

**CFAR-HBCU Collaborative Award for Research Exchange (CFAR-HBCU)
Clinical Trials Not Allowed**

Funding Opportunity Announcement (FOA)

expires 12/31/2022

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CFAR-HBCU Collaborative Award for Research Exchange (CFAR-HBCU) 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 purpose of this Funding Opportunity Announcement (FOA) is to describe a [CFAR-Series](#) funding mechanism intended to foster inter-institutional research synergy between faculty at Atlanta-based Historically Black Colleges and Universities (HBCUs) and faculty at Emory University. The mechanism, CFAR-HBCU Collaborative Award for Research Exchange (CFAR-HBCU), provides funding for a research project to an Atlanta-area HBCU based Principal Investigator (PI) with a Collaborating Research Partner (CRP) from Emory University. The mechanism is designed to help the PI generate preliminary data that will strengthen the competitiveness of subsequent NIH applications in areas that align with [NIH/OAR high-priority areas of HIV research](#). The Center for AIDS Research at Emory University (CFAR) is committed to supporting faculty toward independent investigator status in HIV/AIDS research at the National Institutes of Health (NIH).

For this FOA cycle, projects should be completed in 12-months.

The budget limit for this mechanism is \$50K (direct costs).

NOTES

- Prospective applicants who are considering submitting a Letter of Intent (LOI) may choose to attend a virtual CFAR-HBCU Introductory Session for this mechanism. The introduction will include the opportunity for applicants to ask questions regarding the FOA, request support to identify an Emory University Collaborating Research Partner, and to learn more about available Emory CFAR resources. There will also be a brief presentation regarding the submission process and required grant components.
- Participation in the CFAR-HBCU Introductory Session does *not* commit the attendee to apply for funding. Attendance is *not* required for submission but is recommended.
 - The virtual CFAR-HBCU Introductory Session will be held on September 13, 2022 from 11:00 AM to 12:30 PM EST. Registration link is provided below.

ELIGIBILITY

INCLUSION CRITERIA:

- Faculty or faculty-equivalent position with a regular full-time, regular appointment at an Atlanta-based HBCU.
- The PI must meet the definition of an NIH [“New Investigator” in HIV/AIDS](#). Specifically, an applicant is *ineligible* to serve as PI *only* if he/she/they received prior funding as an NIH independent investigator in HIV/AIDS.
 - Exception: Investigators with prior independent NIH funding in HIV research are eligible if they have not been the PI on *any* NIH HIV research grant within the last five years.

FUNDS AVAILABLE AND ANTICIPATED NUMBER OF AWARDS

- The Emory CFAR intends to commit \$100,000 direct costs to fund up to two awards. Each CFAR-HBCU project budget may not exceed \$50,000 direct costs. Institution's negotiated F&A rate will apply.

SCOPE

1. The CFAR-HBCU mechanism is designed to foster inter-institutional research synergy by facilitating funded collaborations between faculty at Atlanta-area HBCUs and Emory University.
 - Projects are led by a PI from an Atlanta-based HBCU with a Collaborating Research Partner (CRP) from Emory.

