**Post Approval Compliance Monitoring Study Visit Report**

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| **Protocol number/title:** |  |
| **Visit Date(s):** |  |
| **Principal Investigator:** |  |
| **Monitor(s):** |  |
| **Study Staff Attendees:** |  |

**Overall Findings and recommendations:**

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| Context: This is a (remote or in-person) (routine or directed) Post Approval Compliance Monitoring (PACM) Visit report for WRAIR (#) titled “(title).” Enrollment: Funding: (Changes/Period of Performance) |

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| **Subject/Visit Files Reviewed:** |
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| 1. Participant File Review
 |
|  | **YES** | **NO** | **N/A** |
| Were the participant charts reviewed? *If* ***YES****, complete items A. through F*. *If* ***NO****, explain in comments field.*  |[ ] [ ]   |
| Was written informed consent obtained prior to each subject's participation in the trial. |[ ] [ ] [ ]
| Were all participants enrolled according to the inclusion/exclusion criteria written in the protocol? *If* ***NO****, explain in the comments field*. |[ ] [ ] [ ]
| The data required by the protocol are reported accurately on the CRFs and are consistent with the source documents for each participant? |[ ] [ ] [ ]
| Any dose and/or therapy modifications are well documented for each of the trial participant? |[ ] [ ] [ ]
| Adverse events, concomitant medications and inter-current illnesses are reported in accordance with the protocol? |[ ] [ ] [ ]
| Comments:  |

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| 1. Regulatory Binder Review
 |
|  | **YES** | **NO** | **N/A** |
| Was the regulatory binder reviewed? *If* ***YES****, complete items A. through U*. *If* ***NO****, explain in comments field.*  |[ ] [ ]   |
| Initial approved protocol and all protocol amendments on file? |[ ] [ ] [ ]
| Investigator’s Brochure (IB) or Package Insert on file? |[ ] [ ] [ ]
| Sample approved case report forms on file? |[ ] [ ] [ ]
| Were the Laboratory or other Study Manuals on file? |[ ] [ ] [ ]
| FDA Form 1572 on file? |[ ] [ ] [ ]
| For the current completed and signed FDA Form 1572: Have any updates to sections 1-8 been made with subsequent signed versions of the 1572 present in the regulatory binder? |[ ] [ ] [ ]
| FDA 3455 Financial disclosures and/or Sponsor Financial disclosures on file for PI other required study personnel? |[ ] [ ] [ ]
| CV and medical license of Principal Investigator and Sub/Associate Investigators on file and current? |[ ] [ ] [ ]
| CVs of all sub/associate investigators on file and current? |[ ] [ ] [ ]
| Delegation of Authority Log on file with all signatures and current? |[ ] [ ] [ ]
| All IRB/EC approvals on file? |[ ] [ ] [ ]
| Expiration date of current IRB/EC approval(s):  |  |
| Federalwide Assurance (FWA) maintained and up to date? | ☐ | ☐ | ☐ |
| All business agreements maintained and valid? | ☐ | ☐ | ☐ |
| All IRB agreements maintained and valid? | ☐ | ☐ | ☐ |
| All relevant study site/IRB correspondence on file? |[ ] [ ] [ ]
| All relevant study site/Sponsor correspondence on file? |[ ] [ ] [ ]
| All IRB/EC approved informed consent documents on file? |[ ] [ ] [ ]
| All clinical laboratory certifications on file? |[ ] [ ] [ ]
| All clinical laboratory normal reference ranges on file? |[ ] [ ] [ ]
| Subject screening and/or enrollment log on file? |[ ] [ ] [ ]
| All AEs/SAEs/UPs on file? |[ ] [ ] [ ]
| Deviation Log(s) on file? |[ ] [ ] [ ]
| All IND safety reports or other safety notifications on file? |[ ] [ ] [ ]
| Monitor’s Site Visit Log on file and signed on this visit? |[ ] [ ] [ ]
| Comments:  |

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| 1. Facilities and Operations
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|  | **YES** | **NO** | **N/A** |
| Regulatory binder, subject files, and data securely stored with limited access? |[ ] [ ] [ ]
| Site facilities remain appropriate for purpose? |[ ] [ ] [ ]
| Comments:  |

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| 1. Investigational Product
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|  | **YES** | **NO** | **N/A** |
| Is the IP being maintained according to the proper storage times and conditions, in a secure location with limited access? |[ ] [ ] [ ]
| Were the participants provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s)? |[ ] [ ] [ ]
| Was the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately? |[ ] [ ] [ ]
| Did the disposition of unused investigational product(s) comply with applicable regulatory requirement(s) |[ ] [ ] [ ]
| Is there a complete IP log available for review? |[ ] [ ] [ ]
| Comments:  |

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Monitor’s Signature Date