

## CFAR Supplement Announcement in HIV/AIDS –FY2017

The CFAR Program at the National Institutes of Health (NIH) invites applications from currently funded CFARs that are eligible for administrative supplements. CFARs in the last year of their funding cycle are NOT eligible to apply.

### Purpose and Scientific Areas of Interest

The purpose of this administrative supplement opportunity is to **support innovative research projects, shared instrumentation, and inter-CFAR meetings** that address key gaps in HIV/AIDS and will advance the field. This opportunity should build research capacity and be consistent with the recent NIH HIV/AIDS research priorities ([NOT-OD-15-137](#)).

#### 1. Multidisciplinary Research Project from a Scientific Working Group (SWG)

A SWG is defined as a group of investigators who share a common interest in a specific area of scientific focus that is critical to addressing the HIV epidemic, but is neglected or underdeveloped at the CFAR institution. The goal of a SWG is to promote multi-disciplinary collaborations that result in the successful applications for new HIV/AIDS research awards. SWGs should contact [NIH CFAR Steering Committee](#) representatives to discuss high priority scientific areas of interest to assure that the project fills a gap.

For this administrative supplement announcement, SWGs are encouraged to submit a concept proposal to the Developmental Core for review. The Developmental Core must select only one concept proposal to go forward as the SWG supplement application for the CFAR. The SWG supplement application must be led by either an **early career investigator** who has not yet received an NIH award in HIV/AIDS research or an **investigator new to HIV/AIDS research**. The application should include investigators from multiple disciplines and address a significant scientific area within the SWG. Applicants should describe which CFAR Cores will be used to support the research. The application should address future plans for research if the project is funded.

Supplement awards are for one year with maximum funding per application of up to **\$150,000** Direct Costs, not including third party indirect costs.

#### 2. Effect of the Opioid Epidemic on HIV/HCV Infection in Rural and Other Non-urban America

Recent data suggest that there is a growing epidemic of opioid usage outside of traditional central, typically inner city locations in the United States. This includes suburban and exurban areas within metropolitan areas as well as publicized rural outbreaks like the one in Scott County, Indiana which was identified in 2015. Increases in the number of People Who Inject Drugs (PWID) in these areas have resulted in increased risk for outbreaks of HCV and HIV infection. The CDC recently identified a total of 220 counties in the United States where data suggest there is a high risk for similar HCV/HIV outbreaks among PWID. The PWID populations in these locales are younger and more likely to be Caucasian than those seen in previous opioid epidemics and these locations often have little experience with issues related to injection drug use or its consequences like HCV and HIV.

While factors contributing to HCV/HIV transmission among urban PWID have been well studied, little is known about the transmission patterns among PWID in rural and other non-urban areas. Data from the Scott County epidemic suggested that it was highly concentrated in terms of networks, but other epidemics may have more interaction with existing HIV+ networks across a variety of risk groups. More research is needed to better understand the social and structural factors involved in the opioid epidemic in these communities and their impact on HCV/HIV transmission and treatment, including geographic barriers and social stigma.

The purpose of this funding opportunity is to solicit administrative supplement requests from eligible CFARs to stimulate interdisciplinary collaborations between the CDC, state or local health departments and CFARs to engage researchers in these epidemics, including multidisciplinary investigator teams (e.g., virologists, phylogeneticists, social scientists, epidemiologists, mathematical modelers) working together with clinicians, local community stakeholders, and public health officials in monitoring HCV/HIV transmission among rural and other non-urban PWID and to design and test new approaches to prevent and treat HCV/HIV infection and prevent transmission among PWID in these communities. The application should include a description of collaborative activities, including any prior collaborations.

Examples of research include but are not limited to:

- Addressing knowledge gaps regarding HCV/HIV transmission among PWID, including HCV/HIV prevalence within localized rural or other non-urban communities and interaction with transmission networks from established HIV epidemics
- Analysis of phylogenetic HCV/HIV transmission networks in PWID living in rural or other non-urban communities
- Identification of potential methods for addressing structural and societal barriers to service delivery to PWID in rural or other non-urban communities
- Rapid policy and epidemiology assessments that can inform implementation of evidence-based practices (e.g. PrEP, syringe services)
- Identification and pilot testing of promising approaches for implementing evidence-based infection prevention interventions (e.g., PrEP) in rural or other non-urban areas
- Pilot testing of methods to increase the comprehensiveness of syringe services programs (SSPs), including naloxone and/or medication-assisted drug treatment and HIV/HCV testing
- Creation of state or local data systems that would enable long-term assessment of changes in substance use, sexual and injection risk behaviors, HCV and HIV testing, and movement through the HCV and HIV care continuums

