



National Institute of  
Neurological Disorders  
and Stroke

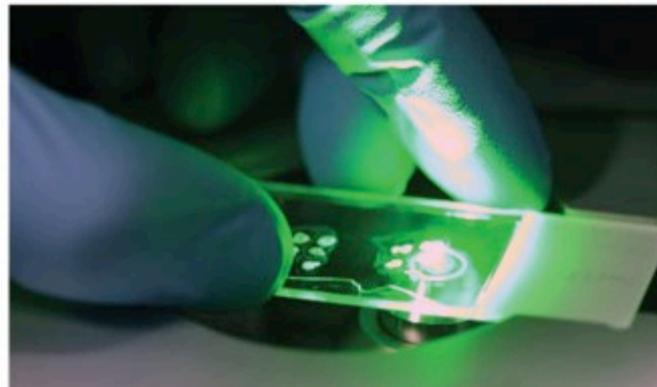
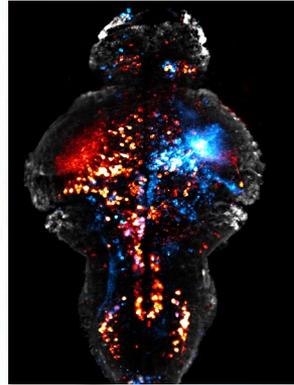
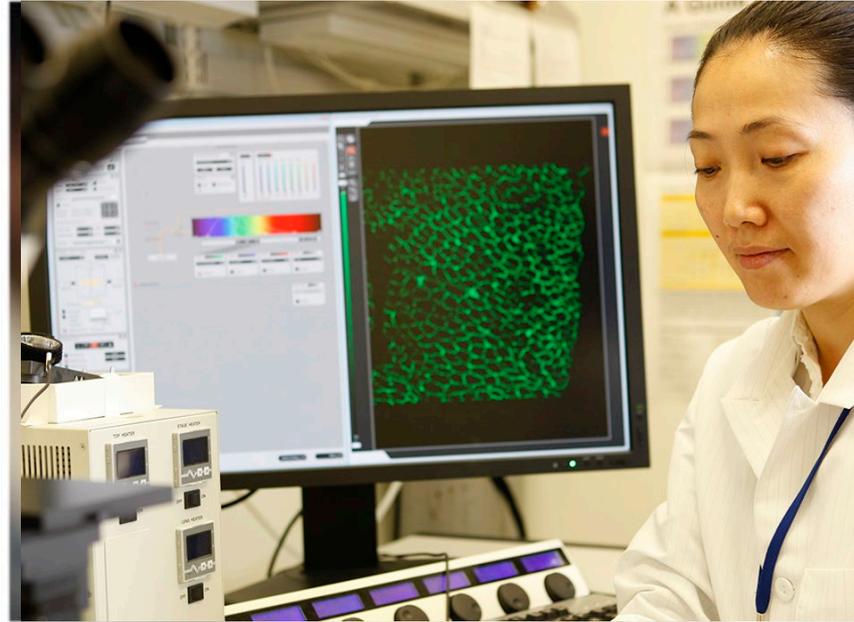
# NINDS Director's Report

*NANDS Council*

February 14, 2019

Walter J. Koroshetz, M.D.

Director, National Institute of  
Neurological Disorders and Stroke, NIH



# Appropriation History

(Dollars in Thousands)

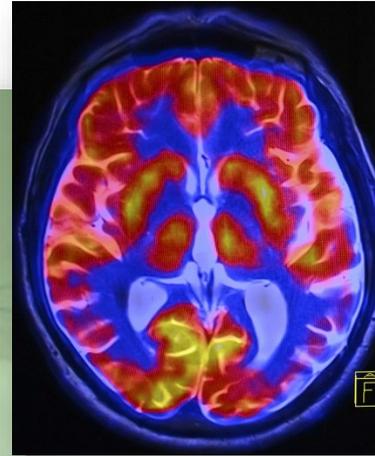
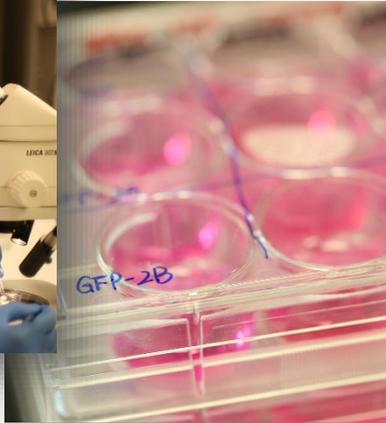
	FY 2013	FY2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2018 with Opioid and Cures	FY 2019 Appropriation	FY 2019 with Opioid and Cures
<b>NINDS</b>	\$1,533,795	1,588,904	1,604,607	1,692,833	1,778,688	1,888,130	2,188,149	1,966,913*	2,274,413
<b>NINDS % Change</b>	-5.6%	3.6%	1.0%	5.5%	5.4%	6.15%	23%	4.17%	3.9%
<b>NIH</b>	\$29,151,462	30,150,853	30,311,349	32,345,549	34,161,349	36,228,080	37,224,080	38,023,000**	39,234,000
<b>NIH % Change</b>	-5.5%	3.4%	0.5%	6.7%	5.6%	6%	8.9%	4.9%	5.4%

- NIH FY 2019 Appropriation with Opioid and Cures is a \$2 billion increase over FY 2018's level.
- In FY 2019, NINDS received \$250m for Pain Research in part of the HEAL Initiative and \$57.5m in CURES Act fund for the BRAIN Initiative.
- In FY 2018, NINDS co-managed approximately \$100 million of the AD/ADRD monies that NIA received. In FY 2019, NINDS expects to co-manage more than \$140m of the AD/ADRD monies under an MOU with NIA.

\* The **FY 2019 Appropriation** column does not include the monies that NINDS received for the HEAL Initiative (\$250m) and CURES Act (\$57.5m).

\*\* The **FY 2019 Appropriation** column does not include the monies that NIH received for the HEAL Initiative (\$500m) and CURES Act (\$711m).

