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| Adverse Event (Part I) |

**DO NOT REPORT ADVERSE EVENTS UNLESS THEY ARE UNANTICIPATED, SEVERE, AND STUDY RELATED.**

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| SAE Submission |

Date(s) and IRB protocol number for the event that occurred:

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1. Subject ID Number (Coded data only, DO NOT use subject name or initials)

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2. Type of report:

○ Initial  
○ Follow-Up

3. IF THIS IS A FOLLOW-UP, please identify the AE tracking number to which this is a follow-up:

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4. Describe the event.

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5. Study relation

○ Unrelated  
○ Related

6. Was this event anticipated in the protocol?

○ Yes  
○ No

7. Did this event occur onsite or offsite?

○ Onsite (BE SURE TO FILL OUT PART II OF THIS FORM)  
○ Offsite (BE SURE TO FILL OUT PART III OF THIS FORM)

8. Severity of event:

○ Mild  
○ Moderate  
○ Severe

9. Has this event been reported in any other study subjects?

○ Yes  
○ No

**As a result of this event:**

10. Do you believe changes to the protocol are required?

○ Yes  
○ No

11. Do you believe changes to the ICF/assent form are required?

○ Yes  
○ No

12. In your opinion, will previously enrolled subjects need to be re-consented and/or notified of this information?

○ Yes  
○ No

13. IF YES TO QUESTION 12, provide specific details regarding who will be consented and how:

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14. Will an addendum ICF/assent or letter of notification be sent to subjects?

○ Yes  
○ No

15. Additional comments and information:

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**IF AVAILABLE, PLEASE ATTACH A DSMB REPORT**

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| If this is an Onsite Adverse Event (Part II) |

16. Event start date (mm/dd/yyyy):

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17. Event stop date or current date (mm/dd/yyyy):

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18. Date event was recognized (mm/dd/yyyy):

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19. Has the event been reported to your sponsor/funding source:

○ Yes  
○ No  
○ Not applicable

20. If the sponsor was not notified, why not:

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21. If the sponsor was notified, date reported (mm/dd/yyyy):

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| If this is an Offsite Adverse Event (Part III) |

22. Attach (in WVU+kc) the MedWatch form 3500 or 3500a or other SAE/safety report forms/IND safety report forms (only for those without DSMBs).

***Please submit this form by attaching it under the Notes & Attachments tab of your protocol in the*** [***WVU+kc***](http://kc.wvu.edu) ***system.***