



# The View from the NIH Office of Extramural Research

Michael S Lauer, MD  
NIH Deputy Director for Extramural Research

GREAT/GRAND Community Forum  
May 12, 2020

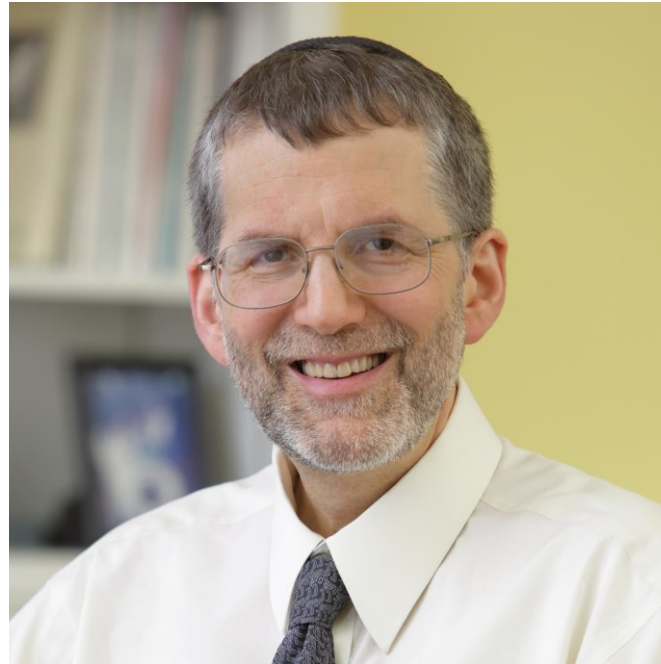
# Get Involved with GREAT and GRAND

Know someone not currently in GREAT or GRAND who might benefit from these conversations and networking? Tell them to email [GREAT@aamc.org](mailto:GREAT@aamc.org) or [GRAND@aamc.org](mailto:GRAND@aamc.org) and ask to join the group.

GREAT and GRAND weekly community calls bring group members together to discuss how their institutions are responding to the coronavirus. To be invited, email Sr. Administrative Associate Emily Outtarac at [eouttarac@aamc.org](mailto:eouttarac@aamc.org).

Next Community Forum on June 10 3:00 – 4:00 pm ET : NIGMS Director's Update with Jon Lorsch, PhD

