Research Disrupted:

Protecting Federal Research Investments and the U.S. Research Workforce from COVID-19 Impacts

Briefing – Senate Labor, Health and Human Services, and Education Subcommittee and affiliated staff

Thursday, July 23, 2020

1:00-1:30pm EST

BRIEFING AGENDA

- Welcome & Introductions (Tannaz Rasouli, AAMC)
- Relief Recommendations
- Research Disruption Examples
  - **Jennifer Lodge, PhD**, Vice Chancellor and Associate Dean for Research, Washington University in St. Louis
  - **Mary L. (Nora) Disis, MD**, Associate Dean, Translational Health Sciences, Professor of Medicine/Oncology, Member, Fred Hutchinson Cancer Research Center, Director, UW Medicine Cancer Vaccine Institute (CVI)
- Questions & Discussion
- Wrap Up (Lizbet Boroughs, AAU)
  - Resources
  - Contacts

RESEARCH DISRUPTION

- Vast majority of non-COVID-19, on-site research slowed or halted in mid-March due to pandemic health emergency and social distancing requirements
- Graduate student experiments, training, and research delayed; degrees delayed; and job offers limited (or rescinded)
- Missed time windows for experiments – growing seasons, animal and plant life cycle development, site-specific research postponed (e.g. access to international field sites etc.)
- Inability to acquire needed PPE, specimens, and other materials necessary for research
- Domestic and international collaborators unable to travel
- Scientific conferences cancelled – lost collaborations
- Some research restarting in modified labs and conditions

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RESEARCH RELIEF RECOMMENDATIONS

- **At least** $26 billion in supplemental appropriations to federal research agencies allocated as follows:
  - National Institutes of Health (NIH) – $10 billion
  - National Science Foundation (NSF) – $3 billion
  - National Aeronautics and Space Administration (NASA) – $2 billion
  - Department of Defense (DOD) – $3 billion
  - Department of Energy (DOE) – $5 billion
  - U.S. Department of Agriculture (USDA) – $380 million
  - NOAA, NIST, EPA, the Institute for Education Sciences, other federal agencies with research budgets greater >$100 million – ~$2.6 billion

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RESEARCH RELIEF RECOMMENDATIONS

- Supplemental appropriations **to federal research agencies** for:
  - Grant and contract cost extensions to cover:
    - Research personnel salary support for graduate students, postdocs, principal investigators, and research staff
    - Reacquisition of donated PPE and testing materials – masks, face shields, gloves, reagents, swabs, etc.
    - Costs of restarting research – recalibrating equipment, reconfiguring labs and projects to allow for social distancing, replenishing supplies including new cell cultures, animal costs and care, etc.
  - Personnel and base operation costs at core research facilities
  - Extension and continuation of graduate and postdoctoral fellowships, traineeships, and support
- Extending regulatory flexibilities for federal research agencies

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Research Investment to Spark the Economy (RISE) Act H.R. 7308

- Original co-sponsors: Representatives DeGette (D-CO), Upton (R-MI), Johnson (D-TX), Lucas (R-OK), Eshoo (D-CA), and Gonzalez (R-OH)
  - 61 cosponsors total

- Bipartisan bill authorizing approximately $26 billion in supplemental funding for federal agencies to offset costs incurred by COVID-19 disruptions

- Includes $10 billion for NIH

Research Disrupted

Washington University in St. Louis

- Sponsored research in FY20 - $865M supports ~900 research groups
  - 73% federal
    - NIH - $547M
    - NSF - $27M
    - DOD - $26M
    - Non-NIH DHHS - $15M
    - NASA - $8M

- Institutional support for research in addition to sponsored funds
  - ~$400M
- Clinical revenues are major source of institutional support for research
  - anticipated 12 month loss = $500M

Research Disrupted

Washington University in St. Louis

unable to make progress

But fixed expenses continue

salaries, animal costs, facility and equipment maintenance.

