

3 CONSORTIUM GROUPS

The Infectious Diseases Clinical Research Consortium (IDCRC) is a coordinated national and global network of scientific experts working to develop and test vaccines and therapeutics to combat infectious diseases. The Leadership Group (LG) of the IDCRC supports the planning and implementation of Consortium research priorities, in alignment with the scientific priorities of DMID/NIAID. The LG organizational structure is composed of a Leadership and Operations Center (LOC), a Clinical Operations Unit (COU), a Laboratory Operations Unit (LOU), and a Statistical and Data Science Unit (SDSU). The IDCRC LG works with the Vaccine and Treatment Evaluation Units (VTEUs), a global Consortium of investigators from clinical research sites, and other groups and committees charged with the scientific management and operational support of the Consortium. Further details concerning these entities are provided in this section. See Figure 3.1 for IDCRC Leadership structure.

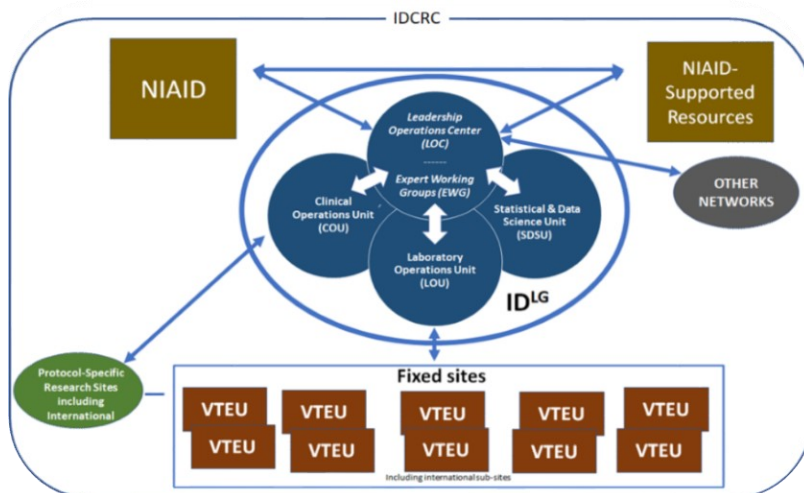
3.1 Consortium Leadership

The IDCRC Consortium is led by two Principal Investigators (PIs) who also serve as co-Chairs of the LG and work in tandem with the Co-Directors of the LOC, LOU and COU and the Director of the SDSU in collaboration with the Expert Working Group (EWGs).

3.1.1 Consortium Co-Principal Investigators

The Consortium co-PIs are individuals selected to reflect the collaborative spirit of the IDCRC. Shared governance allows for a team science approach, optimal decision making and delegation of authority. Responsibilities include managing the IDCRC and sub-units, directing the Consortium and executing its plans as determined by LG, LOC, and NIH partners; ensuring collaboration with other research networks and groups; and serving as the Consortium’s executive representatives. Other responsibilities include but are not limited to maintenance of Consortium policies and procedures, regulatory compliance and performance evaluation, fiscal and administrative management, review of publications, and collaboration with the community.

Figure 3.1. IDCRC Leadership Structure



3.1.2 IDCRC Leadership Group (LG)

The Leadership Group sets the overall scientific agenda of the Consortium. The Consortium co-PIs serve as co-Chairs of the LG; other members include key United States researchers from leading universities and a global network of collaborators who have a historic record of achievement in adult and pediatric infectious diseases research, specifically in vaccines and therapeutics, biologics, and devices for respiratory, enteric, malaria/tropical, and sexually transmitted infections. The LG consists of experienced and collaborative leaders at VTEUs and from the previously funded Sexually Transmitted Infections Clinical Trails Group (STI-CTG) and is linked with numerous other NIAID (National Institute of Allergy and Infectious Diseases) established Consortiums.

