



Request for Proposals  
**August 2017**

## CFAR Mucosal Immunology Group Request for Proposals

The Office of AIDS Research, in collaboration with the National Institute of Allergy and Infectious Diseases/Division of AIDS and the National Institute of Dental and Craniofacial Research, seeks to create a CFAR Mucosal Immunology Group (CFAR-MIG) and thus expand the overall workscope and scientific participation of the previously established Mucosal Immunology Group (MIG) formed several years ago in conjunction with the HVTN under the direction of Dr. Julie McElrath and, currently funded through the NIH to the CFAR at Duke University (PI, Kent Weinhold). In 2009, the HVTN Laboratory established the HIV (MIG), consisting of 3 working groups (Gastrointestinal; Genitourinary; Systems Biology) that were initially tasked with identifying and standardizing best practices for the collection, storage, and analysis of mucosal specimens that are critical for the evaluation of HIV prevention or treatment modalities in future clinical trials. The MIG continues to yield fruitful and collegial, cross-network research collaborations among a diverse group of immunologists, virologists and clinical researchers. This current Request for Proposals will build upon the accomplishments of the MIG by extending scientific participation and support to members of the NIH Centers for AIDS Research (CFAR) network. One of the primary goals of this group is to support innovative, method development studies by CFAR members. **MIG awards are for one year with maximum funding per application of up to \$100,000 Total Costs.** Please note that the number of applications that will be funded for this announcement will be based on funding availability and scientific merit.

### **Purpose and Scientific Areas of Interest**

HIV transmission occurs predominantly through mucosal barriers. Mucosal immune responses to candidate HIV vaccines as well as the pharmacokinetic/pharmacodynamic (PK/PD) properties of other potentially preventive or therapeutic anti-viral agents in the human mucosa are likely distinct from those measured in the circulation. Understanding of both local viral-host immune interactions, as well as long-lived viral sanctuaries in mucosal tissues is critical to establish more successful clinical approaches to end the HIV epidemic.

The purpose of this funding opportunity is to **support innovative research projects from CFAR members toward one or more of the following scientific areas of interest.** This opportunity should be consistent with the recent NIH HIV/AIDS research priorities ([NOT-OD-15-137](#)). The following four scientific areas are of interest to the CFAR-MIG.

1. Develop improved methodologies to analyze the tissue microenvironment, mucosal fluids, and cellular interactions within the human genital, oral, lung and colorectal mucosa as they relate to HIV infection and the effects of vaccines, immunoprophylaxis and immunotherapy.
2. Further advance human mucosal tissue explant models that can better inform product decisions for multiple HIV preventive and therapeutic modalities.
3. Evaluate the role of gut, oral, lung and genital microbiomes (bacteria, fungi, viromes) in modulating the effects of HIV prevention and therapeutic interventions, particularly vaccine-mediated responses, in mucosal tissues and fluid.
4. Explore the dynamics of mucosal HIV-1 latent reservoir formation in breakthrough cases/controls within HIV vaccine, immunoprophylaxis and immunotherapeutic studies, with a goal to gain insight into the contribution of pre- and post-infection immune responses on the reservoir size and kinetics.



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### Eligibility

*This year, because of the aggressive timeline for completion, funding is limited to domestic projects only.*

- This application is open to all CFAR investigators. We strongly encourage early and mid-career investigators to apply.
- Non-faculty applicants must have a faculty sponsor.

### Application Components

Collaborations between investigators at different CFARs/institutions are encouraged. However if funding is requested to support research activities at different institutions, separate applications should be submitted for simultaneous review with the relationship between applications and delineation of project responsibilities clearly stated.

Applicants are eligible to access CFAR Core services from collaborating CFARs. Documentation of intent to use CFAR Cores is encouraged and will be evaluated during the review process. Documentation consists of a letter of support from the Director of a relevant CFAR Core describing the services, materials, expertise, training, or other resources to be provided. Visit the [National CFAR Website](http://www.niaid.nih.gov/research/cfar-site-contacts) for more information about available CFAR Core Resources. <https://www.niaid.nih.gov/research/cfar-site-contacts>

### Application Instructions

Applications should be prepared as a single PDF file, using the proper naming convention (e.g. first initial.lastname.cfar.mig.2017), and uploaded directly to: [upload.CFAR\\_Sm.wa5umi9g7e@u.box.com](mailto:upload.CFAR_Sm.wa5umi9g7e@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 MIG](#).

Applications must include the following elements (All PHS 398 forms are available [here](#))

**1) Completed CFAR MIG Checklist** ([MS Word](#))

**2) PHS 398 Form Page 1** (Face page) – Provide requested information in accordance with the PHS 398 application instructions. ([MS Word](#) [PDF](#))

**3) PHS 398 Form Page 2** Provide requested information in accordance with the PHS 398 application instructions ([MS Word](#) [PDF](#))

**4) A brief proposal** describing the request (with parts 4a and 4b **not exceeding three pages** in total), should include:



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- a. An introduction that clearly states the **scope of the overall request**, anticipated contribution to CFAR-MIG Scientific Areas of Interest, and how the project addresses the [NIH HIV/AIDS Research Priorities](#).
- b. The **research project plan** should include the background and rationale for the proposed application; a description of the activities to be undertaken; expected outcome of these activities; expected follow-up plan upon completion of the proposal; a description of how the award 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 proposal requests are expected to lead to development of the stated goals. Mentorship and collaborations must be explained.

