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

Clinical Research Site Regulatory Inspection Preparation Checklist

Clinical Research Site (CRS) Name: _____CRS Number: _____

Planned Date(s) of Inspection: _____

Regulatory Agency: _____

Person completing this checklist: _____

Instructions: This document should be used to track progress of the inspection preparation tasks at the site. Check each item as it is completed and record pertinent comments. You are strongly encouraged to establish a team of individuals and delegate completion of each section to the appropriate department. One person should be responsible for ensuring that all sections are completed by individual departments.

Administrative					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Notify all parties of impending inspection	DAIDS/Contract Research Organization (CRO)	Ensure key personnel are available and not traveling or out of office during inspection. Allow for individuals to prepare for inspection.	☐	☐	
	Institutional Review Board (IRB)/Ethics Committee (EC)		☐	☐	
	Principal Investigator (PI)/Investigator of Record (IoR)		☐	☐	
	Sub-Investigator(s)		☐	☐	
	Study Coordinator(s)		☐	☐	
	Pharmacy department		☐	☐	
	Laboratory(ies) department		☐	☐	
	Medical Records department		☐	☐	
	Administration department		☐	☐	
	Legal Counsel department		☐	☐	
	Reception Area Staff		☐	☐	
	Other (specify in comments)		☐	☐	

Administrative					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Review Inspection Preparation SOP	Identify who will perform the following: • Act as point of contact for DAIDS. • Act as point of contact for the inspector during the inspection. • Who will be responsible for coordinating all aspects of the inspection before, during, and after. Escort the inspector while on site. • Serve as the scribe (note-taker) for the inspection. • Participate in discussions with the inspector. • Reserve a room for the inspector(s). • Document all records requested to be copied by inspector on the Log of Copied Documents and make two copies of each (one for inspector and one for site). • Reserve room for CRS staff to perform document review and discuss questions asked prior to providing documents or responses to the inspector(s).	Ensure site staff are aware of their roles and responsibilities before, during, and after the inspection.	☐	☐	
Identify/ reserve workspace for the Inspector	Workspace	Ensure a quiet and clean work area equipped with a phone and free of any clinical research records.	☐	☐	

