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2 NETWORK GROUPS

The IMPAACT Network is comprised of a global network of investigators from clinical research sites, the Leadership and Operations Center (LOC), Laboratory Center (LC), Statistical and Data Management Center (SDMC), IMPAACT Community Advisory Board (ICAB), and other groups and committees charged with the scientific management and operational support of the Network. The Network is led by a chair and vice chair, who are accountable to the NIAID Program Officer. Additional information concerning these entities is provided in this section.

2.1 Network Leadership

The IMPAACT Network is led by the Network chair and vice chair in collaboration with the Scientific Leadership Group (SLG), Scientific Committees (SCs), and Management Oversight Group (MOG). The leadership is responsible for ensuring the efficient development and implementation of the IMPAACT research agenda as well as managing and coordinating activities across the Network.

2.1.1 Network Chair and Vice Chair

The Network chair is an investigator with experience reflective of the network’s scientific agenda and operational scope. He or she serves as chair of the SLG and MOG. Responsibilities include managing the IMPAACT LOC; overseeing and managing the network’s finances; directing the network and executing its plans as determined by SLG, MOG, and NIH partners; ensuring collaboration with other research networks and groups; and serving as the network’s executive representative. Other responsibilities include but are not limited to maintenance of network policies and procedures, regulatory compliance and performance evaluation, review of publications, and collaboration with the community. The Network

chair must commit a minimum level of effort of 50% for the term of service, which is the award period of the IMPAACT Network grant.

The SLG (described in Section 2.1.2) elects the Network chair and vice chair. The SLG reviews applicant submissions and SLG voting members elect the chair, after a broad solicitation for individuals with relevant expertise and experience. Applicants need not be associated with an IMPAACT site; however, site leadership experience is considered a strength. Election decisions are generally expected to be based on at least 80% concurrence among voting members. Any current SLG member who applies is recused from the entire review and election process.

A call for applicants and/or nominations for Network chair typically takes place approximately 15 months before beginning a new Network grant funding cycle so that the elected chair can be named in the application for the new grant. The newly elected chair serves in a transitional capacity as Network chair-elect, participating as a non-voting member of the SLG and MOG, until the new grant is awarded, at which time she or he assumes the duties of Network chair.

If it becomes necessary to replace the Network chair ahead of schedule, a special election may be held. The vice chair will serve as chair until the replacement is selected.

The Network vice chair should meet the same requirements as the chair and is elected following the same procedures as the Network chair. The primary duties of the vice chair are to assist the Network chair, assume the powers and duties of the Network chair in her or his absence or in case of potential conflict of interest, and lead meetings in the absence of the Network chair. The Network vice chair also serves as chair of some network committees and groups.

2.1.2 Scientific Leadership Group

The SLG sets the overall scientific agenda of the Network. The Network chair serves as the chair of the SLG; other members include the Network vice chair, SDMC principal investigator (PI), LC PI, Operations Center Director, Study Monitoring Committee (SMC) chair, ICAB chair, five at-large investigators, and NIAID, NICHD, and NIMH representatives. At-large members of the SLG are selected by the MOG to ensure appropriate breadth and depth of scientific expertise and diversity, reflective of the Network's research agenda and geographical scope.

The primary responsibilities of the SLG are to:

- Set the overall scientific agenda of the Network
- Prioritize studies across research areas and the overall research portfolio
- Review evolving HIV/AIDS science and determine implications for the Network
- Review new study proposals
- Identify gaps in the network's research agenda and commission studies to address these
- Liaise with other research networks and groups to foster collaboration

The SLG convenes regularly via teleconference and in person, including periodically with the SC chairs and vice chairs and, as needed, with external advisors. When voting is required, SLG members with conflicts of interest (e.g., part of team developing proposal) abstain from voting, and decisions are generally expected to be based on at least 80% concurrence among voting members. Voting members include all listed SLG members above, with one voting representative from each of the three NIH institutes. To ensure coordination and communication, additional representatives of the Operations Center, SDMC, LC, and NIH sponsoring institutes may participate in SLG meetings as observers.

