

District of Columbia Center for AIDS Research (DC CFAR) Traditional Pilot Awards Program Request for Applications – Fall 2023

Background

The District of Columbia Center for AIDS Research (DC CFAR) is pleased to announce the fall 2023 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.

Scope

- Projects with a focus on HIV/AIDS and related opportunistic illnesses, including basic, clinical, epidemiological, social, behavioral, and prevention science will be considered.
- Applications should focus on the NIH-defined high priority HIV/AIDS research areas (https://www.oar.nih.gov/hiv-policy-and-research/research-priorities) 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.
- Applicants should 1) describe how they will use DC CFAR Core services in their proposed research projects; 2)
 demonstrate how their research project relates to, and could impact, the HIV/AIDS epidemic in the District of
 Columbia; and 3) provide information about how the results from this pilot award will inform the development of a
 specific future NIH proposal.
- <u>Clinical trials</u> and studies involving new drugs, treatments, or devices <u>cannot</u> be funded by the DC CFAR. Please use this NIH tool to determine if your research study idea meets the NIH definition for Clinical Trial.
- Special consideration will be given to applicants collaborating with the DC Cohort, the MACS/WIHS Combined Cohort Study and the DC CFAR Scientific Working Groups (SWGs) and Scientific Interests Groups (SIGs).
 - Co-sponsorship with the DC Cohort: The DC Cohort is supplementing up to 2 pilot awards this cycle with an additional \$12,500 per award in addition to the \$75,000 maximum for a DC CFAR pilot award for a total award of up to \$87,500. This is an opportunity for DC CFAR Investigators to work with a large multicenter cohort which follows people living with HIV of all ages who are receiving care at 14 clinics in DC, which is a priority for this cycle of the program.
 - Applications may include the conduct of secondary data analyses or a pilot study utilizing DC Cohort data in collaboration with one or more of the 14 participating DC Cohort clinical sites. For additional information on this cohort please click here and here to access the DC Cohort Data Dictionaries.
 - Applicants applying for this opportunity must prepare early and consult with the leaders of the DC Cohort to assess what is feasible/available. Investigators interested in exploring such collaborations should contact Drs. Amanda Castel (DC Cohort PI) at acastel@gwu.edu and Anne Monroe (DC Cohort Project Director) at amonroe@gwu.edu by August 14, 2023 via email re: intention to use DC Cohort provide 1-paragraph description of the aims/methods.
 - A meeting will be arranged to discuss the idea, with a concept sheet submitted by August 21, 2023. Please download the concept sheet form here.
 - The additional funds provided through this opportunity could be used to provide incentives for pilot studies, provide coverage for site RAs to collect/supplement ongoing data collection, etc. Proposals involving secondary data analyses must include some effort for analytic support from a DC Cohort analyst.
 - Concept sheets will be reviewed by the DC Cohort leadership. By August 28, 2023 the leadership will identify up to 2 applicants and invite them to submit full pilot award applications.
 - An approved concept sheet and letter of support from the DC Cohort must be submitted in the full pilot award application.
 - Questions? Please contact acastel@gwu.edu and amonroe@gwu.edu.
 - Collaborations are also strongly encouraged with the Multicenter AIDS Cohort Study/Women's Interagency HIV Study Combined Cohort (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). If the use of this cohort is deemed feasible, approved concept sheets and letters of support from

- the cohort must be submitted in the full pilot award application. 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.
- Applications are also encouraged in the focus areas of the DC CFAR Scientific Working Groups (SWGs) in HIV Cure research and Ending the HIV Epidemic and Scientific Interest Groups (SIGs) in Drug User Health; Women and HIV; Aging and Comorbidities; Latina/x/o; Global HIV; and Sexual and Gender Minorities. Applicants are strongly encouraged to contact the relevant SWG and/or SIG leaders to explore possible mentorship or collaboration on their proposals.

