DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD 20892

MEMORANDUM

DATE: 12 September, 2019

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

TO: HIV/AIDS Network Clinical Trial Units (CTU) / Clinical Research Sites (CRSs)

SUBJECT: DAIDS CQMP Policy: Submission Requirements

The Division of AIDS (DAIDS) recently updated policy; Requirement for Clinical Quality Management Plan (CQMP) has been posted to the DAIDS Clinical Research Policies webpage. The 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. The next CRS QA Summary Report will be due on **13 December 2019.** While the type 5 letter states a due date of 01 Dec. 2019, OCSO has extended this date to be 13 December 2019.

The report will be due on 01 June and 01 December in subsequent years.

In addition, based on the revised DAIDS CQMP policy, sites should submit an **updated CQMP** that incorporates new requirements outlined in the policy with the **13 December 2019** submission of the CRS QA Summary Report.

DAIDS is planning a webinar/cross-network CRS Coordinators call to provide additional guidance on the new policy. Sites will be notified of the date when it becomes available.

The CQMP Frequently Asked Questions (FAQ) document is now posted on the DAIDS Clinical Research Frequently Asked Questions webpage for reference.