

District of Columbia Center for AIDS Research (DC CFAR) Traditional Pilot Awards Program Request for Applications – Spring 2024

The District of Columbia Center for AIDS Research (DC CFAR) is pleased to announce the Spring 2024 cycle of soliciting research proposals through its Traditional Pilot Awards Program. *The goal of this program is to provide pilot research funds to early stage and new HIV/AIDS investigators to collect preliminary data that will enable them to then compete successfully for NIH funding in HIV/AIDS research as principal investigators.* This program provides funding of up to **\$75,000 (no indirect costs)** to support research-related activities such as partial salary support for *early stage investigators*, research staff or students; supplies and reagents; participant incentives; and travel expenses (requires pre-approval) to attend national scientific meetings to present research related to the DC CFAR award. The number of awards that are funded will depend on the number and quality of submissions and on the availability of funds. Awards will be made for a one-year period (June 1, 2024 – May 31, 2025), with well justified no-cost extensions considered for a maximum of one additional year.

Scope: Projects must have a focus on HIV/AIDS and related opportunistic illnesses and on the [NIH-defined high priority HIV/AIDS research areas](#).) which broadly include: *HIV cure research; reducing HIV/AIDS incidence; the next generation of HIV therapies; HIV-associated comorbidities, coinfections, and complications; and cross cutting areas of basic research and health disparities.* [Clinical trials](#) and studies involving new drugs, treatments, or devices **cannot** be funded by the DC CFAR. Collaborations are also strongly encouraged with the [DC Cohort](#), the [Multicenter AIDS Cohort Study/Women's Interagency HIV Study Combined Cohort](#). Special consideration will be given to applications in the focus areas of the [DC CFAR Scientific Working Groups \(SWGs\)](#) in *HIV Cure research and Ending the HIV Epidemic* and [Scientific Interests Groups \(SIGs\)](#) in *Drug User Health; Women and HIV; Aging and Comorbidities; Latina/x/o; Global HIV; and Sexual and Gender Minorities.*

Eligibility: Principal Investigators (PI) must: have a terminal degree; hold a current academic faculty appointment at one of the [DC CFAR collaborating institutions](#); be eligible to submit NIH grant applications through their home institution's office of research; and be an [investigator member](#) of the DC CFAR. For membership information, please visit the [DC CFAR website](#). PIs can either be [Early Stage Investigators](#) or [New Investigators](#) as defined by NIH, and must be at the rank of Instructor, Research Scientist, Assistant Professor, Associate Professor, or Full Professor. Clinical fellows are not eligible to apply as PIs. Investigators who have a current DC CFAR Pilot or Transitioning Investigator Award or have ever received one of these awards **are not** eligible to apply and are encouraged to apply directly to the NIH. Applications are especially solicited from newly hired faculty from gender, racial, and ethnic groups who are underrepresented in the HIV research field.

Application Process: Interested applicants are required to submit a [pre-submission form](#) through the DC CFAR website, participate in the consultation call and submit a [full application](#) to lsegarra@gwu.edu by the due dates listed below. Late applications will not be accepted. Full applications must be routed through DC CFAR collaborating institutions' Office of Sponsored Research Projects, or parallel office, for signature. Investigators at GW do not need to route their applications. Resubmission applications will be accepted from investigators who applied for a previous round of the pilot awards program but did not receive funding. Potential applicants should note that this is a highly competitive program with a rigorous review process. Applications will be reviewed concurrently by a DC CFAR Scientific Review Committee. Non-conflicted reviewers will be selected for each proposal by the Developmental Core. Reviewers will assess the scientific merit of the applications using the NIH criteria and community impact by a community reviewer.

Application Procedure/Activity	Due Date
Pre-submission Form	5 PM ET, February 21, 2024
Consultation Call Completion	Mid-March 2024
Core Service Request	Mid-March, 2024
Specific Aims Review	Early April 2024
Full Application	5 PM ET, April 22, 2024
Application Review	May 2024
Anticipated Project Start	June 1, 2024

Award Requirements: Early stage investigators are expected to identify a Primary Mentor who agrees to provide guidance through the application development process and for the duration of the proposed study. PIs are strongly encouraged to utilize DC CFAR Core services in their proposed research projects. PIs are responsible for abiding by DC CFAR’s award guidelines including obtaining Institutional Review Board and/or Institutional Animal Care & Use Committee approval, and follow the fiscal management, reporting and compliance requirements.

