CFAR K-series Mentored Research Supplement (CFAR-K)
Clinical Trials Not Allowed

Funding Opportunity Announcement

expires 7/31/21

Table of Contents

CFAR K-series Mentored Research Supplement (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 by the NIH CFAR re: requirements for Clinical Research Studies](#)**

The Center for AIDS Research at Emory University (CFAR) K-series Mentored Research Supplement mechanism (CFAR-K) is designed to help CFAR members who hold current NIH K-awards 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 NIH K research funding. 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. If needed in order to complete a CFAR-K project's scope of work, a PI whose NIH K award is ending may apply to have their CFAR-K award re-characterized as a CFAR-03, with the timeline extended to up to two years from initial start date.

Maximum direct costs for this mechanism are $40K. All funds must be requested in the first year of the project, and are non-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 must be returned.

- CFAR-K awards may not be used to supplement or extend research that is, or has been, funded by CFAR-03, CFAR-C, or earlier CFAR-K awards. It is up to the applicant to demonstrate that a proposed CFAR-K project meets this requirement.

SCOPE
Examples of the types of projects that might be funded under this RFA include:
- Pilot or feasibility studies for emerging research opportunities in HIV/AIDS;
- 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 R00 (2nd half of a K99/R00) award.

- Untenured Research Track or Tenure Track full time faculty.

- Meets the definition of an NIH "[New Investigator](#)."

EXCLUSION CRITERIA:
- An individuals who is a PI on a current CFAR-K, CFAR-C, or CFAR-K award is not eligible for additional funding through this mechanism while that award is still active.

APPLICATION DEVELOPMENT PROCESS

1. **Contact the Developmental Core**
   Applicants should contact Dr. Kimbi Hagen (404/727-8855) to discuss whether a proposed project matches the mission and objectives of the CFAR-K mechanism.

2. **Confirm participation by at least one NIH K-award mentor** *
   Applicants may include as many NIH K award mentors as they wish on their study team but must confirm the participation of at least one.

3. **Attend a CFAR Developmental Core Award grant writing seminar**
   Attendance at this seminar is recommended but is NOT a requirement of submission

4. **Consider presenting your specific aims and approach to the CFAR Core Directors for feedback**
   This meeting will take place by webinar and presentation slots are limited. Contact Jenny Anderson (jenny.anderson@emory.edu) if you are interested in this opportunity.

5. **Meet with Biostatistics Core faculty to review your data collection and analysis plans** *
   After the meeting, the Core will provide a required letter of verification for inclusion in the application packet

6. **Meet with other CFAR Science Cores, as applicable, to get LOS documenting subsidized Core support to be provided to your project**
   This support may include consultation, services, materials, training, and/or shared equipment / space. As appropriate to the support they are providing, a CFAR Core will provide you with information addressing rigor and reproducibility to include in your Approach section.

7. **Get pre-review comments on the application draft from your NIH K award research mentor(s)** *
   A copy of the application review form is available on the Developmental Core page of the CFAR website

* Steps 2, 5, & 7 are mandatory for all CFAR-K applicants

SCHEDULE / DEADLINES
CYCLE A:

LOI* due	**October 1**
Application due	**November 1**
Study Section held	Normally held the first week in December
Funding announcement	Normally announced the first week in January

CYCLE B:

LOI* due	**April 1**
Application due	**May 1**
Study Section held	Normally held the first week in June
Funding announcement	Normally announced the fourth week in June

*The letter of intent (LOI) should include:
- Funding mechanism being applied to (CFAR-K)
- Title and NIH project number of NIH K-award
- Project title, if different than NIH K-award title
- Contact information, including:
  - PI: name, cell phone, and email
  - NIH K-award mentor(s) included in this project: name and email
  - Co-investigators, and proposed collaborators, if any: name and email
- A list of people who are well qualified to review the application
- A list of individuals who would be considered to be in conflict with reviewing the application and therefore should not be asked to serve as reviewers
- A **one page** research pre-proposal that includes:
  - One to three sentence background of the research problem
  - Proposed research question(s) or hypotheses
  - Proposed specific aims
  - A brief description of the proposed approach

APPLICATION INSTRUCTIONS

Applicants should work with their department's RAS unit to develop, assemble and submit the application. Applications should be prepared using the Cayuse 424 system and then emailed as a single pdf packet to the CFAR. Do **NOT** deliver or rout the application through Emory's OSP office.

