# 9 CONCEPT REVIEW, DEVELOPMENT AND MODIFICATIONS

The IDCRC has an open and iterative process for review of new study proposals designed to efficiently identify for further development those of highest scientific merit, potential public health impact, and appropriateness for implementation within the IDCRC. Consortium studies are developed through a multidisciplinary collaboration among investigators, the Expert Working Groups (EWGs), the Executive Management Team (EMT), Scientific and Operations Governance Committee (SOGC) and DMID/NIAID, as well as representatives from the consortium resources Clinical Operations Unit (COU), Statistical and Data Science Unit (SDSU), Laboratory Operations Unit (LOU), Community Advisory Board (CAB) when indicated, site representatives, and external collaborators as relevant. This process involves sequential development and review steps for both initial and expanded concepts and protocols, described in greater detail in the remainder of this section.

The scientific priority of research proposals is determined by the EMT, after a two-step review process and recommendation by the relevant EWGs, in alignment with the mission and research agenda (outlined in Section 4). New studies may be proposed by VTEU investigators, external investigators, industry partners, DMID/NIAID or may be commissioned by the SOGC. Entities submitting concepts from outside the network will be encouraged to partner with an established VTEU sites or the LG. Regardless of origin, initial review and prioritization is the responsibility of the EWG Liaisons, relevant EWG Co-Chairs and the DMID representative on the EWG, and the EMT. As depicted in Figure 9-1, new study development begins with a short study proposal in the form of an initial concept proposal (ICP) that briefly outlines the proposed study so that a decision can be made about whether further development is warranted. If so, the proposing team is invited to submit an expanded concept proposal (ECP); the ECP is then reviewed (see Figure 9-2 for review criteria) to determine whether the network should commit resources to full protocol development and study conduct.

**Figure 9-1. IDCRC Review Criteria**

*The criteria outlined here are used for all stages of concept review and will be used to assign a score during ECP review. Proposals are assigned numerical scores of 1 to 5, with 1 being the most favorable.*

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|---|---|
| **Scientific Merit**<br><br>Score of 1 to 5<br>Highest = 1<br>Lowest = 5 | • Are the hypotheses scientifically sound and answerable by the proposed design?<br>• Is the study appropriately designed to address the hypothesis?<br>• Is the population appropriate for the research? Do the eligibility criteria specify an appropriate population?<br>• Does the proposal include proper randomization and stratification procedures, as relevant?<br>• Are safety parameters specified? |
| **Public Health Impact**<br><br>Score of 1 to 5<br>Highest = 1<br>Lowest = 5 | • What is the relevance of the concept to the prevention, diagnosis or treatment of infectious diseases? For example, will the resulting data prevent spread, save lives and/or decrease morbidity and if so, to what extent?<br>• What is the value added to the field? For example, will the study extend existing interventions or meet an unmet need?<br>• Does it contribute to a critical pathway that will advance science and impact public health, and if so, how?<br>• If shown to be effective, will the procedures or outcome described in the concept be acceptable and deliverable to key affected stakeholders (communities, clinicians, policy makers, as applicable)? |
| **Feasibility**<br><br>Score of 1 to 5<br>Highest = 1<br>Lowest = 5 | • Is the proposal feasible for implementation?<br>• Is study product produced and available?<br>• Is an appropriate study population available for recruitment?<br>• What is the level of difficulty for study implementation?<br>• What is level of difficulty of meeting target accrual?<br>• Is there capacity to conduct laboratory assays required for the proposed endpoints in a timely and accurate fashion?<br>• Is the study schedule appropriate?<br>• Are there barriers to IRB, ethical and/or regulatory approval? |
| **Fit with VTEU Mission**<br><br>Score of 1 to 5<br>Highest = 1<br>Lowest = 5 | • Is the concept aligned with the scientific priorities of the IDCRC?<br>• Does the proposal benefit from the VTEU model that emphasizes a multi-site, multi-disciplinary collaboration involving different populations?<br>• How is the proposed intervention well-suited for evaluation through the VTEU mechanism? Is this a concept that would otherwise not be evaluated through other mechanisms such as alternative/industry development pathways? |
| **Innovation**<br><br>Score of 1 to 5<br>Highest = 1<br>Lowest = 5 | • Is the concept, approach, population or intervention novel?<br>• Will the proposed trial involve innovative products, treatments, methodologies or assays? |
| **Overall Priority Score**<br><br>Score of 1 to 5<br>Highest = 1<br>Lowest = 5 | • Is the concept proposal of sufficient priority within the IDCRC to commit resources to the development and implementation?<br>• Based on the relevance of the concept proposal to the IDCRC scientific agenda, what is your level of support for the concept proposal? |

