

# Alzheimer's and Related Dementias Research: Policy and Program Updates

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## 2017 Fall ADC Meeting

Richard J. Hodes, M.D.  
Director  
National Institute on Aging

October 14, 2017

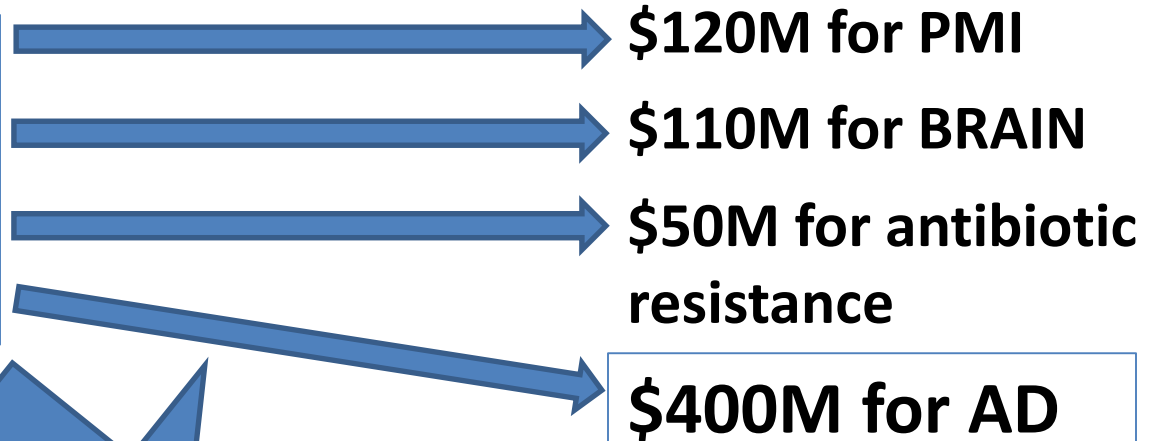


National Institute  
on Aging

# FY17 Budget Status – Funding Increases Across the Board

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**\$34 Billion  
for the NIH**



- **\$2B for the NIA**
- \$48M increase for non-targeted NIA research; percent increase comparable to other ICs
- **All divisions will benefit**
  - DBSR
  - DGCG
  - DAB
  - DN

