v. 12.15.2023

GUIDELINES FOR INTERNAL UAB CFAR PILOT FUNDING APPLICATIONS

The mission of CFAR is to achieve improved diagnosis, treatment, and prevention of HIV/AIDS by fostering the development of new knowledge from multidisciplinary research in service to the pillars of the CFAR scientific mission of HIV Basic Sciences to Impact Clinical Outcomes, Behavioral Epidemiology and Intervention, Population Health Prevention and Treatment, and Community Engaged Research. Ensuring service to these overarching pillars of scientific research unifies our purpose and aligns our goals with those of the National AIDS Strategy and the HIV scientific community.

The UAB CFAR pilot funding program focuses on seeding new or continuing work from early career and senior career new-to-HIV researchers that can be used to acquire larger grants from external sources. We aim to cultivate a highly integrative HIV research environment and successful research teams, essential components of continued research success in the current funding landscape. Only those applications that are aligned with the pillars of the CFAR scientific mission will be considered for funding through this mechanism. We anticipate funding 2 applications **up to $50,000 per year for up to 2 years**. Per NIH guidance, clinical trials are not supported through this mechanism.

Eligibility Criteria:

1. Have an MD or PhD or equivalent terminal degree
2. Have not had an NIH R01 or equivalent grant related to HIV research.
3. Have an appropriate appointment, as follows:
    a. Early career faculty appointment in a UAB Department or Division.
    b. Applicants may be at the instructor, assistant professor, or associate professor level

Principal investigators are encouraged to engage investigators at different levels, community stakeholders, public health representatives and those with lived experience and diverse backgrounds in support of their study.

MPIs are not allowed.

Applicants supported by NIH K awards are eligible if the requested funds support different aims; the research may be on the same topic.

Timeline:

- RFA Release: December 15th, 2023
- Deadline for 2-page Concept Proposal: February 2nd, 2024
- Receipt of notification to Submit Full Applications: February 16th, 2024
- Deadline for Full Applications: March 22nd, 2024
- Notification of Award: May 1st, 2024

v. 12.15.2023

Concept Proposals

To apply for CFAR funding please submit the following information as a single combined PDF including the project description, mentorship, significance, innovation and biosketch for the PI as listed below using this link. For questions, email Dr. Donna Porter. Demographic and diversity information requested in the submission form is optional. Proposals selected to submit full applications will be notified by email. The concept proposal should be 2 pages in length and include the following information.

- **Project Description** Briefly describe the hypothesis, aims, any preliminary data, and brief research design.
- **Mentorship** Briefly describe the role and extent of involvement your mentor will have in your study. The Developmental Core is able to assist pairing you with a mentor, if needed. Contact Mary Thielen.
- **Significance / Added Value** Briefly explain the importance / significance of the proposed project in the context of HIV research and to those with lived experience.
- **Biosketch** Include for the study PI (link to NIH criteria and forms for non-fellowship biosketch) (Does not count toward 2-page limit). Personal statements should be adapted to describe defined role.

Please note: *Clinical trials cannot be funded through this mechanism. Link to this tool to determine if your study meets the definition of a clinical trial. Study leaders and team members representing different academic levels, diverse backgrounds and life experiences are encouraged.

Full Applications

Full Proposals will be submitted to Mary Thielen mthielen@uabmc.edu in one Adobe PDF file. Please copy any mentors on the submission email. The full proposal will be submitted using the PHS 398 forms , following a modified NIH investigator initiated grant application (R01) format. Complete instructions are found here.

Complete the forms as detailed below with the stated modifications.

- In keeping with the NIH's efforts to foster diversity and inclusion from groups that are underrepresented in the biomedical, clinical, behavioral, and social sciences (NIH Notice of Interest in Diversity), the UAB CFAR encourages applications from those representing diverse backgrounds and life experiences.
- Applications of all types should consider engaging with community stakeholders, health departments, or those with lived experiences in the design and/or conduct of the study. Include a description of the impact of the results on affected communities and a plan for disseminating results to these communities.
    - Contact Harriett Reed Pickens (CFAR Community Engaged Research Coordinator) for consultations regarding engaging with the community in research.
- Applicants are encouraged to consult with CFAR Cores for assistance and support, including budgets, research services, methods and materials, equipment, and training, as appropriate.
    - Contact the CFAR Financial Administrator, Megan Pickering, for assistance with budgets.
    - Consultation with the CFAR Clinical Core Biostatistics and Analysis team for help with data collection and analysis plans is advised. Contact Sarah Dougherty Sheff for consultations.
- Do not submit Targeted/Planned Enrollment Tables or Appendices.
- Note the specific NIH funding sources to be targeted with the results from this study.

v. 12.15.2023

The Full Proposal should include the following, in this order, in a single Adobe Portable Document Format (PDF) file.

