8 IDCRC Funding Procedures

The IDCRC is comprised of two components, the **Leadership Group (LG**), that facilitates, plans, and supports the implementation of clinical research that addresses the scientific priorities of NIAID in evaluating vaccines, other preventive biologics, therapeutics, diagnostics, and devices for the treatment and prevention of infectious diseases, and the individual **Vaccine and Treatment Evaluation Units (VTEUs)** that provide the scientific and administrative expertise and infrastructure to implement the clinical research.

Both components are funded as part of the annual allocation of funds from National Institutes of Health/ National Institute of Allergy and Infectious Diseases/ Division of Microbiology and Infectious Diseases (NIH/NIAID/DMID) as separate LG and VTEU awards. LG funds are awarded to Emory University, as the primary awardee of the grant, and are managed and distributed to LG partnering institutions via subawards.

Funding provided to the IDCRC is divided into two main types: **Core Funding** and **Protocol Funding**.

8.1 Core Funding

Core Funds are requested and awarded to support the infrastructure and operations of the IDCRC. Core Funding is requested on an annual basis and is included in the Research Performance and Progress Report (RPPR) package, due 60 days prior to the start of the next funding period (October 1st of each year) and awarded through a NIH Notice of Award (NOA). The LG and VTEUs receive Core Funding directly from NIH/NIAID/DMID through their cooperative agreement awards.

Core Funding may include costs such as:

- Principal Investigators (PIs) and other Key Personnel effort
- Supplies to support personnel
- Travel costs to attend IDCRC meetings
- General training of personnel, such as GCP and HSP
- Costs related to participation in IQA/proficiency testing

Additional costs for the LG may include:

- Personnel comprising the LG units (LOC, COU/FHI, LOU, SDSU) that provide scientific and operational expertise

- Costs to conduct VTEU and unit site visits and performance evaluation reviews

8.2 Protocol Funding

Protocol Funds are requested and awarded to support protocol-related expenses throughout the various phases of a protocol. Funding flow may vary depending on the stage of the protocol and the site(s) that require the funds (see Figure 1).

Figure 1. IDCRC Study Phases and Typical Funding Flow

	Protocol Development (~4-6 mos)	Pre-Implementation (~3 mos)	Implementation (Time Varies by Study)	Closeout (~6-9 mos)
VTEU Sites/ Labs	NIAID ➡ IDCRC LG* ➡ VTEU	NIAID ➡ VTEU	NIAID ➡ VTEU	NIAID ➡ VTEU
VTEU Sub-Sites/ Labs	No Development Funds awarded	NIAID ➡ VTEU ➡ Subsite	NIAID ➡ VTEU ➡ Subsite	NIAID ➡ VTEU ➡ Subsite
non-VTEU Sites/ Labs	No Development Funds awarded	NIAID ➡ IDCRC LG* ➡ Site	NIAID ➡ IDCRC LG* ➡ Site	NIAID ➡ IDCRC LG* ➡ Site
LG Units/ Labs	NIAID ➡ IDCRC LG* ➡ LG Site	NIAID ➡ IDCRC LG* ➡ LG Site	NIAID ➡ IDCRC LG* ➡ LG Site	NIAID ➡ IDCRC LG* ➡ LG Site

