EXHIBIT 39

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*,

v.

Plaintiffs,

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

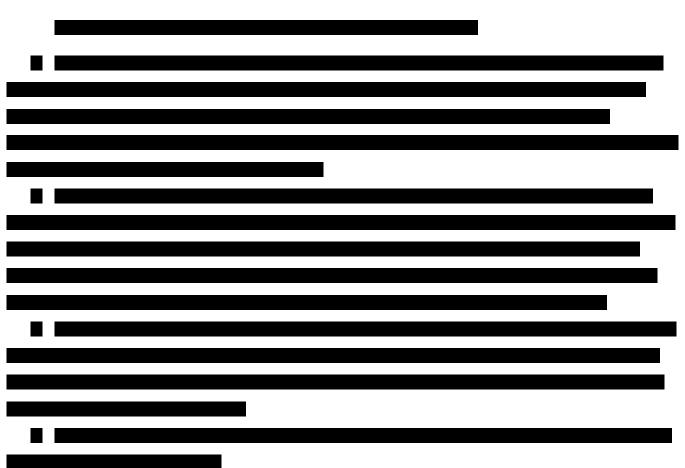
April 24, 2025 (ECF No. 36)

Leave to File Under Seal Granted

NATIONAL INSTITUTES OF HEALTH, *et al.*,

Defendants.

DECLARATION OF UAW MEMBER 10



5. The IRACDA program is funded by the National Institute of Health ("NIH") through the National Institute of General Medical Sciences ("NIGMS"). The grant award number for UCSD's

IRACDA program is 5K12GM068524-22. A true and correct copy of NIH's RePORTER webpage containing information about UCSD's grant is attached hereto as Exhibit A.

6. According to the funding opportunity to which I applied, PAR-19-366, the purpose of the IRACDA Program is to support postdoctoral scholars from diverse backgrounds in their transition to academic independence by combining research and teaching training. As described on UCSD's website, https://hsfacultyaffairs.ucsd.edu/sd-iracda-postdoc-program/index.html, the IRACDA program "provides three years of mentored training in post-doctoral research in biomedical sciences . . . mentored teaching training at our partner institutions [,] and development of critical academic skills needed to conduct high quality research and pursue an independent academic career. The IRACDA program aims especially to develop a diverse group of highly trained biomedical scientists. Other specific objectives are to innovate, redesign, and develop science curriculum at teaching-intensive partner institutions and to establish links between UCSD and our partner institutions to promote collaborations in faculty research and student training." A true and correct copy of PAR 19-366 is attached hereto as Exhibit B.

7. As stated in an email I received from Dr. JoAnn Trejo, one of the UCSD leaders of the IRACDA program, the San Diego IRACDA program has had twenty-two continuous years of funding, with four successful competitive grant renewals. SD IRACDA has trained over 134 postdoctoral fellows. All our alumni are employed in science, sixty-five percent have obtained faculty positions at academic institutions, including thirty percent in R1 (research-intensive institutions), twenty-six percent in R2 (teaching and research) institutions, and eight percent in teaching-focused institutions. Almost all our faculty alumni, ninety percent, are in tenured-track positions, and sixty-one percent of faculty have gained extramural funding from various agencies, including the NIH, NSF, USDA, DOD, AHA and National Geographic. A true and correct copy of the email announcing termination of the IRACDA program is attached hereto as Exhibit C.

8. My research examines how the brain changes during pregnancy to enable adaptive parental behaviors. Specifically, I focus on the hypothalamus to understand molecular and physiological shifts that coordinate parental care. This work addresses longstanding questions in neuroendocrinology and behavioral neuroscience and supports NIH's mission to uncover mechanisms of health-related behavior across the lifespan. My interest in this topic grew from years of studying how internal state and context shape social behavior—from fieldwork to molecular systems. Pregnancy is a time of significant changes to the brain and body, driven by hormonal shifts and the need to support a growing fetus. Studying this dynamic period can reveal how the brain adapts, offering insights into neuroplasticity and the impact of biological and environmental factors on brain function. This research is vital for understanding

pregnancy-related mental health issues, like postpartum depression, and can inform better treatments. It also has broader implications for maternal bonding, parenting, and child development, ultimately improving healthcare and well-being for women and families.

9. This diversity-centered training framework was articulated in the application process and was a significant focus of both my proposed mentoring and teaching activities. I was selected through a competitive review based on scientific merit and alignment with the program's dual focus on high-impact research and inclusive pedagogy. The decision to rescind the award—despite its compliance with the original NOFO criteria—has had a direct and detrimental effect on my research progress and my structured career development plan toward academic independence, as I detail below.

10. The IRACDA application required extensive planning over several months. I collaborated with research and teaching mentors, developed a comprehensive training and research plan, and received feedback through multiple rounds of internal and external review. I consulted with my IRACDA Program Coordinators to ensure the project aligned with programmatic goals and refined my application accordingly. The process reflected a high level of scrutiny and rigor consistent with NIH funding standards.

11. I was awarded the IRACDA Fellowship in May 2024 and am currently in the end of my first year of the three-year program. The training timeline includes mentored research, teaching development, and academic career preparation. The sudden cancellation of the program has disrupted that timeline at a critical career transition point.

12. Since the start of the fellowship, I have launched a new line of research examining maternal brain plasticity. I've developed protocols, completed experiments, mentored undergraduate researchers, and presented my work at invited talks at multiple institutions. I have also participated in IRACDA's structured pedagogy training and built relationships with local institutions that served underrepresented groups in STEM, particularly with San Diego State University ("SDSU"). My engagement with this local institution is rooted in a commitment to mentorship, inclusive teaching, and skill-building for students from historically marginalized backgrounds. At SDSU, I have actively participated in the Maximizing Access to Research Careers ("MARC") and the College Assistance Migrant Program ("CASA"). These programs aim to provide support and resources to students from underserved backgrounds, empowering them to succeed in STEM fields.

13. As part of my engagement, I have led multiple workshops that focus on developing research skills, effective communication, and professional development. These workshops were designed to help students gain confidence and improve their ability to present and discuss their research in both academic

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and professional settings. Additionally, I have provided valuable feedback on student research talks, helping to refine their communication strategies and enhance the quality of their presentations. Through my involvement in these programs, I've been able to contribute to creating an inclusive academic environment that prioritizes access to education and mentorship for students from historically marginalized groups. I believe that supporting underrepresented groups in STEM is not only essential for social equity but also for the continued advancement of scientific discovery. By fostering a diverse and inclusive community, we can ensure that a wider range of perspectives, experiences, and ideas are brought into the field, which ultimately enriches the scientific process and its outcomes.

14. While my teaching and mentoring at SDSU through the MARC and CASA programs is a significant aspect of my outreach work, it represents only a portion of the broader commitment I've made as a postdoctoral fellow to support equity and inclusion in science. At the "UCSD", I am actively involved in the Jail Outreach Program, whose goal is to teach incarcerated individuals about science, aiming to make scientific knowledge accessible and empowering to all, regardless of background or circumstance. I also mentor undergraduate students in the lab, helping them develop technical skills, confidence, and a deeper understanding of the research process. Additionally, I coordinate science outreach activities for elementary school students in rural communities—bringing hands-on learning experiences to students who might otherwise have limited exposure to STEM fields.

15. This work is ongoing and deeply integrated into my academic career. It is not only driven by a commitment to service but also designed to culminate in scholarly outputs, including publications and future faculty job applications. Any disruption to this fellowship jeopardizes far more than short-term research productivity—it puts at risk a comprehensive effort to broaden participation in science and my long-term academic trajectory.

16. The current grant for UCSD's IRACDA program has a project start date of August 1, 2003 and end date of June 30, 2026. On April 2, 2025, less than a year into my IRACDA fellowship, Kenneth D. Gibbs, Jr., Director of the Division of Training and Workforce Development at the NIGMS sent an email titled "NIGMS Funding Update" to Dr. Joann Trejo, program coordinator of the UCSD IRACDA program stating that the IRACDA program had been "terminated" "due to changes in NIH/HHS priorities." See Exhibit C.

17. Both my lab and I made extensive scientific and logistical plans based on the assumption that I would have two more years of funding through IRACDA. This included designing multi-phase experiments, mentoring commitments, and time allocation for both research and pedagogical training.

The loss of this support now forces a major restructuring of these plans, with consequences for personnel, project feasibility, and timelines.

