EXHIBIT 31

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, et al.,

Defendants.

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

DECLARATION OF APHA MEMBER 5

- I, Jason "Jace" Flatt, pursuant to 28 U.S.C. § 1746, depose and say as follows:
- 1. My name is Jace Flatt and I am an Associate Professor in the Department of Social and Behavioral Health at the University of Nevada, Las Vegas, School of Public Health. I am a member of the International Research Grants Program Council of the Alzheimer's Association, the Healthy Brain Initiative Road Map Workgroup on Equity for the Centers for Disease Control and Prevention, the Alzheimer's Association, the Gerontological Society of America, and the American Public Health Association (APHA).
- 2. I am offering this Declaration in my individual capacity and not on behalf of my employer.
- 3. I've spent nearly 30 years focused on how we support individuals and families affected by Alzheimer's and related conditions. I received my master's degree in public health at the University of South Carolina, and went on to receive my PhD from the University of Pittsburgh's School of Public Health, where I also completed my postdoctoral fellowship in the Epidemiology of Aging & Population Neuroscience. While pursuing my PhD, a close family member was diagnosed with Alzheimer's, which further strengthened my dedication to this work.

- 4. My research focuses on understanding the experiences and health concerns related to Alzheimer's disease, Parkinson's disease, and other neurodegenerative conditions among LGBTQIA+ populations and their care partners. Prior to February 2025, I was Co-Principal Investigator of two National Institute on Aging-funded studies. The first was dedicated to recruiting and engaging LGBTQIA+ people with memory loss and their care partners into the RISE (Research Inclusion Supports Equity) Registry, and the second aimed to develop better ways of identifying and including LGBTQIA+ people who are taking care of someone with Alzheimer's disease so they're not left out of future research studies or support services. I study both risk and protective factors within these communities, as well as the needs of caregivers, healthcare providers, and those involved in long-term care.
- 5. I have received NIH funding for my research for more than a decade, and I have applied for and received nine grants from NIH for which I was Principal Investigator over the course of my career.
- 6. The application process for each grant was highly rigorous and time-intensive, often requiring months or even years of preparation. Writing a competitive application demands deep knowledge of the science, strategic team-building and experimental design, and careful alignment with NIH priorities through ongoing conversations with program officers. Once submitted, applications are reviewed by panels of field experts who assess the application's scientific significance, methodology, replicability, and overall rigor, typically with at least three in-depth reviewers per proposal. The process is extremely competitive—out of 40 to 50 reviewed proposals, only a few may be selected. The intensity of this process has historically served as a critical filter for supporting high-quality, meaningful research.
 - 7. I am a member of the APHA and pay \$210 in annual dues.
- 8. The NIH has terminated three grants that supported my research—grant numbers 5K01AG056669, 1R24AG066599, and 5R01AG083177.
- 9. Among these was an R01 grant (5R01AG083177) awarded by the National Institute on Aging on July 31, 2023, of approximately \$3.5 million, titled Enhancing Measurement and Characterization of Roles and Experiences of Sexual and Gender Minority Caregivers of Persons Living with Alzheimer's Disease and Related Dementias. A true and correct copy of the NOA for this R01 grant is attached hereto as Exhibit A.

- 10. Nearly one million sexual and gender minority adults in the U.S. are caregivers, with nearly half of those providing care to someone with Alzheimer's disease or related dementia yet, existing caregiving measures are outdated and fail to reflect the diversity of modern caregiving relationships. Against this backdrop, the project aimed to understand caregiving by sexual and gender minorities (SGM) for those with Alzheimer's disease in order to develop new or modified caregiving measures (such as survey tools, assessments of caregiver burden, or frameworks for evaluating support needs) and ensure that SGM caregivers are included in future caregiving research. The end goal of the project was to create six-eight new or refined measures that can improve support, services, and future research for both SGM and non-SGM caregivers.
- 11. This project used a mixed-methods approach, combining both qualitative and quantitative research to develop and validate more inclusive measures of caregiving for SGM individuals. In the first phase, focus groups and interviews with SGM caregivers would help identify key themes and experiences related to caregiving for those with Alzheimer's disease and related dementia. These insights would guide the creation and refinement of new caregiving measures, with input from experts and community partners through an online feedback process. The revised measures would be refined based on cognitive interviews with caregivers to ensure they are clear, relevant, and accurately reflect their experiences. The research team would pilot-test the refined measures through a survey of an independent sample of SGM and non-SGM caregivers to evaluate their clarity, reliability, and validity across diverse caregiving experiences.
- 12. I applied for the award in response to a Request for Applications (RFA) posted by the National Institute on Aging on June 09, 2022. A true and correct copy of a printout of the RFA webpage, accessed April 18, 2025, is attached hereto as Exhibit B. The RFA invited Research Project Grant (R01) applications for "the development of methods and measures for capturing expanded definitions of 'family' and related concepts relevant to informal caregiving for people living with Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD), and for the implementation of these measures in new and existing studies." Ex. B. The RFA specifically notes, "Existing measures also may fail to capture family structure differences for specific populations. For example, despite increased acceptance and legal recognition of sexual and gender minority (SGM) individuals and their relationships, little is known about how family care patterns vary by SGM status." Id.

