

APPENDIX 2

DAIDS Clinical Quality Management Plan (CQMP): Sample QA Protocol Regulatory File Review Tool

Approval Date 17 MAR 2015

Effective Date 17 APR 2015

DWD-POL-CL-009.04A3

Instructions: Protocol Regulatory File QA Review is conducted to verify adherence to applicable regulatory and sponsor’s essential documents requirements.

- 1. Complete one (1) Sample Protocol Regulatory File QA Review Tool for each Protocol Regulatory File audited during this review period**
- 2. List the protocol number, the date range that the Regulatory File is being reviewed, and the date of the review.**
- 3. Check the appropriate boxes for each question listed in the criteria section.**
- 4. Use the comments section for clarification and action on any “no” entries checked.**

Note: For additional references see, the [DAIDS Clinical Research Site Policies](#) webpage.

Site Name _____

Site Number _____

Protocol Number _____

Reviewed from (date) _____ to (date) _____

Name and role of Reviewer _____

Date of Review _____

Document	Criteria	Yes	No	N/A	Comments
1. Is an organized protocol regulatory file present and on-site?	[Cross-hatched area]				
2. IRB/IEC Submissions to all Required Regulatory Bodies (continued on page 2)	Are the following documents on file with dated proof of submission?				
	Current Protocol Version				
	Current Informed Consent Document				
	Recruitment /Advertisement materials				

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Document	Criteria	Yes	No	N/A	Comments
	Previous versions of the Protocol				
	Previous versions of Informed Consent Documents				
	Investigator Brochure/Package Insert				
	Current FDA Form 1572 / Investigator of Record (IoR)				
	Previous 1572's / IoR				
	CV's of Investigators on 1572 / IoR				
	Current list of laboratory reference ranges				
	Letters of Amendments/Clarification Memos				
	Safety Reports				
	Continuing Review Reports				
	DSMB Summary Reports and documentation to IRB/IEC				
	Is there dated documentation showing that all documents have been submitted to the IRB/IEC and other regulatory bodies as required? E.g MCC submission				
3. IRB/IEC Approvals	Is there dated proof of approval of the following?				
	Recruitment/Advertisement materials				
	Current Protocol				
	Current version of the ICF				
	Previous versions of the ICF				
	Letters of Amendments/Clarification Memos				
	Full Amendments				
	Continuing Review Reports				
	All approvals present from other regulatory bodies as required.				

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Document	Criteria	Yes	No	N/A	Comments
4. DAIDS Approvals	Is the DAIDS Regulatory Support Center (RSC) approval for protocol registration on file?				
	Initial registration				
	Subsequent registrations				
5. Assurances	Is there a current Federal Wide Assurance (FWA) from OHRP?				
	Is the IRB/IEC of record registered with OHRP and linked with this FWA?				
6. Financial Disclosure	Are all required financial disclosure documents on file?				
7. CVs; Biographical Sketches; Licenses	Are CV's/biosketches of PI and other staff signed, current, and show site affiliation (per institutional requirements) ?				
	Are licenses for all required staff present?				
8. Education and Training	Is there documented evidence of GCP/HSP training for all staff within 3 years (per institutional requirements)?				
	Is there documentation of personnel training on site standard operating procedures (SOPs)?				
	Is there documented evidence of protocol training for staff prior to performing trial related activities (per institutional requirements)? (E.g. training logs, slide presentations, meeting minutes etc.)				

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Document	Criteria	Yes	No	N/A	Comments
9. Logs	Is a current signature key/log present for all individuals authorized to make entries in study records?				
	Is a current delegation of duties log on file?				
	Is a current screening log(s) on file?				
	Is a current enrollment log(s) on file?				
	Are monitoring visit logs present?				
10. Laboratory	Are laboratory certifications current and on file?				
	Are laboratory reference ranges current and on file?				
	For research/central labs noted in the protocol, are there any required certificates present?				
11. Site Monitoring Visit Reports (SMRs)	Are all SMR's easily accessible electronically or filed?				
12. Communication	Are relevant communication documents to and from Sponsor and Protocol Team on file and easily accessible? (E.g. letters, email messages, meeting notes etc.)				
	Are relevant communication documents to and from IRB/IEC on file and easily accessible?				
13. Other Documents Reviewed:(list) For ex. Institutional Biosafety Committee (IBC)					

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

Document	Issue	Corrected by/date

Signature of Reviewer: _____

Date: _____