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: _____

List all sources of information (ex: participant self reported, electronic medical records, study record, etc): _____

_____

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. SAE Name and/or Diagnosis _____

   7a. If diagnosis is not known, symptoms/signs: _____
8. Date of SAE onset: _____ (YYYY-MM-DD)

9. 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: 9a. Date of death: _____ (YYYY-MM-DD)

9b. Primary cause of death: _____

9c. Was an autopsy performed? ☐ Yes ☐ No

9d. If known, what were the pertinent findings from the autopsy related to cause of death?

_____

☐ Unknown

10. What is the severity grade of the SAE? Please refer to your protocol assigned definition of severity.

- ☐ Grade 1 / Mild
- ☐ Grade 2 / Moderate
- ☐ Grade 3 / Severe
- ☐ Grade 4 / Life-threatening
- ☐ Grade 5 / Death

PLEASE NOTE: Q11 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.

11. 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 #12)

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*PLEASE NOTE: If relationship of SAE to IP/Intervention determined to be unrelated (see question 13a), skip **expectedness** question in table below.*

11a. 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	Start Date (YYYY-MM-DD)	Stop Date, or Check if Intervention is Ongoing (YYYY-MM-DD)	Action Taken at Time of SAE	Relationship of SAE to IP/ Intervention[2]	Expectedness[3] *Only evaluate expectedness if the event is considered to be related to IP/study intervention.*
							☐ Continued ☐ Lowered ☐ Interrupted ☐ Discontinued ☐ Increased ☐ N/A	☐ Related ☐ Unrelated	☐ Expected, per: ☐ Protocol ☐ Investigator Brochure ☐ Package Insert ☐ Other: _____ ☐ Unexpected ☐ N/A
							☐ Continued ☐ Lowered ☐ Interrupted ☐ Discontinued ☐ Increased ☐ N/A	☐ Related ☐ Unrelated	☐ Expected, per: ☐ Protocol ☐ Investigator Brochure ☐ Package Insert ☐ Other: _____ ☐ Unexpected ☐ N/A

[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. Only evaluate expectedness if the event is considered to be related to IP/study intervention

12. Outcome of SAE:

☐ Ongoing at this time ☐ Resolved without sequelae ☐ Resolved with sequelae

☐ Death ☐ Present at death, not contributing to death

13. Date of SAE resolution: _____ (YYYY-MM-DD) or ☐ Ongoing at end of study

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

☐ Concurrent illness, disease, or condition specify:

_____

☐ Concomitant medication, specify:

_____

☐ Study procedure, specify:

_____

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

_____

☐ Other, specify:

_____

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

15a. If Yes, add each medication below*:

Medication Name	Indication	Dose	Frequency	Route of Administration	Start Date (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Check if Ongoing
							☐
							☐
							☐
							☐

**If the number of concomitant medications received in response to the SAE exceeds the maximum number of rows allowed in the table above, please consider creating an appendix at the end of this form to capture all relevant information.*

16. Did the participant receive any therapies/surgeries/procedures in response to the SAE? ☐ Yes ☐ No ☐ Unknown

16a. If Yes, list each therapy, surgery, and/or procedure below*:

Treatment/Procedure	Start Date (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Check if Ongoing
			☐
			☐
			☐
			☐

**If the number of therapies/surgeries/procedures received in response to the SAE exceeds the maximum number of rows allowed in the table above, please consider creating an appendix at the end of this form to capture all relevant information.*

17. Did the participant undergo any relevant laboratory or diagnostic testing in response to the SAE? ☐ Yes ☐ No ☐ Unknown

17a. 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

**If the number of laboratory or diagnostic testing received in response to the SAE exceeds the maximum number of rows allowed in the table above, please consider creating an appendix at the end of this form to capture all relevant information.*

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18. Narrative/Comments (provide a description of the SAE including chronological clinical presentation and evolution of the SAE and associated signs/symptoms). If 'unknown' was selected for questions 15, 16, or 17, please provide an explanation in the narrative:

19. Statement of Investigator: I have personally reviewed this report and agree with the above assessment. **Prior to signing the form, please save a copy to allow future revisions to be made if requested.**

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