

CFAR Africure Program Request for Applications

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I. Basic Information

I.1. Purpose

Despite years of antiretroviral therapy, viral reservoirs persist in individuals living with HIV-1, resulting in viral rebound if treatment is interrupted. Difficulties of sustained life-long treatment in the millions of people living with HIV worldwide, with a significant burden in sub-Saharan Africa, necessitates research that moves us closer to a sterilizing or functional cure for HIV. Sub-Saharan Africa shoulders a disproportionate burden of the HIV epidemic globally, making it an important region in which to conduct HIV cure research, yet most HIV cure research has been focused on White men living with HIV in high-income countries. Many potential therapeutic strategies are not being designed or tested with most people living with HIV in mind, i.e., those in low- and middle-income countries, especially those on the African continent. There is an urgent need to bring novel insights and approaches rooted in Africa into HIV cure research to address Africa-specific biologic, therapeutic, and implementation issues.

Through the CFAR Africure Program, the NIH-funded <u>Centers for AIDS Research (CFARs)</u> are working to advance HIV Cure research in Africa by providing mentored development to early- and mid-career investigators whose research focuses on HIV Cure strategies.

I.2. <u>Overview</u>

The CFAR Africure Program is funded by the NIH/NIMHD and administered through the Johns Hopkins University CFAR and the Inter-CFAR Sub-Saharan Africa Working Group (IC-SSA-WG).

The AFRICURE program will award five grants of \$150,000 for one year, plus applicable indirect costs. This program intends to attract highly talented early- and mid-career stage investigators from sub-Saharan Africa to address critical questions related to HIV cure research. Recipients of the awards will be mentored by and collaborate with established HIV investigators across CFARs and affiliated institutions in Africa, with the goal of having a transformational impact on the careers of African investigators, their institutions, and the entire HIV cure enterprise.

Africure projects are single Principal Investigator (PI) awards.

CFAR Africure awards are funded for a one-year period.

I.3. Funding

Funding for the CFAR Africure Program is provided by the US National Institutes of Health as a supplement to the Johns Hopkins University CFAR (P30AI094189). Africure awards are contingent on the availability of funds from these sources.

Applicants may request up to \$150,000 for one year, plus applicable indirect costs (8%).

Funding may be used for salaries, technical support, laboratory supplies, equipment, and for researchor training-related activities including but not limited to enrollment in training classes or workshops, travel to the CFAR Mentor's institution, and travel to the research field site.

Requests for no-cost extensions will be discussed on an individual basis and are not guaranteed.

I.4. Eligibility

Scholar eligibility

All scholars will meet the following criteria:

- National or permanent resident of a sub-Saharan African country;
- Early-stage or mid-career scientists who have received their doctoral degree within the last 15

years in disciplines such as (but not limited to) Medicine, Molecular and Cellular Biology, Immunology, Virology, Pharmacology, Genomics/Genetics, Structural Biology, Chemistry/Biochemistry, Physiology, Biophysics, Infectious Diseases and Microbiology, Biotechnology, Behavioral and Social Sciences, Oncology, Metabolism, Cardiovascular, Neurology, Public Health, Health Services Research, Epidemiology, Pathology, Bioengineering, Operations Research, and Implementation Science;

- Committed to professional development;
- Appointment as faculty or equivalent at an institution or organization in sub-Saharan Africa. Grants will not be transferable to institutions outside of sub-Saharan Africa;
 - Post-doctoral fellows are eligible to apply if they have a faculty appointment in place at the time the CFAR Africure project funding begins (anticipated March 1, 2023). A letter from the applicant's department chair, verifying their faculty position and start date, must be included in the application package.
- Strong interest in HIV cure research and demonstrated skills, knowledge, and potential necessary to carry out the proposed research with appropriate support and mentorship.

Mentor eligibility

Each applicant will be required to have two mentors; a primary mentor who is an established investigator at an institution affiliated with an NIH-funded CFAR who has a history of NIH funding in HIV cure-related research, and a local mentor at an institution in the applicant's country with strong mentorship experience and a commitment to participating for the duration of the program.

Applicants who would like assistance in identifying an eligible CFAR mentor may contact Anne Efron, the CFAR Africure Program Administrator (aefron1@jhmi.edu). We encourage applicants to review the list of currently funded CFARs. Each CFAR has a Developmental Core that is tasked with helping to build the HIV research careers of junior faculty at their institution. As a result, Developmental Core staff are familiar with the senior faculty at their institution and may be able to help you locate an appropriate mentor.

