EXHIBIT 23

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; and NICOLE MAPHIS, Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, *in his official capacity as Director of the National Institutes of Health*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*, et al., Defendants.	No. 1:25-cv-10787-BEM

DECLARATION OF GEORGES C. BENJAMIN, M.D.

I, Georges C. Benjamin, do hereby state the following, pursuant to 28 U.S.C. § 1746:

1. I am the Executive Director of the American Public Health Association (APHA). I have served in that role since December 2002.

2. APHA's mission is to: "Build public health capacity and promote effective policy and practice." APHA members include more than 23,000 individual public health professional members, as well as agency members such as organizations interested in health, state and local health departments and health related businesses. APHA also coordinates with state and regional APHA affiliates across the nation. APHA members work in every discipline of public health, in

every state, and in countries across the globe.

3. I make this declaration on behalf of the American Public Health Association in support of its motion to enjoin the National Institutes of Health and the Department of Health and Human Services from implementing or enforcing its directives forcing agency administrators to terminate the federal grants funding APHA's members' critical research.

4. I am a graduate of the Illinois Institute of Technology and the University of Illinois College of Medicine. I am licensed to practice medicine in Maryland and the District of Columbia. I am board-certified in internal medicine and a Master of the American College of Physicians, a fellow of the National Academy of Public Administration, a fellow emeritus of the American College of Emergency Physicians, an elected member of the National Academy of Medicine (formally the Institute of Medicine) of the National Academies of Sciences, Engineering and Medicine, an honorary fellow of the Faculty of Public Health, and an honorary fellow of the Royal Society of Public Health.

5. Following graduation from medical school, I entered active duty in the Army where I completed a residency in internal medicine at the Brooke Army Medical Center in San Antonio, Texas. Upon completion of my residency in 1981, I was assigned to Madigan Army Medical Center in Tacoma, Washington, as faculty and staff in the Department of Emergency Medicine, there I managed a 72,000-patient per year ambulatory care service as chief of the Acute Illness Clinic and was an attending physician within the Department of Emergency Medicine. I was reassigned in 1983 and from then until the spring of 1987, I served as chief of emergency medicine at the Walter Reed Army Medical Center.

6. Following my discharge from the United States Army in 1987, I was appointed as Chair of the Department of Community Health and Ambulatory Care at the District of Columbia General Hospital, serving in that post until December of 1990. From January 1990 to the fall of

1991, I was the Acting Commissioner for Public Health for the District of Columbia, and the Acting Director of the Emergency Ambulance Bureau in the District of Columbia Fire Department. I returned to serve as the Intermin Director of the Emergency Ambulance Bureau from the fall of 1994 to the spring of 1995.

7. I served as the Secretary of the Maryland Department of Health and Mental Hygiene from April 1999 to December 2002, following four years as its Deputy Secretary for Public Health Services.

8. In April 2016, I was appointed by President Obama to the National Infrastructure Advisory Council. In that role, I helped advise the President on how best to assure the security of the nation's critical infrastructure. I served in this capacity until December of 2020.

APHA's Mission, Structure, and Activities.

9. The mission of public health is to "fulfill society's interest in assuring conditions in which people can be healthy."[1] Public health has been defined as "the science and art of preventing disease, prolonging life, and promoting health and efficiency through organized community efforts and informed choices of society, organizations, public and private communities, and individuals."[2]

10. As a discipline, public health involves:

a) identifying health issues and priorities through the study of communities and specifically through a focus on at-risk communities

b) shaping public policies and interventions to address national, regional, and

---

[1] Institute of Medicine, The Future of Public Health. National Academy Press, Washington, DC, 1988.

[2] Winslow, C.E.A. (1920). The untilled fields of public health. Science, 51(1306), 23-33.

local concerns, and

c) ensuring all populations have access to appropriate and affordable health and disease prevention services as well as monitoring and evaluating those services and care.

11. The American Public Health Association was founded in 1872, at a time when scientific advances were helping to reveal the causes of communicable diseases. These discoveries laid the foundation for the public health profession and for the infrastructure to support APHA's work. Since that time, public health has evolved into a broad health discipline involving several different types of practitioners.

12. APHA members work in every discipline of public health, in every state in the country, and in countries across the globe. APHA members are united with a common goal to promote optimal, equitable health and well-being for all.

13. From its inception, APHA has been dedicated to ensuring optimal health of all U.S. residents. Two of its most important functions have been advocacy for adoption by the government of the most current scientific advances relevant to public health, and public education on how to improve individual and community health. Along with these efforts, APHA has also campaigned for developing well-organized governmental health departments at the tribal, federal, state, and local levels to provide the governmental level role to fulfill its statutory obligations.

14. APHA works with key decisionmakers to shape public policy to address today's current and emerging public health concerns. Those include ensuring access to care, protecting, and increasing funding for core public health programs and services and eliminating health disparities. APHA is also working on other critical public health issues including public health and emergency preparedness, food safety, hunger and nutrition, and the full range of

environmental health issues, public health infrastructure, disease control, international health, and tobacco control.

15. APHA also produces statements and resources for public health practitioners, including member-developed policy briefs that provide evidence to use in public health education and advocacy, provide easy access to the latest research and findings in public health, and assist policymakers and regulators in being able to access up-to-date facts and findings as they relate to public health. APHA holds an annual convention, the largest of its kind in public health, where students and published academics alike can present their research and learn from one another.

16. Among an array of other scientific literature, APHA publishes *The American Journal of Public Health*, which is dedicated to publishing ***original*** work in research, research methods, and program evaluation in the field of public health to advance public health research, policy, practice, and education.

Equity and Inclusion are Central to APHA's Activities and the Activities of Its Members

17. The entire field of public health is dedicated to an understanding of and creating interventions to ensure optimal health for all. This includes addressing inequitable access to health and health-related services and to achieve equity in health status. This type of work is essential not only to APHA's own mission but to the discipline of public health itself and society as a whole.

18. APHA and its members work on initiatives to ensure that health and health services are accessible to people in all communities. APHA and its members also study and research the way in which disease, injury, or health related issues affect populations that have been marginalized and excluded from full participation in society or that face resource deficits. Seeking to bring about optimal health through the appropriate distribution of health resources,

ensuring that all communities have access to preventative health services and health care, and understanding the social determinants of health—the way in which nonclinical socio-economic factors, geographic factors, public policies and demographics that affect health-related outcomes—are all central to the field of public health and to the work of APHA and its members.

19. APHA has several programs and activities aimed at eliminating discrimination and exclusion in the provision of health services including prevention and ensuring that the public is educated about both overt discrimination and bias. Its members also are individually and collectively engaged in this work.

20. APHA is involved in and supports research focused on addressing structural racism and developing solutions to mitigate racism within the institutions, including health institutions, in the United States. Many of APHA's members also, individually and collectively through APHA, take part in similar initiatives. For some of these members, such research is not just another component of their work, but the very foundation for their careers.

APHA's Members Rely on NIH Grant Funding for their Work

21. APHA members rely heavily on funding from the Department of Health and Human Services, and from NIH in particular. NIH grants are essential to our members' ability to support a wide range of activities, from tribal, federal, state, territorial and local health departments, to community-based programs, to academic research. APHA members have reasonably relied on the continued receipt of NIH grants that have already been awarded and, in general, on the continued availability of NIH grants to support work that is consistent with congressional mandates of the agency to conduct medical research and protect public health.

22. Accordingly, the indiscriminate termination of grants by the NIH has already severely impacted our members' work by disrupting ongoing programs and community support, making it difficult – if not impossible – to plan for the future. It has directly harmed individuals

whose jobs are supported by this funding, both direct grant recipients and those whom they employ. And if allowed to continue unabated, these terminations will have a severely negative impact on public health.

Partisan Political Considerations Jeopardize Public Health Initiatives

23. APHA members need the flexibility to pursue their work without fear of persecution or disruption in response to emerging threats to public health. Otherwise, precious time will be wasted, and lives will be lost. Such impacts of political pressure on public health are not hypothetical.

24. Congressional action in the 1990s prohibiting federal funds from being used to "advocate or promote gun control" effectively chilled public health research into firearm injury prevention and its effect on communities for decades, as researchers feared having their work shut down if outside groups regarded it as advocacy. Even after the initial language was clarified, it still took years for Congress to expressly allow for funding to be reappropriated and for agencies to feel free to properly investigate a critical public health concern. Firearm injury disproportionately impacts communities of color with African American men receiving the bulk of the injuries and deaths. Firearms are also the leading cause of death for all children and teens regardless of race or ethnicity.

25. Conversely, the history of American public health has demonstrated the importance of continuing research that examines disparate outcomes in marginalized communities, even in the face of partisan pressure not to study these groups. The AIDS epidemic, for instance, required researchers to pay careful attention to racial, gender, and sexual orientation differences in high-risk populations to develop effective interventions for particular communities to slow the spread of the virus. In the absence of such tailored responses, HIV and other sexually transmitted diseases would have wrought considerably more damage among these groups and to

the general population.

26. As a more recent example, the rapidly evolving response to the COVID-19 pandemic also required researchers to quickly account for the needs of different communities, particularly regarding vaccine skepticism among ethnic minorities, some who were directly targeted with misinformation to sow distrust among ethnic minorities. By paying careful attention to these differences, researchers were able to guide authorities to direct resources and tailor responses accordingly, especially regarding vaccine distribution, benefiting the broader population as a result.

27. When researchers are empowered to do their work free from political pressure, public health benefits. When they are discouraged, public health suffers.

APHA Members Have Had Their Projects Cancelled Without Fair Warning

28. Since at least February 2025, NIH has informed APHA members with previously awarded grants – some of which had been in place for years – would be terminated. Others have been informed, either directly or indirectly, that grant proposals they had already submitted would not be considered. These members were informed that these curtailed grants and programs "no longer effectuate agency priorities." Specifically, the NIH targeted projects that dealt – however remotely or tangentially — with "gender identity" (also characterized in grant termination letters as "transgender issues"), and "diversity, equity, and inclusion" or "DEI."

29. Grant recipients were given no particularized justification for why their projects were canceled, or how their projects suddenly failed to "effectuate agency priorities." Instead, they all received the same cut-and-paste response based on the category highlighted by the new directives that their project was judged to deal with.

30. Prior to the recent waves of terminations, I have never been aware of an APHA member having their NIH grant terminated.

31. I am aware of one dues-paying APHA member, who I will refer to as APHA Member 16, who is a named professor at a major private research university. As part of their work, APHA Member 16 has prioritized mentoring and training the next generation of scientists. To do this, they lead NIH-funded programs that have supported training in STEM fields at multiple levels, spanning from undergraduate students to graduate students and post-doctoral scholars.

32. Member 16 was awarded an NIH grant in excess of $600,000 to run a MARC program at their university, with an award term of five years. The goal of the MARC Program, as described in NIH PAR 21-147, is to develop a diverse pool of undergraduates who complete their baccalaureate degree, transition into, and complete bio-medical, research-focused higher degree programs. The MARC program is limited to applications from training programs at baccalaureate degree-granting research-intensive institutions, defined as those that receive an average of $7.5 million per year in NIH funding over the previous three fiscal years. A true and correct copy of the PAR is attached as Exhibit A.

33. MARC awards are part of the NIH Ruth L. Kirschstein National Research Service Awards (NRSA) program, which has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. The PAR explains that these awards are designed to address the NIH's recognition of the "need to diversify the scientific workforce by enhancing the participation of individuals from groups identified as underrepresented" in biomedical research workforce.

34. Based on extensive data to support this definition, NIH describes the benefit of diverse teams as follows:

> 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.

35. Despite NIH's longstanding efforts to diversify the biomedical field, underrepresentation continues to be a problem. The PAR provides citations to support that fact that:

> Individuals from certain groups and backgrounds are underrepresented in the biomedical sciences research workforce as described in NIH's Interest in Diversity. The severity of the underrepresentation of these groups increases throughout the training stages. For example in 2017, students from certain racial and ethnic groups, including Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders comprised ~35 percent of the college age population, but earned only ~25 percent of bachelor's degrees and ~16 percent of Ph.D. degrees in science and engineering. 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 groups underrepresented in the biomedical research workforce, a corresponding increase in the ranks of the faculty in basic science departments at medical schools has not occurred.

36. According to NIH, diversity enhancing institutional training grants to offset the cost of appointed trainee stipends, tuition and fees, and training related expenses, including health insurance, along with provision of activities that build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members have been proven to increase persistence in STEM fields.

37. APHA Member 16 has witnessed the importance of such grants to strengthen the scientific community. Over the years, they have seen many students who were able to gain research experience due to support from NIH institutional training grants who have benefited immensely. They have seen numerous examples of students who were the first in their family to go to college or came from families with very limited financial means, who are now completing residency training in critical fields such as neurosurgery and oncology, MD/PhD degrees to

develop into physician scientists, and PhD degrees in many different fields. Many of these students might never had access to research opportunities without such programs because they would have needed to work to pay for their tuition and/or living expenses. As APHA Member 16 has witnessed, these institutional training grants provide equitable access to research so students with different levels of financial means can understand what it takes to develop the skills to become a member of the biomedical workforce.

38. I understand that applying for a MARC grant is a difficult process. I am told the final proposal was comprised of ~500 pages of information required to evaluate the plans to train undergraduate students who have the goal of pursuing a PhD or MD/PhD.

39. I understand that once a MARC application is completed, it is submitted to NIH and considered for rigorous review by a team of peer reviewers (faculty at other institutions) on the NIH study section that reviews such training and workforce development proposals. Most of these faculty member peer reviewers run similar NIH-funded programs at their own institute, so are very familiar with these programs. The review is very rigorous, with three assigned reviewers tasked to read the entire application and comb through all the data tables to assess the rigor and potential impact of the planned training.

40. APHA Member 16 was awarded the MARC grant in spring of 2023 with an Impact Score of 25. They successfully sought a non-competitive renewal in 2024 and submitted a second non-competitive renewal application by the deadline of October, 2024. They expected that they would receive another non-competitive renewal in 2025. The non-competitive renewal process is significantly less onerous than a competitive NIH application. For the non-competitive renewal, PIs assemble a report of Major Accomplishments, including a report for each supported trainee, including the degree sought, the research mentor, a brief description of the research project, courses taken, conference presentations, contributions to manuscripts,

awards, and professional development activities. The report also includes plans for the next reporting period to accomplish the goals of the application as well as an Outcomes table detailing the trajectory of all supported MARC students, including any terminal degree received, position or training following the terminal degree and subsequent fellowships.

41. APHA Member 16 completed this report in anticipation of renewing their MARC grant. They have never heard of a non-competitive renewal being denied in their nearly 30 years of experience with NIH grants.

42. On April 2, 2025, APHA Member 16 received an email from NIH terminating the MARC grant. A true and correct copy of the email, redacted to remove all identifying information, is attached hereto as Exhibit B.

43. The email states "due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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. We advise against recruiting future cohorts." No further explanation for the termination was provided.

44. The termination has significant impacts on the students being supported, the university hosting them, and APHA Member 16.

45. During the first two years of the grant, APHA Member 16's work included organizing a 1-hour class that the funded MARC scholars attended weekly to support their scholarly and professional development. They also met regularly with each funded scholar and provided detailed feedback on applications to attend summer research programs, for graduate school, for MD/PhD Programs, for post-baccalaureate research opportunities, and many other internship opportunities. APHA Member 16 organized numerous mock interviews as well as

activities beyond the classroom to build a supportive cohort, such as weekend walks at various outdoor locations. A large fraction of the cohort also attended and presented their research at the Annual Biomedical Research Conference for Minoritized Students (ABRCMS) in both Year 1 and Year 2 of the MARC program. Two of the students won awards for their outstanding presentations at these meetings each year.

46. The MARC students rely on MARC funding to pay their tuition. Without the tuition assistance provided by the MARC award, students may incur additional student loan debt because they were awarded $16,000 in tuition funds as a MARC Scholar. The MARC grant also provided an annual research stipend in the amount of $14,340 per year for junior and senior years as of June 2024. This annual stipend allowed students to accept summer research opportunities and to focus on research opportunities during the academic year rather than paid employment. APHA Member 16 is very concerned that these students, many of whom are of low socio-economic status, will now lose access to research opportunities, as they will need to seek other paid positions to pay for tuition, food, and housing.

47. The university will also be injured by the loss of this workforce and the impact that the loss of funding has on critically important research, including end stage liver disease, development of new antimicrobial drugs to combat antibiotic resistance, and skin cancer. These are just a few of the areas current MARC students have contributed to, which will now be impacted by the loss of funding for these individuals and the need for the MARC students to seek other employment.

48. The MARC termination has not only impacted APHA Member 16's salary; it has also affected their professional credentials. Obtaining and maintaining NIH funding is an important aspect of demonstrating one's success in the biomedical field. And the mentoring and training work APHA Member 16 has done, made possible by NIH funding and recognized

through several prestigious awards, is part of the value they bring as a faculty member to their university.

49. APHA Member 16 considered sharing their story publicly, but has declined to do so out of fear that disclosure of their name will lead to retaliation against their university in the form of additional terminated federal grants and the withholding of future federal funding.

50. Another similar program to MARC is the Initiative to Maximize Student Development (IMSD) program. The goal of the IMSD Program, as described in NIH PAR 21-025, is to develop a diverse pool of scientists earning a Ph.D. and who have the skills to successfully transition into careers in the biomedical research workforce. The IMSD program is limited to applications from training programs at research-intensive institutions, defined as those that receive an average of $7.5 million per year in NIH funding over the previous three fiscal years. A true and correct copy of the PAR is attached as Exhibit C.

51. Like MARC awards, IMSD awards are also part of the NIH Ruth L. Kirschsten National Research Service Awards (NRSA) program, described in paragraph 33, above, and serve the same goals and interests. Whereas MARC awards are used to support undergraduate students interested in pursuing higher degrees in bio-medical research, IMSD awards are used to support graduate students as they transition into to graduate training, with the goal of ensuring that they successfully complete their PhDs, creating a stronger biomedical workforce of individuals with advanced degrees.

