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20 SELECTION OF SITES

Typically, one of the following two processes are used for Site Selection: 1) Site Selection by Committee; and 2) Site Selection by HPTN Leadership. The HPTN Leadership will ultimately decide which process will be used. The processes are described below and summarized in Figure 20-1.

1) Site Selection by Committee

   Depending on the study, large studies (typically requiring four or more sites) may be subject to the site selection process through a Site Selection Committee (SSC). If this process is used, an SSC will be formed once the concept is approved for protocol development. Typically, the SSC will be composed of a representative from the following entities who will each serve as one voting member (one equal vote per entity - not individual):

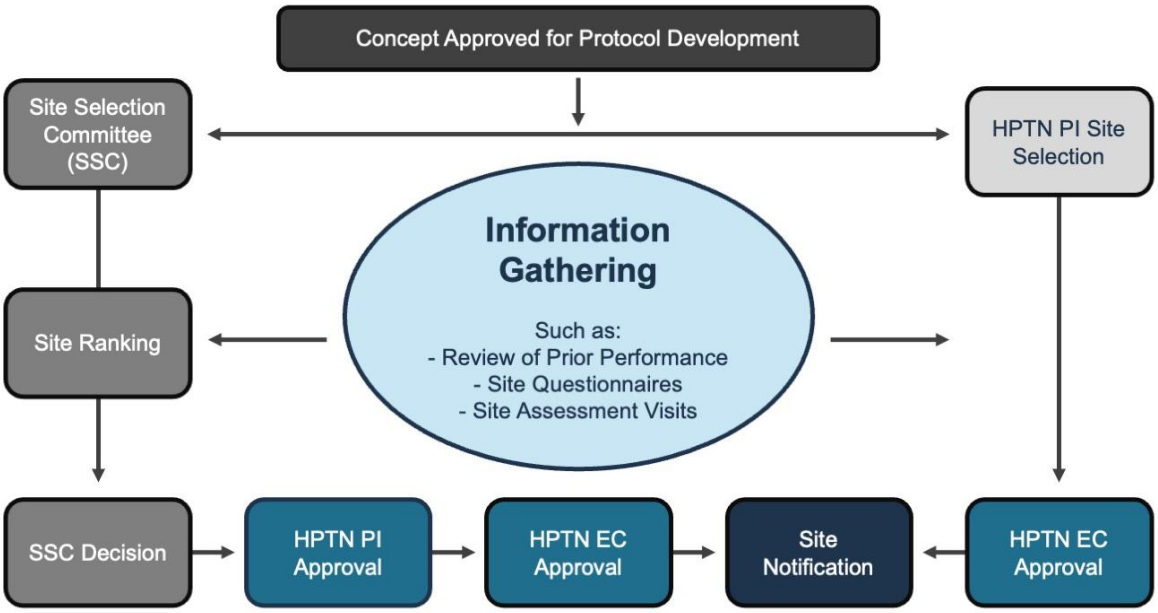
   - Protocol Leadership (Chair or if applicable, Co-Chair, if the Protocol Chair or Co-Chair have an affiliation to any proposed site they will abstain from scoring/voting on the site to which they are affiliated)
   - Laboratory Center (LC) Deputy Director or designee
   - Statistical and Data Management Center (SDMC) Associate Director or designee
   - Leadership and Operations Center (LOC) Project Director or designee
   - Division of AIDS (DAIDS) Office of Clinical Site Oversight (OCSO) representative(s)

   Additional representatives, for example, from other National Institutes of Health (NIH) institutes (if the study is also sponsored by NIDA or NIMH) should be invited to participate as non-voting discussants. It will be the responsibility of the LC, SDMC, LOC and OCSO to assign their respective representatives to the SSC.

2) Site Selection by HPTN Network Principal Investigators

   The process for studies requiring a limited number of sites, early phase studies, studies with fewer number of participants, fast track studies, ancillary studies, and collaborative studies may entail selection of sites by the HPTN Network PIs in consultation with protocol chairs as appropriate. The HPTN Network PIs will select sites for these studies based on study-related and other Network considerations to maximize efficiencies. These decisions may be guided by leadership priorities, funding source, collaboration with other networks, need for accelerated timelines, specific study population or other criteria. The Executive Committee (EC) will review and approve the sites selected by the Network PIs prior to site notification of their selection by the LOC Clinical Research Manager (CRM).

Figure 20-1. Site Selection Processes



Regardless of the process used, the LOC will track and maintain information on the research capacity of HPTN-affiliated sites. Aspects of site capacity that will be tracked include study site facilities and equipment, other on-going research, and access to and size of populations of interest.

Note: If a Protocol Chair is affiliated with a potential site (CTU/CRS), that site is not automatically selected for the study and must be considered as any other site in one of the two processes described above.

20.1 Site Selection by Committee

When site selection by committee is necessary, the SSC will review existing information maintained by the Network about each potential site to first determine a subset of appropriate sites to target for a study within the set of all HPTN-affiliated sites. The LOC CRM will develop a questionnaire with input from the SSC to solicit site interest, as well as obtain any additional information needed about specialized procedures, outreach or practices in the proposed study.

The LOC CRM will facilitate consultation with HPTN leadership regarding the SSC's plan for site selection. After consultation, the LOC CRM will distribute the questionnaire to the Principal Investigators (PIs) of the targeted sites affiliated with the HPTN Network. If additional sites are needed beyond the HPTN Network sites, preference should be given to sites in the following order:

- HPTN protocol-specific sites
- Other DAIDS Network-funded sites
- *Sites that were proposed in existing CTUs, but not funded
- *"New to DAIDS" sites (i.e., sites that have never participated in a DAIDS-funded study)

*Sites that are not fully DAIDS-funded are typically expected to complete the OCSO site activation process (further described in the DAIDS SCORE Manual).

The SSC will agree upon a set of criteria and scoring process for ranking each site. The LOC CRM will facilitate a review and scoring process per the internal LOC standard operating procedure (SOP) on site selection. At the conclusion of this process, the SSC will agree upon the set of proposed sites to bring forward to the HPTN Principal Investigators.

Once agreement has been obtained from the HPTN Principal Investigators, the LOC CRM formally submits the SSC list of proposed sites to the EC for review and approval, along with a summary of the process used to select the sites. 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 vote. 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 LOC CRM will notify all potential sites by email to inform them as to whether or not they have received approval to participate in the study.

20.2 New Sites and Additional Locations 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, either the HPTN Principal Investigators will choose a site or sites, or 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 in priority order as shown below:
    1. HPTN-funded sites
    2. All other DAIDS Network funded sites
    3. Sites that were proposed in existing CTUs, but not funded
    4. "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 via a Proposed Additional Location worksheet provided by DAIDS OCSO (see DAIDS SCORE Manual for additional detail). In addition, a "new to DAIDS site" will require approval by DAIDS via the DAIDS site activation process (see the DAIDS SCORE Manual for additional details).