

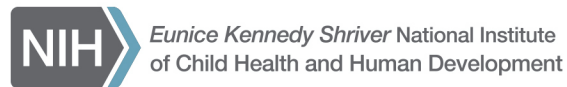
# NICHD Priorities in General OB/GYN

Lisa M. Halvorson, MD

Chief, Gynecologic Health and Disease Branch

NICHD/NIH

May 2, 2019





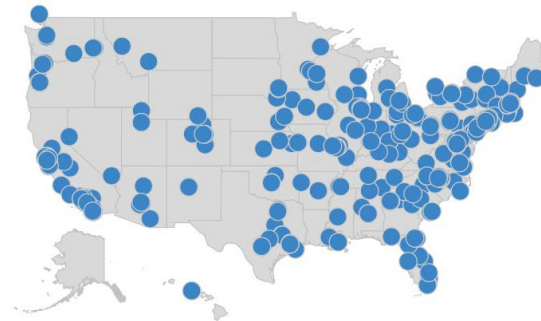
# Outline

- General NICHD Facts
- Gynecologic Health and Disease Branch
- Other NICHD-DER Branch Priorities
- SBIR
- Clinical Trials
- DASH
- NICHD Strategic Plan





# NICHD Intramural and Extramural Research



## • Division of Intramural Research

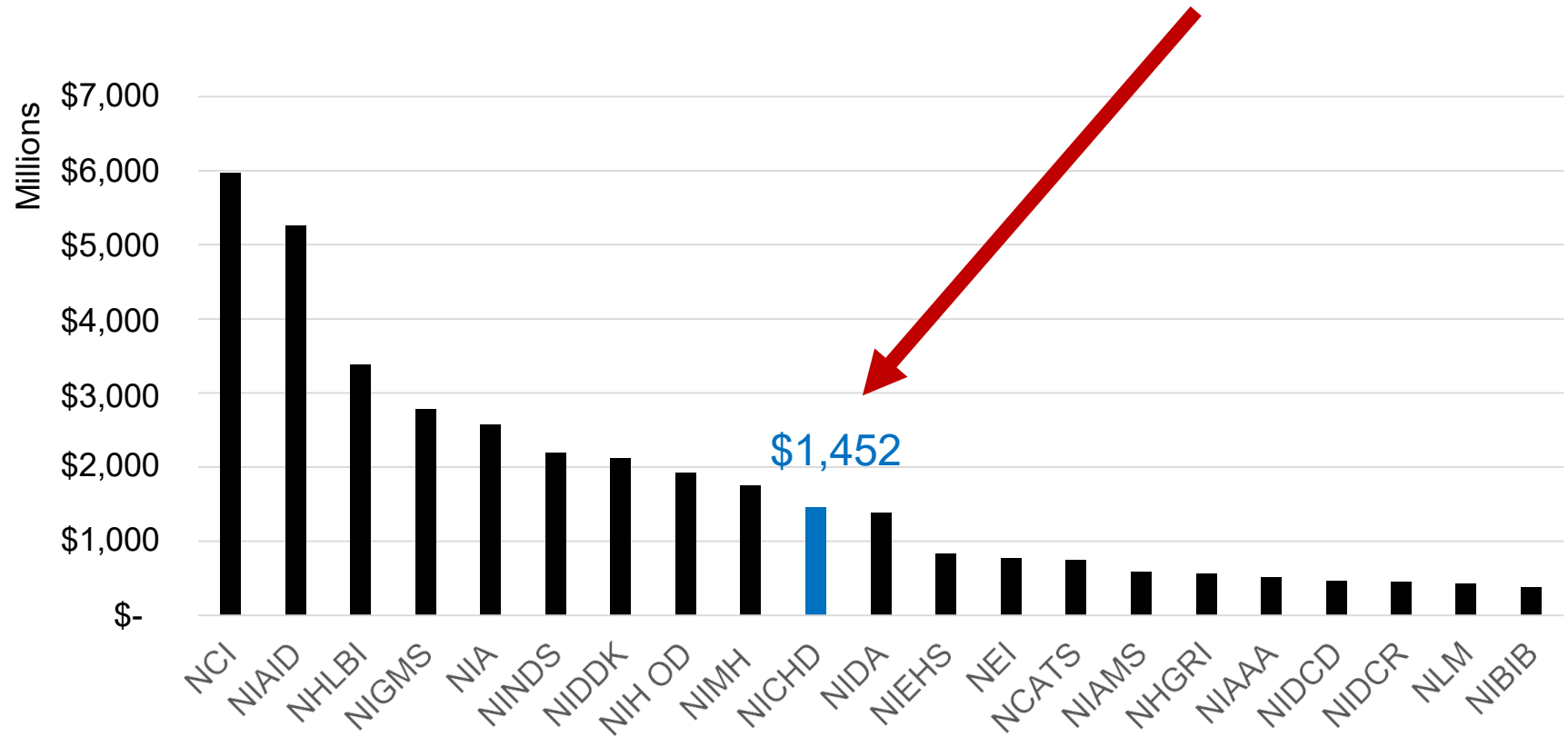
- 1,030 Staff
- 74 PIs
- 335 trainees
- 77 clinical protocols
  - 10% in Detroit

## • Division of Extramural Research

- 2,578 funded grants (new and continuing combined)
- 2,783 PIs (321 ESIs)
- 442 funded institutions