18. This decision is deeply harmful on multiple levels:

- a. **To my career**: The fellowship was designed to bridge me to academic independence. The unexpected loss of fellowship support forces a major shift in my academic career trajectory and jeopardizes my competitiveness for future faculty positions. My long-term goal is to secure a tenure-track faculty position focused on the neural basis of social behavior. The original fellowship was designed to give me financial stability and protected time needed to generate preliminary data, complete publications, and build a competitive research portfolio for the faculty job market within a specific window. Now, with two years of guaranteed stipend support suddenly lost, I will have to accelerate my timeline for applying to faculty positions significantly—by at least a full year. This compressed timeline means I will need to rush key steps in my career development, including the completion of experiments, data analysis, manuscript preparation, and the development of my independent research proposal. As a result, I may go on the job market with fewer completed projects and less mature publications than I had planned, weakening my competitiveness and narrowing the opportunities available to me. In addition, the loss of financial stability will likely require me to divert time toward securing stopgap funding or additional work responsibilities to support myself in the interim. These competing demands will further limit the time I can devote to strengthening my research portfolio at a critical career stage, making the transition to academic independence more difficult and less strategically timed.
- b. To the research: My project investigates how pregnancy reshapes the maternal brain—a question of both fundamental and translational significance. From a *fundamental* perspective, this research seeks to uncover the basic, underlying mechanisms that govern how pregnancy affects neural circuits, brain structure, and behavior. This involves exploring how hormonal changes, genetic factors, and environmental influences during pregnancy lead to either short-term or long-lasting changes in the maternal brain. Understanding these processes is essential to expanding our knowledge of neuroplasticity and the brain's ability to adapt to physiological states. Furthermore, a deeper understanding of brain-body interactions during pregnancy could lead to improved management of health conditions that involve both brain and bodily functions, such as

stress responses, metabolic health, and immune system changes during this critical period. From a *translational* standpoint (i.e., how this research translates to human-focused clinical research), this research holds significant potential for improving clinical outcomes, especially for women who experience pregnancy-related complications like perinatal mood disorders, postpartum depression, or cognitive changes. By translating basic research into clinical applications, we aim to identify potential biomarkers or therapeutic targets that could mitigate or prevent adverse neurological outcomes in mothers. However, the shortened timeline for this research will force experiments to be conducted in a hurried manner, potentially compromising the depth and rigor of the science. This could limit our ability to fully dissect the intricate molecular and behavioral processes at play, thus affecting both the robustness of the data and its broader applicability.

c. To the institution and broader field: UCSD invested in me as a Chancellor's and IRACDA Fellow. My research contributes to NIH priorities in maternal health, brain plasticity, and social behavior. Undermining this work not only wastes invested resources but potentially stalls progress in a vital area of public health.

19. I am seeking to file this declaration under seal because I am concerned about potential repercussions to my career. I fear that disclosure of my name as a participant in this litigation will result in reputational harm, especially given the current climate where individuals have been targeted for expressing principled views on diversity, equity, inclusion, due process, free speech, peaceful protest, or for opposing genocide.

20. I am also concerned that my participation could negatively affect how I am perceived by colleagues, both at my institution and in my broader field. This could impact future collaborations, mentorship opportunities, and the reception of my research. In the current political and institutional climate, we have seen university administrations—including at institutions like Columbia University—fail to protect their own students and faculty from targeted attacks for engaging in peaceful protest or expressing principled views related to free speech, diversity, equity, and inclusion. These precedents raise legitimate concerns that similar punitive or reputational consequences could arise for others, particularly those speaking out on these important issues. I believe that exercising caution in this context is both reasonable and necessary.

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21. I also fear that participating publicly could jeopardize my future eligibility for federal research funding. As an early-career scientist, access to such funding is essential to my long-term academic and research goals. Losing these opportunities would significantly disrupt my career trajectory.

22. I have talked to others in similar positions to me who have shared that they also fear participating in this suit or expressed concerns about my participation. They have privately expressed concern about participating due to fear of professional backlash and the potential impact on future funding or academic positions. They have also expressed support for my decision to proceed under seal.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 20th day of April 2025.



EXHIBIT A

Report > Reporter

Search Results > Project Details

>

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K Back to Search Results

- **Description**
- Details
- Sub-Projects
- Publications
- Outcomes
- L Clinical Studies
- News and More
- 3 History
- Similar Projects

San Diego IRACDA Scholars Program

Project Number 5K12GM068524-22

Former Number 3K12GM068524-18S1

Contact **PI/Project** Leader TREJO. JOANN

Awardee Organization **UNIVERSITY OF CALIFORNIA, SAN DIEGO**

H Description

Abstract Text

ABSTRACT A diverse U.S. biomedical research workforce is essential for developing innovation in basic, clinical, translational research and healthcare and is necessary for improving the nation's health. Despite decades of efforts to increase underrepresented racial / ethnic groups and women in science their proportional representation remains markedly low, especially in academia. The renewal application for the San Diego IRACDA Scholars Program aims to enhance the successful transition of diverse biomedical scientists into independent academic careers. San Diego "SD IRACDA" is a mentored postdoctoral career development training program that provides training in rigorous and reproducible research, teaching training based on scientific principles and professional skill development. SD IRACDA combines a mentored research-intensive experience at the University of California, San Diego (UCSD) and mentored teaching

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training experience at San Diego City College and San Diego State University (SDSU), two large undergraduate institutions that serve diverse student populations. The overarching goal of SD IRACDA is to enhance the transition of diverse biomedical scientists into independent academic careers, thereby increasing the diversity of academic faculty. The specific objectives are to: 1) recruit and train a diverse pool of postdoctoral scholars that conduct rigorous and reproducible research within the scope of the NIGMS-mission, 2) use evidencebased strategies to enhance career skill development and effective mentorship of postdoctoral scholars, and 3) to provide teaching training in scientific teaching principles and evidence-based practices. Other objectives are to enhance the science curriculum at our partner-teaching intensive institutions, and to provide research opportunities for partner institution faculty and students and role models and mentorship of students, thereby increasing the number of diverse students participating in research and entering graduate programs in biomedical sciences. Since its inception in 2003, SD IRACDA has trained 103 scholars, 62% are from underrepresented backgrounds and 59% are women. Program evaluation has demonstrated that 63% of all SD IRACDA scholars and 56% of underrepresented scholars have obtained independent faculty positions (94% tenure-track) including a high percentage at R1 institutions, 32% of all scholars and 34% of underrepresented scholars, respectively. Of SD IRACDA faculty alumni, 55% have received independent grant awards with the highest percentage (31%) from the NIH. SD IRACDA scholars publish, obtain academic faculty positions and receive post-fellowship funding at a greater rate compared to NIH F32-supported postdoctoral fellows at UCSD. SD IRACDA has further benefitted the partner institutions, San Diego City College and San Diego State University, by providing new and improved science curriculum, authentic research experiences and critical mentoring for underrepresented students to enhance academic advancement and train the next generation or scientists.

Public Health Relevance Statement

NARRATIVE The development of a highly skilled diverse workforce that will impact all aspects of health related research efforts is essential to sustain the Nation's research priorities, scientific and economic competitiveness. The San Diego IRACDA Program will address this need by providing rigorous training in research, teaching and critical academic skills to a diverse group of postdoctoral scholars who will seek independent research and teaching careers in academia. The San Diego IRACDA Program will also enrich the science curriculum, improve teaching and learning at two large Hispanic-serving institutions in the San Diego area and provide critical mentoring and research experiences for underrepresented students that will enhance the training of the next generation of scientists.

NIH Spending Category

No NIH Spending Category available.

Project Terms

Academia	Award	Biomedica	l Research				
California	Cities	Clinical					
Educational Curriculum							
Educational process of instructing							
Ethnic Population Evidence based practice							
Faculty	Fellowship	Funding	Goals				
Grant	Health H	lealthcare	Institution				
Mentors	Mentorsh	ip Missio	n				
National Institute of General Medical Sciences							

Details

Contact PI/ Project Leader	Other Pls Not Applicable	Program Official Name
Name TREJO, JOANN 🗗		NELSON, SHAKIRÁ M Contact
Title PROFESSOR Contact		View Email
View Email		

Organization

Name UNIVERSITY OF CALIFORNIA, SAN DIEGO

City LA JOLLA

Country UNITED STATES (US)

Department Type PHARMACOLOGY

Organization Type SCHOOLS OF MEDICINE

State Code CA Congressional District 50

Other Information

Opportunity Number PAR-19-366 Study Section

4/17/25, 8:50 AM	Case 1:25-cv-10787-BEM	Document 3866398T) Reiferen Development Study Section - C[TWD-C]			
		Fiscal Yea 2024	ar	Award Notice 19-June-202	
		Administering Institutes or Centers National Institute of General Medical Sciences			
		CFDA Coo 859	le		
		DUNS Number 804355790 UEI UYTTZT6G9DT1			
		Project Start Date 01-August-2003			
		Project End Date 30-June-2026 Budget Start Date 01-July-2024			
				Project Funding Information for 2024	
		Total Fund \$1,511,03	÷		
		Direct Costs \$1,416,669			
		Indirect C \$94,364	osts		
		Year	Funding IC		
	:	2024 Natio Scien	nal Institute of Ger ces	ne a l Medical	\$1,511,033

Sub Projects

No Sub Projects information available for 5K12GM068524-22

Publications

> Disclaimer

No Publications available for 5K12GM068524-22

Patents

No Patents information available for 5K12GM068524-22

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

No Outcomes available for 5K12GM068524-22

Clinical Studies

No Clinical Studies information available for 5K12GM068524-22

News and More

Related News Releases

No news release information available for 5K12GM068524-22

D History

No Historical information available for 5K12GM068524-22

Similar Projects

No Similar Projects information available for 5K12GM068524-22

EXHIBIT B

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

opportunities and notices.

Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

Funding Opportunity Title

Institutional Research and Academic Career Development Awards (IRACDA) (K12 -

Independent Clinical Trial Not Allowed)

Activity Code

K12 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k12&Search.x=0&Search_y=0&Search_Type=Activity) Physician Scientist Award Program (PSA)

Announcement Type

Reissue of PAR-16-103 (https://grants.nih.gov/grants/guide/pa-files/par-16-103.html)

Related Notices

- July 14, 2022 This PAR has been reissued as PAR-22-212 (//grants.nih.gov/grants/guide/pa-files/PAR-22-212.html)
- May 28, 2021 Notice of Change to the Instructions for Appendices in PAR-19-366. See Notice <u>NOT-GM-21-043</u>
 (<u>https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-043.html</u>).
- March 10, 2020 Reminder: FORMS-F Grant Application Forms & Instructions Must be Used for Due Dates On or After May 25, 2020- New Grant Application Instructions Now Available. See Notice <u>NOT-OD-20-077 (/grants/guide/notice-files/NOT-OD-20-077.html)</u>.
- January 22, 2020 (/grants/guide/notice-files/NOT-OD-20-058.html) Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. See Notice <u>NOT-OD-20-058 (/grants/guide/notice-files/NOT-OD-20-058.html)</u>.

Funding Opportunity Announcement (FOA) Number

PAR-19-366

Companion Funding Opportunity

None

Number of Applications

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

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

93.859

Funding Opportunity Purpose

The Institutional Research and Academic Career Development Award (IRACDA) Program provides support for a mentored postdoctoral research experience at a research-intensive institution combined with an opportunity to develop critical teaching and mentoring skills at a teaching-intensive partner institution with a diverse student population. Accordingly, the IRACDA program requires effective partnerships between a research-intensive institution and <u>a teaching-intensive partner institution that has a historical mission or a demonstrated commitment to educating students from groups underrepresented in the biomedical research workforce.</u>

The primary goal of the IRACDA program is to develop a diverse pool of well-trained biomedical scientists who have the necessary knowledge and skills to pursue independent academic teaching and research careers. An additional goal of the IRACDA program is to benefit the teaching-intensive partner institutions, e.g., by providing research-oriented, early career teachers, mentors, and role models for the students; enhancing science educational offerings; providing research opportunities for the faculty and students; and/or bringing expertise with state-of-the-art research methods and technologies.

This Funding Opportunity Announcement (FOA) does not allow appointed scholars 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 September 9, 2019

Open Date (Earliest Submission Date)

October 13, 2019

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

November 13, 2019; October 1, 2020; October 1, 2021

All applications are due by 5:00 PM local time of applicant organization. All <u>types of applications</u> 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

February-March, 2020; February-March, 2021; February-March, 2022

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Advisory Council Review

May 2020; May 2021; May 2022

Earliest Start Date

July 2020; July 2021; July 2022

Expiration Date

October 2, 2021

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 <u>NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)</u>). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in <u>Section IV</u>. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement Section I. Funding Opportunity Description

Overall Goal

The overall goal of the NIH Research Career Development program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral and clinical research needs. The Institutional Research and Academic Career Development Award (IRACDA) Program provides support for a mentored postdoctoral research experience at a research-intensive institution combined with an opportunity to develop critical teaching and mentoring skills at a teaching-intensive partner institution that has a historical mission or a demonstrated commitment to educating students from groups underrepresented in the biomedical research workforce.

Purpose and Background Information

The National Institutes of Health (NIH) recognizes the need to diversify the scientific workforce by enhancing the participation of individuals from groups identified as <u>underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)</u> in the 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 recognizes the growing need for a diverse cohort of biomedical faculty who are skilled researchers and effective teachers and mentors.

Program Objective

The Overarching Objective of the IRACDA program is to develop a diverse pool of well-trained biomedical scientists, who have 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 to transition successfully into independent academic careers in the biomedical research workforce. The IRACDA program provides support for a mentored postdoctoral research experience at a research-intensive institution combined with an opportunity at a teaching-intensive partner institution with a diverse student body to develop critical skills, including, but not limited to, the ability to:

- · Implement current evidence-based teaching, mentoring, and research training methods;
- Teach scientific research methodologies and findings to individuals from diverse backgrounds;
- · Work well in teams with colleagues from a variety of cultural and scientific backgrounds;
- · Mentor students with sensitivity to cultural differences; and
- Create inclusive, safe, and supportive teaching and learning environments.

An additional goal of the IRACDA program is to benefit the teaching-intensive partner institution(s). Examples of benefits include, but are not limited to, providing research-oriented, early career mentors and role models for the students, enhancing science educational offerings, providing research opportunities for the faculty and students, and bringing expertise with cutting edge research methods and technologies to the institution.

Program Considerations

Funded IRACDA programs must have a strong research base comprised of established scientists who will provide expertise, resources, and mentoring to the IRACDA scholars. The mentored research experience must fall within the scope of the <u>NIGMS</u> <u>mission (https://www.nigms.nih.gov/About/Overview/)</u>.

NIGMS recognizes that combining research and teaching in a single career development program involving partner institutions requires planning and coordination. Therefore, NIGMS intends to fund programs demonstrating strong working partnerships. All partners should be involved in the planning and execution of the various elements of the career development program.

Applicant institutions have latitude in the design of the program; however, career development activities, which should last 2-4 years, must include the following elements:

- A mentored research experience that is typical of other competitive postdoctoral opportunities. Nine-person months (75% of a full-time professional effort) must be spent on this activity. The research mentor will sponsor and oversee the proposed research development program and will ensure that the candidate receives the proper guidance and mentoring required for a potential independent research career. The candidate may conduct collaborative research with other experienced researchers, subject to approval of the IRACDA scholars career development mentor.
- Other mentored and/or didactic experiences to improve technical, operational and professional skills important for an
 individual to prosper in an academic environment. Three-person months (25% of a full-time professional effort) must be spent
 on mentored teaching and other mentored and/or didactic experiences. The timing of the teaching and skills development
 may be flexible over the academic year. For example, a plan might involve a 9-person month block of time devoted to
 research separated by a 3-person month block of time devoted to teaching and skills development. Alternatively, the
 workshops, didactics and mentored teaching may represent 3 person-months (25% of full-time professional effort)
 interspersed with mentored research throughout the year. To ensure the mentored research is maintained throughout the time
 on the award, scholars should not spend two years in mentored research and one year in the mentored teaching experience.

The scholars are expected to be supported full-time using IRACDA funding for up to three years provided their progress toward an independent academic career is on track and satisfactory. Applicants may, and are indeed encouraged to, propose the use of non-IRACDA funds to provide a four-year career development program, with the first or last three years of support from IRACDA and the remaining one year's support from the mentor or other source(s).

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Applicants must justify the proposed program size based on the research environment as well as the pool of research mentors and potential IRACDA scholars at the research-intensive institution, and the pool of teaching mentors available at the partner institution(s). NIGMS anticipates that most programs will have 3-4 scholars per cohort for an average size of 9-12 active scholars supported by the IRACDA funding at any one time. To ensure that a broad range of institutions are represented, NIGMS will cap the number of active scholars in any one program at 12.

Awardees are expected to attend the annual IRACDA Conference. The conference is organized by the grantee institutions on a rotating basis. Program Directors/Principal Investigators (PDs/PIs), as well as IRACDA scholars are expected to attend this meeting. These meetings feature keynote presentations by invited guests who are leaders in the areas of science, education, and public policy and administration. The IRACDA scholars are encouraged to present their career development award-supported research to their peers. The conference also provides an opportunity for the IRACDA PDs/PIs, NIGMS program staff, and scholars to exchange ideas about effective teaching pedagogies, discuss solutions for common challenges, and interact with their peers and NIGMS staff.

The proposed institutional research career development program may complement other, ongoing mentored research and career development programs at the applicant institution, but the proposed career development experiences must be distinct from those career development programs currently receiving Federal support.

