Career Development Series 2025

R01-101: Reflections on My Experience with My First R01 Submission and Other Tips from a New Investigator

UNIVERSITY of WASHINGTON

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Seattle Children's®
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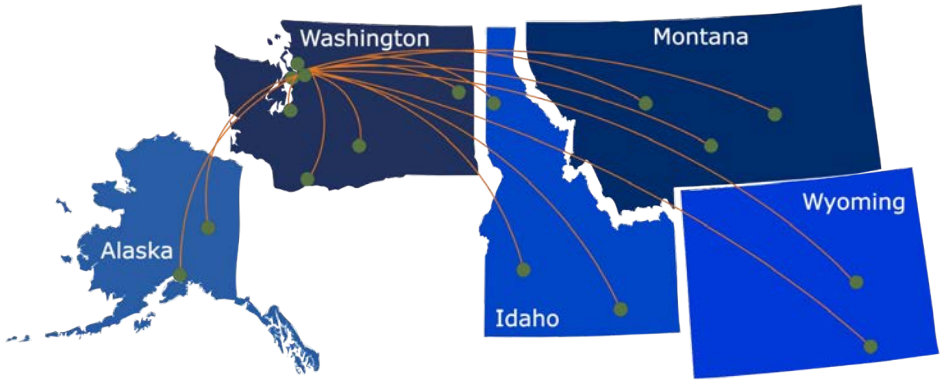


What We Offer:

1. **Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.

2. **Community Engagement:** Members can connect with regional and community based practice networks

3. **Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.

4. **Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

Contact ITHS

Director of Research Development

- Project Consultation
- Strategic Direction
- Resources and Networking

Melissa D. Vaught, Ph.D.
ithsnav@uw.edu
206.616.3875

Scientific Success Committee

- Clinical Trials Consulting
- Guidance on Study Design, Approach and Implementation
- Feedback on Design and Feasibility

https://www.iths.org/investigators/services/clinical-trials-consulting/

Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

Career Development Series 2025

R01-101: Reflections on My Experience with My First R01 Submission and Other Tips from a New Investigator

Presented by:
Germán Gornalusse, PhD, MS

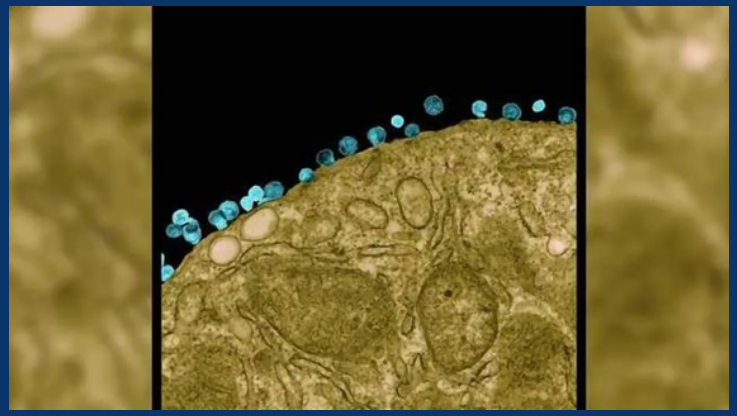
ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Learning Objectives

At the end of the session, participants will be able to:

1. Identify important information to gather before drafting the first R01 application
2. Acquire new tips on how to develop their own research projects and labs
3. Develop and maintain collegial relationships with collaborators and NIH officers to ensure a successful NIH application

R01-101: Reflections on my Experience with my First R01 Submission



Colorized transmission electron micrograph of human immunodeficiency virus (HIV) particles (blue) budding from the surface of a T cell.

Credit: Dourmashkin, Wellcome Images, Cell Image Library.

Emails: germag@uw.edu

ggornalu@fredhutch.org

Germán Gornalusse, PhD MSc

Research Assistant Professor

UW Department of Obstetrics and Gynecology

Adjunct Research Assistant Professor

UW Department of Global Health

Outline of Today's talk

- Who I am?
- What are my research interests?
- Why do I care about mentorship?
- Lessons learned through my Career Developmental Award KL2
- R01_101: Lessons learned while putting together my first R01
- A glimpse into one of my research projects

My Background

- **Argentinean** born and raised—small town outside Buenos Aires
- **First in my family** to complete a college (and doctoral) degree
- **First generation** of immigrant in the US—first one to become US Citizen
- Belong to **LGBTQIA+** community
- **Minority faculty** in UW ObGyn (**1**/89=1.12% of Hispanics when joined in 2017)
- My **two passions**: education (teaching) and finding a cure for HIV

My Journey from Argentina to the US

Seattle, WA, USA
-Second post-doc (2011-2016)
-Staff Scientist (2016-2017)

KL2
-Acting Instructor (2017-2021)
-Acting Assistant Professor (2021-2023)
-Research Assistant Professor (2023-current)
-Adjunct faculty, Ph.D. program in Pathobiology, UW Global Health (2024-current)

San Antonio, TX, USA
-Research Fellow (2002-2004)
-PhD (2004-2010)

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My (Main) Research Interests

We're building a better ClinicalTrials.gov. Check it out and tell us what you think!

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies | About Studies | Submit Studies | Resources | About Site | PRS Login

Home > Search Results > Study Record Detail

Save this study

Trial record **1 of 1** for: gornalusse

Previous Study | Return to List | Next Study

Comparing Immune Activation and Latent HIV Reservoir Size Between People Living With HIV on Tenofovir-containing Versus NRTI-free ART

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT05584397

Recruitment Status : Enrolling by invitation
First Posted : October 18, 2022
Last Update Posted : October 18, 2022

View this study on Beta.ClinicalTrials.gov

My (Main) Research Interests

2) HIV Reservoir and cure. Can immune factors (IL-10, IFNs) enhance HIV-specific responses and control the HIV reservoir?

PAR-23-275 NIAID and NIDDK Research Opportunities for New and "At-Risk" Investigators to Promote Workforce Diversity (R01 Clinical Trial Optional)

Date R01 submission: May 7, 2024. Role: Site PI (Collaboration with UCSF). 7% Percentile. ACTIVE

UW Medicine | Newsroom
News and information for journalists

NEWS ~ DIGITAL ASSETS ~ CONTACT SUBSCRIBE

/ Noteworthy / Tumor-fighting [...]

January 2, 2024

Tumor-fighting genes may diminish HIV reservoirs

Participants who had higher expression of tumor-fighting genes had lower levels of latent HIV, a study indicated.

Media Contact: Barbara Clements - 253-740-5043, bac60@uw.edu

SCIEPRO/Getty Images

Latest posts

January 25, 2024
10-paper series explores link between TBI, chronic pain

January 24, 2024
OB-GYN doc travels to White House to speak on HPV

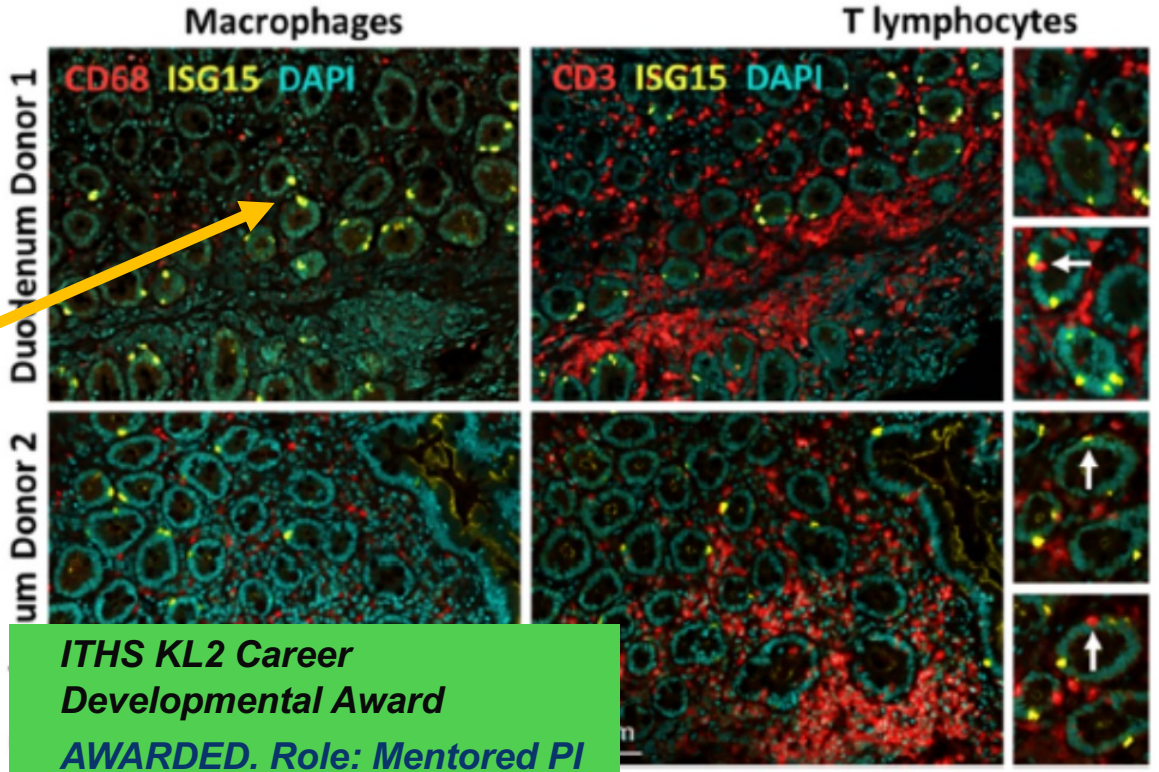
January 11, 2024
Concerned about asthma drug's side effects? Ask a doctor.