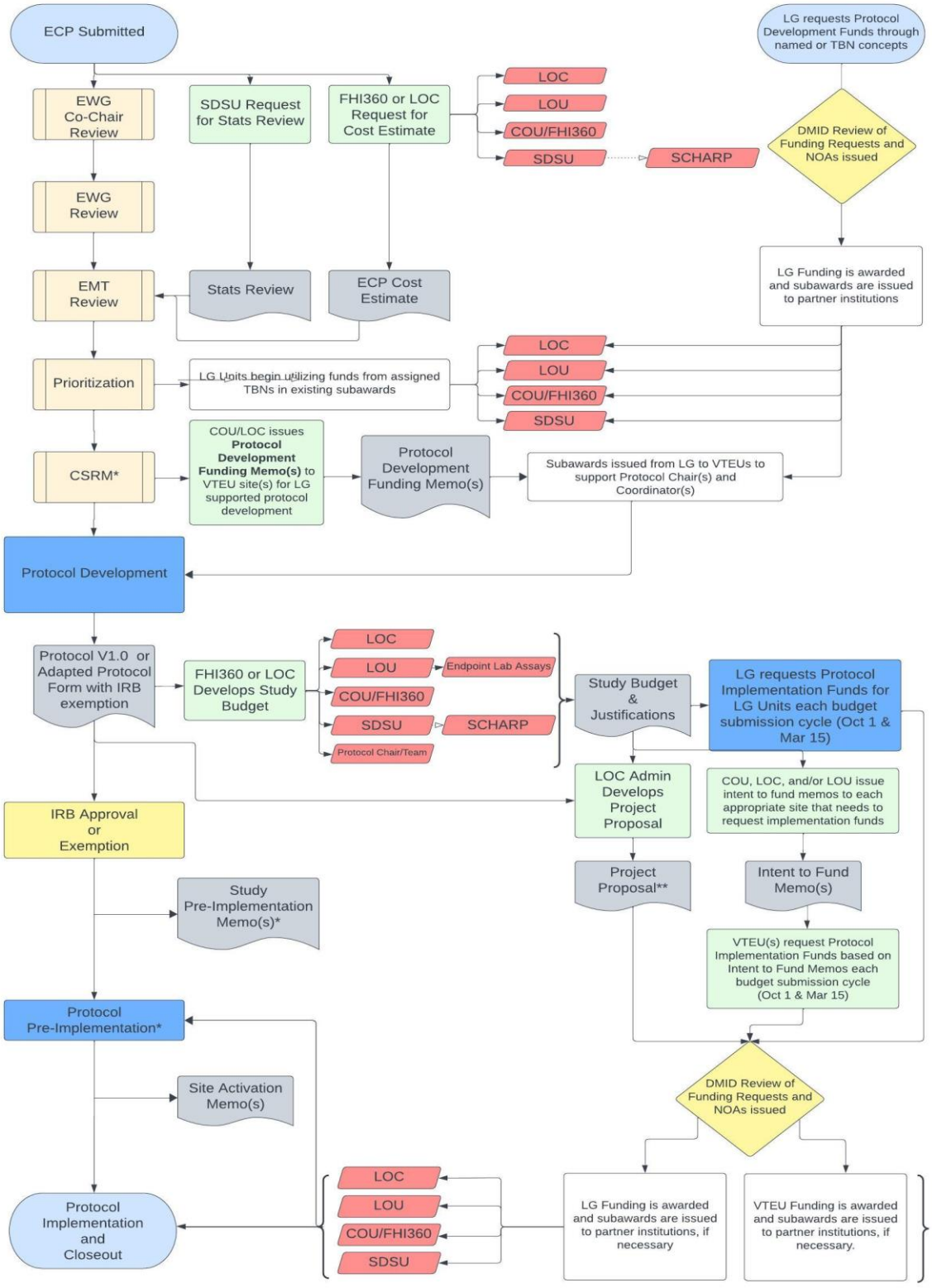
➡ Funds awarded via grant NoA
➡ Funds awarded via subcontract
* IDCRC LG Funds Awarded to Emory University

Funding for the **Protocol Development phase** period for studies flows from NIH/NIAID/DMID to the IDCRC LG (via Emory University) then to the VTEU(s), via subaward, to cover the effort of the approved Protocol Chair and a coordinator from the same institution, effort of site investigator(s)/co-chair(s) from VTEU(s) selected to participate as an implementing site(s), and the LG units involved in these activities. Funds to support protocol development efforts are not typically awarded to VTEU sub-sites or non-VTEU sites.

Funding for **Protocol Pre-Implementation, Implementation,** and **Closeout** flows from NIH/NIAID/DMID directly to the VTEU site(s) implementing the trial and to the IDCRC LG for operational support as well as implementation costs not directly associated with a VTEU (e.g., non-VTEU endpoint laboratories or protocol specific sites). VTEUs that have been approved to use official sub-sites to implement IDCRC protocols request funds on the sub-site's behalf and issue them via subaward.

