Alzheimer's Disease and AD Related Dementias Research: Policy and Program Updates

2022 Fall ADRC Meeting

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Congressional Updates

FY 2023 Budget Status

- **House FY 2023 appropriations bill:**
  - On June 30, 2022, the House Labor-HHS spending bill advanced out of committee. The bill must still be passed by the full House. If enacted, the bill would provide $47.5 billion for NIH, an increase of $2.5 billion over the FY 2022 enacted level, including:
    - **$4.443B for NIA (includes an additional $200M for AD/ADRD research)**
    - $2.75B for ARPA-H
    - $541M for *All of Us*
    - $620M for *Brain Research through Application of Innovative Neurotechnologies (BRAIN) Initiative*
- **Senate FY 2023 appropriations bill:**
  - On July 28, 2022, the Senate Appropriations Committee released its FY23 Labor-HHS appropriations bill. The bill must still be passed by the full Senate. If enacted, the bill would provide nearly $48 billion for NIH, including **$4.34 billion for NIA.**

- The federal government is **currently funded through December 16th, 2022, via a Continuing Resolution**.

Congressional Report on ADRCs

FY23 Senate Appropriations- Labor, Health and Human Services Report Language (abbreviated):

Alzheimer's Disease Research Centers.—The Committee directs NIA to provide Congress a report detailing **the number of individual Alzheimer's patients who have gained access to a clinical trial through the outreach of an ADRC, the number of Alzheimer's disease diagnoses given to patients at an ADRC, and a detailed report on patients' and caregivers' needs that were met through the work of ADRCs that cannot be attained at a provider office**.

- Congress regularly asks for this type of information on federally funded programs. We are alerting you to their interest in the ADRCs.

- We will work with NACC to let you know what information is needed to respond to this request.

Updated Pay Lines

Current Allocations for Competing Research Grant Awards, FY 2023

CSR-Reviewed Research Applications				
	General Pay Line, <$500K	General Pay Line, =>$500K	AD/ADRD Pay Line <$500K	AD/ADRD Pay Line =>$500K
All applications except as noted below	8%	5%	20%	17%
N.I. R01s	11%	8%	23%	20%
E.S.I. R01s	13%	10%	25%	22%

New Investigator (N.I.): An applicant who has not received a prior R01 award or its equivalent.
Early-Stage Investigator (E.S.I.): A new investigator who is within 10 years of finishing research training.
AD/ADRD: Research on Alzheimer's disease and Alzheimer's disease-related dementias.

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Current Interim Pay Lines, FY 2023

NIA-Reviewed Applications (by score)		
	General Pay Line	**AD/ADRD Pay Line**
Program projects	14	28
Other NIA-reviewed research	14	28
Career development awards	18	25
Fellowship awards	20	30

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FY2024 Alzheimer's Disease Bypass Budget

Bypass Budget Language

SEC. 230. Hereafter, for each fiscal year through fiscal year 2025, the Director of the National Institutes of Health shall **prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services and the Advisory Council on Alzheimer's Research, Care, and Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the National Institutes of Health pursuant to the National Alzheimer's Plan**, as required under section 2(d)(2) of Public Law 111–375.

Professional Judgment Budget FY 2024, Projected Costs and Additional Resources Needed

Additional Resources Needed	Amount
Epidemiology/Population Studies	$75,000,000
Disease Mechanisms	$65,500,000
Diagnosis, Assessment, and Disease Monitoring	$44,000,000
Translational Research and Clinical Interventions	$142,500,000
Dementia Care and Impact of Disease	$41,000,000
Research Resources	$80,800,000
Alzheimer's Disease-Related Dementias	$40,000,000
Staffing Needs and Administrative Support	$9,437,000
Total Costs for New AD/ADRD Research	**$498,237,000**
Less: Funding from completed projects that is now available for new AD/ADRD research	**($177,000,000)**
Additional FY 2024 Resources Needed for New AD/ADRD Research	**$321,237,000**

Total Resource Needs, FY 2024

Total Resources Needed	Amount
FY 2022 NIH Estimate (based on FY 2022 enacted dollars) for AD/ADRD Research Spending (baseline estimate)	$3,553,000,000
ADDITIONAL FY 2024 Resources Needed for New AD/ADRD Research	$321,237,000
Total FY 2024 Resources Needed for AD/ADRD Research	**$3,874,237,000**

