**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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