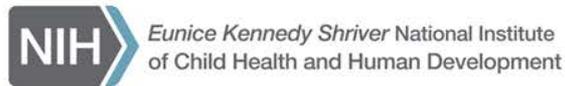


Division of Extramural Research: Update

January 21, 2016
Della M. Hann, Ph.D.





Overview

- Staff Updates
- NIH & NICHD Success Rates and Average Costs
- Implementing Council Recommendations
- Updates
- On the horizon

Staff New to NICHD Extramural



Valerie Cotton - DBSVB

Sue Marden - NCMRR

Kimberly Witherspoon - OCM

Jerusha Murugen - OGH



Staff Transitions in NICHD Extramural



Della White joined PDB
Ruth Brenner joined PTCIB
Eric Lorenzo joined MPIDB
Reiko Toyama joined DBSVB



Staff Retirement in Extramural:

Lynne
Haverkos

Medical Officer

Behavioral
Pediatrics &
Health Promotion





Chinagozi Sarah Ugwu - PPB

Reon Holloway – PTCIB

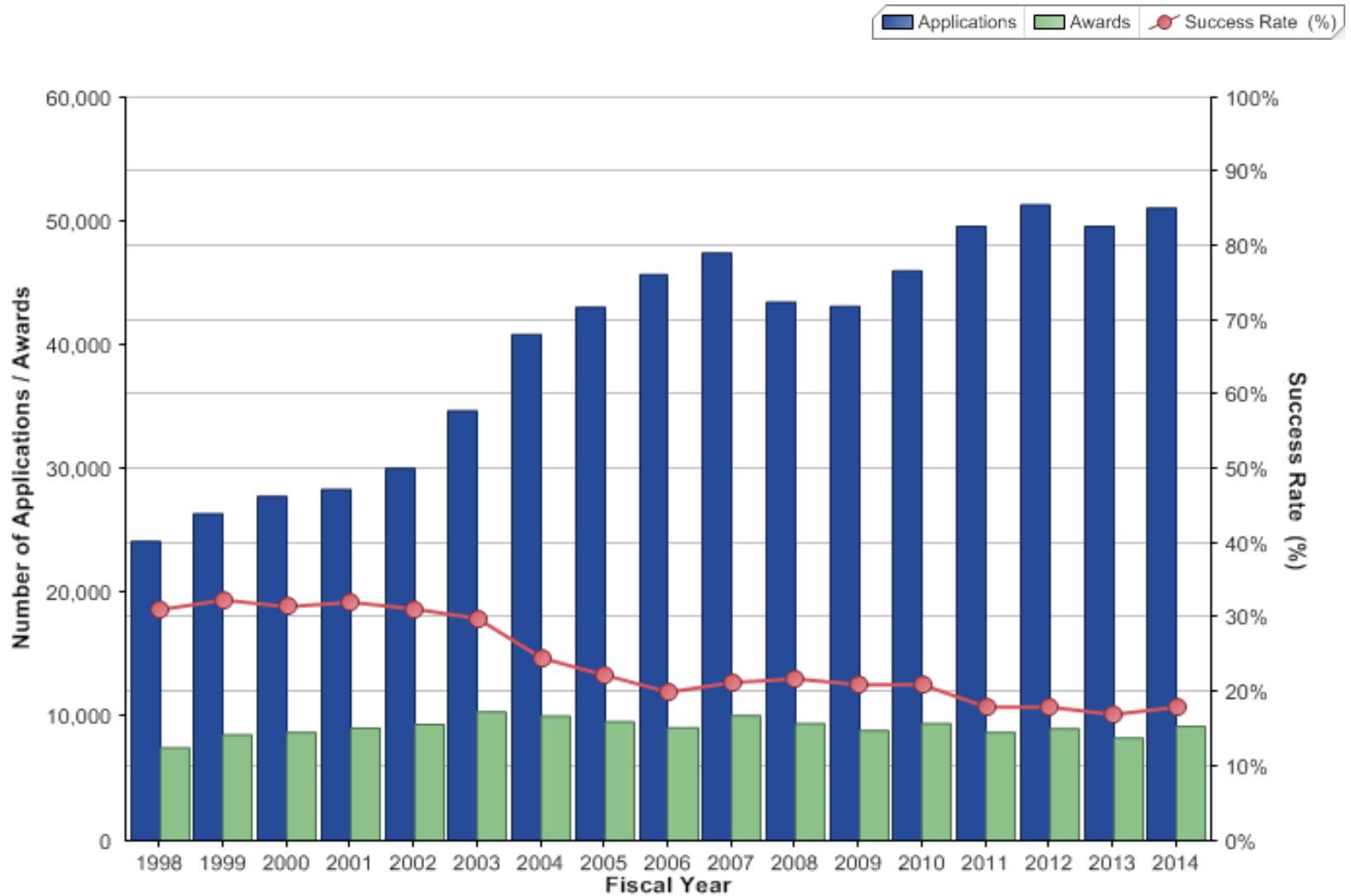
John Dougherty - NCMRR



NIH & NICHD: Success Rates and Average Costs

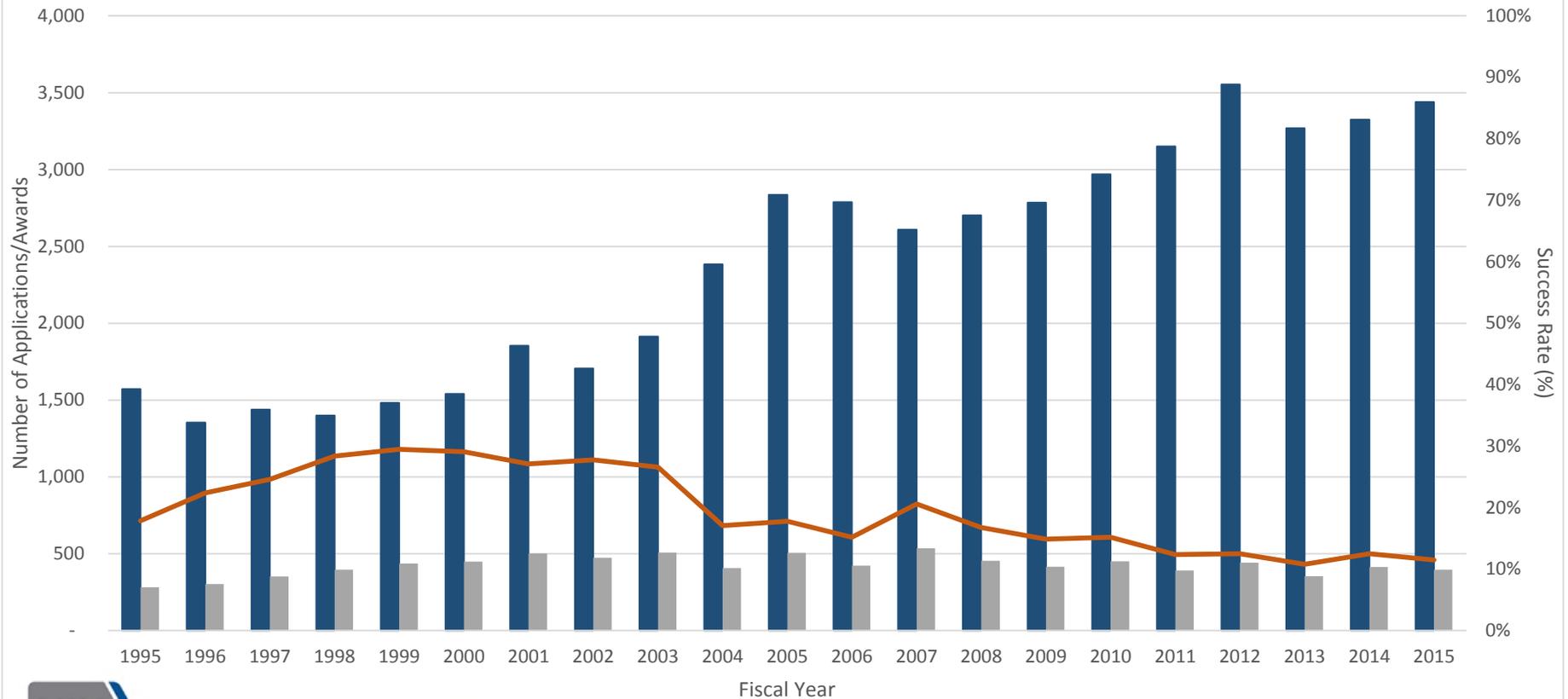
NIH Research Project Grants

Competing applications, awards, and success rates



Success Rates

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

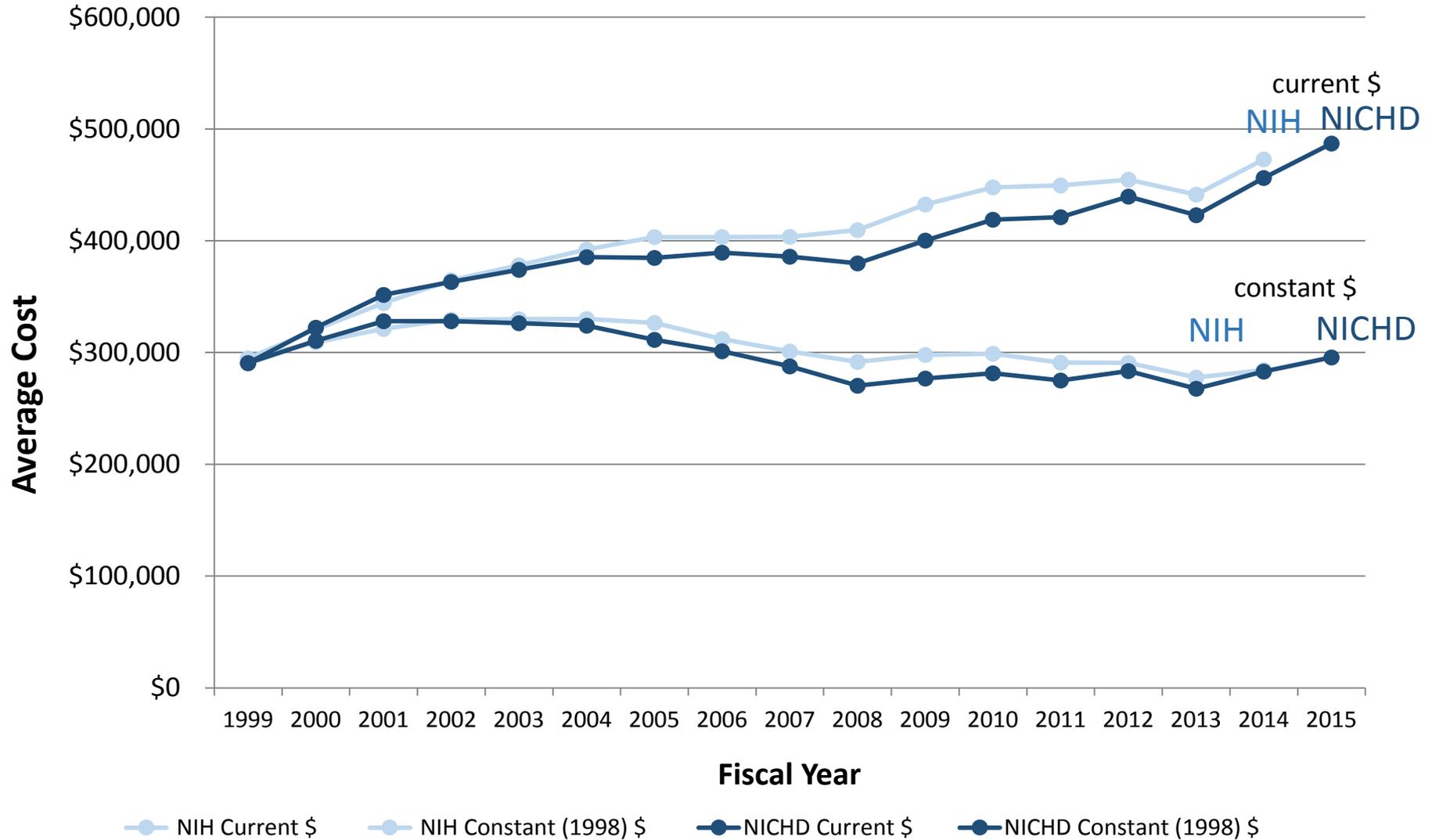


■ Applications
 ■ Awards
 — Success Rate

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



Average Cost of Research Project Grants





Implementing Previous Council Workgroup Recommendations



Office of Health Equity: Grants Program

- Successfully integrated existing grant portfolio into appropriate branches of DER
- Successfully integrated programmatic staff into appropriate branches
 - Reiko Toyama – DBSVB
 - Della White - PDB
- Continue participation in NICHD diversity initiatives