Decisions made by the SLG are communicated in writing to the relevant parties, and updates on plans and activities are provided to SLG members during routine calls or otherwise as needed. Updates to other Network members are provided via email broadcasts, website postings, teleconferences, and other means as appropriate. On a quarterly basis (typically, March, June, September, and December), the SLG reviews and prioritizes new study proposals; review is based on scientific merit, potential public health impact, and feasibility and research advantage of network implementation, as described in Section 9. See Section 6 for details regarding network meetings and communications.

2.1.3 Management Oversight Group

As described in Section 2.1.2, the SLG focuses on the scientific priorities for the Network. Network management and oversight functions are the responsibility of the MOG, which is comprised of a subset of the SLG members. The Network chair serves as the chair of the MOG; other members include the Network vice chair, SDMC PI, LC PI, Operations Center Director, and NIAID, NICHD, and NIMH representatives.

The primary responsibilities of MOG are to:

- Oversee the Network's fiscal matters
- Evaluate and recommend the distribution of resources across network components
- Ensure regulatory compliance
- Develop collaboration agreements
- Monitor network performance and productivity
- Review and approve the Network Manual of Procedures (MOP)
- Carry out other administrative and operational aspects of the network's business

The MOG convenes regularly via teleconference and in person. When voting is required, MOG members with conflicts of interest (e.g., part of team developing proposal) abstain from voting, and decisions are generally expected to be based on at least 80% concurrence among voting members. Voting members include all listed MOG members above, with one voting representative from each of the three NIH institutes. To ensure coordination and communication, additional representatives of the Leadership and Operations Center (including the Finance Office at JHU), SDMC, LC, and NIH sponsoring institutes may participate in MOG meetings as observers.

Decisions made by the MOG are communicated in writing to the relevant parties, and updates on plans and activities are provided to MOG members during routine calls or otherwise as needed. Updates to other Network members are provided via email broadcasts, website postings, teleconferences, and other means as appropriate. See Section 6 for details regarding network meetings and communications.

2.1.4 Scientific Committees

The IMPAACT Network is committed to conducting high quality clinical trials that advance the prevention and treatment of HIV and its complications for infants, children, adolescents, and pregnant and postpartum women globally. The Network's research agenda includes five scientific specific aims, reflecting the following key research areas:

- HIV Treatment
- Tuberculosis
- HIV Prevention
- HIV Cure
- Complications and Comorbidities

For each research area, an SC continually reassesses research priorities in light of emerging science as well as new ideas and opportunities, seeks collaboration with other research networks and entities, and oversees the development and review of study proposals based on scientific priorities. Each SC is composed of experts in the specific field and includes a chair and vice chair, investigators, ICAB representatives, and representatives of the SDMC, LC, Operations Center, and NIH.

The SCs are responsible for:

- Reviewing their respective portfolios of studies in the context of evolving science and standards of care
- Identifying gaps in the science and new interventions for target populations
- Ensuring that new high priority study proposals are developed for consideration by the SLG

SCs convene regularly via conference call and in person. SC chairs and vice chairs periodically meet with the SLG via teleconference or in-person meetings. SCs are expected to collaborate on areas of topical overlap and mutual interest, each drawing upon the expertise of others as needed. See Section 6 for details regarding network meetings and communications.

2.1.4.1 SC Chair and Vice Chair

SC chairs and vice chairs are selected by the SLG to ensure appropriate breadth and depth of scientific expertise and diversity, reflective of the network's research agenda and geographical scope. Chairs and vice chairs are accountable to the SLG. They are responsible for leading their respective SCs and participating in SLG conference calls and meetings as requested to discuss their SC's research agenda and priorities. Each SC also has a designated SLG liaison who is available for Network leadership consultation on an ongoing basis.