# NINDS Invests Across the Research Spectrum



## Basic

*Fundamental Neuroscience  
Disease-Focused Research*

## Translational

*Pipeline through to  
FDA IND/IDE*

## Clinical

*Phase I, II, III Trials  
FDA Review*

Division of Neuroscience

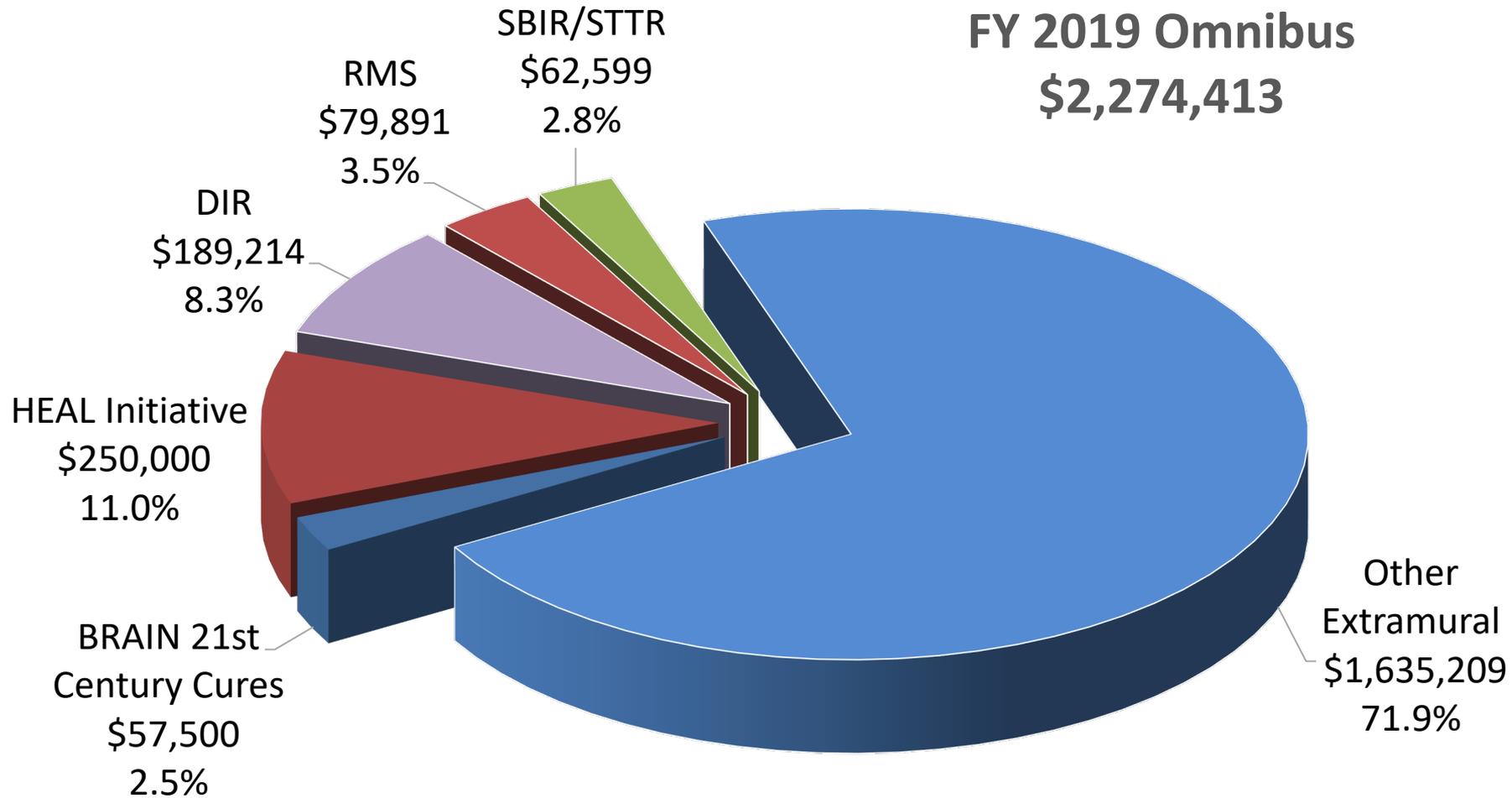
Division of  
Translational Research

Division of Clinical  
Research

Division of Extramural Activities (includes **Training**)

# FY 2019 Appropriation Budget Distribution

**FY 2019 Omnibus  
\$2,274,413**



Dollars in Thousands

# *In memoriam*

**Stephen I. Katz,  
M.D., Ph.D.**

---

**NIAMS Director  
1995 - 2018**



# NIH Leadership Changes



Helene M. Langevin, M.D., C.M. new **Director of National Center for Complementary and Integrative Health (NCCIH)**



Bruce J. Tromberg, Ph.D. new **Director of National Institute of Biomedical Imaging and Bioengineering (NIBIB)**



Noni Byrnes, PhD. **Announced as Director of the Center for Scientific Review (CSR)**

Robert H. Carter, M.D. named Acting Director, NIAMS

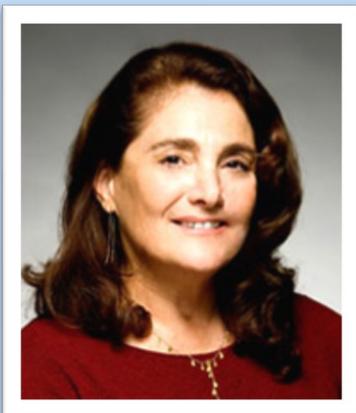
Searches are ongoing for the Directors of:

- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute on Nursing Research (NINR)



# NINDS Leadership Changes

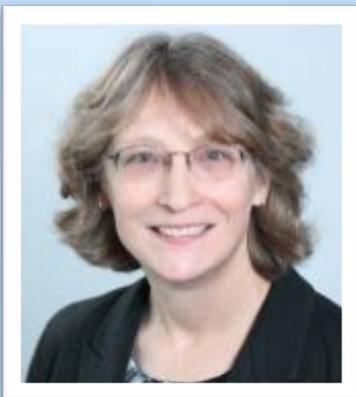
## Scientific Director



**Lorna Role, PhD**

*Previously: SUNY Distinguished Professor*

## Director of Neuroscience



**Lyn Jakeman, PhD**

*Previously: Program Director, Repair and Plasticity*

**BRAIN Director – Candidate selected**



# NIH Helping to End Addiction Long-term (HEAL) Initiative

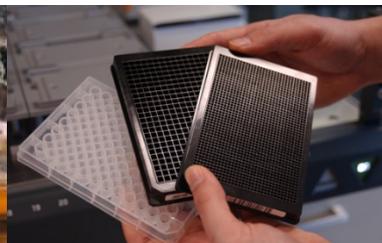
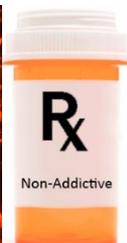
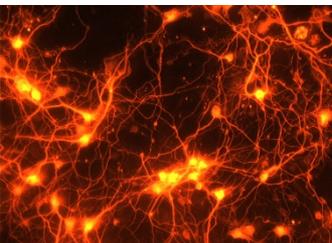
Congress appropriates \$500M/year to:

- Address opioid misuse and addiction
- **Enhance pain management:**
  - Understand biological underpinnings of chronic pain
  - Accelerate discovery and pre-clinical development of non-addictive treatments
  - Advance new non-addictive treatments through the clinical pipeline
  - Establish the best pain management strategies for acute pain and numerous chronic pain conditions