Administrative					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Review staff and clinic schedules	Ensure staff availability by reviewing schedules for scheduled vacations, appointments, miscellaneous time-off, etc.	Ensure key staff, including PI/IoR, study coordinator, pharmacist of record and laboratory director, are on-site and available to answer questions. PI/IoR availability during the inspection is mandatory.	☐	☐	
	Reschedule non-essential visits/meetings if possible.		☐	☐	
Clinic Equipment	Ensure equipment maintenance and calibration records are available and current (e.g. electronic scales, electronic blood pressure cuff, etc.)	Ensure the validity and integrity of the data.	☐	☐	
	Ensure temperature logs for applicable clinic equipment are complete and current (refrigerators, freezers, storage cabinets, etc.)	Ensure the validity and integrity of the data.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	List of all studies performed by the PI/IoR for study being inspected including: • Protocol number • Protocol title, including the product name, and the research or marketing permit number, if available • Name of sponsor (including government agencies and commercial sponsors) • Study dates	This list is used by inspectors to evaluate study workload/resources and for reference in case issues are found on a study.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Protocol Specific Delegation of Duties (DoD) Log- list of personnel and delegated study responsibilities; current and signed	Inspectors will compare Delegation of Duties Log/Signature Log against study documents to ensure that only appropriately trained/experienced and delegated study team members performed duties. Cross check each staff member's training record to ensure training was completed prior to performing tasks. Focus on continuity of documented dates of task delegation during staff turnover.	☐	☐	
	Signature log-list of key site personnel and corresponding signatures; (current and signed; may be combined with the delegation log)	Inspectors will compare DoD Log and Signature Log against study documents to ensure that only appropriately delegated study team performed duties.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Master Participant (Identification) Log- list of all participants including name, contact information, date of birth, enrollment and completion dates	Used by inspectors to cross check participants name and participant identification numbers (PID/PtID), and as a tracking tool when verifying that Informed Consent Forms (ICFs) exist for all participants enrolled.	☐	☐	
	Screening Log - names of all participants screened including screening date and reason for screen failure if applicable	Used by inspectors as a tracking tool when verifying that ICFs exist for all participants screened and reason for screening failure.	☐	☐	
	Enrollment Log including enrollment date (if applicable)	This may be combined with screening log.	☐	☐	
	Randomization Log (if applicable)		☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Protocol (all versions)	Inspectors will want to review and verify prior changes to the protocol and ensure all protocols were approved by the IRB and Regulatory entities/Regulatory Authority (RE/RA), as applicable, before implementation. Will also use as a reference to verify compliance.	☐	☐	
	Protocol amendments and clarification memorandums	same as above	☐	☐	
	Approved ICFs (all versions including specific consent forms, such as screening, biospecimens, etc.)	Inspectors will compare ICF's signed by subjects to the approved ICFs. All ICF translation certificates should be available for each version and language.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Documentation of the informed consent process	Inspectors will want to know: • How did the informed consent process take place (e.g., was this explanation given orally, by video, through a translator, etc.)? • Was the short form used? • Was the participant/Legally Authorized Representative (LAR) given a chance to ask questions before signing the ICF? • Was the participant/LAR provided a copy of the signed ICF?	☐	☐	
	IRB correspondence	Inspectors want to determine the amount of communication/correspondence between the site and the IRB/EC.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Investigator's Brochure(s) and/or Package Insert(s) (all versions)	Ensure IRB/EC acknowledge the receipt of IB and package inserts for participant safety. Ensure protocol and ICFs updated with most current safety information.	☐	☐	
	IRB submission documentation	Sometimes inspectors want to see what documents were submitted to the IRB/EC and whether the IRB/EC sent back any requirements for the site to make prior to the IRB/EC granting approval. The site would be required to demonstrate to the inspectors that they implemented and provided to the IRB/EC the requested changes that supported the IRB/EC approval documentation.	☐	☐	
	IRB/EC initial protocol approval letter		☐	☐	
	IRB/EC protocol amendment(s) approval letter(s)		☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	IRB/EC continuing review approval letters		☐	☐	
	IRB/EC approval letter(s) for revised Informed Consent Forms		☐	☐	
	IRB/EC approval letter(s) for participant recruitment materials (advertisements, videos, handouts, telephone scripts to participants, etc.)	Ensure IRB approval and that the materials accurately reflect what is in the protocol and are not misleading or coercive.	☐	☐	
	Documentation of any delegated CRS staff member abstaining from IRB/EC votes if they are member of the IRB/EC evaluating the protocol	Avoids conflict of interest.	☐	☐	
	Evidence of Serious Adverse Events (SAE) submission to the IRB/EC/DAIDS	Ensure participant safety, evaluation, and PI/IoR oversight.	☐	☐	
	Evidence of identification and reporting of protocol non- compliance such as deviations to the IRB/EC/DAIDS per IRB/EC and protocol requirements	Ensure participant safety, data integrity, and the rights of participants. Ensure appropriate corrective and preventive action is taken to resolve the non-compliance and adherence to regulatory requirements.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Evidence of safety reporting, such as Investigational New Drug (IND) Safety Reports/Memos, 6-months reports, submission to IRB/EC/RE/RA as per applicable requirements	Ensure compliance with regulatory requirements.	☐	☐	
	Evidence of reporting of significant and continuing non-compliance and/or serious breaches to regulatory authorities, IRB/ECs and DAIDS.	Ensure participant safety, data integrity, and the rights of participants. Ensure appropriate corrective and preventive action is taken to resolve significant and/or continuing non-compliance.	☐	☐	
	Data Safety Monitoring Board (DSMB) summary report(s) and documentation of submission to the IRB/EC.	Ensure the review and evaluation of the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy.	☐	☐	
	Documentation of DAIDS protocol registration submission, approval, activation, and deregistration (if applicable)	Ensure DAIDS' requirements are met.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	All DAIDS and DAIDS' representative correspondence	Ensure DAIDS' requirements are met and verify amount of communication/ correspondence between the site and DAIDS.	☐	☐	
	Any other correspondence pertinent to the study (e.g., protocol team)		☐	☐	
	Form FDA 1572 (all versions)	Ensure the form is up to date and accurate and the IoR has signed and accepted the responsibility for the conduct of the clinical trial and all associated activities.	☐	☐	
	Financial Disclosure Forms (PI/IoR and CRS staff listed on the Form FDA 1572)	Ensure forms are compliant with FDA regulations for identifying and reporting potential conflicts of interest and filed per the DAIDS Protocol Registration Manual.	☐	☐	
	Curricula Vitae (CV) (Principal Investigator, Sub-Investigators, and staff working on the clinical trial)	Ensure the qualifications of key personnel to conduct a clinical trial. Ensure CVs are up to date, signed and reflect institute affiliation and current position.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Professional Licenses (Principal Investigator, Sub-Investigators, and other key staff members)	Ensure licenses are current and compliant with institutional, in-country regulatory requirements.	☐	☐	
	Good Clinical Practice (GCP)/ Human Subjects Protection (HSP) training documentation for individuals listed on the Form FDA 1572 and any clinical research site personnel who have more than minimal involvement with the conduct of the research	Ensure all personnel involved in the clinical trial are adequately trained prior to conducting study activities to ensure participant safety and compliance with required regulations.	☐	☐	
	Archiving requirements and storage of documents on-site and off-site		☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Documentation of staff protocol training	Ensure site staff are qualified by training and experience as well as trained on the protocol prior to conducting protocol activities. This includes training on all versions of the protocol/Letter of amendments (LoA), protocol Manual of Operations (MOP)/Study Specific Procedures (SSP), GCP/HSP, DAIDS requirements, Site Standard Operating Procedures (SOPs) (Cross check against Delegation of Duties Log).	☐	☐	
	Documentation of additional staff training (if applicable)		☐	☐	
	Study recruitment and retention plan	Ensure site is getting accurate representation of protocol population.	☐	☐	
	Site SOPs	Ensure sites have procedures in place and are following them.	☐	☐	
	Signed and dated monitoring visit log	Used by inspectors to see monitoring frequency/site communication.	☐	☐	

