**New Clinical Research Site (CRS) Coordinator Checklist**

*Last updated January 22, 2024*

|  |  |
| --- | --- |
| EMPLOYEE: | |
| DEPARTMENT: | |
| JOB TITLE: | HIRE DATE: |

|  |
| --- |
| **PURPOSE** |

The purpose of the Clinical Research Site (CRS) Coordinator Checklist is to provide guidance on onboarding and training for the CRS Coordinator role. This checklist is a tool created based on feedback from the Cross-Network Site Coordinators Working Group (SCWG), to be utilized by the CRS Coordinator, in addition to other DAIDS key personnel. While there is only one CRS coordinator per site, many of the same trainings are applicable to other study coordinators and personnel working on DAIDS studies. The average time to complete onboarding requirements is approximately 6 months.

|  |  |  |
| --- | --- | --- |
| **DIVISION OF AIDS (DAIDS) REQUIREMENTS** | | |
|  | Date Completed | Initials |
| 1. **Have the CTU business official (or CRS Leader if CRS is protocol-specific and not affiliated with CTU) submit an official request for change to key personnel in writing to the OCSO Program Officer (PO)**   Include the following information: Date of change, reason for the change, CRS coordinator full name, full contact information including address, phone, and email, CV signed and dated within the last 3 years, proof of HSP and GCP certification, percentage of time allocated to DAIDS studies, updated other support (for CTU affiliated studies). PO must approve and send out official change in key personnel email notification before the change can occur. |  |  |
| 1. **Confirm access to NIAID CRMS Site Hub**   The NIAID Clinical Research Management System (CRMS) Site Hub Module is used to capture all staff HSP/GCP certifications, as well as provide an electronic form to submit updates to current CRS site profile information for sites that are affiliated with a CTU grant. The CRS Leader and/or CRS Coordinator are required to maintain the current list of CRS personnel in the system and ensure trainings are up to date. Once a staff member is approved to serve in the role of CRS Leader or CRS Coordinator, CRMS Site Hub Access is automatically granted. Other relevant staff may also receive edit access to the Site Hub by contacting CRMS Support at: CRMSSupport@niaid.nih.gov |  |  |
| 1. **Confirm access to the DAIDS Learning Portal (DLP)**   DLP is the online platform that provides all DAIDS training courses, materials, and resources to CRS staff. Visit the DLP at <https://daidslearningportal.niaid.nih.gov> and request an account to obtain access. Once you have an account, please use the Getting Started Guide to take a tour of the DLP. Contact [support-daidslearningportal@niaid.nih.gov](mailto:support-daidslearningportal@niaid.nih.gov) if you have problems accessing any of the training resource links. |  |  |
| 1. **Complete Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training** (~4 hrs.)   HSP and GSP trainings are required for any staff member working with study participants or participant data (refer to the SCORE manual [here](https://www.niaid.nih.gov/sites/default/files/Clinical%20Research%20Site%20Personnel%20Qualifications%20Training%20and%20Responsibilities%20v2.0.pdf)). Certification must be current within the last 3 years. Choose one of the following options to comply:   * + [DAIDS Learning Portal](https://daidslearningportal.niaid.nih.gov/local/pages/?id=7#cgp): available in English, Spanish, and Portuguese   + Comparable HSP/GCP training offered by your institution or company   To document compliance with DAIDS HSP/GCP policy, update the site personnel list in the [CRMS Site Hub module](https://ncrmssso.niaid.nih.gov/daids/sitehub/default.aspx) with the current training completion dates and upload a copy of each certificate. |  |  |
| 1. **Complete Clinical Site Monitoring (CSM) System Training and obtain access to CSM** (~1 hr.)   The CSM System will be used for review and management of monitoring visit reports and related issues. Access is required for clinic and pharmacy staff who interact with the monitors and address monitoring issues in the CSM.   * Provide the names/positions needing CSM access to the OCSO PO for approval (limited accounts available) * Approved personnel must access online CSM Training in the DLP * Upon completion of the DLP CSM training, email certificate of completion to [CRMSsupport@niaid.nih.gov](mailto:CRMSsupport@niaid.nih.gov) to obtain access to the CSM |  |  |
