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. Age	For Item 1, 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.
2. Gender	For Item 2, indicate the participant's gender - Male or Female.
3. Weight	For Item 3, record the participant's weight at the time of the SAE and check the appropriate unit.
4. Height	For Item 4, record the participant's height at the time of the SAE and check the appropriate unit.
5. SAE Term / Symptoms	For Item 5, enter the SAE term and provide diagnosis if known. If diagnosis is unknown, enter the symptoms.
6. Date of Onset	For Item 6, record the date of onset in dd/mmm/yyyy format. Record the date that the event became serious.
7. Severity Grade	For Item 7, 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.
8. Did the participant receive the investigational product or study intervention prior to this SAE?	For Item 8, indicate if the participant received the investigational product (IP) or study intervention prior to this SAE. If Yes is checked, provide additional details regarding the IP or study intervention. If there is no IP or study intervention, check N/A.

9. What action was taken with the investigational product / study intervention?	For Item 9, 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.
10. Outcome of SAE	For Item 10, check the best description for the outcome of the SAE.
11. Date of Resolution	For Item 11, record the date of resolution in dd/mmm/yyyy format. If the SAE is ongoing at the end of the study, check the Ongoing box.
12. Criteria for SAE	For Item 12, 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: • Date of death in the dd/mmm/yyyy format • Primary cause of death • Whether an autopsy was performed
13. Relationship to investigational product / study intervention	For Item 13, 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.
14. If SAE is unrelated to investigational product / study intervention	For Item 14, 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 13.
15. Relevant Concomitant Medications	For Item 15, indicate if any relevant concomitant medications were given in response to the SAE. 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

16. Treatments / Procedures	For Item 16, indicate if the participant received any treatments or procedures in response to the SAE. 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
17. Relevant Laboratory / Diagnostic Tests	For Item 17, 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. Indicate if relevant tests were administered in response to the SAE. If Yes, provide details of the laboratory tests along with the normal ranges.
18. Narrative / Comments	For Item 18, record the narrative description of the SAE, including chronological clinical presentation and evolution of the SAE and associated signs/symptoms.
19. Statement of Investigator and Signature	For Item 19, the investigator signs and dates the form to verify review and agreement with the assessment. Enter the name of the person who completed the form and the date completed.