

Division of AIDS Clinical Trials Unit (CTU) Transition Packet

FY2021 CTU Grant Cycle

Contents

Scenario Definitions_____	2
Scenario Instructions_____	3
Resources_____	4
General_____	4
DAIDS Pharmaceutical Affairs Branch (PAB)_____	5
DAIDS Monitoring Operations Branch (MOB)_____	7
DAIDS Clinical Laboratory Team (DCLOT)_____	9
DAIDS Regulatory Support Center (RSC)_____	11
DAIDS Protocol Registration Office (PRO)_____	12
HIV/AIDS Networks_____	13
HANC_____	19
DAIDS Community Advisory Boards (CABs)_____	21

CRS Scenario Definitions

The Division of AIDS (DAIDS) has placed each Clinical Research Site (CRS) into one of 3 scenarios. Each scenario requires a unique set of items to be completed for seamless flow of continued and/or new protocol activities. This will involve close coordination between the Clinical Trials Unit (CTU), the CRS staff, Office of Clinical Site Oversight (OCSO) Program Officer (PO), and the appropriate Network Staff.

Please view the definitions below and the corresponding actions for each scenario on [page 3](#). Please complete the indicated actions for all CRSs approved in the DAIDS CTU-specific transition letter. The scenario for each CRS will be designated in that letter.

Scenario 1 - Known to DAIDS CRS

A CRS that participated in DAIDS HIV/AIDS Network clinical trials in the prior 7 year grant cycle and has been selected to continue participation in one or more DAIDS HIV/AIDS Network clinical trials in the 2021 grant cycle;

OR

A previously fully funded CRS that has been selected by a Network and DAIDS to continue a specific protocol into the 2021 grant cycle but will be phased-out once the specific protocol is completed and the CRS is deregistered.

Scenario 2 - New to DAIDS CRS

A CRS that has been selected to participate in one or more DAIDS HIV/AIDS Network clinical trials in the 2021 grant cycle that has not participated in any DAIDS HIV/AIDS Network clinical trials in the prior 7 year grant cycle.

Scenario 3 - Phase Out CRS (*or Network Affiliation(s)*)

CRS funded by DAIDS in the previous grant cycle (either fully funded or PS), where a proposed network affiliation(s) was not selected for re-funding in the next grant cycle. The CRS will complete all network protocol activity by November 30, 2021 based on DAIDS and Network Guidance.

NOTE REGARDING ADDITIONAL LOCATIONS: Additional locations (AL) are defined as a physical place (i.e. address) where research data are being collected. The research must be considered “engaged” in accordance with [OHRP Guidance on Engagement of Institutions in Human Subjects Research](#). Location(s) may include medical schools, hospitals, mobile units, community health centers, private practices or other research facilities where the clinical investigation will be conducted. Any proposed ALs should be indicated in the Essential Contacts entry for the applicable CRS and will then be subject to the normal DAIDS process for review and approval. Approval of a CRS in the CTU transition letter does not signify that any AL associated with the CRS is also approved. Contact the OCSO PO with any questions.

CRS Scenario Instructions

Please follow the directions below for the appropriate scenario(s) for each CRS in the CTU, as designated in the table provided in the CTU specific transition letter received from DAIDS. Due dates for completion of requirements are specified for each scenario below. Links throughout the document will connect to applicable resources. Please go to the CTU Transition landing page at <https://www.niaid.nih.gov/daids-ctu/transition-fy2021-grant-cycle>.

Access to the DAIDS Learning Portal (DLP) will be necessary to access required trainings - please visit <https://daidslearningportal.niaid.nih.gov> to create an account.

CRS Scenario 1 - Known to DAIDS CRS

Complete by April 30, 2021

If a CRS falls under scenario 1, please complete the following steps:

1. Complete the indicated sections for Known to DAIDS CRSs in the DAIDS CRS Transition Scenario Checklist. Please complete one checklist for each CRS in the CTU.
 2. Review the resources pages beginning on page 4 for any requirements from other groups within DAIDS, such as pharmacy or regulatory.
 3. Please see links for network study activation [on page 13 - 16](#) or consult the Network for protocol activation requirements for any upcoming studies due to begin after December 2020.
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CRS Scenario 2 - New to DAIDS CRS

Complete within 6 months of notification, or as negotiated with the OCSO PO

If a CRS falls under scenario 2, please complete the following steps:

1. Complete the indicated sections for New to DAIDS CRSs in the DAIDS CRS Transition Scenario Checklist. Please complete one checklist for each CRS in the CTU.
 2. Review the resources pages beginning on page 4 for any requirements from other groups within DAIDS, such as pharmacy or regulatory.
 3. Please see links for network study activation [on page 13 - 16](#) or consult the Network for protocol activation requirements for any upcoming studies due to begin after December 2020.
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CRS Scenario 3 - Phase Out CRS (or Network Affiliation(s))

Complete by November 30, 2021

If a CRS falls under scenario 3, please complete the following steps*:

1. Please see links for Network study close-out activities starting on [page 17](#).
2. Review the resources pages beginning on page 4 for any requirements from other groups within DAIDS, such as pharmacy or regulatory.
3. Complete DAIDS CRS Close-out Checklist. Work with OCSO PO to complete these activities.

