NIDCR Serious Adverse Event (SAE) Form

COMPLETION INSTRUCTIONS

Please complete and email (rho_productsafety@rhoworld.com) or fax (1-888-746-3293) this form to NIDCR's CROMS contractor (Rho). 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	
Type of Report	Select either Initial or Follow-up
Is the research being Conducted under an IND/IDE?	Select Yes or No
Is this study under a single IRB (sIRB)?	Select Yes or No
IRB/IEC name (or local IRB/IEC if not relying on an sIRB)	If the study is subject to the NIH Single IRB policy, enter the name of the IRB of Record. If the study is not subject to the NIH Single IRB policy, enter the name of the local IRB.
Required time frame for reporting SAE to the IRB	Record the per protocol timeline for reporting SAE to the IRB
Date event submitted to local or single IRB	Record the date the event was submitted to the IRB in YYYY-MM-DD format
Required time frame for reporting SAE to the NIDCR	Record the per protocol timeline for reporting SAE to the NIDCR
1. Date investigator became aware of event	Enter the date the investigator became aware of the event in YYYY-MM-DD format

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2. Type of Study	Review the definitions below and select one of the following options: • Interventional - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. • Observational - A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to specific interventions/treatment. • Expanded Access - A way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration (FDA). Also called compassionate use.
3. Age	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.
4. Sex	Indicate the participant's sex at birth - Male or Female.
5. Weight	Record the participant's weight at the time of the SAE and check the appropriate unit of measurement.
6. Height	Record the participant's height at the time of the SAE and check the appropriate unit of measurement.
7. Ethnicity	Check the ethnicity reported by the participant. If not reported or unknown, indicate on the form.
8. Race	Check the race reported by the participant.
9. SAE Name and/or Diagnosis **9a. If diagnosis is not known, symptoms/signs**	Enter the SAE name and provide the diagnosis if known. For Item 9a, if the diagnosis is unknown, enter the symptoms and/or signs.

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10. Date of SAE Onset	Record the date of onset in YYYY-MM-DD format. Record the date that the event became serious (i.e., met one of the criteria to be considered an SAE).
11. Criteria for SAE (check all that apply) **If Fatal:** **11a. Date of death** **11b. Primary cause of death** **11c. Was an autopsy performed?** **11d. If known, what were the pertinent findings from the autopsy related to cause of death?**	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/resulted in death, provide: • 11a: Date of death in the YYYY-MM-DD format • 11b: Primary cause of death • 11c: Whether or not an autopsy was performed • 11d: Pertinent findings from the autopsy related to cause of death, if known. Otherwise, check Unknown.
12. Severity Grade	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.
13. Did the participant receive the IP or study intervention at any time prior to this SAE? **13a. If Yes, identify the IP or study intervention received prior to the SAE**	Indicate if the participant received the investigational product (IP) or study intervention at any time prior to this SAE. If there is no IP or study intervention, check N/A. 13a: If Yes is checked, provide additional details regarding the IP or study intervention, including information regarding causality (Relationship of SAE to IP/Intervention) and expectedness. Refer to the HHS OHRP website for additional guidance as to determining expectedness. (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html) NOTE: Unmasking should occur only per protocol.
14. Outcome of SAE	Check the best description for the outcome of the SAE.
15. Date of SAE Resolution	Record the date of resolution in YYYY-MM-DD format. If the SAE is ongoing at the end of the study, check the Ongoing at end of study box.

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16. If SAE is unrelated to investigational product / study intervention or this is an observational study, select all possible etiologies	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.
17. Did the participant receive any relevant concomitant medications in response to the SAE? **17a. If Yes, add each medication below**	Indicate if any relevant concomitant medications were given in response to the SAE. For Item 17a, If Yes, provide the following for each concomitant medication given: • Medication Name • Indication • Dose • Frequency • Start Date in YYYY-MM-DD format • Stop Date in YYYY-MM-DD format, or • Check if it is Ongoing
18. Did the participant receive any treatments / procedures in response to the SAE? **18a. If Yes, list each treatment and procedure below**	Indicate if the participant received any treatments or procedures in response to the SAE. For Item 18a, If Yes, provide the following for each treatment or procedure given: • Treatment or Procedure • Start Date in YYYY-MM-DD format • Stop Date in YYYY-MM-DD format, or • Check if it is Ongoing
19. Relevant Laboratory/ Diagnostic Tests **19a. If Yes, list each test and results below**	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 19a, If Yes, provide the following for each laboratory or diagnostic test performed in relation to the SAE: • Lab/Diagnostic Test • Date of test in YYYY-MM-DD format • Result • Units • Low Range (of normal limits) • High Range (of normal limits) • Comments

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20. Narrative / Comments	Record the narrative description of the SAE, including chronological clinical presentation and evolution of the SAE and associated signs/symptoms.
21. Statement of Investigator and Signature	The investigator signs and dates the form to verify review and agreement with the assessment. The person who completed the form signs and enters the date completed.