I.5. Project Scope

The proposed research project should be achievable within the award period. Eligible research topics

may include any aspect of science related to HIV cure research, such as (but not limited to):

- 1. The HIV reservoir in women, children, and diverse populations in Africa;
- 2. Effects of TB and other co-infections/comorbidities on HIV reservoirs;
- 3. Effects of latency-reversing agents on African populations;
- 4. Development of standardized pan-subtype reservoir measurement tools and standards that can be implemented in small hospitals or more rural clinics in Africa;
- 5. Differences between female and male populations in the latent reservoir;
- 6. Community engagements strategies to ensure acceptance of HIV cure strategies.

Clinical trials, as defined in <u>NOT-OD-15-015</u>, cannot be funded. This includes any 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. If you are unsure if your approach meets the NIH clinical trial definition, use the <u>NIH clinical trial decision tool.</u>

Some clinical research will require <u>additional NIH review</u>. See the CFAR Africure's <u>FAQ page</u> for more information. If an applicant is unsure if their proposed approach qualifies as clinical research or a clinical trial, or if it will require additional NIH CFAR clinical review, please contact Anne Efron, the JHU CFAR

Program Administrator (aefron@jhmi.edu).

Animal Research will require Institutions to have an Animal Welfare Assurance to receive funding from this program. Institutions with AWA approvals can be found <u>HERE</u>. Awardees will need to have IACUC approval for their specific study.

I.6. Program Benefits

In addition to providing funding for research projects, the CFAR Africure program will also provide:

- One in-person workshop that may be held in conjunction with a major HIV conference
- Regular virtual gatherings, hosted by CFAR Africure program staff, that will include research-inprogress presentations, continuing education/skills-building webinars

II. Application Instructions

CFAR Africure projects are selected through a two-stage process:

- 1. Submitted concept proposals are competitively reviewed
- 2. A subset of reviewed concept proposals is invited to submit full applications

II.1. <u>Timeline / Deadlines</u>

Our anticipated timeline is:

- Concept Proposal due: November 10, 2023
 Notification of Outcome: November 27, 2023
- Invited Applications due: January 22, 2024 Notification of Outcome: February 19, 2024
- Project Period: March 1, 2024 February 28, 2025

II.2. Concept Proposals

Preparation:

Concept Proposal forms and instructions are available on the "<u>How to Apply</u>" page of the Africure website. Questions about proposal content or format should be directed to the JHU CFAR Program Administrator, Anne Efron (<u>aefron@jhmi.edu</u>)

Submission

Submit concept proposals by uploading a completed form packet as a single PDF document to: <u>CFAR@jhmi.edu</u>

Review

A Review Committee composed of CFAR members and others with relevant expertise in HIV Cure research will convene to review submitted concept proposals and select a subset to be invited to go forward as full applications. Only applicants invited to submit a full application will receive feedback on their proposal.

Criteria for review will include:

- 1. How well the proposal addresses the primary aims of the Africure program;
- 2. Feasibility that the proposed project can be executed within the time period and with the available budget; and
- 3. Applicant and proposed mentors' eligibility and experience.

II.3. Invited Applications

Preparation:

Full applications will only be accepted from applicants who have been invited to go forward after competitive Concept Proposal review.

Africure applications should be prepared as if the Scholar is submitting an NIH R03 application, using the Forms G form-set associated with <u>PA-20-200</u>, the NIH Parent R03 FOA.

Page Limits:

All page limits are as standard for an NIH R03. For specific information on page limitations for each section of the application, see <u>this NIH website</u>.

Budget:

- o Use the detailed, not modular budget.
- $\circ~$ Subaward indirect costs must be included in the total project direct costs.
- Requested support for project staff who are not at the same institution as the Scholar must be listed as consultant costs.

If a staff person not at the PI/Scholar's institution *cannot* accept consultancy fees, a subcontract will be issued to their institution. Subcontract costs must be listed in the budget as "**consortium costs**" with applicable indirect costs included.

• Tuition, fees, and stipends for graduate students are *not* allowable.