**Conflicts of Interest**

The consortium follows a strict conflict of interest (COI) policy throughout the ICP and ECP review process and protocol development. All voting members of the IDCRC 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 be documented in the minutes of each meeting. An EWG member with a COI will be removed from the call during the discussion, and/or vote, of that concept.

An EMT member involved in the scientific development of a proposed study or with a financial conflict, must recuse herself or himself from discussion, scoring, and voting on that concept. If the EMT member has only an institutional conflict, they may participate in discussions of the study proposal but refrain from voting on the outcome of the proposal.

## 9.1 Initial Concept Development and Review

### 9.1.1 Development

The first step in proposing a new IDCRC study is to assemble a three-page initial concept proposal (ICP). The ICP template is available on the IDCRC website and includes the elements outlined in Figure 9-3: https://med.emory.edu/departments/medicine/divisions/infectious-diseases/idcrc/concept.html
ICPs may be submitted at any time; the process of review is outlined below.

**Figure 9-3. Elements of IDCRC Concepts**

- Study Title
- Study Location
- Network Affiliation
- Planned Duration of Study (months – to include time for development; implementation; estimated time for enrollment and f/up; thru to closure and analysis)
- Description
- Background & Significance (including public health impact and fit with VTEU mission)
- Objectives
- Design (population, recruitment/enrollment sites; lab testing/key assays and statistical plan)
- Site(s) (proposed as single vs multi-site; possible locations investigators)
- Funding sources/collaborations if external to IDCRC, for example, industry or commercial partnerships
- Timeline for availability of product when relevant
- Estimated Costs if known (based on per participant costs; not binding)

Completed ICPs should be submitted by the proposing investigator(s) to the Leadership Operations Center (LOC) by email, IDCRC@emory.edu, or via the IDCRC website at https://med.emory.edu/departments/medicine/divisions/infectious-diseases/idcrc/concept.html, .

The ICP is then assigned a unique identification number (for example IDCRC ICP 2020-0002-**I**) for tracking purposes, maintained in a pipeline spreadsheet that is updated on Box, and administratively reviewed for completeness by a member of the LOC Administration (Figure 9-1, step 1). If key information is lacking, the ICP will be returned with a query to complete and resubmit. ICPs that are clear and complete will be forwarded to EWG Liaisons to begin the review process (Figure 9-1, step 2).

**Summary of ICP Process**

1. Receipt and preliminary review by LOC Admin – return for more info or proceed to next step
2. Review by EWG Liaisons with a courtesy copy to EMT – return for more information, reject as Administratively not Supported, or proceed to next step
3. Review by SDSU, as appropriate
4. Review by EWG Co-Chairs and DMID representatives – return for more information or proceed to next step
5. Discussion by full EWG – proceed to next step
6. Summary and recommendations presented to EMT by EWG Liaisons/Co-Chairs (do not recommend for ECP; revise/resubmit; recommend for ECP)
7. Review by EMT and DMID for final determination
8. Notification of final determination by LOC Administration

Full details of the review process/procedure are available within the IDCRC_Concept_SOP_Instructions document.

## 9.2 Expanded Concept Development and Review

### 9.2.1 Development

Expanded concept proposals (ECP) are developed in a template format that will be provided by the LOC should one be requested post a favorable ICP/EMT review/recommendation. ECPs are expected to be approximately 10 pages in length (excluding references and budget estimate) and describe the proposed study in greater detail than the ICP.