# The View from the NIH Office of Extramural Research

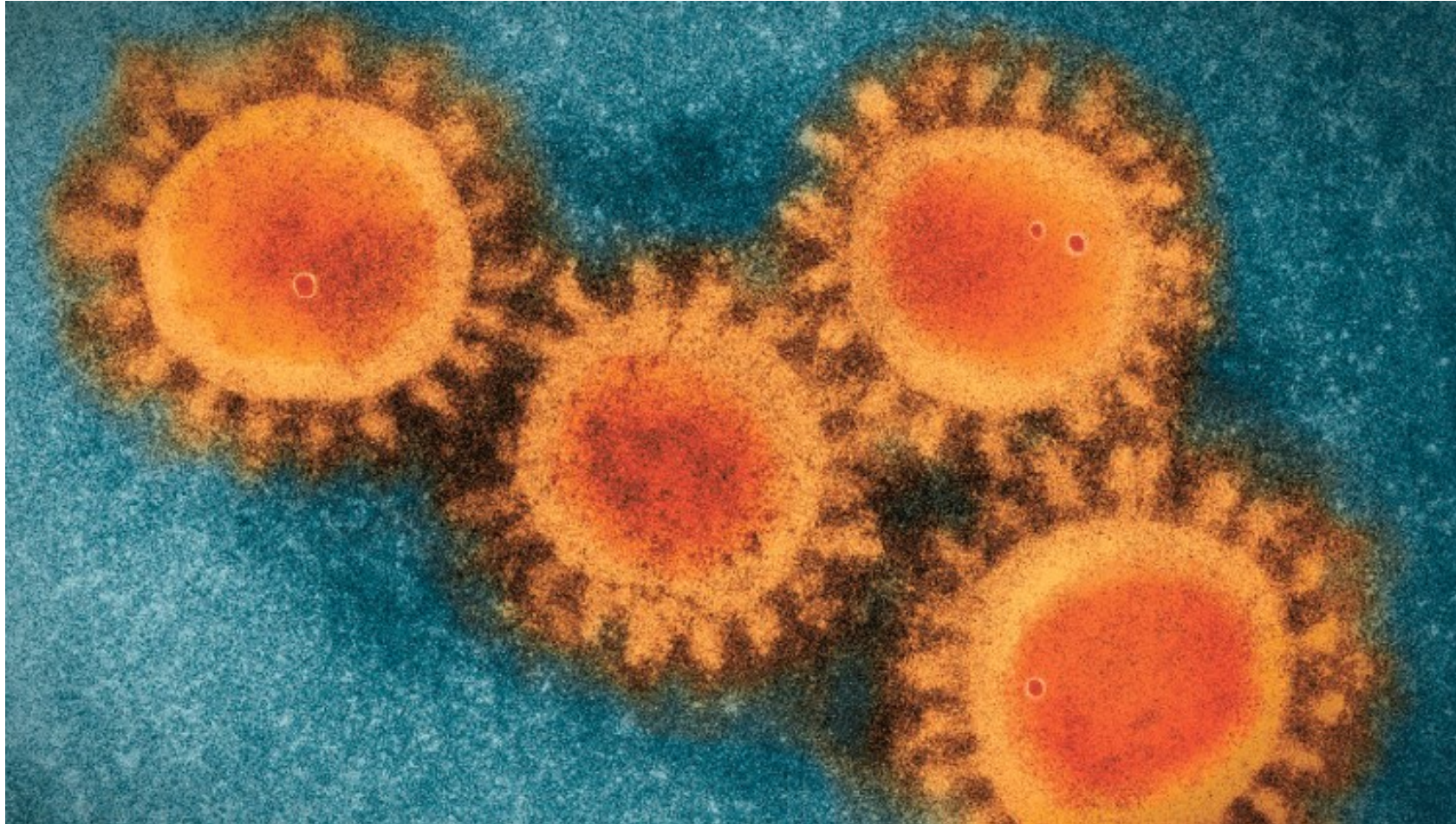


**Michael S Lauer, MD**

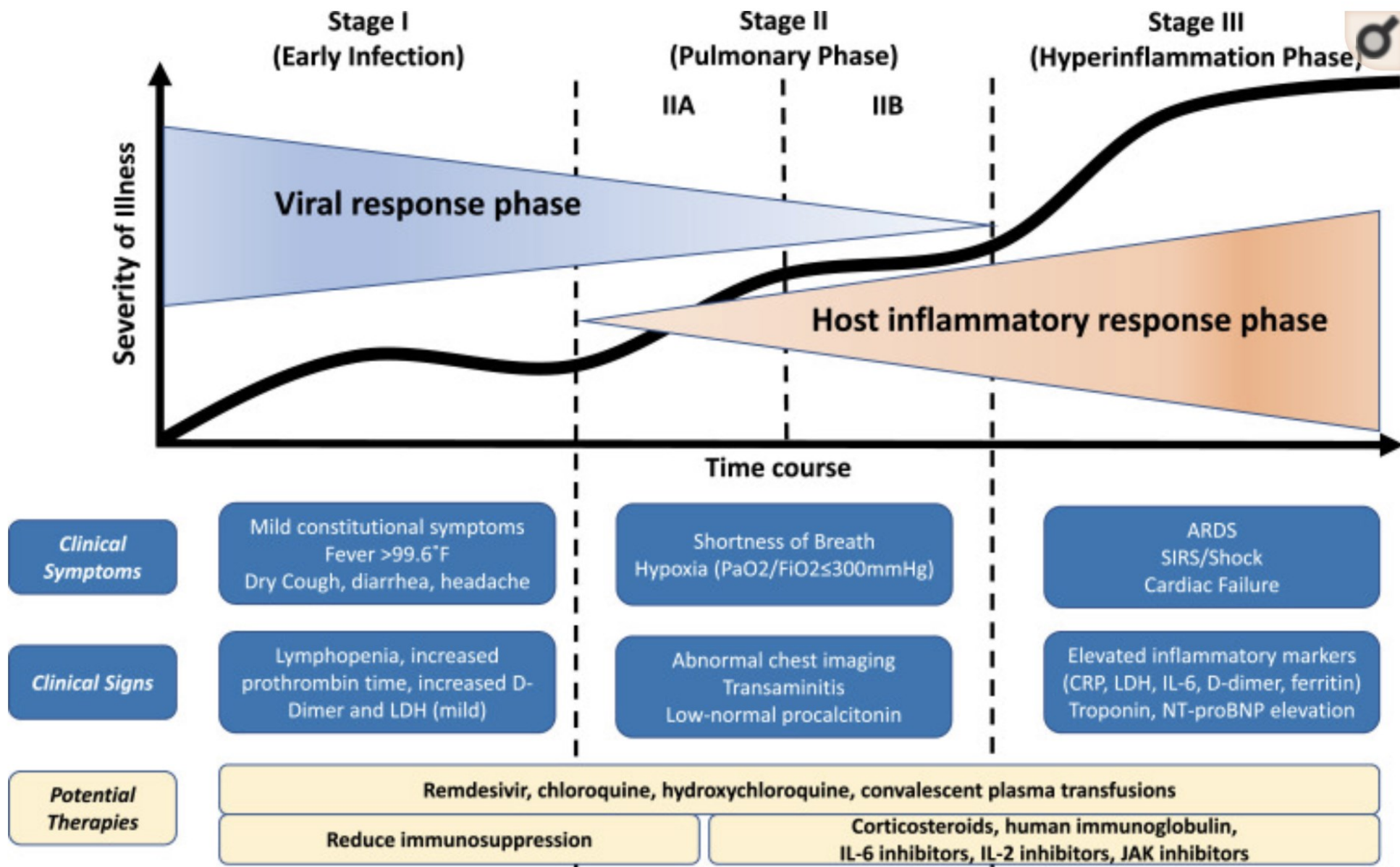
NIH Deputy Director for Extramural Research

[michael.lauer@nih.gov](mailto:michael.lauer@nih.gov)