# NIA Appropriations and President's Budget

## FY 2006-2018

Current versus Constant, FY06 Base Year

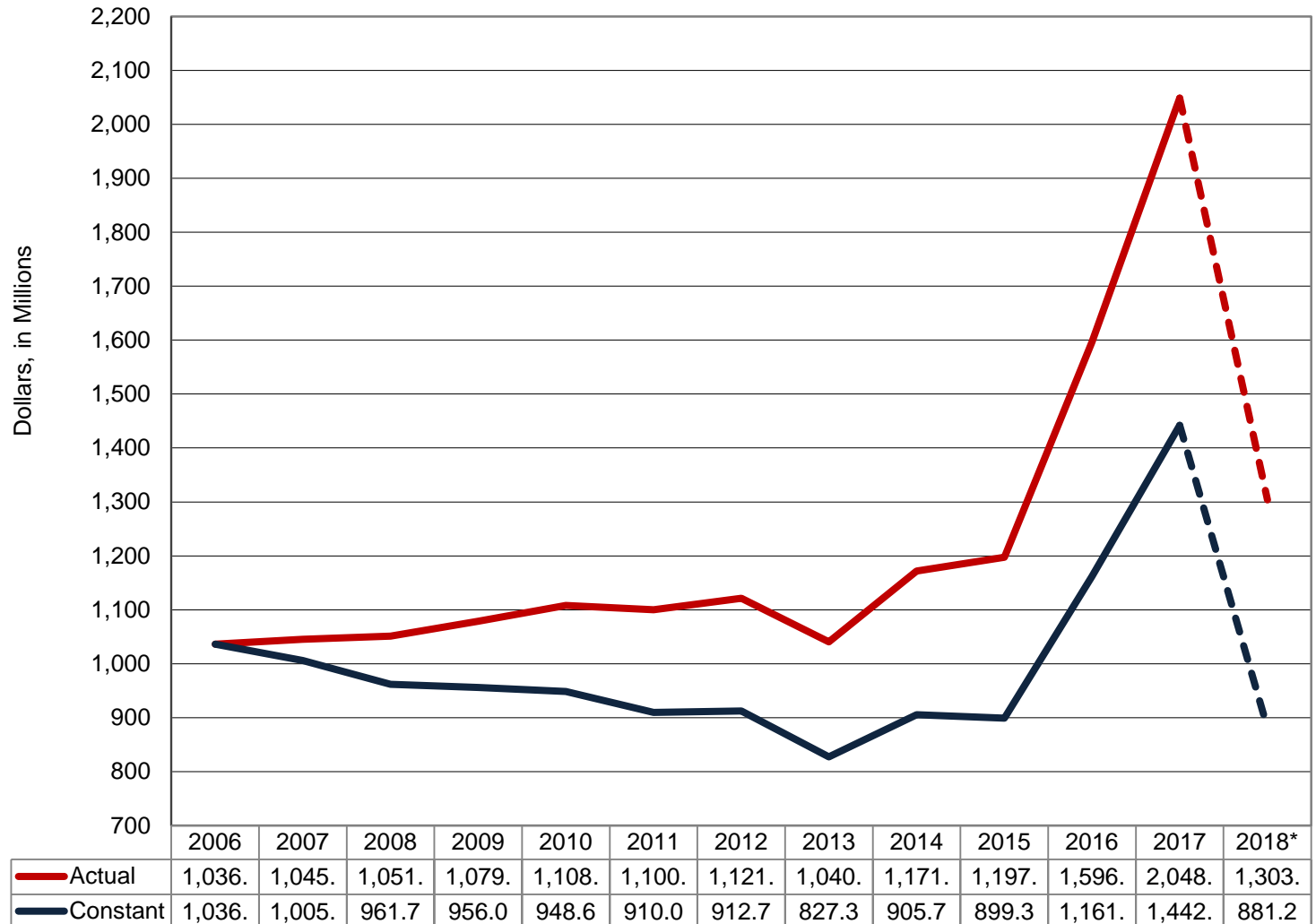
**Difference from  
FY2006**

**In Actual Dollars:  
\$267M Increase**

**25.7% Increase  
FY06-FY18**

**In Constant  
Dollars:  
\$-155M Decrease**

**-15.0% Decrease  
FY06-FY18**



\*President's Budget

# FY18 Budget Status

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- FY18 Appropriations bills include additional NIH/NIA funds above FY17 levels
  - **Senate**
    - Additional \$486.7M for NIA (\$414M for AD)
  - **House**
    - Additional \$409.9M for NIA (\$400M for AD)
- On September 8, 2017, continuing resolution H.R. 601 was signed into law, which funds the government at FY17 levels until December 8, 2017

# Growth of AD and ADRD Research Spending at NIH

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Research/Disease Areas (Dollars in millions and rounded)	FY 2015 Actual	FY 2016 Actual	FY 2017 Estimate (Enacted)
Alzheimer's Disease	\$589	\$929	\$1,348
Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)	\$631	\$986	\$1,414
Alzheimer's Disease Related Dementias (ADRD)	\$120	\$175	\$234
Frontotemporal Dementia (FTD)	\$36	\$65	\$68
Lewy Body Dementia	\$15	\$22	\$23
Vascular Cognitive Impairment/ Dementia	\$72	\$89	\$93

# Allocations for Competing Research Grant Awards, FY 2017

CSR-reviewed Research Applications				
	General Pay line, <\$500k	General Pay line, =>\$500k	ADRD pay line, <\$500k	ADRD pay line, =>\$500k
All applications except as noted below	19	16	28	25
N.I. R01s	22	19	31	28
E.S.I. R01s	25	22	33	30

*New investigator: An applicant who has not received a prior R01 award or its equivalent.*

*Early-Stage Investigator: A new investigator who is within 10 years of finishing research training.*

*First-time renewing; A former new or early-stage investigator's first renewal application when the investigator has no other NIH grant support.*

*ADRD: Research on Alzheimer's disease and on Alzheimer's-related Dementias*

# FY 2017 Pay Lines

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NIA-reviewed Applications		
	General Pay line	ADRD pay line
Program projects (PO1)	35	40
Other NIA-reviewed research	34	40

# FY 2017 Pay Lines

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Training-related Applications		
	General pay line	ADRD pay line
Training grants (T32, T35)	22	27
Career awards	22	36
Fellowships	31	40



# Bypass Budget Language

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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.

