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Welcome! Thank you for joining us for today's webinar. The program will begin shortly. You will not hear the audio until we begin. If you have technical questions,

please email

aamc@commpartners.com.

# **Today's Conversation With...**





*Moderator* **Christa Wagner, PhD** Senior Legislative Analyst Association of American Medical Colleges

Speaker Michael S. Lauer, MD NIH Deputy Director for Extramural Research Director, Office of Extramural Research



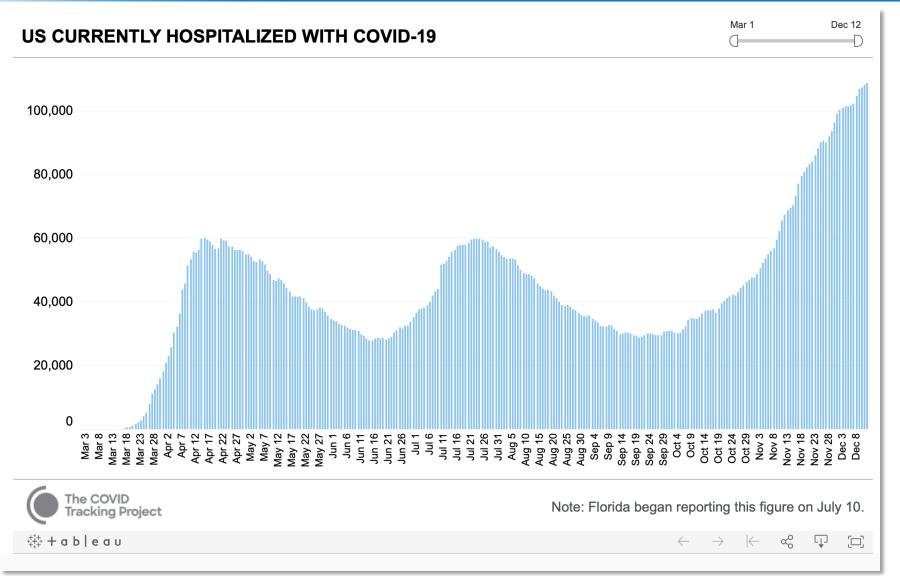
# Update from the NIH Office of Extramural Research

Michael S Lauer, MD NIH Deputy Director for Extramural Research Director, Office of Extramural Research (OER)

AAMC GREAT and GRAND Webinar Tuesday, December 15, 2020



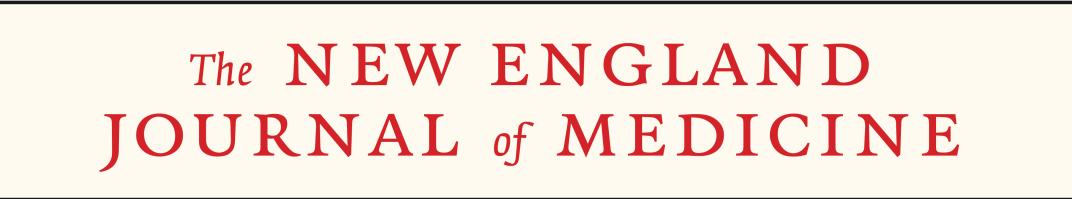
#### 9 Months of COVID-19!





https://covidtracking.com/data/charts/us-currently-hospitalized

4



ESTABLISHED IN 1812

NOVEMBER 5, 2020

VOL. 383 NO. 19

## Remdesivir for the Treatment of Covid-19 — Final Report

J.H. Beigel, K.M. Tomashek, L.E. Dodd, A.K. Mehta, B.S. Zingman, A.C. Kalil, E. Hohmann, H.Y. Chu, A. Luetkemeyer, S. Kline, D. Lopez de Castilla, R.W. Finberg, K. Dierberg, V. Tapson, L. Hsieh, T.F. Patterson, R. Paredes, D.A. Sweeney, W.R. Short, G. Touloumi, D.C. Lye, N. Ohmagari, M. Oh, G.M. Ruiz-Palacios, T. Benfield, G. Fätkenheuer, M.G. Kortepeter, R.L. Atmar, C.B. Creech, J. Lundgren, A.G. Babiker, S. Pett, J.D. Neaton, T.H. Burgess, T. Bonnett, M. Green, M. Makowski, A. Osinusi, S. Nayak, and H.C. Lane, for the ACTT-1 Study Group Members\*

