

# Welcome: NIH BRAIN Director



John Ngai BRITTANY HOSEA-SMALL/UNIVERSITY OF CALIFORNIA, BERKELEY

BRAIN Initiative's first director sets sights on clinical tools

By Kelly Servick | Feb. 4, 2020, 12:40 PM



**John Ngai, Ph.D.**

- Coates Family Professor of Neuroscience, University of California, Berkeley
- Professor of Neurobiology, University of California, Berkeley
- Director, QB3 Functional Genomic Laboratory
- Co-Chair, BRAIN Initiative Cell Census Consortium Steering Group
- B.A. Chemistry and Zoology, Pomona College; Ph.D. Biology, California Institute of Technology

# Thank You for Your Service to the NINDS Advisory Council



## **Larry Abbott, Ph.D.**

William Bloor Professor of Theoretical Neuroscience in the Departments of Neuroscience and Physiology and Cellular Biophysics at **Columbia University, College of Physicians and Surgeons**. Member of the BRAIN MCWG

## **Issam A. Awad, M.D.**

John Harper Seeley Professor of Surgery at the **University of Chicago**, Pritzker School of Medicine and Director of Neurovascular Surgery at the University of Chicago Hospitals

## **Indira M. Raman, Ph.D.**

Bill and Gayle Cook Professor of Biological Sciences in the Department of Neurobiology at **Northwestern University**

## **Steven L. Roberds, Ph.D.**

Chief Scientific Officer of the **Tuberous Sclerosis Alliance**





NANDS COUNCIL | May 27, 2020

# NINDS Director's Report

Walter J. Koroshetz, MD

Director, National Institute of Neurological  
Disorders and Stroke



National Institute of  
Neurological Disorders  
and Stroke

# NIH ME/CFS Research Roadmap



**1** Form a Working Group of the NANS Council to Develop Research Roadmap 

**2** Hold Series of Teleconferences & Draft Research Opportunities 

**3** Solicit Public Comments via ME/CFS Town Hall and Online Crowdsourcing 

**4** Write ME/CFS Research Roadmap 

**5** Present to NANS Council 

A process to guide research for the ME/CFS community, including scientists, advocacy organizations, and federal agencies

What are the research questions?

*The larger Working Group, as well as the topic subgroups, will include representatives from advocacy organizations*

# Appropriation History

(Dollars in Thousands)



	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020 Appropriation
<b>NINDS</b>	1,604,607	1,692,833	1,778,688	1,888,130*	1,947,965*	2,110,256*
<b>NINDS % Change</b>	1.0%	5.5%	5.4%	6.15%	4.17%	7.5%
<b>NIH</b>	30,311,349	32,345,549	34,161,349	36,228,080**	38,023,000**	40,684,000**
<b>NIH % Change</b>	0.5%	6.7%	5.6%	6%	4.9%	6.7%

- In FY 2020, NINDS received \$266m for Pain Research in part of the HEAL Initiative and \$70m in CURES Act fund for the BRAIN Initiative.
- In FY 2020, NINDS will co-manage approximately \$212.5 million of the AD/ADRD monies that NIA received.

\* These columns do not include the monies that NINDS received for the HEAL Initiative and CURES Act for BRAIN Initiative.

\*\* These columns do not include the monies that NIH received for the PHS Evaluation, HEAL Initiative and CURES Act.

NIH and NINDS are deeply concerned for the health and safety of people involved in NIH research, and about the effects on the biomedical enterprise.

