

Director's Report

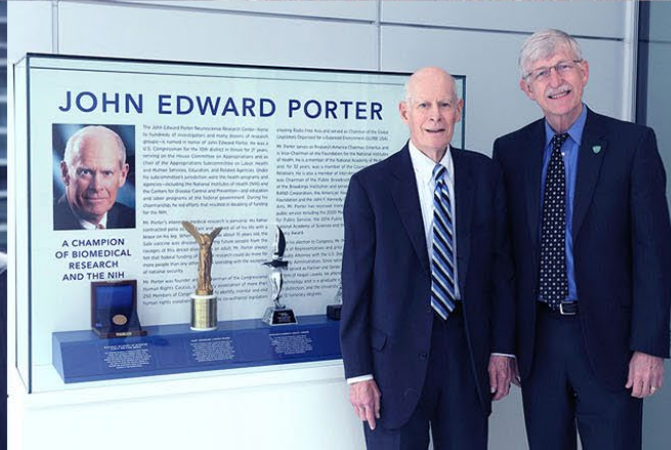
*124th Advisory Committee to the Director Meeting
June 9, 2022*



Lawrence A. Tabak, DDS, PhD
Acting Director, NIH
Department of Health and Human Services



In Memoriam U.S. Rep. John Porter, June 3, 2022



Topics for Today

- Appointments and Departures
- Awards and Honorees
- Budget and Legislative Updates
- Initiative Updates
- Update on NIH Efforts to Redress (Sexual) Harassment
- Two Things that Keep Me Up at Night



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Advisory Committee to the (NIH) Director



Acting NIH Principal Deputy Director



Tara A. Schwetz, PhD

**Acting Associate Deputy
Director, NIH**



Courtney Aklin, PhD

**Acting Director of the
Office of Science Policy**



Lyric Jorgenson, PhD

**Norman E. “Ned” Sharpless, MD
Director, National Cancer Institute**



**Acting Director,
National Cancer Institute (NCI)**



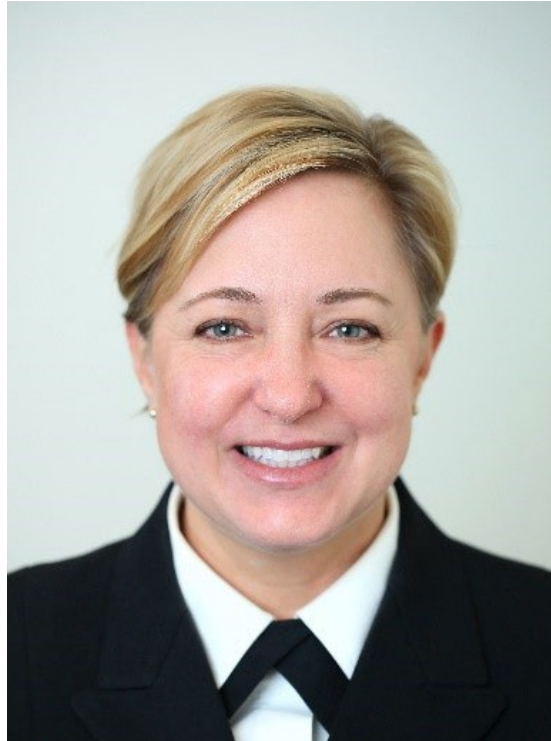
Doug R. Lowy, MD

**Acting Director,
National Center for Advancing Translational Sciences**



Joni L. Rutter, PhD

**Acting Associate Director for Behavioral and Social
Sciences Research; Acting Director of Office of Behavioral
and Social Sciences Research**



Christine Hunter, PhD, ABPP

Acting Chief of Staff



John T. Burklow

Acting Associate Director for Communications and Public Liaison



Renate H. Myles

**Acting Deputy Director of
Advanced Research Projects Agency for Health
(ARPA-H)**



Adam Russell, DPhil

**CEO,
Foundation for the NIH (FNIH)**



Julie Louise Gerberding, MD, MPH

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Congratulations!

Service to America Medal Finalists



Diana W. Bianchi, M.D.

Director, NICHD
COVID-19 Response Finalist



H. Clifford Lane, M.D.

Deputy Director for Clinical Research
and Special Projects, NIAID
Career Achievement Finalist

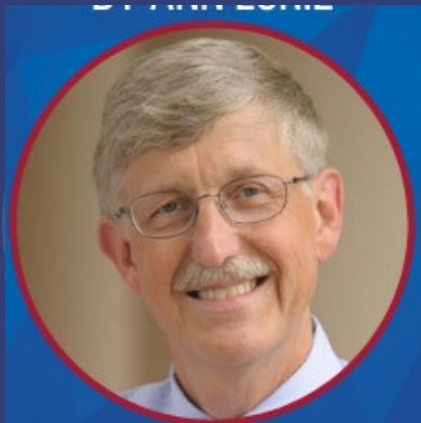


2022

RESEARCH! AMERICA

ADVOCACY AWARDS

**JOHN EDWARD PORTER LEGACY
AWARD, GENEROUSLY SUPPORTED
BY ANN LURIE**



Francis S. Collins, MD, PhD

Acting Science Advisor to the President: Senior Investigator,
Center for Precision Health Research, National Human
Genome Research Institute, NIH

**OUTSTANDING ACHIEVEMENT IN
PUBLIC HEALTH AWARD**



Vivian W. Pinn, MD

Inaugural Director, Office of Research on
Women's Health, NIH (Retired)

