2019 SRAI Annual Meeting
October 19-23

Patrick Shirdon
Director for Management of the National Institutes of Aging (NIA), Bethesda Maryland, USA
Contributing to the NIH and the National effort to cure Alzheimer’s Disease
Our Objective

• A little about me
• Why the investment of Alzheimer’s Disease (AD)
• Help me identify other steps/actions we should have considered at the NIA. History is repeating itself!
• Alzheimer's Disease and other Research at NIA; there is a difference!
• Where to find out about funding opportunities about AD; want to broaden the tent!
• HAVE FUN😊
National Institutes of Health

<table>
<thead>
<tr>
<th>Agency</th>
<th>Abbreviation</th>
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<td>NCI</td>
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NATIONAL INSTITUTES OF HEALTH
National Institute on Aging
Organizational Structure

Office of the Director
Richard J. Hodes, M.D.
Marie A. Bernard, M.D.

Intramural Research Program

Chief Business Officer/Executive Officer

Division of Extramural Activities

Division of Aging Biology

Division of Behavioral and Social Research

Division of Neuroscience

Division of Geriatrics and Clinical Gerontology
One of my favorite books
Copyright 1954
Still relevant today?

• “Today we face another major change. The new technology…..”

• “The human resource, the one least efficiently used.... Holding the greatest promise for improved performance....”

• “How difficult it is to change basic attitudes – even if the need to do so is understood.....”
“I have lost myself.”

- Auguste Deter, 1850-1906
Alzheimer’s Disease Pathology

1906 - Plaques and Tangles Identified in Alzheimer’s disease
Young children and older people as a percentage of the global population: 1950 - 2050
Percent of persons with Alzheimer’s disease by age
The 46.8 million worldwide cases of dementia will almost double every 20 years.
Total estimated worldwide cost of dementia in US dollars
The global impact of dementia

Around the world, there will be 9.9 million new cases of dementia in 2015, one every 3 seconds.

46.8 million people worldwide are living with dementia in 2015. This number will almost double every 20 years.

Much of the increase will take place in low and middle income countries (LMICs) in 2015, 58% of all people with dementia live in LMICs, rising to 63% in 2030 and 69% in 2050.

The total estimated worldwide cost of dementia in 2015 is US$ 818 billion.
By 2018, dementia will become a trillion dollar disease, rising to US$ 2 trillion by 2030.

If global dementia care were a country, it would be the 18th largest economy in the world exceeding the market values of companies such as Apple and Google.

This map shows the estimated number of people living with dementia in each world region in 2015.

The World Alzheimer Report 2016 was independently researched by King's College London and supported by Reis.
The National Alzheimer’s Project Act

- Signed into law in January 2011
- The law calls for
  - An annually updated national plan
  - Annual recommendations for priority actions to
    - improve health outcomes for individuals with AD
    - lower costs to families and government programs
  - The annual evaluation of all federally funded efforts in Alzheimer’s research/care/services – and outcomes
  - The creation of an Advisory Council on Alzheimer’s Research, Care, and Services

https://aspe.hhs.gov/national-alzheimers-project-act
National Plan to Address Alzheimer’s Disease and Related Dementias

Goal 1: Prevent and Effectively Treat Alzheimer’s Disease and Related Dementias by 2025
Goal 2: Enhance Care Quality and Efficiency
Goal 3: Expand Supports for People with Alzheimer’s Disease and Related Dementias and Their Families
Goal 4: Enhance Public Awareness and Engagement
Goal 5: Improve Data to Track Progress
Summer of 2015, 2016, 2017, 2018

- The FY 2016 Budget Process is moving along!
- House and Senate both have large increases in Report Language for Alzheimer's Disease (AD).
- Will the increase materialize or not?
- And if it does, is it a one shot increase, or an increase to the base?
TSUNAMI
NIA Planning Summer 2015

