CFAR Supplement Topics for FY2021

The CFAR Program at the National Institutes of Health (NIH) invites applications on the following topics from currently funded CFARs that are eligible for administrative supplements. CFARs in the last year of their funding cycle, a bridge period, or no-cost extension are NOT eligible to apply. **Each CFAR can submit a maximum of four supplement applications for topics 1-8. CFARs can submit one application each to the equipment topic. Each inter-CFAR group is permitted to submit one meeting application even if there are multiple inter-CFAR groups being led by a single CFAR (e.g. a CFAR can submit two applications for this topic if they are submitting on behalf of 2 different inter-CFAR groups).**

Purpose and Scientific Areas of Interest

The purpose of this administrative supplement opportunity is to **support innovative research projects, inter-CFAR meetings, and shared instrumentation** that address key gaps in HIV research and will help to advance the field. Proposals should aim to build research capacity and be consistent with the recent NIH HIV/AIDS research priorities (NOT-OD-20-018).

1. Uptake and retention for long-acting HIV prevention and treatment

The goals of this opportunity are to: (a) understand multi-factor individual, interpersonal, and structural barriers and facilitators to use of long-acting HIV prevention and treatment (e.g., injectable PrEP, treatment, vaginal ring); (b) develop interventions to improve uptake, consistent use, and persistence on these products; and (c) test implementation strategies for optimal delivery for these interventions.

The number of efficacious long-acting products for HIV prevention and treatment is increasing, with more in the research pipeline. It is critical that a menu of options continue to be developed and tested for potential users. However, although barriers to product use have been explored during clinical trial and open label extension studies, little is known about individual, interpersonal, and structural barriers and facilitators to product use outside of clinical trials.

Research topics may include, but are not limited to:

- Studies of individual, interpersonal, and structural factors that are barriers and/or facilitators to uptake of, adherence to, and persistence on long-acting HIV prevention and treatment when delivered in real world settings
- Studies to determine how to best communicate to potential users around factors such as the effectiveness and the importance of correct and consistent use
- Development and testing of decision aids to assist with patient-provider discussions around HIV prevention and treatment options, and to help people decide on the best option for them
- Implementation science studies to understand implementation barriers and facilitators to delivery of long-acting HIV prevention and treatment in health care settings, as well as other innovative delivery settings, and to optimize delivery in these settings
- Studies conducted among people who use drugs (PWUD), including PWUD who inject drugs and populations among whom PWUD represent a substantial fraction of attributable HIV acquisition risk (e.g., MSM or transgender persons)

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. Interactions and effects of the microbiome and metabolome on comorbidities and co-infections in people with HIV

Though HIV-associated changes in the gut microbiome have been widely observed in recent studies, much remains unknown regarding the interactions between the gut microbiota, microbial metabolites, host tissues and processes, and HIV-associated comorbidities including cancer, coinfections, and complications (CCCs). Dysbiosis may impact host metabolic and physiological processes and contribute to the development of HIV-associated CCCs. Additionally, local and systemic chronic inflammation and immune activation from the damage to gut-associated lymphoid and epithelial tissue may have significant implications for the treatment of HIV-associated CCCs, such as the use of immunotherapy for HIV-associated cancers. This supplement seeks to stimulate mechanistic biological, physiological, and biochemical research to elucidate the interplay between changes in the microbiome, metabolome and HIV-associated CCCs. Projects must pursue "wet lab" approaches and may involve human subjects or animal models for HIV. Studies utilizing epidemiological approaches or reanalysis of existing data are not appropriate for this topic. This supplement opportunity is restricted to early-stage investigators (ESIs) only. Research conducted in either domestic or global settings is allowed.