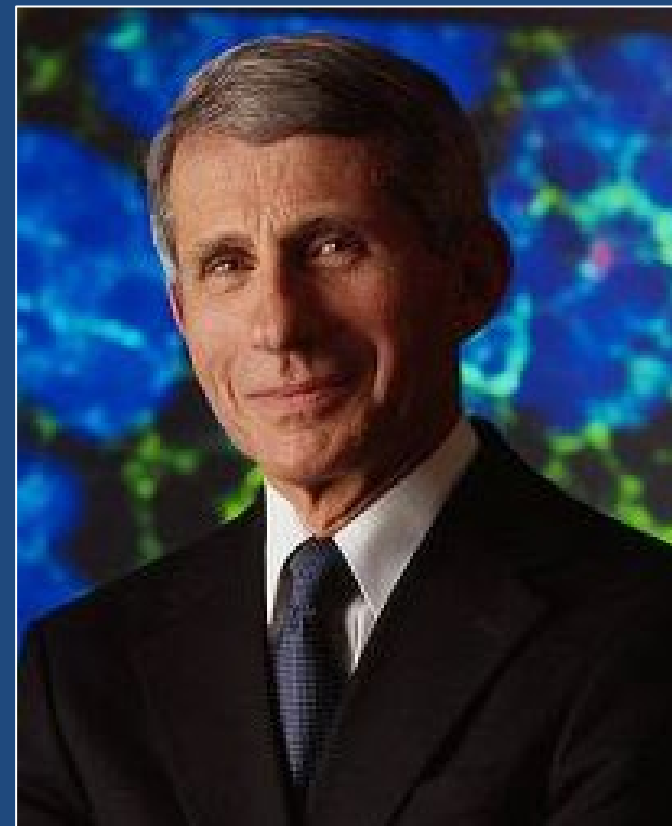
RAPID TRANSLATION AWARD

**Accelerating
COVID-19
Therapeutic
Interventions
and Vaccines
(ACTIVE)**

Elliot L. Richardson Prize for Excellence in Public Service



Francis Collins, MD, PhD



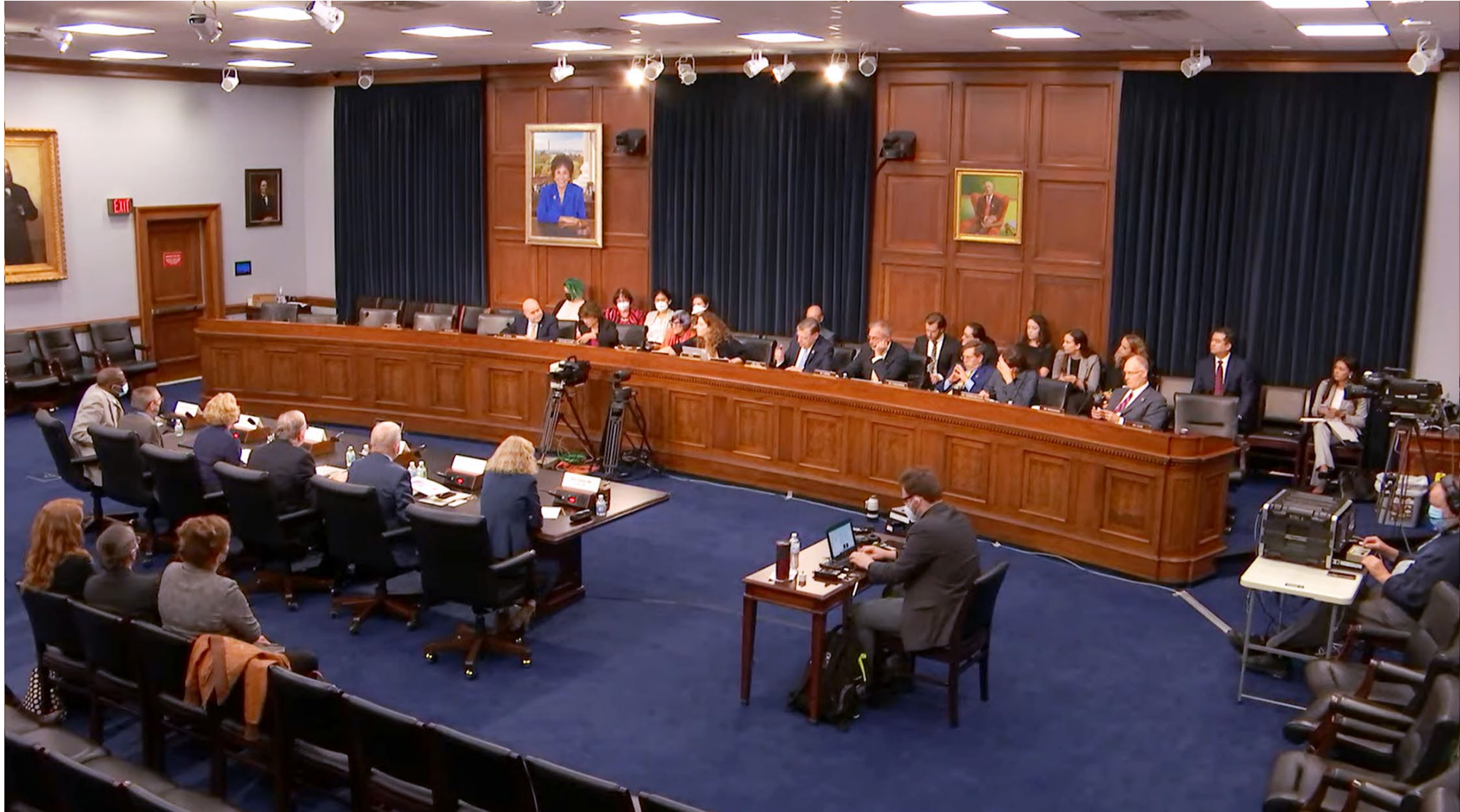
Anthony Fauci, MD

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House Appropriations Committee Hearing



Senate Appropriation Committee Hearing



Budget Update

NIH Director's Report to the Advisory
Committee to the Director
June 9, 2022

Neil K. Shapiro
Associate Director for Budget, NIH



FY 2022 Appropriations Action

- The consolidated appropriations bill, including Labor/HHS/Education, became law on March 15th after four continuing resolutions spanning nearly half the fiscal year.
- It provided NIH with the full-year discretionary appropriation, as well as creating the new Advanced Research Projects Agency for Health (ARPA-H).
- The Type 1 Diabetes mandatory funding was reauthorized last year, but it was reduced by \$8.55 million (to \$141.45 million) due to sequestration.

FY 2022 at a Glance

(\$ in thousands)	FY 2021	FY 2022	Change from FY 2021 (\$)	Change from FY 2021 (%)
NIH Program Level	\$42,812,323	\$42,812,323	+\$3,365,667	+7.9%
<i>ARPA-H (non-add)</i>		<i>\$1,000,000</i>	<i>+\$1,000,000</i>	

- \$3.4 billion increase over FY 2021 final budget.
- \$1 billion for ARPA-H, which was transferred to NIH by the Department in April. The funds are available for obligation over three years.
- General increase for Institutes and Centers of 3.4 percent.

Highlights of Omnibus: Largest Targeted Increases

FY 2023 President's Budget

(\$ in thousands)	FY 2022	FY 2023 PB	Change from FY 2022 (\$)	Change from FY 2022 (%)
NIH Program Level	\$46,177,990	\$62,502,703	+\$16,324,703	+35%
<i>ARPA-H (non-add)</i>	<i>\$1,000,000</i>	<i>\$5,000,000</i>	<i>+\$4,000,000</i>	<i>+400%</i>
<i>Pandemic Prep. (non-add)</i>		<i>\$12,050,000</i>	<i>+\$12,050,000</i>	

- Released March 28th using the continuing resolution level for FY 2022 as the current-year baseline, rather than the omnibus that had just been enacted. Typically, it takes two months or more to develop the Budget.
- Some PB levels are close to or below the FY 2022 enacted level due to the size of the unanticipated congressional increase, not the Administration's intent.

FY 2023 President's Budget (cont.)

- Intended general increase of 2 percent for Institutes and Centers (over continuing resolution).
- Largest targeted increases
 - Opioids/Pain Research (inc. HEAL) \$552M
 - Health Disparities 350
 - Climate Change 100
 - Nutrition Science 96
 - Cybersecurity 60
 - Buildings & Facilities 50

Pandemic Preparedness Proposal

- Preclinical R&D of prototype vaccines/therapeutics against high profile viral families (\$4.0 billion)
- Expansion of laboratory capacity and pilot cGMP manufacturing (\$2.35 billion)
- Development and clinical evaluation of vaccines and therapeutics (\$2.0 billion)
- Establish, expand, and/or improve large and flexible clinical trials networks and infrastructure (\$1.7 billion)
- Biosafety and biosecurity (\$1.0 billion)
- Develop affordable, accessible, and novel diagnostics and innovations in early warning (\$1.0 billion)



Legislative Update

ADRIENNE HALLETT

ASSOCIATE DIRECTOR FOR LEGISLATIVE POLICY & ANALYSIS

JUNE 9, 2022

FY 2023 Appropriations Hearings

- ▶ Themes Discussed:
 - ▶ ARPA-H
 - ▶ Success Rates
 - ▶ Undiagnosed Diseases Network
 - ▶ COVID-19
 - ▶ RECOVER (Long COVID)
 - ▶ Mental Health
 - ▶ Alzheimer's Disease
 - ▶ School Closures during the pandemic



Congressional Areas of Interest

Events held by OLPA

2020

- Topics
 - COVID
 - Grants
 - RADx

Over 50 events

2021

- Topics
 - COVID
 - ARPA-H
 - Diversity
 - CTSA's
 - Maternal Health & COVID
 - RADx
 - Opioids & COVID

Over 300 events

2022

- Topics
 - COVID
 - Mental Health
 - Alzheimer's Disease
 - ALS
 - Long COVID
 - Diversity
 - Women's Health
 - ARPA-H

100 events so far...

