Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual Appendix:

Clinical Quality Management Plan: Clinical Research Site Quality Assurance Summary Report

Instructions: *Please complete this form using Quality Assurance (QA) reviews of protocol activities (i.e., protocol visit documents, regulatory documents) for* ***at least a 3-month consecutive period****. Use information from your chart review tool, protocol regulatory file review tool, and other documents used in your QA activities.*

Site Name _____

Site Number _____

Role and name of Person Preparing report _____

Date of QA report_____

Period of Review (At least 3 consecutive months of protocol activities):

(Start date)_____**to (End date)** _____

1. Summary of Protocols Reviewed

Complete only for protocols which had participants' (hereinafter referred to as PIDs) research records reviewed during the 3-month review period. Please report no more than five protocols, even though the CRS QA review activities may have included more.

If the CRS has more than five active protocols, please choose only five to report at this time. The CRS will be able to rotate protocols reviewed with each submission to account for all active protocols at the CRS.

If the CRS has less than five protocols, then please include all the protocols being conducted at the CRS.

For additional guidance, please refer to the SCORE Manual Appendix, Guidelines for CRS staff on Preparing the Bi-annual Quality Assurance (QA) Summary Report.

At DAIDS' discretion, certain protocols can be requested for inclusion in submission of the QA Summary reports.

Protocol	**Total Number of PIDs Enrolled** *(at the time of completion of this document)*	**Number of PIDs QA Reviewed** *(during this review period)*	**Percent of PIDs QA Reviewed**
Example: Protocol XXXX	*100*	*13*	*(13/100) = 13%*
Example: Protocol YYYY	*150*	*15*	*(15/150) = 10%*

2. List tools used for this QA review.

E.g.: Eligibility Checklist, Participant Chart Review Tool

3. Summary of Key Indicators (KIs) and Number of Associated Findings

These are the Key Indicators (KI) required by DAIDS to be used for QA review. Each CRS may add additional site-chosen KIs in the blank cells, if applicable.

Please note that if there was a review of a KI that yielded no findings, a zero (0) should be placed in that cell. However, if a KI was not applicable during this review period, an "N/A" should be placed in that cell. *For example: If there were informed consents conducted during this review period resulting in no findings, then a "0" should be noted.*
However, if there were no informed consents conducted during this review period, then "N/A" should be noted.

For determining the number of findings, please note that one KI deficiency may have more than one associated criterion applicable to a PID. Each criterion should then be counted as one finding. *For example: A PID has an Informed Consent Form (ICF) with two errors (no signature from Principal Investigator (PI) and version used was obsolete), this will count as "2" findings for that protocol in the ICF Key Indicator (KI) row.*

Please list the protocol number in the line provided under "protocol." Insert rows for additional site-chosen KIs as needed.

Key Indicator(s)	**Number of Findings (per protocol)**				
	Protocol _____	**Protocol** _____	**Protocol** _____	**Protocol** _____	**Protocol** _____
Informed Consent Form (ICF) and Process *(initial or subsequent)*					
Assessment of Understanding of ICF, as applicable					
Eligibility Criteria and Process *(as stated in the protocol)*					
Protocol Required Tests/Procedures					
Visits/Missed Visits					

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol _____	Protocol _____	Protocol _____	Protocol _____	Protocol _____
Concomitant Medications/Prohibited Medication					
Study Product Administration/Dosing					
Adverse Events (AE)/Serious Adverse Events (SAE)/Expedited Adverse Events (EAE) identification and reporting					
Protocol Defined Endpoint identification and reporting as applicable					
Source Documents, signatures, initials and dates					
Investigator File Review Deficiencies					

4. Summary of Deficient Key Indicators (KIs) and Associated Criteria

Please elaborate on the deficient key indicators from the previous section (Section 3). Please report Key Indicator findings from the previously listed protocols, and report on 20 PIDs with findings associated with those protocols. When choosing which PIDs to report, focus on choosing PIDs with as many different identified deficient KI's as possible. If the CRS QA review had less than 20 PIDs with findings, then please include them all.

List one Key Indicator Finding per line for each PID. Capture the criteria associated with the deficient KI. ***Use short and concise statements.***

- If there are more than one criterion per key indicator, capture all associated criteria in one cell. For examples of some criteria, refer to the SCORE Manual Appendix, Participant Chart Review Tool.
- If a PID/ has more than one deficient KI, please list each KI on separate rows. Please note that if there are more than one KI per PID, this will still count as one PID towards the 20 PID maximum requirement.
- List all corrective and preventative actions (CAPAs) associated with each different criterion. If a CAPA was not performed for a KI finding, list "N/A" under the Corrective Actions column and provide a comment if necessary. ***Use short and concise statements.*** (See example in first row).