The EMT may assign staff from the COU, SDSU and LOU to support the development of each ECP. The COU may provide administrative and coordination support to the concept development group. The SDSU statistician(s) provides advice on study design and sample size calculations, and the LOU provides advice on laboratory evaluations, as needed. Proposing investigators may involve other collaborators with relevant expertise in the concept development team.

### 9.2.2 Scientific Review

The ECP review and scoring criteria are shown in Figure 9-1.

ECPs will be submitted to the LOC and will be assigned a unique ECP tracking number upon receipt. As an example, IDCRC ECP 2020-0002-**E**. This number ties to the assigned ICP number with an E versus and I at the end. The ECP is then logged in the pipeline spreadsheet.

**Summary of ECP Process**

- Receipt and preliminary review by LOC Admin – return for more info or proceed to next step
- LOC Admin forward to the EWG Liaisons. EMT is cc'd.
- They will review, request additional information if required, and then send to EWG Co-Chairs, EWG DMID reps, and FHI 360.
- FHI360 will create budget estimate from template; OR request additional information if needed
- ECP estimated budget will be sent to EWG Co-Chairs and LOC Admin (this will ensure documents are aligned regardless of review timelines)
- EWG Co-Chairs assign primary and secondary reviewers and request SDSU review. LOU rep will also provide a formal review.
- EWG Co-Chairs and EWG DMID reps will have pre-meeting call or email discussion about the ECP in advance of the monthly EWG call.
- ECP will be reviewed by EWG on monthly call with budget per EWG timeline. Recommendations will go per timeline to EMT.
- ECP with budget discussed on EMT call. EWG Co-Chair(s) present recommendations. Vote taken.
- If strong positive consensus in EMT on ECP quality and priority—move to protocol development.
- ECP can proceed to protocol development. CSR review, when appropriate, may be done in parallel with protocol development.
- Alternatively, EMT may vote against moving forward, reserve decision while assessing priorities, and/or discuss further with DMID leadership to reach a decision.

Full details of the review process/procedure are available within the IDCRC_Concept_SOP_Instructions document.

## 9.3 Protocol Concepts in a Public Health Emergency

### 9.3.1 Development

While, in general, a concept will be required for all proposed research, circumstances such as public health emergencies may dictate a need for expediting or streamlining the formal process described above. All public health emergencies, as defined by WHO classified pandemics, will be considered high priority. In this case, the key elements of a preparedness response are:

1. The establishment of an emergency leadership team, comprised of representatives from the EMT, and close interaction and communication with all involved agencies and stakeholders;
2. The ability to expand and/or redirect efforts and resources;
3. Representatives from the EMT will serve as the emergency leadership team working closely with DMID to achieve rapid development and execution of critical public health research, while maintaining the scientific and regulatory rigor and quality principles that guide all work under the

IDCRC. If needed, an ad hoc EWG may be assembled to address a single emerging pathogen outside the scope of the standing EWG structure.

4. For high priority studies with urgent need, the EMT in collaboration with representation from the identified EWG and with DMID may approve an ICP for full protocol development – eliminating the ECP development and review step. Likewise, the EMT may commission development of an ECP – eliminating the ICP development and review step.

### 9.3.2 Summary of ICP Process During a Public Health Emergency

1. Receipt and preliminary review by LOC Admin – return for more info or proceed to next step
2. Expedited Review by EWG Liaisons with a courtesy copy to EMT – return for more information or proceed to next step
3. Expedited Review by SDSU, if needed
4. Special call meeting for review by EWG Co-Chairs, DMID representatives, and select EWG membership – proceed to next step
5. Summary and recommendations presented to EMT by EWG Liaisons/Co-Chairs
6. Review by EMT and DMID for final determination
7. Notification of final determination by LOC Admin

### 9.3.3 Summary of ECP Process During a Public Health Emergency

Should an ECP be requested the submission, review and approval would be similar to that outlined in 9.2 with the understanding that each step can be adjusted and/or expedited. All processes during a public health emergency will be expedited/streamlined to the greatest degree possible.

Full details of the review process/procedure are available within the IDCRC_Concept_SOP_Instructions document.