Note: This Funding Opportunity Announcement (FOA) does not allow appointed scholars 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 <u>Section VIII. Other Information</u> for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New Renewal

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

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

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Other Award Budget Information

Personnel Costs

Individuals designing, directing, and implementing the career development program may request salary and fringe benefits appropriate for the person months devoted to the program. Salaries requested may not exceed the levels commensurate with the institution's policy for similar positions and may not exceed the congressionally mandated cap. If mentoring interactions and other activities with scholars are considered a regular part of an individual's academic duties, then any costs for such work representing additional compensation above Institutional Base Salary are not allowable from grant funds.

Limited program-related administrative and clerical salary costs associated distinctly with the program that are not normally provided by the applicant organization may be direct charges to the grant only when they are in accordance with applicable cost principles. When specifically identified and justified, these expenses must be itemized in Sections A and B, as appropriate, of the R&R Budget.

Salary support for the PD/PI/co-Investigators (or combination of multiple PDs/PIs/co-Investigators) is limited to 1.2 person months (i.e., 10% on a 12-month basis).

Salary support for other administrative personnel (e.g., program administrator/program coordinator and/or program assistant) at the research-intensive institution is limited to 6.0 person months.

Salary support for administrative personnel at the teaching-intensive institution(s) is allowed; this support is limited to 0.6 person months (i.e., 5% effort on a 12-month basis) per partner institution.

Salary support for the teaching mentor(s) at the partner institution is limited to 2.4 person months (i.e., 20% effort on a 12-month basis) per partner institution.

Scholar Costs

Scholars are those individuals who benefit from the proposed activities and experiences in the career development program. Scholar costs must be justified as specifically required for the proposed career development program and based on institutional policies for salaries paid to individuals in similar positions, regardless of the source of funds.

The budget request for scholars' cost may include salary/wages and fringe benefits to support full-time effort of the IRACDA scholars. The total salary requested for each scholar must be based on a full-time, 12-month staff appointment. The applicants should use their institutional salary scale that is consistent with the established salary structure at the applicant institution and with salaries provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary/wage structure. Salaries and fringe benefits for planned effort less than full time must be pro-rated accordingly in the application.

The application should clearly indicate the number of IRACDA appointments proposed for each year. The scholars may be supported by IRACDA funding for up to three years provided their progress towards an independent academic career is on track and satisfactory. Programs may not split funds for an awarded slot across two or more individuals. NIGMS will not award more than 12 slots to a program.

Appointed IRACDA scholars are expected to devote 12-person months (equivalent to 100% effort) to the activities described in the Program Considerations section.

Other Program Related Expenses

Consultant costs, equipment, supplies, travel for key persons, and other program-related expenses may be included in the proposed budget. These expenses must be justified as specifically required by the proposed program and must not duplicate items generally available at the applicant institution. The program-related expenses must be itemized in Sections C, D, and F, as appropriate.

The costs of academic skills development workshops up to \$10,000/year are allowed, but these costs must be reasonable and well justified.

Costs of teaching supplies (up to \$2,000/scholar/year), and scholars travel (up to \$2,000/scholar/year) to one career development or national scientific meeting per year. These travel funds are separate from the funds requested to attend the annual IRACDA

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Conference (typically \$1500-2000/scholar/year)

Travel expenses (up to \$5,000/year) are also allowed for the program staff [PDs/PIs, program administrator(s), and program coordinators(s) at the research-intensive and partner institution(s)] to attend the annual IRACDA Conference and should be included in the budget.

Program assessment costs will be limited to up to \$3,000 for the 5-year grant period.

NIGMS will consider a request for supplementary funds to defray the costs of hosting the IRACDA Conference, provided the request is reasonable and well justified.

IRACDA funds cannot be used to recruit scholars (e.g., travel for interviews or recruitment events) or to cover research internships or summer research experiences for undergraduates. Grantees are encouraged to use institutional funds or to apply for <u>diversity</u> <u>supplements (https://grants.nih.gov/grants/guide/pa-files/pa-18-586.html)</u> to support undergraduate summer internships.

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

Section III. Eligibility Information 1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- · Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

An IRACDA program involves a partnership involving a research-intensive, applicant institution and one or more teaching-intensive partner institutions.

Research-Intensive, Applicant Institution

The applicant institution must:

- Serve as the primary site of the mentored postdoctoral research experience;
- Possess the requisite facilities and partnerships to conduct the proposed career development program;
- · Have research mentors within the scope of the NIGMS mission (https://www.nigms.nih.gov/About/Overview/); and
- Be classified as research-intensive (see criterion below).

NIGMS defines research-intensive as institutions with an average of NIH research project grant (RPG)

(<u>https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG)</u> 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 (RPG data are available through <u>NIH RePORT</u>

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(<u>https://report.nih.gov/award/index.cfm</u>)). For example, take the average of FY 2016, FY 2017 and FY 2018 for applications submitted in October 2019.

Teaching-Intensive Partner Institution(s)

The teaching-intensive partner institution(s) must:

- Be public/state or private controlled institutions of higher education;
- Offer associate and/or baccalaureate degrees in science, technology, engineering or mathematics (STEM) fields;
- Have a strong commitment to undergraduate teaching; and
- Have a historical mission or a demonstrated commitment to educating students from diverse backgrounds, e.g., individuals from underrepresented groups (see <u>NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html</u>));

A signed letter is required from each Provost or similar official with institution-wide responsibility verifying the eligibility of the institutions at the time of application submission according to the eligibility criteria indicated above. See the application instructions for the required Letters of Support attachment in <u>Section IV.2</u>.

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 <u>NIH Policy on</u> <u>Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html)</u> states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- <u>Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform)</u> All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- <u>System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/)</u> 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.
 - <u>NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176)</u> Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123</u>) Applicants must have an active DUNS number 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.
- <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300)</u> 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 mentored research program as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Women and individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities are always encouraged to apply for NIH support.

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For institutions/organizations proposing multiple PDs/PIs, visit the <u>Multiple Program Director/Principal Investigator Policy</u> (//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.

NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance the career development program. At least one of the 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 from the teaching-intensive institution, with experience in the science of education, relevant social science disciplines, program evaluation, mentoring, and university administration may be included to achieve the program 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 status of the contact PD/PI changes after the award, the institution must obtain prior program approval. The PD(s)/PI(s) will be responsible for the selection and appointment of scholars to the approved career development program, and for the overall direction, management, administration, and evaluation of the program. The contact PD/PI 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 appropriate adjustments to the program.

2. Cost Sharing

This FOA does not require cost sharing as defined in the <u>NIH Grants Policy Statement.</u> (//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 <u>NOT-OD-11-101</u> (<u>//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html</u>)).

Only one application per institution (normally identified by having a unique <u>NIH Institutional Profile Number</u> (<u>https://public.era.nih.gov/commons/public/quickqueries/ipfNumberByOrgName.era</u>), IPF) is allowed. An institution may hold only one IRACDA grant award.

The IRACDA award may not be transferred from one institution to another.

Mentors (Participating Faculty)

When building a participating faculty team, programs should include individuals who are committed to training, mentoring, and providing supportive, safe and inclusive research environments. Programs are encouraged to build a diverse team of preceptors/mentors that includes, for example, faculty from underrepresented groups (<u>NIH's Interest in Diversity</u> (<u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html</u>)), women, and faculty at different career stages (i.e., early stage as well as senior faculty).

Participating faculty at the research-intensive institution who are directly supervising the IRACDA fellows mentored research experience must have active, externally funded research projects relevant to the <u>NIGMS mission</u> (<u>https://www.nigms.nih.gov/About/Overview/</u>)</u>. Participating faculty must be committed to continuing their involvement throughout the total period of the award. Participating faculty may be added as appropriate to the roster of an ongoing funded IRACDA program without prior NIGMS approval.

The mentors from the partner institution(s) must have a strong record of teaching and mentoring. They are expected to facilitate the postdoctoral scholars' adjustment to the academic environment of the partner institution and provide guidance and mentoring on teaching skills as well as teaching-related challenges and opportunities at the partner institution.

Scholars

Postdoctoral scholars to be supported by the institutional career development program must be at the career level for which the planned program is intended. IRACDA scholars are expected to devote 9-person months (75% of full-time professional effort) to the

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mentored research and the remaining 3-person months (25% of full-time professional effort) to the mentored teaching and other mentored and/or didactic experiences, during their appointment on the K12 award.

By the time of appointment, each scholar must be a citizen or a non-citizen national of the United States who has been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status). Individuals on temporary or student visas are not eligible.

Details on citizenship requirements are available in the <u>NIH Grants Policy Statement</u> (<u>https://grants.nih.gov/grants/guide/url_redirect.htm?id=61135</u>).