January 9, 2024
Distinguishing chronic cancer pain from end-of-life pain

My (Main) Research Interests

3) HIV-associated comorbidities. What are the mechanisms of HIV-associated chronic inflammation? What triggers it? Are all HIV meds equally responsible?

Cells in yellow have heightened immunological activity

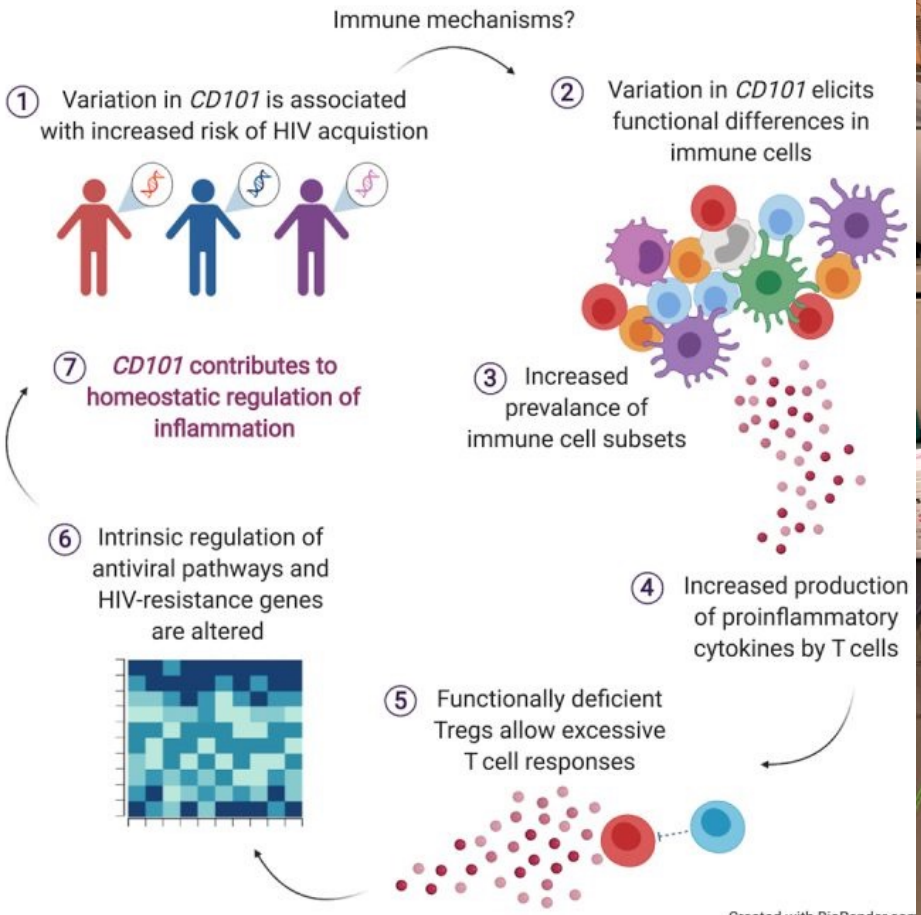


ROYALTY RESEARCH FUND
AWARDED. Role: PI
Application eGC1 number: A201152

ITHS KL2 Career Developmental Award
AWARDED. Role: Mentored PI
Completed on 02/29/24

My (Main) Research Interests

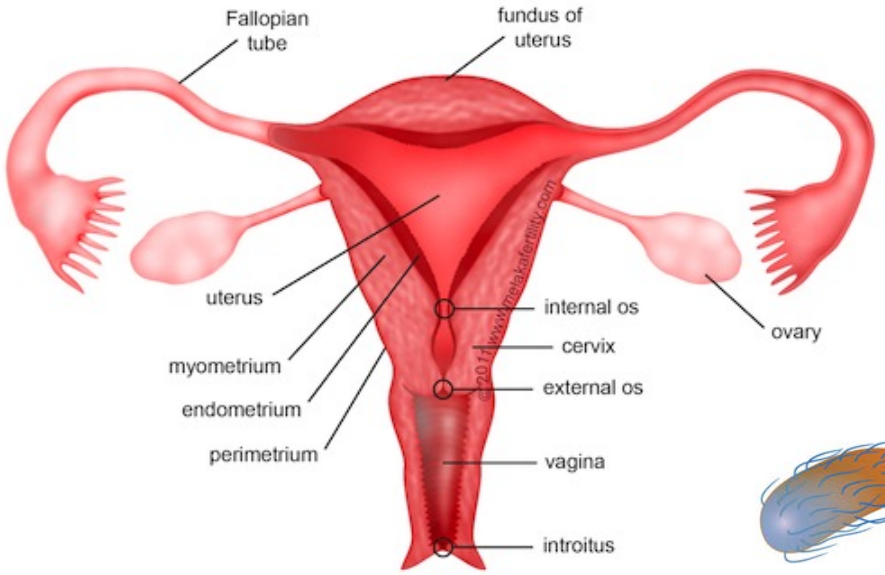
4) HIV-transmission. How genetic mutations in ***CD101*** locus influence both HIV acquisit

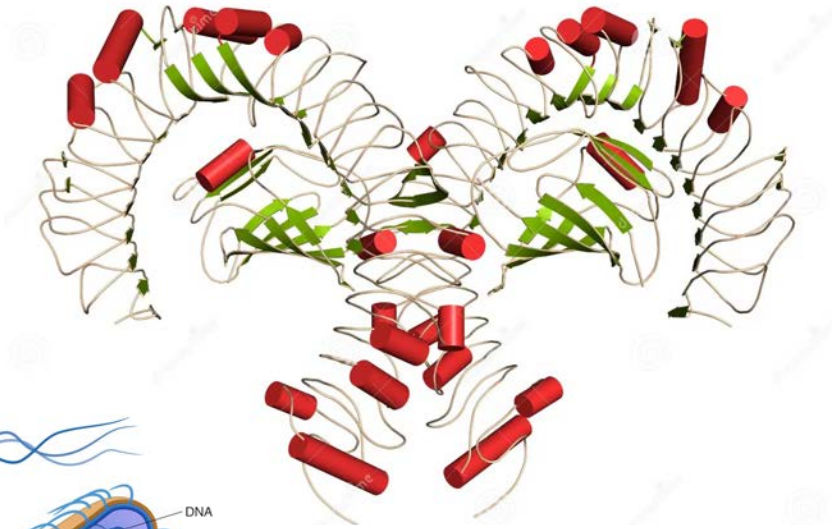


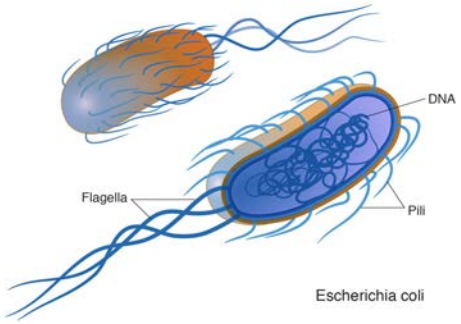
Dr. Maryam Kalatehjari

My (Main) Research Interests

5) Mucosal immunology. What does sTLR4 do in the female genital tract? (sTLR4 is a soluble molecule we recently discovered in secretions from the human cervical vaginal tract).







No grants yet

My (Main) Research Interests

6) Epigenetic studies and addiction to opioids and other illicit drugs. What are the long-term epigenetic modifications of chronic use of heroine and other drugs?

Molecular Human Reproduction, Vol.29, No.3, gaad003, 2023
Advance Access Publication on January 20, 2023 https://doi.org/10.1093/molehr/gaad003

molecular human reproduction

ORIGINAL RESEARCH

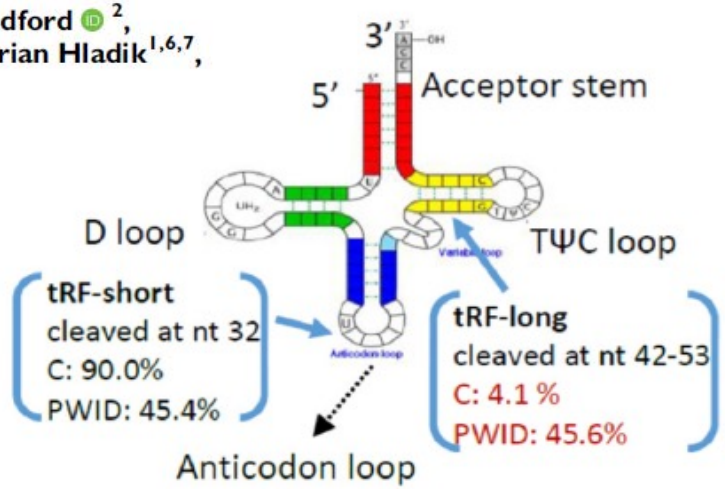
Men who inject opioids exhibit altere tRNA-Gly-GCC isoforms in semen

Germán Gornalusse [1], Ryan M. Spengler[2], Erin Sandford [2], Yeseul Kim[1], Claire Levy[1], Muneesh Tewari[2,3,4,5], Florian Hladik[1,6,7], and Lucia Voitech [1,*]

Alcohol and Drug Abuse Institute (ADAI) University of Washington, Pilot Grant

AWARDED (Role: PI)

Completed on 01/31/2022



My (Other) Research Interests

7) **Inflammation, STIs and HIV acquisition.** Ongoing project with Dr. Alison Roxby on markers of *Chlamydia/*HIV acquisition
8) **Water channels (AQPs: aquaporins), placental angiogenesis and preeclampsia.** Ongoing collaboration with University of Buenos Aires, Argentina.

