20 SELECTION OF SITES

20.1 Site Selection Process and Site Selection Questionnaire

20.2 Addition of New Sites to Ongoing Studies
20 SELECTION OF SITES

Once the concept for a new study has been approved by the Executive Committee (EC) and a first draft of the protocol is available, a Site Selection Committee (SSC) will be formed. The SSC will be composed of the following voting members (one vote per group):

- Protocol Chair and if applicable, Co-Chair (if the Protocol Chair or Co-Chair have an affiliation to any proposed site they will abstain from scoring/voting on the site to which they are affiliated)
- Laboratory Center (LC)
- Statistical and Data Management Center (SDMC)
- Leadership and Operations Center (LOC)

Additional individuals, for example, a National Institutes of Health (NIH) representative and/or Office of Clinical Site Oversight (OCSO) representative, will be invited to participate as non-voting discussants. It will be the responsibility of LC, SDMC, LOC and Division of AIDS (DAIDS) to assign representatives best fit the needs of the study.

After the SSC is assembled, an introductory call is held and the LOC Clinical Research Manager (CRM) will chair the call and will explain the process of site selection to the SSC.

20.1 Site Selection Process and Site Selection Questionnaire

Unless otherwise directed by the EC, the SSC will create a questionnaire that will be submitted to all potential Clinical Trials Units (CTUs) and Clinical Research Sites (CRSs) in the HPTN unless the protocol requirements are unique. This may involve a two-step process of soliciting initial information from all sites and then a follow-up questionnaire to those sites that the SSC determines best fit the needs of the study.

The questionnaire will solicit information pertinent to the Clinical Research Site’s (CRS)/CTU’s (hereto referred to as site) ability to execute the protocol, and will vary according to the requirements of the study. However, some topics that might be covered include:

- Prior experience in HIV prevention research
- Population studied and demographics
- Experience working with/recruiting the population sought for the study
- HIV prevalence in the site’s surrounding area
- HIV incidence including annualized incidence overall, incidence during most recent year, and number of seroconversions (if available) during a specified period of time
- Duration of follow-up and loss to follow-up from previous or ongoing studies
- Experience in performing similar clinical studies
- Anticipated ease/difficulty in meeting recruitment/retention targets within the allocated timeframe
- Site capacity including staff experience, workload, education and other studies ongoing or planned at the site that would compete for staff, infrastructure (clinic space, staff and laboratories) and participant population
- Infrastructure for regulatory support
- Internet access, information technology (IT) infrastructure and adherence to IT best practices
- Additional resources (human, clinical and laboratory equipment, etc.) needed to undertake the study as planned
- Experience in collaborating with Community Advisory Boards (CABs) and the community
- Staff experience, workload, education
- Laboratory facilities and expertise
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Selection of Sites

- Location and type of rooms
- Clinical Laboratory Improvement Amendments (CLIA) or the College of American Pathologists (CAP) certification for United States (US) sites
- Participation in DAIDS External Quality Assurance (EQA) for non-US sites
- Proficiency programs
- Laboratory Data Management System (LDMS) capabilities
- Freezer storage capacity
- Shipping capabilities
- Pharmacy facilities and capabilities

- Other study-specific requirements

Prior to distribution of the questionnaire, the SSC will agree upon a set of criteria and scoring process for ranking each site. Here are examples of site selection criteria and scoring process.

The LOC will distribute the questionnaire to the Principal Investigators (PIs) of the CTUs and CRSs affiliated with the HPTN Network. If CRSs attached to the CTUs currently affiliated with the HPTN do not meet the criteria outlined by the team, the questionnaires will be sent in the following order:

- Other DAIDS Network-funded sites
- Sites that were proposed in existing CTUs, but not funded
- “New to DAIDS” sites

A deadline for responding to the questionnaire will be included with this communication. Sites that do not return a questionnaire will not be considered for the study. Sites that submit late questionnaires may be considered for the study at the discretion of the SSC.

The LOC CRM will distribute the sites’ responses to the SSC for review. After an initial review, the SSC will communicate by teleconference or email if additional data or clarification is needed from a site. Requests for additional information will be compiled by the LOC CRM and forwarded to the sites with a deadline for response. The SSC will discuss whether, beyond the content of a questionnaire, a pre-study site visit will be necessary for a potential site in order for the SSC to consider that site for participation in the study (see Section 10.3.2 for details concerning pre-study visits).

Once clarifying explanations have been received from sites and forwarded to the SSC by the LOC CRM, a teleconference or in-person meeting of the SSC (chaired by the LOC CRM) will be held to discuss the sites’ appropriateness for the protocol. The SSC will evaluate each site based upon topics covered in the site selection questionnaire and score each site based on predefined scoring criteria. The SSC will also consider and discuss any additional factors that are relevant to a site’s consideration for the study.

At the end of this meeting, the LOC CRM will summarize the comments made regarding each site and request that the voting entities score/rank assigned categories for each site (i.e., SDMC will rank the data management section, the LC representative will rank the laboratory sections, etc.). The LOC CRM will tally the section scores into one total score for each site. Upon completion, the LOC CRM will send the call summary and complete site rankings to the members of the SSC for review and approval.

Once approved by all members of the SSC, the LOC CRM will send a letter detailing the site rankings, categories discussed and background materials, such as completed questionnaires, to the EC prior to their next meeting. The EC will review and vote on the recommendations. If an NIH institution providing funding for a particular study is not represented on the EC (e.g., NIDA or NIMH), a representative from that funding institution...
will be invited to participate in the EC call and cast a ballot during the voting. The EC will approve the recommendations of the SSC or make suggestions for changes. If the SSC does not agree with the EC’s recommendations, the SSC will have the opportunity to respond to the EC and provide additional justification or documentation for the sites that are not approved by the EC.

After the final list of sites is approved by the EC, the HPTN PI will communicate the selection of sites to NIH in a letter with supporting information regarding approved sites.

All interested sites will be notified by email whether or not they have received approval to participate in the study. For sites that are not selected, the email will provide the reasoning for why others sites were chosen instead.

### 20.2 Addition of New Sites to Ongoing Studies

During the conduct of a study, the protocol team may decide that the addition of a new site or Additional Location (AL) is necessary, in which case, the SSC will follow the procedures described above. When adding a new site or AL, the following DAIDS principles for site expansion must be considered:

- Site expansion must be considered in the context of a specific study
- Evaluation of expansion sites to meet the needs of a specific protocol must emphasize use of existing DAIDS sites as stated above in 20.1:
  - First, evaluate funded sites for the HPTN
  - Then, evaluate all DAIDS Network funded sites
  - Then, evaluate sites that were proposed in existing CTUs, but not funded
  - Lastly, consider "New to DAIDS" sites
- No core funding provided for the expansion sites
- Consider affiliating protocol specific sites with an existing Network CTU where possible and practical
- The network is responsible for coordinating site assessment, development and training activities (see Section 10). DAIDS will partner with the network to support site expansion and facilitate DAIDS approval requirements

If an AL needs to be added to a CTU that is participating in the study, relevant information about the AL will be obtained. The SSC will evaluate each site based upon topics covered in the site selection questionnaire and score each site based on predefined scoring criteria. The decision of the SSC will be communicated to the EC. The HPTN PI will communicate the selection of sites on behalf of the EC to NIH. In addition, a new site (not currently approved HPTN site) will require approval by DAIDS based on the application process through the Network. Refer to OCSO Policy OCS-01: [Clinical Research Site Approval Process for Network Sites](#).