# A “Novel” Virus





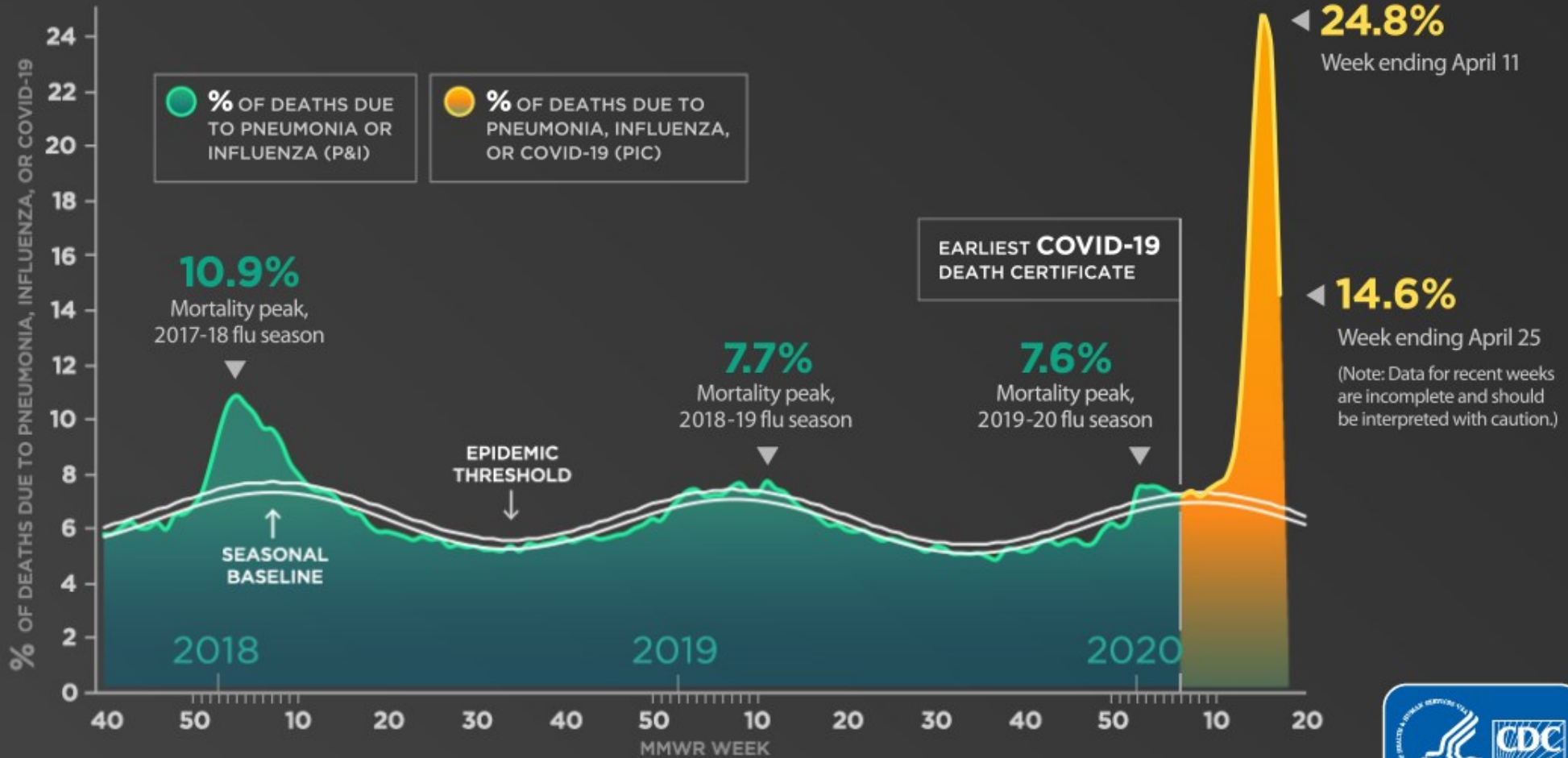


# Interesting Features of COVID-19

- Highly contagious ( $R_0 \sim 2.5$  to 3.0)
- Often asymptomatic
- Two-phase pattern
- “Cytokine storm” leading to respiratory, multisystem failure
- Hypercoagulability
- Extra-pulmonary complications (e.g. CNS, CVS, even toes)
- Disproportionate effects on URM, elderly, chronic disease

# U.S. Mortality: Death Certificates Listing Pneumonia, Influenza, and COVID-19

DATA THROUGH WEEK ENDING APRIL 24, 2020\*



\*Data are preliminary and may change as more reports are received.

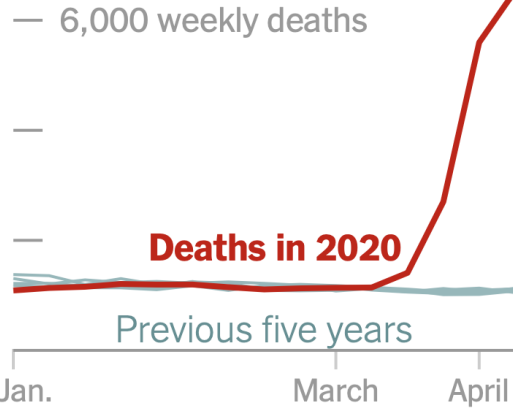
[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

For more NCHS COVID-19 mortality info, see <https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm>

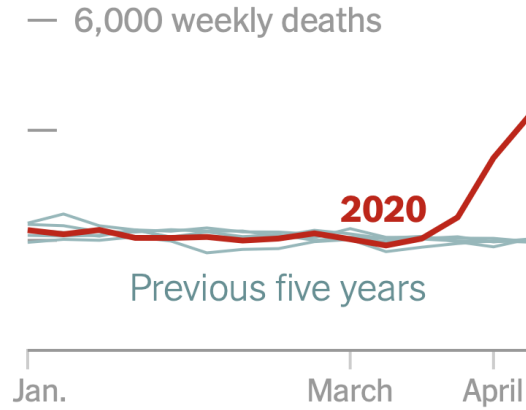


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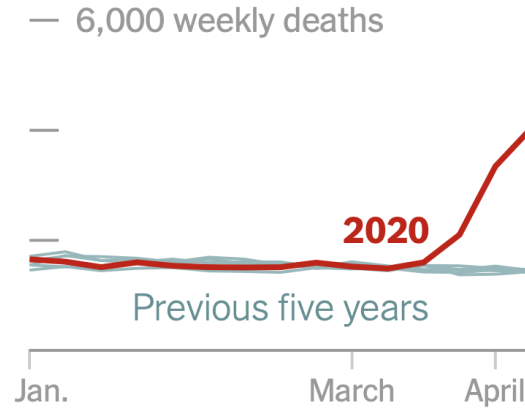
### New York City



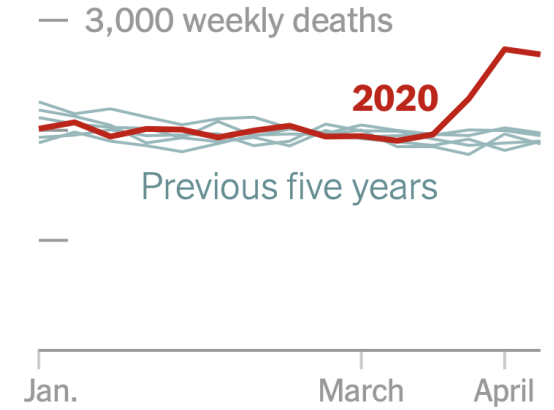
### New York (excluding N.Y.C.)



