NIAID/DAIDS CRSS Team

PPD

NIAID HIV and Other Infectious Diseases Clinical Research Support Services (CRSS)
Contract No. 75N93021D00035
Task Order No.75N93024F00002

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NIAID/DAIDS CRSS Team

PPD

Specimen Repository Audit of

Harmonized ID (HID)	Repository Facility Name - Address

Conducted by PPD

Audit Type: Specimen Repository

Audit Date(s):

Final Report Issued:

Table of Contents

Specimen Repository Report

Report Summary

Repository Facility Name/Location	
Visit Date(s)	
Audit Requestor	
Laboratory Auditor	
Repository Management	
Quality Assurance Unit Manager	
Safety Officer	
Date(s) Last Audited	

Comments:

I. Organization and Personnel

A. Is an organizational chart inclusive of all repository personnel present?	Yes ☐ No ☐ Comments ☐

Comments:

B. Is there a policy or process for determining authorized designees? (If "Yes," please describe.)	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Personnel Records**	
1.	Are personnel records kept? (If "Yes," describe how these records are organized and securely stored.)	Yes ☐ No ☐ Comments ☐
2.	Is a job description/delegation of duties documentation present for all repository personnel involved with protocol-related activities?	Yes ☐ No ☐ Comments ☐
3.	For each repository position, is there a documented profile that lists requirements such as education, experience, and certification/license requirements?	Yes ☐ No ☐ Comments ☐
4.	Are education records maintained for all repository personnel involved with protocol-related activities?	Yes ☐ No ☐ Comments ☐

5.	Are training records for repository personnel kept on file?	Yes ☐ No ☐ Comments ☐
6.	Have all personnel involved in processing and/or testing of DAIDS-supported protocol specimens completed DAIDS Good Clinical Laboratory Practice training? (If "No," indicate the total number of trained versus untrained personnel.)	Yes ☐ No ☐ Comments ☐
7.	Is documentation maintained, indicating the repository has assessed the competency of each employee to perform his/her assigned duties in accordance to the requirements for waived and non-waived testing? (If "Yes," report the methods utilized to assess competency and the frequency of evaluation.)	Yes ☐ No ☐ Comments ☐
8.	Are personnel identification lists (signature/initial/code) present to verify responsible personnel?	Yes ☐ No ☐ Comments ☐
9.	Has the repository defined and established a process for auditing personnel records?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Does the repository have a policy that prohibits retaliation against personnel who communicate study integrity, quality, and/or safety concerns to repository management?**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Communication with External Users**	
1.	Does the repository provide training and/or instruction, and oversight for all aspects of interactions among external users (i.e. sites)?	Yes ☐ No ☐ Comments ☐
2.	Is there a mechanism for the leadership of the repository and the external users to discuss performance issues?	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Did the repository change location since the last audit visit?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Have any new repository employees been hired since the last audit? (If "Yes," document the changes in personnel and management positions.)**	Yes ☐ No ☐ Comments ☐

Comments:

II. Policies and Procedures

A. Is a master list of currently used SOPs maintained by the laboratory?	Yes ☐ No ☐ Comments ☐

Comments:

B. Standard Operating Procedures

Written Procedure Name	Review completed by repository management within two-year interval?	Repository management signature present?
1.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
2.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
3.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
4.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
5.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
6.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
7.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
8.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
9.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
10.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐

Comments:

C. Is there a written document control plan that addresses topics such as procedural relevance, authorization process, reviews, revisions and discontinuation of procedures?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Are all repository SOPs reviewed for accuracy and relevance within two-year intervals?**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Does the repository have a system of documenting that all personnel are knowledgeable of the contents of the SOPs?**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Are the repository SOPs available in the work areas?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Are superseded or retired versions of SOPs identified and archived in the repository? (If "Yes," explain the archiving process and provide the retention time.)**	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Was the auditor able to verify the repository personnel was adhering to the SOPs? (List the SOPs for which a vertical audit was performed.)**	Yes ☐ No ☐ Comments ☐

Comments:

III. Quality Management

1.	Does the repository have a Quality Assurance/Quality Management program? (If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
2.	Does the program include a documented operational plan, to promptly record and investigate, correct (as appropriate), and trend nonconformities or other problems identified in the entire specimen management process?	Yes ☐ No ☐ Comments ☐
3.	Are key indicators of quality monitored and evaluated to detect problems and opportunities for improvement? (If "Yes," list the indicators.)	Yes ☐ No ☐ Comments ☐
4.	Are appropriate corrective action and/or preventive actions taken when opportunities for improvement are identified?	Yes ☐ No ☐ Comments ☐
5.	Is there evidence that CAPAs are monitored through resolution?	Yes ☐ No ☐ Comments ☐
6.	Is quality management documentation surrounding key indicators of quality and CAPAs reviewed by the repository management? (If "Yes," indicate the frequency.)	Yes ☐ No ☐ Comments ☐
7.	Does the repository have an internal auditing program?	Yes ☐ No ☐ Comments ☐

