District of Columbia Center for AIDS Research (DC CFAR)
Pilot Awards Program
Request for Applications – Fall 2017

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. This competitive program seeks to provide pilot research funds to HIV/AIDS investigators who demonstrate potential for competing successfully in the future for federal funding and eventually establishing themselves as independent NIH-funded investigators.

Eligibility Information

Faculty investigators at seven participating DC CFAR institutions (American University, Children's National Medical Center, 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 as Principal Investigators (PI) to the Pilot Awards Program. 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 must have a doctoral degree, hold a current academic faculty appointment, and 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" i.e. established investigators newly transitioning into HIV. PIs must be at the rank of Assistant Professor, Associate Professor, Full Professor or Research Scientist. New and transitioning investigators are those that have not previously served as the PI on an HIV/AIDS-related 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). Clinical fellows are not eligible to apply as PIs. Post-doctoral fellows on a T32 are eligible to apply; however, funds cannot be used for training and stipends already paid for by the T32. For more information, please contact Brandi Robinson at bnrobin@email.gwu.edu.

Applications from the following groups are especially solicited:

- Newly hired faculty at one of the seven DC CFAR institutions who began their academic appointments after July 1, 2015.
- Underrepresented racial and ethnic minority groups
- Women

Investigators who have a current DC CFAR Pilot Award or have ever received a pilot award are not eligible to apply. Previous DC CFAR Award Recipients are encouraged to apply directly to the NIH for future funding. Investigators at non-DC CFAR institutions and clinical and post-doctoral fellows may serve as Co-Investigators and Key Personnel on applications.

Scope of Research

The Pilot Awards Program specifically funds research projects that focus on HIV/AIDS and related opportunistic illnesses. The scope of projects that will be considered for this cycle is broad and includes basic, clinical, epidemiologic, social behavioral, and prevention HIV/AIDS science.

Applications should focus on the NIH high priority HIV/AIDS research areas (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html) which broadly focus on: reducing HIV/AIDS incidence; the next generation of HIV therapies and implementation research on the HIV

continuum of care; cure research; HIV-associated comorbidities, coinfections, and complications; and cross cutting areas in basic research and health disparities.

Applications are also strongly encouraged from investigative teams from at least two of the three DC CFAR Scientific Core Areas (Basic Sciences, Clinical and Population Sciences, and Social and Behavioral Sciences), and/or from at least two different DC CFAR institutions.

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.

Applicants submitting clinical research proposals should see Appendix A for further details about the types of studies that are permissible.

Resubmission Applicants

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

Award Details

1. 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.

2. Awards will be made for a one-year period, with no-cost extensions considered for <u>a maximum of one additional year</u>.

3. 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.

4. Salary support from the Pilot Awards Program is only available for early stage investigators (those within 10 years of completing their terminal degree).

5. Investigators at American, CNMC, Georgetown, Howard, VAMC, and WWH should route their grant applications through their Office of Sponsored Research Projects, or parallel office. Investigators at GW do not need to route their applications.

7. 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)

8. As agreed to by each of the DC CFAR collaborating institutions, indirect costs will <u>*not*</u> be covered. Investigators at American, CNMC, Georgetown, Howard, VAMC and WWH may want to let their Office of Sponsored Research Projects 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 that incorporates 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 **August 28th**. The pre-submission step notifies DC CFAR that an applicant intends to apply and allows us to begin setting up the Application Consultation Calls and identifying mentors, if requested (see below). Applicants should continue preparation on their full applications after submitting the Pre-submission Form and awaiting the next step.

2. Application Consultation – After review of pre-submission forms by the Developmental Core, 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 and guidance including 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 submitted pre-submission form. **Applicants should continue preparation on 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.

3. 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, if possible, should participate in the application consultation call previously discussed. The Mentor would ideally be a senior faculty member with expertise in the scientific focus area of the proposal and 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 encouraged 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.

    If helpful, previously funded investigators at the R01 level transitioning to HIV research are invited to identify (or request through the DC CFAR Developmental Core) a senior HIV investigator who can provide HIV-related input into their proposal.

4. 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 October 27th and can be arranged by contacting Dr. Sam Simmens at simmens@email.gwu.edu.

5. 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, and 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 Scientific Specialist at bnrobin@email.gwu.edu by October 27th.

Key Dates

Pre-submission Form Due Date:	August 28, 2017
Applicant Consultation Meeting/Call Deadline:	September 29, 2017
Core Service Request Deadline:	October 27, 2017
Application Due Date:	November 21, 2017
Application Review:	December 2017
Earliest Anticipated Start Date:	March 2018

Application Forms

DC CFAR Pre-submission Form

DC CFAR Budget Instructions and Template

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 Page One* – Applicant should complete this form as if submitting to NIH. Non-GW investigators should have a signing official from their respective institution sign the form.

2. *Form Page Two* – The project's scientific abstract should be included in the Project Summary space. If funded, the scientific abstract will be posted on the DC CFAR website. **A lay language summary of the project must be submitted on a second Form Page Two** to be considered for funding that follows the scientific abstract and describes the scientific abstract in terms for the general public. The lay summary should also include a brief dissemination strategy detailing how findings will be communicated to the public. Please note this is separate from the Relevance statement requested at the bottom of Form Page Two. This summary will be reviewed by the DC CFAR Community Advisory Board Review Committee, which will assess the project's potential for community impact. All scientific terms need to be clearly defined in this summary and written at about 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.

3. *Form Page Three* – Applicant should include a Table of Contents for the proposal on this form.

4. *Form Page Four/Detailed Budget Template and Budget Justification* – The applicant should review the DC CFAR Budget Instructions and then complete the detailed Budget Template. A Budget Justification should follow that is completed using the Continuation Form.