Supplement awards are for one year with maximum funding per application of up to **\$150,000** Direct Costs, not including third party indirect costs. Only one supplement request may be submitted per eligible CFAR. Note that projects related to needle exchange and syringe services need to be consistent with US Department of Health & Human Services policy: <https://www.aids.gov/pdf/hhs-ssp-guidance.pdf>

### **3. Equipment for CFAR Core(s)**

A single application for one or more instruments and/or equipment upgrades may be submitted by the CFAR for up to a combined total of \$100,000 in Direct Costs. For each equipment request, the research strategy must incorporate scientific justification, including how it will advance HIV/AIDS research and add value for each Core. Information on the investigators

who will use the equipment and projects that will be supported must be included. Describe where and how the equipment will be integrated into the Core. Applicants are encouraged to leverage institutional support, program income, or other donated funds that may offset equipment costs.

Funds may only be requested for the equipment. These supplements will not support staff or service contracts. Include, price quotes or other documentation. Letters of support should be included in the application, if leveraging other resources to offset costs.

One supplement application of up to **\$100,000** Direct Costs may be submitted. Depending on merit and funding availability, not all pieces of equipment in the application may be funded.

#### **4. Inter-CFAR Meeting**

The application should describe the objectives, specific program, and logistical arrangements for the meeting. Applicants should provide a detailed justification for the meeting, including the scientific need, timeliness, and usefulness of the meeting to the CFAR scientific community. Additionally, applicants must include the proposed outcomes for the meeting by the inter-CFAR working group. For inter-CFAR working groups that have been provided funds previously by the NIH to hold a meeting, please provide outcomes from the most recent meeting to demonstrate previous progress.

A maximum request of up to **\$40,000** Direct Costs, not including third party indirect costs can be submitted for each established inter-CFAR group. Applicants are encouraged to leverage institutional or other funding to offset costs. Each inter-CFAR working group is limited to one supplement application. An inter-CFAR working group must work with one lead CFAR to have their application submitted.

#### **Eligibility**

Project leaders for the SWGs and Opioid Epidemic on HIV/HCV Infection research projects are restricted to early career investigators and to established investigators in non-HIV fields who have never received an NIH research award for HIV/AIDS studies. Investigators should be beyond the postdoctoral level to be eligible to apply.

Studies that are a continuation of previously funded CFAR supplements or funded NIH applications that do not address new specific aims are not eligible for funding under this announcement. Additionally, a proposed supplement application that is linked to a proposed application not yet funded is not eligible for funding under this announcement.

#### **Application Instructions**

Requests submitted in response to this opportunity must use the PHS 398 forms (rev. 3/2016; available at <http://grants.nih.gov/grants/funding/phs398/phs398.html>) and include the elements in the request packet as described below. Applicants are strongly encouraged to submit applications as an e-mail attachment, in one file, in PDF format; however, the signature of the institutional official must be clearly visible. Font size restrictions apply as designated within the PHS 398 instructions

1) **Cover Letter** – Citing this Supplement Announcement, a request for an Administrative Supplement, and the following information:

- CFAR Principal Investigator and Supplement Project Director names

- Parent grant number and title
- The scientific area of interest for this supplement request
- Amount of the requested supplement
- Name and title of the authorized institutional official
- Phone, email, and address information for the PI, the PD and the institutional official

The cover letter must be signed by the authorized organizational representative/institutional official.

2) **PHS 398 Form Page 1** (Face page) ([MS Word](#) [PDF](#)) – Provide requested information as follows:

- The title of the project (Box 1) should be the title of the parent award and a descriptive title of the supplement application
- The scientific area of interest should be cited under title in Box 2, and the “yes” box should be checked;
- Enter name of CFAR PI and the name of the project director. (Example: Dr. Bill Jones (CFAR PI) and Dr. John Smith (Project Director)).
- The remaining items on the face page should be filled out in accordance with the PHS 398 application instructions.

3) **PHS 398 Form page 2**

Note: The project “summary” is that of the administrative supplement, not the parent grant. All other information requested on Form Page 2 should be provided.