# NIH Appropriations “to prevent, prepare, and respond to coronavirus”



\$ in millions				
	H.R. 6074 Coronavirus Supp. 1	CARES Act Coronavirus Supp. 3	H.R. 266 Coronavirus Supp. 3.5	HEROES Act (Proposed)
<b>NIH Total</b>	836	945.4	1,806	4,721
<b>NIAID</b>	836			500
<b>NIEHS (transfer from NIAID)</b>	10			
<b>NHLBI</b>		103.4		
<b>NIBIB</b>		60	500	
<b>NLM</b>		10		
<b>NCATS</b>		36		
<b>OD Common Fund</b>		30		
<b>NCI</b>				
<b>NIMH</b>				
<b>OD COVID-19 Research</b>				
<b>OD COVID-19 Impacted</b>				3,000

For worker-based training to prevent and reduce exposure of . . . frontline workers

To accelerate . . . rapid testing related to coronavirus

For offsetting the costs related to reductions in lab productivity resulting from the coronavirus pandemic

to develop, validate, to develop, validate, improve, and implement testing and associated technologies

# COVID-19: ACTIV



## NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

- A collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics.
- Public Private Partnership among government, non-profit, and industry partners.



Science

**To streamline coronavirus vaccine and drug efforts, NIH and firms join forces**

BY JOCELYN KAISER | APR. 17, 2020

Alliance will prioritize which candidates move forward in clinical trials

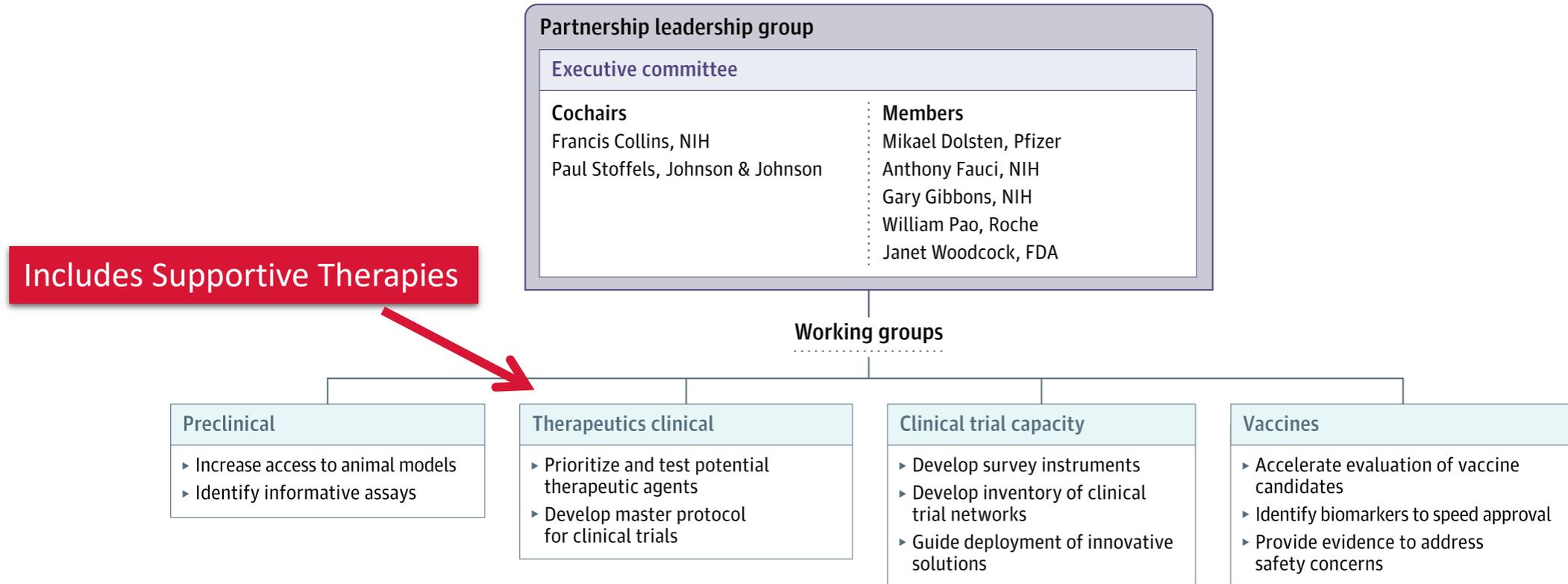


# COVID-19: ACTIV



From: **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV): An Unprecedented Partnership for Unprecedented Times**