*NOTES: (1) If your site is closing out one or more networks, but continuing as fully funded for another network, complete ONLY #1 and #2 for those networks that are closing.

(2) CRSs still participating in MTN studies will be designated as PS for that network until the studies are complete and then they will be phased out for MTN.

General

The CTU Transition Pages on the DLP will provide important resources and links including, but not limited to the following:

- CTU Transition Packet
- CRS Transition Scenario Checklist
- CRS Close-out Checklist
- DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual
- DAIDS Policy Website
- Contact information

Please see the following link to access the CTU Transition Landing Pages.

<https://www.niaid.nih.gov/daids-ctu/transition-fy2021-grant-cycle>

The screenshot shows the NIH website interface. At the top left is the NIH logo and the text "National Institute of Allergy and Infectious Diseases". To the right is a search bar with the placeholder text "Enter a keyword or phrase" and a "Search" button. Below the search bar is a navigation menu with links for "Research", "Diseases & Conditions", "Grants & Contracts", "Clinical Trials", "News & Events", and "About NIAID". The main content area is titled "DAIDS CTU" and "DAIDS CTU Transition For FY2021 Grant Cycle". On the left side of the main content area, there is a sidebar with a dropdown menu showing "DAIDS CTU Transition For FY2021 Grant Cycle" and three options: "CRS Transition - Scenario 1 - Known to DAIDS CRS", "CRS Transition - Scenario 2 - New to DAIDS CRS", and "CRS Transition - Scenario 3 - Phase Out CRS or Network Affiliation". The main content area contains the following text: "After the recent Division of AIDS (DAIDS) Clinical Trial Unit (CTU) grant recompetition, CTUs and corresponding Clinical Research Sites (CRSs) have been selected for funding. DAIDS has placed each CRS into one of 3 scenarios for the transition into the new grant cycle. Each scenario requires a unique set of items to be completed for seamless flow of continued and/or new protocol activities. This will involve close coordination between the Clinical Trials Unit (CTU), the CRS staff, Office of Clinical Site Oversight (OCSO) Program Officer (PO), and the appropriate Network Staff. Please click on the appropriate scenario definition below to open the scenario landing page. Please follow the directions on each page for the appropriate scenario(s) for each CRS in the CTU, as designated in the table provided in the CTU specific transition letter received from DAIDS. Due dates for completion of requirements are specified for each scenario below. Links throughout the pages will connect to applicable resources. Access to the DAIDS Learning Portal (DLP) will be necessary to get started - please visit <https://daidslearningportal.niaid.nih.gov> to create an account." On the right side of the main content area, there are social media icons for Facebook, Twitter, and LinkedIn.

DAIDS Pharmaceutical Affairs Branch (PAB)

The Division of AIDS (DAIDS) requires the Clinical Research Site (CRS) Leader to delegate the responsibility for study product management at the CRS to a licensed/registered pharmacist. This pharmacist is the Pharmacist of Record (PoR) .

The CRS leader is responsible for ensuring that there is a pharmacy that meets the DAIDS requirements for pharmacy personnel (PoR and Associate Pharmacist), pharmacy facilities, and pharmacy equipment as well as all ancillary supplies required for the conduct of DAIDS sponsored and/or supported clinical trials which involve study product(s) at the CRS.

A PAB-approved DAIDS PAB Pharmacy Establishment Plan (PEP) is required for each pharmacy affiliated with a CRS. The CRS PoR should request the DAIDS PAB PEP Template and any applicable PAB PEP Modules from PAB. For pharmacies known to DAIDS (including protocol specific sites) and new to DAIDS, the PEP template and modules are to be completed by the CRS PoR and submitted to DAIDS PAB within 6 weeks of receipt of the CTU Transition Packet for PAB review and approval. PAB will review the submitted documents to determine that the required personnel, facilities, and equipment are available for the conduct of studies requiring product storage under controlled room temperature, as well as any other applicable capabilities. PAB will inform the CRS leader and PoR whether the site pharmacy's storage, equipment, and transportation capabilities meet PAB requirements or if there are any issues regarding the personnel, facilities, or equipment. Once those issues are resolved, the PoR will need to submit an updated PEP, as well as any other applicable modules, for review. The PEP will be approved when all required personnel, facilities, and equipment are in place and operational.

Pharmacies known to DAIDS

- Pharmacies currently operating under a PAB-approved PEP for an existing CRS aligned with a specific DAIDS Network (including protocol specific sites) may continue operating under this plan.
- Pharmacies that will be undertaking additional work because an existing CRS is affiliated with a new Network will be required to submit a new PEP that includes information that reflects the updated Network(s) affiliation within 6 weeks of receipt of the CTU Transition Packet. Approval of the new PEP will be required prior to initiating clinical trials work with the new Network.

Pharmacies new to DAIDS

Pharmacies new to the DAIDS HIV/AIDS Clinical Trials Network will be required to submit a DAIDS PAB PEP Template for approval prior to clinical trial initiation. A pharmacy assessment visit may be conducted by a DAIDS contracted representative prior to approval as feasible.