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The NEW ENGLAND JOURNAL of MEDICINE

## SPECIAL REPORT

# Rapid Scaling Up of Covid-19 Diagnostic Testing in the United States — The NIH RADx Initiative

Bruce J. Tromberg, Ph.D., Tara A. Schwetz, Ph.D., Eliseo J. Pérez-Stable, M.D., Richard J. Hodes, M.D., Richard P. Woychik, Ph.D., Rick A. Bright, Ph.D., Rachael L. Fleurence, Ph.D., and Francis S. Collins, M.D., Ph.D.



https://www.nejm.org/doi/pdf/10.1056/NEJMsr2022263?articleTools=true

#### **Scientific Triumphs: Vaccine**

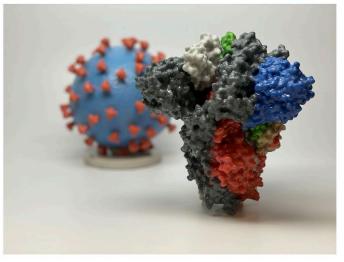
#### NEWS RELEASES

Monday, November 16, 2020

## Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine

#### 🖶 🗹 f 🕑 +

An independent data and safety monitoring board (DSMB) overseeing the Phase 3 trial of the investigational COVID-19 vaccine known as mRNA-1273 reviewed trial data and shared its interim analysis with the trial oversight group on Nov. 15, 2020. This interim review of the data suggests that the vaccine is safe and effective at preventing symptomatic COVID-19 in adults. The interim analysis comprised 95 cases of symptomatic COVID-19 among volunteers. The DSMB reported that the candidate was safe and welltolerated and noted a vaccine efficacy rate of 94.5%. The findings are statistically significant, meaning they are likely not due to chance. 90 of the cases occurred in the placebo group and 5 occurred in the vaccinated group. There were 11 cases of severe COVID-19 out of the 95 total, all of which occurred in the placebo group.



2D print of a spike protein of SAPS CoV 2 the virus that

7



Opinion

#### VIEWPOINT

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

#### Francis S. Collins, MD, PhD

Office of the Director, National Institutes of Health, Bethesda, Maryland.

**Paul Stoffels, MD** Johnson & Johnson, New Brunswick, New Jersey. It has been more than a century since the world has encountered a pandemic like coronavirus disease 2019 (COVID-19), and the rate of spread of COVID-19 around the globe and the associated morbidity and mortality have been staggering.<sup>1</sup> To address what may be the greatest public health crisis of this generation, it is imperative that all sectors of society work together in unprecedented ways, with unprecedented speed. In this Viewpoint, we describe such a partnership. First reported in Wuhan, China, in December 2019, academic experts. Participants sought urgently to identify research gaps and to discuss opportunities to collaborate in an accelerated fashion to address the complex challenges of COVID-19.

These critical discussions culminated in a decision to form a public-private partnership to focus on speeding the development and deployment of therapeutics and vaccines for COVID-19. The group assembled 4 working groups to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines (**Figure**).



#### On the Other Hand ...

# THE WALL STREET JOURNAL.

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https://www.wsj.com/articles/medical-research-is-locked-down-too-11588629492

#### 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

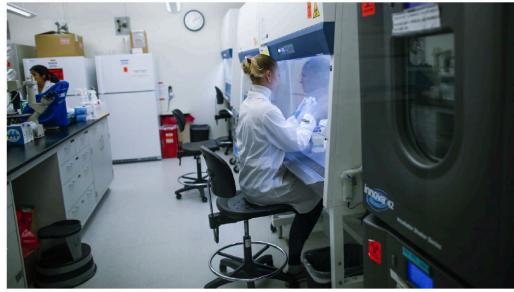
> I lead clinical trials for medications to treat crippling disorders such as stroke and brain hemorrhages. During the past few months, every one of these studies has come to a grin halt. The pandemic has thrown clinical trials, the lifeblood of new treatments, into disar

# STAT

Covid-19 has shuttered scientific labs. It could put a generation of researchers at risk

By Justin Chen

May 4, 2020



Kena Betancur/Getty Images



## **Disproportionate Effects**

# **ARE WOMEN PUBLISHING LESS DURING THE PANDEMIC? HERE'S WHAT THE DATA SAY**

Early analyses suggest female academics are posting fewer preprints than men, and starting fewer projects.