52. I am aware of an APHA Member who has received multiple IMSD awards from NIH. Their most recent award was in excess of $1,020,000, for winter 2023 through winter 2028.

53. This APHA Member received an email from NIH on April 2, 2025, terminating their IMSD grant. A true and correct copy of the email, redacted to remove all identifying information, is attached hereto as Exhibit D.

54. The email states "due to changes in NIH/HHS priorities, the **Initiative for Maximizing Student Development (IMSD)** 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. We advise against recruiting future cohorts."

Harms to APHA Members

55. These experiences are not unique. In the few weeks since NIH issued this new guidance, I have also heard from numerous APHA members expressing concerns about being able to continue research in their chosen area of study based on the termination notices they have received from NIH. These include, for example, terminations of research projects to improve prevention strategies and care for HIV, to help young adults to resist tobacco marketing, and to better reach vulnerable populations. For some members, like those who study minority health or health disparities—a subject to which NIH has a whole institute devoted—the change in NIH priorities means an end to their research careers, for all intents and purposes.

56. I have also heard from APHA members that they are unable to develop new proposals to address pressing public health issues which they reasonably fear will be immediately struck down as inconsistent with NIH's new priorities. APHA members have also articulated fears that they will have to change specific words in their proposals so as not to be flagged for impermissibly promoting DEI in violation of NIH's new priorities. But given the vagueness of the NIH's guidelines—which do not define terms such as "Diversity, Equity, and Inclusion" or "DEI", "amorphous equity objectives," "Transgender issues," "gender identity," and "COVID-related research" while forbidding research "based on" these topics—they do not know how drastic their edits should be, or if any edits would satisfy NIH's scrutiny of certain projects.

57. Aside from the immediate aftershocks this has had on APHA members' ongoing work, NIH's new directives also jeopardize their future plans. There are APHA members who have spent countless hours crafting grant applications that the NIH now outright refuses to consider, and others who exist in limbo, unsure if they will ever be able to submit an application on their areas of study in the future.

58. And aside from the scientific harms imposed by NIH's misguided stance, the directives are also a discriminatory imposition on APHA members' freedoms of speech, inquiry, and association.

59. By categorically banning any study related to what it considers "diversity," "equity," "inclusion," NIH is signaling to the APHA members and the broader scientific community alike that any study that incorporates these elements – however tangentially, and in whatever form – is intrinsically disfavored and will be subject to harsher scrutiny from the federal government.

60. Further, studies that rely on public participation are jeopardized. If would-be grant recipients examine and account for the demographic differences among respondents, they run the risk of having their projects terminated under the new NIH guidelines— despite the fact that accounting for these differences is critical in order to properly fund educational initiatives and federal health care programs such as Medicare and Medicaid. Indeed, even if a study focuses on a homogenized minority population, they risk termination if that population is judged to be invoking "DEI" principles. Given the separate directive on "gender identity," this scrutiny is especially intensified if the study focuses on or even acknowledges the existence of LGBTQ people, and transgender people in particular.

61. As a direct result, APHA researchers are forced to choose whether to continue with important research that is supposedly no longer in accordance with NIH's priorities and risk

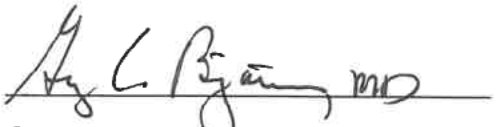
losing their funding, or to cancel any research that deals with racial, sexual, gender, or ethnic minorities in order to retain it.

62. The longer this guidance is in effect, the longer of an impact it will have on individual researchers as well. Interruptions in research can result in loss of research staff as well as unrecoverable delays in students' academic pursuits, potentially with additional financial costs incurred as a result of prolonging their studies while looking for additional support. It would be even worse for faculty members, who can lose years of valuable progress in their career if their studies are interrupted, halted, or prevented from beginning at all.

63. This is only intensified in research that relies on outside participation. Building an accurate, responsive, and representative survey class is an effort that takes both time and money, and programmatic delays in research can impact respondent's willingness to participate in present or future surveys. And in the rare instances where APHA members are participating in clinical research, programmatic delays can become literal life and death matters.

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

Executed this 25th day of April 2025.



Georges C. Benjamin, M.D.

EXHIBIT A

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

Funding Opportunity Title

Maximizing Access to Research Careers (T34)

Activity Code

T34 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t34&Search.x=0&Search.y=0&Search_Type=Activity) MARC Undergraduate NRSA Institutional Grants

Announcement Type

Reissue of PAR-19-219 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-219.html) - Maximizing Access to Research Careers (T34)

Related Notices

- **March 28, 2024** - This PAR has been reissued as PAR-24-138 (//grants.nih.gov/grants/guide/pa-files/PAR-24-138.html)
- **March 15, 2023** - Notice of Informational Webinar on the NIGMS U-RISE and MARC Programs (T34). See Notice NOT-GM-23-037 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-23-037.html)
- NOT-OD-23-012 (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
- **March 4, 2022** - Clarification of Eligibility for Institutions with Multiple Campuses in PAR-21-147. See Notice NOT-GM-23-013 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-23-013.html)
- NOT-OD-22-190 (/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
- **March 4, 2022** - Notice of Informational Webinar on the NIGMS U-RISE and MARC Programs. See Notice NOT-GM-22-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-031.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).
- **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).
- **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)
- **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)
- **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)

- **May 28, 2021** - Notice of Change to the Instructions for Appendices in PAR-21-147. See Notice NOT-GM-21-048 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-048.html).
- **March 19, 2021** - Notice of Informational Webinar on the NIGMS U-RISE and MARC Programs. See Notice NOT-GM-21-034 (/grants/guide/notice-files/NOT-GM-21-034.html).

Funding Opportunity Announcement (FOA) Number

PAR-21-147

Companion Funding Opportunity

Not Applicable

Number of Applications

Only one application per institution is allowed, as defined in Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.859

Funding Opportunity Purpose

The goal of the Maximizing Access to Research Careers (MARC) program is to develop a diverse pool of undergraduates who complete their baccalaureate degree, and transition into and complete biomedical, research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.). This funding opportunity announcement (FOA) provides support to eligible, domestic institutions to develop and implement effective, evidence-informed approaches to biomedical training and mentoring that will keep pace with the rapid evolution of the research enterprise. NIGMS expects that the proposed research training programs will incorporate didactic, research, mentoring, and career development elements to prepare trainees for the completion of research-focused higher degree programs in biomedical fields. This program is limited to applications from training programs at baccalaureate degree-granting research-intensive institutions (i.e., those with an average of NIH Research Project Grant funding greater than or equal to $7.5 million total costs over the last 3 fiscal years).

This Funding Opportunity Announcement (FOA) does not allow appointed trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Key Dates

Posted Date

February 23, 2021

Open Date (Earliest Submission Date)

April 26, 2021

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

May 26, 2021; May 26, 2022; May 26, 2023

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

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

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

October - November 2021, October - November 2022, October - November 2023

Advisory Council Review

January 2022, January 2023, January 2024

Earliest Start Date

June 2022, June 2023, June 2024

Expiration Date

May 27, 2023

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Training (T) Instructions in the SF424 (R&R) Application Guide (//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/)). 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 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) 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. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) (//grants.nih.gov/grants/guide/url_redirect.php?id=41125) website.

Purpose and Background Information

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Each program should provide high-quality research training, mentored research experiences, and additional training opportunities that equip trainees with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design and interpretation of data) and professional (e.g., management, leadership, communication, and teamwork) skills required for careers in the biomedical research workforce.

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) in the biomedical, clinical, behavioral and social sciences (collectively termed "biomedical") research workforce. 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.

NIGMS 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. NIGMS 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. Accordingly, NIGMS developed separate institutional eligibility tracks for review and funding of its undergraduate and graduate diversity enhancing programs based on NIH research project grant (RPG) (https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG) funding levels. The two tracks include research-intensive, i.e., those with an average of NIH RPG funding greater than or equal to $7.5 million total costs per year over the past 3 fiscal years, and research-active, i.e., those with an average of RPG funding less than $7.5 million total costs per year over the past 3 fiscal years (RPG data are available through NIH RePORTER (https://report.nih.gov/award/index.cfm)). To prevent the duplication of diversity enhancing NIGMS programs, each institution will be eligible for one diversity enhancing undergraduate program (either Maximizing Access to Research Careers, MARC (https://www.nigms.nih.gov/training/marc/pages/ustarawards.aspx), or Undergraduate Research Training Initiative for Student Enhancement, U-RISE (https://www.nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx)) regardless of the activity code (R25 or T34), and one diversity enhancing graduate program (either the Initiative to Maximize Student Development, IMSD (https://www.nigms.nih.gov/training/IMSD/pages/default.aspx), or Graduate Research Training Initiative for Student Enhancement, G-RISE (https://www.nigms.nih.gov/training/RISE/Pages/G-RISE-T32.aspx)) regardless of the activity code (R25 or T32). Institutions with MARC, U-RISE, IMSD or G-RISE are eligible to participate in the Bridges to the Baccalaureate and/or Bridges to the Doctorate programs provided other eligibility requirements are met.

Need for the Program

In spite of recent advances, individuals from certain groups and backgrounds are underrepresented in the biomedical sciences research workforce as described in NIH's Interest in Diversity (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 in 2017, students from certain racial and ethnic groups, including Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders comprised ~35 percent of the college age population, but earned only ~25 percent of bachelor's degrees and ~16 percent of Ph.D. degrees in science and engineering (National Center for Science and Engineering Statistics (https://ncses.nsf.gov/pubs/nsb20197/demographic-attributes-of-s-e-degree-recipients#s-e-degrees-by-race-and-ethnicity)). 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 groups underrepresented in the biomedical research workforce, a corresponding increase in the ranks of the faculty in basic science departments at medical schools has not occurred (Gibbs, et al., 2016, eLife 2016, 5:e21393; Valantine, Lund & Gammie, CBE-Life Sciences Education, 2016, 15:fe4).

Several reports (see for example, ACD Working Group on Diversity in the Biomedical Workforce, 2012 (https://acd.od.nih.gov/documents/reports/DiversityBiomedicalResearchWorkforceReport.pdf); PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf); From College to Careers: Fostering Inclusion of Persons with Disabilities in STEM, 2014 (http://www.sciencemag.org/booklets/college-careers); and Increasing College Opportunity for Low Income Students, 2014

(https://obamawhitehouse.archives.gov/sites/default/files/docs/increasing_college_opportunity_for_low-income_students_report.pdf)) recommend supporting programs that strive to recruit, train, and mentor students from underrepresented groups who have an interest in science, technology, engineering and math (STEM) as a means to effectively build a diverse and competitive scientific workforce.

Programmatic Approach

This FOA is intended to enable the community to develop and implement evidence-informed approaches to biomedical research training and mentoring to enhance diversity in the biomedical research workforce. The President's Council of Advisors on Science and Technology (PCAST) report provided evidence that financial concerns and a deficit of peers from similar backgrounds can erode self-confidence and the will to remain in STEM majors (PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf)). NIGMS diversity enhancing institutional training grants offset the cost of appointed trainee stipends, tuition and fees, and training related expenses, including health insurance, in accordance with the approved NIH support levels. Additionally, funded programs are expected to provide activities that will build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members. Programmatic activities include, but are not limited to, providing authentic research experiences, academic enhancements, skills development, and additional mentoring - activities proven to increase persistence in STEM fields (cited in PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf) and Graduate STEM Education for the 21st Century, 2018 (https://www.nap.edu/catalog/25038/graduate-stem-education-for-the-21st-century)). Each program should provide high-quality training that equips individuals with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design, and interpretation of data, conducting research in the safest manner possible) and professional (e.g., management, leadership, communication, and teamwork) skills required for careers in the biomedical research workforce. Funded programs are expected to promote inclusive research environments (i.e., institutional and departmental environments where trainees from all backgrounds feel integrated into and supported by the biomedical research community).

Program Objective

The **Overarching Objective** of the Maximizing Access to Research Careers program is to develop a diverse pool of undergraduates who complete their baccalaureate degree and transition into and complete biomedical, research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.). The long-term goal is to develop a diverse pool of well-trained biomedical scientists, who have the following technical, operational, and professional skills:

- A broad understanding across biomedical disciplines and the skills to independently acquire the knowledge needed to advance their chosen fields;
- Expertise in a biomedical scientific discipline and the skills to think critically and independently, and to identify important biomedical research questions and approaches that push forward the boundaries of their areas of study;
- A strong foundation in scientific reasoning, rigorous research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching and conducting biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting, and presenting rigorous and reproducible biomedical research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds, and to promote inclusive and supportive scientific research environments;
- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills and experiences required to identify and transition into careers in the biomedical research workforce (i.e., the breadth of careers that sustain biomedical research in areas that are relevant to the NIH mission).

Diversity at all levels from the kinds of science to the regions in which it is conducted to the backgrounds of the people conducting it contributes to excellence in research training environments and strengthens the research enterprise. This FOA is intended to support outstanding research training programs that will enhance diversity at all levels. As part of a larger initiative to enhance diversity, the MARC program will support trainees who are earning a baccalaureate degree at research-intensive institutions and who intend to complete a biomedical research higher degree program (e.g., Ph.D., or M.D./Ph.D.).

Program Considerations

NIGMS intends to fund applications that propose feasible academic and research focused training programs that will enhance diversity in the biomedical workforce. Applicants are expected to identify training objectives (i.e., specific, measurable, and obtainable outcomes the program intends to achieve) and to develop plans to implement evidence-informed training and mentoring activities that are grounded in the literature and from evaluations of existing relevant programs. Program objectives must align with the overarching goal of the MARC diversity enhancing program. Funded programs are expected to provide evidence of accomplishing the training objectives in progress reports and when applying for renewal, to make training and career outcomes publicly available, and are strongly encouraged to disseminate successful training practices to the broader community.

Institutional commitment and support for the proposed training program are important elements of the application. The MARC program may complement and synergize with other ongoing federally-supported predoctoral research training programs at the applicant institution (e.g., in the development of skills needed for careers in the biomedical research workforce); however, the MARC program goals and activities to achieve those goals must be distinct from related programs currently receiving federal support at the same institution. In cases where an institution has multiple NIGMS training grants, it is expected that these programs will seek to create administrative and training efficiencies to reduce costs and improve trainee services and outcomes. The training grant should be well integrated within one or more department(s)/program(s) and should exert a strong, positive influence on the development and execution of the outreach and recruitment of potential trainees, curriculum, training opportunities, and mentoring. Training grant funds may not be used solely as a vehicle to provide stipends for trainees to conduct research.

Training grants are usually awarded for five years. The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels. Trainees are typically provided full-time support for two to three years of undergraduate studies. Use of training grant support in the final three years of undergraduate research training is strongly encouraged to allow for the participation in research, training, mentoring, professional development, and cohort-building activities that will prepare the trainees to successfully transition into a biomedical, research-focused higher degree program (e.g., Ph.D. or M.D./Ph.D.).

This FOA does not allow appointed trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

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
Renewal of grants funded through PAR-19-219 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-219.html)
Resubmission

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

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

Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

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

Funds Available and Anticipated Number of Awards

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

Award Budget

Application budgets should reflect the actual needs of the proposed project.

Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

NIGMS recognizes the need of trainees to attend scientific meetings and/or training events, and to build professional networks. NIGMS will provide up to $1,000 per trainee per year for scientific meetings or research training experiences that will enhance scientific development, build science identity, create a sense of belonging in the scientific community, and build professional networks. Plans for trainee travel should be well justified. For MARC-supported institutions outside the continental United States, $1,250 for travel per trainee per year will be provided.

Trainees are required to spend at least one summer in a research training experience. Preferred sites are research-intensive graduate institutions such as those with NIH T32 training programs. Funds for the summer research experience will be provided as follows: $3,000 per MARC trainee, to be used in accordance with the institutional policies as a per diem for a period of up to ten weeks; and an additional $500 for travel to and from the host research training.

NIGMS provides funds for the summer research training experience for up to 50% of the awarded number of MARC trainees at the time a competing award is made. For additional budget guidance on the MARC summer research requirement, see T34 Summer Research Experience Policy (https://www.nigms.nih.gov/training/T34/Pages/sre.aspx). Additional funds will not be provided for students continuing the research training at the host institution.

Plans for trainee travel should be well justified. Foreign travel is not allowed.

Training Related Expenses

NIGMS will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, equipment, research supplies, and faculty/staff travel directly related to the research training program.

The total amount of Training Related Expenses (TRE) that may be requested is limited to a maximum of $8,000/trainee/year. The maximum cap for the TRE portion of a proposed MARC budget is $250,000/year.

Allowable costs include those associated with the following:

- Skills development training activities (e.g., focusing on quantitative and computational skills, problem-solving, critical thinking, scientific writing, effective communication, and project management);
- Seminar speakers, who will serve as role models to the trainees;

- Training or mentoring interventions designed to increase persistence in research careers (e.g., those designed to increase science identity, self-efficacy and a sense of belonging in the scientific community);
- Salary support for the PD/PI or a combination of multiple PD(s)/PI(s)/co-Investigators. Typically, salary support does not exceed 1.8 person months (i.e., 15% effort on a 12-month basis in total) depending on the size and scope of the program;
- Salary support for administrative personnel; typically, the total combined salary support for program administrator/program coordinator and/or program assistant/clerical support does not exceed 3.0 person months (i.e., 25% effort on a 12-month basis) depending on the size and scope of the program.
- Limited program evaluation costs (typically up to $3,000 for the 5-year training grant period) and other program-related expenses may be included within the budget for training-related expenses.

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the *NIH Grants Policy Statement* (//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)

Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

For diversity enhancing programs, NIGMS recognizes separate institutional eligibility tracks: research-intensive, i.e., those with an average of NIH research project grant (RPG) (https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG) funding greater than or equal to $7.5 million total costs per year over the past 3 fiscal years, and research-active, i.e., those with an average of RPG funding less than $7.5 million total costs per year over the past 3 fiscal years (RPG data are available through NIH

RePORTER (https://report.nih.gov/award/index.cfm)). For example, FY 2018, FY 2019 and FY 2020 for applications submitted in May 2021.