Postdoctoral scholars must have received, as of the beginning date of the IRACDA appointment, a Ph.D., M.D., D.D.S., or comparable doctoral degree. Candidates should be early in their postdoctoral stage, with no more than 2 years since the date of their doctoral degree. Candidates must be committed to teaching the next generation of biomedical researchers, and to the biomedical research enterprise.

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 <u>Part 1</u> of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Training (T) Instructions in the <u>SF424 (R&R) Application Guide</u> (//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 <u>Table of Page Limits</u> (<u>//grants.nih.gov/grants/guide/url_redirect.htm?id=61134</u>) 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. Substitute the term scholars for all references to trainees in the SF424 (R&R) Application Guide, and substitute the term career development for all references to training in the SF424 (R&R) Application Guide.

SF424(R&R) Cover

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

Descriptive Title of Applicants Project: Use the format IRACDA at

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 career development program itself requires the scholars to take a workshop or course that will involve human subjects.

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

Project Summary/Abstract. Provide an abstract of the entire application. Include the objectives, rationale, and design of the research career development program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of scholars, and intended scholar outcomes.

Other Attachments.

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An Advisory Committee (1-page maximum) is not a required component of a career development program; however, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the 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 evaluate the overall effectiveness of the program. Advisory Committee members should not be identified or contacted prior to receiving an award. Name the file Advisory_Committee.pdf.

Outcomes Data Collection and Storage Plan (2-page maximum). Funded programs are expected to track scholars for a minimum of 15 years beyond the scholar's participation in the program. The applicant must provide a plan to track the outcomes for all supported scholars. Programs are encouraged to make the aggregate outcome data available on the grantee 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.

Sustainability Plan (1-page maximum). The application must provide a plan for supporting scholars whose appointments will be on-going at the end of the project period. Additionally, to plan for situations in which a Renewal application is deemed to be non-competitive during peer review, Renewal applications must include contingency plans for supporting current scholars so that they may complete their career development activities beyond the funding period. 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 plan to disseminate 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.

The application should also identify the following (when relevant):

- Program Administrator(s) at the research-intensive institutions and teaching intensive institutions
- Teaching mentor(s) at the teaching-intensive institution(s)

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.

Research and Related (R&R) Budget

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

- Include all personnel other than the PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff. Also
 include proposed salary costs for planned scholars.
- Do not complete the section on Participant/Trainee Support Costs.

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:

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Particular attention must be given to the required Postdoctoral <u>Training Data Tables (//grants.nih.gov/grants/guide/url_redirect.htm?</u> <u>id=61169</u>) (Tables 1, 2, 3, 4, 5B, 6B, 8C for all applications and the additional Table 7 for Renewals). Applicants should summarize, in the body of the application, key data from the tables that highlight the characteristics of the applicant pool, faculty mentors, the educational and career outcomes, and other factors that contribute to the overall environment of the program.

Training Program

Program Plan

A. Background

Applicants should describe the rationale for the partnership, including the geographic location of the participating institutions and the strategies for overcoming any logistical challenges. The teaching experience must take place at the partner institution and not be completed through distance learning technologies; therefore, programs with a significant geographic distance between partners must be well justified with a strong plan for overcoming the challenges. If multiple partners are proposed, provide an explanation of the need and the methods for ensuring a strong partnership.

Applicants should provide the following for the research-intensive institution:

- Summaries of the key data from the <u>Training Data Tables (//grants.nih.gov/grants/guide/url_redirect.htm?id=61169)</u> that highlight the characteristics of the research environment with respect to the individuals in the participating departments (<u>Table 1 (https://grants.nih.gov/grants/forms/data-tables.htm</u>)), faculty mentors (<u>Table 2 (https://grants.nih.gov/grants/forms/data-tables.htm</u>)), and the current research training or career development support (<u>Table 3</u> (<u>https://grants.nih.gov/grants/forms/data-tables.htm</u>));
- A justification for the program by demonstrating that the pool of faculty, potential scholars, and research resources are robust enough to support the proposed career development program; and
- Explain what distinguishes this program from other research training or career development programs, and how the programs will synergize, but not duplicate one another.

Applicants should describe the following regarding the teaching-intensive partner(s):

- The student demographics, including the number of students from well-represented and underrepresented groups or backgrounds at the partner institution(s) that major in STEM fields;
- STEM Faculty and workloads. Describe the number of STEM faculty, typical teaching loads, and the extent to which they employ evidence-based approaches to teaching and learning; and
- The academic environment (e.g., the courses offered, the opportunities for developing new courses or revising/updating existing courses, the student and faculty support services, and the degree to which students are exposed to biomedical research and research topics).
- Applicants should describe the ways in which individuals at each of the institutions are provided with supportive, safe, and inclusive environments.

B. Research Career Development Program Plan

a. Program Administration

Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)). The application should describe how the PD(s)/PI(s) will promote the success of the scholars and achieve the program goals. If relevant, describe how each member of the PD/PI team brings a unique perspective and skill set that will enhance the career development program as described in the <u>Eligible Individuals</u> section above. The application should expand on the information in the biosketch(es) to address how the Program leadership has:

- The administrative and career development experience to provide strong leadership, direction, management, and administration of the proposed program;
- The time to commit sufficient effort to ensure the program s success given other professional obligations (the application should indicate the program director's effort in person months in the proposed program);
- At least one member who has 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 developing the next generation of the biomedical research workforce, leading recruitment
 efforts to enhance diversity, and fostering inclusive research environments. The PD(s)/PI(s) should have received training on
 how to effectively mentor individuals from all backgrounds, e.g., from groups underrepresented in the biomedical sciences
 (NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)).

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Administrative Structure. The application must describe the administrative structure, distribution of responsibilities within it, and the leadership succession plan for critical positions (e.g., PD(s)/PI(s)).

Program Administrator(s). If Program Administrator(s) at the research-intensive or teaching-intensive institutions are proposed, provide a description of the qualifications of the individual(s) with respect to the relevant experience with career development, teaching and mentoring, and/or administration.

b. Mentors (Participating Faculty)

In addition to the instructions in the <u>application guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html)</u>, describe the following:

Research-Intensive Participating Faculty. The application should describe how the participating faculty will promote the success of the scholars and the career development program. Describe how the program has or will build a diverse team of participating faculty (e.g., individuals from underrepresented backgrounds (NIH's Interest in Diversity)

(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)), women, and faculty at different career stages) to help trainees gain access to potential role models within the program and to enhance the excellence of the career development environment. Summarize and expand on the material presented in the Training Tables and biosketches. The application should address how the participating faculty::

- Conduct research within the <u>NIGMS mission (https://www.nigms.nih.gov/About/Overview/);</u>
- · Employ the highest standards of scientific rigor and impart those standards to the scholars;
- Have sufficient time to commit to the scholar's mentored research experience given their other professional obligations;
- · Reinforce and augment the curricular material on responsible conduct of research and methods for enhancing reproducibility;
- Engage in activities that promote the scholar's career development (including but not limited to the utilization of Individual Development Plans) and fulfill the need for the scholars to transition into independent academic careers in a timely fashion with the skills, credentials, experiences, and independence to be successful;
- Have received training on how to effectively mentor individuals from all backgrounds, e.g., from groups underrepresented in the biomedical sciences (NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html));
- In the event of a clinical trial mentored research experience for the scholars, provide documentation that the faculty mentor(s) who will supervise the scholars have the expertise, experience, resources and ability to provide appropriate guidance and help to the scholars to meet the timelines.

Teaching-Intensive Participating Faculty. Describe how the program will ensure the participating faculty serving as teaching mentors have the following characteristics:

- · A record of excellence in teaching in a STEM field;
- The time to serve as effective teaching mentors given their other professional obligations;
- · Knowledge and experience with evidence-based approaches to teaching and learning; and
- · Expertise in developing safe and inclusive teaching and mentoring environments.

c. Proposed Training

In addition to following the instructions in the <u>application guide (https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/training-forms-e.pdf)</u>, applicants should describe the following:

- Specific, obtainable, and measurable short-term and long-term objectives of the proposed career development program. The objectives should align with the overarching goals of the IRACDA Program described above. Each career development activity should be designed to ensure that the objectives of the program are met;
- Mentored Research component. Include information about planned courses, seminars, workshops, as well as scientific rigor
 and responsible conduct of research training activities that will be incorporated into the mentored research program. Describe
 the mechanism for matching scholars with the appropriate participating faculty for the mentored research experience. In the
 event that a clinical trial is part of a scholar's mentored research experience, provide documentation of the administrative,
 data coordinating, enrollment and laboratory/testing centers, appropriate for a clinical trial;
- The instructor and mentor training activities. Describe how the teaching mentors will be assigned, the nature of the teaching mentor/scholar interaction, what potential courses are accessible to the scholars to teach at the partner institution(s), and how the scholars will contribute to the teaching mission of the partner institution(s). Describe how the scholars will be trained in the following areas: (1) using evidence-based teaching, mentoring, and research training methods, (2) teaching scientific concepts to individuals from diverse backgrounds, (3) working with colleagues from a variety of cultural and scientific backgrounds, (4) culturally-sensitive mentoring of students, and (5) creating inclusive, safe, and supportive teaching and