Investigator Eligibility Information

- Faculty investigators at the nine participating DC CFAR institutions [American University, Children's National Health System, DC Health, Georgetown University, George Washington University, Howard University, Us Helping Us (UHU), Veterans Affairs Medical Center (VAMC), and Whitman-Walker (WW)] who are full members of the DC CFAR are eligible to apply. Applications for new membership will be accepted just prior to or at time of submission if the PI meets the eligibility criteria. For membership information, please visit the DC CFAR website at: http://dccfar.gwu.edu/.
- Principal Investigators (PI) must: 1) have a terminal degree; 2) hold a current academic faculty appointment; and 3) be eligible to submit NIH grant applications through their home institution's office of research.
- Pls can either be <u>Early Stage Investigators</u> or <u>New Investigators</u>, i.e. have not been funded through an NIH R01 or equivalent grant.
- PIs must be at the rank of Instructor, Research Scientist, Assistant Professor, Associate Professor, or Full Professor.
 Clinical fellows <u>are not</u> 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 <u>are not</u> eligible to apply and are encouraged to apply directly to the NIH.
- Applications are especially solicited from newly hired faculty at one of the nine DC CFAR institutions who began their academic appointments after <u>July 1, 2022</u>; underrepresented racial and ethnic minority groups; and women.

Resubmissions

- Resubmission applications will be accepted from investigators who applied for a previous round of the pilot awards program but did not receive funding.
- Resubmissions must answer reviewers' comments and must be responsive to the previous DC CFAR review.

Award Details

- New: DC CFAR proposals up to \$75,000 will be considered. For this cycle, proposals that involve collaboration with the DC Cohort may request up to \$87,500. The number of awards that are funded will depend on the number and quality of submissions and on the availability of funds. All proposals will be reviewed concurrently using a common review process.
- Awards will be made for a one-year period, with well justified no-cost extensions considered for <u>a maximum of one</u> additional year.
- Award funds can be used for research-related activities such as partial salary support for early stage investigators, research staff or students; supplies and reagents; participant incentives; and travel expenses to attend national scientific meetings to present research related to the DC CFAR award. Travel expenses for meetings must be preapproved. Capital equipment purchases over \$5,000 are not allowable.
- <u>Early stage investigators</u> (those who have completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years) and investigators who have not previously served as PI on <u>any</u> R01 or equivalent award may include up to \$10,000 (not including fringe benefits) for their own salary support as part of their budget request.
- Investigators at American University, Children's National Health System, DC Health, Georgetown University, Howard University, UHU, VAMC, and WW 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.
- Investigators at GW who plan to include a Co-Investigator from an institution other than GW in their proposal to
 whom a sub-award will be made must include the items outlined in Appendix C (letter of intent, subrecipient form,
 scope of work).
- As agreed to by each of the DC CFAR collaborating institutions, indirect costs will <u>not</u> be covered. Investigators at American, Children's, DC Health, Georgetown, Howard, UHU, VAMC and WW 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.

Application Process Procedures

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.

- Pre-submission Form All applicants are required to submit a <u>Pre-submission Form</u> and NIH biosketch by <u>September 1</u>, <u>2023</u>. The pre-submission step notifies DC CFAR that an applicant intends to apply and allows us to begin setting up the Specific Aims Reviews and Consultation Calls and identifying mentors, if requested (see below). <u>Applicants should continue preparation on their full applications after submitting the <u>Pre-submission Form and while awaiting the next step</u>.
 </u>
- 2. Application Consultation Applicants will be invited to a one-hour virtual meeting via Zoom with select members of senior DC CFAR leadership 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. The individuals on the call will be provided with the pre-submission form. Applicants should continue preparation of their application while waiting for the scheduling of the consultation call. Please note: None of the participants on the calls will be asked to review and score the full applications they consulted on.
- 3. 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.
- 4. Mentorship Early stage investigators are expected to identify a Primary Mentor (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. A Mentor should be identified as soon as possible and should participate in the application development and in the consultation. 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 description of the assistance provided by the Mentor along with a letter of support should be included in Appendix A of the application. The letter should acknowledge continuing support if the project is successfully funded.
- 5. Biostatistical Consultation Following the above consultation, applicants with projects involving statistical analyses (or sample size considerations) will be invited to schedule a phone or Zoom meeting with a DC CFAR Biostatistician to review their study design and methodology. Requests for this consultation should be made by mid-October and can be arranged by contacting DC CFAR Clinical and Population Sciences Core Manager, Vivian Kirkham at vkirkham@gwu.edu.
- 6. Core Service Requests Applicants are strongly encouraged to utilize DC CFAR Core services in their proposed research projects. A description of Core service utilization is requested in the application. DC CFAR services are offered through three scientific cores. 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 Sciences Core (CPS). Laboratory services and assays are available through the Basic Sciences Core (BSC). For additional information or to request services, please contact Lorena Segarra at legarra@gwu.edu by mid-October.
- 7. **Other Resources** Applicants will have access to a Dropbox with several guidelines, examples and other resources that might help support your application process, please click <u>here</u> to view the folders. Please note that additional materials could be added once available. If you have any questions or would like additional details, please contact <u>Lorena Segarra</u>.