Regulatory					
Overall Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Current signed and dated Clinical Quality Management Plan (CQMP) in place and approved by DAIDS. Biannual Quality Assurance (QA) Summary Review submitted to DAIDS.	Ensure adherence to DAIDS' requirements and integrity of the data. Should only be provided if requested.	☐	☐	
	Ensure monitoring findings, such as follow-up letters or monitoring reports, are readily available if requested by inspector. Ensure all monitoring issues are resolved in Clinical Site Monitoring system.	Evaluate CRS resolution/follow-up of findings.	☐	☐	
	Protocol Signature Page	On file and signed by PI/IoR.	☐	☐	

Clinical					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Ensure the following has been completed for each participant. Investigate any trends/patterns of non-compliance.	Participant research records are available for each participant (Review source data for good documentation principles and for being Attributable, Legible, Contemporaneous, Original, Accurate and Complete, (ALCOA-C))	Ensure source documents and corresponding Case Report Forms (CRFs) for each participant are present, clearly identified, and systematically organized in binders or folders for ease of retrieval during the inspection. Review documents for inspectional triggers that could raise questions/concerns regarding the quality and/or validity of the reported study data. For any trends of non-compliance found, document and escalate for appropriate corrective and/or preventative action.	☐	☐	
	Source Document SOP or Approved List of Documents to be used as Source	Ensure good documentation practices and clearly identifies which CRFs or site data are considered source and where source is located.	☐	☐	

