



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), Scientific Oversight Governance Committee (SOGC) and the Expert Working Groups (EWGs) to establish the agenda, oversee the activities of the IDCRC^{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 seven KFCs:

- 1) Quality Assurance and Ethics (Zenilman, Co-Chair, Hendrix, Co-Chair),
- 2) Performance Evaluation (Marrazzo, Chair),
- 3) Mentoring and Career Development (Edwards, Chair),
- 4) Collaborations and Publications (Orenstein, Chair),
- 5) Innovations (Spearman, Chair),
- 6) Laboratory Sciences (Gale, Chair, Ahmed, Co-Chair),
- 7) Training and Education (Ofotokun, Chair).

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 an ID^{LG} key personnel member, reports to EMT leadership, and each Chair will sit on the SOGC. 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 ID^{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 initially 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. The scope of work will be completed, and committees formed and active in the first six months of the award. They will meet via teleconferencing 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 via teleconference (monthly) and in person at regularly scheduled annual meetings, including periodically with the LG and other leadership committees, as needed.

5.4. KFCs

As noted, there are 7 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. Quality Assurance and Ethics

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 LG. These strategies will 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. Performance Evaluation

Develops and incorporates policies, methods and approaches for the monitoring and implementation of clinical research conducted by the VTEUs and evaluates the operational performance of the overall LG and each LG element.

There will be overlap between this KFC and the QA KFC.

3. Mentoring and Career Development

Identify robust clinical research experiences, programs and training opportunities for junior investigators. This will take the form of mentoring committees, career development through T, K, or other grants, small clinical research projects, classroom training in clinical research and statistical analysis, participation in LG committees, participation as junior investigators on studies and trials, and exposure to other aspects of clinical research. The LG will develop a program to support effort of young investigators in the IDCRC.

Develop a comprehensive career development program; a two yearly IDCRC Young Investigator Awards program will be developed.

4) 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.

5) Innovations

Key goals are to enhance flexibility, adaptability, efficiency by rapid integration of new concepts in infectious diseases research to advance scientific knowledge and clinical practice

6. Laboratory Sciences

Serve in an advisory and oversight role with the Laboratory Operations Unit.

7. Training and Education

Develop best clinical research practices to enhance quality and efficiency of the IDCRC clinical research. This Committee will be charged to ensure the competence of the workforce, performing LG oversight of all participants regarding documentation of appropriate training & certification and monitoring the number of trainings conducted at sites.

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.