20 SELECTION OF SITES

Based on the design of the study, a site selection process may not be necessary (e.g. a community randomized study). For those studies that do require a selection process, a Site Selection Committee (SSC) will be formed simultaneous to the protocol development process. 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) Deputy Director
- Statistical and Data Management Center (SDMC) Associate Director
- Leadership and Operations Center (LOC) Project Director
- Office of Clinical Site Oversight (OCSO) representative(s)

Additional individuals, for example, a National Institutes of Health (NIH) representatives may be invited to participate as non-voting discussants. It will be the responsibility of LC, SDMC, LOC and Division of AIDS (DAIDS) to assign their respective representatives 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. The SSC will agree upon a set of criteria and scoring process for ranking each site. The HPTN website contains examples of site selection criteria and a scoring process that teams may choose to utilize or alter.

After consultation with HPTN leadership, the LOC will distribute the questionnaire to the Principal Investigators (PIs) of the CTUs and CRSs affiliated with the HPTN Network. Preference should be given to sites in the following order:

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

*Sites that are not fully DAIDS funded are typically expected to complete a DAIDS Site Expansion Information Sheet.

A deadline for responding to the questionnaire will be included with this communication. Sites that submit late questionnaires may be considered for the study at the discretion of the SSC.

At least 2 business days prior to the meeting, 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 inform the HPTN Principal Investigators. Once the CRM has received approval from the HPTN Principal Investigators, a letter detailing the site rankings, categories discussed and background materials such as completed questionnaires, will be sent 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 will be 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.