



## 1 OVERVIEW OF THE INFECTIOUS DISEASES CLINICAL RESEARCH CONSORTIUM (IDCRC)

### 1.1 Background of the IDCRC

The IDCRC is a collaboration of world-renowned leaders in infectious diseases (ID), immunology, and clinical research from ten leading academic institutions, and affiliates, across the country. The programs, faculty, and collaborators at these institutions have exceptional National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID) network and international connectivity, a history of performing outstanding ID clinical research, and the experience and capability to rapidly respond to ID threats.

The IDCRC was formed in 2019 by NIAID Division of Microbiology and Infectious Diseases (DMID) by merging the activities of two long-standing and previously funded research groups: the Vaccine and Treatment Evaluation Units (VTEU) and the Sexually Transmitted Infections Clinical Trials Group (STI CTG). The consortium has two funded arms – the Leadership Group (LG) and the VTEUs (sites), both funded through a seven-year funding cycle cooperative agreement. For reference, the original Funding Opportunity Announcements are accessible here: [RFA-AI-18-047](#) and [RFA-AI-18-046](#).

### 1.2 IDCRC Mission and Scientific Agenda

The **IDCRC LG** will support NIAID with experience, expertise, extensive program linkages and innovative approaches to the planning and implementation of clinical research addressing the scientific priorities of NIAID. Elements of the IDCRC LG are a Leadership Operations Center (LOC), Clinical Operations Unit (COU), Laboratory Operations Unit (LOU) and a Statistical and Data Science Unit (SDSU).

The LOC is the oversight unit of the LG that is responsible for directing science and operations and consists of an Executive Management Team (EMT), Key Function Committees (KFCs) and Expert Working Groups (EWGs). The LOC structure allows effective leadership, governance, and assignment of scientific, administrative, and advisory responsibilities to fully support the mission of the IDCRC.

The EMT is comprised of the IDCRC Chair and Co-Chair, Directors of the LOC, COU, LOU and SDSU and the LOC Administrative Core and is responsible for the daily operations of the respective Units and overall LG activities.

The five aims of the IDCRC are:

1. Establish and operate an integrated, highly-functioning, collaborative, diverse and flexible **IDCRC LG** to serve as the **hub** connecting the currently funded VTEUs, other performance sites and partners, and NIAID, to plan and implement clinical research addressing the scientific priorities of NIAID.
2. Establish and operate the **IDCRC LOC**, which is responsible for the overall administrative leadership for the LG and for the oversight and evaluation of all LG activities, including refining

the research agenda, prioritization of research concepts, protocol development, timely publication and communication of results, and response to infectious diseases public health emergencies. The LOC will also:

- a) Collaborate with NIAID to **identify and implement** clinical research studies, clinical trials and countermeasures that enhance the prevention, diagnosis, and treatment of infectious diseases. These efforts will encompass concepts and products from consortium investigators, external collaborators and products supported by NIAID.
  - b) With NIAID, **prioritize** infectious diseases clinical research implemented by VTEUs using national expertise, including the establishment of **Expert Working Groups (EWGs)** in specific infectious disease areas, and the current public and global health environment as guidance.
  - c) With NIAID, **form collaborative teams** with VTEUs to engage scientists, coordinators, participants, patients, and communities to tackle network scientific problems in NIAID-priority research.
  - d) Establish and operate a **mentoring, career development and training platform** to train and cultivate the IDCRC scientific workforce and leadership of the future.
  - e) Promote the integration of **vulnerable and underserved populations** in IDCRC research.
  - f) 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.
  - g) **Integrate breakthroughs** in areas such as human immunology, systems biology, the microbiome, drug discovery and microbial pathogenesis into IDCRC research capabilities.
  - h) With NIAID, develop and incorporate policies, methods, and approaches for **monitoring the implementation and quality** (including risk assessment and mitigation strategies) of research conducted by the VTEUs and the operational performance of the overall IDCRC.
  - i) **Collaborate** with other NIH-supported networks and other Federal and private sector clinical research programs to share best practices, expertise, resources, procedures, laboratory resources, specimen management and the harmonization of common data elements and data entry interfaces.
3. Establish and operate the **IDCRC COU**, which will **provide leadership on protocol development and implementation planning**, and be responsible for site selection, qualification, and management of protocol-specific sites. Quality, efficiency, ethics, reliability, and flexibility are emphasized.
  4. Establish and operate the **IDCRC LOU** to **manage and oversee clinical and research laboratory services** which include pharmacokinetics, bioanalyses, and specimen characterization; laboratory quality management; monitoring and evaluation of all LG specialized laboratories; sharing of specimens; and harmonization of laboratory activities of the LG and the VTEU- identified laboratories. The LOU is also responsible for rapidly integrating special and innovative laboratory assays (e.g., genomics, proteomics, transcriptomics, metabolomics, glycomics, lipidomics) into IDCRC research capabilities, and for defining ancillary studies to translate novel findings to clinical application.
  5. Establish and operate the **IDCRC SDSU** to provide statistical leadership and data management to support IDCRC research activities and to develop and implement innovative statistical and data science approaches to improve scientific understanding of infectious diseases.

