Federal Updates

- 1. ACL
- 2. AHRQ
- 3. CDC
- 4. NIH

- 5. DOD
- 6. IHS
- 7. FDA
- 8. CMS

National Alzheimer's Project Act Advisory Council on Alzheimer's Research, Care, and Services

Administration for Community Living

July 31, 2023

Alzheimer's Disease Programs Initiative: States and Community Programs

Winter 2023 HHS-2023-ACL-AOA-ADPI-0045

Number of Grants: 12

Project Period: September 1, 2023 – August 31, 2026

Total award amount: \$11,430,358.

Winter 2023 Awardees

1. Athens Community Council of Aging Inc. (GA)

2. Center for Excellence in Aging and Geriatric Health (VA)

3. Chinese American Service League (IL)

4. Florida Atlantic University (FL)

5. Interfaith Carepartners (TX)

6. IONA Senior Services (DC)

7. OPICA Adult Day Program & Counseling Center Inc. (CA)

Somang Society (CA)

9. Southern Mississippi Planning and Development District (MS)

10. STATE of Mississippi Human Services (MS)

11. STATE of Nevada Aging and Disability Service Division (NV)

12. The Catholic Charities of Hawaii (HI)

Administration for Community Living

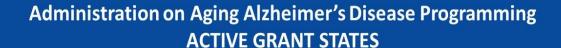
Alzheimer's Disease Programs Initiative: States and Community Programs

NOTICE OF FUNDING OPPORTUNTIY (NOFO)

HHS-2023-ACL-AOA-ADPI-0035

Applications Due August 7, 2023

- Cooperative agreements under the ADPI funding opportunity announcement (FOA), are intended to support and promote the development and expansion of dementia-capable home and community-based service (HCBS) systems in States and Communities.
- The dementia-capable systems resulting from program activities under either option are expected to provide quality, person-centered services and supports that help individuals living with dementia and their caregiver remain independent and safe in their communities.
- Two application options contained in this single NOFO: Grants to States (Option A) and Grants to Communities (Option B).
- No entity is eligible to apply for both State and Community options and no entity is eligible to hold more than one ADPI grant at any one time.





UPCOMING AWARDS

The Alzheimer's Call Center (HHS-2023-ACL-AOA-ADCC-0018)

COMING SOON! New grant award anticipated to be announced and start on or around September 1, 2023

ACL's Lifespan Respite Program

COMING SOON! Look for announcement on new awards this week.

- Lifespan Respite Care Program: State Program Enhancement Grants (HHS-2023-ACL-AOA-LRLI-0014)
- Lifespan Respite Care Program: Grants to New States and States Re-Establishing Their Core Respite Infrastructures (HHS-2023-ACL-AOA-LRLR-0017)

Community Care Corps – <u>New mini-grants in September 2023</u> to support innovative local models in which volunteers provide nonmedical assistance to family caregivers, older adults, or adults with disabilities in order to maintain their independence. https://www.communitycarecorps.org/

National Alzheimer's and Dementia Resource Center

UPCOMING WEBINAR

Memory Connections: Helping Families Navigate Their Dementia Journey with a Menu of Program Options
August 29, 2023 from 3-4 p.m. ET

Memory Connections, an ACL-funded initiative through Senior Services Inc. in North Carolina, is a multi-faceted project that offers support, creativity, education, and engaging activities for people living with dementia and their caregivers. Participants will learn how Senior Services Inc. and their partners including the Maya Angelou Center for Health Equity are working together to create a unique continuum of dementia care. Presenters will highlight the Maya Angelou Center for Health Equity's Caregiver College, a week-long program that educates African Americans about Alzheimer's disease and related dementias. Caregiver College graduates apply their newly acquired knowledge by delivering presentations to their social groups, churches, family members, friends and business connections.

Information on speakers and the registration form can be found here: HERE - Navigating Dementia Journey Program Options

Inter Tribal Council of Arizona: ITCA Powerful Tools for Caregiving and Walk with Me Wednesday, September 20, 2023 from 3-4 p.m. ET

Registration coming soon! NAPA Goals 2, 3, 4

Administration for Community Living Past Webinars

Veterans Health Administration's Strategy to Promote Aging in Place for Veterans (May 25, 2023) (461 Live Attendees)
The Veterans Health Administration (VHA) understands the importance of providing options to Veterans as they age and their care becomes increasingly complex. Allowing Veterans to age in place is VHA's overarching goal for Veterans who both desire and are able to remain safely at home. The most common barriers for seniors to age in place are the increasing levels of assistance needed to maintain activities of daily living and instrumental activities of daily living, as well as transportation and affordable housing. The webinar will provide an overview of VHA's Home and Community Based Programs for all Veterans, including those living with dementia, and how to find additional information and resources. COMING SOON to NADRC website.

It's a Journey: Age Friendly and Dementia Capable Health Systems. (June 20, 2023) (562 Live Attendees)

Age-friendly and the dementia-friendly movements can work together to improve the health and well-being of older adults living with dementia and their families. The John A. Hartford Foundation has led the development of the Age-Friendly Health Systems movement with the Institute for Healthcare Improvement and other partners to spread evidence-based care. ACL's ADPI grantee, MaineHealth is working to become a Dementia Capable health system within the Age Friendly Health Systems movement. By aligning these initiatives with other system programming, there are sustainable and ongoing mechanisms to assess and support individuals in the community with dementia and their caregivers. COMING SOON to NADRC website.

NAPA Goals 2, 3, 4

National Alzheimer's and Dementia Resource Center

New and Updated Resources

- <u>Highlights of Grantee-Developed Resources</u> ACL Alzheimer's program grantees have produced a range of resources on topics most relevant to offering ADRD supports and services. The resources highlighted in this document were developed through ACL grants and determined. The intention is to share these resources with other local providers delivering dementia care services. This document highlights selected resources and examples from across the United States.
- Living with Dementia: Advance Planning Guides (FOUR guides) for Persons with Dementia and Caregivers Guides: 1. Health Care Planning: to help you plan for your future health care needs 2. Planning for Care: to plan for the care and services you may need 3. Financial Planning: to plan how to manage your money and property 4. Making Decisions for Someone with Dementia. The guides on the webpage are designed to allow for co-branding so that agencies using them can include their branding and contact information.