#### **By Giuliana Viglione**



Two separate analyses show that women's posting rate on preprint servers has slowed uarantined with a six-year-old child during the coronavirus pandemic. underfoot, Megan Frederickson wondered how academics were managing

#### All-author analysis

When compared with March and April 2019, the number of male authors on preprints posted to bioRxiv and arXiv has grown faster than the number of female authors in that period this year.

```
Mar–Apr 2019 Mar–Apr 2020
  arXiv: 2019 vs 2020
                        bioRxiv: 2019 vs 2020
```

#### Nature, May 28, 2020

https://media.nature.com/original/magazine-assets/d41586-020-01294-9/d41586-020-01294-9.pdf

### The Virus Moved Female Faculty to the Brink. Will Universities Help?

The pandemic is a new setback for women in academia who already faced obstacles on the path to advancing their research and careers.



Lisa Warner in her lab at Boise State University. Alex Hecht for The New York Times

to write papers during the COVID-19

pandemic. Lockdowns implemented

to stem coronavirus spread meant that, overnight, many households worldwide had

become an intersection of work, school and

home life. Conversations on Twitter seemed





# Research Impact Under COVID-19

FINANCIAL CRISIS AND THE "PANDEMIC NORMAL"

- Restricted access to facilities
- Social distancing, shift-work
- Down-time (e.g. cleaning, COVID+)
- Continuous use of PPE
- New staff for COVID issues
- Disrupted supply chains, visitors
- Disrupted contact with human participants



## **OER Responsiveness**



#### **GRANTS & FUNDING** NIH Central Resource for Grants and Funding Information

HOME	ABOUT GRANTS	FUNDING	POLICY & COMPLIANCE	NEWS & EVER

Home » Policy & Compliance » NIH Extramural Response to Natural Disasters and Other Emergencies » Coronavirus Disease 2019 (COVID-19)

# POLICY & COMPLIANCECoronavirus Disease 2019 (COVID-19): Information for NIHPolicy TopicsApplicants and Recipients of NIH Funding

The NIH is deeply concerned for the health and safety of people involved in NIH research, and about the effects on the b

enterprise in the areas affected by the HHS declared public health emergency for COVID-19. Due to the potential exception

want to assure our recipient community that NIH will be doing our part to help you continue your research.

This is a rapidly evolving situation and we will provide updated guidance and information as it becomes available.

#### Natural Disasters

Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding

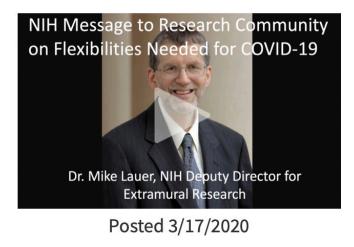
Applicant/Recipient COVID-19 Update History

See page update history.

