

# EXHIBIT 36

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 7**

I, [REDACTED] pursuant to 28 U.S.C. § 1746, declare as follows:

1. My name is [REDACTED] and I am a postdoctoral Research Fellow in the department of Genetics at Harvard Medical School. I graduated from [REDACTED] [REDACTED] I am in the first year of a career development award from the National Institute of Health ("NIH"), and was previously funded by the [REDACTED]

[REDACTED] My postdoctoral studies are critical to my goal of ultimately obtaining an academic faculty position with my own research program at a university. Since 2018, I have co-authored six peer-reviewed articles, including two first-authored articles, on genetics and other biomedical topics in leading scientific journals.

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I am a member of Harvard Academic Workers—United Auto Workers ("UAW"). This means I signed an authorization card expressing unqualified support for UAW to serve as my exclusive bargaining representative in dealings with my employer, Harvard. UAW is currently representing me in negotiations with Harvard for a first-time collective bargaining agreement ("CBA") that will govern the terms and conditions of my employment at Harvard. Once our CBA is finalized, I will be a full, dues-paying UAW member.

4. I am the recipient of a Maximizing Opportunities for Scientific and Academic Independent Careers K99/R00 Postdoctoral Career Transition Award to Promote Diversity (“MOSAIC grant”) awarded by NIH through the National Institute of General Medical Sciences (“NIGMS”). The grant award number is [REDACTED] and the Notice of Award (“NOA”) for the grant is dated [REDACTED]. A true and correct copy of the NOA is attached hereto as Exhibit A.

5. According to the Notice of Funding Opportunity (“NOFO”), PAR-21-271, at 6, MOSAIC grants are issued by NIH “to enhance workforce diversity by facilitating a timely transition of promising postdoctoral researchers from diverse backgrounds ... from their mentored, postdoctoral research positions to independent, tenure-track or equivalent research-intensive faculty positions.” A true and correct copy of the expired PAR is attached hereto as Exhibit B. 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 underrepresented backgrounds in academic science, by facilitating the transition to faculty for scientists who will promote diversity in academia. The MOSAIC grant provides up to five years of support through two phases, funding up to two years of the MOSAIC scholar’s postdoctoral research position (the K99 or “mentored phase”) and up to three years of independent research support in a tenure-track faculty position (the R00 or “independent phase”). MOSAIC scholars apply for tenure track positions at institutions in the last year of the mentored phase, and once accepted to a position, the institution at which the scholar will become faculty submits the application for the independent phase. The program announcement for the MOSAIC grant states that receipt of the R00 phase of the award “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.” *Id.* at 7.

6. MOSAIC grants provide funding both for salary support and research support during the mentored phase. During the independent phase of the award, the MOSAIC grant provides funding for salary and benefits, research costs, and indirect costs reimbursed to the R00 sponsoring institution. The R00 sponsoring institution also commits to providing start-up funds to help the MOSAIC scholar set up their laboratory and some other institutional support. In addition to funding, MOSAIC scholars are provided with mentoring, networking, and professional development activities.

7. I initially applied for the MOSAIC grant on February 12, 2024. The grant is extremely prestigious and competitive, requiring me to go through a rigorous review process before I was selected. My application was 88 pages long, and it took me a month to draft the research statement and assemble the necessary documentation. I also had to submit supplemental information about my project, called "just in time information", before my project was ultimately approved. My grant application included a diversity statement that discussed my previous work advocating for diversity, equity, and inclusion in biomedical sciences, including serving on numerous committees in my graduate institution to promote diversity and improve working conditions for researchers, creating a virtual symposium on diversity in science in 2020, and creating resources to help first generation graduate students navigate graduate school. I also discussed that I am a queer and disabled woman in science, as the NOFO and accompanying NIH information discussed that women and people with disabilities are underrepresented in the field of biomedical research science. Exh. B.

8. My research project studies the role of molecular capacitors in obscuring genetic variation. My work currently focuses on the [REDACTED]

[REDACTED] I am currently in the first year of the mentored phase of my project, which began [REDACTED] in which I have been using gene knockouts in zebrafish to identify [REDACTED]

[REDACTED] In the seven months since receiving this award, I have established novel gene-knockout lines for 33 alleles across 13 [REDACTED] candidate genes, collaborated on developing an automated pipeline that measures [REDACTED] in fish, and identified two previously unreported gene knockouts that [REDACTED] and two previously unreported knockouts that [REDACTED] During the independent phase of my project, my NIH-approved research plan contemplated that I would investigate the role of [REDACTED] in development by abrogating its activity in developing zebrafish to identify tissues and pathways that are sensitive to [REDACTED] To that end, I have also, during the first year of my award, generated test-case transgenic zebrafish lines that carry dominant-negative [REDACTED] expressed in a tissue specific manner.



9. My NOA states that the project period for the mentored phase of my grant runs from [REDACTED] until [REDACTED] with the first year budget period running until [REDACTED]. Exh. A at 1. The award for the first year was [REDACTED] and the NOA recommends that the second year budget award be the same amount, “subject to the availability of funds and satisfactory progress of the project.” Id. at 3. As detailed above, I have made excellent progress on my project.

10. On April 2, 2025, less than a year into my MOSAIC grant, I was extremely distressed to receive an email from Kenneth D. Gibbs, Jr., Director of the Division of Training and Workforce Development at the NIGMS titled “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.

11. The email also states that my “institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.”

12. On [REDACTED] I sent an email to the general email address for NIGMS Training that had been provided, to seek clarification of the April 2, 2025 Gibbs email. The following day, on [REDACTED] I received a response from an unnamed person using the NIGMS Training email address. In response to my inquiries, the unnamed person using the NIGMS Training email address replied inline to my email by writing answers in bolded type directly into the body of the email that I had sent. A true and correct copy of the email I received from NIGMS Training is attached hereto as Exhibit D.