Clinical					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Ensure the following has been completed for each participant. Investigate any trends/patterns of non-compliance.	Completed CRFs available for each participant	Ensures completeness of study data. Signed by PI/IoR as appropriate.	☐	☐	
	Inclusion/exclusion criteria for each participant have been met and documented	The inspector will look to see if only eligible participants were enrolled in the clinical trial.	☐	☐	
	All visits conducted within protocol windows	Be prepared to explain missed visits and what attempts were made to ensure compliance, i.e., what is your process for visit reminders.	☐	☐	
	Correct volume of blood and correct tube type drawn at each visit	Serves to verify that participant safety was protected, and protocol was followed.	☐	☐	
	Laboratory requisitions	To verify correct biospecimens were collected for a visit.	☐	☐	
	Adverse Events (AEs), SAEs and Expedited Adverse Events (EAEs) have been identified and documented appropriately	Inspectors are looking at participant safety, PI/IoR involvement.	☐	☐	

Clinical					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Ensure the following has been completed for each participant. Investigate any trends/patterns of non-compliance.	All EAEs have been reported to the IRB/EC	Inspectors looking at participant safety and IRB/EC reporting timelines.	☐	☐	
	All AEs and EAEs have been reported to DAIDS as per applicable requirements	Inspectors evaluate participant safety and DAIDS' reporting timelines.	☐	☐	
	Protocol endpoints have been identified and reported appropriately	Ensure participant safety and data integrity. Ensure Algorithm for sero-converters followed per protocol.	☐	☐	
	Study product use by all participants has been documented	Ensure participant safety and data integrity.	☐	☐	
	Protocol-required tests/evaluations have been completed and documented appropriately		☐	☐	

Clinical					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Ensure the following has been completed for each participant. Investigate any trends/patterns of non-compliance.	Protocol non-compliances have been identified, reported, and documented appropriately	Ensure the following: • Participant safety and data integrity. • Reviewed for ALCOA-C. • Corrective and preventive action(s) implemented as appropriate. • Protocol non-compliance are documented, such as reported in the CRF or in a Protocol Deviation Log. • Submission to protocol team and DAIDS as appropriate.	☐	☐	
	Concomitant/prohibited medications have been documented and reported appropriately	Ensure participant safety and data integrity.	☐	☐	
	All laboratory reports and other diagnostic test reports are on file and display correct participant identifiers		☐	☐	

Clinical					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Ensure the following has been completed for each participant. Investigate any trends/patterns of non-compliance.	All laboratory results have been graded appropriately by the PI/IoR or qualified and delegated CRS staff member per the DAIDS AE Grading Table and/or protocol-requirements		☐	☐	
	Laboratory reports have been reviewed by the PI/IoR or a qualified and delegated CRS staff member	Ensure participant safety. Demonstrates PI/IoR study oversight/involvement and protection of participant safety.	☐	☐	
	Premature discontinuations of participants are documented appropriately per study requirements		☐	☐	
	Other (please add any additional site-specific participant documents or requirements below)		☐	☐	

Pharmacy					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review essential documents.	CV of pharmacist(s)	Ensure accuracy and completeness of essential documents as well as compliance with *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials.*	☐	☐	
	CVs of key pharmacy personnel		☐	☐	
	Licenses of pharmacy personnel		☐	☐	
	Training records for pharmacy staff (e.g. GCP/HSP, aseptic technique and refresher trainings, pharmacy SOPs and CQMP, initial protocol and updates, any additional protocol trainings required)		☐	☐	
	Form FDA 1572 or IoR agreement		☐	☐	
	Authorized Prescriber signature list		☐	☐	
	Pharmacist signature list, if not included in the DoD		☐	☐	
	Temperature monitoring records		☐	☐	
	DAIDS-approved, signed Pharmacy Establishment Plan and Modules		☐	☐	

Pharmacy					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review essential documents.	Most recent version of the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks*	Ensure accuracy and completeness of essential documents as well as compliance with *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials.*	☐	☐	
	Most recent version of the protocol, LoAs and Clarification Memos for which the site has IRB/EC approval		☐	☐	
	Most recent version of the protocol-specific study procedures (i.e., SSP manual or MOP)		☐	☐	
	Most recent version of Investigator's Brochure(s) or Package Insert(s), Certificate of Analysis (CoA)		☐	☐	

