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 or 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.

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

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NIH Deputy Director for Extramural Research

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A “Novel” Virus

https://jamanetwork.com/collections/46099/coronavirus-covid19
Siddiqi and Mehra. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7118652/]
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
New York City — 6,000 weekly deaths

Massachusetts — 3,000 weekly deaths

New York (excluding N.Y.C.) — 6,000 weekly deaths

Illinois — 3,000 weekly deaths

New Jersey — 6,000 weekly deaths

Maryland — 3,000 weekly deaths

Michigan — 3,000 weekly deaths

Colorado — 3,000 weekly deaths

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 9:56 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 grind 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
Virus Will Cost NIH $10 Billion in Lost Research, Director Warns (1)

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

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

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

Jeannie Baumann
Reporter

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

Visit our page and check back often for updates!
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 to launch public-private partnership for COVID-19 vaccine and treatment options

Health agencies, leading pharmaceutical companies to join for accelerated response.

NIH mobilizes national innovation initiative for COVID-19 diagnostics

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

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**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
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

• 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!

Considerations for Reopening

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

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
At-Risk Investigators

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Expanding Loan Repayment Program

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.
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
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
Increased Attention

United States Senate
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
Committee on Homeland Security and Governmental Affairs
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

Contact: Gordon Loos – gloos@mire.org
JSIR-19-21
December 2019

DISTRIBUTION A: Approved for public release; distribution unlimited.

Fundamental Research Security

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 property and security. Indeed, the values are cherished 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. Our 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 depends on everyone upholding the principles of research.

Some of these 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.
“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

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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