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3 CONSORTIUM GROUPS

3.1 IDCRC Leadership Group (LG)

The IDCRC Leadership Group (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. 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). See Figure 1 below for IDCRC organizational structure.

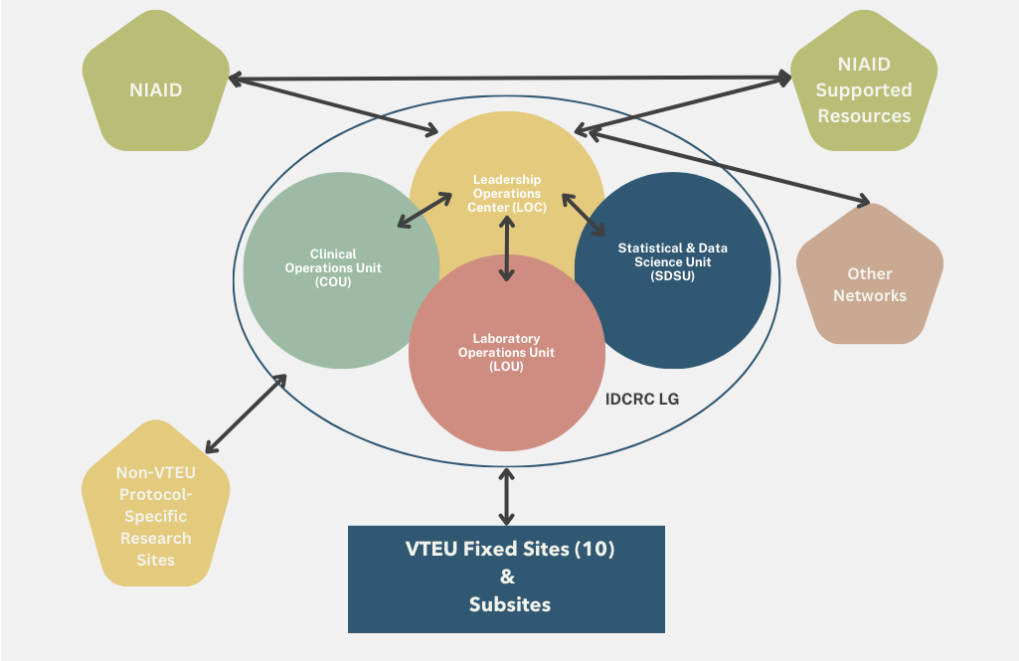

Figure 1. IDCRC Organizational Structure

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

Docusign Envelope ID: 7ED296B8-3C5D-4ADB-B7D2-20E921943671

- Plan and facilitate protocol development, study conduct and close out activities
- Promote the integration of special and under-represented populations of all ages in IDCRC research.
- Identify, engage, and train the next generation of scientists in infectious disease research
- Ensure IDCRC capacity 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, newsletters, and annual meetings, as appropriate.

3.2 LG Leadership

3.2.1 LG Core Executive Leadership Team

The LG is led by a core executive leadership team, comprised of a Chair, a Vice Chair, the LOC co-directors, and an Executive Administrator. These individuals have been carefully selected based on complementary strengths and scientific backgrounds to provide effective oversight of the LG and reflect the collaborative spirit of the IDCRC. Shared governance allows for a team science approach, optimal decision making and delegation of authority. Their specific 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, and review of publications.

As LG funds are awarded to Emory University, the LG Chair serves as the contact Principal Investigator of the award and maintains financial oversight of these funds, with support from the LOC Administrative core and the institution's Research Administration departments.

The core leadership team maintain shared responsibility for financial management and oversight of the IDCRC, by regularly reviewing the overall funding state of the network, using a tracker maintained by the LOC Executive Administrator, using data from concept budget estimates, intent to fund memos, and award information provided by DMID.

3.2.2 Executive Management Team (EMT)

The **Executive Management Team (EMT)** serves as the administrative leadership of the IDCRC LG and is responsible for scientific, administrative, and fiscal decisions. The EMT is composed of the LG Chair, LG Vice Chair, LOC Co-Directors, COU Co-Directors, LOU Co-Directors, SDSU Director, and NIAID representatives. 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

Docusign Envelope ID: 7ED296B8-3C5D-4ADB-B7D2-20E921943671

conflicts of interest, 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 (CRS).

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 relevant partners including annual performance evaluations by the External Advisory Board.

The EMT convenes twice a month via videoconferencing and with other external advisors, as needed. The LG Chair or Vice Chair chairs and approves the agenda for meetings. The agenda is developed by the Executive Administrative Director in consultation with IDCRC LG members prior to the call. Materials are solicited for distribution to the EMT in advance to facilitate discussions and decision-making. Meeting agendas state which items are “for information only” and those where “decisions are needed.” They will also include accomplishments and proposed recommendations to NIAID.

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

3.3 LG Operational Components

3.3.1 Leadership Operations Center (LOC)

The Leadership Operations Center (LOC) is responsible for the overall administrative leadership for the LG, and the oversight and evaluation of all LG activities including refining of the research agenda, prioritizing research concepts, protocol development, timely publication, and communication of results, and responding to infectious diseases public health emergencies.

