District of Columbia Center for AIDS Research (DC CFAR)
Pilot Awards Program
Request for Applications – Spring 2019

Background

The District of Columbia Center for AIDS Research (DC CFAR) is pleased to announce the next round of soliciting research proposals through its 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 as principal investigators.

Scope

- Projects with a focus on HIV/AIDS and related opportunistic illnesses, including basic, clinical, epidemiologic, social behavioral, and prevention HIV/AIDS science.
- Applications should focus on the NIH 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.
- Applications are also strongly encouraged that focus on the following DC CFAR priorities: a) Cure research; b) PrEP c) Continuum of care in DC; d) Opioids; e) Women; and f) Aging.
- Collaborations are strongly encouraged with other large NIH-funded HIV studies in DC including the Women's Interagency HIV Study (WIHS) and the DC Cohort. Investigators interested in exploring such collaborations should contact Ms. Brandi Robinson who will facilitate connectivity to these projects. Investigators will be required to consult with the leaders of the WIHS and DC Cohort to assess what is feasible/available before submitting their applications.
- Clinical trials and studies involving new drugs, treatments, or devices cannot be funded by the DC CFAR.
- Applicants should 1) describe how they will use DC CFAR Core services in their proposed research projects and 2) demonstrate how their research project relates to, and could impact, the HIV/AIDS epidemic in the District of Columbia.

Eligibility Information

- Faculty investigators at the eight participating DC CFAR institutions (American University, Children's National, DC Department of Health, Georgetown University, George Washington University, Howard University, Veterans Affairs Medical Center, and Whitman-Walker Health) 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 doctoral 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.
- PIs can either be "Early Stage Investigators" or "New Investigators." New investigators are those who have not previously served as the PI on any R01 NIH award or equivalent, including R23, R29, R37, and DP2 (for more information, please visit: http://grants.nih.gov/grants/new_investigators/index.htm).
- PIs must be at the rank of Assistant Professor, Associate Professor, Full Professor, or Research Scientist. Clinical fellows are not eligible to apply as PIs.
- Investigators who have a current DC CFAR Pilot Award or have ever received a Pilot Award are not eligible to apply and are encouraged to apply directly to the NIH.
- Applications are especially solicited from the following groups: newly hired faculty at one of the eight DC CFAR institutions who began their academic appointments after July 1, 2017; underrepresented racial and ethnic minority groups; and women.

Resubmissions

- Resubmission applications will be accepted from investigators who applied for a previous round of the awards program but did not receive funding.
- Resubmissions must answer reviewers' comments and also demonstrate that substantial changes were made in response to the reviews provided.

Award Details

- DC CFAR proposals up to $50,000 will be considered. 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, with no-cost extensions considered for <u>a maximum of one additional year</u>.
- 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; and travel expenses to attend national scientific meetings to present research related to the DC CFAR award. Travel expenses for meetings must be pre-approved. Capital equipment purchases over $5,000 are not allowable.
- Salary support is <u>only available for 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).
- Investigators at American, Children's, DOH, Georgetown, Howard, VAMC, and WWH should 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 *not* be covered. Investigators at American, Children's, DOH, Georgetown, Howard, VAMC and WWH 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.

1. Pre-submission Form – All applicants are required to submit a [Pre-submission Form](#) and NIH biosketch by **January 29, 2019**. 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</u> after submitting the Pre-submission Form and awaiting the next step.

2. Specific Aims Review – After review of the pre-submission forms, applicants will be invited to participate in a specific aims review either in person or via conference call with their mentor and 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. In previous pilot award cycles, applicants with clear and reasonable specific aims received better scores.

3. Application Consultation – Applicants will be invited to a one-hour conference call 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: The consultation call will not impact the final score/review of

the full application, as none of the participants on the calls will be asked to review and score the full applications they consulted on.

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 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. 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 B 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 in-person meeting with a DC CFAR Biostatistician to review their study design and methodology. Requests for this consultation should be made by February 11 and can be arranged by contacting Dr. Sam Simmens at simmens@email.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 Appendix C of the application. DC CFAR services are offered through three scientific cores. Consultation is always available through the Developmental Core. Study design support and social-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 the DC CFAR Senior Research Program Manager at bnrobin@email.gwu.edu by February 11.

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.

Key Dates

Procedure/Activity	Due Date
Pre-submission Form	January 29, 2019
Specific Aims Review	Early February
Core Service Request	February 11, 2019
Consultation Call Completion	February 28, 2019
Full Application	April 3, 2019
Application Review	April 2019
Anticipated Project Start	June 1, 2019

Application Instructions

DC CFAR Pre-submission Form – All applicants must submit Pre-submission Form and NIH biosketch by **January 29**

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 Sections *(in suggested order)*

1. *Face Page/Form Page1* – Complete this form as if submitting to NIH. Non-GW applications are required to include the signature of an official from their respective institution.

2. *Form Page 2* – 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. *Second Form Page 2* - A lay language summary of the project must be submitted on a second Form Page Two 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 Advisory Board Review Committee, which will assess the project's potential for community impact. Community engagement resources can be found 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. *Form Page 3* – Include a Table of Contents for the proposal.

5. *Form Page 4* - Review the DC CFAR Budget Instructions and then complete the detailed budget. A Budget Justification should follow that is completed using the Continuation Form.

6. *Biographical Sketch Format Page* – Include a personal biosketch along with biosketches for all collaborating investigators.

