EXHIBIT 35

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, et al.,

Defendants.

Case No. 1:25-cv-10787-BEM

Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF UAW PRE-MEMBER 1

- I, pursuant to 28 U.S.C. § 1746, declare as follows:
- 1. I am a postdoctoral research fellow, performing scientific research in biochemistry and genomics. As a postdoctoral fellow, I work in a scientific lab that is run by a professor who acts as my mentor. Additionally, I am developing the leadership and scientific skill set to move to the next stage of my career as an assistant professor, where I will run my own laboratory.
- 2. I have wanted to be a scientist since the first science class I took in middle school. I was fascinated by trying to understand how living things work, and I enrolled in every science and math class offered in my high school. When I first had the opportunity to do biology research in a high school summer honors program, I loved it and knew that I wanted to pursue a career in science. To that end, I majored in molecular biochemistry and biophysics in college, and performed research in labs starting in the summer after my freshman year. After college, I enrolled in a biophysics PhD program, where I took courses and performed research in a lab run by my thesis adviser. I published multiple papers during my PhD training, and earned my degree in 2017. I then began my postdoctoral training, where I worked in a different mentor's lab, to learn new scientific approaches and gain additional expertise. I have gone through this extensive training period with the goal of being of a professor and running my own scientific laboratory. This is my career goal because it will enable me to continue to perform the scientific research that I love, as well as teach and mentor students. I know from my experience how important and influential engaging science teachers are in a student's life, and I want to pay it forward and play that role for the next generation of students.

3. I am approaching the end of my postdoctoral training at	and have
received a job offer to begin my own independent lab as an assistant professor in the fall	at

- 4. I was awarded an NSF Graduate Research Fellowship during graduate school, and was supported by a T32 training grant at the end of my graduate training. I was also supported by a separate T32 training grant in the beginning of my postdoctoral period, and by a private foundation postdoctoral fellowship.
 - 5. I am offering this Declaration in my individual capacity and not on behalf of my employer.
- 6. I am a member of which is part of United Auto Workers (UAW). This means I signed authorization cards, in 2023 and 2024, expressing unqualified support for UAW to serve as my exclusive bargaining representative in dealings with my employer, I also voted in support of UAW during an NLRB election in April 2024. UAW is currently representing me in negotiations with for a first-time collective bargaining agreement (CBA) that will govern the terms and conditions of my employment at Once our CBA is finalized, I intend to be a full, dues-paying UAW member.
- 7. I was awarded a Maximizing Opportunities for Scientific and Academic Independent Careers K99/R00 Postdoctoral Career Transition Award to Promote Diversity (MOSAIC grant) by NIH through the National Institute of General Medical Sciences (NIGMS). The grant award number is 1K99GM and the Notice of Award (NOA) for the grant is dated January 5, 2022. A true and correct copy of the NOA is attached hereto as Exhibit A. This grant is known as a pathway to independence grant I was awarded two years of postdoctoral funding (the K99 period) to support the end of my postdoctoral training, and three years of funding for my independent lab (the R00 period) that I can activate when I find an independent position as an assistant professor. These awards are designed to facilitate the process of transitioning from a postdoctoral position to independent faculty a process that is notoriously difficult, given the scarcity of faculty job positions.
- 8. I study how cells in the human body communicate with each other during development, and how this goes awry in disease. Specifically, I want to understand at a molecular level how cells change which genes they express in response to signals from other cells. This process is essential for development, and often is inappropriately regulated in diseases like cancer. By better understanding the regulation of gene expression, I hope to identify possible cancer therapeutic strategies.
- 9. The MOSAIC program is a specific type of the generic, or parent, K99/R00 award that is designed to increase the participation of scientists from under-represented backgrounds in academic

science, by facilitating the transition to faculty for scientists who will promote diversity in academia. A true and correct copy of the announcement of this funding opportunity, PAR-19-343, is attached as Exhibit B. I have been dedicated to promoting the inclusion of women in science throughout my scientific training – I ran a mentoring program for women in science during my graduate training and contributed to the development of parental leave and Title IX policies in my graduate institution. I have also been committed to mentoring students from under-represented backgrounds in laboratory research. I wrote about these past experiences and my plans to continue to work to support the inclusion of scientists from all backgrounds in my future career in the diversity statement in my application. Additionally, I belong to two of the NIH's defined categories of groups underrepresented in science: I felt that I was a good fit for the MOSAIC program and decided to apply to it instead of the standard K99/R00 program. I was particularly excited about the fact that the MOSAIC program works on a cohort model – awardees were encouraged to form a network of early career scientists who excel in their fields and are dedicated to making academia more inclusive. Additionally, fellows would be able to participate in professional development training opportunities arranged by scientific societies supported by the MOSAIC-UE5 grants. I thought that being a part of this network would help me be a better professor in my future, as I would be able to learn from the peers in my cohort about how to best lead a laboratory, and we would support each other through this transition to independence.

10. I spent about 5 months preparing the materials for my K99/R00 application. The application required a scientific proposal, a specific aims page, a training plan, a biosketch (essentially a resume in NIH format), mentoring plans from my mentors, letters from my collaborators, recommendation letters, a diversity statement, a description of the institution environment of my postdoctoral institution, commitment from my department to support my training, a plan for training in responsible conduct of research, a plan for sharing of resources with the scientific community, and a budget. In all, my application was 87 pages long. I extensively discussed the scientific plan with my lab mentors and got feedback on my application from many mentors. As I was beginning my work on this proposal, I discussed my application with the program officer (PO) for the grant to ensure that my application aligned with the types of science that they intended to fund.

11. I have finished both years of the K99 portion of my grant and have been planning to apply to activate the R00 portion of my grant this summer, once I have officially accepted a faculty position as an assistant professor.

- 12. The two years of K99 funding enabled me to collect large genomic data sets during my postdoc, which I published in the major academic paper from my postdoctoral training. This funding also allowed me to present my findings at academic conferences, which is an essential step in the process of finding a faculty position. I also have been able to form a network with other MOSAIC K99/R00 fellows through some of the professional development opportunities arranged by the program. Additionally, the cohort of fellow awardees in my local area have supported each other through the job application process, which has been immensely helpful for all of us.
- 13. In the beginning of April 2025, I heard from other MOSAIC K99/R00 awardees that they had received an email from their Program Officer that the MOSAIC program was canceled. I did not get an email at this time, and not all NIH institutes sent out these warning emails at the same time.
- 14. However, on April 11, 2025, I received an email from Kenneth D. Gibbs, Jr., Director of the Division of Training and Workforce Development at the NIGMS entitled "NIGMS Funding Update" notifying me that the MOSAIC program had been "terminated" "due to changes in NIH/HHS priorities." A true and correct copy of the email is attached hereto as Exhibit C.
- 15. I was not given any individualized explanation for the cancelation of my grant. I was simply told that the MOSAIC program as a whole is being cancelled.
- 16. I was simply told that the MOSAIC program was being canceled due to changes in NIH/HHS priorities. I understood this to mean that this is due to the diversity focus of the MOSAIC program, given that the non-MOSAIC K99/R00 awards were not canceled
- 17. My scientific project is not "based on" "DEI"/ "amorphous equity objectives" or "gender identity". I study gene expression in cancer cells. The MOSAIC program considered an applicant's commitment to promoting diversity in science in addition to the excellence of their scientific proposal and research experience, and I understand this to be the reason behind my grant cancelation.
- 18. My scientific project does not specifically acknowledge minority groups or demographic differences.
- 19. My understanding of R00 activation in the past was that it was an administrative process applicants would email their PO with information about their job offer, their new institution, and their budget, to show that their new position and institution would support them and their research. The scientific merits of my grant were already reviewed and positively evaluated when the decision was made to fund my award in 2022. If not for the cancelation of the MOSAIC program, I do not anticipate that I would have had any difficulty activating my R00 award at my new institution.

- 20. I have applied for academic faculty job positions under the assumption that I will be able to activate my R00 funding. The promise of this funding made me a more competitive candidate because I would bring in funding to kick-start my lab, and it showed that I have a successful track record of applying for and being awarded NIH funding. Now, I no longer have the funds, and there is a concern that I will be unable to obtain future funding, given that I have received an award that is considered a "DEI grant". Therefore, without this funding I am now a less competitive candidate for academic jobs. I have received a job offer to begin my own independent lab as an assistant professor, but the offer is not yet finalized. Without my grant funding, my new institution may rescind the job offer.
- 21. If I am able to start my independent position this fall, not having my R00 funding will reduce the total starting funds I have to begin my independent lab by about 42%. This will vastly impair what I am able to do in the lab. I was planning to use the R00 funds to hire a technician to work in my lab – now I will not be able to hire a technician until I obtain additional grant funding. I also planned to use the R00 funding to purchase equipment and experimental supplies, that I now will not be able to purchase. Additionally, having the R00 funding gave me some freedom to focus exclusively on setting up my lab and mentoring my first students. Now, I will have to devote time immediately to applying for other NIH and private foundation grants to fund my lab. This is time I will not be able to devote to teaching my first students how to do experiments in the lab, which will also impair their training and scientific development. In all, this means that my ability to get my new lab up and running will be severely impaired. The consequences of this slow down for my career include the fact that I will have a more difficult time achieving tenure. If I cannot get tenure within a set time period after starting my academic position, I will not be able to keep my job. Tenure is evaluated based on scientific progress and grant funding – not being able to devote the beginning of my lab time to scientific work means I will likely publish fewer papers before I go up for tenure, and will reduce the amount of preliminary data I will be able to generate to include in other grant applications. Beyond the effects on me and my career, this reduction in funding will reduce and impair my scientific output and discoveries.
- 22. I have not appealed the termination because my grant itself has not been terminated yet, although I am aware that the MOSAIC program has been canceled and my grant will be terminated. I do intend to appeal when I receive official termination notice. However, I do not believe the appeal has any chance of success, given the stated change in NIH and HHS priorities away from any "DEI" projects.
- 23. I wish to file my declaration under seal because I am concerned about being blacklisted from future federal funding through the NIH, and the subsequent harm this would create for my career.

- 24. I have concerns about public hostility and harassment due to the current political climate. I am worried that I would be harassed and derisively labeled as a "DEI" hire with the implication that I am not as qualified as other scientists because of my participation in the MOSAIC program. My new job as an assistant professor has not yet been finalized, and I worry that being named in this suit could lead to my job offer being rescinded.
- 25. I also worry that I will be blacklisted from future federal funding opportunities, in particular from the NIH. NIH funding is absolutely essential to my career the expectations for achieving tenure in academia are generally to have at least one active major NIH grant. If I cannot get tenure, I will lose my job as a professor. Additionally, collaborations are a major part of scientific research, including collaborating as co-investigators on grants. If I develop a reputation as being potentially blacklisted by the NIH, potential collaborators will view me as a risk and be less likely to work with me on scientific projects and grant applications. This will limit the scientific work I am able to complete in my career.
- 26. I have spoken with other MOSAIC scientists who have expressed similar fears as I describe above. MOSAIC scholars that are still attempting to secure a position as an assistant professor are concerned about drawing attention to this grant cancelation and reducing their ability to secure a job.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 19th day of April, 2025.