Institutional eligibility for this FOA is limited to baccalaureate degree-granting research-intensive institutions as defined above. Research-active institutions are not eligible to apply for or receive MARC grants. To prevent the duplication of NIGMS diversity enhancing programs, each institution is eligible for one undergraduate program (either MARC (https://www.nigms.nih.gov/training/marc/pages/ustarawards.aspx) or U-RISE (https://www.nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx)) regardless of the activity code (R25 or T34), and one graduate program (either IMSD (https://www.nigms.nih.gov/training/IMSD/pages/default.aspx) or G-RISE (https://www.nigms.nih.gov/training/RISE/Pages/G-RISE-T32.aspx)) regardless of the activity code (R25 or T32). Institutions with NIGMS MARC, U-RISE, IMSD, or G-RISE funding are eligible for the Bridges to the Baccalaureate and/or Bridges to the Doctorate programs provided the other eligibility criteria are met. Applicants are encouraged to consult NIGMS staff to discuss eligibility prior to submission.

An institution funded through the U-RISE or MARC program that changes category due to changes in research project grant funding during the grant cycle should apply to the appropriate program based on their eligibility at the time of renewal. Programs that change category will report on the programs outcomes of the prior funding period(s), up to 15 years, using the appropriate tables.

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program should be detailed in the *Institutional Support Letter* in the **Letters of Support** attachment. Additionally, a signed letter is required from the Provost or similar official with institution-wide responsibility verifying the eligibility of the applicant institution at the time of application submission according to the eligibility criteria indicated above. See the application instructions for the required Letters of Support instructions in Section IV.

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.

Required Registrations

Applicant Organizations

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

- Dun and Bradstreet Universal Numbering System (DUNS) (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/) 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) 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) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. 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 (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) 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 individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

As described in the instructions for the Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) in Section IV.2 below, NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance training. At least one of the training PD(s)/PI(s) should be an established investigator in the biomedical sciences and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. Additional PDs/PIs, including individuals with experience in the science of education, relevant social science disciplines, program evaluation, mentoring, and university administration may be included to achieve the training goals. Any of the PDs/PIs may serve as the contact PD/PI. The contact PD/PI is expected to have a full-time appointment at the applicant institution unless extremely well-justified. If the full-time status of the contact PD/PI changes after the award, the institution must obtain prior program approval to appoint a new PD/PI or request a deviation from the full-time rule. The PD(s)/PI(s) will be responsible for the selection and appointment of trainees to the approved research training program, and for the overall direction, management, administration, and evaluation of the program. The PD(s)/PI(s) will be expected to monitor and assess the program and submit all documents and reports as required. The PD(s)/PI(s) have responsibility for the day-to-day administration of the program and are responsible for appointing members of the Advisory Committee (when applicable) and using their recommendations to determine the appropriate allotment of funds.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

NIGMS will accept only one application per institution, typically defined by a unique identifier, such as DUNS (https://fedgov.dnb.com/webform/) and an NIH Institution Profile File (IPF) (https://public.era.nih.gov/commons/public/quickqueries/ipfNumberByOrgName.era) number.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the 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)).

Preceptors/Mentors (Participating Faculty)

The selected faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support. When building a training team, programs should include faculty who are committed to training, mentoring, and providing supportive and inclusive research environments. Programs are encouraged to build a diverse team of preceptors/mentors that includes, for example, faculty from underrepresented groups (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) and faculty at different career stages (i.e., early-career as well as established faculty).

Trainees

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Trainees should be research-oriented individuals enrolled in a major leading to a baccalaureate degree in a STEM discipline that will prepare the trainee for a biomedical, research-focused higher degree program (e.g., Ph.D. or M.D./Ph.D.). All trainees are required to pursue their research training full time as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments for 2-3 years, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the NIH awarding unit.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace 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 Training (T) Instructions in the SF424 (R&R) Application Guide (//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.

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=61134) must be followed.

Instructions for Application Submission

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

SF424(R&R) Cover

Follow all instructions provided in the SF424 (R&R) Application Guide.

SF424(R&R) Project/Performance Site Locations

Follow all instructions provided in the SF424 (R&R) Application.

SF424 (R&R) Other Project Information

Follow all instructions provided in the SF424 (R&R) Application, with the following modifications:

Are Human Subjects Involved: Check "No" unless the training program itself requires the trainees to take a workshop or course that will involve human subjects.

Are Vertebrate Animals Used: Check "No" unless the training program itself requires the trainees to take a workshop or course that will involve vertebrate animals.

Project Summary/Abstract: Provide an overview of the entire program. Include the mission, objectives, rationale and design of the research training program. Highlight key activities in the training plan that promote skills development and the successful transition into and completion of biomedical, research-focused higher degree programs. Indicate the intended trainee outcomes.

Other Attachments.

Advisory Committee (1-page maximum). An Advisory Committee is not a required component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will assess the overall effectiveness of the program. To avoid conflicts in the review process, only pre-existing Advisory Committee members should be named in the application. Potential Advisory Committee members should not be identified or contacted prior to receiving an award. Please name the file Advisory_Committee.pdf .

Recruitment Plan to Enhance Diversity (3-page maximum). The applicant must provide a *Recruitment Plan to Enhance Diversity*. The application should include outreach strategies and activities designed to recruit potential training program candidates who are from diverse backgrounds, including students from underrepresented racial and ethnic groups, individuals with disabilities, and students from disadvantaged backgrounds (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)). Applicants are encouraged to consult the NIGMS webpage for strategies to enhance diversity in training programs (https://www.nigms.nih.gov/training/diversity/pages/approaches.aspx) when designing their plans. Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee recruitment efforts of the institution. Centralized institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups. Participating faculty are expected to be actively involved in recruitment efforts. Please name the file Recruitment_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Trainee Retention Plan (3-page maximum). The applicant must provide a *Trainee Retention Plan*. The *Trainee Retention Plan* must describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within a program (i.e., retention). Applicants are encouraged to consult the NIH's extramural diversity website to identify promising retention practices (https://extramural-diversity.nih.gov/building-participation/recruitment-retention) and to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee retention efforts of the institution(s). Centralized institutional efforts alone will not satisfy the requirement to implement robust and successful mechanisms to retain all trainees (e.g., participating faculty are expected to be actively involved in trainee retention efforts). Please name the file Retention_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Outcomes Data Collection and Storage Plan (2-page maximum). The applicant must provide an *Outcomes Data Collection and Storage Plan* to track the outcomes for all supported trainees for a minimum of 15 years beyond the trainee's participation in the program. Programs are encouraged to make the aggregate outcome data available on the institution's website. If the applicant intends to make the data available, describe how the aggregate data will be de-identified before public posting. The applicant must include a strategy to ensure the secure storage and preservation of program data and outcomes. Describe how the data will be centralized, safeguarded, and retrievable during leadership changes. Please name the file Data_Collection_Storage_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Dissemination Plan (1-page maximum). The application must provide a specific *Dissemination Plan* to publish or present nationally any findings or materials developed under the auspices of the program. Examples of dissemination may include data or materials from successful training or mentoring interventions via web postings, presentations at scientific meetings, and/or workshops. Please name the file Dissemination_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

The filename provided for each Other Attachment will be the name used for the bookmark in the electronic application in eRA Commons.

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

Follow all instructions provided in the SF424 (R&R) Application with the following modifications.

Biographical sketch. The personal statement should describe a commitment to scientific rigor, research training, mentoring, as well as to promoting inclusive, safe, and supportive scientific environments.

PHS 398 Cover Page Supplement

Follow all instructions provided in the SF424 (R&R) Application.

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the SF424 (R&R) Application Guide.

Training Budget

Follow all instructions provided in the SF424 (R&R) Application Guide.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program

- Faculty, Trainees, and Training Record
- Other Training Program Sections
- Appendix - Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the FOA specifically instructs applicants to do so.

Follow all instructions provided in the SF424 (R&R) Application Guide with the following modifications:

Attention must be given to the required Training Data Tables (//grants.nih.gov/grants/guide/url_redirect.php?id=61169) for undergraduate programs (Tables 2, 3, 4, 5C, and 8D). In the Program Plan, applicants should also summarize key data from the tables that highlight the characteristics of the applicant pool, program faculty, institutional support, student outcomes, and other factors that contribute to the overall training environment of the program.

Training Program

Follow all training instructions provided in the SF424 (R&R) application guide except where instructed to do otherwise below.

Program Plan

The "Program Plan" attachment is required and must adhere to the NIH Table of Page Limits (https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#train), as well as the organization and instructions provided below.

Do not follow the organization and instructions provided in the SF424 (R&R) application guide for the Program Plan attachment; instead applicants must use the instructions below. Start each section with the appropriate heading.

Rationale, Mission, and Objectives

The application should describe how the MARC program will develop a diverse pool of well-trained scientists who have the technical, operational, and professional skills required to conduct research in a safe, ethically responsible and rigorous manner, and to enter the next phase of the career pathway as delineated in the Program Objective. The application should describe how the program will enhance the training environment and not simply provide financial support to the trainees. Specifically, applicants should describe the following:

- The justification for the proposed diversity enhancing research training program. The application should describe the current institutional efforts to promote diversity and to create inclusive research training environments and how the MARC program will enhance, but not duplicate these efforts. The rationale for the program should expand upon the "Training Outcome" data requested below that provides institutional baseline data on previous student outcomes comparing success rates for groups that are well-represented and underrepresented in the biomedical research workforce (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html));
- Current research training environment and student demographics. The application should describe the research training environment including, but not limited to, the relevant background, an overview of the current research training activities of the participating department(s) or unit(s), and areas for improvement in the current research training practices. The application must demonstrate the presence of a sufficient number of potential trainees from diverse backgrounds, for example, those from underrepresented groups (applicants are encouraged to use the Suggested Table Formats A.1, A.2, and A.3 (https://www.nigms.nih.gov/training/MARC/pages/MARCtables.aspx) found on the NIGMS webpage to present the data; any Suggested, or other, Tables must be included in the Training Program section and will count towards the 25-page limit), and of faculty mentors/participating faculty in the appropriate biomedical fields (Tables 2 and 4 (https://grants.nih.gov/grants/forms/data-tables.htm)). The application should also demonstrate the existence of sufficient resources to achieve the training objectives (Table 3 (https://grants.nih.gov/grants/forms/data-tables.htm)); and
- The training mission (i.e., broad statement of purpose of the program), and objectives (i.e., specific measurable outcomes the program intends to achieve). The baseline data, the trainee pool, and the institutional context should inform the objectives and the design of the proposed training program. The program-specific mission and objectives should align with the Overarching Objective of this funding announcement. Objectives should include, but not be limited to, baccalaureate degree completion rates, appropriate time-to-degree, and the rate of transitioning into and completion of research-focused higher degree programs.

Curriculum and Overall Training Plan

The application should describe the following:

- How the courses, structured activities, and research experiences will accomplish the specific training mission and objectives. Explain how these training activities are designed to develop the technical, operational, and professional skills of trainees. The application must include the "Required Training Activities" appendix to provide material to assess the required training elements and may use the "Elective Activities" appendix to provide up to four additional activities;
- Proposed changes to current research training practices to keep pace with the rapidly evolving biomedical research enterprise (e.g., curricular reforms, incorporation of additional quantitative and computational skills development, etc.);
- The mechanisms to ensure that trainees participate in authentic research experiences throughout the training period. Applications that propose classroom-centered research training activities should describe the learning objectives, course attributes, participating faculty, training frequency, and expected trainee outcomes. If trainee research experiences are proposed to include other institutions, describe how the PD(s)/PI(s) will interact with the research mentors to promote trainee success;
- The plans to ensure that MARC trainees complete at least one summer research training experience at a research-intensive institution (either at an external site or at the home institution). Preferable sites are graduate institutions that offer NIH T32 predoctoral programs. To assist with this interaction, NIGMS maintains a list of NIGMS-funded T32 programs (http://www.nigms.nih.gov/training/pages/InstGrantLists.aspx). Other NIH Institutes and Centers also support the T32 predoctoral training program in various research areas. For a query search to identify such programs, visit the NIH Research Portfolio Online Reporting Tools (RePORT (http://report.nih.gov/index.aspx)) website;
- The mechanism for ensuring that the trainees are learning the highest standards of practice in biomedical research (e.g., record keeping and safety);
- How the Participating Faculty will teach laboratory safety throughout the didactic and mentored portions of the program;
- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, inclusion, and professional development;
- The activities that will build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members;
- Representative examples of training programs for individual trainees. Examples may include degree requirements, didactic courses, laboratory experiences, and other training activities, such as seminars, journal clubs, etc. Describe how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated. Discuss the anticipated time required to complete the training program up to degree attainment;
- The trainees academic and research background needed to pursue the proposed training and plans to accommodate differences in preparation among trainees.
- How the training activities will be available to other trainees in the program(s), department(s) or institution(s) from which the supported trainees are drawn;
- For multi-disciplinary and/or multi-departmental programs, indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated, and how they will relate to an individual trainee's experience; and
- The ways, when applicable, that the training plan is distinct from, but will share resources and synergize with, other NIGMS-funded predoctoral training programs at the same institution (i.e., NIGMS predoctoral training programs listed in Table 3 (https://grants.nih.gov/grants/forms/data-tables.htm)). See the "Program Considerations" section above.

Career Development

The application should describe the following:

- How the pool of potential applicants and trainees will be provided with information about the career outcomes of graduates of the program (e.g., on publicly accessible websites) and about the overall biomedical research workforce employment landscape;
- How trainees will be provided with support as well as adequate, appropriate, and timely information regarding the steps required to transition into the next phase of the biomedical research workforce pathway (e.g., when applying to research-focused graduate programs, or funding opportunities);
- How the trainees will be sponsored or mentored by individuals who will enhance their career opportunities (e.g., contacts at national meetings and institutions with NIH-funded T32 training programs, as well as members of scientific societies, and the research community);

Program Oversight, Participating Faculty Selection, and Mentor Training

The application should include the planned strategy and administrative structure to oversee and monitor the program, and to ensure appropriate and timely trainee progress for the duration of the trainees' undergraduate careers (the application may

include the "Evaluation and Assessment Instruments" Appendix to provide blank rubrics or forms). The application should describe how the participating faculty are trained to ensure the use of evidence-informed teaching, training and mentoring practices that promote the development of trainees from all backgrounds, e.g., trainees from underrepresented backgrounds in the biomedical sciences (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)). Applicants should describe the following:

- How the program will ensure that participating faculty employ the highest standards of scientific rigor and impart those standards to their trainees;
- How the program will ensure that participating faculty reinforce and augment the curricular material on responsible conduct of research, and methods for enhancing reproducibility;
- The mechanism for matching trainees with the appropriate participating faculty mentors;
- How the program will ensure that participating faculty engage in activities that promote trainee career development (including but not limited to the utilization of Individual Development Plans) and fulfill the need of the trainees to obtain their degrees in a timely fashion with the skills, credentials, and experiences to transition into the next phase of the biomedical research career pathway that are consistent with the trainees interests and values;
- A mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty displaying unacceptable mentorship qualities from the training program (applicants may use the Appendix labeled Conflict Resolution Protocols to provide details of the plan); and
- If a program coordinator or administrator position is planned to enhance oversight, a description of the person's administrative capabilities that are essential to coordinate the program must be included in the application.

Institutional and Departmental Commitment to the Program

A letter providing assurances of the institutional commitment to the program must be included in the *Institutional Support Letter* in the **"Letters of Support"** section of the application. In addition, applicants may use this section of the Training Program to expand upon the **Facilities & Other Resources** section and the **Letters of Suppor**t section, as necessary, to provide additional information regarding the institutional and departmental commitment to the program. Do not repeat information contained elsewhere in the application.

This section or the *Institutional Support Letter* should address how research training at the undergraduate level is supported. Additional examples of institutional commitment specific to undergraduate biomedical research training may include, but are not limited to:

- Support of an Office of Undergraduate Research;
- Stipend and tuition remission for research-oriented undergraduates;
- Undergraduate biomedical research counting towards course credit hours and/or degree requirements;
- Funds and protected time for faculty to develop course-based undergraduate research experiences that will fulfill degree requirements;
- Funds to sustain research-oriented courses;
- Faculty teaching models that support integrated/interdisciplinary STEM curricula and courses;
- Support of research training administrators and coordinators;
- Supervised student access to research facilities during non-standard work hours; and
- Personnel dedicated to undergraduate student success and oversight (e.g., tutoring and academic support services, infrastructure to identify students in need).

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) will promote the success of the trainees and training program. NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance training as described in the Eligible Individuals section. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The expertise, as well as the administrative and training experience, to provide strong leadership, direction, management, and administration of the proposed research training program;
- The time to commit sufficient effort to ensure the program's success given other professional obligations (the application should indicate the PD(s)/PI(s) s percent effort in the proposed program);
- At least one member of the team who has the scientific expertise in the biomedical sciences and who has a record of using rigorous and transparent methods in experimental design, data collection, analysis, and reporting;

- A demonstrated commitment to training the next generation of the biomedical research workforce, leading recruitment efforts to enhance diversity, and fostering inclusive research environments. As with all participating faculty, the PD(s)/PI(s) should have received training on how to effectively mentor trainees from all backgrounds, e.g., trainees from groups underrepresented in the biomedical sciences (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)); and
- A clearly delineated administrative structure and leadership succession plan for critical positions (e.g., PD(s)/PI(s)).

Preceptors/Mentors (Participating Faculty)

The application should describe how the participating faculty will promote the success of the trainees and training program, as well as conducting responsible and rigorous research. Describe how the program has or will assemble a diverse team of participating faculty (e.g., individuals from underrepresented backgrounds (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-053.html)), women, and faculty at different career stages) to provide potential role models within the training program and to enhance the excellence of the training environment. The application should summarize and expand on the material presented in the Training Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and biosketches and address how the participating faculty:

- Have sufficient time to commit to training given their other professional obligations;
- Receive training in effective, evidence-informed teaching and mentoring practices;
- Promote the use of highest standards of practice to ensure the safety of all individuals in the research environment;
- Cooperate, interact, and collaborate (which can include joint sponsorship of trainee research);
- Promote the development of trainee skills in approaches to rigorous experimental design, methods of data collection, data analysis and interpretation, and reporting;
- Provide opportunities for trainees to initiate, conduct, interpret, and present rigorous, reproducible and responsible biomedical research with increasing self-direction;
- Demonstrate a commitment to effective mentoring, and to promoting inclusive, safe and supportive scientific and training environments; and
- Are evaluated as teachers and mentors.

