Infectious Diseases Clinical Research Consortium

Mentoring and Career Development Committee

2025 Early Career Investigator Pilot Awards RFA

Mentored Pilot Research Project awards (similar to K08, K23, and K99 awards) provide 1 year of funding to support research projects and career development activities that will enhance the applicant's ability to compete successfully for an independent R- or K-series award (e.g., acquisition of preliminary data, training in grant preparation).

Research must align with the scientific priorities of NIAID in evaluating vaccines, other preventive biologics, therapeutics, diagnostics, including prognostic and predictive markers, and devices for the treatment and prevention of infectious diseases. We encourage but do not require projects that are value-added (including secondary analyses) to existing VTEU projects. To maximize success of pilot research projects with funding that is limited to a 12-month period, we strongly encourage submission of pilot proposals that utilize existing data and/or samples that have IRB clearance for the intended use. **Projects using live vertebrate animals for research or testing will not be considered under this funding mechanism.**

Applicants may only submit one application to this program per cycle.

Applicant Eligibility

1. Scientists nearing completion of postdoc or in early faculty positions (Instructor or Assistant Professor). Applicants are required to have an MD or PhD or equivalent terminal degree in order to be eligible to apply and must be eligible for NIH K or R awards.
2. Must not have served as Principal Investigator (PI) or MPI on a Federally funded R-grant other than an R03. Serving as PI on a K-series or other mentored career award does not preclude eligibility. Recipients of a K99/R00 Pathway to Independence Award are not eligible.
3. Strong preference will be given to mentees who are in the IDCRC Mentoring and Career Development Committee's Mentorship Program.
4. Applications must have a single PI (no Co-PI or MPI applications will be accepted).

Funding

- Awards **up to** $60,000 direct costs, depending on scope of project. Funds are non-transferable.
- Matching funds by the applicant's local institution/department/division/VTEU are encouraged, and applications with a clear commitment to matching will be given preference.
- Awards to the institutions will include indirect cost at the institution's federal indirect cost rate.
- All costs must conform to the NIH Grants Policy Statement (GPS) and applicable U.S. Office of Management and Budget OMB circulars for necessity and reasonability, allocability, conformance and consistency, as well as allowability.
- Funding period is December 1, 2025, through November 30, 2026. No cost extensions are not permitted.

Timeline

Tuesday, April 1, 2025 – RFA Release Date
Friday, May 16, 2025 – Pre-Submission Form Due Date
Friday, August 1, 2025, 5:00 p.m. EST – Full Application Due Date
Friday, September 12, 2025 – IDCRC Determination Notification
Friday, October 24, 2025 – IRB determination/approval due, if applicable
October-November – NIAID Review and Funding Determination
December 1 – November 30 – Funding Period

Should an applicant wish to withdraw at any stage, please inform Jacquelyn Manduley, jfmandu@emory.edu.

Please send any questions to: Dr. Igho Ofotokun (iofotok@emory.edu) and Dr. Lara Danziger-Isakov (lara.danziger-isakov@cchmc.org) IDCRC Mentoring and Career Development Committee Co-Chairs.

Application Review Criteria

The evaluation criteria for proposals include:

Applicant
Commitment to a research career
Academic record and accomplishments to date
Potential to become an independent investigator
Applicant is an IDCRC Mentee
Commitment of institutional funding in support of the project

Career Development Plan
Appropriateness of the plan for achieving scientific independence
Consistency with candidate's prior training and career goals
Impact of project on pathway to independence
Impact of proposed mentorship in the investigator's career development

Mentor/Co-mentors
Mentor's research qualifications in the area of the proposed project
Quality and extent of mentor's proposed role in providing guidance to the candidate
Previous mentor success in training early career investigators
History of research productivity

Research Plan (Significance, Innovation, Approach)
Scientific merit of the research question, design, and methodology
Relevance of the proposed research to the applicant's career objectives
Appropriateness of the research plan to the applicant's stage of research development
Appropriateness of the research plan for advancing the career development plan
Appropriateness for the pilot funding mechanism and likelihood to lead to future funding opportunities
Feasibility to complete the project within the 12-month project period

Other considerations: Please also refer to the NIH's Rigor and Reproducibility Guidelines: Does the project take the NIH guidelines on rigor and reproducibility into consideration?

Pre-Submission Process: Complete and submit the pre-submission form on or before **May 16, 2025**. **The pre-submission form is not intended to be a screening process; its purpose is to allow the subcommittee to arrange reviewers in advance of the review period.**

Form Link: https://app.smartsheet.com/b/form/0195a9613798799399e10b0d64925cfb

Investigator name, email, title, and institution

Mentor(s) and collaborator(s)

Project title

Suggested Reviewers (Required: 2 non-conflicted senior investigators from different institutions from each other and the applicant)

Project Summary / Abstract: Please write a summary of the project that includes the project's significance, objectives, and specific aims. Please also describe the research design and methods for achieving the stated goals. This information will be used to identify appropriate reviewers.

Full Application Instructions

Submit the following in one PDF by 5:00 p.m. August 1, 2025.

All items listed below must be included for successful submission of your application.

The proposal should be written on PHS 398 forms and should follow a modified NIH investigator-initiated grant application (R01) format. No appendices are allowed.

1. **Face Page** (PHS 398 Form page 1). Institutional sign-off for non-Emory applicants is required.

   To help determine whether research that involves the use of human data or biological specimens is human subjects research, refer to the Research Involving Human Subjects website.