1. Detailed budget and justification
    a. Prepare PHS 398 detailed budget form page 4 for the first year of funding and form page 5 for the second year (link to forms).
    b. Include a full justification of all costs. No form page necessary.
    c. Maximum direct costs is **$50,000 per year** for up to **two years** in length; Indirect costs are allowed at the UAB rate.
    d. For those requesting a two-year project, second year funding is contingent upon demonstration of satisfactory progress during year one.
    e. All costs must conform to the NIH Grants Policy Statement (GPS) and applicable U.S. Office of Management and Budget OMB circulars for necessity and reasonability, allocability, conformance and consistency, as well as allowability. Link to NIH Grants Policy Statement and refer to section 7.2 for NIH cost principles.
    f. Salary support for faculty is limited to no more than 15% for the PI, unless special permission is granted. Salary support for mentors is not allowable.
    g. Requested support for equipment and technology, including computers, must be fully justified in the budget justification with a clear connection to the scientific aspects of the project and not for general office use.
    h. Tuition, fees and stipends for graduate students are allowable to include salary, fringe, and tuition/fees (NOT-OD-21-049)
    i. Budgeting for travel to conferences/meetings to present project research results is allowable.
    j. Costs associated with Institutional Review Board (IRB) review of human research protocols, or Institutional Animal Care and Use Committee (IACUC) review of animal research protocols, are allowable as direct charges.
2. Biosketches
    a. Include separate biosketches for the study PI and Mentor(s)
    b. Use NIH criteria guidelines and forms for non-fellowship biosketches (link)
    c. Biosketch does not count toward 2-page limit
    d. Personal statements should be adapted to describe defined roles within the project in each biosketch.
3. Research Plan (Maximum 4 pages for a-d below). No form page necessary.
    a. Specific Aims (suggested length ½ page)
    b. Merit / Significance (suggested length 1 page)
    c. Approach (suggested length 2 pages)
        i. Include how your mentorship plan will influence your project and career in addition to a statement of the ways that the proposed work will lead to additional applications for funding.
    d. Innovation (suggested length ½ page)
4. Bibliography and References cited (as needed) No form page necessary.
    a. Bibliography and References cited sections do not count toward the page limit.
5. Protection of Human Subjects (if applicable; maximum 1 page, No form page necessary).
    a. You will be asked for additional Human Subjects forms should you be selected for funding.

6. Vertebrate Animals (if applicable; maximum 1 page, No form page necessary)
7. Letters of Support
    a. Letters from collaborators essential to the proposed project should accompany the application.

Criteria for Clinical Studies, Clinical Trials, and International Components:

(*Including foreign sites or any transfer of funding to a foreign entity)

1. Clinical trials cannot be funded through CFARs
    - NIH definition of a **Clinical Trial** (NOT-OD-15-015)- A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Link to this tool to determine if your study meets the criteria for a clinical trial.

      This includes:

        - Any clinical trial as defined above
        - Studies involving new drugs, treatments, or devices
2. Studies that can be funded via CFAR **but require** additional NIH Clinical review
    - Studies involving **new ways of using known drugs, treatments, or devices** (allowed on a case-by-case basis)
    - Studies that are deemed **above minimal risk** by the Institutional IRB
    - Studies involving **vulnerable populations** (children, pregnant women, transgender, sex workers, prisoners, refugees, individuals who are unable to provide informed consent, etc.)
    - Studies involving **behavioral interventions** (above minimal risk)
        - For studies in this category, please send the clinical research protocol and informed consent documents. Consultation with the Clinical Core is encouraged to ensure completeness of documents prior to submitting to NIH. No human subject work may be initiated until clinical review and approval is completed.
3. Studies that **do not require** additional NIH Clinical review
    - Research activities that do not include vulnerable populations (see above studies that require additional NIH Review) and present **no more than minimal risk** to human subjects as described in the OHRP Expedited Review Categories. Examples include but are not limited to the following:
        - routine blood draws
        - non-invasive procedures routinely employed in clinical practice (e.g. ultrasound, MRI)
        - surveys, focus groups
        - For studies in this category, please include IRB approval dates in the annual progress report.
4. Studies with **foreign components/International sites** require additional review by NIH. Link to the NIH checklist and guidance for this process.