Sexual Harassment Policy

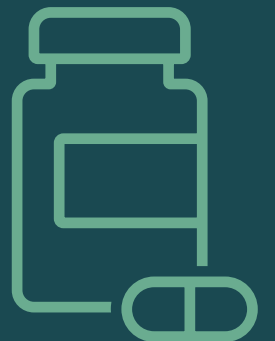
- ▶ NIH will require notification by the NIH-funded institution within 30 days of removal or disciplinary action.
 - ▶ Effective July 8, 2022.

SEC. 239. The Director of the National Institutes of Health shall hereafter require institutions that receive funds through a grant or cooperative agreement during fiscal year 2022 and in future years to notify the Director when individuals identified as a principal investigator or as key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. The Director may issue regulations consistent with this section.



ACT for ALS

- ▶ Implementation for the Accelerating Access to Critical Therapies for ALS Act (ACT for ALS)
- ▶ FOA posted May 12, 2022 to support research utilizing data from expanded access to investigational drugs and biological products for those otherwise not eligible for ALS clinical trials
- ▶ Grants available to phase 3 clinical trials sponsored by small businesses



Bayh-Dole Act

- ▶ Background
 - ▶ Facilitate US technological innovation by establishing a uniform set of federal rules
 - ▶ Enable universities/nonprofit research institutions/small business to own/patent/commercialize inventions supported, in part, by federal funds
- ▶ Two Areas of Congressional Interest
 - ▶ Use of march-in for drug pricing
 - ▶ Concerns about royalties paid to scientists for federally funded inventions.



Future Forecast: Must Pass Provisions

- ▶ FDA User Fee Agreements for medical products
 - ▶ Expires September 30, 2022
- ▶ Small Business Innovation Research Program and Small Business Technology Transfer (SBIR/STTR)
 - ▶ Sunsets September 30, 2022
- ▶ Appropriations
- ▶ Annual Defense Authorization
- ▶ ACA premium increase?

Future Forecast:

May Pass Provisions

- ▶ ARPA-H Authorization
- ▶ Health Omnibus
- ▶ Pandemic Preparedness
- ▶ Cures 2.0
- ▶ U.S. Competes Act

1 **SEC. 30227. PROHIBITION ON FEDERAL FUNDING FOR CER-**
2 **TAIN GAIN-OF-FUNCTION RESEARCH BY A**
3 **FOREIGN ADVERSARY.**

4 (a) IN GENERAL.—No Federal funds may be made
5 available, whether directly or indirectly, or used by an en-
6 tity, to conduct or support any gain-of-function research
7 involving a potential pandemic pathogen by a foreign ad-
8 versary, including—

- 9 (1) China, Russia, Iran, and North Korea; and
- 10 (2) any other country the Secretary of State, in
11 consultation with the Secretary of Defense, the Di-
12 rector of National Intelligence, or any other appro-
13 priate Federal official, determines to be a foreign
14 adversary for the purposes of this section.

15 (b) FUNDING FREEZE FOR VIOLATIONS.—Any entity
16 the Secretary of State finds to have used Federal funds
17 in violation of this section may not receive any Federal
18 funding for a period of 5 years, beginning on the date of
19 such finding.

1 (e) PROHIBITION.—

2 (1) IN GENERAL.—No Federal funds authorized
3 or made available pursuant to this Act may be used
4 or expended to laboratories in China or other coun-
5 tries identified by the United States government as
6 foreign adversaries to conduct gain of function re-
7 search.

1 **SEC. 30227. PROHIBITION ON PROGRAMMING THAT ENDAN-**
2 **TERS NATIONAL SECURITY.**

3 (a) WUHAN INSTITUTE OF VIROLOGY.—Notwith-
4 standing any other provision of law, funds authorized or
5 appropriated by any Act may not be made available for
6 any purpose to the Wuhan Institute of Virology.

7 (b) TECHNOLOGY TRANSFER.—Notwithstanding any
8 other provision of law, funds authorized or appropriated
9 by any Act may not be available for any purpose to con-
10 duct technical exchanges with entities under the direction
11 or control of the Chinese Communist Party or the Govern-
12 ment of the People’s Republic of China.

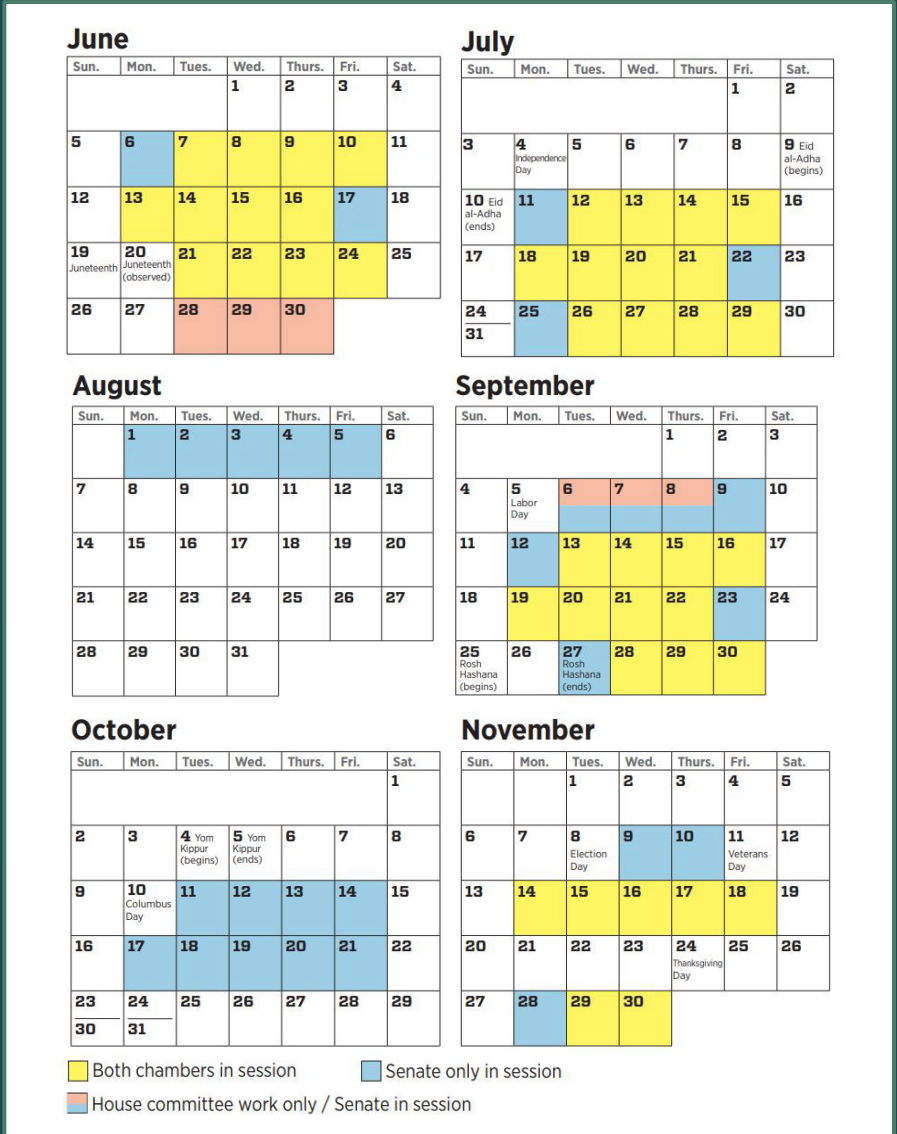
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1 **SEC. 30326. PROHIBITION ON AVAILABILITY OF FUNDS.**

