

NICHD Director's Report to Council

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September 14, 2017



Outline for Today's Talk

- **Budget Update**
 - Continuing Resolution and Budget Update
 - Update on 21st Century Cures Activities
- **Staff Updates**
- **Vision Update**
 - Building Bridges
 - Communicating the Message
 - Strategic Planning



Budget Update

Why Start With Congress?



- Congress appropriates and passes the budget
- BREAKING NEWS: government shutdown averted
- Government will operate through December 8th with a Continuing Resolution, allowing NIH to continue to operate until the regular appropriations acts are enacted



Sept 7, 2017 Breaking News: Senate Approves Increase for NIH's FY18 Budget

- US Senate's appropriations committee approved a funding bill to increase NIH's FY18 budget to \$36.1 billion (a \$2 billion increase from FY17)
- Includes an approximately \$50 million increase for NICHD
- Total NICHD budget, if approved by the house and signed by the president, will be \$1.426 billion
- No change in overhead (indirect) costs



Where Does the Money Go?

- RCDC stands for “Research, Condition and Disease Categorization”
- NIH keeps the public informed as to how tax dollars are spent
- RCDC is a database NIH has maintained since 2009 to categorize and report the amount of funding on more than 280 topics
- Data are generated using the following process:
 - Scientific experts develop definitions and lists of terms for each category
 - Sophisticated text mining is used to apply definitions to the NIH portfolio
 - Final curation and validation by scientific experts
- NIH does not budget by research category – used to **report** spending
- Categories are not mutually exclusive



RCDC Example

https://report.nih.gov/categorical_spending.aspx

SEARCH RESEARCH/ DISEASE AREAS  PRINT  EXPORT  

Research/Disease Areas (Dollars in millions and rounded)	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Estimated (Continuing Res.)	FY 2018 Estimated	2014 US Mortality 19/	2014 US Prevalence (Standard Error) 19/
Aging	\$2,429	\$2,556	\$2,698	\$3,150	\$3,166	\$2,503	-	-
Alcoholism, Alcohol Use and Health 1/	\$437	\$475	\$473	\$486	\$482	\$375	60,442	-
Allergic Rhinitis (Hay Fever)	\$9	\$6	\$5	\$7	\$7	\$5	76	8.0% (0.22%)
ALS	\$39	\$48	\$49	\$52	\$52	\$42	-	-
Alzheimer's Disease	\$504	\$562	\$589	\$929	\$929	\$790	115,766	-
Allergic Rhinitis (Hay Fever)	\$9	\$6	\$5	\$7	\$7	\$5	76	8.0% (0.22%)
ALS	\$39	\$48	\$49	\$52	\$52	\$42	-	-
Alzheimer's Disease	\$504	\$562	\$589	\$929	\$929	\$790	115,766	-
Autism	\$186	\$188	\$208	\$232	\$227	\$181	202	2.2% (0.18%)**



21st Century Cures Act

Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC)

The screenshot shows the NIH website page for the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). The page is titled "Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)" and includes a navigation menu with options like "Health & Research", "Grants & Funding", "Training & Career Development", "News & Media", and "About NICHD". The main content area describes the 21st Century Cures Act's establishment of PRGLAC to advise the Secretary of Health and Human Services on research gaps for pregnant and lactating women. It lists federal members (NIH, NICHD, CDC, OWH, NVP) and non-federal members (medical societies, non-profits, industry). A "Meetings" section lists dates from August 2017 to May 2018. A "More Information" section provides links to a Federal Register Notice (July 13, 2017), the PRGLAC Charter (PDF, 73 KB), another Federal Register Notice (April 18, 2017), a third Federal Register Notice (March 21, 2017), and the U.S. Code authorizing PRGLAC (42 USC 289a-2).

NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development
Health research throughout the lifespan

A-Z Topics | Director

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Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

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The 21st Century Cures Act established PRGLAC to advise the Secretary of Health and Human Services regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women. PRGLAC is tasked with identifying these gaps and will report its findings back to the Secretary.

Federal members include the Directors of NIH, NICHD, the Centers for Disease Control and Prevention, the Office on Women's Health, and the National Vaccine Program Office, as well as the Commissioner of Food and Drugs. Non-federal members include representatives from relevant medical societies, non-profit organizations, and industry.

