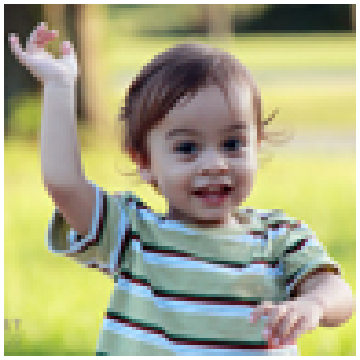
Division of Extramural Research Update

June 8, 2017

Della M. Hann, Ph.D.

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Overview



- Staff Updates
- Understanding NICHD Awards
  - Coming Attractions and New Perspectives
- Progress in Clinical Trial Reforms

Staff Updates

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

New to NICHD Extramural

Joe Bonner
NCMRR

Jill Long
CRB

Donna Mazloomdoost
GHDB

Staff Transitions: Retirements from NICHD Extramural

Marian Willinger
PPB

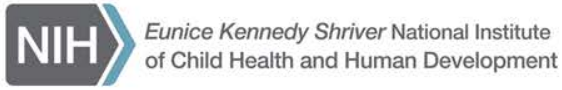
Gilman Grave
PGNB

Susan Newcomer
PDB

In Memoriam

Dr. Ruth Brenner

Understanding NICHD Awards



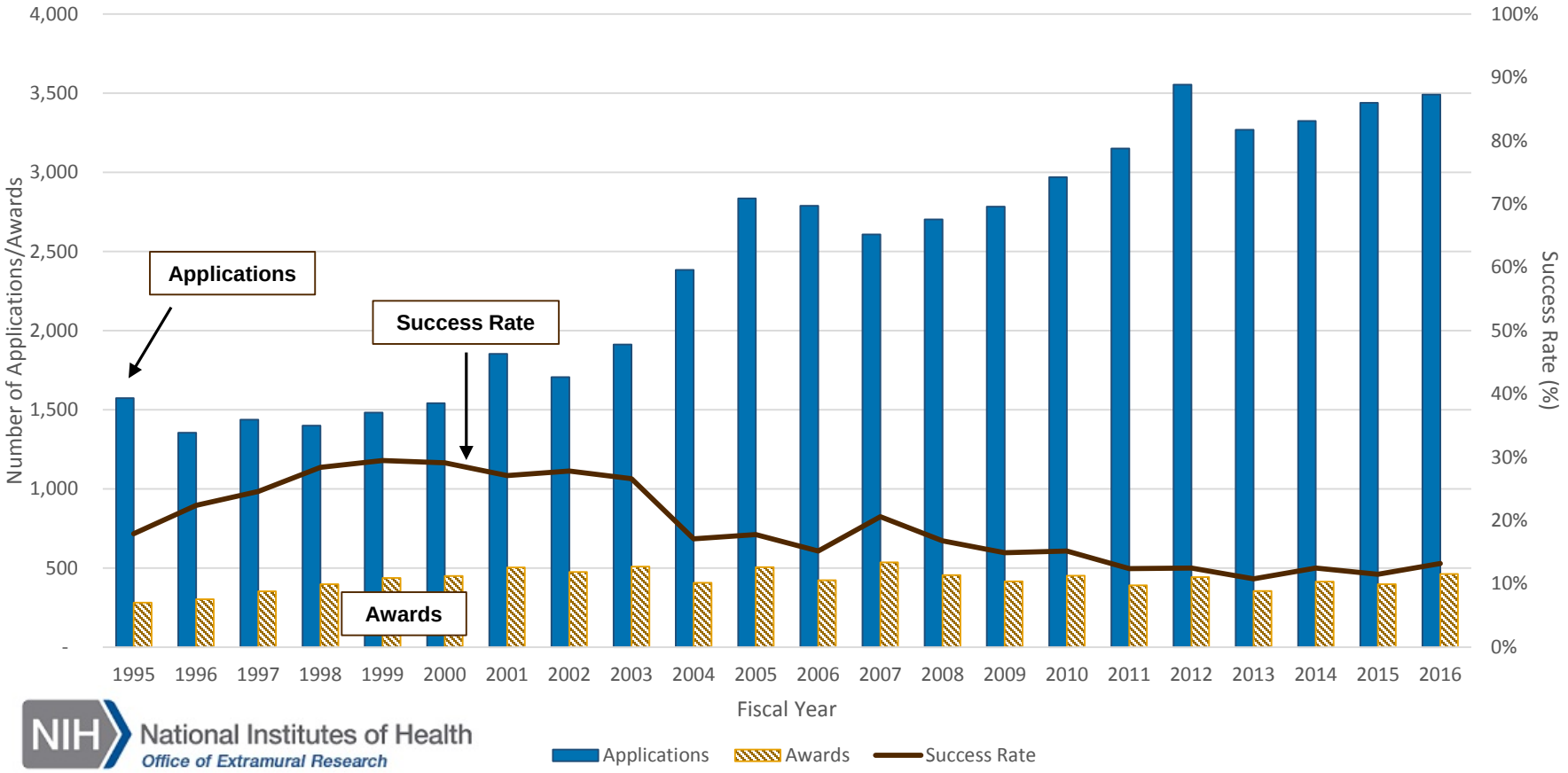
Options for Improving the Payline

