

# Director's Report

*125<sup>th</sup> Advisory Committee to the Director Meeting  
December 8, 2022*



**Lawrence A. Tabak, DDS, PhD**  
Performing the Duties of the NIH Director  
Department of Health and Human Services



# Topics for Today

- Appointments and Departures
- Awards and Honorees
- Special Events
- ESI Update
- eRA Update
- DEIA Strategic Plan Update
- Initiatives Updates
- Budget and Legislative Updates
- Reflection: Leading Through Turbulent Times





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# ACD Departures



**Wendy Chapman, Ph.D**  
*University of Melbourne*



**Rebekah Drezek, Ph.D.**  
*Rice University*



**Kristina Johnson, Ph.D.**  
*Ohio State University*

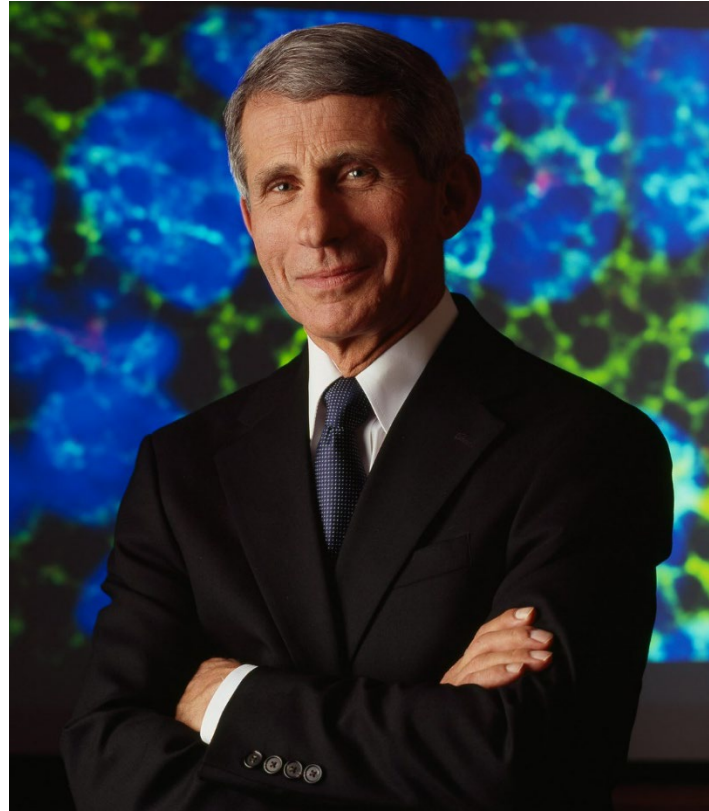


**Dina Katabi, Ph.D.**  
*Massachusetts Institute of Technology*



**Judith Kimble, Ph.D.**  
*University of Wisconsin, Madison*

**Departure:**  
**Director, National Institute of Allergy and  
Infectious Diseases**



**Anthony S. Fauci, MD**

**Selected:  
Acting Director of NIAID**



**Hugh Auchincloss, MD**



**Departure:**  
**Director, Center for Information Technology,  
and NIH Chief Information Officer**



**Andrea Norris, MBA**

**Selected:  
Acting Director, Center for Information Technology**



**Ivor D'Souza**

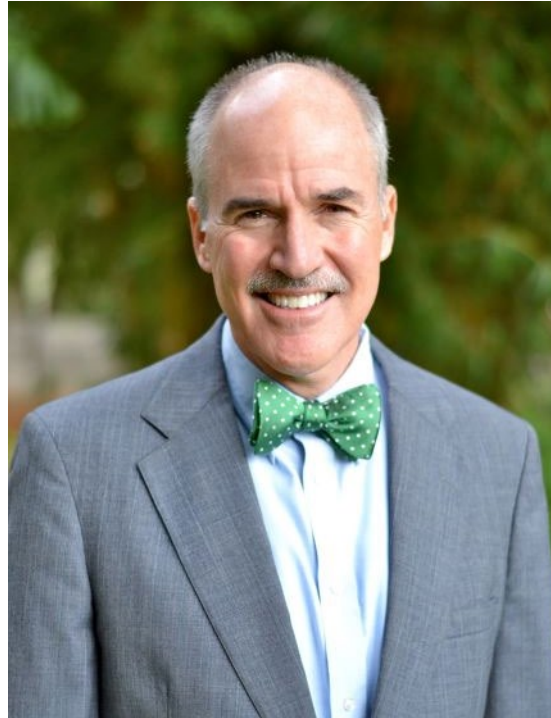


**Departure:**  
**Director, Fogarty International Center**



**Roger Glass, MD, PhD**

**Selected:  
Acting Director, Fogarty International Center**



**Peter Kilmarx, MD**

**Departure:  
NIH Deputy Director and  
Director, Division of Program Coordination, Planning,  
and Strategic Initiatives (DPCPSI)**



