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

Guidelines for Clinical Research Site (CRS) staff on Preparing the Bi-annual Quality Assurance (QA) Summary Report

Purpose

This document provides guidance to Clinical Research Staff (CRS) staff responsible for preparing and submitting bi-annual Quality Assurance (QA) Summary Reports to the Office of Clinical Site Oversight (OCSO) Program Officers (PO).

Preparing QA Summary Reports

The QA reporting process starts with completing a review of selected participant research records and regulatory files spanning at least three consecutive months. DAIDS requires CRSs to use the "Participant Chart and Protocol Regulatory File Review Tools" to conduct bi-annual QA reviews. CRSs may use additional tools to supplement the required DAIDS tools and increase review frequency to meet CRS and clinical trial needs. The tools are located in the SCORE Manual:

- Appendix: [Participant Chart Review Tool](#)
- Appendix: [Protocol Regulatory File Review Tool](#)

CRSs must save all completed tools in an internal folder separate from protocol regulatory files. These completed tools are not auditable by regulatory agencies but must be available for review by DAIDS and DAIDS representatives.

Once CRS staff review participant research records and/or the regulatory files for a period of at least three consecutive months and populate the corresponding review tools (*Participant Chart* and *Protocol Regulatory File Review Tools*), they can prepare the *CRS QA Summary Report* as part of the DAIDS bi-annual submission requirement. Appendix [Clinical Quality Management Plan: Clinical Research Site Quality Assurance Summary Report Template](#) is provided in this Manual.

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QA Summary Report data must come from the CRS's internal QA review. Findings. Trends identified by monitors in a CRS monitoring report are not to be included in the *QA Summary Report*.

The CRS staff must complete the following six sections of the *QA Summary Report.* Each section is on a different tab in the Excel document.

Introduction

Site Name: Enter the CRS name. Write the full name and abbreviation (if applicable) in parentheses. For example: Site A Clinical Research Unit (Site A-CRU).

Site Number: Enter the CRS number (e.g., CRS 1234).

Role and Name of Person Preparing the QA Summary Report: Enter the name of the person preparing the *QA Summary Report*. This does <u>not</u> have to be the same person who conducted the QA review of the participant research records or the regulatory files, or the person who submits the *QA Summary Report* to DAIDS. For example, the Data Manager may conduct the QA review and the Site Coordinator may conduct the regulatory file review. Then, both provide their findings to a Nurse who prepares the *QA Summary Report*, and an administrative assistant submits the Report to DAIDS. Alternately, the same person may complete all tasks.

Date of QA Report completion: Enter the date the *QA Summary Report* itself is completed, not the period of QA review.

Period of QA Review: (Start Date to End date): The period of QA review are the dates when protocol activities are conducted. The review period must span at least three consecutive months of protocol activities. If participant visits occurred in January and March but none in February, the period of review will still be January through March. If participant visits occurred in January, March, and April, enter either "January through March," or "February through April." This review period can start any day of the month (as long as the entire review period spans three consecutive months (e.g., 10 January 2019 to 10 April 2019).

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1. Summary of Protocols Reviewed

Complete this table listing up to five protocols reviewed. Use the data from *Participant Charts Review Tools* completed during the current QA review cycle. For example, if research records of 25 participants were reviewed from seven protocols, only populate this table with data from five protocols; do not report the other two protocols at this time. If nine participant research records were reviewed from three protocols, report all three protocols.

If a CRS has only 1 to 5 protocols, then report on all of them each cycle. If the CRS has more than five active protocols, report on only five of them each cycle. Rotate protocols being reported in the bi-annual *QA Summary Reports.* If the CRS has more than 5 protocols, report on any 5 in June and another combination of 5 in December. Always try to prioritize reporting protocols that have high-impact findings, more findings, or more deficient Key Indicators (KIs). Please note that DAIDS may ask CRSs to include certain protocols in the *QA Summary Report*.

Protocol: Populate with the protocol numbers (e.g., HPTN 100) that are being reported on in the *QA Summary Report*.

Total Number of PIDs Enrolled: Enter the total number of participants enrolled in this protocol at the CRS, from study start to the time the *QA Summary Report* is completed. This number should come from CRS protocol screening and enrollment logs.