EXHIBIT A

Recipient Information

1. Recipient Name



- 2. Congressional District of Recipient
- 3. Payment System Identifier (ID)
- 4. Employer Identification Number (EIN)
- Data Universal Numbering System (DUNS)
- 6. Recipient's Unique Entity Identifier
- 7. Project Director or Principal Investigator

julia rogers@hms.harvard.edu

8. Authorized Official

Federal Agency Information

9. Awarding Agency Contact Information Susan F. South

NATIONAL INSTITUTE OF GENERAL **MEDICAL SCIENCES** southsf@mail.nih.gov 301-594-4495

10. Program Official Contact Information

Kenneth D Gibbs Program Officer, Twd NATIONAL INSTITUTE OF GENERAL **MEDICAL SCIENCES** kenneth.gibbs@nih.gov 301-594-3901

Federal Award Information

- 11. Award Number
- 12. Unique Federal Award Identification Number (FAIN)
- 13. Statutory Authority 42 USC 241 42 CFR 52
- 14. Federal Award Project Title
- 15. Assistance Listing Number
- 16. Assistance Listing Program Title Biomedical Research and Research Training
- 17. Award Action Type **New Competing**
- 18. Is the Award R&D?

Yes

Summary Federal Award Financial Information	1
19. Budget Period Start Date 01/05/2022 - End Date 12/31/2022	
20. Total Amount of Federal Funds Obligated by this Action	\$100,000
20 a. Direct Cost Amount	\$92,593
20 b. Indirect Cost Amount	\$7,407
21. Authorized Carryover	\$0
22. Offset	\$0
23. Total Amount of Federal Funds Obligated this budget period	\$100,000
24. Total Approved Cost Sharing or Matching, where applicable	\$0
25. Total Federal and Non-Federal Approved this Budget Period	\$100,000
26. Project Period Start Date 01/05/2022 - End Date 12/31/2023	
27. Total Amount of the Federal Award including Approved Cost	\$100,000
Sharing or Matching this Project Period	

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award



CAREER TRANSITION AWARD

Department of Health and Human Services
National Institutes of Health



NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA –
Principal Investigator(s):
Award e-mailed to:
Dear Authorized Official:
The National Institutes of Health hereby awards a grant in the amount of \$100,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to
Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.
Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of General Medical Sciences of the National Institutes of Health under Award Number. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.
Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.
If you have any questions about this award, please direct questions to the Federal Agency contacts.
Sincerely yours,
Justin Rosenzweig Grants Management Officer NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
Additional information follows

COnstative Award Color ations lide this Budgen enricol SUSS Dollarise d 04/25/25	Page 11 of 49
Salaries and Wages	\$58,970
Fringe Benefits	\$15,510
Personnel Costs (Subtotal)	\$74,480
Other	\$18,113
Federal Direct Costs	\$92,593
Federal F&A Costs	\$7,407
Approved Budget	\$100,000
Total Amount of Federal Funds Authorized (Federal Share)	\$100,000
TOTAL FEDERAL AWARD AMOUNT	\$100,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$100,000

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$100,000	\$100,000
2	\$100,000	\$100,000

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:

Document Number:

PMS Account Type:

Fiscal Year:

2022

IC	CAN	2022	2023
		\$100,000	\$100,000

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

Award Processed:

SECTION II – PAYMENT/HOTLINE INFORMATION –

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - STANDARD TERMS AND CONDITIONS -

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(Sea SHH1H2D5ePage 17 & To Elfond its.n Dgov/gnems/38ic3/5 war Filed i O4/25/25 for cePage 12 of 49 references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) K99GM144750. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - GM SPECIFIC AWARD CONDITIONS -

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2

- 1. This award is subject to the conditions set forth in PAR19-343, Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 - Independent Clinical Trial Not Allowed), which are hereby incorporated by reference as special terms and conditions of this award. Copies of this PA may be accessed at the following internet address: https://grants.nih.gov/grants/guide/pa-files/PAR-19-343.html
- 2. Since the principal purpose of this award is to transition the principal investigator to an independent investigator, no request to change the principal investigator will be considered.
- 3. A progress report for the -02 year of support should be submitted through the NIH Commons no later than 45 days before the end of the -01 year and must incorporate all application sections noted in the Program Announcement.
- 4. In the event the transition to the R00 phase occurs prior to the current project period end date of 6/30/2023, this K99 award level may be adjusted accordingly.
- MOSAIC K99/R00 scholars will be part of organized scientific cohorts coordinated by MOSAIC Institutionally-Focused Research Education Award to Promote Diversity (UE5) grantees. The PI and their and their primary mentor are expected to participate in mentoring, networking, and professional development activities by the American Society for Cell Biology (ASCB: https://www.ascb.org/career-development/ascb-mosaic-program-amp/).
- 6. None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable.

Current salary cap levels can be found at the following URL:

http://grants.nih.gov/grants/policy/salcap_summary.htm

- 7. As appropriate, the awardee is required to follow the sharing plan(s) for unique research resources (i.e. Data, Model Organism, Genomic Data, or other) associated with this project and may not implement any changes to the plan(s) without the written prior approval of the National Institute of General Medical Sciences.
- 8. This award is issued in accordance with the NIH fiscal policies described in NIH Guide Notice NOT-OD-21-058.
- 9. The Year -01 budget period is slightly less than 12 months in length (full 12-month level of funds provided) so that the anniversary date for future non-competing awards will be January 1. The Research Performance Progress Report (RPPR) will be due 45 days prior to this date (60 days for non-SNAP awards) each year. Guidance on RPPR submission is documented in the RPPR Instruction Guide found at: http://grants.nih.gov/grants/rppr/index.htm.

This anniversary date may change the receipt date for the next competing continuation (Type 2) application. Consult the submission dates/deadlines on the NIH Office of Extramural Research Grants (OER) Home page at http://grants.nih.gov/grants/dates.htm.

SECTION V - NIGMS CONTACTS

The NIGMS WWW home page is at http://www.nigms.nih.gov

SPREADSHEET SUMMAR	Y
AWARD NUMBER:	
INSTITUTION:	

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 14 of 49

Budget	Year 1	Year 2
Salaries and Wages	\$58,970	\$61,156
Fringe Benefits	\$15,510	\$16,084
Personnel Costs (Subtotal)	\$74,480	\$77,240
Other	\$18,113	\$15,353
TOTAL FEDERAL DC	\$92,593	\$92,593
TOTAL FEDERAL F&A	\$7,407	\$7,407
TOTAL COST	\$100,000	\$100,000

Facilities and Administrative Costs	Year 1	Year 2
F&A Cost Rate 1	8%	8%
F&A Cost Base 1	\$92,593	\$92,593
F&A Costs 1	\$7,407	\$7,407

EXHIBIT B

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 16 of 49

This notice has expired. Check the <u>NIH Guide (https://grants.nih.gov/funding/searchguide/)</u> for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute of General Medical Sciences (NIGMS (https://www.nigms.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (http://www.nibib.nih.gov/))

National Institute of Nursing Research (NINR (https://www.ninr.nih.gov/))

National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

National Human Genome Research Institute (<u>NHGRI (http://www.genome.gov/</u>))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Library of Medicine (NLM_(http://www.nlm.nih.gov/))

National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))

National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (http://www.niaaa.nih.gov/))

National Heart, Lung and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

National Institute of Allergy and Infectious Diseases (NIAID (http://www.niaid.nih.gov/))

National Institute of Neurological Disorders and Stroke (NINDS (http://www.ninds.nih.gov/))

National Eye Institute (<u>NEI (http://www.nei.nih.gov/)</u>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (https://www.niams.nih.gov/))

Funding Opportunity Title

Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 - Independent Clinical Trial Not Allowed)

Activity Code

K99 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k99&Search.x=0&Search_y=0&Search_Type=Activity)/R00 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r00&Search.x=0&Search_y=0&Search_Type=Activity) Career Transition Award/Research Transition Award

Announcement Type

New

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=31894) associated with this funding opportunity

- August 17, 2021 This PAR has been reissued as <u>PAR-21-271 (https://grants.nih.gov/grants/guide/pa-files/PAR-21-271.html</u>).
- June 22, 2021 Notice of Change to NOT-NR-19-011. See Notice NOT-NR-21-005 (https://grants.nih.gov/grants/guide/notice-files/NOT-NR-21-005.html).
- **April 23, 2021** Continuation of Temporary Extension of Applicant Eligibility in PAR-19-343. See Notice <u>NOT-GM-21-037</u> (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-037.html).
- April 21, 2021 Notice of NIAMS Participation in PAR-19-343. See Notice NOT-AR-21-020 (//grants.nih.gov/grants/guide/notice-files/NOT-AR-21-020.html).
- March 3, 2021 Notice of NIDDK Participation in PAR-19-343. See Notice NOT-DK-21-012 (//grants.nih.gov/grants/guide/notice-files/NOT-DK-21-012.html).
- **February 25, 2021** Notice of NEI Participation in PAR-19-343. See Notice NOT-EY-21-008 (/grants/guide/notice-files/NOT-EY-21-008.html).
- January 27, 2021 Notice of Special Interest (NOSI): High-Priority Interest to Enhance Data Science Research Training in Addiction Research. See Notice NOT-DA-21-013 (//grants.nih.gov/grants/guide/notice-files/NOT-DA-21-013.html).
- December 08, 2020 Notice of NINDS Participation in PAR-19-343. See Notice NOT-NS-21-015 (/grants/guide/notice-files/NOT-NS-21-015.html).
- December 7, 2020 Notice of Addition of AIDS Application Due Dates to PAR-19-343. See Notice NOT-GM-21-007 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-21-007.html).
- **September 22, 2020** Notice of NIAID's Participation in PAR-19-343. See Notice NOT-AI-20-074 (/grants/guide/notice-files/NOT-AI-20-074.html).
- August 10, 2020 Temporary Extension of Applicant Eligibility in PAR-19-343. See Notice NOT-GM-20-051 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-20-051.html).
- August 5, 2020 Notice of Change to the Eligibility of Foreign Components in PAR-19-343. See Notice NOT-GM-20-049 (/grants/guide/notice-files/NOT-GM-20-049.html).
- July 30, 2020 Notice of Informational Webinar on the NIH Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Program Funding Opportunity Announcements (UE5 and K99/R00). See Notice NOT-GM-20-048 (/grants/guide/notice-files/NOT-GM-20-048.html).
- July 22, 2020 Notice of Change to the Application Instructions for the Candidate Eligibility Statement in PAR-19-343. See Notice NOT-GM-20-038 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-20-038.html).
- July 6, 2020 Notice of Participation of NCCIH in PAR-19-343. See Notice NOT-AT-20-019 (//grants.nih.gov/grants/guide/notice-files/NOT-AT-20-019.html).
- March 10, 2020 Reminder: FORMS-F Grant Application Forms & Instructions Must be Used for Due Dates On or After May 25, 2020- New Grant Application Instructions Now Available. See Notice NOT-OD-20-077 (/grants/guide/notice-files/NOT-OD-20-077.html).
- March 17, 2020 Notice of NIDCR Participation in PAR-19-343. See Notice NOT-DE-20-018
 (https://grants.nih.gov/grants/guide/notice-files/NOT-DE-20-018.html).
- March 6, 2020 Notice of NIDCD Participation in PAR-19-343. See Notice NOT-DC-20-002 (/grants/guide/notice-files/NOT-DC-20-002.html).
- **February 10, 2020** Notice of NIEHS Participation in PAR-19-343. See Notice NOT-ES-20-011 (//grants.nih.gov/grants/guide/notice-files/NOT-ES-20-011.html).
- January 28, 2020 Notice of NIAAA Participation in PAR-19-343. See Notice NOT-AA-20-003 (https://grants.nih.gov/grants/guide/notice-files/NOT-AA-20-003.html).
- <u>January 22, 2020 (/grants/guide/notice-files/NOT-OD-20-058.html)</u> Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. See Notice <u>NOT-OD-20-058 (/grants/guide/notice-files/NOT-OD-20-058.html)</u>.
- **January 15, 2020** Notice of NHLBI Participation in PAR-19-343 .See Notice NOT-HL-19-742 (/grants/guide/notice-files/NOT-HL-19-742.html).
- January 8, 2020 Notice of NIDA Participation in PAR-19-343. See Notice <u>NOT-DA-20-029</u> (https://grants.nih.gov/grants/guide/notice-files/NOT-DA-20-029.html).
- **December 30, 2019** Notice of Participation of NIMH in PAR-19-343. See Notice NOT-MH-20-015 (//grants.nih.gov/grants/guide/notice-files/NOT-MH-20-015.html).