Trainee Positions, Appointment Process, Retention and Support

Through the narrative and summaries of the information presented in the required Training Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and the required attachments the following areas relevant to trainees should be addressed.

- Provide a strong justification for the number of requested trainee positions in the context of the training grant eligible pool described in the rationale section of the application and other training programs at the institution. Potential trainees should be research-oriented individuals enrolled in a major leading to a baccalaureate degree in a STEM discipline that will prepare the individual for a biomedical, research-focused higher degree program (e.g., Ph.D. or M.D./Ph.D.). *For Renewal Applications* - Describe the characteristics of the previously awarded trainees as part of the justification for the requested positions.;
- Explain the proposed training grant support structure, i.e., how many individuals (e.g., 4 per year), at what stage (e.g., third- and fourth-year students), and for how long (e.g., for 2 years); and
- Describe the review process to identify research-oriented candidates for the program. Programs are encouraged to develop a process that considers metrics beyond grade point average, and standardized test scores and that will identify promising candidates who are committed to contributing to the biomedical research enterprise and who, with training and support, will be competitive for research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.).
- Applicants may use this section to expand upon the Trainee Retention Plan (provided in the "Other Attachments") and to provide evidence of the program's commitment to ensuring the well-being and success of all trainees throughout their training.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for training grant eligible students for the proposed program). The application should provide information below about recent outcomes through narrative descriptions and a summary of the data presented in the required training tables (https://grants.nih.gov/grants/forms/data-tables.htm). Although the training tables for new applications only allow for five years of recent outcomes, the application may describe up to 15 years of outcomes in the narrative. Applicants are encouraged to provide outcome data using the Suggested Table Formats B.1, B.2, or B.3

(https://www.nigms.nih.gov/training/MARC/pages/MARCtables.aspx) found on the NIGMS webpage. The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications, or other measures of scientific accomplishment appropriate to the field such as presentations at national meetings and receiving fellowships);
- The rate of baccalaureate degree attainment and time-to-degree for recent graduates. The application must include outcome data regarding the number of former individuals in the program who graduated with a baccalaureate degree in a STEM field (obtained goal), remained in the program (still in training), or did not obtain a baccalaureate degree (attrition). The application should include institutional comparator groups (e.g., students with similar demographics and aptitude metrics who were not in the program) and the graduation rates for all students in the STEM fields represented; and
- The success of former students transitioning to the next phase in the biomedical research workforce pathway (e.g., matriculation to a research-focused higher degree program). Applicants must complete Training Table 8D (https://grants.nih.gov/grants/forms/data-tables.htm), and are encouraged to use the Suggested Table Formats B.1, B.2, or B.3 (https://www.nigms.nih.gov/training/MARC/pages/MARCtables.aspx). Any Suggested, or other, Tables must be included in the Training Program section and will count towards the 25-page limit.

Program Evaluation and Dissemination

NIGMS funded training programs must conduct ongoing evaluations to monitor the success of the training and mentoring activities. The application should describe:

- The evaluation or assessment process to determine whether the overall program is effective in meeting its training mission and objectives, and whether the scientific research climate is inclusive, safe, and supportive of trainee development (the application may include the "Evaluation and Assessment Instruments" Appendix to provide blank survey instruments, rubrics, or forms);
- Plans for being responsive to outcomes analyses, critiques, surveys and evaluations;
- Past activities to track and post the career outcomes of trainees (applicants should expand upon, but not duplicate the information in the Outcomes Data Collection and Storage Plan); and
- Past activities designed to share the outcomes of the training or mentoring interventions with the broader community (applicants should expand upon, but not duplicate the information in the Dissemination Plan).

Plan for Instruction in the Responsible Conduct of Research

Applicants are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in the SF424 (R&R) Application Guide, along with the following additional instructions:

Describe how the Responsible Conduct of Research (RCR) components are well integrated into the overall curriculum, i.e., how they are taught at multiple stages of trainee development and in a variety of formats and contexts. Explain how the teaching of RCR synergizes with elements of the curriculum designed to enhance trainees abilities to conduct rigorous and reproducible research. Describe how all participating faculty will reiterate and augment key elements of responsible conduct when trainees are performing mentored research in their laboratories.

Plan for Instruction in Methods for Enhancing Reproducibility

Applicants are required to provide a Plan for Instruction in Methods for Enhancing Reproducibility

as provided in the SF424 (R&R) Application Guide.

Applicants are encouraged to consult the NIGMS clearinghouse for training modules to enhance data reproducibility (https://www.nigms.nih.gov/training/pages/clearinghouse-for-training-modules-to-enhance-data-reproducibility.aspx) and other resources when developing the plans.

Progress Report (only for Renewal applications)

For applications describing programs that were previously funded under PAR-19-219 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-219.html) follow the instructions provided in the SF424 (R&R) Application Guide with the following exceptions:

For the "Program Overview" section, follow the page limit indicated in the SF424 (R&R) application guide, but follow the instructions below instead:

- Indicate the period covered since the last competitive review.
- Include information to demonstrate that the program successfully trained a diverse pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce.
- Describe successes and challenges with regards to implementing the programmatic elements described in the previous application, including but not limited to the following areas:
    - Incorporating evidence-informed training and mentoring practices into the program.
    - Teaching of rigor and transparency, and the responsible and safe conduct of research throughout the training experience.
    - The challenges and successes for enhancing diversity and inclusion.
    - Overseeing all aspects of the program (e.g., of the mentor/mentee matches, the participating faculty, and trainee progress).
    - Preparing trainees for a broad range of careers in the biomedical research workforce (including but not limited to the use of Individual Development Plans, IDPs).
- Provide justifications for failing to implement previously proposed programmatic elements.
- Provide evidence that the specific and measurable objectives described in the previous application were achieved and if not, provide a justification for failing to achieve the objectives.
- Describe how the funds provided under "Training Related Expenses" were used to benefit the program.
- Provide the methods and results of the evaluations of the program activities. Indicate whether the training activities were effective in contributing to the program objectives.
- Provide evidence that the scientific research climate is inclusive, safe, and supportive of trainee development.
- Expand upon the "Training Outcomes" to highlight successes and areas for improvement.
- Describe how the program responded to outcomes analyses, critiques, surveys and evaluations. Describe the barriers to success and indicate changes to the program designed to address these barriers.
- Describe how the program makes training and career outcomes publicly available.
- Indicate whether the PD(s)/PI(s) disseminated nationally any findings or materials developed under the auspices of the program to the broader training community.
- Indicate the broader impact of the program (e.g., on the curriculum, training environment, or institutional practices).
- Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Participating faculty should provide a personal statement that describes the appropriateness of their research background for the proposed training program, and their commitment to the following:

- Training, mentoring, and promoting inclusive, safe and supportive research environments;
- Maintaining a record of, and providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results;
- Promoting the use of highest standards of practice to ensure the safety of all individuals in the research environment;
- Supporting trainees participating in activities required to identify and transition into careers in the biomedical research workforce that are consistent with the trainees skills, interests, and values; and
- Fulfilling the need of the trainees to complete their degrees in a timely fashion with the skills, credentials, and experiences to transition into research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.).

Letters of Support

Institutional Support Letter (10-page maximum). The application must include a signed letter on institutional letterhead from a President, Provost, Dean, or similar key institutional leader that describes the activities and resources provided by the institution that are designed to ensure the success of the planned training program and its trainees. If this letter is not included, the application will be considered incomplete and will not be reviewed. The institutional commitment to the following areas should be described (as applicable):

- Developing and promoting a culture in which the highest standards of safety, scientific rigor, reproducibility, and responsible conduct are advanced;

- Ensuring sufficient start-up funding to permit early stage faculty to participate in training, and bridge funding to ensure that training may continue if a mentor experiences a hiatus in funds;
- Supporting core facilities and technology resources, and describing how they can be used to enhance training;
- Providing adequate staff, facilities, and educational resources to the planned program;
- Supporting the PDs/PIs and other key staff associated with the planned training program;
- Fostering and rewarding excellence in training (e.g., through institutional polices such as tenure and promotion);
- Supporting the remediation or removal of Participating Faculty from the program who are poorly performing mentors;
- Promoting diversity and inclusion at all levels of the research training environment (trainees, staff, faculty, and leadership);
- Ensuring a positive, supportive and inclusive research and training environment for individuals from all backgrounds;
- Ensuring the research facilities and laboratory practices promote the safety of trainees;
- Guaranteeing the research facilities are accessible to trainees with disabilities;
- Ensuring that proper policies, procedures, and oversight are in place to 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-19-029 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-029.html));
- Providing trainees access to student support services, such as healthcare, counseling services, and housing;
- Providing resources and expertise for evaluating the training outcomes of the program; and
- For institutions that have multiple NIGMS-funded predoctoral training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones.

Institutional Eligibility Letter. (1-page maximum). The Authorized Organization Representative or Business Official or similar official with institution-wide responsibility must certify that all the components of the institution under the applicant DUNS or IPF number together have an average of RPG funding greater than or equal to $7.5 million total costs (both direct and F&A/indirect costs) per year over the past 3 fiscal years, as described in Section III, "Eligible Organization". If this letter is not included, the application will be considered incomplete and will not be reviewed.

Other Letters of Support. Additional letters of support (e.g., from partner institutions or organizations) are permitted; however, these letters may not contain any information required in the Institutional Support Letter.

Combine all Letters of Support into a single PDF file.

Data Tables: The application must include the required Training Data Tables (https://grants.nih.gov/grants/guide/url_redirect.php?id=61169). Applications that do not contain the required tables, or that submit any additional tables in this attachment, will be considered noncompliant 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 theSF424 (R&R) Application Guide instructions.

The Appendix is meant to provide additional details to the following topics but is not meant to substitute for clear descriptions in the body of the application. Do not include items other than the required and allowable materials described below, as doing so will result in administrative withdrawal of the application prior to review. Name the file according to the headings below. A summary sheet listing all the items included in the Appendix may be included in the first Appendix attachment.

The following are required Appendix materials:

- Required Training Activities. To adequately assess the content of the didactic portion of the training program, the application must include syllabi/outlines of all required training activities (e.g., syllabi for courses, mentor training materials, professional development workshops, career exploration opportunities, skills development activities).
- Responsible Conduct of Research Syllabi. In addition to the Plan for Instruction in the Responsible Conduct of Research, the application must provide syllabi/outlines of materials relating to Responsible Conduct of Research and descriptions of when in the trainees career paths the material is taught.

The following are allowable Appendix materials:

- Elective Activities. The application may include summary content from up to four additional elective courses and/or training activities (e.g., syllabi or summaries for courses, mentor training materials, outlines of professional development workshops, career exploration opportunities, or skills development activities).
- Evaluation and Assessment Instruments. The application may include blank surveys, rubrics, and/or forms used to (a) document and monitor trainee progress and (b) determine whether the training and research environment is effective, inclusive, safe, and supportive.
- Conflict Resolution Protocols (3-page maximum). The application may include detailed protocols for addressing problems with trainee and faculty matches, removal of faculty from the training program with unacceptable training/mentoring skills and for conflict resolutions for multi PD(s)/PI(s) and mentor/mentee relationships.

Applications that do not include the required appendices or that exceed the number of allowed appendices or the page limitation of any of the allowed materials will be considered noncompliant and will not be reviewed.

PHS Assignment Request Form

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

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/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//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 intergovernmental review. (//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* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120). The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.php?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

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 How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. 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.

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 (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//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 Center for Scientific Review and NIGMS. Applications that are incomplete or non-compliant will not be reviewed.

Applicants Requesting $500,000 or more for direct costs (less consortium F&A) in any year

Applicants requesting $500,000 or more in direct costs in any year **are not required** to contact a Scientific/ Research Contact prior to submitting an application. The Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide **is not** applicable to this FOA.

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will produce a diverse pool of well-trained scientists who complete their baccalaureate degree and transition into and complete biomedical, research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.). Will the program provide trainees with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design, and interpretation of data), and professional (e.g., management, leadership, communication, and teamwork) skills necessary to conduct rigorous and reproducible research, and transition into research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.), in consideration of the following review criteria and additional review criteria (as applicable for the program proposed)?

Specifically, do the courses, structured training activities, mentoring, and research experiences equip the trainees with:

- A broad understanding across biomedical disciplines;
- Expertise in a basic biomedical scientific discipline and the skills to independently acquire the knowledge needed to advance their chosen fields;

- The ability to think critically and independently, and to identify important biomedical research questions and approaches that push forward the boundaries of their areas of study;
- A strong foundation in scientific reasoning, rigorous research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting, and presenting rigorous and reproducible biomedical research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds, and to promote inclusive and supportive scientific research environments;
- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills and experiences required to identify and transition into careers in the biomedical research workforce (i.e., the breadth of careers that sustain biomedical research in areas that are relevant to the NIH mission)?

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program, 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.

Training Program and Environment

Rationale, Mission, and Objectives

- Does the application provide a compelling rationale for the proposed research training program?
- Does the proposed program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines, program faculty with the appropriate scientific expertise, and resources to achieve the training objectives?
- Are the mission and objectives for the training program specific and measurable and in alignment with the goal of the program?

Curriculum and Overall Training Plan

- Will the courses, structured training activities, mentoring, and research experiences achieve the stated mission and objectives of the proposed training program?
- Does the application propose changes in the program's research training and mentoring practices to effectively address the rapidly evolving biomedical research enterprise and current understanding of evidence-informed training and mentoring approaches?
- Will the trainees participate in authentic research experiences and complete at least one summer research training experience at a research-intensive institution?
- Is the mechanism for ensuring that the trainees are learning the highest standards of practice in biomedical research (e.g., record keeping and safety) robust?
- Will the Participating Faculty teach laboratory safety throughout the didactic and mentored portions of the program?
- Does the training program plan provide a compelling explanation of how the courses, structured training activities, mentoring, and research experiences employ modern, evidence-informed approaches that are likely to enhance the success of the trainees?
- Are the activities likely to build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members?
- Do the required and elective training elements (e.g., syllabi, course descriptions) provide compelling evidence that the trainees will gain the requisite skills for the discipline in a timely fashion and that there are mechanisms to ensure that the trainees will be guided, monitored, and evaluated?
- Are there plans to accommodate differences in preparation among trainees?
- Is it clear how the proposed program will enhance the research training environment and not simply provide financial assistance for the trainees?
- Is it clear how the training activities will be available to other students in the program(s), department(s), or institution(s) from which the trainees are drawn?

- For multi-disciplinary and/or multi-departmental programs, is it clear how the individual disciplinary and/or departmental components of the program are integrated and coordinated, and how each will relate to an individual trainee's experience?
- If applicable, is the proposed program distinct from, but planning to share resources and synergize with other NIGMS-funded predoctoral training programs at the institution?

Career Development

- Is there a mechanism to ensure the pool of potential applicants and trainees will be provided with information about the outcomes of former trainees of the program (e.g., on publicly accessible websites) and about the overall biomedical research workforce employment landscape?
- Will the trainees be provided with support as well as adequate, appropriate, and timely information regarding the steps required to transition into the next phase of the biomedical research workforce pathway (e.g., when applying to research-focused graduate programs, or funding opportunities)?
- Will the trainees be introduced to mentors and sponsors who will enhance their career opportunities (e.g., contacts at national meetings and institutions with NIH-funded T32 training programs, as well as members of scientific societies, and the research community)?

Program Oversight, Participating Faculty Selection, and Mentor Training

- Does the application describe an effective strategy and administrative structure to oversee and monitor the program to ensure appropriate and timely trainee progress for the duration of the trainees' undergraduate careers?
- Is selection of the program faculty based on a commitment to training and mentoring, and not simply research productivity?
- Will the participating faculty be trained to ensure the use of evidence-informed teaching and mentoring practices that promote the development of trainees from all backgrounds?
- Do the participating faculty have a record of employing the highest standards of rigor and transparency in their research, and plans to impart those standards to their trainees?
- Will the program ensure that program faculty reinforce and augment the curricular material on responsible conduct of research, and methods for enhancing reproducibility?
- Is there a clear mechanism for matching the trainees with appropriate program faculty?
- Is there a plan to ensure that the participating faculty engage in activities that promote trainee career development (including but not limited to the utilization of Individual Development Plans), and fulfill the need of the trainees to obtain their degrees in a timely fashion with the skills, credentials and experiences to transition into the next phase of the biomedical research pathway that are consistent with the trainees' interests, and values?
- Is there an effective mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing participating faculty displaying unacceptable mentorship qualities from the training program?
- If a program coordinator or administrator position is planned, will the person's administrative capabilities contribute to the success of the program?

Institutional and Departmental Commitment to the Program

- Will the institutional and departmental commitment to research and training excellence promote the success of the trainees and training program?
- Is there a clear institutional commitment to develop and promote a culture in which the highest standards of safety, scientific rigor, reproducibility, and responsible conduct of research are advanced?
- Does the institution provide sufficient start-up funding to permit early stage faculty to participate in training, and bridge funding to ensure that training may continue if a mentor experiences a hiatus in funds?
- Are the core facilities and technology resources necessary for the success of the program well supported?
- Is there adequate support of the PD(s)/PI(s) and other key staff, facilities, and educational resources associated with the training program?
- Do participating faculty have sufficient protected time available to devote to the training and mentoring activities?
- Is there evidence that the institution rewards excellence in training and mentoring through institutional policies?
- Does the institution support the remediation or removal of Participating Faculty from the program who are poorly performing mentors?
- Are diversity and inclusion efforts promoted at all levels of the research training environment (trainees, staff, faculty, and leadership)?