BID PICT-2021-III-A-00085. Stress of syncytiotrophoblast in the pathophysiology of preeclampsia: Role of Aquaglyceroporins.
AWARDED (Role: International Co-I). Score: 94/100
01/01/2023-12/31/2026

9) **Tolerogenic effects of extracellular vesicles in human reproduction.** Co-Investigator in Dr. Vojtech's lab at UW ObGyn

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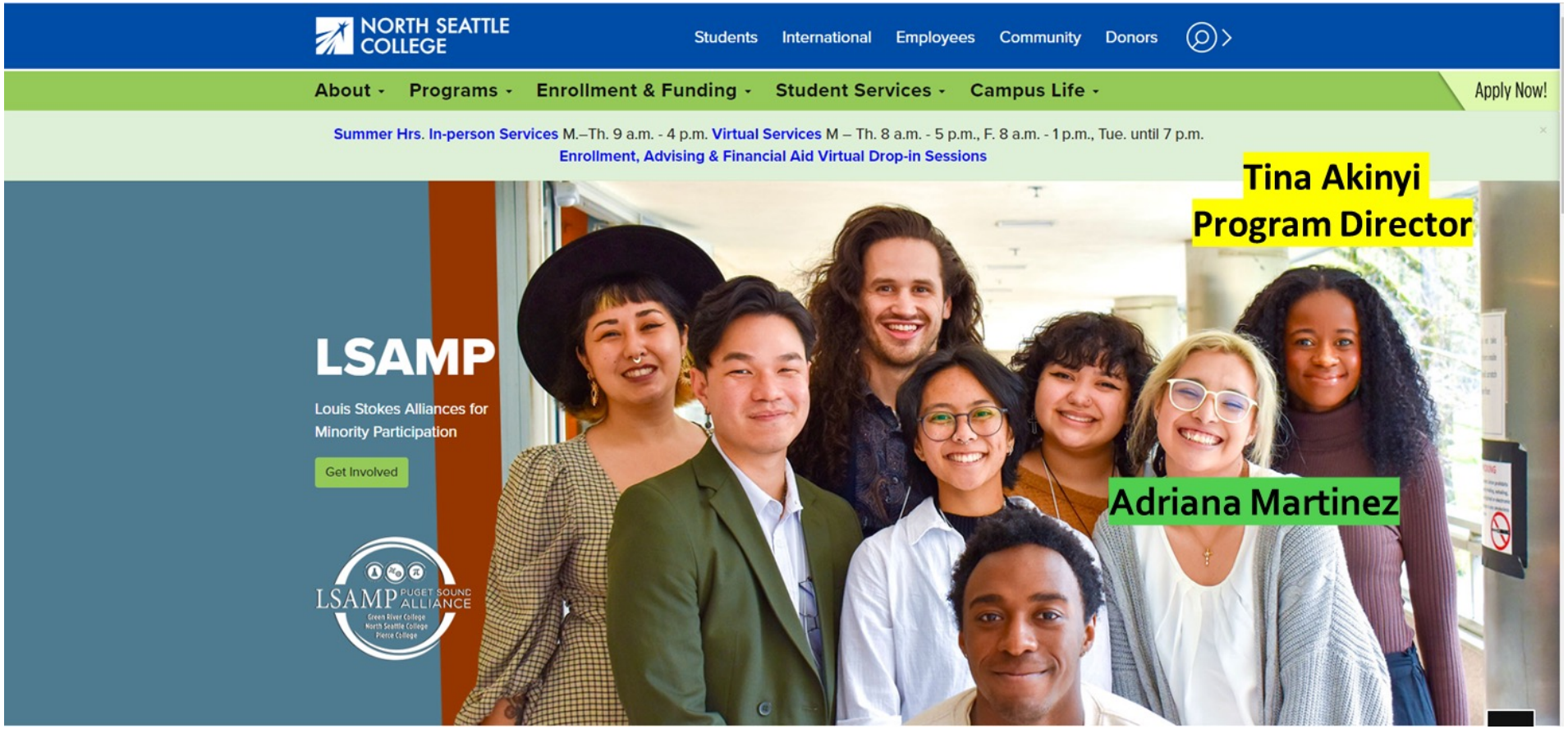
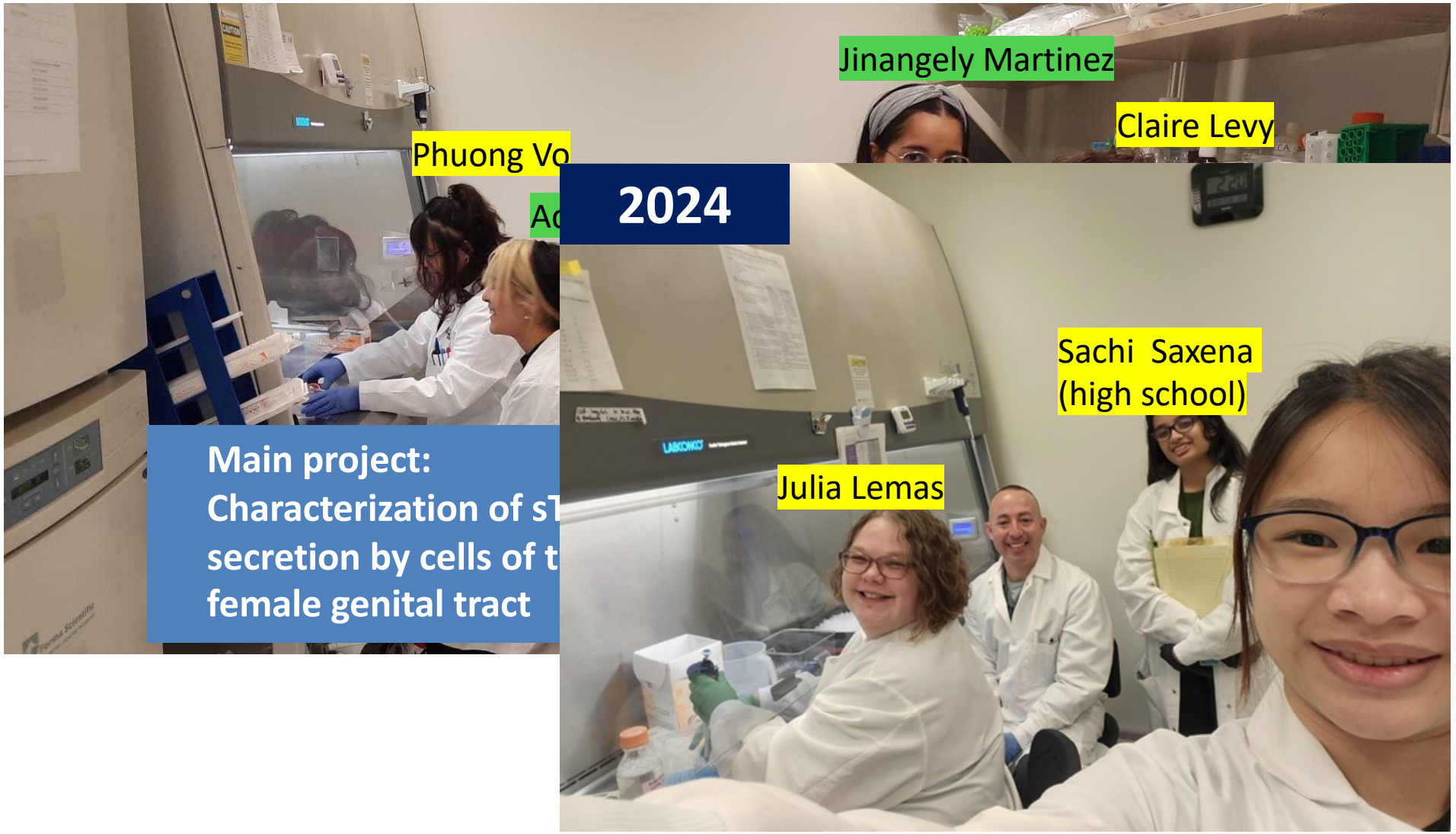
My Personal Core Value



Our LSAMP Experience 2023 and 2024



Bumps in the Road for URM Students

- Few opportunities in research labs
- URM students generally live far away to labs
- Many URM students have 2 jobs and *are students*
- Many URM students are on temporary visas and are away from their families→ Not eligible for many scholarships
- The COVID pandemic made their college lab trainings more scarce
- Fewer publications/research experience due to less time/funds to do internships→ Fewer fellowships → Fewer grants → Fewer URM faculty → Less science by URM!