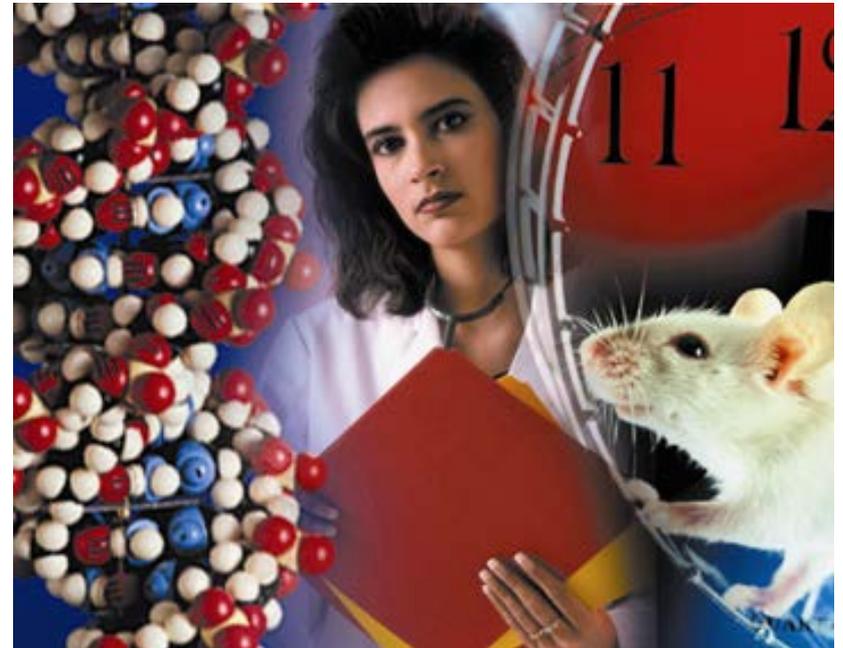


- **Overall Objective: Broad review of NICHD's formal training programs**
- **Address Overarching Questions and Propose Recommendations**
- **Scope of Training Review**
 - Individual NRSA Fellowships (F30, Diversity-F31, Parent F31, F32)
 - Institutional Training Grants (T32)
 - Individual Career Development Awards (K01, K08, K23, K24, K25, K99-R00)
 - Institutional Career Development Awards (K12 programs)
 - T15 / R25 Grants for Short Courses
 - **Council Recommendations in several areas**

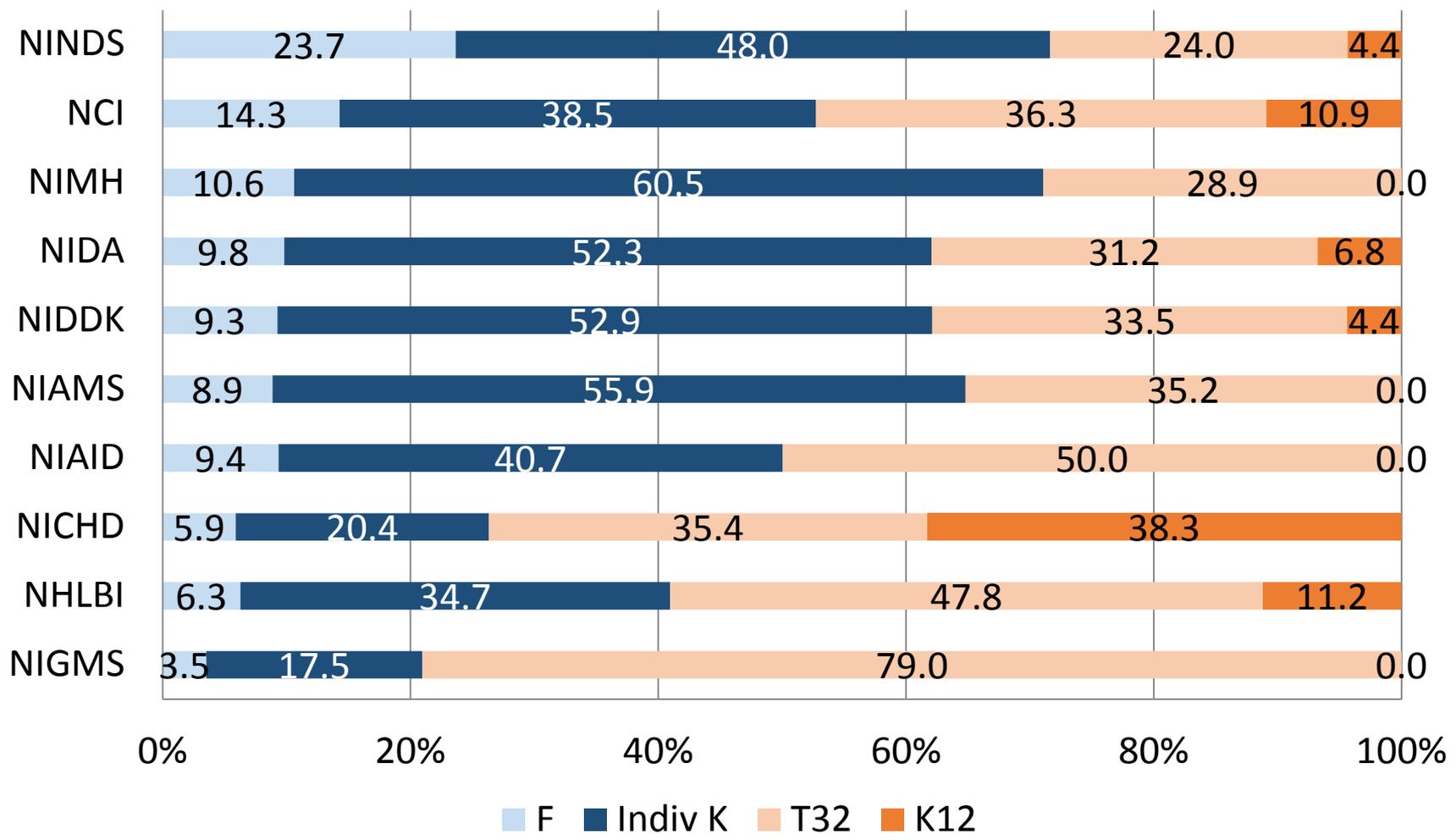


Training Recommendations: Individual Career Awards

- Shift support from institutional K12 to individual K awards
- Increase success rate for K99-R00
- Modify K08 & K23 salary



