

Georgia CTSA K12 (formerly KL2) Program K12-BIRCWH Program

Application Workshops with Janet Gross, PhD

DATES

October 8 & 15, 2026

TIME

9:30 to 11:30 am

K12 APPLICATIONS DUE

February 1, 2027

Henry M. Blumberg, MD
MPI, Georgia CTSA KL2/K12 Program

Clinical and Translational Science Awards (CTSAs)

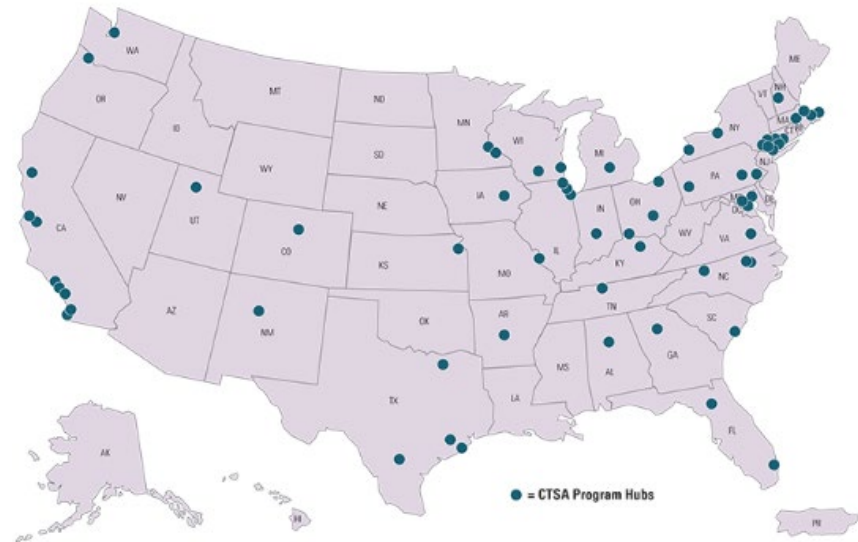
n = 60 in 32 states



- **Georgia CTSA** is one of 61 hubs striving to improve the way clinical & translational science is conducted and **improving health outcomes**.
- **Training the next generation of translational scientists**

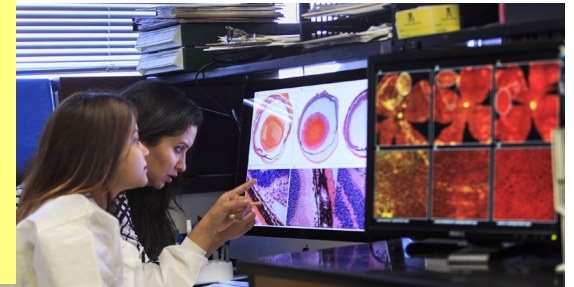
NCATS CTSA funding:
>\$600 M per year

CTSA Clinical & Translational Science Awards™



Research Education Program

Master of Science in Clinical Research (MSCR)*
Certificate Program in Translational Science (CPTS)
Georgia CTSA K12 Program (Early-Career Faculty)
T32: Predoctoral and Postdoctoral CTR/CTS Training



CTR = Clinical and Translational Research; CTS = Clinical and Translational Science

UNDER NIH REVIEW

Georgia CTSA Renewal Applications

Submitted to NIH. Proposed start date: August 2027

UL1



UM1

CTSA hub

KL2



K12

Career development for early-career faculty

TL1



T32s

Pre- and post-doctoral research training



Meet the *Leadership*

- The Emory K12- BIRCW
- those focused on advancing women's health
- Clinical and Translational

Faculty development for

who share interests in health.



Please join us in formally welcoming new BIRCW Leadership (left to right), **Anandi Sheth, MD, MSc**, and **Vasaliki Michopoulos, PhD**, as well as the continued leadership of **Claire Sterk, PhD**. Dr. Sterk, President Emerita and Charles Howard Candler Professor of Public Health, has led Emory BIRCW as a principal investigator since the program's inception in 2015. Dr. Michopoulos, Associate Professor of Psychiatry and Behavioral Sciences and inaugural BIRCW scholar, joins the leadership as a principal investigator after serving on the Steering and Executive Committees. Dr. Sheth, Director of the Division of Infectious Diseases and Professor of Medicine with Tenure, joins the leadership as contact principal investigator after also serving on the Steering and Executive Committees.

scholars will receive 75% focus on research & (up to \$100K plus fringe

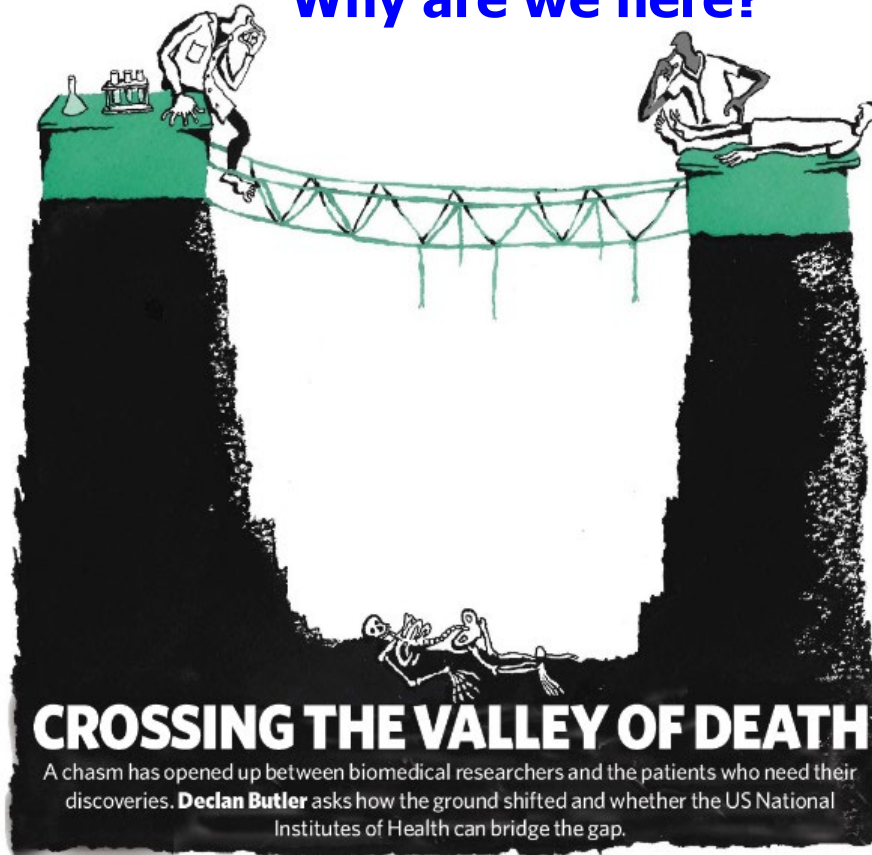
Scope:

- Individualized didactic
- Mentored research health
- Multidisciplinary career development program

- \$40,000 technical budget for research and research training-related expenses

Why are we here?

Nature 2008;453:840



Community



- Need to improve health outcomes

FROM BENCH TO PUBLIC HEALTH

Translational Research Spectrum



T0 Basic research

Translational scientist: Professional involved in the process of translation, either developing interventions or improving the process itself.

Translation: turning lab, clinic and community observations into interventions, such as diagnostics, therapeutics, procedures and behavior changes, that improve health

7 CHARACTERISTICS OF A TRANSLATIONAL SCIENTIST

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public – from diagnostics and therapeutics to medical procedures and behavioral changes. The professionals involved in this process, either developing interventions or improving the process itself, are *TRANSLATIONAL SCIENTISTS*.

RIGOROUS RESEARCHER

Conducts research at the highest levels of rigor and transparency, possesses strong statistical analysis skills, and designs research projects to maximize reproducibility.

BOUNDARY CROSSER

Breaks down disciplinary silos and collaborates with others across research areas and professions to collectively advance the development of a medical intervention.

TEAM PLAYER

Practices a team science approach by leveraging the strengths and expertise and valuing the contributions of all players on the translational science team.