Preserving valuable resources – people, animals, equipment

- Mid March – stopped all but essential research
  - 10% activity, but 80% of expenditures
  - $140M – spent on preservation
- Late May – ramped up to 30% of research
  - $50M – spent on preservation
- Late June – ramped up to 60-80% of research – will continue for ~12 months
  - $120M – spent on preservation

- Total of $310M over one year – some federal and other funders, some institutional

Core facilities – specialized services reduced/non-existent revenues during shutdown

- WUSTL has >100 cores

- Research Imaging Facilities (suite of 9 cores – MRI, CT, PET, Cyclotron)
  - Normal monthly revenues - $1.04M
  - COVID revenues - $0.9M (84% reduction)
  - Only a 14% reduction in expenses

  - Furloughed/laid off 25/54 employees

Impact on clinical research

~$100M in clinical trials per year

Stopped all but visits with a potential benefit to participant (e.g. cancer therapeutics). Slowing starting back.

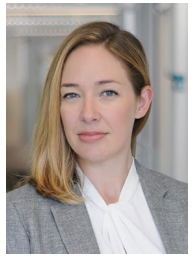
Impact on Alzheimer's research – public-private partnership

- Very long trials
- clinical research visits stopped for 3 months,
- No new enrollment
- restarting slowly with great care (set back 4-5 months)
- will need extended time - to collect data to complete the study

- Devastating, expensive ($200B/yr) disease – delaying development of a therapeutic is expensive and costs lives

Impact on careers – affecting our more junior scientists

Washington University in St. Louis



- Samantha Morris, PhD – Assistant Professor
  - reprograming cells to create test tube intestines
  - Well funded, supporting 2 post-docs, 8 grad students – interruptions to these trainee's careers
  - Experiments had to be halted – lost data, expensive to restart, time lost towards progress,

- Siyung Ding, PhD – relatively new Assistant Professor
  - New assistant professor – studying immune response to rotaviruses (cause diarrhea in young kids)
  - 1 grant, plus start up package, Supporting 3 post-docs, 2 PhD students, one technician
  - Using up resources that are needed to obtain data for grant applications

- Carlos Ponce MD/PhD – New Assistant Professor
  - Neural networks in NHP –expensive to maintain
  - 1 post-doc, 2 students, 1 tech, entirely on startup funding
  - Work is shut down due to COVID

- Cameron Hole PhD – post-doc
  - Post doc – studying fungal diseases
  - Obtained a K22 (scored a 10!), must obtain faculty position within a year
  - Hiring freezes at many universities!! Could lose grant.

- Sukrit Singh – Graduate student
  - studying protein structure (including COVID)
  - Trying to complete PhD
  - Hiring freezes is making his next career move difficult

COVID-19 Impact on Clinical Research at the University of Washington

Mary L. Disis, MD

- Associate Dean, Translational Health Sciences
- Professor of Medicine/Oncology
- Member Fred Hutchinson Cancer Research Center
- Director, UW Medicine Cancer Vaccine Institute (CVI)

Cancer Vaccine Institute (CVI) develops & clinically tests NOVEL CANCER VACCINES & other forms of CANCER IMMUNOTHERAPY:

In the last 5 years:

- ✓ **Developed 4 new investigational drug applications (IND) for vaccine products approved by FDA.**
- ✓ **Launched 10 clinical trials.**
- ✓ **Enrolled over 150 cancer patients.**
- ✓ **March 23, 2020: Six active clinical trials put on hold due to COVID-19.**

Funders: NIH (NCI/Division of Cancer Prevention), DOD (Breast/Ovarian/Lung Programs)

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COVID-19 Impact on Clinical Research at the University of Washington

March 23, 2020 most clinical trials at UW were halted

TIMELINE

May 25, 2020: Restrictions began to get lifted.

- ✓ Phase 2 & 3 trials (patient benefit)
- ✓ Phase 1 trials (selected) for fatal diseases, such as cancer or heart failure

July 13, 2020: Further restrictions lifted.

- ✓ All therapeutic trials
- ✓ Studies to obtain bio-specimens, physical measurements or exams, e.g. knee flex exams for a new device study

IMPACTS

- ✓ All other human subjects research still remains on hold.
- ✓ Studies in the category of non-therapeutic trials that require extended visits; memory testing for Alzheimer's, mental health studies, MRI for fetal brain abnormalities, US to treat kidney stones.
- ✓ UW Clinical Research Unit: April and May 2020 compared to same months in 2019; >300% decrease in clinic visits.

