

NIDCR Serious Adverse Event (SAE) Form

Protocol #: _____

PI Name/Site Name: _____

Participant ID #: _____

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).

Type of Report: Initial Follow-up

Is the research being conducted under an IND/IDE? Yes No

Is this study under a single IRB (sIRB)? Yes No

IRB/IEC name (or local IRB/IEC if not relying on an sIRB): _____

Required time frame for reporting SAE to the IRB: _____

Date event submitted to local or single IRB (DD/MMM/YYYY): _____

Required time frame for reporting SAE to the NIDCR: _____

1. Date investigator became aware of event: _____ (DD/MMM/YYYY)

2. Type of Study: Interventional Observational Expanded Access

3. Age: _____ years months

4. Sex: _____ Male Female

5. Weight: _____ kg lbs

6. Height: _____ cm in

7. Ethnicity: Hispanic or Latino Not Hispanic or Latino Not reported Unknown

8. Race

American Indian or Alaskan Native Asian Black or African American

Native Hawaiian or Other Pacific Islander White Other: _____

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9. SAE Name and/or Diagnosis _____

9a. If diagnosis is not known, symptoms/signs: _____

10. Date of SAE onset: _____ (DD/MMM/YYYY)

11. Criteria for SAE (*Check all that apply*):

Resulted in death

Resulted in a congenital anomaly/birth defect

Life-threatening

Required intervention to prevent one of the other outcomes listed

Resulted inpatient hospitalization or prolongation of existing hospitalization

Important medical event

Resulted in persistent or significant disability/incapacity

If fatal: 11a. Date of death: _____ (DD/MMM/YYYY)

11b. Primary cause of death: _____

11c. Was an autopsy performed? Yes No

11d. If known, what were the pertinent findings from the autopsy related to cause of death?

 Unknown

12. What is the severity grade of the SAE?

Grade 1 / Mild

Grade 3 / Severe

Grade 5 / Death

Grade 2 / Moderate

Grade 4 / Life-threatening

PLEASE NOTE: Q13 asks about investigational product or study intervention, but is not asking you to break the study blind. Unmasking should occur only per protocol.

13. Did the participant receive the investigational product (IP) or study intervention at any time prior to this SAE?

Yes

No

N/A (non-interventional study or expanded access, proceed to #14)

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13a. If Yes, identify the IP or study intervention(s) received prior to the SAE:

IP/Study Intervention (or Control) ¹	Dose	Units	Frequency	Route	Study Visit #/ Name	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Check if Ongoing	Action Taken at Time of SAE	Relationship of SAE to IP/ Intervention ²	Expectedness ³
								<input type="checkbox"/>	<input type="checkbox"/> Continued <input type="checkbox"/> Lowered <input type="checkbox"/> Interrupted <input type="checkbox"/> Discontinued <input type="checkbox"/> Increased <input type="checkbox"/> N/A	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Expected, per: <input type="checkbox"/> Protocol <input type="checkbox"/> Investigator Brochure <input type="checkbox"/> Package Insert <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unexpected
								<input type="checkbox"/>	<input type="checkbox"/> Continued <input type="checkbox"/> Lowered <input type="checkbox"/> Interrupted <input type="checkbox"/> Discontinued <input type="checkbox"/> Increased <input type="checkbox"/> N/A	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Expected, per: <input type="checkbox"/> Protocol <input type="checkbox"/> Investigator Brochure <input type="checkbox"/> Package Insert <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unexpected
								<input type="checkbox"/>	<input type="checkbox"/> Continued <input type="checkbox"/> Lowered <input type="checkbox"/> Interrupted <input type="checkbox"/> Discontinued <input type="checkbox"/> Increased <input type="checkbox"/> N/A	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Expected, per: <input type="checkbox"/> Protocol <input type="checkbox"/> Investigator Brochure <input type="checkbox"/> Package Insert <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unexpected

¹ For masked studies, assignment of active intervention vs. control will not be known. For unmasked studies, treatment assignment should be listed.

² **Related** = Associated with the use of the study intervention; there is a reasonable possibility that the experience may have been caused by the study intervention. Includes possible, probable, and definite. **Unrelated** = Includes unlikely and not related.

³ **Expected** = Described in the Investigator Brochure, Package Insert, protocol, or other document. **Unexpected**: Not consistent with the known foreseeable risks associated with the intervention or procedure at the specificity, severity, or frequency described in the Investigator Brochure, Package Insert, protocol, or other study document, or the expected natural progression of any underlying disease, disorder. May not be recognized as first occurrence, but on second occurrence.

14. Outcome of SAE:

- | | | |
|---|--|---|
| <input type="checkbox"/> Ongoing at this time | <input type="checkbox"/> Resolved without sequelae | <input type="checkbox"/> Resolved with sequelae |
| <input type="checkbox"/> Death | <input type="checkbox"/> Present at death, not contributing to death | |

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15. Date of SAE resolution: _____ (DD/MMM/YYYY) or Ongoing at end of study

16. If SAE is unrelated to investigational product/study intervention or this is an observational study, select all possible etiologies:

- Concurrent illness, disease, or other external factors, specify:

- Concomitant medication, specify:

- Study procedure, specify:

- Accident, trauma, or other external factors, specify:

- Other, specify:

17. Did the participant receive any relevant concomitant medications in response to the SAE? Yes No

17a. If Yes, add each medication below:

Medication Name	Indication	Dose	Frequency	Start Date <small>(DD/MMM/YYYY)</small>	Stop Date <small>(DD/MMM/YYYY)</small>	Check if Ongoing
						<input type="checkbox"/>
						<input type="checkbox"/>
						<input type="checkbox"/>
						<input type="checkbox"/>

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18. Did the participant receive any treatments/procedures in response to the SAE? Yes No

18a. If Yes, list each treatment and procedure below:

Treatment/Procedure	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Check if Ongoing
			<input type="checkbox"/>

19. Did the participant receive relevant laboratory or diagnostic tests in response to the SAE? Yes No

19a. If Yes, provide the name of the test and results with normal ranges and/or supplemental exams below:

Lab/Diagnostic Test	Date (DD/MMM/YYYY)	Result	Units	Low Range	High Range	Comments

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20. Narrative/Comments (provide a description of the SAE including chronological clinical presentation and evolution of the SAE and associated signs/symptoms):

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21. Statement of Investigator: I have personally reviewed this report and agree with the above assessment.

Investigator (print name)

Investigator (signature)

Date (DD/MMM/YYYY)

Person Completing Form (print name)

Person Completing Form (signature)

Date (DD/MMM/YYYY)

Email this form to Rho Product Safety at rho_productsafety@rhoworld.com

Instruction for follow-up: Please communicate the IRB determination of the SAE to rho_productsafety@rhoworld.com