13. In response to my question whether my institution will be able to draw down funds through the duration of my project term for the mentored phase of the grant or whether the April 2<sup>nd</sup> email from Mr. Gibbs constituted a notice that my grant will be terminated, the email from NIGMS Training states “**The email provided updates on future NIGMS funding for certain programs that are no longer supported due to NIH/HHS priorities. NIH staff will follow up with specific information or action needed regarding any individual award. The award will terminate no later than the end of the current budget period. However, awards may terminate sooner based on NIH/HHS priorities. When awards are terminated, grantees will receive a revised notice of award.**”

14. I had also inquired whether MOSIAC R00 awards would no longer be made and if so, whether I could apply to transition to parent R00 grants. Transitioning to a parent R00 grant would allow my funding to continue through a different grant line. In response to my inquiry, the email from NIGMS Training states **“The R00 will not be made, and awardees cannot transfer to the Parent K99.”**

15. The termination of the MOSAIC program, and my loss of funding past the current budget year—ending [REDACTED]—has sent my career into a tailspin. I have dedicated an enormous portion of my time since the April 2<sup>nd</sup> email, perhaps 15 hours a week or more, to seeking clarity from my mentors about their expectations, researching alternate sources of funding, and networking with other disenfranchised scholars to form plans for our futures, which has slowed the pace of my research significantly. Although my mentors have made personal guarantees to find funding for me to continue my research, their lab budgets were predicated on my salary being paid by this grant, additional NIH funding cannot be guaranteed, and my institution does not seem to have a plan to provide any bridge funding to postdoctoral fellows who have lost funding. Not only is my current position precarious, but the loss of potential R00 funds will certainly have an impact on my ability to secure a tenure-track position in two years. Competition for academic positions is fierce and bringing in funding in the form of an R00 grant markedly increases the chances of securing a position. On a personal note, this news has been heartbreaking, and the stress incurred has had impacts on my sleep, motivation, and focus.

16. The loss of this grant will also have a horrible impact on my work, which has important implications for research into the genetic determinants of development and disease within individuals and across populations. One of the great outstanding questions in the study of genetic disorder/disease is why some people who carry a given mutant allele have symptoms of the associated disorder while other individuals who carry the same mutation remain healthy. My work aims to create a model system to interrogate the role of chaperone proteins on obscuring/revealing genetic variation, which I hypothesize may play a role in determining the circumstances in which “disease” alleles actually result in disease traits. My work has the potential to offer novel insight into the environmental circumstances and molecular mechanisms that trigger the revelation of mutations, including those mutations that result in genetically associated human diseases and disorders.

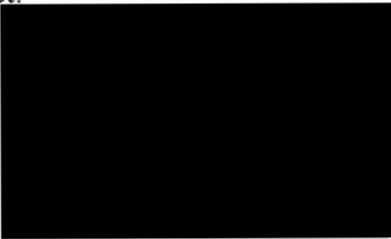
17. I am also very concerned about the long term impact on my generation of scientists who are dependent on these awards to launch a career dedicated to research, scientific development, and progress on the core medical issues of our time. Without the MOSAIC program and other NIH programs like it, far fewer scientists will be able to choose this path. Perhaps even more importantly, there will be a *specific* loss of scientists who are dedicated to improving mentoring, teaching, outreach, and workplace conditions in STEM. The MOSAIC program was explicitly intended to combat the “diversity tax,” which describes the phenomenon where minorities tend to do proportionately more outreach and mentoring. Exh. B at 7. Not only will the loss of this funding result in the loss of brilliant scientists in my cohort who would have been my colleagues, collaborators, mentors, and mentees, and whose research would have been transformative in the biomedical field, but it will have generational consequences as we diminish the number of researchers dedicated to fostering an inclusive environment for the next generation of thinkers.

18. I am currently looking into ways to appeal, but I do not know the chance of success. The research I proposed is research that would have been fundable under the parent K99, however, having been awarded the MOSAIC, I am now ineligible to apply for any other K grant, even if I do not receive the funds that I was awarded. The MOSAIC grant funds brilliant basic and translational research that has the potential to transform our understanding of health and disease—exactly the mission of the NIH. I do not understand how the MOSAIC program is incompatible with agency priorities.

19. I am seeking to file this declaration under seal because I am concerned about public hostility to my involvement in litigation against the NIH. I am worried about long term impacts on my career, both with the potential of being blacklisted from other funding opportunities and for the potential of making it more difficult to secure a faculty position. I am also worried about the potential for retaliation against my institution, as well as against my faculty mentors, and am concerned about negative impacts on their ability to get funding both as individuals and also for their labs.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 20 day of April, 2025.



# EXHIBIT A





## Recipient Information

### 1. Recipient Name

PRESIDENT AND FELLOWS OF HARVARD  
COLLEGE  
25 SHATTUCK ST  
BOSTON, MA 02115

### 2. Congressional District of Recipient

07

### 3. Payment System Identifier (ID)

1042103580C5

### 4. Employer Identification Number (EIN)

042103580

### 5. Data Universal Numbering System (DUNS)

047006379

### 6. Recipient's Unique Entity Identifier

JDLVAVGYJQ21

### 7. Project Director or Principal Investigator

[REDACTED]

[REDACTED]

### 8. Authorized Official

Barbara Rankin

## Federal Agency Information

### 9. Awarding Agency Contact Information

Jenelle C. Kiernan

NATIONAL INSTITUTE OF GENERAL  
MEDICAL SCIENCES  
jenelle.kiernan@nih.gov  
(301) 827-7819

### 10. Program Official Contact Information

Kalynda K Stokes

NATIONAL INSTITUTE OF GENERAL  
MEDICAL SCIENCES  
kalynda.stokes@nih.gov  
301-594-6450

## Federal Award Information

### 11. Award Number

[REDACTED]

### 12. Unique Federal Award Identification Number (FAIN)

[REDACTED]

### 13. Statutory Authority

42 USC 241 42 CFR 52

### 14. Federal Award Project Title

[REDACTED]

### 15. Assistance Listing Number

93.859

### 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

### 19. Budget Period Start Date [REDACTED] - End Date [REDACTED]

### 20. Total Amount of Federal Funds Obligated by this Action

20 a. Direct Cost Amount [REDACTED]

20 b. Indirect Cost Amount [REDACTED]

### 21. Authorized Carryover

### 22. Offset

### 23. Total Amount of Federal Funds Obligated this budget period

### 24. Total Approved Cost Sharing or Matching, where applicable

### 25. Total Federal and Non-Federal Approved this Budget Period

### 26. Project Period Start Date [REDACTED] - End Date [REDACTED]

### 27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period

### 28. Authorized Treatment of Program Income

Additional Costs

### 29. Grants Management Officer - Signature

Justin Rosenzweig

## 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.



CAREER TRANSITION AWARD  
Department of Health and Human Services  
National Institutes of Health