DAIDS PAB *continued*

Pharmacies at Phase Out CRS

Pharmacies at CRS funded by DAIDS in the previous grant cycle (either fully funded or PS), where a proposed network affiliation(s) was not selected for re-funding in the next grant cycle will continue operating under a PAB-approved PEP until the CRS completes all network protocol activities by the end of year 15 (2021) based on DAIDS and Network Guidance.

Pharmacist of Record (PoR)

The PoR is the primary individual whose responsibilities include:

- Performing the day-to-day dispensing and accountability activities
- Establishing internal policies and procedures that includes the pharmacy Quality Management Plan
- Developing and maintaining a study product management system

Refer to the DAIDS PAB *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks* (<https://www.niaid.nih.gov/research/daids-clinical-research-pharmacy-and-study-products-management>) for a complete description of the PoR's responsibilities.

The PoR and all other site pharmacists must be licensed and/or registered to practice pharmacy in the jurisdiction in which they are working.

Ensuring quality work requires that the PoR commit the necessary and appropriate amount of time to meet the pharmaceutical needs and requirements of the DAIDS Clinical Trials.

DAIDS PAB Pharmacy Establishment Plan and Modules

The CTU should provide the PAB section of the DAIDS CTU Transition Packet to the PoR at each CRS within the CTU. Each CRS PoR must complete and submit a DAIDS PAB PEP Template and optional Modules to PAB for review and approval.

The DAIDS PAB PEP Template must be completed for each pharmacy that is associated with a DAIDS CRS. Each DAIDS PAB PEP Template must be completed by the PoR for that pharmacy.

The PoR should email DAIDS PAB PEP at DAIDSPABPEP@niaid.nih.gov to obtain an electronic copy of the following documents:

- DAIDS PAB PEP Template
- DAIDS PAB Modules (if applicable): Refrigerated Storage, -20°C Freezer Storage, -70°C Freezer Storage, Biosafety Cabinet/Isolator, Additional Storage Area, and Transportation/Chain of Custody
- DAIDS PAB Pharmacist of Record Information Sheet (if applicable)
- DAIDS PAB Associate Pharmacist Information Sheet (if applicable)

The PoR must include the affiliated CRS name and number, as well as the CTU name when requesting the above document(s) from PAB.

DAIDS Monitoring Operations Branch (MOB)

As sponsor, NIAID DAIDS is required to monitor DAIDS sponsored and/or supported clinical trials to ensure protection of human subjects, accurate and complete reporting of trial data, and protocol compliance by Clinical Research Sites (CRSs), in accordance with 21 CFR §312.56 and ICH Good Clinical Practices (GCP) Section 5.18. The Monitoring Operations Branch (MOB) directs the monitoring function for DAIDS-sponsored clinical trials to meet the rigor of all applicable regulations and guidelines.

DAIDS Network studies are being conducted in over 20 countries. The monitoring activities at these Clinical Research Site (CRS) locations are conducted by a Clinical Research Organization (CRO) with a regional presence through a contract mechanism. The current NIAID Clinical Site Monitoring (NCSM) Contractor is Pharmaceutical Product Development (PPD) LP. The MOB develops, executes, and provides oversight of the NCSM monitoring contract.

To monitor the progress of the DAIDS clinical trials and adherence to all applicable regulations and DAIDS policies and procedures, PPD Clinical Research Associates (CRA)s in each region perform routine on-site and remote visits at each CRS. The MOB in conjunction with PPD ensures that the monitors are appropriately trained, as required by ICH/GCP.

MOB uses a “risk-based” approach to monitoring. Each study is assigned a risk level (1-3) based on the phase, magnitude and complexity of the trial. The risk level determines the extent and nature of monitoring. Monitoring visits are generally conducted on a quarterly basis lasting three (3) to four (4) days. The assigned CRA will contact site personnel to schedule the monitoring visit. During these visits, the monitors verify study data against participant medical records (source documents), review the regulatory file documents, perform study product accountability, conduct laboratory specimen verification and conduct clinic and pharmacy facilities operations assessments. All site monitoring visits are concluded with a debrief summary meeting with site to review findings and answer any questions.

The monitoring visit findings are documented in a site monitoring visit report and shared with the site personnel via a computer-based system called the NIAID Clinical Research Management System (NIAID CRMS), Clinical Site Monitoring (CSM) module. Upon completion of training, DAIDS will provide assigned site staff access to the CSM module. The monitors have no role in resolving any findings/deviations noted during a monitoring visit. The assigned DAIDS/OCSO Program Officer (PO) will identify significant findings from the monitoring visit report and request that the site implement corrective and preventive action as necessary. In addition to significant findings identified by POs, sites are expected to address all findings in the Site Monitoring Report. The MOB serves as a resource on operational and regulatory issues that may arise from monitoring visits, and ensures that appropriate clinical research standards, policies, and procedures are adhered to by the CRSs.

DAIDS MOB *continued*

The MOB coordinates with all DAIDS programs to align monitoring resource needs for existing and upcoming trial work. Monitoring visit frequency, length of visit or number of monitors at a visit may be adjusted depending on workload, number of active protocols at the site and enrollment metrics.

To enhance human subject protection and the quality of clinical trial data, MOB monitoring oversight focuses on the most important aspects of study conduct and reporting. The MOB has developed and implemented tools to support risk-based monitoring. We continue to evaluate the efficiency and effectiveness of new monitoring strategies and look forward to working with you on this endeavor.