Comments:

IV. Physical Facilities

1.	Is there a documented policy/procedure in place for access control into the repository?	Yes ☐ No ☐ Comments ☐
2.	Is the ventilation, temperature (and humidity, where applicable) adequately controlled in all areas?	Yes ☐ No ☐ Comments ☐
3.	Are security measures in place to ensure the facility and equipment are protected against fire, other environmental hazards and personal intrusion?	Yes ☐ No ☐ Comments ☐
4.	Are ambient room temperature readings (and humidity, where applicable) taken/documented? (If "Yes," report the frequency)	Yes ☐ No ☐ Comments ☐
5.	Have tolerance limits been established/documented for ambient room temperature (and humidity, where applicable)? (If "Yes," list the limits)	Yes ☐ No ☐ Comments ☐
6.	Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐
7.	Is there adequate, conveniently located space, so the quality of work and safety of personnel are not compromised?	Yes ☐ No ☐ Comments ☐
8.	Is there an established, documented inventory control system in operation?	Yes ☐ No ☐ Comments ☐

Comments:

V. Equipment

A.	**Is all repository equipment used for DAIDS protocol-related activities listed on an inventory document?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Is all out-of-service/not-in-use equipment clearly identified as such?**	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Are there documented PM and calibration plans for repository equipment indicated?**	Yes ☐ No ☐ Comments ☐

Comments:

D. Has any DAIDS-related repository equipment been replaced, added, or removed since the last audit? (If "Yes," list the equipment.)	Yes ☐ No ☐ Comments ☐

Comments:

E. Repository Equipment
Verify the following as it applies to equipment used for study-specific repository activities: (List the manufacturer and model of the equipment, where applicable.)

1. Are freezers present? (If “No,” skip to Question 2.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities performed/documented by repository personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are temperature readings taken/documented? (If “Yes,” report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established/documented for temperature readings? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken, in response to out-of-range values?	Yes ☐ No ☐ Comments ☐
f. Is there sufficient freezer storage space? (If “Yes,” note the specimen storage capacity of the facility.)	Yes ☐ No ☐ Comments ☐

Comments:

2. Are liquid nitrogen freezers present? (If "Yes," describe the capacity available. If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by repository personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are liquid nitrogen levels taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for liquid nitrogen levels? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

3.	Is oxygen monitoring equipment present in areas where liquid nitrogen is used? (If "No," skip to Question 4.)	Yes ☐ No ☐ Comments ☐
a.	Are PM activities/services performed and documented?	Yes ☐ No ☐ Comments ☐
b.	Are calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐
c.	Are oxygen levels taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d.	Have tolerance limits been established and documented for oxygen levels? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e.	Is an alarm system with oxygen setpoints available? (If "Yes," report the frequency of alarm testing.)	Yes ☐ No ☐ Comments ☐
f.	Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

4.	Are thermometers present? (If “No,” skip to Question 5.)	Yes ☐ No ☐ Comments ☐
a.	Is a known standard thermometric device available (NIST certified)?	Yes ☐ No ☐ Comments ☐
b.	Have all non-certified thermometers been tested against a standard device? (If "No," to 5.a. and "Yes" to 5.b., describe the procedure performed.)	Yes ☐ No ☐ Comments ☐

Comments:

5.	Are timers present? (If “No,” skip to Question 6.)	Yes ☐ No ☐ Comments ☐
a.	Are calibration procedures performed and documented?	Yes ☐ No ☐ Comments ☐

Comments:

6.	Are weighing scales present? (If “No,” skip to Question 7.)	Yes ☐ No ☐ Comments ☐
a.	Are calibration procedures performed, as described by the manufacturer?	Yes ☐ No ☐ Comments ☐

Comments:

7.	Are additional equipment used for protocol-related assays present? (If “Yes,” describe in the “Comments” section.)	Yes ☐ No ☐ Comments ☐

Comments:

F.	Temperature Monitoring	
1.	Is there a written policy/procedure in place, explaining how temperatures are monitored during the absence of repository personnel?	Yes ☐ No ☐ Comments ☐
2.	Is a computerized alarm system with setpoint temperature ranges utilized for continuous monitoring of freezer and ambient room temperature? (If "Yes," report the frequency of alarm testing; if “No,” specify the system used for continuous temperature monitoring.)	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Is there an SOP in place that describes backup power resources? (If yes, specify how backup power equipment is maintained e.g., logs or SOPs that detail the frequency of maintenance).**	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Are maintenance, repair, and calibration records reviewed and signed monthly by repository management?**	Yes ☐ No ☐ Comments ☐