| 1. **Complete DAIDS Protocol Registration System (DPRS) Training and obtain access to DPRS** (~1 hr.)   The DPRS will be used to prepare, submit, and track protocol registration documents.   * Access online DPRS Training in the DLP * Email certificate of completion to [CRMSsupport@niaid.nih.gov](mailto:CRMSsupport@niaid.nih.gov) to obtain access to the DPRS * (Optional) Complementary training on the DAIDS Protocol Registration Policy and Manual are recommended and available through the DLP |  |  |
| 1. **Complete DAIDS Adverse Experience Reporting System (DAERS) Training and obtain access to DAERS** (~1 hr.)   The DAERS will be used for reporting adverse events for DAIDS protocols. DAERS Training is required for the individuals listed as the “Submitter” on FDA Form 1572 or IOR agreement (must be a physician) as well as any “Reporter” who initiates the report in the system for the submitter. Please refer to the [DAERS Access User Guide for EAE Reporter and Submitter Rights](https://rsc.niaid.nih.gov/sites/default/files/daersaccessguide07.pdf) on the [DAIDS Regulatory Support Center (RSC) website](https://rsc.niaid.nih.gov/clinical-research-sites/summary-resources).   * Access online DAERS Training in the DLP * Email certificate of completion to [CRMSsupport@niaid.nih.gov](mailto:CRMSsupport@niaid.nih.gov) to obtain access to the DAERS * Mail a hard copy signature attestation form to the RSC for any submitter, see guidance in SCORE manual [here](https://www.niaid.nih.gov/sites/default/files/intro-to-daids-systems.pdf) |  |  |
| 1. **Complete all additional DAIDS required training modules in the DLP**   Please review the [Training Required by DAIDS](https://daidslearningportal.niaid.nih.gov/local/pages/?id=7) page on the DLP to determine which trainings are required for your staff role. CRS Coordinators should typically expect to complete all courses under the following headings:   * Clinical Research Records and Monitoring * DAIDS System Trainings |  |  |
| 1. **Review all DAIDS Clinical Research Policies**   All key personnel at each site must review all DAIDS policies and procedures. In order to meet this requirement, key personnel must go to the [DAIDS Clinical Research Policies and Other Information](https://www.niaid.nih.gov/research/daids-clinical-research-policies-and-other-information) site, and read and familiarize themselves with the policies and supporting documents, including the DAIDS SCORE Manual. |  |  |
| 1. **Review the DAIDS SCORE Manual**   The Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials [(SCORE) Manual](https://www.niaid.nih.gov/research/daids-score-manual) describes operational requirements for Clinical Research Sites (CRSs) implementing DAIDS-sponsored clinical research within the DAIDS Clinical Trials Networks. This manual serves as a resource for CRSs by consolidating operational requirements in a central location and providing tools to facilitate compliance with these requirements. |  |  |
| 1. **Review the Clinical Quality Management Plan (CQMP) and Tools**   Each site creates a CQMP and accompanying tools per the DAIDS SCORE manual to demonstrate how the site will ensure quality data for DAIDS-supported studies. Please review your site’s CQMP and [quality management](https://www.niaid.nih.gov/sites/default/files/score-quality-management.pdf) tools to familiarize yourself. Any changes to the CQMP must be reviewed by DAIDS. |  |  |
| 1. **Review Site SOPs**   Please familiarize yourself with your site’s SOPs and ensure you understand which are required by DAIDS per the SCORE manual. |  |  |
| 1. **Complete additional CRS Personnel Training**  * Network, Institutional, and/or Site-specified trainings * Trainings specific to local laws/regulations applicable to clinical trials being conducted by the CRS (ex. U.S. CFR requirements) * Protocol and related documents and study product(s) requirements * Any training specific to your duties/functions which have been delegated to you by the IoR |  |  |
| 1. **Update Site Training Log**   The IoR for each study at a site is responsible for maintaining accurate and current documentation of training. Many sites may maintain a training log to meet this requirement. If your site has a training log, please add yourself to the log and update any responsibilities. Otherwise, please make sure your training is adequately documented in your record. |  |  |

