**Division of Microbiology and Infectious Diseases (DMID)**

**Protocol Deviation Form**

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| Report Date: | (dd/mmm/yyyy) | | Protocol Deviation Date: | (dd/mmm/yyyy) |
| Site Name: |  | | Investigator Name: |  |
| DMID Protocol Number: |  | Protocol Title or Short Name: | | |
| Alternate Protocol Number (if applicable): |  |

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| Subject Number: | N/A, not associated with a subject, skip to ‘Brief deviation description’ in section below. | | | |
| Did the deviation result in an Adverse Event? | | Yes | No | If Yes, complete an Adverse Event form. |
| Did the deviation result in a Serious Adverse Event? | | Yes | No | If Yes, complete a Serious Adverse Event form. |
| Did the deviation result in subject termination of study follow-up? | | Yes | No | If Yes, update the appropriate Completion/Termination form, if applicable. |

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| Brief deviation description: |  | | | | |
| Reason for deviation: | Subject illness  Subject unable to comply  Subject refusal  Other | Pharmacy error  Laboratory error  Investigator/study decision  Clinic error | | | |
| If other, specify: | | | | |
| Deviation category: | Eligibility/enrollment  Vaccination schedule  Follow-up visit schedule  Other | Protocol procedure/assessment  Vaccination/dosing administration  Blinding policy/procedure | | | |
| If other, specify: | | | | |
| Did the protocol deviation affect, or could it potentially affect, product stability? | | | Yes | No | N/A |
| Describe steps taken to resolve or avoid recurrence of the deviation: | | | | | |
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| **This section to be updated by site and kept in site regulatory file.** | | | |
| Does this deviation meet IRB reporting requirements? | | Yes | No |
| If Yes, date IRB notified: | \_\_\_ \_\_\_/ \_\_\_ \_\_\_ \_\_\_/ \_\_\_ \_\_\_ \_\_\_ \_\_\_ (dd/mmm/yyyy) | | |

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| Signature (Only required on copy for site study file): |  | Date (dd/mmm/yyyy) |
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