*The Division of AIDS (DAIDS) has developed this tool to assist the Networks in collecting key information from site leaders who are requesting to expand site services beyond the Main CRS. The Network staff should carefully review and determine if there is a clear and justifiable need to expand beyond the complete list of fully-funded sites that are currently available to the Network to support the specific study. Once the Network staff has made a determination, please submit the completed and signed application to the OCSO Network Liaison for review and internal processing. The final decision will be communicated to all stakeholders by the OCSO Program Officer responsible for the Main CRS and/or CTU proposing to expand their CRS or location.*

**Please direct any questions for application completion to appropriate DAIDS Network Program Officer and/or OCSO Liaison.**

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| Main CRS Information |
| If the request is to expand services for an existing DAIDS CRS, please provide the following information about the requesting CRS. If the requesting site has not conducted DAIDS Clinical Trials Network research within the last grant cycle, it is considered to be “New-to-DAIDS”. If the site is not affiliated to a CTU or CRS, please skip to Expansion Site Information section below: |

|  |  |  |  |
| --- | --- | --- | --- |
| **Requestor Name** |  | **CTU Name** (if known) |  |
| **CRS Name** |  | **Number** (if known) |  |
| **CRS Leader** |  | **Investigator of Record** |  |
| **Address** |  | **State/Province/Region** |  |
| **Address 2** |  | **ZIP/Postal Code** |  |
| **City** |  | **Country** |  |
| **CRS FWA#** |  | **CRS IRB#** |  |
| **CRS is “New-to-DAIDS”  Yes  No. If no, please list all**  **Current CRS- Network affiliations** | |  | |

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| Expansion Site (ES) Information |

**Please provide information for the proposed Expansion Site (ES). Some information may not be known at the time of application, however please provide as much information as possible to avoid processing delays.**

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| **ES Name** |  | **ES Number (if applicable)** |  |
| **ES Leader** |  | **ES Invest. of Record** |  |
| **Address** |  | **State/Province/Region** |  |
| **Address 2** |  | **ZIP/Postal Code** |  |
| **City** |  | **Country** |  |
| **ES FWA#** |  | **ES IRB#** |  |
| **ES FWA# Expiration** |  | **Distance from Main CRS (if applicable)** |  |  | |
| **Proposed Protocol\***  (incl. sub-studies) |  | **How much time will it take to be ready for protocol implementation?** |  |
| ***\*For networks proposing a package of related studies (e.g. HVTN P5), please list all intended studies for this site.*** | | | |
| |  | | --- | | Expansion Site (ES) Staffing | | | | |
| **Will research staff be permanently assigned to this location? YES  NO** | | | |
| **Will staff other than CRS staff be used for this study? YES  NO  If yes, describe the protocol training plan.** | | | |
| **Will you need staff with special expertise (e.g. Oncology, Cardiology, Behavioral/Social Sciences, etc.) for this protocol? YES  NO  If yes, please describe what staff you need, and how this requirement will be satisfied (e.g. staff already at site, need to hire, special arrangements with institution, etc.).** | | | |
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| |  | | --- | |  | |  | | Procedures | | | | |
| **Please check the protocol-related activities and procedures to be performed at this location:**   |  |  |  | | --- | --- | --- | | **ROUTINE ACTIVITIES AND PROCEDURES** | | **SPECIAL PROCEDURES** | | **Recruitment** | **Physical Exam** | **Lumbar Puncture** | | **Consenting** | **Behavioral / Social Science Survey** | **Leukapheresis** | | **Screening** | **Study Product Given to Participant** | **Plasmapheresis** | | **HIV Testing** | **Counseling** | **Biopsy** | | **Phlebotomy** | **Essential Documents Storage** | **Chemo Administration** | | **Urine Testing** | **CRF Storage** | **IV Infusion** | | **Pregnancy Testing** | **Specimen Storage / Shipment** |  | | **Rapid Laboratory Testing** | **Data Collection / Submission** |  | | **Other (Please specify):** | | **Other (Please Specify):** | | | | |
| |  | | --- | | Facilities and Equipment | |  |  |  |  | | --- | --- | | **Type of Facility (check all that apply):** |  | | **Hospital or Hospital-Based Facility** | **Private Facility** | | **University-Affiliated Facility** | **Non-Governmental Facility (NGO)** | | **General Clinical Research Center / Organization** | **Governmental (MOH) Facility** | | **Medical School Affiliated** | **Other (specify):** | | | | | |

**Will the purchase of special equipment be required for this study (e.g. special infection control rooms, chemotherapy administration facilities)? YES  NO**

**If YES, please describe the additional requirements, cost, and anticipated source of funding.**

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**Will space renovations be required for this study (e.g. special infection control rooms, chemotherapy administration facilities)? YES  NO**

**If YES, please describe the additional requirements, cost, and anticipated source of funding.**

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| Laboratory Information **Specimen Processing and Storage** |

L1. Will any biological specimens be obtained?  YES  NO

*If you answered “No”, please skip the* ***“Laboratory Information”*** *section and proceed to the Pharmacy Information section. Otherwise, proceed with questions below.*

**In locations that cannot be monitored for good clinical laboratory practices (e.g. mobile vans), DCLOT or the network may not approve specimen processing that employs instruments that require calibration and/or validation.**

L2. What type of specimens will be obtained? (e.g. whole blood)

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L3. What kind of specimen processing will be performed? (e.g. PBMC processing, whole blood separation)

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L4. Where will specimen processing be performed? (Please complete for EACH laboratory.)

