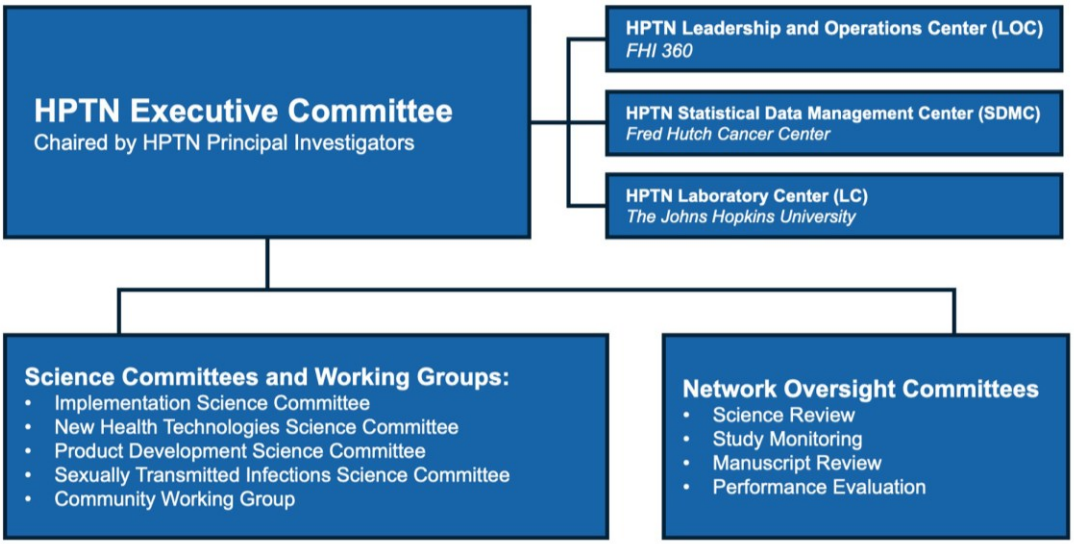
4 HPTN SCIENCE COMMITTEES AND COMMUNITY WORKING GROUPS, NETWORK OVERSIGHT COMMITTEES, AND PROTOCOL TEAMS

Figure 4.1: HPTN Organization Chart



4.1 HPTN Science Committees and Community Working Groups

The HPTN Executive Committee (EC) provides general guidelines for the composition of HPTN Science Committees (SCs) and the Community Working Groups (CWGs). Details are left to the individual groups, and membership of all groups should reflect the various expertise of the Network, including representatives from Central Resources groups, Clinical Trials Units (CTUs)/Clinical Research Sites (CRSs), and community representatives as well as scientists and researchers.

4.1.1 HPTN Science Committees

The HPTN SCs contribute to the development of and guide the scientific agenda of the HPTN. The HPTN SCs are:

- Product Development
- Implementation Science
- New Health Technologies
- Sexually Transmitted Infections

Each HPTN SC is at minimum responsible for:

- Identifying gaps in current HPTN research agenda and identifying emerging scientific ideas worthy of exploration
- Reviewing relevant research concepts submitted to the HPTN for scientific merit, feasibility and alignment with network priorities; prioritizing research concepts and communicating priorities to the HPTN EC
- Seeking collaboration across the HPTN SCs to advance the HPTN research agenda
- Assisting in dissemination of information regarding the HPTN Scientific Research Agenda
- Providing review and approval of scientific deliverables from protocols developed through the HPTN SC, or at the request of the MRC Chair

4.1.1.1 HPTN Science Committee Membership

Each HPTN SC has two Co-Chairs, appointed by the HPTN EC. HPTN SC Co-Chairs are members of the HPTN EC and are expected to attend HPTN EC meetings to represent the HPTN SCs.

The HPTN SC Co-Chairs will determine the composition of the committee within guidelines established by the HPTN EC, and with HPTN EC sign-off. It is recommended that the HPTN SCs have up to seven voting members, inclusive of the Co-Chairs. Non-voting membership in the HPTN SCs includes liaisons to the Central Resources and DAIDS. Some liaison HPTN SC members may serve as voting members, based on expertise.