The primary responsibilities of the LG are to:

- Set the overall scientific agenda of the Consortium
- Support the planning and implementation of infectious diseases clinical research that efficiently addresses the scientific priorities of NIAID
- Foster collaborative team science with NIAID, the VTEUs, members of the previously funded STI-CTG, and other partners to best address infectious diseases priorities
- Review and prioritize innovative concepts
- Enhance integration and efficiency in operations
- Increase collaborations and novel partnerships
- Plan and facilitate protocol implementation
- Promote the integration of special and underserved populations in IDCRC research across the human lifespan
- Engage the next generation of scientists in infectious disease research
- Evaluate ongoing studies and help assure the capacity of the IDCRC to respond rapidly to newly emerging infectious disease threats

Decisions made by the LG are communicated in writing to the relevant parties, and updates on plans and activities are provided to LG members during routine calls/video conferences or otherwise as needed. Updates to other Consortium members are provided via email broadcasts, website postings, video and teleconferences, and other means as appropriate. The LG regularly reviews and prioritizes new study proposals through a formal concept review process; review is based on scientific merit, potential public health impact, feasibility, innovation, and research advantage of Consortium implementation, as described in IDCRC MOP Section 9. See MOP Section 7 for details regarding Consortium meetings and communications.

3.1.3 Leadership Operations Center (LOC)

The Leadership Operations Center (LOC) includes an administrative core and is managed and directed by two Co-Directors. The LOC oversees five standing Expert Working Groups (EWGs) that are responsible for providing recommendations and current public health needs as benchmarks to monitor and prioritize clinical research undertaken by the LG: 1) Respiratory Diseases, 2) Sexually Transmitted Infections, 3) Enteric Diseases, 4) Malaria /Tropical Diseases and 5) Emerging Infectious Diseases. Ad hoc EWGs may be activated in the setting of an urgent public health need (e.g., COVID-19). The LOC has established five internal Key Functions Committees (Innovations; Mentoring, Career Development and Training; Performance Evaluation, Ethics, and Quality Assurance; Laboratory Sciences; and Collaborations and Publications) to execute the scientific agenda, facilitate strategic planning and career development activities, and conduct operations work of the LG. The LOC is also responsible for overseeing interactions with various Advisory Boards as detailed in 3.2.

The primary responsibilities of LOC are:

- Oversight of Concept Evaluation
- Facilitation of Process for Setting Research Priorities and Agendas
- Operationalizing LG Research Priorities
- Innovation
- Mentoring
- Monitoring and Evaluation
- Quality Management
- Collaboration
- Training and Education

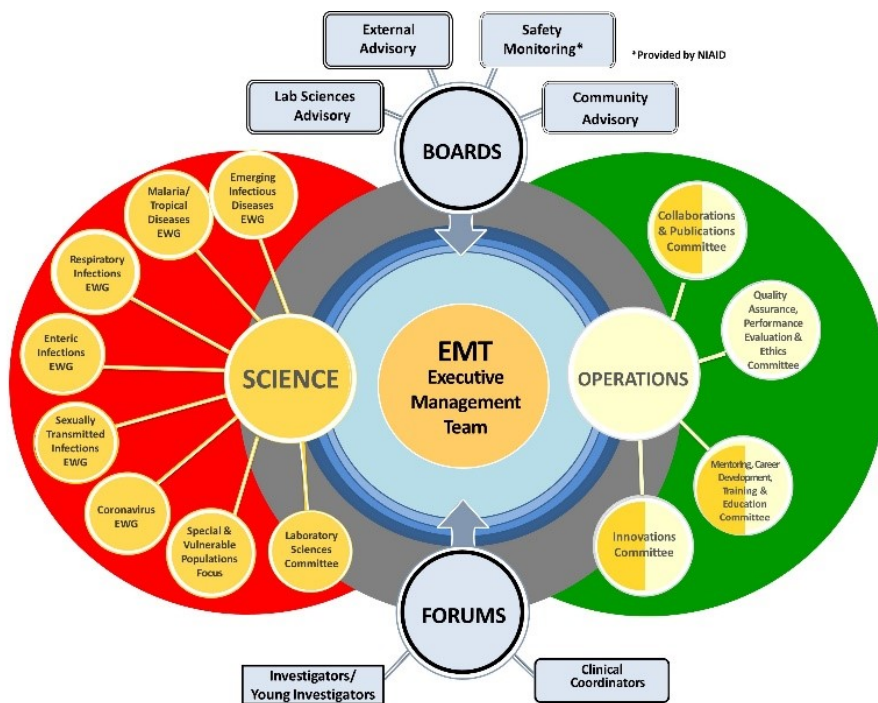
The LOC convenes regularly via video or teleconference and in person. To ensure coordination and effective communication, representatives from the EMT, SDSU, LOU, COU and NIH sponsoring institutes may participate in LOC meetings as required/appropriate.