- December 19, 2019 Notice of NLM Participation in PAR-19-343. See Notice NOT-LM-20-002 (https://grants.nih.gov/grants/guide/notice-files/NOT-LM-20-002.html).
- **December 12, 2019** Notice of Participation of the National Institute on Aging (NIA) in PAR-19-343. See Notice NOT-AG-20-009 (/grants/guide/notice-files/NOT-AG-20-009.html).
- **November 22, 2019** Notice of NIH's Interest in Diversity. See Notice NOT-OD-20-031 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).
- October 30, 2019 NIH Extension Policy for Eligibility Window for Pathway to Independence Awards (K99/R00). See Notice <u>NOT-OD-20-011 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-20-011.html)</u>.
- October 11, 2019 Notice of NHGRI Participation in PAR-19-343 "Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 Independent Clinical Trial Not Allowed)". See Notice NOT-HG-20-004 (/grants/guide/notice-files/NOT-HG-20-004.html).
- **September 27, 2019** NIMHD Announces Participation in PAR-19-343. See Notice NOT-MD-20-003 (/grants/guide/notice-files/NOT-MD-20-003.html).
- **September 23, 2019** Notice of NINR's Participation in PAR-19-343. See Notice NOT-NR-19-011 (//grants.nih.gov/grants/guide/notice-files/NOT-NR-19-011.html).
- **September 20, 2019** Notice of Change to Eligibility Information and Application Instructions in PAR-19-343. See Notice NOT-GM-19-059 (/grants/guide/notice-files/NOT-GM-19-059.html).
- **September 11, 2019** Notice of NIBIB's Participation in PAR-19-343. See Notice NOT-EB-19-020 (/grants/guide/notice-files/NOT-EB-19-020.html).
- August 23, 2019 Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions
 (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-137 (/grants/guide/notice-files/NOT-OD-19-137.html).
- **July 26, 2019** Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-128 (/grants/guide/notice-files/NOT-OD-19-128.html).
- August 19, 2019 Notice of Informational Webinar on the NIH Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Program Funding Opportunity Announcements (UE5 and K99/R00). See Notice NOT-GM-19-058 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-19-058.html).

NOT-GM-19-020 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-19-020.html) NOT-GM-19-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-19-019.html)

Funding Opportunity Announcement (FOA) Number

PAR-19-343

Companion Funding Opportunity

PAR-19-342 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-342.html)

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

 $93.859, \, 93.286, \, 93.361, \, 93.307, \, 93.172, \, 93.866, \, 93.879, \, 93.279, \, 93.233, \, 93.837, \, 93.838, \, 93.839, \, 93.840, \, 93.273, \, 93.113, \, 93.173, \, 93.121, \, 93.213, \, 93.855, \, 93.853, \, 93.867, \, 93.847, \, 93.846$

Funding Opportunity Purpose

The purpose of the MOSAIC Postdoctoral Career Transition Award to Promote Diversity (K99/R00) program is to support a cohort of early career, independent investigators from diverse backgrounds conducting research in NIH mission areas. The long-term goal of this program is to enhance diversity in the biomedical research workforce. The MOSAIC K99/R00 program is designed to facilitate a timely transition of promising postdoctoral researchers from diverse backgrounds (e.g., see NIH's Interest in Diversity (NOT-OD-18-210.html)) from their mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions at research-intensive institutions. The MOSAIC K99/R00 program will provide

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 19 of 49

independent NIH research support before and after this transition to help awardees launch successful, independent research careers. Additionally, MOSAIC K99/R00 scholars will be part of organized scientific cohorts and will be expected to participate in mentoring, networking, and professional development activities coordinated by MOSAIC Institutionally-Focused Research Education Award to Promote Diversity (UE5) grantees.

This Funding Opportunity Announcement (FOA) is designed specifically for applicants proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary study to a clinical trial. Applicants to this FOA are permitted to propose research experience in a clinical trial led by a mentor or co-mentor.

Key Dates

Posted Date

August 15, 2019

Open Date (Earliest Submission Date)

January 12, 2020

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

<u>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111)</u> apply, by 5:00 PM local time of applicant organization. All <u>types of non-AIDS applications</u> allowed for this funding opportunity announcement are due on these dates.

The first standard due date for this FOA is February 12, 2020.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

New Date Standard AIDS dates (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11112) apply.

All applications are due by 5:00 PM local time of applicant organization. All types of AIDS and AIDS-related applications (https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html#Application%20Types%20Allowed) allowed for this funding opportunity announcement are due on the listed dates.

The first AIDS application due date for this FOA is January 7, 2021.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Scientific Merit Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113)

Advisory Council Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

Earliest Start Date

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 20 of 49

Expiration Date

New Date August 17, 2021 per issuance of <u>PAR-21-271 (https://grants.nih.gov/grants/guide/pa-files/PAR-21-271.html)</u>. (Original Expiration Date: January 8, 2023)

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Career Development (K) Instructions in the <u>SF424 (R&R) Application Guide</u> (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the <u>NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)</u>). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in <u>Section IV</u>. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Table of Contents

Part 1. Overview Information

Key Dates

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts

Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Research Career Development program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. NIH Institutes and Centers (ICs) support a variety of mentored and non-mentored career development award programs designed to foster the transition of new investigators to research independence and to support established investigators in achieving specific objectives. Candidates should review the different career development (K) award programs to determine the best program to support their goals. More information about Career programs may be found at the NIH Extramural Training Mechanisms website (https://researchtraining.nih.gov/).

The objective of the NIH Pathway to Independence Award (K99/R00) is to help outstanding postdoctoral researchers complete needed, mentored training and transition in a timely manner to independent, tenure-track or equivalent faculty positions. The K99/R00 award is intended to foster the development of a creative, independent research program that will be competitive for subsequent independent funding and that will help advance the mission of the NIH. The objective of the MOSAIC Postdoctoral Career Transition Award to Promote Diversity (K99/R00) is to enhance workforce diversity by facilitating a timely transition of promising postdoctoral researchers from diverse backgrounds (e.g., see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)) from their mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions at research-intensive institutions.

Background Information

The National Institutes of Health (NIH) recognizes the need to diversify the scientific workforce by enhancing the participation of individuals from groups identified as <u>underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)</u> in the

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 21 of 49

biomedical, clinical, behavioral and social sciences (collectively termed "biomedical") research workforce. Diversity at all levels from the kinds of science to the regions in which it is conducted to the backgrounds of the people conducting it contributes to excellence in research training environments and strengthens the research enterprise. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual interests to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of research, enhancing public trust, and increasing the likelihood that health disparities and the needs of underserved populations are addressed in biomedical research. NIH strives to ensure that future generations of researchers will be drawn from the entire pool of talented individuals, bringing different aptitudes, perspectives, interests, and experiences to address complex scientific problems. NIH seeks to enhance the diversity of the biomedical research workforce by supporting individuals from a variety of backgrounds at multiple training and career stages in a variety of institutions and educational settings across the country.

Need for the Program

Promoting diversity in the extramural scientific workforce is critical to the success of the NIH mission and is consistent with the mandates of the 21st Century Cures Act (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html). While scientific workforce diversity supports the NIH mission, expanding the pool of academic investigators from nationally underrepresented backgrounds in the biomedical research workforce has remained an elusive goal. NIH has a longstanding commitment to training the next generation of biomedical scientists and supporting training of students from diverse backgrounds, for example groups underrepresented in biomedical research, through a variety of fellowships, career development awards, and institutional training and student development programs (https://extramural-diversity.nih.gov/building-participation/commitment-across-nih). In spite of recent advances, individuals from certain groups and backgrounds are underrepresented in the biomedical sciences research workforce as described in the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html). The severity of the underrepresentation of these groups increases throughout the training stages. For example, students from certain racial and ethnic groups, including Blacks or African Americans, Hispanics or Latinos/Latinas, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders comprise ~39 percent of the college age population (Census Bureau (http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml) data), but earn only ~17 percent of bachelor's degrees and ~13 percent of Ph.D. degrees in the life sciences (National Center for Science and Engineering Statistics (https://www.nsf.gov/statistics/datatools.cfm)). Additionally, while the United States has seen a significant increase in the number of Ph.D. degrees in the biomedical sciences earned by scientists from historically underrepresented racial and ethnic groups in the biomedical research workforce, a corresponding increase in the ranks of the faculty in basic science departments has not occurred (Gibbs, et al., eLife 2016 (https://elifesciences.org/articles/21393); Valantine, Lund & Gammie, CBE-Life Sciences Education, 2016 (https://www.lifescied.org/doi/full/10.1187/)). Similarly, women have earned a majority of biomedical Ph.Ds. since 2008 (NSF data (https://ncses.nsf.gov/pubs/nsf19304/)), but only approximately 1/3 of NIH-funded principal investigators are women (NIH Databook (https://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=218&catId=15)).

NIH supports individuals at this important transition point through the K99/R00 program (https://researchtraining.nih.gov/programs/career-development/k99-r00); however, the diversity of K99/R00 awardees does not reflect the demographics of the Nation. For example, over 90% of NIGMS K99/R00 grantees have transitioned to independent faculty positions; however, only 7% of NIGMS K99/R00 applicants are from racial and ethnic groups historically underrepresented, and only 33% have been women.

NIH has undertaken a number of efforts to facilitate the <u>career transition of postdoctoral scientists from diverse groups</u> (https://extramural-diversity.nih.gov/career-pathways/infographic/career) into the professoriate, including the Into the professoriate, including the <a href="https://extramural-diversity.nih.gov/career-pathways/infographic/ca

(https://www.nigms.nih.gov/Research/Mechanisms/Pages/PromoteDiversity.aspx), and re-entry into biomedical research careers (https://www.nigms.nih.gov/Research/Mechanisms/Pages/PromoteReentry.aspx). Additionally, the NIH Common Fund supports the National Research Mentoring Network (NRMN) (https://www.nigms.nih.gov/training/dpc/pages/nrmn.aspx), a nationwide consortium of biomedical professionals and institutions collaborating to provide biomedical trainees from all backgrounds and at all levels with evidence-based mentorship and professional development programming. While these efforts have supported the development of highly trained biomedical scientists who have the necessary knowledge and skills to pursue independent careers in the biomedical research workforce, there remains a compelling need to develop additional strategies to promote transitions to independent faculty positions at research-intensive institutions.