JAMA. Published online May 18, 2020. doi:10.1001/jama.2020.8920

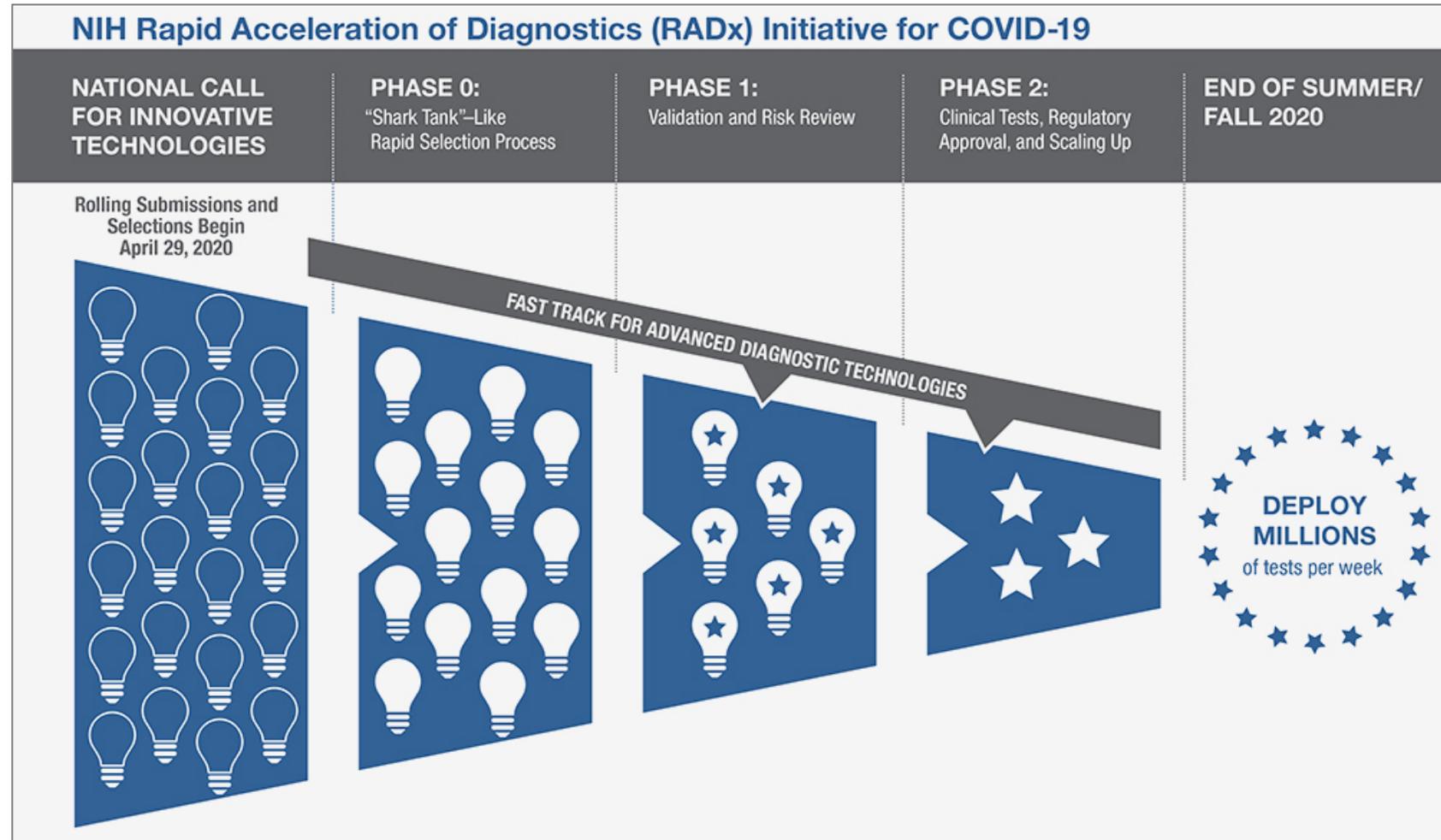


# COVID-19: RADx



## Large NIH COVID-19 Efforts: Rapid Acceleration of Diagnostics (RADx)

- A new initiative aimed at speeding innovation, development, and commercialization of COVID-19 testing technologies.
- RADx will expand the Point-of-Care Technologies Research Network (POCTRN) established several years ago by NIBIB.