Decisions made by the LOC are communicated in writing to the relevant parties, and updates on plans and activities are provided to the consortium members via formal minutes of calls. Updates to other Consortium members are provided via email broadcasts, website postings, video or teleconferences, newsletters, and other means as appropriate. See IDCRC MOP Section 7 for details regarding Consortium meetings and communications.

3.1.3.1 Executive Management Team (EMT) / Consortium Governance

The LOC contains the governance components of the LG composed of a core EMT. See Figure 3.2.

Figure 3.2. IDCRC Governance



The **Executive Management Team (EMT)** of the LOC serves as the administrative leadership of the IDCRC LG and is responsible for scientific, administrative, and fiscal decisions. The ten member EMT is composed of the Co-PIs, LOC Co-Directors, COU Co-Directors, LOU Co-Directors, SDSU Director, and the LOC Executive Administrative Director. The EMT, facilitated by the LOC administrative core, oversees the day-to-day operations of the respective Units, LG activities, and the scientific direction and research agendas of the Consortium. The EMT is responsible for defining the research agenda, prioritizing innovative concepts, strategic planning, and vision, approving, and implementing bylaws, policies, and standard operating practices, addressing performance standards, monitoring for conflicts of interest, and assuring quality, and disseminating and communicating IDCRC research findings in a timely manner. The EMT oversees the distribution of resources of the LG grant and the management of the LG financial and other resources including protocol implementation funds provided through the LG to the VTEUs/ Clinical Research Sites (CRSs).

The EMT will interface with NIAID to ensure the research agenda is consistent with NIH priorities and is responsive to emerging threats. The EMT receives input from and undergo yearly performance evaluations by the EABs.

The EMT convenes regularly (twice per-month) via videoconferencing with NIAID representative(s) included on these calls and with other external advisors as needed. The LG co-PIs will chair and approve the agenda for these meetings. The agenda for these teleconferences will be developed by the Executive Administrative Director in consultation with the IDCRC co-Chairs prior to the call and materials will be solicited for distribution to the EMT in advance to facilitate the discussions and decisions. The agendas will specifically state those items that are “for information only” and those where “decisions are needed.” Agendas for the calls will also include accomplishments and proposed recommendations to NIAID. The EMT is responsible for scientific, administrative, and fiscal decisions of the LG.

When voting is required, EMT members with conflicts of interest (e.g., part of team developing proposal) may participate in discussion however abstain from voting, and decisions are expected to be based on at least 80% concurrence among voting members. Voting members include the Co-PIs, one of the Co-Directors of LOC, LOU, and COU and the Director of the SDSU, the LOC Executive Administrative Director, with one voting representative from NIAID. Voting outcomes, to include quora, notices of abstention due to conflicts or other issues, will be documented and maintained by the LOC Administrative core.

3.1.3.2 LOC Administrative Core (AC)

The AC provides administrative, organizational and communications support to the IDCRC units: LOC (EMT, EWGs, and KFCs), COU, SDSU, and LOU. More specifically, the AC supports IDCRC planning and implementation, coordinates efficient project management to achieve scientific goals, timelines, and milestones, oversees cost-effective management of LG resources, collects and reports information about LG performance and develops plans for changes and improvements, and coordinates communication with NIH, VTEUs and other components of the IDCRC. The AC also provides regulatory oversight, budgets and subaward management, management of financial disclosures, and collaboration with VTEUs and protocol-specific sites. Other functions of the LOC AC:

- Managing the system of tracking and progressing concepts from the initial concept proposal through to extended concept proposal approval, as applicable
- In collaboration with IDCRC partners, developing and maintaining standard operating procedures for the IDCRC in a searchable and comprehensive manual of procedures, and defining the structure, terms of governance and procedures for IDCRC in