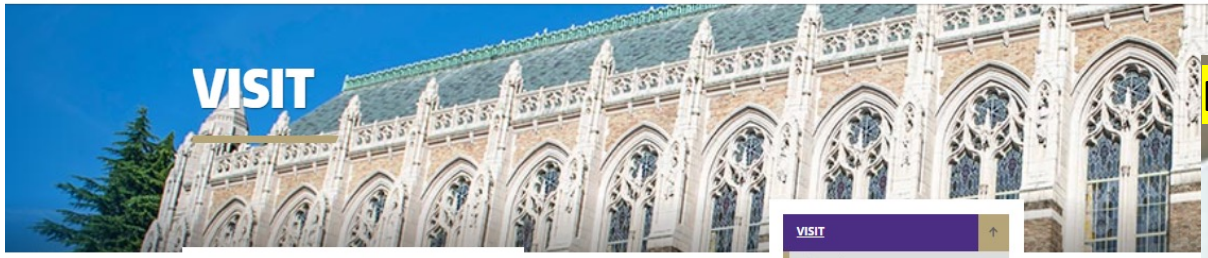
Fostering International Internships/Collaborations

ACCEPT

UNIVERSITY of WASHINGTON

Agents

ABOUT / PROGRAMS / LIFE AT THE UW / STUDENT SERVICES / CONTACT US



Programs › Research Programs › VISIT › Overview

VISIT

- Overview
- Program Details
- How to Apply

Overview

The Visiting International Student Internship & Training (VISIT) program at the University of Washington allows students who are pursuing degrees at universities outside of the United States to participate in full-time, work-based supervised research at the University of Washington.

LENGTH	SCHEDULE	ENGLISH LEVEL	F-1 VISA
3 Weeks–1 Year	Varies 32 Hours/Week	Advanced	Not Eligible

UPCOMING SESSIONS

Winter 2022
Jan 3–Mar 27

Spring 2022
Mar 28–Jun 20

The entire application process takes three to five months. The application is due to the VISIT office from host departments no later than 12 weeks before a student's start date.

APPLY NOW

Dr. Julieta Reppetti

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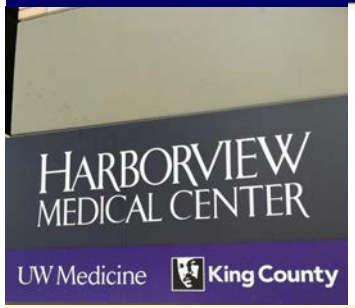
Lesson Learned # 1: Translational Research



UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION

Participant NRTI-5

01/20/2023 03:02 — UNIVERSITY OF WASHINGTON MEDICAL CENTER INCLUDING LABORATORIES AT UWMC, HMC, FHCC — CUMULATIVE SUMMARY

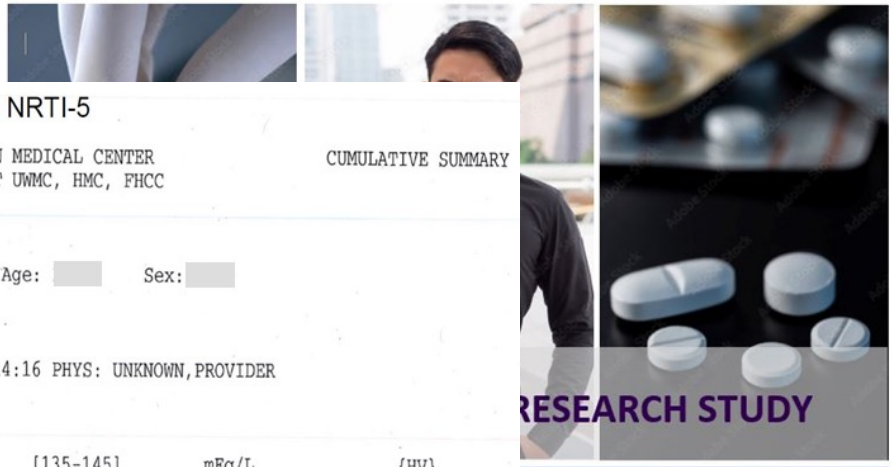
Name: ,NRTI FREE
UWMC Pt #: Loc: RTS Age: Sex:
Acct:

T2641322 COLL: 01/17/2023 11:15 REC: 01/17/2023 14:16 PHYS: UNKNOWN,PROVIDER

Renal Function Panel

Sodium	136	[135-145]	mEq/L	{HV}
Potassium	* **3.4**	[3.6-5.2]	mEq/L	{HV}
Chloride	105	[98-108]	mEq/L	{HV}
Carbon Dioxide, Total	25	[22-32]	mEq/L	{HV}
Anion Gap	6	[4-12]		{HV}
Glucose	76	[62-125]	mg/dL	{HV}
Urea Nitrogen	14	[8-21]	mg/dL	{HV}
Creatinine	0.67	[0.20-1.10]	mg/dL	{HV}
Albumin	3.9	[3.5-5.2]	g/dL	{HV}
Calcium	8.9	[8.9-10.2]	mg/dL	{HV}
Phosphate	* **2.7**	[4.5-6.0]	mg/dL	{HV}
eGFR by CKD EPI 2021			mL/min/1.73_m2	{HV}

Not reported for research locations.



...ications can
... reservoir

...nd whether HIV medications
...ne ("your gut") and affect the
... with HIV.

... same antiretroviral therapy

... Medical Center, (1) general
...2) endoscopy and biopsies in

The safety and scientific validity of this ... study does not mean it has been evaluated by the U.S. Fede...

Service Agreement Contact Information: Kelly Gilmore, kellyg18@uw.edu
RE: Research Coordination Center (RCC) Price Quote for Services

Description of project: German Gornalusse, PhD is requesting support for the research project titled, "Comparing immune activation and latent HIV reservoir size between people living with HIV (PWH) on tenofovir-containing versus NRTI-sparing ART." The CTO Research Coordination Center will provide research coordinator services in support of this project. The assigned research coordinator is responsible for the following:

- Initial screening of patients from list provided
- Coordinate lab specimens
- Assist with study visits
- Distribute and manage compensation
- Manage patients in Clinical Trials Management System

Lesson Learned # 2: NIH Grantsmanship

Contact PD/PI: Gornalusse, German Gustavo

SPECIFIC AIMS

Except for a few isolated cases, HIV infection has neve
host genome ('provirus') and escape from antiretrovira
some of these HIV-harboring cells, HIV persists despit
in some latently infected cells leads to rebound viremia
harboring cells and trigger proviral reactivation remain u

We summarize below the scientific premise underlyin
hyperactive microfold or M cells in the gut create a n
infected bystander CD4⁺ T cells, sporadic HIV react

- Non-human primate studies, autopsies, and clinical
up to 98% of the HIV reservoir and that its immu
reactivation.[3-5] This astonishing anatomical skew of th
the number of latently infected cells and/or preve
major step toward curing HIV. This grant will contri
- We found that **the epithelium of the intestinal**
extremely high levels of type I/III interferon-stim
described by others.[1,8] Notably, this ISG expression a
and also does not coincide with IFN expression by th
these enterocytes are microfold cells (**M cells**),[7] wh
pathogens.[9,10] M cells are ~10% of all enterocytes, b
- **Type I/III IFN pathway stimulation promotes T cell**
bystander T cell proliferation *in vivo*,[12] which likely
reservoir maintenance.[14-16] In addition, IFN-α efficier
in vitro and *ex vivo*.[17] Further, elegant humanized m
blocking type I interferon (IFN-α & -β) signaling (whic
restores T cell function, and reduces the size of the H

Thus, (a) a subpopulation of specialized enterocytes in
and (b) type I IFN signaling supports HIV reservoir
reactivation. The **conceptual innovation of our prop**
role for M cells in HIV latency and/or post-ART viral r
studies of mucosal GI tissues, including tissues from pe
cultures to model and manipulate their effect on HIV lat

Specific Aim 1. Test the hypothesis that interaction
activation and clonality of bystander CD4⁺ T cells. W
in duodenal and rectal tissues from 10 HIV-uninfecte
(source: NCT05584397, PI Dr. Gornalusse; see Aim 2)
will compare CD4⁺ T cells and macrophages located in
located elsewhere in the mucosa. Similarly, we will com
the gut mucosa using the NanoString TCR Profiling Pa

Specific Aim 2. Test the hypothesis that T cells/ma
more frequent in the vicinity of M cells and exhibit
rectal biopsies from a clinical trial of 40 PLH on ART (
copies by digital PCR. In the 10 PLH with the highest tis
relationship of HIV-1 DNA⁺ and mRNA⁺ cells with ISG^high
to Aim 1 CosMx studies, we can also compare the cell
PLH, we will also correlate immune gene expression (b

Specific Aim 3. Use *in vitro* models to test the hypo
reactivation via their increased activity of type I/III IF
the effect of M cells on CD4⁺ T cells latently infected

SUMMARY STATEMENT

PROGRAM CONTACT: Diane Lawrence, 240-627-3202, diane.lawrence2@nih.gov
(Privileged Communication)
Release Date: 12/01/2023
Revised Date:

Application Number: 1R01AI184122-01

Principal Investigator

GORNALUSSE, GERMAN GUSTAVO

Applicant Organization: UNIVERSITY OF WASHINGTON

Review Group:	**HIVD** **HIV Immunopathogenesis and Vaccine Development Study Section** **AIDS**
Meeting Date:	**11/15/2023**
Council:	**JAN 2024**
Requested Start:	**04/01/2024**
Opportunity Number:	**PAR-22-241**
PCC:	**A26D**