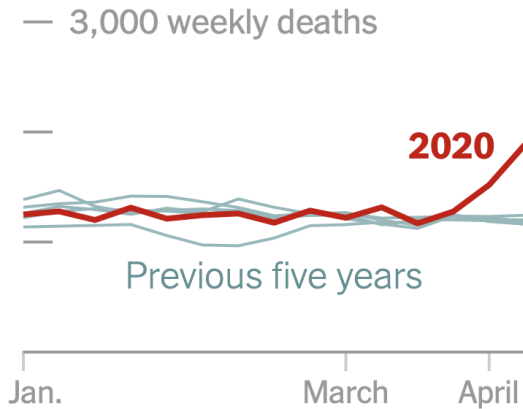
### New Jersey



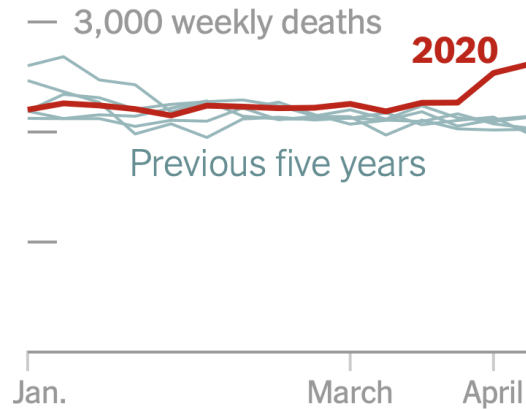
### Michigan



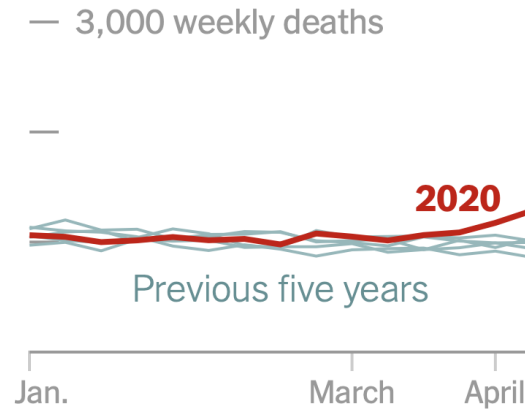
### Massachusetts



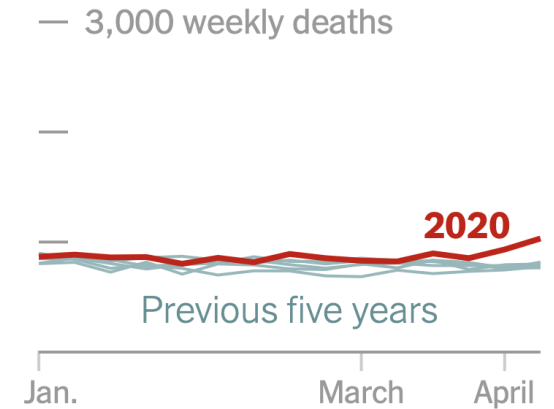
### Illinois



### Maryland



### Colorado





# 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

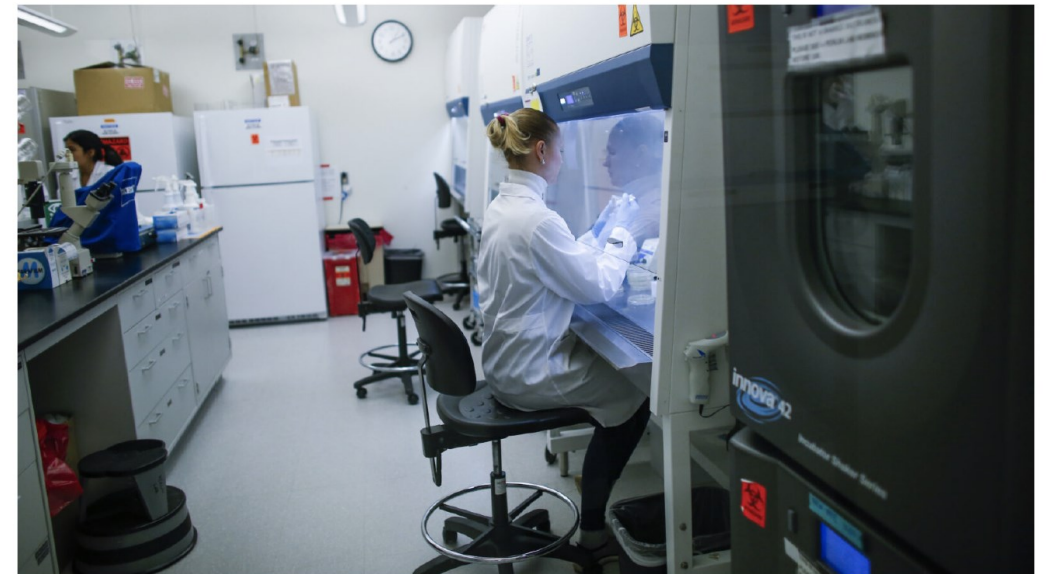
I lead clinical trials for medications to treat crippling disorders such as stroke and brain hemorrhages. During the past few months, every one of these studies has come to a grin halt. The pandemic has thrown clinical trials, the lifeblood of new treatments, into disar

## 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*

Pharmaceutical & Life Sciences News



Francis Collins, director of the National Institutes of Health, testifies during a Senate panel hearing on May 7, 2020.

Photographer: Andrew Harnik/AP Photo/Bloomberg

# Virus Will Cost NIH \$10 Billion in Lost Research, Director Warns (1)

May 7, 2020, 1:35 PM; Updated: May 7, 2020, 3:22 PM

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- NIH's Collins testifies before Senate health panel on testing
- \$10 billion in lost research due to lost productivity, employment costs



Jeannie Baumann  
Reporter

Twitter Email



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# Effects of COVID-19 on the Federal Research and Development Enterprise

April 10, 2020

# Extensive Disruption

- Laboratories closed or nearly so
- Communications suboptimal
- Conferences and meetings cancelled or disrupted
- Supply chains interrupted; resources lost
- Widespread financial losses
- Required telework has disparate effects (e.g. childcare)
- Anxiety high, especially for early career investigators