- 13. I developed the application, including its focus on SGM populations, in explicit response to NIH's specific call for research. Generally, the project was aligned with longstanding NIH goals of advancing health equity, supporting inclusive research, and improving the rigor and relevance of health measurement tools. By developing validated caregiving measures that reflect the experiences of SGM populations, the study supports the broader efforts of NIH and the National Institute on Aging to improve care and outcomes for those affected by Alzheimer's disease and related dementias.
- 14. After learning about the RFA in July 2022—just three months before the application deadline of October 20, 2022—I began developing the proposal while juggling a full-time teaching load and other ongoing research. The process was brutal—I worked on the application whenever I had a second to spare, often during early mornings, late nights, and weekends. The final application was over 200 pages long. After several months of review, NIH responded in April 2023 with a set of critiques, which required a careful, point-by-point written response.
- 15. The project had made strong progress, driven by a team of six graduate students, two fulltime staff, and three principal investigators across institutions, each leading their own research teams. We'd established two active community advisory boards: one of national dementia caregiving experts, and another of LGBTQIA+ senior community leaders. Each board included 10–12 members, all who would receive \$1,000 annual honorariums, totaling about \$24,000 per year over five years. These boards meet multiple times a year and contributed to the study by reviewing materials, supporting participant recruitment, and promoting the project at community events. At the time of termination, we were still in the final data collection phase before interviews, and were preparing to launch the next stage, focused on measure development, with support from the community advisory boards.
- 16. Just over a year into the five-year R01 grant, on March 24, 2025, NIH revised the NOA to terminate the grant, stating that the award "no longer effectuates agency priorities." A true and correct copy of the revised NOA is attached hereto as Exhibit C.
- 17. I had never received any previous indication that my grant was in jeopardy, and there had been no indication that I was not meeting the required milestones in my last progress report.
- 18. The revised NOA does not include any individualized explanation for why the grant was canceled, and fails to discuss any of the data or analysis from our application or related materials. Instead, the revised NOA includes the following language about NIH's decision:

It is the policy of NIH not to prioritize Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Therefore, this project is terminated.

Ex. C.

- 19. I don't understand what the revised NOA means by "gender identity" in relation to my project, or how it was "based on gender identity." I received no communication from NIH officials following up with clarification.
- 20. While the project did involve transgender participants, the research centered on guiding the creation and refinement of new caregiving measures to inform future aging and dementia research, and it was also focused on the development of these caregiving measures.
- 21. Even so, in October 2016, NIH, National Institute on Minority Health and Health Disparities (NIMHD), and the Agency for Healthcare Research and Quality (AHRQ) officially designated SGM as a health disparity population for research, indicating that research concerning this particular group was a priority for NIH. A true and correct copy of a printout of this NIH webpage, accessed April 18, 2025, is attached hereto as Exhibit D. I built expertise in this area of research concerning the SGM population because doing so was something NIH had indicated it wanted from researchers.
- 22. As a mid-career researcher familiar with NIH processes and norms, I know that early termination under these circumstances is highly unusual and inconsistent with established practice. It is extremely rare for a grant to be terminated or not renewed mid-project, especially after several years of work. To my knowledge, the only reasons for such a drastic action would typically involve misconduct or harm to participants. But I have never had any reported adverse events, concerns raised about the use of research funds, or issues related to scientific misconduct on this or any of my projects.
- 23. My other grant terminations were communicated in nearly identical ways, with no individualized explanations as to why the awards were canceled.
- 24. The impacts of the grant termination have been severe. In total, at least 35 people across teams will be losing their jobs or a portion of their income as a result of this grant termination.

This includes graduate students nearing the completion of their degrees, staff members, and collaborators across several institutions.

- 25. Administrative tasks related to the grant termination have overwhelmed my schedule, requiring countless hours of unpaid work to navigate meetings with staff, HR, and school leadership as I proceed with team layoffs.
- 26. The abrupt termination of these grants immediately stopped all work and billing conducted within the scope of the funded project. I am able to continue supporting two full-time staff and six graduate students for 30 days by using funding from a separate foundation grant. Previously, the work funded by this foundation grant had represented only a small portion of my team's time, but it now represents the majority of their workload. Not only has this shift been drastic and abrupt for my team, but it also will not be sustainable—the funding from this grant will dry up in a matter of months, and I do not anticipate being able to secure alternative funding to make up long-term for the salary of these team members.
- 27. I have lost my summer salary and will have to teach a higher course load to compensate, which will also make it harder for me to conduct research.
- 28. The grant termination means I can no longer take on new graduate students, undermining my ability to fulfill my role as a mentor and educator in training the next generation of scientists at my institution. I fear that, in the future, only those graduate students with the resources to selffund or sustain themselves through their education and training will have the means to pursue research as a career, creating potential additional inequities in the field of public health and what projects are seen as most valuable.
- 29. The termination of the grant also led to the abrupt loss of ongoing engagement with the two community advisory boards composed of leaders in LGBTQIA+ aging and caregiving. These advisors brought invaluable lived experience and professional insight and participated in regular meetings, recruitment support, content review, and community outreach.
- 30. While progress on the project has ceased, the scale of these advisors' professional commitments means they must turn to other work and will likely be unavailable for future collaboration even if the project resumed. This represents a significant loss of community partnership, expertise, and trust, which will be difficult—if not impossible—to rebuild.

- 31. After spending nearly two decades building my career and securing an R01—one of the premier grants in my field—having NIH swiftly take it away is a significant personal and professional setback.
- 32. Beyond that, the participants in the study—all LGBTQIA+ caregivers for people with Alzheimer's disease—had each spent over a year answering questions about their caregiving experiences in an effort to develop measures that would be helpful for other caregivers in the future. Since we had to abruptly pause our data collection, we cannot draw conclusions and run analyses, and the anticipated research product focused on measurement development will not be completed.
- 33. Even if I were able to find funding to continue the work, I would almost certainly not be able to have the study's former participants work with me again—the LGBTQIA+ caregivers' trust with the researcher has been broken.
- 34. The loss of this R01 grant additionally undermines efforts to ensure that national data and public health interventions reflect the realities of today's caregiving landscape and account for non-traditional caregivers, such as chosen family members, non-married partners, or those providing care from a distance. As a result, individuals living with Alzheimer's disease or related dementias may be left without support systems that reflect their actual care networks, limiting the effectiveness of interventions designed to improve their quality of life and long-term outcomes.
- 35. I am appealing the terminations, but I do not know how to recharacterize my project in my appeal to fit within the asserted new agency priorities because I do not understand the terms used as the basis for termination. I also do not know whether the appeal has any chance of success, given the language of the termination notice states that the premise of my grant is incompatible with agency priorities.
- 36. I have no sense of whether my past work might be viewed as a liability when applying for future federal grants. This has led me to pause all current NIH grant applications while I await additional guidance, exacerbating my current funding issues.