2.1.4.2 SC Membership

SCs are comprised of a chair and vice chair, at-large members, and representatives from the ICAB, SDMC, Laboratory Center, Operations Center, NIAID, NICHD, and NIMH. At-large member are chosen by the chair and vice chair and confirmed by the SLG after a broad solicitation for individuals with relevant expertise and experience.

SCs convene regularly via teleconference and in person. When voting is required, SC members with conflicts of interest (e.g., part of team developing proposal) abstain from voting. Voting members include all listed members above, with one voting representative from the ICAB, each of the central resource groups, and each of the three NIH institutes. Voting may be considered completed once at least 60% of at-large members plus chair and vice chair have voted; if decisions are mixed or split, the chair and vice chair may determine next steps, based on the results.

To ensure coordination and communication with Network leadership, a liaison from the SLG is also selected to participate in each SC; this person is not considered a voting member. To augment or expand existing expertise within an SC or to replace a departing member, the SC chair and vice chair may propose additional individuals for membership, with appointment to be confirmed by the SLG.

2.1.5 Removal of Any IMPAACT Leadership Member

In the unlikely event that any IMPAACT leadership (SLG or SC) member needs to be removed for cause, a written proposal to remove the member must be submitted with support from at least three voting members. Removal of the member is based on at least 80% concurrence among voting members and requires concurrence from NIAID.

Leadership members include the Network chair, Network vice chair, at-large SLG members, SC chairs and vice chairs, and all other members of the SLG and MOG, with the exception of NIH members.

2.2 Advisory Groups

2.2.1 IMPAACT Community Advisory Board

The IMPAACT Community Advisory Board (ICAB) is responsible for advising the Network leadership, SCs, protocol teams, and other network groups on issues related to the planning and implementation of the IMPAACT research agenda and for supporting local (site) community programs through training and information exchange. The ICAB also communicates and represents the views of local community programs through participation of its representatives in the SLG, SCs, and other network groups. The ICAB convenes regularly by teleconference and in person. The ICAB chair is accountable to the Network chair and the MOG. See more information about the ICAB in Section 5.

2.2.2 Social Behavioral Sciences Core

The Social Behavioral Sciences Core (SBS Core) is core group of experts who support the IMPAACT Network's research agenda by providing guidance on behavioral scientific issues during the development of new study proposals. The SBS Core is led by a chair with the support of up to four primary members; the core may also request input from non-core consultants and experts on an ad hoc basis. The SBS Core is accountable to the SLG.

2.2.3 External Scientific Advisory Group

An external scientific advisory group may be convened periodically to provide constructive feedback on the network's current and planned scientific agenda, including identifying gaps and providing recommendations for prioritization and future directions. The group may be convened either via teleconference or in person. The group includes diverse expertise and experience relevant to the network's research agenda, including pediatric HIV therapy, pediatric TB/HIV co-infection, perinatal HIV transmission, adolescent HIV prevention, pediatric HIV vaccines, pediatric immunology, HIV

reservoirs, metabolic/neuropsychiatric complications of HIV and ARV therapy, and behavioral science. The group also includes community representation. Members must be currently unassociated with IMPAACT and have no current conflict of interest. The group is directly advisory to the SLG. The external scientific advisory function may be fulfilled through alternative means as determined by the SLG.

2.3 Central Resources

The central resources of the IMPAACT Network include:

- Leadership and Operations Center (LOC), located at Johns Hopkins University (JHU) and FHI 360
- Statistical and Data Management Center (SDMC), located within the Harvard School of Public Health and Frontier Science Foundation
- Laboratory Center (LC), located at the University of California Los Angeles (UCLA)

These groups coordinate closely with each other in the development, implementation, and oversight of Network studies and other Network activities.

2.3.1 Leadership and Operations Center

The Leadership and Operations Center (LOC) supports the Network leadership, structure, and functioning. Oversight of the LOC is the responsibility of the Network chair. The LOC includes functions across two institutions: the IMPAACT Finance Office (at JHU) and the IMPAACT Operations Center (at FHI 360).