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learning environments. The mechanism for matching scholars with the appropriate participating faculty at the teachingintensive institution;

- A mechanism to monitor mentoring, including oversight of the effectiveness of the scholar/participating faculty match, and a plan for remediating or removing faculty displaying unacceptable mentorship qualities from the career development program (the application may include the Appendix labeled Conflict Resolution Protocols to provide details of the plan).
- Professional development activities. These activities may include, but are not limited to, skill developing activities in areas such as teamwork, problem solving, communication, time management, leadership, laboratory and project management, and scientific writing (e.g., manuscript and grant writing);
- The programmatic oversight to ensure that the scholars gain the career development skills and are on track to transition into independent academic careers; and
- How the courses, structured activities, and research experiences will accomplish the specific career development objectives. Explain how these activities are designed to develop the technical, operational, and professional skills of the scholars (the application must include the Required Training Activities appendix to provide material for required activities and may use the Elective Activities appendix for up to four additional activities).

d. Program Evaluation

NIGMS funded career development programs must conduct ongoing evaluations to monitor the success of the training and mentoring activities and are expected to disseminate their outcomes to the broader community. The application may include the "Evaluation and Assessment Instruments" appendix to provide blank survey instruments, rubrics, or forms. The evaluation plan should describe the following:

- The evaluation process to determine whether the program is effective in meeting its objectives with respect to the scholars' career development;
- The comparator group (e.g., individuals with similar demographics and aptitude metrics who are at a similar level and will not participate in program activities);
- The metrics and methods to determine whether the partner institution(s) benefit from participation in the IRACDA program, e.g., new or revised courses, enhanced teaching or research collaboration between the institutions, exposure of undergraduate students to research topics and opportunities.
- The mechanism for determining whether the career development environments are inclusive, safe, and supportive of the scholars' development;
- The plans for being responsive to internal and external outcomes analyses, critiques, surveys and evaluations;
- How the program will effectively track scholar and career outcomes, provide information to prospective and current scholars about outcomes, and ensure the data collection and storage methods will be safeguarded and preserved by briefly expanding upon the "Outcomes Data Collection and Storage Plan" attachment.
- How the PD(s)/PI(s) will share the outcomes and effective training or mentoring interventions with the broader community by briefly expanding upon the "*Dissemination Plan*" attachment.
- e. Scholar Candidates

Through the narrative and summaries of the information presented in the required <u>Training Data Tables</u> (//grants.nih.gov/grants/guide/url_redirect.htm?id=61169) and the attachments, the following areas relevant to the scholars should be addressed:

- Provide a strong justification for the number of requested scholar positions in the context of other NIGMS-funded training or career development grants at the institution. Describe the characteristics of the applicant pool, applicants eligible for support, and for renewals only, the eligible scholars appointed to the grant (<u>Training Table 6B (https://grants.nih.gov/grants/forms/datatables.htm</u>));
- Expand upon the Recruitment Plan to Enhance Diversity and explain how it will identify and recruit a diverse pool of potential candidates from a wide variety of institution types and backgrounds (e.g., individuals from underrepresented groups in the biomedical sciences, <u>NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html</u>));
- Describe the plans for a holistic candidate review process (i.e., a process that considers metrics beyond the graduate institution, GPA, and standardized test scores) that will select a diverse group of promising scholars who are committed to contributing to the academic biomedical research enterprise; and
- Define and justify the selection and appointment criteria for scholars (appointment materials must be provided in the "Scholar Selection and Appointment Documents " appendix);
- f. Institutional Environment and Commitment to the Program

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Applicants should use this section to expand upon the Facilities & Other Resources section and the Letters of Support section, as necessary, to provide information regarding the Environment and Commitment to the program. The applicant must provide evidence of support for the proposed program including, but not limited to, assurance that sufficient time will be allowed for the PD(s)/PI(s) and other Participating Faculty to contribute to the proposed program, and that there will be protected time for scholars to participate in the mentored research (9-person months) and teaching activities (3-person months).

g. Qualifications of Scholar Candidates and Admissions and Completion Records

This section is intended to provide outcomes for the program described in the application (or for newly proposed programs describing outcomes for postdoctoral researchers at the research-intensive institution to provide baseline data). The application should include the information below about outcomes through narrative descriptions and a summary of the data presented in the <u>Training Data Tables (//grants.nih.gov/grants/guide/url_redirect.htm?id=61169</u>). The application should describe the following:

- Aggregate data on the diversity (see <u>NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html</u>)) of the scholars (or postdoctoral fellows for new programs); the data should be provided in <u>Training Table 6B</u> (<u>https://grants.nih.gov/grants/forms/data-tables.htm</u>) and described in the narrative;
- Evidence that alumni conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (including peer-reviewed publications in <u>Training Table 5B (https://grants.nih.gov/grants/forms/data-tables.htm)</u> and other measures of scientific accomplishment appropriate to the field, such as applying for and receiving NIH fellowships, awards, and grants (<u>Training Table 8C (https://grants.nih.gov/grants/forms/data-tables.htm</u>));
- The academic career enhancing skills gained during the postdoctoral experience, e.g., proficiency with evidence-based teaching, mentoring, and research training methods, the ability to teach scientific research methodologies and findings to individuals from diverse backgrounds, the capacity to work well in teams with colleagues from a variety of cultural and scientific backgrounds, the ability to mentor students with sensitivity to cultural differences; and an understanding of how to create inclusive, safe, and supportive teaching and learning environments. For newly proposed programs, if there are not current skill building activities for postdoctoral fellows, please indicate that in the application.
- The rate of transitioning into independent academic careers that support the biomedical research enterprise (<u>Training Table</u> <u>8C (https://grants.nih.gov/grants/forms/data-tables.htm</u>)). The application must include detailed outcome data regarding the number of scholars (or postdoctoral fellows for new programs) who transitioned into independent academic positions (obtained goal), remain in the program (in training), or withdrew from the program (attrition) in the body of the text.

C. Recruitment Plan to Enhance Diversity

The applicant must provide a recruitment plan to enhance diversity. The application should include outreach strategies and activities designed to recruit potential candidates who are from diverse backgrounds, including underrepresented racial and ethnic groups, students from low socio-economic backgrounds, and individuals with disabilities (see <u>NIH's Interest in Diversity</u> (<u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html</u>)). Applicants are encouraged to consult the NIGMS webpage for strategies to <u>enhance diversity in training programs</u>

(<u>https://www.nigms.nih.gov/training/diversity/pages/approaches.aspx</u>) when designing their plans. Describe the specific efforts to be undertaken by the program and how these might coordinate with recruitment efforts of the institution(s). 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.

Progress Report (for Renewal applications)

Individuals are required to comply with the instructions for the Progress Report (for Renewal Applications) as provided in the SF424 (R&R) Application Guide with the following additional instructions:

Applicants are encouraged to expand upon the scholar outcome data presented in the *Qualifications of Scholar Candidates and Admissions and Completion Records* section. The Progress Report section must include information on:

- Results from an evaluation of the IRACDA career development program. Provide evidence that the goals described in the previous application were obtained and if not, the changes to the program to address the barriers to success;
- The efficacy of the career development activities, e.g., mentored research and teaching, course work, workshops, seminars;
- Evidence that the teaching-intensive partner benefited from participation in the IRACDA program. If the benefits were limited, describe the steps that will be taken to ensure the teaching-intensive institution will benefit going forward;
- The success of appointed scholars (detailed above) in the context of a matched comparator group with regard to scholarly activities (e.g., peer-reviewed publications, awards, research grants) and career advancement (e.g., securing an independent academic position).

Plan for Instruction in the Responsible Conduct of Research

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Individuals 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, with the following additional instructions:

Describe how the Responsible Conduct of Research (RCR) components are well integrated into the overall career development plan, i.e., how they are taught at multiple stages of the scholar's development and in a variety of formats and contexts. Explain how the teaching of RCR synergizes with elements of the curriculum designed to enhance the scholars ability to conduct rigorous and reproducible research. Describe how all participating faculty will reiterate and augment key elements of responsible conduct when the scholars are performing mentored research in their laboratories. If this plan is not included, the application will be considered incomplete and will not be reviewed.