2. **Project Summary Page**: (PHS 398 Form page 2)
3. **Detailed budget and Budget Justification** for the 12 month period: (PHS 398 Form pages 4 and 5)
4. **Resources page** (PHS 398 Format; maximum length 1 page)
5. **Checklist page (**PHS 398 Format)
6. **Common Forms (Biosketch, Current and Pending Support)** and **NIH Biographical Sketch Supplement** generated and certified in SciENcv for pilot grant applicant and mentor(s) (https://rcra.emory.edu/research-security/sciencv.html)
7. **Applicant Background and Career Development Plan** (1 page). The Pilot Funding mechanism is intended to advance career development and lead to future funding opportunities. Please include a justification of how the aims of this project will lead to future funding opportunities.
8. **Research Plan** Use PHS 398 Continuation Format pages.
   a. Specific Aims (suggested length 1 page)
   b. Research Strategy:
      i. Significance (suggested length ½ page)
      ii. Innovation (suggested length ½ page)
      iii. Approach (suggested length 2 pages). Describe the strategy, methodology, analyses, and feasibility. This section may include the Study population, sample size, and statistical methods, as appropriate.
9. **Bibliography and References** cited (as needed)
10. **HSS Template** (See Appendix A of this RFA. This form is only required if the study meets the definition of human subjects research as described in the Research Involving Human Subjects website.)
11. **Lay Summary:** Please write a summary of the project in plain language, so that a non-scientist can understand the importance of the project.
12. **Mentor's Letter of Support** (should include the statement "I have read and discussed this application with [applicant name] and am supportive of its submission"; maximum 1 page). The letter should also reference the mentor's previous success in mentoring and should include a mentoring plan that describes the method and frequency with which the mentor and applicant will communicate.
13. **Division or Department Chair Letter of Support** This is a letter in support of the application and should describe the commitment of financial support, if any secured.

Just-in-Time Requirements (if requested, Due Oct 24)

Prior Approvals (use of human or animal subjects, international sites): a copy of all Institutional Biohazard and IRB approvals (if applicable).

Genomic Data Sharing Plan (if applicable per NIH policy; maximum 2 pages)

Disclosure of foreign component (if applicable, required even if an unfunded component/contribution)

Post-Award Requirements (if funded)

Mentoring Committee and Agreement: Awardee(s) will draw up a brief written agreement with their mentors and identify members of their mentoring committee.

Reporting and Presentation Requirements: Awardee(s) will be required to submit an interim progress report and a final progress report and may be asked to make an oral presentation at an IDCRC meeting. An interim financial report and enrollment table (if applicable) will also be required.

Publication acknowledgement requirement: IDCRC support (UM1AI148684) must be acknowledged in all publications and presentations derived from IDCRC funding. Publications supported by this award must have PMCID numbers in order to comply with the NIH Public Access Policy.

Appendix A: HSS Record Template

Guide Link: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#1

Below is a template based on NIH guidance available as of March 12, 2025. Please ensure your report aligns with the current guidance linked above should any discrepancies arise.

Section 1: Basic Information

1.1 Study Title:
1.2 Is this study exempt from Federal Regulations: No
1.3 Exemption Number: (none)
1.4 Clinical Trial Questionnaire
- **1.4.1 Does the study involve human participants:**
- **1.4.2 Are the participants prospectively assigned to an intervention:**
- **1.4.3 Is the study designed to evaluate the effect of the intervention:**
- **1.4.4 Is the effect that will be evaluated a health-related outcome:**

Section 2 – Study Population Characteristics

2.1 Conditions or Focus of Study:
2.2 Eligibility Criteria:
2.3 Min Age: Max Age:

2.3.a Inclusion of Individuals Across the Lifespan

For the purposes of the Inclusion of Individuals Across the Lifespan, exclusion of any specific age or age range group should be justified in this section. In addition, address the following points:

- Individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion. See the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects for additional information about circumstances that may justify the exclusion of individuals based on age.
- Include a description of the expertise of the investigative team for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will contribute to a meaningful analysis relative to the purpose of the study.

When children are involved in research, the policies under HHS' 45 CFR 46, Subpart D - Additional Protections for Children Involved as Subjects in Research apply and must be addressed in the Protection of Human Subjects attachment.

Existing Datasets or Resources. If you will use an existing dataset, resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.

2.4 Inclusion of Women and Minorities

Address the following points:

- Describe the planned distribution of subjects by sex/gender, race, and ethnicity.
- Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
- Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
- Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. See the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page for more information.

Existing Datasets or Resources. If you will use an existing dataset, resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources.

2.5 Recruitment and Retention Plan:

Describe how you will recruit and retain participants in your study. You should address both planned recruitment activities as well as proposed engagement strategies for retention.

2.6 Recruitment Status: Not Yet Recruiting

2.7 Study Timeline:

Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates.

2.8 Enrollment of First Participant date (if applicable):

2.9 Inclusion Enrollment Report:

2.9.1 Inclusion Enrollment Report Title: Study Title – Report 0
2.9.2 Using an Existing Dataset or Resource: Yes/No
2.9.3 Location Type: Domestic/Foreign
2.9.4 Enrollment Country:
2.9.5 Enrollment Location (optional):
2.9.6 Comments
Planned Enrollment:

	Non-Hispanic Female	Non-Hispanic Male	Hispanic Female	Hispanic Male
American Indian/ Alaska Native:				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than One Race				

Section 3 – Protection and Monitoring Plans

3.1 Protection of Human Subjects:

Instructions: **Protection of Human Subjects**

3.2 Is this a multi-site study: No

If yes, describe the single IRB plan:

3.3 Data and Safety Monitoring Plan: (generally only applicable to prospective interventional studies)

3.4 Will DSMB be appointed: (generally only applicable to prospective interventional studies)