FY 2024 ADBB Narrative: Prospective Future Research Opportunities

- Organized by six research areas, with an additional cross-cutting area.
  - > Epidemiology/Population Studies
  - > Disease Mechanisms
  - > Diagnosis, Assessment, and Disease Monitoring
  - > Translational Research and Clinical Interventions
  - > Dementia Care and Impact of Disease
  - > Research Resources
  - > *Cross-cutting: Health Equity and Inclusion*

AD/ADRD Progress Report

- Previous versions of the ADBB featured a retrospective progress report.

- This report will now be released separately, in Fall 2022.

- It will feature examples of recent **science advances across multiple research topics**, from basic to clinical research, care/caregiving interventions, and more.

Working Towards Health Equity

NIH's Commitment to Ending Structural Racism

➢ NIH is committed to instituting new ways to support diversity, equity, and inclusion, and identifying and dismantling any policies and practices that may harm our workforce and our science.

➢ NIH established the **UNITE** initiative to address structural racism in biomedical research with the goal of ending racial inequity.

➢ Primary goals of the initiative are:

U Understanding stakeholder experiences through listening and learning

N New research on health disparities, minority health, and health equities

I Improving the NIH culture and structure for equity, inclusion and excellence

T Transparency, communication, and accountability with our internal and external stakeholders

E Extramural research ecosystem: changing policy, culture and structure to promote workforce diversity
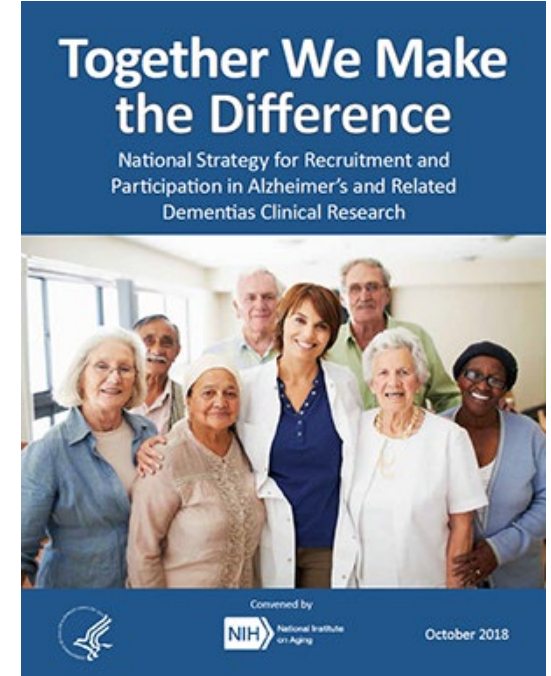
NIA Participation:
Melissa Espinoza- I Committee
Dr. Michele Evans- N Committee Co-Chair
Dr. Patricia Jones- E Committee

nih.gov/ending-structural-racism

NIH National Institutes of Health
Turning Discovery Into Health

NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA)

- The purpose of the NIH-Wide Strategic Plan for DEIA is to articulate NIH's vision for embracing, integrating, and strengthening DEIA across all NIH activities to achieve the NIH mission.

- The DEIA Strategic Plan will capture activities that NIH will undertake to meet its DEIA vision, and will be organized around accomplishments, needs, opportunities, and challenges in addressing DEIA in the NIH workforce, its structure and culture, and the research it supports.

- The Plan is expected to be released in 2022.

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NIA Resources for Recruitment of Diverse Participants for Clinical Trials

- **National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research-** focuses on the pressing need for increased participation in research studies, with a specific emphasis on inclusion of individuals from diverse backgrounds

- **Alzheimer's and Dementia Outreach, Recruitment, and Engagement (ADORE)-** online, searchable database of resources for engagement, recruitment, and retention of study participants into clinical trials and studies on AD/ADRD https://www.nia.nih.gov/research/adore

- **Outreach Pro-** tool to enable health care professionals to more easily produce and brand tailored clinical trial recruitment materials and strategies https://outreachpro.nia.nih.gov/