# NIH Meetings Provided the Basis for Priorities, Milestones, and Budget Estimates

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- 2012 Alzheimer's Disease Research Summit
- 2013 meeting on Alzheimer's Disease-Related Dementias: Research Challenges and Opportunities
- 2013 meeting on Advancing Treatment for Alzheimer's Disease in Individuals with Down Syndrome
- 2015 Alzheimer's Disease Research Summit
- 2016 meeting on Alzheimer's Disease-Related Dementias



**Recommendations used to create milestones for developing the Alzheimer's Disease (and related dementias) Bypass Budget**

# Combined External and Internal Input – FY19 AD Bypass Budget

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Input at 2012-2016 meetings:

- ☐ Academic research community
- ☐ Industry
- ☐ Non-governmental organizations

Other Input:

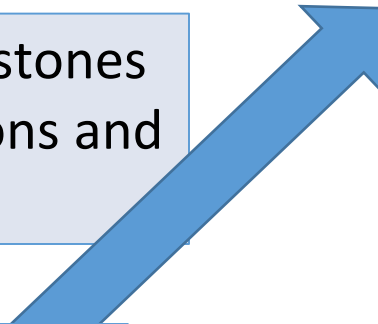
- ☐ 2017 Request for Information



Development of comprehensive milestones  
(NIH staff) – based on recommendations and  
milestones from meetings



Trans-NIH (including NINDS) staff  
discussion; milestones edited to ensure  
comprehensive inclusion of priorities for  
FY19



NIH staff  
“price” the  
milestones



**Final budget  
estimate for  
FY19**

# FY19 Professional Judgment Budget

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Area of Research	Amount (dollars in thousands)
A. Molecular Pathogenesis and Physiology of Alzheimer's Disease	\$110,000
B. Diagnosis, Assessment and Disease Monitoring	\$70,100
C. Translational Research and Clinical Interventions	\$191,000
D. Epidemiology	\$58,025
E. Care and Caregiver Support	\$32,800
F. Research Resources	\$76,375
H. Alzheimer's Disease-Related Dementias	\$55,000
Staff Needs, Support, and Misc.	\$3,800
<b>Total Additional Resources Needed</b>	<b>\$597,100</b>

