CFAR Supplement Announcement in HIV/AIDS –FY2015

The CFAR Program at the National Institutes of Health (NIH) invites applications from currently funded CFARs that are eligible for administrative supplements.

Purpose

The purpose of this administrative supplement opportunity is two-fold:

1. To support a broad range of highly innovative research projects and pilot studies to address key gaps in our understanding of HIV/AIDS.

   and

2. To support early stage investigators who have not yet received an NIH award in HIV/AIDS research as well as established investigators in non-HIV fields who have never received an NIH research award for HIV/AIDS studies. This funding will provide support for development of preliminary data to support an NIH research project grant application.

Background and Scientific Areas of Interest

CFARs are strongly encouraged to submit projects in collaboration with investigators and disciplines not usually involved in HIV research. Involvement and mentoring of early stage investigators is also strongly encouraged. This opportunity should build research capacity at the CFAR institution or at partnering foreign institution in the scientific areas specified below and is intended to complement ongoing domestic and international HIV/AIDS research efforts funded or sponsored by the NIH. Each eligible CFAR is limited to one application per scientific area of interest below for a maximum of four applications total.

1. Advancing PrEP Delivery

Oral HIV antiretroviral pre-exposure prophylaxis (PrEP) confers a strong preventive benefit to individuals who are at-risk for HIV infection when taken with high adherence. PrEP uptake has been slow, and research is needed to better understand the multi-level factors that may influence PrEP uptake and effective use.

Formative research is encouraged to inform better targeting, engagement, and retention of the highest-risk populations in PrEP care. Novel approaches designed to identify appropriate individuals for PrEP and improve understandings of risk perceptions and decision-making could improve PrEP uptake. Models for retention of individuals in all facets of PrEP care will need to be explored in a variety of potential settings. Effective support for adherence and persistence are also critical to maximizing the preventive benefits of oral PrEP.

Responsive studies could include, but are not limited to the following:

- Mixed-methods studies to better understand the multi-level factors that may influence selection of PrEP as a prevention option
- Developmental work to inform communication strategies to promote engagement in PrEP programs and PrEP uptake
- Pilot studies on novel approaches to reach high-risk individuals and link them to PrEP care

- Research to develop and pilot test interventions promoting retention of high-risk groups in PrEP care
- Research to develop and pilot test interventions designed to improve and sustain adherence to oral PrEP
- Studies designed to characterize rates, patterns, and determinants of PrEP uptake, adherence, and persistence under open-label use
- Research examining patterns of PrEP adherence in relationship to patterns of risk behavior.

Supplement awards are for one year with maximum funding per application of **$100,000** Direct Costs.

2. **HIV Transmission and Microepidemics**

There is significant diversity in the levels of HIV prevalence and incidence between and within geographical regions, and even greater diversity when populations are stratified by age, sex, ethnicity, and high risk behaviors. These variations suggest that identifying and focusing on particular high-incidence locations and populations could lead to greater gains in preventing new infections. Furthermore, assessments of viral phylogenetics within these microepidemics have the potential to expand the specificity of HIV transmission dynamics within populations. More detailed knowledge of HIV transmission networks will be important in tailoring the design, implementation and assessment of public health, therapeutic, and behavioral interventions.

The scientific objective of this supplement is to stimulate cross-disciplinary collaborations to identify and target the key microepidemics within high prevalence areas, with the overarching goal to lower HIV prevalence and incidence. Because considerable data are collected in the research and public health spheres, investigators are encouraged to work with their relevant public health agencies to expand the breadth of data available on their local epidemic.

Responsive studies could include, but are not limited to the following:

- Molecular/viral phylogenetics of transmission networks, particularly where data from research can be combined with data collected by relevant public health agencies
- Geospatial mapping
- Identifying transmission dynamics and/or HIV transmission network characteristics. Examples include temporal, spatial, and behavioral dynamics
- Exploring transmission networks in combination with detailed clinical, epidemiological, and behavioral data.