Clarify the Message

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

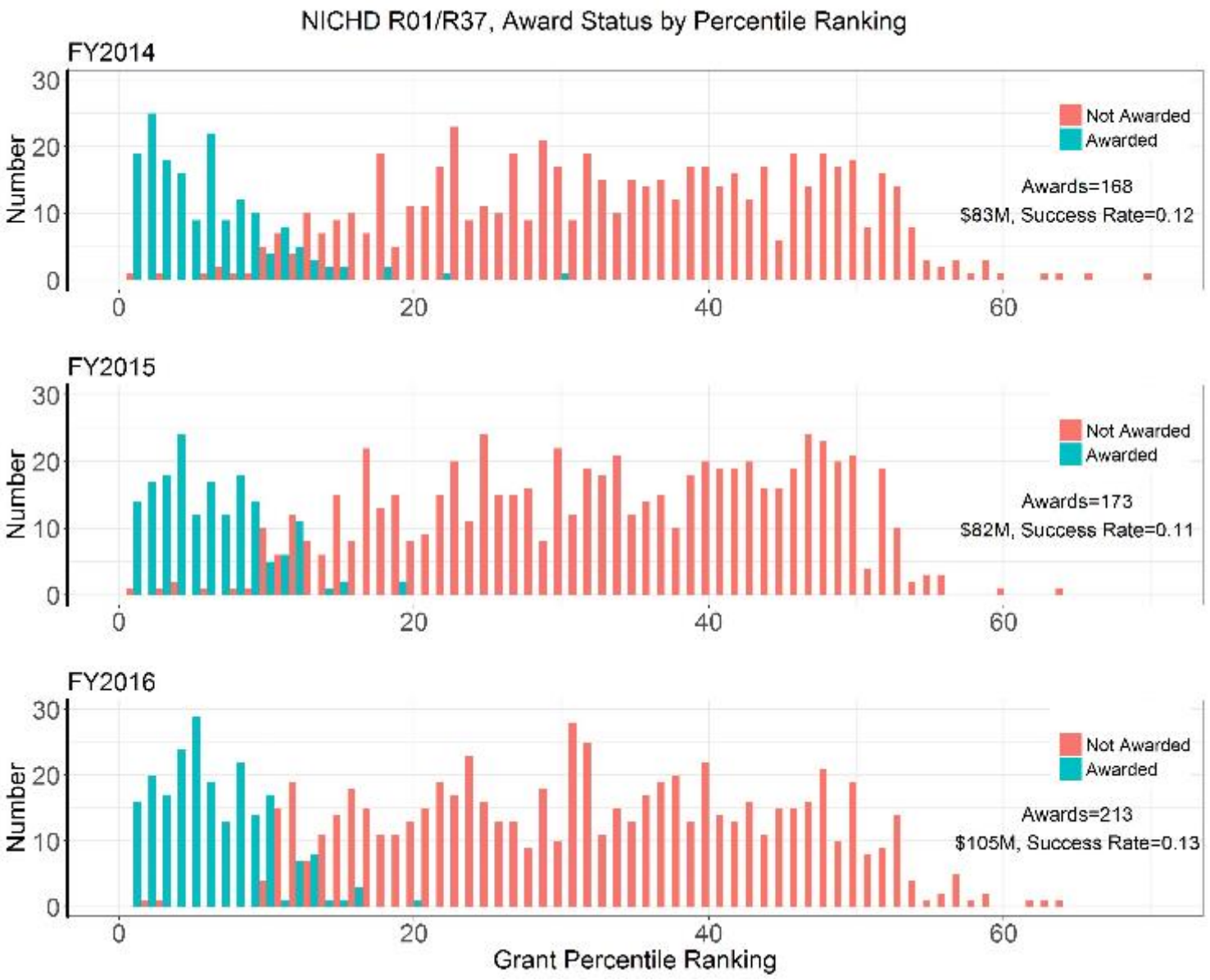
Success Rates

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



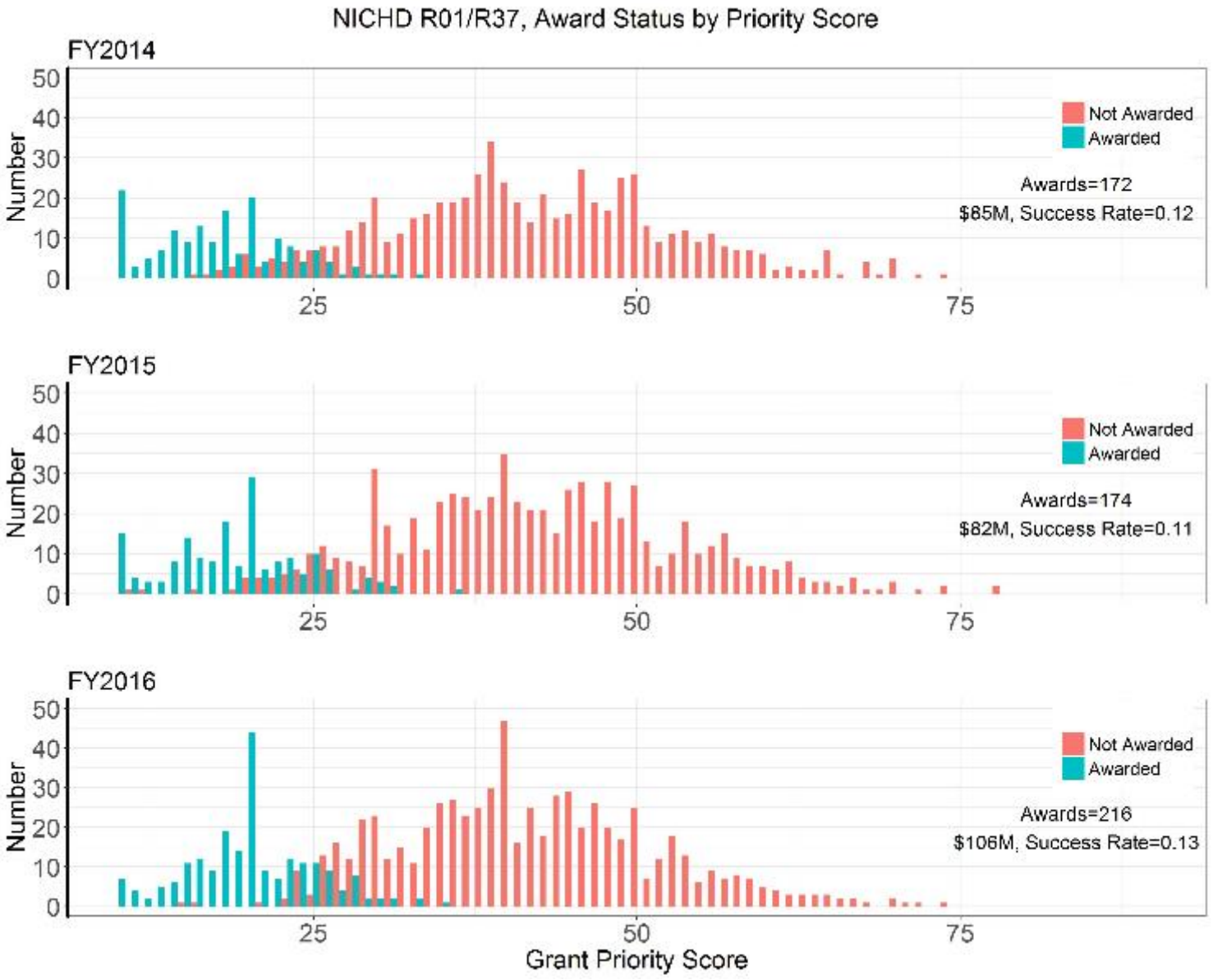
Awards made under Reimbursable Agreements, Appropriations to NIH for Superfund-related activities, Gift Funds and Breast Cancer Research Stamp Funds are not included.
Research Projects (RPG) defined as activities (R00,R01,R03,R15,R21,R22,R23,R29, R33,R34,R35,R36,R37,R55,R56,RL1,RL2,RL5,RL9,P01,P42, PN1,UC1,UC7,U01,U19,U34,UH2,UH3,UM1,DP1,DP2,DP3,DP4,DP5,RC1,RC2, RC3,RC4,UA5,UC1,UC2,UC3,UC4,RF1,UF1,PM1,RM1)
Source: NIH IMPAC, Success Rate File
Courtesy of the Statistical Analysis and Reporting Branch, Office of Extramural Research, NIH