Total Number of active PIDs Enrolled at the beginning of the review period: Enter the total number of participants enrolled in this protocol at the CRS, at the beginning of the review period covered in the report. This number may be different than the total number enrolled and will be used to determine the percentage of PIDs reviewed during the review period.

Number of PIDs QA Reviewed: Enter the number of participant research records reviewed for the reporting period. This number should match the number of *Participant Chart Review Tools* completed per protocol.

Percentage of PIDs QA Reviewed: This value will be automatically calculated once you enter the number of PIDs enrolled and QA reviewed in the previous columns.

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- In the example below, the CRS had two active protocols during their QA review cycle and reviewed 28 PIDs—13 from Protocol XXXX and 15 from Protocol YYYY.

Example Table 1:

Protocol	Total Number of PIDs Enrolled *(from study start to the time of the report)*	Total Number of active PIDs Enrolled at the beginning of the review period	Number of PIDs QA Reviewed *(during this review period)*	Percentage of PIDs QA Reviewed
Ex: Protocol XXXX	120	100	13	(13/100) = 13%
Ex: Protocol YYYY	150	100	15	(15/100) = 15%

2. QA Review Tools Used

List the tools used to conduct the QA review, i.e., the *Participant Chart Review Tool*, the *Protocol Regulatory File Review Tool*, and any other CRS tools used. Please note that tools outside of the *Participant Chart Review Tool* and *Protocol Regulatory File Review Tool* must also be described in the CRS's Clinical Quality Management Plan (CQMP).

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

Each CRS must report the number of findings for the 11 DAIDS-required KIs described in this section of the tool. The CRS may include additional site chosen KIs in this section of the *QA Summary Report* but may not omit any DAIDS-required KIs.

Protocol Number

The protocol number will be automatically populated at the top of this table from the information entered in the "Summary of Protocols Reviewed" tab (Section 1).

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Number of Findings (per protocol): *This reporting is not limited to number of participants; please report all KIs for all participants reviewed from the five reporting protocols.*

- If a KI does not apply to a protocol or the time-period of review, report "N/A" for that KI. For example, for Protocol YYYY below, if all participants have been enrolled and the study is in follow-up, then the KIs for Informed Consent Form (ICF) and Process, Assessment of Understanding of ICF, and Eligibility Criteria and Process can be marked as "N/A."

Example Table 2:

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol Number XXXX	Protocol Number YYYY	Protocol Number	Protocol Number	Protocol Number
Informed Consent Form (ICF) *(initial or subsequent)*		N/A			
Assessment of Understanding of ICF as applicable		N/A			
Eligibility Criteria and Process *(as stated in the protocol)*		N/A			

- If there are no findings for a certain KI for a given protocol, report "0" for that KI. In the example below for Protocol YYYY, if all visits were conducted within the visit window for the period under review, then the KI would be reported as "0".

Example Table 3:

	Number of Findings (per protocol)

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Key Indicator(s)	Protocol Number XXXX	Protocol Number YYYY	Protocol Number	Protocol Number	Protocol Number
Visits/Missed Visits		0			

- If there is more than one finding for a given KI, the number of findings reported for that KI will be the actual number of findings. In the example below for Protocol XXXX, if one participant missed one visit and did not complete another visit within the visit window, the number of findings reported for the "Visits/Missed Visits" KI will be 2.

Example Table 4:

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol Number XXXX	Protocol Number YYYY	Protocol Number	Protocol Number	Protocol Number
Visits/Missed Visits	2				

4. Summary of Deficient Key Indicators and Associated Criteria

Provide details on the deficient KIs reported in the previous section on no more than 20 PIDs. All PIDs must be associated with the five protocols being reported on in this review period (listed in the table in Section 1 of the *QA Summary Report*). When choosing which PIDs to report, focus on including as many different identified deficient KIs as possible.

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PID Number

List the 20 PID numbers selected to report in this column. These PID numbers should belong to the five protocols listed in the table in Section 1 of the *QA Summary Report*. If more than 20 PIDs have deficiencies for the five protocols chosen, only report 20 PIDs in this section. Select high-impact PIDs and/or a variety of KI deficiencies.

Protocol Number

Enter the protocol number associated with the PID number listed in column A of the table. These will be available in the dropdown list in each cell in this column.