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COVID-19 Impact on Clinical Research at the University of Washington

Examples of COVID-19 Pandemic Impact on Clinical Research

Clinical Trial: Meal and memory study

Purpose: To understand how food and the way people metabolize food is abnormal in patients who are at risk for Alzheimer's disease

Funding: National Institute on Aging / Funded by "K" award, a salary support training grant, awarded to Dr. Hanson, MD, junior investigator.

Impact: This award pays most of Dr. Hanson's salary, but the award has been put on hold. She must now find other sources of salary support. Her fledgling research program is at a stop.

Clinical Trial: Lipid MRI study

Purpose: To assess chronic abnormalities on brain imaging

Funding: National Institute on Aging /Funded by an "R01" from the National Institute on Aging

Impact: Study was stopped on March 23, 2020. It has not been able to restart due to current restrictions. No work has been done for 4 months.

Angela Hanson, MD

Assistant Professor
Geriatric Medicine
Memory and Brain Wellness Center
Harborview

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COVID-19 Impact on Clinical Research at the University of Washington

Examples of COVID-19 Pandemic Impact on Clinical Research

Clinical Trial: Clinical & biological signatures of post-traumatic neurodegeneration

Purpose: To study the late effect of traumatic brain injury by examination, MRI, extensive neurologic testing, and collection of blood samples.

Funding: National Institute of Neurologic Disorders and Stroke / A multi-site study.

Impact: Study staff continues to be paid, but soon will need to be laid off. Many patients have not been able to return for their appointments and their data has not been collected. Trying to determine what is needed to restart activities under pandemic restrictions as it will impact assessment strategies.

Jeanne Hoffman, PhD

Associate Professor
Rehabilitation Medicine
Clinical psychologist

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COVID-19 Impact on Clinical Research at the University of Washington

The COVID-19 experience is resulting in a reengineering of the clinical trials system

SHORT TERM OUTCOMES

- ✓ Loss of younger clinical researchers and highly trained study staff– a generation of the clinical research workforce.
- ✓ Markedly increased length to trial completion.
- ✓ Patients lose the chance for participation in research.
- ✓ Uncertainty on how to modify a study for future or continuing COVID-19 holds.

LONG TERM OUTCOMES

- ✓ Design of clinical trials that will allow 'tele-research".
- ✓ Ensure "tele-research" will not increase health disparities.
- ✓ New methods needed to correct for missing data that maintain the integrity of the study.
- ✓ Support for data analysis and study design expertise at the conclusion of impacted trials.

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Questions & Discussion

Wrap Up

RESOURCES

- CRS Report: Effects of COVID-19 on the Federal Research and Development Enterprise (4/10/20) - https://crsreports.congress.gov/product/pdf/R/R46309
- *Nat Hum Behav:* Unequal effects of the COVID-19 pandemic on scientists (7/15/20) - https://www.nature.com/articles/s41562-020-0921-y
- Letter of Support by 33 Senators to Leadership (5/4/20) - https://www.markey.senate.gov/imo/media/doc/CV4%20Research%20Relief.pdf
- Letter of Support by 182 House Members to Leadership (4/29/20) - https://degette.house.gov/sites/degette.house.gov/files/Letter%20to%20House%20Leadership%20on%20Emergency%20Research%20Funding%20Final%204.29.pdf
- AAU-APLU-AAMC-ACE Letter (4/7/20) - https://www.aau.edu/sites/default/files/AAU-Files/AAU-AAMC-APLU-ACE%20COVID19%20Research%20Recommendations%204-7-20.pdf
- AAU-APLU-AAMC-ACE Letter (5/27/20) - https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/COVID-19/1ResearchReliefSenateLetter5-27-20Final.pdf

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Please join us for a virtual briefing for Congressional Staff

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Participating Members of Congress

Representative Diana DeGette (D-CO)
Representative Fred Upton (R-MI)

Speakers

Mark McLellan, Vice President for Research and Innovation
University of North Texas
Roger Wakimoto, Vice Chancellor for Research and Creative Activities
University of California, Los Angeles

Monday, July 27th, 2020
2:30 p.m. EST

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Thank you!