- Does the institution promote a positive, supportive, safe and inclusive research and training environment for individuals from all backgrounds?
- Is there evidence that the research facilities and laboratory practices ensure the safety of trainees?
- Is a process in place to address access issues for trainees with identified disabilities?
- Are appropriate policies and procedures in place to protect trainees from harassment and other prohibited practices?
- Is there evidence of an institutional commitment to providing the trainees access to student support services, such as health care, counseling services, and housing?
- Are the resources and expertise for evaluating the training outcomes of the program appropriate?
- Does the plan describe the changes the program(s), department(s) and/or the institution(s) will make to better support the goals of the training program?
- Does the application adequately address how research training at the undergraduate level is supported?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/PI(s) have the scientific expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) have the time to commit sufficient effort to ensure the program's success, given their other professional obligations?
- Does at least one member of the PD/PI team have a demonstrated record of using rigorous and transparent methods in experimental design, data collection, analysis, and reporting in the proposed scientific field?
- Have the PD(s)/PI(s) received training on how to effectively mentor trainees, including those from underrepresented groups, and promote inclusive, safe, and supportive research training environments?
- Do the PD(s)/PI(s) have a demonstrated commitment to training the next generation of the biomedical research workforce, leading recruitment efforts to enhance diversity, and fostering inclusive research environments?
- Are there a strong administrative structure and leadership succession plan for critical positions (e.g., PD/PI)?

For applications designating multiple PD(s)/PI(s):

- Will the multiple PD/PI leadership approach benefit the trainees and enhance the ability of the program to achieve its training goals?
- Is there a clear leadership plan including the designated roles and responsibilities, governance, conflict resolution procedures, and organizational structure (see Multiple PD/PI Leadership Plan section)?

Preceptors/Mentors (Participating Faculty)

- Do the participating faculty describe a compelling commitment to rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results?
- Do the participating faculty describe a compelling commitment to ethically sound and responsible scientific research?
- Do the participating faculty have plans to promote the use of highest standards of practice to ensure the safety of all individuals in the research environment?
- Do the selected program faculty come from various backgrounds, for example, individuals from groups underrepresented in the biomedical sciences, women, as well as faculty at different career stages (i.e., junior and senior faculty)? If not, are there plans to recruit faculty to enhance the diversity?
- Do the participating faculty have the time to commit sufficient effort to ensure trainee development and success, given their other professional obligations?
- Is there evidence that the participating faculty cooperate, interact, and collaborate (which can include joint sponsorship of trainee research)?
- Do the participating faculty provide opportunities for trainees to initiate, conduct, interpret, and present rigorous and reproducible biomedical research with increasing self-direction?
- Do the participating faculty have plans for ensuring their trainees develop skills in approaches to experimental design, as well as methods of data collection, analysis, interpretation, and reporting?
- Do the participating faculty demonstrate a commitment to effective mentoring, and promoting inclusive, safe, and supportive scientific and training environments?
- Are the participating faculty willing to engage in activities to promote the trainees career goals and to support trainees participating in activities required to identify and transition into careers in the biomedical research workforce that are

consistent with the trainees' skills, interests, and values?
- Do the participating faculty have a commitment to fulfilling the need of the trainees to obtain their degrees in a timely fashion with the skills, credentials, and experiences to transition into research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.)?

Trainee Positions, Appointment Process, and Retention, and Support

- Does the application provide a strong justification for the number of requested funded trainee positions given the pool of potential trainees, the size of the proposed program, the number of participating faculty, and other NIGMS funded training programs?
- Are trainees being appointed at the appropriate stage in order to most strongly benefit from the training program?
- Is the candidate review process likely to identify research-oriented candidates who are likely to transition to the next phase in the biomedical pathway?
- Is there an adequate, data-informed retention plan to ensure the well-being and success of all trainees throughout their training (see the "Trainee Retention Plan" attachment)?

Training Record

Training Outcomes for Trainees (renewals) or Training Grant Eligible Pool (new applications)

- Does the application provide evidence the trainees (or training grant eligible pool) conducted rigorous research that advanced scientific knowledge and/or technologies with increasing self-direction?
- Does the rate of degree attainment and time-to-degree for the trainees (or training grant eligible pool) indicate that these students completed their degrees at a high rate in a timely fashion?
- Are the trainees (or individuals in the training grant eligible pool) transitioning into and completing higher research-oriented higher degree programs (e.g., Ph.D. or M.D./Ph.D.)?

Program Evaluation

- Is there a well thought out evaluation or assessment plan to determine whether the overall program is effective in meeting its training mission and objectives, and whether the training and scientific research climates are inclusive and supportive of trainee development (narrative and "Evaluation and Assessment Instruments" Appendix)?
- Is there evidence that the program has been and/or will be responsive to outcomes, critiques and evaluations?
- Does the training program have an appropriate plan to track trainee outcomes and make the data publicly available (e.g., on the institution's website)?

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.

Training in Methods for Enhancing Reproducibility

Does the Instruction in Methods for Enhancing Reproducibility plan describe how trainees will be instructed in principles important for enhancing research reproducibility including, at a minimum, evaluation of foundational research underlying a project, rigorous experimental design and data analysis, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, data and material sharing, record keeping, and transparency in reporting? Are the rigor and transparency components sufficiently well integrated into the overall curriculum? Are they taught at multiple stages of trainee development and in a variety of formats and contexts? Does the teaching synergize with elements of the curriculum designed to enhance trainees' abilities to conduct responsible research? Is there evidence that all participating faculty reiterate and augment key elements of methods for enhancing reproducibility when trainees are performing mentored research their laboratories? The plan will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

Recruitment Plan to Enhance Diversity

Reviewers will examine the strategies to be used in the recruitment of prospective individuals from underrepresented groups. The plan will be rated as ACCEPTABLE or UNACCEPTABLE, and the consensus of the review committee will be included in an

administrative note in the summary statement.

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 specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) **Format** - Does the plan satisfactorily address the format of instruction, e.g. lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (A plan involving only on-line instruction is not acceptable); 2) **Subject Matter** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, and research ethics? 3) **Faculty Participation** - Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) **Duration of Instruction** - Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) **Frequency of Instruction** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

Are the RCR components sufficiently well integrated into the overall curriculum? Are they taught at multiple stages of trainee development and in a variety of formats and contexts? Does the teaching of RCR synergize with elements of the curriculum designed to enhance trainees' abilities to conduct rigorous and reproducible research? Is there evidence that all participating faculty reiterate and augment key elements of responsible conduct when trainees are performing mentored research their laboratories?

Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

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. Undue weight should not be given for simply responding to previous comments; instead the content of the responses and how the application project will be improved by any proposed changes should be considered.

Renewals

For Renewals, the committee will consider the progress made in the last funding period, including on the Training in Methods for Enhancing Reproducibility Plan, Recruitment Plan to Enhance Diversity, and Training in the Responsible Conduct of Research Plan.

- Did the training grant team successfully implement the proposed programmatic elements?
- Is the program achieving its training objectives?
- Is there evidence that the training environment is inclusive, safe, and supportive?
- Has the program evaluated the quality and effectiveness of the training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are changes proposed that are likely to improve or strengthen the research training experience during the next project period?

- Does the program continue to evolve to reflect changes in the research area in which the training occurs and current evidence-informed training and mentoring approaches?
- Is the program having a broader impact (e.g., are students beyond the trainees directly supported by the program being positively impacted by the program's presence, are training practices and outcomes being shared with the broader biomedical training community)?

Revisions

Not Applicable

Additional Review Considerations

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

Select Agent Research

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

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), convened by the NIGMS Scientific Review (https://www.nigms.nih.gov/training/pages/ReviewProcess.aspx) Branch in accordance with NIH peer review policy and procedures (//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 NIGMS Advisory Council. 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.
- Geographic distribution of the NIGMS training grant portfolio.

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). 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).

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).

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) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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) 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) 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). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=11158).

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 (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the *NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=61170).

The taxability of stipends is described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=41171).

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the recipient institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11171) for additional information on this reporting requirement.

Other Reporting Requirements

- The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.php?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.php?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

- A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.php?id=61189)). Individuals with a Conditional Permanent Resident status must first meet full (non-conditional) Permanent Residency requirements before receiving support.

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

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. Trainees 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 10 years of making awards under this program, NIGMS will assess the program's overall outcomes.

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

- Institution types represented
- Geographical distribution of programs
- Demographics of trainees
- Trainee degree completion rates
- Time-to-degree
- Matriculation into and completion of research-oriented higher degree programs
- Scientific accomplishments of trainees
- Trainee career outcomes

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Commons Help Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)

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

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726

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

Scientific/Research Contact(s)

Kalynda Gonzales Stokes, Ph.D.
National Institutes of General Medical Sciences (NIGMS)
Email: kalynda.stokes@nih.gov (mailto:kalynda.stokes@nih.gov)

Lameese Akacem, Ph.D.
National Institutes of General Medical Sciences (NIGMS)
Email: lameese.akacem@nih.gov (mailto:lameese.akacem@nih.gov)

Peer Review Contact(s)

Stephanie Constant, Ph.D.
National Institute of General Medical Sciences
Email: stephanie.constant@nih.gov (mailto:stephanie.constant@nih.gov)

Financial/Grants Management Contact(s)

Justin Rosenzweig
National Institute of General Medical Sciences (NIGMS)
Email: rosenzwj@nigms.nih.gov (mailto:rosenzwj@nigms.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//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* (//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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Section 487 of the Public Health Service Act as amended (42 USC 288) and under Federal Regulations 42 CFR 66.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?02-26-21)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

EXHIBIT B

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: [redacted]
Subject: [External] NIGMS Funding Update
Date: Wednesday, April 2, 2025 [redacted]

Re: [redacted]

Dear Dr. [redacted]

I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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. We advise against recruiting future cohorts.

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 and include your 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 C

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

Funding Opportunity Title

Initiative for Maximizing Student Development (IMSD) (T32 - Clinical Trial Not Allowed)

Activity Code

T32 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t32&Search.x=0&Search.y=0&Search_Type=Activity)
Institutional National Research Service Award (NRSA)

Announcement Type

Reissue of PAR-19-037 (https://grants.nih.gov/grants/guide/pa-files/par-19-037.html) - Initiative for Maximizing Student Development (IMSD) (T32)

Related Notices

- **November 14, 2023** - This PAR has been reissued as PAR-24-031 (//grants.nih.gov/grants/guide/pa-files/PAR-24-031.html)
- NOT-OD-23-012 (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
- **November 15, 2022** - Notice of a Question and Answer "Office Hour" with NIGMS Staff for IMSD and G-RISE Applicants. See Notice NOT-GM-23-020 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-23-020.html)
- **November 1, 2022** - Clarification of Eligibility for Institutions with Multiple Campuses in PAR-21-025 "Initiative for Maximizing Student Development (IMSD) (T32 - Clinical Trial Not Allowed)". See Notice NOT-GM-23-014 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-23-014.html)
- NOT-OD-22-190 (/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
- **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).
- **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).
- **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)
- **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)
- **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)

- **November 12, 2021** - Notice of Informational Webinar on the NIGMS IMSD and G-RISE Research Training Programs. See Notice NOT-GM-22-008 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-008.html).
- **May 28, 2021** - Notice of Change to the Instructions for Appendices in PAR-21-025. See Notice NOT-GM-21-047 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-047.html).
- **December 09, 2020** - Notice of Change to the Number of Applications that Can Be Submitted by Institutions Applying to PAR-21-025. See Notice NOT-GM-21-011 (/grants/guide/notice-files/NOT-GM-21-011.html).

Funding Opportunity Announcement (FOA) Number

PAR-21-025

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

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

93.859

Funding Opportunity Purpose

The goal of the Initiative for Maximizing Student Development (IMSD) program is to develop a diverse pool of scientists earning a Ph.D., who have the skills to successfully transition into careers in the biomedical research workforce. This funding opportunity announcement (FOA) provides support to eligible, domestic institutions to develop and implement effective, evidence-informed approaches to biomedical graduate training and mentoring that will keep pace with the rapid evolution of the biomedical research enterprise. NIGMS expects that the proposed research training programs will incorporate didactic, research, mentoring, and career development elements to prepare trainees for careers that will have a significant impact on the health-related research needs of the Nation. This program is limited to applications from training programs at research-intensive institutions (i.e., those with NIH Research Project Grant funding averaging greater than or equal to $7.5 million in total costs (direct and F&A/indirect) per year over the last three fiscal years).

This FOA does not allow appointed trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Key Dates

Posted Date

November 20, 2020

Open Date (Earliest Submission Date)

January 26, 2021

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

February 26, 2021; January 28, 2022; January 30, 2023, by 5:00 PM local time of applicant organization. All types of 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.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

June/July 2021, June/July 2022, June/July 2023

Advisory Council Review

October 2021; October 2022; October 2023

Earliest Start Date

February 2022, February 2023, February 2024

Expiration Date

January 31, 2023

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Training (T) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts* (//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 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) 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. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41125) website.

Purpose and Background Information

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Each program should provide high-quality research training, mentored research experiences, and additional training opportunities that equip trainees with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design and interpretation of data) and professional (e.g., management, leadership, communication, and teamwork) skills required for careers in the biomedical research workforce.

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) in the biomedical, clinical, behavioral and social sciences (collectively termed "biomedical") research workforce. 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.

NIGMS 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. NIGMS 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. Accordingly, NIGMS developed separate institutional eligibility tracks for review and funding of its undergraduate and graduate diversity enhancing programs based on NIH research project grant (RPG) (https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG) funding levels. The two tracks include research-intensive, i.e., those with an average of NIH RPG funding greater than or equal to $7.5 million total costs per year over the past 3 fiscal years, and research-active, i.e., those with an average of RPG funding less than $7.5 million total costs per year over the past 3 fiscal years (RPG data are available through NIH RePORTER (https://report.nih.gov/award/index.cfm)). To prevent the duplication of diversity enhancing NIGMS programs, each institution will be eligible for one diversity enhancing undergraduate program (either Maximizing Access to Research Careers, MARC (https://www.nigms.nih.gov/training/marc/pages/ustarawards.aspx), or Undergraduate Research Training Initiative for Student Enhancement, U-RISE (https://www.nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx)) regardless of the activity code (R25 or T34), and one diversity enhancing graduate program (either the Initiative to Maximize Student Development, IMSD (https://www.nigms.nih.gov/training/IMSD/pages/default.aspx), or G-RISE (https://www.nigms.nih.gov/training/RISE/Pages/G-RISE-T32.aspx)) regardless of the activity code (R25 or T32). Institutions with MARC, U-RISE, IMSD or G-RISE are eligible to participate in the Bridges to the Baccalaureate and/or Bridges to the Doctorate programs provided other eligibility requirements are met.

Need for the Program

In spite of recent advances, individuals from certain groups and backgrounds are underrepresented in the biomedical sciences research workforce as described in NIH's Interest in Diversity (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 in 2017, students from certain racial and ethnic groups, including Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders comprised ~35 percent of the college age population, but earned only ~25 percent of bachelor's degrees and ~16 percent of Ph.D. degrees in science and engineering (National Center for Science and Engineering Statistics (https://ncses.nsf.gov/pubs/nsb20197/demographic-attributes-of-s-e-degree-recipients#s-e-degrees-by-race-and-ethnicity)). 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 groups underrepresented in the biomedical research workforce, a corresponding increase in the ranks of the faculty in basic science departments at medical schools has not occurred (Gibbs, et al., 2016, eLife 2016, 5:e21393; Valantine, Lund & Gammie, CBE-Life Sciences Education, 2016, 15:fe4).

Several reports (see for example, ACD Working Group on Diversity in the Biomedical Workforce, 2012 (https://acd.od.nih.gov/documents/reports/DiversityBiomedicalResearchWorkforceReport.pdf); PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf); From College to Careers: Fostering Inclusion of Persons with Disabilities in STEM, 2014 (http://www.sciencemag.org/booklets/college-careers); and Increasing College Opportunity for Low Income Students, 2014 (https://obamawhitehouse.archives.gov/sites/default/files/docs/increasing_college_opportunity_for_low-income_students_report.pdf)) recommend supporting programs that strive to recruit, train, and mentor students from underrepresented groups who have an interest in science, technology, engineering and math (STEM) as a means to effectively build a diverse and competitive scientific workforce.

Programmatic Approach

This FOA is intended to enable the community to develop and implement evidence-informed approaches to biomedical research training and mentoring to enhance diversity in the biomedical research workforce. The President's Council of Advisors on Science and Technology (PCAST) report provided evidence that financial concerns and a deficit of peers from similar backgrounds can erode self-confidence and the will to remain in STEM majors (PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf)). NIGMS diversity enhancing institutional training grants offset the cost of appointed trainee stipends, tuition and fees, and training related expenses, including health insurance, in accordance with the approved NIH support levels. Additionally, funded programs are expected to provide activities that will build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members. Programmatic activities include, but are not limited to, providing authentic research experiences, academic enhancements, skills development, and additional mentoring - activities proven to increase persistence in STEM fields (cited in PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf) and Graduate STEM Education for the 21st Century, 2018 (https://www.nap.edu/catalog/25038/graduate-stem-education-for-the-21st-century)). Each program should provide high-quality training that equips individuals with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design, and interpretation of data, conducting research in the safest manner possible) and professional (e.g., management, leadership, communication, and teamwork) skills required for careers in the biomedical research workforce. Funded programs are expected to promote inclusive research environments (i.e., institutional and departmental environments where trainees from all backgrounds feel integrated into and supported by the biomedical research community).

Program Objective

The Overarching Objective of this Initiative for Maximizing Student Development (IMSD) program is to develop a diverse pool of well-trained Ph.D. biomedical scientists, who have the following technical, operational, and professional skills:

- A broad understanding across biomedical disciplines and the skills to independently acquire the knowledge needed to advance their chosen fields;
- Expertise in a biomedical scientific discipline and the skills to think critically and independently, and to identify important biomedical research questions and approaches that push forward the boundaries of their areas of study;
- A strong foundation in scientific reasoning, rigorous research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching and conducting biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting, and presenting rigorous and reproducible biomedical research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds, and to promote inclusive and supportive scientific research environments;
- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills and experiences required to identify and transition into careers in the biomedical research workforce (i.e., the breadth of careers that sustain biomedical research in areas that are relevant to the NIH mission).