Examples of responsive topics include the following:

- Impact of the microbiome (bacterial, archaeal, viral, fungal) on development of HIV comorbidities
- The effect of the microbiome on cancer treatment outcomes, particularly immunotherapies
- Cofactors that interact with HIV infection to affect the microbiome and CCCs
- Mechanistic research on host/HIV/coinfections/microbiome interactions
- Studies to identify synergies between the microbiome and immune dysfunction that promote the development or progression of tumors either directly or indirectly in people with HIV
- Impact of HIV-related perturbations in gut microbiota composition on progression of CCCs across the lifespan
- Elucidation of microbiome metabolites or other microbiome-derived products that either provoke or prevent pathophysiological processes

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

3. Disparities in Treatment and Outcomes in People with HIV with multiple comorbidities and co-infections

A major part of the complexity of treating people with HIV (PWH) is managing the comorbidities, complications, and co-infections (CCCs) that arise during therapy. Both HIV infection and its treatment with antiretroviral therapy (ART) can lead to the development of noncommunicable conditions (e.g. cardiovascular disease, enteropathy, liver diseases, metabolic disturbances, nephropathy, malignancies, osteoporosis) that decrease quality of life and worsen patient outcomes. With PWH on effective ART regimens achieving longer lifespans, aging-related comorbidities add to the clinical picture as well. Adding to these complexities, PWH who must manage multiple comorbidities with medication are at greater risk of experiencing side effects, complicating management of their diseases. The recent focus on social determinants of health (SDOH) also highlights the necessity of evaluating the contribution of factors such as socioeconomic status, diet and nutrition, housing status, stigma, and discrimination to the development of multiple CCCs in PWH. This supplement opportunity seeks to elucidate various factors responsible for disparity in treatment and outcomes among PWH with multiple CCCs. Topics must be primarily focused on two or more CCCs impacting host physiology or metabolism. Projects that include mental health or

substance abuse disorders must relate them to the development of one or more CCCs impacting host physiology or metabolism. Projects may focus on either US or foreign populations. This supplement opportunity is restricted to early-stage investigators (ESIs) only. Research conducted in either domestic or global settings is allowed.

Examples of responsive topics include the following:

- Impact of health-impeding SDOH; including socioeconomic, cultural, and environmental factors; on patient engagement, prevention, management, and outcomes for HIV noncommunicable comorbidities and/or co-infections
- Impact of health impeding SDOH on physiological or pathophysiological processes contributing to multimorbidity
- Impact of polypharmacy and multimorbidity (e.g. obesity, kidney failure, COPD, cancer, hypertension) on quality of life of PWH
- Improved use of Patient Reported Outcomes to better understand symptoms and treatment outcomes of HIV CCCs
- Foundational research toward understanding the interaction of biological, behavioral, and social mechanisms that contribute to multimorbidity
- Health system research that addresses the comorbidity-free life expectancy gap in PLWH

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

4. Impact of HIV infection and HIV-associated comorbidities, coinfections and complications on hemophiliacs and the hematopoietic system

Following initial HIV infection, the hematopoietic system is affected first and remains affected even after effective antiretroviral therapy. Further research is needed in spite of the fact that it has been challenging to work with the hematopoietic system. The impact of HIV infection and co-infections, such as HCV, on the general health of hemophiliacs, in addition to the hematopoietic system, has also been understudied. For example, early studies in people with hemophilia suggested that abnormal brain MRI studies were more frequent in HIV-positive participants with CD4+ counts < 200 than in HIV-positive participants with CD4+ counts > or = 200 or in HIV-negative participants. This supplement opportunity requires investigators to design studies using the existing data and specimens from the Hemophilia Growth and Development Study (HGDS).

The HGDS is a multi-center, longitudinal observational study of children and adolescents with hemophilia. The primary objective of the study was to measure the effect of HIV infection on study participants through investigation of physical growth and sexual maturation, immune functioning, and neurological and neuropsychological functioning. HGDS represents one of the early cohorts of hemophilia patients with HIV or without HIV but at risk of HIV infection. It is the largest early cohort of hemophiliacs with and without HIV infection and the largest cohort of hemophiliacs who were postnatally infected with HIV (e.g. through transfusion transmission).

Examples of responsive topics include the following:

- Etiologies and mechanisms of HIV-associated comorbidities or coinfections, in the context of hemophilia, through the use of new methods or assays for biomarkers of pathogenesis of HIV-associated comorbidities or coinfections in specimens of the HGDS repository, combined with use of existing data from the early studies
- Impact of HIV latency on the hypothalamic-pituitary-adrenal axis during puberty, correlated with degree of immune dysregulation

- Longitudinal HIV effects on CNS anatomy characterized by serial MRI compared to age and gender matched non-HIV controls

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5. Intersectional Stigma and its Effect on HIV Prevention, Treatment and Care

