



5 KEY FUNCTION COMMITTEES

The Key Function Committees (KFCs) are a key component of the Leadership Operations Center (LOC) and participate with the Executive Management Team (EMT)) and the Expert Working Groups (EWGs) to establish the agenda, contribute to the activities of the IDCRC Leadership Group (LG) clinical, laboratory and statistical Units (COU, LOU, SDSU) and receive input from advisory boards, and forums established within the IDCRC. NIAID will be fully represented across the KFCs. The LOC contains the governance components of the LG and is responsible for the assembly and establishment of the KFCs:

- 1) Performance Evaluation, Ethics and Quality Assurance
- 2) Mentoring, Career Development, and Training,
- 3) Collaborations and Publications
- 4) Innovations
- 5) Laboratory Sciences

5.1 KFC Leadership and Composition

These committees address key areas that are the responsibility of the LOC. Each Key Function committee is chaired by a LG key personnel member or a VTEU member designee and reports to EMT leadership. They bring individual strengths that will facilitate achievement of the IDCRC goals.

The Key Function Committees will also include selected investigators and coordinators who have been nominated (e.g. from VTEU sites), stakeholders from NIAID, community and subject matter advisors, and appropriate representatives from the Operations Units. The LG administrative core will play a key support role. Each committee will generally have one or more early career members.

5.2 KFC Chairs

Each Committee Chair will be appointed from the IDCRC Leadership Group and will serve a 3 year term with the option of extending the term based upon performance and leadership needs.

5.3 KFC Terms and Responsibilities

The Committee Chair will be tasked with assuring engagement and commitment among the team members and lead the group effort of implementing the committee goals and activities. Each committee member will have a clear understanding of the scope of work and their roles and responsibilities. A detailed plan with a clearly defined scope of work will significantly facilitate the performance review process. Proposed membership for the Key Function Committees, 10-15 members each, will be reviewed and approved by the EMT. KFCs will meet virtually monthly or as needed, report to the EMT and will undergo a yearly performance review. The committee subject areas will also be reviewed annually to eliminate those no longer deemed necessary and to consider any new areas of need.

The KFCs will convene regularly virtually (e.g., monthly) and in person when feasible at the annual IDCRC meeting, and periodically with the LG and other leadership committees, as needed.

5.4. KFCs

As noted, there are 5 KFCs. The full scope of duties and activities are outlined in specific Standard Operating Procedures; below is a short paragraph highlighting their main objectives:

1. Performance Evaluation, Ethics and Quality Assurance

Develops and incorporates policies, methods, and approaches for monitoring implementation of clinical research conducted by the VTEUs and affiliated Clinical Research Sites (CRS) and evaluates the operational performance of the overall Leadership Group (LG), each LG element including the Clinical Operations Unit (COU), the Lab Operations Unit (LOU) and the Statistics and Data Sciences Unit (SDSU), the Key Function Committees (KFCs) and Expert Working Groups (EWGs). Additionally, this committee develops strategies for assuring quality management and ensures that the risk assessment and mitigation strategies are an integral part of all research activities within the IDCRC. These strategies complement quality management systems and processes established by NIAID. A key component of this function is ethical conduct of research and performance standards of leaders, investigators, clinical coordinators, laboratory, and other staff.

2. Mentoring, Career Development and Training

Establishes and operates a mentoring, career development and training platform to train and cultivate the IDCRC science workforce and leadership of the future. The Mentoring and Career Development Section fosters the development of early stage investigators in clinical and translational infectious diseases research. The program includes mentoring advisory meetings, lectures and seminars, and other opportunities tailored to the mentee's career goals. The KFC also oversees the New Investigator Pilot Grants Program. The Training Section provides overall IDCRC Leadership Group oversight of training and education activities primarily targeting VTEU research staff. This oversight includes proficiency and regulatory training and training documentation. The committee will engage infectious diseases researchers, coordinators, and staff to develop the ideal training activities for all IDCRC research personnel. The MCDT KFC is overseen by the IDCRC Leadership Operations Center (LOC) Co-Chairs.

3. Collaborations and Publications

Develop pathways and procedures for dissemination of all results emanating from the comprehensive IDCRC research agenda that utilizes the strengths, experience, and expertise of the collaborating organizations of the LG, the IDCRC, and NIAID. All manuscripts covering primary research conducted by the IDCRC must be submitted to the Collaborations and Publications Committee for review and clearance prior to submission to a journal. Following acceptance by a journal or scientific meeting, the primary author will share the accepted manuscript/abstract with the members of the writing group, the IDCRC LG and NIAID, prior to publication/presentation. The CPC, in consultation with the lead author, EMT, and NIAID, will decide if there should be press releases associated with the publication or abstract presentation.

4. Innovations

Innovations in specimen collection and laboratory assays, trial design and statistical analyses,

vaccine and drug delivery, methods to enhance the immune response, and other relevant advances are also a key component of the IDCRC and will be incorporated in trial design and prioritization. We envision cross communication between the LOC Innovations KFC and leadership from the operational units (LOU, COU, SDSU), so that the latest innovations are included in trial planning and design, and appropriate internal or external investigators are engaged at early stages. We envision the studies designed and conducted by the IDCRC as the premier testing ground for innovative ideas and assays relevant to infectious diseases and vaccine evaluation, engaging the brightest minds in the field in collaborative science. The LOC Innovations Committee will identify and evaluate additional new approaches that can shift infectious diseases clinical research paradigms. The committee will also focus on biomedical innovation in infectious diseases, entrepreneurship-utilization of NIAID's small business program, the identification and development of areas of frontier research such as computational biology, immune-engineering and interfaces with the for-profit biomedical sector and the non-profit sector both locally and nationally and will connect to innovation ecosystems developing globally. The committee will also address new approaches to intellectual property issues, data sharing and IDCRC reciprocity agreements.

5. Laboratory Sciences

Serve in an advisory and oversight role with the Laboratory Operations Unit. Activities of the Committee will include protocol standardization across sites, defining pathogen and vaccine specifics, development of universal SOPs for specimen handling and shipping, engaging with working groups to define assays as a priority, development of SOPs regarding biobanking, building a quantitative lab approach, standardization for international site samples, and improving the quarterly IQA process.

5.5 Removal of Any IDCRC KFC Member

In the unlikely event that any IDCRC KFC member needs to be removed for cause, a written proposal to remove the member must be submitted with support from at least three members. Removal of the member is based on a majority among members and requires concurrence from the EMT and DMID.

5.6 Conflict of Interest

All members of the IDCRC will complete a standardized COI form that is submitted to and reviewed by the LOC. If voting is required, KFC members with conflicts of interest will disclose any COI; decisions on recusals, abstaining from voting will be made by the KFC Chair.

Version number	Approval Date DD MMM YYYY	Summary of Changes
2.0		<ul style="list-style-type: none"> • Combined Quality Assurance and Ethics KFC with Performance Evaluation KFC in alignment with active committees. • Combined Training and Education KFC with Mentoring and Career Development KFC in alignment with active committees. • Removed references to SOGC. • Added flexibility to meeting schedule. • Updated KFC objectives to be more descriptive and better align with KFC activities.