Please review the full application instructions and award guidelines below for additional information and requirements before your submission.

Application Instructions

Application Details

Applications must (a) describe how they will use DC CFAR Core services in their proposed research projects. (b) Demonstrate how their research project relates to, and could impact, the HIV/AIDS epidemic in the District of Columbia. (c) Provide information about how the results from this pilot award will inform the development of a specific future NIH proposal and focus on the [NIH-defined high priority HIV/AIDS research areas](#).

[Clinical trials](#) and studies involving new drugs, treatments, or devices **cannot** be funded by the DC CFAR. Need help determining if your study is a clinical trial? Please use [this NIH tool](#) to determine if your research study idea meets the NIH definition for Clinical Trial.

Applicants are strongly encouraged to develop applications focused on the [DC CFAR Scientific Working Groups \(SWGs\)](#) and [Scientific Interests Groups \(SIGs\)](#). Please contact the relevant leaders to explore possible mentorship or collaboration on their proposals.

Consider collaborations with local cohorts: [DC Cohort Longitudinal HIV Study](#) (DC Cohort) and [Multicenter AIDS Cohort Study/Women's Interagency HIV Study Combined Cohort](#) (MWCCS). An approved concept sheet and letter of support from the local cohorts must be submitted in the full pilot award application. Approvals may take a few months to obtain, applicants are strongly encouraged to reach out to leadership as soon as possible.

- MWCCS: Investigators interested in exploring this collaboration should plan to prepare early and review the [procedure to work](#) with this Cohort prior to the pre-submission deadline. Investigators will be required to submit a concept sheet (see guidelines [here](#)) and consult with the leaders of the MACS/WIHS CCS to assess what is feasible/available (working with the local MWCCS site is suggested). Approvals may take a few months to obtain, for additional information on how to work with the MACS/WIHS CCS and next steps please click [here](#).

Review of Applications

Applications will be reviewed by a DC CFAR Scientific Review Committee. Non-conflicted reviewers will be selected for each proposal by the Developmental Core. None of the participants on the Consultation Calls will be asked to review and score the full applications they consulted on. Reviewers will assess the scientific merit

of the applications using the following NIH criteria: overall impact, significance, investigators, innovation, approach, and environment, and community impact by a community reviewer. For additional information, see detailed explanation of [these criteria](#). Incomplete applications will not be reviewed. The DC CFAR Developmental Core will make funding recommendations to the DC CFAR Executive Committee based largely on the scientific merit review while also considering important programmatic factors such as research focus area, strength of plan for future NIH funding, priority group status of PI, proposed use of Core services, and potential for community impact. Each applicant should expect to receive a Summary Statement summarizing the Review Committee’s feedback.

Application Process Procedures and Instructions

Potential applicants should note that the DC CFAR Pilot Awards Program is a highly competitive program with a rigorous review process. Recent successful applications have typically been those that involved substantial advance preparation, including the initial review of the research aims and ongoing mentoring by senior DC CFAR investigators and/or service providers to determine the feasibility of the study and the likelihood of future NIH funding. To enhance each applicant’s likelihood of funding, we have instituted the following procedures to assist investigators with the development of their applications and provided detailed instructions for the full application below.