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



Posted 3/26/2020 Duration 10:41



Duration 8:39



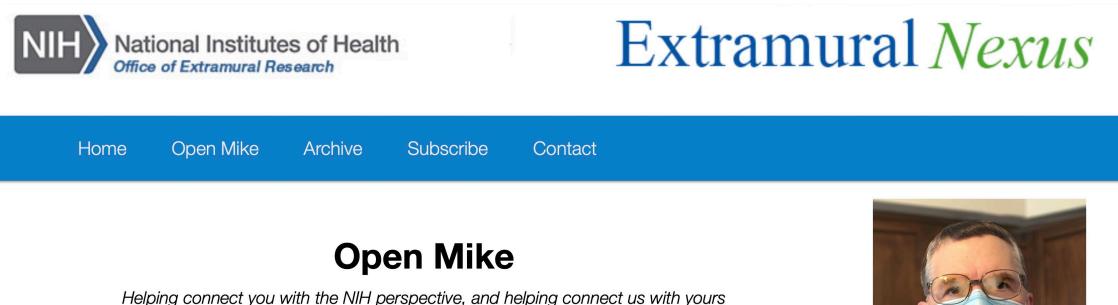
## **Outreach**

NII	National Institutes of Caboratory Anim		Office of La	aboratory Animal We	Bare		Search About OLAW Cont
Po	olicies and Laws 🛛 🗸	Guidance		Education -	Resource	ces 👻	
Home » COVID 19 Pa	ndemic Contingency Planning for Animal Ca	re and Use Programs					
COVID-19 Pandemic Contingency Planning for Animal Care and Use Programs							
The followi COVID-19	NIH GRANT NIH Central Reso	<b>S &amp; FUNDIN</b> Durce for Grants and Funding	G		Search this	Site eRA   NIH Staff 🗎   Glossar	he current
	HOME	ABOUT GRANTS	FUNDING	POLICY & COMPLIANCE	NEWS & EVENTS	ABOUT OER	
		H Extramural Response to Nature		mergencies » Coronavirus Disease 201	9 (COVID-19) » Funding Opportun	ities Specific to COVID-19	
	This page contains a listing of active and expired funding opportunities specific to Coronavirus Disease 2019 (COVID-19).						



https://olaw.nih.gov/covid-19.htm https://grants.nih.gov/grants/guide/COVID-Related.cfm

#### Always Learning ...



Posted on October 5, 2020 by Mike Lauer

Encouraging Participation in Upcoming NIH Surveys to Identify Impacts of COVID-19 on Extramural Research



Dr. Michael Lauer is NIH's Deputy Director for Extramural Research,

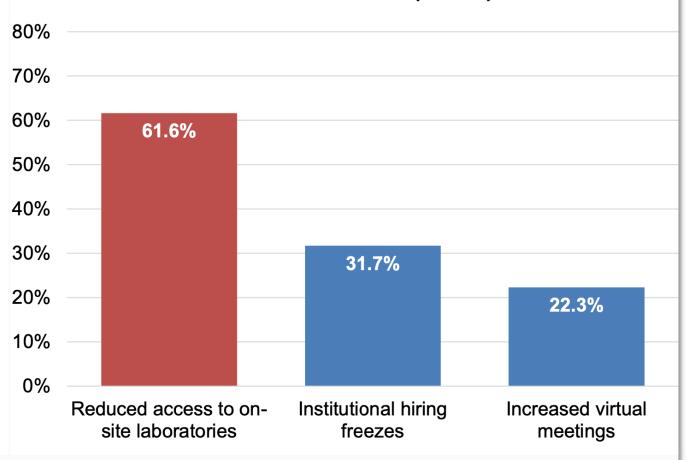


## Leaders: Thank You For Responding!

## **Response Data**

- 32% response rate
- 67% at a Doctorate Granting University
- Minority Serving Institutions accounted for 12% of institutions invited to participate, and 18% of total responses received