2 None of the funds authorized to be appropriated by
3 this Act may be made available to any individual or entity
4 that is related legally or financially to the People’s Repub-
5 lic of China.

Amendments to Watch

Congressional Confirmations

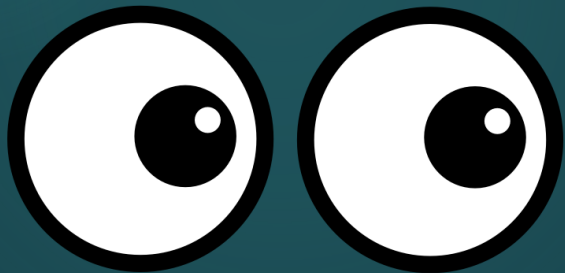


NIH Director

OSTP Director

Retirement Watch

- Who will retire in 2022?
- Leadership changes
- So far...
 - ▶ 33 Democrats
 - ▶ 23 Republicans



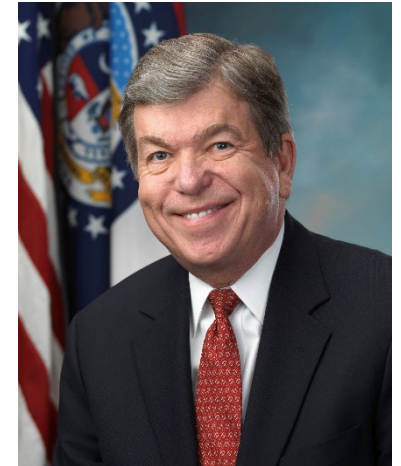
Senator Patrick Leahy

First elected in 1974



Senator Richard Burr

First elected in 1994



Senator Roy Blunt

First elected in 1997

Election Watch 2022

- ▶ The President's party historically loses seats in the midterms.
- ▶ Voter turnout higher than average in 2018, what will happen in 2022?
- ▶ In 2021, there was record high campaign spending for an off-cycle year.
- ▶ The Democratic majority in both Chambers is unusually narrow:
 - ▶ House (+10 Seats)
 - ▶ Senate (Even split)

House Election Watch

- ▶ Redistricting has changed the map.
- ▶ NRCC targeting 72 Democrats in the House.
- ▶ DCCC announced 40 “Districts in play”.

The disappearance of competitive districts will continue in 2022

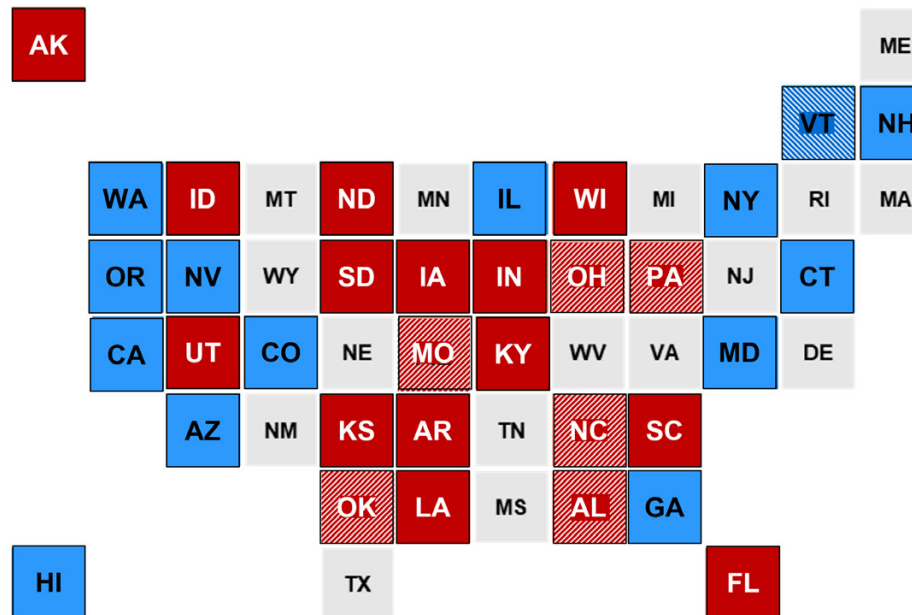
Number of House seats for each party since 1996, according to FiveThirtyEight's partisan lean



Senate Election Watch

Senators up for election in 2022

D Democrat
 R Republican
 Democrat open seat
 Republican open seat



Democrats (14)

Alex Padilla (CA)
 Michael Bennet (CO)
 Richard Blumenthal (CT)
 Brian Schatz (HI)
 Tammy Duckworth (IL)
 Chris Van Hollen (MD)
 Catherine Cortez Masto (NV)
 Maggie Hassan (NH)
 Chuck Schumer (NY)
 Ron Wyden (OR)
 Patty Murray (WA)
 Mark Kelly (AZ)
 Raphael Warnock (GA)

Republicans (20)

Lisa Murkowski (AK)
 John Boozman (AR)
 Marco Rubio (FL)
 Mike Crapo (ID)
 Todd Young (IN)
 Chuck Grassley (IA)
 Jerry Moran (KS)
 Rand Paul (KY)
 John Kennedy (LA)
 John Hoeven (ND)
 James Lankford (OK)
 Tim Scott (SC)
 John Thune (SD)
 Mike Lee (UT)
 Ron Johnson (WI)
OPEN (Shelby) (AL): Solid R
OPEN (Blunt) (MO) Solid R
OPEN (Burr) (NC): Toss Up
OPEN (Portman) (OH): Lean R
OPEN (Toomey) (PA): Toss Up
OPEN (InHofe) (OK): Solid R

OPEN (Leahy) (VT): Solid D



Thank you

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President Biden Reignites the Cancer Moonshot



CANCER MOONSHOT

INITIATIVES 2017-2022

NCI Investments

OVER

70

CONSORTIUMS
OR PROGRAMS

OVER

240

RESEARCH
PROJECTS

President Biden Reignites the Cancer Moonshot



Ambitious Goals Include:

- **Reduce the death rate from cancer by at least 50 percent over the next 25 years**
- **Improve the experience of people and their families living with and surviving cancer— and, by doing this and more**
- **End cancer as we know it today**

