Print Form

# NIDCR Serious Adverse Event Form

| Protocol Number: _____ | Investigator Name: _____ | Subject ID: _____ |
|---|---|---|

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

1. Location of SAE (e.g., at NIH or elsewhere): _____
2. Age: _____ ☐ years ☐ months
3. Gender: ☐ Male ☐ Female
4. Weight: _____ ☐ kg ☐ lbs
5. Height: _____ ☐ cm ☐ in
6. SAE term (provide diagnosis): _____

   6a. If diagnosis is not known, symptoms: _____
7. Date of onset: _____ (dd/mmm/yyyy)
8. What is the severity grade of the serious adverse event?

   ☐ Grade 1: Mild
   ☐ Grade 2: Moderate
   ☐ Grade 3: Severe
   ☐ Grade 4: Life-threatening
   ☐ Grade 5: Death
9. Did the subject receive the investigational product or study intervention prior to this SAE?

   ☐ Yes ☐ No ☐ N/A

   9a. 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 |
|---|---|---|---|---|---|---|---|
| | | | | | | | ☐ |
| | | | | | | | ☐ |
| | | | | | | | ☐ |

10. Action taken with investigational product/study intervention:

☐ Continued ☐ Discontinued

☐ Lowered ☐ Increased

☐ Interrupted ☐ N/A

11. Outcome of SAE:

☐ Ongoing at this time ☐ Death

☐ Resolved without sequelae ☐ Present at death, not contributing to death

☐ Resolved with sequelae

12. Date of resolution: _____ (dd/mmm/yyyy) or ☐ Ongoing at end of study

13. Seriousness criteria? (Check all that apply)

☐ Life-threatening ☐ Disabling/incapacitating

☐ Required hospitalization or prolongation of existing hospitalization ☐ Important medical event

☐ Fatal

☐ Congenital anomaly

If fatal: 13a. Date of death: _____ (dd/mmm/yyyy)

13b. Primary cause of death: _____

13c. Was an autopsy performed? ☐ Yes ☐ No

14. 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.)

☐ Unrelated

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

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

_____

☐ Concurrent medication, specify:

_____

☐ Secondary study procedure, specify:

_____

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

_____

☐ Other, specify:

_____

16. Did the subject receive any relevant concomitant medications in response to the SAE?

☐ Yes ☐ No

16a. If yes, add each medication below:

| Medication Name | Indication | Start Date (dd/mmm/yyyy) | Stop Date (dd/mmm/yyyy) | Check if Ongoing |
|---|---|---|---|---|
| | | | | ☐ |
| | | | | ☐ |
| | | | | ☐ |

17. Did the subject receive any treatments/procedures in response to the SAE?

☐ Yes ☐ No

17a. If yes, list each treatment and procedure below:

| Treatment/Procedure | Start Date (dd/mmm/yyyy) | Stop Date (dd/mmm/yyyy) | Check if Ongoing |
|---|---|---|---|
| | | | ☐ |
| | | | ☐ |
| | | | ☐ |

18. Did the subject receive relevant laboratory or diagnostic tests in response to the SAE?

☐ Yes ☐ No

18a. 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 |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

19. Narrative/Comments (provide a description of the serious adverse event including chronological clinical presentation and evolution of the serious adverse event and associated signs/symptoms):

| |
|---|
| |

20. Completion of form: printed names, signatures and date of signature

| *Person Completing Form (print name)* | *Person Completing Form (signature)* | *Date* |
|---|---|---|
| *Investigator (print name)* | *Investigator (signature)* | *Date* |