**Protocol Deviation Log**

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| **Protocol Deviation** | **Description of Deviation** | **Comments** |
|  | Failure to obtain informed consent prior to initiation of study-related procedures  A research participant met withdrawal criteria or wished to withdraw from the study but was not withdrawn  Inappropriate study drug dosage  Inappropriate randomization  Inadvertent loss of samples or data  Other major violations, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
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