

Advances and Plans from the NIA

Meeting with the Friends of NIA

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Director
National Institute on Aging

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National Institute
on Aging

NIH Updates



Important Changes to Grant Resubmission Policy

- In 2009, the NIH changed its resubmission policy, from allowing two resubmission applications to one (an “A1” submission). If the A1 was not funded, any further applications had to be substantially different in content and scope in order to be eligible for submission as a “new” application.
- Following receipt of feedback from both new and established investigators, the NIH revised its policy effective April 17th, 2014:
 - After an unsuccessful (A1) submission, A “new” application will be considered *without* an association to a previous submission; i.e., the applicant no longer has to discuss how the application has changed or respond to previous reviews.
 - NIH still expects that applicants will nevertheless take advantage of previous reviewers’ comments to strengthen the applications for each submission.
 - NIH's policy for accepting overlapping applications remains in effect; i.e., NIH will not accept duplicate or highly overlapping applications *under review at the same time*.

Improving Grants Management & Review

- Maximizing efficiencies of core facilities
 - Integrating core facilities across NIH and finding efficiencies
- Analysis of Review Group Outputs (ARGO)
 - Using research tools to create a more dynamic structure for peer review that responds to changing trends in science
- Enhancing the NIH biosketch
 - The current biosketch format may rely too much on the impact factor of journals in which applicant has published
 - NIH seeks to better emphasize the applicant's actual contribution (including his/her role in past work) instead of his/her academic and research pedigree

Accelerating Medicines Partnership (AMP)

www.nih.gov/amp

- Aims to distinguish targets of disease most likely to respond to new therapies
- 10 biopharma firms; several nonprofits

Government	Industry	Non-Profit Organizations
FDA	AbbVie	Alzheimer's Association
NIH	Biogen Idec	American Diabetes Association
	Bristol-Myers Squibb	Foundation for the NIH
	GlaxoSmithKline	Geoffrey Beene Foundation
	Johnson & Johnson	Lupus Foundation of America
	Lilly	Lupus Research Institute / Alliance for Lupus Research
	Merck	PhRMA
	Pfizer	Rheumatology Research Foundation
	Sanofi	
	Takeda	USAgainstAlzheimer's

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AMP

Alzheimer's Disease Scientific Design

- **Identification of theragnostic biomarkers that predict clinical outcomes:**
 - **Project A** will develop AD biomarkers and help qualify them for use in registration trials, to reduce the number of research participants and time it takes to evaluate and secure approval for promising therapeutic interventions.
- **Integrated network analysis in Alzheimer's disease brain tissue:**
 - **Project B** will expand the application of integrated network analysis (including RNA and proteomic studies) in human AD brain samples to identify biologic nodes and networks that are linked to the development or progression of AD.

NIH/NIA Congressional & Budget Updates



Congressional Activities

- On February 26, Francis Collins, Director, NIH; accompanied by Richard Hodes, Director, NIA; and Story Landis, Director, NINDS; testified on **Alzheimer's Disease** before the Senate Appropriations Subcommittee on Labor, HHS, and Education.
- On March 10 and 21, Kathy Hudson, NIH Deputy Director for Science, Outreach, and Policy; Richard Hodes, Director, NIA; and Neil Buckholtz, Director, NIA Division of Neuroscience (along with NIDDK and NIAMS leadership) briefed the House and Senate staff on the **Accelerated Medicines Partnership**.
- On April 4, Francis Collins, Director, NIH; accompanied by several IC Directors, testified on the **NIH FY15 budget request** before the Senate Appropriations Subcommittee on Labor, HHS, and Education. Alzheimer's disease was a focus of several questions.

Public Law 113-76, 2014 Consolidated Appropriations Act



- Provides \$1 billion increase for NIH over the post-sequester funding level of FY2013
- Additional funds for NIA research - \$130 million more than last year, including a focus on Alzheimer's disease.