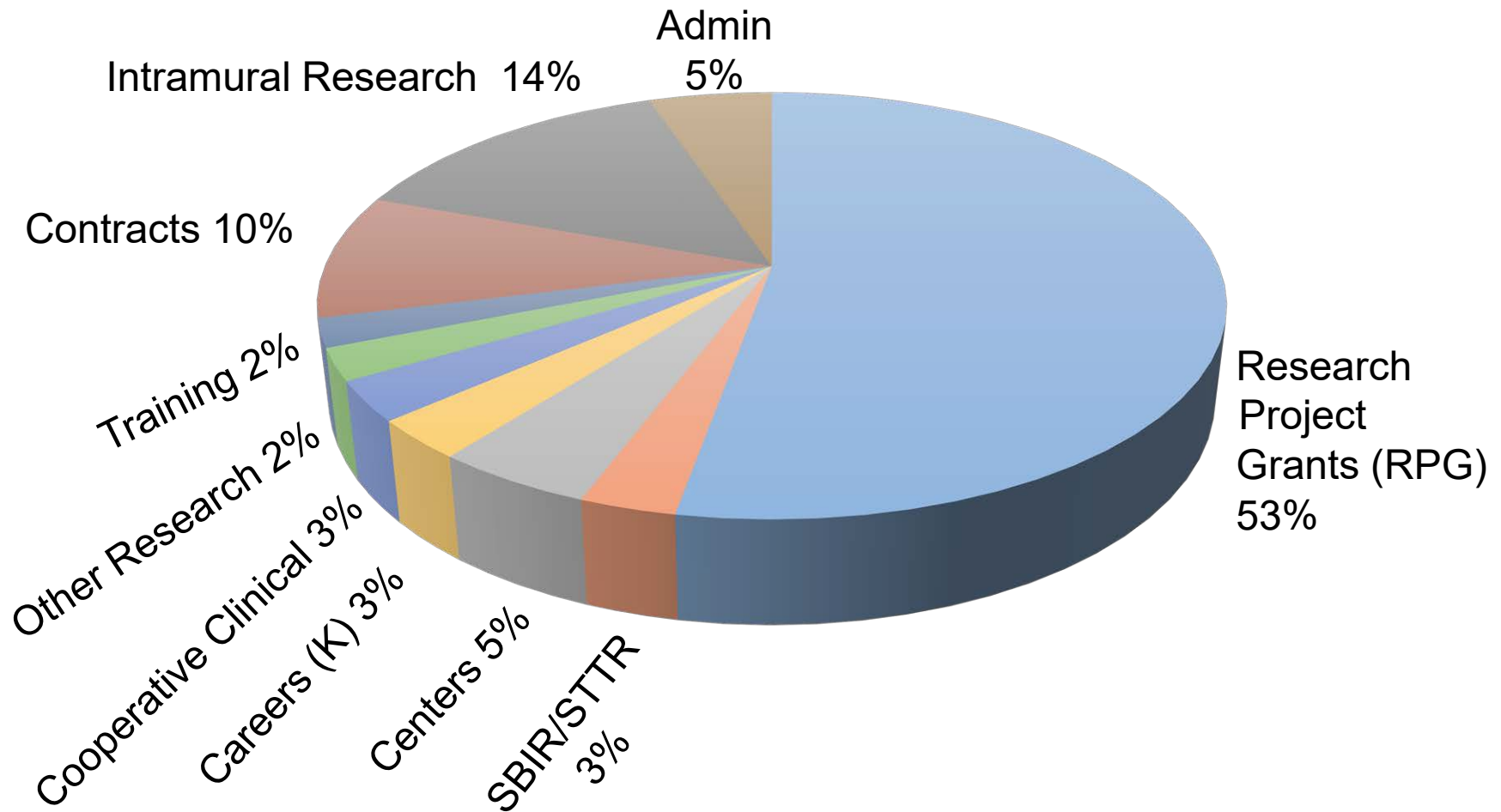


# NIH Appropriations FY2018



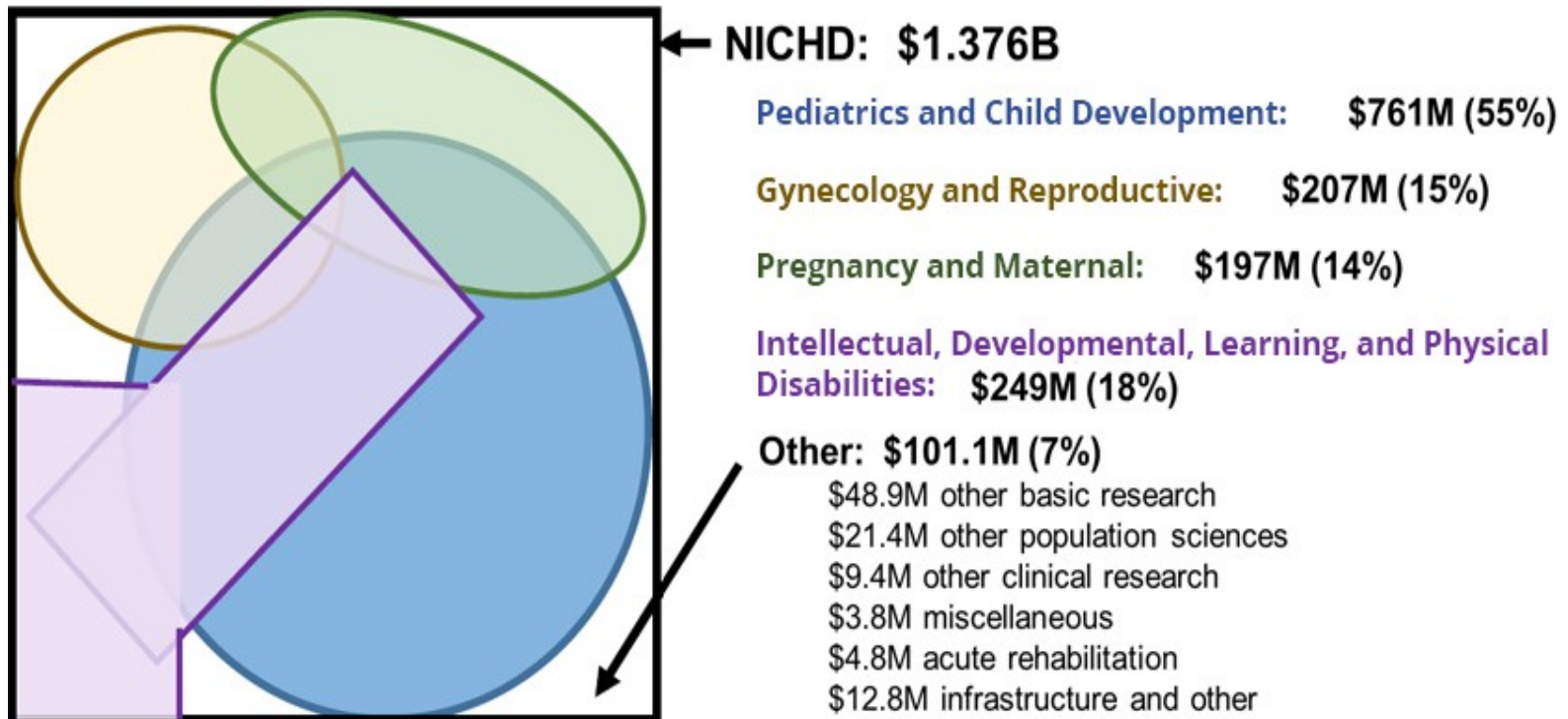


# NICHD FY 17 Expenditures by Budget Mechanism





# NICHD Spending by Broad Public Health Category (FY2017)



Source: NIH Research, Condition, and Disease Categories (RCDC) system.

Data for Intellectual, Developmental, Learning and Physical Disabilities are unofficial and have not been fully validated through the RCDC process.



# NICHD: Division of Extramural Research Scientific Branches

Gynecologic Health  
and Disease

Fertility and Infertility

Contraception  
Research

Pregnancy and  
Perinatology

Child Development  
and Behavior

Population Dynamics

Intellectual and  
Developmental  
Disabilities

Pediatric Growth and  
Nutrition

Pediatric Trauma  
and Critical Illness

Developmental  
Biology and  
Structural Variation

Maternal and  
Pediatric Infectious  
Disease

Obstetric and  
Pediatric  
Pharmacology/  
Therapeutics



# Gynecologic Health and Disease Branch Initiated Fall, 2013

Significant morbidity associated with gyn disorders beyond impact on fertility or contraceptive choices

## Aims

- Support basic, translational and clinical research programs to improve prevention, diagnosis and treatment of gynecologic disorders throughout the reproductive lifespan
- Support training and career development programs for investigators interested in an academic career in women's reproductive health





# Gynecologic Health and Disease Branch (GHDB)

## Research Areas

- Menstrual Disorders
- Uterine fibroids
- Endometriosis
- Adenomyosis
- Pelvic floor disorders
  - Pelvic organ prolapse
  - Urinary incontinence
  - Fecal incontinence
  - Obstetric fistula
- Pain disorders
  - Chronic pelvic pain
  - Vulvodynia
  - Dysmenorrhea

Socioeconomic, racial, and ethnic disparities



# GHDB Staff Members



Lisa Halvorson, MD  
Chief, GHDB  
Endometriosis,  
Adenomyosis, and  
WRHR



Donna Mazloomdoost, MD  
Project Scientist, PFDN  
Program Officer, Pelvic Floor  
Disorders



Candace Tingen, PhD  
Program Officer  
Menstruation, Fibroids



Jennie Conroy PhD  
Program Officer  
Gynecologic Pain