Rx and Illicit Drug Summit



HEAL Advances

- Discovery and validation of novel targets for safe & effective pain management
 - 2 patents for small-molecule modulators of pain receptors to treat chronic pain, migraine
 - Investigational New Drug, a first-in-class, non-addictive drug candidate for treating chronic pain
- Novel therapies for opioid use disorder and overdose
 - 50+ compounds being developed, 23 INDs filed with FDA, study of opioid vaccine
- Devices targeting nerve signaling to treat pain and opioid use disorder

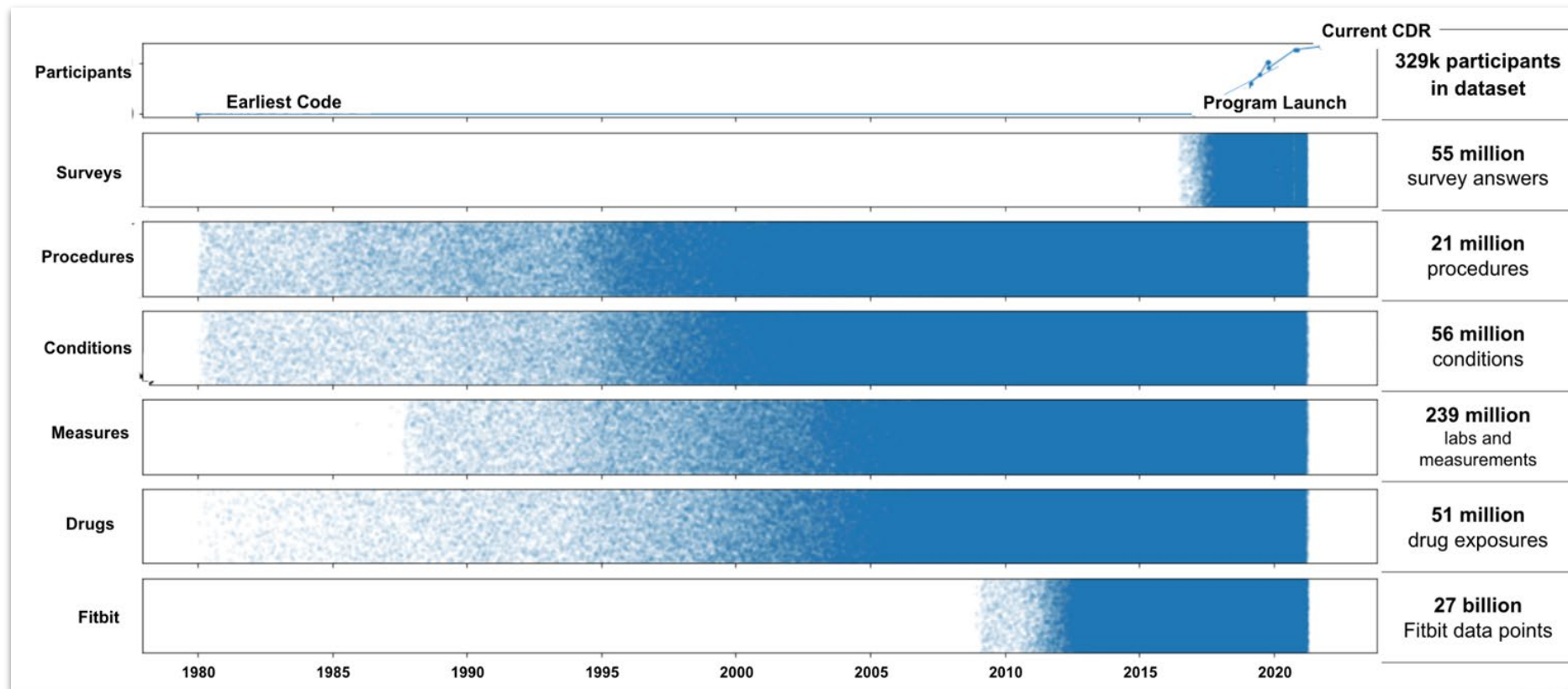
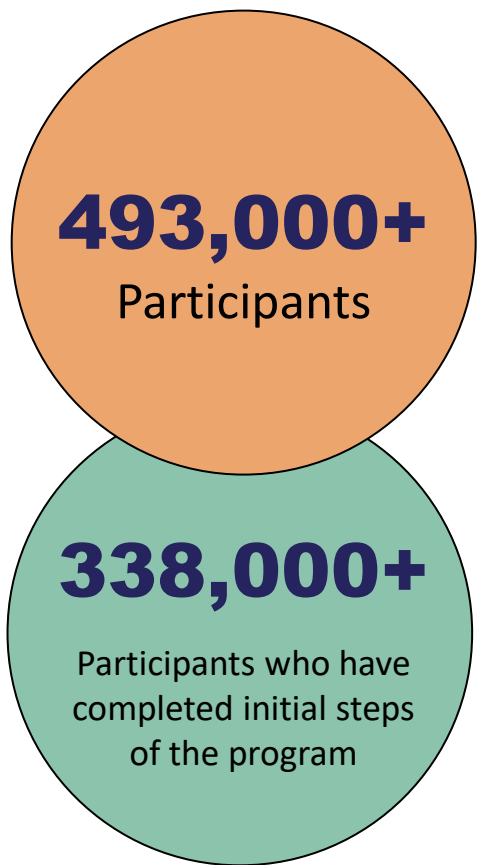
VPOTUS Maternal Health Action Plan Cabinet Meeting



Maternal Health Action by NIH

- NIH is committed to understanding and reducing maternal morbidity and mortality and disparities in maternal health
- In FY2021, NIH budget directed >\$422 million to maternal health research with >\$240 million specifically addressing maternal morbidity and mortality
- Increasing research by early-career and underrepresented researchers
- NIH-wide IMPROVE initiative—Implementing a Maternal health and PRenancy Outcomes Vision for Everyone
- NICHD supported studies leading to the first medicine, Orlissa, approved by the FDA to treat pain associated with endometriosis

Available data in the *All of Us* Research Program (as of May 16, 2022)