NIA Appropriations FY 2004-2014

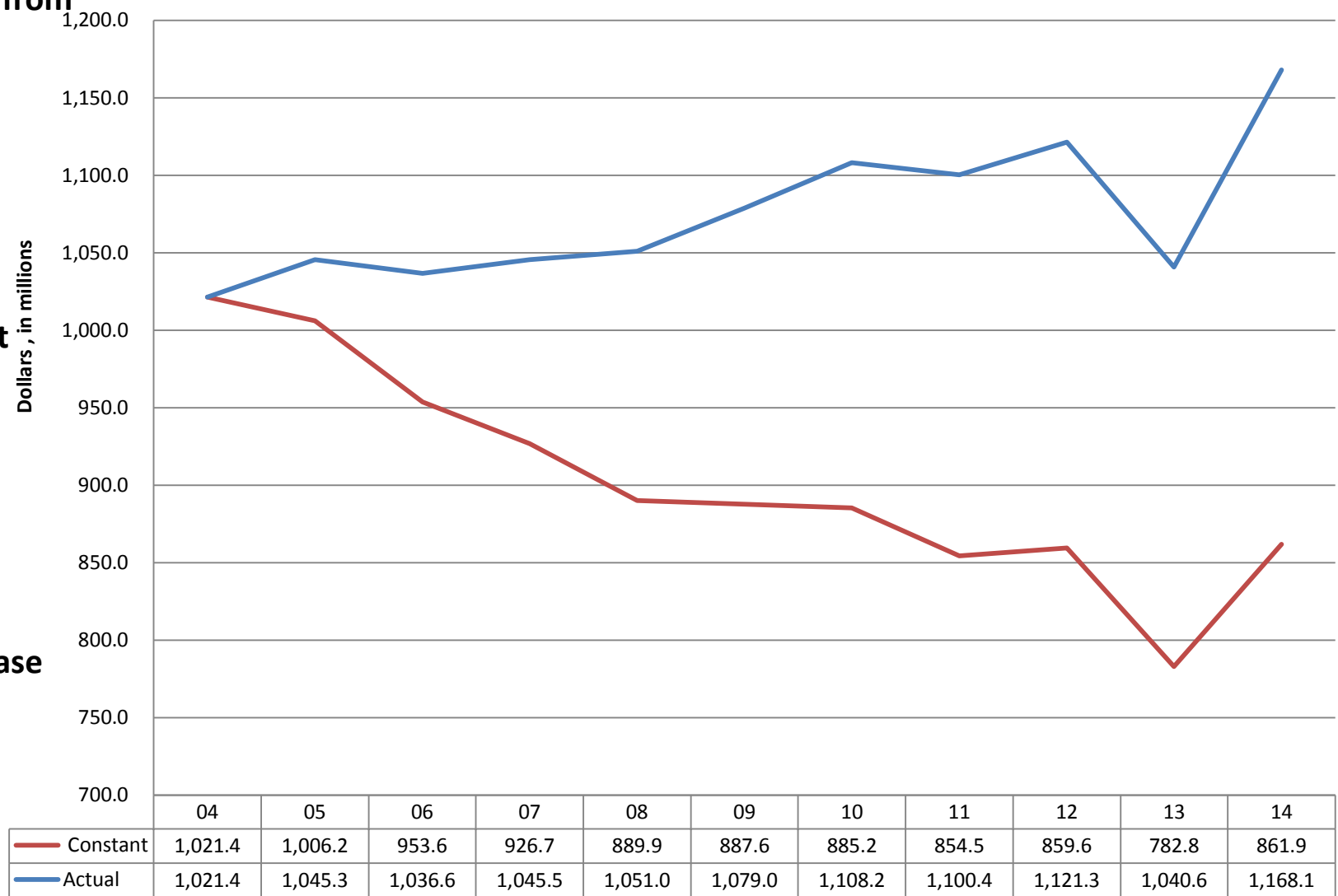
Current versus Constant, FY04 Base Year

**Difference from
FY2004**

**In Current
Dollars:
\$146.7M
Increase**

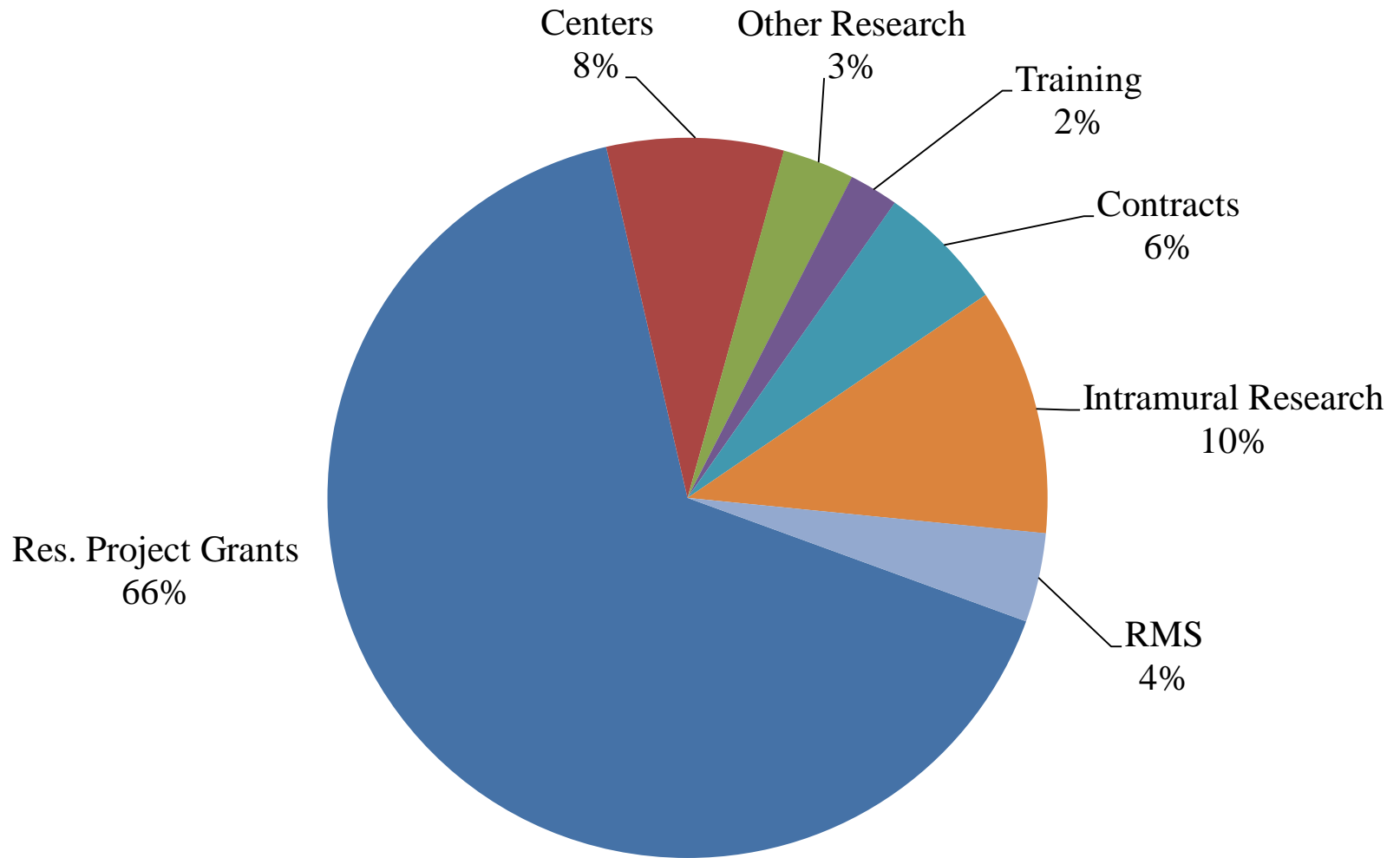
**In Constant
Dollars:
\$159.5M
Decrease**