# COVID-19 Funding



NIH has received funding for COVID-19-related research activities.

**To expedite getting these funds to the research community, NIH is using Urgent and Emergency competing revisions and administrative supplements to existing grant awards.**

- Emergency Competitive Revision FOAs can only be used by NIH Institutes and Centers (ICs), such as NIBIB, that have received special emergency funding,
- Urgent Competitive Revision FOAs can be used by any NIH ICs, including NINDS, that are addressing a specific aspect of this public health crisis

NIH is providing many administrative flexibilities to help the research continue.

Funding through competing supplements, administrative supplements, new awards

**Information is available on the main NIH website and from your program officers**

This is a rapidly  
evolving situation

Stay Up to  
Date



Visit our page and check back often for updates!

<https://grants.nih.gov/policy/natural-disasters/corona-virus.htm>

# Administrative Flexibilities



## NIH is allowing:

- Pre-award costs to be incurred
- Extensions of post-award reporting
- Prior approval requirement waivers
- Numerous flexibilities regarding expenditures of funds

## If unable to work on grant or training activities, salaries and stipends may be charged to NIH grants

- Ensure that your organization's policy allows such charges from federal and non-federal funds
- Prior approval is not required to divert faculty from research to clinical work related to COVID-19 until the end of the public health emergency period.

FAQs: [grants.nih.gov/faqs#/covid-19.htm](https://grants.nih.gov/faqs#/covid-19.htm)

# Administrative Flexibilities



## Accommodations for Loss of Research Time

- Extensions for early stage investigator eligibility due to COVID-19-related disruptions will be considered
- NIH will be flexible with extending time constraints for fellowship, career development, and training awards, including phased awards
- NIH will accept late applications for the May 25 due date for T32 and T35 institutional training grants through June 30
  - **NOTE:** NINDS T32 application receipt dates are extended to June 29, 2020

FAQs: [grants.nih.gov/faqs#/covid-19.htm](https://grants.nih.gov/faqs#/covid-19.htm)

# Potential Neurological Effects of COVID-19



## Virus:

- Can be found in the brain
- Brain endothelial cells express ACE2 via which virus to enter cells
- Infection is associated with prothrombotic state, large artery stroke, as well as thrombosis in small blood vessels in the brain, heart, lungs and other organs
- Triggers a “cytokine storm” linked to a number of parainfectious neurological conditions.

## Neurological Complications of infection:

- Potential for long term cognitive disability (Acute Respiratory Distress Syndrome, issues with cognition and fatigue)
- Stroke
- Following recovery from COVID-19 infection, rare cases of acute necrotizing hemorrhagic encephalopathy, transverse myelitis, Guillain Barre Syndrome, and Kawasaki syndrome (Multisystem inflammatory syndrome in children) have been reported

THE OPEN MIND

### Coronavirus Disease 2019 Pandemic Acute Respiratory Distress Syndrome Survivors: Pain After the Storm?

Alessandro Vittori, MD,\* Jerrold Lerman, MD, FRCPC, FANZCA,† Marco Cascella, MD,‡  
Andrea D. Gomez-Morad, MD,§ Giuliano Marchetti, MD,\* Franco Marinangeli, PhD, MD,||  
and Sergio G. Picardo, MD\*

Journal of the American College of Cardiology  
May 2020  
DOI: 10.1016/j.jacc.2020.05.001



RESEARCH LETTER

Just Accepted

### Association of Treatment Dose Anticoagulation with In-Hospital Survival Among Hospitalized Patients with COVID-19

Ishan Paranjpe, Valentin Fuster, Anuradha Lala, Adam Russak, Benjamin S. Glicksberg, Matthew A. Levin, Alexander W. Charney, Jagat Narula, Zahi A. Fayad, Emilia Bagiella, Shan Zhao and Girish N. Nadkarni