Plan for Instruction in Methods for Enhancing Reproducibility

A Plan for Instruction in Methods for Enhancing Reproducibility attachment is required (not to exceed three pages). The plan must describe how scholars will be instructed in principles important for enhancing research reproducibility including, at a minimum, critical evaluation of foundational research underlying a project, rigorous experimental design and data interpretation, 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. Applicants are encouraged to consult the <u>NIGMS clearinghouse</u> for training modules to enhance data reproducibility (<u>https://www.nigms.nih.gov/training/pages/clearinghouse-for-training-modules-to-enhance-data-reproducibility.aspx</u>) and other resources when developing the plans. Describe how instruction strategies are sufficiently well integrated into the overall career development program, that is, how they are taught at multiple stages of the scholar's development and in a variety of formats and contexts. Describe how all participating faculty will reiterate and augment key elements of methods for enhancing scientific rigor and reproducibility when scholars are performing research in their laboratories. If this plan is not included, the application will be considered incomplete and will not be reviewed.

Faculty, Trainees, And Training Record Section

Participating Faculty Biosketches

Participating faculty should provide a personal statement within the biosketches that describes the appropriateness of their research and training backgrounds for the proposed 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;
- Supporting scholars participation in activities required to identify and transition into independent academic careers in the biomedical research workforce; and
- Supporting the timely transition of the scholars into independent academic careers in the biomedical research workforce.

Letters of Support

Combine all Letters of Support into a single PDF file.

Institutional Support Letter (10-page maximum). The application must include a letter on the lead institution's institutional letterhead that is signed by each participating institution's central administration (e.g., President, Provost, Dean, or similar key institutional leader). The letter must describe the activities and resources provided by the institutions that will ensure the success of the planned program. The letter must outline each institution's respective role in administering the program, and these roles must be consistent with the goals and objectives of the proposed IRACDA program.

As applicable, the letter should also address how the institution(s): promotes a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced; provides opportunities for early stage faculty and those with a hiatus in research support to participate in training; supports core facilities and technology resources that can be used to enhance training; provides adequate staff, facilities, and educational resources to the planned program; supports the PDs/PIs and other key staff associated with the planned training program; ensures that faculty have protected time available to devote to mentoring, training and research; fosters and rewards excellence in training and mentoring (for example, through institutional policies); provides support for remediation or removal of participating faculty who are poorly performing mentors; promotes diversity and inclusion at all levels of the research environment (trainees, staff, faculty, and leadership); ensures that the research and clinical facilities are accessible to scholars with disabilities; promotes a positive, supportive, safe, and inclusive research, clinical and training environment for individuals from all backgrounds; ensures 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

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PD/PI status; see <u>NOT-OD-19-056 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-056.html</u>)); ensures scholar support services, such as health care, counseling services, and housing; and provides resources and expertise for evaluating outcomes of the program. For institutions that have multiple federally funded STEM training or education programs, the letter should also explain how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential scholars, and resources are sufficiently robust to support both the proposed and existing programs. All information related to institutional support, as defined above, must be included within the 10-page limit of this letter. If this letter is not included, the application will be considered incomplete and will not be reviewed.

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

Teaching-Intensive Institutional Eligibility Letter(s). For each teaching-intensive partner institution, the Provost or similar official with institution-wide responsibility must certify that the institution is a (1) public/state or private controlled institution of higher education, (2) offers associate and/or baccalaureate degrees in STEM fields, (3) has a strong commitment to teaching undergraduates, and (4) has a historical mission or a demonstrated commitment to educating students from diverse backgrounds, e.g., individuals from underrepresented groups (see <u>NIH's Interest in Diversity</u>

(<u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html</u>)). If the partner institution letter(s) is not included, the application will be considered incomplete and will not be reviewed.

Other Letters of Support. Additional letters of support are permitted; however, these letters may not contain any information requested in the Institutional Support Letter.

Data Tables

The application must include the required <u>Training Data Tables (https://grants.nih.gov/grants/guide/url_redirect.htm?id=61169)</u> for postdoctoral programs (Tables 1, 2, 3, 4, 5B, 6B, 8C for all applications and the additional Table 7 for Renewals). Applications that do not contain these 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 the SF424 (R&R) Application Guide instructions.

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

The following are required Appendix materials:

- Required Training Activities. To adequately assess the content of the didactic portion of the career development program, the application must include syllabi/outlines of all required training activities (e.g., courses, mentor training, 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 scholars career path the material is taught.
- Scholar Selection and Appointment Documents (3 pages maximum). In the Program Plan, the application must outline the criteria for scholar selection and the process for scholar appointment. Materials for this appendix may include appointment protocols and/or blank applications.

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 scholar progress and (b) determine whether the career development environment is effective,

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inclusive, safe, and supportive.

 Conflict Resolution Protocols (3-page maximum). The application may include detailed protocols for addressing problems with scholar/faculty matches, remediating or removing faculty from the career development program with unacceptable training/mentoring skills and for conflict resolutions for multi PD(s)/PI(s) and mentor/mentee relationships.

Applications 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

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

Note: <u>Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy)</u> does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

If you answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must complete a Delayed Onset Study.

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 <u>Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.htm?</u> id=82380), the application deadline is automatically extended to the next business day.

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

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

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

For assistance with your electronic application or for more information on the electronic submission process, visit <u>How to Apply</u> <u>Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html)</u>. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the <u>Dealing with System Issues</u> (<u>https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm</u>) guidance. For assistance with application submission, contact the Application Submission Contacts in <u>Section VII.</u>

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

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 and NIGMS. Applications that are incomplete or non-compliant will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in <u>the policy</u> (//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 <u>NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149)</u> 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 program will prepare individuals for successful, productive scientific research careers and thereby exert a sustained influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the proposed career development 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 impact.

Career Development Program and Environment

- Are the research-intensive and teaching-intensive institution(s) appropriate and likely to provide supportive, safe, and inclusive career development environments?
- Is there evidence of a strong and functional partnership? If multiple partners are proposed, is the plan for maintaining the partnerships reasonable?
- Will the scholars benefit from the unique features of the institutional environments?
- Does the proposed program clearly outline obtainable and measurable objectives with respect to scholar outcomes and the benefit to the teaching-intensive partner institution?
- Will the mentored research experiences provide the scholars with the skills to conduct biomedical research?

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- Will the courses and structured activities develop the scholars professional skills needed to transition into an independent academic career, e.g., proficiency with evidence-based teaching, mentoring, and research training methods; the ability to teach scientific research methodologies and findings to individuals from diverse backgrounds; the capacity to work well in teams with colleagues from a variety of cultural and scientific backgrounds; the ability to mentor students with sensitivity to cultural differences; and an understanding of how to create inclusive, safe, and supportive teaching and learning environments?
- Are the content, phasing, and proposed duration of the career development plan appropriate for achieving independence in a biomedically-related academic career?
- Are there sound plans for ensuring that each scholar is progressing with respect to career development and a timely transition to independence?
- Is there sufficient assurance that the required effort on the part of the scholars will be devoted directly to the research, career development, and related activities?
- When applicable, is there adequate documentation describing the responsibilities of the advisory committee with regard to the provision of input, guidance, and oversight of the program?
- Will the institutional and departmental commitment to research and training excellence promote the success of the scholars and the goals of the career development program?

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

- Do the PD(s)/PI(s) and Program Administrator (if applicable) have the experience to develop, direct, and administer the proposed program?
- Are the research qualifications, scientific stature, previous leadership and mentoring experience, and track record(s) of the PD(s)/PI(s) appropriate for the proposed career development program?
- If proposed, does the program coordinator(s) have the experience and stature to effectively coordinate the mentored teaching component of the program at the respective partner institution(s)?
- Is there evidence that an appropriate level of effort will be devoted by the program leadership to ensure program objectives?
- Have the PD(s)/PI(s) received training on how to effectively mentor scholars, including those from underrepresented groups, and promote inclusive, safe, and supportive career development environments?
- If a multi-PD/PI leadership team is proposed does each person bring complementary and integrated expertise to the program? Is a strong leadership plan evident, including the designated roles and responsibilities, governance, and organizational structure?

Mentors (Participating Faculty)

Research-Intensive Participating Faculty Serving as Research Mentors

Do the participating faculty designated for the mentored research component come from diverse 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 designated for the mentored research component have the following:

- A commitment to training and mentoring? For example, have they received training on how to effectively mentor individuals from all backgrounds, e.g., from groups underrepresented in the biomedical sciences (<u>NIH's Interest in Diversity</u> (<u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html</u>))?
- Strong records as researchers and active research funding within the NIGMS mission?
- A record of rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results?
- A record of conducting ethically sound and responsible scientific research and the willingness to reinforce and augment the curricular material on responsible conduct of research and methods for enhancing reproducibility?
- The time to commit sufficient effort to ensure scholar development and success, given their other professional obligations?
- Demonstrate a commitment to effective mentoring and promoting inclusive and supportive scientific and career development environments?
- Express a willingness to engage in activities that promote the scholars career development (including, but not limited to the utilization of Individual Development Plans)?
- Display a commitment to supporting a timely transition of scholars from their laboratories into independent academic careers in the biomedical research workforce?
- If the program will support clinical trial research experience for the Scholars, do the mentor(s) who will supervise the Scholars have the expertise, experience, resources and ability to provide appropriate guidance and help the Scholars to meet the timelines?