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

FORM PAGES

☐ Applications should be prepared using updated **FORMS-F** forms and NIH FOA **PA-20-200** (the current Funding Opportunity Announcement for investigator-initiated applications for 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

- Internet website addresses (URLs) should not be used to provide information necessary to the review because reviewers are not obligated to view the Internet sites.

☐ File names for each pdf upload to the application packet should follow the following heuristic: "PI Last Name.SectionName.pdf."
For example:
- "Doe.SpecificAims.pdf" (**Limit=1 page**)
- "Doe.ResearchStrategy.pdf" (**Limit=6 pages**)

☐ 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 being conducted with human subjects, vertebrate animals, or materials (e.g. blood, tissue, cell lines) from human or vertebrate animal subjects must fully address sex as a biological variable in the research plan
- Read NOT-OD-15-102-Guidance
- Read (https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable)

☐ The Approach section should include a project activities timeline.

REQUIRED ATTACHMENTS.
Applications that fail to include the four required attachments listed below will be returned without review.

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

☐ **Attachment #2: Future Plans for NIH Applications:** (Limit = 1 page)
This attachment should describe how the findings from the proposed research will be useful in helping the PI gain NIH independence. Outline the remaining experiments, if any, that need to take place prior to the submission of an application based on this work.

- ***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 this attachment cannot be overstated***

☐ **Attachment #3: CFAR Scientific Core Statement:** (Limit = 1 page)
This attachment should include one of the three options below:
1. A description of the CFAR Science Core support to be used during implementation of the project, referencing the appended Core letter(s) of support (limit: 1 paragraph per Core). *Note: to avoid being marked down on review, the narrative text should recapitulate and be consistent with the description of support provided in each attached Core LOS.*

2. A statement that no CFAR core exists that can provide access to consultation, services, training, materials, and/or shared equipment / research space needed for the proposed study *Note: Applications will be marked down on review if, in the opinion of the reviewers, the applicant is overlooking opportunities to collaborate with / seek appropriate research support from the CFAR Cores*

3. A statement explaining any other reason why the applicant is not planning to use any of the CFAR cores.

☐ **Attachment #4: Letters of verification / support:**

- A letter signed by the Director or Associate Director of the CFAR Biostatistics and Biomedical Informatics Core, verifying that Core faculty reviewed and approved the proposed data collection and analysis plans;

- If applicable, a letter signed by the Director of each CFAR Science Core that will provide services for the proposed project. Letters should clearly describe specific assistance to be provided and the amount / limits of that assistance. (Provide a separate letter from each Core to be used);

- A letter 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 project and the production of publications based on project findings;

- If applicable, letters of support from named research collaborators and consultants. For paid consultants, letters should include rate/charge for consulting services;

- A letter from the PI's Department Chair or Division Director, approving the application's submission.

APPENDICES
Follow the guidelines contained in NIH NOT-OD-17-098 (released 8/02/17).
This FOA contains no FOA-specific appendices.

BUDGET (Use the R&R [i.e. detailed, NOT modular] budget):
Stipulations:
- CFAR-K applications may not include salary for the PI.

- Funds may be requested for travel and activities associated with writing an NIH RO1 proposal based on project findings and/or attending meetings to establish collaborations or to present project-related data. Unless permission of the Developmental Core administration has been granted to extend the travel deadline, supported travel must be completed within one year of the end of the project period.

- Do not request:

  o Salary or travel for senior faculty
  o Equipment purchases of > $5,000
  o Indirect Costs (although these may be awarded later, depending on the source(s) of funding used to support the award)
  o Funds for services that a CFAR Core has agreed to subsidize
    See Appendix A. In accordance with NIH CFAR protocol, Core services in facilitation of an active CFAR-K award are subsidized by the CFAR Administrative Core so requests for research support that can be provided by one or more CFAR cores should not normally* be included in the budget. Subsidized research support is not unlimited in scope or in time however and the *description* and *limits* of all CFAR-provided services, equipment, consultation, training, or materials ("research

support") to be provided to a project should be agreed upon in advance and that agreement documented in a letter of support from the Director of the applicable Core(s).