Program Goal

The Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program is part of NIH's efforts to enhance diversity within the academic biomedical research workforce, and is designed to facilitate the transition of talented postdoctoral

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 22 of 49

researchers from diverse backgrounds, for example individuals from groups <u>underrepresented in the biomedical research workforce at the faculty level, (https://grants.nih.gov/grants/guide/pa-files/PAR-19-343.html)</u> into independent faculty careers in research-intensive institutions. The program has two components: an institutionally-focused research education cooperative agreement (UE5) and an individual postdoctoral career transition award (K99/R00) to enhance diversity. The objective of the MOSAIC Postdoctoral Career Transition Award to Promote Diversity (K99/R00) is to enhance workforce diversity by facilitating a timely transition of promising postdoctoral researchers from diverse backgrounds (e.g., see <u>Notice of NIH's Interest in Diversity</u> (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)) from their mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions at research-intensive institutions.

Program Considerations

The MOSAIC K99/R00 program is intended to foster the development of creative, innovative, independent researchers who will be competitive for subsequent independent biomedical research funding, and who will enhance diversity in the biomedical research workforce.

The specific NIH Institute and Center scientific areas supported through this FOA include the following:

NIGMS supports basic research that increases our understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS' research mission is aimed at understanding the principles, mechanisms, and processes that underlie living systems. It also supports research in specific clinical areas that affect multiple organs, particularly those related to injury and critical illness: sepsis, trauma, burn, wound healing, anesthesiology, and clinical pharmacology. For more information see https://www.nigms.nih.gov/about/overview/pages/default.aspx (https://www.nigms.nih.gov/about/overview/pages/default.aspx).

Individuals must be in mentored, postdoctoral training positions to be eligible to apply to the K99/R00 program. The K99 is not intended to extend time in the postdoctoral lab while an individual is on the job market. Individuals who are applying or interviewing for tenure track (or equivalent) faculty positions at research-intensive institutions are not the intended candidates for the MOSAIC K99/R00 Transition Award. If an applicant achieves independence (any faculty or non-mentored research position) before a K99 award is made, neither the K99, nor the R00 award, will be made.

The K99/R00 award will provide up to 5 years of support in two phases. The initial (K99) phase will provide support for up to 2 years of mentored postdoctoral research training and career development. The second (R00) phase will provide up to 3 years of independent research support, which is contingent on satisfactory progress during the K99 phase and an approved, independent, tenure-track (or equivalent) faculty position. The two award phases are intended to be continuous in time. Although exceptions may be possible in limited circumstances, R00 awards will generally only be made to those K99 PDs/PIs who accept independent, tenure-track (or equivalent) faculty positions by the end of the K99 award period.

Additional Information for Physician-Scientists: For the purposes of this program, physician-scientists include individuals with an MD, DO, DDS/DMD, DVM/VMD, or nurses with research doctoral degrees who devote the majority of their time to biomedical research. The K99/R00 is intended for those physician-scientists who already have substantial research training and are dedicated to initiating a strong, research-intensive career as physician-scientists. The K99/R00 program is designed to facilitate a timely transition of outstanding physician-scientists from mentored, research positions to independent, tenure-track or equivalent faculty positions, and to provide independent NIH research support during the transition. Individuals who need a longer period of mentored career development before they are prepared to begin the transition to research independence should consider the K08 or K23 program (see: K Kiosk (https://researchtraining.nih.gov/programs/career-development)).

Applicants must have no more than 4 years of postdoctoral research experience at the time of the initial or the subsequent Resubmission application. Candidates are strongly encouraged to apply no later than the third year of their postdoctoral training to ensure awardees receive maximum benefit from both the K99 phase of the award, and to facilitate a timely transition to independence.

The K99/R00 award is intended for individuals who require at least 12 months of mentored research training and career development (K99 phase) before transitioning to the R00 award phase of the program. Consequently, the strongest applicants will require and propose a well-conceived plan for 1 2 years of substantive mentored research training and career development that will help them become competitive candidates for tenure-track faculty positions and prepare them to launch robust, independent research programs. An individual who cannot provide a compelling rationale for at least one year of additional mentored research training at the time of award is not a strong candidate for this award (e.g., individuals who are actively applying or interviewing for independent positions at research-intensive institutions). If an applicant achieves independence (any faculty or non-mentored research position) before a K99 award is made, neither the K99, nor the R00 award, will be made.

MOSAIC K99/R00 scholars will be expected to participate in additional mentoring, networking, and professional development activities coordinated by the institutionally-focused research education awardees (MOSAIC UE5) as part of the candidate's Plan for Career

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 23 of 49

Development. The integrated program of research and mentoring is expected to provide awardees with the mentoring and professional networks that will prepare them to transition into, advance, and succeed in independent academic research careers at research intensive institutions.

Pre-Submission Consultation

Applicants are *strongly encouraged* to consult with NIH scientific/research staff when planning an application. Early contact provides an opportunity for NIH scientific/research staff to provide guidance on program scope and appropriateness of the proposed research and training for potential funding in response to this FOA. Applicants should contact NIH scientific/research staff as early as possible before the due date.

Note: This Funding Opportunity Announcement (FOA) is designed specifically for applicants proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary study to a clinical trial. Applicants to this FOA are permitted to propose research experience in a clinical trial led by a mentor or co-mentor. See <u>Section VIII. Other Information</u> for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

Resubmission

The <u>OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116)</u> and the SF424 (R&R) Application Guide provide details on these application types.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

Note: Applicants may propose to gain experience in a clinical trial led by a mentor/co-mentor as part of their research career development.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/quide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Award budgets are composed of salary and other program-related expenses, as described below.

Award Project Period

The total project period may not exceed 5 years.

Other Award Budget Information

Salary

Mentored Phase (K99)

The total cost for the mentored phase (K99) may not exceed \$100,000 per year at either an NIH intramural or an extramural sponsoring institution site.

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 24 of 49

Salary Support: NIH will contribute up to \$60,000 per year plus fringe benefits toward the salary of the career award recipient for the K99 phase. Further guidance on budgeting for career development salaries is provided in the SF424 (R&R) Application Guide. See also NOT-OD-17-094 (https://grants.nih.gov/grants/guide/notice-files/not-od-17-094.html)

Research Support: Up to \$20,000 per year for the K99 phase.

Intramural: Mentored candidates in the NIH intramural program will be supported by intramural funds provided by the NIH Institute/Center intramural laboratory in which they are conducting their research. Budget details for the mentored phase will be negotiated with the sponsoring intramural laboratory. Salary will be consistent with that offered scientists in similar, intramural NIH positions.

Extramural: Mentored candidates at an extramural sponsoring institution/organization will be supported by NIH extramural funds. The requested salary must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members with equivalent qualifications, rank, and responsibilities in the department concerned. Further guidance on budgeting for career development salaries is provided in the SF424 (R&R) Application Guide.

The total salary may not exceed the legislatively mandated salary cap. See: https://grants.nih.gov/grants/policy/salcap_summary.htm).

Independent Phase (R00)

The total cost for the independent phase (R00) may not exceed \$249,000 per year. This amount includes salary, fringe benefits, research costs, and applicable indirect costs. Indirect costs will be reimbursed at the extramural sponsoring institution's indirect cost rate. Indirect costs requested by consortium participants are included in the total cost limitation.

Other Program-Related Expenses

Research development costs may include (a) tuition and fees related to career development activities; (b) supplies, equipment and technical personnel; and (c) statistical services including personnel and computer time. Research development costs must be justified and consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities.

The application may request up to \$5,000 annually to defray the cost of participation in professional meetings (excluding MOSAIC associated meetings, the costs of which will be covered by the UE5 awardees).

Salary for mentors, secretarial and administrative assistants, etc. is not allowed.

Indirect Costs

For the extramural K99 phase, Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs. For the R00 phase, indirect costs will be reimbursed at the extramural sponsoring institution's indirect cost rate.

NIH grants policies as described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)</u> will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- · Public/State Controlled Institutions of Higher Education
- · Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- · Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- · Tribally Controlled Colleges and Universities (TCCUs)

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 25 of 49

- · Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- · State Governments
- · County Governments
- · City or Township Governments
- · Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- · Eligible Agencies of the Federal Government
- · U.S. Territory or Possession

Other

- · Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- · Faith-based or Community-based Organizations
- · Regional Organizations

The sponsoring institution may be private (profit or nonprofit) or public, including the NIH Intramural Programs and other Federal laboratories.

The applicant institution will be the mentored phase (K99) institution. All institution/organization types listed above are eligible for both the mentored (K99) and independent (R00) phase, with the following exceptions: (1) Eligible agencies of the Federal government, such as the NIH intramural program, are eligible only for the mentored phase; and (2) Eligibility of organizations, other than institutions of higher education, for the R00 phase depends on the nature of the appointment, and the ability of the PD/PI to conduct independent research and apply for NIH research (R01 or R01-equivalent) grants.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.

Foreign components, as <u>defined in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118)</u>, **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- <u>Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform)</u> All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- <u>System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/)</u> (formerly CCR) Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 26 of 49

- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176)
 Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u> Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any candidate with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her mentor and organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities, women and individuals from disadvantaged backgrounds are always encouraged to apply for NIH support. Multiple PDs/PIs (https://grants.nih.gov/grants/glossary.htm#MultipleProgramDirectorPrincipalInvestigator) are not allowed.

Candidates for the K99/R00 award must have a clinical or research doctorate (including PhD, MD, DO, DC, ND, DDS, DMD, DVM, ScD, DNS, PharmD or equivalent doctoral degrees). Clinicians (including those with MD, DDS, DVM and other licensed health professionals) in a clinical faculty position that denotes independence in clinical responsibilities but not in research may also be eligible for the K99/R00 award.

By the time of award, the individual must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status). K99/R00 applicants must have no more than **4 years** of postdoctoral research experience as of the relevant application due date regardless of whether it is a New or Resubmission application. Individuals must be in mentored, postdoctoral training positions to be eligible to apply to the K99/R00 program. If an applicant achieves independence (i.e., any faculty or non-mentored research position) before a K99 award is made, neither the K99 award, nor the R00 award, will be issued.

Parental, medical, or other well-justified leave for personal or family situations is not included in the 4-year eligibility limit, nor is clinical training with no research involvement (e.g., full-time clinical residency training). Part-time postdoctoral research training, related to personal or family situations or occurring during a research residency or fellowship, will be pro-rated accordingly. In addition, time spent conducting postgraduate clinical training that does not involve research is not considered as part of the 4-year research training eligibility limit. Only time dedicated to research activities would count toward the 4-year limit.

NIH will consider extensions of the 4-year eligibility window for life events (e.g., childbirth or adoption, military service, health-related issues, natural disasters) that impact research progress during the 4-year eligibility window. Applicants seeking an extension of the 4-year eligibility window must contact a Scientific/Research Contact at least 8 weeks before submitting the application.

Enhancing Diversity

The overarching goal of this program is to enhance the diversity of independent investigators conducting research within the NIH mission. Fostering diversity by addressing underrepresentation in the scientific research workforce is a key component of the NIH strategy to identify, develop, support and maintain the quality of our scientific human capital. In spite of tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. NIH encourages institutions to diversify their student, postdoctorate and faculty populations to enhance the participation of individuals from groups identified as underrepresented in the biomedical sciences (e.g., see the Notice of NIH's of Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)).