The Finance Office administers and disperses grant and other funding for support of the Network leadership, protocol chairs, clinical research sites, specialty laboratories, the Operations Center, and other central resources. The Finance Office also executes contracts with pharmaceutical companies and other collaborators to support Network studies.

The Operations Center provides a central point of coordination, communications, and support for all aspects of the Network. The Operations Center supports the scientific agenda; coordinates the development, implementation, and reporting of IMPAACT studies; supports all Network groups, committees, and protocol teams; and arranges and supports all network meetings and leadership travel. The Operations Center Director serves as a voting member of the SLG and MOG.

The LOC's specific operational responsibilities, by functional area, are summarized in Table 2-1.

2.3.2 Statistical and Data Management Center

Through a separate but linked and fully collaborative grant, the Statistical and Data Management Center (SDMC) is responsible for helping to shape the Network's scientific agenda and plays a key role in all phases of science generation and protocol development. The SDMC also provides comprehensive biostatistical and data management leadership, specifically in the design and implementation of network studies and in the collection, quality control, and analysis of study data in accordance with study protocols and in collaboration with other team members, following the principles of Good Clinical Data Management Practices (GCDMP) and Good Clinical Practices (GCP).

The SDMC is comprised of a Statistical and Data Analysis Center (SDAC), located at the Center for Biostatistics in AIDS Research at the Harvard School of Public Health, and a Data Management Center

(DMC), located at Frontier Science Foundation. The SDMC PI has fiscal responsibility for the SDMC grant, is accountable to the NIAID Program Officer and the Network chair, and serves as a voting member of the SLG and MOG.

The SDMC's specific operational responsibilities, by functional area, are summarized in Table 2-2.

2.3.3 Laboratory Center

Through a separate but linked and fully collaborative grant, the Laboratory Center (LC) is responsible for helping to shape the network's scientific agenda and plays a key role in all phases of science generation and protocol development. The LC is also responsible for leadership, oversight, and support of laboratory aspects of network studies and other activities including site laboratory preparedness and performance and coordination and oversight of the networks' specialty laboratories. The LC plays a leadership role in cross-network activities, updating, harmonizing and streamlining laboratory procedures used in other networks and groups.

The LC is located at the University of California Los Angeles. The LC PI has fiscal responsibility for the LC grant, is accountable to the NIAID Program Officer and the Network chair, and serves as a voting member of the SLG and MOG.

The LC staff maintains regular communication with IMPAACT sites and confirms that sites are able to perform study-required laboratory procedures and tests prior to site activation for the study. The LC staff also visit sites, as necessary, to assess laboratory facilities and procedures.

The LC's specific operational responsibilities, by functional area, are summarized in Table 2-3.