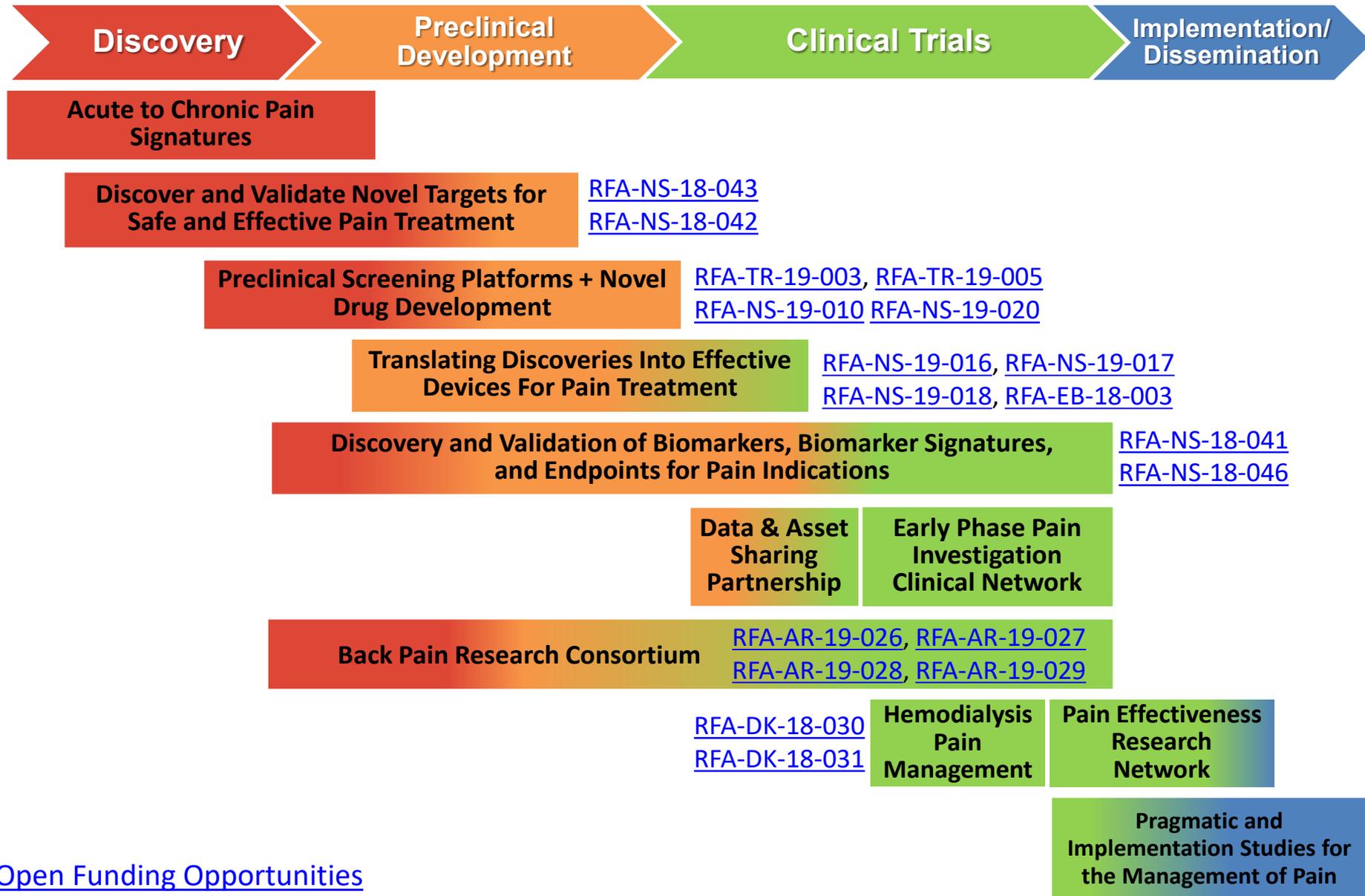


Read about the research plan:

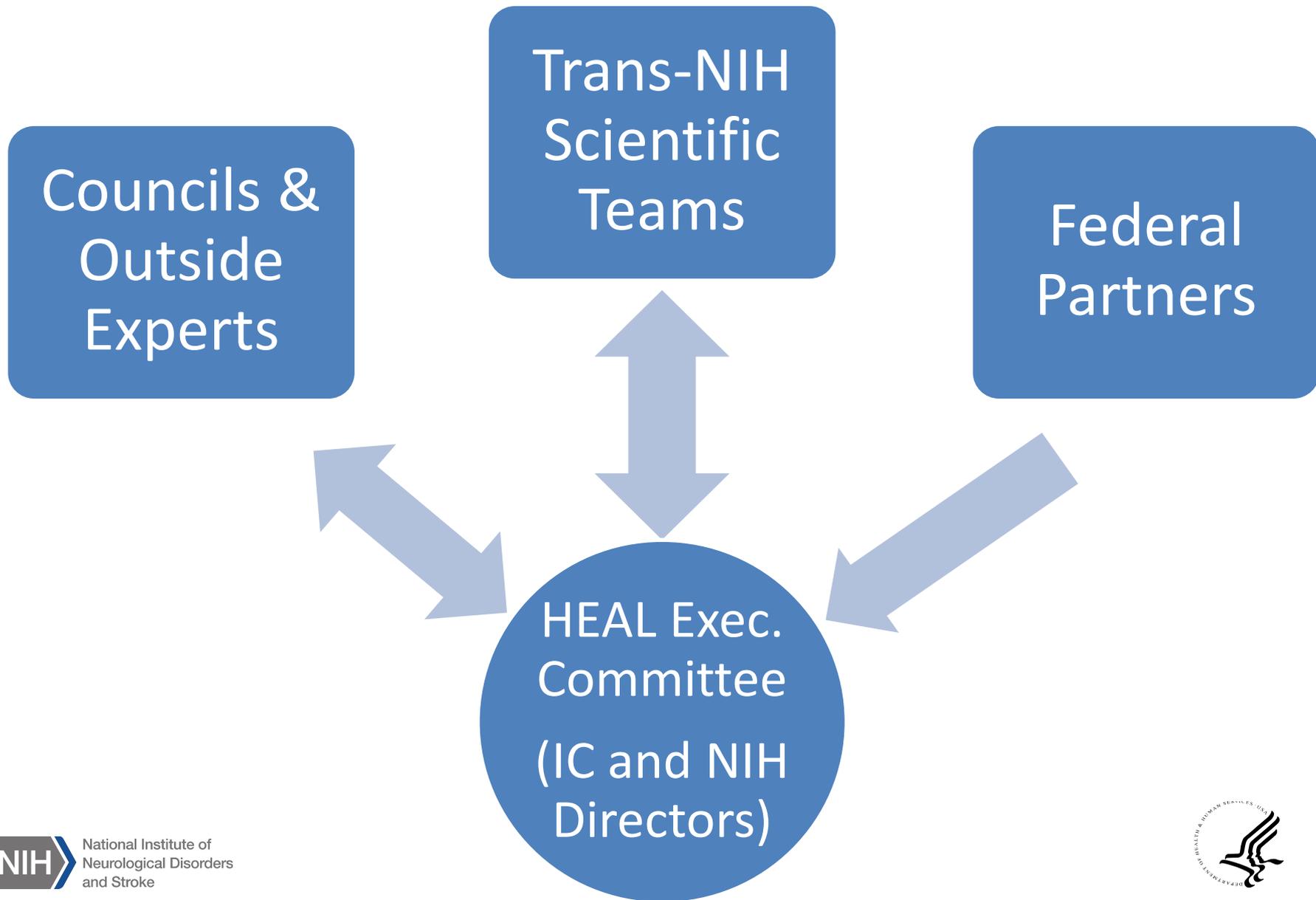
[www.nih.gov/heal-initiative](http://www.nih.gov/heal-initiative)