Diversity at all levels from the kinds of science to the regions in which it is conducted to the backgrounds of the people conducting it contributes to excellence in research training environments and strengthens the research enterprise. This FOA is intended to

support outstanding research training programs that will enhance diversity at all levels. As part of a larger initiative to enhance diversity, the IMSD program will support trainees earning a Ph.D. at research-intensive institutions.

Program Considerations

NIGMS intends to fund applications that propose feasible academic and research focused training programs that will enhance diversity in the biomedical workforce. Applicants are expected to identify training objectives (i.e., specific, measurable, and obtainable outcomes the program intends to achieve) and to develop plans to implement evidence-informed training and mentoring activities that are grounded in the literature and from evaluations of existing relevant programs. Program objectives must align with the overarching goal of the IMSD diversity enhancing program. Funded programs are expected to provide evidence of accomplishing the training objectives in progress reports and upon renewal, to make training and career outcomes publicly available, and are strongly encouraged to disseminate successful training practices to the broader community.

Institutional commitment and support for the proposed training program are important elements of the application. The IMSD program may complement and synergize with other ongoing federally-supported predoctoral research training programs at the applicant institution (e.g., in the development of skills needed for careers in the biomedical research workforce); however, the IMSD program goals and activities to achieve those goals must be distinct from related programs currently receiving federal support at the same institution. In cases where an institution has multiple NIGMS training grants, it is expected that these programs will seek to create administrative and training efficiencies to reduce costs and improve trainee services and outcomes. The training grant should be well integrated within one or more graduate department(s)/program(s) and should exert a strong, positive influence on the development and execution of the outreach and recruitment of potential trainees, graduate curriculum, training opportunities, and mentoring. Training grant funds may not be used solely as a vehicle to provide stipends for trainees to conduct research.

NIGMS does not accept applications for predoctoral T32 programs proposing only short-term research training. Programs proposing short-term research training should apply to the Kirschstein-NRSA Short-Term Institutional Research Training Grant Program (T35) exclusively reserved for predoctoral, short-term research training (see PA-20-162 (https://grants.nih.gov/grants/guide/pa-files/PA-20-162.html) and subsequent reissuances but note that NIGMS does not participate in that FOA). NIGMS will not accept applications proposing combined predoctoral and postdoctoral training under this FOA.

Training grants are usually awarded for five years. The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels. Students are typically provided full-time support for two to three years of graduate studies. Use of training grant support in the first three years of graduate research training is strongly encouraged to provide maximum flexibility in the participation in courses, laboratory rotations, professional development, and cohort-building activities.

This FOA does not allow appointed trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

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

Resubmissions
Renewal of applications submitted to PAR-19-037 (https://grants.nih.gov/grants/guide/pa-files/par-19-037.html)

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

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

Note: Appointed trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

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

Funds Available and Anticipated Number of Awards

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

Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

Grantees are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

NIGMS recognizes the need of trainees from diverse backgrounds, including those from underrepresented groups, to attend scientific meetings and/or training events, and to build professional networks. NIGMS will provide up to $1,000 per trainee per year to travel to scientific meetings or training experiences that will enhance scientific development, build science identity, create a sense of belonging in the scientific community, and build professional networks. Plans for trainee travel should be well justified. For IMSD-supported institutions outside the continental United States, $1,250 for travel per trainee per year will be provided.

Training Related Expenses

NIGMS will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, equipment, research supplies, and faculty/staff travel directly related to the research training program. Training related expenses are limited to a maximum of $6,400/trainee/year.

Allowable costs include those associated with the following:

Skills development training activities (e.g., focusing on quantitative and computational, problem-solving, critical thinking, scientific writing, effective communication, and project management);

Seminar speakers, who will serve as role models to the trainees

Training or mentoring interventions designed to increase persistence in research (e.g., those designed to increase science identity, self-efficacy and a sense of belonging in the scientific community);

Typically, salary support for the PD/PI or in a combination of multiple PD(s)/PI(s)/co-Investigators does not exceed 1.8 person months (i.e., 15% effort on a 12-month basis in total) depending on the size and scope of the program;

Salary support for administrative personnel; typically, the total combined salary support for program administrator/program coordinator and/or program assistant/clerical support does not exceed 3.0 person months (i.e., 25% effort on a 12-month basis) depending on the size and scope of the program.

Limited program evaluation costs (typically up to $3,000 for the 5-year training grant period) and other program-related expenses may be included within the budget for training-related expenses.

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIGMS does not permit automatic carryover from one budget period to the next. NIH grants policies as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

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)

Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

For diversity enhancing programs, NIGMS recognizes separate institutional eligibility tracks: research-intensive, i.e., those with an average of NIH research project grant (RPG) (https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG) funding greater than or equal to $7.5 million total costs per year over the past 3 fiscal years, and research-active, i.e., those with an average

of RPG funding less than $7.5 million total costs per year over the past 3 fiscal years (RPG data are available through NIH RePORTER (https://report.nih.gov/award/index.cfm)). For example, FY 2018, FY 2019 and FY 2020 for applications submitted in January 2021.

Institutional eligibility for this FOA is limited to research-intensive institutions as defined above. Research-active institutions are not eligible to apply for or receive IMSD grants. To prevent the duplication of NIGMS diversity enhancing programs, each institution is eligible for one undergraduate program (either MARC (https://www.nigms.nih.gov/training/marc/pages/ustarawards.aspx) or U-RISE (https://www.nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx)) regardless of the activity code (R25 or T34), and one graduate program (either IMSD (https://www.nigms.nih.gov/training/IMSD/pages/default.aspx) or G-RISE (https://www.nigms.nih.gov/training/RISE/Pages/G-RISE-T32.aspx)) regardless of the activity code (R25 or T32). Institutions with NIGMS MARC, U-RISE, IMSD, or G-RISE funding are eligible for the Bridges to the Baccalaureate and/or Bridges to the Doctorate programs provided the other eligibility criteria are met.

An institution funded through the G-RISE or IMSD program that changes category due to changes in research project grant funding during the grant cycle should apply to the appropriate program based on their eligibility at the time of renewal. Programs that change category will report on the programs outcomes of the prior funding period(s), up to 15 years, using the appropriate tables.

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program should be detailed in the *Institutional Support Letter* in the **Letters of Support** attachment. Additionally, a signed letter is required from the Provost or similar official with institution-wide responsibility verifying the eligibility of the applicant institution at the time of application submission according to the eligibility criteria indicated above. See the application instructions for the required Letters of Support instructions in Section IV. (https://grants.nih.gov/grants/guide/pa-files/PAR-21-025.html#_Section_IV._Application)

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.

Required Registrations

Applicant Organizations

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

- Dun and Bradstreet Universal Numbering System (DUNS) (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/) 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.htm?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.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) 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 individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

As described in the instructions for the Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) in Section IV.2 below, NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance training. At least one of the training PDs/PIs should be an established investigator in the biomedical sciences and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. Additional PD(s)/PI(s), including individuals with experience in the science of education, relevant social science disciplines, program evaluation, mentoring, and university administration may be included to achieve the training goals. Any of the PDs/PIs may serve as the contact PD/PI. The contact PD/PI is expected to have a full-time appointment at the applicant institution unless extremely well-justified. If the full-time status of the contact PD/PI changes after the award, the institution must obtain prior program approval to appoint a new PD/PI or request a deviation from the full-time rule. The PDs/PIs will be responsible for the selection and appointment of trainees to the approved research training program, and for the overall direction, management, administration, and evaluation of the program. The PDs/PIs will be expected to monitor and assess the program and submit all documents and reports as required. The PDs/PIs have responsibility for the day-to-day administration of the program and are responsible for appointing members of the Advisory Committee (when applicable) and using their recommendations to determine the appropriate allotment of funds.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the 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)).

Preceptors/Mentors (Participating Faculty)

The selected faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support. When building a training team, programs should include faculty who are committed to training, mentoring, and providing supportive and inclusive research environments. Programs are encouraged to build a diverse team of preceptors/mentors that includes, for example, faculty from underrepresented groups (see Notice of NIH's Interest in Diversity) and faculty at different career stages (i.e., early-career as well as established faculty).

Trainees

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the NIH awarding unit. Use of training grant support in the first three years of graduate research training is strongly encouraged to provide maximum flexibility in the participation in courses, laboratory rotations, professional development, and cohort-building activities.

The IMSD program is not intended for health-professional students who wish to interrupt their studies for a year or more to engage in research training.

Predoctoral trainees must be enrolled in a program leading to a Ph.D. in a biomedical discipline.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace 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 Training (T) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?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.

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed.

Instructions for Application Submission

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

SF424(R&R) Cover

Follow all instructions provided in the SF424 (R&R) Application Guide.

SF424(R&R) Project/Performance Site Locations

Follow all instructions provided in the SF424 (R&R) Application.

SF424 (R&R) Other Project Information

Follow all instructions provided in the SF424 (R&R) Application, with the following additional modifications:

Are Human Subjects Involved: Check "No" unless the training program itself requires the trainees to take a workshop or course that will involve human subjects.

Are Vertebrate Animals Used: Check "No" unless the training program itself requires the trainees to take a workshop or course that will involve vertebrate animals.

Project Summary/Abstract. Provide an overview of the entire program. Include the mission, objectives, rationale and design of the research training program. Highlight key activities in the training plan that promote skills development and successful transitions into careers in the biomedical research workforce. Indicate the planned duration of appointments, the projected number of trainees and intended trainee outcomes.

Other Attachments.

Advisory Committee (1-page maximum). An Advisory Committee is not a required component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will assess the overall effectiveness of the program. To avoid conflicts in the review process, only pre-existing Advisory Committee members should be named in the application. Potential Advisory Committee members should not be identified or contacted prior to receiving an award. Please name the file Advisory_Committee.pdf .

Application and Admissions Data. The applicant must provide *Application and Admissions Data* to allow for the evaluation of the ability of participating departments/interdepartmental programs to recruit training grant eligible individuals. These data are useful

in assessing the admissions and recruitment process, the diversity of the pool, and the appropriate number of training positions to be awarded. Provide the numbers and characteristics of training grant eligible (I) applicants, (II) admitted individuals, and (III) matriculants for each of the past 5 academic years as well as the average over those years. Applicants are encouraged to use the Suggested Table Format Table A (https://www.nigms.nih.gov/training/instpredoc/Pages/predoctoral-nih-data-tables-data-formats.aspx) provided on the NIGMS website and to report on the categories listed in NIH s Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html) listed below. Demographic data should be from voluntary self-reporting.

- Total. The total number of individuals in the relevant category (e.g., applicants, admitted individuals, or matriculants). In cases of interdepartmental programs, provide aggregate data for all the participating departments.
- Number from Underrepresented Racial and Ethnic Minority (URM) Groups. Number of individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in biomedical research on a national basis (i.e., Black or African Americans, Hispanic or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders; see https://grants.nih.gov/grants/guide/notice-files/not-od-15-089.html (https://grants.nih.gov/grants/guide/notice-files/not-od-15-089.html))
- Number with a Disability. If data are available, the number with disabilities, defined as those with a physical or mental impairment that substantially limits one or more major life activities as described in the Americans with Disabilities Act of 1990, as amended (https://www.ada.gov/pubs/adastatute08.htm).
- Number from Disadvantaged Backgrounds. If data are available, the number from disadvantaged backgrounds (see NIH s Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)).
- Number of applicants who identify as women.
- Number of individuals from an institutionally defined underrepresented group. If relevant, number of applicants from a racial or ethnic group that can be demonstrated convincingly to be underrepresented by the grantee institution. For more information on racial and ethnic categories and definitions, see the OMB Revisions to the Standards for Classification of Federal Data on Race and Ethnicity (https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm (https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm)). Add columns as needed.

If the training program is interdepartmental with separate admissions for each department, provide the number of training grant eligible (I) applicants, (II) admitted individuals, and (III) matriculants in the relevant departments described in the application for each of the past 5 academic years. Please name the file Application_Admissions_Data.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Recruitment Plan to Enhance Diversity (3-page maximum). The applicant must provide a *Recruitment Plan to Enhance Diversity*. The application should include outreach strategies and activities designed to recruit potential training program candidates who are from diverse backgrounds, including students from underrepresented racial and ethnic groups, individuals with disabilities, and students from disadvantaged backgrounds (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)). Applicants are encouraged to consult the NIGMS webpage for strategies to enhance diversity in training programs (https://www.nigms.nih.gov/training/diversity/pages/approaches.aspx) when designing their plans. Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee recruitment efforts of the institution. Centralized institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups. Participating faculty are expected to be actively involved in recruitment efforts. Please name the file Recruitment_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Trainee Retention Plan (3-page maximum). The applicant must provide a *Trainee Retention Plan*. The *Trainee Retention Plan* must describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within a program (i.e., retention). Applicants are encouraged to consult the NIH's extramural diversity website to identify promising retention practices (https://extramural-diversity.nih.gov/building-participation/recruitment-retention) and to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee retention efforts of the institution(s). Centralized institutional efforts alone will not satisfy the requirement to implement robust and successful mechanisms to retain all trainees (e.g., participating faculty are expected to be actively involved in trainee retention efforts). Please name the file Retention_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Outcomes Data Collection and Storage Plan (2-page maximum). The applicant must provide an *Outcomes Data Collection and Storage Plan* to track the outcomes for all supported trainees for a minimum of 15 years beyond the trainee's participation in the program. Programs are encouraged to make the aggregate outcome data available on the institution's website. If the applicant

intends to make the data available, describe how the aggregate data will be de-identified before public posting. The applicant must include a strategy to ensure the secure storage and preservation of program data and outcomes. Describe how the data will be centralized, safeguarded, and retrievable during leadership changes. Please name the file Data_Collection_Storage_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Dissemination Plan (1-page maximum). The application must provide a specific *Dissemination Plan* to publish or present nationally any findings or materials developed under the auspices of the program. Examples of dissemination may include data or materials from successful training or mentoring interventions via web postings, presentations at scientific meetings, and/or workshops. Please name the file Dissemination_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

The filename provided for each Other Attachment will be the name used for the bookmark in the electronic application in eRA Commons.

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

Follow all instructions provided in the SF424 (R&R) Application with the following modifications.

Biographical sketch. The personal statement should describe a commitment to scientific rigor, training, mentoring, as well as to promoting inclusive, safe, and supportive scientific environments.

PHS 398 Cover Page Supplement

Follow all instructions provided in the SF424 (R&R) Application.

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the SF424 (R&R) Application Guide.

Training Budget

Follow all instructions provided in the SF424 (R&R) Application Guide with the following additional modifications:

- Include all allowable categories of funds requested to support trainees in the program.
- As per the instructions, request actual amounts for tuition/fees and provide justification. The amounts may be adjusted at the time of award.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program
- Faculty, Trainees, and Training Record
- Other Training Program Sections
- Appendix- Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the FOA specifically instructs applicants to do so.

Follow all instructions provided in the SF424 (R&R) Application Guide with the following additional modifications:

Attention must be given to the required Training Data Tables (//grants.nih.gov/grants/guide/url_redirect.htm?id=61169) for **New** or **Renewal** applications. Guidance for preparing the Training Data Tables (https://www.nigms.nih.gov/training/instpredoc/Pages/predoctoral-nih-data-tables-data-formats.aspx) is found on the NIGMS website. **Table 6A is not required for NIGMS Predoctoral Training Grant applications, and applicants must not include it.** In the Program Plan, applicants should also summarize key data from the tables that highlight the characteristics of the applicant pool, program faculty, institutional support, student outcomes, and other factors that contribute to the overall training environment of the program.

Training Program

Follow all training instructions provided in the SF424 (R&R) application guide except where instructed to do otherwise below.

Program Plan

The "Program Plan" attachment is required and must adhere to the NIH Table of Page Limits (https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#train), as well as the organization and instructions provided below.

Do not follow the organization and instructions provided in the SF424 (R&R) application guide for the Program Plan attachment; instead applicants must use the instructions below. Start each section with the appropriate heading.

Rationale, Mission, and Objectives

The application should describe how the IMSD program will develop a diverse pool of well-trained scientists who have the technical, operational, and professional skills required to conduct research in a safe, ethically responsible and rigorous manner, and to enter careers in the biomedical research workforce as delineated in the Program Objective. The application should describe how the program will enhance the training environment and not simply provide financial support to graduate trainees. Specifically, applicants should describe the following:

- The justification for the proposed diversity enhancing research training program. The application should describe the current institutional efforts to promote diversity and to create inclusive research training environments and how the IMSD program will enhance, but not duplicate these efforts. The rationale for the program should expand upon the "Training Outcome" data requested below that provides institutional baseline data on previous student outcomes comparing success rates for groups that are well-represented and underrepresented in the biomedical research workforce (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html));
- Current research training environment. The application should describe the research training environment including, but not limited to, the relevant background, an overview of the current research training activities of the participating department(s) or unit(s), and areas for improvement in the current research training practices. Applicants must demonstrate the presence of a sufficient number of potential trainees in appropriate disciplines (Table 1 (https://grants.nih.gov/grants/forms/data-tables.htm)) and program faculty with the appropriate biomedical expertise (Tables 2 and 4 (https://grants.nih.gov/grants/forms/data-tables.htm)) as well as the current research training resources (Table 3 (https://grants.nih.gov/grants/forms/data-tables.htm)); and
- The training mission (i.e., broad statement of purpose of the program), and objectives (i.e., specific measurable outcomes the program intends to achieve). The baseline data, the trainee pool, and the institutional context should inform the objectives and the design of the proposed training program. The program-specific mission and objectives should align with the Overarching Objective of this funding announcement. Objectives should include, but not be limited to, Ph.D. completion rates and appropriate time-to-degree.