5. *Biographical Sketch Format Page* – Applicant should include a personal biosketch along with biosketches for all collaborating investigators.

6. *Resource Page* – Applicant should identify the facilities to be used and the scientific environment in which the research will be conducted.

7. *Research Plan / Continuation Page Form* – The research plan should be no more than <u>six pages</u>. 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: http://www.niaid.nih.gov/researchfunding/grant/pages/appsamples.aspx.

8. *Other Narrative Sections and Forms* – If appropriate, the applicant should follow the PHS 398 instructions for the completion of the following sections, using the appropriate forms: Protection of Human Subjects, Inclusion of Women and Minorities, Targeted / Planned Enrollment, Inclusion of Children, Vertebrate Animals, and Select Agent Research.

9. *Letters of support* – Applicant should 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.

10. *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. It should also verify that the Mentor was given the opportunity to review the draft application and provide feedback, and 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 Scientific Specialist 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 be not utilized.

11. *Appendix B* - Applicants are required to complete and include the following for administrative review:

   a)   A DC CFAR Developmental Award Checklist (to be found in Appendix B of this document).

   b)   If applicable, <u>funded</u> studies will need to complete the Clinical Research or International Studies Checklist (see Appendix B of this document for details). These checklists do <u>not</u> need to be completed at the time of application. They are included in the RFA for reference purposes only.

12. *Appendix C* – GW applicants that 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. 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

13. *Appendix D* - Please submit a <u>1-page scope of work detailing your responsibilities by specific aim</u>. 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, CNMC, Georgetown, Howard, VAMC and WWH) or used for the PTA setup (investigators at GW).

Applicants may also include 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 recently adopted 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* – Applicant should 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* – Applicant should italicize, bracket or otherwise highlight text or sections that have been substantially revised.

Submission of Materials

1. To be eligible to submit a full application, the Pre-submission Form should be emailed by **5 pm ET on August 28, 2017** to the DC CFAR Scientific Specialist, Ms. Brandi Robinson, at bnrobin@email.gwu.edu.

2. The final application should be emailed to the DC CFAR Scientific Specialist, Ms. Brandi Robinson, at bnrobin@email.gwu.edu by **5 pm ET on November 21, 2017**. The final application should be submitted as a single, combined MS Word or PDF document. Please note: 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 change himself/herself and resubmit the entire application packet. Items submitted after the deadline will not be accepted.

Review of Applications

1. 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.

2. 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.

3. Each applicant should expect to receive a Summary Statement (aka "pink sheets") summarizing the Review Committees feedback.

Funding Requirements

1. Ongoing consultation with a Primary Mentor is required throughout project and thereafter as appropriate for support in 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.

2. Principal Investigators are required to notify the Developmental Core in writing if significant changes to the research plan or budget will be made.

3. Principal Investigators 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.

4. If applicable, a copy of the PI's IRB 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 or IACUC approval copy at all times, and renewal approvals and study closure forms should also be submitted to us in a timely manner.

5. 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 or IACUC approval if not previously submitted. If the project extends beyond its original end date, additional interim progress reports may be required.

6. 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.

7. 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.

8. 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
Phone: 202-994-4730
Email: bnrobin@email.gwu.edu

Budget and Institutional Routing Questions
Faye Hillman
Phone: 202-994-0757
Email: fhillman@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 <u>if funded</u> you will be required to complete and include the CFAR Clinical Checklist (see page 8).

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 <u>if funded</u> you will be required to complete and include the International Studies Checklist (see page 9).

4. Does this study involve animals?

    ☐ Yes   ☐ No

Appendix C

GW applicants that 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 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

CFAR CLINICAL RESEARCH STUDIES

NIH Definition of a **Clinical Trial**- A prospective study of human subjects designed to answer questions about biomedical and behavioral interventions, e.g., drugs, treatments, or devices or new ways of using known treatments to determine whether they are safe and effective.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html

I.   **Studies that <u>cannot</u> be funded through the CFAR**

- Studies involving new drugs, treatments, or devices are not allowed through the CFAR.

  These studies must go through the NIH R34 process.

- Studies that include randomization to one or more low risk interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (<u>NOT-15-015</u>).

II. **Studies that can be funded via CFAR but <u>require</u> additional NIH review**

- Studies involving **new ways of using known drugs, treatments, or devices** (allowed on a case-by-case basis)
- Studies that are deemed **above minimal risk** by the Institutional IRB
- Studies involving **vulnerable populations**
  Studies involving **behavioral interventions** (above minimal risk)

  For studies falling in the above two research areas, funded studies will need to complete the CFAR Clinical Checklist which can be found here:

  http://www.niaid.nih.gov/LabsAndResources/resources/cfar/Pages/guidelines.aspx

III. **Studies that <u>do not require</u> additional NIH review**
     Please include IRB approval letter in the annual progress report.
     This guidance is based on the OHRP guidelines of research that would go through an expedited review procedure.

     This may include research activities that present **no more than minimal risk t**o human subjects. Examples include but are not limited to the following:

- routine blood draws
- non-invasive procedures routinely employed in clinical
- practice (e.g. ultrasound, MRI)
- surveys, focus groups

  For more information, please go to: http://www.hhs.gov/ohrp/policy/expedited98.html

GUIDANCE for CFAR INTERNATIONAL STUDIES

For studies involving an international component, funded studies will need to complete the International Studies Checklist which can be found at: *https://www.niaid.nih.gov/research/cfar-research-project-guidelines*

Additional guidance on research objectives for CFAR-supported international studies, including human subjects' protection and examples, can be found on this same web page along with specific guidance for India and Brazil projects.