• The Research Community will they be ready?
• How much risk is acceptable?
• Engagement of other NIH Institutes
• NIA internal processes
  • Staffing (Grants, Review, Budget/Finance, Program, Support, others?)
  • Scenario planning – who knows!
  • Intramural?
  • Space (We were in the middle of substantial space reductions)
  • Demands on Leadership
Implementation of Additional AD Funding

• Twenty-two AD/ADRD FOAs were released by the NIA between 2014-2016 for potential funding
  • They cover a range of research areas spanning

Basic Research  Translational Research  Clinical Research
FY 2019 Budget Status

H.R. 6157

- On September 28, 2018, the President signed the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, giving the NIH a full Fiscal Year budget.

- The Act provides
  - $39B for NIH (~$2B increase)
  - $500M for research related to Opioids
  - $100 for Cancer Moonshot
  - $40M for universal flu vaccine
  - $425M additional funds for AD research
  - $3.1B for NIA (including the $425M for AD)
  - $86M for All of Us
  - $29M for the BRAIN initiative
FY 2019 Budget Status – Funding Increases Across the Board

$39 Billion for the NIH

$40M for universal flu vaccine
$29M increase for BRAIN
$86M increase for All of US

$425M increase for AD/ADRD

• $3.1B for the NIA
• $84M increase for NIA research; percent increase comparable to other ICs
• All divisions will benefit
  ➢ DBSR  ➢ DAB
  ➢ DGCG  ➢ DN
NIA Appropriations FY 2008-2019
Current & Constant, FY08 Base Year dollars

Difference from FY2008

In Current Dollars: $2,030M Increase

In Constant Dollars: $1,207M Increase
Fiscal Years 2010 to 2019 Appropriations History & Fiscal Year 2020 Budget Projections

(President’s Budget, H.R. 2740, Senate draft language)
FY 2016 NIH Operating Plan Budgets

#7 IC based on budget
FY 2017 NIH Operating Plan Budgets

Dollars (in millions)

#5 IC based on budget

NCI, NIAID, NHLBI, NCGS, NIA, NIDDK, NINDS, OD, NIMH, NCIHD, NIDA, NIEHS, HLC, NCATS, NIAAMS, NIGMS, NIAAA, NICHD, NICR, NLM, NIBB, NIMHD, NINR, NCCSH, FIC
## AD/ADRD Targeted Increases

<table>
<thead>
<tr>
<th>Year</th>
<th>National Alzheimer’s Project Act (NAPA)</th>
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</thead>
<tbody>
<tr>
<td>2011</td>
<td>$50 M* redirected within NIH budget</td>
</tr>
<tr>
<td>2012</td>
<td>$40 M* redirected within NIH budget</td>
</tr>
<tr>
<td>2013</td>
<td>$100 M additional approp</td>
</tr>
<tr>
<td>2014</td>
<td>$25 M additional approp</td>
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<tr>
<td>2015</td>
<td>$350 M additional approp</td>
</tr>
<tr>
<td>2016</td>
<td>$400 M additional approp</td>
</tr>
<tr>
<td>2017</td>
<td>$414 M additional approp</td>
</tr>
<tr>
<td>2018</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td></td>
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</table>

*one-year money

$425 M in additional appropriations as of 09/28/18

Years displayed are Fiscal Years
NIA Appropriations
FY 2013-2019

Dollars, in millions

- 2013: $1,046
- 2014: $1,171
- 2015: $1,199
- 2016: $1,600
- 2017: $2,049
- 2018: $2,574
- 2019: $3,083

- NIA Base
- Additional AD Funds
How are we preparing for the unknown?

• Regularly re-assessing our funding lines: https://www.nia.nih.gov/research/blog/2018/02/art-reading-tea-leaves

• Modeling the impact of using single-year funding vs multi-year funding under multiple appropriations scenarios:
  • How will commitments made now impact our future ability to support new competing awards?
  • Under what conditions might a “steady state” be reached?