Should new members need to be added after the committee is initially composed, the HPTN SC Co-Chairs must first consult with HPTN leadership. Upon HPTN leadership approval, the HPTN SC Co-Chairs will reach out to the potential new member on behalf of HPTN leadership.

4.1.2 Community Working Groups

The HPTN Community Working Group (CWG) and protocol-specific CWGs will:

- Integrate participation of people with lived experiences
- Promote understanding of community needs and issues among HPTN researchers and other Network members
- Support collaboration and partnership at the CTU/CRS, and Network levels
- Advise and advocate for Network efforts in research, evaluation, and training addressing community participation at all levels of HPTN research

4.1.2.1 HPTN Community Working Group

At the Network level, the purpose of the HPTN Community Working Group (CWG) is to ensure that the principles of community involvement are the foundation of all community engagement activities at each clinical research site (CRS) and to facilitate community participation throughout the research process (concept development, study implementation, results dissemination, and post-trial access to interventions that are found to be effective).

Members of the HPTN CWG participate in quarterly calls, meetings and workshops, which may be held in person or virtually

The HPTN CWG is responsible for the following:

- Assure that research conducted within the HPTN is done in partnership with trial site communities and integrates community perspectives
- Increase HPTN researchers understanding and appreciation of the social context of participants in HIV prevention research
- Provide input in the science generation process

4.1.2.1.1 HPTN Community Working Group Membership

The HPTN CWG Chair and Co-Chair are selected by the HPTN CWG, appointed by HPTN leadership, and serve a minimum three-year term, renewable at the discretion of HPTN leadership. The CRS Leader or designee appoints a Community Educator (CE) to serve on the HPTN CWG and the local Community Advisory Board (CAB) will elect the CAB member to serve on the HPTN CWG.

HPTN CWG members who serve on internal and external research teams are selected by the HPTN CWG and appointed by the HPTN CWG Chair and Co-Chair. The HPTN CWG Chair and Co-Chair and HPTN Community Engagement Program staff determine the composition of the HPTN CWG within guidelines established by HPTN leadership. This includes members both internal and external to the HPTN.

Voting Members**:**

- HPTN CWG Chair and Co-Chair (one US-based and one non-US-based)
- Representatives from CAB members and Community Educator (CE) from HPTN Clinical Research Site (CRS)

Non-Voting Members**:**

- HPTN Leadership and Operations Center (LOC) Community Engagement staff
- HPTN Principal Investigators (as needed)
- Division of AIDS (NIAID/NIH) representative
- Ad-hoc external scientific advisors and advocacy representatives

4.1.2.2 Protocol-Specific Community Working Groups

At the study level, protocol-specific CWGs are established for some HPTN studies and are comprised of CWG members from the CRSs conducting the study. Protocol-specific CWG meetings (in-person or virtual) take place on a routine basis. Participation in protocol team and other network committee meetings occur as appropriate.

Protocol-specific CWGs are responsible for the following:

- Provide input into protocol development, adapting sample consent forms for local use and developing other study-related materials
- Participate in protocol-specific training and regional workshops
- Help to inform strategies for recruitment, retention, and product adherence Assist in monitoring any emerging issues in the community
- Facilitate the accurate and appropriate dissemination of study results to the community

4.1.2.2.1 Protocol-Specific Community Working Group Membership

Voting Members:

- HPTN CWG Chair and/or Co-Chair
- One person with lived experience relative to the protocol
- Representative from CRS (number of sites will determine max number for this role)

Non-Voting Members**:**

- Protocol assigned HPTN LOC Community Engagement staff
- Ad-hoc external scientific advisors and advocacy representatives as needed

4.1.2.3 HPTN Community Working Group Steering Committee

The HPTN CWG Steering Committee provides guidance and support to the HPTN CWG and advises HPTN Leadership on matters concerning community engagement in all aspects of the HPTN research agenda. The HPTN CWG Steering Committee serves as a liaison between the HPTN CWG and HPTN leadership. HPTN CWG Steering Committee members participate in routine meetings (in-person and virtual).