PROCESS INNOVATOR

Seeks to better understand the scientific and operational principles underlying the translational process, and innovates to overcome bottlenecks and accelerate that process.

DOMAIN EXPERT

Possesses deep disciplinary knowledge and expertise within one or more of the domains of the translational science spectrum ranging from basic to clinical to public health research and domains in between.

SKILLED COMMUNICATOR

Communicates with understanding with all stakeholders in the translational process across diverse social, cultural, economic and scientific backgrounds, including patients and community members.

SYSTEMS THINKER

Evaluates the complex external forces, interactions and relationships impacting the development of medical interventions, including patient needs and preferences, regulatory requirements, current standards of care, and market and business demands.

CALL FOR APPLICATIONS

Georgia CTSA K12 Program and K12-BIRCWH

Career development for early-career faculty

Applications Deadline:
February 1, 2027



Didactic Research Training (choose one)

MSCR

Certificate (CPTS)

“Menu”



Mentored Research Training

Clinical and translational research/science project under the guidance of mentoring team

Who can apply

Full-time early-career faculty

Georgia CTSA K12

Emory, MSM, GT, UGA

K12-BIRCWH

Emory

Personalized Training Pathways

OTHER ONGOING INITIATIVES: PROFESSIONAL DEVELOPMENT

Georgia CTSA K12 and K12-BIRCWH



Leadership training

Dr. Michael Sacks et al.



Team science training



Mentor training

Senior faculty, early-career faculty, trainees



Scientific communication training



Professional coaching



I-Corps

Entrepreneurial training



K-ADVANCE

K to R conversion mentoring program

GRANT WRITING SUPPORT

Grant Writing for K12 Scholars



Janet Gross, PhD



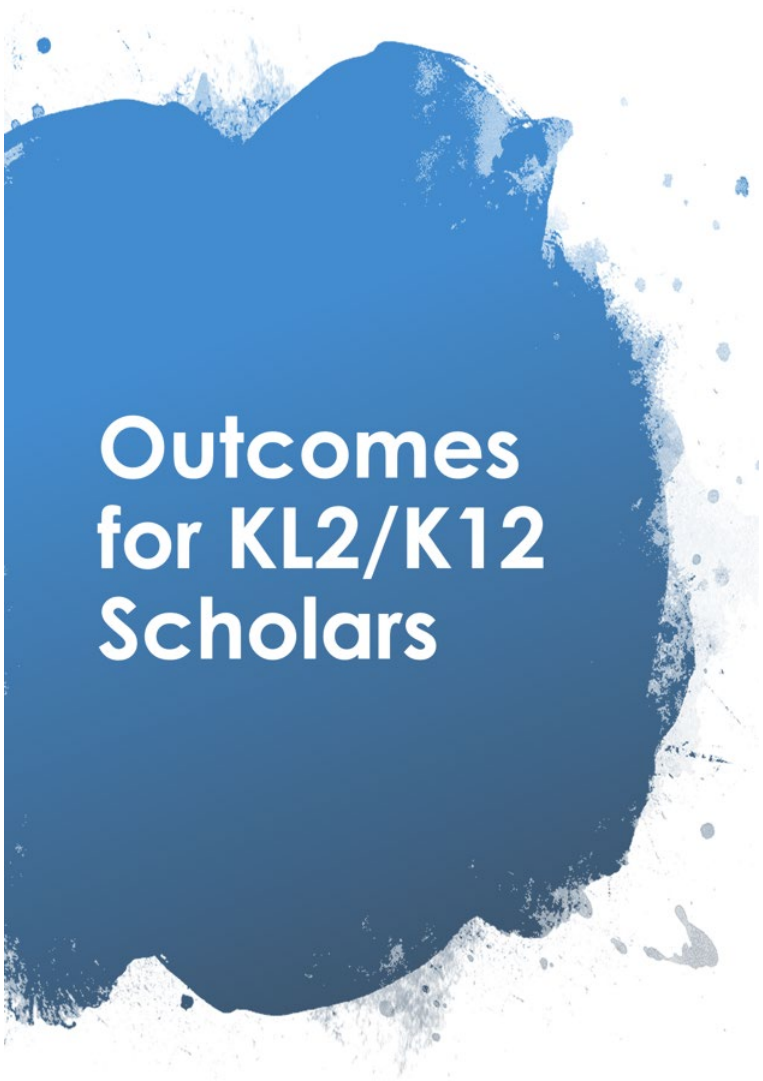
Scientific and Grant Writing

MSCR 594: didactic and peer learning



One-on-one coaching

Hands-on feedback on your application

A large, irregular blue splash graphic with a textured, watercolor-like appearance, featuring various shades of blue and white speckles. It occupies the left side of the slide.

Outcomes for KL2/K12 Scholars

- **Career that encompasses CTR and/or Clinical and Translational Science (CTS)**
 - Academic
 - Federal (e.g., CDC, NIH, FDA)
 - Industry (e.g., Pharma, Biotechnology)
- **Metrics**
 - Grants
 - Publications
 - Other: leadership roles, mentorship, team science, appointment

Georgia CTSA KL2/K12 Program Outcomes

76 KL2 Scholars have completed training

97%

remain in CTS careers

74 of 76 KL2 graduates remain in careers spanning CTR & CTS: 67 in academia, 4 industry, 3 federal agencies (2 at CDC, 1 NIH).

73%

have obtained federal funding as PI

Exceeds the ~50% rate reported in published multi-institutional evaluations across CTSA hubs.

\$521M

in external research funding as PI/MPI

Former scholars have secured \$465M federal (primarily NIH) and \$56M non-federal funding

3,751

peer-reviewed publications

Cited 139,443 times. **High impact:** SCImago Journal Rank (**SJR**) 2.07, Relative Citation Ratio (**RCR**) 2.60.

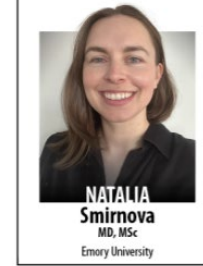
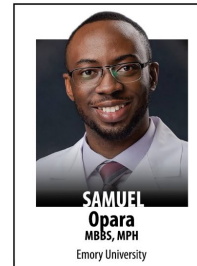
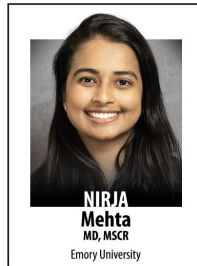
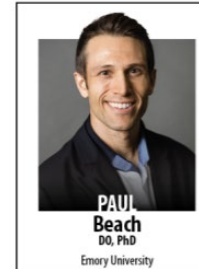
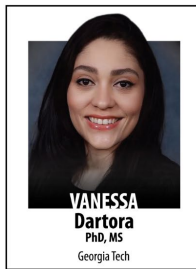
KL2 Scholars feel prepared for Clinical and Translational Science (CTS) careers

Scholars consistently describe the program as foundational to their professional development.

"I would not be where I am today professionally without the KL2 Program."

"The KL2 [Program] has had a profound impact on my career development as a translational scientist."

Current Georgia CTSA KL2 Scholars (n=10)



First Year

Second Year

CAREER DEVELOPMENT FOR EARLY-CAREER FACULTY

Georgia CTSA K12 and K12-BIRCWH Programs

Mentored and didactic clinical and translational research/science training
For Instructors and Assistant Professors (or equivalent)

NIH Requirements

-  **Full-time faculty**
-  **U.S. citizen or permanent resident**
-  **75% effort**
Research and research training

50% effort allowed for
surgery/surgical subspecialties

K12: 2 years of support

	CTSA K12	BIRCWH
Salary	Up to \$120K	Up to \$100K
(75% effort)	+ fringe	+ fringe
Technical budget	\$30K/year	\$40K/year

Applying to both? Use CTSA K12

BEFORE YOU APPLY

Georgia CTSA K12 and K12-BIRCWH Applications



APPLICATIONS DUE

**February 1,
2027**

Competitive selection. This workshop will help you build a strong application.