# Notice of Award



NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

## SECTION I – AWARD DATA – [REDACTED]

### Principal Investigator(s):

Award e-mailed to: spa\_award@hms.harvard.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of [REDACTED] (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD MEDICAL SCHOOL in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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 [REDACTED]. 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

### Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	\$ [REDACTED]
Fringe Benefits	\$ [REDACTED]
Personnel Costs (Subtotal)	\$ [REDACTED]
Materials & Supplies	\$20,000
Travel	\$3,000
Other	\$2,000

Federal Direct Costs  
 Federal F&A Costs  
 Approved Budget  
 Total Amount of Federal Funds Authorized (Federal Share)  
**TOTAL FEDERAL AWARD AMOUNT**

\$ [REDACTED]  
 \$ [REDACTED]  
 \$ [REDACTED]  
 \$ [REDACTED]  
 \$ [REDACTED]

**AMOUNT OF THIS ACTION (FEDERAL SHARE)**

\$ [REDACTED]

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)			
YR	THIS AWARD		CUMULATIVE TOTALS
1	[REDACTED]	[REDACTED]	[REDACTED]
2	[REDACTED]	[REDACTED]	[REDACTED]

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

**Fiscal Information:**

Payment System Identifier: 1042103580C5  
 Document Number: [REDACTED]  
 PMS Account Type: P (Subaccount)  
 Fiscal Year: 2024

IC	CAN	2024	2025
GM	8472199	[REDACTED]	[REDACTED]

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

**NIH Administrative Data:**

PCC: T256KK / OC: 41033 / Released: [REDACTED]  
 Award Processed: [REDACTED] 12:10:38 AM

**SECTION II – PAYMENT/HOTLINE INFORMATION – [REDACTED]**

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 – [REDACTED]**

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:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- 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.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain 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 obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI 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) [REDACTED] 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/>.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm>.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.



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 (FAPIS)). 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

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**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 for NIH definition of Clinical Trial.

1. This award is subject to the conditions set forth in PAR-21-271, Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity, 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-21-271.html>

Additional information on the MOSAIC Programs may be found at the following internet address:

<https://www.nigms.nih.gov/training/careerdev/Pages/MOSAIC.aspx>

2. This award reflects an allowable increase in the budget in accordance with [NOT-GM-22-045](#).

**3. IMPORTANT: 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 primary mentor are expected to participate in mentoring, networking, and professional development activities by the American Society for Cell Biology (<https://www.ascb.org/career-development/ascb-mosaic-program-amp/>). The PI is expected to report on their interactions with the UE5 grantee in section B.4 of the RPPR.**

4. 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.

5. 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.

6. 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 September 1. The Research Performance Progress Report (RPPR) will be due 45 days prior to this date 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>.

7. In the event the transition to the R00 phase occurs prior to the current project period end date of [REDACTED], this K99 award level may be adjusted accordingly.

8. As appropriate, the grant recipient 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.

9. Unobligated Balances: As indicated in Section III of this Notice of Award, an unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval. In accordance with section 8.1.1.1 of the NIH GPS, NIGMS staff reserve the right to make budgetary reductions to award commitments in cases where recipients have accrued excessively large unobligated balances.

### NIGMS' OFFICIAL WEBSITE

For more information, please visit: <http://www.nigms.nih.gov>

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the [Final NIH Policy for Data Management and Sharing](#) applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement [Section 8.2.3](#) for more information on data management and sharing expectations.

### SPREADSHEET SUMMARY

AWARD NUMBER: [REDACTED]

INSTITUTION: HARVARD MEDICAL SCHOOL

Budget	Year 1	Year 2
Salaries and Wages	[REDACTED]	[REDACTED]
Fringe Benefits	[REDACTED]	[REDACTED]
Personnel Costs (Subtotal)	[REDACTED]	[REDACTED]
Materials & Supplies	\$20,000	\$20,000
Travel	\$3,000	\$3,000
Other	\$2,000	\$2,000
TOTAL FEDERAL DC	[REDACTED]	[REDACTED]
TOTAL FEDERAL F&A	[REDACTED]	[REDACTED]
TOTAL COST	[REDACTED]	[REDACTED]

Facilities and Administrative Costs	Year 1	Year 2
F&A Cost Rate 1	8%	8%
F&A Cost Base 1	[REDACTED]	[REDACTED]
F&A Costs 1	[REDACTED]	[REDACTED]

# EXHIBIT B

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

## Department of Health and Human Services

### Part 1. Overview Information

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#### Participating Organization(s)

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

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#### Components of Participating Organizations

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

National Eye Institute ([NEI \(https://www.nei.nih.gov/\)](https://www.nei.nih.gov/))

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

National Human Genome Research Institute ([NHGRI \(https://www.genome.gov/\)](https://www.genome.gov/))

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

National Institute on Alcohol Abuse and Alcoholism ([NIAAA \(https://www.niaaa.nih.gov/\)](https://www.niaaa.nih.gov/))

National Institute of Allergy and Infectious Diseases ([NIAID \(https://www.niaid.nih.gov/\)](https://www.niaid.nih.gov/))

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

National Institute of Biomedical Imaging and Bioengineering ([NIBIB \(https://www.nibib.nih.gov/\)](https://www.nibib.nih.gov/))

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

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

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

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

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

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

National Institute of Neurological Disorders and Stroke ([NINDS \(https://www.ninds.nih.gov/\)](https://www.ninds.nih.gov/))

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

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

National Library of Medicine ([NLM \(https://www.nlm.nih.gov/\)](https://www.nlm.nih.gov/))

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

Eunice Kennedy Shriver National Institute of Child Health and Human Development ([NICHD \(https://www.nichd.nih.gov/\)](https://www.nichd.nih.gov/))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Research on Women's Health ([ORWH \(https://orwh.od.nih.gov/\)](https://orwh.od.nih.gov/))

Office of Behavioral and Social Sciences Research ([OBSSR \(https://obssr.od.nih.gov/\)](https://obssr.od.nih.gov/))

Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the [Table of IC-Specific Information, Requirements and Staff Contacts](https://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx) (<https://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx>).



website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

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## 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)

