DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MEMORANDUM

DATE: March 13, 2017

FROM: Manizhe Payton, Director, Office of Clinical Site Oversight (OCSO), DAIDS, NIAID

Bariatu Smith, Nurse Consultant, Office of Clinical Site Oversight (OCSO), DAIDS, NIAID

TO: Clinical Research Site (CRS) Leaders
Clinical Trials Unit Coordinators
Clinical Research Site Coordinators

SUBJECT: CRS Quality Assurance Summary Report will not be due in April 2017

The current DAIDS *Clinical Quality Management Plans* policy requires sites to submit a CRS QA Summary Report to DAIDS, on a biannual basis. However, CRSs will not be required to submit a completed CRS QA Summary Report to their DAIDS Program Officer on April 1st 2017 as OCSO continues to refine the requirements for quality management.

DAIDS has made significant revisions to the template report to eliminate any potential confusion, reduce effort required to complete the tool and also incorporated site coordinator feedback. In conjunction with a group of CRS Coordinators we plan to pilot the template report prior to official implementation.

Our continued focus is to collect quality assurance data that is of value to both the sites and sponsor which will provide assurance of data integrity and human subjects' protection. So while you will not submit your quality assurance reports to DAIDS at this time, you are expected to continue with relevant QA and Quality Control (QC) activities of your operations to ensure the integrity, completeness and quality of data being collected.

We anticipate that the next submission will be in October 2017. Once this date is confirmed, OCSO will send out additional communication to all sites.

If you have any questions, please email your OCSO Program Officer who will provide further guidance.