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| Deviation/Exception/Violation |

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| Description of Event |

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

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1. Describe the exception, deviation or other event:

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| Risk to Subject or Others |

2. Did this result in risk to subject(s) or others?

○ Yes  
○ No

3. Please describe the risk(s) to the subject(s) or others resulting from this event:

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| Deviation/Exception/Violation |

4. Explain why this event occurred

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5. What steps were taken to resolve this particular occurrence?

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6. What is being done to prevent similar occurrences in the future?

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7. Is a change in the consent form(s) needed as a result of this event?

○ Yes  
○ No

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| Change to Consent Form |

8. IF YOU ANSWERED YES TO QUESTION 7, please describe the change in the consent form that is needed as a result of this event. Please note that a separate amendment to the study must be submitted to the IRB in order to change the consent form.

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| Adverse Event |

9. Did the occurrence result in an adverse event for a participant or an exception to the rights of a human subject (e.g., violation of privacy)?

○ Yes  
○ No

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| Adverse Event or Unanticipated Problem |

10. Has the event been reported as an adverse event or an unanticipated problem involving risks to subjects or others (UPIRTSO)?

○ Yes  
○ No

11. IF YOU ANSWERED NO TO QUESTION 10, explain why not.

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| Deviation/Exception |

12. Will the participant continue with the research?

○ Yes  
○ No

13. Was/were the study sponsor (if one exists) and/or all other required regulatory agencies notified of the occurrence within the required timeframe of the protocol?

○ Yes  
○ No  
○ No sponsor

***Please be sure that any sponsor report letters are also reported to the IRB.***

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