DAIDS Clinical Laboratory Team (DCLOT)

The DAIDS Clinical Laboratory Team (DCLOT), made up of DAIDS laboratory staff from the vaccine, therapeutic and prevention Programs at DAIDS, is responsible for lab establishment, oversight and implementation of laboratory policies, evaluation of lab performance, and follow-up on lab-related issues. DCLOT members serve as Point of Contacts (POC) to each of the funded clinical trial Networks. Working closely with the respective DCLOT POC, each Network has a laboratory management and oversight team that also supports Network site laboratories, focusing on protocol-related laboratory issues.

DAIDS and Network Laboratory Contacts				
Network	ACTG	HPTN	HVTN	IMPAACT
DCLOT POC	Daniella Livnat dlivnat@nih.gov	Usha Sharma usharma@niaid.nih.gov	Nina Kunwar Nina.kunwar@nih.gov	Naana Cleland clelandn@niaid.nih.gov
Network Lab Center	ACTG.labcenter@fstrf.org	hptnlc-lab@jhmi.edu	vtn.site.lab.support@hvtn.org	impaact.qaqc@fstrf.org

The Network, together with DCLOT, has the final word on a laboratory's readiness to participate in a study. Ensuring quality laboratory testing requires laboratories to perform testing in compliance with Good Clinical Laboratory Practices (GCLP) and generate reliable test results. To ensure GCLP compliance, DAIDS has developed guidelines and monitors laboratories' compliance with GCLP through periodic visits/audits performed by NIAID DAIDS HIV Clinical Research Support Services (CRSS) contractors. Because clinical laboratories operating in the US must adhere to CLIA regulations, which are similar to GCLP and include regular inspections, annual GCLP audits are generally not performed but DAIDS may perform periodic visits or for-cause audits at US clinical labs.

DCLOT *continued*

Ensuring reliable laboratory test results is accomplished through the monitoring of results obtained by laboratories on proficiency testing samples. DAIDS employs a few laboratory quality assurance contracts that work closely with DCLOT, the Networks and site laboratories to help ensure the quality of testing:

DAIDS Laboratory Quality Assurance Contracts	
Contract Name	Target Support
IQA	The Immunology Quality Assessment contract (IQA), administered by Duke University, provides proficiency testing services for CD4 testing and PBMC cryopreservation. The contract also assists US specimen processing and Endpoint laboratories resolve GCLP audit observations.
VQA	The Virology Quality Assurance contract (VQA), administered by Duke University, provides proficiency testing services for virological testing.
SMILE	Patient Safety Monitoring in International Laboratories (SMILE) provides proficiency testing services for all other testing mandated by study protocols (e.g. safety and diagnostic tests) at international laboratories. SMILE also helps laboratories resolve observations resulting from the GCLP assessments at international laboratories.

The laboratories that will be used for Network studies will be supported by one or more of the above resources. US clinical laboratories must perform proficiency testing according to CLIA regulations; therefore, proficiency testing is not provided by DAIDS for US clinical laboratories.

Each CRS will soon be contacted by DAIDS and the Network(s) to further discuss the laboratory component of future Network studies, including specimen and data management needs.

DAIDS Regulatory Support Center (RSC)

The DAIDS RSC is a DAIDS contractor responsible for providing day-to-day support to DAIDS and its collaborators for all regulatory activities using the NIAID Clinical Research Management System (NIAID CRMS) at <https://ncrms.niaid.nih.gov>.

The DAIDS RSC works with Clinical Research Sites (CRSs) regularly to:

- Maintain records of site personnel in the NIAID CRMS Master Contact module
- Register to protocols using the NIAID CRMS Protocol Registration System (DPRS)
- Report adverse events using the NIAID CRMS Adverse Event Reporting System (DAERS)

How does the DAIDS RSC interface with sites?

Activity Type	DAIDS RSC Office	DAIDS RSC Office Role	Site Role	Applicable NIAID CRMS Module
Site Personnel	Clinical Study Information Office (CSIO) CSIO@niaid.nih.gov 301-897-7100	Receives and abstracts protocol and/or contact information into the NIAID CRMS for use by DAIDS and its collaborators in support of DAIDS-supported clinical trials	Submits and maintains site personnel information	Site Hub DPRS DAERS
Protocol Registration	Protocol Registration Office (PRO) Protocol@tech-res.com 301-897-1707	Receives and processes protocol registration information from sites such as: <ul style="list-style-type: none"> • Site informed consent forms • IRB/EC approval letters • Form FDA 1572/DAIDS IoR Form • Investigator of Record CVs • Medical license (ML) or equivalent 	Submits protocol registration materials via the DPRS in NIAID CRMS	DPRS
Adverse Event Reporting	Safety Office DAIDSRSCSafetyOffice@tech-res.com 301-897-1709 or 1-800-537-9979	Receives and processes serious adverse events reported by sites participating in DAIDS-supported studies Processes the events for review by the DAIDS Medical Officer Prepares the reports for transmittal to the appropriate regulatory agency (e.g. the US Food and Drug Administration [FDA]), if required	Submits adverse events via the DAERS in NIAID CRMS	DAERS

CRMS Modules can be accessed at <https://ncrms.niaid.nih.gov> once individual access has been obtained.