- The CRP is a faculty member from Emory University. The CRP's official role should be designated based on the scientific requirements for the project (e.g., Co-I, Co-PI, MPI). The CRP should be selected to enhance the proposed study with particular scientific expertise or to fill a PI identified research gap. It is expected that the CRP will facilitate access to Emory CFAR resources for the project. The PI and CRP are expected to work together to foster cross-institutional collaborations to ensure project success. Applicants should contact the Emory CFAR for assistance if a CRP has not already been identified.
 - Funded project activities may take place at either of the participating institutions or in a community-based domestic or international setting. Domestic projects will be given priority on review.
2. CFAR-HBCU awards are designed to enable the collection of pilot data that will be used to support an NIH K (e.g., K01, K23) or R (e.g., R16, R21, R34, R01) level application in an NIH-designated high priority area of HIV research.
- CFAR-HBCU funds may not be used to supplement research currently funded by NIH.
 - Proposed projects should be responsive to one or more of the high priority areas of HIV research identified by the [NIH Office of AIDS Research](#) (OAR).
 - CFAR-HBCU funded activities should be designed to take one year to complete.
 - Submission of a CFAR-HBCU application does not preclude prior or concurrent submission of an NIH application containing substantially the same research proposal. Should the NIH application be funded, the CFAR may request that the CFAR-HBCU award be returned.
 - Applicants are required to consult with the Atlanta-area HBCU affiliated biostatistician or [CFAR Biostatistics and Bioinformatics Core](#) regarding the data collection and analysis plan. There is no cost for the consultation with the [CFAR Biostatistics and Bioinformatics Core](#).
 - Applicants can visit bit.ly/CFARCoreServiceRequest to request the consultation with the [CFAR Biostatistics and Bioinformatics Core](#). After meeting with the Atlanta area HBCU-affiliated biostatistician or Bios Core faculty, applicant should request a letter of verification for inclusion in the application packet.
 - Awardees will have priority access to research support services available through the five Emory CFAR science cores: [Prevention and Implementation Sciences](#), [Clinical Research](#), [Biostatistics and Bioinformatics](#), [Systems Immunology](#), and [Virology and Molecular Biomarkers](#).
 - The CFAR Administrative Core can facilitate access to CFAR Cores.
 - Cores may provide *limited* access to services at no charge to CFAR-HBCU awardees. After the limit is reached, services are available on a fee for service basis.
 - Applicants who identify relevant services through a CFAR Core should consult with the relevant CFAR Core Director regarding study requirements to determine appropriate services and any associated costs.
 - Applicants are eligible to apply for a [Core Voucher](#) (post-award) to cover any costs associated with the use of a CFAR Core. The Core Voucher funding is limited to \$2,500, however, additional funding may be approved with proper justification and if the funds are available.
 - Early career investigators with limited research experience (e.g., limited prior funding), must identify at least one mentor and include a mentoring plan with the application. If appropriate, the CRP may also serve as a project mentor.
 - The mentoring plan should include 1) the type of mentoring provided, 2) a proposed schedule for mentor/mentee engagement, and the mentor's name, rank, and institutional affiliation.
 - See [Appendix A](#) for examples of mentor categories that may be beneficial to the applicant.
 - Applicants have access to Emory CFAR resources to assist them with the development of NIH-style grant applications, including the '[K-Club](#)' and [Planning for Success](#).

- In addition to the virtual CFAR-HBCU Introductory Session on September 13th, applicants also have the opportunity to present their specific aims and proposed research approach to expert HIV researchers from Atlanta-area HBCUs and Emory University for feedback during a Pre-submission Presentation Session. Only applicants who submit an LOI by the deadline are eligible to attend. The Pre-submission Presentation Session will take place via Zoom in early October (date and time TBD)

APPLICATION DEVELOPMENT PROCESS

1. Contact the Emory CFAR Developmental Core

Applicants may contact Dr. Galina Terbova (galina.terbova@emory.edu) with questions regarding the proposed project and its fit with the CFAR-HBCU mechanism.

2. Attend the *optional* CFAR-HBCU Introductory Session via Zoom

As described above, participation in the CFAR-HBCU Introductory Session is not a requirement of submission. See table below to register for this session.

3. Submit a Letter of Intent (LOI) (required, but not binding)

4. Present your research proposal at the Pre-Submission Presentation Session to Emory CFAR Core Leadership and members of the Emory-Morehouse School of Medicine Working Group.

Participation in this webinar is optional. This session provides the opportunity for the applicant to ask and answer questions regarding the research proposal. Information about the date, time, and format of the Zoom meeting will be provided to prospective participants later.

5. Meet with Atlanta-area HBCU affiliated biostatistician or CFAR Biostatistics and Bioinformatics Core faculty to review your data collection and analysis plan (required)

If applicant elects to consult with the CFAR Biostatistics and Bioinformatics Core, please visit bit.ly/CFARCoreServiceRequest to request the consultation. After meeting with the Bios Core faculty or an HBCU-affiliated biostatistician, applicant should request a letter of verification for inclusion in the application packet.