- **Clinical Studies Recruitment Planning Guide-** outlines strategies for improving community-based research participation https://www.nia.nih.gov/research/alzheimers-dementia-outreach-recruitment-engagement-resources/recruitment-planning-guide

Together We Make the Difference
National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research

Convened by NIH National Institute on Aging   October 2018

Diversity and Early Career Researchers
NIA-Specific Programs

For PhD Students

- R36 Aging Research Dissertation Awards to Increase Diversity (PAR-19-394)

For ESIs

- Butler Williams Scholars Program
- GEMSSTAR Medical Transition to Aging Research (RFA-AG-23-031)
- K76 Beeson Emerging Leaders Award in Aging (RFA-AG-21-020, 021)

For AD/ADRD

- Diversity in Translational Research for Alzheimer's Disease and Related Dementias F31 (PAR-21-218), F32 (PAR-21-217), K99/R00 (PAR-21-220)
- Small Research Grants for the Next Generation of Clinical Researchers in AD/ADRD (PAS-19-391, 392, 393)

NIA/NIH Updates

New NIH Policy on Data Management and Sharing

- In October 2021 NIH issued a new *NIH Policy for Data Management and Sharing* that applies to all NIH-supported research that results in the generation of scientific data.

- This new policy will come into effect on January 25, 2023.

- It will require NIH funded researchers to prospectively submit a plan outlining how scientific data from their research will be managed and shared.

Policy: https://grants.nih.gov/grants/policy/data_sharing/

Implementation Details: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html

Save the Date: 2023 Dementia Care & Caregiving Research Summit

The 2023 Dementia Care & Caregiving Research Summit

March 20-22, 2023

Virtual

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AD/ADRD Cleared Concepts From September 2022 NACA Meeting

AD/ADRD Cleared Concepts From September 2022 NACA Council

Approved concepts indicate areas of special interest for NIA and often evolve into funding opportunity announcements to spur activity in given areas of research
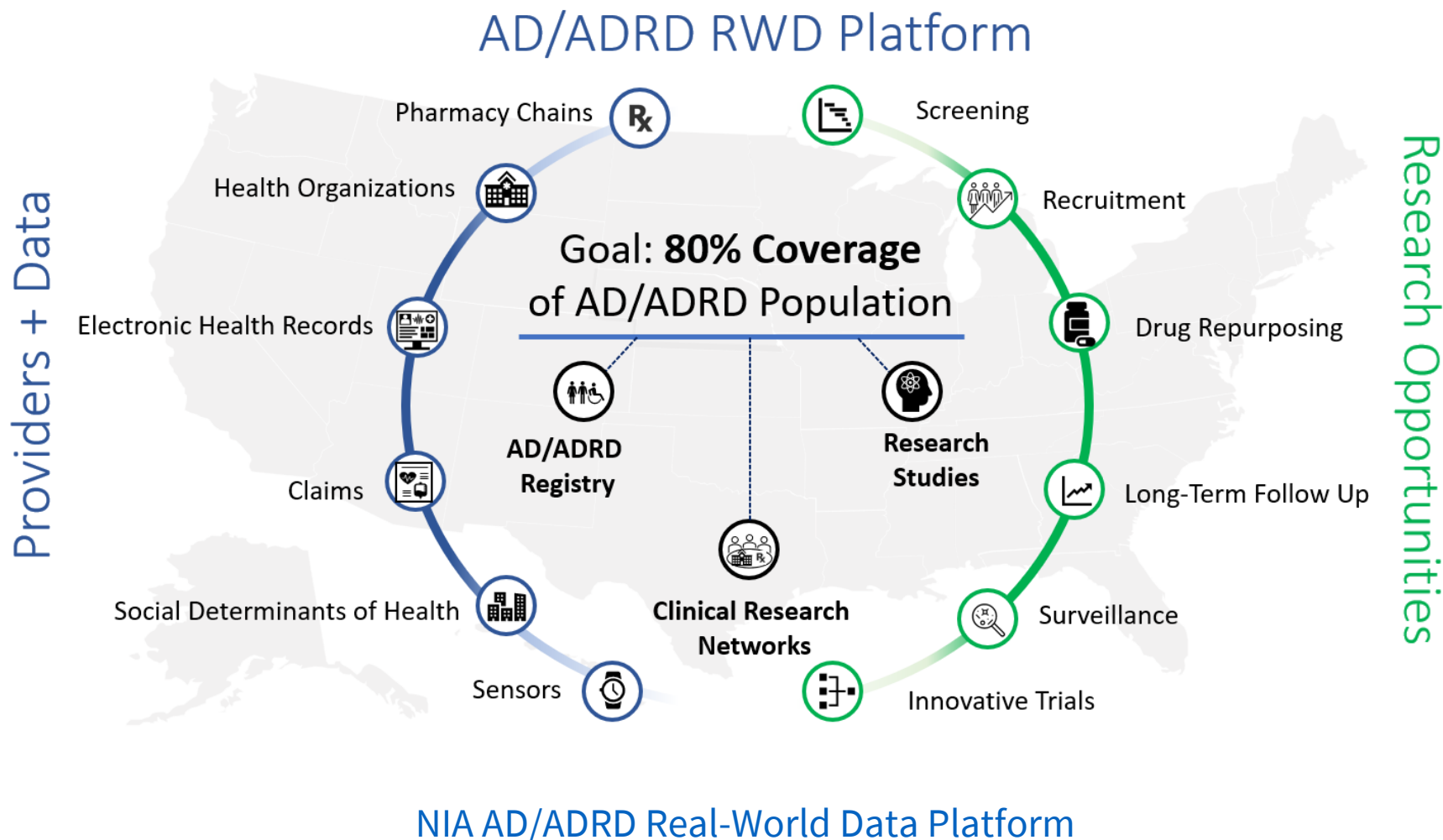
- Alzheimer's Disease Research Centers (ADRCs) Program Renewal
- The Health and Retirement Study and the Harmonized Cognitive Assessment Protocol Joint Renewal
- Microphysiological Systems to Advance Precision Medicine for AD/ADRD Treatment and Prevention
- NIA AD/ADRD Real-World Data Platform
- Preclinical Studies to Characterize the Impact of Toxicants on Brain Aging and AD/ADRD
- Quantifying the Impact of Environmental Toxicants on AD/ADRD Risk in Cohort Studies
- Research Coordinating Center on the Exposome and AD/ADRD: Elucidating the Role of Social and Behavioral Determinants of Health in AD/ADRD Etiology and Disparities
- Understanding Gene Environment Interactions in Brain Aging and AD/ADRD

