CFAR Mentored Research Award to Support K-Series Projects (CFAR-K)
Clinical Trials Not Allowed

Notice of Funding Opportunity (NOFO)

expires 12/31/2024

Table of Contents

NOTES .................................................................................................................. 1
SCOPE .................................................................................................................. 1
ELIGIBILITY ......................................................................................................... 1
EXCLUSION CRITERIA: ....................................................................................... 1
APPLICATION DEVELOPMENT .......................................................................... 2
SCHEDULE / DEADLINES .................................................................................. 2
LETTER OF INTENT (LOI) INSTRUCTIONS ...................................................... 2
APPLICATION INSTRUCTIONS ......................................................................... 3
  COVER LETTER .................................................................................................. 3
  FORM PAGES .................................................................................................... 3
  PHS 398 RESEARCH PLAN .............................................................................. 3
  LETTERS OF SUPPORT (LOS) / VERIFICATION (LOV) ................................. 4
  CFAR REQUIRED INFORMATION ................................................................. 4
  BUDGET ............................................................................................................ 5
  SUBMISSION PROCEDURE .............................................................................. 5
APPLICATION REVIEW ....................................................................................... 6
RELEASE OF FUNDS ......................................................................................... 6
CONTACTS ............................................................................................................. 6
APPENDIX A: CFAR-K REVIEW CRITERIA ....................................................... 7
CFAR Mentored Research Award to Support K-Series Projects (CFAR-K)
Clinical Trials: Not Allowed

- NIH revised definition of Clinical Trials
- NIH Clinical Trials definition FAQ
- Determine if your proposed study is a Clinical Trial
- See also this document from the NIH CFAR re: requirements for Clinical Research Studies

The Center for AIDS Research at Emory University (CFAR) K-series Mentored Research Award to Support K-Series Projects mechanism (CFAR-K) is designed to help CFAR investigators who have an active NIH K-series award move more rapidly toward independent investigator status in HIV/AIDS research at the National Institutes of Health (NIH) by providing funds that fill in or extend funding provided by the NIH K mechanism. The findings from CFAR-K projects are intended to anchor subsequent R01 or other R-level NIH applications in areas that align with NIH/OAR high priority areas of HIV research (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-018.html).

CFAR-K projects are single PI.

The project period for a CFAR-K award is equal to the remaining time in the PI’s NIH K award. A CFAR-K PI whose NIH K award is ending may apply to have their CFAR-K award re-characterized as a CFAR-03 award, with the timeline extended to up to two years from initial start date of the CFAR-K award if needed to complete the original CFAR-K award scope of work.

The maximum direct costs for this mechanism are $40K. This is a one-time award, and funds are not renewable.

NOTES
- Submission of a CFAR-K application does not preclude concurrent submission of an NIH application containing substantially the same research proposal. Should both applications be funded, the CFAR award will be terminated, and any unspent funds must be returned.
- CFAR-K awards may not be used to supplement or extend research previously funded by a CFAR-Series award. The applicant must demonstrate that the proposed CFAR-K project meets this requirement.

SCOPE
Examples of the types of projects that might be funded under this NOFO include:
- Pilot or feasibility studies for emerging research opportunities in HIV;
- Secondary analysis of existing data;
- Small, self-contained research projects;
- Development of research methodology or research technology.

ELIGIBILITY

INCLUSION CRITERIA:
- Current recipient of an NIH K01, K07, K08, K23, K25, or K99/R00

EXCLUSION CRITERIA:
- Serving as PI or MPI on an active CFAR-Series award (current awardees are not eligible to hold multiple active CFAR-series awards)
APPLICATION DEVELOPMENT

1. Contact the Developmental Core
   Applicants should contact Dr. Rama Amara (ramara@emory.edu) for basic and preclinical science applications and either Dr. Drenna Waldrop (drenna.waldrop@emory.edu) or Dr. Kimbi Hagen (kbs.hagen@emory.edu) for social/behavioral or clinical science applications to discuss whether a proposed project matches the objectives of the CFAR-K mechanism.

2. Attend the optional CFAR-Series Introductory Session via Zoom (Spring Cycle Only)
   As described above, participation in the CFAR-K Introductory Session is not a requirement of submission.