For additional guidance and examples, please refer to the SCORE Manual Appendix, "Guidelines for Clinical Research Site (CRS) staff on Preparing the Bi-annual Quality Assurance (QA) Summary Report." If additional lines are needed, please use the SCORE Manual Appendix Clinical Quality Management Plan: Clinical Research Site Quality Assurance Summary Report – Section 4 Additional lines.

PID # (list only 1 PID per line)	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**
123456	*A1000*	*Informed Consent*	*1. Informed consent process not documented in source* *2. Participant was not offered copy of signed ICF*	*1. Documentation by appropriate CRS staff added in the research record of the* *2. Participant that the participant was called, asked to return to clinic, and offered a copy.*	*Revise informed consent (IC) checklist to include review of IC requirements including proper documentation prior to participant departure from clinic.* **This preventative action plan applies to both criteria associated with the deficient KI.*

PID # *(list only 1 PID per line)*	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**

PID # *(list only 1 PID per line)*	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**

PID # *(list only 1 PID per line)*	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**

PID # *(list only 1 PID per line)*	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**

PID # *(list only 1 PID per line)*	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**

PID # *(list only 1 PID per line)*	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**

PID # *(list only 1 PID per line)*	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**

PID # *(list only 1 PID per line)*	**Protocol #**	**Deficient Key Indicator(s)**	**Criteria Associated with Deficient KIs**	**Describe Corrective Actions Implemented**	**Describe Preventative Actions Implemented**

5. Regulatory File Review

Based on findings identified in the Protocol Regulatory File Review Tool(s), complete the following:

a. Complete the table below for the previously listed protocols for which a QA review was conducted during this review period.

b. Specify the protocol and the document finding(s) and the associated criteria. **Use short and concise statements.**

- If there are more than one criterion, capture all associated criteria in one cell. For examples of some criteria, refer to the SCORE Manual Appendix, "Protocol Regulatory File Review Tool". List all corrective and preventative actions associated with each different criterion in one cell.
- If there is more than one document finding for the same protocol, please list each of them in a separate row.

c. If a QA Regulatory File Review was not conducted for any of the protocols listed in Section 1 "Summary of Protocols Reviewed" during this review period, please provide an explanation. (See example in table below).

Protocol #	Was a Regulatory File review conducted?	If no review was done, provide an explanation:	Document findings	Criteria associated with deficient documents	Describe corrective actions implemented	Describe preventative actions implemented
A1000	*NO*	*Regulatory file review conducted during previous review period.*	*n/a*	*n/a*	*n/a*	*n/a*
A1500	*YES*	*n/a*	*DAIDS Approvals*	*1) Initial DAIDS Protocol Registration Office (DAIDS PRO) notification not on file.* *2) Subsequent confirmation of submission not on file.*	*Locate DAIDS PRO approval letters and file in regulatory binder.*	*Implement a filing system for all documents on a weekly basis. Delegate task to research assistant.* **This preventative action plan applies to both criteria associated with the document finding.*

Protocol	Was a Regulatory File review conducted?	If no review was done, provide an explanation:	Document findings	Criteria associated with deficient documents	Describe corrective actions implemented	Describe preventative actions implemented

Protocol	Was a Regulatory File review conducted?	If no review was done, provide an explanation:	Document findings	Criteria associated with deficient documents	Describe corrective actions implemented	Describe preventative actions implemented

Protocol	Was a Regulatory File review conducted?	If no review was done, provide an explanation:	Document findings	Criteria associated with deficient documents	Describe corrective actions implemented	Describe preventative actions implemented

6. CQMP Revision

a. Does the CQMP need revision based upon site review of the QA findings included in this CRS QA Summary Report?

☐Yes ☐No

b. If Yes, please specify areas of your CQMP to be revised in the box below:

E.g., Quality Control tools for informed consent revised *E.g., New process implemented for Regulatory File Review*

Revision History

There were four previous versions of this appendix, including the APP-A28-OCS-003.00 approved by DAIDS Quality Management System, published on the DAIDS Clinical Research Policies webpage prior to the implementation of the DAIDS SCORE Manual.

This version has been revised to adjust terminology to the SCORE Manual.