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: June 28, 2021

FROM: Manizhe Payton, Director Office of Clinical Site Oversight

Payton, Manizhe (NIH/NIAID) [E] Digitally signed by Payton, Manizhe (NIH/NIAID) [E] Date: 2021.06.28 10:29:41 -04'00'

TO: NIAID/DAIDS HIV/AIDS Network Leadership, Operations Center Principal Investigator(s), Clinical Trial Unit (CTU) Principal Investigators, Clinical Research Site (CRS) Leaders, CTU Coordinators, CRS Coordinators, Data Management Center Directors

RE: ***Minor Updates to DAIDS SCORE Manual Sections: Quality Management, Pharmacy Requirements, Laboratory Requirements***

We launched the DAIDS SCORE Manual in January 2021 to define general operational requirements of clinical research sites participating in DAIDS sponsored clinical trials. Since that time, we have identified minor updates to the content and those impacted sections are currently under revision. We anticipate the following changes will be available on the NIAID website within the next month. However, please note that these changes are effective immediately.

A. Appendix to Quality Management Section: List of Standard Operating Procedures (SOPs) Required at Clinical Research Sites

With the introduction of the Electronic Information Systems (EIS) Policy, DAIDS reevaluated the requirements for Clinical Site Data Collection and Reporting SOPs. DAIDS has determined that the following SOPs are **no longer required** of sites unless the site owns or hosts a locally installed version of an electronic system that falls under the scope of the EIS policy (https://www.niaid.nih.gov/sites/default/files/electronic-information-systems-policy.pdf).

1. System Set-up and Installation
2. Security
3. Information Security
4. Change Control
5. Data Collection Training
6. Data Integrity
7. System Maintenance
8. Data Back-up, Recovering and Contingency Plans
9. Randomization Procedures
10. Use of Electronic Systems

If the site does not own or host a local version of an electronic system that falls under the scope of the EIS policy, then the above SOPs are no longer required. Please note that DAIDS still requires the following site SOP(s) to address site data collection and reporting processes: Access and Authentication, and Data Collection and Handling.

B. Pharmacy Requirements Section. CRS Pharmacy Requirements (page 3 of 5)

Correction to email address PoR may send questions to regarding PEP submission and approval process. The correct email address is DAIDSPABPEP@niaid.nih.gov.

C. Laboratory Requirements Section. DAIDS Good Clinical Laboratory Practices Standards (page 4 of 6, and page 6 of 6).

Correction to link to DAIDS GCLP Standards Manual. The correct link is: https://www.niaid.nih.gov/sites/default/files/gclpstandards.pdf.

We recognize the tremendous efforts made by our sites to comply with DAIDS requirements and we value our strong partnership. As we transition to this new CTU grant cycle we continue to strive to ensure transparency and alignment with applicable regulations and standards without placing unnecessary burden on our sites. If you have any questions about these changes, please reach out to your OCSO Program Officer.