3. Present your specific aims and approach to the CFAR Core Directors for feedback
   This meeting will take place via Zoom and presentation slots are limited. Contact Dr. Galina Terbova (galina.terbova@emory.edu) if you are interested in this opportunity.

4. Consult with Biostatistics and Bioinformatics (Bios) Core faculty to review your data collection and analysis plan *
   Please visit bit.ly/CFARCoreServiceRequest to request the consultation. After the meeting, the Bios Core will provide the required verification letter for inclusion in the application packet.

5. Meet with other CFAR Science Cores, as applicable, to get Letter(s) of Verification (LOV) documenting Core services provided for your project
   Support may include consultation, services, materials, training, and/or shared research space/equipment. As appropriate to the support proposed, CFAR Cores can also provide you with information addressing rigor and reproducibility to include in your Significance/Approach section. Learn about the Cores here. Please visit bit.ly/CFARCoreServiceRequest to request services and/or consultation.

6. Get pre-review comments on the application draft from your K award mentor *

* Steps 4 & 6 are mandatory for all CFAR-K applicants.

SCHEDULE / DEADLINES

Fall 2024 (CYCLE Y26A):

<table>
<thead>
<tr>
<th></th>
<th>DATE</th>
<th>SUBMISSION LINK</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOI due (required but non-binding)</td>
<td>September 3, 2024</td>
<td>bit.ly/EmoryCFAR-Series-LOI</td>
</tr>
<tr>
<td>Application due</td>
<td>October 1, 2024</td>
<td>bit.ly/EmoryCFAR-Series-APP</td>
</tr>
<tr>
<td>Study Section held</td>
<td>First week in November 2024 (anticipated)</td>
<td></td>
</tr>
<tr>
<td>Funding decisions announced</td>
<td>End of November 2024 (anticipated)</td>
<td></td>
</tr>
</tbody>
</table>

LETTER OF INTENT (LOI) INSTRUCTIONS

An electronic LOI, including a one-page research pre-proposal attachment, is required but non-binding. See deadline and online submission link above.

The pre-proposal (submitted in PDF format) must include:
- A 1-3 sentence summary of the research problem
- Proposed research question(s) or hypotheses
- Proposed specific aims
- A brief description of the proposed approach
- References (not included in the 1-page limit)

Applicants contact CFAR-Series Program Officer, Galina Terbova (galina.terbova@emory.edu) with questions.
APPLICATION INSTRUCTIONS
Applicants should work with their department’s Research Administration Services unit to develop, assemble, and submit the application packet. Applications may be prepared using the Cayuse 424 system and then submitted as a single PDF packet, using the submission link on pg.2.

Do NOT deliver or route the application through Emory’s OSP office.

IMPORTANT: CFAR-K applications must include certain components not required by the NIH. Please refer to the checklist provided for ALL required components, including CFAR-specific items.

Applicants without prior experience writing NIH-style applications may want to review the NIH “How to Apply – Application Guide” website.

COVER LETTER
The PI, PI’s Chair/Division Director, and the PI’s NIH-K Research Mentor should all sign the cover letter. Restrict information provided in the letter to the following:

- PI name(s), department(s), and contact information
- Application title
- Application type (New or Resubmission)
- Direct Costs requested
- Post Award administrator name and contact information
- A statement, if applicable, confirming that the PI’s Research Mentor provided pre-review comments on a final draft of the new or resubmitted application

FORM PAGES

- Applications should be prepared using NIH FORMS-H forms and NIH FOA PA-20-200, the current Funding Opportunity Announcement (FOA) for investigator-initiated applications using the NIH Small Research Grant Program (R03) mechanism upon which the CFAR-K is based.

- Except when CFAR-specific instructions are provided below, applicants should follow NIH instructions for completing an SF424 form set.

PHS 398 RESEARCH PLAN

- Format all documents per NIH rules
  - See NIH Forms-H Application Guide
- Rigor and Reproducibility: The research plan should fully address rigor and reproducibility.
  - See NIH FAQs for NOT-16-011
- Inclusion Across the Lifespan: For projects including human subjects, the research plan must fully address inclusion across the lifespan.
  - Read NIH NOT-OD-18-116

- Sex as a Biological Variable: All research projects conducted with a) human subjects, b) vertebrate animals, and/or c) materials from human or vertebrate animal subjects (e.g. blood, tissue, cell lines) must fully address sex as a biological variable in the research plan
  - Read NOT-OD-15-102-Guidance
- The Approach section should include a project activities timeline.
LETTERS OF SUPPORT (LOS) / VERIFICATION (LOV)

☐ CFAR Biostatistics and Bioinformatics Core LOV, verifying that Core faculty reviewed and approved the proposed data collection and analysis plans.