Visit the DAIDS RSC Website (<https://rsc.niaid.nih.gov/>) for important information about these and other regulatory processes, quick reference guides, web tours, relevant DAIDS procedural manuals, tools, and other useful links to support regulatory activities at your sites.

In addition, please refer to the DAIDS SCORE Manual sections on Introduction to DAIDS Systems, Protocol Registration, and Safety Reporting, for more information on the RSC and regulatory topics. <https://www.niaid.nih.gov/research/daids-score-manual>

DAIDS Protocol Registration Office (PRO)

This section provides general guidance for clinical research sites (CRSs) regarding protocol registration requirements related to the FY 2021 CTU Grant awards.

Below are instructions for each CRS scenario. Links to the protocol registration policy, manual, and training are located at the end of this section.

Known to DAIDS

After receiving the DAIDS' transition letter, an existing CRS should review their current Form FDA 1572s and/or DAIDS IoR Forms to determine if any changes (i.e., the addition or removal of site staff, the addition or removal of a location where research will be conducted, etc.) are required.

If changes are required, a CRS must submit an updated Form FDA 1572 and/or DAIDS IoR Forms to the DAIDS PRO within 30 days of receipt of the DAIDS' transition letter.

New to DAIDS

Once the site activation requirements have been met and the site has received the OCSO site activation email, a new CRS can begin making submissions to the DAIDS Protocol Registration Office (PRO) via DPRS. Upon completion of the DPRS training, site personnel will receive a username and password allowing them to make submissions to the DAIDS PRO. A link to the DPRS training is at the end of this section.

Phase-out CRS

CRSs in phase-out status can remain registered to any ongoing studies where participants are being treated or followed. However, CRSs in phase out status will not be able to register to any new studies without the approval of OCSO. Upon completion of a study, a CRS must submit deregistration materials to the DAIDS PRO and complete the DAIDS' deregistration process. Additional information regarding the DAIDS' deregistration process can be found in the DAIDS Protocol Registration manual in the link below.

Useful links for protocol registration materials and trainings:

- [DAIDS Protocol Registration Manual](#)
- [DAIDS Protocol Registration Policy](#)
- [Form FDA 1572 and DAIDS IoR Form](#)
- [DAIDS Protocol Registration Training and Resources](#)

Should you have any questions or need more information, please contact the DAIDS Protocol Registration Team (PRT) at NIADOPCROPRTeam@niaid.nih.gov

Networks and HANC

For Scenario 1 - Known to DAIDS CRS

For Scenario 2 - New to DAIDS CRS

DAIDS continues to partner with HIV/AIDS Networks in the new grant cycle. The 4 networks include:

- AIDS Clinical Trials Group (ACTG)
- HIV Vaccine Trial Network (HVTN)
- HIV Prevention Trial Network (HPTN)
- International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)

Below you will find links to resources for each network as well as contact information. Please direct any questions about protocol activation or continuation to the network contacts.

Network Protocol Activation Resources		
Network	Resources/Links	Contacts
ACTG	<p>First, request access to ACTG Members Web-site (password required to access other links): https://actgnetwork.org/new-member/</p> <p>Please see links below for information on the indicated topics:</p> <p>General overview: https://actgnetwork.org/leadership-and-organizational-matrix/ https://actgnetwork.org/about-the-actg/</p> <p>ACTG Group Presentation: https://member.mis.s-3.net/cms/res/6163/16689</p> <p>Detailed overview (multiple resources): Leadership and Operations Center (LOC): https://member.mis.s-3.net/cms/res/6163/12359 Performance Evaluation Committee (PEC): https://member.mis.s-3.net/cms/res/6163/16687</p> <p>List of other resources: https://member.mis.s-3.net/cms/res/8875/6168</p> <p>Protocol activation resources: Site Activation Checklist training: https://member.mis.s-3.net/cms/folder/12358 ACTG SOPs: https://member.mis.s-3.net/cms/res/6163/16690</p>	<p>Contact the following individuals at the ACTG for additional information:</p> <p>ACTG Network Coordinating Center - Site Coordination Akbar Shahkolahi ACTGSiteCoordination@DLHCorp.com</p> <p>Initiation of Site Sub-award - ACTG Leadership and Operations Center Alexis Sexton ASexton@mednet.ucla.edu Licet Garcia LicetGarcia@mednet.ucla.edu</p> <p>ACTG Laboratory Center ACTG.LabCenter@FSTRF.org</p> <p>ACTG Data Management Center Frontier Science User Support 716-834-0900 (ext. 7302) user.support@fstrf.org</p> <p>ACTG Training dmc.training@fstrf.org</p> <p>Detailed Contacts list at: https://member.mis.s-3.net/cms/ffile/8875/10423</p>

