



Protocol Team Fact Sheet

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

Membership

The Scientific Committee (SC) Chair designates the Protocol Team Chair, who then identifies protocol team members except for those positions assigned by the Coordinating and Operations Center (CORE), SDMC, Network Lab (NL), and National Institutes of Health (NIH). Membership of each protocol team will vary according to the protocol, but membership should include:

- Protocol Team Chair
- Principal Investigator (PI) or a designated investigator from each participating Clinical Trial Unit (CTU)
- Community Representative(s)
- CORE Clinical Research Manager (CRM)/Prevention Specialist (PS)
- SDMC Lead Statistician
- SDMC Project Manager (PM)
- Network Lab (NL) QAC
- Division of AIDS (DAIDS) Medical and/or Program Officer
- NIAID collaborating institute representative (if applicable)
- DAIDS Pharmacist (if applicable)
- Pharmaceutical or industry representative (if applicable)
- Ethics Working Group (EWG) representative

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

Protocol Team Responsibilities

The Protocol Team Chair will provide scientific leadership during the development, implementation, and reporting of the study and will assume responsibility for completion of protocol team responsibilities. The CORE CRM/PS provides technical and administrative support throughout the process. Although individual protocol team members have different roles in fulfilling specific protocol team responsibilities, all members are expected to provide scientific, operational, or site-specific input, as appropriate, to protocol team activities. Protocol team responsibilities include:

- Developing the study concept plan and protocol, including responding to requests made by the SRC and DAIDS Prevention Science Review Committee (PSRC) for revisions in the draft protocol
- Soliciting community input during protocol development and review
- Providing detailed estimates of the resources required to conduct the study, including site-specific study costs and requirements for NL and SDMC resources to the HPTN Leadership, as requested
- Developing data collection instruments and instructions for the completion of these instruments, with the SDMC
- Developing the study-specific procedures (SSP) manual, with the CORE

- Defining, in collaboration with CORE, SDMC and NL, protocol milestones for monitoring performance
- Overseeing accrual and retention of study participants and management of these individuals as specified in the protocol
- Monitoring participant safety
- Conducting ancillary study review and, when necessary, advocating for additional resources
- Monitoring conduct of the study through reports produced by the SDMC concerning screening, recruitment, retention, data management quality, adherence to intervention, endpoint assessment completion, and safety
- Developing and carrying out corrective action plans for problems with study implementation
- Overseeing study conduct and implementation, including compliance with all applicable standards and requirements
- Producing scientific publications and making presentations related to study findings in a timely manner

Protocol team business is planned and managed by the Protocol Team Chair, in consultation and with the support of the CORE CRM/PS 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.

Roles of Key Protocol Team Members

Protocol Team Chair

- Lead protocol team meetings and calls
- Lead protocol development
- Establish subcommittees and working groups of protocol team to complete specific activities, as needed
- Monitor study implementation across sites
- Participate in DSMB meetings, if applicable
- Develop plan for and lead writing of manuscripts and dissemination of study results

Site Investigators

- 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/Ethics Committees (IRB/ECs)
- Review and comment on study-specific procedures (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 Community Advisory Board (CAB):
 - During development of protocol and informed consent
 - During study conduct, bringing community concerns and issues to the attention of the protocol team
- Work with protocol team and CABs to develop and implement plans for dissemination of study results to the community, as needed

CORE CRS/ PS

- With Protocol Chair, provide scientific and operational input to the protocol, coordinate and lead development of protocol
- Organize and document protocol team conference calls and meetings
- Review study budget with sites and CORE financial staff
- Submit protocol for required HPTN and DAIDS reviews (SRC, PSRC, Regulatory, Medical Officer) and manage response/revision process
- Develop and produce study specific procedures (SSP) manual with input from SDMC, NL and other team members
- Provide onsite study-specific training with SDMC and NL counterparts and coordinate development of training plan and materials to provide onsite training
- Provide technical assistance and oversight to CTUs 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 and report results to Study Operations Group, PMG, EC, and DAIDS.
- Summarize SRC and SMC reviews and distribute as appropriate
- Collaborate with DAIDS (PAB) and the pharmaceutical companies to coordinate the acquisition and distribution of study drug.
- Collaborate with SDMC to develop CRFs and test them in the field before implementation
- Collaborate with NL to enable CTUs to meet proficiency requirements
- Coordinate and track site activation requirements

SDMC Lead Statistician

- Provide design, statistical and scientific input during protocol development and throughout the conduct of the study
- Develop statistical components of the protocol
- Develop randomization and treatment allocation scheme, if needed
- Conduct data analyses and generate SMC and DSMB reports
- Provide ongoing support for statistical questions
- Participate in manuscript preparation

The Protocol Team Chair may identify working groups to address specific needs/activities during protocol development and study conduct. The Protocol Team Chair appoints protocol team members to these protocol team committees and working groups. Examples might include working groups to address:

- Development and/or oversight of specialized behavioral procedures for a study
- Development and/or oversight of specialized clinical procedures for a study
- Development of specialized data collection modules (in collaboration with SDMC)
- Ongoing monitoring of study participant safety data such as a Protocol Safety Review Team
- drafting and submission of manuscripts and presentations

The CORE CRM/PS facilitates and participates in the conference calls and meetings of these working groups. Where applicable, the CRM/PRS provides summaries to the protocol team for these working group meetings and conference calls.

Additional Information and Contact Details

HPTN Website: <http://www.hptn.org>

HPTN Leadership and Operations Center Community Involvement Program

FHI 360

359 Blackwell Street, Suite 200

Durham, North Carolina 27701 USA

(919) 544-7040 community@hptn.org