## **HPTN Manual of Operations**

# **HPTN** Leadership

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#### 2 HPTN LEADERSHIP

#### 2.1 HPTN Principal Investigators

The HPTN Principal Investigators (PIs) are the leaders of the entire Network and also serve as the PIs of the Leadership and Operations Center (LOC). The PIs are responsible for ensuring the efficient development and implementation of the HPTN research agenda as well as managing the Network and coordinating activities across the three Central Resource groups: the LOC, Laboratory Center (LC), and Statistical and Data Management Center (SDMC).

The chairmanship of the Executive Committee (EC) will be held by one PI for the first three years (administrative PI), followed by the other PI. The function of the chair is to:

- Coordinate and facilitate EC responsibilities, including development and implementation of the HPTN research agenda
- Schedule and chair regular and special meetings and conferences calls of the EC and communicate the decisions and action items to HPTN investigators
- Ensure coordination of Network activities across Central Resources and provide regular and effective communications with the Clinical Trials Unit (CTU)/Clinical Research Site (CRS) Investigators

A special election of the voting members shall be held if it becomes necessary to replace the Network PI ahead of schedule. The rotation of the network PIs at three years will start the selection process for the new PIs. This will allow a continuum of leadership that is consistent, yet changing.

### 2.2 Executive Committee

The EC, under the direction of the HPTN PIs, with the assistance of the United States (US) National Institutes of Health (NIH) Consortium, sets the research priorities of the HPTN and directs its scientific activities. The EC:

- Sets the overall HPTN research agenda
- Reviews Scientific Committees (SCs)/Working Groups (WGs) research plans including the review and prioritization of concepts
- Evaluates and recommends the distribution of resources among the different components of the Network
- Recommends to National Institute of Allergy and Infectious Diseases (<u>NIAID</u>) that funds be released for specific protocol implementation
- Approves policies and procedures of the HPTN, including the governing structure and membership of standing committees
- Establishes key standing Network committees (for example, Science Review Committee, Study Monitoring Committee, Performance Evaluation Committee, Manuscript Review Committee)
- Reviews and resolves site-related issues as needed
- Pursues new partnerships and funding opportunities

The EC, in conjunction with NIH, determines the overall capacity for the HPTN, as well as the capacity of individual CTUs and CRSs or other sites. With members serving as liaisons to each SC/WG, the EC will ensure that the specific areas of prevention science addressed by SCs/WGs are effectively coordinated and are aligned with the priority areas. The EC will delegate the management of certain functions (e.g., protocol review, monitoring the study during

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implementation) to the oversight committees as described below. The structure and composition of all SCs and WGs is described in Section 4. All committees are ultimately accountable to the EC.

The EC conducts conference calls at least monthly and holds in-person meetings at least annually. The table below shows both voting and non-voting membership. A quorum, defined as two-thirds of the voting membership, must be present for key decisions and votes to be taken.

#### 2.2.1 Membership

The EC membership includes representatives from the LOC, the SDMC, the LC, community, CRS and NIH. Representatives of the CRSs may rotate off the EC every two years.

When new members are solicited, all CRS nominees will submit a brief biosketch to the EC administrator or designee. Biosketches for nominees will be compiled, attached to the voting ballot and sent to EC members. EC members will be asked to vote for their top two choices, indicating first and second choice. Votes will be collated. If a nominee receives a majority vote, she/he will be elected. If not, the list will be narrowed down to the top three candidates and another vote will take place.

Voting Members	Nonvoting Members
PI (Administrative), Network	Group Director LOC
PI, Network	Finance Manager, LOC
Non-US Lead Investigator	Deputy Director, LC
Past PI, Network	Research Program Manager, SDMC
Past Co-PI, Network	
PI, LC	
PI SDMC	
Director, LOC	
Community Representative	
2 Site Representatives	
2 Representatives from NIH	

#### 2.3 HPTN Leadership Group

A subset of the EC (without the NIH representatives) and members of the Central Resource groups meet routinely to discuss operational and fiscal issues related to the ongoing studies and provide timely feedback to the study teams.

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