Deficient Key Indicator(s)

List deficient KIs in this section of the table associated with the PID number in column A. KIs should come from the "Indicator" column in the DAIDS *Participant Chart Review Tool*. These will be available in the dropdown list in each cell in this column. If the site added site chosen KIs in tab 3, these will appear at the bottom of the dropdown list.   If a PID has more than one deficient KI, use additional rows to list KIs with the same PID number in column A and protocol number in column B. **Please note:** A PID with more than one deficient KI identified, still counts as 1 PID toward the 20 PID maximum.

Criteria Associated with Deficient Key Indicators

List the criteria associated with the deficient KI. These criteria will be available in the dropdown list in each cell in this column and will be based on the KI chosen in the previous column (Column C). If a PID has more than one deficient criteria per KI, list each criterion in a separate row with the same KI and PID number.

The example below shows one KI deficiency for Protocol XXXX but two criteria for that KI. Report each finding for this protocol in a separate row.

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Example Table 5: Summary of Key Indicators and Number of Associated Findings (Section 3 of the QA Summary Report)

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol Number XXXX	Protocol Number	Protocol Number	Protocol Number	Protocol Number
Informed Consent Form (ICF) and Process *(initial or subsequent)*	2				
Visits/Missed Visits					

Example Table 6: Summary of Deficient Key Indicators and Associated Criteria (Section 4 of the QA Summary Report)

PID # *(list only 1 PID per line)*	Protocol #	Deficient Key Indicator(s)	Criteria Associated with Deficient KIs	Issue Description (brief explanation, if applicable)	Describe Corrective Actions Implemented	Describe Preventative Actions Implemented
123456	XXXX	Informed Consent Form (ICF) and Process	Informed Consent/Assent process, including participant education, not documented in the participant record	Source ICF checklist missing checkmarks	Documentation by appropriate CRS Staff added in participant research records.	Revise IC checklist to include review of IC requirements including proper documentation

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						prior to participant departure from the clinic
123456	XXXX	Informed Consent Form (ICF) and Process	No documented evidence that the participant was provided a copy of the signed/dated Informed Consent/Assent	N/A	Participant was called, asked to return to the clinic and offered a copy	Revise IC checklist to include review of IC requirements including proper documentation prior to participant departure from the clinic

The example below highlights Protocol YYYY which has one KI deficiency for "ICF and Process" and one KI deficiency for "Visits/Missed Visits." Report each of these deficiencies separately in section 4.

Example Table 7: Summary of Key Indicators and Number of Associated Findings (Section 3 of the QA Summary Report)

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol Number YYYY	Protocol Number	Protocol Number	Protocol Number	Protocol Number
Informed Consent Form (ICF) and Process *(initial or subsequent)*	1				
Visits/Missed Visits	1				

Example Table 8: Summary of Deficient Key Indicators and Associated Criteria (Section 4 of the QA Summary Report)

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PID # *(list only 1 PID per line)*	Protocol #	Deficient Key Indicator(s)	Criteria Associated with Deficient KIs	Issue Description (brief explanation, if applicable)	Describe Corrective Actions Implemented	Describe Preventative Actions Implemented
78910	YYYY	Visits/Missed Visits	All visits not conducted within protocol defined windows	Participant missed visit 15/month 4	Documentation by appropriate CRS staff added in participant research records.	Participants will be called to remind them of their study visits 3 days before visit day.
78910	YYYY	Informed Consent Form (ICF) and Process	Signature and date of the most current, IRB/IEC approved version of the Consent/Assent Form not on file	Participant was provided the wrong version of the ICF	Participant was asked to return to clinic and sign the correct version.	CRS will add a QC step to ensure correct version of ICF on the ICF checklist.

Description of Issue: Please briefly describe the details of the issue (as applicable) so that the PO has context for the review of the corrective and preventative actions. **Be as concise as possible.**

Describe Corrective Actions Implemented: Describe corrective actions (if applicable) that the CRS has implemented or plans to implement. Provide an implementation timeline for corrective actions that have not been implemented yet. If multiple corrective actions are implemented for one KI, describe them all briefly in the same cell.

Describe Preventative Actions Implemented: Describe preventative actions (if applicable) that the CRS has implemented or plans to implement. Provide an implementation timeline for preventative actions that have not been implemented yet. If multiple preventative actions are implemented for one KI, describe them all briefly in the same cell.

