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).

Please select 'initial' for type of report when reporting the SAE initially and provide all information known at the time of submission of the initial report.
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. When submitting the initial report, ensure "Initial" is checked. When submitting subsequent versions of the form for an event (i.e., update to the event status/details, response to queries, etc.), ensure "Follow-Up" is checked.
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 timeline for reporting SAE to the IRB. This information may be available in the protocol, MOP, or other study documents.
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 timeline for reporting SAE to the NIDCR. This information may be available in the protocol, MOP, or other study documents, and may be the same as the timeframe to report to the IRB.
List all sources of information (ex; participant self-reported, electronic medical records, study record, etc.)	Record all sources of information used to complete the form.

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1. Date investigator became aware of event	Enter the date the investigator became aware of the event in YYYY-MM-DD format
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. If weight is not known at the time of the SAE, then use the last known available weight 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.

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7. SAE Name and/or Diagnosis **7a. If diagnosis is not known, symptoms/signs**	Enter the SAE name (Influenza) and provide the diagnosis if known. For Item 7a, if the diagnosis is unknown, enter the symptoms and/or signs. The SAE name should be the diagnosis, if known, not the signs or symptoms.
8. 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).
9. Criteria for SAE (check all that apply) **If Fatal:** **9a. Date of death** **9b. Primary cause of death** **9c. Was an autopsy performed?** **9d. If known, what were the pertinent findings from the autopsy related to cause of death?**	Check the criteria that qualifies the event as an SAE. Check all that apply. • results in death; • is life-threatening (places the subject at immediate risk of death from the event as it occurred); • results in inpatient hospitalization or prolongation of existing hospitalization; • results in a persistent or significant disability/incapacity; • results in a congenital anomaly/birth defect; • required intervention to prevent one of the other outcomes listed; • important medical event (based upon medical judgement, may jeopardize the subject's health and may require medical or surgical intervention At least one criterion must be met. If the SAE was fatal/resulted in death, provide: • 9a: Date of death in the YYYY-MM-DD format • 9b: Primary cause of death • 9c: Whether or not an autopsy was performed • 9d: Pertinent findings from the autopsy related to cause of death, if known. Otherwise, check Unknown.
10. Severity Grade **Please refer to your protocol assigned definition of severity.**	Select 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.

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11. Did the participant receive the IP or study intervention at any time prior to this SAE? **11a. 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. 11a: 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. If dose, unit, and frequency don't apply to the intervention, then leave blank. 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) Only evaluate expectedness if the event is considered to be related to the IP/study intervention. If relationship of SAE to IP/Intervention determined to be unrelated (see question 11a), select N/A for the expectedness question. NOTE: Unmasking should occur only per protocol.
12. Outcome of SAE	Check the best description for the outcome of the SAE. • Ongoing at this time (event is still ongoing) • Resolved without sequelae (event is resolved) • Resolved with sequelae (event is resolved, but patient has some permanent condition as a consequence of the event) • Death • Present at death, not contributing to death
13. 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.
14. 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 to the etiology of the SAE. Provide specific details of each checked factor. If a possible contributing factor is not listed, check Other and describe the suspected contributing factor.

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15. Did the participant receive any relevant concomitant medications in response to the SAE? **15a. If Yes, add each medication below** **(If the number of concomitant medications exceeds the maximum number of rows allowed in the table, please consider creating an appendix at the end of this form to capture all relevant information).**	Indicate if any relevant concomitant medications were given in response to the SAE. If the information is not known (for any reason), check Unknown, and ensure to provide a justification in the narrative (item 18). For Item 15a, If Yes, provide the following for each concomitant medication given: • Medication Name • Indication • Dose • Frequency • Route of Administration • Start Date in YYYY-MM-DD format • Stop Date in YYYY-MM-DD format, or • Check if it is Ongoing
16. Did the participant receive any therapies/surgeries/procedures in response to the SAE? **16a. If Yes, list each therapy, surgery, and/or procedure below** **(If the number of therapies/surgeries/procedures exceeds the maximum number of rows allowed in the table, please consider creating an appendix at the end of this form to capture all relevant information).**	Indicate if the participant received any therapies, surgeries, and/or procedures in response to the SAE. If the information is not known (for any reason), check Unknown, and ensure to provide a justification in the narrative (item 18). For Item 16a, 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

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17. Relevant Laboratory/ Diagnostic Tests **17a. If Yes, list each test and results below** **(If the number of laboratory/diagnostic testing exceeds the maximum number of rows allowed in the table, please consider creating an appendix at the end of this form to capture all relevant information).**	Indicate if relevant tests were performed in response to the SAE. If the information is not known (for any reason), check Unknown, and ensure to provide a justification in the narrative (item 18). 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 17a, 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
18. Narrative / Comments **If 'Unknown' was selected for questions 15, 16, or 17, please provide an explanation in the narrative.**	Record the narrative description of the SAE, including chronological clinical presentation and evolution of the SAE. The narrative should summarize the entire course of the SAE, from presenting symptoms/signs to diagnosis, management/treatment/therapy, through resolution and/or stabilization. Additionally, provide an explanation regarding any "Unknown" responses in the form.
19. Statement of Investigator and Signature **Prior to signing the form, please save a copy to allow for future revisions to be made if requested.**	The investigator signs and dates the form to verify the information and agree with the assessment. The person who completed the form signs and enters the date completed in YYYY-MM-DD format.