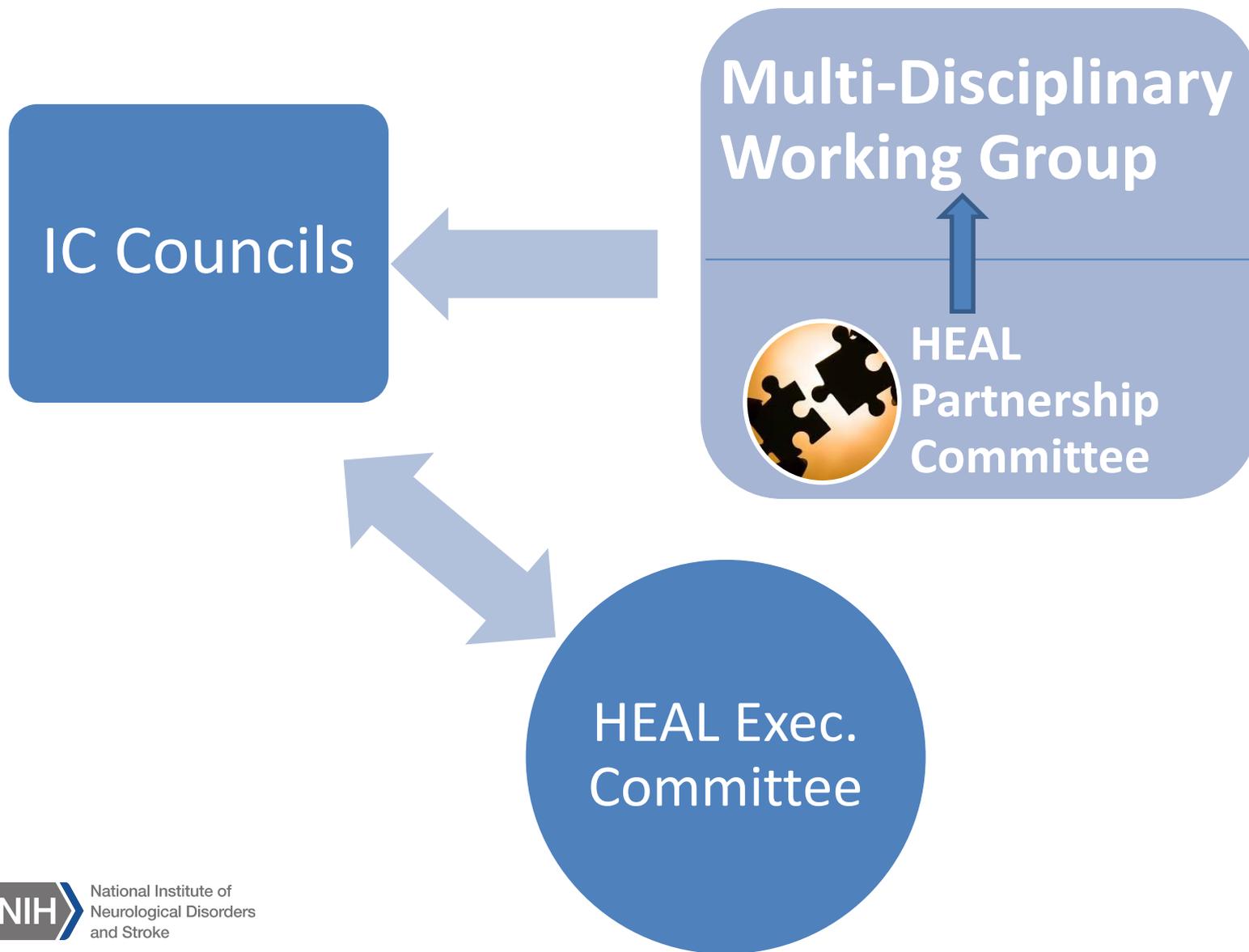
# HEAL Programs for Pain Cover Research Spectrum



# HEAL Decision-Making



# HEAL Decision-Making



# BRAIN Neuroethics Guiding Principles and International Efforts



THE  
BRAIN  
INITIATIVE

NATIONAL INSTITUTES OF HEALTH

JNeurosci  
THE JOURNAL OF NEUROSCIENCE

## Neuroethics Guiding Principles

1. Make assessing safety paramount
2. Anticipate special issues related to capacity, autonomy, and agency
3. Protect the privacy and confidentiality of neural data
4. Attend to possible malign uses of neuroscience tools and neurotechnologies
5. Move neuroscience tools and neurotechnologies into medical or nonmedical uses with caution
6. Identify and address specific concerns of the public about the brain
7. Encourage public education and dialogue
8. Behave justly and share the benefits of neuroscience research and resulting technologies

The Journal of Neuroscience, December 12, 2018 • 38(50):10583–10585 • 10583

JNeurosci  
THE JOURNAL OF NEUROSCIENCE

Commentary

## Neuroethics for the National Institutes of Health BRAIN Initiative

©Diana W. Bianchi, Judith A. Cooper, ©Joshua A. Gordon, Jill Heemskerk, ©Richard Hodes, George F. Koob, ©Walter J. Koroshetz, David Shurtleff, Paul A. Sieving, ©Nora D. Volkow, ©James D. Churchill, and ©Khara M. Ramos  
National Institutes of Health, Bethesda, Maryland 20892