Resources

Network Protocol Activation Resources		
Network	Resources/Links	Contacts
ACTG continued	<p>Lab Resources: https://member.mis.s-3.net/cms/folder/12361</p> <p>DMC Resources: https://member.mis.s-3.net/cms/folder/12360</p> <p>CAB Resources: https://member.mis.s-3.net/cms/res/6163/16691</p>	
HPTN	<p>The HPTN hosts public study documents on individual study webpages on hptn.org. Private documents are hosted on a Microsoft Team that users can obtain access to by creating a Microsoft account and requesting access from Laura Long.</p> <p>General overview: https://www.hptn.org/about https://www.hptn.org/sites/default/files/inline-files/HPTN%20Fact%20Sheet_June%202020_FINAL.pdf</p> <p>HPTN Manual of Operations https://www.hptn.org/resources/manual-of-operations</p> <p>Protocol Activation Resources: Site selection and activation checklist: https://www.hptn.org/sites/default/files/2019-01/Section%2010%20FINAL%20DEC2018%281%29.pdf</p> <p>Lab resources: http://pathology.jhu.edu/department/divisions/hptn/ https://www.hptn.org/sites/default/files/2019-01/Section%2013%20FINAL%20DEC2018%281%29.pdf</p> <p>DMC Resources: https://www.fredhutch.org/en/research/divisions/vaccine-infectious-disease-division/research/bio-statistics-bioinformatics-and-epidemiology/statistical-center-for-hiv-aids-research-and-prevention.html</p>	<p>Contact the following individuals at the HPTN Leadership and Operations Center for questions:</p> <p>HPTN Leadership Operations Center HPTNLOCMGMT@hptn.org</p> <p>Finance Questions hptninvoice@fhi360.org</p> <p>HPTN Laboratory Center HPTN-LC-QMT@jhmi.edu</p> <p>HPTN Data Management Center Lynda Emel lemel@fredhutch.org</p> <p>HPTN Microsoft Teams Access Laura Long lsmith@fhi360.org</p>

Resources

Network Protocol Activation Resources		
Network	Resources/Links	Contacts
HVTN	<p>The HVTN Clinical Trials Managers will work with new sites to establish access to the HVTN Members Website where all HVTN materials and resources can be found. If sites have questions prior to getting a CTM assignment, please contact the LOC Operations Team Leads.</p> <p>General Overview: http://www.hvtn.org/en/about.html</p> <p>Site Establishment: https://members.hvtn.org/MOP%20Documents/Site%20Establishment.pdf</p> <p>Protocol Registration and Activation Resources: https://members.hvtn.org/MOP%20Documents/Protocol%20Registration%20and%20Activation.pdf</p> <p>Lab resources: https://members.hvtn.org/MOP%20Documents/Composition%20and%20Responsibility%20of%20Laboratory%20Program.pdf</p> <p>DMC resources: https://members.hvtn.org/MOP%20Documents/Composition%20and%20Responsibility%20of%20Statistical%20and%20Data%20Management%20Center.pdf</p> <p>HVTN MOP: https://members.hvtn.org/MOP%20Pages/MOP%20Main.aspx</p>	<p>Contact the following individuals at the HVTN Leadership and Operations Center for questions:</p> <p>HVTN LOC Site Operations Team Leads Niles Eaton and Carissa Karg vtn.core.ctm@hvtn.org</p> <p>HVTN LOC Fiscal Team for Initiation of Site Sub-award Jennie Dodson vtn.fiscal@hvtn.org</p>
IMPAACT	<p>General Overview: https://www.impaactnetwork.org/DocFiles/Index/IMPAACTOverview.pdf https://www.impaactnetwork.org/about-us/</p> <p>Site Selection and Protocol Activation Resources https://www.impaactnetwork.org/DocFiles/MOP/10_SiteSelection.pdf</p> <p>Template Protocol Activation Checklist: https://www.impaactnetwork.org/DocFiles/MOP/Template_IMPAACTXXXX_SiteActivationChecklist_CRSXXX_DDMMYY_28SEP2020.pdf</p>	<p>Contact the following individuals at the IMPAACT Leadership and Operations Center (FHI 360) for questions:</p> <p>IMPAACT Operations Center impaact.operationscenter@fstf.org</p> <p>IMPAACT Laboratory Center impaact.qaqc@fstf.org</p>

Resources

Network Protocol Activation Resources		
Network	Resources/Links	Contacts
IMPAACT continued	<p>Lab resources: University of California, Los Angeles https://www.impaactnetwork.org/about-us/LaboratoryCtr.htm</p> <p>DMC resources: The Harvard School of Public Health https://www.hsph.harvard.edu/cbar/</p> <p>Frontier Science Foundation (FSTRF) https://www.frontierscience.org/index.html</p>	<p>IMPAACT Data Management Center Frontier Science User Support 716-834-0900 (ext. 7302) user.support@fstrf.org</p>

Resources

For Scenario 3 - Phase out CRS

If your CRS is in this scenario, below you will find links to close out resources and contact information for each network. Please direct any questions about network protocol phase out to the network contacts.