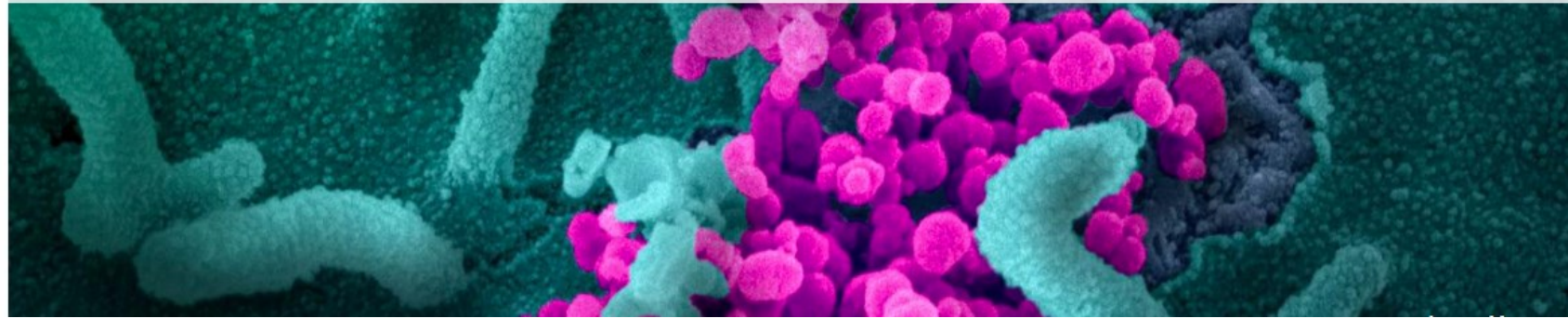
<https://crsreports.congress.gov/product/pdf/R/R46309>

Stay Up  
to Date

- This is a rapidly evolving situation
- Information provided in this presentation is current as of May 10, 2020

## CORONAVIRUS DISEASE 2019 (COVID-19)

Information for Applicants and Recipients



Visit our page and check back often for updates!

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



# Patient Care and Researcher Safety is the First Priority

- The NIH is deeply concerned for the health and safety of people involved in NIH research, and about the effects of the COVID-19 public health emergency on the biomedical enterprise.
- NIH is providing many administrative flexibilities to help the research continue.

# COVID-19 Funding Opportunities

- Funding through competing supplements, administrative supplements, new awards
- Many opportunities listed on [Coronavirus Disease 2019 \(COVID-19\): Information for NIH Applicants and Recipients of NIH Funding](#) website



# NIH Efforts



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## ! COVID-19 is an emerging, rapidly evolving situation

Get the latest public health information from CDC: <https://www.coronavirus.gov>  
Get the latest research information from NIH: <https://www.nih.gov/coronavirus>

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## NEWS RELEASES

Friday, April 17, 2020

### NIH to launch public-private partnership for COVID-19 vaccine and treatment options

*Health agencies, leading pharmaceutical companies to join for rapid response.*



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## ! COVID-19 is an emerging, rapidly evolving situation.

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Get the latest research information from NIH: <https://www.nih.gov/coronavirus>

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## NEWS RELEASES

Wednesday, April 29, 2020

### NIH mobilizes national innovation initiative for COVID-19 diagnostics

*Initiative aims to speed delivery of accurate, easy-to-use, scalable tests to all Americans.*



Institute/Center

[NIH Office of the Director \(OD\)](#)

Contact

[NIH Office of Communications](#)  
301-496-5787

Connect with Us



# Already Some Results

## NEWS RELEASES

Wednesday, April 29, 2020

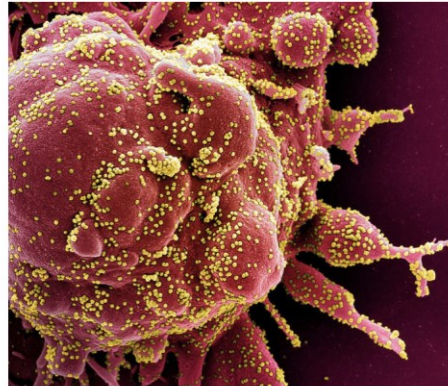
### NIH clinical trial shows Remdesivir accelerates recovery from advanced COVID-19



Hospitalized patients with advanced COVID-19 and lung involvement who received remdesivir recovered faster than similar patients who received placebo, according to a preliminary data analysis from a randomized, controlled trial involving 1063 patients, which began on February 21. The trial (known as the [Adaptive COVID-19 Treatment Trial](#), or ACTT), sponsored by the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#), part of the National Institutes of Health, is the first clinical trial launched in the United States to evaluate an experimental treatment for COVID-19.

An independent data and safety monitoring board (DSMB) overseeing the trial met on April 27 to review data and shared their interim analysis with the study team. Based upon their review of the data, they noted that remdesivir was better than placebo from the perspective of the primary endpoint, time to recovery, a metric often used in influenza trials. Recovery in this study was defined as being well enough for hospital discharge or returning to normal activity level.

Preliminary results indicate that patients who received remdesivir had a 31%



Colorized scanning electron micrograph of an apoptotic cell (red) heavily infected with SARS-CoV-2 virus particles (yellow), isolated from a patient sample. Image captured at the NIAID Integrated Research Facility (IRF) in Fort Detrick, Maryland. *NIAID*

## NEWS RELEASES

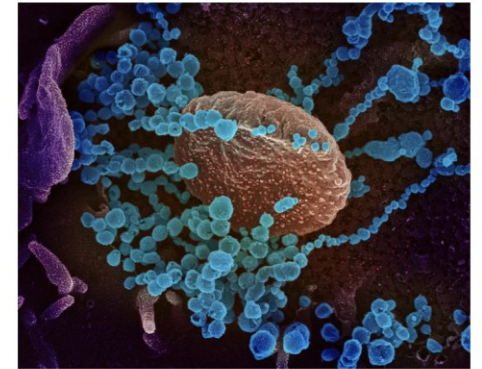
Friday, May 8, 2020

### NIH clinical trial testing antiviral remdesivir plus anti-inflammatory drug baricitinib for COVID-19 begins



A randomized, controlled clinical trial evaluating the safety and efficacy of a treatment regimen of the investigational antiviral remdesivir plus the anti-inflammatory drug baricitinib for coronavirus disease 2019 (COVID-19) has begun. The trial is now enrolling hospitalized adults with COVID-19 in the United States. The trial is expected to open at approximately 100 U.S. and international sites. Investigators currently anticipate enrolling more than 1,000 participants. [National Institute of Allergy and Infectious Diseases \(NIAID\)](#), part of the National Institutes of Health, is sponsoring the trial.