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## Activity Code

K99 ([https://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=k99&Search.x=0&Search.y=0&Search\\_Type=Activity](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k99&Search.x=0&Search.y=0&Search_Type=Activity))/R00 ([https://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r00&Search.x=0&Search.y=0&Search\\_Type=Activity](https://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

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## Announcement Type

Reissuance of [PAR-19-343](https://grants.nih.gov/grants/guide/pa-files/par-19-343.html) (<https://grants.nih.gov/grants/guide/pa-files/par-19-343.html>) - Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 - Independent Clinical Trial Not Allowed)

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## Related Notices

See [Notices of Special Interest](https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=35766) ([https://grants.nih.gov/grants/guide/NOSIs\\_targetingList.cfm?GuideDocID=35766](https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=35766)) associated with this funding opportunity

**July 23, 2024** - This PAR has been reissued as [PAR-24-225](https://grants.nih.gov/grants/guide/pa-files/par-24-225.html) (<https://grants.nih.gov/grants/guide/pa-files/par-24-225.html>)

**June 4, 2024** - Guidance Regarding Reduction of Effort for NIMHD Individual Mentored K Awards. See Notice [NOT-MD-24-017](https://grants.nih.gov/grants/guide/notice-files/NOT-MD-24-017.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-MD-24-017.html>)

**May 7, 2024** - Notice of Information: NIAID to Increase K99, K25, and K01 Salary and Research Support and R00 Years of Support. See Notice [NOT-AI-24-038](https://grants.nih.gov/grants/guide/notice-files/NOT-AI-24-038.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-AI-24-038.html>)

**December 5, 2023** - Notice of NIEHS Increase in Salary Support for "Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00)" Notice of Funding Opportunities. See Notice [NOT-ES-24-003](https://grants.nih.gov/grants/guide/notice-files/NOT-ES-24-003.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-ES-24-003.html>)

**August 21, 2023** - Notice of Informational Webinar on the NIH Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Program Notices of Funding Opportunity (K99/R00 and UE5). See Notice [NOT-GM-23-053](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-23-053.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-GM-23-053.html>)

[NOT-OD-23-012](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html>) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available

[NOT-OD-22-190](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-190.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-190.html>) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022

**September 7, 2022** - Notice of Increase to NIGMS K99 Support Levels. See Notice [NOT-GM-22-045](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-045.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-045.html>)

**August 19, 2022** - Notice of Informational Webinar on the NIH Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Program Funding Opportunity Announcements (K99/R00 and UE5). See Notice [NOT-GM-22-044](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-044.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-044.html>)

**July 27, 2022** - Notification to the community of change in maximum salary provided by NINDS K award mechanisms for clinician-scientists. See Notice [NOT-NS-23-005](https://grants.nih.gov/grants/guide/notice-files/NOT-NS-23-005.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-NS-23-005.html>)

**May 3, 2022** - Understanding the Basic Mechanisms of Immune-related Adverse Events (irAEs) in Cancer Immunotherapy. See Notice [NOT-CA-22-063](https://grants.nih.gov/grants/guide/notice-files/NOT-CA-22-063.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-CA-22-063.html>).

**March 4, 2022** - Notice of NICHD Participation in PAR-21-271. See Notice [NOT-HD-22-005](https://grants.nih.gov/grants/guide/notice-files/NOT-HD-22-005.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-HD-22-005.html>).

**December 8, 2021** - Notice to Extend Eligibility for Submission of "Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00)" Applications Due to COVID related Disruptions. See Notice [NOT-GM-22-020](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-020.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-020.html>).

**October 28, 2021** - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice [NOT-OD-22-018](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html>).

**September 13, 2021** - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice [NOT-OD-21-181](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html>).

**August 5, 2021** - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice [NOT-OD-21-169](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html>).

**August 5, 2021** - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice [NOT-OD-21-170](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html>).

**April 20, 2021** - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice [NOT-OD-21-109](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html>).

See [Notices of Special Interest](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-22-045.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-MH-22-045.html>) related to this opportunity

[NOT-OD-22-013](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-013.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-013.html>) - Notice of Participation of OBSSR in PAR-21-271

[NOT-GM-21-061](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-061.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-061.html>) - Notice of Informational Webinar on the NIH Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Program Funding Opportunity Announcements (K99/R00 and UE5)

[NOT-GM-21-057](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-057.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-057.html>) - Continuation of Temporary Extension of Applicant Eligibility in "Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00)" Funding Opportunity Announcements

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## Funding Opportunity Announcement (FOA) Number

PAR-21-271

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## Companion Funding Opportunity

[PAR-21-272](https://grants.nih.gov/grants/guide/pa-files/PAR-21-272.html) (<https://grants.nih.gov/grants/guide/pa-files/PAR-21-272.html>) - Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 Independent Clinical Trial Required)

[PAR-21-273](https://grants.nih.gov/grants/guide/pa-files/PAR-21-273.html) (<https://grants.nih.gov/grants/guide/pa-files/PAR-21-273.html>) - Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 Independent Basic Experimental Studies with Humans Required (BESH))

[PAR-21-277](https://grants.nih.gov/grants/guide/pa-files/PAR-21-277.html) (<https://grants.nih.gov/grants/guide/pa-files/PAR-21-277.html>) - Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Institutionally-Focused Research Education Award to Promote Diversity (UE5 Clinical Trial Not Allowed)

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## Number of Applications

See [Section III. 3. Additional Information on Eligibility](#).

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**Assistance Listing Number(s)**

93.859, 93.213, 93.867, 93.172, 93.837, 93.838, 93.839, 93.840, 93.233, 93.866, 93.273, 93.855, 93.846, 93.286, 93.279, 93.173, 93.121, 93.847, 93.113, 93.242, 93.307, 93.853, 93.361, 93.879, 93.313, 93.865

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**Funding Opportunity Purpose**

The purpose of the Maximizing Opportunities for Scientific and Academic Independent Careers (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 [Notice of NIH's Interest in Diversity \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) from their mentored, postdoctoral research positions to independent, tenure-track or equivalent research-intensive faculty positions. The MOSAIC K99/R00 program will provide 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 clinical trial. Applicants to this FOA are permitted to propose research experience in a clinical trial led by a mentor or co-mentor. Applicants proposing a clinical trial or an ancillary clinical trial as lead investigator, should apply to the companion FOA [PAR-21-272 \(https://grants.nih.gov/grants/guide/pa-files/PA-21-272.html\)](https://grants.nih.gov/grants/guide/pa-files/PA-21-272.html).