Other training and mentoring activities, such as grant writing workshops, mixers, and research brown bags, 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.

Timeline for Proposals for DC Cohort Co-Sponsorship

Procedure/Activity for DC Cohort Co-sponsorship	Due Date
Email of Intent with Brief Description	August 14, 2023
Concept Sheet Deadline	August 21, 2023
Applicants Invited to Submit Full Applications	August 28, 2023

Timeline for All DC CFAR Pilot Award Applications

Procedure/Activity	Due Date
Pre-submission Form	September 1, 2023
Grant Writing Workshop	September 8, 2023
Consultation Call Completion	Mid-September 2023
Core Service Request	Mid-October, 2023
Specific Aims Review	Mid-October 2023
Full Application	5 PM ET, November 3, 2023
Application Review	November-December 2023
Anticipated Project Start	January 1, 2024

Application Instructions

DC CFAR Pre-submission Form – All potential applicants must submit the <u>Pre-submission Form</u> and NIH biosketch by **September 1, 2023.**

Download the application form here. Please use Arial 11 font for the application.

NIH Guidance and Forms - Unless specified otherwise, please use the appropriate NIH PHS 398 guidance and forms for the sections required below:

- Guidance: https://grants.nih.gov/grants/funding/phs398/phs398.pdf
- Forms: http://grants.nih.gov/grants/funding/phs398/phs398.html

Application Form Section Instructions

- **1.** *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.
- **2.** *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.
- 3. 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. The lay summary should also include a brief dissemination strategy detailing how findings will be communicated to the public. This summary will be reviewed by the DC CFAR Community Partnership Council (formerly the Community Advisory Board) Review Committee, which will assess the project's potential for community impact. For additional resources, a DC CFAR guide entitled "Advancing Equity and Fostering Change: A Guide for Academic-Community Partnerships in the DC Center for AIDS Research" is available here. All scientific terms need to be clearly defined in this summary and written at an 8th grade reading level. Please also include a concluding statement describing the potential for community impact locally, as well as nationally and internationally, if appropriate.
- **4.** Research Grant Table of Contents Include a Table of Contents for the proposal.

- **5. Detailed Budget** Review the allowable expenses and then complete the detailed budget. *DC Cohort Co-sponsorship:* secondary data analyses must include some effort for analytic support from a DC Cohort analyst.
- 6. Budget Justification
- 7. Biosketches Include a personal biosketch along with biosketches for all key personnel/collaborating investigators.
- 8. Resources Identify the facilities to be used and the scientific environment in which the research will be conducted.
- **9.** Research Plan The research plan should be no more than <u>six pages</u> total. It should include both the specific aims (up to 1 page) and the research strategy with 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: https://www.niaid.nih.gov/grants-contracts/sample-applications.

10. References

- 11. Applicant Statement Applicants are required to include the following for peer review:
 - 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 "Application Process Procedures", which are outlined in a previous section of this RFA. 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.

12. DC CFAR Developmental Award Checklist

13. 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 (investigators at American, Children's National, DC Health, Georgetown, Howard, UHU, VAMC and WW) or used for the award setup (investigators at GW).