Established lead mentor

For example, an NIH-funded investigator



Research project and training plan

Your proposal needs both



Start early

You need time to prepare the application
Give your mentors time to review drafts

NIH POLICY CHANGE WITH K12 IMPLICATIONS

K Awards and Clinical Trials

NIH Notice NOT-OD-26-098 (August 2026)

NIH K award funds can't pay for

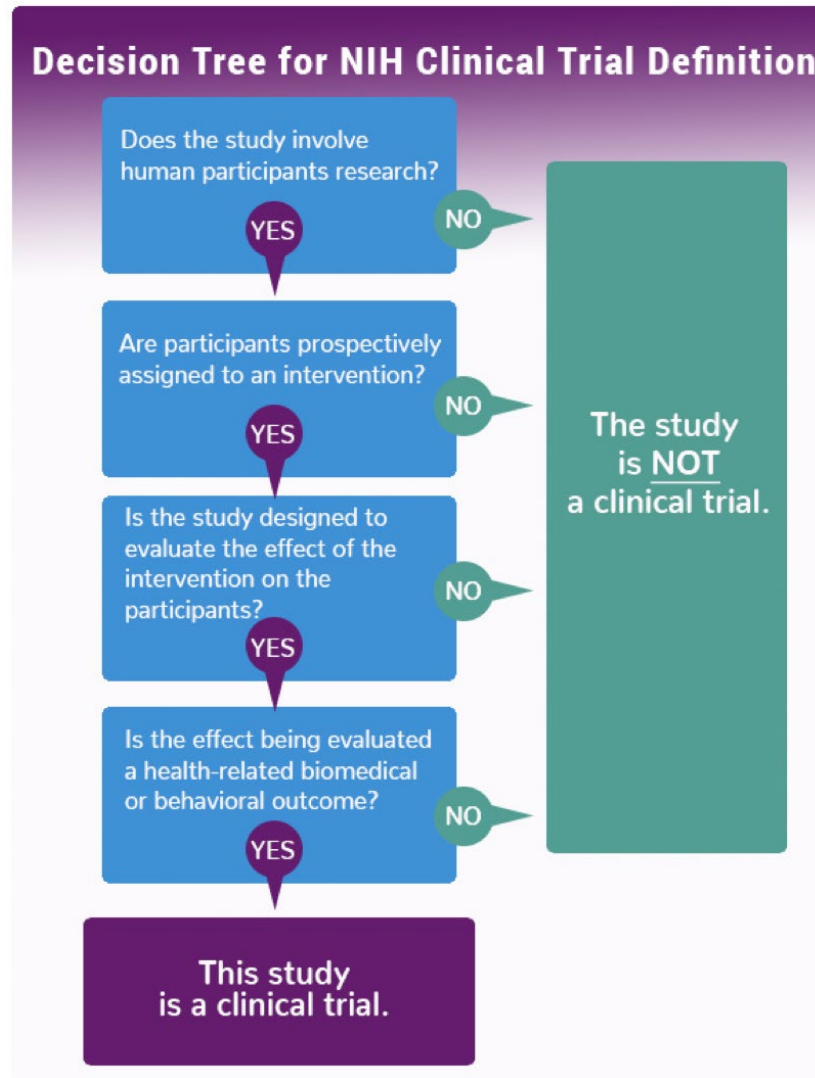
- ✗ Conducting a clinical trial
- ✗ A clinical trial feasibility study
- ✗ An ancillary study to an existing clinical trial

NIH K Awardees and K12 Scholars can still

- ✓ Join a trial led by a mentor
- ✓ Lead a clinical trial as PI, but only with separate funding
Institutional, philanthropic, other grants

Takes effect: NIH K applications due on or after October 12, 2027

What is the NIH definition of a clinical trial?



For clinical trial, must answer yes to *all* 4 questions. If one “no”, then not a clinical trial.

Update (2026)

Basic Experimental Studies with Humans (BESH) are no longer considered clinical trials by NIH

NIH Notice NOT-OD-26-032

<https://tinyurl.com/4zunhxzf>

NIH Loan Repayment Programs (LRPs): ~\$100 M per year

Nov 19th deadline

- **Up to \$50K/year in educational loan repayment**
Depending on debt level
- **Also, pays Federal taxes resulting from the LRP**
- **2-year initial contract**
2-yr competitive renewals
- **~ 1,400 researchers funded each year**
- **~50-60% overall application success rate for LRPs**

>95% success for KL2/K12 graduates!



www.lrp.nih.gov

QUESTIONS?

Georgia CTSA K12 & K12-BIRCWH Program Directors

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CASE EXAMPLE: IS IT A CLINICAL TRIAL?

Blood Pressure, Brain Oxygen, and Walking in Parkinson's/ α SYNs

Goal 1: Does BP falling on standing lower brain blood flow and oxygen, even without symptoms?

Goal 2: Are drops in brain oxygen linked to slower walking and shorter steps?

1. Does the study involve human participants?

Yes: patients with Parkinson's and healthy controls

↓ Yes

2. Prospectively assigned to an intervention?

Yes: every participant gets a tilt test

↓ Yes

3. Evaluates the intervention's effect?

Yes: tilt's effect on brain blood flow and oxygen

↓ Yes

4. Health-related biomedical outcome?

Yes: brain blood flow and oxygen levels

What's a tilt test?

Table tilts the patient from flat to upright, triggering the BP drop.

NIH generally considers this an intervention.

All 4 yes, but...

Not a clinical trial

Basic Experimental Studies with Humans (BESH)

are no longer clinical trials under NIH policy (2026)

CASE EXAMPLE: IS IT A CLINICAL TRIAL?

Precision Palliative Care for Outpatients with COPD

Goal 1: Can EHR data (e.g., oxygen use, flare-ups) flag patients with high palliative needs?

Goal 2: How do clinicians decide on palliative care, and would they use EHR alerts?

1. Does the study involve human participants?

Yes: 147 COPD patients and 250 clinicians

↓ Yes

2. Prospectively assigned to an intervention?

No: surveys and EHR data only; nothing is given

No

Not a clinical trial

Observational: patient cohort plus clinician survey

3. Evaluates an intervention's effect?

Not reached

4. Health-related outcome?

Not reached

Proposed next step: K23 pilot

The EHR alert is an intervention, so the K23 pilot is a clinical trial.

OK in a K23 now; for NIH K applications after Oct 12, 2027, cannot use NIH funds to support.

CASE EXAMPLE: IS IT A CLINICAL TRIAL?

GLP-1 Drugs, Muscle, and Bone in Older Women

Aim 1: Do GLP-1 drugs raise fracture risk? (existing EHR data)

Aim 2: What do 6 months of semaglutide do to muscle and bone? (20 with T2D)

Applying the 4 questions to Aim 2

1. Does the study involve human participants?

Yes: 20 women over 65 with type 2 diabetes

↓ **Yes**

2. Prospectively assigned to an intervention?

Yes: all start semaglutide per protocol

↓ **Yes**

3. Evaluates the intervention's effect?

Yes: muscle and bone changes over 6 months

↓ **Yes**

4. Health-related biomedical outcome?

Yes: grip strength, walking test, bone density

Aim 1: not a trial

EHR analysis using target trial emulation. Nothing is assigned (no intervention).

Aim 2: all 4 yes

Clinical trial

Feasibility clinical trial. No NIH K12 funds allowed to support this clinical trial.

