



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) Enteric, 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 two Co-Chairs 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. Early-career investigators from the IDCRC will also be asked to serve as non-voting members 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

Two EWG Co-Chairs will be selected by the LOC based on their areas of scientific expertise and leadership experience and will serve a two-year term. EWG Co-Chairs must represent different institutions to avoid institutional COI. Efforts will be made to appoint each VTEU PI to at least one EWG Co-Chair position. After a two-year term, the Co-Chairs will either rotate off the EWG or become a voting member of the EWG. In some cases, a Co-Chair may be asked to stay on for an additional one or two-year term.

4.1.2 EWG Composition, Terms and Responsibilities

1. Voting members of the EWGs will generally serve a three-year term, with staggered starts 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 yearly to nominate at least one individual to serve as a Co-Chair or voting member for each EWG. Nominations will be reviewed by the LOC. 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 related scientific expertise, and general clinical trial experience 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 more early-career nominees to serve a two-year term as a non-voting, member-in-training on one EWG. The individual may subsequently be invited at the discretion of the LOC to become a voting member with a two-year term.
4. Early Career members of the Mentoring and Career Development Committee (MCDC) will submit a request to serve on an EWG that aligns with their research interests. These requests will be approved by the LOC and the MCDC Co-Chairs. These individuals will serve a two-year term as a non-voting member-in-training and may subsequently be invited to convert to a voting member.
5. 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, who will serve as EWG liaisons/advisors on concepts to all of the EWGs and not as EWG ex-officio members of an individual EWG.
6. Additional ad hoc EWG members may be recruited for individual concept review purposes if needed to provide sufficient expertise. 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.
7. Each EWG will have one voting DMID 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 video conference (generally monthly) and in person (or by remote access) 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 for initial concept proposals (ICP) are communicated by the LOC administrator to the EMT for concurrence, on behalf of the EWG Co-Chairs. Reviews and recommendations for extended concept proposals (ECP) 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 in the form of an online poll. This process will include scientific, financial, and institutional conflicts and will be documented in the minutes of each meeting, as well as the poll record. A voting EWG member involved in the scientific development of the concept or with a financial conflict will be recused from closed discussion and voting. If the voting member only discloses an institutional conflict, that member may participate in discussion but must refrain from voting.

Version number	Approval Date DD MMM YYYY	Summary of Changes
1.3		<ul style="list-style-type: none"> • Updated Section 4.1 to reflect change in EWG co-chair structure (not requiring a VTEU PI) as well as early-career investigators (will allow >1 per EWG) • Section 4.1.1 updated to same language as 4.1 • Section 4.1.2 changed voting member term and replaced EMT with LOC for nomination review of EWG members. • Section 4.1.2 revised early career term and added language (4.1.2.4) about members of the MCDC • Section 4.1.2.6 removed language about ad hoc reviewers • Section 4.1.2 updated language about EWG recommendations on ICP/ECP to EMT • Section 4.3 updated COI language to reflect addition of Zoom poll, as well as distinction of COI terms for participation in discussion/voting.