

**CFAR 03 Mentored Research Award (CFAR-03)
Clinical Trials Not Allowed**

Notice of Funding Opportunity

expires 05/31/2024

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CFAR Mentored Research Award (CFAR-03) 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's (CFAR) mentored research award mechanism (CFAR-03) is designed to help move early stage investigators toward independent investigator status in HIV/AIDS research at the National Institutes of Health (NIH). CFAR-03 funding is designed to generate preliminary data that will strengthen the competitiveness of subsequent NIH R-level 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-03 projects may be single or dual PI.

It is expected that projects be designed to take one year or less to complete; however, if necessary, project activities and spending may be extended over the duration of a two-year project period.

Direct costs for this mechanism are \$40K. Proposals requiring a larger budget (e.g., proposals promoting team science or community engagement) may be considered with appropriate justification. Please contact the Developmental Core leadership to discuss. (See 'Contact the Developmental Core' on pg. 3.)

NOTES

- Submission of a CFAR-03 application does not preclude concurrent submission of an NIH application containing substantially the same research proposal. Should a related NIH proposal be funded, the CFAR-03 award may be terminated, and unspent funds recovered.
- CFAR-03 awards may not be used to supplement research currently funded by NIH or to provide interim support of projects under NIH review.
- CFAR-03 awards may not be used to supplement or extend research that has been previously funded by a CFAR-Series award. The applicant must demonstrate that a newly proposed CFAR-03 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:

- Eligibility to be PI on an NIH R-level grant.
- Faculty or faculty-equivalent position with a full-time appointment at Emory University or the Morehouse School of Medicine as of CFAR-03 award start date.
- Meet the definition of an NIH "[New Investigator](#)" in HIV/AIDS. Specifically, prior funding as an NIH independent investigator makes an applicant ineligible ONLY IF that funding has been in the field of HIV.
 - Exception: Investigators with prior independent NIH funding in HIV are eligible if they have not been the PI on *any* NIH HIV grant within the last five years.

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-03 mechanism.

2. Identify a CFAR-03 Research Mentor, if applicable *

Applicants without a history of R01-equivalent funding must have a research mentor on the study team.

3. Attend the optional CFAR-Series Introductory Session via Zoom on February 19, 2024 at 2 PM.

As described above, participation in the CFAR-HBCU Introductory Session is not a requirement of submission. Complete a [CFAR-Series Info Session interest form](#) to receive more information.

4. Consider presenting your specific aims and approach to the CFAR Core Directors for feedback.

This optional pre-submission webinar will take place by Zoom and presentation slots are limited. Contact Dr. Galina Terbova (galina.terbova@emory.edu) if you are interested in this opportunity.

5. 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 letter of verification for inclusion in the application packet.

6. Meet with other CFAR Science Cores, as applicable, to get Letter(s) of Support (LOS) 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 or consultation.

7. Get pre-review comments on the application draft from your CFAR-03 research mentor*

* Steps 2 & 6 are mandatory for any applicant with no prior history of NIH R01-equivalent funding.

** Step 4 is mandatory for all applicants.

SCHEDULE / DEADLINES

Fall 2023 (CYCLE Y25A):

	DATE	SUBMISSION LINK
LOI due (required but non-binding)	March 1, 2024	bit.ly/EmoryCFAR-Series-LOI
Application due	April 1, 2024	bit.ly/EmoryCFAR-Series-APP
Study Section held	First week in May 2024 (anticipated)	
Funding decisions announced	End of May 2024 (anticipated)	

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:

- 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
- References (not included in the 1-page limit)

Applicants should 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 (RAS) unit to develop, assemble, and submit the application packet. Applications may be prepared using Cayuse 424 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-03 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, when applicable, the PI's Research Mentor should all sign a 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 resubmission 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-03 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](#)
 - Read (<https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable>)
- The Approach section should include a project activities timeline.

LETTERS OF SUPPORT / VERIFICATION

- CFAR Biostatistics and Bioinformatics Core LOV, verifying that Core faculty reviewed and approved the proposed data collection and analysis plans.
- As applicable, 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 costs that should be included in the project budget.

- As applicable, LOS signed by the PI's CFAR-03 Research Mentor, verifying participation in the development of the CFAR-03 application and, if funded, in the implementation of the CFAR-03 project and the production of publications based on project findings.
- As applicable, LOS from named research collaborators and consultants. For paid consultants, letters should include rate/charge for consulting services, and services 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. Please note that each of these documents should be saved as a separate PDF file and individually uploaded 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 be useful for future NIH applications. Outline the remaining experiments, if any, that need to take place prior to an eventual NIH 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 the two documents described above cannot be overstated.

- Emory CFAR Scientific Core Statement:** (Limit = 1 page)
This section should include one of the three options below:
 1. A description of the Emory CFAR Science Core support to be used during implementation of the project, referencing the appended Core letter(s) of verification (limit: 1 paragraph per Core).
Note: to avoid being marked down on review, 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 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 Emory CFAR Cores.
 3. A statement explaining any other reason why 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? How did you generate this research idea and how was community input gathered? How will you share results with the research participants?

2. 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:

- It is not required that the PI(s) request salary. If PI salary costs are requested, they may not exceed \$8,000 (including fringe benefits) without prior permission from the CFAR-series program officer, Dr. Galina Terbova.
- 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.
- Do not request:
 - Salary or travel 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 reasonably 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 letters of verification provided with the application.** If services requested exceed those described in a Core's letter of verification, investigators may be required to cover the cost of those services with a non-CFAR Speed Type. For this reason, **it is extremely important that applicants fully understand the full range of, and limits to, subsidized research support available to CFAR-03 grantees** and that they discuss the full range of required research support with applicable CFAR Cores during 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.

APPENDIX

Follow the guidelines contained in NIH [NOT-OD-17-098](#) (released 8/02/17). This CFAR-03 FOA contains one FOA-specific appendix:

- CFAR-03 mentoring plan (if applicable):** (Limit = 1 page).

Include:

- Brief description of each member of the mentoring team
- Goals of the mentoring plan
- Brief description of each mentoring activity included in the plan
- How, and how often, the mentoring team will meet
- How success at meeting the identified goals will be assessed.

SUBMISSION PROCEDURE

CFAR-03 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 April 1, 2024. See submission link on pg. 2.

APPLICATION REVIEW

- Members of the Emory CFAR Scientific Review Group review proposals in an NIH-style 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 necessary institutional approvals must be provided to the CFAR prior to 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-03 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?	<ul style="list-style-type: none"> 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?	<ul style="list-style-type: none"> Entire narrative

25%	<p>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?</p> <p>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?</p> <p>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?</p>	<ul style="list-style-type: none"> 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%	<p>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?</p>	<ul style="list-style-type: none"> Research Strategy: (a) “Significance” “Applicability to NIH/OAR Research Priorities” statement
	<p>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?</p>	<ul style="list-style-type: none"> Research Strategy: (b) “Innovation”
	<p>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?</p>	<ul style="list-style-type: none"> Biosketches Dual PI Leadership Plan Mentoring Plan
	<p>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?</p>	<ul style="list-style-type: none"> Resources page Letters of support CFAR scientific core statement