Additional proposal requirements:

In addition to the application form above, include the following in the final proposal:

- Letters of support Letters of support are required from the Primary Mentor 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.
- 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 here to complete the Protection of Human Subjects section. If funded, you will be required to submit all PHS Human Subjects and Clinical Trials Information about your project to the DC CFAR.
- 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 here for the completion of this section.

Applicants may also include additional documents as needed; however, they should *not* be used to circumvent the page limits of the Research Plan. Pertinent graphs, tables, and charts necessary for the understanding of the research project should be included within the body of the Research Plan. Examples of appropriate documentation for the Appendix may include: study timeline, staffing, research instruments, and informed consent or confidentiality forms.

Additional Requirements for Resubmitting Applications

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. The following additional materials are requested for resubmission applications:

- 1. 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"). It is highly recommended that resubmitting applicants contact the DC CFAR Developmental Core to set up a meeting to review the initial feedback received.
- 2. *Identification of Scientific Changes in Current Proposal* Italicize, bracket or otherwise highlight text or sections that have been substantially revised.

Application Submission Details

- To be eligible to submit a full application, the <u>Pre-submission Form</u> should be submitted by 5 pm ET on September 1, 2023
- The final application should be emailed to Lorena Segarra at lsegarra@gwu.edu by 5 pm ET on November 3, 2023. Late applications will not be accepted.
- The final proposal should be submitted as a single, combined <u>PDF document</u> and include the following: 1) completed application form; 2) letters of support; and 3) appropriate Protection of Human Subjects and/or Vertebrate Animals information, if applicable.
- 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 themself and resubmit the entire application packet.
- The funding period is January 1, 2024 through December 31, 2024.

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. 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 a detailed explanation of these criteria, please see
 http://grants.nih.gov/grants/funding/sbirsttr_ReviewCriteria.htm. 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 (a.k.a. "pink sheets") summarizing the Review Committee's feedback.

Funding Requirements

- 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.
- Principal Investigators are required to notify the Developmental Core in writing and receive approval if significant changes to the research plan or budget will be made.
- Pls are required to notify the Developmental Core in writing if external funding becomes available for the same scope of work as is proposed for this funded project through the DC CFAR and it is possible that funds may be rescinded.
- CFAR funded projects involved with certain types of human participants research must receive a <u>reliance agreement</u>. The DC CFAR will work with you to obtain the reliance with GW.
- If applicable, a copy of the PI's IRB and/or IACUC approval should be submitted to us as soon as possible upon receipt. As required by the NIH, the DC CFAR must always have a current IRB and/or IACUC approval copy. Renewal approvals and study closure forms should also be submitted to us in a timely manner.
- A project may require additional NIH review before commencing if it: a) involves new ways of using known drugs, treatments, or devices; b) is deemed above minimal risk by the Institutional IRB; c) involves vulnerable populations (children, pregnant women, transgender, sex workers, prisoners, refugees, individual who are unable to provide informed consent, etc.); or d) involves behavioral interventions above minimal risk.
- 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.
- A progress report (1-2 pages including figures) will be expected at six months from the award start date. 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 your IRB and/or
 IACUC approval if not previously submitted. If the project extends beyond its original end date, additional interim
 progress reports may be required.

- Funds may be rescinded if the project has not progressed substantially at the time of the review of progress by the DC CFAR.
- A final report (maximum three pages including figures) will be expected two months after the end of the funding period. 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.
- The award recipient will be asked to give a presentation of the proposed and completed research at seminars organized by the Developmental Core. The recipient may also be asked on other occasions to speak at or participate in other DC CFAR meetings and/or seminars.
- The award recipient will be 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 must cite the DC CFAR's NIH award number (P30Al117970) and must be compliant with NIH's <u>public access policy</u>. Please visit our website for more information about how to acknowledge the DC CFAR.

Contact Information

Application and Content Questions
Lorena Segarra, Senior Research Program Manager

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Budget and Institutional Routing Questions
Quinn Benson, Research Program Assoc, Pod 2

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