Comments:

VI. Records and Reports

A.	**Are copies of network lab-specific manuals, protocols and appendices available?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	Specimen Tracking Forms	
1.	Are forms readily available and retrievable within 24 hours?	Yes ☐ No ☐ Comments ☐
2.	Are the forms retrievable for the entire protocol? (If "Yes," explain how archiving is accomplished and provide the retention time[s].)	Yes ☐ No ☐ Comments ☐

Comments:

C.	Specimen Chain of Custody	
1.	Is specimen chain of custody/audit trail adequately documented?	Yes ☐ No ☐ Comments ☐
2.	Does documentation reflect that specimens are received within the acceptable amount of time from shipping?	Yes ☐ No ☐ Comments ☐

3.	Are samples checked against the shipping manifest upon receipt of incoming shipments in the repository?	Yes ☐ No ☐ Comments ☐
4.	Are specimens received (without discrepancies) inventoried and committed within an acceptable timeframe? (Indicate the time to commitment.)	Yes ☐ No ☐ Comments ☐
5.	Are discrepancies with each shipment documented, tracked and recorded in a standardized format, and communicated with the site within an acceptable amount of time from shipment receipt? (If "Yes," describe the report and timeframe.)	Yes ☐ No ☐ Comments ☐
6.	Are corrective actions taken and documented for discrepancies within an acceptable timeframe, with the assistance of the appropriate site? (Indicate the time to resolution.)	Yes ☐ No ☐ Comments ☐
7.	Does the tracking system provide secure transport of specimens, and ensure that specimens are delivered to the intended recipient?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Does the repository archive records (e.g. shipping, CAPAs, PM and calibration etc.)? (If "Yes," explain how archiving is accomplished, and how long records are archived. If "No," skip to Section VII.)**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Are the archived records accessible to only authorized personnel?**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Are records protected from flood and fire?**	Yes ☐ No ☐ Comments ☐

Comments:

VII. Specimen Transport and Management

A.	**Is there a documented policy/procedure to identify and assess the quality of specimens received in the repository?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Specimen Transport**	
1.	Are systems in place to differentiate specimens that have similar identification information (e.g., serum and plasma on same PID)?	Yes ☐ No ☐ Comments ☐

2.	Are systems in place to recognize and handle specimens drawn at different visits (e.g., if specimens from more than one visit are included in the same batch)?	Yes ☐ No ☐ Comments ☐
3.	For specimens submitted to the repository from remote sites, is there a documented tracking system to ensure all specimens are actually received?	Yes ☐ No ☐ Comments ☐
4.	Are documented procedures available for checking the condition of the shipment upon receipt? (If 'No', skip to question 5)	Yes ☐ No ☐ Comments ☐
	a. Is there an adequate process for documenting and communicating problems identified during shipment receipt?	Yes ☐ No ☐ Comments ☐
5.	Is there a policy/procedure in place for transporting samples (transported in a sturdy, non-breakable, closable container labeled "biohazard")? (If "No," skip to Question 6.)	Yes ☐ No ☐ Comments ☐
	a. Does the document address transport within the facility?	Yes ☐ No ☐ Comments ☐
	b. Does the document address transportation between clinics/laboratories and the repository?	Yes ☐ No ☐ Comments ☐
6.	Are appropriate shipping containers utilized to ensure required temperatures are maintained during transit?	Yes ☐ No ☐ Comments ☐
7.	Do the shipping containers comply with current domestic and international transportation regulations and International Air Transportation Associations (IATA) guidelines?	Yes ☐ No ☐ Comments ☐
8.	Are required shipping licenses and permits on file for specimen import, storage, and distribution?	Yes ☐ No ☐ Comments ☐
9.	Does the repository monitor the time required to disburse specimens to domestic and international sites from the point of requisition? (If "Yes," describe the time to disbursement achieved by the repository.)	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Shipping Certification/Training**	
1.	Is there a training plan in place for shipping certification?	Yes ☐ No ☐ Comments ☐
2.	Is there documentation of persons trained for shipping?	Yes ☐ No ☐ Comments ☐
3.	Are shipping certifications renewed every 2 years?	Yes ☐ No ☐ Comments ☐
4.	Is there a policy in place for shipping samples internationally?	Yes ☐ No ☐ Comments ☐

Comments:

VIII. Personnel Safety

A.	Safety-Related Incidents	
1.	Is there a safety manual/program in place to document safety-related incidents?	Yes ☐ No ☐ Comments ☐
2.	Is there documentation of all safety-related incidents? (If "No," skip to Question 4.)	Yes ☐ No ☐ Comments ☐
3.	Is the documentation reviewed and signed monthly by the repository management?	Yes ☐ No ☐ Comments ☐
4.	Is there a mechanism to evaluate safety incidents?	Yes ☐ No ☐ Comments ☐
5.	Is prophylaxis treatment available (e.g., hepatitis B vaccinations and post-pathogen exposure options)?	Yes ☐ No ☐ Comments ☐
6.	Does a physician provide a documented review of all exposure events?	Yes ☐ No ☐ Comments ☐