# Research Planning and Initiatives

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## **Concept Approvals:**

<https://www.nia.nih.gov/approved-concepts>

## **General FOAs:**

<https://www.nia.nih.gov/research/funding>

## **Alzheimer's Disease FOAs:**

<http://www.nia.nih.gov/AD-FOAs>

# Opportunities for Small Business – AD/ADRD specific

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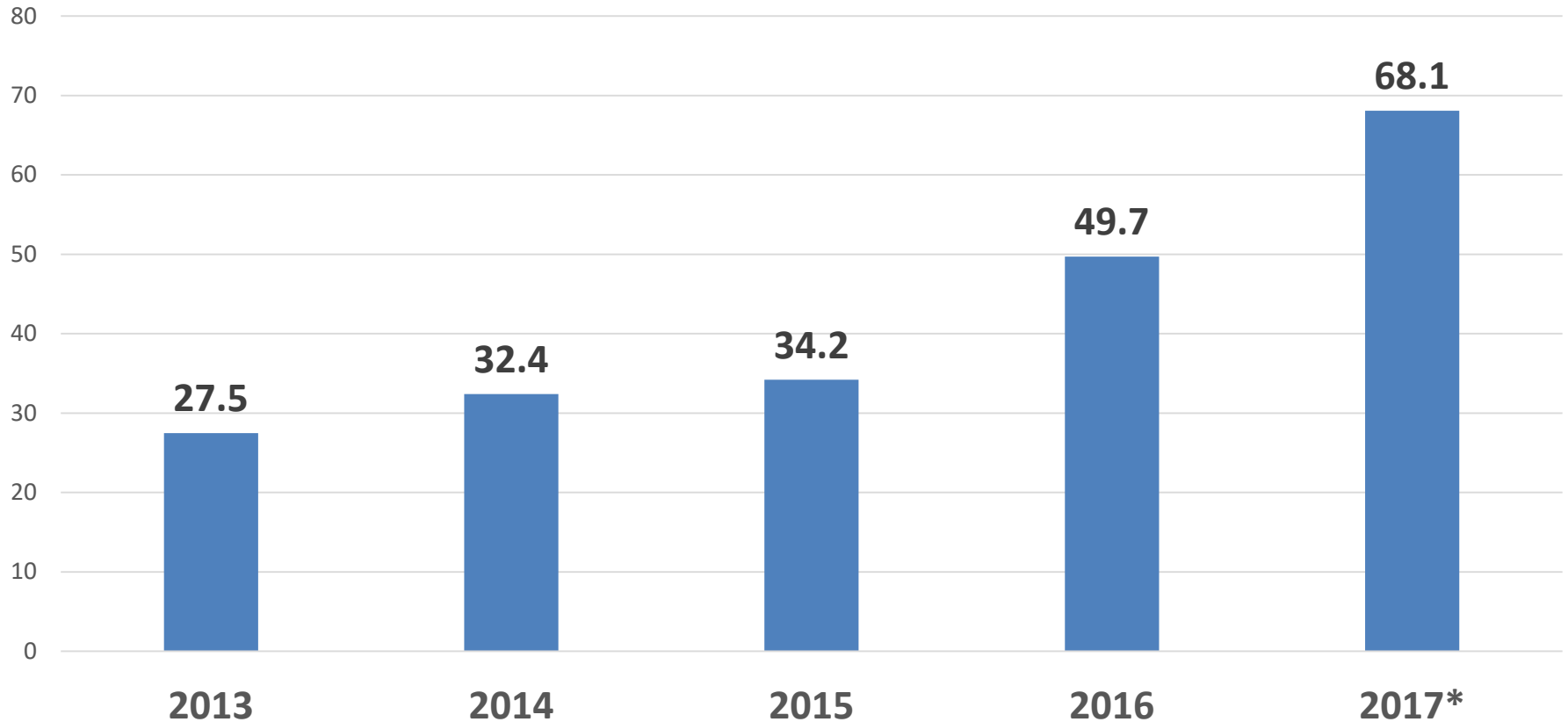
- **Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R41/R42/R43/R44)**
- **Tools for Clinical Care and Management of Alzheimer's Disease (AD) and its Comorbidities (R41/R42/R43/R44)**
- **Development of Socially-Assistive Robots (SARs) to Engage Persons with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and their Caregivers (R41/R42/R43/R44)**

<https://www.nia.nih.gov/research/grants-funding/small-business-innovation-research-and-technology-transfer-programs>

# NIA SBIR/STTR Obligations

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\$ in Millions



\* Estimate

# AHRQ-National Academies Study

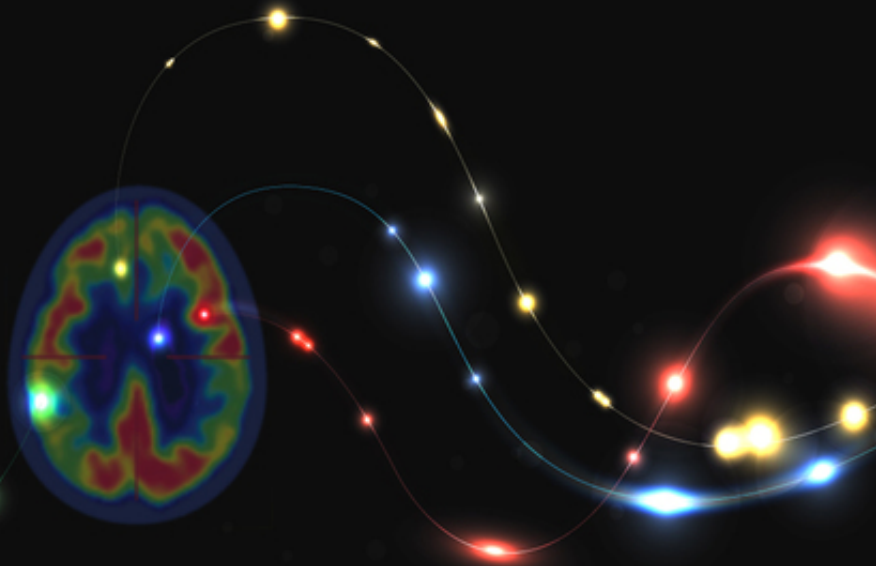
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- Two-part assessment of **interventions** to *prevent* AD-type dementia, amnestic MCI, and age-related cognitive decline
- 13 categories of interventions explored
- Final AHRQ evidence report now available:

<https://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2417>



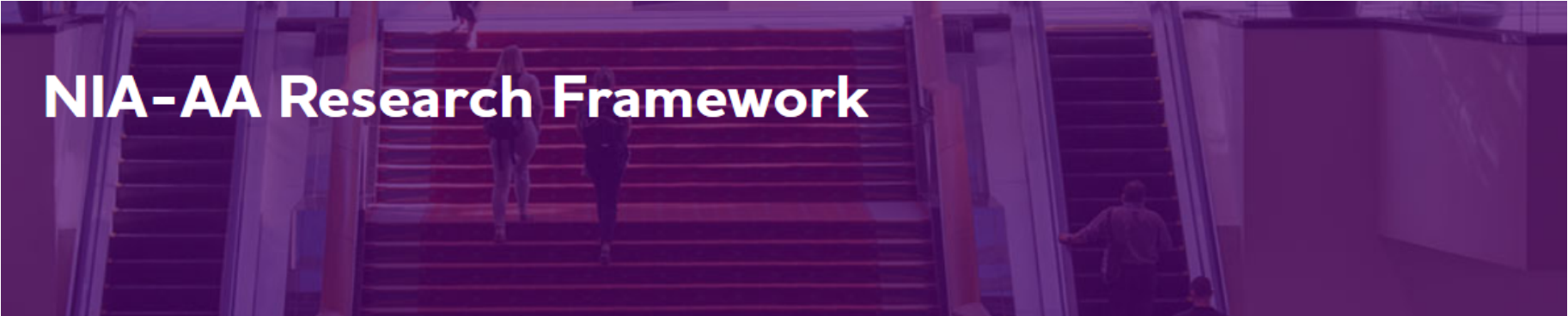
REPORT



PREVENTING  
COGNITIVE DECLINE  
AND DEMENTIA

A WAY FORWARD

- Encouraging but inconclusive evidence:
  - Cognitive training
  - Blood pressure management in hypertensives
  - Increased physical activity



# NIA-AA Research Framework

## NIA-AA Research Framework

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In 2011, the National Institute on Aging (NIA) at National Institutes of Health (NIH) and the Alzheimer's Association published revised guidelines (NIA-AA) for modernization of the diagnosis of Alzheimer's disease. In these guidelines, the workgroups identified Alzheimer's disease as a continuum with three distinct stages: Preclinical, Mild Cognitive Impairment and Dementia. A number of studies noted the need to develop a framework to describe the changes throughout the disease continuum, including the clinical context and the pathophysiologic changes, for an individual. In 2016, the NIA and Alzheimer's Association convened an international workgroup of scientific experts tasked with the evaluation of the existing guidelines. The workgroup discussions are on going.

The NIA-AA workgroup's goal is to define Alzheimer's disease and stage it across both the pathophysiologic and clinical continua. The NIA-AA workgroup proposes that Alzheimer's disease should be defined as a pathophysiological construct. As in other diseases, such as osteoporosis or diabetes, biomarkers would alone define the presence of the disease in a living person regardless of their symptoms. Clinical symptoms assist in staging the clinical severity of the disease. Here the NIA-AA workgroup shares an update on their discussions of this conceptual model for the proposed framework and the research needed to validate it.

The goal of the framework is to advance the field in understanding the pathophysiology of Alzheimer's and allow for testing of hypotheses related to development and progression of disease in diverse populations and settings. Discussions during the Alzheimer's Association International Conference (AAIC) contributed to the workgroup's thinking and revision process. An updated draft as of September 19, 2017 is posted in the link below for comment. The committee will review and discuss all comments.

[DRAFT 2018 NIA-AA Research Framework to Investigate the Alzheimer's Disease Continuum](#) (Sept. 19, 2017)

### Research Framework

NEW DRAFT as of September 19

*Edited based on prior feedback.*

*Available for comment.*

# alz.org/NIA-AA

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# Policy Updates

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# Notice of Intent to Publish a Funding Opportunity Announcement for Alzheimer's Disease Centers (P30)

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**Notice Number:** NOT-AG-17-016

## Key Dates

**Release Date:** September 27, 2017

**Estimated Publication Date of Announcement:** November 2017

**First Estimated Application Due Date:** May 2018

**Earliest Estimated Award Date:** January 2019

**Earliest Estimated Start Date:** April 2019

## Related Announcements

None

## Issued by

National Institute on Aging ([NIA](#))

## Purpose

The National Institute on Aging intends to publish a Funding Opportunity Announcement (FOA) to solicit applications for NIA-designated Alzheimer's Disease Centers (ADCs) to foster research on the nature of Alzheimer's disease and related dementias and serve as major sources of development of more effective approaches to prevention, diagnosis, care and treatment. ADCs are expected to contribute significantly to the development of shared resources that support dementia relevant research, collaborate and coordinate their research efforts with NIH-funded programs and investigators, and disseminate research findings for the benefit of the community.