#### Factors that Most Negatively Impacted Research Functions (n=222)

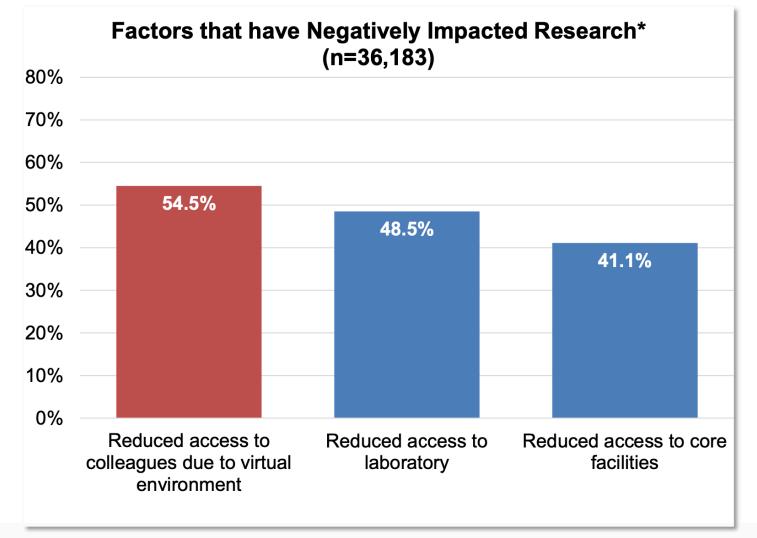




## **Researchers: Thank You for Responding!**

#### **Response Data**

- 19% response rate
- 77% at academic institutions
- 53% faculty members



\* Note: Number displayed may change upon data cleaning

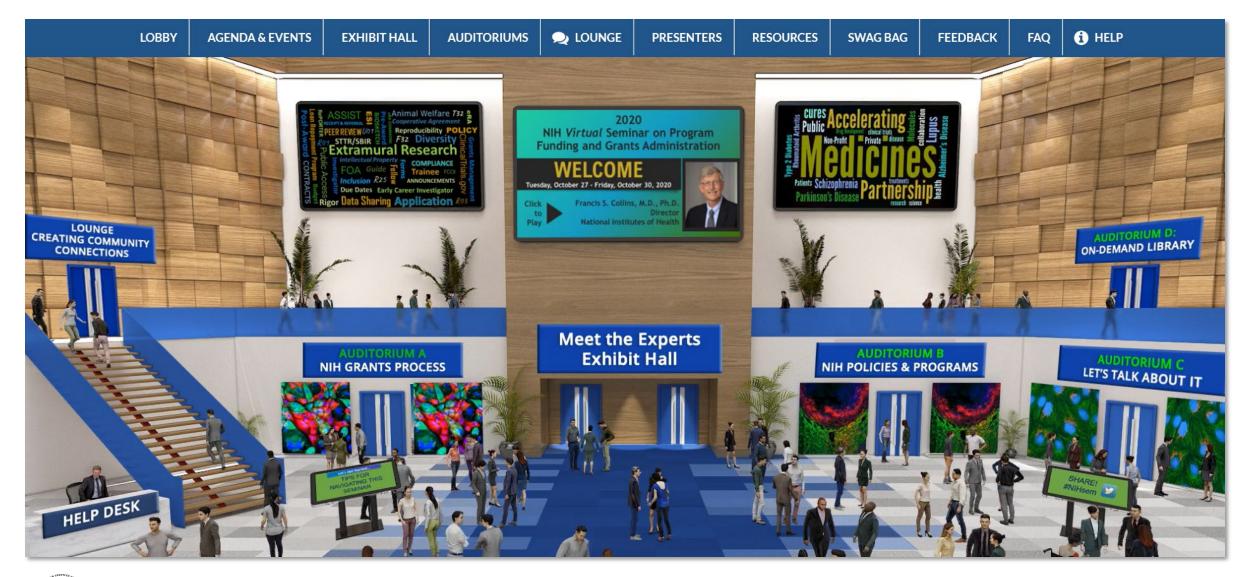




"The COVID19 crisis has magnified the systemic issues plaguing academic research ... oftenstifling excess requirements in publication, tenure, and grant processes; the reliance on funding from national agencies that is catered towards senior level researchers; and the lack of diversity in academic research due to the attrition of women and racial or ethnic minorities during early career stages ... An unprecedented opportunity to reset ... will require a concerted effort between funding agencies, universities, and the public to rethink how we support scientists, with a special emphasis on early career researchers."



#### Unprecedented ....





https://nihvirtualseminar2020.vfairs.com/



**Department of Justice** 

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, November 12, 2020

#### University Researcher Pleads Guilty to Lying on Grant Applications to Develop Scientific Expertise for China

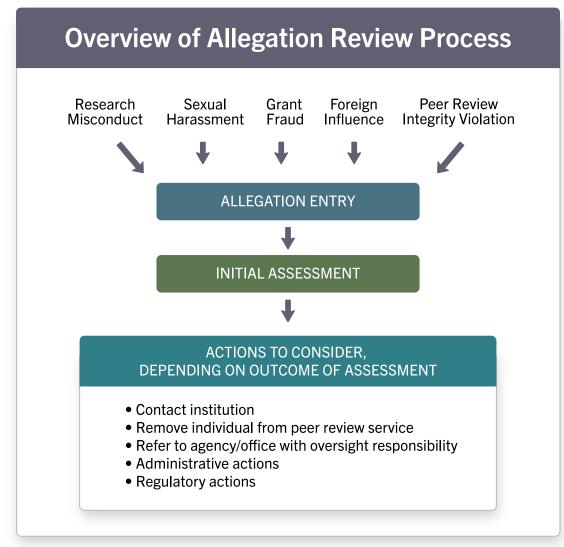
A rheumatology professor and researcher with strong ties to China pleaded guilty to making false statements to federal authorities as part of an immunology research fraud scheme.