https://www.nia.nih.gov/approved-concepts#Sept2022

AD/ADRD Real-World Data Platform

Goals:

- Harness longitudinal real-world data via public/private partnerships to establish Real World Data Infrastructure

- Leverage the power of new technologies (i.e., artificial intelligence, machine learning) to catalyze cost- and time-efficient research and clinical trials on AD/ADRD in diverse populations

AD/ADRD RWD Platform

Providers + Data

Research Opportunities

- Pharmacy Chains Rx
- Health Organizations
- Electronic Health Records
- Claims
- Social Determinants of Health
- Sensors

Goal: **80% Coverage** of AD/ADRD Population

AD/ADRD Registry

Clinical Research Networks

Research Studies

- Screening
- Recruitment
- Drug Repurposing
- Long-Term Follow Up
- Surveillance
- Innovative Trials

NIA AD/ADRD Real-World Data Platform

Microphysiological Systems to Advance Precision Medicine for AD/ADRD Treatment and Prevention

Microphysiological systems (MPS) are small platforms that mimic human organs and diseases. This concept is designed to:

- stimulate more predictive AD/ADRD models that encompass key features of human pathophysiology and operate as precision medicine research tools

- spur development of standardized and deeply phenotyped AD/ADRD MPS models, establishing the translational validity of these MPS models to recapitulate the molecular and network perturbations identified in AD/ADRD

- develop MPS technologies that allow for the testing of potential AD/ADRD therapies in a manner that incorporates disparities and differences in the specific pathogeneses across populations

- provide MPS models to all qualified researchers for their use in preclinical therapy and transparent reporting of research methodology and preclinical efficacy testing findings

Microphysiological Systems to Advance Precision Medicine for AD/ADRD Treatment and Prevention

Exposome-Related Concepts

A variety of exposures in the environments where people live, work, pray, and play across their lives shape health outcomes, including AD/ADRD outcomes. Together, this comprehensive set of exposures across domains (e.g., physical, chemical, social, psychological, economic) constitute the "exposome."