**16% decrease
FY04-FY14**



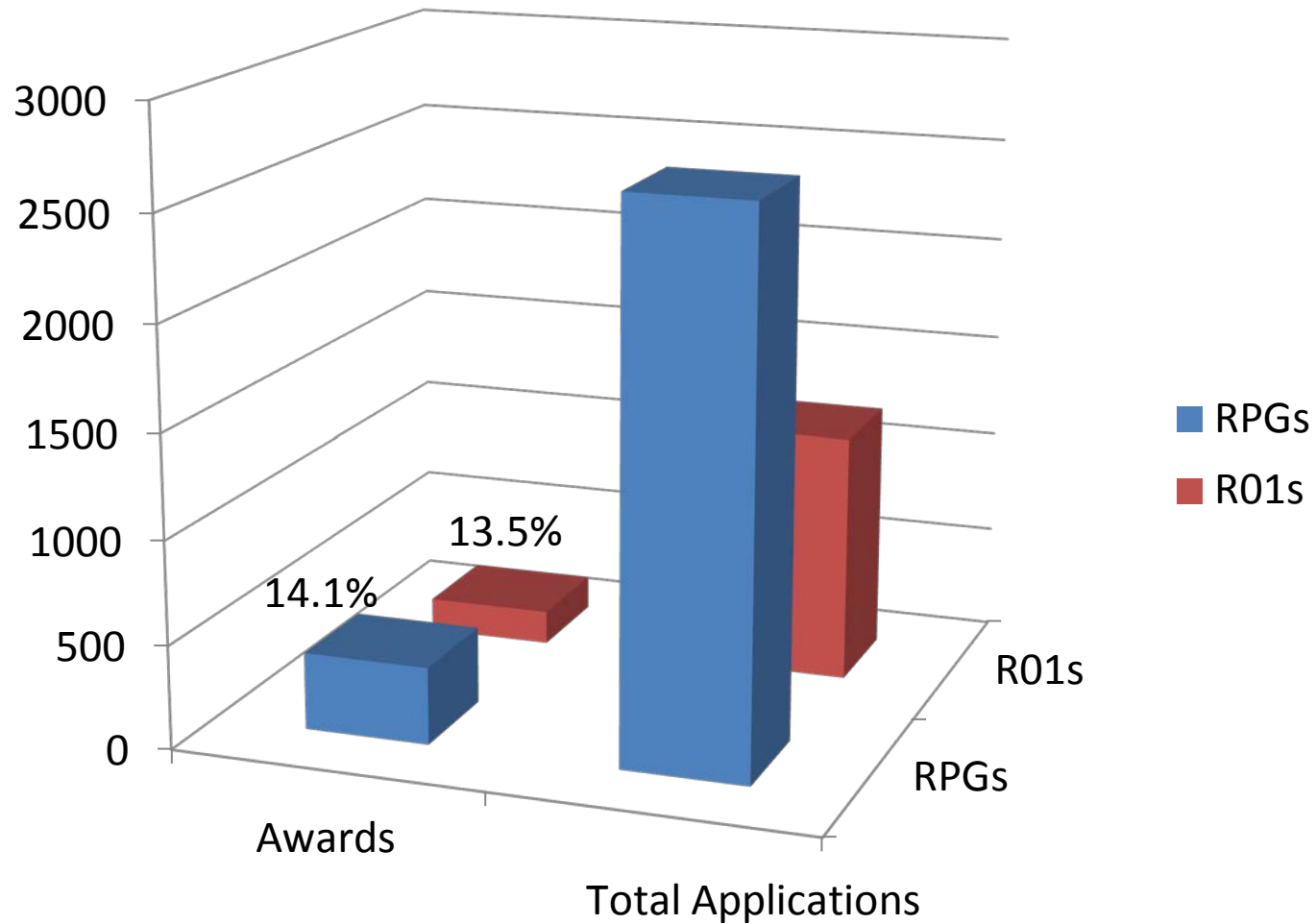
Distribution of Obligations by Budget Category