NAPA Goals 2, 3, 4

Administration for Community Living

Commit to Connect

- · Established: June 2021
- Mission: To increase the availability of programs and strategies that address social isolation and loneliness and grow social connection for older/aging adults, people living with disabilities, and caregivers. In addition to producing consumer and professional resources.
- Activities: Established a Nationwide Network of Champions. Making a no cost online resource hub available for community for leaders dedicated to ending social isolation and loneliness.
 - Serves almost 300 leaders and 210 community-based organizations across 37 states.

Coming Soon!

<u>Commit to Connect</u> Topical Guide: Supporting the Social Connection of People Living with Dementia (expected July 2023)

National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) Grantee Outputs – Alzheimer's/Dementia

Enhancing Neurocognitive Health, Abilities, Networks, & Community Engagement Center, ENHANCE
NIDILRR-funded grant at Cornell University (FY19-23) Activities

- Dr. Walter Boot gave a talk featuring ENHANCE to Emory University's Goizueta Alzheimer's Disease Research
 Center (ADRC) as part of BrainTalk Live in February. BrainTalk Live is a weekly webinar that provides educational
 information on Alzheimer's disease and related dementia, aging, COVID, disease prevention, health promotion,
 and other topics as indicated by their audience's interests. https://www.youtube.com/watch?v=nGzNhm14o-0
- ENHANCE graduate student Edie Sanders will be presenting findings from her study "Investigating usability of
 the smartwatch as an everyday prospective memory aid for older adults with and without cognitive
 impairment" at the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA)
 conference in July.
- The following abstract will be presented at the American Congress of Rehabilitation Medicine conference in October: Lydon, E. A., Trotter, K. N., Rogers, W. A., Czaja, S. J., Boot, W., Charness, N., & Mudar, R. A., The Use of Complex Discourse Production for Characterizing Mild Cognitive Impairment. This study provides evidence for the use of this discourse task as a measure of early changes in cognition in individuals with MCI. This task may be well suited as a quick screening measure of cognition, easily administered by clinicians across various healthcare settings, and enjoyed by participants.

Assistive Technology Act Programs

North Dakota Assistive

North Dakota Assistive contracts with the Alzheimer's Association of ND. A few of their employees across North Dakota have recently joined our Assistive Technology Ambassador Program where they will carry our message in rural North Dakota as well as their own. Ambassadors attend health fair and other community activities using Assistive Technology cases filled with AT equipment.

Connecticut

The CT Assistive Technology Act Project partnered with the CT Alzheimer's Association to engage in outreach and awareness activities

Thank you!

Erin Long, MSW
Team Lead
Alzheimer's Disease Programs Initiative (ADPI)
Office of Supportive and Caregiver Services
Administration on Aging
Administration for Community Living
Erin.Long@acl.hhs.gov
202-795-7389

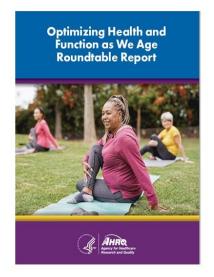
Agency for Healthcare Research and Quality

UPDATES FOR THE ADVISORY COUNCIL ON ALZHEIMER'S RESEARCH, CARE, AND SERVICES

Optimizing Health and Function as We Age Roundtable Report



- AHRQ's Optimizing Health and Function as We Age Roundtable Report explores opportunities including for developing a person-centered care system, and integrating the voices of older adults, caregivers and communities in designing effective models of care for improving older adults' health and well-being.
- Multidisciplinary experts came together to discuss how AHRQ can impact and research, dissemination and implementation of evidence to improve the organization and delivery of healthcare with the goal of optimizing the health, functional status and well-being of the US population as it ages.



15

CDC UPDATES

LISA C. MCGUIRE, PHD



WEBSITE REFRESH











cdc.gov/aging

17



COMING SOON!



CDC-RFA-DP23-0010

BOLD Public Health Programs to Address Alzheimer's Disease and Related Dementias

- Fulfills the BOLD Infrastructure for Alzheimer's Act (P.L. 115-406)
- This NOFO will fund state, local, and tribal public health departments

5-year awards (approx. 35 awards)

2 Components:

- Component 1

Phase 1 – Planning (years 1-2)

Phase 2 – Implementation (years 3 - 5)

- Component 2 - Implementation (years 1-5)

<u>Healthy Brain Resource</u> <u>Center</u> (HBRC)





The Healthy Brain Resource Center (HBRC) is a one-stop, easy-to-navigate website that helps users find credible information and materials to support implementing the Healthy Brain Initiative Road Map.

There are currently features over 300 publicly available resources.

- CDC-verified resources and information all in one location.
- Robust search functions to quickly access information.
- A <u>user manual</u> and <u>orientation video</u> provide guidance on how to use the HBRC.
- Rolling content submissions accepted

19

New Searchable Resource: ADRD PLANS





https://www.cdc.gov/aging/dementia/strategic-plans.html

NEW PUBLICATION





Dementia Risk Reduction Summit May 16-17, 2023 Atlanta, GA





Summit Recordings



Public health strategies to promote brain health, address dementia, and help support caregivers











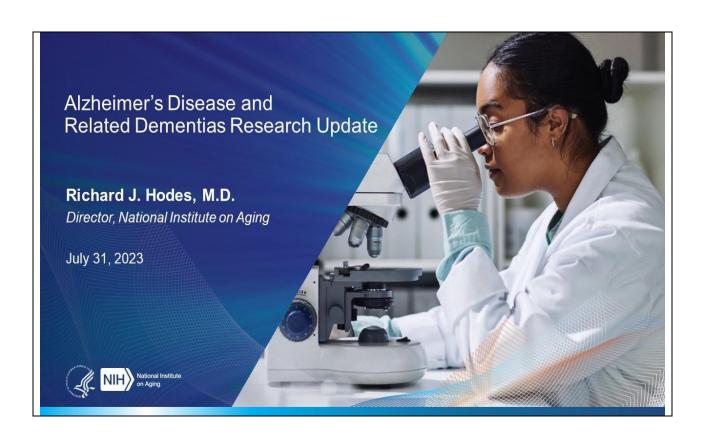
www.cdc.gov/aging



CHARTING THE COURSE TO BETTER BRAIN HEALTH

This presentation's slides can be found as a separate file.