The National Advisory Council on Aging approved several concepts centered on exposome infrastructure and research at NIA. Some examples include further quantifying the impact of environmental toxicants on AD/ADRD risk and using exposome data to better understand the role of social and behavioral determinants of health on AD/ADRD.

- Preclinical Studies to Characterize the Impact of Toxicants on Brain Aging and AD/ADRD
- Quantifying the Impact of Environmental Toxicants on AD/ADRD Risk in Cohort Studies
- Research Coordinating Center on the Exposome and AD/ADRD: Elucidating the Role of Social and Behavioral Determinants of Health in AD/ADRD Etiology and Disparities
- Understanding Gene Environment Interactions in Brain Aging and AD/ADRD

NIA Welcomes New Deputy Director- Amy Kelley, MD, MSHS

- Dr. Amy Kelley joined NIA as Deputy Director in September 2022.

- Dr. Kelley provides strategic leadership, supervises daily operations, and serves as an ambassador and spokesperson for the institute. Additionally, she oversees NIA's diversity, equity, inclusion, and accessibility (DEIA) initiatives.

- Dr. Kelley joins NIH from the Icahn School of Medicine at Mount Sinai, where she was a professor and vice chair for health policy and faculty development, Hermann Merkin Professor in Palliative Care in the Brookdale Department of Geriatrics and Palliative Medicine, and senior associate dean for gender equity in research affairs.
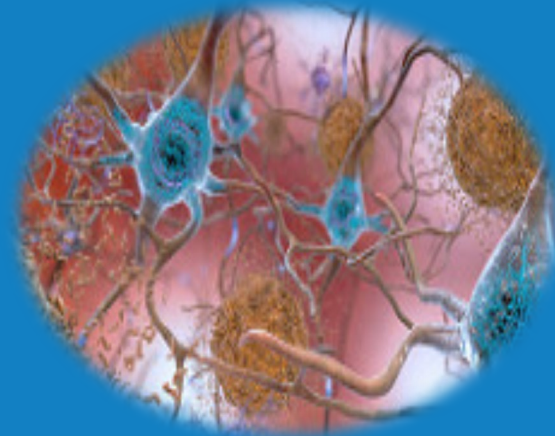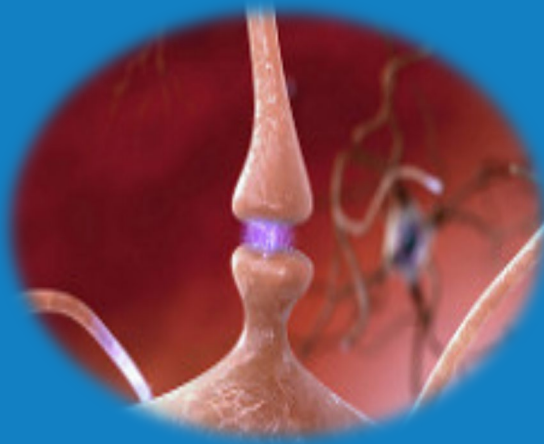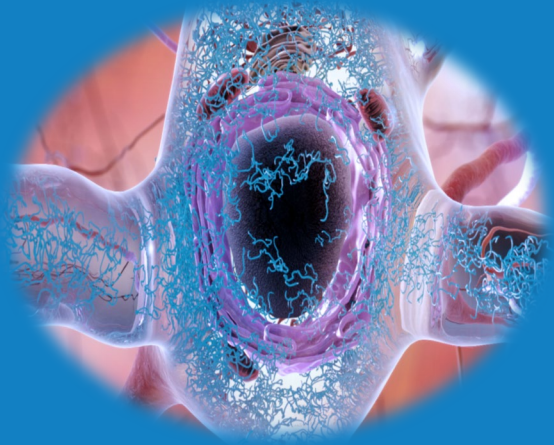

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Ways to Stay Informed and Connected

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

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

Subscribe to our blog and stay up to date on the latest NIA news: **https://www.nia.nih.gov/research/blog**

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