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Teaching-Intensive Participating Faculty

Do the participating faculty serving as teaching mentors have the following characteristics:

- · A record of excellence in teaching in a STEM field?
- The time to serve as effective teaching mentors given their other professional obligations?
- Knowledge and experience with evidence-based approaches to teaching and learning?
- Expertise in developing safe and inclusive teaching and mentoring environments?

Scholars

- Is the recruitment plan proposed likely to attract a diverse pool of candidates with a commitment and potential to pursue academic research careers?
- · Are there well-defined and well-justified selection strategies?
- Does the program have a sound and holistic candidate review process?
- Is there evidence of a sufficiently large, competitive scholar pool to warrant the proposed size of the career development program?

Training Record

Program Evaluation and Dissemination

- Is there a well thought out evaluation or assessment process to determine whether the overall program is effective in meeting its mission and short, intermediate and long-term objectives? Does the plan include comparator groups as well as appropriate metrics and methods for determining the success?
- Is there a mechanism for determining whether the career development environments are inclusive, safe, and supportive of the scholars development?
- Is there evidence that the program has been and/or will be responsive to internal and external critiques and evaluations?
- Are effective mechanisms in place for obtaining feedback from current and former scholars?
- Does the program have a feasible plan to track outcomes and make the aggregated data available to potential applicants and current scholars (narrative and "*Outcomes Data Collection and Storage Plan*" attachment)?
- Does the program have a robust plan to ensure the preservation of and access to program data (narrative and "Outcomes Data Collection and Storage Plan" attachment)?
- Does the application provide an effective plan to share the outcomes and successful training or mentoring activities with the broader community (narrative and Dissemination Plan attachment)?

Outcomes (for new programs)

- Does the application provide evidence that former postdoctoral fellows at the research-intensive institution working with the proposed participating faculty conducted rigorous research that advanced scientific knowledge and/or technologies with increasing self-direction (e.g., peer-reviewed publications listed in Table 5B, and other accomplishments appropriate to the field)?
- Does the application contain information about the current rate that postdoctoral fellows in the laboratories of the proposed participating faculty transition into academic careers to be used as a baseline for future evaluations for the proposed IRACDA program?

Outcomes (for renewals)

- Does the application provide the results from an evaluation of the IRACDA career development program, including evidence that the goals described in the previous application were obtained and if not, the changes to the program to address the barriers to success?
- Does the application include data regarding the efficacy of the career development activities?
- Does the application provide evidence that the teaching-intensive partner benefited from participation in the IRACDA program? If the benefit to the partner institution(s) were limited, did the application include a description of the steps that will be taken to ensure the teaching-intensive institution will benefit going forward?
- Does the application describe the success of appointed scholars in the context of a matched comparator group with regard to scholarly activities (e.g., peer-reviewed publications, awards, research grants), professional skill attainment (e.g., teaching, mentoring skills), and career advancement (e.g., securing an independent academic position)?

Additional Review Criteria

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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 scholars will be instructed in principles important for enhancing research reproducibility including, at a minimum, evaluation of foundational research underlying a project (i.e., scientific premise), rigorous experimental design, 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 the scholars development and in a variety of formats and contexts? Does the teaching synergize with elements of the curriculum designed to enhance the scholars' abilities to conduct responsible research? Is there evidence that all program faculty reiterate and augment key elements of methods for enhancing rigor and reproducibility when scholars are performing mentored research in their laboratories?

The plan 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

Not Applicable

Renewals

For Renewals, the committee will consider the progress made in the last funding period, including on the Recruitment Plan to Enhance Diversity, and Training in the Responsible Conduct of Research. Does the application describe the program's accomplishments over the past funding period(s)? Are changes proposed that would improve or strengthen the career development experience? Is there evidence of a successful past training record of the PD/PI and mentors, including the success of former scholars in seeking independent support and establishing productive scientific research careers?

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.

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 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

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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 scholar experience, and the particular circumstances of the scholars, 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, 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 scholar development and in a variety of formats and contexts? Does the teaching of RCR synergize with elements of the curriculum designed to enhance scholars abilities to conduct rigorous and reproducible research? Is there evidence that all participating faculty reiterate and augment key elements of responsible conduct when scholars 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.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

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 NIGMS in accordance with <u>NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154</u>), using the stated <u>review criteria</u>. Assignment to a Scientific Review Group will be shown in the eRA Commons. Site visits may be employed as part of this process; however, applicants should not assume that site visits are automatic.

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 submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate 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.

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 <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u>. Refer to Part 1 for dates for peer review,

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advisory council review, and earliest start date

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

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 <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157</u>).

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

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

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the <u>NIH Grants Policy Statement</u> (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the <u>NIH Grants Policy</u> <u>Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?</u> id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants. <u>Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159</u>). More information is provided at <u>Award Conditions</u> 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 law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator s scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html (https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html (https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html), and https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html), and https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html), and https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html), and http

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and Linguistically Appropriate Services in Health and Health Care at <u>http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53</u> (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

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

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 <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=61131)</u>.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the <u>Research Performance Progress Report (RPPR)</u> (//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 scholar appointed or reappointed to the IRACDA career development 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 <u>xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183)</u>. 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 (<u>PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189</u>)). Individuals with a Conditional Permanent Resident status must first meet full (non-conditional) Permanent Residency requirements before receiving support.

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

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory

requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

4. Evaluation

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

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

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

- Institution types represented
- Geographical distribution of programs
- Demographics of scholars
- · Scientific and scholarly accomplishments of scholars
- Scholar 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: <u>http://grants.nih.gov/support/ (//grants.nih.gov/support/)</u> (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: <u>GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov)</u> (preferred method of contact) Telephone: 301-945-7573

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

Scientific/Research Contact(s)

Desir e L. Salazar, Ph.D. National Institutes of General Medical Sciences (NIGMS) Email: <u>desiree.salazar@nih.gov (mailto:desiree.salazar@nih.gov)</u>

Peer Review Contact(s)

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

Financial/Grants Management Contact(s)

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

Section VIII. Other Information

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Recently issued trans-NIH <u>policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163)</u> may affect your application submission. A full list of policy notices published by NIH is provided in the <u>NIH Guide for Grants and Contracts</u> (//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 <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)</u>.

Authority and Regulations

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

<u>Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?09-13-19)</u> <u>NIH Funding Opportunities and Notices (/grants/guide/index.html)</u>



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



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EXHIBIT C



NIGMS Funding Update - IRACDA Terminated

1 message



Dear Fellows

I am saddened to inform you that the NIH/NIGMS San Diego IRACDA program has been terminated (see email below) after 22 years of continuous funding, and 4 successful competitive renewals.

I am very proud of the work we have done to advance the careers of so many talented postdocs that are leading initiatives and training the next generation of scientists as detailed below.

SD IRACDA has trained over 134 postdoctoral fellows. All our alumni are employed in science, 65% have obtained faculty positions at academic institutions, including 30% in R1 research-intensive institutions, 26% in R2 (teaching and research) institutions, and 8% in teaching-focused institutions. Almost all our faculty alumni, 90%, are in tenured-track positions, and 61% of faculty have gained extramural funding from various agencies, including the NIH, NSF, USDA, DOD, AHA and National Geographic.

What's next? While I am confirming with grants management, it appears that we will be able to fund IRACDA postdocs through June 30, 2025. There will be no funding available after **June 30, 2025**. In addition, we plan to continue some critical aspects of the IRACDA program for postdocs for the next year to help them prepare for an independent position. I am also hopeful that a new opportunity for training postdocs for academic careers will become available in the near future, and rest assured we will be ready to apply. Finally, I will likely appeal this decision by the NIH in case the termination action becomes part of a lawsuit, and this may enable us to recover funds if the action is reversed. Thanks for your understanding,

JoAnn

From: Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov> Date: Wednesday, April 2, 2025 at 10:18 AM To: Trejo, Joann <jotrejo@health.ucsd.edu> Subject: NIGMS Funding Update

Re: GM068524-22

Dear Dr. Trejo,

I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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.

4/11/25, 5:05 PM Case 1:25-cv-10787-BEM Doctain proteins and g Up trile at Autor Page 47 of 47 If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include your

If you have specific follow up questions, please email highstrainingmail@highs.hin.gov and incligrant number.

Kenneth D. Gibbs, Jr., PhD, MPH Director, Division of Training and Workforce Development National Institute of General Medical Sciences National Institutes of Health