The concept of intersectional stigma combines theories on intersectionality with those on stigma related to multiple marginalized social positions and identities. This conception is critical to understanding its manifestation, its effect on HIV prevention and care, and its implications for addressing health disparities. HIV-related disparities originate in systems that differentially structure power and privilege for groups at distinct intersectional sociodemographic positions (e.g., race, ethnicity, sexual and gender identity). Providers and those seeking care come together and interact with each other based on experience and habits developed over time within these systems, that impact how they provide and receive information, share experience and access or deliver biomedical technologies. Understanding the patterns of client-provider interactions influenced by social position and identities can be used to develop novel strategies to improve social relations in the clinic and improve health outcomes.

This supplement opportunity seeks to support research projects to examine intersectional stigma in at risk populations, including MSM, sex workers, people who use drugs, and health disparity populations. Stigma can be a barrier to HIV testing and subsequent treatment and retention in care, and therefore its presence is an impediment to the integrity of the HIV continuum. Applicants can develop and assess the feasibility and accessibility of novel interventions designed to overcome intersectional stigma. Studies deemed responsive will identify and test strategies that may be effective in overcoming intersectional stigma and result in improved health outcomes along the health care continuum. Examination of how enacting identities and social positions in clinical interactions influence and affect intersectional stigma and may improve health outcomes for stigmatized populations either at high risk of HIV acquirement or PLWH, are particularly encouraged.

Responsive studies may address, but are not limited to:

- Manifestation of intersectional stigma in interactions between PLWH and different kinds of providers, such as nurse practitioners, physician assistants, doctors, nurses, social workers and community health workers
- Impact of intersectional stigma on providers and their patients/clients who are at risk for HIV i.e., discussions of risk and the provision of PrEP and other prevention care
- Impact of intersectional stigma on the delivery and/or uptake of evidence-based treatment and care including referrals for housing, food, mental health, drug treatment and other services
- Effect of shared intersectional identities and other social similarities/differences on the ability to share experience and information that lead to improved health outcomes

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

6. Increasing the Integration of Substance Abuse Services and HIV Prevention and Care

HIV prevention and care among substance users often benefits from integration of substance use services such as syringe exchange programs and drug treatment with HIV care and other infectious disease services. For example, recent research indicates that participation in drug treatment is associated with better ART adherence and response and similar outcomes are likely with PrEP.

Needle exchange has demonstrated population-level reductions in HIV acquisition and CDC has been encouraging integration of HIV services into syringe service programs. This supplement opportunity would support investigations that pilot test or inform the development of interventions that facilitate integrations of substance use services with HIV prevention and care. Research is limited to domestic settings.

Examples of responsive topics include the following:

- Formative research to develop onsite PrEP or ART initiation programs conducted through syringe exchange or drug treatment programs
- Development of enhanced substance abuse screening and linkage to services in HIV prevention and care settings
- Formative research and acceptability testing to develop Telehealth programs (direct service and consultation models like ECHO) that facilitate integration of HIV prevention and care with specialty substance use services, including linkage to substance use treatment, follow-up HIV and/or MAT medication monitoring, and case management
- Utilize health records and other electronic clinical databases to develop pilot programs that better integrate HIV services and substance use services (e.g., medication assisted drug treatment)
- Model service integration programs that incorporate high need activities such as HCV or endocarditis screening and linkage to care which may help increase motivation to participate in HIV care and prevention by people who inject drugs
- Quality improvement activities related to existing efforts to integrate substance use and HIV care and prevention
- Research considering how injectable PrEP may be integrated into substance use treatment

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

7. Understanding HIV Reservoir Establishment, Maintenance, Control, and Clearance

Despite long-term suppression of HIV replication by antiretroviral therapy (ART) in people living with HIV (PLWH), a reservoir of HIV persists in long-lived cells that seeds viral rebound within a few weeks of stopping ART. The purpose of this supplement topic is to support basic and translational research on the HIV reservoir, its cellular and anatomical location, dynamics, and novel approaches to eliminate the cells harboring it. Research should focus primarily on one or more of the following five key aspects of the reservoir that remain understudied to date:

- **HIV reservoir dynamics.** A significant proportion of HIV reservoir cells are clonal and expand and contract over time. Understanding the mechanisms of proviral persistence, clonal proliferation, reservoir decay, spontaneous in vivo reactivation of latent provirus, and the origins of viral rebound will help to inform the development of curative strategies for HIV.
- **Enhancing susceptibility of reservoir cells to death or clearance.** Most attempts to eradicate the HIV reservoir have focused on combinations of strategies to reverse latency, enhance the immune response to HIV, and/or specifically target T cell reservoir cells expressing HIV antigens. Understanding the factors that impact susceptibility of reservoir cells to death, and the development of approaches to enhance reservoir cell death, are needed to complement existing strategies and facilitate reservoir decay.
- **CD8 T cells in reservoir maintenance, clearance, and control.** New approaches to combating CD8 T cell exhaustion or optimizing CD8 specificity for autologous HIV reservoir sequences are needed to help enhance reservoir clearance strategies. Moreover, recent reports suggest that non-cytopathic effects of CD8 cells may influence HIV latency in infected

CD4 T cells. Understanding these mechanisms would aid in the optimization of reservoir eradication or control strategies.

- **HIV reservoir detection and monitoring.** The application of new, cutting edge technologies and detection strategies to the development of new approaches to detect, visualize, and monitor reservoirs in tissues in vivo and ex vivo would help to increase our understanding of HIV persistence and rebound in specific tissues.
- **Non-canonical (i.e. non-CD4$^+$ T cell and non-lymphoid tissue) reservoirs.** To date, characterization of the reservoir has focused primarily on CD4+ T cells and lymphoid tissues. Other potential sources of viral persistence and rebound include follicular dendritic cells (FDCs), macrophages, platelets, heart tissue, adipose tissue, and other tissues and cell types.

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

8. Natural History of Reservoir Establishment in Infants

Globally, regions confront different manifestations of the HIV/AIDS epidemic despite a sustained public health effort. Although multiple antiretroviral treatments and microbicides are available and used as prevention tools and greater focus is now placed on the emotional and mental wellbeing of PLWH, these gains are not universal. Further complicating the ability to cure HIV is its ability to establish stable reservoirs of infected cells in the blood and various tissues. To address this challenge, significant advances have been made in the development of more sensitive assays for the detection of proviruses. Gaps remain in the understanding of how the HIV reservoir is established and maintained in infants and the complex interplay between environment and biology. Use of secondary data from appropriate sources is acceptable.

Responsive studies could include, but are not limited to:

- Natural History of HIV cell and tissue reservoir capacity during pregnancy and lactation in mothers and offspring treated or not with ART
- Studies of maternal exposures, effectors and co-infections during development that may determine HIV reservoir dynamics in infants
- Identification of HIV virus subtypes and viral factors that modulate reservoir establishment and persistence in lymphoid and myeloid cells and tissue reservoirs
- Innovative approaches that reduce the number of cells needed to identify and measure rebound-competent latent HIV reservoirs in infants
- Studies on how co-infections may modulate the HIV reservoir

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

9. 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 $150,000 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 associated 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, recovered costs/Core recharge, 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 **$150,000** Direct Costs may be submitted. Depending on merit and funding availability, not all pieces of equipment in the application may be funded.

10. Inter-CFAR Meeting

The application should describe the objectives, specific program, and logistical arrangements for the meeting. Requests should also consider the possibility of a virtual 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 (WG). For inter-CFAR WGs 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.

Applicants are encouraged to leverage institutional or other funding to offset costs. Letters of Support should be included in the application if these types of resources are available. Meeting requests for new inter-CFAR WGs should include Letters of Support from participating CFARs. 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.

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**.**

Eligibility

Project leaders for all scientific areas of interest are restricted to early career investigators who have never received an R01-equivalent, P-series or U-series research grants. Established investigators in non-HIV fields who have never received an NIH research award for HIV/AIDS studies are also eligible, unless specified in the topics above. Post-doctoral fellows are eligible to apply if they will assume a faculty position by the time the supplement project and funding begins. Established investigators can be the project leaders for the core equipment and inter-CFAR meeting topics.

Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are especially encouraged to apply for NIH support.