## Key Dates

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**Posted Date**

August 17, 2021

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**Open Date (Earliest Submission Date)**

September 27, 2021

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**Letter of Intent Due Date(s)**

Not Applicable

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**Application Due Date(s)**

The first due date for New applications is October 27<sup>th</sup>, 2021 by 5:00 PM local time. The first due date for Resubmission applications is November 12, 2021 by 5:00 PM local time.

[Standard dates \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11111\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11111) apply, for all subsequent receipt dates, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.

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.

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**AIDS Application Due Date(s)**

[Standard AIDS dates \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11112\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11112) apply, by 5:00 PM local time of applicant organization. All [types of AIDS and AIDS-related applications \(https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html#Application%20Types%20Allowed\)](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. 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.

The first AIDS application due date for this FOA is January 7, 2022.

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### Scientific Merit Review

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11113\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11113) apply

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### Advisory Council Review

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11113\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11113) apply

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### Earliest Start Date

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11113\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11113) apply

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### Expiration Date

**New Date** July 23, 2024 per issuance of [PAR-24-225 \(https://grants.nih.gov/grants/guide/pa-files/PAR-24-225.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-24-225.html) (Original Expiration Date: September 08, 2024 )

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### 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 [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](https://grants.nih.gov/grants/guide/)). 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 [Section IV](#). 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](#)

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#### [Section I. Funding Opportunity Description](#)

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#### [Section III. Eligibility Information](#)

#### [Section IV. Application and Submission Information](#)

#### [Section V. Application Review Information](#)

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## 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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=41159\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=41159) website.

The objective of the NIH Pathway to Independence Award (K99/R00) is to help rigorous and promising 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 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) from their mentored, postdoctoral research positions to independent, tenure-track or equivalent research-intensive faculty positions.

## 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 [underrepresented \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html) in the biomedical, clinical, behavioral and social sciences (collectively termed "biomedical") research workforce. Individuals from all backgrounds deserve an equitable opportunity to engage in the biomedical research enterprise, to pursue their scientific interests and further their careers. Moreover, 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 is integral to scientific excellence 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 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html). While scientific workforce diversity supports and is integral to the NIH mission, expanding the pool of academic investigators from nationally underrepresented backgrounds in the biomedical research workforce has remained an elusive goal (see [Policy Supporting Next Generation Researchers Initiative \(https://grants.nih.gov/grants/guide/notice-files/not-od-17-101.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-17-101.html)). 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 \(https://extramural-diversity.nih.gov/building-participation/commitment-across-nih\)](https://extramural-diversity.nih.gov/building-participation/commitment-across-nih). In spite of recent advances, individuals from certain groups and backgrounds remain underrepresented in the biomedical sciences research workforce as described in the [Notice of NIH's Interest in Diversity \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). The severity of the underrepresentation of these groups increases throughout the training stages. For example, students from certain racial and ethnic groups, including Black or African American, Hispanic or Latina/o/x, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander comprise ~38 percent of the college age population ([Census Bureau \(https://data.census.gov/cedsci/\)](https://data.census.gov/cedsci/) data), but earn only ~22 percent of bachelor's degrees and ~14 percent of Ph.D. degrees in the life sciences ([National Center for Science and Engineering Statistics \(https://www.nsf.gov/statistics/data-tools.cfm\)](https://www.nsf.gov/statistics/data-tools.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, corresponding increases in the ranks of the faculty in basic science departments ([Gibbs, et al., eLife 2016 \(https://elifesciences.org/articles/21393\)](https://elifesciences.org/articles/21393); [Valantine, Lund & Gammie, CBE-Life Sciences Education, 2016 \(https://www.lifescied.org/doi/full/10.1187/\)](https://www.lifescied.org/doi/full/10.1187/) or NIH-funded investigators ([Hoppe et al, 2019 \(https://advances.sciencemag.org/content/5/10/eaaw7238\)](https://advances.sciencemag.org/content/5/10/eaaw7238); [Lauer, 2020 \(https://nexus.od.nih.gov/all/2020/08/12/institute-and-center-award-rates-and-funding-disparities/\)](https://nexus.od.nih.gov/all/2020/08/12/institute-and-center-award-rates-and-funding-disparities/)) have not occurred. Similarly, women have earned a majority of biomedical Ph.Ds. since 2008 ([NSF data \(https://nces.nsf.gov/pubs/nsf19304/\)](https://nces.nsf.gov/pubs/nsf19304/)), but only approximately 1/3 of NIH-funded principal investigators are women ([NIH Databook \(https://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=218&catId=15\)](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) (<https://researchtraining.nih.gov/programs/career-development/k99-r00>); however, the diversity of K99/R00 awardees not reflect the demographics of the available talent pool of well-trained Ph.D. biomedical scientists. For example, for the [Parent K99/R00 funding announcement](https://grants.nih.gov/grants/guide/pa-files/PA-20-188.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-20-188.html>), over 90% of NIGMS K99/R00 grantees have transitioned to independent faculty positions; however, only 7% of applicants have been from racial and ethnic groups historically underrepresented, and only 33% have been women.

NIH has undertaken a number of efforts to facilitate the [career transition of postdoctoral scientists from diverse groups](https://extramural-diversity.nih.gov/career-pathways/infographic/career) (<https://extramural-diversity.nih.gov/career-pathways/infographic/career>) into the professoriate, including the [Institutional Research and Academic Career Development Awards \(IRACDA\)](https://www.nigms.nih.gov/Training/CareerDev/Pages/TWDInstRes.aspx) (<https://www.nigms.nih.gov/Training/CareerDev/Pages/TWDInstRes.aspx>), research supplements to [promote diversity in health-related research](https://grants.nih.gov/grants/guide/pa-files/PA-21-071.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-21-071.html>) and [re-entry into biomedical research careers](https://www.nigms.nih.gov/Research/Mechanisms/Pages/PromoteReentry.aspx) (<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) (<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-informed mentorship and professional development programming. These efforts have supported the development of highly trained biomedical scientists from diverse backgrounds who have the necessary knowledge and skills to pursue independent careers in the biomedical research workforce. NIH also recognizes that efforts aimed at achieving scientific workforce diversity are hindered by organizational structures, systems, and policies that perpetuate exclusion and inequity based on race and gender. Organizational structures, policies, practices, and social norms that perpetuate bias, prejudice, discrimination, and racism also limit the pace of scientific progress. Therefore, there remains a compelling need to develop additional strategies to promote transitions to independent, research-intensive faculty positions for scientists from diverse backgrounds.