For the purpose of this announcement, institutions are strongly encouraged to identify candidates who will enhance diversity on a national basis. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be demonstrated convincingly to be underrepresented by the grantee institution should be encouraged to participate in this program.

Individuals are NOT eligible if they:

• Have currently or previously held an independent research faculty or tenure-track faculty position, or its equivalent, in academia, industry or elsewhere; or

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 27 of 49

- Have more than 4 years of related postdoctoral research training at the time of initial application or resubmission; or
- Have been an independent PD/PI on NIH research grants (e.g. R01, R03, R21), NIH career development awards (e.g., K01, K07, K08, K23, K25), or other peer-reviewed NIH or non-NIH research grants over \$100,000 direct costs per year, or project leaders on sub-projects of program project (P01) or center (P50) grants.

Ph.D. (or equivalent research doctorate degree) candidates in positions other than postdoctoral fellow positions: It is recognized that some institutions appoint postdoctoral fellows in positions with other titles although they are still in non-independent, mentored training positions. Candidates in such positions are encouraged to obtain confirmation of their eligibility from the relevant IC before they begin to prepare their applications. It is incumbent upon the candidate to provide evidence that his or her position complies with the intent of this eligibility requirement. If a potential applicant is in a position that is not clearly identifiable as a postdoctoral training position, the request for an exception must be accompanied by an official statement of the institution's policy (e.g. published position description in an official institutional document) which documents the position as a mentored, postdoctoral training position.

Clinicians (including those with M.D., D.D.S, D.V.M. and other licensed professionals) in positions not designated as postdoctoral positions: Following clinical training or fellowship training periods, clinicians often obtain a clinical faculty position that denotes independence in clinical responsibilities but not in research. A clinical faculty member who does not hold an independent research faculty position may be eligible for the K99/R00 award, and should contact a Program Director at the relevant NIH Institute for guidance. Clinicians in such positions are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications. Such individuals may also wish to consider other career awards (see K Kiosk (//grants.nih.gov/training/careerdevelopmentawards.htm)) available for junior faculty development.

The following is provided as an aid to distinguish independent from non-independent positions: However, it is not sufficient merely to cite one or more of the following items to document eligibility.

Evidence for non-independence may include:

- The candidate's research is entirely funded by another investigator's grants.
- The candidate's research is conducted entirely in another investigator's assigned space.
- According to institutional policy, the candidate cannot hire postdoctoral fellows or technical staff or be the responsible supervisor
 of graduate students.
- According to institutional policy, the candidate is not allowed to submit an application as the PD/PI of an NIH research grant application (e.g., R01).
- · The candidate lacks other rights and privileges of faculty, such as attendance at faculty meetings.

Conversely, evidence for independence, and therefore lack of eligibility, includes:

- The candidate has a full-time faculty position.
- The candidate received a start-up package for support of his/her independent research.
- The candidate has research space dedicated to his/her own research.
- The candidate may attend faculty meetings, be the responsible supervisor for graduate students, and/or hire technical support or postdoctoral fellows.
- The candidate is eligible to apply for independent research funding as the PD/PI of an NIH research grant.

2. Cost Sharing

This FOA does not require cost sharing as defined in the (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct, and each is from a different candidate.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. An individual may not have two or more competing NIH career development applications pending review concurrently. In addition, NIH will not accept:

• A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 28 of 49

- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html))

Level of Effort

At the time of award, the candidate must have a full-time appointment at the academic institution. Candidates are required to commit a minimum of 75% of full-time professional effort (i.e., a minimum of 9 person-months) to their program of career development during the mentored phase. Candidates may engage in other duties as part of the remaining 25% of their full-time professional effort not covered by this award, as long as such duties do not interfere with or detract from the proposed career development program. Candidates who have VA appointments may not consider part of the VA effort toward satisfying the full time requirement at the applicant institution. Candidates with VA appointments should contact the staff person in the relevant Institute or Center prior to preparing an application to discuss their eligibility.

After the receipt of the award, adjustments to the required level of effort may be made in certain circumstances. See NOT-OD-09-036 (https://grants.nih.gov/grants/guide/url redirect.htm?id=51125) for more details.

R00 Phase. Although candidates are required to devote no less than 75% of their full-time, 12-month professional effort to research (i.e., full-time for 9 person-months), the required 9 person-months of research effort need not be devoted exclusively to the R00-supported research.

Mentor(s)

Before submitting the application, the candidate must identify a mentor who will supervise the proposed career development and research experience. The mentor should be an active investigator in the area of the proposed research and be committed both to the career development of the candidate and to the direct supervision of the candidate's research. The mentor must document the availability of sufficient research support and facilities for high-quality research. Candidates are encouraged to identify more than one mentor, i.e., a mentoring team, if this is deemed advantageous for providing expert advice in all aspects of the research career development program. In such cases, one individual must be identified as the primary mentor who will coordinate the candidate's research. Candidates also are encouraged to propose a mentoring team that will provide additional guidance, typically focused on professional aspects of the candidate's career development. Mentors are expected to promote inclusive, safe and supportive research environments (i.e., institutional and departmental environments where trainees from all backgrounds feel integrated into and supported by the biomedical community).

The candidate must work with the mentor(s) in preparing the application. The primary mentor, regardless of career stage, should be committed to ensuring that the scholar will receive the mentorship needed to advance the scholar's career. If the primary mentor, or a member of the mentor team, is a well-established investigator, the mentor should have a successful track record of mentoring individuals at the candidate's career stage.

Institutional Environment

The applicant institution must have a strong, well-established record of research and career development activities and faculty qualified to serve as mentors in biomedical, behavioral, or clinical research. The applicant institution should have a clear commitment to enhancing diversity in the biomedical research workforce and promoting inclusive and supportive scientific research environments, as described in the Institutional Environment Letter.

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in <u>Part 1</u> of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Career Development (K) Instructions in the <u>SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000)</u> except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit <u>Frequently Asked Questions Application Guide, Electronic Submission of Grant Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=41137).</u>

Page Limitations

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 29 of 49

All page limitations described in the SF424 Application Guide and the <u>Table of Page Limits</u> (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Project Summary/Abstract

Include a description of your current research and the research you propose to continue in the independent phase.

Other Attachments

Candidate Eligibility Statement: The application must include a signed statement from the candidate and an institutional official establishing the eligibility of the candidate for support under this program. The statement must, number of years of postdoctoral experience, and a description of how this particular candidate would further the goals of the MOSAIC Postdoctoral Career Transition Award to Promote Diversity.

Applications lacking a Candidate Eligibility Statement will not be reviewed.

Diversity Statement (1-page maximum). The application must include a diversity statement from the candidate applying for the K99/R00 award (i.e., the postdoctoral fellow). The Diversity Statement should include a description of the individual's commitment to diversity in the biomedical sciences, and any past or present leadership, mentoring and outreach activities to enhance diversity especially involving groups underrepresented in the biomedical research enterprise (e.g., certain racial/ethnic groups, persons with disabilities, students from disadvantaged backgrounds, women, and other groups as described in the NIH Notice of Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)). Describe planned activities during the career award to develop or enhance skills in working effectively with talented scientists from a wide variety of backgrounds and to promote inclusive and equitable scientific biomedical research environments.

Applications lacking a Diversity Statement will not be reviewed.

The filename provided for each document added to the section Other Attachments will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

The Primary Mentor should address the following in the biosketch personal statement:

- Maintaining a record of, and training in rigorous and unbiased experimental design, methodology, analysis, interpretation and reporting of results;
- Efforts taken to enhance diversity in the biomedical research workforce, and to ensure the research environment is inclusive, safe, and supportive for trainees from all backgrounds.
- Commitment to fulfilling the need of the trainees to complete their training in a timely fashion with the skills, credentials and experiences to transition into independent careers in the biomedical research workforce.

R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Provide itemized budget information for each budget period covered under the K99 phase.

Itemized budget information is not required for the R00 phase; a total requested amount for each budget period is acceptable. However, some basic information must be completed in order for NIH to successfully process the budget form. For each budget period of the R00 phase:

- · Select the appropriate Budget Type
- · Provide the Budget Period Start Date and End Date

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 30 of 49

- In Section A: Senior/Key Persons provide an entry for the PD/PI, including the appropriate level of effort, \$0 for Requested Salary and \$0 for Fringe Benefits
- In Section F: Other Direct Costs add a line item titled R00 Independent Phase and provide the total request for that period (up to \$249,000).

At the time of transition to the R00 phase, the R00 applicant institution will submit a detailed budget for each budget period of the R00 project period that reflects the direct and indirect costs at the R00 applicant institution.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Career Development Award Supplemental Form

The PHS 398 Career Development Award Supplemental Form is comprised of the following sections:

Candidate

Research Plan

Other Candidate Information

Mentor, Co-Mentor, Consultant, Collaborators

Environment & Institutional Commitment to the Candidate

Other Research Plan Sections

Appendix

All instructions in the SF424 (R&R) Application Guide must be followed.

Candidate Section

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Candidate Information and Goals for Career Development

Candidate's Background

- Describe the candidate's commitment to a career in an independent biomedical research field specified in the Program Considerations section above.
- Describe the candidate's potential to develop into a successful, independent investigator.

Career Goals and Objectives

- Describe the candidate's current and long-term research and career objectives.
- Present a scientific history that: (1) shows a logical progression from the candidate's prior research and training
 experiences to the training and research experiences proposed for the mentored phase of the award (K99) and
 subsequently to the independent phase of the award (R00); and (2) justifies the need for further mentored career
 development to become an independent research investigator.
- If currently supported by an institutional training grant or individual fellowship award (such as provided through the Ruth L. Kirschstein NRSA program), describe the candidate's current research training or fellowship program.
- Describe how the candidate plans to separate scientifically from his/her mentor and advance to research independence.
- If the candidate is applying for the first time in her/his fourth year, explain why support at this stage is appropriate and why support was not sought earlier.

Candidate's Plan for Career Development/Training Activities During Award Period

- A systematic plan should be presented for obtaining the biomedical science background, research experience, and career
 development activities necessary to launch the stated independent research career. Describe current activities and how
 they relate to the candidate's career development plans and career goals.
- Describe proposed activities, e.g., those that will lead to new and/or enhanced research skills and knowledge such as the development of quantitative, computational, or other technical skills, as well as development of professional skills such as grant-writing, communication, leadership, and laboratory management. The career development plan must be specifically tailored to meet the needs of the candidate and the goal of achieving independence as a researcher.
- Describe how the activities provided by the MOSAIC Institutionally-Focused Research Education Award (UE5) will be integrated into career development activities available at the candidate's home institution to create synergies.
- The candidate should provide a list of up to 10 keywords regarding their scientific area as well as a prioritized list of areas of professional development to aid in matching scholars into scientific and career development cohorts.