• Improving efficiency with the release of a “Parent” FOA, including nine topics of research interest in AD/ADRD: https://www.nia.nih.gov/research/blog/2018/02/long-story-about-strange-way-publish-funding-opportunities-or-just-another
Total Budget vs. Extramural FTEs
Percentage Change (NIA)
Over 8300 unique projects - 4200 funded by NIH
From more than 35 funding organizations across 11 countries
Diversity of AD/ADRD Research

- Aging metabolic changes in AD
- Comparative biology of neurodegeneration
- Basic Biological Processes of AD
- Geroscience
- Research on Disease Mechanisms
- Cognitive outcomes in Population Studies
- Biomarkers
- Research on Care and Caregiver Support
- Disparities, Sex differences, and AD risk

Alzheimer’s Research
R01 and RF1 AD/ADRD Awardees
FY2015-2018

Definitions

**Established Investigators:** An investigator who had previously received substantial, independent funding from NIH.

**New Investigators:** An investigator who has not previously received substantial, independent funding from NIH.

**Early Stage Investigators:** An investigator who is within 10 years of their terminal degree. (A sub-set of NI)

**New to AD/ADRD Field (NTF):** An investigator who had no prior AD/ADRD application or award from NIH
**R01 and RF1 AD/ADRD Awardees**
**FY2015-2018**

<table>
<thead>
<tr>
<th>Number of Awardees</th>
<th><strong>NI</strong>: New Investigator (Includes both NI and ESI)</th>
<th><strong>EI</strong>: Established Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ESI</strong>: Early Stage Investigator</td>
<td><strong>NTF</strong>: New to AD/ADRD Field</td>
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<tr>
<td><strong>Total Awardees</strong></td>
<td>695</td>
<td></td>
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<tr>
<td><strong>New to the Field (NTF)</strong></td>
<td>NTF: 261 (38%)</td>
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<tr>
<td><strong>New Investigator (NI)</strong></td>
<td>NI: 106 (41%)</td>
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<tr>
<td></td>
<td>EI: 155 (59%)</td>
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**New to the Field (NTF):** Awardees with no AD/ADRD award or application prior to FY2015 from NIH
R01 and RF1 AD/ADRD Awardees
FY2015-2018

Media Recognition

Science
The Alzheimer's gamble
Jocelyn Kaiser

Science 361 (6405), 838-841.
DOI: 10.1126/science.361.6405.838

To cast an even wider net, NIA is offering 1-year funding supplements to researchers already funded by NIH in other areas who want to add an Alzheimer's component to their research. The hope is that the extra money will lead to full-fledged proposals.

Alzheimer's grants are now much easier to get than other NIA grants: For most Alzheimer's proposals this year, those ranked in the top 28th percentile by peer-review panels get money. For non-Alzheimer's grants, that pay line is the 19th percentile. The competition for grants is still stiff, Hodes stresses.

For proposals in less-explored areas, such as the role of protective genes, how neurodegeneration affects other animal species, and how metabolic changes might contribute to Alzheimer's. "This brought in many people who were reluctant to submit an Alzheimer's application in part because they thought, 'We're never going to do well, we're going to be outsiders,'" Hodes says. At a recent Senate hearing, he pointed out that of

funding injection could improve everyone's chances of funding," says Duke psychologist Terrie Moffitt, a member of NIA's advisory council.

