

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

## **MEMORANDUM**

DATE: October 23, 2020

FROM: Bariatu Smith, Acting Branch Chief, DAIDS Monitoring Operations Branch (MOB),

OCSO

TO: NIAID/DAIDS HIV/AIDS Clinical Trial Units (CTU) Principal Investigators,

Clinical Research Sites (CRS) Leaders, CTU Coordinators, CRS Coordinators

SUBJECT: DAIDS Clinical Quality Management Plan (CQMP) QA Summary Report:

December 2020 Submission Requirements

The Division of AIDS (DAIDS) Requirement for CQMP policy requires that DAIDS supported and/or sponsored Clinical Research Sites (CRSs) report a summary of Quality Assurance (QA) activities bi-annually to their DAIDS Program Officer. Due to the ongoing COVID-19 public health crisis and operational challenges at sites, the next CRS QA Summary Report due for submission on 01 December 2020 will be delayed.

Sites are expected to continue conducting Quality Assurance and Quality Control activities of their operations to ensure the integrity, completeness and quality of data being collected.

Sites that are funded will be required to submit a biannual QA summary along with the completion of other requirements for transitioning into the next grant cycle in a letter expected to go out to the CTUs/CRSs in January 2021.

Please refer to the CQMP Frequently Asked Questions (FAQ) document posted on the DAIDS Clinical Research Frequently Asked Questions <u>webpage</u>.

Also contact your Program Officer with any questions.