Required Components	
Pre-Application	Pre-Submission Form – All applicants are required to submit a Pre-submission Form by <u>February 21, 2024 at 5 PM ET</u> . Applicants should continue preparation on their full applications after submitting the Pre-submission Form and while awaiting the next step.
	Application Consultation Call – Applicants will be invited to a virtual meeting with select members of DC CFAR leadership and Community Partnership Council based on the proposed scope of work outlined in their pre-submission forms. The purpose of this consultation is to receive scientific and administrative feedback alongside possible recommendations to consult with other DC CFAR Core Directors and service providers as appropriate. Primary Mentors should participate in this consultation as well. <u>Applicants should continue preparation of their application while waiting for the scheduling of the consultation call.</u>
	Specific Aims Review – Applicants will be invited to participate in a specific aims review with appropriate DC CFAR Service Providers. The purpose of this review is to present and receive feedback on one of the most important and often most difficult parts of the application to articulate. Clear and reasonable specific aims are an essential component of successful applications. This review is <u>not required yet highly recommended</u> .
	Mentorship – <u>Early stage investigators are expected to identify a Primary Mentor</u> (or request one through the DC CFAR Developmental Core) who agrees to provide scientific and grant writing guidance through the application development process, including review of a draft version of the application, and for the duration of the study, if successfully funded. The Mentor will ideally be a senior faculty member with expertise in the scientific focus area of the proposal who has been successful in securing grant funding from the NIH. Mentors may be selected either from a DC CFAR institution or from another research institution and must agree, as evidenced by a letter of support, to participate in this role. Applicants are strongly encouraged to allow the proposed mentor adequate time for a substantive review of the proposal prior to its submission. Continued support by the Mentor will be expected for the publication of study results and the writing of a subsequent NIH grant application. A letter of support is requested in the application.
	Core Services – Applicants are strongly encouraged to utilize DC CFAR Core services in their proposed research projects (and described in the application). Consultation is always available through the Developmental Core. Study design support and social or behavioral research consultations are available through the Social and Behavioral Sciences Core (SBS) Core. Support for epidemiologic study design, biostatistics, writing clinical research protocols and access to clinical populations and specimens are available through the Clinical and Population

	<p>Sciences Core (CPS). <i>Applicants with projects involving statistical analyses (or sample size considerations) are invited to schedule a meeting with a DC CFAR Biostatistician to review their study design and methodology.</i> Laboratory services and assays are available through the Basic Sciences Core (BSC). <u>For additional information or to request services, please contact Lorena Segarra by mid-March.</u></p> <p>Other Resources – Other training and mentoring activities may be scheduled during the cycle to further support investigators with the development of their applications. Applicants will be invited to participate in these events should they become available. Applicants will have access to a Dropbox with several guidelines, examples and other resources that might help support your application process. Please note that additional materials may be added once available.</p>
<p>Full Application</p>	<p>Application Form (Download DOC) – Please use Arial 11 font and submit as a combined PDF document to Lorena Segarra by <u>April 22, 2024 at 5 PM ET.</u></p> <p>Investigators at CFAR institutions must route their grant applications through their Office of Sponsored Research Projects, or parallel office, for signature. Investigators at GW do not need to route their applications.</p> <p><i>DC CFAR staff cannot make changes to or alter applications in any way once submitted. If an application is submitted before the deadline and changes need to be made, the applicant must make those changes themselves and resubmit the entire application packet.</i></p> <p>Unless specified otherwise, please use the appropriate NIH PHS 398 guidance and forms for the sections required below:</p> <p><i>Applicants may also include additional documents as needed including: study timeline, staffing, research instruments, and informed consent or confidentiality forms.</i></p> <p>Face Page – Complete this form as if submitting to NIH. Non-GW applicants are required to include the signature of an official from their respective institution.</p> <p>Project Summary, Relevance, Project/Performance Sites – Provide the project’s scientific abstract in the Project Summary space. If funded, the scientific abstract will be posted on the DC CFAR website.</p> <p>Lay Summary – A lay language summary of the project must be submitted to be considered for funding. This summary follows the scientific abstract and describes the abstract in terms understandable to the general public. <u>The lay summary should also include a brief dissemination strategy detailing how findings will be communicated to the public and a concluding statement describing the potential for community impact locally, as well as nationally and internationally, if appropriate.</u> This summary will be reviewed by the DC CFAR Community Partnership Review Committee, which will assess the project’s potential for community impact. For additional resources, a DC CFAR guide for Academic-Community Partnerships. All scientific terms need to be clearly defined in this summary and written at an 8th grade reading level.</p> <p>Research Grant Table of Contents – Include a Table of Contents for the proposal.</p> <p>Detailed Budget and Justification – Review the NIH allowable expenses and then complete the detailed budget request of up to \$75,000. As agreed to by each of the DC CFAR collaborating institutions, indirect costs will not be covered. <i>Investigators may want to let their Office of Sponsored Research Projects (OSRP) know this in advance, as OSRP may want a copy of the RFA indicating this stipulation prior to or at the time of institutional routing of your grant application.</i></p> <p>Award funds can be used for research-related activities such as: partial salary support for <i>early stage investigators</i> (up to \$10,000 not including fringe benefits), research staff or students (<i>not for senior career faculty or mentor coverage</i>); equipment (purchases over \$5,000 are not allowable), supplies and reagents; participant incentives; and travel expenses to attend national scientific meetings to present research related to the DC CFAR award (if funded must be pre-approved before).</p>