Supplement awards are for one year with maximum funding per application of **$100,000** Direct Costs.

3. Projects that Highlight the Value Added from Inter-CFAR Collaborations

The CFAR program has several inter-CFAR collaborations with different names (e.g. working group, network, and consortium) that profess to the importance of cross collaborations across different CFARs. The goal of this topic is to request research projects that can be clearly identified as value added to the CFAR program. Below is a list of existing inter-CFAR collaborations that are eligible to apply for a supplement under this topic. Applications must propose a research project that is within the scope of the eligible groups.

- CFAR HIV Continuum of Care Working Group
- CFAR Network of Integrated Clinical Systems (CNICS)
- CFAR Social and Behavioral Sciences Research Network (SBSRN)
- Inter-CFAR HIV/AIDS Related Malignancy (iCHARM) Working Group
- Inter-CFAR Collaboration on HIV Research in Women
- CFAR Global AIDS Research Consortium (CGARC)
- CFAR HIV/TB Co-Infection Consortium
- CFAR–CFAR Collaboration on HIV in Corrections (CFAR–CHIC)
- CFAR Biostatistics Network
- CFAR Sub-Saharan Africa Working Group
- Inter-CFAR Cytometry Interest Group (CIG)
- HIV and Aging Inter-CFAR Working Group

The idea behind this supplement topic is to request supplements from members of these inter-CFAR collaborations that support some research project that will provide value added to the inter-CFAR group and build on ongoing group collaborations. The proposed work has to include investigators from at least two or more CFARs that are members of the group. The supplement should be driven by a research project. For example, the iCHARM Working Group may submit a supplement where two or more iCHARM members propose a research project in cancer that brings together different expertise from the different members. The CFAR Biostatistics Network can submit a supplement that proposes novel biostatistical methods. The CFAR–CFAR Collaboration on HIV in Corrections could propose a project focused on barriers to HIV care or mental health services issues for people in jail or recently released.

Each supplement request requires that investigators from at least **two** different CFARs be involved in the supplement application. The team would have to decide which investigator at one of the participating CFARs would be the lead PI and thus the submitting CFAR; all other inter-CFAR investigators would be key personnel. In addition to a research plan, the supplement application requires a section where the investigators describe how this supplement will add value to the inter-CFAR collaboration and how it will serve as catalyst to more productive inter-CFAR collaborations. The supplement must also describe the role of each inter-CFAR member on the project.

This topic cannot be used to propose support for a meeting, conference, mentoring session or working group meeting. This supplement will not allow travel unless highly justified as critical to the success of the project. Project leaders for this topic also must be early stage investigators or investigators new to HIV. One application per CFAR will be allowed.

Supplement awards are for one year with maximum funding per application of **$100,000** Direct Costs.

4. Glycomics in HIV Co-Morbidities

Even with successful sustained antiretroviral therapy (ART)-mediated viral suppression a spectrum of chronic conditions including, cancer, cardiovascular disease, neural disease, hepatic and renal disease continue to pose major health risks.

Protein glycosylation is one of the most common, post-translational modifications and plays a fundamental role in many biological processes and disease pathogenesis including HIV. More recently, microarray technology has been used to analyze the glycome of intact HIV-1 virions.

Understanding of the mechanisms of viral evasion as well as modulation of the immune response has also been enhanced by new developments and research in glycomics. At the same time, in the past few years, alterations in glycosylation profile have been reported to be associated with many chronic conditions outside the context of HIV infection. Development of new tools and novel approaches in glycomics has presented opportunities for teams of multi-disciplinary investigators to exploit glycans as possible biomarkers by assessing them in a dynamic range of body fluids. This has led to studies to evaluate these glycans and antibodies to glycans or changes in glycan binding proteins in development of glycomic biomarkers for non-invasive screening and complementary diagnostic tools. Such studies have revealed the potential utility of glycan biomarkers in diseases such as lung cancer, myeloma, neurodegenerative disease, hepatic disease, cardiovascular disease and renal diseases. Some studies have also linked aberrant glycosylation to imparting disease phenotype. However, the relevance of these biomarkers and their potential in screening/diagnosis/risk assessment of similar co-morbidities in the context of HIV has not been fully explored. Additionally, biospecimens from similar disease conditions in HIV and non HIV have not been comparatively profiled. As a result, the discovery and detailed characterization of glycoprotein disease biomarkers in the context of HIV remains an area of potential research.