Network Close Out Resources		
Network	Resources/Links	Contacts
ACTG	<p>Password is required to access to ACTG Members Website and links below.</p> <p>Network close out activities: https://member.mis.s-3.net/page/1770</p> <p>Lab Resources: https://member.mis.s-3.net/cms/folder/12366</p> <p>DMC Resources: https://member.mis.s-3.net/cms/folder/12365</p>	<p>Contact the following individuals at the ACTG for additional information:</p> <p>ACTG Network Coordinating Center - Site Coordination Akbar Shahkolahi ACTGSiteCoordination@DLHCorp.com</p> <p>Closeout Site Sub-award - ACTG Leadership and Operations Center Alexis Sexton ASexton@mednet.ucla.edu Licet Garcia LicetGarcia@mednet.ucla.edu</p> <p>ACTG Laboratory Center ACTG.LabCenter@FSTRF.org</p> <p>ACTG Data Management Center Frontier Science User Support 716-834-0900 (ext. 7302) user.support@fstrf.org</p> <p>Detailed Contacts list at: https://member.mis.s-3.net/cms/ffile/8875/10423</p>
HPTN	<p>Network close-out activities: https://www.hptn.org/sites/default/files/2019-01/Section%2018%20FINAL%20DEC2018%281%29.pdf</p>	<p>Contact the following individuals at the HPTN Leadership and Operations Center for questions:</p> <p>HPTN Leadership Operations Center HPTNLOCMGMT@hptn.org</p> <p>HPTN Laboratory Center HPTN-LC-QMT@jhmi.edu</p> <p>HPTN Data Management Center Lynda Emel lemel@fredhutch.org</p>

Resources

Network Close Out Resources		
Network	Resources/Links	Contacts
HVTN	Please contact Niles Eaton and Carissa Karg for more information and guidance on site closeout.	<p>Contact the following individuals at the HVTN Leadership and Operations Center for questions:</p> <p>HVTN LOC Site Operations Team Leads Niles Eaton and Carissa Karg vtn.core.ctm@hvtn.org</p>
IMPAACT	<p>Network close out activities: www.impaactnetwork.org/resources/manual-procedures</p> <p>Please contact the IMPAACT Operations Center with any questions about close out.</p>	<p>Contact the following individuals at the IMPAACT Leadership and Operations Center (FHI 360) for questions:</p> <p>IMPAACT Operations Center impaact.operationscenter@fstrf.org</p>
MTN	<p>Network close-out activities: MTN MOP Section 18: https://mtnstopshiv.org/manual-operational-procedures</p>	<p>Contact the following individuals at the MTN Leadership and Operations Center for questions:</p> <p>MTN Regulatory mtnregulatory@mtnstopshiv.org, Copy Cheryl Richards crichards@mwri.magee.edu</p> <p>MTN Laboratory Center mtnnetworklab@mtnstopshiv.org</p> <p>SDMC sc.mtn.sdmc@ssharp.org</p>



An Overview of HANC for Clinical Research Sites

The Office of HIV/AIDS Network Coordination (HANC) works with the NIAID HIV/AIDS clinical trials networks to create a more integrated, collaborative and flexible research structure. Based at the Fred Hutch in Seattle, Washington, USA, HANC has provided leadership and logistical support for cross-network coordination efforts since 2004.

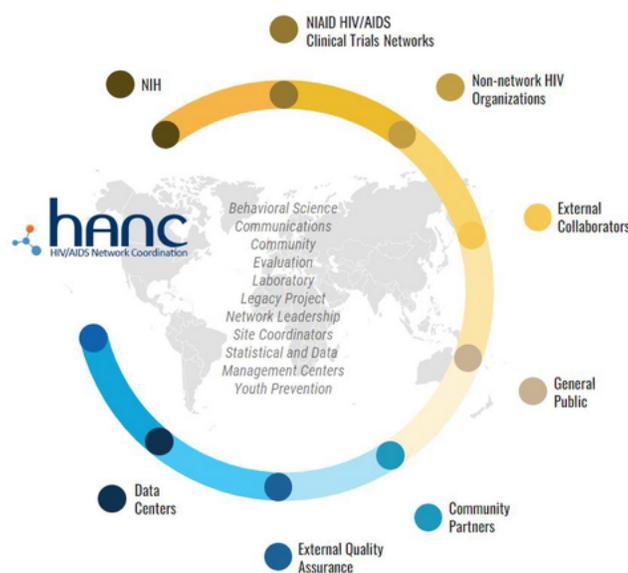


Our Mission

To support the science and operations of the networks by increasing efficiency and resource-sharing through coordination of critical activities across networks and with other research and advocacy partners.

Our Activities

HANC offers training, resources, channels for information sharing, and coordination of cross-network groups that communicate critical information across a number of program areas, including site operations, data management, laboratory, and community.



HANC Partners and Areas of Coordination

+ GENERAL RESOURCES

WEBINARS

HANC host webinars throughout the year, addressing a range of topics including HIV and aging, cure research, undeserved communities, and other hot topics in HIV research. Past webinars are recorded and available in the [webinar library](#) on the HANC website.

TRAINING

Find [training supplements](#) for use by NIAID HIV/AIDS clinical trials network staff and collaborators. Highlights include:

- HIV Research Counseling and Testing (HRCT)
- Women & Biomedical HIV Prevention
- HIV Prevention Research (HPR)

STAY CONNECTED!

Email hancadmin@hanc.info to join the HANC collaborator mailing list and receive monthly HANC newsletters, webinar announcements, and other news.