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 31 of 49

- Describe how the skills and knowledge obtained during the mentored phase will enhance research productivity and facilitate the development of new approaches and directions for investigation. Describe how the career development plan will promote the candidate's success and transition to scientific independence. Candidates must justify the need for the award, particularly the mentored (K99) phase, and must provide a convincing case that the proposed period of support (1-2 years as a mentored candidate followed by up to 3 years as an independent scientist) will substantially enhance her/his career and/or will allow the pursuit of a novel or promising approach to a particular research problem. Candidates should make clear why additional mentored research training and career development are critical before transitioning to research independence and pursuit of the proposed independent phase research.
- The candidate must describe a plan, including a timeline with milestones, for evaluation of his/her progress during the mentored phase and for the transition to the independent phase.
- The candidate and K99-phase mentor (see below) must describe a specific plan for the transition to the independent phase.

Research Plan Section

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy

- The research plan must span both phases of the K99/R00 award. The candidate should clearly indicate the research planned for each phase. This narrative should describe what the candidate will accomplish during the mentored phase research that will enable him/her to launch an independent research program (i.e., what does the candidate still need to accomplish during the mentored phase in order to compete successfully once independence is achieved).
- The research plan should state the significance, innovation and approach of the proposed research during the K99 and R00 phases of the award. The research plan should provide a detailed rationale, experimental approach, and expected/alternative outcomes for the proposed studies. Although it is anticipated that candidates will be best able to describe their current and past research, the research plan for the R00 phase of the award should be described in sufficient detail for reviewers to evaluate the merit of this component of the application.
- Describe the relationship between the mentor's research and the candidate's proposed research. Describe how the candidate will gain independence from his/her mentors and separate his/her scientific research program from that of the mentor(s).
- If the applicant is proposing to gain experience in a clinical trial, ancillary study to a clinical trial or a clinical trial feasibility study as part of his or her research career development, describe the relationship of the proposed research project to the clinical trial.

Training in the Responsible Conduct of Research

 All applications must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). See SF424 (R&R) Application Guide for instructions.

Mentor, Co-Mentor, Consultant, Collaborators Section

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Plans and Statements of Mentor and Co-mentor(s)

- The application must include a statement from the primary mentor that provides: 1) information on his/her research qualifications and previous experience as a research supervisor; 2) a plan describing the nature of the supervision and mentoring that will occur during the proposed K99 award period, including how the candidate's scientific and professional independence will be promoted; 3) a description of the elements of the planned research training and career development, including any formal course-work; 4) a plan for transitioning the candidate from the mentored phase to the independent phase of the award and a description of how the mentor will help the candidate achieve scientific independence from his/her mentor(s); 5) a statement identifying the components of the proposed research that the K99 applicant can take when he/she transitions to research independence and that can be part of his/her independent (R00) phase award; and 6) when appropriate, a statement affirming any resources and reagents that can be taken by the applicant to the independent phase of the award. If the primary mentor has limited training experience, a co-mentor with a strong, successful track record as a mentor should be included.
- The mentor should have sufficient independent research support to cover the costs of the proposed K99 research project in excess of the allowable costs of this award, and should state that needed costs will be covered. If funds are needed beyond what will be provided by the mentor, the source of additional funds should be identified and documented in a letter signed by the responsible individual.

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 32 of 49

- Similar information must be provided by all co-mentors. If more than one mentor is proposed, the respective areas of
 expertise, the responsibility of each, and the nature of the involvement with the candidate should be explicitly described.
 Co-mentors should describe clearly how they will coordinate with the primary mentor and the candidate to provide an
 integrated mentoring effort.
- The primary mentor must agree to write and provide annual evaluations of the candidate's progress for the initial mentored phase as required in the annual progress report.
- The mentor must agree to assist the candidate in transitioning to an independent research position by guiding the candidate during the job search and negotiation process and by commenting on the R00 phase application.
- The mentor must describe their willingness to participate in conferences organized by the MOSAIC Institutionally-Focused Research Education Award to Promote Diversity (UE5) to exchange ideas and employ evidence-based approaches to enhance diversity and improve mentoring relationships.
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, the mentor or a member of the mentoring team must include a statement to document leadership of the clinical trial, and appropriate expertise to guide the applicant in any proposed clinical trials research experience.

Letters of Support from Collaborators, Contributors and Consultants

- Signed statements must be provided by all collaborators and/or consultants confirming their participation in the project
 and describing their specific roles. Unless also listed as senior/key personnel, collaborators and consultants do not need
 to provide their biographical sketches. However, information should be provided clearly documenting the appropriate
 expertise in the proposed areas of consulting/collaboration.
- Advisory committee members (if applicable): Signed statements must be provided by each member of the proposed
 advisory committee. These statements should confirm their participation, describe their specific roles, and document the
 expertise they will contribute. Unless also listed as senior/key personnel, these individuals do not need to provide their
 biographical sketches.

Environmental and Institutional Commitment to the Candidate

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Description of Institutional Environment

- The sponsoring institution must document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with key faculty members and other investigators capable of productive collaboration with the candidate.
- Describe how the institutional research environment is particularly suited for the development of the candidate's research career and the pursuit of the proposed research plan.

Institutional Commitment to the Candidate's Research Career Development

- The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, independent investigator, i.e. conducting the proposed mentored research and career development during the K99 phase and competing for, and transitioning to, a tenure-track assistant professor position at an academic institution. While the K99 phase sponsoring institution is not responsible for sponsoring the applicant during the R00 phase, it should be supportive of the candidate prior to initiation of the R00 phase.
- Provide assurance that the candidate will be able to devote a minimum of 9 person-months (75% of full-time professional
 effort) to the development of his/her research program. The remaining effort should be devoted to activities related to the
 development of the candidate's career as an independent scientist.
- Provide assurance that the research facilities, resources, and training opportunities, including faculty capable of
 productive collaboration with the candidate, will be available for the candidate's planned career development and
 research programs during the K99 award period.
- Provide assurance that appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan will be available during the K99 award period.
- For individuals in postdoctoral positions with other titles although still in non-independent, mentored training positions, provide evidence of eligibility for the K99/R00 program.
- If the candidate is not a U.S. Citizen or permanent resident, the sponsoring institution must include information about the candidate's visa status, an assurance that the candidate's visa provides sufficient time to complete the K99 phase of the award at a U.S. institution, and assurance that there are no known obstacles (e.g. home country requirement) to the candidate obtaining a visa at the time of the R00 transition.

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 33 of 49

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

• For FOAs that do not allow independent clinical trials, do not complete Section 4 Protocol Synopsis information or Section 5 - Other Clinical Trial-related Attachments.

Delayed Onset Study

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

Reference Letters

Candidates must carefully follow the SF424 (R&R) Application Guide, **including the time period for when reference letters will be accepted**. At least three, but no more than five, reference letters are required. The letters should be from individuals not directly involved in the application, but who are familiar with the applicant's qualifications, training, and interests. *The sponsor/co-sponsor(s) of the application cannot be counted toward the three required references*. Applications lacking the appropriate required reference letters will not be reviewed. This is a separate process from submitting an application electronically. Reference letters are submitted directly through the <u>eRA Commons Submit Referee Information link (//grants.nih.gov/grants/guide/url_redirect.htm?id=41146)</u> and not through Grants.gov.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

<u>Part I. Overview Information</u> contains information about Key Dates and Times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or <u>Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.html?id=82380)</u>, the application deadline is automatically extended to the next business day.

Organizations must submit applications to <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128)</u> (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u>, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)</u>.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm? id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. <u>Section III. Eligibility Information</u> contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit <u>Applying Electronically (//grants.nih.gov/grants/guide/url_redirect.htm?id=11144)</u>. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the <u>Guidelines for Applicants Experiencing System Issues (//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines)</u>. For assistance with application submission, contact the Application Submission Contacts in <u>Section VII</u>.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See <u>Section III</u> of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the NIH Center for Scientific Review . Applications that are incomplete or non-compliant will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy. (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following: Reviewers should evaluate the candidate's potential for obtaining a tenure-track or equivalent faculty position and developing an independent research program that will make important contributions to the field. Reviewers should consider in their evaluation the likely value of the proposed K99 phase research and career development in facilitating transition to research independence, and the feasibility of the proposed research project as a vehicle for developing a successful, independent research program after transition to the R00 award phase. Reviewers should assess the potential for the candidate to further the goals of the MOSAIC Postdoctoral Career Transition Award to Promote Diversity program. Reviewers should note that candidates are encouraged to apply early in their postdoctoral tenure in order to have sufficient time to develop their skills, knowledge and career plans during the mentored K99 phase of an award. Therefore, applicants should not be expected to already have publications from their postdoctoral work but should instead present evidence that their previous and current studies and future plans are likely to support a successful independent research career.

Overall Impact

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 35 of 49

Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Candidate

- Based on the candidate's prior research and training experience, track record (relative to career stage), referee's evaluations, and the quality and originality of prior research and the current application, what is the candidate's potential to become a highly successful, independent investigator who will contribute significantly to her/his chosen field of biomedical research?
- Considering the years of experience to date, does the candidate have a strong record of rigorous, high-quality scientific research?
- What is the appropriateness of the candidate's pre- and postdoctoral research training, with respect to development of appropriate scientific and professional skills?
- Given the candidate's prior training, proposed career development plan, and the referees evaluations, is it reasonable to expect that the candidate will be able to achieve an independent, tenure-track or equivalent faculty position within the time period requested for the K99 phase of this award?
- Does the candidate articulate a compelling commitment to diversity in the biomedical sciences, and robust plans to develop or enhance their skills in working effectively with scientists from diverse backgrounds and promoting inclusive and equitable scientific biomedical research environments?

Career Development Plan/Career Goals and Objectives

- Are the content and duration of the proposed components of the career development plan appropriate and well-justified for the candidate's current stage of scientific and professional development and proposed research career goals?
- To what extent does the proposed career development plan enhance or augment the applicant's research training and skills acquisition to date?
- Are there plans to integrate the scholar's career development plans with activities provided by the MOSAIC Institutionally-Focused Research Education Award (UE5) to create synergies?
- Is the proposed career development plan likely to contribute substantially to the scientific and professional development of the candidate, and facilitate his/her successful transition to independence?
- To what extent are the plans for evaluating the K99 awardee's progress adequate and appropriate for guiding the applicant towards a successful transition to the independent phase of the award?
- Is the timeline planned for transition to the independent phase of the award appropriate for the candidate's current stage
 of scientific and professional development, anticipated productivity, and the career development proposed for the K99
 phase of the award? If the candidate is applying for the first time in her/his fourth year as a postdoctoral fellow, is there a
 strong justification for not having applied earlier?
- · If proposed, will the clinical trial experience contribute to the applicant's research career development?

Research Plan

- Is the proposed K99 phase research significant and scientifically sound?
- Is the prior research that serves as the key support for the proposed project rigorous?
- Has the candidate included plans to address weaknesses in the rigor of prior research that serves as the key support of the proposed project?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Are the scientific and technical merits of the K99 research appropriate for developing the research skills described in the career development plan, and appropriate for developing a highly successful R00 research program?
- Is the proposed R00 phase research significant, scientifically sound, and a logical extension of the K99 phase research? Is there evidence of long-term viability of the proposed R00 phase research plan?
- Does the R00 phase project address an innovative hypothesis or challenge existing paradigms? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies?
- To what extent is the proposed R00 phase research likely to foster the career of the candidate as a successful, independent investigator in biomedical research?