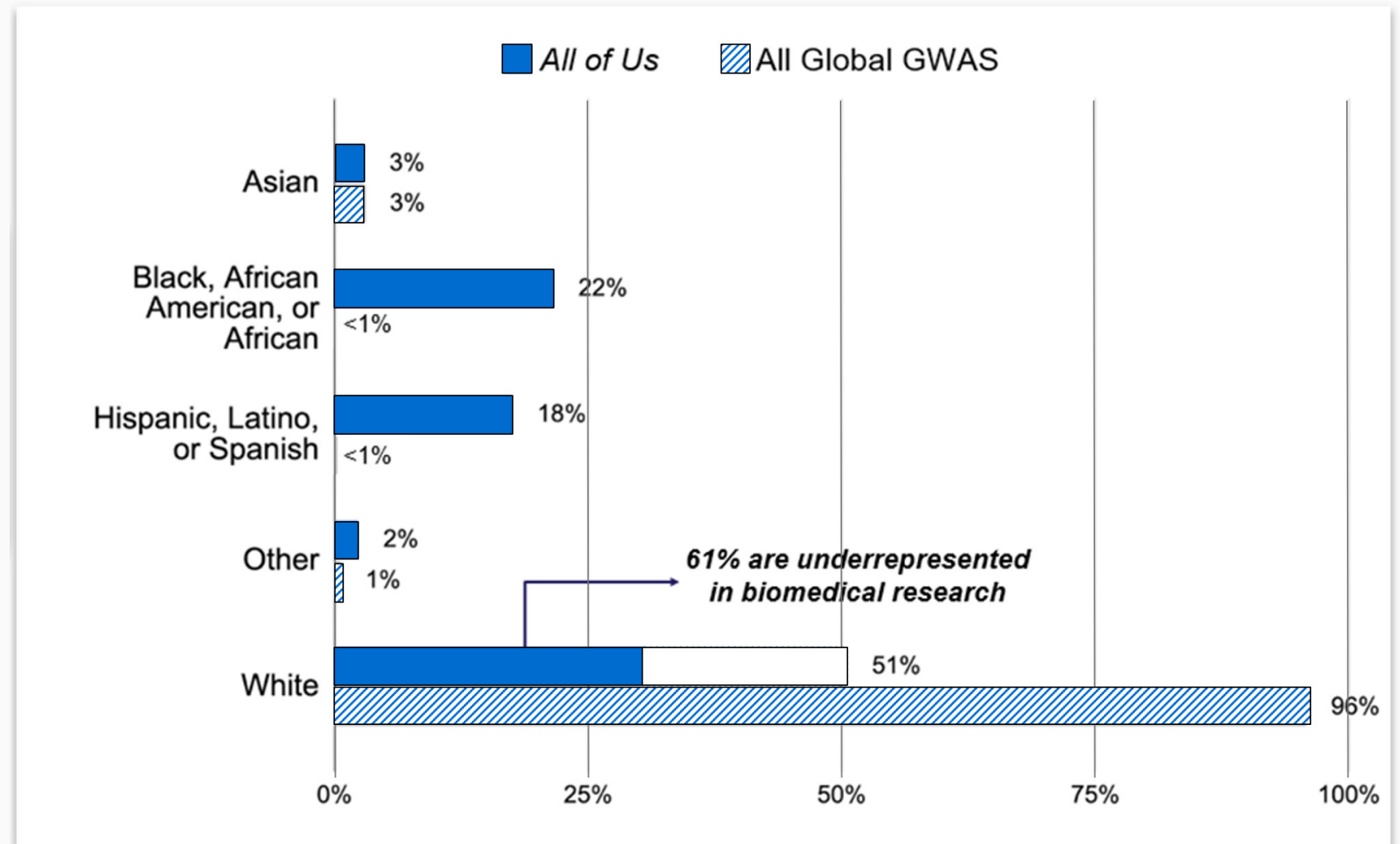
Plus: ~100k whole genomes + ~165K arrays

All of Us' Inclusion of Underrepresented Groups will Enhance Diversity of Genomic Studies

First genomic data set

~50% diverse by race/ethnicity,

80% underrepresented in biomedical research



New Clinical Center Pharmacy Ribbon Cutting



New Clinical Center Pharmacy



- Outpatient Pharmacy Opens

- Unit-dose Pharmacy Opens

- Intravenous Admixture Unit Opens

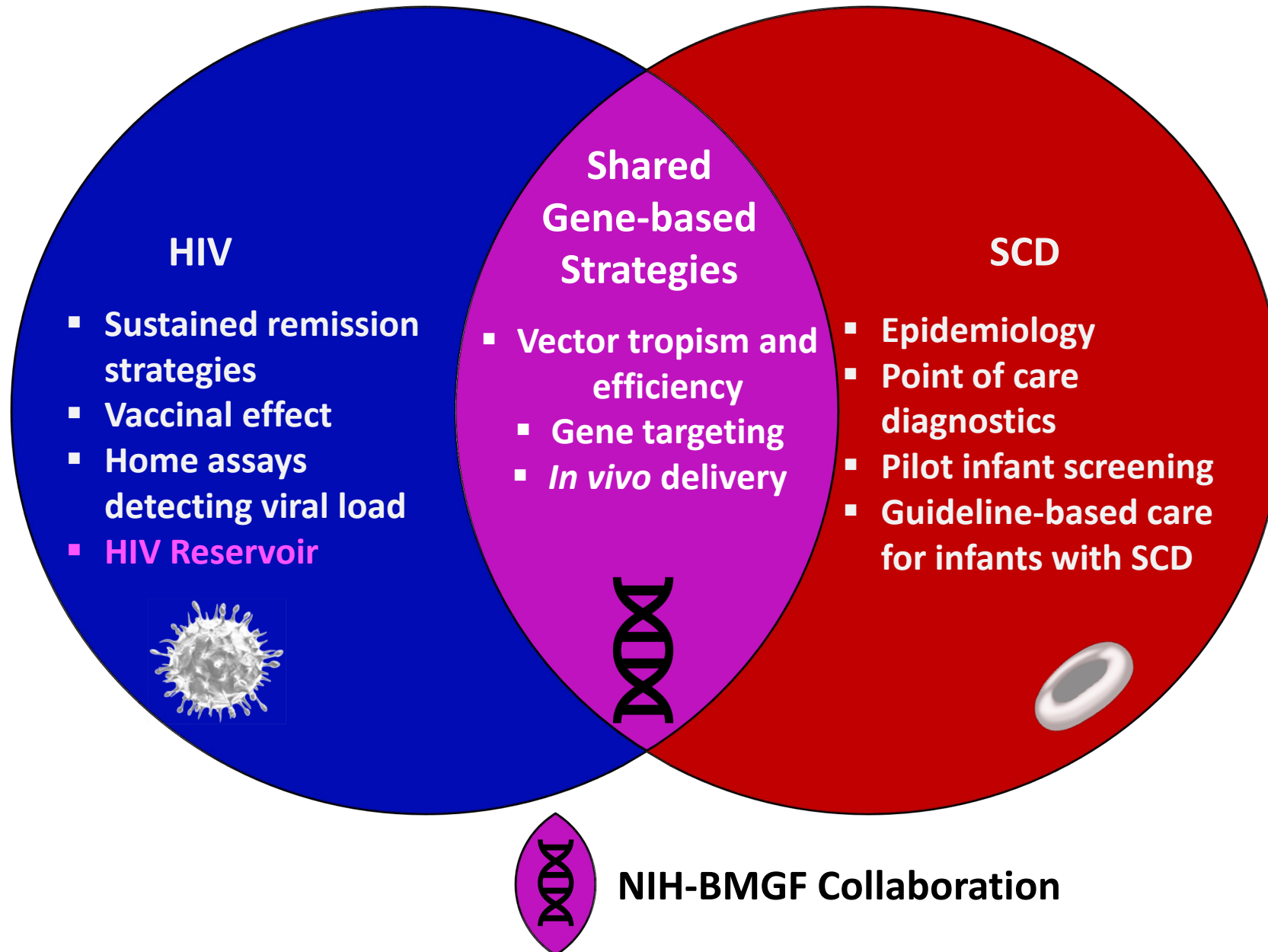
John Lewis National Institute of Minority Health Disparities (NIMHD) Research Endowment Revitalization Act of 2021



John Lewis National Institute of Minority Health Disparities (NIMHD) Research Endowment Revitalization Act of 2021

- The NIMHD Research Endowment Program (REP) aims to help institutions:
 - Build research infrastructure
 - Recruit, train, maintain a diverse student body and faculty
- Provides funding to the endowments of academic institutions (up to 5 years)—does not directly fund research projects
- Endowment funds must be invested and maintained for at least 20 years after the award period ends
- New law expands eligibility to include former NIMHD and HRSA Centers of Excellence