SCHEDULE / DEADLINES

FALL 2022

	DATE	SUBMISSION LINK
Virtual CFAR-HBCU Introductory Session	September 13, 2022 11:00 AM-12:00 PM EST	bit.ly/EmoryCFAR-HBCU-INTRO
LOI due (<i>required but non-binding</i>)	October 3, 2022	bit.ly/EmoryCFAR-Series-LOI
Application due	November 2, 2022	Submitted by e-mail to galina.terbova@emory.edu
Study Section held	First week in December (anticipated)	
Funding decisions announced	December 2022 (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-HBCU Program Officer, Galina Terbova (galina.terbova@emory.edu) with questions.

APPLICATION INSTRUCTIONS

The Emory CFAR Developmental Core can provide support to applicants to develop and assemble applications should their institution not provide pre-award support. Applications must be approved by and submitted through the school's Office of Sponsored Programs (or equivalent) and sent via email delivery as a single PDF packet to the CFAR.

Applicants without prior experience writing NIH-style applications may find reading the NIH "[How to Apply – Application Guide](#)" a useful first step.

COVER LETTER

The PI and CPR should both sign the letter. Restrict information provided in the letter to the following:

- PI name(s), department(s), and contact information
- Application title
- Application type (New)
- Post Award research administrator name and contact information

APPLICATION FORMAT

Applicants are encouraged, but not required, to prepare applications using NIH [Forms-G](#) and NIH Funding Opportunity Announcement (FOA) [PA-20-200](#), upon the CFAR-HBCU mechanism is based. If the applicant elects not to use NIH [FORMS-G](#), NIH formatting guidelines described [HERE](#) should still be followed.

APPLICATION COMPONENTS

- Specific Aims (1 page limit)
- Research Plan (6 pages limit), which MUST include the following sections:
 1. Rigor and Reproducibility: The research plan should fully address rigor and reproducibility.
 - See [NIH FAQs](#) for [NOT-16-011](#)
 2. 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](#)
 3. 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>)
- Project activities timeline.
- References
- NIH-style [biosketches](#) for all Key/Senior Personnel
- Institution's Negotiated Indirect Cost Rate Agreement, if F&A costs are requested. If the Institution does not have a negotiated indirect cost rate, a de minimis rate of 10% will apply.

CFAR REQUIRED INFORMATION.

Application packets that do not include the following two required documents will be returned without review. These sections do not count against the 6 page Research Plan limit

- 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 40% of the overall impact score is based on the proposed project's potential to contribute to a future NIH application, the importance of these two documents cannot be overstated.

DETAILED BUDGET (Applicants may, but are not required to, use the [NIH R&R budget form](#))

Stipulations:

- It is not required that the PI(s) request salary. If PI salary costs are requested, the cost may not exceed 20% of the budget or \$10,000 (including fringe benefits) without prior permission from the CFAR Developmental Core.
- If requested, salary support for the Emory Collaborating Research Partner should be included in the budget.
- 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.
- [NIH rules regarding spending allowability must be followed.](#)

Budgets may NOT include:

- Travel funds for senior faculty (e.g., funded Associate or Full Professors)
- Equipment purchases per applicant institution's established criteria.
- Funds for services subsidized by the Emory CFAR Core
 - **Please Note:** CFAR Cores are not required to subsidize research support that was not negotiated and documented *prior* to application submission or for any assistance provided that was not included in a letter of support appended to the application. Applicants are encouraged discuss the research support requirements with the CFAR Cores prior to application submission

LETTERS OF SUPPORT (LOS)/ LETTERS OF VERIFICATION (LOV)

- A confirmation e-mail/ LOV from a biostatistician of choice or CFAR Biostatistics and Bioinformatics Core, verifying that the proposed data collection and analysis plans were reviewed and approved.
- As applicable, LOV or e-mail confirmation each of CFAR Science Core and/or HBCU Resource providing support and/or services for the proposed project. Provide a separate LOV/ e-mail from each Resource to be used;
Limited subsidized support may be available through CFAR Cores. A Core's LOV should describe agreed on services and the limits on those services. It should also describe and quantify which Core services and costs above those that the Core has agreed to subsidize should be included in the project budget.
- As applicable, LOS from named research collaborators and consultants. Any consultant costs associated with the proposed project must be included in the project budget.
- LOV from the PI's Department Chair or Division Director stating that the PI will have protected time to complete the research project.
- For early career applicants with limited research experience:* A LOV signed by the applicant's mentor, confirming participation in the application development and support to the applicant for development of any future NIH K or R level funding.