Protocol Funds are typically requested twice a year, during the RPPR period as well as during the grant year, and are awarded/revised through the NIH Notice of Award (NOA) document with each approved request. The various processes and aspects associated with funding flow for IDCRC studies are illustrated in Figure 2 and detailed below.

Figure 2: IDCRC Protocol Funding Flow Diagram



*Clinical studies only
**Protocol Funds for study start-up during pre-implmeentation may be requested prior to the completion of a project proposal.

8.2.1 Budget Aspects of Concept Approval

Once an extended concept proposal (ECP) has been received, an FHI360 budget analyst (for clinical studies) or an LOC administrator (for lab studies) will begin the process of developing the high-level study cost estimate by using the information in the ECP and requesting additional information from the LOU for laboratory assays, oversight costs from all applicable LG units, and for statistical and data management from SDSU/SCHARP, usually in the case of non-IND studies. This estimate is preferred, but not required, for EWG review of the ECP. However, the budget should accompany the recommendations from the EWG when the Executive Management Team (EMT) reviews and considers the concept.

If, at any point during the concept review process, significant changes are recommended to the study design and/or an amended ECP is requested, FHI360 or the LOC will ensure that any financial impacts are accounted for, and a revised cost estimate must be made available to the EMT prior to a vote being conducted.

The EMT vote will determine whether a concept fits into the IDCRC priorities and is scientifically valid to warrant it proceeding to prioritization, which involves a determination of funding availability and priority relative to other studies in the pipeline by the IDCRC LG PIs and LOC. Prioritization is expected to occur at least quarterly, and concept submitters will be informed of this approximate timeline when notified of EMT approval.

Once a study is prioritized, FHI360 or the LOC will be informed that the ECP is able to begin preparations for the protocol development phase and will be responsible for working with the concept submitter on appropriate next steps, including DMID's Clinical Science Review Meeting (CSRM) process for all clinical trials.

8.2.2 Protocol Development

Protocol development effort is funded by IDCRC LG via subawards from Emory University to both LG operating units and VTEU institutions of the selected protocol chair and co-chair(s), in the case of multi-site trials. The funding processes start once a study is prioritized for protocol development.

Once a study passes CSRM and/or is officially in the protocol development phase, the COU or LOC, in the case of lab concepts, will provide the participating VTEU(s) with a **Protocol Development Funding memo** that outlines the site's available protocol development funds from the LG. Once received, sites must submit a budget and accompanying justification to Emory that can be used to initiate the subaward. Should protocol development effort span across multiple grant years, the LG will issue a new subcontract at the beginning of each new funding year.

The IDCRC provides a standardized level of support for study leadership during the protocol development phase, based on recommended percent efforts and average salaries across VTEUs:

- Protocol Chair - up to 10% effort of the current NIH salary cap.
- Protocol Co-Chair– up to 10% effort of the current NIH salary cap. Co-Chairs are typically only funded for multi-site studies, usually at a second site, and must be pre-approved by the COU.
- Protocol Development Coordinator – up to 15% effort of the current average VTEU coordinator salary, as calculated each year through an annual survey of costs at each site. The coordinator identified must come from the same VTEU as the Protocol Chair.

Funds to provide salary support during protocol development are only awarded to official VTEU institutions, via subawards from the LG. Restrictions on third party or third tier subawards, per NIAID policy, prevent VTEUs for redistributing these funds to a subsite. Redistribution of protocol development funds outside these recommended amounts are allowable at each site, as long as the total dollar amount remains within the limits provided above, as determined by the LG each year.

The protocol development period is typically budgeted for six (6) months for clinical trials and four (4) months for lab studies. The COU/LOC may decide to extend this period if a protocol is not ready to move into start-up, assuming funds are available, and will issue a revised Protocol Development Funding memo to the VTEU site(s). Protocol Development funds issued by the LG may not be drawn down simultaneously with Protocol funds issued by NIAID for pre-implementation/implementation/closeout.

