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| UPIRTSO |

**THE PRINCIPAL INVESTIGATOR OR DESIGNEE SHOULD COMPLETE THIS FORM.**

1. Date(s) and IRB protocol number for the problem that occurred:

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2. Date reported to the sponsor (if any):

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**IF APPLICABLE, YOU MUST ALSO ATTACH THE REPORT TO THE SPONSOR IN THE WVU+KC SYSTEM**

3. Study site where problem occurred (if known):

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4. Please provide a brief description of the problem:

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5. If you are able, please tell us why the problem occurred and what were the circumstances?

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6. Describe steps taken to resolve the problem and procedures implemented to avoid similar problems in the future:

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7. In the investigator’s opinion, was this problem unanticipated?

○ Yes  
○ No

8. In the investigator’s opinion, was this problem related to the research?

○ Yes  
○ No

9. Does this problem affect the safety or welfare of current or future subjects?

○ Yes  
○ No

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| Describe Affect on Safety/Welfare of Subjects |

10. (IF YOU ANSWERED YES TO QUESTION 9) You indicated that this problem may affect the safety or welfare of current or future subjects, please describe:

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|  |
| Reported |

11. Has this problem been reported to someone or some organization other than the sponsor and the appropriate IRB?

○ Yes  
○ No

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| Reported to Whom |

12. (IF YOU ANSWERED YES TO QUESTION 11) You indicated that this problem has been reported to someone or some organization other than the sponsor and the appropriate IRB. To whom has the problem been reported?

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