The HPTN CWG Steering Committee goals are to:

- Inform, facilitate and guide the development of a community-centered, relevant, effective and ethical research agenda
- Proactively identify challenges related to community engagement and/or research implementation to ensure the ethical and scientific rigor of HPTN research
- Inform the HPTN EC of the HPTN CWG's decisions, concerns and activities
- Advise the HPTN EC on strategies to address community related challenges and issues of concern
- Develop mechanisms for sharing experiences, lessons learned and best practices for community engagement in HPTN research

4.1.2.3.1 HPTN CWG Steering Committee Membership

Voting Members:

- HPTN CWG Chair and Co-Chair
- HPTN Performance Evaluation Committee CWG Representative
- HPTN Science Review Committee CWG Representative
- HANC Community Partners CWG Representatives.

Non-Voting Members:

- One member of the LOC community program
- DAIDS representative

4.2 Network Oversight Committees

The HPTN EC Chair recommends, and the HPTN EC approves, the Chair(s) and membership of the Network Oversight Committees. Committee members serve for the duration of the cooperative agreement, and Chairs serve three-year terms unless otherwise specified. Terms of committee Chairs may be extended with the approval of the HPTN EC Chair.

The five key HPTN Oversight and Operations Committees include:

- Science Review Committee (SRC)
- Study Monitoring Committee (SMC)
- Manuscript Review Committee (MRC)
- Performance Evaluation Committee (PEC)
- Policy and Procedures Group (PPG)

4.2.1 Science Review Committee

The SRC ensures that study protocols are scientifically rigorous, accurate, consistent, complete and standardized to the extent possible relative to other HPTN protocols. The SRC also reviews the protocol for operational feasibility, focusing on key issues such as site participation, infrastructure and capacity, relevance to the community and any ethical concerns.

4.2.1.1 Science Review Committee Membership

The SRC membership for each protocol is composed of appointed and *ad hoc* members and includes representatives of relevant disciplines including, at a minimum, prevention science, biostatistics, and clinical trial operations. Membership of the SRC, as proposed by the protocol team, is approved by the SRC Chair and is comprised of individuals who are not directly involved with the protocol.

Voting Members/SRC conference call participants:

- SRC Chair (the HPTN Principal Investigator [PI] acts as designee in case of conflict of interest)
- SDMC Statistician (PI or designee)
- NIH Representative
- Ad hoc Scientific Reviewer (one or more voluntary experts knowledgeable in the research area)

Contributing non-voting reviewers from:

- HPTN LOC
- SDMC Operations
- LC
- CTU/CRS Investigator
- Site Coordinator
- HPTN CWG

Note: The SRC may be observed by HPTN leadership.

The SRC convenes as needed. The SRC reviews are conducted via conference call with the voting members and the HPTN CRM for the study.

As noted above, voting members are not directly involved with the protocol under discussion. If a voting member does have a conflict of interest with the protocol under consideration (e.g., is a protocol team member), they are recused and a designee votes in the member's place.

Ad hoc members may include:

- Representatives (ex officio) from NIH institutes
- One or two research area experts external to the HPTN

Once an SRC is constituted for a protocol review, every attempt is made to maintain the same composition should the protocol need to be resubmitted for review.

A written review is provided to the team within 5 working days following the review. Refer to Section 9.2.2.1 for more details.

4.2.1.2 HVTN/HPTN Joint Science Review Committee

For concepts or protocols jointly led between the HVTN and the HPTN, the HVTN/HPTN Joint Science Review Committee (JSRC) ensures that the concepts or protocols have scientific merit, high public health impact, are scientifically rigorous, accurate, consistent, and standardized to the extent possible relative to other joint network protocols. As much as feasible, the majority of the protocol text for joint protocols are derived from the HVTN/HPTN mAb template for cross-protocol consistency and comparability.

Membership

The JSRC membership is a standing committee including representatives from both networks based on the positions below. Currently, the HPTN and the HVTN Laboratory Scientists who are voting members of the committee serve as the JSRC co-chairs.

