

APPENDIX 1

DAIDS Clinical Quality Management Plan (CQMP): Sample QA Participant CHART Review Tool

Approval Date 17 MAR 2015

Effective Date 17 APR 2015

DWD-POL-CL-009.04A2

Instructions: Participant Quality Assurance (QA) chart review is conducted to verify adherence to protocol, GCP,HSP, site procedures, regulatory and sponsor's requirements .

- 1. Complete one (1) Sample QA Chart Review Tool (CRT) per participant record 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 # _____ to Visit # _____”**

Source documentation should be compared to Case Report Form (CRF) and protocol for agreement.

Note: Please refer to DAIDS [Clinical Research Site Policies](#) webpage

Participant Identification (PID)

Protocol # _____

Reviewed from (Visit #) _____ through (Visit #) _____

Name and Role of Reviewer

Date of Review _____

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Indicator	Criteria	Yes	No	N/A	Comments
1. Consent/Assent (As applicable)	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 record signed and dated appropriately?				
	Was the Informed Consent/Assent process, including participant education, documented in the participant record?				
	Did the participant sign/date (in ink) consent/assent, prior to study-specific procedures?				
	Is there documented evidence that the participant was offered a copy of the signed/dated Informed Consent/Assent?				
2. Assessment of Understanding	Was assessment of understanding related to the Informed Consent Form conducted and documented in the source notes?				
3. Eligibility	Are all inclusion and exclusion criteria met and documented in source notes?				
	Is there source documentation to address each pertinent negative?				
4. HIV Prevention Counseling	Was counseling provided per protocol, and documented at each required visit?				

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Indicator	Criteria	Yes	No	N/A	Comments
5. Protocol Required Tests/ Procedures	Were all protocol required tests/ procedures completed and documented?				
	Are all lab or other diagnostic reports signed, dated, QC'ed, and on file in the participant record?				
	Are any missed tests documented, with rationale provided?				
	Are actual specimen collection times accurately reflected on lab reports?				
6. 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?				
7. Concomitant Meds (Con. Med.)/ Prohibited Meds	Is participant Con. Med. CRF consistent with source documentation?				
	Is participant taking any protocol-defined prohibited meds?				
	If yes, have the prohibited meds been documented appropriately?				

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Indicator	Criteria	Yes	No	N/A	Comments
8. Study Product Administration (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.)				
9. AE/SAE/EAE Reporting	Are adverse events (AE) recorded and reported per protocol requirements?				
	Are all abnormal protocol required labs 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/IEC/other regulatory entities?				
	Have all identified SAE's/EAE's been reported to the Sponsor?				

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Indicator	Criteria	Yes	No	N/A	Comments
10. Endpoints	Did the participant reach any protocol-defined endpoints?				
	If yes, are all specific details (Labs, diagnosis) documented per protocol requirements?				
	Are protocol defined endpoints CRFs completed?				
11. Source Documents, signatures, initials, dates	Are all source documents present in attributable, legible, contemporaneous, original and accurate (ALCOA) 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?"				
12. Site to add any additional chosen site specific indicators					

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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 of Reviewer: _____

Date: _____