**NIH** National Institute of  
Neurological Disorders  
and Stroke

## NEURON: SPECIAL ISSUE ON NEUROETHICS

06 February 2019



GLOBAL NEUROETHICS  
SUMMIT

**Neuron**

# Special Council Review

- **Who:** Researchers with NIH research support exceeding \$1M in direct costs at the time of the Council meeting, including the pending application
- **What:** Special Council Review, with a percentile payline that is ½ of the NINDS payline
- **When:** Now. This Council meeting is the first time the new Policy will be implemented
- **Excluded:** Training, conferences, core facilities, research resources, SBIR/STTR
- **Exceptions** will be made for
  - Inherently expensive research
  - Applications involving Congressionally directed funds (BRAIN, HEAL, ADRD, etc)

## NINDS Announces Modifications to Special Council Review Policy

**Notice Number:** NOT-NS-18-060

**Key Dates**

**Release Date:** April 27, 2018

**Related Announcements**

None

**Issued by**

National Institute of Neurological Disorders and Stroke (NINDS)

**Purpose**

This Notice announces modifications to the Special Council Review (SCR) policy, which pertains to well-funded Program Director(s)/Principal Investigator(s) [PD(s)/PI(s)] submitting applications to NINDS. The new policy: (1) lowers the funding threshold that requires special review of a pending application by the National Advisory Neurological Disorders and Stroke (NANDS) Council and; (2) sets a more stringent payline for pending applications that cause a PD/PI to exceed this threshold.



**Walter J. Koroshetz** @NINDSdirector · May 3

NINDS hoping to improve the health of neuroscience. Peer review is always at the core of funding decisions. Adjust the bar to enable early stage & vulnerable PIs to contribute.



**NIH's neuroscience institute will limit grants to well-funded labs**  
Policy aimed at freeing up funds for new and at-risk researchers  
[sciencemag.org](http://sciencemag.org)



# INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE)

Launched in June 2018 in response to \$22.2 million Congressional Directive

**Goal:** Trans-NIH research initiative on critical health and quality-of-life needs for individuals with Down syndrome.

## **Research Priorities:**

- (1)** Targeted high risk - high reward basic science studies;
- (2)** Development of a cohort to perform deep phenotyping and study co-existing conditions; and
- (3)** Establishing a clinical trials network
- (4)** Led at NINDS by Dr. Nina Schor



# NINDS P30 Program

Stated goal: Centers should offer services and expertise that would be difficult or impractical to support in individual labs. The Centers are expected to capitalize on economies and synergies associated with shared resources, and to foster a collaborative environment among neuroscientists at host institutions

## Department of Health and Human Services

### Part 1. Overview Information

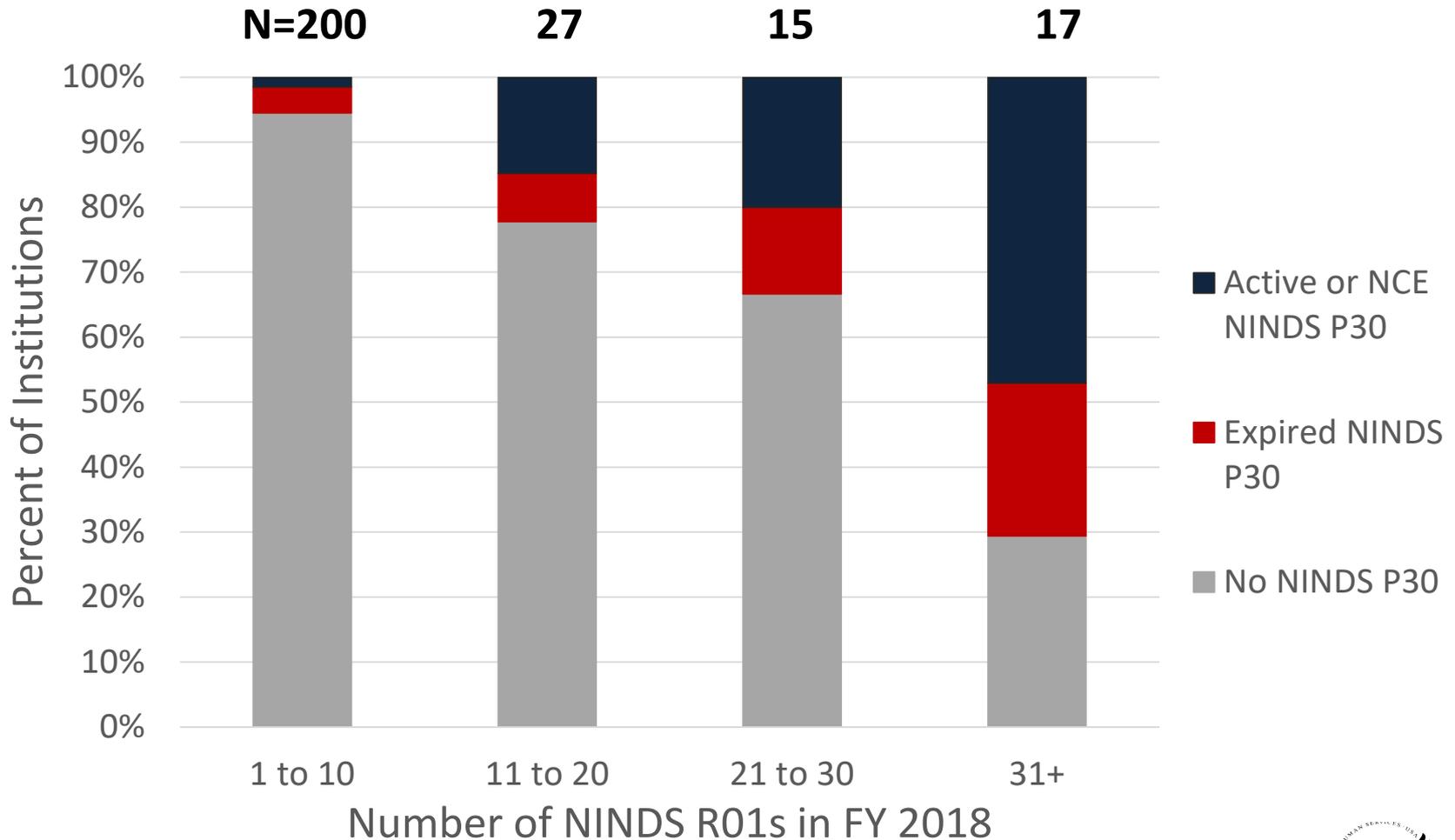
Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Neurological Disorders and Stroke (NINDS)
Funding Opportunity Title	NINDS Institutional Center Core Grants to Support Neuroscience Research (P30)
Activity Code	P30 Center Core Grants
Announcement Type	Reissue of RFA-NS-16-004
Related Notices	None
Funding Opportunity Announcement (FOA) Number	RFA-NS-17-011

# 2016 P30 Discussion with Council

Council agreed with NINDS decision to pause their current P30 program:

- Difficult to judge whether the added NINDS support still has high impact.
  - Most expenditures cover personnel
  - Funding institutions where facilities and equipment already in place
- Other trans-NIH programs can also provide resources

# NINDS P30 Investments Concentrated in Well-Funded Institutions

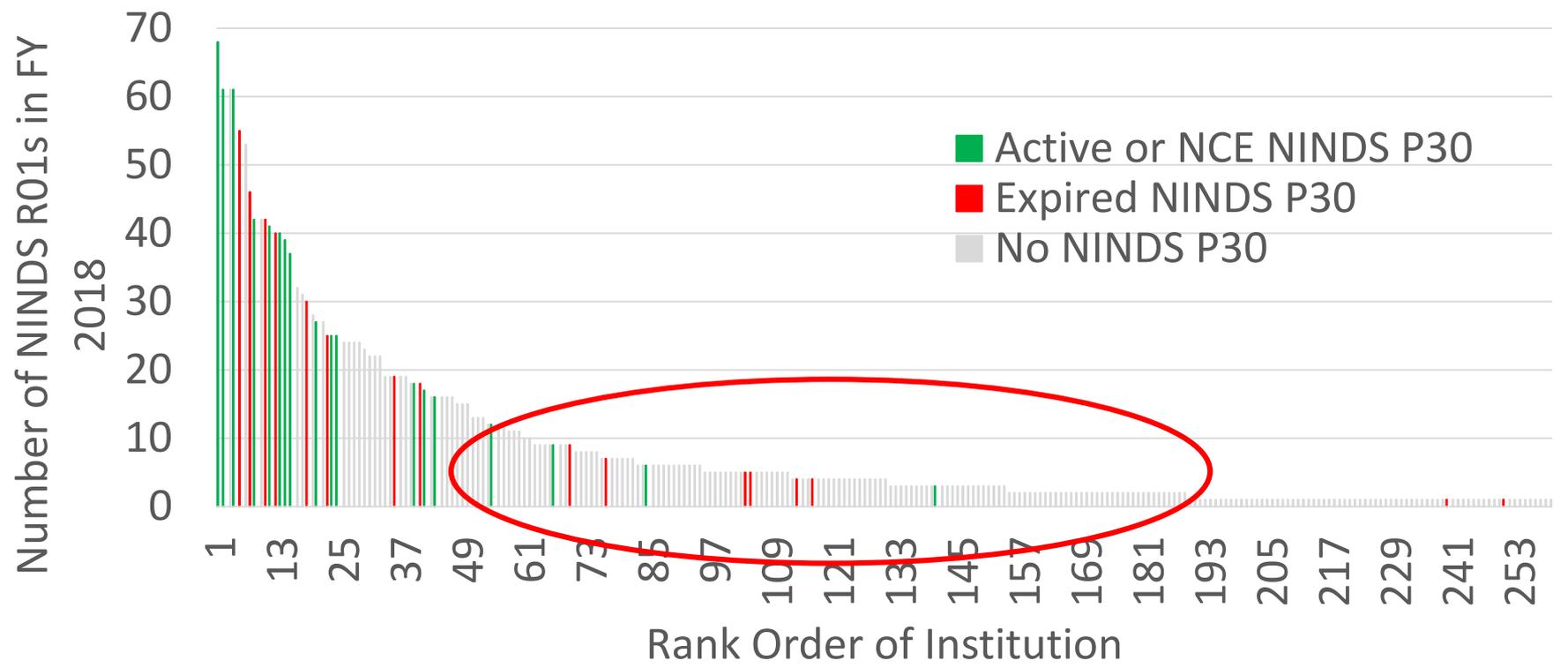


# Additional Concerns About the Impact of Current NINDS P30 Program

- The current set of awards have had long-term funding
  - The average length of current awards is 12 years (longest running awards are 16 years)
  - We have not funded a new P30 Center since 2011
  - When the current award cycle is finished all active P30s will have had at least 10 years of funding
- All institutions support a wide variety of other research cores, suggesting current P30 not having a unique impact
- Time for the current P30s to transition to self-sustaining models (for example, a fee-for-service model)

Next Step: Sunset the current NINDS P30 Program

# Would we have Greater Impact if NINDS targets start up of Core Facilities at Universities Committed to Invigorating their Neuroscience Programs?



# NINDS's Core Dilemma

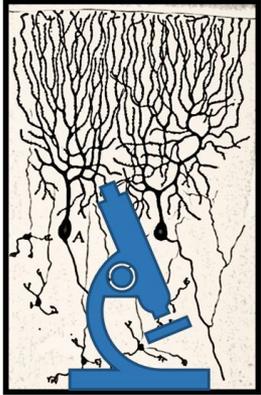
- Given the critical importance of Neurotechnology core facilities to perform high level neuroscience across our grantee institutions, how should NINDS apportion its limited core resources to have the greatest impact?
  - i.e., Can't afford to fund cores at all sites that need them, but everyone needs them
- Discussion later today about how we might approach this dilemma

# NINDS Strategic Planning: *Setting the Stage*

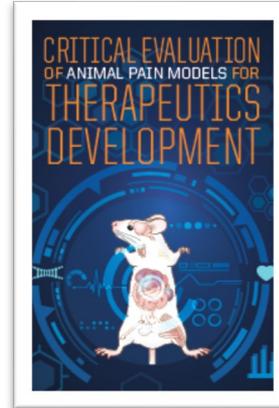
- Beginning in the last Council meeting, NINDS is presenting an overarching vision of the major NINDS Divisions/high priority topic areas so Council members can understand how these efforts integrate across the NINDS portfolio.
- Ultimately, this deeper understanding should help inform Council's input on guiding major directions for the Institute, enhancing our efforts to achieve our mission, and setting the stage for Strategic Planning discussions.
- September 2018 Council: Division of Translational Research
- Today: Division of Clinical Research, Training

**Dr. Nina Schor, NINDS Deputy Director, is leading the Strategic Planning effort**

# Recent NINDS Workshops



A Visionary Resource for Instilling Fundamental Principles of Rigorous Neuroscience Research Workshop



A Critical Evaluation of Animal Pain Models



Bridging the Translational Gap in Stroke Recovery & Rehabilitation Research Workshop



SCI 2020: Launching a Decade for Disruption in Spinal Cord Injury Research



Discovery and Validation of Biomarkers to Develop Non-Addictive Therapeutics for Pain