- JSRC Voting Members
- HPTN and HVTN Network PIs
- HPTN and HVTN Laboratory Scientists
- HPTN and HVTN Statisticians
- HPTN and HVTN Clinical Scientists
- HPTN and HVTN Community Representatives
- NIH Representatives

JSRC Observers

- Network LOC Directors
- NIH/DAIDS Medical Officers
- Protocol Operation Teams (Protocol Team Leads, Clinical Research Managers/Clinical Trials Managers, Clinical Trials Assistants)

It is strongly encouraged that individuals who have primary conflicts (e.g., are active members of the study team) find alternative representatives to serve on the JSRC as a voting member.

Additional observers should be added as needed per protocol.

The JSRC convenes as needed and reviews are conducted via conference call with the voting members and observers.

4.2.2 Study Monitoring Committee

The Study Monitoring Committee (SMC) is assigned by the HPTN EC to oversee how HPTN studies are conducted. Most active studies are reviewed by an SMC while they are underway. Within a month after the first participant is enrolled, the SDMC Principal Investigator (PI), working with HPTN leadership, decides whether an SMC review is needed and how often it should happen. For studies expected to finish in less than a year, the HPTN EC may choose to skip SMC review.

For studies under a Data Safety Monitoring Board (DSMB), an SMC is not required. For trials without a DSMB, an SMC is required; exceptional circumstances will be discussed by HPTN leadership.

SMC reviews have two parts:

- **Open Session**: The SMC looks at how the study is being run — including participant enrollment and retention, how well the intervention is being followed, whether key data are being collected, and other performance measures. If the study uses an FDA-approved drug, safety data (summarized by site) may also be reviewed here.
- **Closed Session**: The SMC reviews safety data for investigational drugs (INDs), as well as endpoint rates, grouped by study arm. The DAIDS Medical Officer, SMC Chair, and Protocol Chairs together decide how often the safety data reviews should occur.

4.2.2.1 Study Monitoring Committee Membership

The PI (or designee) of each of the Central Resource components (HPTN LOC, SDMC, and LC) and the DAIDS PSP Chief (or designee) are standing members of the SMC. The HPTN LOC works with the SDMC, LC, DAIDS Medical Officer(s) and Protocol Chairs to determine the composition of the SMC for each protocol.

Voting members must not be directly involved with the protocol under review. If a voting member has a conflict of interest with the protocol under consideration (e.g., is a protocol team member), a designee must be appointed to participate in their place.

Voting Members:

- SMC Chair (a Senior Statistician from the SDMC)
- HPTN LOC Representative (PI or designee)
- LC Representative (PI or designee)
- SDMC Statistician
- One or two *ad hoc* members
- One or two experts (internal or external to HPTN) with relevant subject matter expertise, who are not affiliated with the study, have no conflict of interest. If the SMC will review safety data, at least one *ad hoc* member must be a physician.
- PSP Chief or Designee

Observers (Open session):

- Protocol Chairs
- HPTN PIs
- DAIDS Medical Officer
- DAIDS PAB Pharmacist
- LC Deputy Director or Designee
- LC QA/QC Coordinator
- SDMC Director and/or Senior Clinical Data Manager (SDMM)
- SDMC SMC report team (statisticians, statistical programmers and CDM)
- HPTN LOC Director
- HPTN LOC CRM and CTA
- HPTN Pharmacist, as applicable
- Representative(s) from other collaborating NIH institutes
- Representatives from study partner organizations

A schedule of routine SMC reviews (based on the phase and need of the study) should be established in advance to maximize availability of voting members for initial and subsequent reviews. However, members may appoint designees from their organizations, as needed, to ensure a quorum for each review. A SMC quorum consists of the SMC Chair and at least three (3) other members. A SMC review call can only be scheduled if this minimum requirement is met. In exceptional situations, the SMC Chair may convene a call without the required quorum, or request that a review be carried out in their absence and identify a designee to serve as SMC Chair in their stead.