**5) Budget PHS398 Form** ([MS Word](#) [PDF](#)) Include a justification that details the items requested, including Facilities and Administrative costs, as well as a justification for all personnel and their role(s) in this project. Note the budget should be appropriate for the work proposed in this request. **Applicants may request up to \$100,000 in total costs for 1 year.**

Restrictions: No travel is allowed and PI effort is capped at 5%.

- c. **Biographical Sketch** for all Senior/Key Personnel and for mentors. Use the new biosketch format located [here](#). Please note the personal statement should be related to the CFAR-MIG project.
- d. **Human Subjects/Vertebrate Animal documentation** (if applicable). Include a current Human Subjects/Institutional Review Board (IRB) or Vertebrate Animals/Institutional Animal Care and Use Committee (IACUC) approval date, if applicable. Otherwise, this information will be required at time of funding. All appropriate IRB and IACUC approvals must be in place prior to an award being made.

**NOTE:** Studies funding [clinical trials](#) are not allowed, however data analysis and use of archived samples from ongoing or completed clinical trials is permitted.

- e. **PHS 398 Checklist Form** ([MS Word](#) [PDF](#))
  - i. TYPE OF APPLICATION. Check NEW box;
  - ii. Applicants must state that all federal citations for PHS grants will be met (e.g., human subjects, animal welfare, data sharing, etc).
- f. NO other support.
- g. NO resource page (unless there are new resources that will be used for this request)
- h. NO appendices
- i. Submit a letter(s) of collaboration endorsing the proposed request from all substantial participants.
- j. Budget and Funding Information  
Funding will be supported by the CFAR NIH co-funding Institutes and NIDCR. **The maximum funding allowed per application is \$100,000 Total Cost.** The number of applications that will be funded for this announcement will be based on funding availability and scientific merit.



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### RFP Schedule

- Due Date for Proposals 11:59 PM (EDT) on October 1, 2017
- Application Review mid-October 2017
- Projected Award Date November 1, 2017
- Period of Award One year from award date\*

\*Any extension to this timeline must be approved by the CFAR MIG and will need to show clear progress on milestones at time of request.

### Conditions of Award

- ✓ CFAR Mucosal Immunology Group Awards provide funding for one year. (Any extension to this timeline must be approved by the CFAR MIG and will need to show clear progress on milestones at time of the request.)
- ✓ You will be required to submit an interim and final progress report to the Duke CFAR.
- ✓ You must acknowledge CFAR support in all publications and manuscripts derived from CFAR funding with the following language: "*This publication/presentation/grant proposal was made possible with help from the Duke University Center for AIDS Research (CFAR), an NIH funded program (5P30 AI064518).*"
- ✓ Prior to funding, you must forward a copy of all Institutional Biohazard, Animal Care and IRB approvals to the CFAR Administrator. If the project involves human subjects and the institutional IRB Committee has deemed the study "more than minimal risk", you must submit an Implementation Plan before funding is released. In addition, these studies and any study involving vulnerable populations will require a medical officer review before initiation.
- ✓ Successful applicants will be invited to attend MIG calls, webinars, and meetings.

### Review Process

Projects to be funded will be prioritized for scientific merit by decision of the CFAR MIG Scientific Review Committee (SRC). The SRC will be patterned after the successful HVTN MIG-SRC infrastructure that selected and shaped the eight collaborative projects originally funded by the 2009 and subsequent DAIDS supplements to establish the charter and ongoing HIV-MIG program.

Awardees will be notified in writing and be expected to begin the project immediately.



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## **Inquiries**

Prospective applicants are encouraged to send questions concerning the application or submission to [CFAR MIG](#)

## CFAR Mucosal Immunology Group Operating Committee Members

Kent Weinhold  
Director, Duke Center for AIDS Research

Georgia Tomaras  
Director, Immunology Core,  
Duke Center for AIDS Research

Sarah Mudrak  
Program Manager, Duke Center for AIDS Research, MIG Working Group

Mary Gross  
Program Manager, Fred Hutchinson Cancer Research Center, MIG Working Group

Mary Oris  
Administrator, Duke Center for AIDS Research

## **Co-funding partners for this opportunity**

- ❖ Office of AIDS Research (OAR)
- ❖ National Institute of Dental and Craniofacial Research (NIDCR)

The CFAR program emphasizes the importance of interdisciplinary collaboration, especially between basic and clinical investigators, translational research in which findings from the laboratory are brought to the clinic and vice versa, and an emphasis upon inclusion of minorities and of prevention and behavioral change research.