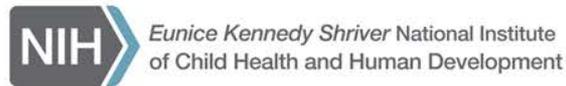


Division of Extramural Research Update

January 31, 2017

Della M. Hann, Ph.D.





Overview

- Staff Updates
- Understanding NICHD Awards
- FY 2017 Funding Strategy
- Upcoming Changes: Clinical Trials
- Overview of the Public Council Archive Pages



Priscah Mujuru

Scientific
Review
Officer

New to NICHD Extramural



Kelly Fritz
GMB



Helen Huang
SRB



Minki Chatterjii
SRB



Kimberly Houston
SRB

New to NICHD Extramural



Juanita Chinn
PDB



Meredith
Temple-O'Connor
DER



Jennifer Jackson
NCMRR



Miguelina Perez
OCM



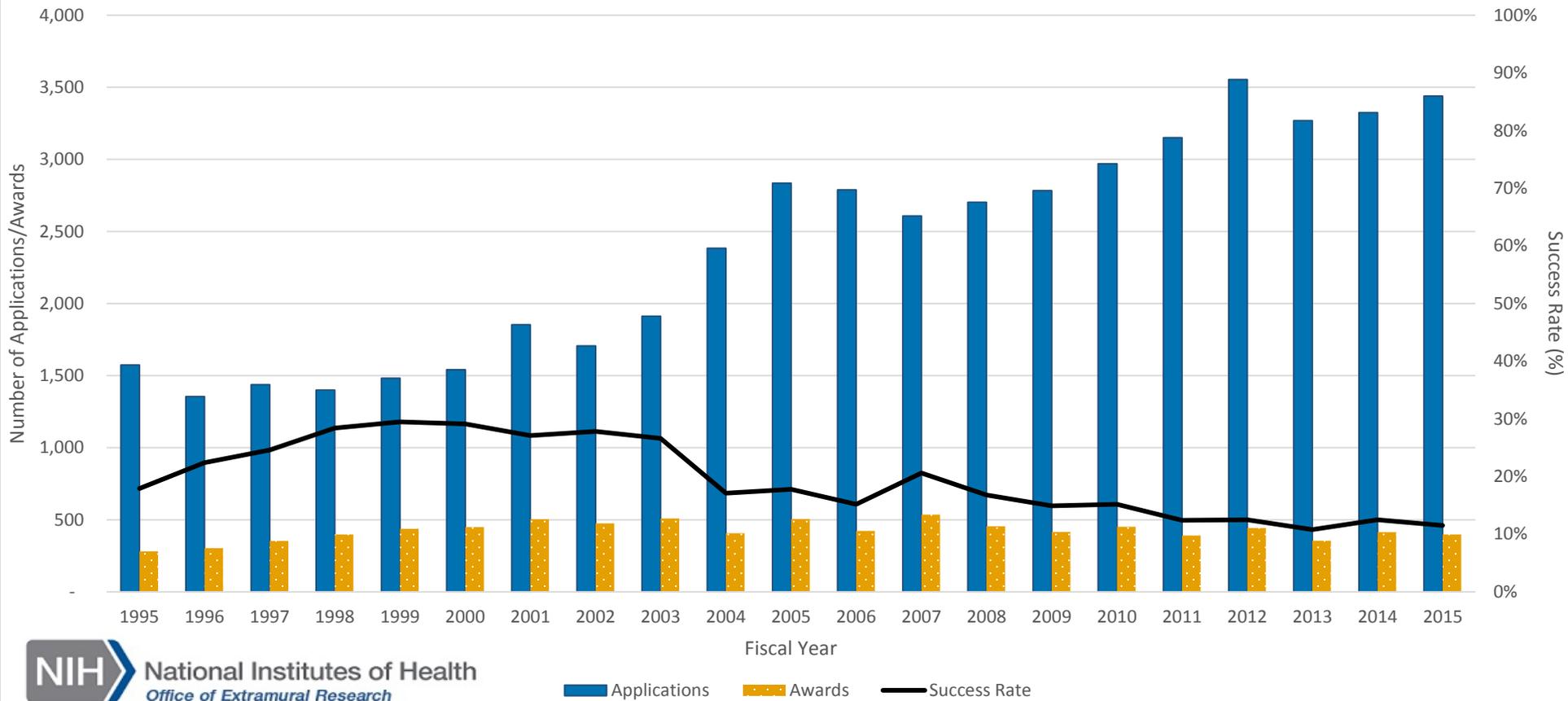
Samantha Calabrese
MPIDB



Understanding NICHD Awards

*Data on Research Training
&
Principal Investigators by Degree*

NICHD Research Project Grants: Competing Applications, Awards, and Success Rates

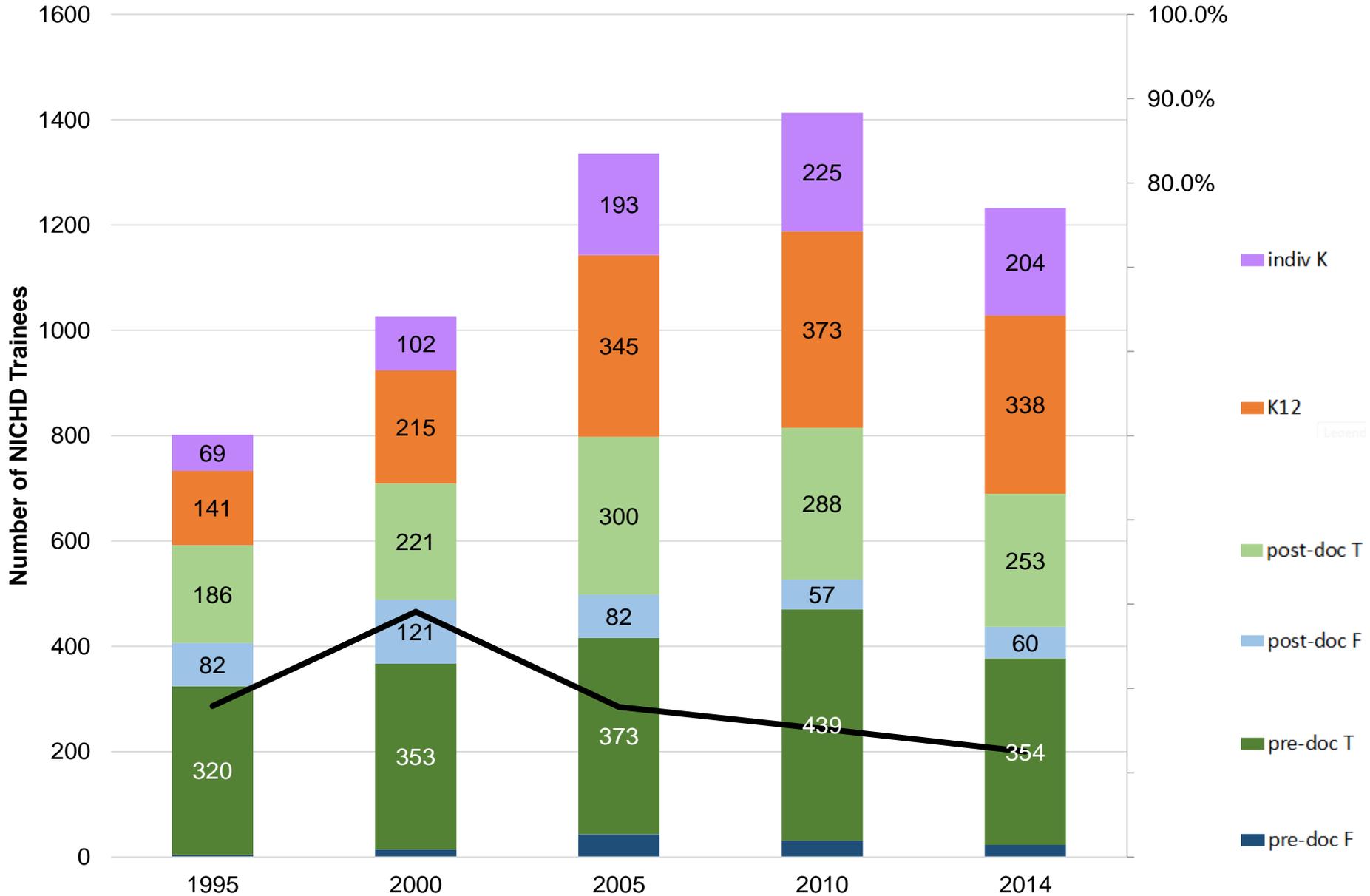


NIH National Institutes of Health
Office of Extramural Research

Applications Awards Success Rate

Awards made under Reimbursable Agreements, Appropriations to NIH for Superfund-related activities, Gift Funds and Breast Cancer Research Stamp Funds are not included. Research Projects (RPG) defined as activities (R00,R01,R03,R15,R21,R22,R23,R29, R33,R34,R35,R36,R37,R55,R56,RL1,RL2,RL5,RL9,P01,P42, PN1,UC1,UC7,U01,U19,U34,UH2,UH3,UM1,DP1,DP2,DP3,DP4,DP5,RC1,RC2, RC3,RC4,UA5,UC1,UC2,UC3,UC4,RF1,UF1,PM1,RM1) FY 2009 and 2010 exclude awards made under the American Recovery and Reinvestment Act of 2009 (ARRA) and all ARRA solicited applications and awards. An estimate for FY 2015 RPG applications shows 53599 NIH applications and 3551 NICHD applications, These numbers are subject to change. Source: NIH IMPAC, Success Rate File