List "N/A" in each column if a Corrective Action and Preventive Action (CAPA) was not performed or needed for a KI finding. Include a comment if necessary.

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5.   Regulatory File Review

Populate this section with the findings identified during the Regulatory File review. Use the *Protocol Regulatory File Review Tool* to conduct the regulatory file review.

Protocol: Identify the protocols that were reviewed during this period of review. These will be the same protocols reported in sections 1 and 3 of the *QA Summary Report*. These will be available in the dropdown list in each cell in this column.

Was a Regulatory File Review Conducted? Indicate whether the regulatory file review was conducted. If not, provide a reason in the next column as to why regulatory review was not conducted. If no regulatory review was conducted, Columns D through H will be grayed out in the Excel document.

Deficient Documents:. These broad categories classify the regulatory file review findings. These will be available from the dropdown list in each cell in this column. If there is more than one document deficiency for a given protocol, list each of them in a separate row.

Criteria Associated with Deficient Findings: These criteria will be available in the dropdown list in each cell in this column and will be based on the deficient document chosen in the previous column. If more than one criteria is associated with the document of a given protocol, list each criterion in a separate row with the same Deficient Document and Protocol Number.

The example below shows one Document finding category for Protocol YYYY but two criteria for that Document category. In this instance, report two findings for Protocol YYYY in Section 5 of the *QA Summary Report*. Since the Regulatory review was not performed for Protocol XXXX, report N/A in Section 5 of the *QA Summary Report*.

Example Table 9: Summary of Key Indicators and Number of Associated Findings Table (Section 3 of the QA Summary Report Template)

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol Number	Protocol Number	Protocol Number	Protocol Number	Protocol Number

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	XXXX	YYYY			
Investigator File Review Deficiencies	N/A	2			

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Example Table 10: Regulatory File Review (examples are from the Section 3 of the QA Summary Report Template).

Protocol	Was a Regulatory File review conducted?	If no review was done, provide an explanation:	Document findings	Criteria associated with deficient documents	Issue Description (brief explanation, if applicable)	Describe corrective actions implemented (if applicable)	Describe preventative actions implemented (if applicable)
XXXX	*NO*	*Regulatory file review conducted during previous review period.*					
YYYY	*YES*	*N/A*	*DAIDS Approvals*	*DAIDS Protocol Registration Office (DAIDS PRO) approval for initial registration not on file*	*Initial notification not on file.*	*Locate DAIDS PRO approval letters and file in regulatory binder.*	*Implement a system to file all documents weekly. Delegate task to research assistant.*
YYYY	*YES*	*NA*	*DAIDS Approvals*	*DAIDS Protocol Registration Office (DAIDS PRO) approval for subsequent registrations not on file*	*Subsequent confirmation of submission not on file. (Version 3.0)*	*Locate DAIDS PRO approval letters and file in regulatory binder.*	*Implement a system to file all documents weekly. Delegate task to research assistant.*

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Description of Issue: Please briefly describe the details of the issue so that the PO has context for the review of the corrective and preventative actions. If there is more than one issue with the same associated criteria, capture the issues in the same cell. **Be as concise as possible.**

Describe Corrective Actions Implemented: Describe corrective actions that the CRS has implemented or plans to implement. Provide an implementation timeline for corrective actions that have not been implemented yet. If multiple corrective actions have been implemented for one type of document finding, describe them all briefly in the same cell.

Describe Preventative Actions Implemented: Describe the preventative actions that the CRS has already implemented or plans to implement. Provide an implementation timeline for preventative actions that have not been implemented yet. If multiple preventative actions have been implemented for one type of document finding, describe them all briefly in the same cell.

List "N/A" in each column if a Corrective Action and Preventive Action (CAPA) was not performed or needed for a document finding. Include a comment if necessary.

6. CQMP Revision

When a revision to the CQMP is needed, submit a copy of the revised CQMP to the assigned OCSO PO for review and approval. Indicate if the revision is based on findings from a QA review period and what revisions were made. Revision plans can encompass clarifications, additional processes, or a major update of the CQMP and/or CRS tools.

7. Submission instructions

Please submit the completed *QA Summary Report* to the assigned OCSO PO and copy the CRS leader on this communication.

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Revision History

Revision	Summary of Changes
1.0	Original version; became effective on 1/19/2021
02	The document number and format were updated to meet current requirements.