Institutional K Awards Tutorial

Planning and writing an institutional K grant to the
GA CTSA & BIRCWH K12 Award

Session #1 October 7, 2026

Presented by Janet Gross, Ph.D.

jsgros2@emory.edu

Class #1 Objectives

- ▶ Role of Grants Tutorial Instructor
 - ▶ Unique aspects of preparing a K and other Mentored CDA
 - ▶ Getting Ready to Prepare a K application
 - ▶ K Grant Writing Nuts and Bolts
 - ✓ Biosketch
 - ✓ Budget
-

Class #2 Objectives

Candidate section

Letters of Support

- Plans and Statements of Mentor and Co-Mentor(s), Consultants, Collaborators
- Chair or Division Chief's statement of commitment to you for this award

Research Plan (Specific Aims & Research Strategy)

- ▶ Examples
- ▶ Organization
- ▶ Clarity
- ▶ Styles of writing

Using reviewers' comments to highlight:

- ▶ Qualifications issues
 - ▶ Level of detail in writing
 - ▶ Integration of Research Plan in other sections
 - ▶ Integration of Training Plan
-

Ga CTSA Grant Writing Resources

- ▶ 2-session K12 application prep tutorial (4 hrs total)
 - ▶ Dropbox site for lots of resources
 - Examples of recently funded GA CTSA K12 (formerly KL2) and K12 awards
 - Other grant writing resources focused on the NIH K
 - pdf and video of today's talk posted on Dropbox
 - ▶ I will work with you to develop and refine your proposal (~5 hrs/candidate) based on email agreement
-

Overview

	GA CTSA K12	BIRCWH K12
2 years, 75% protected time - 50% for surgical specialties	-salary support up to \$120,000/yr for 75% effort - technical budget of \$30,000/yr - plus fringe	-salary support \$100,000/yr for 75% effort - technical budget of \$40,000/yr -plus fringe
Goal is for you to generate strong preliminary data for for the NIH K23, K08 (or similar)		
Qualified MD or PhD (or similar) with a full-time faculty appointment by Aug 1, 2027	Emory, Morehouse SOM, GaTech, UGA (select colleges) – all GA CTSA partners	Emory only
Commitment to a research and/or academic research career in:	Clinical investigation and/or translational research	Women's health and/or sex/gender life science
Application due date	February 1, 2027	February 1, 2027
Required mentor and career development plan	MSCR, CPTS (or menu option with approval)	Self-designed with guidance from BIRCWH leadership
Who funds this award?	National Center for Advancing Translational Science (NCATS) GA CTSA Institutional Career Development KL2 (Blumberg K12 & Taylor ULI)	NIH Office of Research on Women's Health / NICHD Building Interdisciplinary Research Careers in Women's Health K12 (Sheth & Sterk)

Clearly justify and describe your choice of Didactic Training options

- **MSCR** may be appropriate for faculty who have had limited prior didactic research training
 - **CPTS** would be an option for faculty depending on career interest
 - If you select the **Personalized Pathway Menu** option, you need to be explicit in the didactic program you will follow and tell us why you've chosen this selection
-

Didactic Training Options

- **MSCR** (Emory or MSM) – 30 credits
 - ***Preferred training option***

 - **Certificate Program in Translational Science (CPTS)** –16 credits (previously Certificate Program in Translational Research (CPTR))
 - Flexible so that you can sub out for similar courses you've already taken

 - **“Menu” Option (*new – reflects the personalized training pathway for those who have already had MSCR/CPTS training*)** – must include these 5 required courses from MSCR/CPTS curriculum
 - MSCR/CPTS 593 Research Ethics (required by NIH) [1 credit]
 - MSCR/CPS 594 Scientific and Grant Writing [2 credits]
 - MSCR/CPTS 761 Introduction to Clinical and Translational Science (CTS) [2 credits]
 - MSCR/CPTS 591 Community Engagement and Health Equity [1 credit]
 - MSCR 592 Clinical and Translational Science Colloquium [1 credit]
 - Electives (based on applicant's needs—can be at any of the Georgia CTSA institutions or workshops, etc.)
-

Preview the NIH K to set the stage for your K12

One Stop Shop for [NIH Career Development Awards](#)

- ▶ Specific Program Announcement (PA) for each kind of K
- ▶ Each K has its own particular requirements
- ▶ Each K funder may have particular requirements /rules /restrictions
- ▶ Mentored (K23, K01) vs. Non-mentored (K22; R00 phase of K99/R00); **the names of these Ks are changing, stay tuned..**
- ▶ Other resources for K awards and other Career Development Awards
 - ▶ DoD, American Heart Assn, other foundations

Study the NIH K procedures to gain a context for what reviewers are looking for

- ▶ K Funding Opportunity Announcement
 - ▶ <https://researchtraining.nih.gov/programs/career-development>
 - ▶ NIH Career Development Application Instructions
 - ▶ <https://grants.nih.gov/grants/how-to-apply-application-guide.html>
 - ▶ See **K Career Development Instructions** (this gets updated regularly – be sure you are using the most updated version as rules change)
-

Career Path for a NIH K23 – Mentored Patient-oriented Research Career Development Award

Training to date

- MD
- MS in clinical research (MSCR)
- **KL2 to develop new data on transfusion related necrotizing enterocolitis in premature infants**



Mentored CDA

5 yr K23:

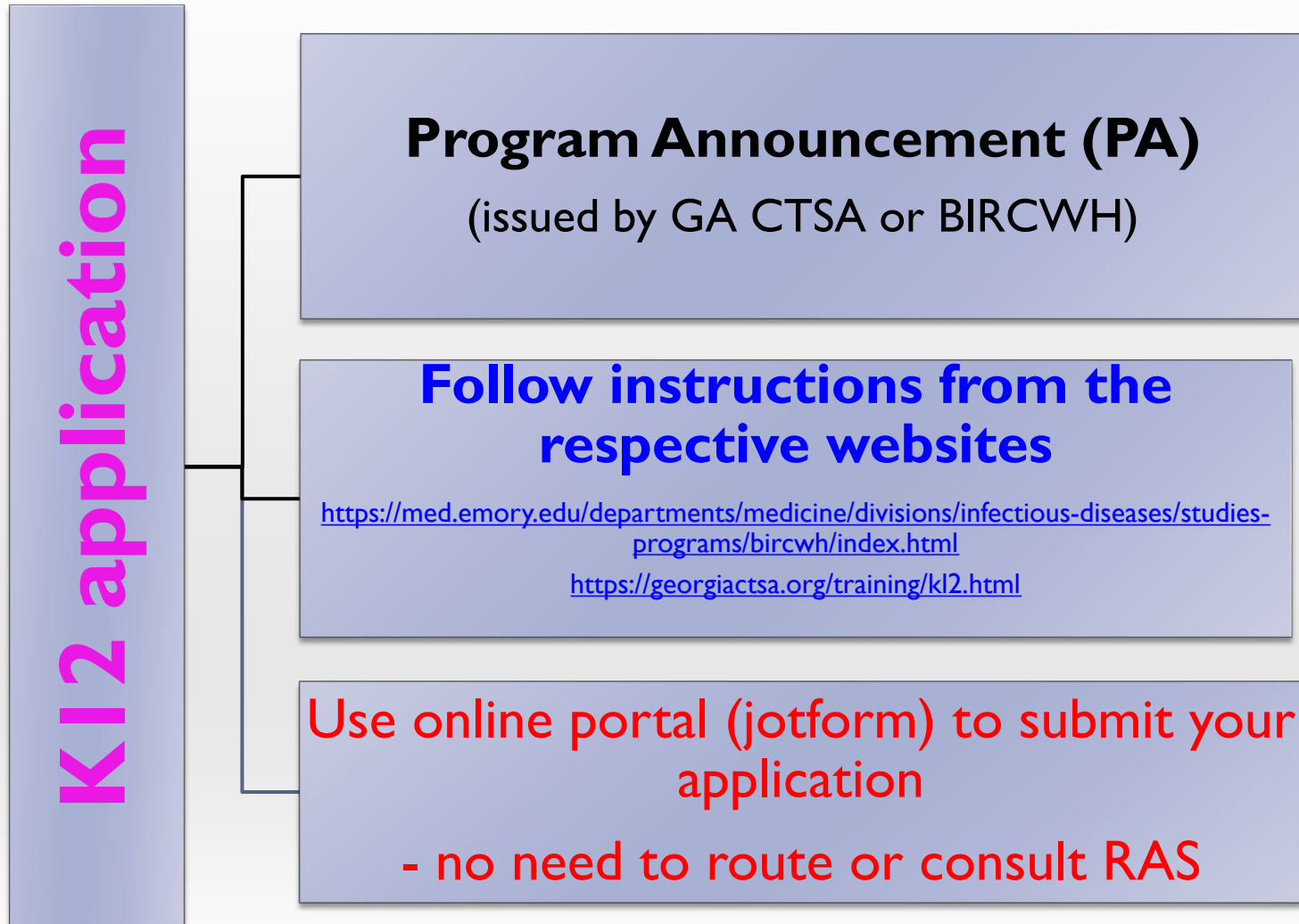
- Red blood cell transfusion biology
- Near infrared spectroscopy
- Probiotic therapy in infants