Relative Proportions of Individual and Institutional Training and Career Development Programs by IC (FY 2014)





New Salary and Research Cost Allowances for K08 and K23 Career Development Awards

Notice Number: NOT-OD-16-032

Key Dates

Release Date: December 17, 2015

Related Announcements

None

Issued by

National Institutes of Health ([NIH](#))

Purpose

The purpose of this Guide Notice is to announce new NIH policy on salary and research cost allowances for K08 and K23 awards.

Background

In June 2014, a Working Group of the Advisory Committee to the NIH Director (ACD) issued a report on the Physician Scientist Workforce (<http://acd.od.nih.gov/psw.htm>). The Working Group identified several challenges confronting physician-scientists, including individuals with MD, DO, DDS/DMD, DVM/VMD, or nurses with research doctoral degrees who devote the majority of their time to biomedical research. The Working Group made several recommendations to the ACD about the funding and training of physician scientists in order to attract and retain well-qualified individuals in research careers, including the modification of some current NIH programs.

Implementation

Effective with new (Type 1) K08 and K23 applications due on February 12, 2016, and subsequently, several NIH Institutes and Centers (ICs) will contribute up to \$100,000 toward the awardee's salary to offset the requested effort (e.g. 9 person months) that will be devoted to research and career development. It should be noted that a number of ICs already contribute salary at this level or higher, and this policy does not impact their current practice. This policy applies to new (Type 1) applications as well as all continuation (Type 5) applications submitted for FY 2017 funding.

In addition, ICs may, at their discretion, annually increase their salary and research cost contributions for their K08 and K23 awards.

Applicants and awardees are encouraged to consult each funding opportunity announcement and contact appropriate IC staff to determine the salary and research cost contributions for their K08 and K23 applications or awards:

Salary Increase in FY 17 to \$100,000

Results in an additional \$25,000 per NICHD awardee

Initial Implementation



Keep overall training and career development at 5-6% of NICHD budget

AND:

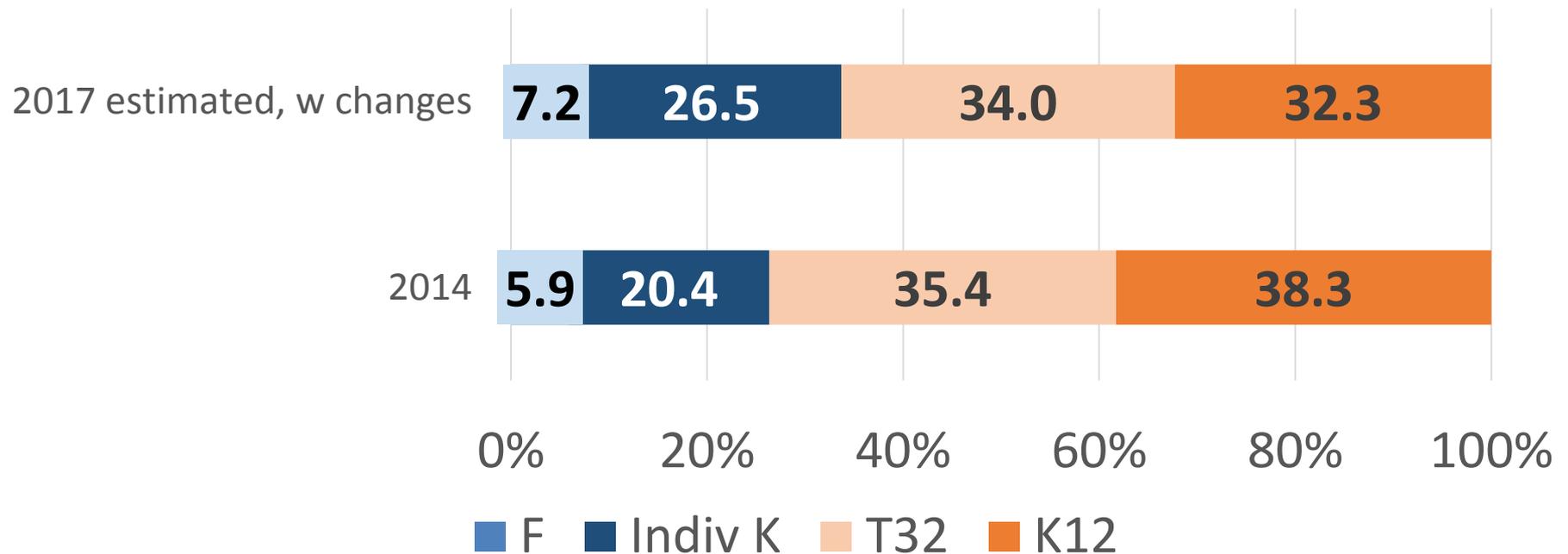
- Absorb the mandated increase in K08 & K23 salary
- Improve K99-R00 success rate
- Improve success rate for individual training/career awards