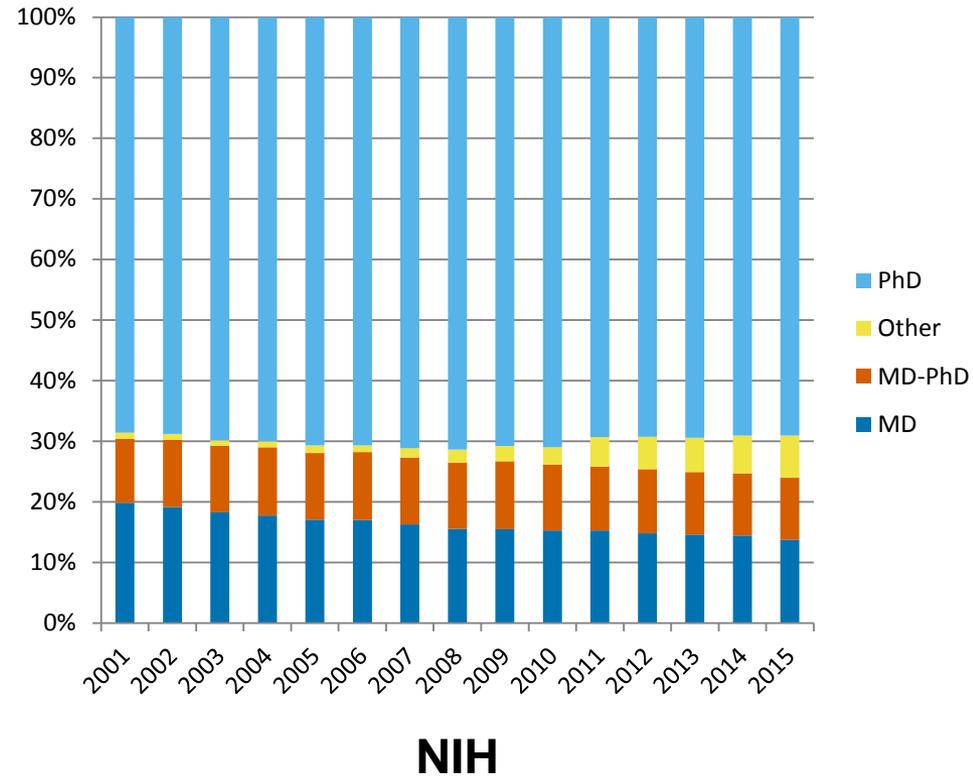
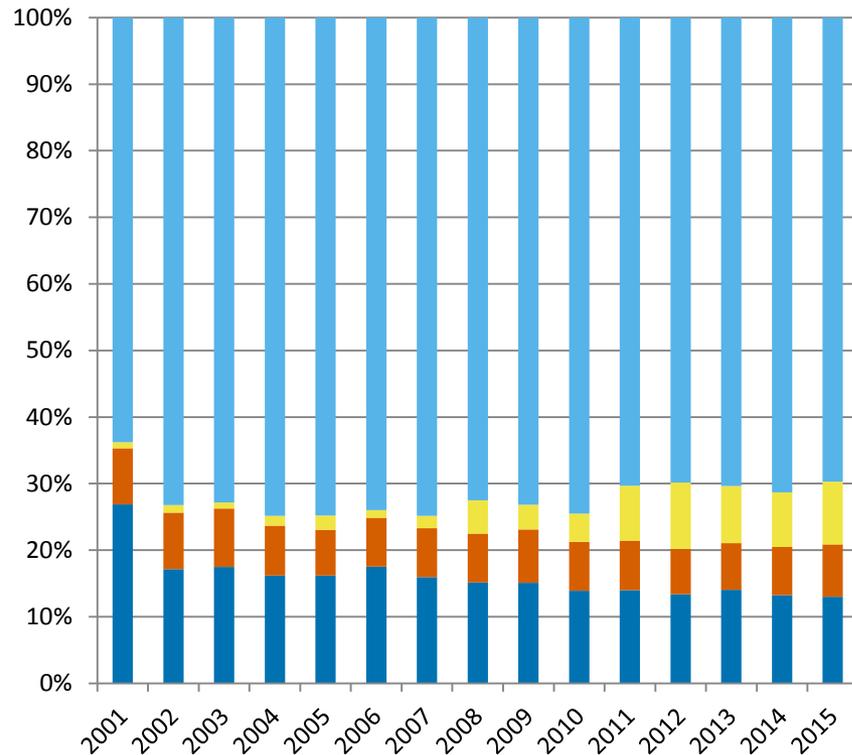
Individuals Supported by F, K, T's and NICHD Success Rate 1995-2014