# GHDB Scientific Vision Meeting May, 2016

Gynecology: Executive Summary

## Gynecologic Health and Disease Research at the Eunice Kennedy Shriver National Institute of Child Health and Human Development *A Scientific Vision*

Candace M. Tingen, PhD, Donna Mazloomdoost, MD, and Lisa M. Halvorson, MD

In May 2016, the newly formed Gynecologic Health and Disease Branch in the Eunice Kennedy Shriver National Institute of Child Health and Human Development invited experts to a 2-day meeting aimed at identification of emerging opportunities in gynecologic investigation. Four primary disorders were chosen for emphasis because they represent the majority of the current Gynecologic Health and Disease Branch portfolio: uterine leiomyomas, endometriosis, pelvic floor disorders, and gynecologic pain conditions. Discussions generated a set of seven cross-cutting themes, which encompass both gaps in our current knowledge and potential directions for further research. These themes formed a continuum for understanding these disorders beginning with the need for classification systems, improved understanding of the natural history and etiology of these disorders, development of novel diagnostics, identification of opportunities for prevention, and the generation of new treatments using cutting-edge approaches. Along with these themes, three broad strategies were proposed to facilitate future research. First, investigators should

improve utilization of existing research resources and focus on developing new resources to include databases, biospecimen repositories, animal models, and patient cohorts. Second, multidisciplinary scientific partnerships should be strengthened to bring new insights and approaches to gynecologic research. Third, patient and health care provider education must be promoted to ensure timely and accurate diagnosis and optimize treatment of gynecologic disorders. This article provides a summary of the workshop themes and suggestions, several of which have already been implemented through the development of program priorities and funding opportunity announcements aimed at improving women's reproductive health.