The scientific objective of this supplement is to stimulate novel areas of research in glycomics of HIV associated co-morbidities by supporting pilot and preliminary investigations. Cross-disciplinary research collaboration is needed between HIV researchers, glycobiologists and other relevant disease researchers to effectively formulate questions and to carry out proposed research in this area. Collaborations between CFAR investigators within the various CFAR working groups such as CNICS and iCHARM and glycobiologists such as investigators that are a part of the consortium for glycomics are encouraged.

Responsive studies could include, but are not limited to the following:

- Research addressing gaps in comparing glycan biomarkers in HIV comorbidities with similar non-HIV comorbidities to assess the impact of underlying HIV
- Serum glycan analysis and glycan profiles for cancers in people with and without HIV
- Discovery of glycan-biomarkers in liver disease in people with and without HIV
- Differences in glycomic profiles in infection associated cancers in people with and without HIV.

Supplement awards are for one year with maximum funding per application of **$100,000** Direct Costs.

Eligibility

CFARs are encouraged to collaborate with other CFARs. Core and Scientific Working Groups within the CFAR are encouraged to collaborate on their applications, and to collaborate with appropriate individuals not currently involved in AIDS research. Contact Ann Namkung Lee to discuss eligibility.

Project leaders are restricted to early stage investigators (please see NIH definition of new and early stage investigator) and to established investigators in non-HIV fields who have never received an NIH research award for HIV/AIDS studies. Mentorship and collaboration with established AIDS investigators is required.

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

Applications must be submitted before or on **May 22, 2015.** Requests submitted in response to this opportunity must use the PHS 398 forms (rev. 8/2012; 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 PHS398 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 project (with parts 4a and 4b not exceeding five pages in total), should include:

a. An introduction that clearly states the **scope of the overall project** and the anticipated contribution of the requested supplement.
b. The **research project plan** should include the background and rationale for the proposed study; 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 research activities are expected to lead to development of the stated goals. Mentorship and collaborations must be explained.

c. **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.
d. **Biographical Sketch** for all new Senior/Key Personnel and for mentors 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 letter, if applicable. Otherwise, this letter 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 (NOTE: this includes the CFAR Clinical Research Studies Checklist requirement).
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 study)
j. NO appendices

Budget and Funding Information

Funding for supplements will be supported by the CFAR NIH co-funding Institutes.

Supplemental funds will be provided to the Developmental Core of the CFARs. Progress reports for supplements should be included in the annual CFAR noncompeting renewal.

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 FY2015.

Awards are dependent upon the scientific merit of the applications and funding availability.

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, 2015** to the Program Officer listed below. If an application is received after that date, it will be returned to the applicant without review.

Ann Namkung Lee
National Institute of Allergy and Infectious Disease
Telephone: (240) 627-3099
Email: anamkung@niaid.nih.gov

Submit a letter(s) of collaboration endorsing the proposed study from each of the following participants: investigator performing the study and any collaborators, foreign investigator(s) (if applicable), foreign institution (if applicable), and collaborating CFAR PI (if applicable).

[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. Applicants may submit applications in paper format, although paper applications are strongly discouraged. Do NOT send both an electronic and a paper version of the same administrative supplement.]

Review Considerations

Upon receipt, applications will be reviewed by the CFAR Program Officer 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 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. Each of these criteria will be addressed and considered by the reviewers, weighing them as appropriate for each request. The administrative supplement request does not need to be strong in all categories in order for it to receive a favorable evaluation. Factors to be considered in the evaluation of each application include:

Significance – The effect that a collaborative administrative supplement would have on the development of research in the stated scientific area of interest at the institution(s).

