DAIDS CRS Transition Scenario Checklist: FY 2021

National Institute of Allergy and Infectious Diseases

The following pages detail the required action items for clinical research sites (CRSs) entering the grant period beginning December 1, 2020. Please complete ONE checklist for EACH CRS in your Clinical Trial Unit (CTU) and submit to your OCSO Program Officer (PO).

Scenario 1 - Known to DAIDS CRSs:

Please review the applicable portions of the CRS Scenario Checklist and complete items as neccessary. If an item is not relevant to the CRS, please indicate N/A in the comments. If information for an item has not changed, please indicate no change in the comments.

Scenario 2 - New to DAIDS CRSs:

A CRS can participate in DAIDS Network protocols through a two-step process:

1. **OCSO Site Activation** is coordinated through the DAIDS Office of Clinical Site Oversight (OCSO). Required items are listed in this document - please review and complete all items. Any questions about the Site Activation process should be directed to your OCSO Program Officer (PO).
2. **Network Protocol Activation** is protocol-specific and coordinated through the Network Leadership Operations Center (LOC) for the Network coordinating each protocol. ***The lab assessment and data management components of activation will be covered in the Protocol Activation checklist***. Refer to the Network resource section of the transition packet or consult your Network for a copy of the Protocol Activation checklist.

Some components of these two steps may occur simultaneously, but issuance of OCSO Site Activation must precede Network Protocol Activation. After completion of the OCSO Site Activation requirements in this checklist, a Site Activation email will be issued by your OCSO PO and protocol registration may take place. A separate Network Protocol Activation notice is required prior to protocol implementation.

Once both Site and Network Protocol Activation approvals are obtained, you may begin screening and enrollment into the protocol.

Network(s):	CRS Leader:
Clinical Trial Unit (CTU) PI Name: *(if applicable)*	Primary Site Point of Contact (POC) *Please designate a primary contact to work with the OCSO PO during the transition period.* Name: Email: Phone:
Site Name:	
Site Number:	

Key: ✔ Complete section as described ⚠ Review section and make changes as necessary

Scenario 1 - Known to DAIDS CRS	Scenario 2 - New to DAIDS CRS
Current CRSs with no changes or new locations, continuing PS work	CRSs that have not conducted DAIDS trials in the current grant cycle

The DAIDS Learning Portal (DLP) is an online platform that provides all DAIDS training courses to CRS staff, and access will be necessary to complete the checklist. Visit the DLP at https://daidslearningportal.niaid.nih.gov and request access. Contact support-daidslearningportal@niaid.nih.gov if you have problems accessing any of the training resource links.

Scenario 1 Known	Scenario 2 New	Item	Action Item & Resources	Site and PO Comments	Completion Date
⚠	✔	1	**Obtain access to NIAID CRMS Site Hub.** Designate 1 or 2 CRS personnel to obtain access to the Site Hub to upload HSP/GCP certifications and keep the list of CRS personnel current. Contact CRMSSupport@niaid.nih.gov for access if you do not already have access.		
✔	✔	2	**Review population characteristic data for the CRS in NIAID CRMS Site Hub.** Population characteristic data from the CTU applications was uploaded to the Site Hub. CRS personnel should QC this data to make sure it is correct.		
⚠	✔	3	**Complete or update Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training.** Please see the DAIDS Required Training page on the DLP https://daidslearningportal.niaid.nih.gov/local/pages/?id=7 for more information about what is required.		

Scenario		Item	Action Item & Resources	Site and PO Comments	Completion Date
1 Known	2 New				
✓	✓	4	**Submit a current CV for the CRS Leader and the CRS Coordinator.** CVs should be current within the last 3 years, signed and dated.		
✓	✓	5	**Complete and submit a Pharmacy Establishment Plan (PEP) and PEP modules (if applicable) to the DAIDS Pharmaceutical Affairs Branch (PAB) for review and approval within 6 weeks of notification.** Please refer to the Pharmacy Resource Section of the Transition Packet for more information on how to request and complete a PEP.		
N/A	✓	6	**Prepare for Site Assessment Visit (SAV). (if applicable)** SAVs may be conducted at the request of the OCSO PO. To prepare for the SAV, contact the OCSO PO for a copy of the site assessment tool.		