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

Executed this 21st day of April, 2025.

Jace Flatt

EXHIBIT A

Federal Award Date

07/31/2023

Recipient Information

1. Recipient Name

BOARD OF REGENTS OF NEVADA SYSTEM OF HIGHER EDUCATION 4505 S MARYLAND PKWY LAS VEGAS, NV 89154

- 2. Congressional District of Recipient 01
- 3. Payment System Identifier (ID) 1886000024A3
- 4. Employer Identification Number (EIN) 886000024
- 5. Data Universal Numbering System (DUNS) 098377336
- 6. Recipient's Unique Entity Identifier DLUTVJJ15U66
- 7. Project Director or Principal Investigator JASON DANE FLATT, PHD (Contact) **Assistant Professor** jason.flatt@unlv.edu
- 8. Authorized Official

702-895-5586

Jill Tuley

Federal Agency Information

9. Awarding Agency Contact Information Lesa McQueen

NATIONAL INSTITUTE ON AGING lesa mcqueen@nih.gov 301-496-1472

10. Program Official Contact Information

Melissa S Gerald Health Science Administrator NATIONAL INSTITUTE ON AGING geraldmel@nia.nih.gov 301-402-4156

Federal Award Information

11. Award Number

1R01AG083177-01

12. Unique Federal Award Identification Number (FAIN)

R01AG083177

13. Statutory Authority

42 USC 241 42 CFR 52

14. Federal Award Project Title

Enhancing Measurement and Characterization of Roles and Experiences of Sexual and Gender Minority Caregivers of Persons living with Alzheimer's Disease and **Related Dementias**

15. Assistance Listing Number

93.866

16. Assistance Listing Program Title

Aging Research

17. Award Action Type

New Competing

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information					
19. Budget Period Start Date 08/01/2023 - End Date 04/30/2024					
20. Total Amount of Federal Funds Obligated by this Action	\$729,919				
20 a. Direct Cost Amount	\$542,474				
20 b. Indirect Cost Amount	\$187,445				
21. Authorized Carryover					
22. Offset					
23. Total Amount of Federal Funds Obligated this budget period	\$729,919				
24. Total Approved Cost Sharing or Matching, where applicable	\$0				
25. Total Federal and Non-Federal Approved this Budget Period					
26. Project Period Start Date 08/01/2023 – End Date 04/30/2028					
27. Total Amount of the Federal Award including Approved Cost	\$729,919				
Sharing or Matching this Project Period					

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

Ryan Blakeney

30. Remarks

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

Notice of Award



RESEARCH
Department of Health and Human Services
National Institutes of Health



NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R01AG083177-01

Principal Investigator(s):

Joel G. Anderson, PHD Norca Maritza Dowling, PHD JASON DANE FLATT (contact), PHD

Award e-mailed to: osp@unlv.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$729,919 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF NEVADA LAS VEGAS in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG083177. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Ryan Blakeney Grants Management Officer NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	\$164,555
Fringe Benefits	\$36,385
Personnel Costs (Subtotal)	\$200,940
Consultant Services	\$6,800
Materials & Supplies	\$10,700
Travel	\$5,400
Other	\$48,484
Subawards/Consortium/Contractual Costs	\$264,350
Publication Costs	\$4,600
ADP/Computer Services	\$1,200
Fordered Direct Coate	¢542.474
Federal Direct Costs	\$542,474
Federal F&A Costs	\$187,445
Approved Budget	\$729,919
Total Amount of Federal Funds Authorized (Federal Share)	\$729,919
TOTAL FEDERAL AWARD AMOUNT	\$729,919
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$729,919

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)				
YR	THIS AWARD	CUMULATIVE TOTALS		
1	\$729,919	\$729,919		
2	\$702,329	\$702,329		
3	\$693,417	\$693,417		
4	\$678,056	\$678,056		
5	\$666,077	\$666,077		

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

Fiscal Information:

Payment System Identifier:1886000024A3Document Number:RAG083177APMS Account Type:P (Subaccount)

Fiscal Year: 2023

IC	CAN	2023	2024	2025	2026	2027
AG	8033157	\$729,919	\$702,329	\$693,417	\$678,056	\$666,077

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

NIH Administrative Data:

PCC: 2BFAMGE / **OC**: 41021 / **Released**: Blakeney, Ryan 07/20/2023

Award Processed: 07/31/2023 12:17:54 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1R01AG083177-01

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

SECTION III - STANDARD TERMS AND CONDITIONS - 1R01AG083177-01

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

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

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01AG083177. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

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

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

 The description of the programs in compliance with applicable federal religious nondiscrimination laws, see https://www.hts.gov/conscience/religious-freedom/index.html.