Research Focus of the NIH-BMGF Collaboration



Project outcomes

Phenotype data (associated with genotype data)

- Demographic information
- Anthropometric data
- Disease and health related phenotype data

Genomic data, human and pathogen

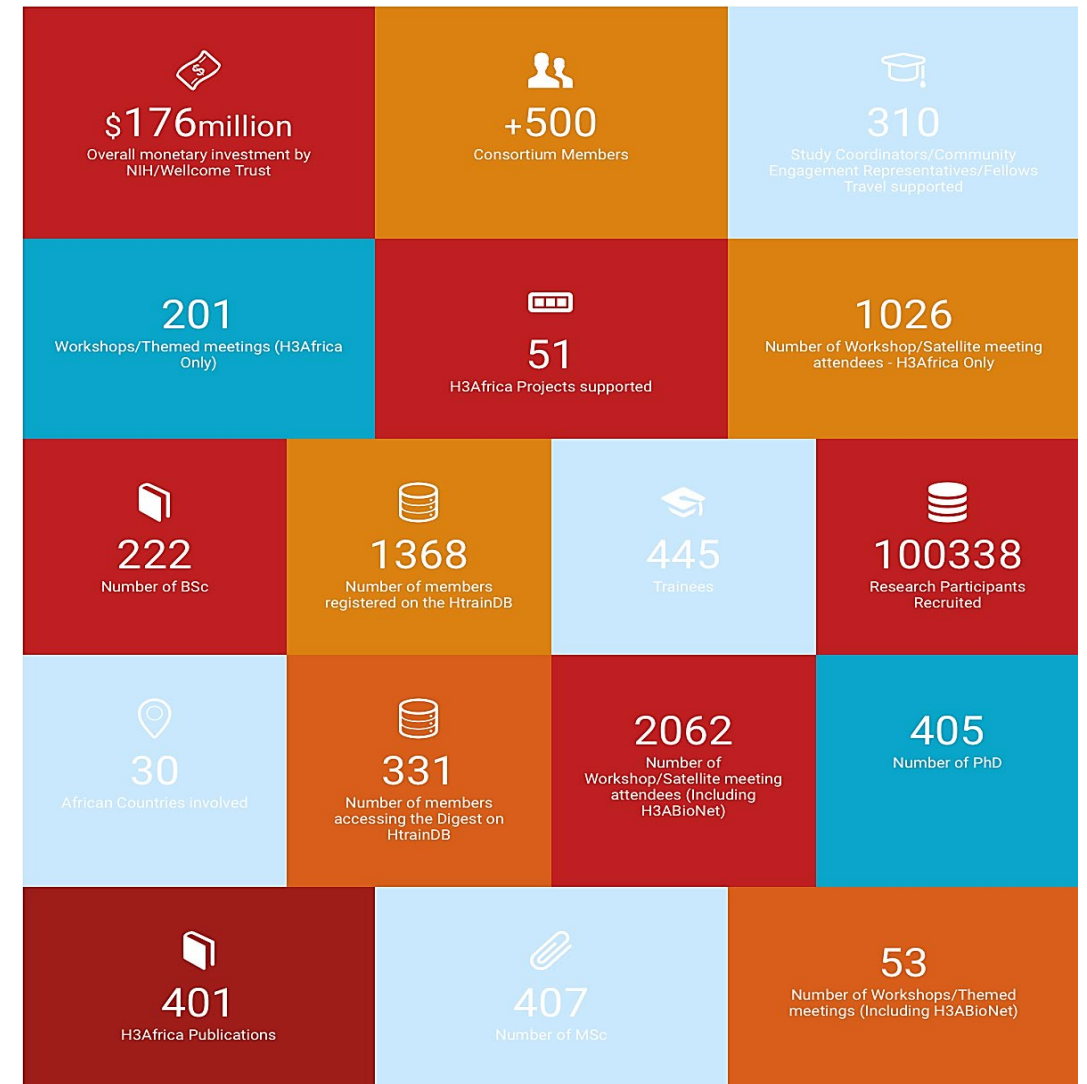
- Sequence data (whole genome, exome, targeted)
- Genotyping chip array data
 - >60,000 samples run on H3Africa chip
- Epigenetic data
- Transcriptomic data

Microbiome sequence data

- Patient/sample phenotypes
- Non-human 16S rRNA sequence data for microbiome
- Non-human full genome sequence data for microbiome

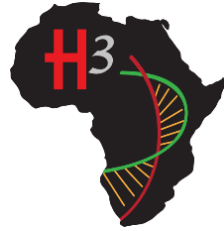
Qualitative data

- Focus groups and surveys
- Deliberative workshops



New discoveries: novel genetic associations, risk factors, analysis methods, and research and training modalities (>650 publications and counting)

Resources

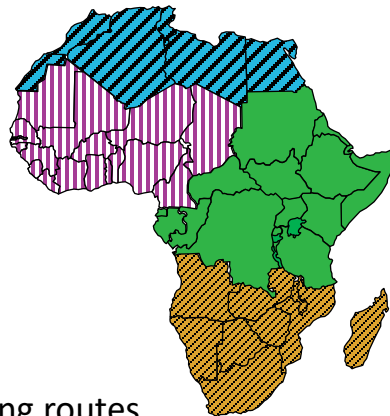


Policies and guidelines:

- H3Africa Guidelines for Community Engagement
- H3Africa Guidelines for Informed Consent
- Framework for African Genomics and Biobanking
- H3Africa Data Sharing, Access & Release Policy
- H3Africa Data and Biospecimen Access Committee Guidelines
- Recommendations for Feedback of Findings

Regional Biorepositories:

- Located in Nigeria, Uganda, and South Africa
- ISBR compliant
- Support for collection, processing, storage, retrieval, and shipping
- LIMS and catalog of samples
- Regional distribution, training & support
- Effective, affordable, & reliable regional courier shipping routes

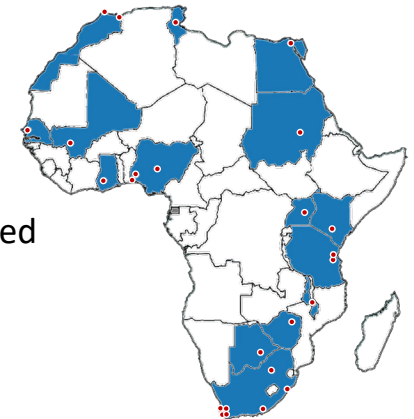


Research tools and products:

- Phenotype harmonization
- Cardiovascular disease harmonized data
- Training modules and trained personnel
- Population genetics studies
- ADME study
- H3Africa genotyping array

Bioinformatics Network:

- 135TB genomic data stored
- 1.2 PB available for storage
- 80TB genomic data transferred
- 3432 cores for processing
- 18 computing facilities
- 4 containerized workflows



www.h3abionet.org

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Congress Strengthens NIH's Ability to Address Harassment

H.R.2471 – Consolidated Appropriations Act, 2022

Section 239: “The Director of the [NIH] shall hereafter require institutions that receive funds through a grant or cooperative agreement during fiscal year 2022 and in future years to notify the Director when individuals identified as a principal investigator or as key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. The Director may issue regulations consistent with this section.”