### 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 promising postdoctoral researchers from diverse backgrounds, for example individuals from groups [underrepresented in the biomedical research workforce at the faculty level](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html), (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>) into independent, research-intensive faculty careers. 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 [Notice of NIH's Interest in Diversity](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>) (<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 research-intensive faculty positions.

### 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. Additionally, it is widely recognized that scientists from underrepresented groups often assume disproportionate academic service and outreach loads, even during their training, and that these contributions to the research environment are generally not appropriately recognized and rewarded in the measures of career advancement (i.e., "the diversity tax"). The MOSAIC K99/R00 program seeks to support early career scientists with demonstrated and compelling commitments and contributions to enhancing diversity in the biomedical sciences. The specific NIH Institute and Center scientific areas supported through this FOA can be found at the [Table of IC-Specific Information, Requirements and Staff Contacts](https://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx) (<https://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.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. 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 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 Clinician Scientists:** For the purposes of this program, clinician 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 clinician scientists who already have substantial research training and are dedicated to initiating a strong, research-intensive career as clinician scientists. The K99/R00 program is designed to facilitate a timely transition of rigorous clinician 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 \(https://researchtraining.nih.gov/programs/career-development\)](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.** Because the program aims to support the career development of scholars early in their postdoctoral training, candidates who have not yet published a first-author manuscript during their postdoctoral training, but whose previous and current studies and future plans are likely to support a successful independent research career are encouraged to apply.

The K99/R00 award is intended for individuals who require at least 12 months of mentored 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 12 years of substantive mentored 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 career development at the time of award is not a strong candidate for this 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.

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 Development. Appropriate institutional leaders (e.g., K99 phase mentors and R00 phase department chairs) are also expected to participate in MOSAIC UE5 activities. Information about MOSAIC UE5 awards can be found on the [MOSAIC website \(https://www.nigms.nih.gov/training/careerdev/Pages/MOSAIC.aspx\)](https://www.nigms.nih.gov/training/careerdev/Pages/MOSAIC.aspx). 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, tenure-track or equivalent research-intensive faculty positions.

### 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 career development 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 clinical trial. Applicants to this FOA are permitted to propose research experience in a clinical trial led by a mentor or co-mentor. Those proposing a clinical trial or an ancillary study to an ongoing clinical trial as lead investigator, should apply to the companion FOA, [PAR-21-272 \(https://grants.nih.gov/grants/guide/pa-files/PAR-21-272.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-21-272.html).

See [Section VIII. Other Information](#) 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 [OER Glossary \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11116\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.

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**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? \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

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**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.

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**Award Budget**

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

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**Award Project Period**

The total project period may not exceed 5 years.

## Other Award Budget Information

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**Salary****Mentored Phase (K99)**

Salary and fringe benefits may be requested to the level provided by the awarding Institute or Center. Candidates should consult the [Table of IC-Specific Information, Requirements and Staff Contacts \(https://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx\)](https://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx) for IC-specific, programmatic and budgetary information.

**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](https://grants.nih.gov/grants/policy/salcap_summary.htm) ([https://grants.nih.gov/grants/policy/salcap\\_summary.htm](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.

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**Other Program-Related Expenses**

The participating NIH Institutes and Centers will provide research development support for the award recipient (see the [Table of IC-Specific Information, Requirements and Staff Contacts \(http://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx\)](http://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx)). These funds may be used for the following expenses: (a) tuition and fees related to career development activities; (b) research-related expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training (excluding MOSAIC associated meetings, the costs of which are covered by the UE5 awards); and (d) 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.

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

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### 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 [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) 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)
- Predominantly Black Institutions (PBI)
- Tribally Controlled Colleges and Universities (TCCUs)
- American Indian/Alaska Native Serving, Non-Tribal Institutions (AI/AN)
- 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 [defined in the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11118\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11118), **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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](https://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.

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - 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.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) (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.
  - [NATO Commercial and Government Entity \(NCAGE\) Code \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11176\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - 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 \(https://grants.nih.gov/grants/glossary.htm#MultipleProgramDirectorPrincipalInvestigator\)](https://grants.nih.gov/grants/glossary.htm#MultipleProgramDirectorPrincipalInvestigator) are not allowed.

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.

Consistent with the NIH Extension Policy for Early Stage Investigator Status (ESI), NIH will approve an extension of one year for childbirth within the 4-year K99 eligibility window. Applicants who will be PD/PIs on a K99 application must provide the child's date of birth in the extension request justification submitted to IC program officials and/or scientific/research contacts listed in the FOA at least 12 weeks before submitting an application.

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 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 counts toward the 4-year limit. Please refer to [NIH Extension Policy for Eligibility Window for Pathway to Independence Awards \(K99/R00\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-011.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-011.html>).

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.

### 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-20-031.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.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
- 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 or the equivalent.

**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, candidate should provide the relevant NIH Institute or Center 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 \(/grants.nih.gov/training/careerdevelopmentawards.htm\)](https://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 NIH Grants Policy Statement.

## 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.
- 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 \(/grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

### Level of Effort

**K99 Phase.** 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. 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 \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=51125\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 appropriate facilities for rigorous 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 tailored 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 [Part 1](#) 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 [SF424 \(R&R\) Application Guide](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=12000](https://grants.nih.gov/grants/guide/url_redirect.php?id=12000)) 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 [Frequently Asked Questions Application Guide, Electronic Submission of Grant Applications](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=41137](https://grants.nih.gov/grants/guide/url_redirect.php?id=41137)).

## Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11133](https://grants.nih.gov/grants/guide/url_redirect.php?id=11133)) must be followed.

## Instructions for Application Submission

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing (DMS) Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

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.



## Other Attachments

**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 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.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.

## Project Summary/Abstract

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

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

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

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 and early career scientists 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.

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
- 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

### Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the

amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

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 career development 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 of postdoctoral training, explain why support at this stage is appropriate.