7. *Resources Format Page* – Identify the facilities to be used and the scientific environment in which the research will be conducted.

8. *Research Plan/Continuation Format Page* – The research plan should be no more than six pages 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. References may follow and will not be counted towards the page limit. 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

9. *Other Narrative Sections and Forms* – If appropriate, the applicant should follow the PHS 398 instructions for the completion of the following sections using the applicable forms: PHS Human Subjects and Clinical Trials Information, Inclusion of Women and Minorities, Inclusion of Children, Vertebrate Animals, and Select Agent Research.

10. *Letters of support* – Include appropriate letters of support from co-investigators, collaborators or consultants, the Primary Mentor, and the PI's Department Chair or Division Director. Letters are not required from DC CFAR service providers.

11. *Appendix A* - 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 with the DC CFAR Senior Research Program Manager 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 not utilized.

12. *Appendix B* - Applicants are required to complete and include the DC CFAR Developmental Award Checklist at Appendix B for administrative review.

13. *Appendix C* - GW applicants who plan to include a Co-Investigator(s) from an institution other than GW to whom a sub-award will be made must include, in addition to biosketches for all key personnel:

a) A letter of intent signed by the institution's signing official. See appendix C for a sample.
b) A subrecipient Commitment Form
(https://sponsoredprojects.gwu.edu/sites/sponsoredprojects.gwu.edu/files/downloads/Subrecipient_Commitment_Form.pdf)
c) A site-specific scope of work

14. *Appendix D* - 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, DOH, Georgetown, Howard, VAMC and WWH) or used for the PTA setup (investigators at GW).

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

For consistency with NIH's policy, 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 (aka 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 Pre-submission Form should be submitted by **5 pm ET on January 29, 2019** at the following website: https://dccfar.gwu.edu/pre-submission-form.
- The final application should be emailed to the DC CFAR Senior Research Program Manager, Ms. Brandi Robinson, at bnrobin@email.gwu.edu by **5 pm ET on April 3, 2019**.
- The final application should be submitted as a single, combined PDF document.
- 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 himself/herself and resubmit the entire application packet. Items submitted after the deadline will not be accepted.
- The funding period is June 1, 2019 through May 31, 2020.

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. 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 Executive Committee will make final funding decisions 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 (aka "pink sheets") summarizing the Review Committees' 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 if significant changes to the research plan or budget will be made.
- PIs 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. Funds may be rescinded if the project has not progressed substantially at the time of notification and review by the DC CFAR.
- 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 have a current IRB and/or IACUC approval copy at all times. Renewal approvals and study closure forms should also be submitted to us in a timely manner.
- Projects 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.
- 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.
- A final report (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 (P30AI117970) 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
Brandi Robinson
DC CFAR Senior Research Program Manager
Phone: 202-994-4730
Email: bnrobin@email.gwu.edu

Budget and Institutional Routing Questions
Kate Angevine
Senior Sponsored Projects Administrator, Grants Management
Phone: 202-994-0757
Email: kangevine@email.gwu.edu

Appendix B

DEVELOPMENTAL AWARD CHECKLIST

*Please note, this form MUST be completed and included in the Appendix of your application.

Please check the appropriate responses:

1. Does your proposed study include vulnerable populations?

   ☐ Yes   ☐ No

   If yes, please select which vulnerable populations are included:

   ☐ Pregnant women, neonates, or fetuses
   ☐ Prisoners
   ☐ Children (note: the NIH defines children as **birth to 18 years of age**)
   ☐ Refugees
   ☐ Other vulnerable population

2. Does your proposed study involve procedures or behavioral interventions deemed above minimal risk?

   ☐ Yes   ☐ No

   If you answered yes to question 1 or 2, please note that if funded, your study will be required to undergo additional NIH clinical review. **No human subject work may be initiated until clinical approval is received.**

3. Will any research (human or non-human) or other work be conducted in a foreign country?

   ☐ Yes   ☐ No

   If you answered yes to question 3, please note that if funded, you will be required to complete the International Studies Checklist and your study will undergo additional NIH review. **No international work may be initiated until approval is received.**

4. Does this study involve animals?

   ☐ Yes   ☐ No

Appendix C

GW applicants who plan to include a Co-Investigator(s) from an institution other than GW to whom a sub-award will be made must include, in addition to biosketches for all key personnel:

      a) A letter of intent signed by the institutions signing official

      b) A subrecipient Commitment Form (https://sponsoredprojects.gwu.edu/sites/sponsoredprojects.gwu.edu/files/downloads/Subrecipient_Commitment_Form.pdf)

      c) A site-specific scope of work

SAMPLE LETTER OF INTENT

GW PI name and address

Dear Dr. GW PI Name:

This letter declares INSTITUTION's intent to collaborate in the application entitled "xxx" in response to funding opportunity xxx.

Dr SUB-AWARD PI Name is the Principal Investigator for INSTITUTION.

Attached is a description of the effort and resources that INSTITUTION will commit to this project, along with a budget. The proposed budget period is for five years, from xx/xx/xx, through xx/xx/xx. The total budget for INSTITUTION is $XXX.

Our organization is subject to and compliant with the requirements of OMB A-133. To support the DC CFAR program INSTITUTION agrees to not request any indirect costs for any DC CFAR Pilot Awards granted to INSTITUTION investigators.

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

Sincerely,

INSTITUTIONAL AUTHORIZED OFFICIAL

Attachments: Statement of Work, Budget