Song Guo Zheng, 58, of Hilliard, appeared in federal court today, at which time his guilty plea was accepted by Chief U.S. District Judge Algenon L. Marbley.



https://www.justice.gov/opa/pr/university-researcher-pleads-guilty-lying-grant-applications-develop-scientific-expertise

## **Multiple Integrity Concerns**



National Institutes of Health

https://grants.nih.gov/grants/policy/harassment/actions-oversight/allegation-process.htm

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### **Integrity Outreach Efforts**



Search this Site Q	
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 NEWS & EVENTS
 ABOUT OER

Home » Policy & Compliance » Protecting U.S. Biomedical Intellectual Innovation

#### Protecting U.S. Biomedical Intellectual Innovation

**Policy Topics** 

POLICY & COMPLIANCE

Protecting U.S. Biomedical Intellectual Innovation NIH and the biomedical research enterprise have a long history of International collaborations with rules of engagement that allow science to advance while also protecting intellectual capital and proprietary information of the participating countries. These rules of engagement also are designed to limit bias in the design, conduct, and reporting of NIH-supported research. This page describes actions that NIH, institutions, and researchers can take to protect U.S. biomedical intellectual innovation. The principles described here align with those announced by the White House's Office and Science and Technology Policy in June 2020.

#### https://grants.nih.gov/policy/protecting-innovation.htm



#### **OSTP JCORE Trans-Government Efforts**

OF THE

## Enhancing the Security and Integrity of America's Research Enterprise

#### The White House Office of Science and Technology Policy

www.whitehouse.gov/ostp www.ostp.gov @WHOSTP





https://www.whitehouse.gov/wp-content/uploads/2020/07/Enhancing-the-Security-and-Integrity-of-Americas-Research-Enterprise.pdf

### On the Horizon ...

#### **Open Mike**

Helping connect you with the NIH perspective, and helping connect us with yours

Posted on October 29, 2020 by Carrie Wolinetz

# NIH Releases New Policy for Data Management and Sharing

Guest post by Carrie Wolinetz, Ph.D., NIH Associate Director for Science Policy, originally released on the <u>Under the Poliscope blog</u>

Today, nearly twenty years after the publication of the Final NIH Statement on Sharing Research Data in 2003, we have released a Final NIH Policy for Data Management and Sharing. This represents the agency's continued commitment to share and make broadly available the results of publicly funded biomedical research. We hope it will be a critical step in moving towards a culture change, in which data management and sharing is seen as integral to the conduct of research. Responsible data management and sharing is good for science; it maximizes availability of data to the best and brightest minds, underlies reproducibility, honors the participation of human participants by ensuring their data is both



Carrie Wolinetz, Ph.D.,
 Associate Director for Science
 Policy, NIH

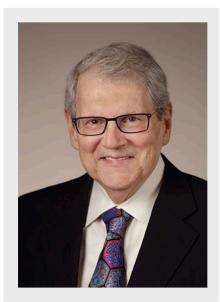
#### **Open Mike**

Helping connect you with the NIH perspective, and helping connect us with yours

Posted on November 9, 2020 by Mike Lauer

#### Introducing the Stephen I. Katz Early Stage Investigator Research Grant Program

Stephen I. Katz, M.D., Ph.D., led the National Institute of Arthritis and Musculoskeletal Diseases from 1995 until his passing in 2018. Dr. Katz was a talented physician scientist, NIH leader, and civil servant throughout his career who was profoundly dedicated to mentoring and training the next cadre of scientists. During his memorial service at NIH, you can see this dedication on full display. I, along with countless NIH colleagues, were blessed with Dr. Katz's mentoring and sage advice. That is why, in his honor, we are pleased to announce the publication of Funding Opportunity Announcements for the Stephen I. Katz Early Stage Investigator Research Project Grant program (PAR-21-038 and PAR-21-039).



— Stephen I. Katz, M.D., Ph.D.