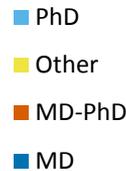
Proportion of Type 1 Applicants by Degree



NICHD



NIH

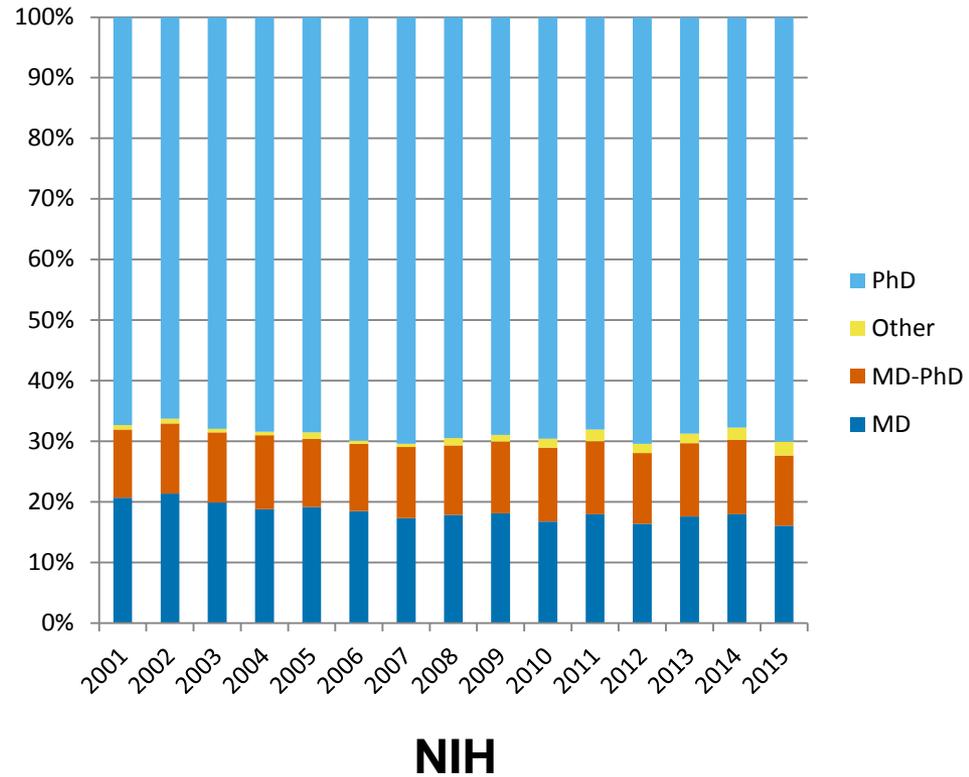
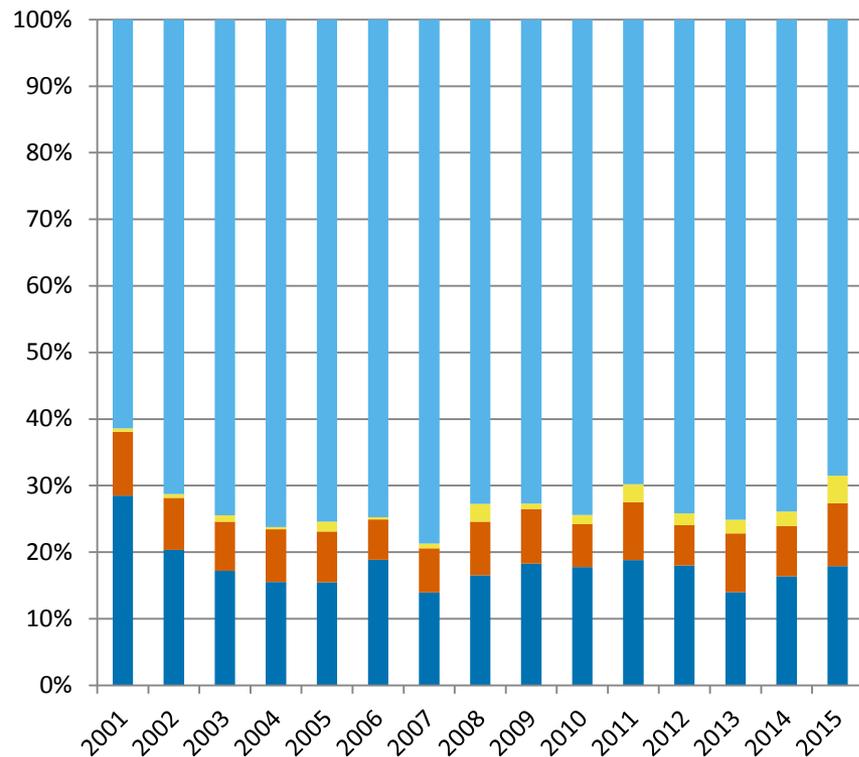