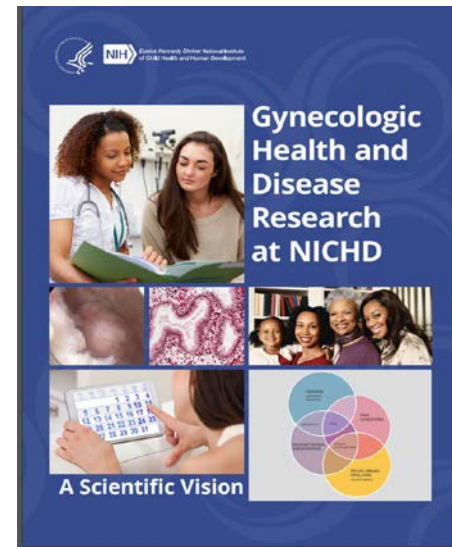
(*Obstet Gynecol* 2018;132:987-98)  
DOI: 10.1097/AOG.0000000000002877

Founded in 1962, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) is dedicated to understanding the dynamic biological, behavioral, and social processes that dictate physical, emotional, and cognitive growth.

Coinciding with its 50th anniversary, the NICHD underwent a year-long scientific vision process to identify the most promising scientific opportunities and address the health needs of children, adolescents, and

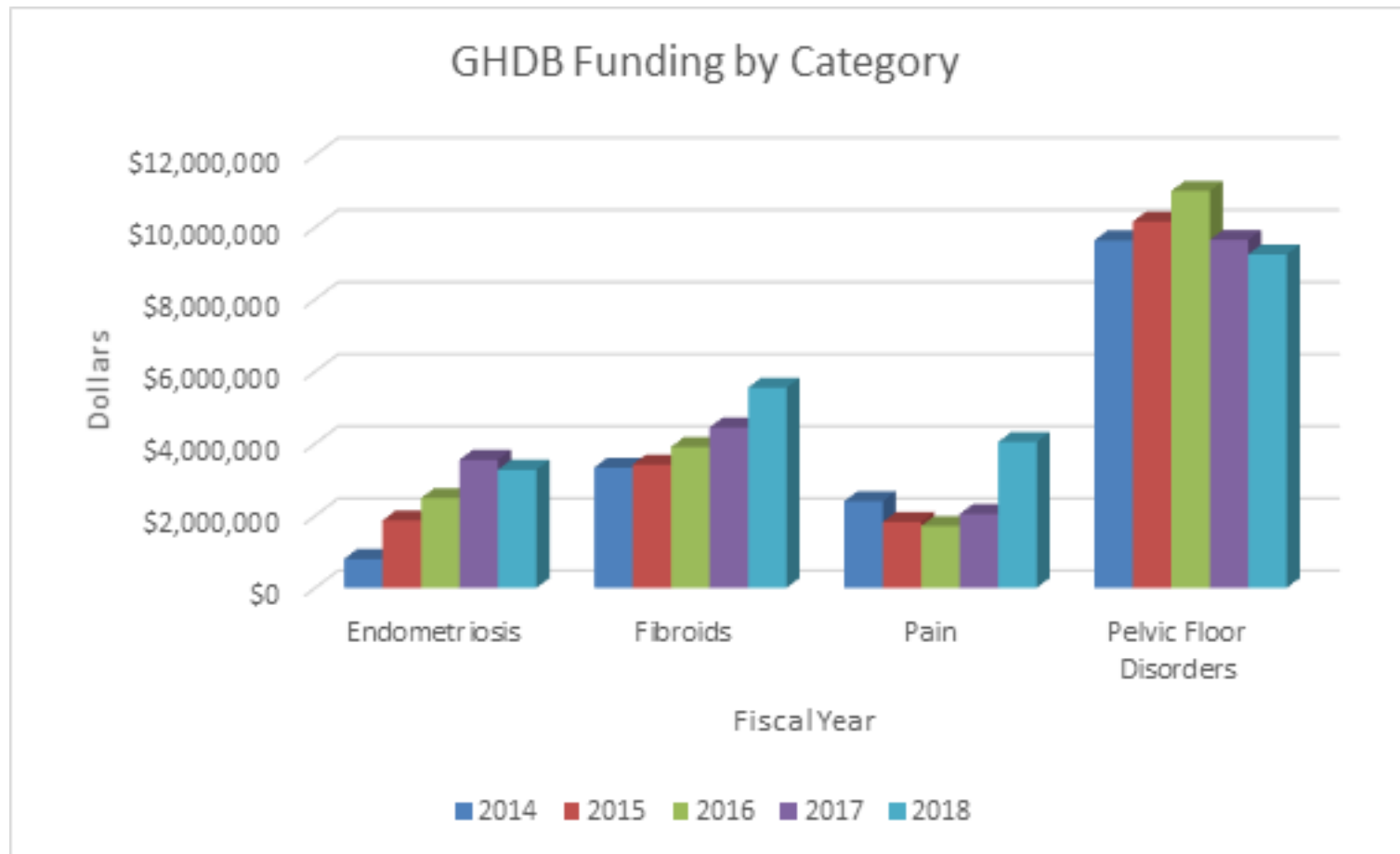
*From the Gynecologic Health and Disease Branch, Division of Extramural Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland.*

