Request for Letters of Intent for Pilot Projects in HIV Research

The Center for Interdisciplinary Research on AIDS (CIRA) at Yale University seeks letters of intent for Pilot Projects in HIV/AIDS Prevention Research. **Pilot awards are intended to support preliminary and/or feasibility studies in HIV-related research that will lead to larger grant submissions for junior investigators, and/or to support community-university research partnerships.**

Implementation Science (IS) is a central focus at CIRA and we are particularly interested in innovative IS research. Further, priority will be given to proposals that focus on reducing HIV inequities and/or incorporate key health justice constructs (e.g., social determinants of health, stigma and discrimination). Investigators should address how the population and content of their proposal relates to Implementation Science, and how the proposed methods and results may help reduce HIV inequities. We expect studies to focus on populations at highest risk of HIV infection and seek to understand how to reduce disparities in HIV incidence, prevalence and outcomes among marginalized populations, including those with common co-morbidities such as substance use and mental health disorders. Research that focuses exclusively on the biology of HIV, new HIV treatments, and/or projects with a focus on co-morbidities will not be considered.

To be competitive for eventual NIH funding, the proposed research should align with the NIH HIV/AIDS Research Priorities outlined in NOT-OD-20-018. See Annex A for the priorities and examples of both aligned and non-aligned research.

**CIRA plans to fund up to two projects in this cycle with a maximum award for individual projects of $25,000.** The project period is for one year and dependent on IRB and NIMH approval. If you have any questions about this announcement or a project you are considering for submission, please contact Trace Kershaw, Director of CIRA’s Development Core, via email (trace.kershaw@yale.edu).

**LETTER OF INTENT:** Applicants must complete the online survey by Friday, March 20, 2020, setting out the title and preliminary abstract of the project, the names and contact information of all key personnel, and which of the NIH HIV/AIDS Research Priorities the proposal is best aligned to (see Annex A).

**APPLICATION PROCESS:** Invitation to apply will be contingent upon (1) the project’s alignment with CIRA’s mission, (2) the feasibility of the project, and (3) the potential for the project to lead to a larger research study. We strongly recommend that applicants attend the CIRA talk, “Implementation Science for Small-Scale Projects” on March 3rd. Additionally, in order to expedite the process, we ask applicants to start the IRB process prior to submitting their full pilot application. See Annex B and the CIRA website for further information on the review criteria and process.

**Full applications will be due on Friday, May 1, 2020.**

**ELIGIBILITY:** Emerging and new investigators (including Post-Doctoral Students, Research Associates, and Assistant Professors) at Yale University, the Institute for Community Research (ICR), and the Institute for Collaboration on Health, Intervention, and Policy (InCHIP) at UConn are eligible to apply as PIs. Investigators from other universities or colleges and community-based organizations are eligible to apply in collaboration with a Principal Investigator based at Yale, ICR, or InCHIP. It is our expectation that awardees will hold an appointment at one of these institutions for at least one year past the award date.
TIMELINE:
Request for Letters of Intent issued: February 21, 2020
Letter of intent due: March 20, 2020
Application deadline: May 1, 2020
Pilot Project Review Panel meets: May -June 2020
Awards announcement expected: June 2020
Earliest start date: July 1, 2020 (dependent on IRB and NIMH approval)
ANNEX A

OVERARCHING NIH HIV/AIDS RESEARCH PRIORITIES FOR FY 2021 TO FY 2025:

1. Reduce the Incidence of HIV, including supporting the development of safe and effective vaccines, microbicides and pre-exposure prophylaxis.
2. Develop next-generation therapies for HIV with improved safety and ease of use.
3. Conduct research toward an HIV Cure.
4. Address HIV-associated comorbidities, coinfections, and complications through research designed to decrease and/or manage these conditions.
5. Advance cross-cutting areas of research in the basic sciences, behavioral and social sciences, epidemiology, implementation science, information dissemination, and research training.