Once a SMC is constituted for a study, every attempt is made to maintain the same membership throughout the study. Each study will develop a study-specific charter that outlines the SMC membership, roles and responsibilities and review procedures, including SMC review frequency.

4.2.3 Manuscript Review Committee

The primary responsibility of the MRC is to ensure that abstracts, presentations, and manuscripts that contain data or statistically related content from HPTN studies are developed, reviewed and endorsed, according to the HPTN Publications Policy (Section 21) prior to submission for publication. Reviews are conducted mainly via email with written feedback provided to the submitting author(s).

4.2.3.1 Manuscript Review Committee Membership

Members of the MRC include:

- MRC chair(s)
- SDMC PI
- LOC representative
- Science reviewers
- LC representative

Further details of the MRC review process are found in the HPTN Publications Policy (Section 21).

4.2.4 Performance Evaluation Committee

The PEC is responsible for overseeing a comprehensive evaluation of clinical research sites conducting HPTN studies (see Section 19 for more information about Network Evaluation).

The primary purpose of the evaluation is to provide data to determine if the sites are contributing effectively to the protocols that they have undertaken and to elicit corrective action, if necessary, so that all sites are functioning at peak performance level.

4.2.4.1 Performance Evaluation Committee Membership

Members of the PEC include:

- PEC Chair
- SDMC Associate Director
- LC representative
- HPTN LOC representative
- HPTN LOC Evaluation Coordinator
- CTU/CRS PI
- CTU/CRS Study Coordinator

- HPTN LOC Community Program representative
- DAIDS/PSP representatives
- Community representative

An HPTN LOC staff member serves as the Evaluation Coordinator and is responsible for compilation, production, and distribution of evaluation results as well as facilitation of the work of the PEC.

The PEC convenes by conference call as necessary. A quantitative evaluation report is produced annually and is submitted to the HPTN PIs for review and then the final version is submitted to NIAID.

4.2.5 Policy and Procedures Group

The Policies and Procedures Group (PPG) is an operations committee tasked with developing and maintaining the HPTN Manual of Procedures (MOP). The MOP is typically reviewed on an annual basis and revised as necessary.

4.2.5.1 Policy and Procedures Group Membership

Members of the PPG include representatives from the HPTN LOC, SDMC, LC, and DAIDS.

4.3 Protocol Teams

Protocol teams assume primary responsibility for scientific and operational leadership in the development, implementation, and day-to-day oversight of HPTN studies and dissemination of their results.

4.3.1 Protocol Team Membership

The Protocol Chairs identify protocol team members except for those positions assigned by the HPTN LOC, SDMC, LC, and NIH. Membership of each protocol team will vary according to the protocol, but membership should include:

- Protocol Chairs
- CTU PI, CRS Leader, or a designated investigator from a participating CTU/CRS
- Community representative(s) (sites)
- HPTN LOC Community Engagement Program representative(s)
- HPTN LOC CRM
- SDMC lead statistician
- SDMC lead CDM
- LC QA/QC Coordinator (protocol specialist)
- LC Investigator
- DAIDS Medical Officer
- DAIDS PAB Pharmacist (if applicable)
- HPTN Pharmacist (if applicable, see Section 23)
- NIAID collaborating institute representative (if applicable)
- Pharmaceutical or industry representative (if applicable)

Additional members, as required for a specific protocol, may include a pharmacologist, virologist, behavioral scientist, immunologist, etc.

4.3.2 Protocol Chair Selection

Scientific priorities are decided by the HPTN EC. Concepts addressing these priorities are either generated centrally by the HPTN leadership or by investigators and HPTN SCs (see Section 9.1.1). For the concepts developed centrally, the Protocol Chairs for approved concept are selected by soliciting nominations for this leadership position. For the concepts developed by investigators or by the HPTN SCs, the concept teams can nominate the Protocol Chairs. Nomination and selection as a Protocol Chair does not imply that the affiliated site (if any) will be selected for the study. Final approval of Protocol Chairs is made by HPTN EC.