8.2.3 Study Budget

When a protocol nears Version 1.0, a formal study budget is prepared that includes all site(s) and LG costs throughout the pre-implementation, implementation, and closeout periods of the study. Costs in the Study Budget may include:

- Salary support for VTEU site/sub-site and LG unit investigators and staff needed to carry out tasks that are attributable to the specified protocol(s) and not covered under core funded activities
- Site-Specific Study start-up/pre-implementation costs (e.g., study-specific staff training) not covered by core or protocol development funds
- Participant recruitment and retention
- Protocol required tests and evaluations
- Participant reimbursement
- Institutional Review Board costs to maintain shared IRB
- Study closeout (data cleaning/query responses, etc.)
- Shipping costs

- Study-specific equipment and supplies
- Community education and engagement structures and activities

The IDCRC has developed **standardized costing and levels of effort** to be used when creating site implementation budgets.

Once a full study budget is ready to be prepared, the budget analyst contacts the Protocol Chair and other relevant study team members to discuss the budget template and gather study specific information and details. The budget analyst will use this information to develop the initial draft of the budget. The Protocol Chair will be asked to review the draft to ensure all study activities have been captured and/or communicate any needed changes or special circumstances that need to be accounted for. This communication/collaboration continues throughout the budget development process to arrive at a final budget. Should a site's costs be outside the norm of the IDCRC standard rate, approval from the COU/LOC would be required to adjust costing and the budget analyst would seek this approval. Once the study budget has been finalized and approved by the PI, the budget analyst will submit the final budget to the COU/LOC for approval.

Standardized costs will be updated annually for new studies and adjusted as needed by the FHI360 Budget Analyst who will solicit individual costs and time requirements from the VTEU sites on annual basis. A template will be provided to the sites to populate with their costs. The FHI360 budget analyst will compile the submissions and compute an average cost for each of the items/tasks in the template. This average/standardized cost and effort will be used as the basis when creating study specific budgets.
The template provided to the VTEU sites will include:

- Laboratory tests
- Common assay panels
- Subject Remuneration/Participant Reimbursement
- General site costs (F&A rate, shipping costs, fringe benefit rate, etc.)
- Salaries
- Procedure/activity time requirement
- Other routine activities (to be filled out by the site if not already included)

In addition to site costs, each LG unit submits a budget that captures costs for the scope of work for the entire project period, accompanied by a budget narrative that provides written justifications for their budgeted costs. The LOU will also be asked to provide endpoint laboratory assay budgets and will work with the endpoint laboratories to provide detailed budget narratives. The SDSU/SCHARP will be asked to provide statistical and data management costs, if applicable. This study budget is intended to be an estimate of the total cost of the study and will form the basis of funding requests for the study on a year-by-year basis as well as used to determine site funding levels.

8.2.4 Project Proposals

With the completion of the study budget, a project proposal is also prepared and submitted to DMID, prior to any funding decisions. The project proposal is a package of materials for an IDCRC study preparing for implementation, including a complete budget and research narratives submitted to IDCRC LG Program Officer (PO) as considerations for implementation funding take place. The proposal includes the following components, as is applicable, based on the stated version of the protocol:

- Cover page with Title, Table of Contents, and Protocol Version
- Protocol Title, Abstract, and Timeline Milestones
- Budget Summary
- Budget Narrative: Study Leadership
- Budget Narrative: Clinical Site Costs
- Budget Narrative: Laboratory Costs
- Budget Narrative: COU FHI 360
- Budget Narrative: LOC Emory
- Budget Narrative: LOU FHCC
- Budget Narrative: SDSU FHCC
- Research Strategy
- Protocol Summary

The LOC is responsible for completing these project proposals using several protocol documents, and the LOC submits the project proposals to the PO prior to the release of protocol implementation funds.

Note: Given the limited number of times protocol funds can be requested throughout a grant year, the IDCRC may consider a recommendation for protocol funds to the study site(s) for pre-implementation/start-up costs only. In these cases, this funding request may be considered and awarded prior to the submission of the project proposal.

8.2.5 Protocol Implementation Intent to Fund Memos

Funding for protocol pre-implementation/start-up activities (not funded during protocol development), implementation, and closeout activities are requested by and awarded to the LG and VTEUs separately, one grant year at a time, from NIH/NIAID/DMID. The LG utilizes **Intent to Fund memos** to guide VTEUs on the funding to request, based on the projected needs of the study.