RESULTS:

- Gradual reduction to K12 programs over time



Training and Career Development Mechanism Groups for NICHD, FY 2014 and Effect of Planned Changes for FY 2017





Adolescent Brain Cognitive Development

Teen Brains. Today's Science. Brighter Future.

Ten year longitudinal study of 10,000 children starting at ages 9-10 to assess factors that influence individual brain development trajectories and functional outcomes

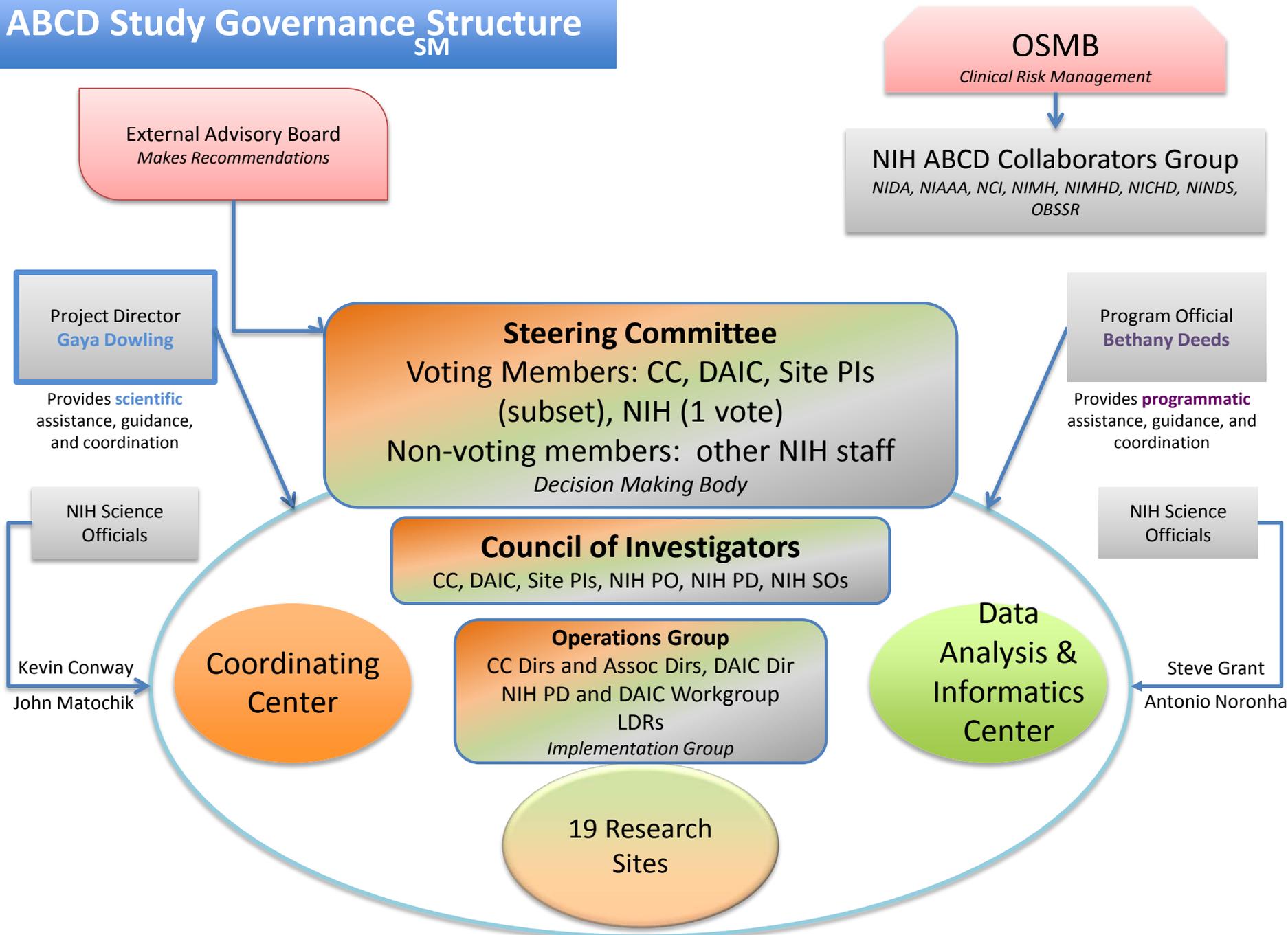
An NIH Collaboration:
NIDA, NIAAA, NCI, NIMH,
NIMHD, NICHD, NINDS, OBSSR