4.3.3 Protocol Chair Responsibilities

The Protocol Chairs will provide scientific leadership during the development, implementation, and reporting of the study and will assume responsibility for completion of protocol team responsibilities within the projected budget and timeline. In some instances, studies will identify a co-chair to whom the chair may delegate some specific areas of responsibility, but the ultimate responsibility for execution of the study and final decision-making authority rests with the designated chair.

Because of the time commitments necessary to successfully implement and oversee a protocol, **investigators cannot simultaneously chair or co-chair more than two HPTN studies**.

Protocol Chairs will need to familiarize themselves with the HPTN processes and adhere to them. First time Protocol Chairs will be subject to specific training in Network processes and Protocol Chair responsibilities as outlined in Section 11. An agreement outlining responsibilities will be provided to Protocol Chairs for their review and signature.

Protocol team business is planned and managed by the Protocol Chairs, in consultation with the HPTN CRM and other core team members. Specifics of protocol team management vary according to the type of study (Phase I, II, III, research area, etc.), the number and location of sites involved, and individual leadership and management approaches.

In addition to duties as a protocol team member, the Protocol Chairs are responsible for:

- Providing overall leadership to ensure that the protocol adheres to the projected budget and is completed by the projected timeline
- Working with the Central Resource partners, to provide detailed projections to the HPTN Leadership of the resources required to conduct the study, including site-specific study costs as well as costs associated with study drug and any potential outside contractors or vendors, where applicable
- Facilitating final decision making within the protocol team to achieve agreement on scientific or operational issues brought before it, including reviewing and approval of secondary objectives; if agreement cannot be reached, referring the issue to the SC for consideration
- Participating as a member of the Clinical Management Committee
- Together with the lead protocol statistician, reporting on the status of the study at open sessions of the DSMB
- Coordinating the establishment and dissolution of protocol-specific working groups as necessary to achieve efficiency in the development, implementation, and reporting of the study

- Overseeing the establishment of writing teams during manuscript preparation (designates writing team members, reviews schedules, monitors progress, helps prioritize analysis, communicates publication plans, responds to the MRC review, and advocates for additional resources as required)
- Ensuring review and approval of all manuscripts, abstracts and presentations related to study endpoints.
- Providing status updates to HPTN leadership, as needed

The Protocol Chairs will act as a liaison between the team and the:

- HPTN SC, HPTN EC, and its standing committees with responsibilities for protocol oversight (SRC, SMC, MRC, and PEC)
- HPTN LOC and DAIDS to facilitate development, review, approval, and implementation of the protocol in accordance with all applicable clinical trials requirements with available resources
- LC in the development of the protocol design and its implementation, particularly regarding assay evaluation, protocol training and testing as needed, development and review of study-specific laboratory procedures, and establishment of quality assurance guidelines
- SDMC in the design, development, implementation, and reporting of the study

In addition, the Protocol Chairs and team have the responsibilities outlined in the next section.

4.3.4 Protocol Team Responsibilities

The HPTN CRM provides technical and operational input throughout the process. Although individual protocol team members have different roles in fulfilling specific protocol team responsibilities (see table below), all members are expected to provide scientific, operational, or site-specific input, as appropriate, to protocol team activities.

Protocol team responsibilities include:

Roles of Key Protocol Team Members	
Team Member	**Primary Roles and Responsibilities**
Protocol Chairs (see Section 4.4.3 for further details of Protocol Chair responsibilities)	▪ Provide leadership in development of the protocol including judicious inclusion of the primary and secondary objectives, and tertiary and exploratory objectives if funding allows • Ensure that the protocol adheres to the projected budget and is completed by the projected timeline • Lead protocol team meetings and calls • Lead protocol development with HPTN LOC representative • Establish subcommittees and working groups of protocol team to complete specific activities, as needed • Monitor study implementation across sites • Participate in SMC and DSMB meetings, if applicable • Develop plan for and lead writing of manuscripts and dissemination of study results
Site Investigators (see Section 3.4.1.3 for further details of Site Investigator responsibilities)	• Provide site-informed input into protocol development • Provide detailed site estimates of costs for study implementation • Submit protocol and other required study documents to Institution Review Boards (IRBs)/Ethics Committees and relevant regulatory authorities, if necessary • Review and comment on all SSP manuals and data collection forms • Manage study implementation at sites • Participate in manuscript development
Community Representative(s)	• Provide perspective of community and potential participants; facilitate communication with site CAB: - during development of protocol and informed consent - during study conduct, bringing community concerns and issues to the attention of the protocol team - during manuscript development • Work with protocol team and CABs to develop and implement plans for dissemination of study results to the community, as needed

