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: January 31, 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 Monitoring Process

In an effort to continue to implement process improvements and gain efficiencies for our monitoring processes the OCSO Monitoring Operations Branch (MOB) would like to inform you of some upcoming changes for the Work Order checklist and the Record Review Tool (RRT) Part B.

Site staff receive an email notification from the DAIDS NCRMS system with the Pre-visit letter and announced Work Order for monitoring visits. You can also access these documents by logging into the NCRMS Clinical Site Monitoring (CSM) module. In addition, immediately prior to the start of the monitoring visit you are provided the Full Work Order (FWO) for the visit. The FWO can also be accessed through the NCRMS CSM the morning of the visit.

In the past, site staff signatures were obtained on the FWO at the conclusion of the monitoring visit and a copy of this document was left on site. This information is also entered electronically in the NCRMS CSM module resulting in duplication of effort for the monitors. Starting with February monitoring visits the sites will no longer be required to sign the FWO and a copy will not be left at the site.

The RRT Part B is the document where monitors note record review related findings during the monitoring visit. The site staff signed this document at the conclusion of the visit and a copy of each RRT was left on site. For very busy sites participating in multiple Networks and protocols this resulted in the need to make numerous copies. The site staff signatures will no longer be required for the RRT Part B and copies of these forms will no longer be left on

site. The record review summary in the site monitoring report provides detail of the observations noted during the monitoring visit.
The monitors will still review observations in detail with site staff at the debrief meeting(s) during the visit.

Please contact the Monitoring Operations Branch (MOB) at ocsomob@niaid.nih.gov for any questions.