Meetings

- [August 21-22, 2017](#)
- [November 6-7, 2017](#)
- [February 26-27, 2018](#)
- [May 14-15, 2018](#)

More Information

- [Federal Register Notice - July 13, 2017](#)
- [PRGLAC Charter](#) (PDF - 73 KB)
- [Federal Register Notice - April 18, 2017](#)
- [Federal Register Notice - March 21, 2017](#)
- [U.S. Code Authorizing PRGLAC \(42 USC 289a-2\)](#)

Web page created to inform the public:

<https://www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx>



NICHD Pregnancy and Lactation Literature Analysis 2006-2017: Results for Pregnancy

- RCTs rare in almost all areas
- 5 Exceptions:
 - Gestational diabetes
 - Hypertension
 - Preterm labor
 - Labor pain medication
 - Opioids and tobacco

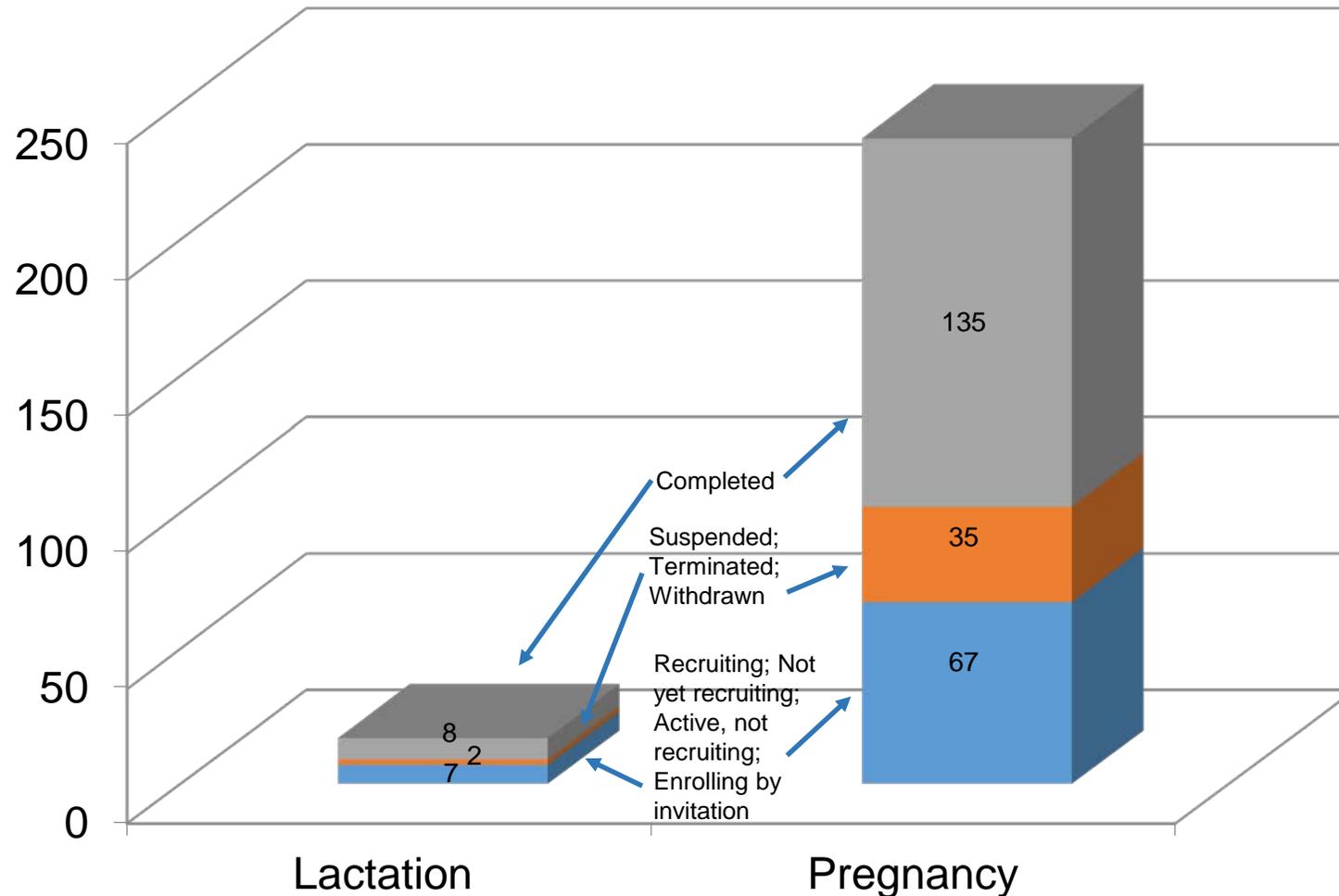
	Condition	Basic	PK/PD	Pop/DB	RCT
Hypertension	Hypertension	127	9	18	40
Mental Health	Anxiety	16	0	3	2
	Bipolar	1	0	1	0
	Depression	21	4	21	4
	Schizophrenia	11	0	1	0
Pain	Labor Pain	5	0	7	49
	Headache/migraine	0	0	5	1
Preterm labor	Preterm labor	152	21	35	169
Substance Abuse	Alcohol	26	0	0	0
	Cocaine	6	0	1	0
	Meth/amph	10	3	1	0
	Opioids	22	3	9	25
	Tobacco	22	3	16	27

Interventional Trial Status in the US

Industry sponsored

Search terms include

Study type: "interventional"
Study phase: "Early Phase 1;
Phase 1; Phase 2; Phase 3;
Phase 4"
Funder type: "industry"