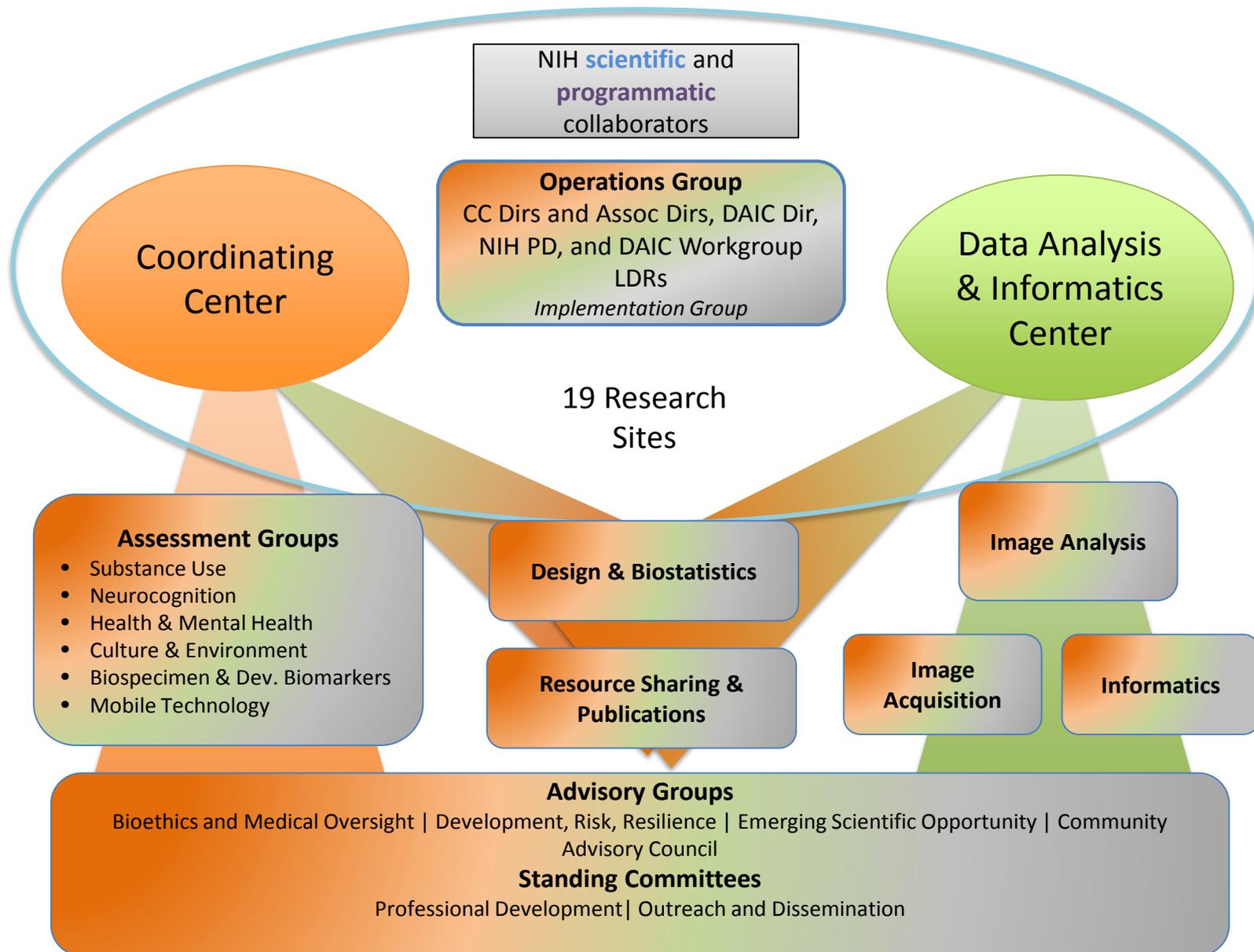
- Identification of individual developmental trajectories (e.g., brain, cognitive, emotional, academic), and the factors that can affect them.
- Development of national standards of normal brain development in youth.
- The role of genetic vs. environmental factors on development, enriched by comparisons of twin participants (800 pairs will be recruited into the study).
- The effects of physical activity, sleep, as well as sports and other injuries on brain development and other outcomes.
- The onset and progression of mental disorders, factors that influence their course or severity, and the relationship between mental disorders and substance use.
- How exposure to different substances like alcohol, marijuana, nicotine, caffeine, and others, individually or in combination, affect various developmental outcomes and vice versa.

