



HIV VACCINE  
TRIALS NETWORK

## HIV Mucosal Immunology Group



### Request for Proposals

The HIV Vaccine Trials Network Laboratory Center (HVTN LC), in collaboration with the National Institute of Allergy and Infectious Diseases/Division of AIDS, seeks to enhance and broaden the overall scientific scope of the HIV Mucosal Immunology Group (MIG). The MIG was established in 2009 by the HVTN LC under the scientific direction of Dr. Julie McElrath and focused on enhancing mucosal immunologic assessments in the setting of HIV clinical trials. Through the activities of three working groups--Gastrointestinal, Genitourinary, and Systems Biology—the MIG has identified and standardized optimal practices for the collection, storage, and analysis of mucosal specimens that are critical for the evaluation of HIV prevention or treatment modalities in clinical studies. The MIG continues to yield fruitful and collegial, cross-network research collaborations among a diverse group of immunologists, virologists, and clinical researchers.

Recent technologic advances and high dimensional analyses afford new opportunities to investigate HIV and host interactions in the mucosa, including specialized human studies into the local tissue immune environment and associated microbial communities. The integration of this knowledge contributed by different research and clinical disciplines can advance the goals of NIH-supported HIV vaccine, prevention and therapeutic clinical trial networks. This current Request for Proposals will build upon the accomplishments of the MIG by extending scientific participation and support primarily for innovative, hypothesis-generated and method development studies. **MIG awards will be granted for one year with maximum funding per application of up to \$90,000 in Total Costs (direct + indirect).** 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 directed 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 MIG:

- 1. Develop improved methodologies to interrogate and analyze the tissue microenvironment, mucosal fluids, and cellular and molecular interactions within human genital, oral, lung, and colorectal mucosa as these factors relate to HIV infection and/or immune responses to HIV.***
- 2. Develop and advance human mucosal tissue models that may more closely mimic HIV interactions in an intact mucosal environment and provide potentially more predictive value to better inform product decisions for multiple HIV preventive and therapeutic modalities.***
- 3. Evaluate the role of gut, oral, lung and genital microbiomes (bacteria, fungi, viruses) in modulating the effects of HIV prevention and therapeutic interventions, particularly vaccine-mediated responses, in mucosal tissues and fluids.***
- 4. Explore the dynamics of mucosal HIV 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.***

Although method development studies may require the use of relevant animal models for piloting initial experimental approaches, this funding opportunity is primarily intended for clinical studies and the use of human mucosal specimens. Therefore, research studies involving animal models should clearly define the translational relevance of the proposed model (and key limitations thereof) to human immunobiology, and if proposed, must represent a minor proportion of the studies and the funding request. Also, funding will not be awarded for costs associated with animal procurement or housing.

## Eligibility and Criteria

This application is open to all investigators eligible for NIH-funded awards. We strongly encourage early and mid-career investigators to apply.

Non-faculty applicants must have a faculty sponsor.

Successful applications will demonstrate the ability to make substantial progress on project research goals upon receipt of funds, if funds are awarded. Such demonstration should include detailed estimated project timelines and when appropriate, the availability of archived study samples or the existence of established processes to readily procure fresh mucosal samples, including current IRB approvals for use of human samples if required.

*Because of aggressive timelines for completion and longer federal approval timelines for foreign investigators/institutions, this funding opportunity is primarily intended for domestic research. Collaborations that involve foreign investigators with unique expertise in mucosal studies are eligible and will be considered only if the timeline requirements stated above are deemed feasible.*

## Application Components

Collaborations between investigators at different 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. For collaborative applications, the funding limit of \$90,000 (Total Costs) applies to total costs for combined budgets from all investigators/institutions seeking awards in the collaborative application.

## Application Instructions

Applications should be prepared as a single PDF file (please minimize absolute file size to 10MB or less), using the proper naming convention (e.g., first initial.lastname.mig2018). Upload applications directly to the MIG public website at: [HIV Mucosal Immunology Group](#). You should 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 [MIG2018-RFP](#).

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

### 1) Completed 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 research proposal** describing the request (with parts 4a and 4b **not exceeding three pages** in total length, excluding references) should include:

- a. An introduction that clearly states the **scope of the overall request**, anticipated contribution to 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 research proposed; a description of the activities to be undertaken in the form of specific aim(s) and estimated timeline with contingencies for their completion; 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; 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 application 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 \$90,000 in total costs for 1 year.**

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

**NOTE:** Applications that exceed the 3-page limit (Item 4a and 4b above) and/or exceed \$90,000 total costs in the budget (Item 5) will not be reviewed.

**6) 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 MIG project.

**7) 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.

**8) 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).

**9) NO** other support, resource page (unless there are new resources that will be used for this request), or appendices are required.

**10)** Submit letter(s) of collaboration endorsing the proposed studies from all substantive participants.

**11)** Include a signed institutional **Letter of Intent**. In order to issue sub-award(s), a separate LOI is required for each PI or co-PI on the application).

### **Budget and Funding Information**

Funding will be supported by NIAID. **The maximum funding allowed per application is \$90,000 Total Cost.** The number of applications that will be funded for this announcement will be based on funding availability and scientific merit.

## RFP Schedule

- Due Date for Proposals: 11:59 PM (EDT) on September 4, 2018
- Application Review Period: September 5 to mid-September 2018
- Review Comments Returned: ~October 1, 2018
- Projected Award Duration: Up to 1 year from date of award\*

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

## Conditions of Award

- ✓ Mucosal Immunology Group Awards provide funding for one year. (Any extension to this timeline must be approved by the MIG and NIAID will need to show clear progress on milestones at time of the request.)
- ✓ You will be required to submit an interim report (due mid-June, 2019) and final progress report to the MIG upon completion of the awarded activities.
- ✓ You must acknowledge HVTN MIG support in all publications and manuscripts derived from MIG funding with the following language: “*This publication/presentation/grant proposal was made possible with help from the HIV Vaccine Trials Network Mucosal Immunology Group Program, an NIH funded program (HVTN LC Grant UM1AI068618).*”
- ✓ Prior to funding, you must forward a copy of all Institutional Biohazard, Animal Care and IRB approvals to the MIG 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 HIV-MIG Scientific Review Committee (SRC).

All applicants will be notified in writing of SRC recommendations and if funds are awarded, successful applicants will be expected to begin the project immediately and make substantial progress on project research goals upon receipt of funds.

## Inquiries

Prospective applicants are encouraged to send questions concerning the application or submission to [MIG2018-RFP](#).

## Mucosal Immunology Group Operating Committee Members:

Julie McElrath  
PI and SRC-Chair  
Fred Hutchinson Cancer Research Center

Georgia Tomaras  
SRC Co-Chair  
Duke University

Mary Gross  
Sr Project Manager, Fred Hutchinson Cancer Research Center, MIG Program

Bonita Kroon  
Fiscal Manager, Fred Hutchinson Cancer Research Center, MIG Program

**Co-funding partner for this opportunity**

❖ ❖ National Institute of Allergy and Infectious Disease (NIAID)

The MIG 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 on prevention and behavioral change research.