*The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institutes of Health.*



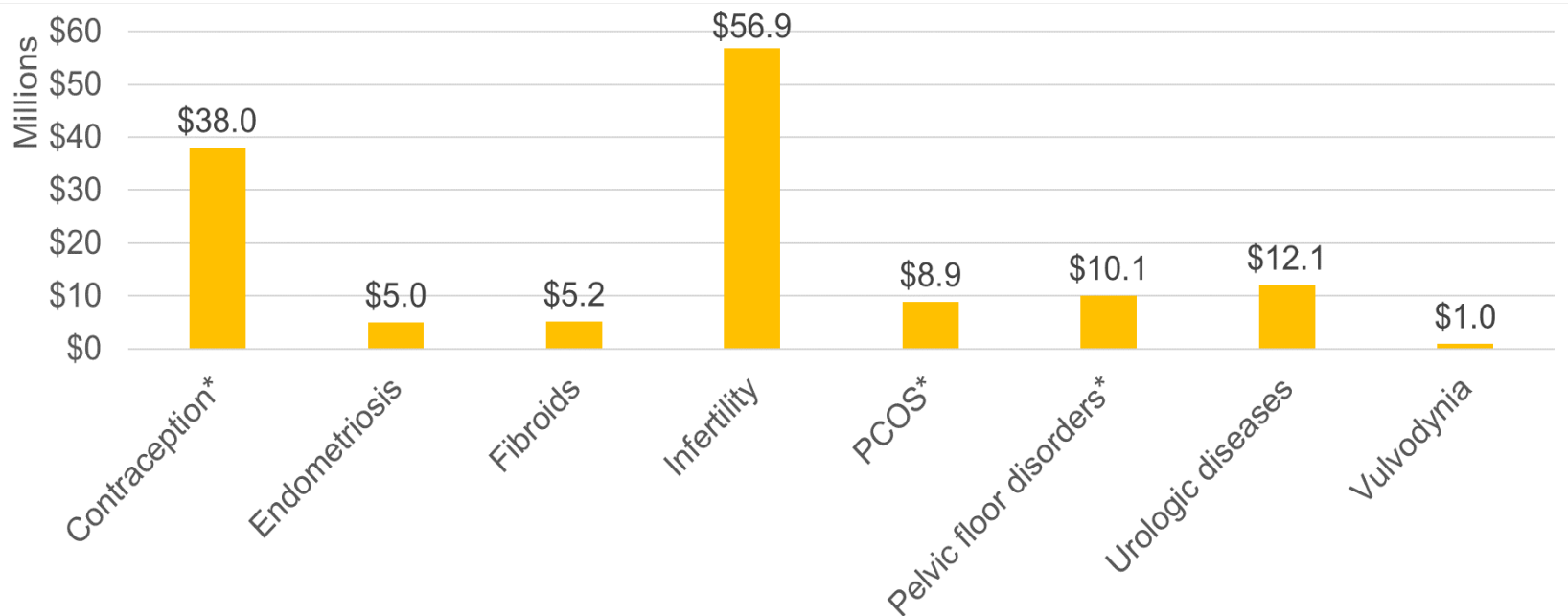


# GHDB: Distribution of Award Dollars by Category





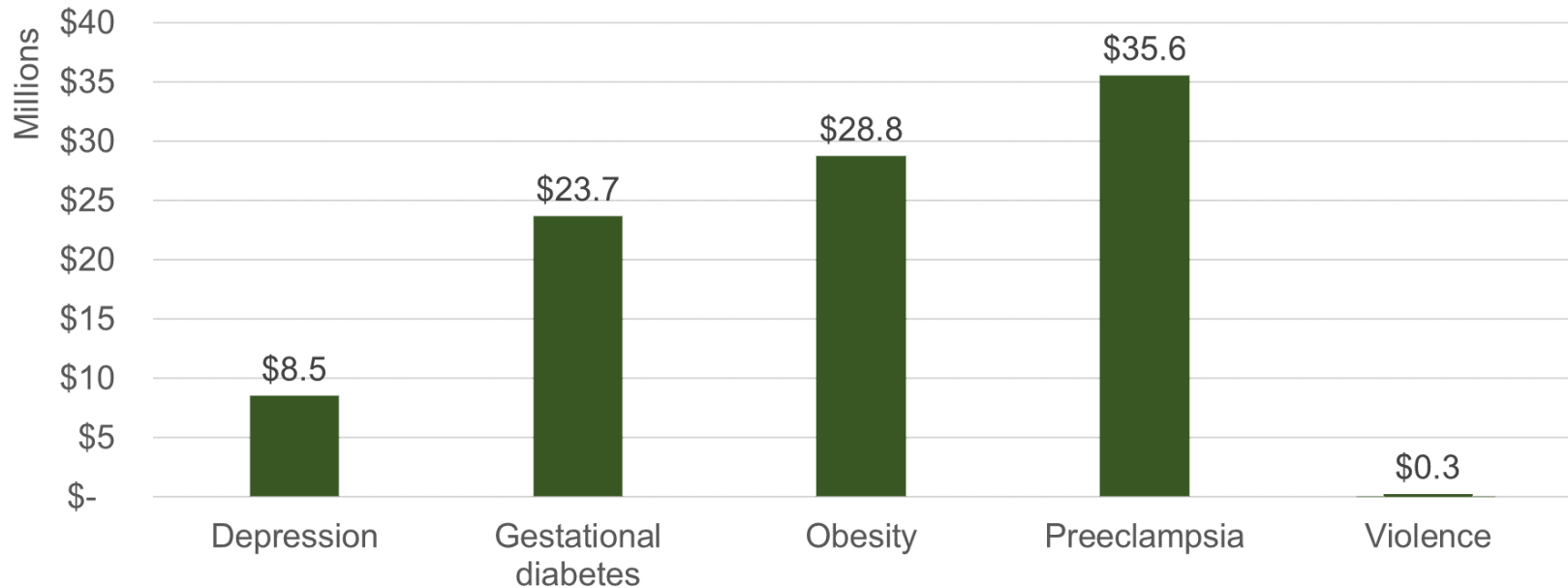
# NICHD Gynecology and Reproductive Health Research Portfolio by Condition, FY 2017



Sources: NIH Research, Condition, and Disease Categories (RCDC) system and (\*) NICHD Child Health Information Retrieval Program (CHIRP). Categories are overlapping and should not be added.



# NICHD Pregnancy and Maternal Health Research Portfolio by Condition, FY 2017



Sources: NIH Research, Condition, and Disease Categories (RCDC) system and (\*) NICHD Child Health Information Retrieval Program (CHIRP). Categories are overlapping and should not be added.