Source: www.clinicaltrials.gov (Site accessed 09 Aug 2017)

Slide courtesy of Christina Bucci-Rechtweg, MD,
Novartis Pharmaceuticals Corporation



21st Century Cures Act: Next Generation of Researchers Initiative

- 21st Century Cures Act – Section 2021. Investing in the Next Generation of Researchers
- Dr. Tabak spoke at June’s Council Meeting about the Grant Support Index (GSI)
- Next Generation of Researchers Initiative (NGRI) eliminates the GSI
- NIH Guide notice (NOT-OD-17-101) published August 31, 2017: Policy Supporting the Next Generation Researchers Initiative





Definitions

- An **early stage investigator (ESI)** is a Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.
- An **early established investigator (EEI)** is an investigator who is within 10 years of receiving their first substantial, independent competing NIH research award as an ESI and who will no longer retain their ESI status because they received a substantial award).



Staff Updates



Best Wishes to NICHD Staff Who Are Retiring

- Dr. Germaine Buck-Louis, Director of the Division of Intramural Population Health Research (DIPHR), will begin a new adventure as Dean of the College of Health and Human Services at George Mason University on October 1st. Dr. Constantine Stratakis will serve as Acting Director of DIPHR.
- Dr. Mike Weinrich, Senior Advisor for Device Development, Biotechnology and Bioengineering, will retire at the end of September. He also served as Director of the National Center for Medical Rehabilitation Research at the NIH from 2000 to 2014.





Vision Update

Vision Update

- **Building Bridges**
 - NICHD/ECHO/NIDA (Opioids)
 - Human Placenta Project
 - *All of Us*
 - Johns Hopkins Children's Center Visit
 - Perinatology Research Branch in Detroit
- **Communicate the Message**
 - Voice of the Patient
- **Strategic planning process in early 2018**



Building Bridges: Neonatal Opioid Withdrawal (NOW) Syndrome

- Funding from Dr. Francis Collins for Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW)
 - Builds a bridge between NICHD/ECHO/IDeA states network/NIDA/NIGMS
- Breakfast session with Chairman Sessions and Dr. Collins at the US Capitol
- Upcoming: Women's Congressional Policy Institute Briefing on September 26
- Concept presented to Council later this morning



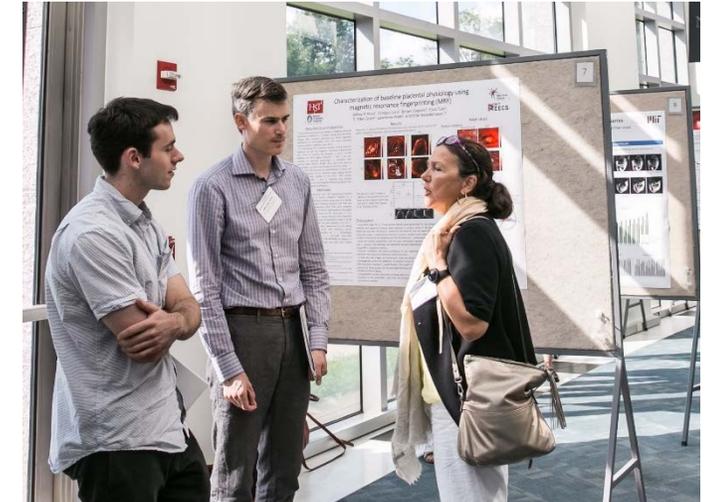


4th Annual Human Placenta Project Meeting



July 24-25, 2017

Grantee updates, poster session and demos





All of Us
RESEARCH PROGRAM

The
Precision
Medicine
Initiative

<https://grants.nih.gov/grants/guide/notice-files/NOT-PM-17-004.html>

- Request for information from the public. Due SEPT 22
- What are the most significant precision medicine research questions that could be addressed by inclusion of pediatric populations?
- What are key gaps in pediatric study designs that might be appropriate to address through enrollment of children?
- What are the research resources that the inclusion of children into the *All of Us* program could generate?



Building Bridges: Johns Hopkins Children's Center Visit

- Visit on August 30 to Johns Hopkins Children's Center
- Continuing efforts to identify opportunities for collaboration with local partners in clinical care, intramural research and education
- Tina Cheng, M.D., Chair of Pediatrics at Hopkins, is on the *All of Us* Pediatric Advisory sub-committee





Building Bridges: Perinatology Research Branch in Detroit



Detroit Mayor Mike Duggan



Congresswoman Debbie Dingell

Communicating the Message: Voice of the Patient



- Welcome Voice of the Patient speaker, Ms. Megan Connolly!
- She will be speaking about her experience in the NICHD-supported Oncofertility Consortium.

What's Ahead? Strategic Planning Process

- Strategic planning process in early 2018
- Group of ~50 people
- Will include both internal and external stakeholders
- More information will be forthcoming



Questions?