DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
And Infectious Diseases
Rockville, MD 20852
5601 Fishers Lane

MEMORANDUM

DATE: May 2, 2019

FROM: Bariatu Smith, Acting Branch Chief, Monitoring Operations Branch (MOB)/Office of Clinical Site Oversight (OCSO)

TO: Clinical Trial Unit (CTU) Principal Investigators
Clinical Research Site (CRS) Leaders
Clinical Trial Unit (CTU) Coordinators
Clinical Research Site (CRS) Coordinators

SUBJECT: Revised Announced Work Order

The NIAID Clinical Research Management System (CRMS) was recently updated, and this release resulted in changes to the Announced Work Order (AWO). For Protocols in the Medidata Rave database only the protocol ID will be listed and Participant Identification numbers (PIDs) will no longer be captured in the AWO.

Previous versions of the AWO captured all PIDs anticipated to be reviewed during a monitoring visit, however with the implementation of Medidata Rave, all enrolled PIDs for which data has been entered in the database would populate the AWO. Subsequently, the PID list no longer accurately reflects the data that the monitor(s) could review during one monitoring visit. (e.g. if a site enrolled 85 PIDs in one protocol, all 85 PIDs would be identified as potential PIDs for monitoring while in reality fewer PIDs would be reviewed during a monitoring visit). As a result, the AWO will now only identify the protocol ID for a protocol in Medidata Rave.

There are several reports in Medidata Rave used to assess the status of electronic case report forms (eCRFs); such as Page Status; Comprehensive Page Status; and Page Status V2.0. The Comprehensive Page Status report is a report sites can use as a tool to identify PIDs and protocol visits eCRFs which require monitoring/verification using the "Page Requiring Action" section of the report. All eCRFs which require verification are available to be monitored but based on volume only a subset will be monitored during a visit. Site personnel have access to this report for SCHARP and FSTRF studies and should contact the data management center helpdesk for any questions.

While the AWO will no longer display PIDs for protocols in Medidata Rave in advance of the monitoring visits, we expect sites to ensure that all participant data is audit ready. Sites

should continue to use their quality checks to maintain data integrity of their source documents and CRFs. Additionally, due to the nature of monitoring process in Medidata Rave, an increased number of PIDs enrolled at your site will be monitored by study completion.

Please note that the AWO **will** continue to display the PID list for protocols not in the Mediata Rave platform.

Please contact the Monitoring Operations Branch (MOB) at ocsomob@niaid.nih.gov or your Program Officer (PO) for any questions.