

Background and Purpose of Funding Opportunity on PLWH and Monkeypox

A new monkeypox outbreak continues to spread in Europe and worldwide, with over 11,000 cases identified as of July 12, 2022. The monkeypox virus (MPV) is transmitted through close personal contact, including skin-to-skin contact, kissing, contact with clothing or linens, and has been well documented from sexual activity. Monkeypox is related to smallpox but is less severe, typically causing flu-like symptoms, swollen lymph nodes and a rash that progresses from small red bumps to fluid- or pus-filled blisters. The rash can occur on the face, in the mouth or anywhere on the body, but in the current outbreak symptoms notably may not follow the classical pattern. Some people have only one or a few lesions, often on the genitals or in the anal area, which may resemble more common sexually transmitted diseases such as herpes or syphilis. In the current outbreak, most transmissions have also been linked to social networks connected largely by sexual activity. Although persons infected with monkeypox usually fully recover without treatment, the current monkeypox strain circulating in Europe has a fatality rate of around 1%. However, monkeypox can cause more severe illness in children, pregnant women and immunocompromised persons. Complications may include pneumonia, sepsis, encephalitis and corneal infection leading to vision loss. Overall, there is limited data on monkeypox and people living with HIV (PLWH) in the current outbreak, but previous studies suggest co-infection may exacerbate monkeypox lesions and associated complications as well as increase mortality.

The purpose of this funding opportunity is to support research aimed at evaluating all issues at the intersection of the current monkeypox outbreak and PLWH. Proposals on basic biology, pathogenesis/immunology, epidemiology, clinical care, vaccines, and sociobehavioral considerations, will all be considered. Proposals must focus on PLWH cohorts and not monkeypox monoinfections, except for the purposes of a comparison or control. Studies on persons currently on PrEP are also acceptable. Proposals that include efforts to counteract stigmatization are also of particular interest, as are those including evaluation of sexual and racial minorities, women, and healthcare access and equity. Collaborative proposals engaging non-traditional CFAR investigators at Duke are highly encouraged. The award is for up to \$60K in direct costs for up to 1 year.

RFP Schedule

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|---------------------------------|----------------------------|
| • Due Date for Letter of Intent | Monday, August 22, 2022 |
| • Due Date for Proposals | Monday, September 30, 2022 |
| • Projected Award Date | October 15, 2022 |
| • Period of Award | Award period is 12 months |

Eligibility

- The proposal must be submitted by a faculty-level investigator interested in HIV/AIDS research. Investigators who are not currently a CFAR member are invited to register here: <https://cfar.duke.edu/get-involved/become-cfar-member>. We strongly encourage inclusions of an experienced CFAR member as a collaborator, particularly for those who have not previously submitted HIV/AIDS grants

- All proposals must adhere to [NIH HIV/AIDS Research Priority](#)
- Post-doctoral and Clinical fellows are eligible as co-investigators or co-PIs on proposals led by a faculty-level collaborator (T32 awardees cannot use CFAR award for training or stipends).
- Applicants with a current K award must have an approval letter from the K award program officer.
- Questions concerning the application or submission should be directed to the [CFAR Developmental Core](#).

Letter of Intent

A letter of intent is not required, is non-binding and does not enter into the review of a subsequent application. However, the LOI is required to access CFAR Core services such as Specific Aims review; Biostatistical Consultation, etc.

Email your LOI to [CFAR Developmental Core](#) on or before August 15, 2022.

Please include the following information:

1. Principal Investigator
2. Title of proposed research
3. Project Summary
4. Collaborators

Additional Considerations

Projects with an International Component: Please refer to this [Guidance for NIH Approval Process for CFAR-Supported International Studies](#)

Projects with a Clinical Component: CFARs are unable to fund clinical trials, however, projects involving clinical research (e.g., observational studies or sub-studies using existing data from an ongoing clinical trial) may be funded by the CFARs. The [NIH definition of a clinical trial](#) is very broad. Some investigators conducting human subjects' research may not be aware that NIH considers their study to be a clinical trial. For guidance, [click here](#) and refer to the [revised Guidance on CFAR Clinical Research Studies](#) for CFAR-funded clinical research.

- Start dates for funded awards involving clinical research entailing greater than minimal risk to the subjects will dependant on IRB approvals and the date that the NIH issues clearance for the project. The Duke CFAR Finance Administrator will provide guidance to Awardees on the NIH clearance process.
- Research effort is allowed on the grant (no admin or clerical). *Faculty effort must comply with primary department policy.*
- Sub awards for external collaborations are allowable and [will incur F&A](#). Consultation with departmental grant manager pre-application is recommended to comply with [Duke Sub-award policies](#).
- Travel is restricted and must be in support of project completion or presenting results from the CFAR Developmental Project Award.