Table 2-1. IMPAACT LOC Operational Responsibilities

Functional Area	Responsibilities
Leadership and governance	<ul style="list-style-type: none"> • Serve on and provide logistical and administrative support to the SLG, MOG, SCs, ICAB, SBS Core, MPRG, SMC, NEG, and other Network committees and groups • Participate in the overall management of the Network and development of the IMPAACT scientific agenda • Provide operational leadership to the Network • Coordinate development and management of the Network MOP • Coordinate and support Network evaluation processes (see Section 18)
Protocol management and support See Section 4 for a full listing of roles and responsibilities for the protocol CTS.	<ul style="list-style-type: none"> • Facilitate the development, review, approval, and tracking of capsules, concepts, ancillary studies, and other related study proposals • Assign a Clinical Trials Specialist (CTS) to each IMPAACT protocol • In collaboration with the protocol chair, plan and manage protocol team business in consultation and with the support of other protocol team members • Facilitate communication between protocol teams, study sites, Network leadership, and other Network and sponsor entities as needed
Technical assistance to sites	<ul style="list-style-type: none"> • Coordinate development and implementation of study-specific training plans • Coordinate and facilitate responses to inquiries from site staff on logistics and procedures for IMPAACT studies in collaboration with protocol team members and other Network entities as applicable
Coordination of, facilitation of, and participation on oversight committees	<ul style="list-style-type: none"> • Serve as member of and coordinate MPRG (see Section 9), SMC (see Section 13), and Network Evaluation Group (NEG; see Section 18) activities • Facilitate preparation and distribution of relevant review materials; prepare and distribute review outcome reports and associated communications, as applicable
Community engagement See Section 5 for a full description of roles and responsibilities for the Operations Center community program staff.	<ul style="list-style-type: none"> • Facilitate broad community involvement through community representation on key Network committees and, as applicable, by working with sites to develop and enhance the IMPAACT Community Advisory Board (ICAB) • Support the work of the ICAB and IMPAACT CAB Leadership Group (ILG)
Communication and information dissemination	<ul style="list-style-type: none"> • Develop and maintain the IMPAACT website, including relevant information on sites and IMPAACT studies • Support and coordinate Network-level communication through conference calls, in-person meetings, electronic and written materials, announcements, and postings on the IMPAACT website • Support and organize Network meetings • Develop and maintain email groups and directories for the IMPAACT communication system in collaboration with the DMC • Maintain inventory of site- and study-related information and provide requested information to Network leadership and other committees as needed • Support the NIAID CRMS by providing current study-specific information and documents in real time
Financial management and support for sites	<ul style="list-style-type: none"> • Evaluate the adequacy of financial resources provided to sites, as necessary • Assist NIH Grants Management Branch (GMB), DAIDS Prevention Sciences Program (PSP), OCSO, and IMPAACT leadership in analysis of site funding requests and all other Network financial matters • Develop an annual funding plan based on the needs of the scientific agenda implemented during the funding cycle

Table 2-2. IMPAACT SDMC Operational Responsibilities

Functional Area	Responsibilities
Leadership and governance	<ul style="list-style-type: none"> • Serve on the SLG, MOG, SCs, MPRG, SMC, NEG, and other Network committees and groups • Participate in the overall management of the IMPAACT Network and development of the IMPAACT scientific agenda • Provide statistical and data management leadership to the IMPAACT Network • Contribute to Network evaluation processes (see Section 18)
Protocol management and support See Section 4 for a full listing of roles and responsibilities for the statistician, PDM, and LDM.	<ul style="list-style-type: none"> • Participate in the review of capsules, concepts, ancillary studies, and other related study proposals • Assign a statistician, a protocol data manager (PDM), and a laboratory data manager (LDM) to each IMPAACT protocol • Participate in the protocol-related groups, as applicable • Design and maintain the study databases • Provide centralized data entry and data management • Provide reports to fulfill Investigational New Drug (IND) reporting requirements, as applicable • Review and provide study data and reporting to pharmaceutical partners under the terms of the Clinical Trials Agreement (CTA), as applicable • Develop and implement data quality control (QC) systems • Provide needed information to the DAIDS Clinical Site Monitor to assist with site-monitoring visits
Technical assistance to sites	<ul style="list-style-type: none"> • Participate in development and implementation of study-specific training plans • Respond to inquiries from site staff in collaboration with protocol team members and other Network entities as applicable • Provide operational assistance to sites, the LC, and protocol teams for specimen tracking and retrieval, including labeling and specimen tracking sheets to facilitate specimen entry into the specimen tracking system, the Laboratory Data Management System (LDMS), and reports of LDMS entry errors and discrepancies between LDMS and CRF databases
Information technology support	<ul style="list-style-type: none"> • Develop and maintain software systems and related procedures for transmitting, receiving, processing, analyzing, and storing study data and meeting reporting requirements • Assist sites in set-up and maintenance of data collection material relay systems
Participation on oversight committees	<ul style="list-style-type: none"> • Serve as a member of MPRG (see Section 9), SMC (see Section 13), and NEG (see Section 18)
Clinical data safety monitoring	<ul style="list-style-type: none"> • Provide clinical review of relevant laboratory and safety data for accuracy, consistency, and completeness • Provide QC and coding of adverse event (AE) data • Verify completeness of expedited adverse event reporting through reconciliation of AEs reported to DAIDS and those reported to the SDMC