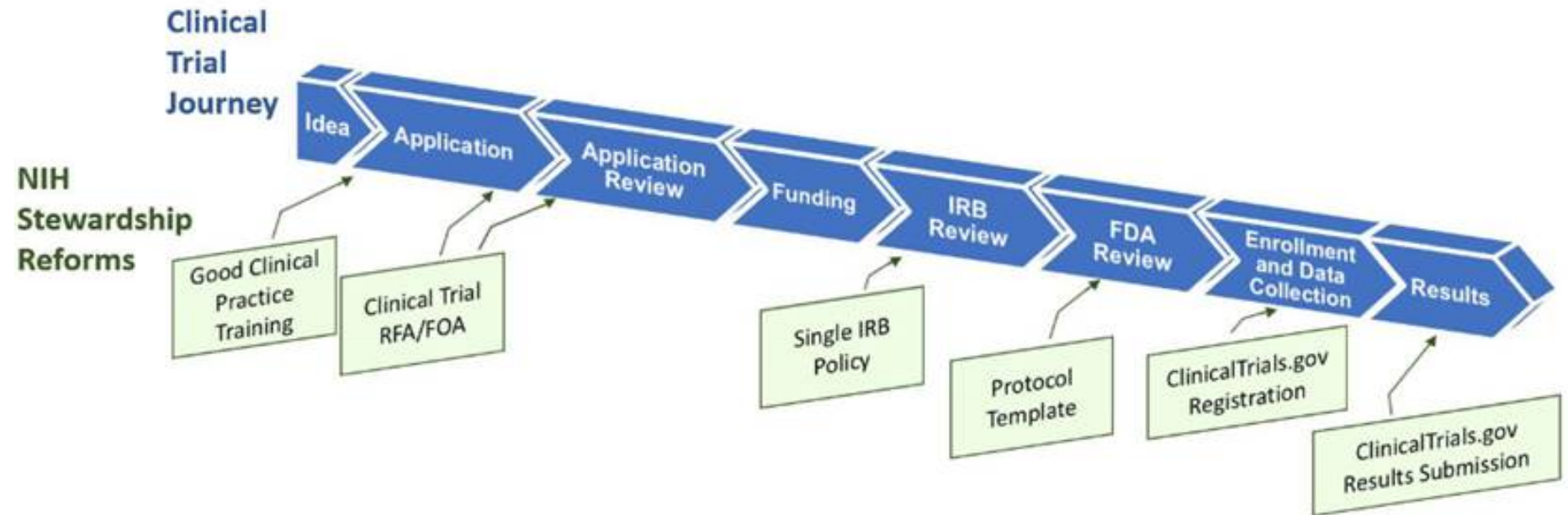
This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and responsive projects.

The FOA is expected to be published in Fall 2017 with an expected application due date in Spring 2018.

This FOA will utilize the P30 activity code. This will require existing NIA-funded P50 Alzheimer's Disease Centers to convert their operations by applying for the P30 FOA in the final

# Clinical Trial Policy Changes

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# National Research Summit on Care, Services and Supports for Persons with Dementia and Their Caregivers

NIH Campus, Natcher Building #45 | 45 Center Drive | Bethesda, Maryland

**October 16-17, 2017**

Registration opening soon  
More information at link below



Convened by the National Institute on Aging at the NIH with support from the Foundation for the National Institutes of Health.