# Gynecologic Health and Disease Branch (GHDB)

## High Program Priorities

- Stem/Progenitor Cells in Gynecologic Health and Disease
  - Pathophysiology and treatment
- ‘-Omics’ in Gynecologic Disorders
  - Genome, epigenome, transcriptome on development, progression or treatment response.
- Non-hormonal Treatments
  - Primarily pharmacologic
- Non-Invasive Diagnostic and Assessment Tools
  - Biomarkers and imaging



# Gynecologic Health and Disease Branch (GHDB)

## High Program Priorities

- Mechanisms of Gynecologic Pain Syndromes
  - Focus on genetic, cellular, molecular, and psychosocial factors in etiology
- Transdisciplinary Research
  - Engineering, neurobiology, vascular biology, immunology, cell biology, skeletal and smooth muscle biology
- Longitudinal Gynecologic Studies
  - Natural history starting in adolescence





# Fertility and Infertility Branch (FIB)

## High Program Priorities

- Fertility Status as a Marker of Overall Health
- Reproductive Transitions
  - Biomarkers to study transitions (puberty, repro aging)
- Early Pregnancy Loss
  - Focus on gamete quality and preplacental processes
- Epigenetics and Reproduction
  - Identify critical windows for transgenerational inheritance
- Genetic Basis of Idiopathic Infertility
- Metabolism, Nutrition, and Reproduction
- Technology and Models for Infertility and Fertility Preservation



# Contraception Research Branch (CRB)

## High Program Priorities

- Effect of Contraceptive Use on Human Health
  - STDs, vaginal microbiome
- New and Improved Contraceptive Methods
  - Non-steroidal, on-demand, MPTs
- Targeted Research to Facilitate Development of New Methods
  - Identify/validate novel drug targets
  - Reproductive tract, spermatogenesis
  - Understand blood-testis barrier
  - Improved devices and delivery systems
  - Novel animal models (genetically modified)



# Pregnancy and Perinatology Branch (PPB)

## High Program Priorities

- Burden of Stillbirth and SIDS
  - Develop predictive algorithms (physiologic, biochemical, genetic)
- Diabetes during Pregnancy
  - Understand pathogenesis of relationship with fetal loss, pre-eclampsia, PTL, macrosomia, congenital malformations)
- Eliminate Neonatal Pain
  - Diagnostics, monitoring and therapeutic devices
- Global Perinatal Health
  - Maternal and infant mortality in international settings



# Pregnancy and Perinatology Branch (PPB)

## High Program Priorities (continued)

- Normal and Abnormal Placental Biology
  - Physiological, cellular, molecular
  - Invasion, spiral artery remodeling
- Perinatal Health Disparities
  - Social factors, physical environment, genetic/epigenetic determinants
- Preterm Birth
  - Molecular, psychosocial, environmental causes
  - Mitigating factors
    - Intracranial hemorrhage, BPD, CP, retinopathy of prematurity



## Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Programs

- Stimulate technological innovation
- Use small business to meet federal R&D needs
  - ( $\leq 500$  employees, individually owned)
- Set-aside as portion of extramural research dollars

	SBIR (R43/R44)	STTR (R41/R42)
Set-aside	3.2%	0.45%
Payline	33PS/30PS	30PS/20PS



# NIH SBIR/STTR 3-Phase Program



*Discovery*

Phase I

## Phase I Feasibility Study

**Budget Guide:** \$150K for SBIR and STTR

**Project Period:** 6 months (SBIR); 1 year (STTR)



*Development*

Phase II

## Phase II Full Research/R&D

\$1M for SBIR and STTR, over two years

Phase IIB

## Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/Tools to FDA

Many, but not all, IC's participate

Varies~\$1M per year; up to 3 years



*Commercial-ization*

Phase III

## Phase III Commercialization Stage

NIH, generally, not the “customer”

Consider partnering and exit strategy early



# Clinical Trials at NIH

- ✓ Accountability
- ✓ Transparency
- ✓ Efficiency
- ✓ Dissemination

“Despite the **ethical mandate** and expressed values of academic institutions, there is poor performance and noticeable variation in the dissemination of clinical trial results across leading academic medical centers.”

BMJ 2016;352:i637

<https://grants.nih.gov/policy/clinical-trials.htm>

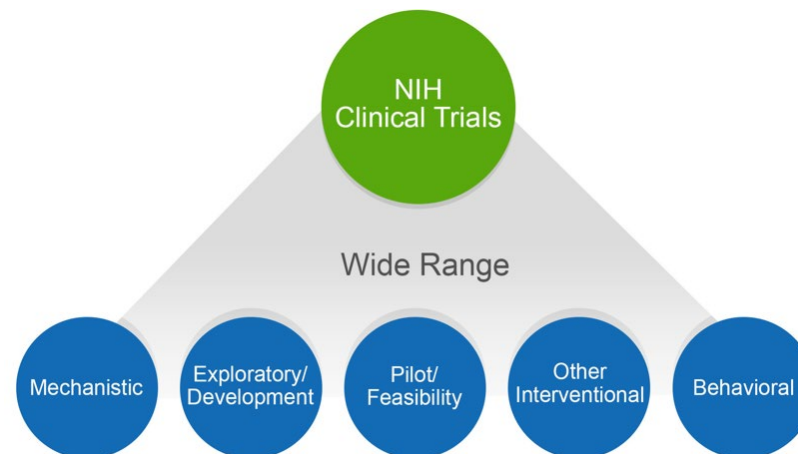


# Questions to Ask Yourself

## Does your study...

- ✓ Involve one or more **human subjects**?
- ✓ Involve one or more **interventions**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Have a **health-related biomedical or behavioral outcome**?