Fiscal Year 2013

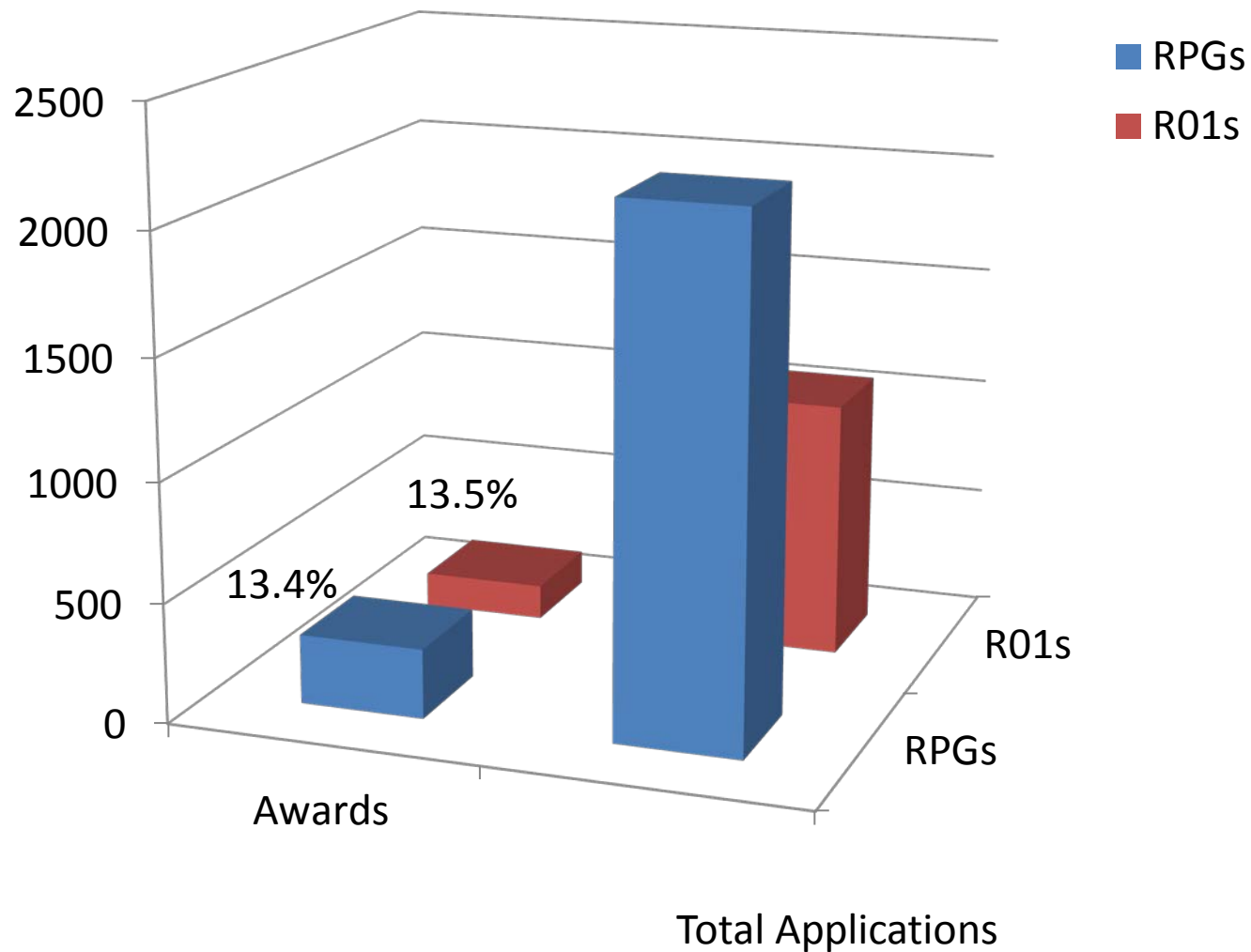


Total NIA: \$1,040,634,000

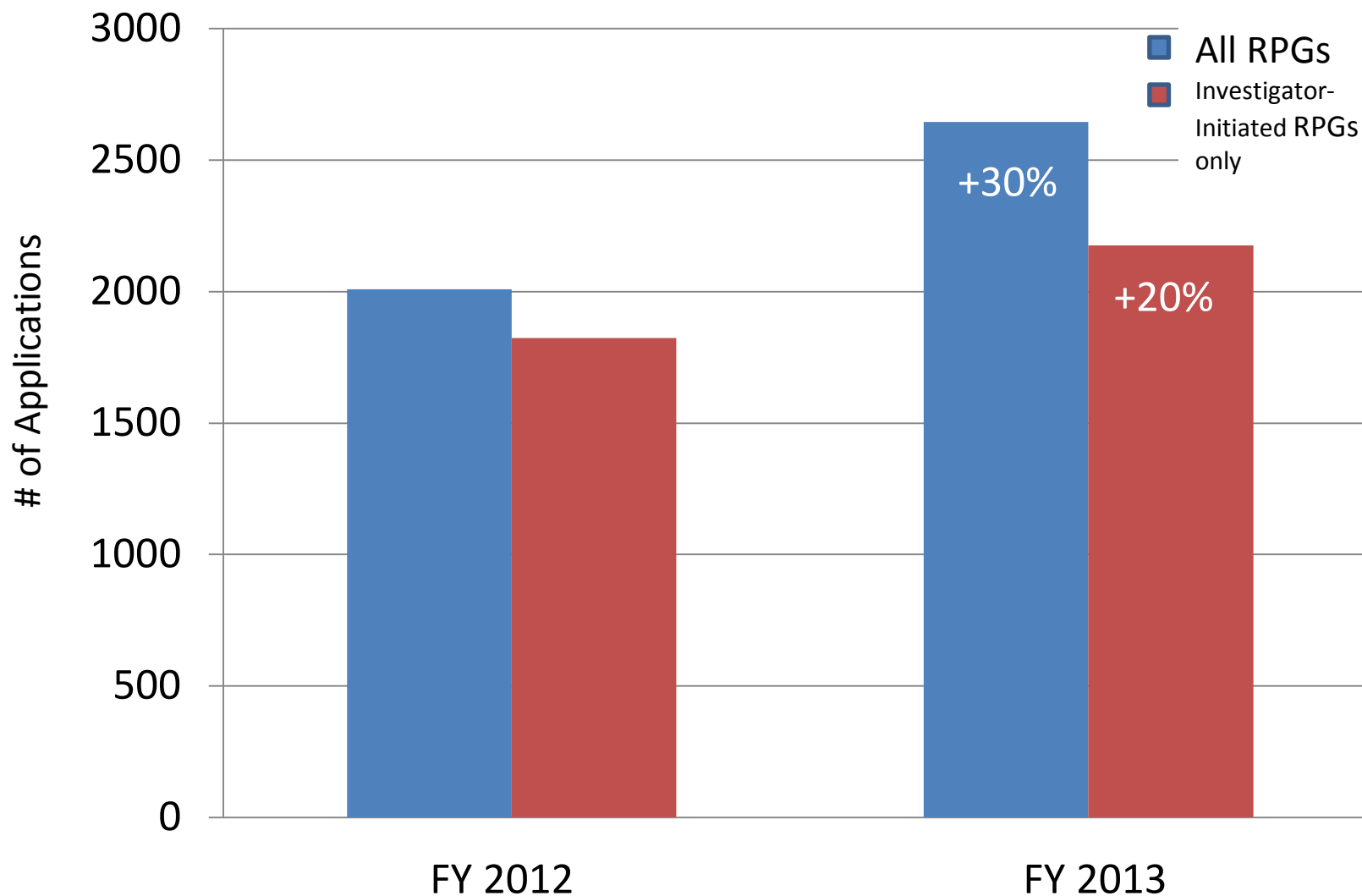
NIA SUCCESS RATE FOR FY 2013



NIA SUCCESS RATE FOR FY 2013 excluding RFAs



RPGs APPLICATIONS FOR FY 2012 & FY 2013



COLLABORATIONS & LEVERAGING OF FUNDS

NIA & Patient Centered Outcomes Research Institute (PCORI) Collaboration

RFA on Falls Prevention Issued in July 2013

- Falls are a common but serious problem among the elderly
- The best prevention strategy is not known
- The goal of the collaboration is to fund a single large-scale, multi-pronged clinical trial on prevention of fall-related injuries in non-institutionalized older adults

Roles and timeline:

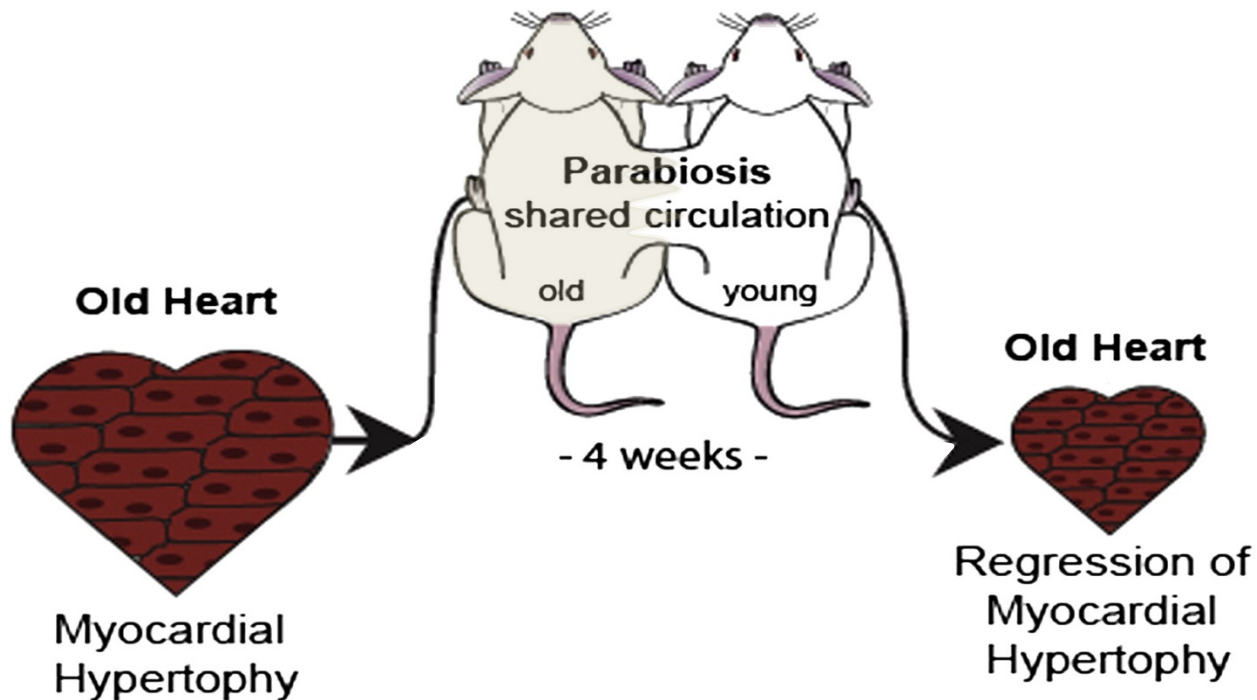
- RFA released in July 2013; application review complete
- PCORI has committed up to \$30 million for the project
- Study site has been identified, not publicly announced yet

NIA Research Updates



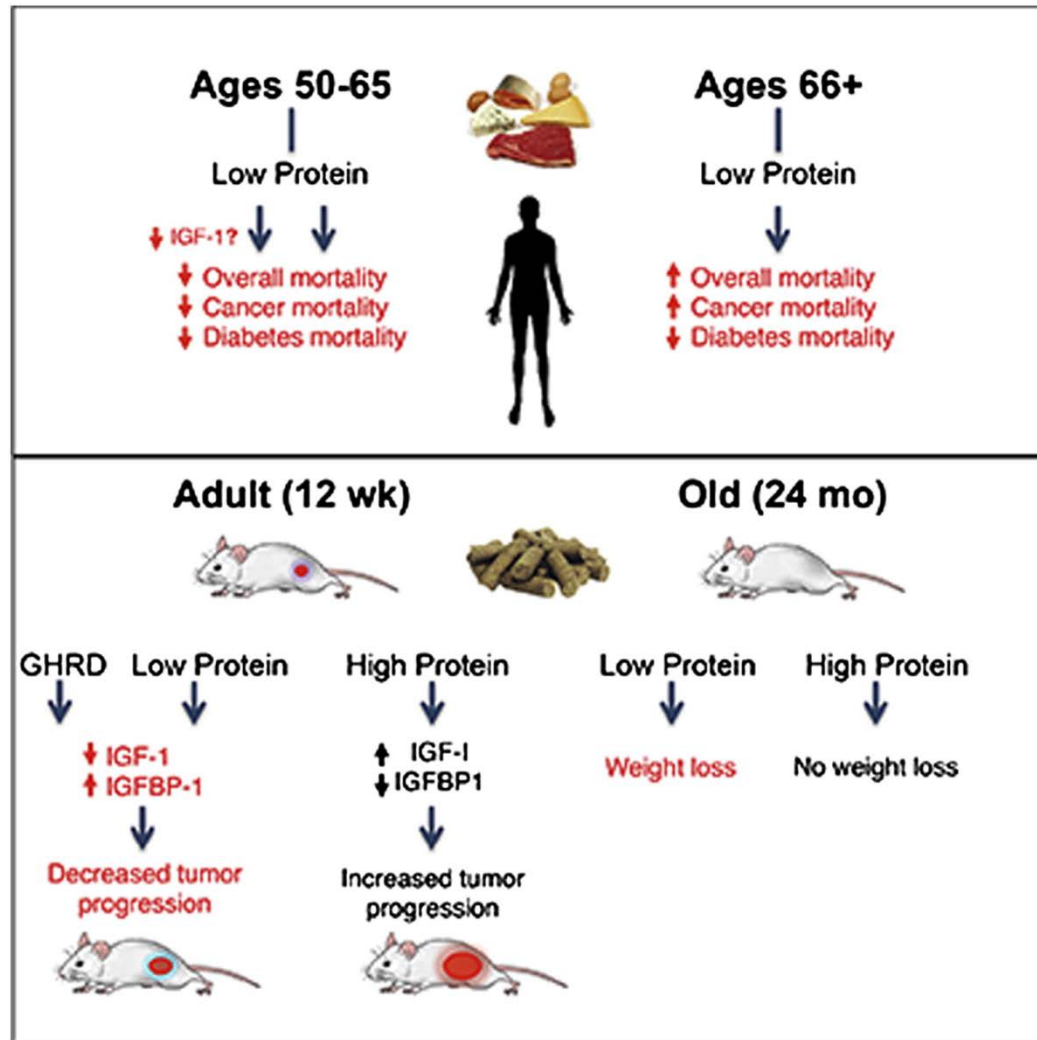
Circulating factors reverse age-related pathology

Or: How can you repair a broken heart?