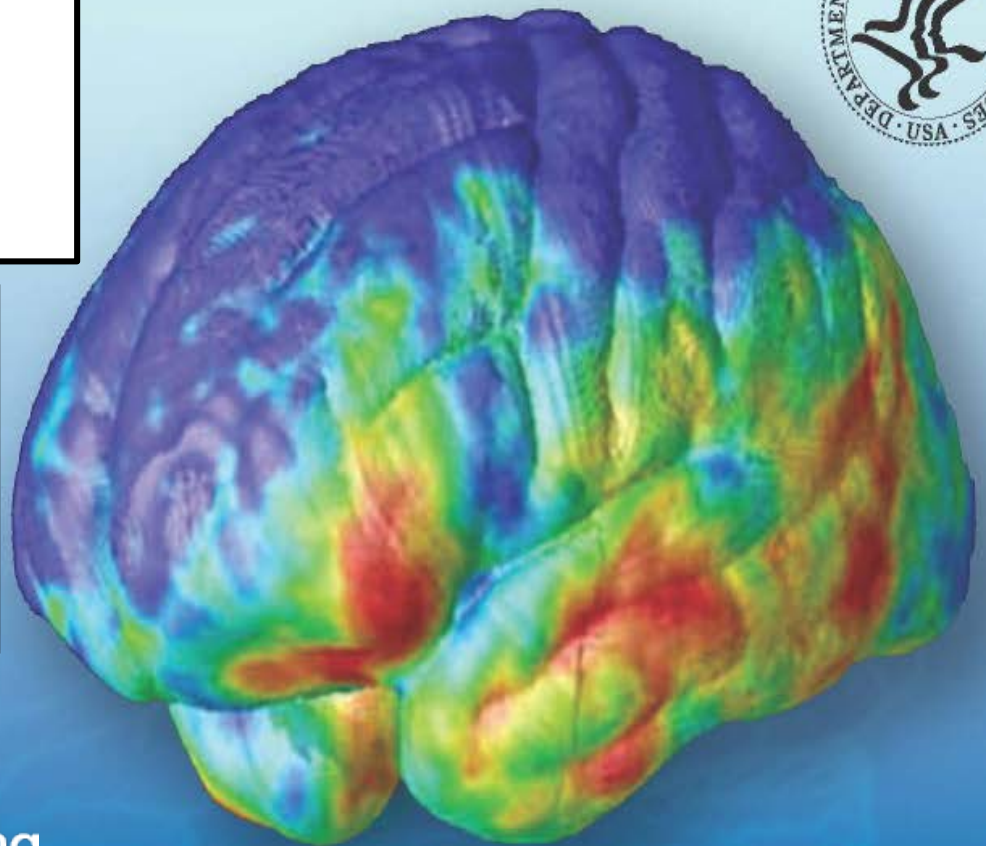
<https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>

# Save the Dates!

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Alzheimer's Disease  
Research Summit (III)  
**March 1-2, 2018**  
Bethesda, MD

ADRD Summit (III)  
**March 14-15, 2019**  
Bethesda, MD



National Institute on Aging  
*Turning Discovery Into Health*





# Clinical Trial Policy Changes



National Institutes of Health  
Office of Extramural Research

## Grants & Funding

NIH's Central Resource for Grants and Funding Information

Entire Site

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## NIH Definition of Clinical Trial Case Studies

The case studies provided below are designed to help you identify whether your study would be considered by NIH to be a clinical trial. **Expect the case studies and related guidance to evolve over the upcoming year.** For continuity and ease of reference, case studies will retain their original numbering and will not be renumbered if cases are revised or removed.

### FAQs

[Printable PDF](#)

### Updated 9/8/17

The simplified case studies apply the following four questions to determine whether NIH would consider the research study to be a clinical trial:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health related biomedical or behavioral outcome?



### Related Resources

[FAQs](#)

[Training Resources](#)

[Important Terms](#)

[Research Involving Human Subjects](#)

[Resource on Research Methods](#)

# Clinical Trial Policy Changes

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## Relevant Example

- Case #18b: The study involves the recruitment of healthy volunteers and mild cognitive impairment patients who are administered a series of standard cognitive tasks while undergoing a brain scan or imaging procedure (e.g., fMRI). The purpose of administering these standard cognitive tasks (or behavioral tasks or presentation of stimuli) is to assess brain activity under standardized laboratory conditions and compare this activity between healthy individuals and mild cognitive impairment groups.
- **Does the study involve human participants?** Yes, the healthy volunteers and individuals with mild cognitive impairment are human participants.
  - **Are the participants prospectively assigned to an intervention?** No, not in this context. The standard cognitive tasks and the fMRI are being performed to measure and describe brain activity, but not to modify it.

**X This study is not a clinical trial.**

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