NIA HAS HAD TO BE CREATIVE to cope with the tide of applications for the Alzheimer's bounty, agency officials say. After a crushing scramble to process grant proposals last summer, this year NIA called early for proposals

452 investigators who won new Alzheimer's and related dementia grants from 2015 to 2017, 27% were receiving their first independent NIH grant, like Baker, and 36% were established researchers who had never had NIH support for Alzheimer's. (Some had funding from Alzheimer's foundations, however.) "We're not just repeating the things that failed and hoping we get a different result," Hodes says.
Supplements by Institute/Center FY 18
Supplements by Institute/Center FY 19
~300 AD/ADRD administrative supplements awarded to NIH grantees with awards not focused on AD/ADRD

~1/3 of the 2018 supplement awardees submit R01s or R21s

>20% of this 1/3 are successful in receiving funding on their first try

FY18

FY19*

*as of September 30, 2019
NIA Planning Post Appropriation for FY 2019

• Must be different tomorrow than we are today
• Revisit decisions made prior to Appropriation
• All hands on deck – break through organizational silos
• Must be used on additional AD relevant research – our call. And want a solid/justifiable definition of AD
• BI-Weekly AD meeting 5-7 in the evening.
• New committees to review:
  • Grants not initially coded as AD, but program thinks should be
  • Grants from other Institutes
• NIA internal processes
  • Information flow
  • New IT system to track and manage funding decisions
  • Documentation of decisions
# Payline Update FY 2019

<table>
<thead>
<tr>
<th>CSR-reviewed Research Applications</th>
<th>General Payline, &lt;$500k</th>
<th>General Payline, =&gt;$500k</th>
<th>AD/ADRD Payline, &lt;$500k</th>
<th>AD/ADRD Payline, =&gt;$500k</th>
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<tr>
<td>All applications except as noted below</td>
<td>15</td>
<td>12</td>
<td>28</td>
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<tr>
<td>N.I. R01s</td>
<td>18</td>
<td>15</td>
<td>31</td>
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<tr>
<td>E.S.I. R01s</td>
<td>20</td>
<td>17</td>
<td>33</td>
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</table>

**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 Disease-related dementias
# Payline Update FY 2019 cont’d

<table>
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<tr>
<th>NIA-reviewed Applications</th>
<th>General Payline</th>
<th>AD/ADRD Payline</th>
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<tr>
<td>Program projects (PO1)</td>
<td>20</td>
<td>38</td>
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<tr>
<td>Other NIA-reviewed research</td>
<td>20</td>
<td>38</td>
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<tr>
<th>Training-related Applications</th>
<th>General Payline</th>
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<td>Training grants (T32, T35)</td>
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<td>Career awards</td>
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<tr>
<td>Fellowships</td>
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AD/ADRD & Non-AD Payline
All Applications Except N.I. or E.S.I. R01s
FY 2014-2019
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.
AD Bypass Budget

• Language in SEC. 230 of the FY 2015 Appropriations Act requires a bypass budget for NIH Alzheimer’s disease research to be submitted to the President.

• The HHS Secretary may review and comment, but not alter, the NIH budget submission.

• The budget will be estimated based on the NIH components of the National Alzheimer’s Plan.
Trans-NIH Input for FY 2020 ADBB

Thirteen Institutes and Centers provided feedback that contributed to the development of this year’s professional judgment budget:

- **NIA** *(National Institute on Aging)*
- **NINDS** *(National Institute on Neurological Disorders and Stroke)*
- **NIMH** *(National Institute of Mental Health)*
- **NINR** *(National Institute of Nursing Research)*
- **NIGMS** *(National Institute of General Medical Sciences)*
- **NICHD** *(National Institute of Child Health and Human Development)*
- **NIEHS** *(National Institute of Environmental Health Sciences)*
- **NIDDK** *(National Institute of Diabetes and Digestive and Kidney Diseases)*
- **NIDCR** *(National Institute of Dental and Craniofacial Research)*
- **NHLBI** *(National Heart, Lung, and Blood Institute)*
- **NIAAA** *(National Institute on Alcohol Abuse and Alcoholism)*
- **NCATS** *(National Center for Advancing Translational Sciences)*
- **FIC** *(Fogarty International Center)*
# FY 2020 Professional Judgment Budget

