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

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Site Activation Process

For a new Clinical Research Site (CRS) to participate in an DAIDS Clinical Trials Network protocol, there are two activation processes to follow:

1. Office of Clinical Site Oversight (OCSO) Site Activation -- Completion of this process ensures adequate site operational capacity/infrastructure to be considered for participation in DAIDS-sponsored clinical trials. The OCSO Program Officer coordinates this process.
2. Network Protocol Activation – Completion of this process ensures that a CRS has met all requirements for participation in a specific clinical trial and indicates that a site may begin enrollment. The Network Leadership and Operations Centers(Network LOC) works closely with the site to coordinate this process.

The OCSO Site Activation must precede Network Protocol Activation, although steps in both processes may happen concurrently. Both processes may take several months to complete.

Note: Screening and enrollment can only begin after **both Site and Network protocol activation approvals** have been obtained.

Office of Clinical Site Oversight Site Activation for a New Clinical Research Site

A new CRS must complete a comprehensive list of action items known as the *OCSO Site Activation Checklist* which is provided by the OCSO PO along with instructions for completion. Once the new CRS receives the checklist, the timeline to complete it and to provide documents to OCSO PO and Pharmaceutical Affairs Branch (PAB) will be negotiated.

The CRS will receive a unique site number to identify it in the NIAID Clinical Research Management System (NIAID CRMS) and in the Network Data Management Center(s) (DMC[s]) database.

A primary point of contact (usually the CRS coordinator) must be designated to work closely with the OCSO PO during the process. Also, a designated staff member from the Clinical Trials Unit (CTU) administrative site (or, if it is a protocol-specific site, from the CRS) will receive access to the Site Hub in the NIAID CRMS. This individual will be required to complete the *Essential Contacts and Site Profile* section for the new CRS; this section includes site contact information for key personnel as well as the site's laboratory, pharmacy, and regulatory components. Once completed, the OCSO PO and a PAB representative will review the section for completeness and then upload it to the NIAID CRMS.

Some other required checklist items include:

- Providing current curricula vitae (CVs) for the CRS Leader and CRS Coordinator
- Completing and documenting DAIDS-required trainings
- Submitting the Pharmacy Establishment Plan (PEP) to PAB for review and approval
- Submitting a Clinical Quality Management Plan (CQMP) for review and approval

Additional details can be found in other sections of this manual and in the *OCSO Site Activation Checklist*. For example, DAIDS' requirements for CVs and key personnel/staff training, in addition to training requirements to gain access to DAIDS systems are available in both the Clinical Research Site Personnel Qualifications, Training and Responsibilities and in the Introduction to DAIDS Systems sections of this manual, respectively.

Any item that does not apply to a specific CRS or location will be indicated as such on the *OCSO Site Activation Checklist*. The OCSO PO will review the completed checklist to ensure that all requirements are met and then issue a Site Activation notification by email. OCSO Site Activation must be obtained prior to DAIDS Protocol Registration, which is usually one of the last requirements of Network Protocol Activation.

Network Protocol Activation

While OCSO Site Activation takes place only when the CRS is participating in its first DAIDS Network Clinical Trials protocol, Network Protocol Activation occurs for every new protocol that CRSs conduct. That said, both processes can happen concurrently.

The Network Protocol Activation process is protocol-specific and is coordinated through the affiliated Network LOC. The process may vary from network to network, but each participating CRS receives a checklist with instructions of required items to activate the protocol. The Network Laboratory Center and DMC will work closely with the site to complete the specific laboratory and data management requirements. The CRS staff must also refer to the Network standard operating procedures (SOPs) or Manual of Operations/Procedures for additional details.

Initial registration notification from the Regulatory Support Center (RSC) Protocol Registration Office is one of the requirements for Network Protocol Activation, as outlined in the Protocol Registration Manual. Related information can also be found in the DAIDS Protocol Registration and Institutional Review Board/Ethics Committee Communications section of this manual. Depending on the type and details of the protocol and site, examples of possible requirements for Network Protocol Activation may include:

- Clinical trials insurance was procured.
- Supplies are on site.
- Laboratory proficiency testing is taking place.
- Import permits for study products/supplies are in place.

- CRS pharmacy is confirmed/prepared to participate in the protocol.
- Study product was ordered, as appropriate, and is present on-site.
- Data management training is taking place, including database access and electronic case report form completion.
- Current GCP and Human Subject Protection (HSP) training is documented.
- Required protocol-specific SOPs are in place.
- Protocol-specific training has been completed.
- Delegation of Duties Log is complete.

Once the Network confirms that all activation requirements are met, it will issue a Protocol Activation approval notification allowing the CRS to begin enrolling participants in the study.

Office of Clinical Site Oversight Approval of an Additional Location

If a CRS plans on using an Additional Location (AL) 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. The OCSO PO can provide the *Request for the Use of an Additional Location form* upon request from the CRS. Once completed, the worksheet will be reviewed by the OCSO PO, PAB, and a representative from the DAIDS Clinical Laboratory Oversight Team (DCLOT) and corresponding Network Leadership and Operations Centers (LOCs). 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 see 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

For more information on the definition of an additional location and examples refer to the Clinical Research Site Facility Requirements (Clinic, Laboratory and Additional Locations) section of the manual.

References

1. U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 54, 56, 312 and 812
2. International Council for Harmonisation Good Clinical Practice (ICH E6)
3. FDA Guidance: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects [Oct 2009]
4. Office for Human Research Protections
5. Protocol Registration Manual

Version History

V1.0	1/19/2021	Original Version
V2.0	5/3/2022	Pg 4 – Added information about additional locations.
V3.0	10/2/2023	Pg 2 - Updated descriptions of OCSO Site Activation and Network Protocol Activation; clarified required requirements to initiate enrollment.