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

Treatment of Program Income:

Additional Costs

SECTION IV - AG SPECIFIC AWARD CONDITIONS - 1R01AG083177-01

Clinical Trial Indicator: No

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

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on 5/1. The Research Performance Progress Report (RPPR) is due 45 days prior to this date for SNAP awards or 60 days prior for non-SNAP awards

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL:

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

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

This award includes funds awarded for consortium activity with George Washington University in the amount of \$57,786 (\$45,862 direct costs + \$11,924 facilities and administrative costs), University of Texas Knoxville in the amount of \$70,157 (\$45,854 direct costs + \$24,303 facilities and administrative costs), Emory University in the amount of \$71,076 (\$45,416 direct costs + \$25,660 facilities and administrative costs), Alzheimer's Disease and Related Disorders Association, Inc. in the amount of \$65,331 (\$51,850 direct costs + \$13,481 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:

http://grants.nih.gov/grants/policy/nihgps/HTML5/section 15/15 consortium agreements.htm

In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

SPREADSHEET SUMMARY

AWARD NUMBER: 1R01AG083177-01

INSTITUTION: UNIVERSITY OF NEVADA LAS VEGAS

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$164,555	\$164,555	\$156,555	\$156,555	\$147,663
Fringe Benefits	\$36,385	\$36,385	\$34,209	\$34,209	\$32,164
Personnel Costs (Subtotal)	\$200,940	\$200,940	\$190,764	\$190,764	\$179,827
Consultant Services	\$6,800	\$4,000	\$6,800	\$4,000	\$7,030
Materials & Supplies	\$10,700	\$200	\$200	\$200	\$200
Travel	\$5,400	\$5,400	\$5,400	\$5,400	\$5,400
Other	\$48,484	\$47,921	\$47,921	\$37,921	\$37,921
Subawards/Consortium/Con	\$264,350	\$308,406	\$309,603	\$313,428	\$313,428

tractual Costs					
Publication Costs	\$4,600	\$4,600	\$4,600	\$4,600	\$4,600
ADP/Computer Services	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200
TOTAL FEDERAL DC	\$542,474	\$572,667	\$566,488	\$557,513	\$549,606
TOTAL FEDERAL F&A	\$187,445	\$129,662	\$126,929	\$120,543	\$116,471
TOTAL COST	\$729,919	\$702,329	\$693,417	\$678,056	\$666,077

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	51%	51%	51%	51.5%	51.5%
F&A Cost Base 1	\$367,540	\$254,240	\$41,144	\$234,064	\$226,157
F&A Costs 1	\$187,445	\$129,662	\$20,983	\$120,543	\$116,471
F&A Cost Rate 2			51.5%		
F&A Cost Base 2			\$205,720		
F&A Costs 2			\$105,946		

EXHIBIT B

This notice has expired. Check the NIH Guide

(https://grants.nih.gov/funding/searchguide/) for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

Funding Opportunity Title

Measures and Methods for Research on Family Caregivers for People Living with Alzheimer's Disease and Related Dementias (AD/ADRD) (R01 Clinical Trial Not Allowed)

Activity Code

R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search_y=0&Search_Type=Activity) Research **Project Grant**

Announcement Type

New

Related Notices

NOT-OD-22-190 (/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022

Funding Opportunity Announcement (FOA) Number

RFA-AG-23-022

Companion Funding Opportunity

RFA-AG-23-023 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AG-23-023.html), R21 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R21&&Search.x=0&&Search_y=0&&Search_Type=Activity) Exploratory/Developmental Grants

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.866

Funding Opportunity Purpose

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This Funding Opportunity Announcement (FOA) invites Research Project Grant (R01) applications for the development of methods and measures for capturing expanded definitions of "family" and related concepts relevant to informal caregiving for people living with Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD), and for the implementation of these measures in new and existing studies.

High-risk/high-payoff projects that lack preliminary data may be more appropriate for the companion FOA, <u>RFA-AG-23-023</u>, (https://grants.nih.gov/grants/guide/rfa-files/RFA-AG-23-023.html) which invites Exploratory/Developmental Research Grant (R21) applications.

Key Dates

Posted Date

June 09, 2022

Open Date (Earliest Submission Date)

September 20, 2022

Letter of Intent Due Date(s)

September 20, 2022

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
October 20, 2022	Not Applicable	Not Applicable	February 2023	May 2023	July 2023

All applications are due by 5:00 PM local time of applicant organization.

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.

No late applications will be accepted for this Funding Opportunity Announcement.

Expiration Date

October 21, 2022

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the <u>SF424 (R&R) Application Guide</u> (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.php?id=11164)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in <u>Section IV</u>. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Table of Contents

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Key Dates

Part 2. Full Text of Announcement

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Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts

Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background

Family members, particularly spouses and children, are the major sources of unpaid care for adults living with Alzheimer's disease (AD) and Alzheimer's diseaserelated dementias (ADRD). Nevertheless, changes in family structure and composition over the past several decades — including lower rates of marriage and fertility, increased rates of divorce and cohabitation, the separation of marriage from child-raising, and growth in one-person households, as well as multigenerational and extended families — are altering the makeup of families and potentially the roles of family members as caregivers. An increasing share of more recent cohorts of adults are aging without spouses or biological children, leaving older adults with limited access to the most common current sources of unpaid care.

At the same time, the prevalence of other ties, such as step-kin and non-marital romantic partners, is increasing. Members of "blended families" (e.g., step-children), "families of origin" (e.g., surviving siblings), "families of choice" (e.g., personal communities of people such as friends, partners, and other people with whom individuals share a kin-like relationship, but are not connected by biological or legal ties), and other individuals may play a key role in providing informal care for people who do not have spouses or children, or whose spouses or children are unable or unwilling to serve in a caregiver role. Measures and methods to assess these families, including the types of ties that comprise these families and the expectations for, and exchanges of, care therein, are critical for identifying potential sources of unpaid care for individuals living with AD/ADRD, consistent with recommendations from the National Academy of Sciences, Engineering, and Medicine's (NASEM) Decadal Survey of Behavioral and Social Science Research on AD/ADRD (https://www.nia.nih.gov/research/dbsr/decadal-survey-behavioral-and-social-science-research-alzheimers-disease).

