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

Clinical Quality Management Plan: Protocol Regulatory File Review Tool

Instructions: Protocol Regulatory File Quality Assurance (QA) Review is conducted to verify adherence to applicable regulatory and DAIDS's essential documents requirements.

1. Complete one *Protocol Regulatory File 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.

Site Name_____

Site Number_____

Protocol Number_____

Reviewed from (date)_____**to (date)** _____

Name and Role of Reviewer _____

Document	Criteria	Yes	No	N/A	Comments
1. Is an organized protocol specific regulatory file present and on- site?		☐	☐	☐	
2. Institutional Review Board(IRB)/Ethics Committee (EC) Submissions to all Required Regulatory Bodies	Are the following documents on file with dated proof of submission?				
	Current Protocol Version	☐	☐	☐	
	Current Informed Consent Form (ICF)	☐	☐	☐	
	Recruitment /Advertisement materials	☐	☐	☐	

Document	Criteria	Yes	No	N/A	Comments
2. IRB/EC Submissions to all Required Regulatory Bodies *(cont'd)*	Previous versions of the Protocol	☐	☐	☐	
	Previous versions of Informed Consent Documents	☐	☐	☐	
	Investigator Brochure/Package Insert	☐	☐	☐	
	Current Form FDA 1572/Investigator of Record (IoR) Form	☐	☐	☐	
	Previous 1572s/IoR Forms	☐	☐	☐	
	Curiculum Vitaes (CVs) of Investigators on 1572/IoR Form	☐	☐	☐	
	Current list of laboratory reference ranges	☐	☐	☐	
	Letters of Amendments/Clarification Memos	☐	☐	☐	
	Safety Reports	☐	☐	☐	
	Continuing Review Reports	☐	☐	☐	
	Data Safety Monitoring Board (DSMB) Summary Reports and documentation to IRB/EC	☐	☐	☐	
	Is there dated documentation showing that all documents have been submitted to the IRB/EC and other regulatory bodies as required? E.g submission to South African Health Products Regulatory Authority (SAHPRA)	☐	☐	☐	
3. IRB/EC 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	☐	☐	☐	

Document	Criteria	Yes	No	N/A	Comments
	Letters of Amendments/Clarification Memos	☐	☐	☐	
	Full Amendments	☐	☐	☐	
	Continuing Review Reports	☐	☐	☐	
	All approvals present from other regulatory bodies as required	☐	☐	☐	
4. DAIDS Approvals	Is the DAIDS Protocol Registration Office (PRO) approval for protocol registration on file?				
	Initial registration	☐	☐	☐	
	Subsequent registrations	☐	☐	☐	
5. Assurances	Is there a current Federal Wide Assurance (FWA) from Office of Human Research Protections (OHRP)?	☐	☐	☐	
	Is the IRB/EC 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 CVs/biosketches of Principal Investigator (PI)/IoR 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 Good Clinical Practice (GCP)/Human Subject Protection (HSP) training for all staff within 3 years (per institutional requirements)?	☐	☐	☐	

Document	Criteria	Yes	No	N/A	Comments
	Is there documentation of personnel training on site Standard Operating Procedures (SOPs)?	☐	☐	☐	
	Is there documented evidence of protocol-specific training for staff prior to performing trial related activities (per Sponsor and institutional requirements)? (E.g., training logs, slide presentations, meeting minutes etc.)	☐	☐	☐	
	Is there documented evidence of protocol-specific training of Clarification Memos and Amendments as applicable?	☐	☐	☐	
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 laboratories 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?	☐	☐	☐	

Document	Criteria	Yes	No	N/A	Comments
12. Communication	Are relevant communication documents to and from DAIDS and Protocol Team on file and easily accessible? (E.g. letters, email messages, meeting notes etc.)	☐	☐	☐	
	Are relevant communication documents to and from IRB/EC on file and easily accessible?	☐	☐	☐	
13. Other Documents Reviewed:(list) For example: Institutional Biosafety Committee (IBC)		☐	☐	☐	

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

Document	Issue	Corrected by/date

Signature and role of Reviewer: _____

Date: _____

REVISION HISTORY

There were four previous versions, , including the APP-A28-OCS-002.00 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.