Scenario 1 Known	Scenario 2 New	Item	Action Item & Resources	Site and PO Comments	Completion Date
⚠	✔	**7**	**Complete systems trainings for Clinical Research Management System (CRMS) modules listed below within the DAIDS Learning Portal (DLP)* and obtain access to the modules for the applicable CRS personnel.** • **Clinical Site Monitoring (CSM) System** • **DAIDS Protocol Registration System (DPRS)** • **DAIDS Adverse Event Reporting System (DAERS)** Please see the DAIDS SCORE Manual (https://www.niaid.nih.gov/research/daids-score-manual) section on DAIDS Systems and Training or the DAIDS Required Training Page on the DLP (https://daidslearningportal.niaid.nih.gov/local/pages/?id=7) for more information about what is required. Completion of these trainings should also be captured in a site training log maintained at the site. Please reference template training log(s) in the DAIDS SCORE Manual.		
✔	✔	**8**	**Complete all additional DAIDS required training modules in the DLP.** Please review the DAIDS Required Training Page in the DLP (https://daidslearningportal.niaid.nih.gov/local/pages/?id=7) to determine which trainings are required for each staff member. Document the date of completion in the Site Training Log.		

Scenario 1 Known	Scenario 2 New	Item	Action Item & Resources	Site and PO Comments	Completion Date
✔	✔	9	**Develop DAIDS Required SOPs.** Please review the list of DAIDS Required SOPs (https://www.niaid.nih.gov/sites/default/files/sops-required-at-clinical-research-sites.pdf) in the DAIDS SCORE Manual and submit those that are required for review and approval to OCSO PO. Site should submit a list of all SOPs for OCSO PO review.		
✔	✔	10	**Review DAIDS policies and procedures on the DAIDS website under Site Implementation and Operations page.** Clinical, pharmacy, and laboratory CRS staff should read and familiarize themselves with these policies and supporting documents.		
⚠	✔	11	**Submit a Clinical Quality Management Plan (CQMP) and Tools.*** Create a CQMP and accompanying tools per instructions in the DAIDS SCORE Manual. (https://www.niaid.nih.gov/sites/default/files/score-quality-management.pdf) * Known to DAIDS CRSs should review their CQMP, make any changes if necessary, and submit to the OCSO PO.		
✔	N/A	12	**Submit a QA Summary Report.** Known to DAIDS CRSs should complete a QA Summary report and submit to the OCSO PO per instructions in the DAIDS SCORE Manual in the Quality Management section. (https://www.niaid.nih.gov/sites/default/files/score-quality-management.pdf) Training on the QA Summary Report is also available in the DLP.		

Scenario		Item	Action Item & Resources	Site and PO Comments	Completion Date
1 Known	2 New				
N/A	✓	13	**Prepare for Site Initiation Visit (SIV).* (if applicable)** SIVs may be conducted at the request of the OCSO PO. To prepare for the SIV, contact the OCSO PO for a copy of the blank SIV report. * SIVs may also be conducted for known to DAIDS CRSs with new additional locations		
N/A	✓	14	**Resolve all issues identified during SAV and/or SIV prior to site activation.* (as applicable)** Visit reports are available approximately 3 weeks after each visit. SIV reports are available in the CSM and SAV reports are provided by the OCSO PO. Pharmacy issues will be handled by PAB either through the CSM (SIV) or through email (SAV). The site is required to submit resolution and/or corrective action for any issues identified on the report(s) or by the OCSO PO or PAB.		

For OCSO Use Only

Final Site Activation/Approval Date ⟶ _____