Review Criteria

A Scientific Selection Committee consisting of members from the CFAR Executive Committee and peers with relevant expertise will review the applications. Criteria for selection are primarily based upon the scientific

merit, investigative team, significance, approach, innovation, and pathway to independence using the following criteria. Written reviews will be provided to the investigator.

- Scientific Merit of the proposal and its likelihood to provide information that can significantly advance the understanding of HIV and/or provide preliminary data that is likely to lead to independent research grant funding. The project will be evaluated for its significance to the U.S. National HIV/AIDS Strategy, and the NIH's HIV research high or medium priority areas.
- Significance – What will be the potential effect of these studies on the concepts or methods that drive the field of HIV research? Does the study address an important problem consistent with the objective to advance our understanding of HIV? If the aims are achieved, how will scientific knowledge be advanced? Is the impact on communities adequately described? Were appropriate, are community stakeholders, public health departments, or those with lived experiences engaged in the study?
- Investigator – Are the PI, mentor(s), collaborators, and other researchers well suited to the project? Does this person have appropriate experience and training? If the project is collaborative, do the investigators have complementary and integrated expertise? Are representatives from affected communities advising the team or participating in the study?
- Approach – Are the conceptual framework, design, methods, and statistical analysis plan adequately developed, well integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternatives? Does the study design account appropriately for differences by sex or gender?
- Innovation – Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- Pathway to Independence - Applications should describe how the results of this award will prepare the applicant to secure independent NIH funding (K- or R-level) and note potential NIH funding sources to be targeted.
- The use of CFAR Core Services is strongly recommended. Inclusion of LOS is encouraged.

Award Details

Pre-Award Approvals

Funding will be awarded by the UAB CFAR Finance Office. A detailed notice of award will be provided by email. All questions regarding the award of funding should be directed to the contact listed in the notice of award. Prior to the award of funding, the following information must be provided, where applicable:

1. Institutional Review Board and Animal Care approvals, if applicable, must be obtained prior to receipt of an award, but are not required to submit an application.
    - Prior to receipt of an award involving human subjects, IRB approval from all participating sites and human subjects training certification for all key personnel will be required. For more information about human subjects approval, see: http://www.hhs.gov/ohrp/.
    - Prior to funding, a copy of all Institutional Biohazard, Animal Care and Institutional Review Board (IRB) approvals must be forwarded to the post-award administrator. For more information on animal care approvals, see: http://grants.nih.gov/grants/olaw/olaw.htm.
    - If IRB review is not applicable to your study, please confirm by email to the CFAR Administrative Core.
2. If your study undergoes IRB review, the NIAID may require an additional administrative review (Clinical Review). Similarly, studies with foreign components may be required to undergo an International Review by the NIH.

- Review the guidelines for the NIH Clinical and/or International Reviews in the Full Application section.
- Please note that NIH clinical and/or international reviews will delay the release of your funds by 4-6 months, depending on the complexity of the review. Salary may be charged to the study during this process.
- CFAR will submit the required information for you to NIH/NIAID for the Clinical and International reviews only.

Post-Award Requirements

- Awardees are expected to maintain regular and frequent interactions with their mentor(s). Contact the CFAR if additional expertise is needed or a change in mentor is desired.
- Yearly progress reports will be requested. Awardees will be contacted to request updates on additional productivity after the award ends (i.e., abstracts, publications, grants).
- Applicants chosen for funding may be asked to present the details of their study to the CFAR Research Community during the course of the project or at the conclusion of the study.
- Applications that include the use of human subjects will be contacted by CFAR Administration to collect required human subjects' documentation.
- Support from this mechanism must be acknowledged in all publications and presentations. Visit the CFAR website for language describing the appropriate acknowledgement of this funding source.
- If for any reason the awardee is unable to fulfill the requirements or adhere to the policies of the award, at the discretion of the funding mechanism leadership, the award may be revoked or the funding adjusted.

For questions, contact Mary Thielen at mthielen@uabmc.edu, UAB CFAR Program Director or

Dr. Donna Porter Crawford donnaporter@uabmc.edu CFAR Associate Director

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