*Applicants may request funds for CFAR Core research support in excess of what a Core has agreed in advance to subsidize, but the request must be well justified in the Budget Justification.

If a study section reviewing a CFAR-K application judges that a requested budget item can reasonably be provided by the CFAR they will deny that budget item request. **Cores are not required to subsidize research support that was not negotiated and documented prior to application submission** and Cores may request that a non-CFAR Speed Type be provided to pay for any research support not included in a letter of support included in the application. For this reason **it is extremely important that applicants be conversant with the full range of research support available to CFAR-K grantees** and that they discuss any and all needed research support needs with the CFAR Cores during application development.

Applicants may request funds for support provided by non-CFAR cores and entities and, as described above, for research support in excess of what a CFAR Core has agreed in advance to subsidize, but the request for those funds must be well justified in the Budget Justification.

See Appendix A. In accordance with NIH CFAR protocol, Core services in facilitation of an active CFAR-K award are subsidized by the CFAR Administrative Core so requests for research support that can be provided by one or more CFAR cores should not normally* be included in the budget. Subsidized research support is not unlimited in scope or in time however and the *description* and *limits* of all CFAR-provided services, equipment, consultation, training, or materials ("research support") to be provided to a project should be agreed upon in advance and that agreement documented in a letter of support from the Director of the applicable Core(s).

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Applicants may request funds for support provided by non-CFAR cores and entities and, as described above, for research support in excess of what a CFAR Core has agreed in advance to subsidize, but the request for those funds must be well justified in the Budget Justification.

COVER LETTER
The PI and, when applicable, the PI's Research Mentor should both sign a cover letter including 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 resubmission application

SUBMISSION PROCEDURE
All documents must be submitted as NIH-compliant pdf files.

CFAR-K applications do NOT have to be routed for approval through the PI's Department / School. They must, however, include a letter signed by the PI's department/division chair indicating approval for the application's submission

Do NOT submit the completed application package to OSP. Instead, email a pdf of the application to the CFAR-series Program Officer, Dr. Kimbi Hagen (kbs.hagen@emory.edu), cc'ing Jenny Anderson (jenny.anderson@emory.edu).

APPLICATION REVIEW

- Members of the Emory CFAR Scientific Review Group review 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, 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 B) 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 pink sheets and proof of all necessary institutional approvals must be provided to the Center for AIDS Research prior to release of funds. Additional stipulations may also be included in the Notice of Award.