Includes R01 R03, R21, P, and U activity codes

Proportion of Type 1 Awardees by Degree



NICHD



NIH

- PhD
- Other
- MD-PhD
- MD

Includes R01 R03, R21, P, and U activity codes

Summary



- NICHD success rate has been around 11-12% since 2011
 - Large increase in applications during and since doubling, without increase in budget
- Number of NICHD supported trainees on F, T, and Ks also increased during the doubling –nearly doubled
 - Recently have decreased numbers in training – yet proportion of NICHD budget in training has remained approximately 6% of budget
 - Through 2014 continued to support over 1,200 trainees a year – even during time of low success rates for research grants
- NICHD trends in applicant and awardee professional degree for Type research grants very similar to those for NIH overall since 2001
 - Largest pool has and remains to be PhDs
 - Slow decline in proportion of MD applicants and awardees
 - Relative stability in proportion of MD-PhD
 - Some growth in the proportion of “other” professions



FY 17 Funding Strategy

Funding the Best Science



Clarify the Message

- ✓ Tighten referral guidelines
- ✓ Tighten transfer acceptance
- ✓ Clinical trials by FOA
- ✓ Stricter methods for large grant acceptance
- ✓ Limit PA, PAR, and secondary assignments
- ✓ Communicate priorities



Communicate Priorities



- Each branch developed up to 7 priority topics
 - Vision Document
 - Strategic Plans
 - Portfolio Assessment
- Identifying gaps and science needed to address
- Post on branch websites





- Increase flexibility for discretionary funding
 - No fixed pay line for investigator-initiated R01, R21, R03, R13 and R15
 - Using branch priorities, portfolio balance, and availability of funds
 - In practice for FY 17
- Be more strategic about our investments:
 - Mechanisms
 - Acceptance of large grants
 - Participation in FOAs
 - Refining referral guidelines





Clinical Trials

Changes in Policy & Implementation

Concerns about NIH Clinical Trials



- IOM Report 2010 & GAO Report 2016
 - Large investment, \$3 billion/year
 - Variable quality of trial design
 - Incomplete registration and reporting of trial results
 - Inconsistent oversight and monitoring
 - Inability to assess across IC's



Nature Reviews Drug Discovery | Published online 3 May 2016; doi:10.1038/nrd.2016.87