Roles of Key Protocol Team Members	
Team Member	**Primary Roles and Responsibilities**
HPTN CRM (see Section 3.1.1 for further details of LOC responsibilities)	• With Protocol Chairs, provide scientific and operational input to the protocol, coordinate and lead development of protocol • Organize protocol team conference calls and meetings and document key decisions after protocol is approved by SRC • Review study budget with sites and HPTN LOC financial staff • Submit protocol for required HPTN and DAIDS reviews (SRC, PSRC, Regulatory, Medical Officer) and manage response/revision process • Develop and produce SSP manuals with input from SDMC, LC, and other team members • Provide onsite study-specific training with SDMC and LC counterparts and coordinate development of training plan and materials to provide onsite training, as needed • Provide technical assistance and oversight to CTUs/CRSs during study conduct, enabling the sites to respond to problems and issues that arise during implementation of studies and dissemination of findings • Track site progress on activation requirements and review related Standard Operating Procedures (SOPs) • Assess the performance of CTUs/CRSs and report results, in conjunction with the SDMC, to the HPTN EC, PEC, and DAIDS • Summarize SRC and SMC reviews and distribute as appropriate • Collaborate with DAIDS Pharmaceutical Affairs Branch (PAB), HPTN Pharmacist (if applicable), and the pharmaceutical companies to meet study product supply needs • Collaborate with SDMC to develop Case Report Forms (CRFs) and test them in the field before implementation • Collaborate with LC to enable CTUs/CRSs to meet applicable laboratory proficiency standards
SDMC Lead Statistician (see Section 3.2.1 for further details of SDMC responsibilities)	• Provide design, statistical and scientific input during protocol development and throughout the conduct of the study • Develop statistical components of the protocol • Develop Statistical Analysis Plan (SAP) • Develop randomization and treatment allocation scheme, if needed • Conduct data analyses and generate SMC and DSMB reports • Provide internally reviewed analysis reports for primary and secondary objectives • Participate in manuscript preparation

Roles of Key Protocol Team Members	
Team Member	**Primary Roles and Responsibilities**
SDMC Lead CDM	• Collaborate in development of protocol • Lead and collaborate in development and production of the data-related SSP manual • Lead the development of data collection instruments (e.g., CRFs, computer-based questionnaires) and instructions • Collaborate with CRM on review of site SOPs related to data management and randomization prior to activation • Collaborate with CRM and DAIDS PAB Pharmacist and/or HPTN Pharmacist (if applicable) on study product distribution as it relates to randomization and data collection • Conduct data management and data collection instrument (e.g., CRF) training at sites • Develop plan for and provide regular reports to protocol team and CTUs/CRSs (enrollment, retention, adherence, specimen storage, data management quality) • Coordinate development and production of SMC and DSMB reports • Provide support for data collection and management • Collaborate with CRM to provide support for operational matters that may influence study data • Assess the data management quality of CTUs/CRSs and report results to protocol team • Conduct data management site visits as needed • Collaborate with LC on quality assurance testing of specimens • Facilitate closeout of data collection and cleaning