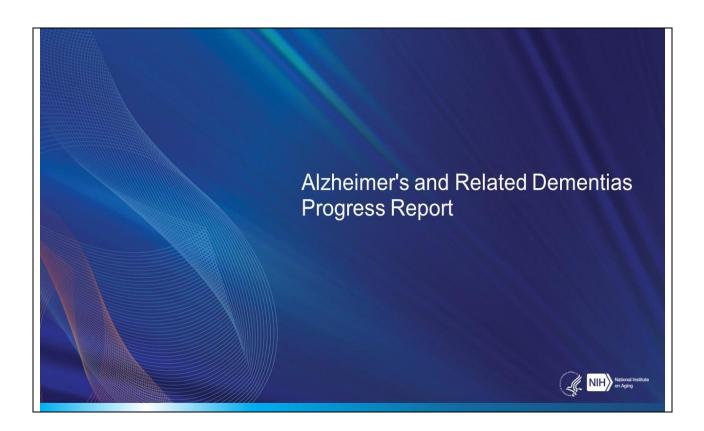




FY 2025 Professional Judgment Budget

This presentation's slides can be found as a separate file.





Alzheimer's and Related Dementias Progress Report

 Summarizes significant NIH-funded dementia research advances from the last ten years.



https://www.nia.nih.gov/about/bypass-budget-proposal-archive



6

Overview of Accomplishments from the Last Decade

- Advancing our understanding of the risk factors, genetics, and mechanisms of dementia
- Diversifying and de-risking the therapeutic pipeline for disease-modifying drugs
- · Accelerating drug repurposing and combination therapy development
- · Developing tools to detect, diagnose, and monitor dementia
- · Advancing clinical research on lifestyle interventions
- Increasing our understanding of how social and environmental factors affect dementia risk and disparities
- Expanding research on dementia care and care partner supports





Implementation Tracking

- Web-based tool for tracking funding initiatives and activities: https://www.nia.nih.gov/research/milestones
 - > Newly revised + now searchable
 - > Aimed at addressing the research milestones associated with NAPA
 - > Includes information on milestone activities, status, etc.
- IADRP: http://iadrp.nia.nih.gov/
 - > Will continue to offer detailed tracking of awards under the CADRO categories





Notice of Upcoming EUREKA Challenge

NIH Early Prediction of AD/ADRD Open Innovation Challenge

Purpose: The National Institute on Aging (NIA) is developing a challenge prize competition **to**

discover the best data, methods, and strategies for the early prediction of Alzheimer's disease (AD) and AD-related dementias (ADRD). This includes an emphasis on building diverse teams and solutions that generalize to groups that historically have been excluded from participation in AD/ADRD research, despite

being disproportionately impacted by these conditions.

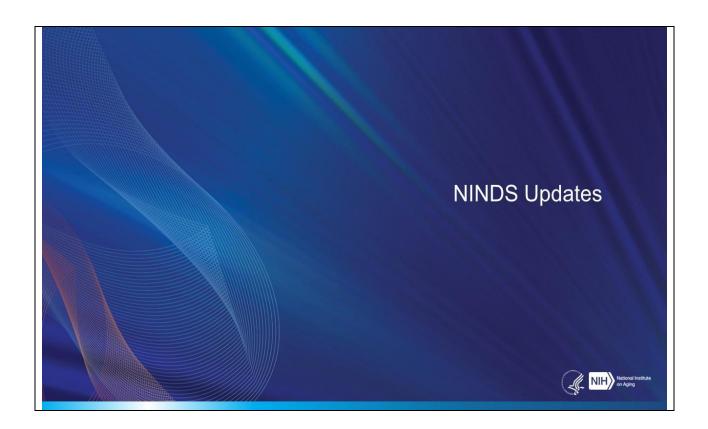
Launch Date: Anticipated September 1, 2023

Prize/Award: The challenge intends to offer cash awards totaling \$650,000, to be distributed

across three phases of the competition

Notice Link: https://grants.nih.gov/grants/guide/notice-files/NOT-AG-23-040.html





ADRD Funding Initiatives and Plans for FY2024



NINDS led 14 funding announcements in FY2023

There are 13 AD/ADRD funding announcements currently open that NINDS participates in:

https://www.ninds.nih.gov/funding/find-funding-opportunities (Search "ADRD")

Fourteen new NINDS funding announcement concepts planned for FY2024

WORKFORCE

RESEARCH

Diversity Training Career

- Social Determinants
- Modifiable Risk(s)
- Mechanisms & Pathology
- Microbiome
- Covid-19 & Dementia
- Translational
- Biomarkers & Diagnosis
- biolilarkers & Diagnosis
- Clinical Trial:
 - o Phase-III for VCID

See the NINDS Focus on Alzheimer's Disease and Related Dementias page for details: https://www.ninds.nih.gov/current-research/focus-disorders/alzheimers-related-dementias







NINDS ADRD Current and FY2024 Planned Funding Announcements:

Training and Disease Mechanisms

NOUNCEMENT	TITLE			
NOT-NS-21-047	Administrative Supplements to Promote Diversity for NINDS AD/ADRD Awardees; Multiple due dates, through March 2024			
PAR-23-113	NINDS Institutional AD/ADRD Research Training Program (T32); Standard dues dates, Expiration: May 25, 2024			
PAR-22-022	NINDS AD/ADRD Advanced Postdoctoral Career Transition Award to Promote Diversity (K99/R00); Standard dues dates, Expiration: July 13, 2024			
PAR-23-140	Blood Brain Barrier Response to Antibodies Targeting Beta-Amyloid (Re-issue of PAR-22-235), Due Date: June 2, 2023			
PAR-23-154	Development and Validation of Models for ADRD Due Dates: June 20, 2023; October 20, 2023			
PAR-22-093	Research on Current Topics in ADRD (R01); Multiple due dates, through November 12, 2024 (NIA leads)			
PAR-23-218	Development & Characterization of Experimental models of post-TBI ADRD			
PAR-23-211	Mechanistic Investigations into ADRD Multiple Etiology Dementias			
PAR-23-212	Investigating Distinct and Overlapping Mechanisms in TDP-43 Proteinopathies, including in LATE, FTD, and other ADRDs			
PAR-23-214	Neuropathological Interactions Between COVID-19 and ADRD			
RFA-NS-24-009	Optimization Genome Editing Therapeutics for ADRD (Re-issue of <u>RFA-NS-23-017</u>)			
RFA-NS-24-011	Center Without Walls for PET Ligand Development for the ADRDs (Re-issue RFA-NS-19-014)			



NINDS AD/ADRD Current and FY2024 Planned Funding Announcements:

Clinical Trials, Clinical Research and Translation

ANNOUNCEMENT	TITLE
RFA-NS-24-001	Using Multimodal Biomarkers to Differentially Diagnose ADRDs for Clinical Trials (U19), Due Date: June 01, 2023
RFA-NS-24-010	Early-Stage Therapy Development for ADRD (Re-issue of <u>RFA-NS-22-059</u>)
RFA-NS-24-003	Assessment of TBI-related ADRD Pathology Related to Cognitive Impairment and Dementia Outcomes (U01 - Clinical Trial Not Allowed)
PAS-22-196	Advancing Research on AD/ADRD SBIR/STTR Programs(R43/R44) (Clinical Trial Optional); Standard due dates, Expiration: September 06, 2025 (NIA leads)
PAS-22-197	Advancing Research on AD/ADRD SBIR/STTR Programs(R41/R42) (Clinical Trial Optional); Standard due dates, Expiration: September 06, 2025 (NIA leads)
Concept approved	Anti-amyloid Efficacy in ADRD (VCID) populations
PAR-23-195	Simultaneous and Synergistic Multi-Target Validation for Alzheimer's Disease-Related Dementias (R61/R33 Clinical Trial not allowed)

15 NINDS ADRD funding initiatives for FY 2024, for more information see: https://www.ninds.nih.gov/Current-Research/Focus-Disorders/Alzheimers-Related-Dementias

No RFA is needed to apply!! NINDS special AD/ADRD payline applies to investigator-Initiated research applications to the NIH Parent R01 and the NINDS R21 (PA-21-219)





Workshop: September 28-29, 2023

Anti- $A\beta$ Passive Immunotherapy for Alzheimer's Dementia and Amyloid-Related Imaging Abnormalities (ARIA): What's Next?

Goals

- 1) Understand mechanisms of BBB injury associated with anti-A β passive immunotherapy
- 2) Identify patients at risk for ARIA; e.g. with comorbidities/treatments, such as anti-coagulants
- 3) Potential therapeutic strategies and research ideas to protect patients at risk

Point of Contact: Dr. Francesca Bosetti

This workshop will be both in person (Bethesda, MD) and virtual.

Ways to Stay Informed and Connected



Sign up to receive updates and resources delivered to your inbox.

https://nia.nih.gov/sign-up



Tweet NIA on Twitter: https://twitter.com/NIHAging



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Follow NIA on LinkedIn: https://www.linkedin.com/company/ national-institute-on-aging/



Search all active NIA funding opportunities: https://www.nia.nih.gov/research/funding



Like NIA on Facebook: https://www.facebook.com/NIHAging/

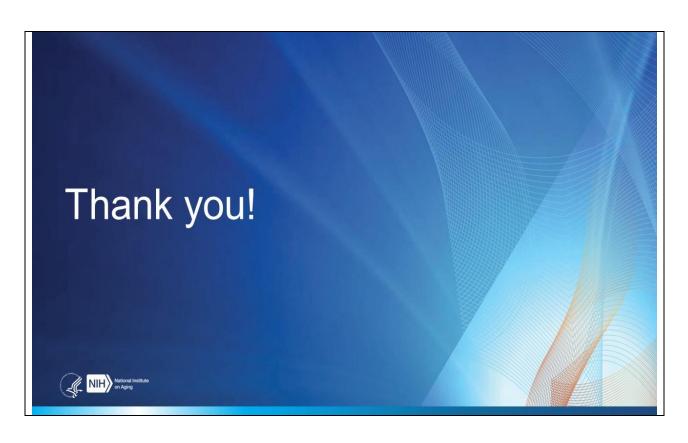


Review the latest approved concepts: https://www.nia.nih.gov/approved-concepts



Subscribe to NIA on YouTube: https://www.youtube.com/user/ NatlInstituteOnAging







Vision and Mission



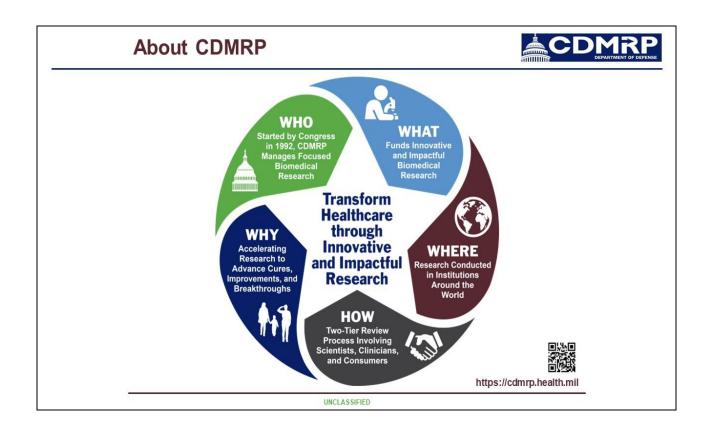


Vision

Transforming health care through innovative and impactful research

Mission

Responsibly manage collaborative research that discovers, develops, and delivers health care solutions for Service Members, Veterans, and the American public