1. Evidence that the proposed project(s) will enhance new multidisciplinary collaborations, which may include international collaboration, collaboration with industry, collaboration with early stage or minority investigators, collaboration with other CFAR sites, or collaboration with investigators inside or outside of CFAR who have expertise in the stated scientific area of interest;
2. The extent to which the supplement will address development of new strategies for the field of HIV/AIDS (“value-added” of the supplemental monies);

Approach – The quality of the CFAR scientific project proposed, including planning, management, and training (as appropriate) process.

3. Project design and appropriate Core selection;

4. Utilization of existing resources and/or development of unique and appropriate expertise, technology, and resources at the CFAR institution(s), and at the international site, as appropriate;
5. The adequacy of the described plans to monitor the impact of the competitive supplemental award;
6. The quality and appropriateness of mentorship and collaboration;

Innovation - The identification of a unique approach to solve a significant question or gap in the field of HIV/AIDS specifically in the scientific area of interest indicated.

7. The degree of variety/novelty of scientific disciplines that is included in proposed scientific project;
8. The degree of innovation in project selection and experimental design;

Investigator - Choice of appropriate scientists to lead the identification and development of the collaborative administrative supplement project.

9. Choice of appropriate competitive supplement project leader and participating investigators for individual collaborative projects proposed: scientific qualifications, commitment, and experience;
10. The choice of collaborators and mentors available within and outside of the CFAR, as appropriate;

Environment – The likelihood that the proposed project will lead to the development of a new strategy in the scientific area of interest indicated.

11. Availability of appropriate scientific expertise;
12. The potential and intent to collaborate with other institutions and to coordinate program activities with related efforts of other CFARs, NIH programs, other federal agencies (e.g., CDC and USAID), international organizations (e.g., UNAIDS), and NGOs;
13. Evidence that scientific collaborative areas and projects arise from the complementary scientific environment at the CFAR institution(s);

Reviewers will also examine the appropriateness of the budget, in consideration of the research environment, for the scientific projects and cores.

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 study, and must be fully justified.

Please contact the CFAR Program Officer if you are considering a project that involves a foreign component.

Schedule for Applications

Announcement Release Date: ***3/30/15***

Application Receipt Date: ***5/22/15***

Review Date: ***6/10/15***

Earliest Anticipated Award (Start) Date: ***6/30/15***

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. For the inter-CFAR topic, the submitting CFAR is required to include a progress report of the supplement in the annual progress report of the parent grant.

Award Criteria

The following will be considered in making awards:

- quality of the proposed project as determined by the NIH convened internal review panel, and relevance to the ability of the proposed project to lead to scientific advances in the field of HIV;
- funding availability;
- programmatic priorities.

Inquiries

Prospective applicants are strongly encouraged to discuss their applications, including proposed collaborating countries and institutions, 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

For questions concerning a specific scientific area of interest:

- **Advancing PrEP Delivery**

  Christopher Gordon, Ph.D.
  National Institute of Mental Health
  Telephone: (240) 627-3867
  Email: cgordon1@mail.nih.gov

- **HIV Transmission and Microepidemics**

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

- **Projects that highlight the value added from inter-CFAR collaborations**

  Geraldina Dominguez, Ph.D.
  National Cancer Institute
  Telephone: (301) 496-3204
  Email: domingug@mail.nih.gov

- **Glycomics in HIV Co-Morbidities**

  Kishor Bhatia, Ph.D.
  National Cancer Institute
  Telephone: (301) 435-9013
  Email: bhatiak@mail.nih.gov

For questions concerning budget and fiscal matters:

Leslie Boggs
National Institute of Allergy and Infectious Diseases
Telephone: (240) 669-2970
Email: boggsl@mail.nih.gov