☐ As applicable, an LOV signed by the Director of each CFAR Science Core that will provide services for the proposed project. Provide a separate LOV from each Core to be used.

   Limited subsidized support may be available through CFAR Cores. A Core’s financial support beyond the agreed-on subsidy must be included in the project budget on a fee-for-service basis. A Core’s LOV should describe agreed on services and the limits on those services. It should also describe and quantify any Core services and the costs, if any, to include in the project budget.

☐ LOS signed by the PI’s NIH-K Research Mentor, verifying participation in the development of the CFAR-K application and, if funded, in the implementation of the CFAR-K project and the preparation of publications based on project findings.

☐ As applicable, LOS from named research collaborators and consultants. For paid consultants, letters should list the rate/fee for consulting services, and these expenses must be included in the application budget.

CFAR REQUIRED INFORMATION

Application packets that do not include the following four required documents will be returned without review. Note: Each of these documents should be saved as a separate PDF file and uploaded as individual documents through the electronic application portal.

☐ Applicability to NIH/OAR Research Priorities: (Limit = 1 paragraph)
   See NOT-OD-20-018. This document should identify which High Priority topic the proposed project addresses and describe how the proposed project will address that topic.

☐ Future Plans for NIH Applications: (Limit = 1 page)
   This document should describe how the findings from the proposed research will contribute to future NIH applications. Outline the remaining investigations, if any, that need to take place prior to a future NIH application based on this project.

Given that almost half (40%) of an application’s overall impact score will be based on the proposed project’s potential to contribute to a future NIH application, the importance of the two documents described above cannot be overstated.

☐ Emory CFAR Scientific Core Statement: (Limit = 1 page)
   This document should include one of the three options below:
   1. A description of support provided by the Emory CFAR Science Core(s) during implementation of the project, referencing the appended Core LOV (limit: 1 paragraph per Core).
      Note: the narrative text should re-state and be consistent with the description of support provided in each attached Core LOV.
   2. A statement that no Emory CFAR Core will provide consultation, services, training, materials, and/or shared equipment / research space for the proposed study. Note: If in the opinion of the reviewers, the applicant has overlooked opportunities to collaborate with / seek appropriate research support from the Emory CFAR Cores, the application may be marked down on review.
   3. A statement explaining any other reason the applicant is not planning to use any of the Emory CFAR Cores.

☐ Community Impact Section: (Limit = 1 page)
   This section should describe, in lay terms, the project and its potential impact on community (e.g., persons with HIV or persons placed at-risk for HIV) and should answer the following questions:
   1. What is the potential benefit of your study to persons with HIV or persons placed at risk for HIV?
   2. How did you generate this research idea and how was community input gathered?
3. How will you share results with the research participants?
4. Why should persons with HIV, or persons placed at risk for HIV, care about this project?

BUDGET (Use the R&R, NOT modular, budget)

Stipulations:

- CFAR-K applications may not include salary for the project PI.
- Funds may be requested for travel and activities associated with writing an NIH research grant proposal based on project findings and/or attending meetings to establish collaborations or to present project-related data. Supported travel must be completed within the award’s project period.
- Investigators must include a justification of the activities connected with Data Management and Sharing that will incur costs. This justification must be labeled as "Data Management and Sharing Justification" within the budget justification attachment, followed by the estimated dollar amount.
- Do not request:
  - Salary or travel support for senior faculty
  - Equipment purchases of > $5,000 (NOTE: items like computers or tablets fall under the “supplies” category, unless they are a part of a larger equipment system).
  - Indirect Costs (although these may be awarded later, depending on the source(s) of funding used to support the award)
  - Funds for services that a CFAR Core has agreed to subsidize

  If the study section judges that a requested budget item should be subsidized by a CFAR Core, the budgeted item will be denied. **Cores are not required to subsidize the cost of services beyond what is negotiated and documented in their LOV provided with the application.**

  If services requested exceed those described in a Core’s LOV, investigators may be required to cover the cost of those services with a non-CFAR Speed Type if services requested exceed those described in the letter of support included in the application. For this reason, **it is extremely important that applicants fully understand the full range of, and limits to, subsidized research support available to CFAR-K grantees** and that they discuss the full range of required research support with applicable CFAR Cores during the application development.