	<p>Biosketches – Include a personal biosketch and for all key personnel/collaborating investigators. Follow the NIH guidelines.</p> <p>Resources – Identify the facilities to be used and the scientific environment in which the research will be conducted.</p> <p>Research Plan – No more than <u>six pages total</u> (including a one-page specific aims). The research strategy should be appropriately labeled section headings for Significance, Innovation, and Approach. We encourage applicants to review examples of successful applications to NIH prior to writing your research plan. <i>Pertinent graphs, tables, and charts necessary for the understanding of the research project should be included within the body of the Research Plan (do not circumvent the page limit).</i></p> <p>References – Provide a bibliography of any references cited in the Research Plan.</p> <p>Applicant Statement – (a) A statement of how the findings of this proposal may lead to a future NIH grant application. (b) A description of the steps taken to satisfy the pre-application process. This should describe the role that the Primary Mentor played in supporting the application and will play if the project is funded. Applicants are required to verify that the Mentor was given the opportunity to review the draft application in advance of the submission date and provide feedback. Applicants should describe the extent to which the feedback was incorporated into the application. (c) A description of DC CFAR Core service(s) that will be utilized for the proposed project. If after consultation it is determined that the appropriate services are not available through the DC CFAR, then a statement must be included that explains why services will not be utilized.</p> <p>DC CFAR Developmental Core Checklist – Fill out the checklist included in the full application form.</p> <p>Scope of Work - Submit a 1-page scope of work detailing your responsibilities by specific aim. This document is required for administrative purposes only. If your award is funded, the document will be attached to the sub-award agreement or used for the award setup.</p> <p>Letters of Support – Letters of support are required from the Primary Mentor (with the description of assistance and acknowledging continuing support if the project is successfully funded) and the PI’s Department Chair or Division Director. In addition, include appropriate letters of support from co-investigators, collaborators or consultants. Letters are not required from DC CFAR service providers.</p> <p>Human Subjects Information – If your study involves human participants, specimens and/or data, the Protection of Human Subjects information must be submitted or your application will be incomplete. Please follow the SF424 instructions to complete the Protection of Human Subjects section. <u>If funded, you will be required to submit all PHS Human Subjects and Clinical Trials Information about your project to the DC CFAR.</u></p> <p>Vertebrate Animals Information – If your study involves live vertebrate animals, information on how you will use and care for the animals must be submitted or your application will be incomplete. Please follow the SF424 instructions.</p>
<p>Re-submissions</p>	<p><i>The DC CFAR Pilot Awards Program does not limit the number of resubmissions from applicants who submitted an application in a previous round of the Program and were not selected for funding.</i></p> <p>One Page Summary of Key Revisions – Summarize the major revisions made to the current research plan that address the feedback received in the Application Review Form (a.k.a. Summary Statement/“pink sheets”). <u>It is highly recommended that resubmitting applicants contact the DC CFAR Developmental Core to set up a meeting to review the initial feedback received.</u></p> <p>Identification of Scientific Changes in Current Proposal – Italicize, bracket or otherwise highlight text or sections that have been substantially revised.</p>

Award Guidelines

Institutional Review Board (IRB) and Institutional Animal Care & Use Committee (IACUC) Approval, and Ethical Oversight