Coming Attraction: Award Status Graphs for All ICs



Award count, total awarded dollar amount, and success rate are based on awards with percentile ranking. Awards without the ranking were excluded.
Courtesy of the Statistical Analysis and Reporting Branch, Office of Extramural Research, NIH

Coming Attraction: Additional NICHD Award Graphics

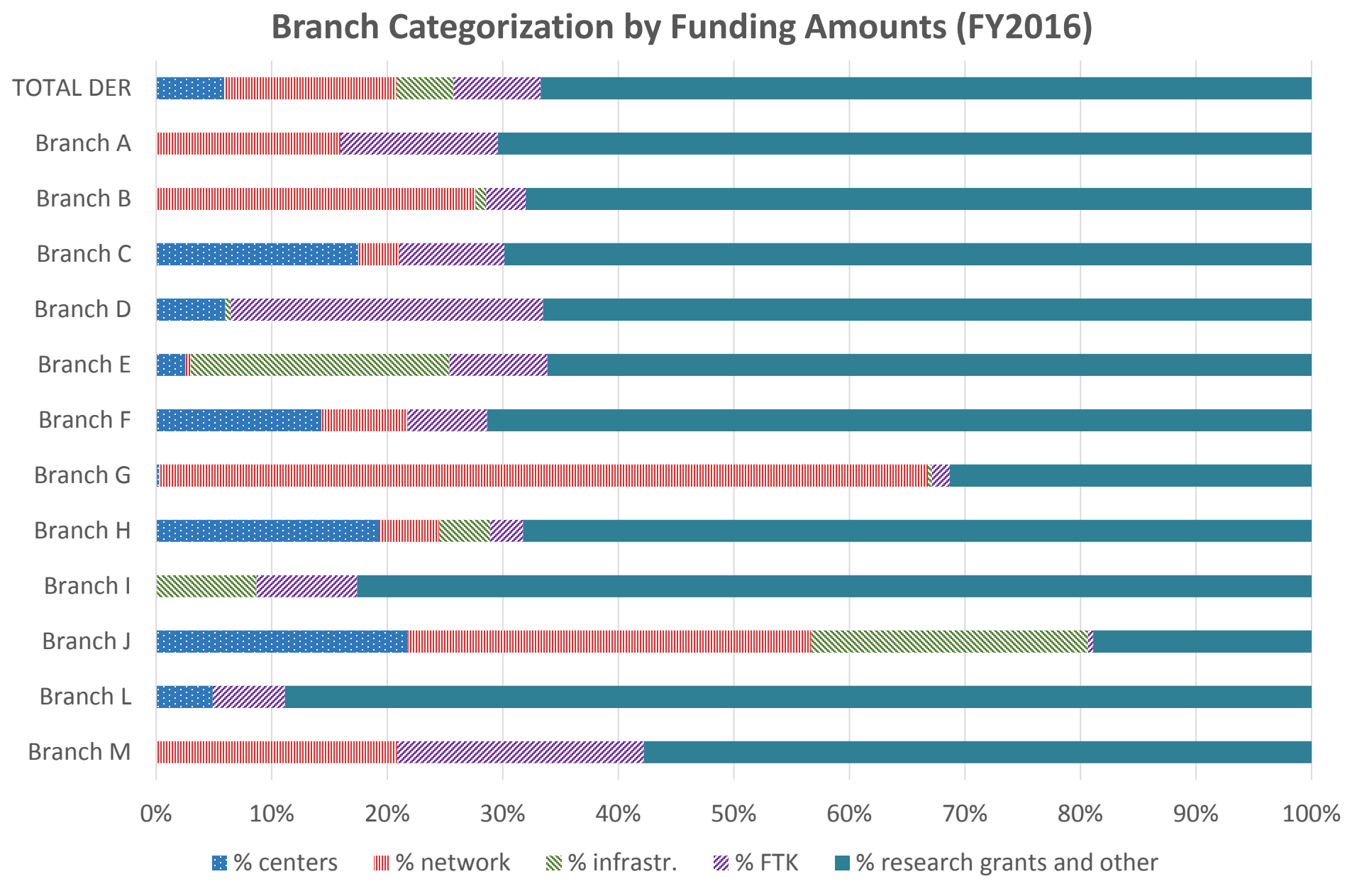


Award count, total awarded dollar amount, and success rate are based on awards with priority score. Awards without the score were excluded.
Courtesy of the Statistical Analysis and Reporting Branch, Office of Extramural Research, NIH

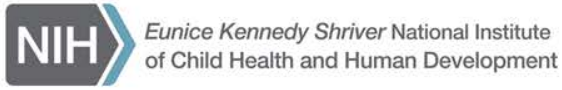
FY 17 Funding Strategy: Funding the Best Science