Existing surveys and current measures and methods are limited in their ability to assess many of the relationships that characterize today's families, or the differences in the criteria individuals use to define "family" (e.g., biological and/or legal ties, emotional closeness, etc.). The extent to which today's families provide, or are expected to provide, care for older adults may depend on factors such as the life course timing of the initiation of the relationship, the nature of the relationship and its quality, and the presence of competing relationships. These factors are also not often captured in existing studies. For example, though stepfamilies are increasingly common, which increases the number of family members who could *potentially* provide care, the extant literature suggests that step-relationships are not as emotionally close as biological relationships. This may translate into a lower *likelihood* of caregiving by a step-relative, or lower care recipient satisfaction with the caregiver. On the other hand, "less care" provided by more people may translate into more care overall — and less care provision per person. This might, in turn, reduce caregiver strain and burnout, and increase care recipient satisfaction and care quality. Yet, empirical tests of these possibilities require methods and measures to assess whom older adults consider family, whom they consider family who might provide care, and how to characterize those ties.

Existing measures also may fail to capture family structure differences for specific populations. For example, despite increased acceptance and legal recognition of sexual and gender minority (SGM) individuals and their relationships, little is known about how family care patterns vary by SGM status. The United States is also becoming more racially and ethnically diverse. Definitions of family, expectations and obligations regarding who should provide care, and even how "care" is defined may differ by sociocultural and acculturation factors.

Understanding the increasingly complex forms that families take on and their roles as caregivers for older people is especially important in the AD/ADRD context. As highlighted during the 2020 National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers (https://www.nia.nih.gov/2020-dementia-care-summit), the monetary costs of dementia are large, and unpaid caregiving — primarily done by family members — accounts for a substantial share. Further, some of the same factors that predict elevated AD/ADRD risk are also associated with family relationships that are not currently fully captured in existing studies. For example, lower levels of education are associated with both an elevated risk for AD/ADRD and a greater likelihood of never marrying, having step-relatives, and cohabiting. Because some of the same factors (e.g., education) that are predictive of being in the kinds of families that are not well-captured

using existing measures are also associated with elevated AD/ADRD risk, a better characterization of these complex family relationships and dynamics is especially important for understanding AD/ADRD health disparities. In addition, complex family forms are more common among more recent birth cohorts. Thus, understanding these families will become increasingly important for capturing the demand for, and supply of, family caregivers, as well as for other necessary supports and services, including paid care. Fully characterizing the broad range of family types will also inform intervention development to support all family caregivers. Because most current caregiver interventions focus on "primary" caregivers and do not consider the unique needs of complex family care networks, including those for the complex families described above, advances in measurements hold potential for improving the reach of intervention efforts.

In sum, demographic changes in families raise key questions about who individuals consider to be "family" and the roles they play in care for persons living with AD/ADRD – questions that cannot be answered with existing measures and survey methods. As such, researchers and policymakers lack the tools to assess whether all persons living with AD/ADRD and their family care partners are getting the care and services they need. By better understanding family structure and the potential roles family members play in providing care for people living with AD/ADRD, policymakers will have the knowledge needed to enhance and/or modify Medicare and Medicaid, private health insurance plans, and services in long term services and supports (LTSS) to address issues related to unmet needs and care quality.

Research Objectives

This Funding Opportunity Announcement (FOA) supports the development of methods and measures for capturing expanded definitions of "family" and related concepts relevant to informal caregiving for people living with AD/ADRD, and the implementation of these measures in new and existing studies.

Potential measures include, but are not limited to, those that capture the following:

- Population heterogeneity in how individuals define "family"
- Sense of obligation for caregiving, expectations of care to be given or received, and other aspects of the positive and negative
 "content" of relationships relevant for caregiving, such as trust in family members and concerns about burden that are not captured by
 standard social support measures, as well as relationship closeness indicators such as estrangement
- Dynamic aspects of relationships salient to caregiving, such as changes over time (or life course stage) in relationship quality or in who
 people expect/prefer will care for them versus who actually provides care
- · Geographically proximate and distal family connections
- · Step-kin, ex-kin, fictive kin
- · Relationships that are alternatives to marriage, including living apart together (LAT) and cohabitation
- · Attitudes, beliefs, and resources relevant for paid caregiving as a substitute or complement to unpaid family caregiving
- · Self-identification of sexual and gender minority status in conjunction with the measures above

Methodological developments include, but are not limited to, the following:

- Tools across survey modes (e.g., web, telephone, mobile devices) to comprehensively capture family relationships in ways that do not
 overburden respondents
- · Longitudinal analytical approaches to dynamically assess changes in family structure/composition and function relevant to caregiving
- · Network-level approaches to characterize families and individuals' ties to unpaid care partners

Populations of interest include, but are not limited to the following health disparity populations:

- · Sexual and gender minority individuals
- · Low-socioeconomic individuals
- · Racial and ethnic minorities
- · Immigrant groups
- · People living alone

Applicants are encouraged to refer to the <u>National Institute on Aging (NIA) Health Disparities Research Framework</u> (https://www.nia.nih.gov/research/osp/framework) to learn about NIA priority populations, the integration of multi-level factors, and the incorporation of a life course perspective.

Proposed projects may include those that implement new measures and methods into nationally-representative studies with existing family caregiver measures (e.g., Health and Retirement Study (HRS) and its international sister studies, National Health and Aging Trends Study (NHATS), National Survey of Caregiving (NSOC), Panel Study of Income Dynamics (PSID), Add Health Parents Study, and the Midlife Development in the United States (MIDUS) survey). Studies that will collect measures in populations not well-captured in existing studies (e.g., SGM populations, immigrant groups) are encouraged. Mixed methods studies that incorporate qualitative interviews to inform the development of survey instruments are also appropriate.

Resources for Applicants

<u>Data Resources for Behavioral and Social Research on Aging (https://www.nia.nih.gov/research/dbsr/data-resources-behavioral-and-social-research-aging)</u>

- NASEM's Decadal Survey of Behavioral and Social Science Research on AD/ADRD (http://www.nia.nih.gov/research/dbsr/decadal-survey-behavioral-and-social-science-research-alzheimers-disease). The committee conducted a decadal survey focusing on developing a research agenda for the next decade in the behavioral and social sciences as it relates to AD/ADRD. Drawing on extensive input from the scientific community and other stakeholders, the committee assessed the role of the social and behavioral sciences, including data sources and other resources, in reducing the burden of AD/ADRD.
- 2020 National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers
 (https://www.nia.nih.gov/2020-dementia-care-summit).