#### *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. Information on the MOSAIC UE5 programs can be found on the MOSAIC program website: <https://www.nigms.nih.gov/training/careerdev/Pages/MOSAIC.aspx> (<https://www.nigms.nih.gov/training/careerdev/Pages/MOSAIC.aspx>).
- 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.
- 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 career development is 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 career development activities, 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.
- 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.
- 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-informed 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.

#### **Description of Institutional Environment (2 pages maximum)**

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.
- Describe any institutional career development resources and activities that will be available to contribute to the candidate's career development (e.g., an office of postdoctoral affairs, a seminar series for future faculty, etc.).
- Describe any institutional policies and practices that are expected to contribute to the candidate's research and career development success, such as policies and procedures to (a) promote diversity and inclusion in the research training environment, (b) ensure that the institution's facilities are accessible to those with disabilities, (c) foster a positive, supportive, and safe research and training environment, and (d) prevent discriminatory harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (e.g., requesting a change of PD/PI status; see [NOT-OD-15-152 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-152.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-152.html) and [NOT-OD-18-172 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-172.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-172.html)).

Applicant's should disregard the following warning message "The Description of Institutional Environment attachment on the PHS 398 Career Development Award Supplemental Form is limited to 1 page." This FOA permits 2 pages for this attachment.

##### **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.

**Description of Candidate's Contribution to Program Goals.** As this is a diversity-related FOA, applications must include the [Description of Candidate's Contribution to Program Goals \(https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplemental-form.htm#12.\)](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplemental-form.htm#12.) on the Career Development Award Supplemental form. The *Description of Candidate's Contribution to Program Goals* is distinct from the *Diversity Statement* in the *Other Attachments* Section, and it must be signed by an institutional official (in most cases the dean or the chair of the department). Applications lacking the Description of Candidate's Contribution to Program Goals attachment will be considered incomplete and will not be reviewed.

## Appendix

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, interests, and who can elaborate on the candidate's potential to contribute to program goals. *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 [eRA Commons Submit Referee Information link \(https://grants.nih.gov/grants/guide/submit\\_referee\\_information.html\)](https://grants.nih.gov/grants/guide/submit_referee_information.html) 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

[Part I. Overview Information](#) 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 [Federal holiday \(https://grants.nih.gov/grants/guide/submit\\_referee\\_information.html\)](https://grants.nih.gov/grants/guide/submit_referee_information.html), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(https://grants.nih.gov/grants/guide/submit\\_referee\\_information.html\)](https://grants.nih.gov/grants/guide/submit_referee_information.html) (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 [eRA Commons](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11123](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)), 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 ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11142](https://grants.nih.gov/grants/guide/url_redirect.php?id=11142)) intergovernmental review. ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11142](https://grants.nih.gov/grants/guide/url_redirect.php?id=11142))

## 6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120)).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11143](https://grants.nih.gov/grants/guide/url_redirect.php?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. [Section III. Eligibility Information](#) contains information about registration.

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

### 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 [Section III](#) 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](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11146](https://grants.nih.gov/grants/guide/url_redirect.php?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](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82299](https://grants.nih.gov/grants/guide/url_redirect.php?id=82299)).

# Section V. Application Review Information

## 1. Criteria

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the [NIH mission \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11149\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 candidate's demonstrated track record and proposed plans with respect to advancing and promoting diversity in the biomedical research enterprise. 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

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 rigor of prior research and the current application, what is the candidate's potential to become a successful, independent investigator who will contribute to her/his/their chosen field of biomedical research?
- What is the suitability 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?
- Has the candidate demonstrated a compelling commitment and contributions to enhancing diversity in the biomedical sciences?
- Does the candidate have 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?
- Will the plans to incorporate activities provided by the MOSAIC Institutionally-Focused Research Education Award (UE5) into the scholar's career development plans create synergies to enhance the scholar's career development?
- Is the proposed career development plan likely to contribute substantially to the scientific and professional development of the candidate, and facilitate her/his/their 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/their fourth year as a postdoctoral fellow, is this well justified and appropriate?
- If proposed, will the clinical trial experience contribute to the applicant's research career development?

### Research Plan

- Does the research proposed in the K99 and R00 phases address an important problem or a critical barrier to progress in the field? Is the research proposed in the K99 and R00 phases scientifically sound? Will the proposed research goals, if achieved, improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields?
- 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 aspects of the K99 research appropriate for developing the research skills described in the career development plan, and appropriate for developing a successful R00 research program?
- Does the R00 phase research appropriately build upon the K99 phase research? Are the themes and/or topics of the R00 phase research plan substantive and appropriate for long-term pursuit?
- Does the project develop or employ, as appropriate, novel or innovative concepts, approaches, methodologies, tools, or technologies? Will creative strategies be employed as needed and appropriate to address the research questions posed?
- If proposed, will the clinical trial experience contribute to the research project?

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

- Are the research qualifications and mentoring plans of the mentor(s) appropriate for the candidate's career development needs?
- To what extent do(es) the mentor(s) describe clear and robust 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 at the candidate's career stage?
- 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-informed 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 her/his/their 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 an appropriate environment 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 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 appropriate 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 \(//grants.nih.gov/grants/guide/redirect.php?id=11175\)](https://grants.nih.gov/grants/guide/redirect.php?id=11175).

### Inclusion of Women, Minorities, and Individuals Across the Lifespan

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 [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/redirect.php?id=11174\)](https://grants.nih.gov/grants/guide/redirect.php?id=11174).

### 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 \(//grants.nih.gov/grants/guide/redirect.php?id=11150\)](https://grants.nih.gov/grants/guide/redirect.php?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

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

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) [Data Sharing Plan \(//grants.nih.gov/grants/guide/redirect.php?id=11151\)](https://grants.nih.gov/grants/guide/redirect.php?id=11151); (2) [Sharing](#)

[Model Organisms \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11152\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11153\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 ["Update on the Requirement for Instruction in the Responsible Conduct of Research" \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html) for more information about NIH requirements for Responsible Conduct of Research.

## 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 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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11154\)](https://grants.nih.gov/grants/guide/url_redirect.php?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.
- Contributions to portfolio breadth and diversity.



### 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 [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer 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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11156\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 recipient's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). 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 [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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

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.

### 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11158). More specifically, for K Awards, visit the [Research Career Development \( K \) Awardees section of the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=51164\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=51164).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> (<https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html>) and <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<https://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>).