Table 2-3. IMPAACT LC Operational Responsibilities

Functional Area	Responsibilities
<p>Leadership and governance</p>	<ul style="list-style-type: none"> • Serve on the SLG, MOG, SCs, MPRG, SMC, NEG, and other Network committees and groups • Participate in the overall management of the Network and development of the IMPAACT scientific agenda • Contribute to Network evaluation processes (see Section 18)
<p>Protocol management and support See Section 4 for a full listing of roles and responsibilities for the LC representative and LT. See Section 17 for a full listing of roles and responsibilities for the Laboratory Center.</p>	<ul style="list-style-type: none"> • Participate in the review of capsules, concepts, ancillary studies, and other related study proposals • Assign a Laboratory Center representative to each IMPAACT protocol; facilitate assignment of a Laboratory Technologist, in consultation with Laboratory Technologist Committee, to each IMPAACT protocol • Review and define appropriate laboratory testing methods and materials to be used in IMPAACT studies • Participate in protocol-related groups, as applicable • Collaborate with other NIH-sponsored HIV clinical trial networks to harmonize laboratory methods and maximize the efficiency of protocol development, implementation, and analysis • Collaborate with IMPAACT specialty labs to perform protocol-specified testing
<p>Technical assistance to sites</p>	<ul style="list-style-type: none"> • Participate in development and implementation of study-specific training plans • Respond to inquiries from site staff in collaboration with protocol team members and other Network entities as applicable • Provide operational assistance to sites, the LC, and protocol teams for specimen tracking and retrieval, including labeling and specimen tracking sheets to facilitate specimen entry into the specimen tracking system, the Laboratory Data Management System (LDMS), and reports of LDMS entry errors and discrepancies between LDMS and CRF databases
<p>Participation on oversight committees</p>	<ul style="list-style-type: none"> • Serve as a member of MPRG (see Section 9), SMC (see Section 13), and NEG (see Section 18)

2.4 Oversight Groups

Three additional Network groups provide oversight on behalf of the SLG and MOG:

- Multidisciplinary Protocol Review Group (MPRG)
- Study Monitoring Committee(s) (SMC)
- Network Evaluation Group (NEG)

These committees have both standing and *ad hoc* members and convene via teleconference as needed.

2.4.1 Multidisciplinary Protocol Review Group

The Multidisciplinary Protocol Review Group (MPRG) reviews protocols on behalf of the SLG prior to submission to the NIAID Sciences Review Committees. The purpose of the MPRG review is to ensure IMPAACT protocols are scientifically rigorous, accurate, consistent, complete, and standardized to the extent possible. The MPRG critically reviews protocols for scientific and design integrity, operational feasibility, focusing on key issues such as site participation, infrastructure and capacity, relevance to the community, and any ethical, logistical or potentially regulatory concerns. The review is multidisciplinary to streamline and avoid multiple sequential review steps. This group has authority to approve protocols, request revision and re-submission, or to disapprove them, based on network-specified criteria.

The MPRG is comprised of the Network vice chair (who serves as MPRG chair); the chair or vice chair of the relevant SC; standing representatives of the Operations Center, SDMC, LC, and ICAB; the IMPAACT pharmacist; designated NIH representatives; and 1-2 external reviewers with expertise in the content area of the protocol.

See Section 9 for additional detail on the MPRG.

2.4.2 Study Monitoring Committee

In support of the management and oversight functions of the MOG, for designated studies, a Study Monitoring Committee (SMC) monitors participant safety and the progress and quality of IMPAACT study conduct. The scope of SMC reviews varies across studies, reflective of protocol specifications.