• If proposed, will the clinical trial experience contribute to the research project?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- Are the mentor's research qualifications, experience and mentoring plans (and for established mentors, track record) appropriate for the applicant's career development needs?
- To what extent does the mentor(s) articulate clear plans to ensure that the applicant will progress successfully to independence? For experienced mentors, to what extent does the mentor(s) have a strong track record in training future independent researchers?
- Is the supervision proposed for the mentored phase of support adequate, and is the commitment of the mentor(s) to the applicant's career development appropriate and sufficient?
- Do(es) the mentors have a clear commitment to enhancing diversity in the biomedical research workforce and to ensuring the research environment is inclusive, safe and supportive to trainees from all backgrounds?
- Does the mentor describe their willingness to participate in meetings/conferences organized by the MOSAIC
 Institutionally-Focused Research Education Award to Promote Diversity (UE5) to exchange ideas, and employ evidence-based approaches to enhance diversity and improve mentoring relationships?
- Does the mentor provide an appropriate plan that addresses the candidate's training needs, and that is likely to foster the candidate's continued development and transition to independence?
- Does the mentor describe an acceptable plan for clear separation of the candidate's research and research career from the mentor's research, including identifying the components of the research plan that the K99 candidate may take to an independent research position?
- If applicable are the consultants /collaborators research qualifications appropriate for their roles in the proposed K99 phase of the award? Do they provide letters of support that affirm their commitment?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?

Environment & Institutional Commitment to the Candidate

- To what extent does the institution provide a high quality environment appropriate for the candidate's development during the K99 phase of the award?
- To what extent are the research facilities and educational opportunities, including collaborating faculty, adequate and appropriate for the candidate's research and career development goals during the K99 phase of the award? Is adequate evidence provided that the K99 sponsoring institution is strongly committed to fostering the candidate's development and preparation for transition to independence?
- Is there adequate assurance that the required minimum of 9 person-months (75% of the candidate's full-time professional effort) will be devoted directly to the research training, career development, and research activities proposed for the K99 phase of the award?
- Does the institution have a clear commitment to enhancing diversity in the biomedical research workforce, and promoting inclusive, safe and supportive scientific research environments? Has it undertaken sufficient efforts to achieve these goals?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url redirect.htm?id=11175).

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 37 of 49

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the <u>Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174)</u>.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) <u>Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151)</u>; (2) <u>Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152)</u>; and (3) <u>Genomic Data Sharing Plan (GDS)</u> (//grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant's career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) *Format* - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) *Subject Matter* - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) *Faculty Participation* - the role of the mentor(s) and other faculty involvement in the fellow's instruction; 4) *Duration of Instruction* - the number of contact hours of instruction (at least eight contact hours are required); and 5) *Frequency of Instruction* instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as *ACCEPTABLE* or *UNACCEPTABLE*, and the summary statement will provide the consensus of the review committee. See also: NOT-OD-10-019 (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html).

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 38 of 49

be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- · Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center.

Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board.

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- · Availability of funds.
- · Relevance of the proposed project to program priorities
- · Portfolio balance

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRefer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in <u>Section IV.5. Funding Restrictions</u>. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the <u>Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158)</u> website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

There will not be a formal Notice of Award (NoA) associated with the K99 phase of the award conducted in the NIH intramural program. The awarding Institute will transmit to the successful candidate an approval letter which will include the terms and conditions of the NIH intramural K99 award, as well as expectations for the transition to the R00 phase of the award.

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 39 of 49

Awardees are expected to participate in career development activities and convenings coordinated by MOSAIC institutionally-focused research education awardees (UE5).

Specific to applications proposing clinical trials, ancillary or feasibility studies

Additionally, ICs may specify any special reporting requirements for the proposed clinical trial to be included under IC-specific terms and conditions in the NoA.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials, or a new ancillary study to an ongoing clinical trial. By law (Title VIII, Section 801 of Public Law 110-85), the lead investigator must register and submit results information for certain applicable clinical trials on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov). NIH expects registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that the application as well as all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement

(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm? id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158). More specifically, for K Awards, visit the Research Career Development (K) Awardees section of the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=51164).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (https://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html); and

http://www.hhs.gov/ocr/civilrights/understanding/index.html (https://www.hhs.gov/ocr/civilrights/understanding/index.html). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html

(https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports,

for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

In accordance with the statutory provisions contained in Section 872 of the *Duncan Hunter National Defense Authorization Act of Fiscal Year 2009* (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Transition to the Independent Phase

Transition from the mentored phase to the independent phase is intended to be continuous in time and, except in unusual, extenuating circumstances, the awarding NIH Institute/Center will not extend the K99 phase beyond the 2-year limit. ICs may, at their discretion, make exceptions to this time limitation when individuals have been invited for faculty job interviews but final decisions have not yet been made by the potential R00 institution or, rarely, because of unusual, extenuating circumstances. To activate the independent phase of the grant, individuals must have been offered and accepted a tenure-track, full-time assistant professor position (or equivalent) by the end of the K99 project period.

An eligible R00 institution will have appropriate infrastructure to support the proposed research program and a history of external research funding. Applicants are free to apply for independent phase positions within the NIH intramural research program (IRP). However, should the individual accept such a position in the IRP, the independent phase of the award will not be activated. This is because NIH intramural scientists are supported directly by NIH intramural funds and are not eligible for NIH extramural grant awards. Such outcomes are consistent with the goals of the K99/R00 award initiative. Eligibility of for-profit organizations for the R00 phase depends on the nature of the appointment, and the ability of the PD/PI to conduct independent research and apply for NIH R01 or R01-equivalent research grants. PIs are encouraged to discuss job offers at for-profit organizations with NIH Program staff well in advance of accepting such an offer.

To avoid potential problems in activating the independent phase, applicants are strongly encouraged to contact their NIH program official as soon as plans to apply for and, assume an independent position develop, and not later than 6 months prior to the termination of the K99 phase of the award.

At that time, individuals should discuss plans for transition to, and application for, the R00 phase with their NIH program official. The application for the R00 phase of the award should be submitted no later than 2 months prior to the proposed activation date of the R00 award by the R00 phase grantee organization.

The independent phase institution will submit an application on behalf of the candidate for the R00 award using the PHS 398
Application (//grants.nih.gov/grants/guide/url_redirect.htm?id=22000)). The R00 application must include:

- A new face page signed by the R00 phase institutional representative;
- A new project description page (the project summary or abstract should be updated to reflect current plans for the R00 phase);
- · Detailed budget pages for a non-modular budget;
- Biographical sketches for the PD/PI and any other Key Personnel;
- A new Resources page;
- A brief description of progress made during the K99 phase that will serve as the Final Progress Report for the K99 phase;
- An updated research plan (the specific aims should be updated to reflect current plans for the R00 phase and the updated research plan should be briefly described in less than 5 pages);
- Updated Protections for Human Subjects and Inclusion of Women, Minorities and Children (as appropriate);
- Updated Vertebrate Animals (as appropriate);
- Updated Biohazards (as appropriate); and
- A new checklist.

These materials should be sent directly to the awarding Institute or Center (IC). The original application plus one copy (preferably in PDF format) are to be mailed (or e-mailed) to the Financial or Grants Management contact person of the awarding NIH Institute or Center listed in the Notice of Award. The R00 application will be evaluated by extramural Program staff of the awarding component for completeness and appropriateness to the program.

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 41 of 49

Two additional documents are included with the R00 application. A letter from the R00 Department or Division Chairman must be submitted that describes the R00 institution's commitment to the candidate and plans for his/her career development (see below). If not already provided, the final evaluation statement by the K99 phase mentor, must be provided.

An institutional commitment agreement will be required at the time of activation of the independent phase of the award. This agreement should satisfy the criteria described in the Career Development Award Section of the SF424(R&R) Application Guide (//grants.nih.gov/grants/funding/424/index.htm).

In addition to space, facilities, resources, and other support needed to conduct the proposed research, the sponsoring institution must provide protected research time (minimum of 9 person-months or 75% of the candidate's full time professional effort) at least for the duration of the R00 award. The start-up package and other institutional support must be described in detail and must be comparable to that given to other faculty recently hired into tenure-track or equivalent faculty positions. Institutions must provide a startup and salary package equivalent to that provided to a newly hired faculty member who does not have a grant; R00 funds may not be used to offset the typical startup package or to offset the usual institutional commitment to provide salary for tenure-track (or equivalent) assistant professors who are hired without grant support. The R00 sponsoring institution must describe the candidate's academic appointment, bearing in mind that it must be tenure-track assistant professor (or equivalent), and confirm that the appointment is not contingent on the transfer of the award to the institution. The R00 phase institution must describe how the awardee's ability to apply for and secure independent research grant (e.g., R01, R35 ESI MIRA, etc.) support will be fostered and supported during the R00 phase of the award. The R00 phase institution must describe its commitment to diversity, efforts taken to ensure research environments are inclusive, safe and supportive, and strategies it employs to promote the success of early-stage faculty.

The R00 award requires that a minimum of 9 person-months (75% of the candidate's full time professional effort) be devoted to research activities. Consequently, teaching, clinical duties and other non-research activities should be minimal during the R00 award period. NIH staff may review start-up packages and other commitments between the institution and candidate prior to activating the independent phase of the award. It is suggested that the applicant and/or the hiring institution discuss the institutional commitment with the relevant NIH institute Program Official prior to finalizing the offer. NIH will not activate the independent phase if the institutional commitment is deemed inadequate. Applicants who are approved to transition will receive a Notice of Award reflecting the new R00 grant mechanism, the dollar amount, and the new recipient organization (if applicable).

The K99/R00 award is intended to facilitate successful transition to independence. Consequently, a requirement for activation of the R00 phase is successful completion of this transition. Applicants are encouraged (but not required) to apply for independent positions at departments and institutions different from where they conducted their mentored research. It is important for all applicants, but especially so for applicants who intend to stay at the mentored phase institution for the independent phase, to provide a plan by which they will separate from their mentor and advance to independence. Awardees are also encouraged to include a plan and timeline for submitting an independent research grant application in a research area relevant to the mission of NIH soon after beginning their independent position.

Candidates who are not approved to transition will receive written notification from the awarding component communicating the rationale for the disapproval. This notification typically will be sent within 60 days of receipt of the R00 application.

Although the financial plans of the NIH Institute or Center provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

Termination of the K99 award phase

If transition from the K99 phase at an extramural institution to the R00 phase occurs at the originally scheduled end date of the K99 award, then no specific steps to terminate the K99 award are necessary. If the transition at an extramural institution occurs prior to the scheduled end date, then a revised Notice of Award will be issued to terminate the K99 phase award. Carry-over of unspent funds from a partially completed year in the K99 phase into the R00 phase may be permitted.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120). The Supplemental Instructions for Individual Career Development (K) RPPRs must be followed. The Mentor's Report must include an annual evaluation statement of the candidate's progress.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal

Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Within ten years of making awards under this program, NIH will assess the program's overall outcomes, gauge its effectiveness in enhancing diversity, and consider whether there is a continuing need for the program. Upon the completion of this evaluation, NIH will determine whether to (a) continue the program as currently configured, (b) continue the program with modifications, or (c) discontinue the program.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

- Subsequent participation in research or employment in a STEM field
- Authorship of scientific publications in a STEM field
- · Subsequent independent research grant support from NIH or another source
- · Subsequent participation in activities to enhance biomedical workforce diversity

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this FOA, prospective applicants are **strongly encouraged** to consult with NIH staff before submitting an application to assess responsiveness to the requirements of one of the participating NIH ICs.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)

Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)

Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Rob Rivers, PhD

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 43 of 49

Telephone: 301-443-8415

Email: robert.rivers@nih.gov (mailto:robert.rivers@nih.gov)

Carol Shreffler, PhD

National Institute of Environmental Health Sciences (NIEHS)

Telephone: 984-257-3322

Email: shreffl1@niehs.nih.gov (mailto:shreffl1@niehs.nih.gov)

Kenneth D. Gibbs, Jr., Ph.D., MPH

National Institute of General Medical Sciences (NIGMS)
Email: kenneth.gibbs@nih.gov)

Joan Greve, Ph.D.