Examples of research ALIGNED with the NIH HIV/AIDS Research Priority areas: (list is not ranked and is not all inclusive)

- Reduce incidence of HIV/AIDS, including develop safe, effective, practical, and affordable HIV vaccines, microbicide and pre-exposure prophylaxis candidates and methods of delivery, especially those that improve adherence; and develop, test, and implement strategies to improve HIV testing and entry into prevention services.
- Research focused at fundamental scientific questions with a clear or credible link to HIV/AIDS to understand the mechanisms of HIV transmission and acquisition, virus/host cell interactions and pathogenesis, and the structure and dynamics of HIV proteins to prevent ART drug resistance; immune dysfunction and persistent inflammation; host microbiome and genetic determinants; and other fundamental issues that underpin the development of high priority HIV prevention, cure, co-morbidities, and treatment strategies.
- Next generation HIV therapies with better safety and ease of use including develop and test HIV treatments that are less toxic with fewer side effects and complications, longer acting, easier to take and adhere to than current regimens.
- Long-term treatment or prevention strategies for HIV-relevant coinfections and comorbid conditions across the lifespan
- Effective socio-behavioral interventions to achieve uptake of HIV prevention and treatment strategies and reduce health disparities.
- Implementation research designed to ensure biomedical and other prevention and treatment strategies, are initiated as soon as possible, increased retention and engagement in treatment services, and maintenance of optimal prevention and treatment responses are achieved.
- Research toward a cure including development of novel approaches and strategies to study viral persistence, latency, reactivation, and eradication; identify and eliminate viral reservoirs that could lead toward a cure or long-term remission.
- Research training of the multidisciplinary workforce required to conduct High Priority HIV/AIDS or HIV/AIDS-related research.
- Research that includes people (or biological specimens from people) who with HIV, are HIV exposed, and/or are at elevated risk for HIV infection as part of a broader sample or as a comparative cohort.
- Research that examines health and social issues, such as other infectious or non-infectious conditions and substance use or mental health disorders, clearly linked with HIV. (transmission/acquisition, pathogenesis, morbidity and mortality, stigma) in populations or settings with high HIV prevalence or incidence.
- Research that meaningfully includes HIV/AIDS (or SIV) outcomes/endpoints.
• Development of innovative technologies, such as sensitive assays, biomarkers, and imaging methods, coupled with cutting-edge studies of biology, virology, pharmacology, and immunology to advance durable and scalable prevention, treatment and cure in people with HIV.

Examples of research NOT ALIGNED* with the NIH HIV/AIDS Research Priority areas: (list is not ranked and is not all inclusive)

• Research on natural history and epidemiology that is entirely focused on a co-morbidity and does not have any focus on or inclusion of HIV.
• Research on co-infecting pathogens, but not in the context of HIV infection, basic immunology studies of general relevance, but not specific to HIV; basic cancer-related immunology studies not in the context of HIV infection; or studies on co-morbidities of general relevance, but not in the context of HIV.
• Data analysis and systems tools that are not HIV-related, e.g., genomics and other omics studies with little or no relevance to HIV.
• Studies of behaviors (e.g., sexual activities, drug use activities) or social conditions where HIV/AIDS is only one of many outcomes without a focus on how HIV/AIDS is unique in that context.
ANNEX B

REVIEW PROCESS
Applications will be reviewed by a Pilot Project Review Panel drawn from CIRA affiliates and including a member of the Community Advisory Board, and representatives from the IRM Core and CIRA’s training programs, in addition to the Development Core Director and senior/mid-level CIRA scientists to determine suitability. Applicants will receive feedback from the panel.

REVIEW CRITERIA
Reviewers will use the NIH scoring system and the criteria listed below:

1. **Scientific merit**: Does the proposed research explore original and/or innovative concepts, approaches or methodologies, tools, or technologies?
2. **Feasibility**: Is the team qualified? What is the rationale for the recruitment plan and is it feasible? Can the study be done in one year? Can this project be completed with the funds requested? If the setting is international, is the project feasible in the host country setting?
3. **Approach**: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
4. **Significance**: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Has the literature been reviewed and is it clear how it supports the proposal?
5. **Implementation Science**: Does the project promote the adoption and integration of evidence-based practices, interventions and policies into routine health care and public health settings? What is the prior evidence demonstrating effectiveness or efficacy of the intervention to be implemented?
6. **Likelihood of externally awarded funding**: Is the pilot project targeted at development of an NIH style grant proposal? Is there a referenced RFA? Will completion of the pilot project increase the probability of obtaining AIDS funding from NIH?
7. **Relevance to CIRA’s mission and emphasis on social justice**: Is the proposal innovative, interdisciplinary research that combines behavioral, social, and biomedical approaches focused on the implementation of HIV prevention and treatment and the elimination of HIV disparities?
8. **Alignment with NIH HIV/AIDS Research Priorities**: Does the work align with the research topics of high priority as designated by the OAR in NOT-OD-20-018?