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| Continuing Review |

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| Study Status |

1. Indicate the current status of the study:

○ No enrollment to date   
○ Enrolling subjects  
○ Closed to enrollment

2. If closed to enrollment, please indicate the date the study was closed to enrollment:

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3. If closed to enrollment, check all activities that are being performed or are planned:

□ Treatment and/or active follow-up continues  
□ Long-term follow-up of subjects (e.g., following for survival)  
□ Data analysis/manuscript preparation

4. What does this research involve (select all that apply):

□ Subjects  
□ Medical records  
□ Samples

5. Please select the applicable statement:

○ There is no new information that might affect a subject's willingness to continue participating in this research study.  
○ New information may affect a subject's willingness to continue participating in this research study. This information has NOT been previously submitted to the IRB.

6. Please specify the new information here. Include publications, interim findings or other relevant information.

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7. Are there revisions or changes that are being submitted with this application?

○ Yes  
○ No

8. If yes, please specify the changes:

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9. Please put any additional comments/explanations here:

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10. Since the last IRB review, have any participants or others complained about the research?

○ Yes  
○ No

11. Since the last IRB review, have there been any unanticipated problems (UPIRTSOs) and/or study-related serious events at WVU or WVU-affiliated hospitals involving subjects recruited by WVU researchers?

○ Yes  
○ No

12. Since the last IRB review, have all deviations been submitted as required?

○ Yes  
○ No  
○ N/A

13. Summarize the deviations, complaints, and/or UPIRTSOs to date:

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14. Summarize any benefits to date:

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15. Discuss changes to the risk-benefit relationship to date:

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16. Is there a DSMB report and/or other report that has not been previously submitted to the IRB (If yes, please also attach the most recent DSMB or other study-related report to your protocol)?

○ Yes  
○ No

17. If the study was monitored/audited since the last IRB review, please indicate by whom:

□ Sponsor or designated monitor  
□ Federal agency or accrediting body  
□ WVU IRB audit

□ Other (please ensure that other is identified in the description or report)  
□ Not applicable

18. Please provide a brief description of the findings or attach the report(s):

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| Subjects |

19. Were any subjects enrolled onsite during the lifetime of the study?

○ Yes  
○ No

20. If yes, indicate the total number of subjects enrolled:

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21. Were any subjects enrolled since the last review?

○ Yes  
○ No  
○ Not applicable

22. If yes, indicate the total number of subjects enrolled since the last review:

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23. Did any subjects withdraw their participation from the study since the last review?

○ Yes  
○ No  
○ Not applicable

24. If yes, summarize the reason(s):

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25. Have any subjects been withdrawn by the PI or sponsor since the last review?

○ Yes  
○ No  
○ Not applicable

26. If yes, summarize the reason(s):

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27. Are any subjects being followed?

○ Yes  
○ No  
○ Not applicable

28. Number of subjects that are being followed:

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29. Are you seeking to increase enrollment?

○ Yes  
○ No

30. If yes, please justify your request for increase:

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| Race/Gender/Vulnerable Populations |

Please copy this section into this form for each race/ethnicity included in your study.

31. Race/ethnicity:

○ Caucasian  
○ Black or African American  
○ Asian  
○ American Indian/Alaskan  
○ Hispanic or Latino  
○ Hawaiian or Pacific Islander  
○ Mixed race or ethnicity  
○ Unknown or not reported

32. Total number of males (including children):

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33. Total number of females (including both children and pregnant women)

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34. Total gender unknown/not collected (including children)

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35. Number of pregnant women:

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36. Number of fetuses:

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37. Number of children (under 18):

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38. Number of WVU students or employees:

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39. Number of cognitively impaired:

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40. Number of prisoners:

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41. Number of other vulnerable populations:

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| Medical Records |

42. Were any medical records reviewed?

○ Yes  
○ No

43. If yes, total number of medical records reviewed:

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| Samples |

44. Were any samples collected?

○ Yes  
○ No

45. If yes, total number of samples collected:

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***Please also attach to the protocol any relevant documents related to this continuing review (e.g., investigator’s brochure, user manuals, written statement from non-affiliated physician, informed consent, etc.)***

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