|  |  |  |
| --- | --- | --- |
| **NETWORK REQUIREMENTS** | | |
|  | Date Completed | Initials |
| **[ACTG / IMPAACT] Obtain access to Frontier Science Portal** |  |  |
| **[ACTG] Create a new account on the ACTG Members’ Site** |  |  |
| **[HPTN / HVTN] Obtain access to Atlas** |  |  |
| **[All] Obtain access to relevant databases and programs in use by the network studies (Medidata Rave, OpenClinica, iDatafax, etc.)** |  |  |

|  |  |  |
| --- | --- | --- |
| **INSTITUTIONAL REQUIREMENTS** | | |
|  | Date Completed | Initials |
| 1. **Complete institutional training requirements (Ex. HIPAA, environmental health and safety training, infection control, shipping training for transportation of biological material and dry ice (IATA), etc.** |  |  |
| 1. **Obtain access to institutional electronic medical record (EMR) system** |  |  |

|  |  |  |
| --- | --- | --- |
| **SITE REQUIREMENTS** | | |
|  | Date Completed | Initials |
| 1. **Obtain access to office and work equipment** |  |  |
| 1. **Obtain access to electronic systems, appropriate network email aliases, and network member portal** |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **SAMPLE 4-WEEK ORIENTATION** | | | |
|  | **Orientation** | **Training / Document Review** | **Practice** |
| WEEK 1 | \*Review job description and organization unit procedures  \*Office set-up and equipment  \*Organization structure overviews (Institution / CRS; CTU; HIV/AIDS Clinical Trials Networks)  \*Regulatory Processes  \*Review active protocols | \*DAIDS SCORE Manual  \*Required trainings |  |
| WEEK 2 | \*Overview of clinical process  \*Quality Management: CQMP/QA Processes  \*Review protocols | \*Required trainings  \*Source Documentation SOP  \*Universal paperwork (consents, HIPAA, Medical Release forms, general SOPs)  \*Quality Management SOP  \*Recruitment/Retention SOP  \*Study Consents/HIPAA  \*Protocol paperwork (flowsheets/lab requisitions/eligibility checklist, etc.)  \*Participant records/case report forms (CRF) | \*Begin shadowing site mentor |
| WEEK 3 | \*Orientation: Regulatory  \*Orientation: Data management  \*Review protocols | \*DAIDS Pharmacokinetics Tutorial | \*Continue shadowing site mentor  \*Begin conducting visits  \*Review source documentation and CRF paperwork completion  \*Begin recruitment activities  \*Begin QA/QC process |
| WEEK 4 | \*Review protocols  \*Assess processes/further training needs |  | \*Conduct visits  \*Review source documentation and CRF paperwork completion  \*Recruitment activities  \*QA/QC |