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| --- | --- | --- | --- |
| **Lab Name** |  |  |  |
| **Main Contact**  **(PI / Lab Director / Lab Mgr)** |  | **LDMS #** (if known) |  |
| **Address** |  | **State/Province/Region** |  |
| **Address 2** |  | **ZIP/Postal Code** |  |
| **City** |  | **Country** |  |

|  |  |
| --- | --- |
|  | This location participates in the IQA- or HVTN-administered cryopreservation Proficiency Testing Program |
|  | Will specimens will also be stored at this location?  YES  NO |

If specimens will not be stored at the above lab location, please indicate the Address, City, State/Province/Region, Country and ZIP/Postal Code of the storage location.

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L4a. What specimens will be stored?

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L4b. In what conditions will specimens be stored? (e.g. room temperature, liquid nitrogen, dry ice)

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L4c. How long will specimens be stored?

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L5. Describe how specimens will be transported (e.g. means of transportation, maintenance of cold-chain when relevant, travel distances, time frames).

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L6. Describe the method for specimen tracking from acquisition, processing, and storage to shipping.

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L7. Do you expect laboratory testing will be done?  YES  NO If yes, please list the expected tests.

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| Pharmacy Information |
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The following information should be completed in collaboration with the primary Pharmacist who will be responsible for day-to-day dispensing and accountability activities and establishing the internal policies and procedures for developing and maintaining a study product management system. If a Pharmacist has not yet been hired, then the CRS Pharmacist of Record should assist with this information.

Each question must be answered as instructed. The answers should NOT reference SOPs or approved Pharmacy Establishment Plan (if applicable) and should address the question directly.

P1. Does this protocol involve study product(s)?  YES  NO

*If you answered “No” please skip the* ***“Pharmacy Information”*** *section. Otherwise, proceed with the questions below.*

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| P2. Is there a DAIDS-PAB approved Pharmacy Establishment Plan for this proposed expansion site?  YES  NO |
|  |  |
| If yes, provide the DAIDS Pharmacy Organization ID. |  |

*If the DAIDS Pharmacy Organization ID is provided, then please skip question P3. Otherwise, proceed with the questions below.*

P3. Describe the pharmacy facility that will be used (either the proposed expansion site  or CRS ), including study product storage areas, computers, and phones. Please include dimensions of the pharmacy.

*A pharmacy floor plan will be helpful. If available, please send electronically with this application.*

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P4. If secure, sufficient pharmacy space is not in place at the pharmacy that will be used (either the proposed expansion site  or CRS ), describe what actions must be done to get the space in order and the timeline to complete these actions.

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P5. For each piece of pharmacy equipment, check all applicable boxes below indicating the equipment is outfitted with the required features.

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| --- | --- | --- | --- | --- | --- | --- |
| **Pharmacy Equipment** | Available?  (Yes or No) | **Equipment Features** | | | | |
| Primary Continuous Temperature Monitoring and Recording Device | Secondary Continuous Temperature Monitoring Device\* | Alarm System (notifies pharmacist immediately) | Back-up Power | Connected to Back Up Power |
| AC | Yes  No |  |  |  |  |  |
| Heater | Yes  No |  |  |  |  |  |
| Refrigerator | Yes  No |  |  |  |  |  |
| -20 Freezer | Yes  No |  |  |  |  |  |
| -70 Freezer | Yes  No |  |  |  |  |  |
| Biological Safety Cabinet/Isolator | Yes  No |  |  |  |  |  |

\*From which daily min/max and real time temperatures are/can be recorded manually.

P6. Verify the equipment listed in question P5 is installed, working properly, and has all the required features for this protocol.

1. If the equipment is not installed, working properly, or is not equipped with/connected to the requested features, outline what is needed and provide a timeline for procuring and installing pending items.
2. Are there funds to purchase equipment if needed?

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**Pharmacy Personnel**

P7. For this protocol, how will the pharmacy activities conducted at the proposed expansion site impact the pharmacy workload being conducted at the main CRS? Will any pharmacists from the main CRS be involved in the pharmacy activities conducted at the location? If so, please describe.

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| P8. How many additional pharmacists are needed to manage the workload for this protocol? |  |

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P9. Please provide the timeline for hiring these pharmacist(s) if applicable:

**Pharmacy Logistics**

P10. If participant-specific study product is to be transported from the pharmacy being used to the proposed expansion site clinic, describe procedures for maintaining integrity of study product until given/administered to study participant.

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P11. Please provide the name and email of the primary pharmacist who will serve as contact regarding any questions.

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| Proposed Expansion Site Leader Signature |
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**The signature below indicates that I have reviewed and agreed with the information above, and that I am interested in pursuing site expansion.**

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| --- | --- |
| **Proposed Expansion Site Leader Signature & Date** |  |

|  |  |
| --- | --- |
| **CTU PI Signature & Date (if applicable)** |  |

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| Network Use Only |

Please provide justification for this proposed site expansion.

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Please describe how the committed funding will be provided for this expansion site. Provide the proposed funding plan and estimated cost to support this expansion site (e.g. CTU to site, Network directly to additional location). Also, please address funding for special equipment and renovations if applicable.

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| Network Signature and Routing Instructions |

*The signatures below certify that we have (check all that apply):*

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| --- | --- |
|  | Evaluated funded sites for this Network. |
|  | Evaluated all DAIDS funded sites. |
|  | Evaluated sites that applied but were not selected for funding. |

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| --- | --- | --- | --- |
| ***Signature of Person Completing on behalf of Network*** |  | ***Signature of Network PI*** |  |

**Once completed, save and send the application and any supporting documentation via email to the corresponding DAIDS OCSO Liaison and the NLG PO.**

|  |  |  |  |
| --- | --- | --- | --- |
| ***DAIDS OCSO Liaison:*** | Enter e-mail address | ***NLG Program Officer:*** | Enter e-mail address |