Ikon Images/Alamy Stock Photo

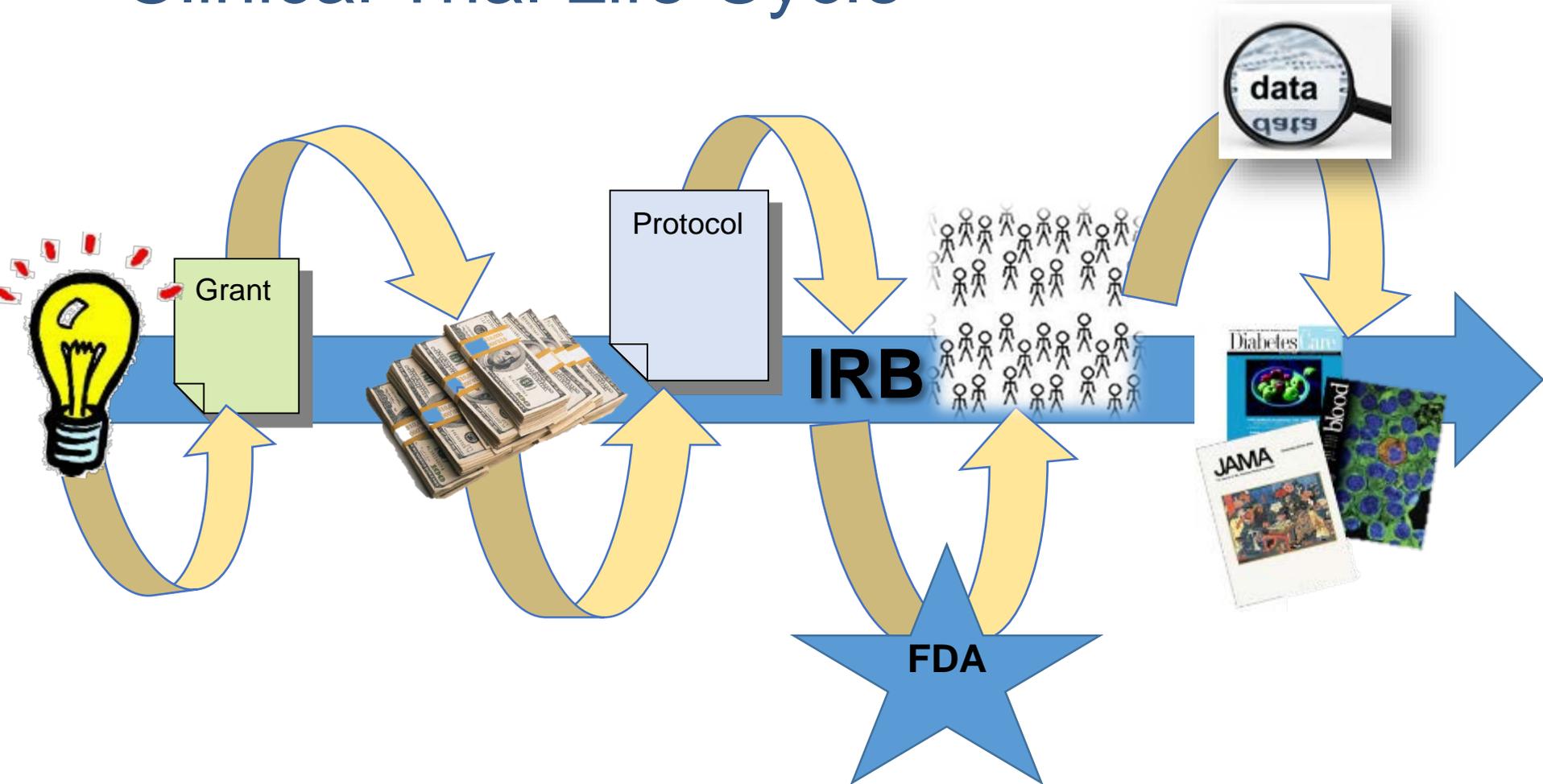


NIH tackles clinical trial shortcomings

The NIH is developing new tools, and overhauling its clinical trial funding system, to improve the stewardship of NIH-funded clinical trials



Clinical Trial Life Cycle



NIH Policy Changes for Clinical Trials



- Revised Definition of Clinical Trials
 - Notice [NOT-OD-15-015](#); Effective October 2014
- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
 - Notice [NOT-OD-16-094](#); Effective September 27, 2017
- Policy on Funding Opportunity Announcements (FOA) for Clinical Trials
 - Notice [NOT-OD-16-147](#); Effective September 27, 2017
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
 - Notice [NOT-OD-16-149](#); Effective January 18, 2017
- Policy on Good Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials
 - Notice [NOT-OD-16-148](#); Effective January 1, 2017





Revised NIH Definition of Clinical Trial

A **research study** in which one or more **human subjects** are **prospectively assigned** to one or more **interventions** (which may include placebo or other control) to evaluate the effects of those interventions on **health-related biomedical or behavioral outcomes**.

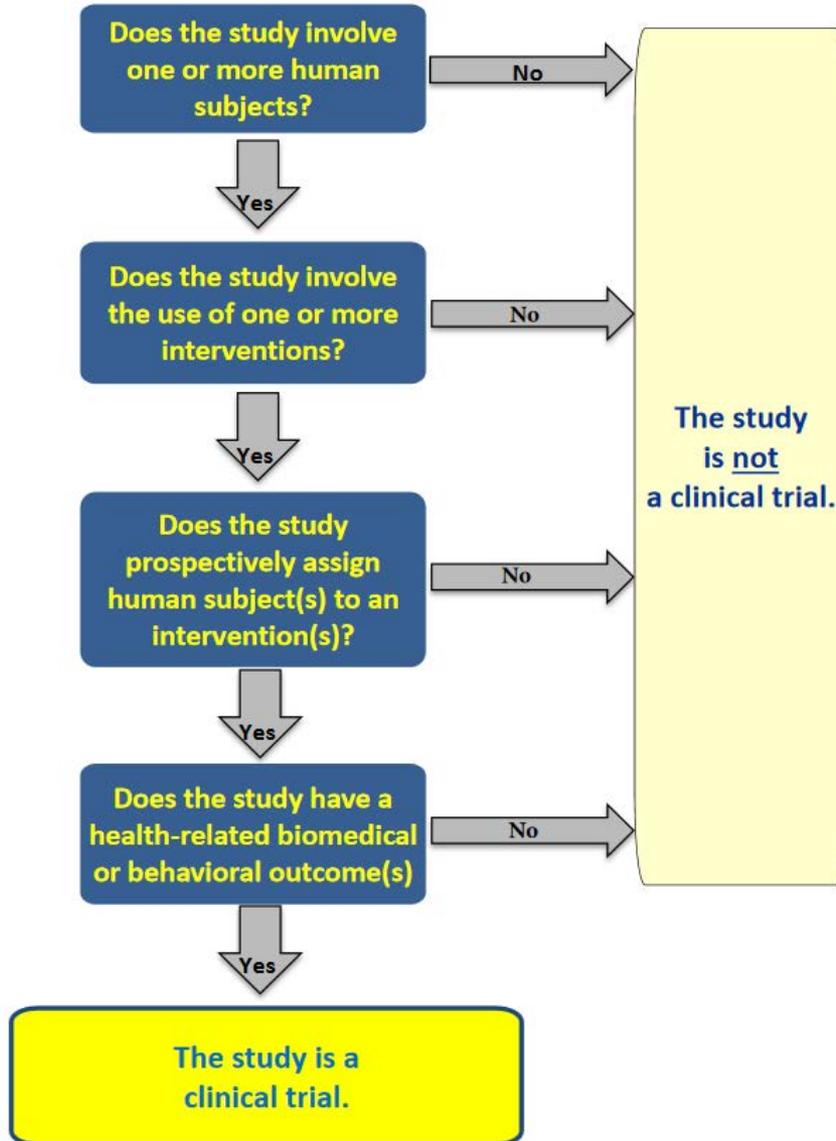
[NOT-OD-15-015](#) : Effective January 25, 2015