COVID-19 IS A HEALTH CRISIS.  
**SO IS A STROKE. KNOW THE SIGNS.**  
**ACT IN TIME. CALL 9-1-1.**

STROKE.NIH.GOV



# NINDS Notices of Special Interest Related to Coronavirus



## Notice of Special Interest (NOSI): Availability of Urgent Competitive Revisions and Administrative Supplements For Research on Biological Effects of the 2019 Novel Coronavirus on the Nervous System

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Notice Number: NOT-NS-20-051

### Key Dates

**Release Date:** April 30, 2020

**First Available Due Date:** May 01, 2020

**Expiration Date:** April 15, 2021

## Notice of Special Interest regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for the Establishment and Maintenance of a Research Database for Neurological Manifestations of the SARS-CoV-2

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Notice Number: NOT-NS-20-046

### Key Dates

**Release Date:** April 14, 2020

**First Available Due Date:** April 06, 2020

**Expiration Date:** May 09, 2020

# Impact of COVID-19 on Research



## Downstream impact on the research workforce

- Gathering of preliminary data for grant submissions in June, September was halted.
- Trainees due to transition to next career stage may not be able to matriculate if hiring freeze in place:
  - Postdocs to future postdoc or faculty position
  - Finishing PhD students moving to post doc.
  - Summer research internships cancelled
- Research delays derail progression of all.
- Milestoned research projects will not achieve initial expectations and require more time and \$s.
- Researchers on work visas may need to return home, could be forced out of US academia
- Gender-related decrease in journal submissions likely due to heavy care burdens in the home

Science Contents News Careers Journals

ROBERT NEUBECKER

in 'It will not be easy.' As labs begin to reopen, enormous challenges remain

2 By David Grimm | May. 6, 2020, 12:00 PM



# Impact of COVID-19 on Research



## Restarting the neuroscience research enterprise

- Non-COVID clinical, translational, and basic research predominantly paused in March.
- Restarting non-COVID-19 research likely to take months at increased costs
- Challenges in:
  - Rebuilding animal colonies
  - Safely providing access to labs and core facilities

## Clinical trial enrollments disrupted

- Most NINDS clinical trials are on pause, some with phone or telemedicine follow-up
- Use of tele-research may increase post COVID with enhanced efficiency and safety
- Medications can be mailed but other treatments and neurological exams must be done on site

OPINION | COMMENTARY

## *Medical Research Is Locked Down, Too*

Clinical trials grind to a halt as patients are told to stay home and research personnel are redeployed.

By *Kevin Sheth*

May 4, 2020 5:58 pm ET

I lead clinical trials for medications to treat crippling disorders such as stroke and brain hemorrhages. During the past few months, every one of these studies has come to a grinding halt. The pandemic has thrown clinical trials, the lifeblood of new treatments, into disarray. The consequences will be significant. Some studies won't be able to restart. Others will be delayed for years.

THE CORONAVIRUS CRISIS



## Coronavirus Pandemic Brings Hundreds Of U.S. Clinical Trials To A Halt

April 11, 2020 · 7:02 AM ET

Heard on [Weekend Edition Saturday](#)



# Restarting Research Activity



## Near-term Recovery

- Additional resources will be needed to re-start research, which will likely open in phases.
- NIH will be flexible, and leadership is committed to assisting in the recovery.

## Questions for Discussion

- What is the biggest challenge you/your lab/your research institution is facing?
- What is the most important thing NIH/NINDS can do to help between now and the next Council meeting in September?