Independent
academic clinician
scientist

specializing in
complex diseases of
prematurity

All the moving parts for this grant application



NIH Review Criteria

<u>F- Fellowship Grants</u>	<u>K - Career Development</u>
Fellowship Applicant	Candidate
Sponsors, Collaborators and Consultants	Career Development Plan / Career Goals
Research Training Plan	Research Plan
Training Potential	Mentors, etc.
Institutional Environment and Commitment to Training	Environment and Commitment to Candidate

- All component/factor scores range from 1-9
- Assigned reviewers share these with the rest of the reviewers in the room.
- Then, each reviewer in the room is asked to rate the application using a score between 10=best – 90=worst

<u>Standard Grants</u> (R, U, P, etc.)
Factor 1. Importance of the Research (Significance and Innovation) (scored 1-9)
Factor 2. Rigor and Feasibility (Approach) (scored 1-9)
Factor 3. Expertise and Resources (Investigator(s) and Environment) (scored YES/NO)

NIH K Scoring System

- Follows NIH review criteria and process
- Component scores are rated 1 (best) to 9 (worst)
 - These 5 component scores are only given by main reviewers (you will not see these for the KL2 review – you will only see your Overall Impact Score)
- Generally, all component scores must be at least **Excellent** to be funded
- Your total score = Overall Impact Score** (a fundable score is generally <30)
 - Everyone in the room votes based on their own reading and/or what they've learned from the main reviewers using a 10-90 point range
 - Your overall impact score is not the average of the main reviewers' component scores
- Any one of the 5 review criteria with a fatal flaw will result in **NO SCORE (or Not Discussed)**

Overall Impact or Criterion Strength	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor
Other Designations for Final Outcome		
ND	Not Discussed	

Overall Impact range is 10 best - 90 worst

Center for Scientific Review

1. Scoring System and Procedures
2. Watch the Mock Review session video (excellent overview)
3. See the review criteria

**Getting ready to
prepare
the K application**



Am I Competitive?

- **Publication record**
 - >I first author publication, preferably experimental research, in your current field, related to the aims of the K
 - Published with your mentor(s)
 - **Biosketch that shouts “I’m on the career path to becoming a (NIH) funded independent investigator”**
 - *Personal Statement* states this explicitly
 - Track record is the evidence
 - **Other professional activities - awards, invited presentations, co-I, association memberships, etc.**
 - *Remember, you will be competing against people who are at the same career level as you*
-

Research Ideas → Research Plan

- A mentored CDA requires training in an area where you are currently **not** a recognized expert
 - NEW laboratory methods, analytical methods, modeling schemes, comparative systems, new animal models, etc.
 - Coursework, preferably the MSCR or CPTR
 - Hypothesis-driven work is highly valued
 - If you are already an expert in what you are proposing, you won't fulfill the criteria of a CDA.
 - Branch out in a new exciting direction
 - What new training would you need to complete the aims?
 - What is a reasonable amount / type of new training given the duration of the award and the timing of the aims
-

Vet your research idea with LOTS of smart people

- ▶ **Is your Research Plan scientifically sound?**
 - ▶ How do you know this?
 - ▶ Let others see your work – review and feedback from peers (not just your mentor)
 - ▶ Do you have preliminary data? How compelling is it?
 - ▶ **How will you write about research in an area where you are not an expert?**
 - ▶ Get advice from your mentors
 - ▶ e.g., explaining new techniques for analyses in your proposed aims
 - ▶ You have to sound ‘smart enough’ but not a published expert (or why would you need the K?)
-

Examples of Reviewers' Comments:

Career Development Plan / Career Goals & Objectives

- *Training focused on reading textbooks and some hands-on training sessions by busy mentors is informal and weak.*
- *It is not clear if the whole of MSCR or only a part of it is included in the training plan*
- *Wet lab experience is lacking; plans to obtain this expertise are rather vague – terms like lab “rotations” not well defined in terms of location and duration*

Mentors, co-mentors, consultants, collaborators

- *There is concern about the lack of an individual with sufficient documented behavioral scientist or education expertise in the mentoring team, especially considering the major focus of the research activity.*

Research Plan

- *Rationale for duration of follow-up (6 months) is unclear*
-

Seek Career Advice and Guidance

- **Mentoring is key in a K12 and NIH K**
 - Who is promoting you and your career?
 - Mentoring vs. pseudo-mentoring
 - Name names – this is an internally reviewed award
 - **Institutional Support**
 - You must have a faculty position as of **August 1, 2027**, that is **NOT CONTINGENT** on you receiving the K12
 - Do you have Departmental support for resources as well as the balance of funds needed - salary, materials
 - The typical K12 cannot be supported solely on the K12 research budget – why? Research is expensive.
 - **BE VERY CLEAR IN THE BUDGET JUSTIFICATION HOW YOU WILL COVER ALL EXPENSES** including tangible support from mentor, co-mentors, etc.
-

CAREER DEVELOPMENT AWARDS want to know:

WHAT ARE YOUR CAREER GOALS?

- ▶ What are your career goals, i.e., whose job would you like?
 - ▶ **Mentoring Plan** - discuss your career goals (in detail) with your mentor and at least one other respected faculty member (division chief, etc.)
 - ▶ What is the NEW TRAINING you will seek?
 - ▶ Will you be supported - professionally, financially, etc.?
 - ▶ Are your career and research goals realistic?
 - ▶ This is where you make certain there is **NOT SUBSTANTIAL OVERLAP** in scientific aims with your mentor's R01
 - ▶ Can the award budget support your proposed research? (probably not)
 - ▶ Have you thought about a budget? Will you 'piggyback' on another project?
 - ▶ **All roads → NIH K submission**
 - ▶ **Your goal through the institutional K is to generate sufficient preliminary data / results to inform / support an NIH K application**
-

K Grant Writing Nuts and Bolts



K12 Required Sections

- a) Cover page (see respective cover sections)
 - b) Cover Letter from Applicant
 - c) Abstract (30 lines)
 - d) Research Training Plan (13 pages total; upload in order specified in jotform)
 - ▶ Introduction to Application (1 page; resubmissions only)
 - ▶ Specific Aims (1 page)
 - ▶ Candidate Section + Research Strategy (12 pages)
 - ▶ Human Subjects Protection / DSMP (if needed; no page limit)
 - e) Facilities and Other Resources (2 pages)
 - f) Human Subjects / Data Safety and Monitoring Plan (no limit)
 - g) Literature Citations (no page limit)
 - h) Budget and Budget Justification (2 pages)
 - i) NIH Biosketch and Other Support page (NIH instructions)
 - ▶ Applicant and all mentors' and advisory committee members
 - j) Letters of Support
 - ▶ Department Chair's Letter (or division chief)
 - ▶ Lead Mentor (followed by any other co-mentors, advisors, collaborators; 5 slots)
-

Each PDF gets uploaded into its 'slot'

- ▶ Use online portal to submit grant
 - ▶ Questions:
 - ▶ GA CTSA: Rachel Hardison rachel.hardison@emory.edu
 - ▶ BIRCWH: Shannon Walker shannon.walker@emory.edu
-

NIH Review Criteria

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Factor 1. Importance of the Research (Significance and Innovation) (scored 1-9)
Factor 2. Rigor and Feasibility (Approach) (scored 1-9)
Factor 3. Expertise and Resources (Investigator (s) and Environment) (scored YES/NO)

You are not your research, but you are your biosketch

Crafting the NEW NIH Biosketch

OMB No. 3145-0279 (Expiration Date 10/31/2026)

NIH Biographical Sketch Common Form

Name: Moran, Caitlin

Persistent Identifier (PID) of the Senior/Key Person: <https://orcid.org/0000-0001-8436-0465>