Pharmacy					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review essential documents.	Accountability for the study product, including receipt, storage, preparation and dispensation, return and final disposition: • Shipment records (Ordering/shipping receipts - sorted, marked and filed chronologically) • Study product accountability record – maintained by lot # • Inventory lot #s and expiration dates/beyond use dates • Chain of Custody (CoC) records • Final disposition (Return of study products to the CRPMC for US sites or destruction of study products at international sites) • Documentation of study drug transfers (if applicable)	Ensure participant safety and data integrity.	☐	☐	
	Participant prescriptions (Correlate with accountability records and correct dose per protocol)		☐	☐	

Pharmacy					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review essential documents.	Participant-specific study product preparation worksheets, including all appropriate elements required for appropriate management handling and administration (e.g. storage conditions, preparation time, expiration time, and/or beyond-use time) assigned to prepared study product		☐	☐	
	Randomization Information		☐	☐	
	Labeling requirements of study drug		☐	☐	
	Participant-specific profiles (if applicable)	Requirements may vary among sites.	☐	☐	
	Required pharmacy operations SOPs as listed on study activation checklist	Ensure participant safety and data integrity.	☐	☐	
	Secure storage of study products / appropriate segregation of study products by protocol / restricted access to investigational pharmacy		☐	☐	
	Calibration and maintenance records for all pharmacy equipment		☐	☐	

Pharmacy					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review essential documents.	Incident Reports with corrective action plans for: • Identified temperature excursions (as applicable) • Important Protocol deviations		☐	☐	
	All communications sent/received from Pharmaceutical Affairs Branch/ Clinical Research Products Management Center (CRPMC) such as incident reports, temperature excursion reports, notes to file, etc.		☐	☐	
	Other (please add any additional site-specific pharmacy documents below)	Should have copy of local and institutional requirements.	☐	☐	

Laboratory					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	CV of Laboratory Director	Ensure education, training and experience align with assigned job responsibilities.	☐	☐	
	CVs of key laboratory personnel	Ensure education, training and experience align with assigned job responsibilities.	☐	☐	

Laboratory					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Licenses of laboratory personnel (if applicable)	Ensure laboratory personnel licenses **(**if applicable) are current and compliant with institutional, In-country regulations.	☐	☐	
	Laboratory staff training records		☐	☐	
	Laboratory certifications	Ensure laboratory certifications (if required) are current and compliant with institutional, In-country regulations and applicable DAIDS laboratory requirements.	☐	☐	
	Laboratory normal ranges and updated during the clinical trial conduct	Ensure laboratory normal ranges are verified or established for assigned test.	☐	☐	
	Laboratory Data Management System (LDMS) records	Ensure LDMS validation, accurate reporting, test result audit trail and authorized access and security control.	☐	☐	
	Copies of laboratory audits, action plans, and corrective action reports	Ensure audit related documents are well documented and available to support a robust Quality Assurance Plan/Quality Management to program.	☐	☐	

Laboratory					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Biospecimen logs (present and readily available for review)	Ensure availability and validity of laboratory records and reports for potential troubleshooting and attesting to credibility of test results; and if necessary, for full study reconstruction or other similar auditing purposes.	☐	☐	
	Chain of Custody SOP (or similar process document)		☐	☐	
	Corresponding control data for assays where laboratory result AEs and EAEs were identified		☐	☐	
	Temperature logs for applicable equipment (e.g., refrigerators, freezers, storage cabinets)		☐	☐	
	Calibration and maintenance records for all laboratory equipment (if applicable)		☐	☐	
	Corrective action reports for identified temperature excursions		☐	☐	
	Vertical audit of laboratory results and corresponding Quality Control (QC) data for results of a randomly selected sample		☐	☐	
	Process of laboratory notification of abnormal values to PI/IoR		☐	☐	

Laboratory					
Task	**Item**	**Rationale**	**Yes (Done/ Available)**	**No (Provide comment)**	**Comments**
Locate, compile, organize, and review documents for accuracy and completeness.	Process of laboratory corrections when wrong participant identification number (PID/PtID) was used		☐	☐	
	Packaging/Shipment/Storage process for samples		☐	☐	
	Other (please add any additional site-specific laboratory documents below)		☐	☐	