- accordance with US federal regulations and NIAID policies and procedures
- Providing research administration pre-award support for supplemental funding requests
- Providing research administration post-award support for financial management and organization of the core and protocol funding awards
- Providing support for all LG committees and expert working groups, including scheduling, hosting and summarizing routine and ad hoc conference calls and meetings and development and distribution of agendas, meeting materials and minutes
- Producing routine and ad hoc progress and status reports as determined by the IDCRC and NIAID; maintaining tracking mechanisms for monitoring network activities and timelines as well as setting up mechanisms (share sites) to share files and data
- Organizing in-person and virtual meetings and conferences, including arranging travel for participants as needed; provide support to the annual program meetings
- Establishing and supporting IDCRC performance evaluation program/approach with the Performance Evaluation, Ethics and Quality Assurance (PEQ) KFC and produce evaluation reports in collaboration with PEQ KFC, COU, LOU, and SDSU partners for review by the EMT and NIAID
- Establishing and supporting the administration of the Mentoring and Career Development Program
- Establishing and supporting documentation and mitigation of financial conflicts of interest for IDCRC members
- Designing and maintaining a network website and/or portal for sharing of network information, study materials, publications, educational materials, and other resources
- Establishing and maintaining email alias lists for all study teams and network committees and groups to facilitate communication
- Responsible for the management of core and protocol funds including LOC, COU, LOU and SDSU resources
- Assisting in the creation of study budgets for review by the LOC based on protocol specifications, with input from the protocol team, COU and SDSU, and responsible for development and tracking of overall IDCRC funding
- Working closely with NIAID/DMID administration and preparing for audits and other oversight review
- Execution of and providing oversight of subcontract with FHI 360, an international nonprofit organization with experience partnering with NIAID in conduct of clinical research and management and coordination of research consortia
- Execution of and providing oversight of subaward with each partnering institution that receives funding from NIAID through the Leadership Group

To provide effective administrative, financial, communications, IT and managerial support for the LG, the administrative core includes effort contributed by a LOC Executive Administrative Director, an Associate Executive Administrative Director, an LOC Program Director, a COU Program Director, a Communications Director and additional administrative support staff as needed. The AC reports to the Executive Management Team (EMT).

The COU, LOU and SDSU administrators will dually report to the AC and the EAD as well as to unit directors.

3.1.4 Clinical Operations Unit (COU)

The COU has a multi-investigator leadership structure with three co-Directors who bring extensive experience in clinical trial and network operations. The COU is integrated with, overseen by and reports to the IDCRC LOC and interfaces with the EWGs, the KFCs, the LOU and SDSU. The COU's primary responsibilities include: (1) providing effective operational

support, efficient management, and oversight for the LG's clinical research, (2) rapidly developing approved concepts into quality clinical trials protocols, (3) moving the protocols through regulatory and IRB approvals, (4) site selection, and (5) implementing them in diverse populations across the lifespan at the selected clinical trials sites. There is also a strong commitment by the COU and the IDCRC LG to provide opportunities for young investigators in the conduct of clinical research.

The COU in conjunction with FHI 360 coordinates closely with the LG, the VTEUs, NIAID staff, and NIAID-provided research support programs. The COU manages and oversees protocol teams for all LG activities, and establishes efficient and equitable systems for resource distribution and reallocation in response to evolving priorities identified by the LG and NIAID. The COU also ensures the provision of specialized training for clinical trials, related laboratory procedures, and data management for VTEU staff in support of IDCRC activities. The COU is responsible for management, protocol development and the optimal balance of sites for implementation of the clinical research.

The COU is administratively based at Emory University, which, with the support of the LOC Administrative Core, coordinates the administrative and operational components of the COU, including financial operations, budget development, and operational coordination. The team is enhanced by a partnership with FHI360, a nonprofit human development organization dedicated to improving lives throughout the world including clinical trials design and implementation.

The COU meets via videoconference several times per week – at least once per week as a working group and another regular weekly videoconference that includes the LG co-PIs and the LOC co-Chairs; DMID representatives are included in these calls every other week.

The COU also houses the protocol Clinical Site Selection Committee (CSSC). For details regarding site selection, please see MOP Section 10.