Curriculum and Overall Training Plan

The application should describe the following:

- How the courses, structured activities, and research experiences will accomplish the specific training mission and objectives. Explain how these training activities are designed to develop the technical, operational, and professional skills of trainees. The application must include the "Required Training Activities" appendix to provide material to assess the required training elements and may use the "Elective Activities" appendix to provide up to four additional activities;
- Proposed changes to current research training practices to keep pace with the rapidly evolving biomedical research enterprise (e.g., curricular reforms, incorporation of additional quantitative and computational skills development, etc.);
- The mechanism for ensuring that the trainees are learning the highest standards of practice in biomedical research (e.g., record keeping and safety);
- How the Participating Faculty will teach laboratory safety throughout the didactic and mentored portions of the program;
- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, inclusion, and professional development;
- The activities that will build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members;
- Representative examples of training programs for individual trainees. Examples may include degree requirements, didactic courses, laboratory experiences, qualifying examinations, and other training activities, such as seminars, journal clubs, etc. Describe how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated. Discuss the anticipated time required to complete the training program up to degree attainment;
- The trainees academic and research background needed to pursue the proposed training and plans to accommodate differences in preparation among trainees (e.g., training and mentoring interventions provided in the summer before starting graduate courses and supplementary instruction throughout the training experience).
- How the training activities will be available to other trainees in the program(s), department(s) or institution(s) from which the supported trainees are drawn;

- For multi-disciplinary and/or multi-departmental programs, indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated, and how they will relate to an individual trainee's experience; and
- The ways, when applicable, that the training plan is distinct from, but will share resources and synergize with, other NIGMS-funded predoctoral training programs at the same institution (i.e., NIGMS predoctoral training programs listed in Table 3 (https://grants.nih.gov/grants/forms/data-tables.htm)). See the "Program Considerations" section above.

Career Development

The application should describe the following:

- How the pool of potential applicants and trainees will be provided with information about the career outcomes of graduates of the program (e.g., on publicly accessible websites) and about the overall biomedical research workforce employment landscape;
- How trainees in the program will be provided with adequate and appropriate information regarding the variety of careers in the biomedical research workforce for which their training would be useful;
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them; and
- How the training program or institution will provide experiential learning opportunities (e.g., internships, shadowing, informational interviews, teaching opportunities) that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce.

Program Oversight, Participating Faculty Selection, and Mentor Training

The application should include the planned strategy and administrative structure to oversee and monitor the program, and to ensure appropriate and timely trainee progress for the duration of the trainees' graduate careers (the application may include the "Evaluation and Assessment Instruments" Appendix to provide blank rubrics or forms). The application should describe how the participating faculty are trained to ensure the use of evidence-informed teaching, training and mentoring practices that promote the development of trainees from all backgrounds, e.g., trainees from underrepresented backgrounds in the biomedical sciences (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)). Applicants should describe the following:

- How the program will ensure that participating faculty employ the highest standards of scientific rigor and impart those standards to their trainees;
- How the program will ensure that participating faculty reinforce and augment the curricular material on responsible conduct of research, and methods for enhancing reproducibility;
- The mechanism for matching trainees with the appropriate participating faculty (e.g., laboratory rotations, faculty forums, and interviews);
- How the program will ensure that participating faculty engage in activities that promote trainee career development (including but not limited to the utilization of Individual Development Plans) and fulfill the need of the trainees to obtain their Ph.D. degrees in a timely fashion with the skills, credentials, and experiences to transition into careers in the biomedical research workforce that are consistent with the trainees interests and values;
- A mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty displaying unacceptable mentorship qualities from the training program (applicants may use the Appendix labeled Conflict Resolution Protocols to provide details of the plan); and
- If a program coordinator or administrator position is planned to enhance oversight, a description of the person's administrative capabilities that are essential to coordinate the program must be included in the application.

Institutional and Departmental Commitment to the Program

A letter providing assurances of the institutional commitment to the program must be included in the **"Letters of Support"** section of the application. Applicants may use this section to expand upon the Facilities & Other Resources section and the Letters of Support section, as necessary, to provide additional information regarding the institutional and departmental commitment to the program. Do not repeat information contained elsewhere in the application.

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) will promote the success of the trainees and training program. NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance training as described in the Eligible Individuals section. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The expertise, as well as the administrative and training experience, to provide strong leadership, direction, management, and administration of the proposed research training program;
- The time to commit sufficient effort to ensure the program's success given other professional obligations (the application should indicate the PD(s)/PI(s) s percent effort in the proposed program);
- At least one member of the team who has the scientific expertise in the biomedical sciences and who has a record of using rigorous and transparent methods in experimental design, data collection, analysis, and reporting;
- A demonstrated commitment to training the next generation of the biomedical research workforce, leading recruitment efforts to enhance diversity, and fostering inclusive research environments. As with all participating faculty, the PD(s)/PI(s) should have received training on how to effectively mentor trainees from all backgrounds, e.g., trainees from groups underrepresented in the biomedical sciences (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)); and
- A clearly delineated administrative structure and leadership succession plan for critical positions (e.g., PD(s)/PI(s)).

Preceptors/Mentors (Participating faculty)

The application should describe how the participating faculty will promote the success of the trainees and training program, as well as conducting responsible and rigorous research. Describe how the program has or will assemble a diverse team of participating faculty (e.g., individuals from underrepresented backgrounds (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-053.html)), women, and faculty at different career stages) to provide potential role models within the training program and to enhance the excellence of the training environment. The application should summarize and expand on the material presented in the Training Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and biosketches and address how the participating faculty:

- Have sufficient time to commit to training given their other professional obligations;
- Receive training in effective, evidence-informed teaching and mentoring practices;
- Promote the use of highest standards of practice to ensure the safety of all individuals in the research environment;
- Cooperate, interact, and collaborate (which can include joint sponsorship of trainee research);
- Promote the development of trainee skills in approaches to rigorous experimental design, methods of data collection, data analysis and interpretation, and reporting;
- Provide opportunities for trainees to initiate, conduct, interpret, and present rigorous, reproducible and responsible biomedical research with increasing self-direction;
- Demonstrate a commitment to effective mentoring, and to promoting inclusive, safe and supportive scientific and training environments; and
- Are evaluated as teachers and mentors.

Application Process, Trainee Positions, Retention, and Support

Through the narrative and summaries of the information presented in the required Training Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and the required attachments (i.e., *Application and Admissions Data* for all applications) the following areas relevant to trainees should be addressed.

Application Process

- Describe the admissions data provided in the required "Application and Admissions Data" attachment in "Other Attachments", including the characteristics of training grant eligible (I) applicants, (II) admitted individuals, and (III) matriculants for each of the past 5 academic years. Applicants are encouraged to report on the numbers and averages for the categories listed in NIH s Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). If the program is an interdepartmental training program with separate admissions, describe the data in the required attachment regarding the number and averages of training grant eligible (I) applicants, (II) admitted individuals, and (III) matriculants in the relevant departments for each of the past 5 academic years. Application and admissions data should inform the recruitment plans in the training grant application.
- Expand upon the "Recruitment Plan to Enhance Diversity" (provided in "Other Attachments"). Explain how the program will identify and recruit a diverse pool of potential candidates from a wide variety of institutions and backgrounds (with a focus on identifying effective recruitment strategies for individuals from nationally underrepresented groups in the biomedical sciences,

see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) who have the potential to strongly benefit from, and with proper training and support succeed in the program.
- Describe plans for a candidate review process that will allow a broad group of trainees, who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise, the ability to participate in the training program. The process should consider metrics beyond undergraduate institution, GPA, and standardized test scores. If the program trainees are drawn from multiple departments, describe how the PD(s)/PI(s) will ensure that the review process is consistent across all relevant departments.
- If the training program does not conduct its own recruitment and admissions for Ph.D. students entering the university and instead appoints students who were admitted by university departments or other graduate programs, provide a strong rationale for taking this approach.

Trainee Positions

- Describe how large the program will be *across all cohorts* (i.e., the total number of individuals enrolled in the proposed program ranging from the entering cohort to those nearing graduation). For interdepartmental programs, describe the expected number of individuals in the program from each scientific discipline.
- Provide a strong justification for the number of requested funded slots per year in the context of the training grant eligible pool, the size of the proposed program, the number of participating faculty, and other NIGMS-funded training grants at the institution. *For Renewal Applications* - Describe the characteristics of the previously awarded training positions (Table 7) as part of the justification for the requested positions.
- Explain the proposed training grant support structure, i.e., how many individuals (e.g., 4 per year), at what stage (e.g., first-year entrants), and for how long (e.g., for 1 year). Note: NIGMS typically funds trainees during years 1-3 of the Ph.D. program.
- Define and justify the selection and re-appointment criteria for the training grant supported trainees in the program.

Retention and Support

- Applicants may use this section to expand upon the Trainee Retention Plan (provided in the "Other Attachments") and to provide evidence of the program's commitment to ensuring the well-being and success of all trainees throughout their graduate training.
- Describe the ability for participating department(s) and/or the institution(s) to support trainees for the duration of their graduate careers.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for training grant eligible students for the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required training tables (https://grants.nih.gov/grants/forms/data-tables.htm). Although the training tables for new applications only allow for five years of recent outcomes, the application may describe up to 15 years of outcomes in the narrative. The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in Training Table 5A (https://grants.nih.gov/grants/forms/data-tables.htm), or other measures of scientific accomplishment appropriate to the field);
- The rate of Ph.D. degree attainment and time-to-degree for recent graduates (Training Table 8A (https://grants.nih.gov/grants/forms/data-tables.htm)). Verify in the text that the time-to-degree was calculated according to the table instructions;
- A description or analysis of how the Ph.D. degree attainment, time-to-degree data, and evidence of scholarly productivity (e.g., peer-reviewed publications, or other measures of scientific accomplishment appropriate to the field) for recent program graduates from underrepresented groups (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) compares to the data for recent program graduates from well-represented groups; and
- The success of recent graduates transitioning to careers in the biomedical research workforce (Training Table 8A (https://grants.nih.gov/grants/forms/data-tables.htm)).

Program Evaluation and Dissemination

NIGMS funded training programs must conduct ongoing evaluations to monitor the success of the training and mentoring activities. The application should describe:

- The evaluation or assessment process to determine whether the overall program is effective in meeting its training mission and objectives, and whether the scientific research climate is inclusive, safe, and supportive of trainee development (the application may include the "Evaluation and Assessment Instruments" Appendix to provide blank survey instruments, rubrics, or forms);
- Plans for being responsive to outcomes analyses, critiques, surveys and evaluations;
- Past activities to track and post the career outcomes of trainees (applicants should expand upon, but not duplicate the information in the Outcomes Data Collection and Storage Plan); and
- Past activities designed to share the outcomes of the training or mentoring interventions with the broader community (applicants should expand upon, but not duplicate the information in the Dissemination Plan).

Plan for Instruction in the Responsible Conduct of Research

Applicants are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in the SF424 (R&R) Application Guide, along with the following additional instructions:

Describe how the Responsible Conduct of Research (RCR) components are well integrated into the overall curriculum, i.e., how they are taught at multiple stages of trainee development and in a variety of formats and contexts. Explain how the teaching of RCR synergizes with elements of the curriculum designed to enhance trainees abilities to conduct rigorous and reproducible research. Describe how all participating faculty will reiterate and augment key elements of responsible conduct when trainees are performing mentored research in their laboratories.

Plan for Instruction in Methods for Enhancing Reproducibility

Applicants are required to provide a Plan for Instruction in Methods for Enhancing Reproducibility as provided in the SF424 (R&R) Application Guide.

Applicants are encouraged to consult the NIGMS clearinghouse for training modules to enhance data reproducibility (https://www.nigms.nih.gov/training/pages/clearinghouse-for-training-modules-to-enhance-data-reproducibility.aspx) and other resources when developing the plans.

Progress Report (only for Renewal applications)

For applications describing programs that were previously funded under PAR-19-037 (https://grants.nih.gov/grants/guide/pa-files/par-19-037.html) follow the instructions provided in the SF424 (R&R) Application Guide with the following exceptions:

For the "Program Overview" section, follow the page limit indicated in the SF424 (R&R) application guide, but follow the instructions below instead:

- Indicate the period covered since the last competitive review.
- Include information to demonstrate that the program successfully trained a diverse pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce.
- Describe successes and challenges with regards to implementing the programmatic elements described in the previous application, including but not limited to the following areas:

  o Incorporating evidence-informed training and mentoring practices into the program.

  o Teaching of rigor and transparency, and the responsible and safe conduct of research throughout the training experience.

  o The challenges and successes for enhancing diversity and inclusion.

  o Overseeing all aspects of the program (e.g., of the mentor/mentee matches, the participating faculty, and trainee progress).

  o Preparing trainees for a broad range of careers in the biomedical research workforce (including but not limited to the use of Individual Development Plans, IDPs).

- Provide justifications for failing to implement previously proposed programmatic elements.
- Provide evidence that the specific and measurable objectives described in the previous application were achieved and if not, provide a justification for failing to achieve the objectives.
- Describe how the funds provided under "Training Related Expenses" were used to benefit the program.
- Provide the methods and results of the evaluations of the program activities. Indicate whether the training activities were effective in contributing to the program objectives.
- Provide evidence that the scientific research climate is inclusive, safe, and supportive of trainee development.

- Expand upon the "Training Outcomes" to highlight successes and areas for improvement.
- Describe how the program responded to outcomes analyses, critiques, surveys and evaluations. Describe the barriers to success and indicate changes to the program designed to address these barriers.
- Describe how the program makes training and career outcomes publicly available.
- Indicate whether the PD(s)/PI(s) disseminated nationally any findings or materials developed under the auspices of the program to the broader training community.
- Indicate the broader impact of the program (e.g., on the curriculum, training environment, or institutional practices).
- Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Participating faculty should provide a personal statement that describes the appropriateness of their research background for the proposed training program, and their commitment to the following:

- Training, mentoring, and promoting inclusive, safe and supportive research environments;
- Maintaining a record of, and providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results;
- Promoting the use of highest standards of practice to ensure the safety of all individuals in the research environment;
- Supporting trainees participating in activities required to identify and transition into careers in the biomedical research workforce that are consistent with the trainees skills, interests, and values; and
- Fulfilling the need of the trainees to complete their Ph.D. degrees in a timely fashion with the skills, credentials, and experiences to transition into careers in the biomedical research workforce.

Letters of Support

Institutional Support Letter (10-page maximum). The application must include a signed letter on institutional letterhead from a President, Provost, Dean, or similar key institutional leader that describes the activities and resources provided by the institution that are designed to ensure the success of the planned training program and its trainees. If this letter is not included, the application will be considered incomplete and will not be reviewed. The institutional commitment to the following areas should be described (as applicable):

- Developing and promoting a culture in which the highest standards of safety, scientific rigor, reproducibility, and responsible conduct are advanced;
- Ensuring sufficient start-up funding to permit early stage faculty to participate in training, and bridge funding to ensure that training may continue if a mentor experiences a hiatus in funds;
- Supporting core facilities and technology resources, and describing how they can be used to enhance training;
- Providing adequate staff, facilities, and educational resources to the planned program;
- Supporting the PDs/PIs and other key staff associated with the planned training program;
- Fostering and rewarding excellence in training (e.g., through institutional polices such as tenure and promotion);
- Supporting the remediation or removal of Participating Faculty from the program who are poorly performing mentors;
- Promoting diversity and inclusion at all levels of the research training environment (trainees, staff, faculty, and leadership);
- Ensuring a positive, supportive and inclusive research and training environment for individuals from all backgrounds;
- Ensuring the research facilities and laboratory practices promote the safety of trainees;
- Guaranteeing the research facilities are accessible to trainees with disabilities;
- Ensuring that proper policies, procedures, and oversight are in place to 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-19-029 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-029.html));
- Providing trainees access to student support services, such as healthcare, counseling services, and housing;
- Ensuring that trainees will continue to be supported when they transition from the training grant to other sources of support;
- Providing resources and expertise for evaluating the training outcomes of the program; and
- For institutions that have multiple NIGMS-funded predoctoral training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones.

Institutional Eligibility Letter. (1-page maximum). The Provost or similar official with institution-wide responsibility must certify that all the components of the institution under the applicant DUNS or IPF number together have an average of RPG funding greater than or equal to $7.5 million total costs (both direct and F&A/indirect costs) per year over the past 3 fiscal years, as described in Section III, "Eligible Organization". If this letter is not included, the application will be considered incomplete and will not be reviewed.

Other Letters of Support. Additional letters of support (e.g., from partner institutions or organizations) are permitted; however, these letters may not contain any information required in the Institutional Support Letter.

Combine all Letters of Support into a single PDF file.

Data Tables: The application must include the required Training Data Tables (https://grants.nih.gov/grants/guide/url_redirect.htm?id=61169). For New applications: Tables 1, 2, 3, 4, 5A, and 8A Part III. For Renewals: Tables 1, 2, 3, 4, 5A, 7, and 8A. Applications that do not contain the required tables, or that submit any additional tables in this attachment, will be considered noncompliant 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 theSF424 (R&R) Application Guide instructions.

The Appendix is meant to provide additional details to the following topics but is not meant to substitute for clear descriptions in the body of the application. Do not use the Appendix to circumvent page limits. Do not include items other than the required and allowable materials described below, as doing so will result in administrative withdrawal of the application prior to review. Name the file according to the headings below. A summary sheet listing all the items included in the Appendix may be included in the first Appendix attachment.

The following are required Appendix materials:

- Required Training Activities. To adequately assess the content of the didactic portion of the training program, the application must include syllabi/outlines of all required training activities (e.g., syllabi for courses, mentor training materials, professional development workshops, career exploration opportunities, skills development activities).
- Responsible Conduct of Research Syllabi. In addition to the Plan for Instruction in the Responsible Conduct of Research, the application must provide syllabi/outlines of materials relating to Responsible Conduct of Research and descriptions of when in the trainees career paths the material is taught.