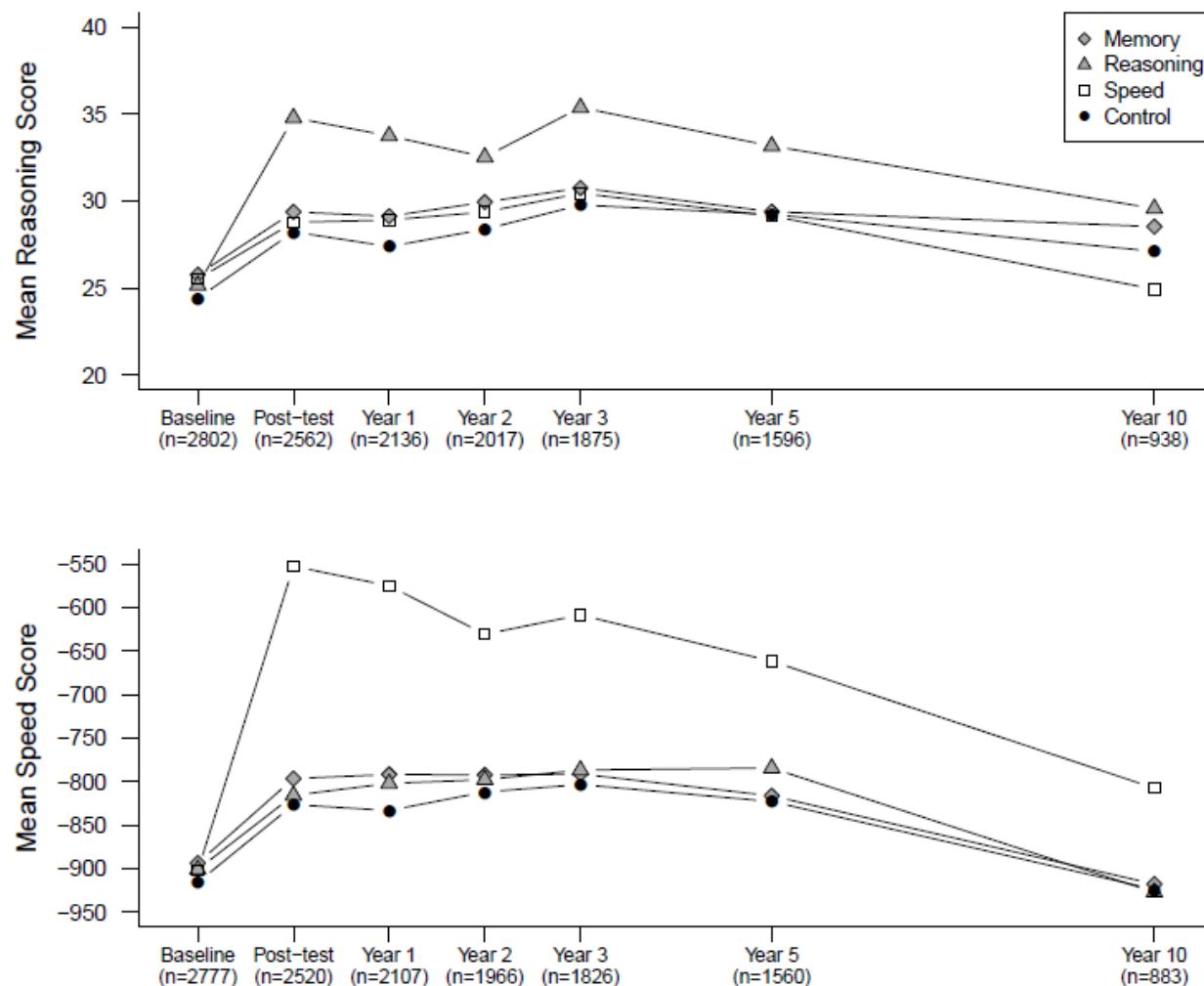


Is a high protein diet good for you?

