



4 EXPERT WORKING GROUPS

The Expert Working Groups (EWGs) are a key component of the LOC created to review IDCRC concept proposals and provide recommendations to the LG. The LG will use EWG recommendations and current public health needs as benchmarks to monitor and prioritize clinical research undertaken by the LG. The Leadership Operations Center (LOC) contains the governance components of the LG and is responsible for the assembly and establishment of five EWGs : 1) Respiratory 2) Sexually Transmitted Infections (non-HIV), 3) Enterics, 4) Malaria/Tropical Diseases, and 5) Emerging Infectious Diseases. Each EWG will emphasize and promote the integration of special and underserved populations into the IDCRC research agenda across the entire human lifespan.

4.1 EWG Leadership

Each EWG will be led by at least one VTEU PD/PI or their designee and include 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. Areas of expertise anticipated on each EWG include content expertise, experience in leading and conducting relevant research, clinical trials design, vaccine or therapeutic agent evaluation, laboratory experience such as immunology or pharmacokinetics (PK), experience in special or underserved populations, and (as relevant) international experts knowledgeable in the relevant content and location of study conduct. An early-career investigator from the IDCRC will also be asked to serve as a non-voting member on EWGs. In the event of a public health emergency or as decided by the LG and DMID, additional *ad hoc* expert working groups can be formed to provide specific scientific expertise in protocol development and implementation. Ad hoc members may also be added to EWGs as needed for specific concept reviews requiring additional expertise.

4.1.1 EWG Co-Chairs

PIs from the VTEUs will initially serve as one of two Co-Chairs for the EWGs depending on their areas of expertise. After a two-year term, the PI will either become a voting member of the same EWG or rotate to a Co-Chair position or voting member position on another EWG, depending on expertise and/or leadership needs. EWGs will always have at least one VTEU PI as a Co-Chair.

4.1.2 EWG Composition, Terms and Responsibilities

1. Voting members of the EWGs will generally serve a three-year term with initial staggered terms to avoid full turnover at one time. While IDCRC leadership will strive for diverse representation on the EWGs by emphasizing appropriate term limits and orderly transitions, terms beyond three years may occasionally be considered when particular expertise is needed.
2. Each VTEU will be asked to nominate at least one member to serve as a Co-Chair or voting member for each EWG. Nominations will be reviewed by the EMT. Expertise in the relevant content as measured by prior experience serving as a leader for relevant clinical trial(s) and/or publications in

- the field, will be the major criteria for EWG membership. EWG voting members will be expected to participate in the majority of scheduled calls to maintain their active status on the working group.
3. Each VTEU will designate one or two early-career nominees to serve a one-year term as a non-voting, member-in-training on one EWG. The individual may subsequently be invited at the discretion of the Co-Chairs to become a voting member with a two-year term.
 4. Members of the IDCRC Executive Management Team (EMT) will serve as ex-officio, non-voting members of EWGs. The exception to this will be two members of the LG (currently Paul Spearman and Robert Atmar, who will serve a two-year term) who will serve as liaisons/advisors on concepts to all of the EWGs and not as EWG ex-officio members of an individual EWG.
 5. Additional ad hoc EWG members may be recruited for individual concept review purposes if needed to provide sufficient expertise. A list of potential ad hoc reviewers with disease-specific expertise will be compiled. Ad hoc members will be asked to complete COI forms and non-disclosure agreements prior to participating (if not already in place). Pathogen-specific ad hoc EWGs may be added in the setting of major outbreaks such as COVID-19.
 6. Each EWG will have one voting DMID Branch representative and one or more back-up DMID Branch member(s) (non-voting unless voting on behalf of the voting representative in their absence or as a consensus vote from DMID). DMID Branch representatives will be selected for their expertise in the EWG's scientific focus, and will serve as a liaison between the EWG and DMID/NIH, communicating content related to concept suitability, alignment with NIH priorities, and budget.

The EWG convenes regularly via teleconference (monthly) and in person (or by Zoom) at regularly scheduled annual meetings, including periodically with the LG and other leadership committees, as needed. Voting members include all listed EWG members (excluding ex-officio and early career members), with one voting representative presenting a consensus vote from NIH.

Concept reviews and recommendations made by the EWG are communicated by the EWG Co-Chairs in writing to the EMT for initial concept proposals, and reviews and recommendations for extended concept proposals are provided by the EWG Co-Chairs to the EMT during routine calls.

4.2 Removal of Any IDCRC EWG Member

In the unlikely event that any IDCRC EWG member needs to be removed for cause, a written proposal to remove the member must be submitted with support from at least three voting members. Removal of the member is based on at least 80% concurrence among voting members and requires concurrence from the EMT and DMID.

4.3 Conflict of Interest

The consortium follows a strict conflict of interest (COI) policy throughout the ICP and ECP review process. All members should complete a standardized COI form annually to have on file. This form is focused on financial or potential financial conflicts.

Prior to, and at the beginning of each EWG meeting, the facilitator will solicit/confirm COIs from each member, related to concepts for review. This process will include scientific, financial, and institutional conflicts and will be documented in the minutes of each meeting. A voting EWG member with a COI will be removed from the call during the discussion, and/or vote, of that concept.