Characteristics of harassment cases reported to NIH Office of Extramural Research

Characteristic	2018	2019	2020	2021	2022
Total N (%)	33 (6.9)	110 (23.0)	108 (22.6)	160 (33.5)	67 (14.0)
Allegation: Sexual Harassment Only	16 (48.5)	57 (51.8)	36 (33.3)	56 (35.0)	10 (14.9)
Allegation: Sexual Harassment Plus Other	12 (36.4)	30 (27.3)	19 (17.6)	28 (17.5)	2 (3.0)

Findings and Outcomes of Harassment Cases Reported to NIH Office of Extramural Research (2018- May 2022)

Finding/Outcome	Sexual Harassment Only	Sexual Harassment Plus Other
Total N (%)	175 (36.6)	91 (19.0)
Contact with Institution	131 (74.9)	67 (73.6)
Formal Investigation	114 (65.1)	58 (63.7)
Allegation Substantiated	61 (34.9)	23 (25.3)
Principal Investigator Removed	52 (29.7)	14 (15.4)
Other Grant Actions	16 (9.1)	13 (14.3)
Left Institution	54 (30.9)	22 (24.2)
Removed from Peer Review	90 (51.4)	36 (39.6)

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Funding by Ranks

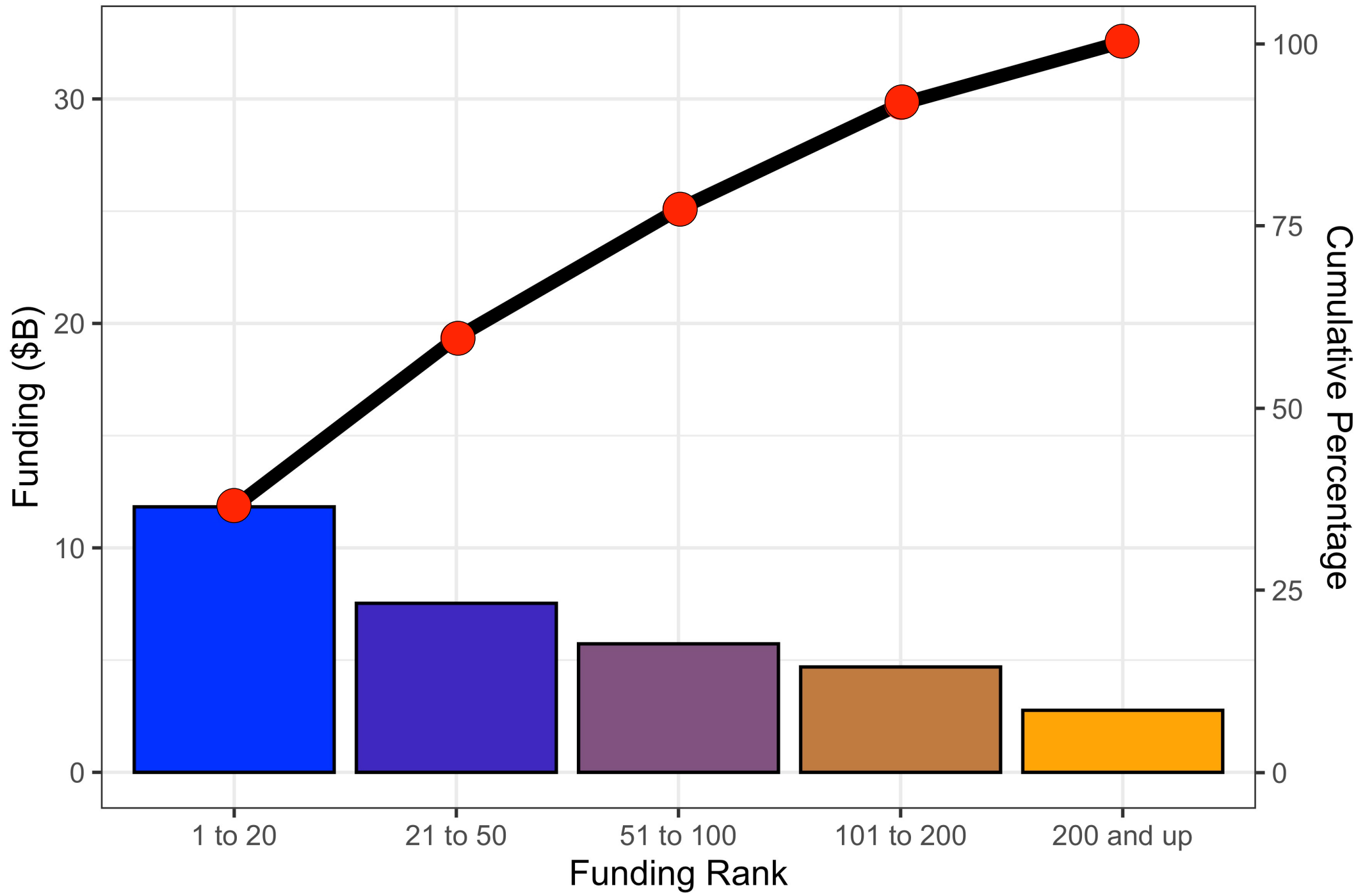
FY2021, Domestic Non-Profits

Ranking	Funding (\$Billion)	Percent Total Funding	Cumulative Percent
1 to 20	11.83	36.36	36.36
21 to 50	7.53	23.14	59.5
51 to 100	5.73	17.61	77.11
101 to 200	4.69	14.41	91.52
200 and up	2.76	8.48	100

Data from RePORT, [Awards by Location](#)

Non-profits only (N=1026)

Total FY2021 funding = \$32.54 Billion



(Lack of) Trust in Science

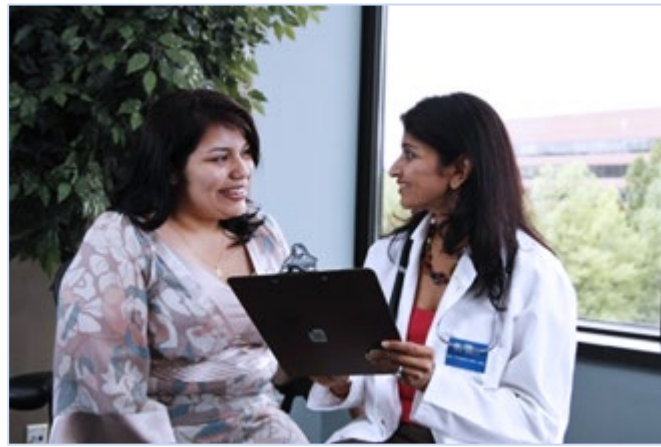


Misinformation in and about science

Jevin D. West^{a,1}  and Carl T. Bergstrom^b 

^aInformation School, University of Washington, Seattle, WA 98195; and ^bDepartment of Biology, University of Washington, Seattle, WA 98195

Humans learn about the world by collectively acquiring information, filtering it, and sharing what we know. Misinformation undermines this process. The repercussions are extensive. Without reliable and accurate sources of information, we cannot hope to halt climate change, make reasoned democratic decisions, or control a global pandemic. Most analyses of misinformation focus on popular and social media, but the scientific enterprise faces a parallel set of problems—from hype and hyperbole to publication bias and citation misdirection, predatory publishing, and filter bubbles. In this perspective, we highlight these parallels and discuss future research directions and interventions.



NIH...

Lawrence.Tabak@nih.gov

[@NIHDirector/Twitter](https://twitter.com/NIHDirector)

Turning Discovery Into Health