4) A **brief proposal** describing the request (with parts 4a and 4b **not exceeding five pages** in total), should include:

- An introduction that clearly states the **scope of the overall request**, the anticipated contribution of the requested supplement, and how the project addresses the NIH HIV/AIDS Research Priorities ([NOT-15-137](#)).
- The **research project plan, equipment and/or meeting request** should include the background and rationale for the proposed application; a description of the activities to be undertaken, and roles of key staff; expected outcome of these activities; expected follow-up plan upon completion of the supplement; a description of how the supplement and follow-up plan are expected to achieve this outcome (“value-added”); and plans to monitor and evaluate the ability of the activities to achieve the outcome. Most importantly, applicants must clearly indicate how the proposed activities outlined in the supplement requests are expected to lead to development of the stated goals. Mentorship and collaborations must be explained.
- Budget** for the supplement with a justification that details the items requested, including Facilities and Administrative costs and a justification for all personnel and their role(s) in this project. Note the budget should be appropriate for the work proposed in the supplement request. If funding for travel to a scientific meeting is included, it must be for the early stage investigator and must be for the purpose of presenting data from this supplement award.

A statement regarding the expenditure of currently available unobligated grant funds. The applicant must describe plans to spend remaining funds in order to demonstrate the need for additional funds.

- Biographical Sketch** for all new Senior/Key Personnel and for mentors. Use the new biosketch format in [MS Word](#). Please note the personal statement should be related to the CFAR supplement project.

- e. **Human Subjects/Vertebrate Animal documentation** (if applicable). Include a current Human Subjects/Institutional Review Board (IRB) or Vertebrate Animals/Institutional Animal Care and Use Committee (IACUC) approval date, if applicable. Otherwise, this information will be required at time of funding. All appropriate IRB and IACUC approvals must be in place prior to a supplement award being made. NOTE: Studies involving [clinical trials](#) are not allowed.
- f. Further NIH-initiated administrative actions and approvals are required for ALL international studies (NOTE: this also includes the [CFAR International Checklist](#) requirement) and any clinical studies deemed above minimal risk or involving vulnerable populations.
- g. **PHS 398 Checklist Form** [MS Word](#) [PDF](#)
  - i. TYPE OF APPLICATION. Check REVISION box and enter your CFAR grant number;
  - ii. Applicants must state that all federal citations for PHS grants will be met (e.g., human subjects, animal welfare, data sharing, etc).
- h. NO other support. This information will be required for all applications that will be funded. NIH will request complete and up to date “other support” information at an appropriate time after review.
- i. NO resource page (unless there are new resources that will be used for this request)
- j. NO appendices
- k. Submit a letter(s) of collaboration endorsing the proposed request from all substantial participants. For the Opioid Epidemic on HIV/HCV Infection topic, a letter of support must be provided from the collaborating state or rural and non-urban health department.

## **Budget and Funding Information**

Funding for supplements will be supported by the CFAR NIH co-funding Institutes. The maximum funding allowed per application is described within each scientific area of interest above. Funding for administrative supplements to existing CFAR grants will be available for one-year in FY2017.

Supplemental funds for the Scientific Working Groups and Opioid Epidemic on HIV/HCV Infection research projects will be provided to the Developmental Core of the CFARs. Supplemental funds for equipment will be provided to the appropriate Core. Supplements for inter-CFAR working groups will be provided to the Administrative Core.

## **How to Apply**

This is a one-time announcement.

## **Do not send applications to the NIH Center for Scientific Review.**

Applications must be signed by the authorized institutional official and submitted on or before **May 22, 2017**. If an application is received after that date, it will be returned to the applicant without review.

Applications should be emailed to:

Elaine Wong  
National Institute of Allergy and Infectious Disease  
Telephone: (240) 627-3100  
Email: [wongelai@niaid.nih.gov](mailto:wongelai@niaid.nih.gov)

Applicants are strongly encouraged to submit applications electronically as an e-mail attachment in a single PDF file to the Program Officer; however, the signature of the institutional official must be clearly visible. Files should be named [XYZ] CFAR – [Project PI Last Name] [Indicate topic: SWG/Opioid/Equipment/Meeting] [2017]. Example: “University CFAR – Smith SWG 2017”.

## **Review Considerations**

Upon receipt, applications will be reviewed by the CFAR Program Officers for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to this announcement, the application will be returned without review.