<table>
<thead>
<tr>
<th>Area of Research</th>
<th>Amount (dollars in thousands)</th>
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<tr>
<td>A. Molecular Pathogenesis and Physiology of Alzheimer’s Disease</td>
<td>$82,000</td>
</tr>
<tr>
<td>B. Diagnosis, Assessment and Disease Monitoring</td>
<td>$24,000</td>
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<tr>
<td>C. Translational Research and Clinical Interventions</td>
<td>$138,000</td>
</tr>
<tr>
<td>D. Epidemiology</td>
<td>$51,000</td>
</tr>
<tr>
<td>E. Care and Caregiver Support</td>
<td>$26,215</td>
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<tr>
<td>F. Research Resources</td>
<td>$107,100</td>
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<td>H. Alzheimer's Disease-Related Dementias</td>
<td>$45,687</td>
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<td>Staffing Needs, Support, and Misc.</td>
<td>$3,710</td>
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<tr>
<td><strong>Total Additional Resources Needed</strong></td>
<td><strong>$477,712</strong></td>
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</table>
Distribution of *Additional* Budget Funding Request Across Research Areas, FY 2020

- **TOTAL**: $477,712,500

  - **Staffing Needs and Administrative Support**: $3,710,000 (0.8%)
  - **Molecular Pathogenesis and Pathophysiology of Alzheimer’s Disease**: $82,000,000 (17%)
  - **Diagnosis, Assessment, and Disease Monitoring**: $24,000,000 (5%)
  - **Translational Research and Clinical Interventions**: $138,000,000 (29%)
  - **Epidemiology**: $51,000,000 (11%)
  - **Care and Caregiver Support**: $26,215,000 (5%)
  - **Research Resources**: $107,100,000 (22%)
  - **Alzheimer’s Disease-Related Dementias**: $45,687,500 (10%)
1020 active NIA staff, before the 2018 shutdown
11 active NIA staff, during the 2018 shutdown

Responsibilities during shutdown:
- Human Resources
- Workforce Flexibilities
- Workforce Planning
- Budget
- Ethics
- Guidance for Supervisors and Managers
- IT Guidance
- Commission Corps guidance
- Presidential Appointees Guidance
- Managing maintenance of federal facilities
- Management of Orderly phase-down/suspension of operations
- General employee guidance
- Coordination with HHS leadership
- Coordination with NIH leadership
- Coordinate animal care
- Coordinate patient care
- Manage the status of ongoing scientific experiments

Employees not working (1009) 98.5%

Essential staff (11) 1%
How did we do in FY 2018?

