



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

## MEMORANDUM

DATE: 15-February-2018

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

TO: HIV/AIDS Network Clinical Trials Units (CTUs)/Clinical Research Sites (CRSs)

RE: Clinical Quality Management Plan (CQMP) Quality Assurance (QA) Summary  
Report and Quality Management (QM) Activities

*Karen Reese  
for  
Bariatu Smith*

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The current Division of AIDS (DAIDS) CQMP policy, requires that DAIDS sponsored and/or supported CRSs provide a summary report of QA activities biannually to DAIDS. The submission of the QA Summary report **will not** be required on **April 2, 2018**.

Recently, DAIDS has undergone various Sponsor audits and a number of observations were noted related to Sponsor responsibilities for oversight of Quality Management (QM) activities at DAIDS sponsored and/or supported sites. References to the FDA Code of Federal Regulations (CFR) and the International Council for Harmonisation (ICH) E6 (R2), which was effective November 2016, specifically relating to Quality Management, were cited throughout the reports.

DAIDS has been reviewing the findings, along with the cited references and recommendations within these reports. We are committed to fulfilling our Sponsor responsibilities while also ensuring that we provide clear, meaningful guidance to sites, in order to provide assurance of data integrity and human subject protection. With a renewed emphasis on Quality Management activities and Sponsor oversight, DAIDS has decided to re-evaluate the tool used for submission of site QA summaries to ensure we are meeting our regulatory obligations. Therefore, we will not be requiring submission of the QA Summary Report due April 2, 2018. Further guidance will be forthcoming.

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.

Thank you