Is this a Clinical Trial?



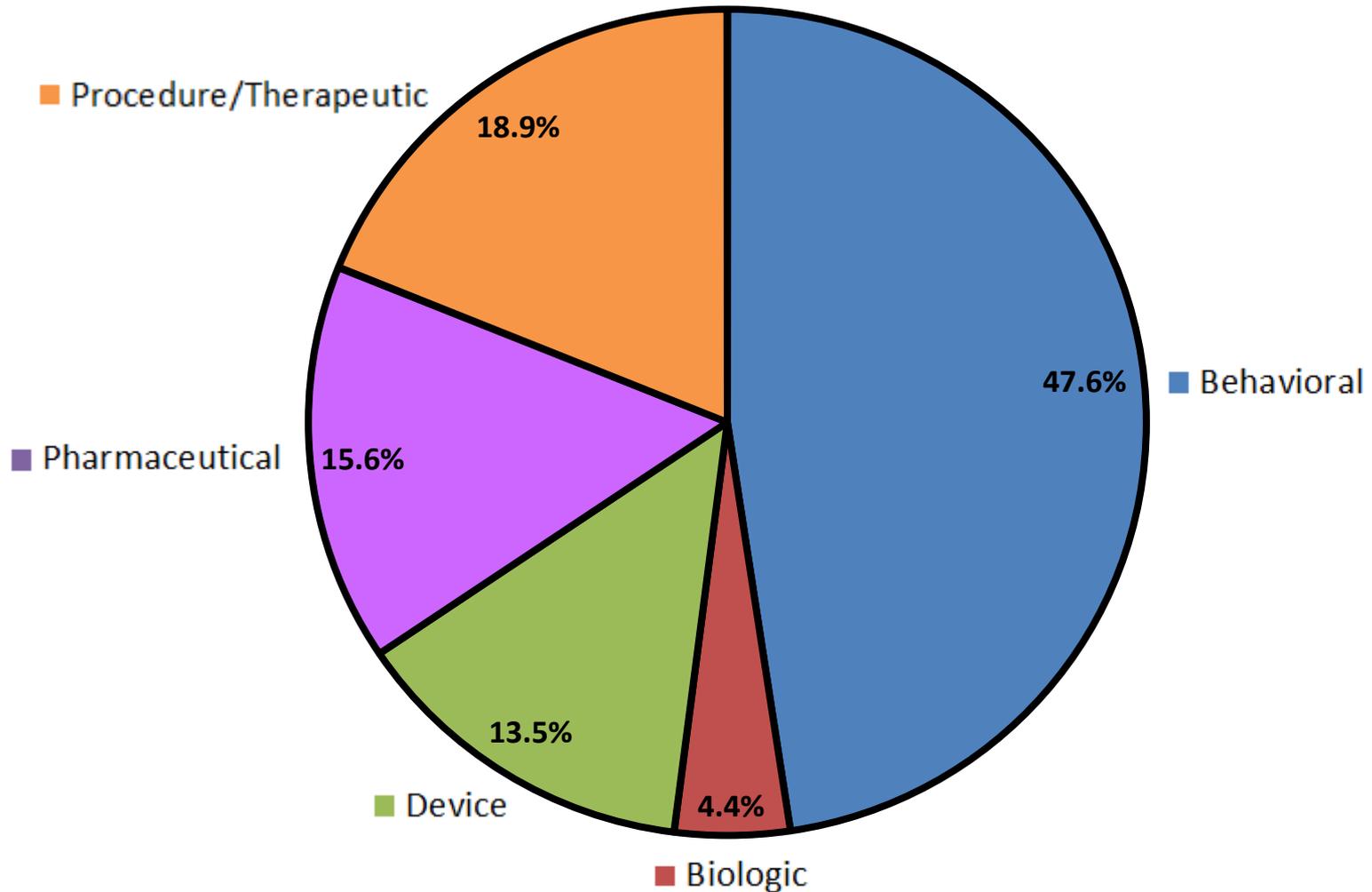
- Purpose: Study development of reasoning ability
 - Cross-sectional with cohorts from 2.5 – 12 years
- Methods: Use MRI to examine neural reactions when presented with a reasoning task
 - Also, test changes in reasoning/MRI activity with and without memory scaffolding exercise
- Outcomes:
 - Neural correlates of reaction times during reasoning task
 - Distribution of correct/incorrect responses to task
 - Changes in neural correlates and responses following memory exercise

