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 (YYYY-MM-DD): _____

Required time frame for reporting SAE to the NIDCR: _____

---

1. Date investigator became aware of event: _____ (YYYY-MM-DD)
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: _____

9. SAE Name and/or Diagnosis _____

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

10. Date of SAE onset: _____ (YYYY-MM-DD)

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

- ☐ Resulted in death
- ☐ Life-threatening
- ☐ Resulted inpatient hospitalization or prolongation of existing hospitalization
- ☐ Resulted in persistent or significant disability/incapacity
- ☐ Resulted in a congenital anomaly/birth defect
- ☐ Required intervention to prevent one of the other outcomes listed
- ☐ Important medical event

If fatal: 11a. Date of death: _____ (YYYY-MM-DD)

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 2 / Moderate
- ◯ Grade 3 / Severe
- ◯ Grade 4 / Life-threatening
- ◯ Grade 5 / Death

PLEASE NOTE: Q13 asks about investigational product or study intervention, but is <u>not</u> 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)

NIDCR Serious Adverse Event (SAE) Form

Protocol #: ___________	PI Name/Site Name: ________________________	Participant ID #: _____________

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

IP/Study Intervention (or Control)[1]	Dose	Units	Freq-uency	Route	Study Visit #/ Name	Start Date (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Check if Ongoing	Action Taken at Time of SAE	Relationship of SAE to IP/ Intervention[2]	Expectedness[3]
								☐	◯ Continued ◯ Lowered ◯ Interrupted ◯ Discontinued ◯ Increased ◯ N/A	◯ Related ◯ Unrelated	◯ Expected, per: ☐ Protocol ☐ Investigator Brochure ☐ Package Insert ☐ Other: ____________________ ◯ Unexpected
								☐	◯ Continued ◯ Lowered ◯ Interrupted ◯ Discontinued ◯ Increased ◯ N/A	◯ Related ◯ Unrelated	◯ Expected, per: ☐ Protocol ☐ Investigator Brochure ☐ Package Insert ☐ Other: ____________________ ◯ Unexpected
								☐	◯ Continued ◯ Lowered ◯ Interrupted ◯ Discontinued ◯ Increased ◯ N/A	◯ Related ◯ Unrelated	◯ Expected, per: ☐ Protocol ☐ Investigator Brochure ☐ Package Insert ☐ Other: ____________________ ◯ 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:

◯ Ongoing at this time ◯ Resolved without sequelae ◯ Resolved with sequelae
◯ Death ◯ Present at death, not contributing to death

15. Date of SAE resolution: _____ (YYYY-MM-DD) 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 (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Check if Ongoing
						☐
						☐
						☐
						☐

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 (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Check if Ongoing
			☐
			☐
			☐
			☐

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 (YYYY-MM-DD)	Result	Units	Low Range	High Range	Comments

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

21. Statement of Investigator: I have personally reviewed this report and agree with the above assessment.		
Investigator (print name)	*Investigator (signature)*	*Date (YYYY-MM-DD)*
Person Completing Form (print name)	*Person Completing Form (signature)*	*Date (YYYY-MM-DD)*

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