Roles of Key Protocol Team Members	
Team Member	**Primary Roles and Responsibilities**
LC QA/QC Coordinator (protocol specialist) (see Section 3.3.2 for further details of LC responsibilities)	• Provide scientific input during protocol development, including drafting laboratory related study objectives and the design of sub-studies, as applicable • Provide input on laboratory-related issues of the protocol and direct development of the laboratory section of the protocol • Define appropriate laboratory testing methods and materials and sub-studies, as necessary • Lead and collaborate in development and production of the Laboratory Manual • Provide training for CTU/CRS laboratories in protocol- specified laboratory tests, as needed • Coordinate and perform (as applicable) protocol-specified laboratory testing • Monitor technical quality of protocol test results; provide assistance to local laboratories, as needed • Provide laboratory expertise in eCRF development • Provide support to the study team as laboratory issues arise during implementation of the protocol • Ensure regulatory compliance for LC activities related for IND-enabling studies • Participate in manuscript development
LC Investigator	• Provide scientific input during protocol development, including drafting laboratory related study objectives and the design of sub-studies, as applicable • Provide input on laboratory-related issues of the protocol and direct development of the laboratory section of the protocol • Define appropriate laboratory testing methods and materials and sub-studies, as necessary • Monitor technical quality of specialized protocol test results • Provide assistance to local laboratories, as needed, for specialized tests • Participate in manuscript development • Draft manuscripts for laboratory related aspects of study protocols, as applicable
DAIDS Medical Officer	• Participate in protocol team discussions and decisions • Facilitate communication between protocol team and DAIDS groups and staff • Provide timely Medical Officer review • Provide oversight of safety monitoring

Roles of Key Protocol Team Members	
Team Member	**Primary Roles and Responsibilities**
DAIDS PAB Pharmacist (For HPTN Pharmacist role see Section 23)	• Provide expertise on all pharmaceutical and study product-related aspects of protocol development and conduct • Develop the study product/pharmacy section of the protocol and Pharmacy Study-Specific Procedure (SSP) Manual for each study • Coordinate and oversee the supply, management, and distribution of study products for DAIDS-sponsored studies • Collaborate with pharmaceutical companies and other external partners to ensure study product supply • Conduct protocol-specific training for CRS and pharmacy staff • Provide support to the protocol team and sites on protocol-specific pharmacy-related issues

4.3.5 Relationship of HPTN Executive Committee and Protocol Team

The HPTN EC monitors each HPTN protocol team with regards to protocol development, implementation, analysis, and reporting. This oversight is accomplished through the HPTNSC, SMC, PEC, and MRC by a mixture of formal review of key documents produced by the protocol teams (study protocol, protocol summaries, open reports to the DSMB, and primary and secondary manuscripts) as well as review of reports prepared by the HPTN SC, SDMC, PEC, and LOC.

In addition to oversight provided by the SMC or DSMB and the standing and *ad hoc* committees, routine EC oversight includes:

- Evaluation of study progress in relation to key implementation benchmarks established by the PEC and information from the protocol teams and SDMC (e.g., timeliness of enrollment and follow-up targets, routine reports to the DSMB, and progress in data analysis and reporting). The HPTN EC identifies and communicates recommended actions on delayed protocols and unexpected problems in protocol implementation
- Assistance to DAIDS in determining the need for additional resources, for example, because of unexpected costs associated with planned study procedures or in order to support ancillary studies endorsed by the protocol teams
- Adjudication of conflicts that cannot be resolved within the protocol teams and/or the relevant SC. If all reasonable attempts to adjudicate conflicts or address problems with the protocol team and the SC fail, the HPTN EC may direct that the protocol team membership or its leadership be modified

4.3.6 Conflict Resolution

Conflicts within the HPTN are handled by referring the issue in dispute to the next level of the HPTN organizational structure.

4.3.6.1 Conflicts within Protocol Teams

- If a conflict arises within a protocol team and cannot be resolved between the members involved, the issue is referred to the Protocol Chairs
- If the issue cannot be resolved, it is referred to HPTN Leadership

4.3.6.2 Conflicts between HPTN Investigators and HPTN Committees

If an HPTN investigator is not satisfied with a decision of an HPTN committee (SRC, SMC) or a finding of the PEC, and the issue cannot be resolved through discussion and negotiation with the chair of that committee, the investigator or the committee chair may refer the issue to the HPTN EC.