#### And of Course, ... The Budget ...

## **NIH Operates Under a Continuing Resolution**

Notice Number: NOT-OD-21-009

## **Key Dates**

#### **Release Date:**

October 21, 2020

#### **Related Announcements**

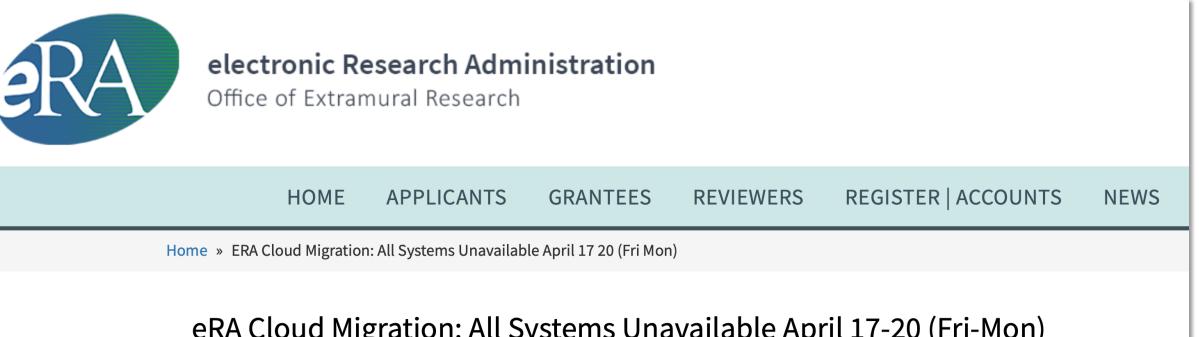
NOT-OD-20-065 - Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2020

NOT-OD-20-066 - Notice of Legislative Mandates in Effect for FY 2020

NOT-OD-20-068 - Notice of Fiscal Policies in Effect for FY 2020

NOT-OD-20-070 - Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2020



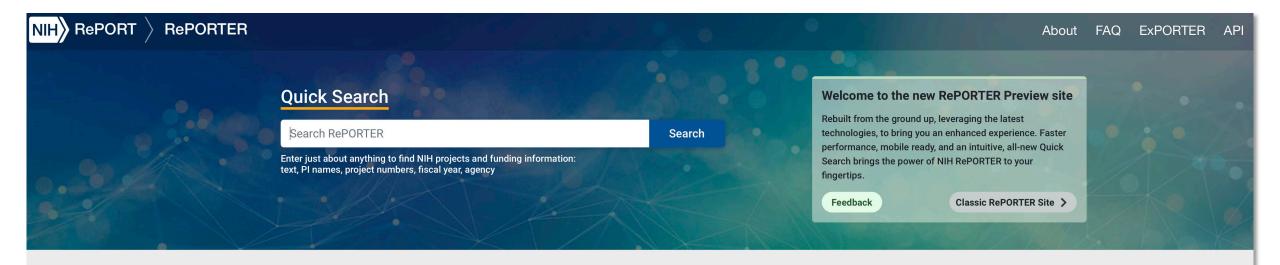


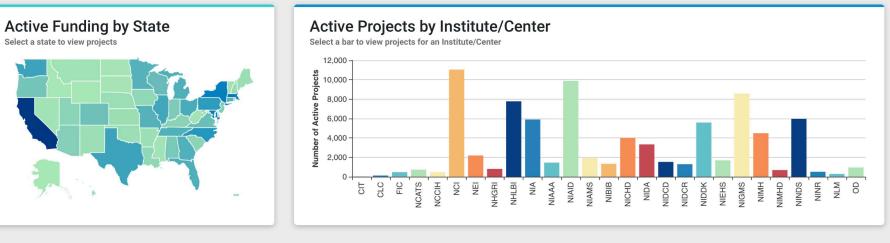
## eRA Cloud Migration: All Systems Unavailable April 17-20 (Fri-Mon)

https://era.nih.gov/era-cloud-migration.htm



## **Aiming for Even Better**





#### **Advanced Projects Search**

Matchmaker



https://reporter.nih.gov

- A bipolar year
  - Scientific triumphs: treatments, diagnosis, vaccines
  - Unprecedented disruptions and anxiety
  - Long-term effects evolving and unclear
- Multiple integrity concerns
- Outreach efforts in virtual world
- On the horizon: data sharing, early career



# Discussion

CONTACT Michael S. Lauer, MD NIH Deputy Director for Extramural Research Michael.Lauer@nih.gov



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