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Telephone: 301-451-6649

Email: joan.greve@nih.gov (mailto:joan.greve@nih.gov)

David Banks, PhD, MPH, RN

National Institute of Nursing Research (NINR)

Telephone: 301-496-9558

Email: david.banks@nih.gov (mailto:david.banks@nih.gov)

Nathan Stinson, Jr., PhD, MD

National Institute on Minority Health and Health Disparities (NIMHD)

Telephone: 301-594-8704

Email: stinsonn@mail.nih.gov (mailto:stinsonn@mail.nih.gov)

Heather A. Colley, M.S.

National Human Genome Research Institute (NHGRI)

Telephone: 301-480-2332

Email: junkinsh@mail.nih.gov (mailto:junkinsh@mail.nih.gov)

NIA Training Office

National Institute on Aging (NIA)

Email: NIAtraining@nih.gov (mailto:NIAtraining@nih.gov)

Hua-Chuan Sim, MD

National Library of Medicine (NLM)

Telephone: 301-594-4882

Email: simh@mail.nih.gov (mailto:simh@mail.nih.gov)

James D. Churchill

National Institute of Mental Health (NIMH)

Phone: (301) 443-3621

Email: churchillj@mail.nih.gov (churchillj@mail.nih.gov)

Albert Avila, Ph.D.

Director, Office of Diversity and Health Disparities

National Institute on Drug Abuse (NIDA)

Telephone: 301-496-8804

Email: aavila@nida.nih.gov (mailto:aavila@nida.nih.gov)

Nicole Redmond, M.D., Ph.D., M.P.H.

Division of Cardiovascular Sciences

National Heart, Lung, and Blood Institute (NHLBI)

Telephone: 301-435-0379

Email: nicole.redmond@nih.gov (mailto:nicole.redmond@nih.gov)

Traci Heath Mondoro, Ph.D.

Division of Blood Diseases and Disorders

National Heart, Lung, and Blood Institute (NHLBI)

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 44 of 49

Telephone: 301-435-0050

Email: NHLBI_Blood_Training@nhlbi.nih.gov (mailto:NHLBI_Blood_Training@nhlbi.nih.gov)

Marquitta White, PhD
Division of Lung Diseases

National Heart, Lung, and Blood Institute (NHLBI)

Telephone: 301-827-4822

Email: marquitta.white@nih.gov (mailto:marquitta.white@nih.gov)

Melissa Green Parker, Ph.D.

Center for Translation Research and Implementation Science

National Heart, Lung, and Blood Institute (NHLBI)

Telephone: 301-496-1051

Email: melissa.greenparker@nih.gov (mailto:melissa.greenparker@nih.gov)

Jenica Patterson, Ph.D.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Telephone: 301-827-6166

Email: jenica.patterson@nih.gov (mailto:jenica.patterson@nih.gov)

Alberto L. Rivera-Rentas, Ph.D.

National Institute on Deafness and Other Communication Disorders (NIDCD)

Telephone: 301-496-1804

Email: riverara@nidcd.nih.gov (mailto:riverara@nidcd.nih.gov)

Lynn Mertens King, PhD

National Institute of Dental and Craniofacial Research

Telephone: 301-594-5006

Email: lynn.king@nih.gov)

Lanay M. Mudd, PhD

National Center for Complementary and Integrative Health (NCCIH)

Phone: (301) 594-9346

Email: lanay.mudd@nih.gov (mailto:lanay.mudd@nih.gov)

Deborah Philp, Ph.D.

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: (301) 761-7766

Email: <u>AITrainingHelpDesk@niaid.nih.gov (mailto:AITrainingHelpDesk@niaid.nih.gov)</u>

Michelle Jones-London, Ph.D.

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-451-7966

Email: jonesmiche@ninds.nih.gov (mailto:jonesmiche@ninds.nih.gov)

Amanda Taylor Boyce, Ph.D.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Phone: 301-594-5055

Email: boycea@mail.nih.gov (mailto:boycea@mail.nih.gov)

Peer Review Contact(s)

John F. Connaughton, PhD

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-594-7797

Email:connaughtonj@extra.niddk.nih.gov (mailto:connaughtonj@extra.niddk.nih.gov)

Manana Sukhareva, Ph.D.

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Telephone: 301-451-3397

Email: sukharem@mail.nih.gov)

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 45 of 49

Stephanie Constant, Ph.D.

National Institute of General Medical Sciences (NIGMS)

Email: stephanie.constant@nih.gov (mailto:stephanie.constant@nih.gov)

Weiqun Li, M.D., Chief, Scientific Review Branch National Institute of Nursing Research (NINR)

Telephone: 301-594-5966

Email: wli@mail.nih.gov (mailto:wli@mail.nih.gov)

Thomas M. Vollberg, Sr., PhD

National Institute on Minority Health and Health Disparities (NIMHD)

Phone: 301-594-8696

Email: vollbert@mail.nih.gov (mailto:vollbert@mail.nih.gov)

Rudy Pozzatti, Ph.D.

National Human Genome Research Institute (NHGRI)

Phone: 301-402-8739

Email: pozzattr@exchange.nih.gov (mailto:pozzattr@exchange.nih.gov)

Zoe Huang, MD

National Library of Medicine (NLM)

Telephone: 301-496-4253

Email: huangz@mail.nlm.nih.gov (mailto: huangz@mail.nlm.nih.gov)

Dharmendar Rathore, PhD

National Institute on Drug Abuse (NIDA)

Telephone: 301-402-6965

Email: dharmendar.rathore@nih.gov)

Director, Office of Scientific Review

National Heart, Lung, and Blood Institute (NHLBI)

Telephone: 301-435-0270

Email: NHLBIChiefReviewBranch@nhlbi.nih.gov (mailto:NHLBIChiefReviewBranch@nhlbi.nih.gov)

RV Srinivas, Ph.D.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Telephone: 301-451-2067 Email: srinivar@mail.nih.gov

Yasaman Shirazi, Ph.D.

National Institute of Dental and Craniofacial Research

Telephone: 301-594-5593

Email: <u>yasaman.shirazi@nih.gov (mailto:yasaman.shirazi@nih.gov)</u>

Ernest Lyons, PhD

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-496-9223

Email: <u>LyonsE@ninds.nih.gov (mailto:LyonsE@ninds.nih.gov)</u>

Financial/Grants Management Contact(s)

Aricia M. Ajose, MPA

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-594-9023

Email: ajosea@mail.nih.gov (mailto:ajosea@mail.nih.gov)

Jenny Greer

National Institute of Environmental Health Sciences (NIEHS)

Telephone: 984-287-3332

Email: jenny.greer@nih.gov (mailto:jenny.greer@nih.gov)

Justin Rosenzweig

National Institute of General Medical Sciences (NIGMS)

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 46 of 49

Email: rosenzwj@nigms.nih.gov (mailto:rosenzwj@nigms.nih.gov)

Monique Binger, Ph.D.

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Telephone: 301-451-4787

Email: monique.day@nih.gov (mailto:monique.day@nih.gov)

Ron Wertz

National Institute of Nursing Research (NINR)

Telephone: 301-594-2807

Email: wertzr@mail.nih.gov (mailto:wertzr@mail.nih.gov)

Priscilla Grant, JD

National Institute on Minority Health and Health Disparities (NIMHD)

Telephone: 301-594-8412

Email: pg38h@nih.gov (mailto:pg38h@nih.gov)

Devon Bumbray-Quarles

National Human Genome Research Institute (NHGRI)

Telephone: 301-451-7928

Email: devon.bumbray-quarles@nih.gov

Traci Lafferty

National Institute on Aging (NIA) Telephone: 301-496-8987 Email: laffertt@nia.nih.gov

Samantha Tempchin

National Library of Medicine (NLM)

Telephone: 301-496-4221

Email: tempchins@mail.nih.gov (mailto:tempchins@mail.nih.gov)

Terri Jarosik

National Institute of Mental Health (NIMH (http://www.nimh.nih.gov/index.shtml))

Telephone: 301-443-3858

Email: tjarosik@mail.nih.gov (mailto:tjarosik@mail.nih.gov)

Yinka Abu

National Institute on Drug Abuse (NIDA)

Telephone: 301-827-6691

Email: aa286f@nih.gov (mailto:aa286f@nih.gov)

Shaheed Ziyout

National Heart, Lung, and Blood Institute (NHLBI)

Telephone: 301-827-8152

Email: shaheed.ziyout@nih.gov (mailto:shaheed.ziyout@nih.gov)

Ms. Judy Fox

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Telephone: 301-443-4704

Email: jfox@mail.nih.gov (mailto:jfox@mail.nih.gov)

Christopher Myers

National Institute on Deafness and Other Communication Disorders (NIDCD)

Telephone: 301-402-0909

Email: myersc@mail.nih.gov (mailto:myersc@mail.nih.gov)

Dede Rutberg, MBA

National Institute of Dental and Craniofacial Research (NIDCR)

Telephone: 301-594-4798

Email: rutbergd@mail.nih.gov (mailto:rutbergd@mail.nih.gov)

Case 1:25-cv-10787-BEM Document 38-35 Filed 04/25/25 Page 47 of 49

Shelley Carow

National Center for Complementary and Integrative Health (NCCIH)

Telephone: 301-594-3788

Email: carows@mail.nih.gov)

Tamia Powell

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: (240) 669-2982

Email: tamia.powell@nih.gov (mailto:tamia.powell@nih.gov)

Chief Grants Management Officer

National Institute of Neurological Disorders and Stroke (NINDS)

Email: ChiefGrantsManagementOfficer@ninds.nih.gov (mailto:ChiefGrantsManagementOfficer@ninds.nih.gov)

Yen Thach

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Phone: (301) 594-3505

Email: thachy@mail.nih.gov (mailto:thachy@mail.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?08-16-19) NIH Funding Opportunities and Notices (/grants/guide/index.html)





(https://www.hhs.gov/) Department of Health and Human Services (HHS)



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EXHIBIT C



Outlook

NIGMS Funding Update

From Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov>
Date Fri 4/11/2025 3:21 PM
To
Cc

I am writing to let you know that due to changes in NIH/HHS priorities, the NIH Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC) program has been terminated. Further awards, including the R00, will not be made, and NIGMS will not permit nocost extensions.

NIGMS grants management staff will follow up if there is any specific information or action needed regarding your award.

When awards are terminated, grantees will receive a revised notice of award which will include close out documentation requirements.

This email is coming after other scholars to ensure those who don't have an active award (i.e., who are between the K99 and R00 phases) are aware of how changes in NIH/HHS priorities will affect future years.

Kenneth D. Gibbs, Jr., PhD, MPH

Director, Division of Training and Workforce Development National Institute of General Medical Sciences National Institutes of Health