Hallmarks





- Manages targeted research funds added by Congress to the DOD budget
- Integrates consumers as the foundation and "True North" of CDMRP and as full participants throughout the process
- Annually adapts each program's vision and investment strategy, allowing rapid response to changing needs
- · Avoids duplication with other funding agencies
- Targets unfunded/unmet research gaps
- Publicly announces and competes funding opportunities publicly announced and competed
- Follows the National Academy of Medicine-recommended model for application review
- · Funds high-impact, innovative research
- Maximizes funding available for research through low management costs and efficient processes
- Maintains transparency and accountability to stakeholders

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CDMRP FY23 Appropriations



Research Program	FY23 \$M	Research Program	FY23 \$M \$15.0
Alcohol and Substance Use Disorders	\$4.0	Orthotics and Prosthetics Outcomes	
Amyotrophic Lateral Sclerosis	\$40.0	Ovarian Cancer	\$45.0
Autism	\$15.0	Pancreatic Cancer	\$15.0
Bone Marrow Failure	\$7.5	Parkinson's	\$16.0
Breast Cancer	\$150.0	Peer Reviewed Alzheimer's	\$15.0
Chronic Pain Management *	\$15.0	Peer Reviewed Cancer (20 Topics)	\$130.0
Combat Readiness Medical *	\$5.0	Peer Reviewed Medical (50 Topics)*	\$370.0
Duchenne Muscular Dystrophy	\$10.0	Peer Reviewed Orthopaedic	\$30.0
Epilepsy	\$12.0	Prostate Cancer	\$110.0
Hearing Restoration	\$5.0	Rare Cancers	\$17.5
Joint Warfighter Medical *	\$25.0	Reconstructive Transplant	\$12.0
Kidney Cancer	\$50.0	Spinal Cord Injury	\$40.0
Lung Cancer	\$25.0	Tick-Borne Disease	\$7.0
Lupus	\$10.0	Toxic Exposures	\$30.0
Melanoma	\$40.0	Traumatic Brain Injury and Psychological Health	\$175.0
Military Burn	\$10.0	Tuberous Sclerosis Complex	\$8.0
Multiple Sclerosis	\$20.0	Vision	\$20.0
Neurofibromatosis	\$25.0	TOTAL = \$1.52B	

* Topics include those related to neuroscience

The Peer Reviewed Alzheimer's Research Program (PRARP)



History

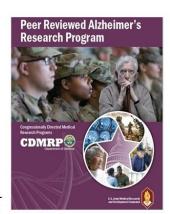
The PRARP was initiated in fiscal year 2011 (FY11). Appropriations for the PRARP from FY11 through FY22 totaled \$168 million (M). The FY23 appropriation is \$15M.

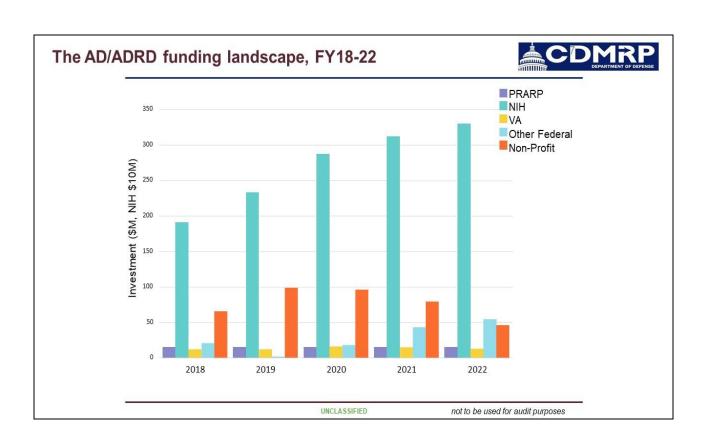
Vision

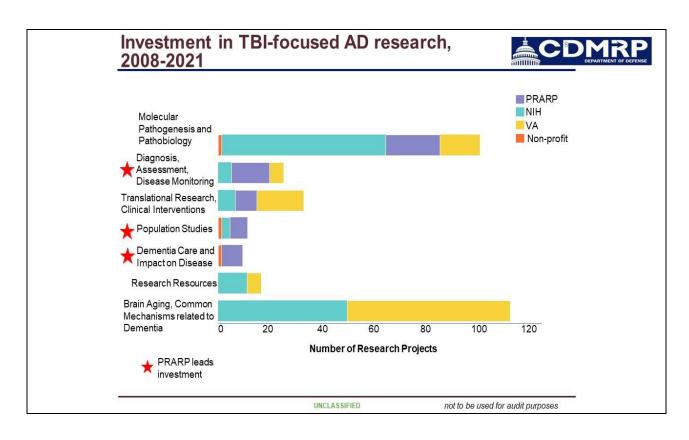
To address and mitigate long-term implications of traumatic brain injury and military service as they pertain to Alzheimer's disease and Alzheimer's disease-related dementias

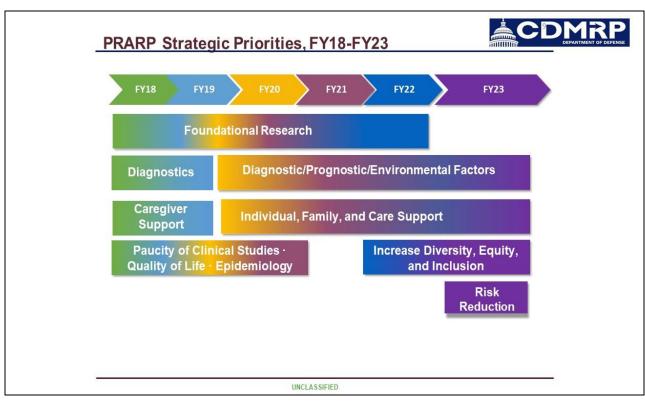
Mission

Support research to (1) understand the association between TBI and other military service-related risk factors and Alzheimer's disease/Alzheimer's disease-related dementias, and (2) improve quality of life and reduce the burden on affected individuals and caregivers for the military, Veterans, and the public









Community Collaboration



- Required for all clinical research in TRA
- Required in the TDA and TCA

Optimizing Research Impact
Through Community Collaboration:
Research funded by the FY23 PRARP should be responsive to the needs of people living with AD/ADRD.
Establishment and utilization of effective and equitable collaborations and partnerships with members of the AD/ADRD lived experience, family, and care partner communities, maximizes the translational and impact potential of the proposed research.