The clinical trial is the next iteration of NIAID's [Adaptive COVID-19 Treatment Trial \(ACTT\)](#), which began on Feb. 21 to evaluate remdesivir, an investigational broad-spectrum antiviral treatment developed by Gilead Sciences, Inc. That trial closed to enrollment on April 19 after recruiting 1,063 participants at 47 U.S. and 21 international sites. An independent data and safety monitoring board (DSMB) overseeing the trial met on April 27 and shared their preliminary analysis with the study sponsor, NIAID. Their analysis showed that **patients who received remdesivir had a statistically significant shorter time to recovery compared to patients who received placebo**. More detailed information about



This scanning electron microscope image shows SARS-CoV-2 (round blue objects) emerging from the surface of cells cultured in the lab. SARS-CoV-2, also known as 2019-nCoV, is the virus that causes COVID-19. The virus shown was isolated from a patient in the U.S. Image captured and colorized at NIAID's Rocky Mountain Laboratories (RML) in Hamilton, Montana. *NIAID*

# NIH is Open for Business

- Extramural staff are working remotely
- We continue to process applications and make awards
- We are conducting peer review meetings virtually
- We are working diligently to provide funding opportunities to support COVID-19 research



# Accommodations and Flexibilities

- Application deadlines
- Donating research supplies
- Salaries and stipends
- Human subject research, clinical trials
- Animal research, guidance to IACUCs
- Extensions on reporting; flexibility on expenditures
- Accommodations for loss of time

# Advice for Applicants & Recipients


- For general questions regarding COVID-19 flexibilities, contact NIH's Office of Extramural Research at [grantspolicy@nih.gov](mailto:grantspolicy@nih.gov)
- For questions specific to your NIH award, contact the grants management or program staff at the funding institute or center



FAQs frequently updated. Check back often!

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

# Considerations for Reopening

 **Duke University School of Medicine** Search

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## Reopening Research Laboratories



Duke University policies for employees approved to return to research laboratories in phase 3 of the response to the COVID-19 pandemic

[General Principles](#)

[Daily Reporting](#)

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## COVID-19

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## A Plan for a Phased Reopening Guided by Public Health Principles

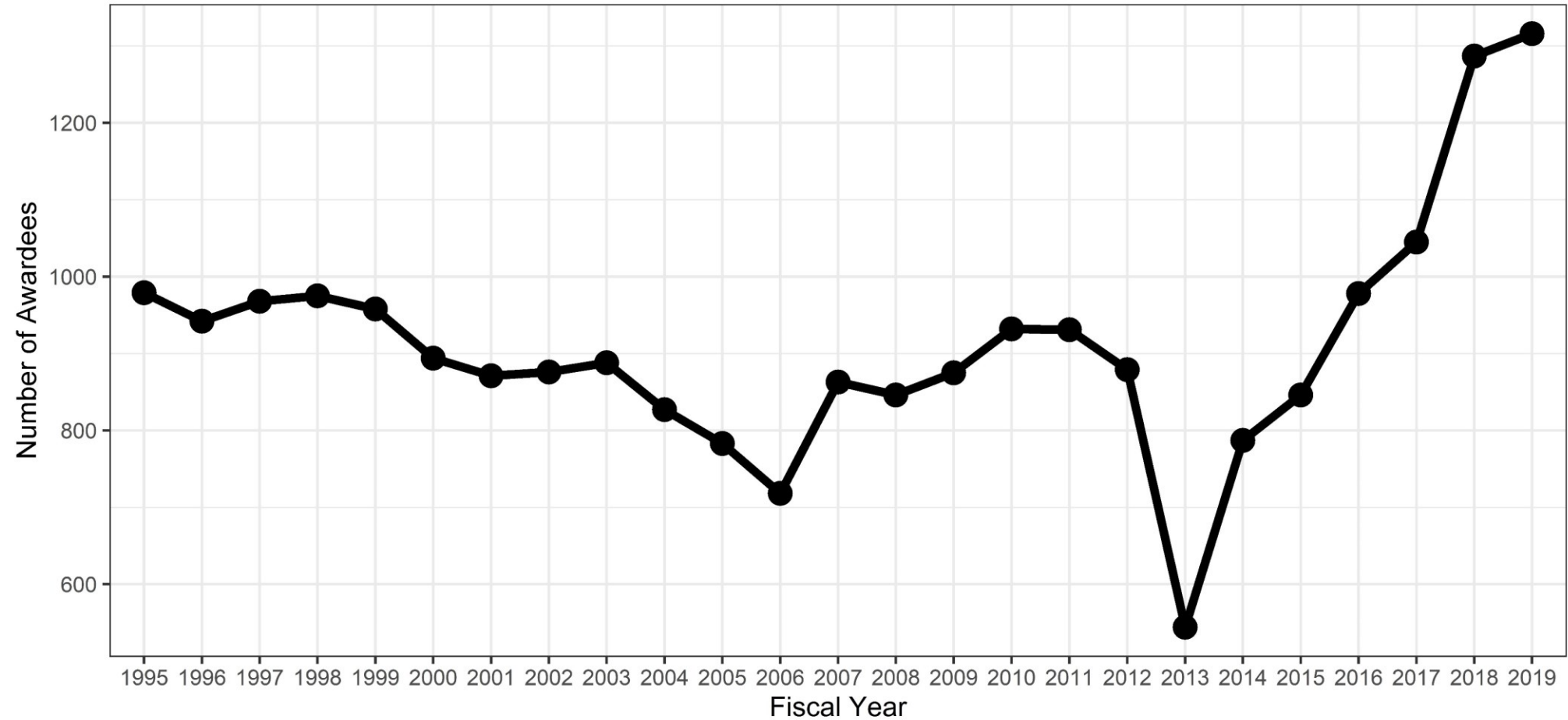
A report from the Johns Hopkins Center for Health Security aims to help governors navigate the process