3.1.5 Laboratory Operations Unit (LOU)

The LOU leads the development, implementation and evaluation of the IDCRC laboratory research agenda. The LOU is co-Directed by experienced network laboratory leaders at the Fred Hutchinson Cancer Research Center (Fred Hutch) and University of Washington who serve on the EMT. The LOU leadership fosters collaboration within the LG, including the LOC, COU, SDSU and EWGs, and harmonization of laboratory activities within VTEU site-associated laboratories. The LOU also works with NIAID staff, and NIAID-provided research support programs.

The LOU oversees the IDCRC clinical and research laboratory services including (1) overall coordination of the endpoint laboratories supporting IDCRC laboratory objectives (e.g., selection of laboratories to conduct endpoint assays, review of budgets, and monitoring and review of data reports); (2) sample collection in coordination with the COU; (3) processing and handling of study specimens; (4) specimen management in coordination with the SDSU or Emmes; (5) specimen sharing; (6) development of ancillary lab-based projects; (7) laboratory quality management; and (8) harmonization of laboratory activities of the LG and the VTEU and other protocol-specific laboratories. The LOU is also responsible for rapidly integrating special and innovative laboratory assays into IDCRC research capabilities. The Key Function Laboratory Science Committee (KFLSC) and the Executive Management Team (EMT) of the LOC will be responsible for approval and oversight of the LOU research agenda in collaboration with NIAID.

The LOU meets via videoconference several times per week – at least once per week with the internal LOU team, and regular weekly videoconference that includes the LG co-PIs; DMID

representatives are included in these calls every other week. As part of the EMT, the LOU leadership attends all face to face and virtual IDCRC LG meetings and participates in all monthly EMT teleconference calls to ensure that the defined research agenda is clearly understood and approved.

3.1.6 Statistical and Data Science Unit (SDSU)

The Statistical and Data Science Unit (SDSU) provides statistical leadership and data management to support IDCRC research activities and develops and implements innovative statistical and data science approaches to improve scientific understanding of infectious diseases.

The type of SDSU support varies depending on the IND sponsor as described in Table 3.3. As noted, DMID may request that SDSU serve as the analytical, clinical and laboratory data coordinating center for DMID-held IND studies on an as needed basis.

Table 3.3. SDSU Support for IDCRC Trials

| IND Sponsor | Leadership / biostatistics services | Study design | Interpretation and publication of results | Analysis | Clinical and laboratory data management systems | Compliance with federal regulations and global security standards |
|--------------------|-------------------------------------|--------------|---|-----------|---|---|
| Non-NIAID held IND | • | • | • | • | • | • |
| NIAID held IND | • | • | • | As needed | As needed | As needed |
| Non IND | • | • | • | • | • | • |

The Director of the SDSU is an expert in statistical design and analysis of clinical trials from the University of Washington (UW) and Fred Hutchinson Cancer Research Center (FHCRC). A team of UW and FHCRC faculty are also available to lend their expertise and provide leadership to the SDSU. The SDSU will work collaboratively with the Leadership Group (LG), Laboratory Operations Unit (LOU), Leadership and Operations Center (LOC), Clinical Operations Unit (COU), VTEUs and NIAID to achieve objectives to ensure the integrity of study design, data management, data analyses and compliance with regulatory requirements, as appropriate; provide effective data communication systems for the network; provide data management training; standardize and harmonize statistical and data management activities both within the network and with other NIH-supported networks or other Federal and private sector clinical trial programs when required; and collect and store data in accordance with standards of the Clinical Data Interchange Standards Consortium (CDISC), as required.

The SDSU Director also serves on the EMT to ensure collaboration and efficiency with the overall leadership and the operational units.

3.1.7 Expert Working Groups (EWGs)

The EWGs review IDCRC concept proposals and provide recommendations to the LG. The LG use EWG recommendations to monitor and prioritize clinical research undertaken by the IDCRC. The LOC has established standing EWGs in the following areas: 1) Respiratory Diseases, 2) Sexually Transmitted Infections (non-HIV), 3) Enteric Diseases, 4) Malaria/Tropical Diseases, and 5) Emerging Infectious Diseases. The topics may be subject to modification as the research agenda evolves or in the case of public health emergencies. For instance, the IDCRC established an ad hoc COVID-19 EWG in response to the pandemic. Within the EWGs, the LOC emphasizes and promotes integration of special and underserved populations into the IDCRC research agenda across the entire human lifespan.