- Applicants may request funds for support provided by non-CFAR cores and entities. All requests for funds to cover CFAR and non-CFAR Core provided services should be well described in the Budget Justification.

SUBMISSION PROCEDURE

CFAR-K applications do NOT have to be routed for approval through the PI’s Department / School and must NOT be submitted to the Emory OSP.

The application packet should be submitted directly to the CFAR as a single PDF file via an electronic portal that will open on October 1, 2024. See submission link on pg. 2.
APPLICATION REVIEW

- Members of the Emory CFAR Scientific Review Group evaluate proposals in an NIH study section format, with two reviewers assigned to each proposal. Outside reviews will be requested as needed.

- In assigning an NIH-style impact score (1-9), CFAR reviews are not limited to the five NIH review criteria (approach, significance, innovation, investigators, and environment). Over half (60%) of a reviewed application’s overall Impact score will take into consideration two additional, CFAR-specific criteria: ‘Potential to contribute to a future NIH application’ and ‘quality of writing.’ See Review Criteria table (Appendix A) for additional details.

- A written critique will be prepared for each proposal. These critiques, formally known as a “Summary Statement” and informally known as “pink sheets,” will be forwarded to the applicant approximately three weeks following completion of the study section.

RELEASE OF FUNDS

A response to the reviewer comments and proof of all required institutional approvals must be received by the CFAR prior to the release of funds. Additional stipulations may also be included in the Notice of Award.

CONTACTS

Administrative Questions
CFAR-Series Program Officer
Galina Terbova, DPA
E-mail: galina.terbova@emory.edu

Scientific Questions
Rama Amara, PhD
Email: ramara@emory.edu

Drenna Waldrop, PhD
E-mail: drenna.waldrop@emory.edu

Kimbi Hagen, EdD
E-mail: kbs.hagen@emory.edu
## APPENDIX A: CFAR-K REVIEW CRITERIA

<table>
<thead>
<tr>
<th>Weight</th>
<th>Item</th>
<th>Section of application scored</th>
</tr>
</thead>
</table>
| 40%    | **Future**: Does the proposed project have a high potential of contributing to a future NIH application? | • Entire narrative  
• "Future Plans for NIH Applications" statement  
• "Applicability to NIH/OAR Research Priorities" statement |
| 20%    | **Writing**: Does the quality of writing in the application (including grammar and spelling) meet the standard found in successful NIH applications? | • Entire narrative |
| 25%    | **Approach**: Does the application describe how the experimental design and methods will achieve robust and unbiased results? Does the proposal explain how biological variables, including sex, are factored into research designs and analyses? For example, is strong justification provided for applications proposing to study only one sex?  
Are the overall strategy, methodology, and analyses well-reasoned and appropriate for accomplishing the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented?  
If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? If the project involves human subjects research, are the plans for 1) protection of subjects from research risks, and 2) decisions about the inclusion or not of minorities, women, children, and/or vulnerable peoples justified in terms of the scientific goals and research strategy proposed? | • Specific Aims  
• Research Strategy: (c) “Approach”  
• CFAR scientific core statement  
• Letters of support  
• Inclusion of Individuals Across the Lifespan  
• Inclusion of Women and Minorities  
• Vertebrate Animals |
| 15%    | **Significance**: Does the proposal describe a research problem considered to be High Priority by NIH/OAR? Does the proposal describe the scientific premise for the proposed project? Will successful completion of the aims lead to larger research studies that can change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? | • Research Strategy: (a) “Significance”  
• "Applicability to NIH/OAR Research Priorities" statement |
| 15%    | **Innovation**: Does the application seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are they novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? | • Research Strategy: (b) “Innovation” |
|        | **Investigators**: Is the research team well suited to the project? Do the PI(s) have appropriate experience and training? If dual PI, do the PIs have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project? | • Biosketches  
• Dual PI Leadership Plan  
• Mentoring Plan |
|        | **Environment**: Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the CFAR scientific environment, subject populations, or collaborative arrangements? | • Resources page  
• Letters of support  
• CFAR scientific core statement |