 The goal of the Summit was to bring together individuals with a variety of backgrounds to identify evidence-based programs, strategies, approaches, and other research that can be used to improve the care, services, and supports of persons living with AD/ADRD and their care partners.

Non-Responsiveness Criteria

Applications that do not clearly articulate the proposed project's relevance to caregiving for people living with AD/ADRD will be considered non-responsive to this FOA and will be withdrawn prior to review.

Frequently Asked Questions

Responses to frequently asked questions about this FOA will be posted on the following webpage:

https://www.nia.nih.gov/research/dbsr/behavioral-and-social-research-funding-opportunities-and-applicant-resources (https://www.nia.nih.gov/research/dbsr/behavioral-and-social-research-funding-opportunities-and-applicant-resources). See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

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

Clinical Trial?

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

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

Funds Available and Anticipated Number of Awards

NIA intends to commit \$3,960,000 in fiscal year 2023 to fund up to 6 awards.

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.

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

Section III. Eligibility Information

1. Eligible Applicants

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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)

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

- · State Governments
- · County Governments
- · City or Township Governments
- · Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Government

- · Eligible Agencies of the Federal Government
- · U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- · Faith-based or Community-based Organizations
- · Regional Organizations
- · Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) are eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations are eligible to apply.

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

Required Registrations

Applicant Organizations

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

System for Award Management (SAM)— (https://grants.nih.gov/grants/guide/url_redirect.php?id=82390). Applicants must complete and
maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the

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initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- <u>eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)</u> Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; 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.php?id=82300)</u> Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per <u>2.3.7.4 Submission of Resubmission Application (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.7_policies_affecting_applications.htm#Submissi)</u>. 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>2.3.9.4 Similar</u>, <u>Essentially Identical</u>, <u>or Identical Applications</u>
 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar,)

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 instructions in the Research (R) Instructions in the <u>SF424 (R&R) Application Guide</u> (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this funding opportunity announcement to do

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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.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIA staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- · Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- · Names of other key personnel
- Participating institution(s)
- · Number and title of this funding opportunity

The letter of intent should be sent to:

Amelia Karraker, Ph.D.

National Institute on Aging (NIA)

Telephone: 301-496-3136

Email: Amelia.Karraker@nih.gov (mailto:Amelia.Karraker@nih.gov)

Page Limitations

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

R&R or Modular Budget

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

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

If the application includes new measures relevant to family caregiving for people living with AD/ADRD, the application must clearly articulate how these measures move beyond existing measures to reveal new insights.

If the application includes measurement or methodological developments focused on a particular population or implemented in an existing study, this choice must be justified.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

All applications, regardless of the amount of direct costs requested for any one year, must address a <u>Data Sharing Plan</u> (https://grants.nih.gov/grants/guide/url_redirect.php?id=11151). The plan should provide details for what will be shared - including data and data collection instruments and tools, how it will be organized to enhance the user experience, and any limitations/restrictions on access to resources and data produced by the project. The data sharing plan should ensure maximum availability to the research community beyond the study team (accounting for human subjects considerations).

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: <u>Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy)</u> does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

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

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11137), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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

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

4. Submission Dates and Times

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

Organizations must submit applications to <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?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 (https://grants.nih.gov/grants/guide/url_redirect.php?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 <u>intergovernmental review.</u>
(https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

Important reminders:

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

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

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

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

In order to expedite review, applicants are requested to notify the NIA Referral Office by email at Ramesh. Vemuri@nih.gov when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful 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 scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability,

and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA:

If the study includes new measures relevant to family caregiving for people living with AD/ADRD, how likely is it that the study will yield new insights into aspects of family caregiving for people living with AD/ADRD?

If the study includes measurement or methodological developments focused on a particular population or implemented in an existing study, how well-justified is this choice?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Specific to this FOA:

Reviewers will comment on whether the <u>Data Sharing Plan (https://grants.nih.gov/grants/guide/url_redirect.php?id=11151)</u> is reasonable. How adequate are the applicant's plans to share, organize, and store resources, including data collection instruments and tools, and data?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

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

Protections for Human Subjects

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

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

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

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not Applicable

Renewals

Not Applicable

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.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

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).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Sharing Model Organisms (https://grants.nih.gov/grants/policy/model_organism/); and (2) Genomic Data Sharing Plan (GDS) (https://osp.od.nih.gov/scientific-sharing/policies).

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

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

(file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

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.

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section 2/2.4.2 appeals of initial scientific review.htm) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned 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 National Advisory Council on Aging. 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.

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 (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)</u>. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the <u>NIH Grants Policy Statement</u> (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

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

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

Any application awarded in response to this FOA will be subject to terms and conditions found on the <u>Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm)</u> website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php? id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php? id=11159), including of note, but not limited to:

- Federalwide Research Terms and Conditions

 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section 3/3.1 federalwide standard terms and conditions for research grants.htm)
- <u>Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)</u>

Acknowledgment of Federal Funding
 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section-4/4.2.1 acknowledgement of federal funding.htm)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html) (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

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

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

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, recipients will be required to submit the <u>Research Performance Progress Report (RPPR)</u> (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the <u>NIH Grants Policy Statement</u>. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section 8/8.4.1 reporting.htm)

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A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

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

(https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.1.8 federal funding accountability and transparency act ffata .htm) for additional information on this reporting requirement.

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

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 Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

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

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

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

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

Telephone: 301-480-7075

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)

Amelia Karraker, Ph.D.