- 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

Another Perspective on Funding Strategically



Progress in Clinical Trial Reforms

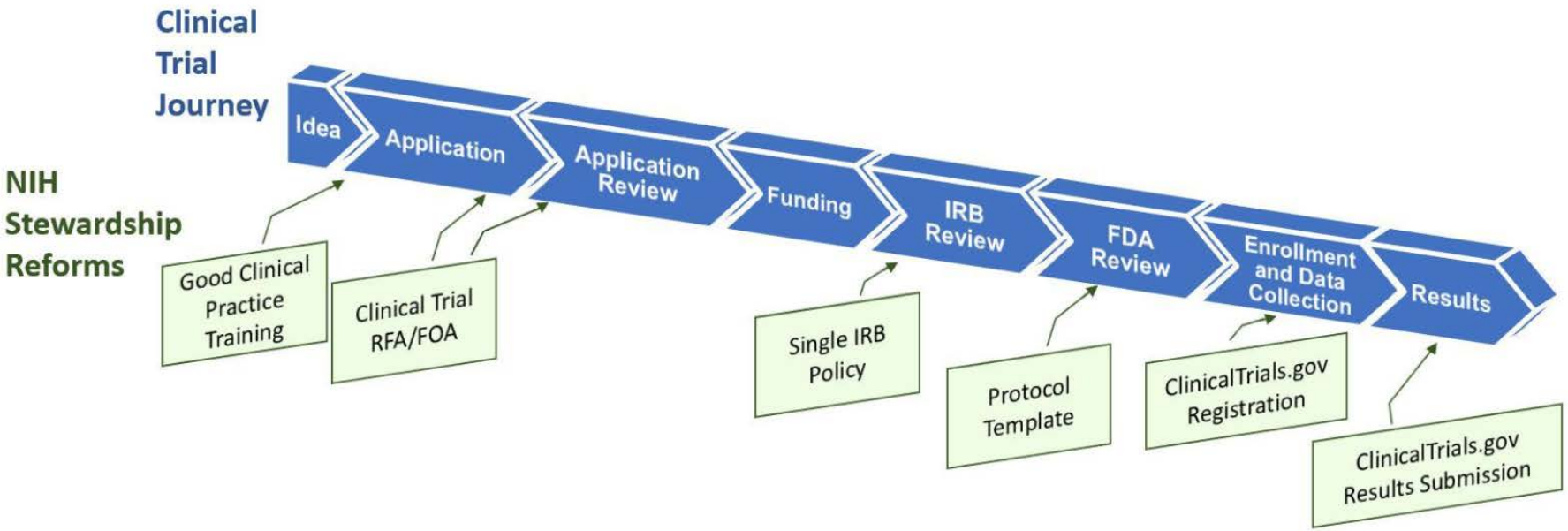


Concerns about NIH Clinical Trials

- 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

Slide from Mike Lauer

Reforms over the clinical trial lifecycle



https://nexus.od.nih.gov/all/2016/09/16/clinical-trials-stewardship-and-transparency/

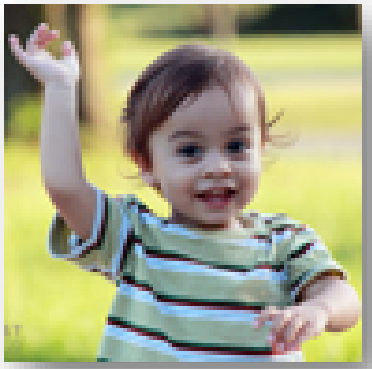
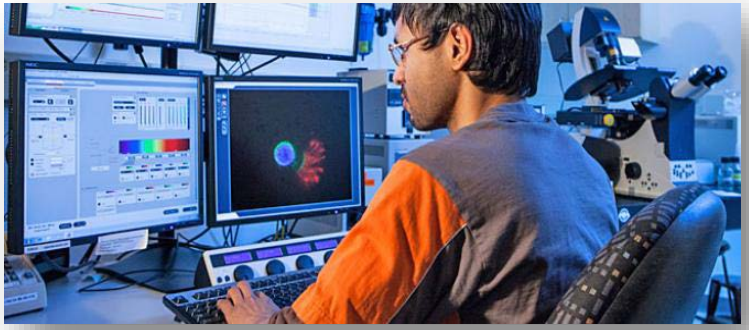
Progress & Current Activities

- **Completed**
  - ✓ **Revised Definition of Clinical Trials**
    - NOT-OD-15-015; Effective October 2014
  - ✓ **Policy on Good Practice Training for NIH Staff Involved in the Conduct, Management, and Oversight of Clinical Trials**
    - NOT-OD-16-148; Effective January 1, 2017
  - ✓ **NIH-FDA Clinical Trial Protocol Template Tool**
    - NOT-OD-17-064; Released May 2, 2017
- **Implementation underway**
  - **NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information**
    - NOT-OD-16-149; Effective January 18, 2017
  - **Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research**
    - ~~NOT-OD-17-027; Effective September 25, 2017~~
    - **JUST IN: Effective January 2018**
  - **Policy on Funding Opportunity Announcements (FOA) for Clinical Trials**
    - NOT-OD-17-043; Effective January 25, 2018

FOA Planning

- Background
  - As of January 25, 2018:
    - Applications with clinical trials will no longer be permitted to "parent" NIH FOAs
    - All FOAs have to specify whether trials are accepted or not
- NICHD efforts underway
  - Identify a "strategy" for receiving investigator-initiated applications involving clinical trials
  - Examine all existing FOAs to determine whether they accept clinical trials or not
- Timeline
  - Target date: New or revised FOAs released by November 25, 2017

Funding the Best Science at NICHD…



to Advance Science & Health for All