+ TOPIC-SPECIFIC RESOURCES



Community

COMMUNITY

- Recommendations for Community Involvement in NIAID HIV/AIDS Clinical Trials Networks
- Bill of Rights and Responsibilities
- Flyers explaining Long-Acting Antiretroviral Injectables (LAARVI) and Community Engagement Resources.



Investigators

INVESTIGATORS

- Links for current and future network investigators to scholars programs, data and specimen repositories, and network study proposal pages



Laboratory

LABORATORY

- Cross-Network SOPs including PBMC Processing, Cold Chain Guidelines, Tuberculosis Sourcebook, and Back-Up Lab and Lab Equipment Guidelines
- ACTG/IMPAACT Laboratory Manual, Specimen Shipping Guidelines, and FBS Ordering Procedure.
- CLIA and CAP Certificate Library
- Primary Network Lab Assignments and Network Affiliations



DAIDS

DAIDS

- Memos from the DAIDS Office for Policy in Clinical Research Operations (OPCRO) and Office of Clinical Site Oversight (OCSO)
- OPCRO/OCSO presentation slides and recordings
- OCSO Monitoring Operations Branch (MOB) Newsletters



Data & IT

DATA MANAGEMENT & IT

- IT Best Practices & Standards for DAIDS Sites



Site Management

SITE MANAGEMENT

- NIAID HIV/AIDS Clinical Trials Networks Financial Disclosure and COI Guidelines SOP

+ ADDITIONAL HANC PROGRAMS



The Legacy Project

THE LEGACY PROJECT

- The [Legacy Project](#)'s mission is to build trust and collaboration between historically underrepresented communities most impacted by the U.S. HIV epidemic, researchers, and research institutions; enhance cultural competence; and initiate scientific investigation to increase clinical research participation.



BTG

BE THE GENERATION

- [Be the Generation \(BTG\)](#) promotes community awareness, understanding, and support for HIV prevention research.

DAIDS Community Advisory Board (CAB)

Global (network-level) and local (site-level) Community Advisory Boards are an essential aspect of NIAID's HIV clinical research enterprise. CABs are designed to represent the interests of diverse communities impacted by HIV and give local populations a voice in the research. They help ensure that the research agenda and specific studies reflect the needs of people with HIV, and also help protect the interests of study participants.

CABs advocate for broad inclusion of diverse populations in DAIDS sponsored and/or supported clinical trials, and for innovative approaches to ensure the inclusion of those who are traditionally under-represented in studies. At the network level, the community is involved in developing research plans, setting research priorities and serving on scientific committees and protocol teams. At the site level, community-research partnerships help facilitate an exchange of information to ensure that community opinions and suggestions are discussed and addressed by the research team. Local CAB members may be called upon to articulate community perspectives relevant to protocol design and development, advise on the accrual and retention of participants, and provide input on communications pertaining to research progress and results.

Guidance on effective ways to create and maintain CABs is useful for new and established sites. We strongly encourage that investigators and site staff working with CABs, as well as CAB members themselves, to review the Recommendations for Community Engagement in HIV/AIDS Research and other training tools from DAIDS and the Office of HIV/AIDS Network Coordination. The Recommendations are intended to help research staff and community representatives expand and deepen existing partnerships and forge new ones, with the ultimate goal of facilitating effective community engagement in all aspects of clinical trials research. Good Participatory Practices (GPP) are also essential in working with community stakeholders; optional training and additional materials are available on the AVAC website: <https://www.avac.org/gpp-training-tools>

New Sites / Known to DAIDS Sites

Sites should work closely with their affiliated Network(s) to ensure their local CAB is adequately represented and engaged in the community. Local organizations can help identify individuals who can serve as CAB members, who will in turn help facilitate communications to the broader community and other stakeholders. To support these CAB efforts, site staff and CABs should work together to establish communication pathways, develop a cadence for reoccurring meetings, construct a comprehensive community outreach plan, and identify the roles and responsibilities of the CAB and relevant staff.

DAIDS CAB *continued*

Phase-out Sites

Site closures have a marked impact on communities. Attendance at CAB meetings by Principal Investigators, and/or other key personnel, to discuss plans for site closure and communication with the local community during the phase-out period is essential.

Considerations for Effectively Communicating Site Closure to CAB

Community engagement through the CAB and/or other engagement strategies is required while participants remain on study. If monthly meetings cannot be maintained, bi-monthly or quarterly meetings, and written communications should be considered. Site closure directly impacts study participants as well as the CAB members that have been working closely with the site. Open and ongoing communication between researchers and their CABs around site closure is critical so that there is a clear understanding of what will happen to participants on study and what future research efforts might look like at the sites. Given the importance of community participation to the success of any study, it is strongly recommended that sites remain engaged with their communities even after the transition period. If the site is interested in participating in trials at a later point in time, an informed community will be invaluable, and ongoing communication will help build future community support and trust.

Consider the following during phase-out:

- Socially and culturally appropriate messaging strategies
- Expressions of sincere gratitude for the time, commitment, and energy of participants and CAB members
- Projected timeline for study closeout and CAB closeout and plan for communicating this to stakeholders
- Timelines regarding participant referral/transfer
- Plans to anticipate, monitor and address community concerns related to site closure
- Plan for continuation of CAB meetings and frequency
- Considerations for post phase-out communications with the community regarding study results and/or other communications