NIDCR Serious Adverse Event (SAE) Form

Protocol #: _____	PI Name/Site #: _____	Participant #: _____

Please email (rho_productsafety@rhoworld.com) or fax (1-888-746-3293) this form to Rho Product Safety. If you have general questions about SAE reporting, you may contact Rho Product Safety by email or telephone (1-888-746-7231).

1. Age: _____ ☐ years ☐ months
2. Gender: ☐ Male ☐ Female
3. Weight: _____ ☐ kg ☐ lbs
4. Height: _____ ☐ cm ☐ in
5. SAE term (provide diagnosis): _____

   5a. If diagnosis is not known, symptoms: _____
6. Date of onset: _____ (DD/MMM/YYYY)
7. What is the severity grade of the SAE?

   ☐ Grade 1: Mild ☐ Grade 4: Life-threatening

   ☐ Grade 2: Moderate ☐ Grade 5: Death

   ☐ Grade 3: Severe
8. Did the participant receive the investigational product or study intervention prior to this SAE?

   ☐ Yes ☐ No ☐ N/A

   8a. If Yes, identify the investigational product or study intervention received prior to the SAE:

Investigational Product/Study Intervention	Dose	Units	Frequency	Route	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Check if Ongoing
							☐
							☐
							☐

9. What action was taken with the investigational product/study intervention?

   ☐ Continued ☐ Discontinued

   ☐ Lowered ☐ Increased

   ☐ Interrupted ☐ N/A

10. Outcome of SAE:

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

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

12. Criteria for SAE (Check all that apply):

- ☐ Life-threatening
- ☐ Disabling/incapacitating
- ☐ Required hospitalization or prolongation of existing hospitalization
- ☐ Important medical event
- ☐ Congenital anomaly
- ☐ Fatal

If fatal: 12a. Date of death: _____ (DD/MMM/YYYY)

12b. Primary cause of death: _____

12c. Was an autopsy performed? ☐ Yes ☐ No

13. Relationship to investigational product/study intervention:

- ☐ 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)

14. If SAE is unrelated to investigational product/safety intervention, select all possible etiologies:

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

_____

- ☐ Concurrent 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

15a. If Yes, add each medication below:

Medication Name	Indication	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Check if Ongoing
				☐
				☐
				☐
				☐

16. Did the participant receive any treatments/procedures in response to the SAE?

☐ Yes ☐ No

16a. If Yes, list each treatment and procedure below:

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

17. Did the participant receive relevant laboratory or diagnostic tests in response to the SAE?

☐ Yes ☐ No

17a. 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	Low Range	High Range	Comments

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

19. Statement of Investigator: I have personally reviewed this report and agree with the above assessment.	
Investigator Signature	*Date (DD/MMM/YYYY)*
Name of Person Completing Form	*Date (DD/MMM/YYYY)*