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 follow instructions outlined in PA-20-272. Administrative supplement requests must be submitted through Grants.gov using electronic submission processes (NOT-OD-20-128). Follow all instructions in the SF424 (R&R) Application Guide to ensure all appropriate required and optional forms are completed, with the following additional guidance:

1) **SF424 R&R Cover Form:**
    a. Select “Revision” in the “Type of Application” field.
    b. Cover Letter Attachment – Citing this Supplement Announcement, a request for an Administrative Supplement, and the following information:
        i. CFAR Principal Investigator and Supplement Project Director names
        ii. Supplement topic for the supplement request
        iii. Total Cost amount of the requested supplement

2) **R&R Other Project Information Form:**
    a. If applicable to the supplement activities, attach PDF documents in the “Other Attachments” field indicating that the proposed research experience was approved by the Institutional Animal Care and Use Committee (IACUC) or human subjects Institutional Review Board (IRB) at the grantee institution. Name the documents “IACUC Documentation.pdf” and/or “IRB Documentation.pdf”. Adherence to the NIH policy for including women and minorities in clinical studies must also be ensured, if additional human subjects’ involvement is planned for the supplement. If proposing a study involving vertebrate animals, the CFAR parent grant must be already coded (Code 30) to allow for vertebrate animal involvement. All appropriate IRB and IACUC approvals must be in place prior to Notice of Award. NOTE: Studies involving clinical trials are not allowed.
    b. Project summary and narrative is that of the administrative supplement, not the parent grant.
    c. For any study involving international components, further NIH-initiated administrative actions and approvals are required (NOTE: this includes the CFAR International Checklist requirement). Any clinical studies deemed above minimal risk or involving vulnerable populations must require CFAR clinical approval.
    d. NO Facilities and Other Resources page (unless there are new resources that will be used for this request)

3) **Project/Performance Site Location(s) form**: Include the primary site where the proposed supplement activities will be performed. If a portion of the proposed supplement activities will be performed at any other site(s), including international sites, identify the locations in the fields provided.

4) **Sr/Key Person Profile (Expanded) form**: List the PD/PI as the first person (regardless of their role on the supplement activities), include Supplement PI and any other Senior/Key Personnel who are being added through this supplement, or for whom additional funds are being requested through this supplement; include a biographical sketch for each.
    a. **Biographical Sketch** for all new Senior/Key Personnel and for mentors. Please note the personal statement should be related to the CFAR supplement project.
    b. NO Other Support. Complete and up-to-date “other support” information will be requested as part of Just-in-Time information collection.

5) **Budget forms (e.g., R&R Budget, PHS 398 Training Budget)**:
    a. **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 career investigator and must be for the purpose of presenting data from this supplement award.

b. A statement regarding the expenditure of currently available unobligated grant funds of the parent CFAR grant will be required. The CFAR must include a description of the plans to spend remaining funds in order to demonstrate the need for additional funds.

6) **Research Plan form (e.g., PHS 398 Research Plan form, PHS 398 Research Training Program Plan):**
   a. 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-20-018). **Limit one page.**
   b. **Specific aims page** must concisely state the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved. Aims described in the proposed study should be feasible given the available time, funds, and resources to do the work. **Limit one page.**
   c. The **research strategy** 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. **Limit four pages.**
   d. **Letter(s) of Support**
      i. Submit a letter(s) of collaboration endorsing the proposed request from all substantial participants.
      ii. If applicable, please include letters of support or approvals for projects requiring access to data, samples, tissues, cutting edge technologies, etc. Include evidence to support the feasibility of enrollment, including descriptions of prior experiences and yield from research efforts employing similar referral sources and/or strategies for projects involving recruitment of participants.
      iii. For transitioning post-doctoral fellows, please include a letter from your institution confirming the transition to a faculty position that includes the start date.
   e. NO appendices

7) **PHS Human Subjects and Clinical Trials Information form**: If new recruitment or use of an additional existing dataset or resource is proposed in the supplement application, the Study Record should be revised and new Inclusion Enrollment Reports created, as well as other required sections, as appropriate for supplemental activities. NOTE: Studies involving clinical trials are not allowed.

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 topic above. Funding for administrative supplements to existing CFAR grants will be awarded in FY2021 with a budget period of up to one year.

Supplemental funds for the research supplements will be provided to the Developmental Core of the CFARs. Supplemental funds for meeting supplements will be provided to the Administrative Core and equipment supplements will be provided to the applicable core.

How to Apply

This is a one-time announcement. Application must be submitted electronically through grants.gov.