Project Title:	**Role of intestinal microfold (M) cells in creating a hotspot environment for HIV reservoir persistence and reactivation**
SRG Action:	**Impact Score:36 Percentile:24**
Next Steps:	**Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects:	**30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects:	**10-No live vertebrate animals involved for competing appl.**
Gender:	**1A-Both genders, scientifically acceptable**
Minority:	**1A-Minorities and non-minorities, scientifically acceptable**
Age:	**3A-No children included, scientifically acceptable**

Project Year	Direct Costs Requested	Estimated Total Cost
1	476,868	830,686
2	476,426	829,916
3	490,359	854,186
4	462,852	806,270
5	463,705	807,756
TOTAL	2,370,210	4,128,814

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.
NEW INVESTIGATOR

M) cells in creating a hotspot environment for HIV tion	
	Council: 01/2024
tunities for New and "At-Risk" Investigators to Clinical Trial Optional)	
	Accession Number: 4873954
/ASHINGTON	
cology	
	Expedited: N
	New Investigator: Y Early Stage Investigator: N
	Role Category:
	PD/PI
	Co-Investigator
	Co-Investigator
	Co-Investigator
	Co-Investigator
	Co-Investigator

Lesson Learned # 3: Lab Management

The Full House

Lesson Learned # 4: Successful Collaborations

PLOS PATHOGENS

PLoS Pathog 19(11): e1011114. https://doi.org/10.1371/journal.ppat.1011114

Editor: Guido Silvestri, Emory University, UNITED STATES

Received: January 11, 2023

Accepted: November 1, 2023

Published: November 29, 2023

RESEARCH ARTICLE

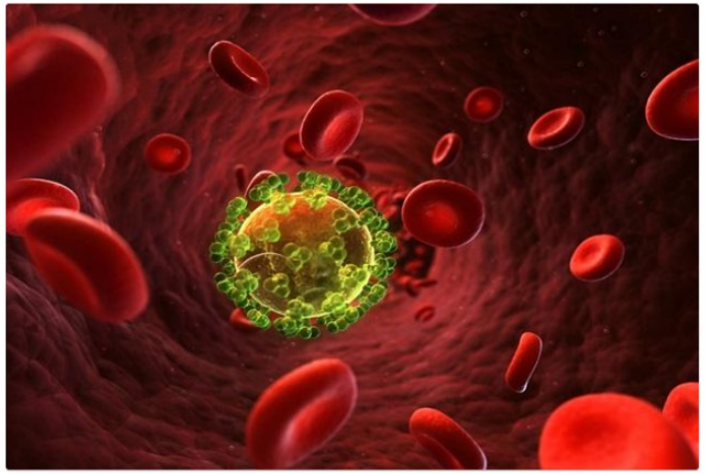
A cohort-based study of host gene expression: tumor suppressor and innate immune/inflammatory pathways associated with the HIV reservoir size

January 2, 2024

Tumor-fighting genes may diminish HIV reservoirs

Participants who had higher expression of tumor-fighting genes had lower levels of latent HIV, a study indicated.

Media Contact: Barbara Clements - 253-740-5043, bac60@uw.edu



SCIEPRO/Getty Images

Latest posts

January 25, 2024
10-paper series explores link between TBI, chronic pain

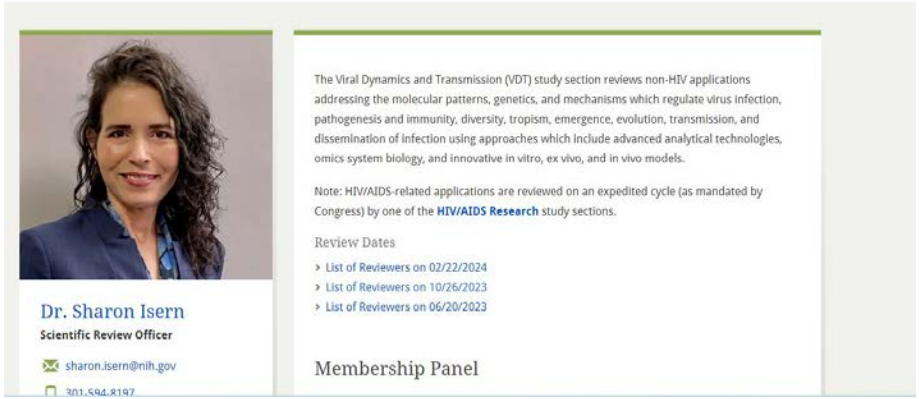
January 24, 2024
OB-GYN doc travels to White House to speak on HPV

January 11, 2024
Concerned about asthma drug's side effects? Ask a doctor.

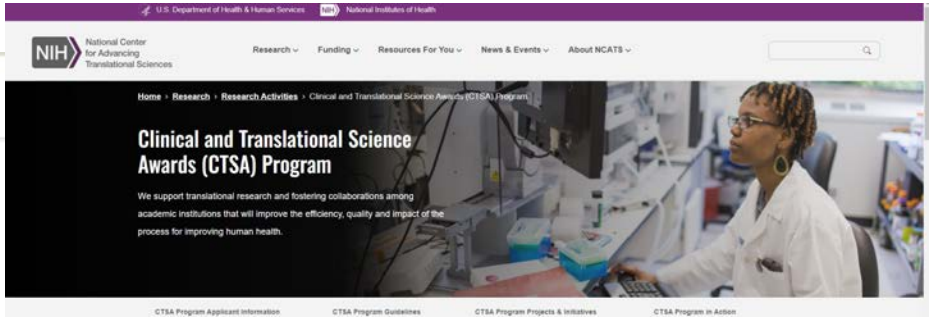
January 9, 2024
Distinguishing chronic cancer pain from end-of-life pain

Lesson Learned # 5: Interactions with NIH

Early Career Reviewer (ECR)



Spring CTSA Meeting (from NCATS)



NIAID Program Officer

Lesson Learned #6: Networking at Conferences

Meet potential NIH study section members

Potential references for promotion to Associate Professor

Advice from my Experience as a New Investigator

Early Stage Investigator (ESI) Policies

An ESI is a Program Director/Principal Investigator who has completed their terminal research degree or end of post-graduate clinical training, whichever is later, within the past 10 years and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award. Read on to learn about NIH policies and how NIH support for ESIs helps promote the growth, stability, and diversity of the future biomedical research workforce.

ESI Infographics	Early Stage Investigator Status Infographic	
Early Stage Investigator	A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award. See our list of NIH grants that a PD/PI can hold and still be considered an ESI.	R01-equivalent ESI applications with meritorious scores will be prioritized for funding.
New Investigator	A New Investigator (NI) has not previously competed successfully for a Substantial research grants from NIH.	NIH Institutes and Centers

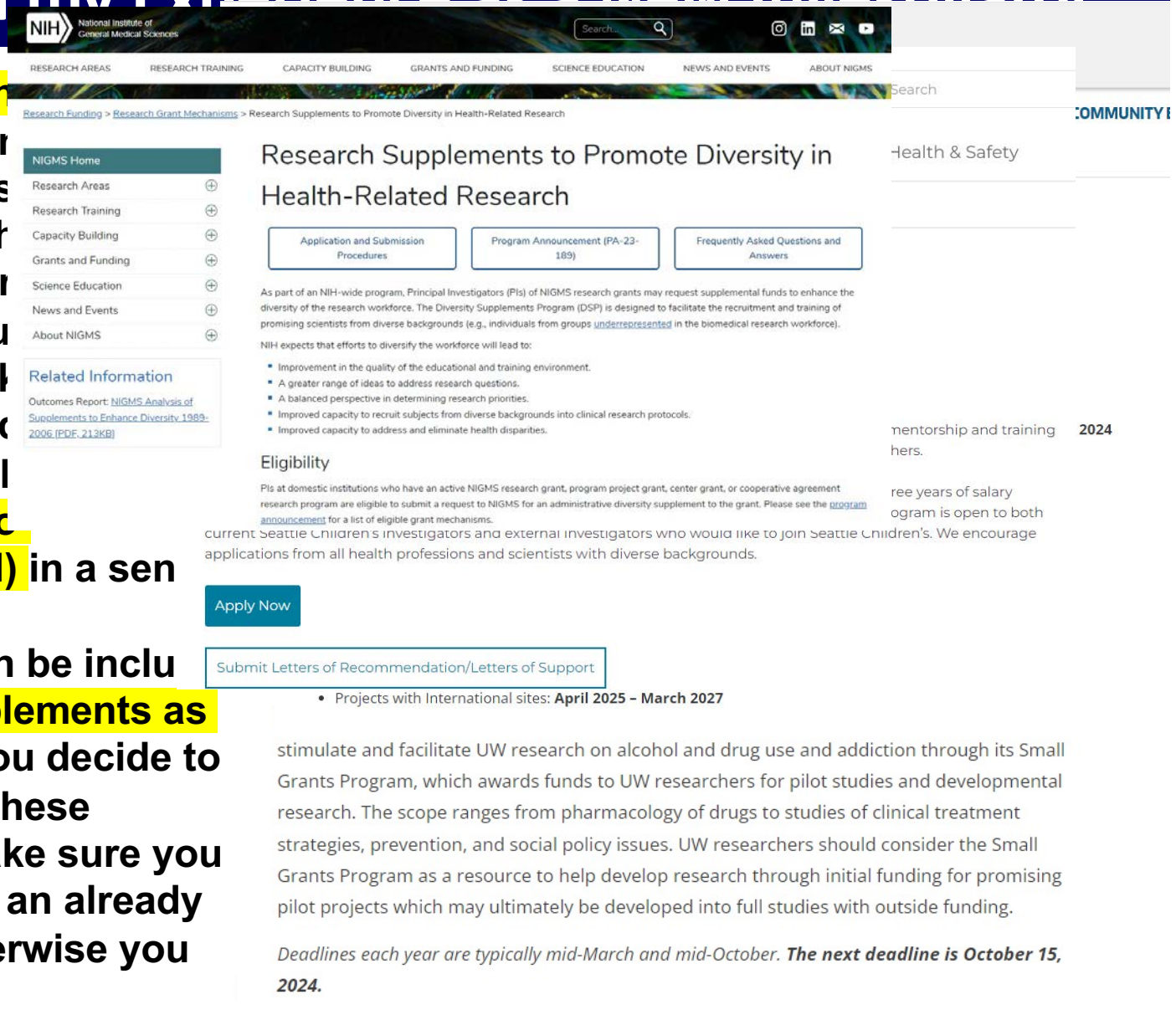
Got an early stage investigator policy question? I'll help get you to a related FAQ. I [illegible], but I'm [illegible]

Use your ESI/NI status as a PI for a R01! Don't waste your calories in a R21!