The primary responsibilities of LOC are:

- Identify and implement clinical research studies, clinical trials and countermeasures that enhance the prevention, diagnosis, and treatment of infectious diseases, by establishing and operating a concept evaluation process.
- Identify and prioritize infectious diseases clinical research implemented by VTEUs using national expertise, including the establishment of **Expert Working Groups (EWG)** in specific infectious disease areas, and the current public and global health environment as guidance.
- Form collaborative teams with VTEUs to engage scientists, coordinators, participants,

Docusign Envelope ID: 7ED296B8-3C5D-4ADB-B7D2-20E921943671

patients, and communities to tackle network scientific problems in NIAID-priority research.
- Establish and operate a mentoring, career development and training platform to train and cultivate the IDCRC science workforce and leadership of the future.
- Promote the integration of vulnerable and underserved populations in IDCRC research.
- Adopt innovative, study and trial designs, approaches to public-private partnerships, and statistical techniques that will increase the outcomes, quality, and efficiency of IDCRC research via multisite trials.
- Integrate breakthroughs in areas such as human immunology, systems biology, the microbiome, drug discovery and microbial pathogenesis into IDCRC research capabilities.
- With NIAID, develop and incorporate policies, methods and approaches for monitoring the implementation and the quality (including risk assessment and mitigation strategies) of research conducted by the VTEUs and the operational performance of the overall IDCRC.
- Collaborate with other NIH-supported clinical research networks and other Federal and private sector clinical research programs to share best practices, expertise, resources, procedures, laboratory capabilities, specimen management and the harmonization of common data elements and data entry interfaces

The LOC also houses an Administrative Core (AC), responsible for providing administrative, organizational and communications support to the IDCRC units and groups. More specifically, the AC supports IDCRC planning and implementation, supports the EWG concept review process, 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.

3.3.2 Clinical Operations Unit (COU)

The Clinical Operations Unit (COU) provides effective operational support, efficient management, and oversight for the LG's clinical research. The COU works to rapidly develop EMT-approved and prioritized concepts into quality clinical trials protocols, moving the protocols through regulatory and IRB approvals, and then implementing them in diverse populations across the lifespan at selected clinical trials sites

The primary responsibilities of the COU include:

- Provide effective operational support, management, and oversight for the IDCRC clinical research, with close coordination between the LG, the VTEUs, NIAID staff, and NIAID-provided research support programs.

Docusign Envelope ID: 7ED296B8-3C5D-4ADB-B7D2-20E921943671

- Efficiently implement IDCRC clinical research protocols by managing and overseeing protocol teams during protocol development, study budget preparation, implementation, and closeout.
- Oversee the Clinical Site Selection process for IDCRC studies in development, adding new sites for ongoing IDCRC studies, and for protocol-specific sites, as outlined in Section 10 of the IDCRC MOP.
- Provides specialized training for clinical trials, related laboratory procedures, and data management for IDCRC staff in support of IDCRC activities.
- Support the mentoring and training of the next generation of ID clinical investigators by providing opportunities for young Investigators in the conduct of clinical research.

The COU partners closely with FHI360 to carry out these responsibilities, a nonprofit human development organization dedicated to improving lives throughout the world including clinical trials design and implementation.

3.3.3 Laboratory Operations Unit (LOU)

The Laboratory Operations Unit (LOU) leads the development, implementation, and evaluation of the IDCRC laboratory research activities.

The primary responsibilities of the LOU include:

- Provide 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)
- sample collection in coordination with the COU;
- processing and handling of study specimens;
- specimen management in coordination with the SDSU or Emmes;
- specimen sharing;
- development of ancillary lab-based projects;
- laboratory quality management; and
- 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.

3.3.4 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.

Docusign Envelope ID: 7ED296B8-3C5D-4ADB-B7D2-20E921943671

The responsibilities of the SDSU can vary depending on the IND sponsor as described in Table 1. 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 1. 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[1]	•	•	•	•	•	•

1-When SDSU provides data management support.

3.4 Vaccine Treatment and Evaluation Units (VTEUs)

IDCRC studies are primarily conducted at VTEUs that have been established and funded by DMID/NIAID. These ten sites, listed below, are critical resources for evaluating vaccines, other preventive biologics, therapeutics, diagnostics, and devices for the treatment and prevention of infectious.

IDCRC VTEU Primary Sites

1. Baylor College of Medicine
2. Cincinnati Children's Hospital Medical Center
3. Emory University
4. Kaiser Permanente Washington Health Research Institute
5. New York University School of Medicine
6. Saint Louis University
7. University of Maryland School of Medicine
8. University of Rochester
9. University of Washington
10. Vanderbilt University Medical Center

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 Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) in all aspects of study conduct. These practices include

Docusign Envelope ID: 7ED296B8-3C5D-4ADB-B7D2-20E921943671

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.

VTEU investigators and staff 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.

3.4.1 VTEU Subsites

Each VTEU also has an approved list of subsites, both domestic and international, where clinical research may be conducted. These subsites allow for additional reach to special populations or to expanded capacity and may be considered for IDCRC protocols if needed. Investigators and staff at these subsites may participate in Consortium activities, when appropriate and supported by the VTEU Principal Investigator(s). VTEU PIs are expected to provide oversight of their approved subsites for any IDCRC activities they participate in.

3.5 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 for additional details.

Docusign Envelope ID: 7ED296B8-3C5D-4ADB-B7D2-20E921943671

REVISION HISTORY:

Version number	Approval Date DD MMM YYYY	Summary of Changes
2.0	09 OCT 2024	Updated LG Leadership Section to reflect shift to single PI model with Core Executive Leadership Team structure. Updated unit sections to provide a broad overview of functions.