Do not send applications to the NIH Center for Scientific Review or CFAR Program Officers.

Applications must be submitted electronically on or before **April 19, 2021**. If an application is received after that date, it will be rejected without consideration.

At the time of submission, applicants are requested to send an email notification of applications submitted that includes the below information for each. This information will assist in planning for review.

a. Supplement Project Director name
b. Supplement topic for the supplement request
c. Project title
d. Total cost amount of the requested supplement

Information should be sent to:
Annalise Schoonmaker
National Institute of Allergy and Infectious Disease
Telephone: 240-669-5577
Email: annalise.schoonmaker@nih.gov

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 HIV/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 scientific applications, unless noted. Reviewers will also examine the appropriateness of the budget, in consideration of the research environment and the supplement request.

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 (including CFAR Cores) 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 research project;
7. Choice of appropriate project PI and co-investigators (e.g., scientific qualifications, commitment, and experience), as well as the collaborations with other institutions, if applicable;
8. Appropriateness of the budget, in consideration of the research environment, for the scientific projects and cores;
9. Feasibility to complete the project within the project period (e.g., this will range between 8-12 months depending on the parent CFAR grant).

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. Sufficient progress demonstrated if funds were provided for previous meeting;
3. Appropriate format, agenda, and timeliness of the meeting request to achieve specific goals;
4. Suitable key personnel and proposed speakers well suited for roles in the meeting;
5. Institutional or other support as appropriate.

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.

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

Announcement Release Date:	***2/09/2021***
Application Receipt Date:	***4/19/2021***
Review Date:	***5/18/2021***
Earliest Anticipated Award (Start) Date:	***7/01/2021***

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 the supplement projects and outcomes.

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:

Elaine Wong, M.S.
National Institute of Allergy and Infectious Diseases
Telephone: 240-627-3100
Email: elaine.wong@nih.gov

For questions concerning a specific scientific area of interest, please communicate with the appropriate scientific contact below:

Uptake and retention for long-acting HIV prevention and treatment

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

Interactions and effects of the microbiome and metabolome on comorbidities and co-infections in people with HIV

and

Disparities in Treatment and Outcomes in People with HIV with multiple comorbidities and co-infections

Peter J. Perrin, Ph.D.
National Institute of Diabetes & Digestive & Kidney Diseases
Telephone: 301-451-3759
Email: Peter.Perrin@nih.gov

Geraldina Dominguez, Ph.D.
National Cancer Institute
Telephone: 240-781-3420
Email: geraldina.dominguez@nih.gov

Impact of HIV infection and HIV-associated comorbidities, coinfections and complications on hemophiliacs and the hematopoietic system

Shimian Zou, Ph.D.
National Heart, Lung, and Blood Institute
Telephone: 301-827-8301
Email: shimian.zou@nih.gov

Intersectional Stigma and its Effect on HIV Prevention, Treatment and Care

Rick Berzon, Dr.P.H., P.A.
National Institute on Minority Health and Health Disparities
Telephone: 301-594-8949
Email: rick.berzon@nih.gov

Rebecca Henry, Ph.D., B.S.N., R.N.
National Institute on Nursing Research
Telephone: 301-594-5976
Email: rebecca.henry@nih.gov

Increasing the Integration of Substance Abuse Services and HIV Prevention and Care

Richard Jenkins, Ph.D.
National Institute of Drug Abuse
Telephone: 301-443-1923
Email: jenkinsri@nida.nih.gov

Understanding HIV Reservoir Establishment, Maintenance, Control, and Clearance

Eric Refsland, Ph.D.
National Institute of Allergy and Infectious Diseases
Telephone: 301-761-7193
Email: eric.refsland@nih.gov

Natural History of Reservoir Establishment in Infants

Denise Russo, Ph.D.
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Telephone: 301-435-6871
Email: denise.russo@nih.gov

Inter-CFAR Meetings and Equipment

Elaine Wong, M.S.
National Institute of Allergy and Infectious Diseases
Telephone: 240-627-3100
Email: elaine.wong@nih.gov

For questions concerning budget and fiscal matters:

Roberta Wolcott, J.D.
National Institute of Allergy and Infectious Diseases
Telephone: 240-669-2964
Email: wolcottr@niaid.nih.gov