

DAIDS  
Bethesda, MD USA

ARCHIVED APPENDIX

Sample Clinical Quality Management Regulatory File Review Tool

Approval Date: 26 FEB 2010

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No.: DWD-POL-CL-009.03A3

## Sample Clinical Quality Management Regulatory File Review Tool

(SAMPLE ONLY. The template below is provided for your convenience as an example of how this information may be provided. You may modify this as appropriate.)

Instructions: List the protocol number, the date range that is being reviewed and the date of the review. Once the review begins, check the appropriate boxes for each question listed in the criteria section. When the review is completed for all applicable documents, the QA reviewer will sign and date the form. Use the comments section for clarification and action on any “no” entries checked.

Site Name \_\_\_\_\_ Site Number \_\_\_\_\_

Name of Reviewer \_\_\_\_\_ Date of Review \_\_\_\_\_

Protocol Number \_\_\_\_\_ Version # \_\_\_\_\_

Reviewed from (date) \_\_\_\_\_ to (date) \_\_\_\_\_

<i>Document</i>	<i>Criteria</i>	<b>Present</b>		
		<b>Yes</b>	<b>No</b>	<b>N/A</b>
IRB/EC approval	Approval?			
Other Regulatory if applicable	Approval?			
	Informed Consent Approvals Present?			
	Revision Approvals (if applicable) Present?			
	Continuing Approvals Present?			
	Approvals for all protocol amendments present?			
	Communication and reports from IRB/EC and other regulatory bodies present?			
	Other written material given to participants Approvals Present?			
	Revision Approvals (if applicable) Present?			
	Screening Logs Present?			
<b>DAIDS approvals</b>	Is the DAIDS (RCC) approval for protocol registration present?			

<b>Assurances</b>	Is there a currently approved assurance from OHRP?			
<b>Safety Reports</b>	Are EAE reports present?			
	Have these safety reports been submitted to IRB/IEC?			
	Are SAE, AE Local and Regional Reports present? Have these been submitted to the IRB/EC?			
<b>Protocol</b>	Is a current copy of the protocol on file?			
	Is the approved Master Informed Consent on file?			
	Are all previous versions on file?			
<b>Case Report Forms</b>	Are blank copies present? Are blank copies of all revisions present?			
<b>1572/IOR agreement</b>	Is there a 1572 (for IND studies), or an Investigator of Record Agreement on file?			
	Is the document current and accurate?			
	Is the PI CV on file and up to date?			
	PI CV/Biosketch on file, but not with Form 1572			
<b>Other agreements (list)</b>				
<b>CVs;Biographical Sketches; Licenses</b>	Present for all key personnel and current/updated?			
	Are GCP/HSP training certificates current and up-to-date?			
<b>Financial Disclosure/Job description</b>	Are financial disclosure forms for all key personnel present?			
	Are job descriptions for all personnel present?			
<b>Site Monitoring Visit Reports</b>	Are all visit reports present?			
<b>Investigator Brochures</b>	Are Investigator Brochures including revisions and applicable package inserts present for investigational products?			
<b>Laboratory</b>	Are laboratory certifications and normal ranges present for labs?			
	For other labs in protocol, are there any required certificates present? (include updates)			