APPENDICES

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

- **CFAR-HBCU mentoring plan (if applicable):** (Limit = 1 page). As described above, early career applicants with limited research experience are required to identify at least one mentor.-
 - If applicable, the mentoring plan should 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

SUBMISSION PROCEDURE

The application must be routed through the applicant institution's Office of Sponsored Programs (or equivalent) and be submitted by the appropriate institutional official.

The application packet should be submitted directly to the Emory CFAR as a single PDF file via email to Galina Terbova at galina.terbova@emory.edu

APPLICATION REVIEW

- Proposals will be reviewed in an NIH study section format, with two reviewers assigned to each proposal. Study sections comprise faculty from Atlanta-area HBCUs, Emory CFAR, and other experts as needed from institutions both local and national.
- In assigning an NIH-style impact score (1-9), CFAR-HBCU application reviews will not be limited to the five NIH review criteria (approach, significance, innovation, investigators, environment).. 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 summary statements and proof of all necessary institutional approvals (e.g., IRB/HIC, IACUC), must be provided to the CFAR prior to release of funds. A reliance agreement will be required for studies involving human subjects research. Additional stipulations may also be included in the Notice of Award. Funding will be distributed via subaward agreement with the PI's home institution. Additional documentation may be required at the time of the award.

CONTACTS

Application, Budget, and/or Administrative Questions

Dr. Galina Terbova, Assistant Director Research Programs
Emory CFAR
email: galina.terbova@emory.edu

Scientific/Propoal Development Questions:

Dr. Erica Johnson, Associate Professor
Morehouse School of Medicine
e-mail: ejohnson@msm.edu

Dr. Drenna Waldrop, Professor
Emory University School of Nursing
e-mail: drenna.waldrop@emory.edu

APPENDIX A: MENTORING PLAN (IF APPLICABLE)

Early career investigators with limited research experience (e.g., limited prior funding), must identify at least one mentor and include a mentoring plan with the application. The CRP may also serve as a mentor if appropriate to the project.

Examples of mentor categories that may be beneficial to the applicant are listed below. Mentors may come from inside or outside the PI's home institution.

Grantsmanship Mentor – An individual with experience writing successful NIH grant applications.

Grantsmanship mentors may help to develop and hone the NIH-style grant-writing skills by giving feedback on drafts of an application produced in response to this FOA and drafts of any follow-on applications to the NIH.

Peer Mentor – Person at the same academic or skill level as the applicant. Peer mentors provide assistance in networking within a new (to the applicant) scientific field and/or offer consultations in areas outside the applicant's area of expertise.

Research Mentor – Person with scientific knowledge or skills that would specifically benefit the proposed project. Research mentors provide consultation and assistance in the design and implementation of research and/or the communication of research findings.

Career Mentor – Career mentors provide assistance in selecting the activities – including the choice and timing of grant applications – that help advance the PI's professional career goals. Early career faculty may benefit from working with a Career mentor.

APPENDIX B: CFAR-HBCU REVIEW CRITERIA

Weight	Item	Section of application scored
40%	Future: Does the proposed project have a high potential of contributing to a future NIH K or R-level application in an NIH OAR High Priority area?	<ul style="list-style-type: none"> * Entire narrative • “Future Plans for NIH Applications” statement • “Applicability to NIH/OAR Research Priorities” statement
10%	Writing: Does 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 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?</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 • Protection of Human Subjects • Inclusion of Women and Minorities • Inclusion of Children • Vertebrate Animals
25%	<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 (if required)
	<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