National Institute on Aging (NIA) Telephone: 301-496-3136

Email: Amelia. Karraker@nih.gov (mailto: Amelia. Karraker@nih.gov)

Elena Fazio, Ph.D.

National Institute on Aging (NIA) Telephone: 301-496-3136

Email: Elena.Fazio@nih.gov (mailto:Elena.Fazio@nih.gov)

Melissa Gerald. Ph.D.

National Institute on Aging (NIA) Telephone: 301-496-3136

Email: Melissa.Gerald@nih.gov (mailto:geraldmel@mail.nih.gov)

Liz Necka, Ph.D.

National Institute on Aging (NIA) Telephone: 301-496-3136

Email: Liz.Necka@nih.gov (mailto:Liz.Necka@nih.gov)

Peer Review Contact(s)

Ramesh Vemuri, Ph.D.

National Institute on Aging (NIA) Telephone: 301-402-7700

Email: Ramesh. Vemuri@nih.gov (mailto:Ramesh. Vemuri@nih.gov)

Financial/Grants Management Contact(s)

Ryan Blakeney

National Institute on Aging (NIA) Telephone: 301-451-9802

Email: Ryan.Blakeney@nih.gov (mailto:ryan.blakeney@nih.gov)

Section VIII. Other Information

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

(//grants.nih.gov/grants/quide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

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

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?06-10-22) NIH Funding Opportunities and Notices (/grants/guide/index.html)





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



NIH... Turning Discovery Into Health®

EXHIBIT C

Recipient Information

1. Recipient Name

BOARD OF REGENTS OF NEVADA SYSTEM OF HIGHER EDUCATION 4505 S MARYLAND PKWY LAS VEGAS, NV 89154

2. Congressional District of Recipient 01

3. Payment System Identifier (ID) 1886000024A3

4. Employer Identification Number (EIN) 886000024

5. Data Universal Numbering System (DUNS) 098377336

6. Recipient's Unique Entity Identifier DLUTVJJ15U66

7. Project Director or Principal Investigator

JASON DANE FLATT, PHD (Contact) **Assistant Professor** jason.flatt@unlv.edu 702-895-5586

8. Authorized Official

Jill Tuley

Federal Agency Information

9. Awarding Agency Contact Information Morgan Amanda Granetz

NATIONAL INSTITUTE ON AGING morgan.granetz@nih.gov

10. Program Official Contact Information

Melissa S Gerald Health Science Administrator NATIONAL INSTITUTE ON AGING geraldmel@nia.nih.gov 301-402-4156

Federal Award Information

11. Award Number

5R01AG083177-02

12. Unique Federal Award Identification Number (FAIN)

R01AG083177

13. Statutory Authority

42 USC 241 42 CFR 52

14. Federal Award Project Title

Enhancing Measurement and Characterization of Roles and Experiences of Sexual and Gender Minority Caregivers of Persons living with Alzheimer's Disease and Related Dementias

15. Assistance Listing Number

93.866

16. Assistance Listing Program Title

Aging Research

17. Award Action Type

Non-Competing Continuation (REVISED)

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 05/01/2024 - End Date 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	\$0
20 a. Direct Cost Amount	\$0
20 b. Indirect Cost Amount	\$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	\$702,329
24. Total Approved Cost Sharing or Matching, where applicable	\$0
25. Total Federal and Non-Federal Approved this Budget Period	\$702,329
26. Project Period Start Date 08/01/2023 - End Date 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost	\$1,432,248
Sharing or Matching this Project Period	

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

Philip E. Smith

30. Remarks

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

Notice of Award





NATIONAL INSTITUTE ON AGING

SECTION I - AWARD DATA - 5R01AG083177-02 REVISED

Principal Investigator(s):

Joel G. Anderson, PHD Norca Maritza Dowling, PHD JASON DANE FLATT (contact), PHD

Award e-mailed to: osp@unlv.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF NEVADA LAS VEGAS in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG083177. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Philip E. Smith Grants Management Officer NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative	e Award Calculations for	r this Budget Period	(U.S. Dollars)
<u> </u>	1 147		•

Samulative / tivara Salsalations for time Baaget remote (5:5: Bollato)	
Salaries and Wages	\$164,555
Fringe Benefits	\$36,385
Personnel Costs (Subtotal)	\$200,940
Consultant Services	\$4,000
Materials & Supplies	\$200
Travel	\$5,400
Other	\$47,921
Subawards/Consortium/Contractual Costs	\$308,406
Publication Costs	\$4,600
ADP/Computer Services	\$1,200
Federal Direct Costs	\$572,667
Federal F&A Costs	\$129,662
Approved Budget	\$702,329
Total Amount of Federal Funds Authorized (Federal Share)	\$702,329
TOTAL FEDERAL AWARD AMOUNT	\$702,329

	SUMMARY TOTALS FOR ALL YEAR	S (for this Document Number)
YR	THIS AWARD	CUMULATIVE TOTALS
2	\$702,329	\$702,329

\$0

Fiscal Information:

Payment System Identifier: 1886000024A3

Document Number: RAG083177A

PMS Account Type: P (Subaccount)

AMOUNT OF THIS ACTION (FEDERAL SHARE)

Fiscal Year: 2024

IC	CAN	2024
AG	8033157	\$702,329

NIH Administrative Data:

PCC: 2BFAMGE / OC: 41025 / Released: 03/21/2025 Award Processed: 03/24/2025 12:04:16 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5R01AG083177-02 REVISED

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

SECTION III - STANDARD TERMS AND CONDITIONS - 5R01AG083177-02 REVISED

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

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

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01AG083177. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy/htm#qps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at:

https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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

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

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

Treatment of Program Income:

Additional Costs

SECTION IV - AG SPECIFIC AWARD CONDITIONS - 5R01AG083177-02 REVISED

Clinical Trial Indicator: No

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

It is the policy of NIH not to prioritize Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.. Therefore, this project is terminated. UNIVERSITY OF NEVADA, LAS VEGAS may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with <u>2 C.F.R. § 200.340</u> as implemented in <u>NIH GPS Section 8.5.2</u>. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

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Supersedes Notice of Award issued 05/07/2024 Previous terms and conditions apply:

This award includes funds awarded for consortium activity with George Washington University. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section 15/15 consortium agreements.htm

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

SPREADSHEET SUMMARY

AWARD NUMBER: 5R01AG083177-02 REVISED

INSTITUTION: UNIVERSITY OF NEVADA LAS VEGAS

Budget	Year 2
Salaries and Wages	\$164,555
Fringe Benefits	\$36,385
Personnel Costs (Subtotal)	\$200,940
Consultant Services	\$4,000
Materials & Supplies	\$200
Travel	\$5,400
Other	\$47,921
Subawards/Consortium/Contractual Costs	\$308,406
Publication Costs	\$4,600
ADP/Computer Services	\$1,200
TOTAL FEDERAL DC	\$572,667
TOTAL FEDERAL F&A	\$129,662
TOTAL COST	\$702,329

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	51%
F&A Cost Base 1	\$254,240
F&A Costs 1	\$129,662

EXHIBIT D

Sexual and Gender Minority Populations in NIH-Supported Research

Notice Number: NOT-OD-19-139

Key Dates

Release Date: August 28, 2019

Related Announcements

• **September 6, 2024** - Updating the Definition of Sexual and Gender Minority Populations in NIH-Supported Research. See Notice NOT-OD-24-169.

Issued by

Sexual and Gender Minority Research Office (SGMRO)

Purpose

The purpose of this Notice is to announce the revision of the definition of sexual and gender minority (SGM) populations for research purposes at the NIH, as well as to provide a summary of information about SGM health research at the NIH. It is expected that this Notice will help to enhance the representation of SGM individuals in the agency's research portfolio and to stimulate the development of novel research projects and strategies to better understand and advance SGM health.

Implementation Timeline

This Notice is effective upon its release date.

The Sexual & Gender Minority Research Office

The NIH Fiscal Years 2016-2020 Strategic Plan to Advance Research on the Health and Well-Being of Sexual and Gender Minorities was released in 2015. The plan elucidated goals and objectives to encourage the advancement of basic, clinical, behavioral, population, and social sciences research to improve the health of SGM individuals. One of the objectives of the strategic plan was to establish a central office to coordinate SGM-related research and activities at the NIH. Established in 2015, the Sexual & Gender Minority Research Office (SGMRO) resides within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the NIH Office of the Director.

The NIH laid out four overarching goals in its FY 2016-2020 SGM strategic plan: (1) Expand the knowledge base of SGM health and well-being through NIH-supported research; (2) Remove barriers to planning, conducting, and reporting NIH-supported research about SGM health and well-being; (3) Strengthen the community of researchers and scholars who conduct research relevant to SGM health and well-being; and (4) Evaluate progress on advancing SGM research. The SGMRO pursues these goals by convening and participating in events involving SGM health priorities, managing dissemination of information about SGM health research, and working with NIH Institutes, Centers, and Offices (ICOs) to leverage resources and develop initiatives to promote SGM health and research.

Definition of Sexual and Gender Minorities

At the NIH, the term sexual and gender minority originally encompassed individuals who identify as lesbian, gay, bisexual, transgender, queer, or intersex, as well as those who do not self-identify with one of these terms, but whose sexual orientation, gender identity, or reproductive development varies from traditional, societal, cultural, or physiological norms. The NIH has heretofore opted to use this definition to maintain inclusivity and consistency in reporting. However, after consultation with several NIH groups that possess contemporary expertise in SGM health and research, the NIH is releasing an updated SGM definition to foster and expand

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inclusion of SGM individuals in health research by better clarifying the populations who fall under the SGM umbrella. The definition of SGM is revised to read as follows:

SGM populations include, but are not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.

The SGMRO would like to make clear that this change in definition is not intended to exclude any person or population previously included under the former definition of SGM populations.

SGM as a Health Disparity Population

SGM individuals face unique health challenges, and a continually growing body of evidence suggests that SGM individuals suffer disproportionately from a variety of conditions and diseases. In October 2016, the National Institute on Minority Health and Health Disparities (NIMHD), in collaboration with the Agency for Healthcare Research and Quality (AHRQ), announced that SGM populations had been officially designated as a health disparity population for NIH and AHRQ research. This designation has since facilitated the creation of tailored research projects, programs, and activities intended to tackle the distinct issues encountered by SGM individuals. In addition, ascertainment of SGM status in ongoing and planned population studies has been enhanced. However, SGM-specific health disparities persist today, and novel methods to measure, address, and prevent them are still needed.

Addressing SGM-Specific Health Disparities

To help eliminate these disparities, the 21st Century Cures Act, which authorized funding to accelerate research in several key public health areas at the NIH, included provisions specifically intended to increase participation of SGM populations in NIH-supported clinical research and to facilitate the development of methods for conducting SGM research. In support of this, the NIH SGM Research Working Group (SGM RWG), a working group of the NIH Council of Councils, recommended in its 2019 Mid-Course Strategic Plan Review that the NIH encourage applicants for clinical research funding to demonstrate consideration of inclusion of SGM populations whenever appropriate. Increased data collection and analyses on SGM populations may help to illuminate important information needed to address the health of these communities.

Inquiries

Please direct all inquiries to:

Karen L Parker, PhD, MSW Division of Program Coordination, Planning, and Strategic Initiatives Sexual & Gender Minority Research Office

Telephone: 301-451-2055? Email: <u>klparker@mail.nih.gov</u>

Weekly TOC for this Announcement NIH Funding Opportunities and Notices