<table>
<thead>
<tr>
<th>MECHANISM</th>
<th>FY2018 Operating Plan Amount ($k)</th>
<th>FY 2018 Actual Amount ($k)</th>
<th>Balance ($k)</th>
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<tbody>
<tr>
<td>Research Grants:</td>
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<tr>
<td>Noncompeting</td>
<td>$837,330</td>
<td>$846,439</td>
<td>-$9,109</td>
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<td>Administrative Supplements</td>
<td>$177,078</td>
<td>$177,065</td>
<td>$13</td>
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<td>Competing:</td>
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<tr>
<td>Renewal</td>
<td>$113,892</td>
<td>$112,483</td>
<td>$1,409</td>
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<tr>
<td>New</td>
<td>$801,462</td>
<td>$791,547</td>
<td>$9,915</td>
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<tr>
<td>Supplements</td>
<td>$5,490</td>
<td>$5,422</td>
<td>$68</td>
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<td>Subtotal, Competing</td>
<td>$920,444</td>
<td>$909,452</td>
<td>$11,992</td>
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<tr>
<td>Subtotal, RPGs</td>
<td>$1,935,252</td>
<td>$1,932,956</td>
<td>$2,296</td>
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<td>SBIR/STTR</td>
<td>$87,296</td>
<td>$87,483</td>
<td>-$187</td>
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<td>Research Project Grants</td>
<td>$2,022,548</td>
<td>$2,020,439</td>
<td>$2,109</td>
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<td>Research Centers:</td>
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<tr>
<td>Specialized/Comprehensive</td>
<td>$133,270</td>
<td>$133,824</td>
<td>-$554</td>
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<tr>
<td>Comparative Medicine</td>
<td>$567</td>
<td>$567</td>
<td>$0</td>
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<td>Research Centers</td>
<td>$133,837</td>
<td>$134,391</td>
<td>-$554</td>
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<tr>
<td>Other Research:</td>
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<tr>
<td>Research Careers</td>
<td>$45,085</td>
<td>$45,355</td>
<td>-$270</td>
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<tr>
<td>Other</td>
<td>$50,057</td>
<td>$50,906</td>
<td>-$849</td>
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<tr>
<td>Other Research</td>
<td>$95,142</td>
<td>$96,261</td>
<td>-$1,119</td>
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<td>Total Research Grants</td>
<td>$2,251,527</td>
<td>$2,251,091</td>
<td>$436</td>
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<tr>
<td>Ruth L. Kirschstein Training Awards:</td>
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<tr>
<td>Individual Awards</td>
<td>$6,210</td>
<td>$5,981</td>
<td>$229</td>
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<td>Institutional Awards</td>
<td>$23,737</td>
<td>$24,622</td>
<td>-$885</td>
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<tr>
<td>Total Research Training</td>
<td>$30,947</td>
<td>$30,603</td>
<td>-$656</td>
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<tr>
<td>SBIR/STTR (non-add)</td>
<td>$78,986</td>
<td>$76,995</td>
<td>$1,991</td>
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<td>Intramural Research</td>
<td>$148,506</td>
<td>$148,566</td>
<td>-$60</td>
</tr>
<tr>
<td>Research Management and Support</td>
<td>$82,296</td>
<td>$64,183</td>
<td>-$1,104</td>
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<tr>
<td>Total, NIA</td>
<td>$2,571,502</td>
<td>$2,571,438</td>
<td>$64</td>
</tr>
</tbody>
</table>
New AD Funding Opportunities

Inside NIA A Blog for Researchers

Get weekly updates on NIA funding policies and research priorities.

We have a budget for FY 2019!
October 24, 2018

Amid all the news coming out of Washington these days, you may have heard that, for the first time in decades, a portion of the Federal budget was passed by Congress and signed into law by the President at the beginning of the 2019 fiscal year.

Richard Hodes,
Director,
Office of the Director (OD).
Ways to stay informed and connected

• Visit

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

to search all active NIA funding opportunities

• Subscribe to our blog to stay up to date with the latest from NIA

https://www.nia.nih.gov/research/blog
Implementation Tracking

• **IADRP:** [http://iadrp.nia.nih.gov/](http://iadrp.nia.nih.gov/)
  - Will continue to offer detailed tracking of initiatives and awards with respect to our research milestones, under the CADRO categories

• **Web-based tool for tracking funding initiatives and activities:** [https://www.nia.nih.gov/alzheimers/milestones](https://www.nia.nih.gov/alzheimers/milestones)
  - Developed by the NIH and other AD funding organizations
  - Aimed at addressing the research milestones associated with NAPATracks funding initiatives and activities aimed at addressing the research milestones associated with goal one of the National Plan
  - Facilitates strategic coordination and collaborations
  - Spans the entire AD research landscape including basic, translational, clinical and health services research
Tracking Funding Opportunities

Funding Opportunity Announcements:

• NIA Alzheimer’s Disease and Related Dementias FOAs:
  http://www.nia.nih.gov/AD-FOAs

• Supplements to Other ICs:

• NINDS Alzheimer’s Disease and Related Dementias FOAs:
  https://www.ninds.nih.gov/Current-Research/Research-Funded-
  NINDS/Translational-Research

Additional Resources:

• Follow our “Inside NIA” blog:
  https://www.nia.nih.gov/research/blog
Thank You

Questions?

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