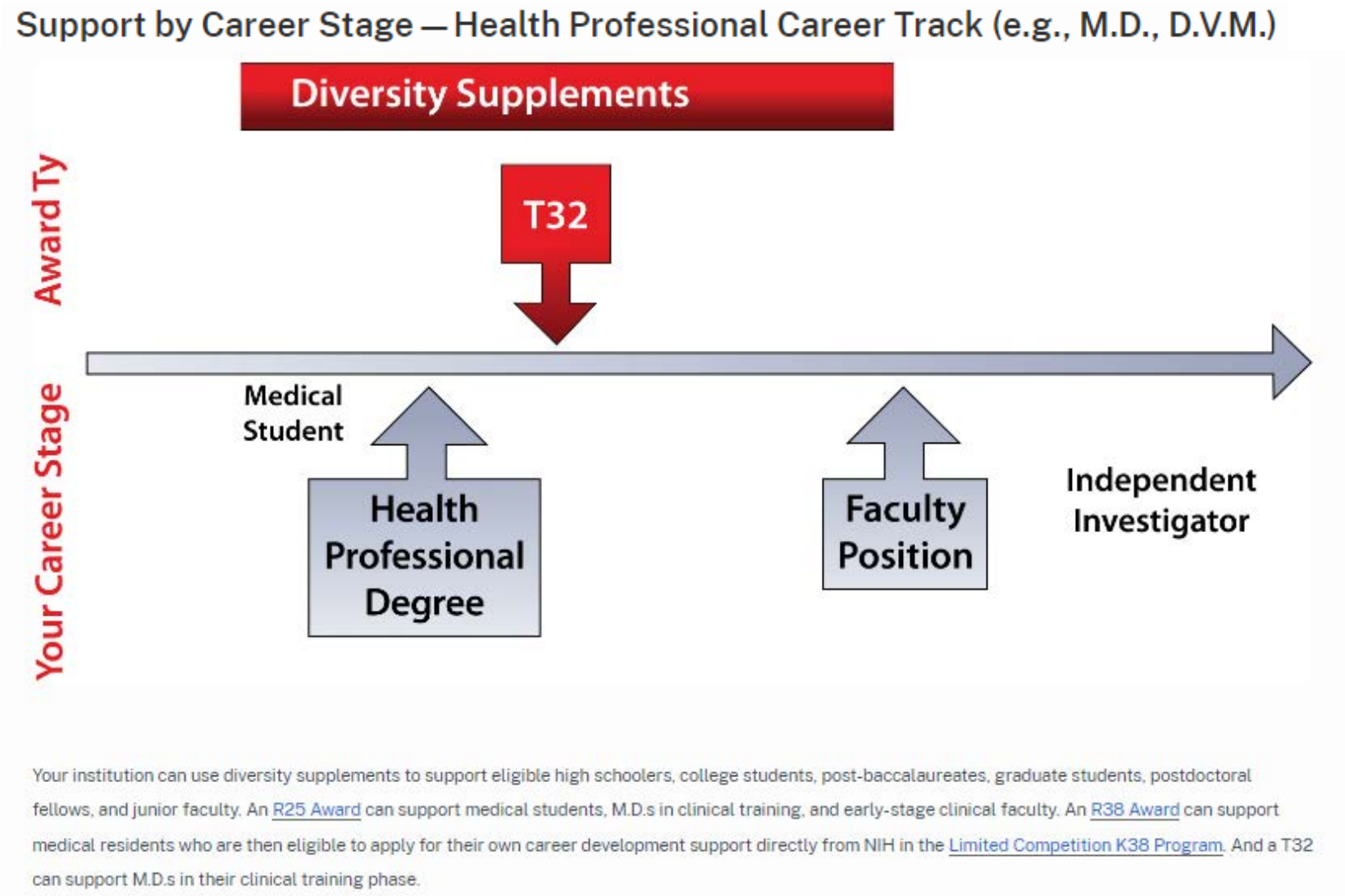
https://grants.nih.gov/policy-and-compliance/policy-topics/early-stage-investigators

Advice from my Experience as a New Investigator

- ✓ **Diversify your fun portfolio. Don't ur foundation grants CFAR, Fred Hutch Children's Resear etc.) because you demonstrate PI sk**
- ✓ **If you are not reac your first R01 as I be included as Co Investigator (Co-I) in a sen PI's grant.**
- ✓ **For URM, you can be inclu in Diversity Supplements as mentored PI. If you decide to apply for one of these supplements, make sure you don't get paid by an already existing R01 otherwise you won't be eligible!**



Advice from my Experience as a New Investigator



https://www.niaid.nih.gov/grants-contracts/choose-award-career-stage

Advice from my Experience as a New Investigator

- ✓ If you are doing clinical studies/trials, make sure you have a fluent communication with both IRB and Research Coordinator. Start early thinking about the billing process. Think about broader ways of recruitment study participants (it is OK to include digital media platforms if the IRB approves them!).
- ✓ For patients/participants' recruitment, a good source of resources (websites, research coordinators, power stats for studies) is UW ITHS.
- ✓ Develop a good relationship with your Program Officer. Try to meet with your PO periodically and ask for advice on Specific Aims and Notice of Funding Opportunities (NOFO's). Look for URM NOFOs.
- ✓ Seize your benefit/effort ratio in each collaboration. Authorship? Opportunities for future MPI, Co-PI grants? (Don't lose your niche).
- ✓ Look for opportunities to share your research. Oral presentations? Invitations to external institutions/networks?
- ✓ Mentorship is not linear. Take advantage of non-conventional mentors. Many times, a senior collaborator can "operate" as a non-direct mentor! Their Letters of Support will be helpful for promotion to Associate Professor!
- ✓ Know the structure of your supporting personnel of your department. They may save you time sharing some docs (budgets, human subjects, etc.)

Outline of Today's talk

- Who I am?
- What are my research interests?
- Why do I care about mentorship?
- Lessons learned through my Career Developmental Award KL2
- R01_101: Lessons learned while putting together my first R01

Tips for R01 Submissions—Think before applying

✓ **For funding, search for NOFOs that are tailored for URMs**

Department of Health and Human Services

Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Underrepresented Populations in the U.S. Biomedical, Clinical, Behavioral and Social Sciences Research Enterprise

7. Grew up in one of the following areas: a) a U.S. rural area, as designated by the Health Resources and Services Administration (HRSA) Rural Health Grants Eligibility Analyzer (https://data.hrsa.gov/tools/rural-health), or b) a Centers for Medicare and Medicaid Services-designated Low-Income and Health Professional Shortage Areas (https://www.qhpcertification.cms.gov/s/LowIncomeandHPSAZipCodeListingPY2020.xlsx?v=1) (qualifying zip codes are included in the file). Only one of the two possibilities in #7 can be used as a criterion for the disadvantaged background definition.

Students from low socioeconomic (SES) status backgrounds have been shown to obtain bachelor's and advanced degrees at significantly lower rates than students from middle and high SES groups (see ***https://nces.ed.gov/programs/coe/#indicators),*** and are subsequently less likely to be; represented in biomedical research. For background see Department of Education data at, https://nces.ed.gov/ ; ***https://nces.ed.gov/programs/coe/#indicators ;*** https://www2.ed.gov/rschstat/research/pubs/advancing-diversity-inclusion.pdf .

All other aspects of the NOFO remain unchanged.

Activity Code	R01 Research Project Grant
Announcement Type	Reissue of PAR-22-241
Related Notices	See Notices of Special Interest associated with this funding opportunity • **July 8, 2024** - NIAID and NIDDK Research Opportunities for New and "At-Risk" Investigators to Promote Workforce Diversity (R01 Clinical Trial Optional). See Notice NOT-AI-24-063. • **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198. • **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189.