If “yes” to ALL of these questions, your study is considered a clinical trial







## Clinical Trial Designations for FOAs

All FOAs include one of the following designations in Section II of the FOA:

- ✓ Clinical Trial Required
- ✓ Clinical Trial Not Allowed
- ✓ Clinical Trial Optional
- ✓ Basic Experimental Studies with Humans Required (BESH)

**Tip:** Contact your Program Official listed in Section VII of the FOA to ensure you are submitting to the correct announcement



# NICHD Data and Specimen Hub (DASH)

## What it is:

- Data repository for de-identified data from NICHD-funded studies
- Access data and associated biospecimens

## What it is NOT:

- A biospecimen bank

## Fun facts:

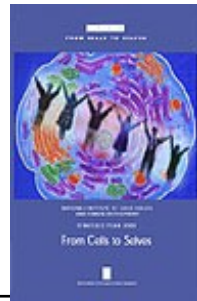
- Approximately 120 studies
- 112 requests from 60 institutions
- 10 publications



<https://dash.nichd.nih.gov/>



# NICHD Strategic Plan FY2020-2024



NICHD  
Strategic  
Plan FY  
2020-  
2024

<b>Year Published</b>	2000	2012	2019
<b>Type</b>	Strategic Plan for NICHD	Vision for the field	Strategic Plan for NICHD
<b>Level of specificity</b>	Specific NICHD-focused objectives and implementation steps (via thematic plans)	Defined gaps & priorities for the fields NICHD represents	Specific NICHD-focused objectives
<b>Participants</b>	Mostly internal	Mostly external	Mix of internal and external



# NICHD Strategic Plan FY2020-2024

- **What it is**

- A blueprint for supporting initiatives in the DER and DIR that has high public health significance, addresses research gaps, is NICHD-centric and can be realistically accomplished in a finite time span

- **What it is not**

- A plan that prohibits support for ongoing research efforts in high program priority areas.
- A visioning (e.g., wish-list) exercise



# NICHD Strategic Planning: Purpose

- Enable internal and external stakeholders to look at NICHD's portfolio with a fresh perspective
- Review and refocus NICHD's science
- Align resources with scientific priorities
- Improve the health of the populations we serve





# Why Have a Strategic Plan?

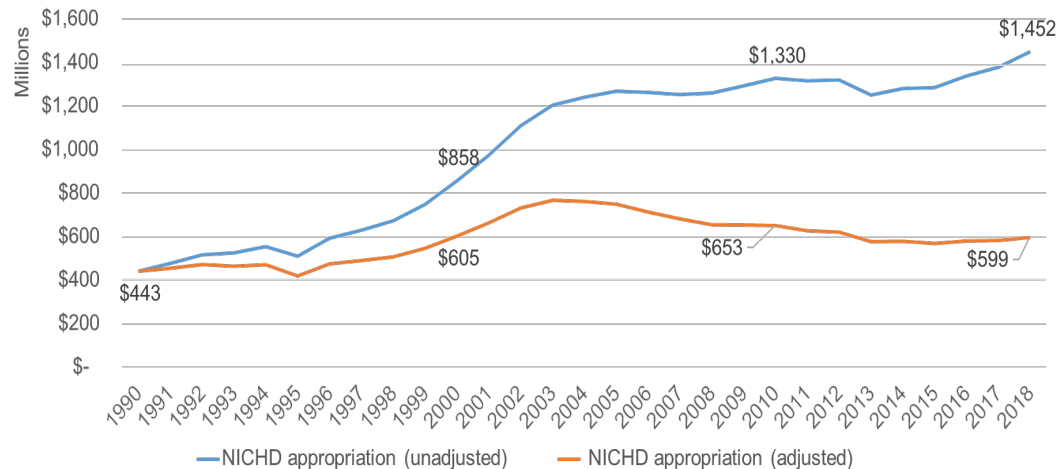
- Need to answer the following questions:
  - What is the identity of the Institute?
  - Do we want to continue our focus on health and development or shift our priorities to specific diseases or conditions?
  - Do we focus more on clinical, basic or translational research?
  - How do we integrate and align our broad areas of science and our many stakeholders?
    - Email questions or ideas to:  
[NICHDStrategicPlan@nih.gov](mailto:NICHDStrategicPlan@nih.gov)



# NICHD Strategic Planning: Why Now?



- Advances in technology, genetics, and techniques are changing science rapidly
- The Institute needs to determine what types of funding, training, and infrastructure are needed in response to change



Note: Figures do not include ARRA funding.



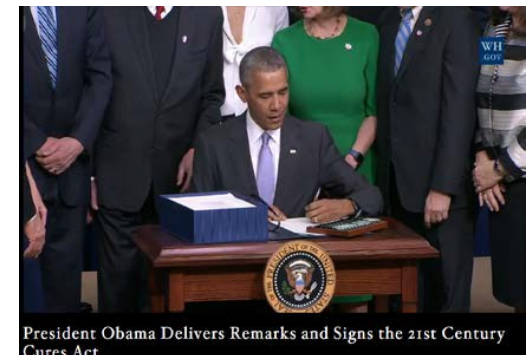
# Legislative Mandate: 21<sup>st</sup> Century Cures Act

**Signed:** December 13, 2016

**Primary Aim:** accelerate medical product development

## **SEC. 2031. NIH Strategic Plan**

Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.