# NINDS: A Year in Review

## Director's Corner

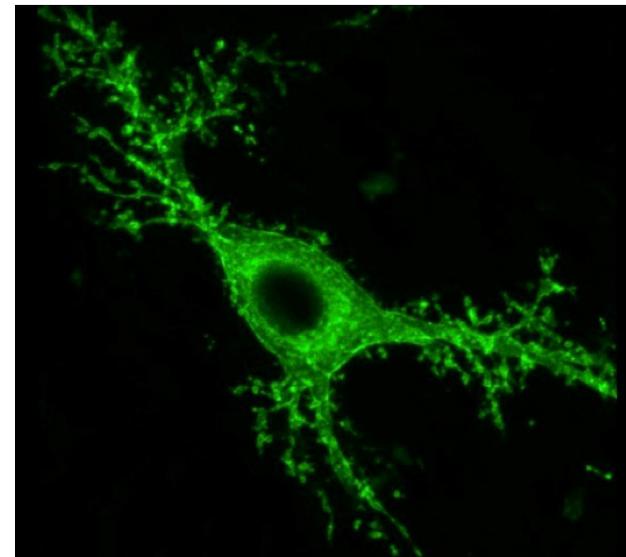
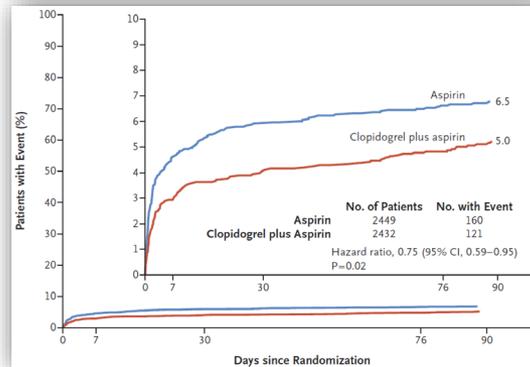
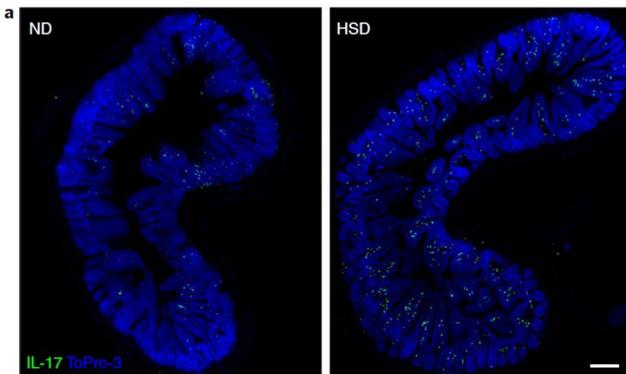
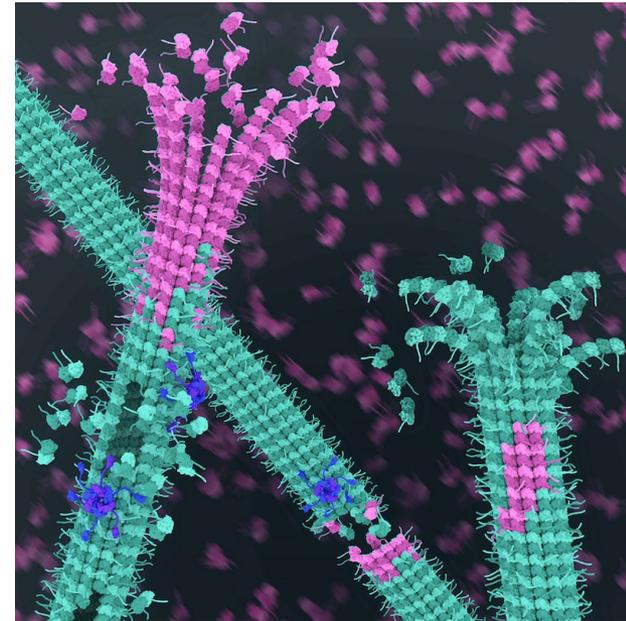


## NINDS: Looking Back on 2018

Monday, January 28, 2019

As we begin the new year, and on behalf of everyone at NINDS, I would like to thank our investigators, research subjects, and our partners representing those suffering from neurological disorders for helping us make 2018 a success.

[Read complete Director's Message](#)



# SPRINT MIND: Intensive blood pressure control may reduce risk of mild cognitive impairment, but does not affect dementia

JAMA | Original Investigation

## Effect of Intensive vs Standard Blood Pressure Control on Probable Dementia A Randomized Clinical Trial

The SPRINT MIND Investigators for the SPRINT Research Group

- No difference in the primary outcome of probable dementia risk
- Secondary results suggest that intensive blood pressure control may reduce risk for mild cognitive impairment (MCI)
- Part of larger SPRINT trial, which compared effects of standard (systolic <140 mmHG) vs. intensive (systolic <120 mmHG) blood pressure control on cardiovascular health. Trial was stopped early- intensive BP control showed clear benefits.

Table 2. Incidence of Probable Dementia and Mild Cognitive Impairment by Treatment Group

Outcomes	Treatment Group				Hazard Ratio (95% CI) <sup>a</sup>	P Value
	Intensive		Standard			
	No. With Outcome/Person-Years	Cases per 1000 Person-Years	No. With Outcome/Person-Years	Cases per 1000 Person-Years		
Probable dementia	149/20 569	7.2	176/20 378	8.6	0.83 (0.67-1.04)	.10
Mild cognitive impairment <sup>b</sup>	287/19 690	14.6	353/19 281	18.3	0.81 (0.69-0.95)	.007
Composite of mild cognitive impairment or probable dementia	402/19 873	20.2	469/19 488	24.1	0.85 (0.74-0.97)	.01

<sup>a</sup> Intensive treatment group vs standard treatment group based on Cox proportional hazards regression.

<sup>b</sup> Participants adjudicated as having probable dementia at the first follow-up visit (year 2) do not contribute to the analyses of mild cognitive impairment.



The New York Times

Study Offers Hint of Hope for Staving Off Dementia in Some People

CW

Lowering blood pressure could cut risk factor for dementia

# Thank You!

**Walter J. Koroshetz, M.D.**

**Director**

**National Institute of Neurological Disorders and Stroke**

**Email: [koroshetzw@ninds.nih.gov](mailto:koroshetzw@ninds.nih.gov)**

**Website: <http://www.ninds.nih.gov/>**



**Follow me @NINDSdirector**

# International Stroke Conference 2019 Highlights



## Stroke Hyperglycemia Insulin Network Effort

Dr. Karen Johnston, UVA

Dr. Bruno Askiel, Medical College of Georgia

Dr. Chris Hall, UT Southwestern

- Comparative effectiveness study of glucose management after acute ischemic stroke
- Primary results found that intensive glucose control (target glucose 80-130 mg/dL via IV insulin) did not improve 90-day outcomes compared to standard glucose control (target glucose < 180 mg/dL via insulin shots)
- Risk of hypoglycemia with intensive treatment
- The SHINE results found the best strategy is standard glucose control



## Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation, Phase III

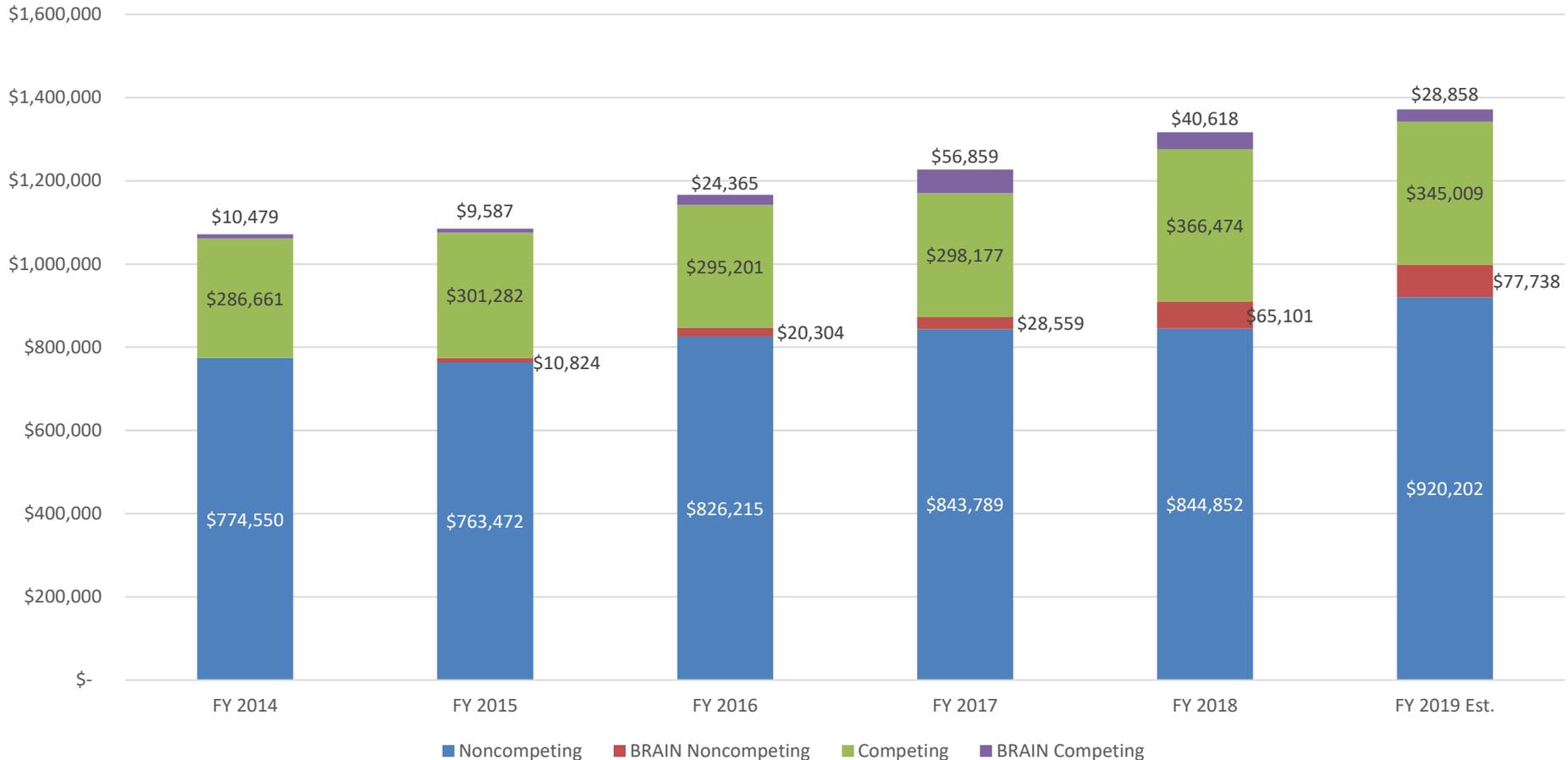
Dr. Dan Hanley, Johns Hopkins University

Dr. Issam Awad, University of Chicago

Dr. Mario Zuccarello, University of Cincinnati

- This trial compared the MISTIE treatment (removing clot with minimally invasive surgery plus tPA) to standard medical management
- Despite an overall 43% improvement in good functional outcome by all patients, the MISTIE procedure was not superior to standard care on 1-year outcomes
- Exploratory secondary results suggest improved outcomes in patients who had clots reduced to 15 mL or less

# Noncompeting and Competing Trends



(Dollars in Thousands)

# NINDS P30 History

(Dollars in Thousands)

	FY 2014		FY 2015		FY 2016		FY 2017		FY 2018		FY 2019 estimated		FY 2020 estimated	
	#	Dollars	#	Dollars	#	Dollars	#	Dollars	#	Dollars	#	Dollars	#	Dollars
<b>Competing</b>	6	\$3,420	4	\$2,566	6	\$3,721	5	1,800	2	\$855	-	-	-	-
<b>Non-Competing</b>	21	\$14,917	20	\$12,383	14	\$7,766	16	\$9,656	13	7,682	11	\$5,926	5	\$2,209
<b>TOTAL</b>	<b>27</b>	<b>\$18,337</b>	<b>24</b>	<b>\$14,949</b>	<b>20</b>	<b>\$11,487</b>	<b>20</b>	<b>\$11,456</b>	<b>15</b>	<b>\$8,537</b>	<b>11</b>	<b>\$5,926</b>	<b>5</b>	<b>\$2,209</b>

# 116<sup>th</sup> Congress Committee Leadership of Interest to NIH (*new = new to position*)

## House Appropriations Committee

- Chairwoman: **Nita M. Lowey (NY)** *new*
- Ranking member: **Kay Granger (TX)** *new*

## House Appropriations Subcommittee on Labor, HHS, Education and Related Agencies

- Chairwoman: **Rosa DeLauro (CN)** *new*
- Ranking member: **Tom Cole (OK)** *new*

## House Energy and Commerce Committee

- Chairman: **Frank Pallone Jr. (NJ)** *new*
- Ranking member: **Greg Walden (OR)** *new*

## House Energy and Commerce Committee Subcommittee on Health

- Chairman: **Anna Eshoo (CA)** *new*
- Ranking member: **Michael C. Burgess (TX)** *new*

## Senate Appropriations Committee

- Chairman: **Richard Shelby (AL)**
- Ranking member: **Patrick Leahy (VT)**

## Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies

- Chairman: **Roy Blunt (MO)**
- Ranking member: **Patty Murray (WA)**

## Senate Committee on Health, Education, Labor & Pensions

- Chairman: **Lamar Alexander (TN)**
- Ranking member: **Patty Murray (WA)**