



National Institutes of Health  
National Institute of Allergy  
And Infectious Diseases  
Rockville, MD 20852  
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MEMORANDUM

DATE: December 10, 2019

FROM: Bariatu Smith, Acting Branch Chief, Monitoring Operations (MOB)/ Office of Clinical Site Oversight (OCSO) *BS*  
Ruth Ebiasah, Branch Chief, Pharmaceutical Affairs Branch (PAB)/Office of Clinical Site Oversight (OCSO) *RE*

TO: Clinical Trial Unit (CTU) Principal Investigators  
Clinical Research Site (CRS) Leaders  
Clinical Trial Unit (CTU) Coordinators  
Clinical Research Site (CRS) Coordinators  
Pharmacists of Record (PoR)

SUBJECT: New Pharmacy Operations Monitoring Assessment

In an effort to continue to implement efficient processes and to enhance site-level pharmacy oversight by the Site Leader, the PAB and MOB would like to inform you of upcoming changes to pharmacy assessments being performed. PAB has developed an annual Pharmacy Operations Visit (POV), which will streamline the reports provided to the Site Staff and improve oversight of site activities. Each pharmacy will receive a POV once per year, which will occur in conjunction with a routine Interim Site Monitoring Visit (ISMV) at the site.

**When will this change take place?**

Site Staff (CRS Leader/CRS Coordinator) will start to receive POV related documents beginning January 7, 2020.

**How will this benefit Site Staff?**

The POV will provide Site Staff a more in-depth assessment of day-to-day pharmacy operations and pharmacy equipment, on an annual basis.

**What are the changes for Site Staff?**

**Pre-Visit Letter (PVL) and announced Work Order (WO)** – For routine ISMVs, Site Staff will continue to receive a PVL and WO. For the POV, Site Staff will receive a separate PVL and WO.

**Monitoring Visit Reports** – For routine ISMVs, Site Staff will continue to receive a Site Monitoring Report (SMR). Previously, as part of the SMR, the Protocol Specific Investigational Drug Audit (PSIDA) report for each protocol assessed was appended at the end of the SMR. Effective January 7, 2020, the

PSIDA report will no longer be part of the SMR. Instead, in addition to the SMR, Site Staff will receive a separate report for the POV, which will include any relevant pharmacy information.

**What are the changes for PoRs?**

**Pre-Visit Letter (PVL) and announced Work Order (WO)** – For routine ISMVs, PoRs receive a PVL and WO. For the POV, PoRs will also receive a separate PVL and WO.

**Monitoring Visit Reports** – For routine ISMVs, PoRs will continue to receive the PSIDA and are responsible for addressing issues that have been identified. In addition, the PoRs will receive a separate report for the POV and, similar to the PSIDA, are responsible for addressing issues identified.

**What documents are Site Staff required to acknowledge?**

Site Staff will be required to acknowledge/view each PVL, announced WO and visit report for the ISMV and POV. Site Staff will receive an email notification from the DAIDS NIAID Clinical Research Management System (NCRMS) notifying you that the PVL and announced WO, which includes a POV, is available. You can then access these documents by logging into the NCRMS Clinical Site Monitoring (CSM) module

**What documents are Site PORs required to acknowledge?**

PoRs will be required to acknowledge/view each PVL, announced WO and visit report for the ISMV and POV. PoRs will receive an email notification from the DAIDS NIAID Clinical Research Management System (NCRMS) notifying you that the PVL and announced WO, which includes a POV, is available. The PoR can then access these documents by logging into the NCRMS Clinical Site Monitoring (CSM) module.

The tables below demonstrate the view/acknowledgement process for the PoR, Site Staff of the site in which the POV visit is being conducted, and Site Staff of the other sites if a single pharmacy supports multiple sites.

**How will this affect a single pharmacy that supports multiple sites?**

For a single pharmacy that support multiple sites, the PVL, WO and POV report will be shared with all sites that the pharmacy supports; however, only the Site Staff for which the visit is conducted will be required to acknowledge the PVL, WO and POV report. Individuals at the other sites supported by the pharmacy will be able to view the PVL, WO and POV report, but will not be required to acknowledge the documents.

Process for ISMV Acknowledgement/View			
Report	Roles		
	Site Pharmacist (PoR)	Site Staff (of the site at which ISMV is being conducted)	Site Staff (of the other site if pharmacy supports multiple sites)
Pre-Visit Letter	Acknowledge**	Acknowledge	N/A
Work Order	Acknowledge**	Acknowledge	N/A
PSIDA Assignment Report	Acknowledge	N/A	N/A
SMR	View**	Acknowledge	N/A

Process for POV Acknowledgement/View			
Report	Roles		
	Site Pharmacist (PoR)	Site Staff (of the site at which ISMV is being conducted)	Site Staff (of the other site if pharmacy supports multiple sites)
Pre-Visit Letter	Acknowledge	Acknowledge	View
Work Order	Acknowledge	Acknowledge	View
POA Assignment Report	Acknowledge	N/A	N/A
POV Visit Report	Acknowledge	Acknowledge	View

\*\* If pharmacy assignments are included as part of site visit.

Please contact the MOB at [ocsomob@niaid.nih.gov](mailto:ocsomob@niaid.nih.gov) or PAB at [NIAIDDAIDSPABMonitoring@mail.nih.gov](mailto:NIAIDDAIDSPABMonitoring@mail.nih.gov) for any questions.