section [10](#)).

4. Serious Criteria

Check each of the following 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 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

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follow-up report enter the discharge date, outcome and resolution date. Provide a copy of the discharge summary when it becomes available.

- **Life-threatening:** If the patient is at immediate risk of death, then check this box.
- **Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions:** Check the box if the patient is unable to conduct normal life functions as qualified.
- **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.

5. Adverse Event of Special Interest (AESI)

If reporting an AESI, check the box, “Reporting required by protocol” and complete the form. ONLY check AESI if expedited reporting to OSRO Safety is required per the protocol.

If the AESI meets serious criteria, then check the criteria as indicated under “Serious Criteria” (Section 4). Do not check “Important Medical Event” in the Serious Criteria section unless the AESI is serious by definition.

6. Adverse Event Information

6.1. **Date of Event Onset:** Date the PI considers the event to have met one of the serious criteria.

6.2. **Date PI Notified of Event:** Date the PI was informed of the event.

6.3. **Date PI Assessed Event as Serious:** Date the PI determined the event met one of the serious criteria.


6.4. **Outcome of Event and Date of Resolution:** Select the event outcome from the drop-down list.

Choices are:

- Recovered/Resolved (See Step 6.4.1)
- Recovering/Resolving
- Not Recovered/Not Resolved/Ongoing (See Step 6.4.2)
- Recovered/Resolved with Sequelae (See Step 6.4.1)
- Fatal
- Unknown

6.4.1. For “Recovered/Resolved” or “Recovered/Resolved with Sequelae,” provide the date of resolution; select the resolution date from the drop-down calendar. Note: SAEs will be followed until resolution. For “Recovered/Resolved with Sequelae,” indicate the sequelae as an event in the Event Terms table (Section 8). 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, i.e. until the PI does not expect any further improvement or worsening. Document the date of stabilization as the

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“resolution date” and outcome as “Recovered/Resolved with Sequelae” and note the sequelae in the Event Terms table (Section 8).

6.4.2. Note: If at the time of the initial report, the event is ongoing, then a follow-up report must be submitted to provide final outcome and resolution date.

7. Study Interventions

List all study interventions that are part of the IND and commercial products being used to test the research hypothesis.

Provide a sequential number and the name for each study intervention (investigational and FDA approved, if applicable). Note: the intervention names entered on SAE Report Form page 3 will be transferred automatically to the Event Terms table.

Provide the following administration information for each intervention:

- Actual dose given prior to the SAE
- 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.
- Route
- Date of first dose
- Date of last dose prior to the SAE
- Frequency (or regimen)
- Action taken – select the action from the drop-down list


If more than 3 study interventions exist, then click <Add Page> to duplicate page 3. Note: the intervention names entered on the duplicate page(s) are not transferred automatically to the Event Terms table.

8. Event Terms

In the Event Terms table, 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 (only serious events should be listed, not AEs). 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.

8.1. **Event Term #:** Number the event terms sequentially using the drop-down list.

8.2. **CTCAE Term:** Provide a valid CTCAE term according to the CTCAE version designated in the protocol to identify the Serious Adverse Event primary event that met serious criteria. Do not list AEs.

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Provide the medical diagnosis or syndrome and not a list of symptoms.

Enter the CTCAE Term in the cell located directly underneath the Event Term number.

8.3. **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. Definitions of the CTCAE grading may be found at https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm.

8.4. **Intervention:** List the study interventions which the patient received. The first 3 intervention names will be populated automatically from the entries made on SAE Report Form page 3. Subsequent interventions must be entered manually. If more than 5 interventions, then enter them in the next Event Term # row. Number the row the same as that of the Event Term # for interventions 1 – 5.

8.5. **Attribution:** Provide assessment for each study intervention based on the current information available. Select related or unrelated.

- **Related:** There is a reasonable possibility that the study intervention 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 in the provided text field. For example, for an SAE of “back pain” which was unrelated to the study intervention, document that the “back pain was related to a fall.”

8.6. When only signs and symptoms are identified, as a diagnosis has not been made yet, 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 SAE description (Section [10](#)) 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.

The Form contains a default table for reporting one page of event terms. If you require additional space for your reporting, click the <Add Page> button at the bottom of the page. If more than one term is reported, the study team will be queried to confirm serious criteria, onset date, and resolution for each term.

9. Previous AE or SAE

Consider 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?” If the answer is yes, then provide the details of the dosing schedule change and the event that prompted the change.

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10. 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.

11. Supporting Documentation

List any diagnostic tests, specialty consults or other notes performed as part of the SAE evaluation. Attach a copy of all reports referenced to the submitting email. Label the reports/notes with Protocol number and Protocol Patient ID number. All patient Personally Identifiable Information (PII) must be redacted from the diagnostic reports.

12. 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.

13. Reporter Information Section

The individual completing the Form must provide his/her name, credential/title, CCR branch, email address and phone number.

Checking Form Completeness: When you believe the form is complete and wish to ensure all fields are accounted for, click the "Check Form" button (at the bottom of the page, under signature). Any missing mandatory information will be highlighted. This must be entered before the document can be signed.

Note about Coordinating Centers: If you are the coordinating center for a multisite study, the SAE Report form must be checked for completeness, including appropriate supporting documentation prior to submitting to OSRO Safety.

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14. PI Signature

The PI (or someone listed on the 1572 form) must provide the signature on the SAE Report form. While OSRO expects all SAE Report forms to be either digitally signed by the PI or wet-signed by the PI, OSRO understands that due to teleworking and technical issues with the documents, some PIs may have difficulty signing the SAE Report form digitally or do not have access to a printer and scanner to wet-sign the document.

For the duration of the COVID-19 extended telework period, OSRO will accept an **unsigned** SAE Report form as long as the two conditions below are met:

- 14.1. The SAE Report form is sent to NCIOSROSafety@mail.nih.gov directly from the e-mail account of a clinician licensed to diagnose and listed on the 1572; and
- 14.2. The e-mail containing the SAE Report form includes the following attestation: "Due to COVID-19 remote telework limitations, I cannot sign the attached SAE Report form. I confirm that I have approved the content of the attached SAE Report form, for participant [Enter PID] in study [enter Study Number] as correct and complete."


The deviation from the normal submission process will end once NIH Group D is allowed to return to the NIH physical space. OSRO expects all other SAE Report forms to be signed appropriately. As a reminder, pasting of a signature image into the SAE Report form is never acceptable.

Prior to signing, click the <Check Form> button to have the application automatically review the form for errors. Correct any identified errors.

In order for the PI to digitally sign the SAE Report, save the report to the computer which has the PI's PIV card inserted. Once the SAE Report form is signed the form cannot be modified.

If the PI is not available to sign the Form, then the Form should be signed by the "covering" PI (a clinician licensed to diagnose and listed on the 1572). If no PI is available to sign the report, then send the unsigned SAE Report immediately and provide the PI-signed SAE Report within 24 hours.

Email the signed SAE Report form and supporting documentation (identified in Section [11](#)) to NCIOSROSafety@mail.nih.gov.

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15. Follow-Up Reports

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(s) 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 updated to reflect changes in assessment of the event based on supporting evidence.