CONTACTS

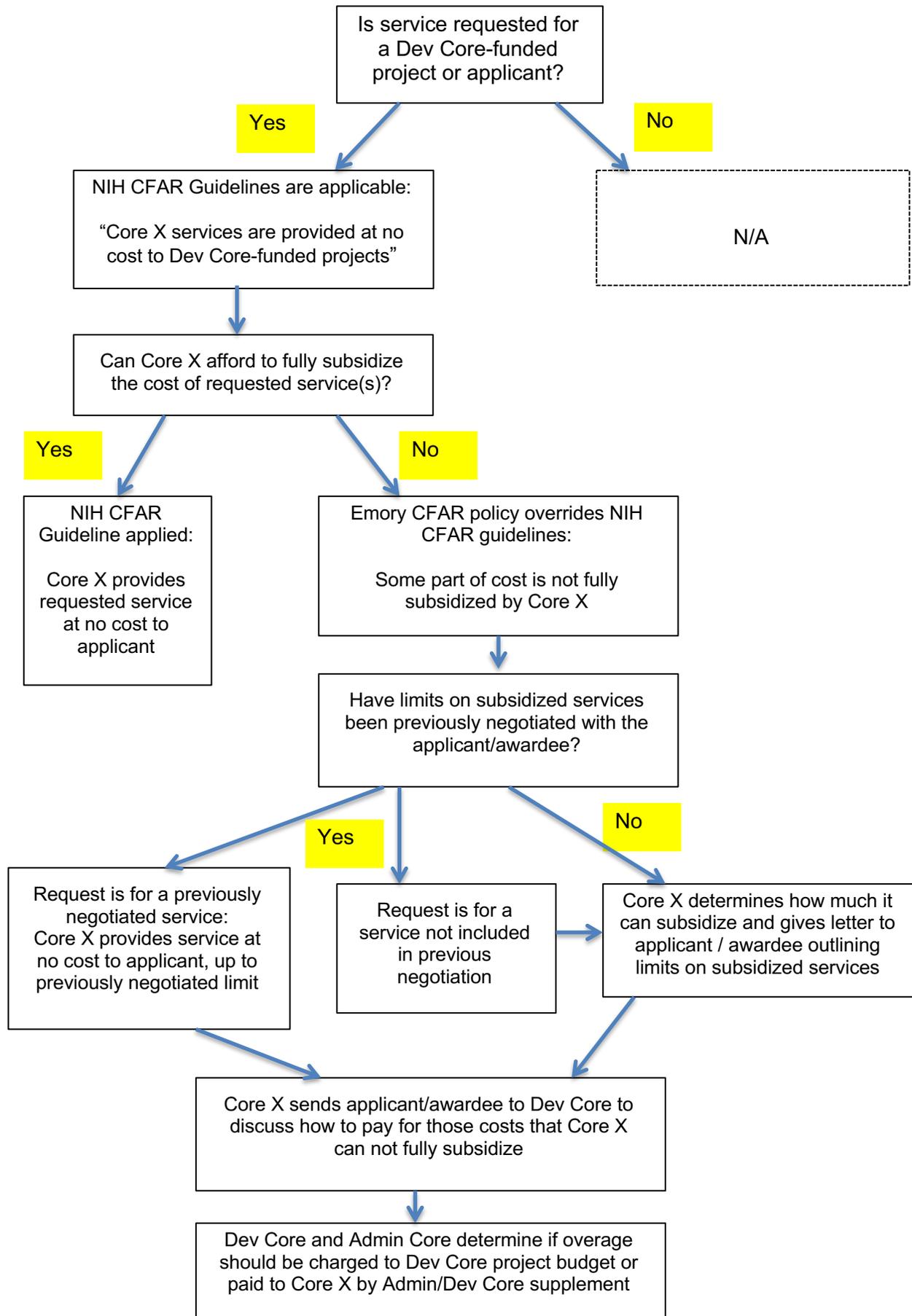**CFAR-series Program Officer**
Dr. Kimbi Hagen
phone: 404.727.8855
e-mail: kbs.hagen@emory.edu

Scientific Questions
Dr. Dennis Liotta
e-mail: dliotta@emory.edu

Administrative Questions
Ms. Jenny Anderson
phone: 404.727.2924
email: jenny.anderson@emory.edu

APPENDIX A: SUBSIDIZED CORE SUPPORT DECISION TREE

Is service requested for a Dev Core-funded project or applicant?

Yes → NIH CFAR Guidelines are applicable:

"Core X services are provided at no cost to Dev Core-funded projects"

No → N/A

Can Core X afford to fully subsidize the cost of requested service(s)?

Yes → NIH CFAR Guideline applied:

Core X provides requested service at no cost to applicant

No → Emory CFAR policy overrides NIH CFAR guidelines:

Some part of cost is not fully subsidized by Core X

Have limits on subsidized services been previously negotiated with the applicant/awardee?

Yes → Request is for a previously negotiated service:
Core X provides service at no cost to applicant, up to previously negotiated limit

Request is for a service not included in previous negotiation

No → Core X determines how much it can subsidize and gives letter to applicant / awardee outlining limits on subsidized services

Core X sends applicant/awardee to Dev Core to discuss how to pay for those costs that Core X can not fully subsidize

Dev Core and Admin Core determine if overage should be charged to Dev Core project budget or paid to Core X by Admin/Dev Core supplement

APPENDIX B: CFAR-K REVIEW CRITERIA

Weight	Item	Section of application scored
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 quality of writing in the application (including grammar and spelling) meet the standard found in successful NIH applications?	• Entire narrative

Weight	Item	Section of application scored
25%	**Approach**: Does the application describe how the experimental design and methods will achieve robust and unbiased results? Does the proposal explain how relevant biological variables, such as 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
	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? Does the PI have appropriate experience and training?	• Biosketches
	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