APRIL 17, 2020

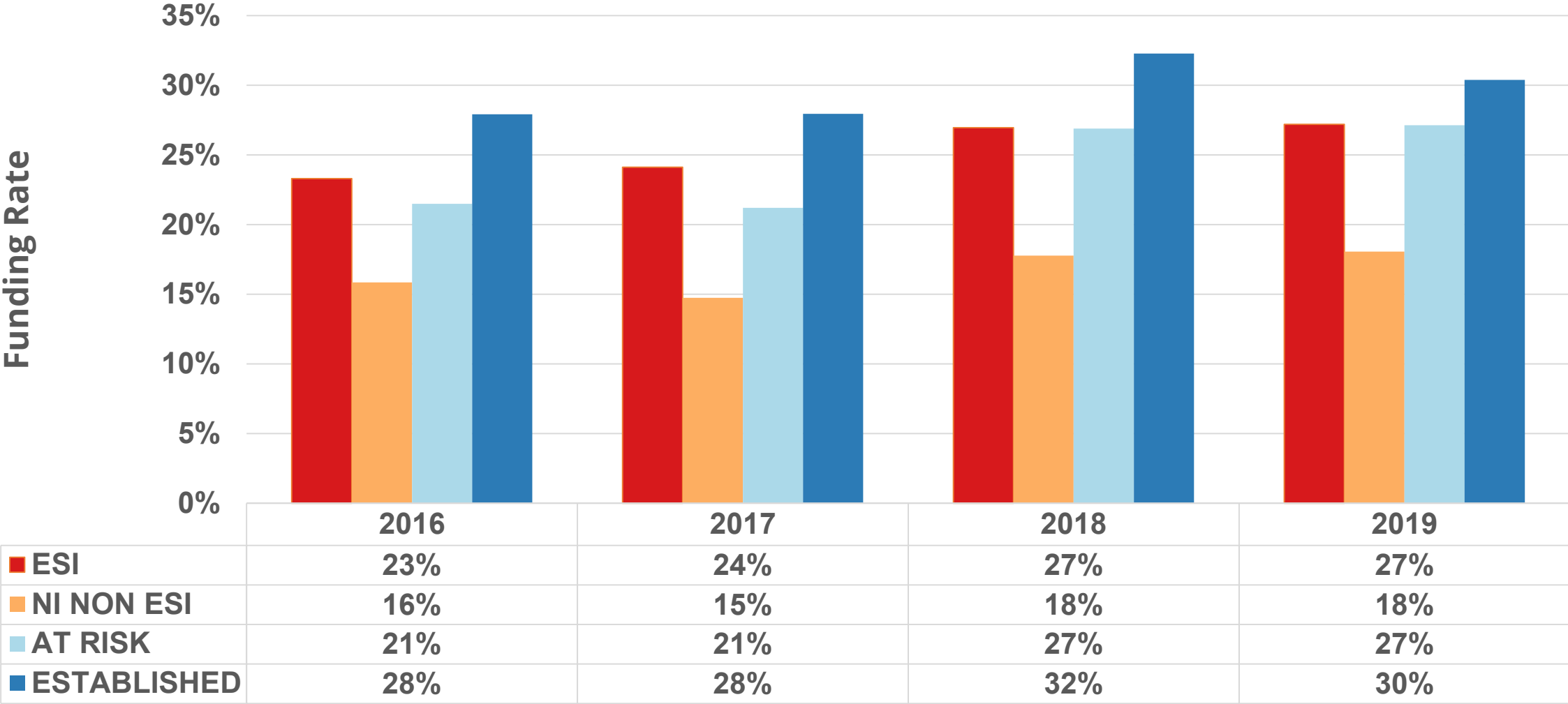
The U.S. is collectively and eagerly awaiting Reopening Day.

# Other NIH Priorities: NGRI

NIH Type 1 R01-Equivalent ESI Awardees



# At-Risk Investigators





# Expanding Loan Repayment Program

U.S. Department of Health & Human Services National Institutes of Health

FAQs A-Z Index

**NIH** National Institutes of Health  
Division of Loan Repayment

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Awards are now up to \$100,000 over a two-year period. Use the repayment calculator to get an estimate on the amount of your award. >

APPLY AWARD RENEW

# Addressing Sexual Harassment

## CHANGING THE CULTURE TO END SEXUAL HARASSMENT

December 2019

Working Group  
report to the  
Advisory  
Committee to  
the NIH  
Director (ACD)

# Addressing Sexual Harassment: Themes

- Transparency and accountability in reporting
- Establish mechanisms for restorative justice
- Ensure safe, diverse, and inclusive research and training environments
- Create system-wide change to ensure safe, diverse, and inclusive research environments

# Foreign Interference



## Department of Justice

FOR IMMEDIATE RELEASE  
THURSDAY, DECEMBER 19, 2019  
[WWW.JUSTICE.GOV](http://WWW.JUSTICE.GOV)

Office of Public Affairs  
(202) 514-2007  
TTY (866) 544-5309

### **DEPARTMENT OF JUSTICE REACHES \$5.5 MILLION SETTLEMENT WITH VAN ANDEL RESEARCH INSTITUTE TO RESOLVE ALLEGATIONS OF UNDISCLOSED CHINESE GRANTS TO TWO RESEARCHERS**

WASHINGTON — The Department of Justice announced today that Van Andel Research Institute (VARI) has agreed to pay \$5,500,000.00 to resolve allegations that it violated the False Claims Act by submitting federal grant applications and progress reports to the National Institutes

# Much Activity

OPINION

## University of Florida swiftly addressed foreign research controversy | Column

The university worked with NIH and law enforcement and stemmed the problem quickly, writes the chair of UF's board of trustees.

FOREIGN INFLUENCE

## Florida center details fired scientists' links to China

Report finds six cancer researchers didn't disclose Thousand Talents deals

By Jeffrey Mervis

THE WALL STREET JOURNAL.

POLITICS | NATIONAL SECURITY

## Harvard Chemistry Chairman Charged on Alleged Undisclosed Ties to China

Charles Lieber is accused of lying to Defense Department, National Institutes of Health about Chinese government funding

 NEWS

## Emory professor hit with criminal charge, linked to Chinese government program

Xiojiang Li was a member of the Thousand Talents plan, a Chinese program that a Senate report last year said was designed to steal sensitive research.