Position Title: Associate Professor of Medicine

Organization and Location: Emory University School of Medicine Division of Infectious Diseases, Atlanta, Georgia, United States

PROFESSIONAL PREPARATION

INSTITUTION AND LOCATION	DEGREE	Start Date	Completion Date	FIELD OF STUDY
Emory University Laney Graduate School, Atlanta, Georgia, United States	Master of Science (MS)	08/2015	05/2017	Clinical Research
Emory University School of Medicine, Atlanta, Georgia, United States	Fellow	07/2014	06/2017	Infectious Diseases
University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, United States	Resident	06/2011	06/2014	Internal Medicine
Georgetown University School of Medicine, Washington, District of Columbia, United States	Doctor of Medicine (MD)	08/2007	05/2011	Medicine
Saint Joseph's University, Philadelphia, Pennsylvania, United States	Bachelor of Science (BS)	08/2003	05/2007	Chemistry

Appointments and Positions

2023 - present	Associate Professor of Medicine, Emory University School of Medicine Division of Infectious Diseases, Atlanta, Georgia, United States
2025 - present	Faculty, Emory University Laney Graduate School, Atlanta, Georgia, United States
2025 - present	Associate Director, Emory Center for AIDS Research (CFAR) Clinical Research Core, Atlanta, Georgia, United States
2025 - present	Co-site leader, The Ponce de Leon Center Clinical Research Site, Atlanta, Georgia, United States
2017 - 2023	Assistant Professor of Medicine, Emory University School of Medicine Division of Infectious Diseases, Atlanta, Georgia, United States

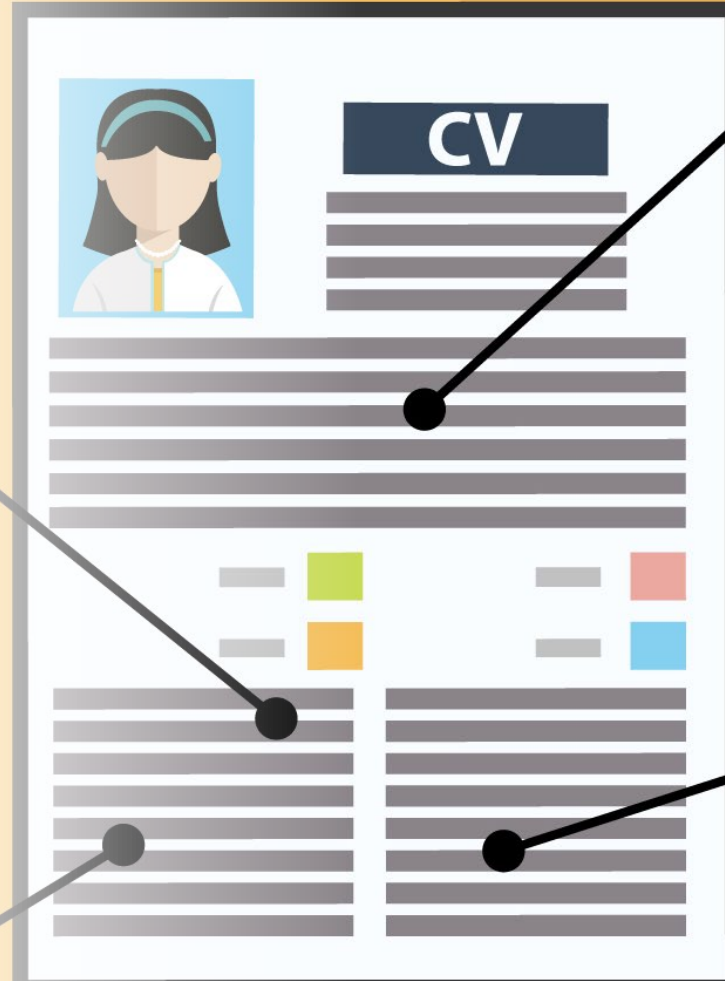
Products

Products Closely Related to the Proposed Project

1. Moran CA, Weitzmann MN, Ofotokun I. Bone Loss in HIV Infection. Curr Treat Options Infect Dis. 2017 Mar;9(1):52-67. PubMed Central PMCID: [PMC5388454](https://pubmed.ncbi.nlm.nih.gov/25388454/).
2. Moran CA. Weitzmann MN. Ofotokun I. The protease inhibitors and HIV-associated bone loss. Curr Opin HIV AIDS. 2016

The NIH Biosketch

- A highly formatted, brief curriculum vitae (cv)
- Often the first part of an NIH grant (and often others) that a reviewer reads
- **The biosketch enables reviewers to evaluate you and your team**
- Sections include:
 - Education/training
 - Personal statement
 - Honors/awards
 - Relevant publications
 - Contributions to science



What is a reviewer looking for?

Are you the right person for the work?

- Is there a good match between your track record (training, current activities) and the research aims?
- Are **you** a good match for the type of grant you are submitting?
- Do you have any related publications?
 - reflection that you are competent in the research techniques proposed and you are likely to publish good science in the future





SciENcv: Science Experts Network Curriculum Vitae

A researcher profile system for all individuals who apply for, receive or are associated with research investments from federal agencies. SciENcv is available in My NCBI.

- **HINT:** google “How do I create an NIH biosketch”

**The NIH biosketch
MUST BE created
with this app -
SciENcv**

Steps to Create a New NIH Biosketch in SciENcv:

<https://www.ncbi.nlm.nih.gov/sciencv/>

- **Access SciENcv:** Go to your My NCBI dashboard and click "Manage SciENcv".
- **Create New Document:** Click the "+ New Document" button.

SciENCv

My Profile Edit

Name: Anne M. Fitzpatrick, PhD, APRN
Title/Department: Professor of Pediatrics and Nursing
Emory University
ORCID ID: <https://orcid.org/0000-0002-2933-5926>

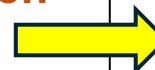
My Documents

Helpful Links

[About SciENCv](#)

[How to Use SciENCv](#)

If you already have a biosketch posted in SciENCv → Create a new document and select **NIH Biographical Sketch Common Form**



+ NEW DOCUMENT

Last Updated ↓	Title	Format	Delete
1/12/26	NIH Biosketch RESTRAIN R01 Jan7 2026	NIH Biographical Sketch Common Form	
1/12/26	NIH Biosketch Adjoa Andoh K23 Jan12 2026	NIH Biographical Sketch Common Form	
1/8/26	NIH Biosketch SCAPISH R01 Jan8 2026	NIH Biographical Sketch Common Form	
1/8/26	Fitzpatrick Other Support Jan8 2026	DOE Current and Pending (Other) Support	

There are 2 forms that you will construct using the SciENcv app

1) Biographical Sketch Common Form

2) NIH Biographical Sketch Supplement

- Content is similar to what was in the former NIH Biographical Sketch
- But with new rules & new formatting
- You can edit, tailor and save customized updates for each grant you submit
- Follow the directions carefully!!!
- You attest and get a **'certified'** pdf created by SciENcv
- Formatting violations → **ERROR** in submitting the proposal to NIH!!!

1) NIH Biographical Sketch Common Form

see SciENcv
'how to' pdf
for
instructions
in our
Dropbox

OMB No. 3145-0279 (Expiration Date 10/31/2026)

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Products

Products Closely Related to the Proposed Project

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2. Moran CA, Weitzmann MN, Ofotokun I. The protease inhibitors and HIV-associated bone loss. Curr Opin HIV AIDS. 2016

1) NIH Biographical Sketch Common Form

- **Identifying information** – Name, Persistent Identifier (i.e., ORCID) which is linked to eRA commons Personal Profile, Position Title
- **Organization and Location**
- **Professional Preparation** - education and training
- **Appointments and Positions** - list
- **Products** – publications, etc.
 - must be citable and accessible, can use ‘et al’, can hyperlink the actual URL text (not hidden behind a word)
 - Up to 5 products closely related to the proposed project
 - Up to 5 other significant products that highlight your Contributions to Science
- **Certification** – e-signature on the pdf within 12 months of submission of the proposal

Research Products

- **Publications**
- Audio or video products
- Conference proceedings
- Patents
- Data & research materials
- Databases
- Educational aids/curricula
- Instruments/equipment
- Models
- Protocols
- Software
- Interim: preprint, pre registration

Example: Bar DZ, Atkatsk K, Tavarez U, Erdos MR, Gruenbaum Y, Collins FS. Biotinylation by antibody recognition- A novel method for proximity labeling. BioRxiv 069187 [Preprint]. August 11, 2016 [cited 2017 Jan 12]. Available from: <https://doi.org/10.1101/069187>.