Community Engagement

Mission Towards the Community: The Duke CFAR supports collaborative and community-centered research by facilitating connections and communication between CFAR researchers and community members. We aim to inform research at Duke by centering community needs and feedback, and enhance the reach and impact of Duke studies by assisting researchers in the sharing and application of findings in community settings.

All proposals should include a statement on how the study findings will be disseminated to the community or could involve the community. Direct outreach, consultation, collaboration, and empowerment are also possible methods of involvement. Proposals should consider how dissemination of findings impact the health literacy of community members, and also consider avenues to involve community-based organizations and community-leaders in scientific research when possible.

Pre-Submission Consultation and Review

Applicants are encouraged to utilize CFAR Cores' pre-submission services, at no cost. These services should be requested with the LOI submission. Grant preparation support services include but are not limited to:

- Statistics/Bioinformatics Review
- Specific Aims Review
- Study Design, Implementation and Analysis
- Specimen ID/ Procurement
- Scientific Consultations
- Community Engagement Support
- Database and Biorepository Access
- Quality Assurance
- Experimental Design
- Research Question Review
- Literature Reviews
- Letters of Support

Application and Submission

Applications must contain the following components *in order* and be submitted as one complete PDF document. (No SPS Record required)

1. The completed CFAR Grant Cover Sheet *with signatures*, [2022CFAR.MPCoverSheet](#)
2. The CFAR Grant Checklist. [2022CFAR.MPChecklist](#)
3. Document addressing the "Authentication of Key Biological and/or Chemical Resources" as discussed in [NIH notice NOT-OD-17-068](#)
4. Research Proposal (\$60K Award)

3 Page maximum: Suggested format: Specific Aims 1/2 page, Research Strategy 2 1/2 pages

The Research Strategy should include sections to address Significance, Innovation and Approach. In the Significance section, applicants should address "...the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project." In the Approach section, applicants should "describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project.' <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-228.html>

5. A current NIH Biosketch of PIs [NIH format page](#)
6. For a multi-PI application, include a Project Leadership Plan, [per NIH guidelines](#).
7. Budget and Budget Justification on [NIH 398](#) form pages.

Applications should be prepared as a single PDF file, using the proper naming convention (e.g. first initial.lastname.cfar.sept2022), and uploaded directly to:

Sept202.q1k09bw75io7vv07@u.box.com

Simply email your completed Application to the above address. You will receive a confirmation email stating that your upload was successful. *If you do not receive a confirmation within a few minutes of submission, your application was not submitted, and you should try again.*

Questions concerning the application or submission should be directed to the [CFAR Developmental Core](#).

Review Process

Applications will be reviewed by the CFAR Study Section, comprised of Leaders from the CFAR Cores. If necessary, outside expertise may be used to evaluate the scientific merit of a proposal. All applications are subject to NIH approval and all applicants will receive a written review of their proposals, regardless of funding.

The Committee will review the application based on the following criteria:

- Overall scientific merit, level of innovation, and relevance of the proposal to the intersection of HIV/AIDS and monkeypox research
- Potential for generating independent funding
- Potential for drawing investigators from other fields into AIDS research
- Potential for developing new interactions between or among CFAR investigators.
- [NIH Next Generation Researchers Policy](#)
- [NIH HIV/AIDS Priority Areas and Office of AIDS Research HIV/AIDS Research Priorities](#)

Awardees will be notified in writing. All applicants will receive a written review of their proposals, regardless of funding.

Duke Center for AIDS Research Mission

The principal mission of the Duke Center for AIDS Research (CFAR) is to provide, establish, and enrich infrastructure support for research and to promote collaboration and coordination among the community of HIV/AIDS investigators at Duke and its principal international research partners.

NIAID Division of AIDS created the CFAR program in 1988 and most recently renewed in 2017. CFARs are co-funded by ten NIH Institutes:

1. National Institute of Allergy and Infectious Diseases (NIAID)
2. National Cancer Institute (NCI)
3. *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
4. National Heart, Lung, and Blood Institute (NHLBI)
5. National Institute on Drug Abuse, (NIDA)
6. National Institute of Mental Health (NIMH)
7. National Institute on Aging (NIA)
8. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
9. National Institute on Minority Health and Health Disparities (NIMHD)
10. National Institute of Dental and Craniofacial Research (NIDCR)
11. National Institute of Nursing Research (NINR)

The CFAR program is scientifically managed by these NIH Institutes:

- Office of AIDS Research (OAR)
- Fogarty International Center (FIC)