Each EWG is led by at least one VTEU PD/PI or their designee and includes up to 15 total members including DMID, VTEU, ex-officio IDCRC members, and experts from outside the network who are recognized leaders in their specific scientific fields. PIs from the VTEUs serve as Chairs and co-Chairs of the EWGs depending on their areas of expertise and program needs. Two members of the IDCRC LG serve as liaisons/advisors to the EWGs. The EWG liaisons communicate regularly with the EWG Chairs, participate in EWG calls to remain familiar with the early research concept discussions, and advise both the EWG membership and independently the LOC and EMT about research priorities and the pipeline of concept submissions. The EWG Chairs and co-Chairs report to the LOC co-Directors.

3.2 Advisory Boards

The LOC is responsible for establishing Advisory Boards for the Consortium including the External Advisory Board, the Laboratory Sciences Advisory Board, and the Community Advisory Board. A fourth, the Safety Advisory Board, will be provided by NIAID.

3.2.1 IDCRC External Advisory Board

The IDCRC External Advisory Board (EAB) is composed of six to twelve accomplished individuals knowledgeable in the field of infectious diseases and their prevention and treatment, clinical investigation, product development, policy, or other disciplines chosen by the EMT in conjunction with NIAID. They conduct an annual review of the IDCRC LG and evaluate performance and advise on scientific direction. These boards will meet annually via videoconferencing or as part of the annual meeting.

3.2.2 Laboratory Sciences Advisory Board

The Laboratory Sciences Advisory Board (LSAB) will be made up of five to six experts in fields such as immunology, omics, microbial pathogenesis, pharmacokinetics, and drug/device design. The LSAB conducts an annual review of the laboratory research conducted within the IDCRC and advises on opportunities for innovation and ancillary studies. Ad hoc meetings of the LSAB may also be convened as needed to address scientific questions or provide guidance on prioritization.

3.2.3 Community Advisory Board

The Community Advisory Board (CAB) will be made up of six to eight community stakeholders (selected by the LOC and NIAID and including public health leaders, parent and community focused groups, minority representatives including sexual minorities, and the elderly) who meet with the EMT to share community perspectives and ideas, questions, and concerns about ID research so they can be proactively addressed.

3.3 Protocol Teams

Protocol teams assume primary responsibility for scientific leadership in the development, implementation, and day-to-day oversight of IDCRC studies; protocol teams are also responsible for timely dissemination of study results.

3.4 Vaccine Treatment and Evaluation Units (VTEUs)

IDCRC studies are conducted at VTEUs funded by the DMID/NIAID. Through cooperative agreements with each VTEU and the IDCRC LG. DMID provides resources to fund the research

infrastructure and study implementation at the VTEUs.

The ten VTEUs in the IDCRC are located at institutions across the United States.

Table 3.4. IDCRC VTEU Primary Sites

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|--|
| Baylor College of Medicine |
| Cincinnati Children's Hospital Medical Center |
| Emory University |
| Kaiser Permanente Washington Health Research Institute |
| New York University School of Medicine |
| Saint Louis University |
| University of Maryland School of Medicine |
| University of Rochester |
| University of Washington |
| Vanderbilt University Medical Center |

Investigators and other representatives of these sites participate in all levels of the Consortium structure. The active participation of site investigators is critical to the IDCRC's scientific mission. These sites bring extensive clinical trials capacity and a wealth of experience for implementation of the Consortium's scientific agenda.

The IDCRC VTEU sites are experienced in implementing clinical trials, monitoring, and reporting adverse events, achieving high participant retention rates, and rigorously adhering to study protocols. Site staff are skilled in applying the principles of 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. 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:

- VTEU Investigator and Site/Study 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
- Participant outreach, recruitment, and retention staff
- QA/QC staff
- Administrative staff

3.4.1 VTEU Sub sites

When necessary to reach special populations or to expand capacity, VTEUs have identified specific sub sites that could be queried about their interest and capacity to participate in IDCRC protocols.

3.4.2 Protocol-Specific Sites

Sites that are not affiliated with a VTEU network or the IDCRC through NIAID may be funded to implement specific IDCRC studies as “protocol specific sites” if needed to meet the study objectives. See IDCRC MOP Section 10 (Site Selection) for additional details.