NIDCR Serious Adverse Event (SAE) Form

COMPLETION INSTRUCTIONS

Please email (rho_productsafety@rhoworld.com) or fax (1-888-746-3293) this form to Rho Product Safety. If you have general questions about SAE reporting, you may contact Rho Product Safety by email or telephone (1-888-746-7231).

In the initial reporting of the SAE, provide all information known at this time. Additional information may be reported or requested as follow-up to the initial reporting.

Serious Adverse Event (SAE) Form	
1. Type of Study	For Item 1, use the link below to review the definition and check the appropriate response for this study. https://www.nidcr.nih.gov/research/human-subjects-research/types-of-human-subjects-research
2. Age	For Item 2, enter the participant's age at the time of the event onset. If the participant is >2 years old, enter the age in whole years, rounding down to the completed year. If the participant is <2 years old, enter the age in months, rounding down to the completed month. Check the appropriate box, months or years.
3. Gender	For Item 3, indicate the participant's gender - Male or Female.
4. Weight	For Item 4, record the participant's weight at the time of the SAE and check the appropriate unit of measurement.
5. Height	For Item 5, record the participant's height at the time of the SAE and check the appropriate unit of measurement.
6. Ethnicity	For Item 6, check the appropriate ethnicity reported by the subject. If not reported or unknown, indicate on the form.
7. Race	For Item 7, check the appropriate race reported by the subject.
8. SAE Term (provide diagnosis) **8a. If diagnosis is not known, symptoms**	For Item 8, enter the SAE term and provide the diagnosis if known. For Item 8a, if the diagnosis is unknown, enter the symptoms.

9. Date of Onset	For Item 9, record the date of onset in DD/MMM/YYYY format. Record the date that the event became serious.
10. Severity Grade	For Item 10, check the highest severity grade of the event. If there is follow-up to the event, the highest severity grade should be checked, even if the follow-up information lowers the severity grade.
11. Did the participant receive the investigational product or study intervention at any time prior to this SAE? **11a. If Yes, identify the investigational product or study intervention received prior to the SAE**	For Item 11, indicate if the participant received the investigational product (IP) or study intervention at any time prior to this SAE. For Item 11a, if Yes is checked, provide additional details regarding the IP or study intervention. If there is no IP or study intervention, check N/A.
12. What action was taken with the investigational product / study intervention?	For Item 12, check the best description for action taken with the listed investigational product/study intervention as a result of the SAE. If there is no IP or study intervention, check N/A.
13. Outcome of SAE	For Item 13, check the best description for the outcome of the SAE.
14. Date of Resolution	For Item 14, record the date of resolution in DD/MMM/YYYY format. If the SAE is ongoing at the end of the study, check the Ongoing at end of study box.
15. Criteria for SAE (check all that apply) **If Fatal: 15a. Date of death** **15b. Primary cause of death** **15c. Was an autopsy performed?**	For Item 15, check the criteria for "seriousness" met by the SAE. Check all that apply. At least one criterion must be met. If the SAE was Fatal, provide: • For Item 15a, date of death in the DD/MMM/YYYY format • For Item 15b, primary cause of death • For Item 15c, whether an autopsy was performed
16. Relationship to investigational product / study intervention	For Item 16, check the item that describes the relationship between the event and the investigational product/study intervention. This relationship must be assessed by the investigator or designee. If the study is non-interventional, check that box and proceed to #17.

17. If SAE is unrelated to investigational product / study intervention or this is a non-interventional study, select all possible etiologies	For Item 17, if the SAE is unrelated to investigational product / study intervention, check all factors that apply. Provide specific details of each checked factor. If a possible contributing factor is not listed, check Other and describe the suspected contributing factor. Leave this item blank if Related is checked for Item 16.
18. Did the participant receive any relevant concomitant medications in response to the SAE? **18a. If Yes, add each medication below**	For Item 18, indicate if any relevant concomitant medications were given in response to the SAE. For Item 18a, If Yes, provide the following: • Medication Name • Indication • Start Date in DD/MMM/YYYY format • Stop Date in DD/MMM/YYYY format, or • Check if it is Ongoing
19. Did the participant receive any treatments / procedures in response to the SAE? **19a. If Yes, list each treatment and procedure below**	For Item 19, indicate if the participant received any treatments or procedures in response to the SAE. For Item 19a, If Yes, provide the following: • Treatment or Procedure • Start Date in DD/MMM/YYYY format • Stop Date in DD/MMM/YYYY format, or • Check if it is Ongoing
20. Relevant Laboratory / Diagnostic Tests **20a. If Yes, list each test and results below**	For Item 20, indicate if relevant tests were administered in response to the SAE. Please note that laboratory and/or diagnostic tests should be recorded on this form only if the investigator considers them to be relevant to the SAE. For Item 20a, If Yes, provide the following: • Lab/Diagnostic Test • Date of test • Result • Low Range/High Range • Comments
21. Narrative / Comments	For Item 21, record the narrative description of the SAE, including chronological clinical presentation and evolution of the SAE and associated signs/symptoms.
22. Statement of Investigator and Signature	For Item 22, the person who completed the form signs and enters the date completed. The investigator signs and dates the form to verify review and agreement with the assessment.