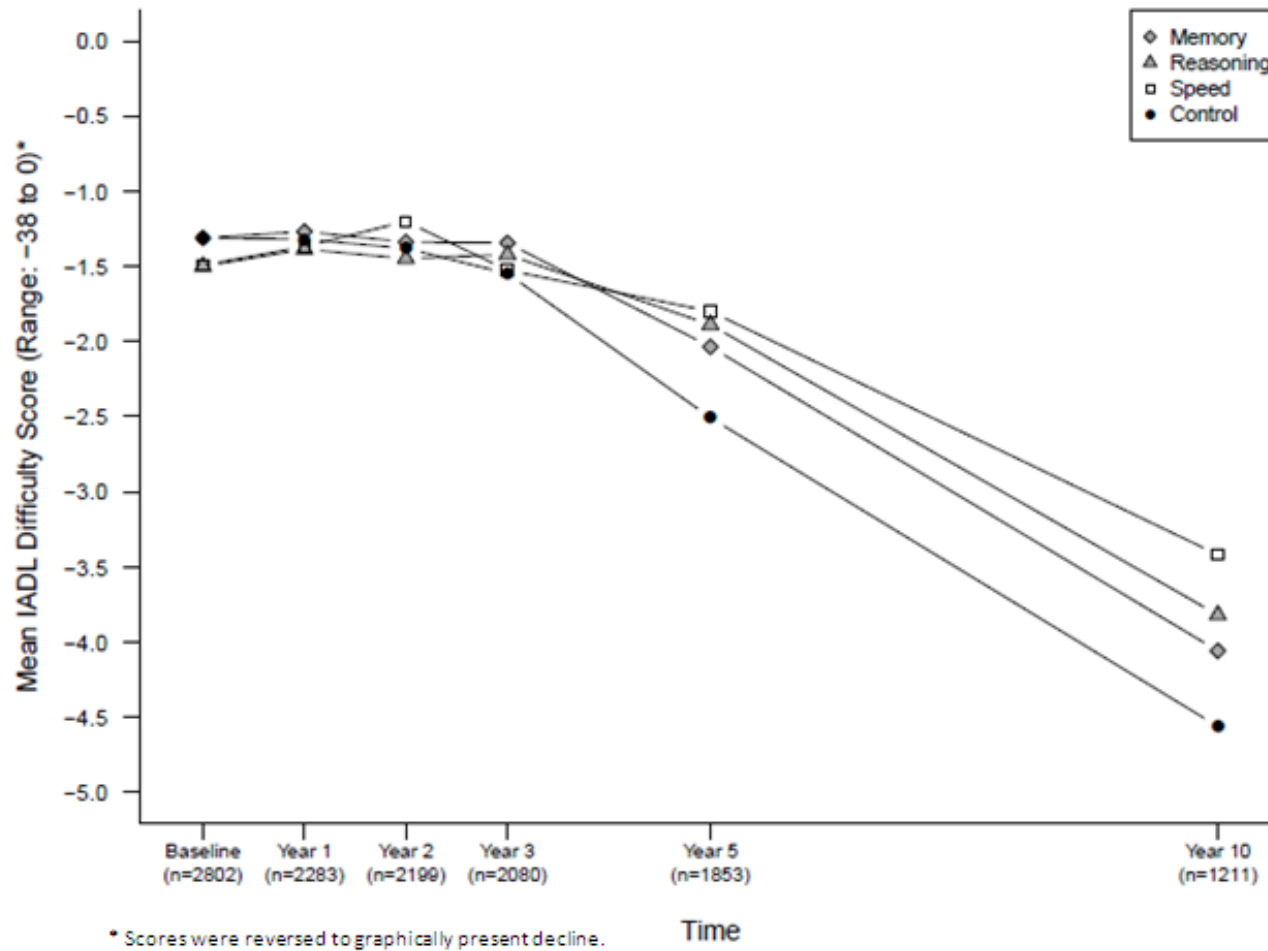
It depends on your age



Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) Shows 10-Year Benefit in Reasoning and Speed of Processing



Approximately 60% of ACTIVE Participants Maintained or Improved Instrumental Activities of Daily Living (IADLs) At 10 Years



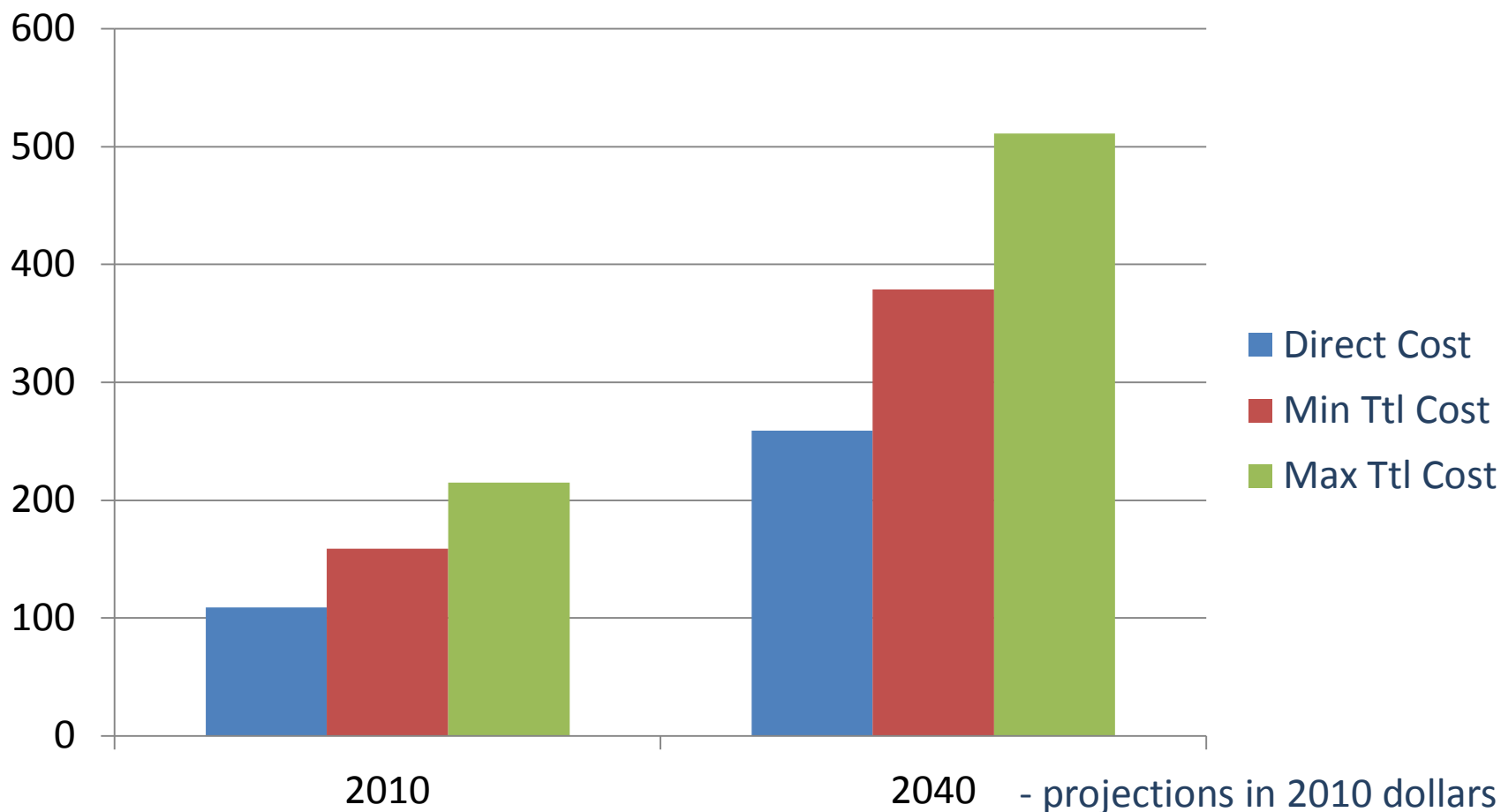
Database on Genetic Epidemiology Research on Aging (GERA)

Funded by NIA, NIMH, and the NIH Director's Office

- Genetic and health data on over 78,000 members of the Kaiser Permanente Northern California system available on the NIH database of Genotypes and Phenotypes (dbGaP)
- Ethnically diverse GERA cohort (average age 63 years) - largest group deposited in dbGaP
- Dataset includes: genome-wide association data on all cohort members and information on diseases and conditions

The Monetary Costs of Dementia in the U.S.

