Sample Clinical Quality Management Plan Annual Summary Report

(SAMPLE ONLY. The template below is provided for your convenience as an example of how this information may be provided. The Division of AIDS (DAIDS) requires site personnel to evaluate both their Clinical Quality Management Plans (CQMP) and overall Quality Management (QA and QC) activities annually. Documentation of these evaluations may be satisfied with the submission of the Non-competition Grant Progress Report (type 5 annual reports). While completing this report will satisfy the documentation requirements for these evaluations, submitting the information below in any format is acceptable. DAIDS would consider it acceptable for a site to document compliance with the DAIDS CQMP policy by documenting the following information.)

Site Name:______________________________________ Site Number________________

Person Preparing Report____________________________ Date of Report______________

List # of PIDS reviewed by protocol

The Division of AIDS (DAIDS) requires site personnel to evaluate Clinical Quality Management Plans (CQMPs) annually. Please summarize Quality Management (QM) activities over the past year. Please complete this form and submit it utilizing the DAIDS specified format e.g., Type 5 grant progress report.

1. What opportunities for improvement have been identified during the past year as a result of ongoing Quality Assurance (QA) and Quality Control (QC) activities? Describe.

2. Which key indicators reviewed during your QM processes revealed a need for improvement?

   - Informed consent form and process
   - Eligibility criteria
   - Scheduled tests and procedures
   - Missed visits, tests or procedures
   - Concomitant/prohibited medications
   - Study product administration/dosing
   - Clinical endpoint identification
   - Identification and reporting of Serious Adverse Events (SAE), DAIDS
   - Expedited Adverse Events (EAE) and Adverse Events (AE)

3. For QA/QC problem trends or ineffective processes and tools that were identified, what corrective action plans were put into place? Describe.

4. What QA/QC tools are included in your CQMP? List all.

5. Were all QA/QC activities defined within the CQMP performed? Were all stated frequencies of review met? Describe.