The SMC is comprised of the SMC chair (a Network investigator); the Network chair or vice chair; the chair or vice chair of the relevant SC; standing representatives of the Operations Center, SDMC, and LC; designated NIH representatives; and additional content area reviewers when needed.

See Section 13 for additional detail on the SMC.

2.4.3 Network Evaluation Group

The Network Evaluation Group (NEG), on behalf of the MOG, develops performance metrics for the various network entities. Evaluation reports are shared with the entities whose work was evaluated and with network sponsors, as appropriate. A primary component of network evaluation is the CRS Performance Report. This report focuses on critical aspects of study implementation at the site level, such as participant accrual and retention, data quality, laboratory performance, and regulatory issues. At the request of the MOG, the NEG may evaluate and report on other network entities in a similar manner.

The NEG is comprised of the Network vice chair (who serves as the NEG chair); standing representatives of the Operations Center (the Network Evaluation Coordinator), SDMC, and LC; and designated NIH staff.

See Section 18 for additional detail on the NEG.

2.5 Protocol Teams

Protocol teams assume primary responsibility for scientific leadership in the development, implementation, and day-to-day oversight of IMPAACT studies; protocol teams are also responsible for timely dissemination of study results. Further detail on the composition and functions of protocol teams are contained in Section 4.

2.6 Clinical Research Sites

IMPAACT studies are conducted at clinical research sites (CRSs) funded by NIAID and NICHD throughout the world. Investigators and other representatives of these sites, including community representatives, participate in all levels of the Network structure. The active participation of site investigators is critical to IMPAACT's scientific mission. These sites bring extensive clinical trials capacity and a wealth of experience for implementation of the Network's scientific agenda. When necessary to reach special populations or to expand capacity, additional sites may be engaged as "protocol-specific" sites for selected IMPAACT studies (see Section 10).

IMPAACT sites are experienced in implementing clinical trials, monitoring for and reporting adverse events, achieving high participant retention rates, and rigorously adhering to study protocols. Site staff are skilled in applying the principles of Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) in all aspects of study conduct. These practices include obtaining informed consent and assent; performing clinical, pharmacy and laboratory study procedures; maintaining study product accountability; performing data management and quality management processes; and collecting, labeling, processing, testing, storing, and shipping biological specimens. In addition, each site obtains community input on the research process through its community advisory board(s), although a site may refer to this structure by another locally chosen name or establish an alternative structure.

Staffing at each site may vary based on the structure of the site, the number and type of studies being conducted, and any local requirements. Some staff members may have general functions that apply across studies and others may have study-specific responsibilities. Site staff often include the following:

- CRS Leader and CRS Coordinator
- Study-specific Investigators of Record (IoR) and sub-investigators
- Study-specific Coordinators
- Pharmacist of Record, study-specific Pharmacists of Record, and other pharmacists and pharmacy technicians
- Research nurses and clinicians
- Data managers and technicians
- Laboratory directors, managers, technologists, and technicians
- Counselors and social workers
- Community educators and liaisons
- Participant outreach, recruitment, and retention staff
- QA/QC staff
- Administrative staff

2.6.1 NIAID Sites

The Division of AIDS at NIAID funds sites worldwide to participate in Network studies. Each site is part of a Clinical Trials Unit (CTU); CTUs may be comprised of multiple sites. NIAID provides resources to fund research infrastructure and study implementation through cooperative agreements with CTU and through the LOC.

2.6.2 NICHD Sites

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) funds sites worldwide to participate in Network studies. NICHD provides resources to sites to fund research infrastructure and study implementation through the NICHD Coordinating Center.

2.6.3 Protocol-Specific Sites

Sites that are not affiliated with the Network through NIAID or NICHD may be funded to implement specific Network studies if needed to meet the study objectives. See Section 10 for additional details.