Products

Products Closely Related to the Proposed Project

1. Moran CA, Weitzmann MN, Ofotokun I. Bone Loss in HIV Infection. Curr Treat Options Infect Dis. 2019;11(3):333-42. PubMed Central PMCID: [PMC5388454](#).
2. Moran CA, Weitzmann MN, Ofotokun I. The protease inhibitors and HIV-associated bone loss. Curr Opin HIV AIDS. 2016 May;11(3):333-42. PubMed Central PMCID: [PMC4838480](#).
3. Ofotokun I, Collins LF, Titanji K, Foster A, Moran CA, Sheth AN, Lahiri CD, Lennox JL, Ward L, Easley MN. Antiretroviral Therapy-Induced Bone Loss Is Durably Suppressed by a Single Dose of Zoledronic Acid in Naïve Persons with Human Immunodeficiency Virus Infection: A Phase IIB Trial. Clin Infect Dis. 2020 Oct 1;79(4):e1663. PubMed Central PMCID: [PMC7755092](#).

acceptable URL format

Other Significant Products, Whether or Not Related to the Proposed Project

5. Moran CA, Jacob BW, Mehta CC, Sheth AN, Krier S, Causey Pruitt ZL, Jones Weiss D, Easley MN, Cohen J, Goparaju L, Holman S, Adedimeji A, Lahiri CD. Predictors of Retention in the WASHINGTON STATE HIV COHORT, 2011-2019. 30th Conference on Retroviruses and Opportunistic Infections; 2023 February; Atlanta, GA.

No URL included here

2) NIH Biographical Sketch Supplement

- **Identifying information**
 - **Organization and Location**
 - **Personal Statement** – no citations (max. 3,500 characters)
 - **Honors** – (max. 15)
 - **Contributions to Science** – up to 5 entries;
 - max. ½ page and 2,000 characters
 - may reference up to 5 products listed in Other Significant Products from the Common Form (can use a brief citation style)
 - may include ‘works in progress’, and ‘manuscripts under review’
 - **Certification** – e-signature on the pdf within 12 months of submission of the proposal
- 

NIH Biographical Sketch Supplement

Personal Statement

- Directions are the same as in old biosketch - it is your story – use first person
- no citations (max. 3,500 characters)
- Include ongoing and completed research projects from the past 3 years that you want to highlight
- Probably the hardest part of the biosketch



Personal Statement instructions

- Describe why you are well-suited for your role in the project
- If you wish to explain factors that affected your past productivity, you may address them here
- Indicate whether your products/publications appear under another name

- You can be somewhat creative here
- Recommendation – refer to the type of proposal you are submitting

NIH BIOGRAPHICAL SKETCH SUPPLEMENT

Name: Moran, Caitlin

Persistent Identifier (PID) of the Senior/Key Person: <https://orcid.org/0000-0001-8436-0465>

Position Title: Associate Professor of Medicine

Organization and Location: Emory University School of Medicine Division of Infectious Diseases, Atlanta, Georgia, United States

Personal Statement

I am delighted to serve as co-Investigator on the project entitled “Intersection of Periodontitis with HIV-Antiretroviral Therapy-Induced Immune Reconstitution Bone Loss, on Alveolar Bone and Tooth Loss, in People Living with HIV” (MPI Weitzmann/Umeizudike). In this role, I will oversee clinical operations at the Emory site. I am an Infectious Diseases physician and clinician-researcher, and the primary emphasis of my research is on elucidating the pathophysiology of HIV-associated comorbidities with a particular focus on cardiovascular and bone health. I have extensive experience conducting clinical research in people living with HIV (PLWH), serving as Associate Director of the Clinical Research Core of the Emory Center for AIDS Research (CFAR), and site PI for the ACTG protocols of the Ponce de Leon Clinical Research Site. In my early work, I found that the relationship between inflammatory biomarkers and subclinical cardiovascular disease (CVD) progression in women with HIV differed compared to women without HIV, suggesting that different mechanisms account for CVD in women with and without HIV (Moran et al. 2018). This work led to an NHLBI-funded K23 award leveraging the MACS/WIHS Combined Cohort Study (MWCCS) to study on the effects of HIV on reproductive aging and estrogen receptors as a potential mechanism for this difference. I am now Project Director for the cardiovascular project of the NICHD-funded U19 Study of Treatment And Reproductive Outcomes (STAR) investigating the role of HIV and reproductive aging on vascular function and hypertension in reproductive-aged women.

I have a long history of collaboration with Dr. Weitzmann on projects studying immune reconstitution bone loss (Moran et al. 2016, 2017). I was co-investigator on a clinical trial led by Dr. Weitzmann and Dr. Igho Ofotokun that found that a single dose of zoledronic acid prevents antiretroviral therapy-induced bone loss for up to three years in antiretroviral therapy-naïve people living with HIV (Ofotokun et al. 2020), and am MPI with Dr. Weitzmann and Dr. Oliver Ezechi on an R01 investigating the role of the microbiome in immune reconstitution bone loss in people living with HIV. My background as an ID clinician and expertise in HIV-associated biomarkers leaves me well-placed to oversee clinical operations for this study.

Ongoing and recently completed projects that I would like to highlight include:

U19 HD119884

Alcaide/Sheth (MPI), Role: Research Project 1 Director

09/12/2025 – 08/31/2030

Study of Treatment And Reproductive Outcomes

R01 AR079298

Weitzmann/Ezechi/Moran (MPI)

09/21/2021 – 08/31/2026

Predictors of Antiretroviral Immune Reconstitution Bone Loss – the Gut and the Microbiome

U54 AG062334

UM1 AI069418

Writing the Personal Statement

- Customize/speak directly to purpose of grant
- Length (3,500 characters max.)
- Convey excitement and passion to do this work
- Depending on the type of grant, emphasize your role for:
 - Leadership (PI of a R grant, Mentor on a F or K grant)
 - Training potential for you to advance in your field (F31, F32 or K)
 - Track record and experience to support the proposed aims
 - Tone should be confident but not arrogant
 - Don't just walk us through your accomplishments but speak to the science in this proposal

Additional Suggestions

- Early investigators can call attention to Early Stage Investigator (ESI) status
- Emphasize relevance of recent research contributions and training
- Mention mentor
- Ask others read this over for you and offer suggestions for writing, ease of understanding, compellingness

Funded KL2 → K01 → R21 → R01

.....

Once we have thoroughly characterized both the behavioral and neurophysiological effects of stimulation at the amygdala in biasing, I will be poised to make the **next step to a K01 project** wherein I hope to establish an independent lab to systematically examine the contributions of limbic regions (also frequently implanted in epilepsy patients) to emotional perceptual bias, and to broaden our focus to include other measures of affective system function. Emory is the ideal environment for the implementation of the proposed brain stimulation research: in addition to the availability of rare DBS patients, we have a world-renowned epilepsy surgical team, which provides access to approximately 1 patient per week with implanted electrodes in the limbic system **making this KL2 and a future a K01 project highly feasible.**

Writing Suggestions

3. Lots of overlap with Candidate Section in K grant
 4. Be succinct, revise this several times after you have developed the Candidate section essays
 5. All these sections need to be great – reviewers really care about these sections
 6. Could be a place to remind the reviewers which didactic training plan you've chosen and why (in brief), i.e., MSCR, CPTS, menu
-

Honors



Honors

- Travel awards, LRP, teaching awards, service awards, honor societies (clarify specific awards); conference presentation awards
- Maximum = 15

Contribution to Science

Briefly describe up to **5 of most significant contributions to science**. For each:

- 1) **Historical background** that frames the scientific problem
- 2) The **central finding(s)**
- 3) The **influence** of the finding(s) on the progress of science or the application of those finding(s) to health or technology
- 4) Your **specific role** in the described work.