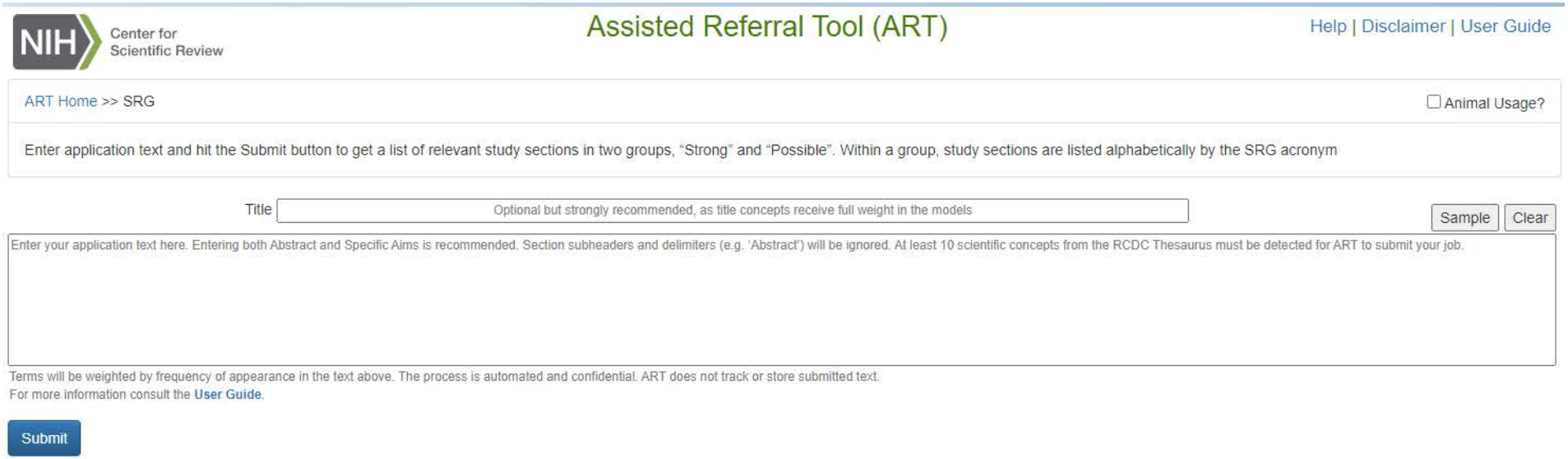
Example: https://grants.nih.gov/grants/guide/pa-files/PAR-23-275.html

Tips for R01 Submissions—Think before applying

- ✓ **Start early (~1-1.5 year) about which project you can transform into an R01. Can you use some of the samples or resources you will have achieved during your K/T training or as your tenure as junior faculty?**
- ✓ **Think BIG but also think about feasibility. Are the experiments/study proposed doable? Will you have enough enrollment? Is your area of expertise aligned with the R01?**
- ✓ **If there is a topic in your grant that you do not have too much experience, add a collaborator as co-I and get a Letter of Support.**
- ✓ **Sign up to be included in the listserv of NIH specific institutes…they keep you posted on updated NOFOs.**
- ✓ **Draft the Specific Aims page early (~6 months). Make sure your aims are both significant and innovative (*conceptual* innovation is good too!).**
  Get feedback beyond your "comfort zone" circle. For example, submit your draft to different "mock study sections" or interdisciplinary teams.
- ✓ **Keep your niche. Don't dilute your ideas across your collaborators' ideas (especially if you work with more senior faculty as co-Investigators!).**
- ✓ **Use as templates grants that have been successfully funded. Your department as well as the institutions that are supporting your career development awards (Ks, Ts, etc.) always have good examples!**

Tips for R01 Submissions—Think before applying

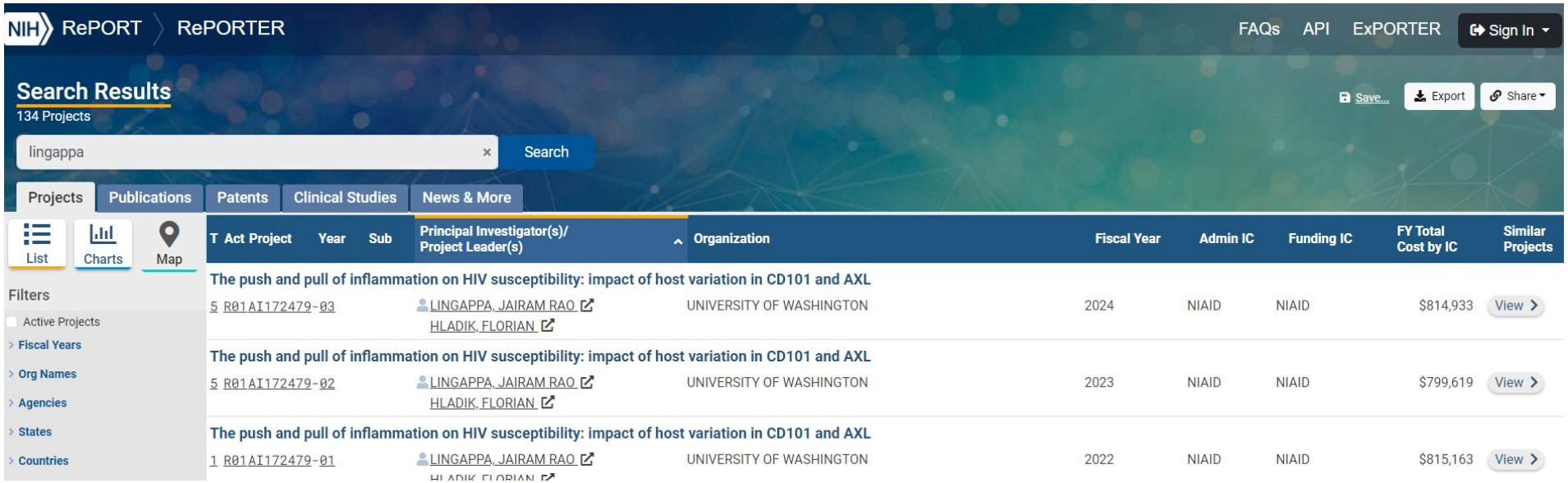
- ✓ **Use CSR's Assisted Referral Tool (ART) to match your abstract or specific aims to a study section/scientific review group.**



https://public.csr.nih.gov/ForApplicants/PlanningAndWriting/TargetYourApplication

Tips for R01 Submissions—Think before applying

- ✓ **Use NIH/eRePORTER to locate funded applications in your field and know about: 1) NIH institutes; 2) Study sections 3) Program Officers (POs)**



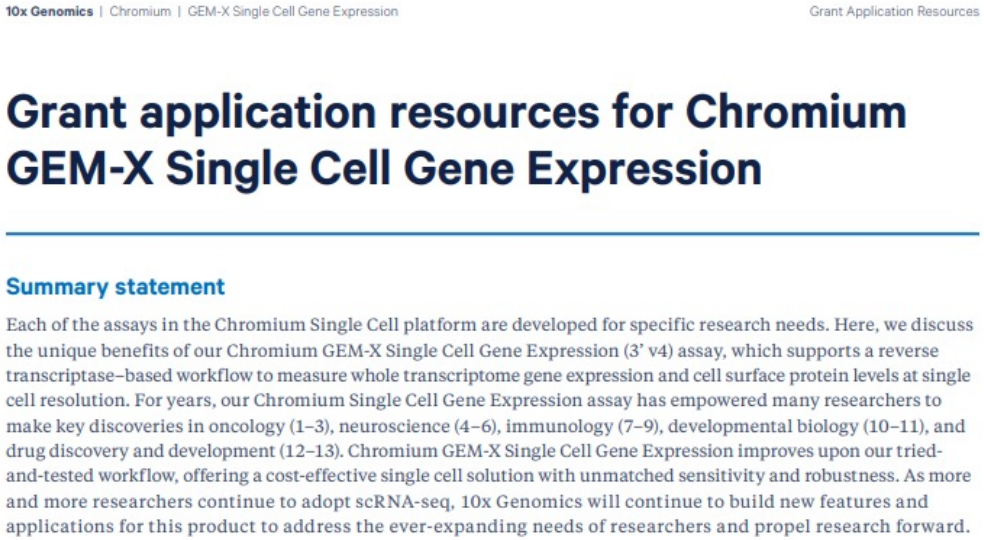
https://reporter.nih.gov/

Tips for R01 Submissions—Application itself

- ✓ **Make sure your Aims are focused and not dependent on each others' susccess! Add power analysis, expected results, caveats/limitations, alternative approaches.**
- ✓ **Clarity is KEY. I recommend adding a unifying figure wherein the aims are graphically depicted.**
- ✓ **Add summary sections. The most important one is Summary of Significance. You need to be explicit and explain how the field is going to move after you accomplish what you propose (even if the hypotheses are wrong).**
- ✓ **Spend lots of time in the Significance. Try to show clinical relevance, if you can. Are the aims mechanistic and focus or diffuse? Can you think other areas of applicability beyond your scope? Tip here: get advice from someone whose professional degree (or faculty track) complements yours (MD from PhD and vice versa). If you spend too much time, write a review!**
- ✓ **Look for "loose ends" in published papers or reviews. Keep up with updated literature! Revise your papers between initial submission and resubmissions. Not too many abbreviations.**
- ✓ **If possible, try to learn a state-of-the art technique while acquiring preliminary data.**
- ✓ **Don't be shy and quote your Preprints (e.g., BioRx, MedRxIV, etc.) and conference abstracts as references. Stick strictly with formatting rules!**

Tips for R01 Submissions—Application itself

- ✓ **For Approach part of your R01, if you are not very familiar with the technology or platforms, get support from companies' resources. (Sometimes, they can offer a signed Letter of Support)**



Tips for R01 Submissions—Application itself

- ✓ **As new Investigator/Early-Stage Investigator (NI/ESI), get a good Letter of Support from your mentor & Chair, highlighting leadership and potential for independence.**
- ✓ **Spend enough time writing your Part A (Personal Statement) of your NIH Biosketch. Show leadership skills t**

In my first submission, my

In my most recent R01, those skills moved up!