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Career Initiation and Transition Partner Option

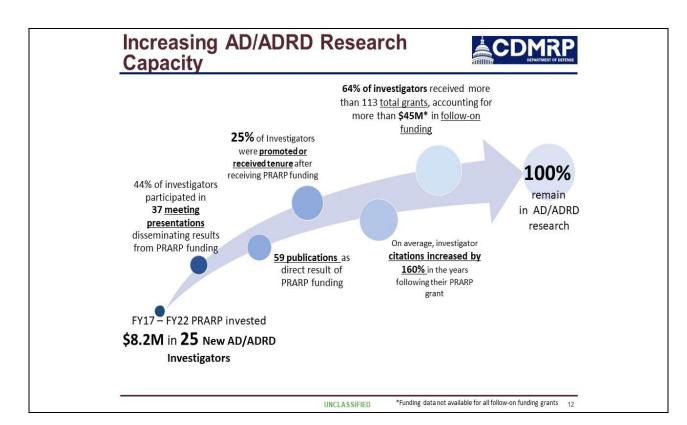


Partnering PI:



- Both Pls contribute significantly to the development of the proposed project.
- PIs may have experience in similar or disparate scientific disciplines, but each must distinctly contribute.
- If recommended for funding, each PI will be named to an individual award within their respective organization.
- PIs may be from the same or different organization.

- Career initiation PI:
 - 3 or more years following terminal degree but no more than 7 years into an independent position.
 - Letter of Support from institution to serve as PI.
- Career transition PI:
 - New to the AD/ADRD or TBI fields
 - Nominal, if any, research support or publications.
 - Transition can occur at any career stage.



PRARP Research Outcomes



From August 2022 to July 2023, PRARP-supported efforts resulted in the following outcomes:

- 72 publications
- 56 presentations
- · 2 patent applications
- 5 follow-on funding grants obtained
- New biotech company, CircCure Corporation, started up based on results from PRARP-funded award

Published online 19 December 2022

Nucleic Acids Research, 2022, Vol. 50, No. 22 12979-12996

RNA editing of microtubule-associated protein tau circular RNAs promotes their translation and tau tangle formation

Justin Ralph Welden¹, Giorgi Margvelani², Karol Andrea Arizaca Maquera², Bhavani Gudlavallet², Sandra C. Miranda Sardori², Alexandre Rosa Campos³, Noómie Robil¹, Daniel C. Lee^{1,3}, Alavra G. Hernander², Wang-Xia Wang^{1,2}, Jing Di², Pierre de la Grange⁴, Peter T. Nelson^{1,2} and Stefan Stamm ^{2,2}.

"Sanders-Brown Center on Aging, University of Kinetucky, Lessington, KY, USA: "Department of Molocular and Cellular Biochemistry, University of Kinetucky, Lessington, KY, USA: "Sanderd Burnham Phelys Medical Discoursey Institute Proteomics Core, La Jolla, CA, USA: "Georificipies, Paris, France, "Alzheimer's Disease Research Center Neuroscience, University of Kentucky, Leongron, KY, USA: "And Services Facility, University of Hinsics, University of Kentucky, Leongron, KY, USA and "Alzheimer's Disease Research Center and Department of Pathology and Laboratory Medicine, University of Kentucky, Lucingson, KY, USA.



Questions? For more information, please visit:





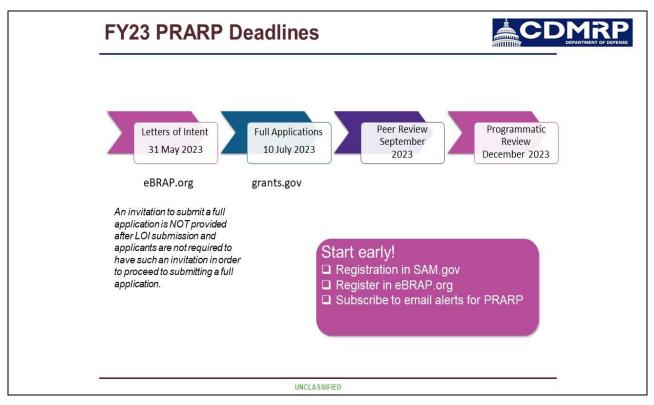
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Additional information







FY23 Transforming Care Award



Focus Area:

Individual, Family, and Care-Partner Support

May include, but is not limited to:

Improving the realities of everyday living with AD/ADRD

Navigating the AD/ADRD diagnosis and care path throughout the disease progression

Integration of care partner/caregiver education in the community

Improvements to the at-home care of a person living with dementia and their family/care/social communities, or aging in place

Overcoming care partner/caregiver stress

Key Mechanism Elements

- Person-centered research
- · Focus on outcomes
- Interventional (clinical trial) studies are allowed

Key Funding Opportunity Features

- \$1M total costs/\$1.2M total costs CITPO
- · 4-year period of performance
- Eligibility: All career levels, CITPO available
- Community collaboration required
- Milestone meeting required in Year 3

UNCLASSIFIED

FY23 Transforming Diagnosis Award



Focus Area:

Diagnostic, Environmental, Prognostic Factors

May include, but is not limited to:

Riphehavioral markers

Accelerating technologies and methods for early and premortem diagnosis

Validation and implementation of tests in clinic and community

Challenges with diagnosis access

Reducing patient burden, including at-home testing

Key Mechanism Elements

- Near-term applicability
- Person-focused research
- Prospective recruitment of study participants

Key Funding Opportunity Features

- \$2.5M total costs
- · 4-year period of performance
- Eligibility: All career levels
- CITPO available
- Community collaboration required
- Community feedback meeting required in Year 1

FY23 Transforming Research Award



Focus Area

Prevention and Risk Reduction

May include, but is not limited to:

Identification of risk factor environmental, genetic, epig lifestyle

Strategies to reduce risk and p cognitive problems

Social determinants of health in reduction

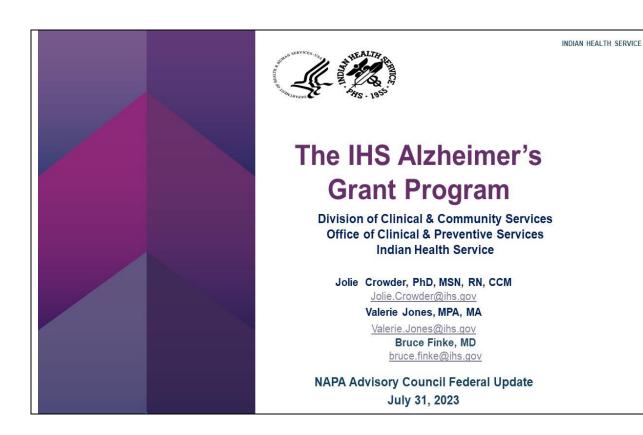
Epidemiology of environmental/ leading to AD/ADRD

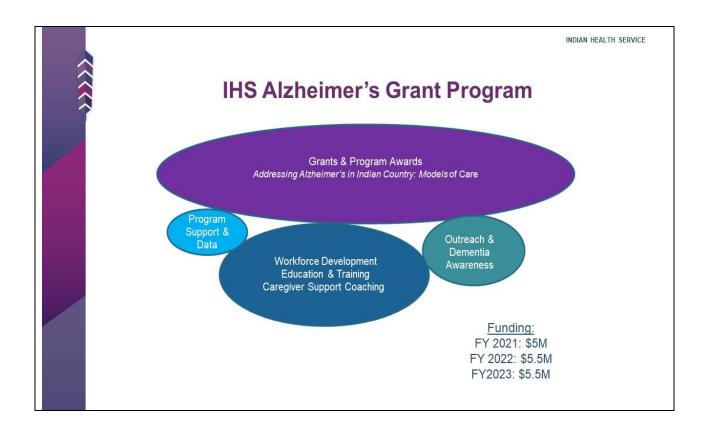
Key Elements

- Robust research
- Non-incremental Research
- Feedback to the community

Key Features

- \$1M Total Costs
- 3-year period of performance
- Eligibility: All career levels
- CITPO Available
- Clinical Research allowed





Grants & Program Awards Addressing Dementia in Indian Country: Models of Care

"...to support the development of models of comprehensive and sustainable dementia care and services in Tribal and Urban Indian communities that are responsive to the needs of persons living with dementia and their caregivers."

2023 - funding available for at least 6 awards

- 11 eligible applications
- · Review in process, anticipate awards in August

2022 Awardees - entering into their second year

- · The Indian Health Board of Minneapolis, Inc.
- The Indian Health Council, Inc.
- · The Nez Perce Tribal Health Authority
- · The Northern Valley Indian Health



Workforce Development

Indian Health Geriatric Scholars Pilot

- 15 Scholars from 10 IHS, Tribal, and Urban programs in the 2022 cohort
 - Completed local improvement efforts in dementia detection and/or diagnosis (9), medication management (3), falls (1)
- · 16 Geriatric Scholars accepted for the 2023 cohort
 - From 14 sites, 7 IHS, 6 Tribal, and 1 Urban representing 7 IHS Areas

Early Dementia Detection Initiative in Dental Clinics

- Successfully completed the IHS Department of Oral Health (DOH) pilot with 5 IHS/Tribal programs integrating dementia detection into care
- · Exploring expansion with DOH

Geriatric ED Accreditation Initiative – IHS Division of Nursing

(Collaboration with ACEP, funding from the John A. Hartford & West Foundations)

- · 9 IHS and Tribal EDs accredited
- 3 new sites interested in accreditation and 1 site interested in advancing a level of accreditation – IHS supported

INDIAN HEALTH SERVICE

Workforce Development

Nurse Fellowship Pilot in development with the IHS DON

- Training options to meet the needs of nurses in a variety of roles
- · Funding to sponsor the program to support time for training
- · Goal-directed with a commitment to improving care
- · Expected launch September 2023

Additional Training

- 28 APRNs completed a 28 module Dementia Care Specialist Course
 - Provided evaluation of the course for relevance in the care of the population they serve and value as a training resource
- 32 RNs completing the same course
 - They will also provide us with insight into the utility of this course for RN training
- Webinars on dementia detection and diagnosis for local facilities and as a part of a national Best Practices conference



Workforce Development

Northwest Portland Area Indian Health Board (NPAIHB) Indian Country ECHO Program Funded by the IHS Alzheimer's Grant Program

Indian Country Dementia Clinical ECHO

- First session, May 11, from 11am -12 pm PT
- Continuing regularly the 2nd Thursday of each month at 11 am PT
- Case-based learning to strengthen Primary Care knowledge and confidence to:
 - Detect Cognitive Impairment
 - Diagnose Alzheimer's disease and related dementias
 - Manage care for American Indian and Alaska Native people living with dementia and their caregivers

Indian Country Dementia Caregiver Support ECHO

- First session, June 22, from 11am -12 pm PT
- Continuing regularly on the 4th Thursday of every month at 11am PT
- Training and mentorship for Indian Health staff providing coaching and support for caregivers