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.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides 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 <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html>) and <https://www.lep.gov> (<https://www.lep.gov>). 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 <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

- 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>).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>); <https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html>; and <https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf> (<https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf>). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm> (<https://grants.nih.gov/grants/policy/harassment.htm>).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see <https://www.hhs.gov/conscience/conscience-protections/index.html> (<https://www.hhs.gov/conscience/conscience-protections/index.html>) and <https://www.hhs.gov/conscience/religious-freedom/index.html> (<https://www.hhs.gov/conscience/religious-freedom/index.html>).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> (<https://www.hhs.gov/ocr/about-us/contact-us/index.html>) or call 1-800-368-1019 or TDD 1-800-537-7697.

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 (FAPIS) requirements. FAPIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIS, 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. 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 recipient organization.

The independent phase institution will submit an application on behalf of the candidate for the R00 award using the [PHS 398 Application \(//grants.nih.gov/grants/guide/redirect.php?id=22000\)](https://grants.nih.gov/grants/guide/redirect.php?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 Individuals across the Lifespan (as appropriate);
- Authentication of Key Biological and/or Chemical Resources (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.

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.

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, NIGMS 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 an NIH awarding component.

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.

### Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_8/8.2.3\\_sharing\\_research\\_resources.htm#Data\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

### 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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11161\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11170\)](https://www.fsrs.gov) on all subawards over \$25,000. See the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11171\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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:

- Aggregate number and demographic characteristics of applicants and awardees
- Successful transition of awardees to an independent tenure-track or equivalent faculty position
- Authorship of scientific publications during both mentored and independent career phases
- 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 applications **MUST** consult the [Table of IC-Specific Information, Requirements, and Staff Contacts](https://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx) (<https://www.nigms.nih.gov/training/careerdev/mosaic/Pages/MOSAIC-K99-Independent-Clinical-Trial-Not-Allowed-PAR-21.aspx>) to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

### 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/> (<http://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) (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-480-7075

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) (<mailto:support@grants.gov>)

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## Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.php?id=11163) ([http://grants.nih.gov/grants/guide/url\\_redirect.php?id=11163](http://grants.nih.gov/grants/guide/url_redirect.php?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](http://grants.nih.gov/grants/guide/url_redirect.php?id=11164) ([http://grants.nih.gov/grants/guide/url\\_redirect.php?id=11164](http://grants.nih.gov/grants/guide/url_redirect.php?id=11164)). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.php?id=11120) ([http://grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](http://grants.nih.gov/grants/guide/url_redirect.php?id=11120)).

Please note that the NIH Loan Repayment Programs (LRPs) are a set of programs to attract and retain promising early-stage investigators in research careers by helping them to repay their student loans. Recipients of career development awards are encouraged to consider applying for an extramural LRP award.

### 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.

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[Weekly TOC for this Announcement](http://grants/guide/WeeklyIndex.cfm?08-20-21) (<http://grants/guide/WeeklyIndex.cfm?08-20-21>)

[NIH Funding Opportunities and Notices](http://grants/guide/index.html) (<http://grants/guide/index.html>)

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National Institutes of Health (<http://grants/oer.htm>)  
Office of Extramural Research



[\(https://www.hhs.gov/\)](https://www.hhs.gov/)

Department of Health  
and Human Services (HHS)



[\(https://www.usa.gov/\)](https://www.usa.gov/)

NIH... Turning Discovery Into Health®



# EXHIBIT C



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## NIGMS Funding Update

1 message

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**Gibbs, Kenneth (NIH/NIGMS) [E]** <kenneth.gibbs@nih.gov>

Wed, Apr 2, 2025 at 1:49 PM

To: [REDACTED]

Re: [REDACTED]

Dear [REDACTED]

I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

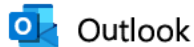
NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: <https://www.nigms.nih.gov/training/Pages/TWDPrograms>.

If you have specific follow up questions, please email [nigmstrainingmail@nigms.nih.gov](mailto:nigmstrainingmail@nigms.nih.gov) and include the grant number.

**Kenneth D. Gibbs, Jr., PhD, MPH**

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

# EXHIBIT D



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Fwd: [EXTERNAL] Question regarding [REDACTED]

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From [REDACTED]  
Date Fri 4/11/2025 7:42 PM  
To Olga Akselrod <OAkselrod@aclu.org>

---

**This Message Is From an External Sender**

This message came from outside your organization.

----- Forwarded message -----

From: **NIGMS Training** <[NIGMSTrainingMail@nigms.nih.gov](mailto:NIGMSTrainingMail@nigms.nih.gov)>  
[REDACTED]

Subject: RE: [EXTERNAL] Question regarding [REDACTED]

NIGMS Training

<[NIGMSTrainingMail@nigms.nih.gov](mailto:NIGMSTrainingMail@nigms.nih.gov)>

CC: Lynch, Jennifer (NIH/NIGMS) [E] <[jennifer.lynch@nih.gov](mailto:jennifer.lynch@nih.gov)>, Stokes, Kalynda (NIH/NIGMS) [E]  
<[kalynda.stokes@nih.gov](mailto:kalynda.stokes@nih.gov)>

---

From: [REDACTED]  
Sent: [REDACTED]  
To: NIGMS Training <[NIGMSTrainingMail@nigms.nih.gov](mailto:NIGMSTrainingMail@nigms.nih.gov)>  
Subject: [EXTERNAL] Question regarding [REDACTED]

Hi there--

I recently received notification that the MOSAIC program was terminated. The email said that my "institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement." To that end, I had some clarifying questions.

Can my institution continue to draw funds for the duration of my award term (through [REDACTED] believe)? Or does this notice constitute some sort of advance warning that this grant will be

terminated? **The email provided updates on future NIGMS funding for certain programs that are no longer supported due to NIH/HHS priorities. NIH staff will follow up with specific information or action needed regarding any individual award. The award will terminate no later than the end of the current budget period. However, *awards may terminate sooner* based on NIH/HHS priorities. When awards are terminated, grantees will receive a revised notice of award.**

The award seems to indicate that MOSAIC R00 awards will no longer be made. Am I eligible to apply to transition to parent R00 grants? **The R00 will not be made, and awardees cannot transfer to the Parent K99.**

The award also specifies that no NCEs will be allowed. Are other allowable extensions allowed (ie parental leave)? **Please follow up with Kalynda and Jennifer for the specifics if needed during the active award period.**

Many thanks

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.