### 1.3 IDCRC Organization

The LG is functionally and administratively divided into Units, Committees and Working Groups, emphasizing a functional specialized infrastructure that encompasses the work defined under all areas as

a unified program. It is supported by an administrative and financial team, the **LOC**, that ensures maximal efficiency and financial stewardship. The **LG** organizational structure supports the science and operations of the IDCRC, and is composed of the **LOC** including the **EWGs**, the **COU**, the **LOU** and the **SDSU**. These groups are further described in Section 3 of the MOP.

The LOC works closely with NIAID to ensure the research agenda is consistent with NIAID's infectious diseases research priorities. NIAID members participate in regular LOU, COU and SDSU calls, serve on the Executive Management Team (EMT) and the EWGs to facilitate engagement.

The LOC and COU have support from FHI 360. FHI 360, a non-profit global organization supporting clinical research, has extensive experience in supporting clinical trials in infectious diseases, and in working with NIAID and NIAID networks (STI CTG, HPTN).

#### 1.4 IDCRC Operational Policies

The organizations and individuals that comprise the IDCRC consortium adhere to relevant US Federal regulations, NIH Grants Policy statement and NIH/NIAID/DMID policies as a condition of receipt of Federal funding. The IDCRC and the individual VTEUs will also comply with the terms and conditions outlined in their awards. Each VTEU/clinical research site also adheres to relevant local regulations and policies. In addition, IDCRC-specific procedures guide consortium investigators, site staff, and other members in meeting relevant requirements and standardizing site operations for each IDCRC study. These procedures are contained in the following:

- **IDCRC Manual of Procedures (MOP):** This manual provides general guidelines for consortium work members and describes IDCRC procedures for all sites, study teams, and staff. The IDCRC LOC and COU coordinate development and maintenance of the MOP in collaboration with representatives from the SDSU, LOU and EMT. Representatives of the EMT are responsible for reviewing sections prior to their release.
- **Study-specific Implementation Materials (e.g., MOP, Central Assay Plan [CAP], Participant Enrollment and Data Collection Materials):** In addition to study protocols, conduct of each IDCRC study may be guided by study-specific implementation materials, including a study-specific MOP, CAP, and participant enrollment and data collection materials. The materials provide instructional and reference resources and are generally developed for each individual study. Note that study requirements and procedures (including those described in site and study-specific standard operating procedures [SOPs]) must be conducted in accordance with the study protocol. In the event study-specific implementation materials or tools are inconsistent with the protocol, the specifications of the protocol take precedence. See Section 12 for further details regarding study-specific implementation materials.
- **Site and Study-specific SOPs:** SOPs for site operations and for study operations ensure standard, uniform performance of site and study-related tasks and compliance with IDCRC procedures, [International Conference on Harmonisation Good Clinical Practices](#) (ICH GCP) guidelines, and [US Food and Drug Administration](#) (FDA) regulations, where applicable.

#### 1.5 Governmental Organizations Involved in IDCRC Research

As described above, financial support for IDCRC is provided by NIAID. The consortium works with

governmental regulatory agencies including the US [Food and Drug Administration](#) (FDA), the US [Office of Human Research Protection](#) (OHRP), and similar agencies in other countries where IDCRC research is conducted.

### **1.5.1 National Institute of Allergy and Infectious Diseases/Division of Microbiology and Infectious Disease**

DMID is one of the six Divisions within the NIAID of the National Institutes of Health (NIH). DMID has substantial scientific and programmatic involvement in the IDCRC through technical assistance, advice, and coordination. The role of the NIH staff is to support and stimulate the research activities by collaborating in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities.

Within NIAID, DMID supports research to control and prevent diseases caused by virtually all human infectious agents except HIV. DMID staff participate on IDCRC protocol teams, as described in Sections 9a and 12, and governing committees, as described throughout the IDCRC MOP. They also facilitate the communication between other partners, such as other funding agencies, pharmaceutical companies, the US FDA, and IDCRC leadership. DMID contracts with a number of organizations to support site/clinical monitoring, statistical and data management, study product and specimen management, regulatory support, pharmacovigilance, and safety oversight committees.

For the IDCRC, DMID is responsible for protocol review, including review and approval of sample informed consent language. The approved language is subsequently distributed with the protocol for relevant Institutional Review Board/Ethics Committee (IRB/EC) review and approval.

#### **1.5.1.1 US Office for Civil Rights**

For studies conducted in US settings in institutions that are covered entities, compliance with the [Health Insurance Portability and Accountability Act](#) (HIPAA) must be assured. Each institution is responsible for ensuring its own compliance. For non-US institutions, each institution is responsible for determining whether it is a covered entity under HIPAA, and, if so, each covered entity is responsible for ensuring compliance with this requirement, as set forth in [Title 45 CFR 160](#) and [164](#).