# 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)

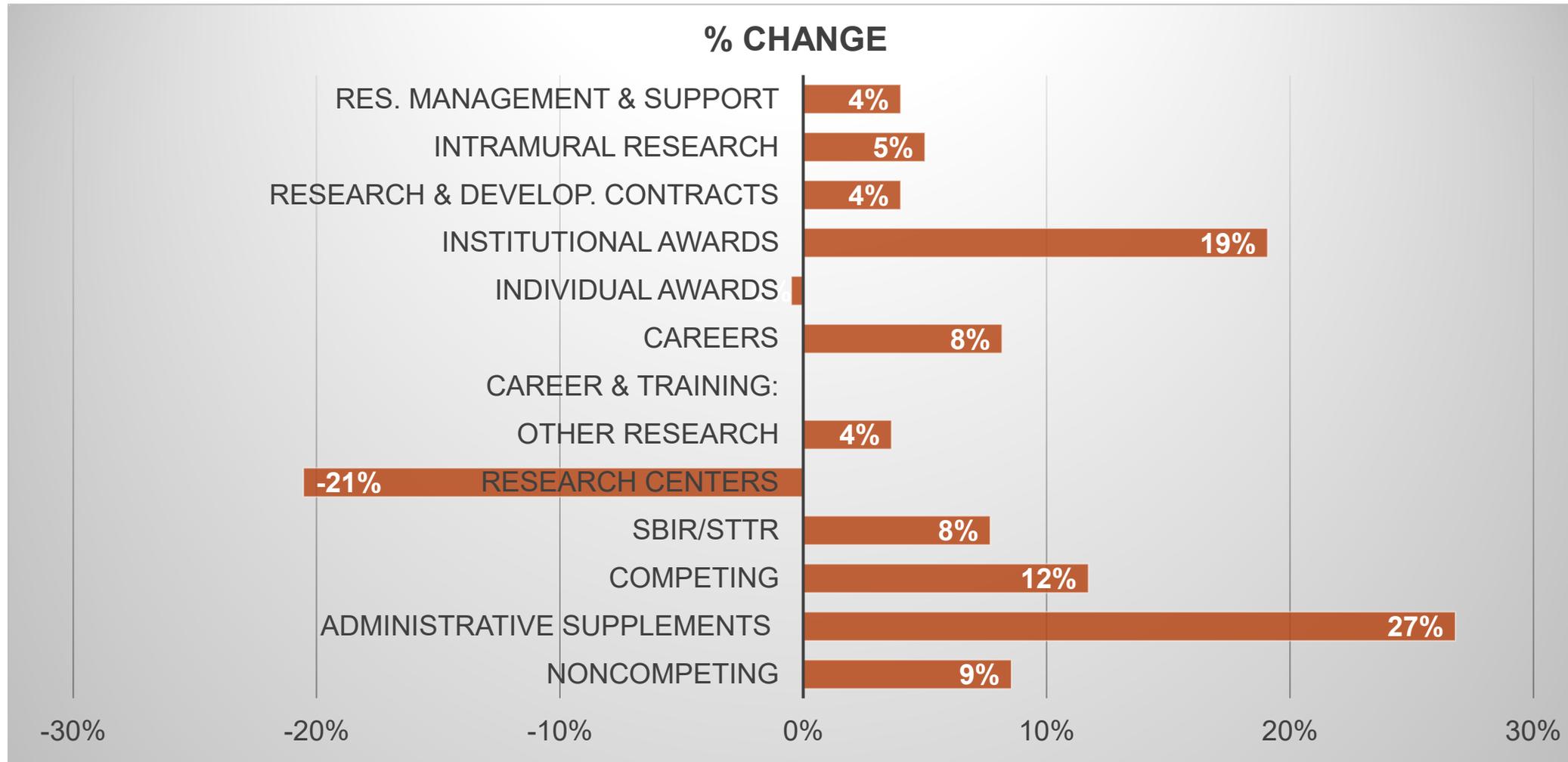
Website: <http://www.ninds.nih.gov/>



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# Comparing FY 2020 Operating Budget to FY 2019: *NINDS Overall 8% Change*



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- The FY 2021 President's Budget has an average cut of 9% cut across NIH ICs.
- FY 2021 21<sup>st</sup> Century Cures for BRAIN is \$100M (\$50M to NINDS, \$50M to NIMH).

\* These columns do not include the monies that NINDS received for the HEAL Initiative and CURES Act.

\*\* These columns do not include the monies that NIH received for the PHS Evaluation, HEAL Initiative and CURES Act.

