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

Clinical Quality Management Plan: Participant Chart Review Tool

Instructions: *Quality Assurance (QA) review of participant research records are conducted to verify adherence to protocol, Good Clinical Practice (GCP), Human Subject Protection (HSP), Clinical Research Site (CRS) procedures, Institutional Review Board/Ethics Committee (IRB/EC), Regulatory and DAIDS requirements.* ***Source documentation should be compared to Case Report Form (CRF) and protocol for agreement.***

1. Complete one *Participant Chart Review Tool* per participant audited for the review period.
2. Check the appropriate boxes for each question listed in the criteria section.
3. Use the comments section for clarification and action and for any "no" entries checked.
4. Record the date range of the review using the "Reviewed from (Visit #/Date)_____ through (Visit #/Date)_____".

Participant Identification (PID) # _____

Protocol # _____

Reviewed from (Visit #/Date)_____**through (Visit #/Date)** _____

Name and Role of Reviewer _____

Indicator	Criteria	Yes	No	N/A	Comments
1. Informed Consent Form (ICF) and Process	Did the participant sign and date the most current, IRB/IEC approved version of the Consent/Assent Form?	☐	☐	☐	
	Are all required signatures present? (Parent signature, PI, witness etc.)	☐	☐	☐	
	Are previous applicable versions of Informed Consent /Assent in the participant research record signed and dated appropriately?	☐	☐	☐	
	Was the Informed Consent/Assent process, including participant education, documented in the participant record?	☐	☐	☐	
	Did the participant sign/date consent/assent, prior to study-specific procedures?	☐	☐	☐	
	Is there documented evidence that the participant was provided a copy of the signed/dated Informed Consent/Assent?	☐	☐	☐	
2. Assessment of Understanding of ICF, as applicable	Was assessment of understanding related to the Informed Consent Form conducted and documented in the source notes?	☐	☐	☐	
3. Eligibility Criteria and Process	Are all inclusion and exclusion criteria met and documented in source notes?	☐	☐	☐	
	Is there source documentation to address each pertinent negative?	☐	☐	☐	

Indicator	Criteria	Yes	No	N/A	Comments
4. Protocol Required Tests/ Procedures	Were all protocol required tests/ procedures completed and documented?	☐	☐	☐	
	Are all laboratory or other diagnostic reports signed, dated, quality controlled (QC'ed), and on file in the participant research record?	☐	☐	☐	
	Are any missed tests documented, with rationale provided?	☐	☐	☐	
	Are actual specimen collection times accurately reflected on laboratory reports?	☐	☐	☐	
	Were all samples collected, processed and stored correctly as per protocol?	☐	☐	☐	
5. Visit /Missed Visits	Has the participant missed any visits? If yes, are missed visits documented adequately?	☐	☐	☐	
	Are all visits conducted within protocol defined windows? If no, are reasons for out of window visits documented?	☐	☐	☐	
6. Concomitant Medication (Con. Med.)/ Prohibited Medication	Is participant Con. Med. CRF consistent with source documentation?	☐	☐	☐	
	Is participant taking any protocol-defined prohibited medication?	☐	☐	☐	
	If yes, have the prohibited medications been documented appropriately?	☐	☐	☐	

Indicator	Criteria	Yes	No	N/A	Comments
7. Study Product Administration/ Dosing (When study product is administered in the clinic)	Study product administered per protocol and documented in the source notes?	☐	☐	☐	
	Is there documentation that the clinic staff checked the study product label against the PID # prior to administration?	☐	☐	☐	
	Is there documentation that the clinic staff addressed any potential safety concerns prior to administration of study product? (E.g., Abnormal labs, suspected illness etc.)	☐	☐	☐	
8. Adverse Events (AEs)/Serious Adverse Events (SAEs)/Expedited Adverse Events (EAEs) Identification and Reporting	Are adverse events (AEs) recorded and reported per protocol requirements?	☐	☐	☐	
	Are all abnormal protocol required laboratory results graded and documented?	☐	☐	☐	
	Are there any missed (unreported) AEs?	☐	☐	☐	
	Are there any missed (unreported) SAEs?	☐	☐	☐	
	Are there any missed (unreported) EAEs?	☐	☐	☐	
	Are all identified SAE's/EAE's reported to IRB/EC/other regulatory entities?	☐	☐	☐	
	Have all identified SAE's/EAE's been reported to the Sponsor?	☐	☐	☐	
9. Protocol Defined Endpoint Identification	Did the participant reach any protocol-defined endpoints?	☐	☐	☐	
	If yes, are all specific details (Laboratory results, diagnosis) documented per protocol requirements?	☐	☐	☐	
	Are protocol defined endpoints CRFs completed?	☐	☐	☐	

Indicator	Criteria	Yes	No	N/A	Comments
10. Source Documents, signatures, initials, dates	Are all source documents present in attributable, legible, contemporaneous, original, accurate and complete (ALCOA-C) format?	☐	☐	☐	
	Are all entries signed, initialed and dated including credentials as applicable?	☐	☐	☐	
	Is there a document on file listing each CRF designated to be used as source Document?*	☐	☐	☐	
	Are all error corrections properly executed per DAIDS Source Documentation Requirements?	☐	☐	☐	
	For each CRF reviewed are all entries verifiable in the source notes unless the CRF has been designated as source?	☐	☐	☐	
11. Site to add any additional chosen site-specific key indicators	*Example: KI - HIV Prevention Counseling: Was counseling provided per protocol, and documented at each required visit?*	☐	☐	☐	
		☐	☐	☐	

**Sites often use printed copies of blank CRFs as source documents. If this approach is adopted by the site, ensure the site has a document listing of the CRFs that will be used as source documents for that specific protocol.*

Findings/Results of Review, Description of issues noted in this review. If additional rows needed copy page:

PID # _____

Indicator	Specific Issue(s)	Visit #/Date	Corrected by/date

Signature and role of Reviewer: _____

Date: _____

REVISION HISTORY

There were four previous versions, including the APP-A28-OCS-001.00 approved by DAIDS Quality Management System, of this appendix 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.