President Obama Delivers Remarks and Signs the 21st Century Cures Act

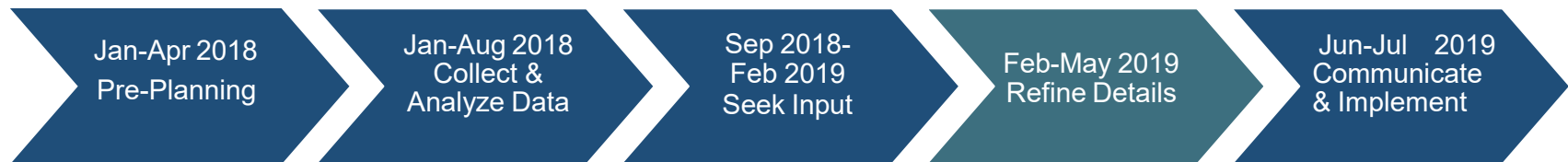




# NICHD Strategic Planning Process

## Guiding Principles:

- Focus on the science
- Guided by evidence
- Informed by our communities
- Emphasis on transparency and accountability





# Strategic Planning: Emphasis Areas

- Theme #1: Understanding Early Human Development
  - Novel tools and techniques – single cells
  - Genes and regulatory networks
  - Environmental exposure
  - Normal and abnormal (infertility, SAB, birth defects)
  - Animal models
- Theme #2: Setting the Foundation for a Healthy Pregnancy and Lifelong Wellness
  - Developmental origins of health and disease (DoHAD)
  - Pregnancy course, placental function



## Strategic Planning: Emphasis Areas (cont.)

- Theme #3: Promoting Gynecological, Andrological and Reproductive Health
  - Development reproductive tissues/organs
  - Menstruation, fibroids, endometriosis, pelvic pain, vulvodynia, pelvic floor disorders
  - Focus on pediatric gynecology
  - Undescended testes, varicocele, spermatogenesis
  - Manage fertility- infertility treatment and contraception
  - Basic science through clinical trials



## Strategic Planning: Emphasis Areas (cont.)

- Theme #4: Identifying Sensitive Time Periods Throughout Development to Optimize Health Interventions
  - Greatest susceptibility to disease or trauma
  - Greatest responsiveness to intervention (medical, physical, behavioral, educational): ‘plasticity’
  - Intellectual, developmental, and learning disabilities
  - Rehabilitation population
- Theme #5: Improving Health During the Transition from Adolescence to Adulthood
  - Hormonal, genetic behavioral, cognitive, social, environmental (sleep, nutrition, social media)
  - Identify, intervene



## Strategic Planning: Emphasis Areas (cont.)

- Theme #6: Ensuring Safe Therapeutics and Devices
  - At risk, understudied, under-enrolled populations
  - Pregnant and lactating women
  - Children
  - Individuals with disabilities



# NICHD Funding Myths

Myth: NICHD has the lowest funding rate at NIH

Fact: Low but improving. No longer using payline for R awards

Myth: NICHD does not fund R21 grants

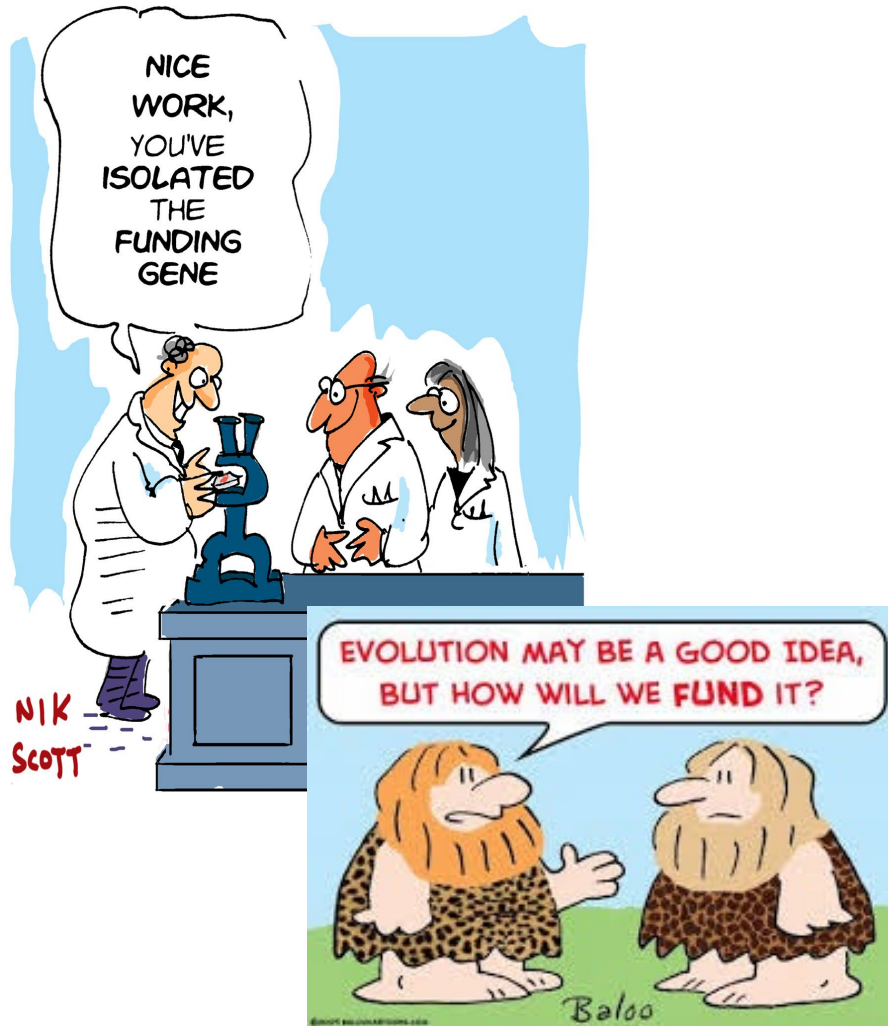
Fact: NICHD does not participate in the Parent R21 but has published separate R21 FOAs

Myth: NICHD is not interested in clinical networks

Fact: NICHD has evaluated networks and may change from cooperative 'U' mechanisms to other collaborative mechanisms for some networks but is still committed to clinical trials



## GREAT MOMENTS IN SCIENCE



Questions???

Lisa Halvorson, MD  
[lisa.Halvorson@nih.gov](mailto:lisa.Halvorson@nih.gov)