ABCD Study Governance Structure

SM



ABCD Functional Organization



ABCD Consents and Protocols



- Initial consents, assents, protocols drafted
- Ongoing discussion of how to deal with many ethical challenges that may come up, e.g., parental notification of substance abuse
- Will have OSMB, Bioethics & Medical Oversight working group, IRB, and External Advisory Board, which includes bioethicist & community member, as well as Community advisory groups



Zika Virus: What you need to know



Zika is:

- ♦ A virus spread through *Aedes* species mosquito bites. *Aedes* mosquitoes also spread dengue and chikungunya viruses.
- ♦ A risk to anyone traveling to a region of the world where Zika virus is found.

Global risk

Outbreaks have occurred in parts of Africa, Southeast Asia, and the Pacific Islands. In May 2015, Brazil reported the first outbreak of Zika virus in the Americas.

Zika virus is not currently found in the United States. However, cases of Zika have been previously reported in returning travelers.

For information on where Zika virus is found, see: <http://www.cdc.gov/zika/geo/index.html>.

Traveling? For country-specific travel information and recommendations, visit www.cdc.gov/travel.

Signs and symptoms of Zika virus disease (Zika)

- ♦ Symptoms usually begin 3—7 days after being bitten by an infected mosquito.
- ♦ Common symptoms include fever, rash, joint pain, or red eyes. Other symptoms include muscle pain, headache, pain behind the eyes, and vomiting.
- ♦ The illness is usually mild with symptoms lasting for several days to a week.
- ♦ Severe disease is uncommon. Deaths have not been reported.



- Mosquito borne flavivirus
- Suspected to cause microcephaly
- May 2015: First infection in Brazil
- October 2015: Brazil noted increase in microcephaly cases in public and private healthcare facilities in the NE region
- Zika virus confirmed in postmortem brain, amniotic fluid or placental tissue in 7 infants with microcephaly
- First case of microcephaly reported outside Brazil (Colombia)
- 15 confirmed cases of Zika infection in US



HHS Response

- Teleconferences across HHS to coordinate efforts (NIH, CDC, ASPR, OGA, BARDA)
- Level 2 travel advisory issued by CDC (1/15/16)
- Surveillance and laboratory activities (Council of State and Territorial Epidemiologists)
- Sample sharing (CDC/OGA/ASPR)
- Workshop planned for March 2016



Research Gaps

- Zika virus – microcephaly link
 - Causality
 - Etiology
- Maternal to fetal transmission
 - Viral RNA found in fetal tissue, amniotic fluid, placenta from microcephalic infants and tissue from fetal losses. Did virus cause the fetal losses?
- Implications of exposure at different trimesters
- Forms of transmission: Placental transfer, postpartum, breast milk
- Follow up of Zika exposed and infected infants without microcephaly, is there an unidentified sequelae
- Treatment
- Vaccine



NICHD Opportunities

- Positioned to leverage existing international and domestic infrastructure to address research gaps
- Maternal-fetal medicine and infectious disease expertise at our sites are or will be the front line for referral and clinical management in mothers and infants
- PA-16-031 *Advancing Understanding, Prevention, and Management of Infections Transmitted from Women to their Infants (R21)*
 - Interest on basic and clinical research on Zika virus



Request for Information on Enhancing Timely Data Sharing from NICHD Funded Clinical Studies

Notice Number: NOT-HD-15-034

Key Dates

Release Date: November 10, 2015

Response Date: December 21, 2015

Related Announcements

None

Issued by

Eunice Kennedy Shriver National Institute of Child Health and Human Development ([NICHD](#))

Purpose

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) is soliciting comments and suggestions from the public on ways to enhance the timely sharing of high quality data generated by NICHD funded clinical studies. Responses to this Request for Information (RFI) will be used to inform NICHD policy development.

Background

Data sharing has been a longstanding expectation of the research that the National Institutes of Health (NIH) funds and supports (e.g., see the Final NIH Statement on Sharing Research Data published in the NIH Guide in 2003 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>)). Data sharing can achieve many important goals for the scientific community, including but not limited to:

- promoting new research, testing of new or alternative hypotheses and methods of analysis
- facilitating education of new researchers
- enabling the exploration of topics not envisioned by the initial investigators
- supporting re-analysis and reproducibility of findings



Thank You!