# Increased Attention

United States Senate  
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS  
Committee on Homeland Security and Governmental Affairs  
Rob Portman, Chairman  
Tom Carper, Ranking Member

## Threats to the U.S. Research Enterprise: China's Talent Recruitment Plans

STAFF REPORT

PERMANENT SUBCOMMITTEE ON  
INVESTIGATIONS

UNITED STATES SENATE



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF SCIENCE AND TECHNOLOGY POLICY  
WASHINGTON, D.C. 20502

September 16, 2019

Letter to the United States Research Community

Dear Colleagues,

As a fellow researcher and former university vice president for research, I know firsthand that the open and internationally collaborative nature of the United States research enterprise has been critical to our success in research, and that this success has underpinned our Nation's prosperity and security. Indeed, the values we cherish as Americans are the ethos of research itself; namely, the freedom to explore new frontiers, the commitment to openness and transparency through the sharing of methods and results, the ability to debate difficult issues thoughtfully and with civility, and the passion to work with and improve the lives of others. By adhering to these values and operating with due regard to principles of integrity – including reciprocity, openness, and transparency – your work has made America the world leader in science and technology. The Nation is indebted to you.

Yet we must not take our research enterprise or its global leadership position for granted. Over the past several years, some nations have exhibited increasingly sophisticated efforts to exploit, influence, and undermine our research activities and environments. As researchers, we must acknowledge the changing geopolitical and international scientific landscape: United States policies and practices must evolve thoughtfully and appropriately to meet current and future challenges. The success of our research enterprise is dependent on *everyone* upholding the principles of research.

Some of those recent efforts to exploit America's research enterprise have come through foreign government-sponsored talent recruitment programs. Historically, researchers at United States institutions could in many cases participate in a talent program and simultaneously receive both foreign and United States government support. Under some circumstances, this may still be acceptable. However, it has become clear that features of some talent programs are unacceptable and inconsistent with our research values and research principles. Breaches of research ethics, both within talent programs and more generally, include the failure to disclose required information such as foreign funding, unapproved parallel foreign laboratories (so-called shadow labs), affiliations and appointments, and conflicting financial interests. Other inappropriate behaviors include conducting undisclosed research for foreign governments or companies on United States agency time or with United States agency funding, diversion of intellectual property or other legal rights, and breaches of contract and confidentiality in or surreptitious gaming of the peer-review process.

Ultimately, these inappropriate behaviors, whether or not they arise through participation in a foreign talent program, interfere with the allocation of Federal funding in a fair manner based on merit. As a result, these breaches of research security and integrity position others to reap the benefits of your hard work without bearing the associated risks or making the investments borne by American taxpayers and other funders. These activities ultimately undermine the integrity of the research enterprise and, thus, our economic and national security.

## Fundamental Research Security

Contact: Gordon Long – [glong@mitre.org](mailto:glong@mitre.org)

JSR-19-2I

December 2019

DISTRIBUTION A: Approved for public release; distribution unlimited.

JASON  
The MITRE Corporation  
7515 Colshire Drive  
McLean, Virginia 22102  
(703) 983-6997

# Off the Press



## AMERICA CHALLENGES CHINA'S NATIONAL TALENT PROGRAMS

BY DAVID ZWEIG AND SIQIN KANG | No. 4 | MAY 2020

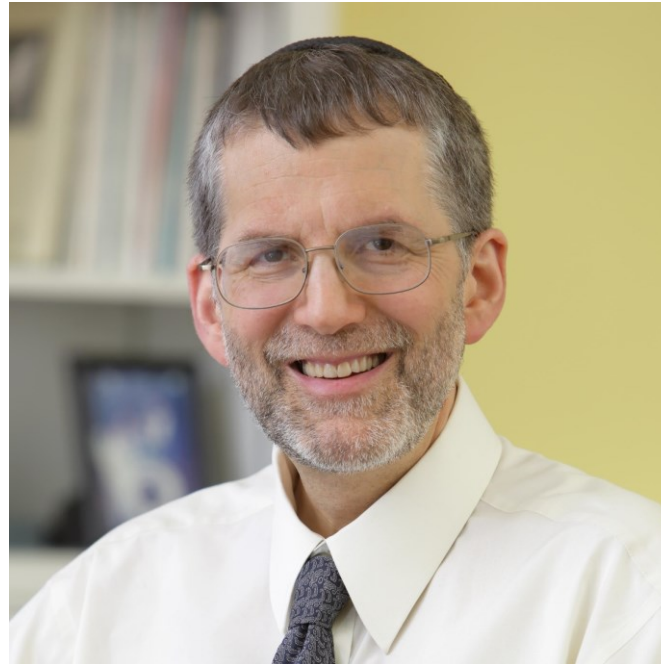
“Another major problem is the Foreign Thousand Talents Plan, through which China hires senior American researchers, sometimes in secret, who transfer the product of their own research to China. However, while such action is not necessarily illegal, it does transfer IP created with U.S. taxpayer funds to China for which American researchers receive handsome rewards. Going forward, China should make the TTP more transparent, the U.S. should be more transparent about its investigations, and the two sides should carry out extensive dialogue.”

<https://www.csis.org/analysis/america-challenges-chinas-national-talent-programs>

# Closing Thoughts

- “Novel” coronavirus, novel challenges
- COVID-19 science exciting, rapid, yielding findings
- Severe disruptions of the research enterprise
- NIH is offering accommodations and flexibilities
- Complex decisions regarding reopening
- NIH priorities continue: NGRI, anti-sexual harassment, foreign interference

# Discussion



**Michael S Lauer, MD**

NIH Deputy Director for Extramural Research

[michael.lauer@nih.gov](mailto:michael.lauer@nih.gov)

# Next GREAT/GRAND Community Forum

- **NIGMS Director's Update**

- June 10 3:00 – 4:00 pm ET

- Jon R. Lorsch, PhD

- Director of the NIH National Institute of General Medical Sciences (NIGMS)



- NIGMS support of faculty and trainees during the COVID-19 pandemic
- Progress of MIRA (R35) awards for early-career and established investigators
- Update on revised NIGMS T32 training programs
- Support for regional facilities and lab safety in training environments





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