Comments:

B.	Safety Data Sheets (SDS) or Material Safety Data Sheets (MSDS)	
1.	Are SDS or MSDS on file or available online? (If "No," skip to Section C.)	Yes ☐ No ☐ Comments ☐
2.	Are SDS or MSDS readily available to all repository personnel?	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Is there an initial and ongoing safety training program with documented participation of all repository personnel? (If "Yes," briefly describe the training and list the provider as well as the frequency of training.)**	Yes ☐ No ☐ Comments ☐

Comments:

D.	Safety Policies	
1.	Is a written Standard Precautions Policy available?	Yes ☐ No ☐ Comments ☐
2.	Is a written Chemical Hygiene/Hazardous Materials Plan available?	Yes ☐ No ☐ Comments ☐
3.	Is there a written policy for the handling and disposal of biohazardous materials and regulated medical waste? (If "Yes," list what mechanism is used for disposing biohazardous waste.)	Yes ☐ No ☐ Comments ☐
4.	Are policies, procedures and practices in place for use of liquid nitrogen?	Yes ☐ No ☐ Comments ☐
5.	Are policies, procedures and practices in place for use of dry ice (solid carbon dioxide)?	Yes ☐ No ☐ Comments ☐

6.	Is an emergency preparedness policy available?	Yes ☐ No ☐ Comments ☐
7.	Are safety policies and procedures readily available to all personnel?	Yes ☐ No ☐ Comments ☐
8.	Is there evidence of review within a two-year interval of all safety policies and procedures by the repository management?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Is safety equipment such as eyewashes, safety showers, fire extinguishers, and sharps containers, spill kits, smoke detectors/fire alarms, hand washing sinks, and basic first aid kits present in the repository? (If "Yes," provide frequency of documented functional checks for the equipment.)**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Personal Protective Equipment (PPE)**	
1.	Is PPE (gloves, gowns, masks/respirators, eye protectors, etc.) available to repository personnel?	Yes ☐ No ☐ Comments ☐
2.	Is PPE correctly worn and utilized by repository personnel?	Yes ☐ No ☐ Comments ☐
3.	Is PPE maintained in a sanitary and reliable condition in all technical work areas in which blood and body substances are handled and in circumstances during which exposure is likely to occur?	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Emergency Evacuation**	
1.	Does the repository have a documented and workable evacuation plan that is available to all repository employees and visitors?	Yes ☐ No ☐ Comments ☐
2.	Have all repository employees (and visitors, if appropriate) been properly trained in the evacuation plan/policy?	Yes ☐ No ☐ Comments ☐
3.	Are annual fire drills conducted with documented participation by repository personnel?	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Are reviews of safe work practices performed and documented at least annually?**	Yes ☐ No ☐ Comments ☐

Comments:

IX. Laboratory Data Management System (LDMS)

A.	**Does this laboratory facility contain an LDMS? (If "Yes," provide the LDMS ID in the comments section; If "No," disregard the rest of Section IX and explain how specimen storage/shipping data are maintained.)**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**LDMS Reports Verified by the Auditor**	
1.	Detailed Imported Specimen Report	Yes ☐ No ☐ Comments ☐
2.	Storage Detail Report	Yes ☐ No ☐ Comments ☐
3.	Shipped Specimen Report–Detail	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Specimen Verification**	
1.	Can the PID, date, protocol, derivative, and additive for specimens be verified with the LDMS?	Yes ☐ No ☐ Comments ☐
2.	Does the LDMS accurately reflect the number, type, and volume of all specimen aliquots as well as their storage location and shipping record?	Yes ☐ No ☐ Comments ☐
3.	Is a unique identifier utilized for samples received by the repository? (If "Yes," describe the system of identification.)	Yes ☐ No ☐ Comments ☐
4.	Can the physical presence of specimens be verified with the LDMS Storage Detail Report?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Is the current LDMS manual available in the repository?**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**LDMS Backup**	
1.	Is the LDMS backed up daily?	Yes ☐ No ☐ Comments ☐
2.	Is the LDMS backup device stored in a different location than the LDMS computer?	Yes ☐ No ☐ Comments ☐

Comments:

F. Is the LDMS connected to a backup power source?	Yes ☐ No ☐ Comments ☐

Comments:

G. Do the repository SOPs include implementation and compliance with DAIDS-network mandates regarding LDMS usage?	Yes ☐ No ☐ Comments ☐

Comments: