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Document Title: SCORE Manual: Clinical Research Site Facility Requirements (Clinic Laboratory and Additional Locations)		

Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual: Clinical Research Site Facility Requirements (Clinic, Laboratory and Additional Locations)

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Clinical Research Site Facility Requirements (Clinic, Laboratory, and Additional Locations)

Overall Clinical Research Site Requirements

A Clinical Research Site (CRS) facility should be clean, secure, and designed to ensure proper conduct of the clinical trial, as well as participants' safety, privacy, and confidentiality. It should offer the following, as applicable:

- Hazard free entrance area and, if possible, handicap accessibility
- Reception area where a participant can sign in/register and wait for CRS staff
- Private setting(s) for informed consent discussions and counseling
- Adequately equipped examination rooms to conduct study visits and procedures, as required by any local laws and regulations
- Participant treatment area and/or post-treatment observation area
- Adequate infection-control equipment and processes
- Rest area, where participants can relax between pharmacokinetic (PK) sample collections, as appropriate
- Injection and/or infusion rooms
- Synchronized clocks throughout the clinic, laboratory, and pharmacy for studies involving time-critical processes between clinic and pharmacy or between clinic and laboratory
- Access to a sink and safety equipment in the laboratory [per local institutional safety regulations and DAIDS Good Clinical Laboratory Practices (GCLP) Standards]
- Power back-up system to ensure continuity of electricity, internet connection, etc.
- Adequate space for monitoring visits
- Data management area
- Office/workspace
- Record storage area/room
- Emergency facilities

Note: For information on pharmacy requirements for pharmacy facilities, refer to the [Pharmacy Requirements](#) section of this manual.

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Equipment Maintenance

All equipment used to conduct or support study procedures must demonstrate that it functions properly and can generate reliable data. Equipment may include:

- Weight scales
- Blood pressure monitors
- Electrocardiograms (EKGs)
- X-ray machines
- Computerized tomography (CT) scanners
- Centrifuges
- Refrigerators
- Freezers
- Incubators
- Thermometers/probes
- Back-up generators
- Clocks, etc.

An in-house department or qualified vendor should periodically maintain/calibrate the equipment as often as the CRS/institution standard operating procedures (SOPs) define or the manufacturer recommends, whichever is more frequent. Clocks should be synchronized periodically if the clinical trial involves time-critical processes.

Current maintenance documentation for all equipment is to be posted directly on the equipment or be readily accessible in the CRS files. Documentation includes at a minimum:

- Identification of equipment (e.g., serial number and/or model number, asset identification number)
- Maintenance activities performed
- Date of maintenance/calibration
- Due date of next cycle of maintenance
- Identification of the individual/organization/department conducting the maintenance
- Results of maintenance/calibration
- Any necessary maintenance/calibration follow-up actions taken
- Review and approval by designated CRS staff

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All previous equipment maintenance records must be filed at the CRS and retained for the duration of the study, per the [Essential Records](#) section of this manual or the applicable local laws/regulations, whichever is more stringent. If an in-house department is responsible for maintaining the equipment, the Principal Investigator (PI)/Investigator of Record (IoR) is still responsible for keeping the maintenance records in the CRS file or readily accessible if filed elsewhere.

Environmental Monitoring

The CRS must ensure appropriate environmental monitoring throughout the facility, as follows:

- For the study's duration, documentation must be maintained of the environmental monitoring (temperature/humidity, as applicable) of any biospecimens/aliquots testing or storage unit or area.
- If instruments, equipment, kits, or supplies have specific temperature ranges for proper operation, storage, or use, records showing that those ranges have been maintained must be documented.
- Any evidence of temperature excursion(s) noted during periodic review of environmental monitoring must be communicated/documented and corrective and preventive actions (CAPA) implemented.

Note: Temperature excursions must be reported to appropriate CRS staff (laboratory, pharmacy), Office of Clinical Site Oversight (OCSO) Program Officer (PO) and/or Pharmaceutical Affairs Branch (PAB), DAIDS Clinical Laboratory Oversight Team (DCLOT), the Network Leadership and Operations Center (LOC), and the Network Laboratory Center (LC), as applicable.

- Only pharmacist-labeled, participant-specific study product may be transported to or stored within the clinic. Additionally:
 - If the clinic will store study product for any period of time, then temperature monitoring of the study product storage unit/shelf must be ensured according to the protocol and other related documents.
 - If the study product has humidity requirements and the clinic will store that study product before administering it to the participant, then humidity monitoring of the study product storage area must be ensured and documented.

Emergency Procedures

The CRS is required to have a process/procedure in place to handle any emergencies during a participant visit. Refer to the “List of SOPs required at DAIDS CRSs” in the [Quality Management](#) section of this manual. The following should be in place, as applicable:

- Arrangements with a local emergency service to transport a participant quickly and provide treatment in the event of an emergency. Such arrangements should be in writing, with emergency numbers posted in visible locations, and the process tested annually, at a minimum.
- An emergency cart/trolley to assist with emergency situations. CRSs must follow all local regulatory requirements for emergency carts/trolleys, as follows:
 - Refer to local laws and regulations and the protocol about the emergency cart/trolley contents.
 - Always keep the emergency cart/trolley sealed/locked when not in use, and document periodic (monthly) content checks for expiration dates and replacement needs.
 - Periodically check the functionality of any on-site Automated External Defibrillators (AEDs) that are CRS property, as per CRS SOPs.

Records Storage Facility

CRSs must store clinical research records (CRRs) in a way that ensures privacy, confidentiality, security, and accessibility throughout the clinical trial.

To ensure the files’ integrity in storage CRRs must be stored in a location requiring authorized access. Use of double locks and/or electronic entry systems is mandated.

The following should also be considered as part of the storage facility to ensure the integrity of the files:

- The presence of fire extinguishers within or around the archives, according to local regulations.
- Use of automated fire detection system and an automated fire suppression system.
- Protection of the study records from water (rain/flood)
- Pest control measures must be in place.

- Use of temperature and humidity controls to avoid deterioration of files in regions where fluctuations in these parameters exist.
- Protection of electronic storage devices from degradation, erasure, deletion, or corruption.

After the study is completed, the PI/IoR must maintain CRRs in a secure location. If they are not kept by the institution.

The PI/IoR should be aware of long-term storage capabilities at the CRS. If space is unavailable, appropriate plans for off-site storage must be made and a process put into place for document retrieval.

Refer to the “Essential Records” section of this manual for additional information relating to DAIDS requirements for storage and retention of clinical research records.

Laboratory

The Clinic laboratory usually includes one or several small areas within or near the CRS where study biospecimens are collected, processed, and/or stored. In addition, the laboratory ships biospecimens according to protocol requirements.

Clinic laboratories do not typically conduct complex biospecimen analysis but may do Point-of-Care Testing (POCT), such as rapid tests for Human Immunodeficiency Virus (HIV), pregnancy, urinalysis, etc.

When biospecimens are collected on site (whether in an examination room, phlebotomy station, or section of the laboratory), appropriate licenses to perform those activities should be in place as per local regulations. In addition, the following activities must occur as applicable:

- Verification of expiration dates on collection tubes and containers before biospecimen collection
- Documentation of:
 - Chain of custody for biospecimens from time of collection to centrifugation (as applicable), to testing and/or time of storage (as applicable), to outgoing shipment/pick-up
 - Policy/procedure for biospecimen collection, processing, and transport to the testing/storage facility

- Policy/procedure for reporting laboratory results to the study clinician
- Policies/procedures related to laboratory personnel safety as required by local laws and regulations and DAIDS GCLP Standards

If POCT is conducted in the examination rooms, phlebotomy station, or laboratory, the following processes (as applicable) should be in place:

- Qualification, verification, or validation and proficiency testing documentation of POCT assays as appropriate
- Quality control check and documentation of new lots of POCT kits
- Documentation of the lot numbers and expiration dates of the POCT kits in the participant source records

For information on central and complex testing laboratories facility requirements, please refer to the [Laboratory Requirements](#) section of this manual and the [DAIDS GCLP Standards](#).

Additional Locations

At times, a CRS may require the use of an additional location (AL) in order to conduct participant visit procedures (which may be infeasible at the main CRS) or to access a specific study population.

ALs are physical addresses where clinical trial data are collected. The clinical trial must be considered “engaged” in accordance with the Office for Human Research Protections (OHRP) *Guidance on Engagement of Institutions in Human Subjects Research*. ALs may include, but are not limited to medical schools, hospitals, community health centers, private practices, or other research facilities where the participant visit procedures will be conducted. ALs are extensions to the main CRS and cannot function in a stand-alone manner.

Office of Clinical Site Oversight Approval of an Additional Location

If a CRS plans to use an additional location to conduct a clinical trial, the PI/IoR must obtain approval from the OCSO PO and IRB/EC before conducting any protocol activities at the location.

For a new site, this AL information should be included in the Essential Contacts Site Profile form (OCS_TL_07) that is submitted to the OCSO PO and will be reviewed at that time. For any AL request after the site has been initially activated by OCSO, the site should use the Site Hub to submit a new AL request. Once submitted, the AL request will be reviewed by the OCSO PO and PAB, as well as a representative from the DAIDS Clinical Laboratory Oversight Team (DCLOT), if appropriate. The

corresponding Network Leadership and Operations Centers (LOCs) will also be consulted. If approved, the site will receive a notification of approval via email from the OCSO PO to use the location. If the initial request for the use of an AL was protocol specific or if the scope of use for the DAIDS approved AL changes significantly, the CRS must contact the OCSO PO to determine if additional approvals are needed. Examples of when additional approvals may be needed are:

- AL begins to function independently from the main CRS
- Use of a new Pharmacy and need for Pharmacy Establishment Plan
Additional laboratory requirements

Location Changes

If the clinic or the laboratory needs to move or change locations during the study, the CRS must:

- Notify the OCSO PO.
- Refer to the *Laboratory Relocation Planning Guide and Checklist* (laboratory specific), which the DCLOT provides.
- Follow the [Protocol Registration Manual](#) to revise and submit the Form FDA 1572/DAIDS IoR Form for each protocol.
- Communicate the plan to change clinic or laboratory location to the Institutional Review Board (IRB)/Ethics Committee (EC) and/or Regulatory Authority (RA)/Regulatory Entity (RE) as applicable.
- Update Informed Consent Forms, advertisements, and other IRB/EC-approved documents (provided to participants during the study conduct, such as participant diaries, communication cards, etc.) with new address and phone numbers. Seek IRB/EC approval.
- Communicate change to participants.

Study activities are not to be implemented at any new location until all activities listed above are completed and the OCSO PO and/or DCLOT have approved the clinic and/or laboratory for use at the new location. Once approved, CRS will update the *Essential Contacts Form* with the name and address of the new location and send it to the OCSO Program Officer.

A Site Operations Visit or Site Assessment Visit (SAV) may be conducted by the DAIDS monitoring contractor before DAIDS grants approval of a new location.

Adjunct/Alternative Venues

Adjunct/alternative venues are used in rare or emergency instances. They are considered an extension of a DAIDS-approved CRS and are co-located with or next to the main CRS.

Adjunct/alternative venues can be used for infection control or space constraints. Examples include use of:

- Outdoor spaces
- Tents
- Garages
- Other appropriate venues (e.g., trailers, portable containers, mobile units, etc.)

The use of adjunct/alternative venues must adhere to protocol requirements and comply with institutional policies, local laws, and regulations. Relevant approvals must be secured, as required. The CRS should have procedures in place for the use of such spaces.

A CRS should extend the same precautions and protections at these additional venues as it typically would when interacting with participants in the main facility. The CRS must consider the following when using adjunct/alternative venues:

- Participant safety and confidentiality
- Research staff safety
- Study product integrity, including cold chain management and chain of custody
- Biospecimen handling and integrity, including chain of custody
- Data confidentiality and integrity, including security and chain of custody for participant records

Although DAIDS approval is **not necessary** for using adjunct/alternative venues, DAIDS should always be informed of the intent to use such spaces beforehand, and CRSs must document how these spaces are used in their CRS files.

Contact your OCSO PO if you have any questions related to adjunct/alternative venues.

References

1. [Protocol Registration Manual](#)
2. [Guidance on Engagement of Institutions in Human Subjects Research](#)
3. [DAIDS Good Clinical Laboratory Practices \(GCLP\) Standards \(MAN-A-OD-001\)](#)

Revision Summary

Revision/ Version	Summary of Changes
V1.0	Original Version and became effective 1/19/2021
V2.0	Pg 5 – Update to Record Storage Facility section to clarify which measures are required and which are recommended. Pg 6-7 – Update to information on Additional Locations Became effective on 5/4/2022.
V3.0	Reflects changes in SAV process – SIVs are no longer a type of visit, now that function would be fulfilled by an SAV. Reflects the addition of Additional Location (AL) content previously in the Site Activation section. Became effective on 11/4/2024.
01	DAIDS-OCS-A28-MAN-00007 rev 01 is the first revision of this manual in Master Control: • The document number and format were updated to meet current requirements. • Terminology and references were aligned with ICH GCP E6(R3) throughout the document.