Applications that are complete and responsive to the announcement will be evaluated for scientific and technical merit, and alignment with the NIH AIDS research priorities by an internal NIH review group convened by the NIAID in accordance with standard NIH review procedures.

## **Review Criteria**

The following criteria apply to all applications, unless noted. Reviewers will also examine the appropriateness of the budget, in consideration of the research environment and the supplement request.

### **SWG Project**

1. Evidence that the proposed project will enhance new multidisciplinary collaborations and exert a sustained, powerful influence on HIV/AIDS research;
2. Extent to which the supplement will address scientific gaps and/or development of new strategies which include a variety of scientific disciplines;
3. Adequacy that the strategy, methodology, and analyses are well reasoned and appropriate to accomplish the specific aims;
4. Utilization of existing resources and/or development of unique and appropriate expertise, technology, and resources at the CFAR institution(s) and other sites, as appropriate;
5. Degree of innovation in project selection and experimental design;
6. Quality and appropriateness of mentorship and collaboration for the SWG research project;
7. Choice of appropriate project PI and co-investigators (e.g., scientific qualifications, commitment, and experience).

### **Opioid Epidemic on HIV/HCV Infection**

1. Evidence that the proposed project will enhance new multidisciplinary collaborations, including the local health department, and exert a sustained, powerful influence on HIV/AIDS research;
2. Extent to which the supplement will address scientific gaps and/or development of new strategies
3. Adequacy that the strategy, methodology, and analyses are well reasoned and appropriate to accomplish the specific aims;
4. Utilization of existing resources and/or development of unique and appropriate expertise and resources at the CFAR institution(s) and other sites, as appropriate;



5. Degree of innovation in project selection and experimental design;
6. Quality and appropriateness of mentorship and collaboration for the research project;
7. Choice of appropriate project PI and co-investigators (e.g., scientific qualifications, commitment, and experience).

### **Equipment**

1. Extent to which the requested equipment will advance the knowledge and understanding of HIV/AIDS research;
2. Adequate justification for the equipment and clear evidence of major users/projects
3. Appropriate technical expertise to make effective use of the requested equipment
4. Institutional or other support as appropriate

### **Inter-CFAR Meeting**

1. Evidence that the meeting request addresses an area within the NIH HIV/AIDS research priorities and how outcomes from the meeting will advance the HIV/AIDS field;
2. Appropriate format, agenda, and timeliness of the meeting request to achieve specific goals;
3. Suitable key personnel and proposed speakers well suited for roles in the meeting
4. Institutional or other support as appropriate

### **Allowable Costs**

Funding may be requested for any category normally funded by a CFAR grant that is required to fulfill the goals of the proposed request, and must be fully justified.

### **Schedule for Applications**

<b><i>Announcement Release Date:</i></b>	<b><i>3/01/17</i></b>
<b><i>Application Receipt Date:</i></b>	<b><i>5/22/17</i></b>
<b><i>Review Date:</i></b>	<b><i>6/14/17</i></b>
<b><i>Earliest Anticipated Award (Start) Date:</i></b>	<b><i>6/30/17</i></b>

### **Terms of Award**

A formal notification in the form of a Notice of Award (NoA) will be provided to the grantee organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

### **Reporting**

Awarded administrative supplements will be required to submit a progress report to be included in the annual progress report of the parent grant. Progress reports should include a summary of SWG and Opioid Epidemic on HIV/HCV Infection research progress, utilization information of new equipment, and summary and outcomes of meeting support.

## **Award Criteria**

The following will be considered in making awards:

- Relevance to NIH HIV/AIDS research priorities;
- Scientific and technical merit of the proposed project as determined by NIH convened internal review panel;
- Funding availability and;
- Program balance.

## **Inquiries**

Prospective applicants are encouraged to discuss their applications, including proposed collaborators, with the NIH contacts below.

For questions concerning eligibility of the CFAR to respond to this announcement, and any other administrative issues:

Ann Namkung Lee, M.P.H.  
National Institute of Allergy and Infectious Diseases  
Telephone: (240) 627-3099  
Email: [anamkung@niaid.nih.gov](mailto:anamkung@niaid.nih.gov)

For questions concerning budget and fiscal matters:

Roberta Wolcott  
National Institute of Allergy and Infectious Diseases  
Telephone: (240) 669-2964  
Email: [wolcottr@niaid.nih.gov](mailto:wolcottr@niaid.nih.gov)