- up to 5; max. ½ page and 2,000 characters
- may reference up to 5 products listed in Other Significant Products from the Common Form (can use a brief citation style)
- may include ‘works in progress’, ‘manuscripts under review’

Thinking about my “Contributions to Science”

- What goes here?
- How do I organize this?
- What do I report?
- Some ideas
 - ✓ In your previous research experiences, what did the team do and what exactly did you do? Name names.
 - ✓ What did you learn from what you did?
 - ✓ Can you reflect on what you found and how it may have led to the current proposal?
 - ✓ Be aspirational – express your professional hopes and desires

C. Contributions to Science

1. **Enhancing understanding of target site and new drug anti-TB drug pharmacokinetics.** My ongoing research focuses on the target site penetration of anti-TB drugs. This work began by finding that *M. tuberculosis* isolates recovered from cavitory lesions among M/XDR TB patients undergoing surgical resection had increased drug resistance compared to isolates from sputum. To investigate whether this was related to decreased drug penetration into severe lung lesions we developed a research model using a microdialysis method to study the concentrations of second-line TB drugs inside resected human cavitory lesions. We have completed studies for levofloxacin, pyrazinamide, moxifloxacin and linezolid. This research has provided novel data to help us understand the tissue penetration of TB drugs and our study of pyrazinamide provided the first measure of the lung tissue pH in resected lung TB lesions in >50 years. Contrary to current thinking, we showed most lesions had an acidic pH which has important implications for treatment as many drugs are more active in low pH. The ultimate goal of our TB pharmacology research is to provide information that may help clinicians customize drug regimens and improve clinical outcomes.

Bold subheader

Key finding supporting the proposed aims

methodology supporting the proposed aims

Advancing the paradigm and building the scientific premise for proposed aims

Translational objectives

C. Contribution to Science

3. Early caffeine therapy is associated with a lower risk of bronchopulmonary dysplasia

Caffeine therapy is widely used to treat apnea related to prematurity. A landmark international, multicenter trial demonstrated that caffeine reduces the risk of bronchopulmonary dysplasia, a serious and chronic respiratory complication of prematurity. My research has focused on examining the comparative effectiveness of various approaches to initiation of caffeine therapy. Initial studies at our center, which we later validated in a large US cohort of over 60,000 very low birth weight infants, showed earlier initiation of caffeine therapy, compared to later initiation, was associated with a lower risk of bronchopulmonary dysplasia. Our initial novel findings have recently been replicated by several other research groups in the US and internationally.

Recommendations

- Each new grant proposal should prompt you to revise your biosketch, especially the Personal Statement (and possibly Contributions to Science), so that it speaks *directly* to this particular grant proposal
 - within ScienCV you can name new biosketches each time you revise one
- Pay attention to aesthetics and layout – spacing, font, page break
 - Does your printed out biosketch look like the example?
 - Do you need to customize any subheaders to make a point – e.g., teaching or curriculum development
- Reviewers are looking for specific information in particular places – make it easy for the reviewer by following the rules and the formatting

If you are the PI of the grant....

- ▶ Even if you are a postdoctoral fellow, you need to read / review / edit the Personal Statement of all other contributors to this proposal
 - ▶ WHY?
 - ▶ Because this is the PI's job
 - ▶ Each Personal Statement must reflect that writer's role on the project
 - ▶ If someone is sponsoring / mentoring / collaborating with you, that should be mentioned in that person's Personal Statement
-

Recommendations

- ▶ Follow the directions – use the example as a model
 - ▶ Chances are as a junior investigator you will have between 1-3 (maybe 4) Contributions to Science
 - ▶ Do not misrepresent any facts
 - ▶ List all publications as they would appear in PubMed or in any other searchable database
 - ▶ *Advice from a sage academician:*
 - ▶ *“Extraordinary evidence for extraordinary claims”*
 - ▶ *“The magnitude of your supposed accomplishment must align with your tangible contributions”*
 - ▶ *“Self-aggrandizing will certainly backfire. Probably better to lean towards humility to increase likability factor”*
-

Planning the Budget



K Budget



- ▶ This is a **non-modular** budget
 - ▶ There are only 2-line items in a K budget –
 1. **Salary support for PI (you)**
 2. **Technical Budget**
 - ▶ Plan in advance to be sure you can do the work for the money
 - ▶ Reviewers will ask: *Can this work be carried out with this budget?*
-

Technical Budget

@\$30,000/yr for GA CTSA K12

@\$40,000/yr for BIRCWH K12

- a) tuition and fees related to career development (allot \$10,000 for MSCR for Year 1; if you are not taking the MSCR, you have more discretion)
 - b) research expenses, such as supplies, equipment and technical personnel
 - c) travel to research meetings or training
 - d) statistical services including personnel and computer time
 - e) Maximum \$2,500/yr for travel (airfare, lodging, per diem)
-

Required Expenses to itemize in your Budget Justification

From within the technical budget, you need to allocate

1. \$10,000 tuition for MSCR in Year 1 (if applicable)
 2. Annual Ga CTSA scientific meeting at Callaway Gardens (expected)
 - ▶ Hotel, travel by car, registration (this is cheap or free)
 3. Annual NCATS Association for Clinical and Translational Science meeting in Washington, DC (see *PA instructions*)
 - ▶ Airfare and hotel
 - ▶ Discounted registration (Alexey will register you)
 - ▶ Poster / talk preparation
-

Budget Justification (narrative; 2 pages)

A. Senior/Key Person – describe in narrative form why you are PI of this proposal (will be redundant with other sections) – do not include any salary for or description of mentors in this section

(B – E indicate n/a)

F. Other Direct Costs (cap of \$30K or \$40K)

F.I. Materials and Supplies – in this section you detail the expenses to carry out your research. If you are getting money from the department or elsewhere to do the work, be clear what costs are coming from the grant and what are coming from elsewhere. Using standard budget categories will make this easier.

- travel expenses go here



RESEARCH COST

Supplies

Microdialysis (μD): A total of \$10,190 is requested for μD supplies including the following: \$2,895 for a CMA 107 μD pump. \$6,475 for 28 CMA 60 μD probes (\$231.25 per probe), \$430 for 40 CMA syringe pumps, \$285 for 250 μD microvials, and \$105 for 5 CMA pump batteries.

AFB Culture and Drug Susceptibility Testing: A total of \$2,100 is requested for supplies including the following: \$800 for 100 MGIT tubes, \$1,000 for DST reagents, and \$300 for 100 tissue grinders.

Genome Sequencing: A total of \$1,263 is requested for genetic sequencing supplies including the following: \$633 for 250 DNA Qiagen Mini-Kits, and \$630 for reagents necessary for freezing MTB isolates and DNA.

Lab supplies: A total of \$319 is included for miscellaneous lab supplies including gloves and N95 respiratory masks.

Total = \$13,872

Travel: All travel during year 1 will be supported by an ongoing NIH Fogarty TB research-training grant (#D43TW007124).

Coursework: Emory courtesy scholarship for faculty (5 credits/semester) will cover coursework in Year 1.

...

Patient enrollment costs: A total of \$2,000 is requested to pay study staff in the Republic of Georgia to perform all the tasks required for patient enrollment including collecting informed consent, data collection, blood draw, DNA extraction, freezing MTB isolates, microdialysis, and shipping samples. (4 patients * \$500 per patient).

Total = \$10,128

Reviewer's Comments regarding the Budget for an NIH K23

Overall budget is reasonable, but it will be good to see a breakdown of the \$25,000 Research Support. This seems to include a lot of travel. Patient costs itself will cover about \$13,000 (160 women x 2 visits x \$40/visit). This doesn't leave much for a Research Coordinator, Database manager and Biostatistics support.



Learn from funded proposals

- ▶ See KL2-BIRCWH folder on DROPBOX
- ▶ NIH RePORTER for K awards similar to yours