|  |
| --- |
| **APPENDIX A: FREQUENTLY ACCESSED RESOURCES** |

1. [DAIDS Learning Portal](https://daidslearningportal.niaid.nih.gov/)
   * [DAIDS Required Training Modules](https://daidslearningportal.niaid.nih.gov/local/pages/?id=7) Table of trainings required by the Division of AIDS.
   * [DAIDS Group Training Pages](https://www.niaid.nih.gov/daids-ctu/group-training-pages) Dedicated landing pages for DLP trainings related to selected groups within DAIDS. Includes the Monitoring and Operations Branch (MOB), DAIDS Clinical Laboratory Operations Team (DCLOT), Pharmaceutical Affairs Branch (PAB), and Office for Policy in Clinical Research Operations (OPCRO).
   * [SCORE Manual Training Page](https://www.niaid.nih.gov/daids-ctu/score) Access DLP trainings related to the SCORE manual and access links to the SCORE manual and FAQ.
   * [Community Engagement Page](https://www.niaid.nih.gov/daids-ctu/community-engagement) Information, training, and resources related to community engagement.
   * [Transgender Training Resources](https://daidslearningportal.niaid.nih.gov/local/pages/?id=15) Contains the Transgender Training Curriculum (eLearning course and in-person training tools), guidance documents, selected publications, and links to other helpful resources.
2. [DAIDS Clinical Research Policies](https://www.niaid.nih.gov/research/daids-clinical-research-policies-and-other-information)
   * [Clinical Research Terms Glossary](https://www.niaid.nih.gov/research/daids-clinical-research-glossary)
   * [DAIDS Acronyms](https://www.niaid.nih.gov/research/daids-acronyms)
   * [DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual](https://www.niaid.nih.gov/research/daids-score-manual)
3. [DAIDS Regulatory Support Center (RSC)](https://rsc.niaid.nih.gov/) The DAIDS RSC provides day-to-day support for all regulatory activities.
   * [Summary of Resources for Clinical Research Sites](https://rsc.niaid.nih.gov/clinical-research-sites/summary-resources)
   * [DAIDS Adverse Event Grading Tables](https://rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-event-grading-tables)
   * [DAIDS Protocol Registration Policy and Procedures Manual](https://rsc.niaid.nih.gov/clinical-research-sites/daids-protocol-registration-policy-and-procedures-manual)
   * [Investigator’s Brochure (IB) Table](https://rsc.niaid.nih.gov/clinical-research-sites/ib-table)
   * [Manual for Expedited Reporting of Adverse Events to DAIDS](https://rsc.niaid.nih.gov/clinical-research-sites/manual-expedited-reporting-adverse-events-daids)
   * [Package Insert (PI) Table](https://rsc.niaid.nih.gov/clinical-research-sites/pi-list)
4. [Good Clinical Practice (GCP)](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/good-clinical-practice) U.S. Food & Drug Administration (FDA) resources to support good clinical practice (GCP) in clinical trials.
5. [Good Participatory Practice (GPP)](https://www.avac.org/gpp-training-tools) Guidance for how to effectively engage with community and broader stakeholders in the design and conduct of biomedical HIV prevention trials.
6. [HANC Public Site](http://www.hanc.info) The Office of HIV/AIDS Network Coordination (HANC) works with the HIV/AIDS Clinical Trials Networks to promote cross-network collaboration, resource sharing, and integration.
   * [Community Resources](https://www.hanc.info/resources/sops-guidelines-resources/community.html)
     1. [Bill of Rights and Responsibilities for HIV Research](https://www.hanc.info/resources/sops-guidelines-resources/community.html#bill) This document lists rights and responsibilities for participants in a clinical trial and is meant to be used by site staff alongside informed consent forms.
     2. [DAIDS Community Advisory Board (CAB) / Community Working Group (CWG) Directory](https://www.hanc.info/content/dam/hanc/documents/community/DAIDS%20CAB%20Directory%20April%202022.pdf)
     3. [Guidance for Gender-Inclusive HIV Research Practices](https://www.hanc.info/resources/sops-guidelines-resources/community.html#gender-inclusive) Recommendations to facilitate gender inclusion in study design, data collection, and data reporting.
     4. [How to Critically (and Quickly) Read a Protocol](https://www.hanc.info/resources/sops-guidelines-resources/community.html#How-to)
     5. [Long-Acting Antiretroviral Injectables Info Sheet](https://www.hanc.info/resources/sops-guidelines-resources/community.html#antiretroviral)
     6. [NIAID HIV Language Guide](https://www.hanc.info/resources/sops-guidelines-resources/community.html#language-guide) Suggested language for communicating about HIV and related topics without perpetuating stigma.
     7. [Recommendations for Community Engagement](https://www.hanc.info/resources/sops-guidelines-resources/community.html#community-engagement) Recommendations for good community practice and engaging community in research processes.
     8. [Tuberculosis Resources for Communities](https://www.hanc.info/resources/sops-guidelines-resources/community.html#tb-community) Resources covering the intersection of tuberculosis and HIV, including talking points for the PHOENIx study.
   * [DAIDS Resources](https://www.hanc.info/resources/sops-guidelines-resources/daids.html) Includes recent announcements from DAIDS, memos from the Office of Clinical Site Oversight (OCSO) and Office for Policy in Clinical Operations (OPCRO), DAIDS Organization charts, recorded presentations from DAIDS.
   * [Site Management](https://www.hanc.info/resources/sops-guidelines-resources/site-management.html) Resources Includes a library of site SOP templates from the networks and DAIDS, Financial Disclosure SOP, as well as recordings and slides from the two-part webinar series on Electronic Informed Consent.
   * [Webinar Library](https://www.hanc.info/resources/webinars-and-presentations.html) Recordings of past webinars hosted by HANC.
7. [NIAID Clinical Research Management System (CRMS)](https://ncrms.niaid.nih.gov/NCRMS/Main/Login.aspx) Includes the following modules: Site Hub, DAIDS Protocol Registration System (DPRS), Clinical Site Monitoring (CSM) System, and DAIDS Adverse Experience and Reporting System (DAERS). Reference [DAIDS SCORE Manual](https://www.niaid.nih.gov/sites/default/files/intro-to-daids-systems.pdf) for more information on NIAID CRMS.

|  |  |
| --- | --- |
| **APPENDIX B: ACRONYMS** |  |

CAB Community Advisory Board

CAPA Corrective and Preventive Actions

CFR U.S. Code of Federal Regulations

CQMP Clinical Quality Management Plan

CRMS Clinical Research Management System

CRS Clinical Research Site

CSM Clinical Site Monitoring

CWG Community Working Group

DAERS DAIDS Adverse Experience and Reporting System

DAIDS Division of AIDS

DCLOT DAIDS Clinical Laboratory Operations Team

DLP DAIDS Learning Portal

DPRS DAIDS Protocol Registration System

EMR Electronic Medical Record

FDA U.S. Food & Drug Administration

GCP Good Clinical Practice

GPP Good Participatory Practice

HANC Office of HIV/AIDS Network Coordination

HSP Human Subjects Protection

MOB DAIDS Monitoring and Operations Branch

NIAID National Institute of Allergy and Infectious Diseases

NIH National Institutes of Health

OCSO DAIDS Office of Clinical Site Oversight

OPCRO DAIDS Office for Policy in Research Operations

RSC DAIDS Regulatory Support Center

SCORE DAIDS Site Clinical Operations and Research Essentials Manual

SOP Standard Operating Procedure