Attachments:

- <u>Mentoring Plan</u> (maximum 2 pages) Content of the Mentoring Plan should include, at a minimum:
 - List of the Scholar's professional development goals
 - o For each professional development goal on the list, a two-column table that includes:
 - Proposed **mentoring**, education, and/or training activity(s) that will support progress in achieving the goal;
 - One or more **SMAART outcome objectives** that will allow periodic evaluation of progress toward achieving the goal.
 - A communication plan that describes:
 - The method(s) that CFAR Africure Scholar and Mentors (Local Mentor and CFAR Mentor) will use to meet (e.g., in person, online, by phone, email, etc.);
 - \circ The frequency that the Scholar and Mentors intend to meet in pairs or as a group;
 - The circumstances under which the Scholar and Mentors will be in contact with each other between regularly scheduled meetings.
- Letters:

In addition to any other Letters of Support (LOS) included in the application, applicants should

include letters from:

- The Scholar's Department Chair:
 - Verifying the Scholar's faculty/appointment status
- The Scholar's CFAR and Local Mentors
 - Indicating a minimum one-year commitment to mentoring the scholar and participating in CFAR Africure-sponsored meetings

Submission

The application package should be submitted via email to <u>CFAR@jhmi.edu</u> as a single .pdf document.

<u>Review</u>

Each application will be assigned a minimum of two reviewers.

The evaluation criteria will be standard for an NIH R03 application with the addition of the following Africure-specific criteria:

Mentoring Plan:

- Are the PI's professional development goals for the project period defined?
- Is the proposed list of mentoring, education, and/or training activities appropriate for meeting the stated professional development goals?
- Is the proposed list of SMAART outcome objectives appropriate for assessing progress in meeting the stated professional development goals?
- Is a communication plan provided that describes the frequency, under what circumstances, and how members of the CFAR Africure Team will be in formal and informal contact with each other?
 - Does the proposed communication plan and accompanying CFAR Africure mentoring meeting schedule demonstrate a commitment to meeting the goals and objectives described in the mentoring plan?

Budget:

- Is the budget fully justified?
- Is it reasonable in relation to the proposed research?
- Does it meet the constraints of the Africure program?

III. Award Requirements

- Regulatory Approvals
 - Copies of all required regulatory approvals must be on file with the CFAR Africure postaward project coordinator prior to the initiation of the research implementation period.
 - As appropriate, these may include NIH CFAR clinical research approval and NIH CFAR international research approval. Learn more <u>here</u>.
 - Applicants who anticipate conducting clinical and/or international research, or research that fits any of the sub-bullets below, should contact Anne Efron, the CFAR Africure Program Administrator (<u>aefron@jhmi.edu</u>) prior to applying to discuss the NIH CFAR's rules and regulations regarding your project.

- Studies that are deemed above minimal risk by the Institutional IRB
- Studies involving <u>vulnerable populations</u> (children, pregnant women, prisoners, individuals who are unable to provide informed consent, etc.)
- Studies with populations with additional considerations for **confidentiality and safety** (transgender, sex workers, refugees, etc.)
- Studies involving behavioral interventions (above minimal risk)

• Meeting Attendance:

- All **Scholars** will be required to attend regularly scheduled virtual meetings hosted by program staff, including continuing education/skills-building webinars.
- All CFAR and Local Mentors will be invited to attend periodic conference calls hosted by program staff to discuss upcoming events and expectations relevant to their mentee (Scholar).
- All CFAR Africure Scholars and their mentors will attend a CFAR Africure workshop that will be held at a major scientific meeting or as a standalone meeting.
- Note: Travel expenses for attendance by the Africure Scholar to the annual meeting should be included in applicant budgets. Travel expenses for CFAR Mentors and Local Mentors of Scholars are covered by the Africure program and should not be included in applicant budgets.

• Presentations:

- Each CFAR Africure Scholar will be required to present research findings (including preliminary findings) at a CFAR Africure program meeting.
- Reporting:
 - <u>Four-month Report</u>: Toward the end of the four-month research preparation period, each Scholar's CFAR and Local Mentors are expected to submit a brief report describing whether their mentee (the Scholar) has made sufficient progress in achieving the professional development goals described in their Mentoring Plan.
 - <u>Annual Progress Reports</u>: Awardees (Scholars) will be required to submit annual progress reports while the project is active and for five years following its conclusion.

IV. CFAR Africure Contacts

Program Officer: Haneefa Saleem, PhD, MPH haneefa.saleem@jhu.edu

Scientific Steering Committee Chair: Joel Blankson, MD, PhD jblanks@jhmi.edu

Program Administrator: Anne Efron aefron1@jhmi.edu

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