NIH Definition of Clinical Trial Decision Tree



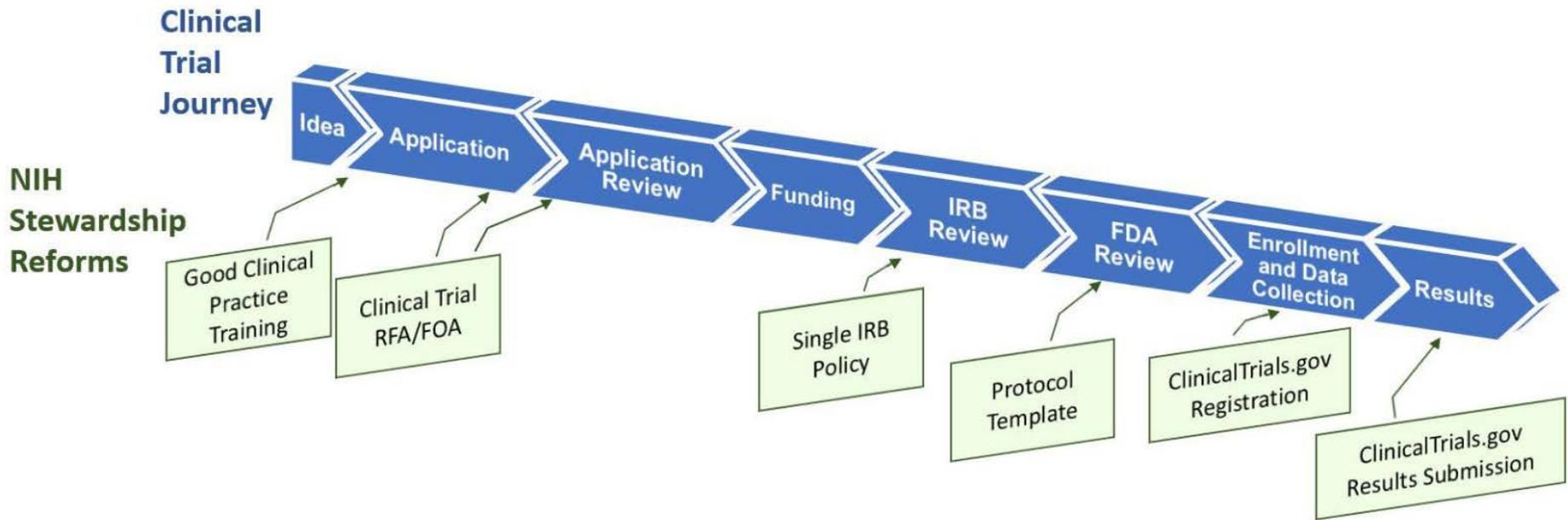


Clinical Trials Protocol Level Records by Primary Intervention Type (n=540)





Reforms over the clinical trial lifecycle



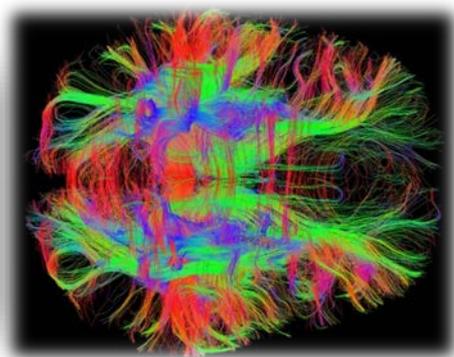


Overview of the Public Council Archive Pages

Demo provided by Sandi Delcore



Funding the Best Science at NICHD...



to Advance Science & Health for All