\$s in Billions



Hurd et al, *NEJM*, 4/4/13

New NIA Alzheimer's Research Initiatives

- RFA-AG-14-012: Human Cell Reprogramming for Functional Genetics of Alzheimer's Disease (R01)
- RFA-AG-14-002: Optogenetic Tools for the Study of Neural Systems in Aging and Alzheimer's Disease (R01)
- PAR-12-183: National Institute on Aging Analysis of Alzheimer's Disease Genome Sequencing Project Data [U19](with new expiration date of January 1, 2015)
- Funding Opportunity Announcement for Planning Grants for Alzheimer's Disease Translational Centers for Predictive Drug Development: <http://grants.nih.gov/grants/guide/rfa-files/RFA-AG-14-017.html>

Newly Funded Clinical Trials

- **Dominantly Inherited Alzheimer Network Trial (DIAN-TU)** - Trial of anti-amyloid agents gantenerumab and solanezumab in presymptomatic to mildly symptomatic autosomal dominant AD mutation carriers.
- **Alzheimer's Prevention Initiative (API)-APOE4 trial** – Trial of an amyloid-modifying treatment (specific compound TBD) in 650 cognitively unimpaired 60-75 year-old apolipoprotein E4 homozygote carriers (APOE4).
- **Anti-Amyloid Treatment in Asymptomatic AD (A4 Trial)** - Trial of anti-amyloid agent solanezumab in clinically normal older individuals (aged 65-85) A β + on PET imaging.

Alzheimer's Disease Sequencing Project (ADSP)

National Alzheimer's Project Act – Treat/Prevent AD by 2025

- NIA and NHGRI conducted a large scale sequencing project to Identify AD risk and protective gene variants and to facilitate identification of new pathways for therapeutic approaches and prevention

Data Release Dates to Qualified Investigators:

- Whole genome sequence (WGS) data (582 subjects in 111 families) – complete March 2014
- Whole exome sequence data (5,000 cases and 5,000 controls) and from 1,000 additional cases - summer 2014

INTERNATIONAL ALZHEIMER'S DISEASE RESEARCH PORTFOLIO (IADRP)

<http://iadrp.nia.nih.gov/cadro-web/>

Home

Advanced Database Search

About IADRP

About CADRO

Visualize Data

Help

What is IADRP?

What is CADRO?

Data Visualization

apolipoprotein

Alzh

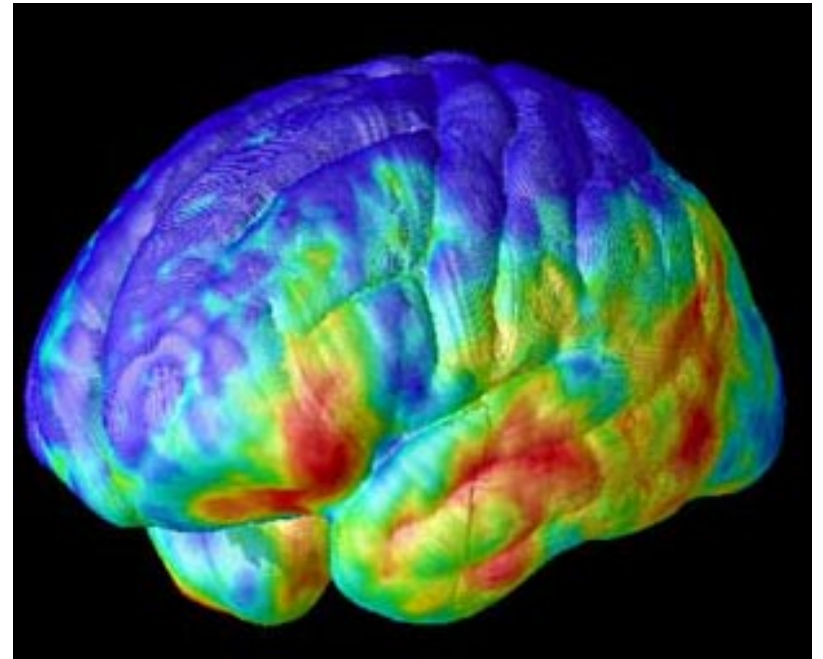
The goal of the International Alzheimer's Disease Research Portfolio (IADRP) project is to enable funding agencies to assess the changing landscape of Alzheimer's Disease (AD) research and coordinate funding strategies in order to enhance efficiency and avoid duplication of funding efforts.

Learn more

- ❑ Web-based portal developed by NIA and the Alzheimer's Association: Alzheimer's and related dementias research funded projects 2008 to 2012.
- ❑ Currently includes: Federal agencies (including NIH, AHRQ, CDC, AoA, VA and DoD), Alzheimer's Association, Alzheimer's Drug Discovery Foundation, and Alzheimer's Research UK, Alzheimer's Society UK, Alzheimer's Society of Canada, and Alzheimer's Australia.

SAVE THE DATE

**Alzheimer's Disease
Research Summit 2015**



February 9-10, 2015

National Institutes of Health

U.S. Department of Health & Human Services

Bethesda, MD



G8 Dementia Summit Declaration and Communique

- Identify a cure, or a disease-modifying therapy, for dementia by 2025
- Significantly increase the amount spent on dementia research
- Increase the number of people involved in clinical trials and studies

G8 Summit Legacy Meetings 2014-2015

- Social impact investment – United Kingdom
- New care and prevention models – Japan
- Academia-industry partnerships – Canada and France
- International research coordination – treatment, cure, and prevention – USA

<http://dementiachallenge.dh.gov.uk/2013/12/12/g8-dementia-summit-agreements/>

G8 Summit and Dementia Challenge

- On January 15, 2014, NAPA Council Members Richard Hodes, George Vradenburg, and Harry Johns reported to the House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations on the December 11, 2013, G8 Dementia Summit in London.

G8 UK
United Kingdom
2013