Intent to Fund memos are LG-generated documents that provide VTEUs with the funding details that should be requested for each implementing IDCRC protocol, based on the approved study budget, planned enrollment targets, and visit schedules for the funding period. Intent to Fund memos are issued separately to each implementing VTEU for specific protocol costs, and,

where applicable, for endpoint assay lab costs. Participating sites are expected to use these memos when preparing funding requests to NIH/NIAID/DMID.

If the implementing VTEU(s) and endpoint lab(s) are located at the same institution, or are a subcontractor of the VTEU, the LOC, COU, and LOU will work to issue one Intent to Fund memo to the site. If endpoint laboratories are located at different institutions, not associated with an existing VTEU, separate Laboratory Intent to Fund memos and Clinical Intent to Fund memos will be generated and issued by the LOU and COU/LOC, respectively.

Intent to Fund memos are issued to sites at least four (4) weeks in advance of NIAID funding request submission deadlines.

Intent to Fund memos are intended to capture all activities that will take place during the funding period, regardless of whether they have been funded in a previous period. The IDCRC LG and VTEUs are responsible for projecting the activities that will take place and the funds that will be required to support those activities, without regard to previous awarded funds or available balances. This approach of capturing activities that shift between grant years in the annual and midyear funding requests differs from typical grant funding processes. Requests for carryover require prior approval from both the IDCRC and NIAID/DMID and require strong justification. Carryover is not typically approved because funds issued through the annual and midyear funding requests are intended to capture all projected budgeted activities.

The Intent to Fund memo includes a standardized level of support for study leadership during the pre-implementation, implementation, and closeout phases based on recommended percent efforts and average salaries across VTEUs:

- Protocol Chair - up to 5% effort of the current NIH salary cap.
- Protocol Co-Chair– up to 5% effort of the current NIH salary cap. Co-Chairs are typically only funded for multi-site studies, usually at a second site, and must be pre-approved by the COU.
- Protocol Development Coordinator – up to 15% effort of the current average VTEU coordinator salary, as calculated each year through an annual survey of costs at each site. The coordinator identified must come from the same VTEU as the Protocol Chair.

Redistribution of study leadership funds outside these recommended amounts is allowable at each site, as long as the total dollar amount remains within the limits provided above, as outlined within the Intent to Fund memo.

Intent to Fund memos are created based on timeline and enrollment assumptions made at the time of issuance. Approval to drawdown funds awarded require LG notification, as described below, and should take place in alignment with the efforts detailed in the provided budget tables and must not exceed the performance of the grant activities. Should the study timeline

or pace of enrollment not match these projections, the funds associated with those activities should not be spent. The LG will work to provide revised guidance on funding when significant changes to timelines or assumptions occur, via amendments to Intent to Fund memos.

For new clinical studies, funds issued by NIAID for **pre-implementation** activities, which need to occur to prepare for activation, should not be drawn down until the IDCRC LG (via the COU) notifies the implementing sites, via a **Study Pre-Implementation Memo**. This memo is typically issued once a study level IRB approval is obtained on an implementable protocol version for multi-site studies or once institutional level IRB approval is requested on an implementable protocol version for single-site studies. Once approval for pre-implementation is provided, any site being supported by LG-issued funds for protocol development must cease drawdown from their subcontract and transition to the NIAID-issued funds.

Drawdown of funds to support **implementation** activities should only begin once a site receives their **Site Activation Memo**, as described in the Study Pre-Implementation MOP.

Funding to support site **closeout** activities for IDCRC clinical protocols are typically budgeted for up to nine (9) months after implementation ends. Protocol teams with plans for additional publications and/or exploratory analyses may formally request an extension to this period prior to completion of participant follow-up. All requests must be made in writing by the protocol chair to the COU co-directors and should provide a strong justification for the need for the extension and outline activities that will take place during this time (e.g., maintaining IRB, study SharePoint, team calls, etc.). Availability of LG funding and staffing will be considered in reviewing these requests, as well as ensuring that any external reporting requirements will still be met. Approved closeout extensions will be considered a study budget change and follow the process outlined below.