Contact PD/PI: Gornalusse, German Gustavo

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **GORNALUSSE, GERMÁN GUSTAVO**

eRA COMMONS USER NAME (credential, e.g., agency login): **GERMAG**

POSITION TITLE: **ACTING ASSISTANT PROFESSOR**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Buenos Aires, and Biochemistry, Buenos A			
University of Texas Health S Antonio, San Antonio, Texa			
University of Texas Health Science Center at San Antonio, San Antonio, Texas, USA	Postdoctoral	04/2011	Microbiology and Immunology
University of Washington, Seattle, Washington, USA	Postdoctoral	09/2016	Hematology (Gene Therapy)

(*) This degree is akin to a U.S. Master's in Science (6-year program). Graduated with Honor Diploma.

A. Personal Statement

As a biochemistry student and as part of the Argentinean certification, I rotated in the Department/Infectious Disease Division in the Hospital de Clínicas, Buenos Aires, Argentina. There, many of my interactions were with HIV-positive newborns and their mothers, and from this experience, I gained a keen interest in learning to understand the host determinants of HIV-1/AIDS pathogenesis. Due to the 2002 socioeconomic crisis in Argentina, I had to interrupt my Ph.D. graduate studies and pursued a career outside of my country.

In terms of my background I self-identify as an Underrepresented Minority (URM) scientist. I am a first-generation immigrant in the US and became a US Permanent Resident in 2016 and a US citizen in 2020. I am the first member in my family to complete a college (and doctoral) degree; none of my parents completed a Bachelor's degree program in Argentina. Additionally, I grew up in a small town outside Buenos Aires city, akin to the ones described for individuals with disadvantaged background in America.

At the end of 2002, I was recruited by Dr. Sunil Ahuja at the University of Texas Health Science Center, San Antonio, Texas (UTHSCSA). I worked as Research Fellow until August 2004, when I was accepted into the PhD program in Microbiology and Immunology at UTHSCSA, which I completed in August 2010.

During my graduate studies, I was particularly interested in understanding the role of epigenetic mechanisms, mainly DNA methylation, in the regulation of the expression of CCR5, which is the main HIV-1 co-receptor. Up to the early 2000s, most studies had focused on epigenetic regulation of cancer-related genes, whereas very few papers had studied epigenetic regulation of immune related genes; so, our work was pioneering for the HIV/AIDS field. In our *PNAS* paper, we shed light on some long-standing conundrums in the field. For example, our work explained why levels of CCR5 differ dramatically across different individuals despite bearing identical functional CCR5 sequences and why some subjects fail to upregulate CCR5 upon T cell activation, conferring them a "protective trait" against HIV-1 infection.

While working on my PhD in Dr. Ahuja's lab, I also became interested in understanding the genetic complexity of genes encoding β-chemokines. One of my research passions is to link epigenetic mechanisms with genetics and environmental stimuli (e.g., how other STDs impinge on the epigenetic landscape of CCR5).

Biosketches Page 35

Contact PD/P

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INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Buenos Aires, School of Pharmacy and Biochemistry, Buenos Aires, Argentina	Biochemist (*)	10/2001	Biochemistry
University of Texas Health Science Center at San Antonio, San Antonio, Texas, USA	PhD	08/2010	Microbiology and Immunology
University of Texas Health Science Center at San	Postdoctoral	04/2011	Microbiology and

(*) This degree is akin to a U.S. Master's in Science (6-year program). Graduated with Honor Diploma.

A. Personal Statement

I am an Assistant Professor in the Department of Obstetrics and Gynecology at the University of Washington. I will be able to apply my expertise in genomics and mucosal immunology to the HIV/AIDS field, and in particular, to the proposed R01 application. My long-standing interest is to develop novel strategies to interfere with the HIV reservoir and potentially to be able to eradicate HIV-1 in people living with HIV (PLWH). Some of my work at UW has centered on primary epithelial cells derived from the female lower reproductive tract. I spearheaded experiments that are beginning to unravel the mechanisms of endogenous HIV-1 reactivation. For my 2020 *Journal of Virology* paper, I set up difficult experiments that involved working with mucosal tissues, establishing primary mucosal epithelial cell lines from patients, and conducting complex *ex vivo* co-cultures with various read-outs to dissect the endogenous stimuli provided by the mucosal tissue environment to latently HIV-infected cells. I was also second author of a study in *Retrovirology* that characterized deficiencies in cellular innate immune responses inherent to cells latently infected with HIV-1. This work revealed a previously unknown role for type 1 IFN in regulating HIV latency, which may be exploited to design curative therapies aimed at eradicating the reservoir. In both of these projects, I gained experience in mucosal immunology, HIV-1 latency, and analysis of innate immunity, including the interferon system.

My road to becoming an independent investigator started when I was awarded a 3-year KL2 Career Developmental Award. The project title is "Characterizing the effects of NRTIs (Nucleoside Reverse Transcriptase Inhibitors) and non-NRTI ARTs on the activation of type I/III interferon-associated pathways". During this training, I co-first authored a new report in *PLoS Pathogens* on the relationship between host genomics and the HIV reservoir –we demonstrated that innate immune responses (particularly IL-10) and IFN signaling may influence the size of the reservoir even during chronic ART. For my KL2 and my recently awarded R01, I am leading a combination of *ex-vivo* and *in vitro* studies (in gastrointestinal systems), mechanistically defining the effects of the new NRTI-sparing HIV regimens on interferon signaling and the HIV-1 reservoir. This work may reveal pathways that can be targeted to treat chronic immune activation in PLWH. For this purpose, I recently launched a new clinical study (NCT05584397), for which I serve as the PI/Director. I have led activities related to study design, IRB approval, and budgeting. The duodenal and rectal biopsies I am obtaining from

Tips for R01 Submissions—Post submission

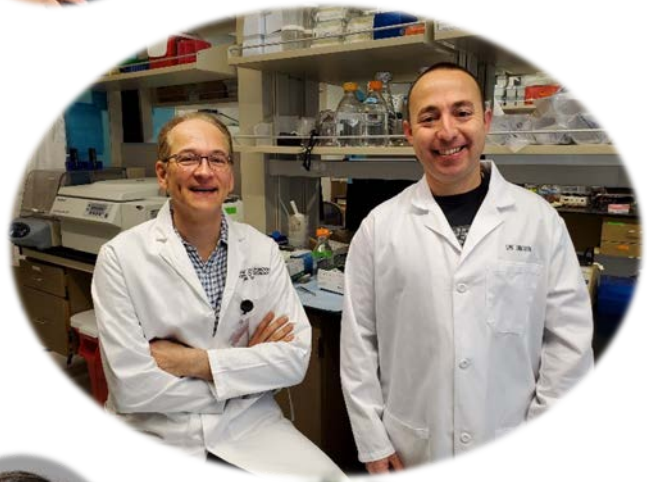
- ✓ **Develop a strong relationship with your NIH PO.** Try to schedule a follow-up Zoom/Team call where you can see your PO. If there is a meeting that is in common with the field of the PO, try to arrange to meet them in-person (or at least, invite the PO to your talk/poster).
- ✓ **Let sometime pass** between you receive your Summary Statement (SS) and you reply to it. Share your SS with your group/lab and get feedback. Use previous examples as templates.
- ✓ In your reply to the SS, you can **add additional references**. Make sure you make your point (it is OK to disagree but still be thankful for the study section's review!).
- ✓ Sometimes the PO can use a **Rebuttal Letter (RL)** and recommend your grant to NIH Council. Use previous examples of RLs (it is wise to add more preliminary data in this RL).
- ✓ If your grant gets funded, they will send **you a request for Just-in-Time (JIT) documents.** If the score is good, you can anticipate and request each co-I, co-PI, etc. to complete the required trainings before the JIT deadline. The turnaround is very fast, so my recommendation is to be on top of these documents before the notice of JIT.

Many-Many thanks to my Lab…

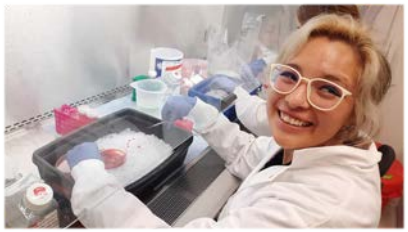









Many-Many thanks to my ObGyn Department and others…

UW Obstetrics and Gynecology
Dr. Barbara Goff
Dr. Barbara Norquist
Kelly Gilmore
Dr. Roni Katz
Dr. Romel Mackelprang
Estrella Weaver
Dr. Kristina Adams Waldorf
Nicole Wothe
Daisy Ganal
Winston Chiu
Sheri Yoo
Debbie Kirkpatrick

Harborview Medical Center
Dr. Brian Balmadrid

UW Microbiology
Dr. Jason Smith
Jessica Porter

UW Department of Global Health
Dr. Jairam Lingappa
Dr. Jennifer Lund
Dr. Lorenzo Giacani

SURF Career Development Program
Dr. Michelle Terry

Fred Hutch Cancer Center
Dr. Martin Prlic
Dr. Ann Duerr
Dr. Rachel Bender Ignacio

Center for AIDS Research (CFAR)
Lindsay Legg

UW Grant Services
Katie Kolarich