The following are allowable Appendix materials:

- Elective Activities. The application may include summary content from up to four additional elective courses and/or training activities (e.g., syllabi or summaries for courses, mentor training materials, outlines of professional development workshops, career exploration opportunities, or skills development activities).
- Evaluation and Assessment Instruments. The application may include blank surveys, rubrics, and/or forms used to (a) document and monitor trainee progress and (b) determine whether the training and research environment is effective, inclusive, safe, and supportive.
- Conflict Resolution Protocols (3-page maximum). The application may include detailed protocols for addressing problems with trainee and faculty matches, removal of faculty from the training program with unacceptable training/mentoring skills and for conflict resolutions for multi PD(s)/PI(s) and mentor/mentee relationships.

Applications that do not include the required appendices or that exceed the number of allowed appendices or the page limitation of any of the allowed materials will be considered noncompliant and will not be reviewed.

PHS Human Subjects and Clinical Trials Information

Generally, not applicable. All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional modifications:

Study Record: PHS Human Subjects and Clinical Trials Information

DO NOT USE. Attempts to submit a full, detailed study record will result in a validation error.

Delayed Onset Study

Generally, not applicable. Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a program that will not start immediately (i.e., delayed start).

PHS Assignment Request Form

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

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/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?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 intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120). The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

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 How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your

control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. 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.

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 (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

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

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

Applicants Requesting $500,000 or more for direct costs (less consortium F&A) in any year

Applicants requesting $500,000 or more in direct costs in any year **are not required** to contact a Scientific/ Research Contact prior to submitting an application. The Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide **is not** applicable to this FOA.

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

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

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will produce a diverse pool of well-trained scientists with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design, and interpretation of data), and professional (e.g., management, leadership, communication, and teamwork) skills necessary to conduct rigorous and reproducible research, and transition into careers in the biomedical research workforce, in consideration of the following review criteria and additional review criteria (as applicable for the program proposed).

Specifically, do the courses, structured training activities, mentoring, and research experiences equip the trainees with:

- A broad understanding across biomedical disciplines;
- Expertise in a basic biomedical scientific discipline and the skills to independently acquire the knowledge needed to advance their chosen fields;
- The ability to think critically and independently, and to identify important biomedical research questions and approaches that push forward the boundaries of their areas of study;
- A strong foundation in scientific reasoning, rigorous research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting, and presenting rigorous and reproducible biomedical research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds, and to promote inclusive and supportive scientific research environments;

- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills and experiences required to identify and transition into careers in the biomedical research workforce (i.e., the breadth of careers that sustain biomedical research in areas that are relevant to the NIH mission).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program 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.

Training Program and Environment

Rationale, Mission, and Objectives

- Does the application provide a compelling rationale for the proposed research training program?
- Does the proposed program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines (Table 1), program faculty with the appropriate scientific expertise (Tables 2 and 4), and resources to achieve the training objectives (Table 3)?
- Are the mission and objectives for the training program specific and measurable and in alignment with the goal of producing a diverse pool of well-trained scientists with the technical, operational, and professional skills necessary to transition into careers in the biomedical research workforce?

Curriculum and Overall Training Plan

- Will the courses, structured training activities, mentoring, and research experiences achieve the stated mission and objectives of the training program?
- Does the application propose changes in the program's research training and mentoring practices to effectively address the rapidly evolving biomedical research enterprise and current understanding of evidence-informed training and mentoring approaches?
- Is the mechanism for ensuring that the trainees are learning the highest standards of practice in biomedical research (e.g., record keeping and safety) robust?
- Will the Participating Faculty teach laboratory safety throughout the didactic and mentored portions of the program?
- Does the training program plan provide a compelling explanation of how the courses, structured training activities, mentoring, and research experiences employ modern, evidence-informed approaches that are likely to enhance the success of the trainees?
- Are the activities likely to build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members?
- Do the required and elective training elements (e.g., syllabi, course descriptions) provide compelling evidence that the trainees will gain the requisite skills for the discipline in a timely fashion and that there are mechanisms to ensure that the trainees will be guided, monitored, and evaluated?
- Are there plans to accommodate differences in preparation among trainees?
- Is it clear how the proposed program will enhance the research training environment and not simply provide financial assistance for the trainees?
- Is it clear how the training activities will be available to other students in the program(s), department(s), or institution(s) from which the trainees are drawn?
- For multi-disciplinary and/or multi-departmental programs, is it clear how the individual disciplinary and/or departmental components of the program are integrated and coordinated, and how each will relate to an individual trainee's experience?
- If applicable, is the proposed program distinct from, but planning to share resources and synergize with other NIGMS-funded predoctoral training programs at the institution (listed in Training Table 3, and reinforced in the Institutional Support Letter)?

Career Development

- Will the applicants and trainees be provided with information about the career outcomes of graduates of the program and about the overall biomedical research workforce employment landscape?
- Will the trainees be provided with adequate and appropriate information regarding the wide variety of careers in the biomedical research workforce for which their training may be useful?
- Will the program engage with potential employers to ensure that the trainees acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them?
- Will the training program or institution provide experiential learning opportunities (e.g. internships, shadowing, informational interviews) that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce?

Program Oversight, Participating Faculty Selection, and Mentor Training

- Does the application describe an effective strategy and administrative structure to oversee and monitor the program to ensure appropriate and timely trainee progress for the duration of the trainees' graduate careers?
- Is selection of the program faculty based on a commitment to training and mentoring, and not simply research productivity?
- Will the participating faculty be trained to ensure the use of evidence-informed teaching and mentoring practices that promote the development of trainees from all backgrounds?
- Do the participating faculty have a record of employing the highest standards of rigor and transparency in their research, and plans to impart those standards to their trainees?
- Will the program ensure that program faculty reinforce and augment the curricular material on responsible conduct of research, and methods for enhancing reproducibility?
- Is there a clear mechanism for matching the trainees with appropriate program faculty (e.g., laboratory rotations, faculty forums and interviews)?
- Is there a plan to ensure that the participating faculty engage in activities that promote trainee career development (including but not limited to the utilization of Individual Development Plans), and fulfill the need of the trainees to obtain their Ph.D. degrees in a timely fashion with the skills, credentials and experiences to transition into careers in the biomedical research workforce that are consistent with the trainees' interests, and values?
- Is there an effective mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing participating faculty displaying unacceptable mentorship qualities from the training program?
- If a program coordinator or administrator position is planned, will the person's administrative capabilities contribute to the success of the program?

Institutional and Departmental Commitment to the Program

- Will the institutional and departmental commitment to research and training excellence promote the success of the trainees and training program?
- Is there a clear institutional commitment to develop and promote a culture in which the highest standards of safety, scientific rigor, reproducibility, and responsible conduct of research are advanced?
- Does the institution provide sufficient start-up funding to permit early stage faculty to participate in training, and bridge funding to ensure that training may continue if a mentor experiences a hiatus in funds?
- Are the core facilities and technology resources necessary for the success of the program well supported?
- Is there adequate support of the PD(s)/PI(s) and other key staff, facilities, and educational resources associated with the training program?
- Do participating faculty have sufficient protected time available to devote to the training and mentoring activities?
- Is there evidence that the institution rewards excellence in training and mentoring through institutional policies?
- Does the institution support the remediation or removal of Participating Faculty from the program who are poorly performing mentors?
- Are diversity and inclusion efforts promoted at all levels of the research training environment (trainees, staff, faculty, and leadership)?
- Does the institution promote a positive, supportive, safe and inclusive research and training environment for individuals from all backgrounds?
- Is there evidence that the research facilities and laboratory practices ensure the safety of trainees?
- Is a process in place to address access issues for trainees with identified disabilities?
- Are appropriate policies and procedures in place to protect trainees from harassment and other prohibited practices?

- Is there evidence of an institutional commitment to providing the trainees access to student support services, such as health care, counseling services, and housing?
- Is there a commitment to ensure that trainees will continue to be supported when they transition from the training grant to other sources of support?
- Are the resources and expertise for evaluating the current and future training outcomes of the program appropriate?
- Does the program plan describe the changes the graduate program(s), department(s) and/or the institution(s) will make to better support the goals of the training program?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/PI(s) have the scientific expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) have the time to commit sufficient effort to ensure the program's success, given their other professional obligations?
- Does at least one member of the PD/PI team have a demonstrated record of using rigorous and transparent methods in experimental design, data collection, analysis, and reporting in the proposed scientific field?
- Have the PD(s)/PI(s) received training on how to effectively mentor trainees, including those from underrepresented groups, and promote inclusive, safe, and supportive research training environments?
- Do the PD(s)/PI(s) have a demonstrated commitment to training the next generation of the biomedical research workforce, leading recruitment efforts to enhance diversity, and fostering inclusive research environments?
- Is there a strong administrative structure and leadership succession plan for critical positions (e.g., PD/PI)?

For applications designating multiple PD(s)/PI(s):

- Will the multiple PD/PI leadership approach benefit the trainees and enhance the ability of the program to achieve its training goals?
- Is there a clear leadership plan including the designated roles and responsibilities, governance, conflict resolution procedures, and organizational structure (see Multiple PD/PI Leadership Plan section)?

Preceptors/Mentors (Participating Faculty)

- Do the participating faculty describe a compelling commitment to rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results?
- Do the participating faculty describe a compelling commitment to ethically sound and responsible scientific research?
- Do the participating faculty have plans to promote the use of highest standards of practice to ensure the safety of all individuals in the research environment?
- Do the selected program faculty come from various backgrounds, for example, individuals from groups underrepresented in the biomedical sciences, women, as well as faculty at different career stages (i.e., junior and senior faculty)? If not, are there plans to recruit faculty to enhance the diversity?
- Do the participating faculty have the time to commit sufficient effort to ensure trainee development and success, given their other professional obligations?
- Is there evidence that the participating faculty cooperate, interact, and collaborate (which can include joint sponsorship of trainee research)?
- Do the participating faculty provide opportunities for trainees to initiate, conduct, interpret, and present rigorous and reproducible biomedical research with increasing self-direction?
- Do the participating faculty have plans for ensuring their trainees develop skills in approaches to experimental design, as well as methods of data collection, analysis, interpretation, and reporting?
- Do the participating faculty demonstrate a commitment to effective mentoring, and promoting inclusive, safe, and supportive scientific and training environments?
- Are the participating faculty willing to engage in activities to promote the trainees career goals and to support trainees participating in activities required to identify and transition into careers in the biomedical research workforce that are consistent with the trainees' skills, interests, and values?
- Do the participating faculty have a commitment to fulfilling the need of the trainees to obtain their Ph.D. degrees in a timely fashion with the skills, credentials, and experiences to transition into careers in the biomedical research workforce?

Application Process, Trainee Positions, Retention, and Support

Application Process

- Is a candidate review process proposed that will allow a broad group of trainees, who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise, the ability to participate in the training program? Does the process consider metrics beyond undergraduate institution, GPA, and standardized test scores?
- If the program trainees are drawn from multiple departments, is the review process consistent across all relevant departments?
- Is the training program's approach to recruiting and admitting students appropriate (e.g., direct admissions as first year Ph.D. students into the program versus appointment of students admitted to other departments or Ph.D. programs)?

Funded Positions

- Does the application provide a strong justification for the number of requested funded trainee positions given the pool of potential trainees, the size of the proposed program, the number of participating faculty, and other NIGMS funded training programs?
- Are there well-defined and justified selection and re-appointment criteria for trainees in the training program?
- Are trainees being appointed at the appropriate stage in order to most strongly benefit from the training program (e.g., in the first three years)?

Retention and Support

- Is there an adequate, evidence-informed retention plan to ensure the well-being and success of all trainees throughout their graduate training (see the "Trainee Retention Plan" attachment)?
- Does the institution have the resources to support trainees for the duration of their graduate careers?

Training Record

Training Outcomes for Trainees (renewals) or Training Grant Eligible Pool (new applications)

- Does the application provide evidence the trainees (or training grant eligible pool) conducted rigorous research that advanced scientific knowledge and/or technologies with increasing self-direction (e.g., peer-reviewed publications listed in Table 5A, and other accomplishments appropriate to the field)?
- Does the rate of Ph.D. degree attainment and time-to-degree for the trainees (or training grant eligible pool) indicate that these students completed their degrees at a high rate in a timely fashion (Training Table 8A)?
- Are completion rates, time-to-degree, and scholarly outcomes for the trainees (or training grant eligible pool) from underrepresented groups (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) comparable to those from well-represented groups?
- Are the trainees (or individuals in the training grant eligible pool) transitioning to careers in the biomedical research workforce (i.e., the breadth of careers involved in the conduct and support of biomedical research in areas that are relevant to the NIH mission; Training Table 8A)?

Program Evaluation

- Is there a well thought out evaluation or assessment plan to determine whether the overall program is effective in meeting its training mission and objectives, and whether the training and scientific research climates are inclusive and supportive of trainee development (narrative and "Evaluation and Assessment Instruments" Appendix)?
- Is there evidence that the program has been and/or will be responsive to outcomes, critiques and evaluations?
- Does the training program have an appropriate plan to track trainee outcomes and make the data publicly available (e.g., on the institution's website)?

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.

Training in Methods for Enhancing Reproducibility

Does the Instruction in Methods for Enhancing Reproducibility plan describe how trainees will be instructed in principles important for enhancing research reproducibility including, at a minimum, evaluation of foundational research underlying a project, rigorous experimental design and data analysis, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, data and material sharing, record keeping, and transparency in reporting? Are the rigor and transparency components sufficiently well integrated into the overall curriculum? Are they taught at multiple stages of trainee development and in a variety of formats and contexts? Does the teaching synergize with elements of the curriculum designed to enhance trainees' abilities to conduct responsible research? Is there evidence that all participating faculty reiterate and augment key elements of methods for enhancing reproducibility when trainees are performing mentored in research their laboratories? The plan will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

Recruitment Plan to Enhance Diversity

Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of prospective individuals from underrepresented groups. The plan will be rated as ACCEPTABLE or UNACCEPTABLE, and the consensus of the review committee will be included in an administrative note in the summary statement.

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 specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) **Format** - Does the plan satisfactorily address the format of instruction, e.g. lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (A plan involving only on-line instruction is not acceptable); 2) **Subject Matter** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, and research ethics? 3) **Faculty Participation** - Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) **Duration of Instruction** - Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) **Frequency of Instruction** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

Are the RCR components sufficiently well integrated into the overall curriculum? Are they taught at multiple stages of trainee development and in a variety of formats and contexts? Does the teaching of RCR synergize with elements of the curriculum designed to enhance trainees' abilities to conduct rigorous and reproducible research? Is there evidence that all participating faculty reiterate and augment key elements of responsible conduct when trainees are performing mentored research their laboratories?

Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

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. Undue weight should not be given for simply responding to previous comments; instead the content of the responses and how the application project will be improved by any proposed changes should be considered.

Renewals

For Renewals, the committee will consider the progress made in the last funding period, including on the Training in Methods for Enhancing Reproducibility Plan, Recruitment Plan to Enhance Diversity, and Training in the Responsible Conduct of Research Plan.

- Did the training grant team successfully implement the proposed programmatic elements?
- Is the program achieving its training objectives?
- Is there evidence that the training environment is inclusive, safe, and supportive?
- Has the program evaluated the quality and effectiveness of the training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are changes proposed that are likely to improve or strengthen the research training experience during the next project period?
- Does the program continue to evolve to reflect changes in the research area in which the training occurs and current evidence-informed training and mentoring approaches?
- Is the program having a broader impact (e.g., are students beyond the trainees directly supported by the program being positively impacted by the program's presence, are training practices and outcomes being shared with the broader biomedical training community)?

Revisions

Not Applicable

Additional Review Considerations

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

Select Agent Research

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

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), convened by the NIGMS Scientific Review (https://www.nigms.nih.gov/training/pages/ReviewProcess.aspx) Branch in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

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

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the National Advisory General Medical Sciences Council. 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.

- Geographic distribution of the NIGMS training grant portfolio.

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.htm?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.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

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

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

Awardees must comply with any funding restrictions described in 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.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

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 (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the *NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=61170).

The taxability of stipends is described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171).

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the grantee institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

Other Reporting Requirements

- The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Grantees must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.
- A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)). Individuals with a Conditional Permanent Resident status must first meet full (non-conditional) Permanent Residency requirements before receiving support.
- Termination Notice: Within 30 days of the end of the total support period, the institution must submit a Termination Notice (PHS Form 416-7 (//grants.nih.gov/grants/guide/url_redirect.htm?id=41179)) via xTrain (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183) for each trainee appointed for eight weeks or more.

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

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. Trainees 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 10 years of making awards under this program, NIGMS will assess the program's overall outcomes.

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

- Institution types represented
- Geographical distribution of programs
- Demographics of trainees
- Trainee Ph.D. completion rates
- Time-to-degree
- Scientific accomplishments of trainees
- Trainee career outcomes

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Commons Help Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)

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

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Shakira Nelson, Ph.D.
National Institute of General Medical Sciences (NIGMS)
Email: shakira.nelson@nih.gov (mailto:shakira.nelson@nih.gov)

Mercedes Rubio, Ph.D.
National Institute of General Medical Sciences (NIGMS)
Email: rubiome@mail.nih.gov (mailto:rubiome@mail.nih.gov)

Peer Review Contact(s)

Stephanie Constant, Ph.D.
National Institute of General Medical Sciences
Email: stephanie.constant@nih.gov (mailto:stephanie.constant@nih.gov)

Financial/Grants Management Contact(s)

Justin Rosenzweig
National Institute of General Medical Sciences
Email: rosenzwj@nigms.nih.gov (mailto:rosenzwj@nigms.nih.gov)

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Section 487 of the Public Health Service Act as amended (42 USC 288) and under Federal Regulations 42 CFR 66.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?11-20-20)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

(https://www.usa.gov/)

NIH... Turning Discovery Into Health®

EXHIBIT D

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: [redacted]
Subject: [External] NIGMS Funding Update
Date: Wednesday, April 2, 2025 [redacted]

Re: [redacted]

Dear Dr. [redacted]

I am writing to let you know that due to changes in NIH/HHS priorities, the **Initiative for Maximizing Student Development (IMSD)** 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. We advise against recruiting future cohorts.

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 and include your 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