INDIAN HEALTH SERVICE



Outreach & Awareness

Models of Care Webinar Series (5 sessions) in the Spring

- · Increase interest in the Grant Program
- Stimulate thinking about the adaptation of models of care for Tribal and Urban Communities
- 217 participants with representation from all 12 IHS region

ACL Title VI Program National Technical Assistance Training in April

- Pre-conference workshop of IHS Grantees and ACLADPI Tribal Grantees. and CDC BOLD Grantees
- · Alzheimer's Association participated
- Participation in a conference-wide listening session

Subscribers to the Eldercare listserv have increased by 250% since September 2022





For More Info

The IHS Alzheimer's Grant Program

www.ihs.gov/alzheimers/

2023 Alzheimer's Grant Program funding opportunities

• www.ihs.gov/alzheimers/fundingopps/2023fundingopp/

Education and training resources and opportunities

· www.ihs.gov/alzheimers/alztraining/

Dementia information and links

 <u>www.ihs.gov/alzheimers/informationresources/alzde</u> mentiaresources/

Stay Connected and join the IHS Elder Care Listserv at www.ihs.gov/alzheimers/



FDA Updates

Teresa Buracchio, MD Acting Director, Office of Neuroscience Center for Drug Evaluation and Research



Lecanemab

 Lecanemab (Leqembi) was converted from an accelerated approval to a traditional approval on July 6, 2023, based on results from a Phase 3 randomized, controlled clinical trial (CLARITY AD)

www.fda.gov



Study 301 (CLARITY AD)

- An 18-month (78-week) multicenter, randomized, double-blind, placebo-controlled, parallel-group study in patients with mild cognitive impairment due to Alzheimer's disease (AD) or mild AD dementia
- Randomization to placebo (n=897) or lecanemab 10 mg/kg biweekly (n=898) in a 1:1 ratio
- <u>Statistically significant treatment effects</u> were demonstrated on the primary endpoint and secondary endpoints
 - Primary endpoint: change from baseline in the Clinical Dementia Rating Sum of Boxes (CDR-SB) at 18 months of treatment (reduction in decline (-0.45[-27%], p=0.00005)
 - Secondary endpoints:
 - Brain amyloid plaque levels as measured by PET(-59.1 Centiloids, p<0.00001)
 - Alzheimer's Disease Assessment Scale Cognitive Subscale (ADAS-Cog 14) (p=0.00065)
 - Alzheimer's Disease Composite Score (ADCOMS) (p=0.00002)
 - Alzheimer's Disease Cooperative Study Activities of Daily Living Mild Cognitive Impairment (ADCS-ADL-MCI) (p<0.00001)

www.fda.gov



Safety

- Updated labeling includes:
 - A boxed warning for the risk of ARIA and potential for serious outcomes and increased risk of ARIA in ApoE ε4 homozygotes
 - Recommendation for ApoE ε4 genotype testing to inform risk
 - Contraindication for patients with serious hypersensitivity to lecanemab

www.fda.gov





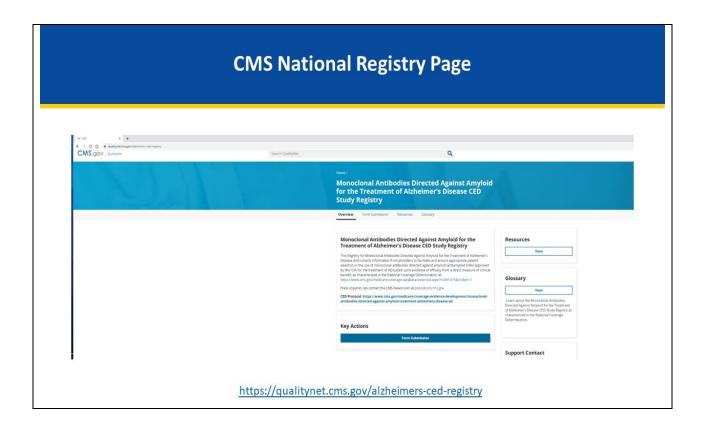
NAPA Advisory Council Federal Update July 31, 2023

Medicare Coverage of Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

- National Coverage Determination (NCD) established Coverage with Evidence Development (CED) in April 2022.
- For monoclonal antibodies approved by the FDA for the treatment of AD based upon evidence of efficacy from a direct measure of clinical benefit, Medicare coverage may be provided in CMS-approved prospective comparative studies; study data may be collected in a registry.
- On July 6, 2023, FDA approved Leqembi™ (lecanemab) for treatment of Alzheimer's disease based on a clinical endpoint. On the same day, CMS launched the Anti-Aβ mAb CED Study (CMS National Registry).

Information at: Broader Medicare Coverage of Legembi (Lecanemab) Available Following FDA Traditional Approval

(Strategy 1.E)



Proposed NCD on Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease

- On July 17, 2023, CMS posted a proposed NCD to end coverage with evidence development (CED) for positron emission tomography (PET) beta amyloid imaging and to permit Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors (MACs).
- Public comment period is open to 08/16/2023.
 - ➤ Please see: https://www.cms.gov/medicare-coverage-database/view/nca.aspx?ncaid=308&ncacaldoctype=all&status=all&sortBy=status&bc=17

CY 2024 Physician Fee Schedule (PFS) Proposed Rule

Caregiver Training Services

- CMS is proposing to pay for new caregiver training services (CTS), so that practitioners can train and involve caregivers in supporting patients with certain diseases or illnesses (e.g., dementia) with carrying out a treatment plan.
- CMS is proposing to pay for these services when furnished by a physician or a nonphysician practitioner (e.g., nurse practitioners, and physician assistants) or therapist
 (e.g., physical therapist, occupational therapist, or speech language pathologist) under
 an individualized treatment plan or therapy plan of care.

Principal Illness Navigation (PIN) Services

• CMS is proposing to pay for principal illness navigation (PIN) services to help people with serious, high-risk conditions connect with appropriate clinical and support supports

Information at: CY 2024 Physician Fee Schedule (PFS) Proposed Rule

(Strategy 3.B)