- If applicable, award recipients may not begin their study until IRB approval, approved reliance agreement with GW and/or IACUC approval is received. Once awarded, we encourage investigators to work on obtaining the necessary approvals as soon as possible to avoid a delay in the start date.
- Projects may require additional advance NIH review before award recipients can begin if by NIH and/or IRB determination, it:
 - involves new ways of using known drugs, treatments, or devices;
 - is deemed above minimal risk by the Institutional IRB;
 - involves vulnerable populations (children, pregnant women, transgender, sex workers, prisoners, refugees, individual who are unable to provide informed consent, etc.); or
 - involves behavioral interventions above minimal risk.
- For studies in these categories, the clinical research protocol and informed consent documents of funded studies must be sent to NIH for review and no human subjects work may be initiated until clinical approval is received.
- Funded investigators who plan to recruit human participants will be required to submit the appropriate Human Subjects Information, including but not limited to, the planned enrollment and inclusion across the lifespan.
- CFAR projects must adhere to the [Single IRB policy](#). Reliance agreements are required for any CFAR pilot projects involving human participants that are subcontracted out to another institution, even if the parent institution (GW) is not engaged in the research protocol. The DC CFAR will work with award recipients to obtain the reliance with GW through the SMART IRB platform (the use of a paper IAA will be reviewed on a case-by-case basis) where GW relies on the institution's IRB review and approval. Investigators must work with their IRB office to determine any other requirements (for example, the protocol may need to be amended) to add GW as a relying site.
 - As required by the NIH, the DC CFAR must have a current IRB or IACUC approval copy at all times, and renewal approvals and study closure forms should also be submitted to us in a timely manner.
 - Award recipients are responsible for notifying the DC CFAR if there are any reportable events associated with the study. This includes events that are required as prompt reports by the GW or other governing IRB, NIH, or as otherwise requested by the DC CFAR. Specifically, participant death, hospitalization, or injury, participant or community social harms or complaints, concerns about fraud, theft, or falsified data, or other serious events. Should one of these events related to the study occur, they must be reported to the Developmental Core in writing within 72 hours of the event along with a copy of the report to the IRB.

Fiscal Management

- The management of award funds and the completion of the activities outlined in the proposal and budget justification. Expenses must adhere to [NIH](#), DC CFAR and the institution's guidelines on allowable expenditures.
- Funds may be rescinded if the project has not progressed substantially at the time of the review of progress by the DC CFAR.
- Investigators may request domestic travel expenses to present research findings or training related to the DC CFAR award. Submit the request to lsegarra@gwu.edu at least one month prior to the travel date for expedited review from the Developmental Core. Pre-approval must be requested before booking any travel; any travel not pre-approved may not be reimbursed.

- Requests for international travel may be considered to present research findings , but cannot be guaranteed even if funding is available in the pilot award. Submit the request to lsegarra@gwu.edu at least two months prior to the travel date for expedited review from the Developmental Core. Pre-approval must be requested before booking any travel; any travel not pre-approved may not be reimbursed.

Reporting and Compliance

- Investigators are required to notify the Developmental Core in writing if significant delays or changes to the research plan will be made after the project has started.
- Foreign institutions must provide access to copies of all electronic data, and documentation that supports the research outcomes as described in the progress report, to the DC CFAR in compliance with the [NIH policy](#).
- A progress report (two pages including figures) will be required at six months from the award start date (January 2025). This report should include scientific progress to date, summary of DC CFAR Core services and mentoring consultations, a listing of any resulting publications, funding applications or collaborations; and, if applicable, a copy of the IRB or IACUC approval, if not previously submitted. If the project extends beyond its original end date, additional interim progress reports may be required.
- A final report (three pages including figures) will be expected two months after the end date of the award. This report should provide a summary of DC CFAR Core services and mentoring consultations since last progress report, and preliminary scientific findings and plans for follow-up, including publications, funding applications and/or future research. Both interim and final progress reports must be sent to Lorena Segarra.
 - Please note that after the award has ended, the Core will request details on subsequent grants and publications related to the pilot project. It is the grantee's responsibility to track accomplishments associated with the pilot award and be responsive to data requests.
- Ongoing consultation with a Primary Mentor is required throughout the project and thereafter, as appropriate, to support publishing results and submitting a subsequent NIH grant application. The Mentor must sign off on the submitted application, and if funded, the notice of award.
- If invited, the award recipient is expected to present their research at CFAR meetings and events, including the annual DC CFAR Research Symposium, Research-in-Progress seminars, and other events organized by the Developmental Core or the DC CFAR.
- Award recipients are responsible for completing brief outcome reports for the DC CFAR detailing any subsequent publications, funding awards, or collaborations resulting from this grant award for the next five years.
- The DC CFAR should be acknowledged in all above listed project outcomes whenever appropriate. Please note that any publications resulting from this award, DC CFAR services and/or mentorship must cite the DC CFAR's NIH award number (AI117970) and must be compliant with [NIH's public access policy](#). Please visit our website for more information about how to [acknowledge the DC CFAR](#).

Contact Information :

Application and Content Questions
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Budget and Institutional Routing Questions
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