8.2.6 Protocol Implementation Funding Requests

Requests for protocol implementation funding may be submitted twice per year by both the LG and VTEUs: in the RPPR, due Oct 1st, and again in the Midyear submission, due on March 15th of each grant year. The Midyear submission may utilize PA-20-272 as the program announcement.

VTEU sites are to use the LG-issued Intent to Fund memos to inform their site funding requests. Funds should only be requested for the current grant year and should follow the IDCRC parent award budget period (i.e., 12/1 – 11/30 for RPPR submissions, 5/1 – 11/30 for Midyear submissions). Site budget justifications should include the following statement: “These costs are based upon the intent to fund memo sent by the IDCRC LG on xx-xx-xxxx and are consistent with the overall study budget.” Should a site identify any gaps in the provided Intent to Fund memo, they must seek LG approval for those items by submitting a written request to the COU for consideration at least two (2) weeks prior to a funding request submission deadline.

Completed project proposals and copies of Intent to Fund memos will be made available to the DMID Program Officers who will make recommendations for funding based on VTEU funding requests submitted.

Materials for funding request applications, including subcontracts for VTEU partners are to be combined and routed through the prime VTEU institution based on their own institutional policies and submitted to NIH, in compliance with the NIH Grants Management Policy.

Each implementing study site will be responsible for creating an HSS and IER record, based on an COU-issued template, which can be linked to the study record in clinicaltrials.gov.

Emory University will be responsible for combining and submitting protocol implementation funding requests for all LG operating units.

8.2.7 Publication Fee Funding

The IDCRC LG budget includes a small amount of funds to support publications expenses for primary manuscripts for IDCRC protocols. To request personal reimbursement, authors may send publications expense receipts and a signed Emory Supplier Information form to the IDCRC LG Finance Director. Support for these expenses is based on available funding and is not guaranteed. Fees related to open access will not typically be supported, but requests for exception to this policy may be submitted to the IDCRC Collaborations and Publications Committee and may be considered for manuscripts with a strong need for global access, a high public health impact, and without alternatives for sharing of the research findings.

8.2.8 Study Budget Changes

Protocol changes made after EMT approval of a study budget that have cost implications are reviewed by the FHI360 budget analyst for clinical studies or LOC administrator for laboratory studies, in collaboration with the LOU (if laboratories are affected), and DMID.

If these changes occur during a funding cycle, the LG will work with all affected sites to determine the financial impact. If the changes result in increased costs, the LG will work with the sites and DMID to determine whether the increase can be absorbed with the current level of funding. If additional funds are needed, they may be requested during the Midyear funding request.

Requests for additional funds not associated with specific protocol changes (e.g., additional personnel effort, infrastructure costs) may be requested in writing to the COU with a justification and will typically only be considered during the RPPR funding period.
Changes that increase an overall study budget by more than 10% must be reviewed and approved by the IDCRC EMT before they can be implemented. If approved, these changes will be documented as an addendum to the project proposal and provided to IDCRC LG PO.

Approvals for study budget changes will be communicated via Intent to Fund memos to the affected implementing sites.

Requests for additional LG unit costs over 10% of their costs included in the original overall study budget must be reviewed and approved by the LOC co-chairs prior to being submitted in a budget request.

8.3 Financial Reporting

Requirements for financial reporting for the IDCRC LG and VTEUs are determined based on the terms and conditions of each institution's Notice of Award.

The IDCRC LG is responsible for tracking the overall funding allocated to the LG and VTEUs each year and forecasting expenses in outyears through the end of the grant cycle. The LOC maintains this tracker based on available information from concepts, study budgets, and DMID-provided award information for each site.

Additionally, the LG may request reports on study spend and financial projections from operating units and VTEUs to determine funding needs throughout the grant year, as needed.

REVISION HISTORY:

Version number	Date Reviewed DD MMM YYYY	Summary of Changes
2.0	12Feb2025	• Updated to reflect increase to 10% protocol chair support during protocol development, 5% thereafter. • Added intent to fund memo clarity regarding activities that shift between funding periods. • Improved clarification of pre-implementation period timing. • Added guidance regarding publication fee funding.