**James M. Anderson, MD, PhD**



**Selected:**  
**Acting Director, Division of Program Coordination,  
Planning, and Strategic Initiatives**



**Bob Eisinger, PhD**

## **Departure:**

**Chief Scientific Officer, Scientific Director of the NIH Clinical Center, Associate Director for Clinical Research in the Office of Clinical Research, OD**



**John Gallin, MD**

**Departure:**  
**Director, NIH Office of Strategic Coordination**



**Elizabeth (Betsy) Wilder, PhD**



**Appointment:  
Director, National Center for Advancing Translational Sciences**



**Joni L. Rutter, PhD**

**Appointment:  
Deputy Director, Intramural Research**



**Nina Schor, MD, PhD**

**Appointment:  
Director, National Cancer Institute**



**Monica M. Bertagnolli, MD**



**Appointment:  
Inaugural Director,  
Advanced Research Projects Agency for Health (ARPA-H)**



**Renee Wegrzyn, PhD**

**Appointment:  
Director, Office of Equity, Diversity, and Inclusion**



**Kevin Williams, JD**

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# Nobel Prize in Chemistry 2022



**Carolyn R. Bertozzi, PhD**

Prize share: 1/3



**K. Barry Sharpless, PhD**

Prize share: 1/3



# Lasker Awards

## 2022 Basic Medical Research Award



**Richard O.  
Hynes, PhD**



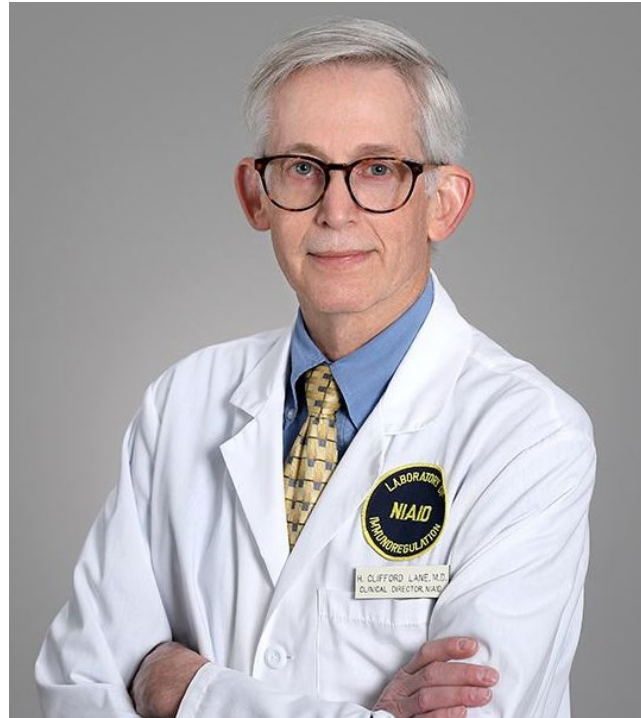
**Erkki Ruoslahti,  
MD, PhD**



**Timothy A.  
Springer, PhD**



**Service to America Awards 2022**  
**Paul A. Volcker Career Achievement**

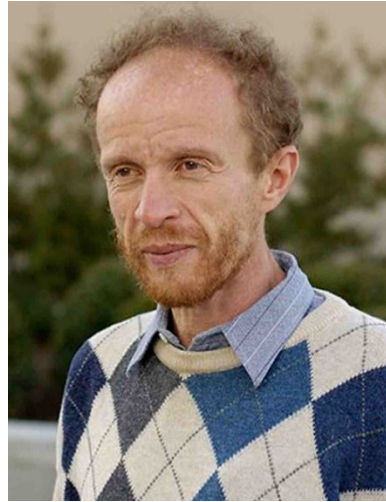


**H. Clifford Lane, MD**  
**NIAID**

# 2022 National Academy of Medicine New Members



**Carlos Blanco, MD, PhD**  
**NIDA**



**Eugene V. Koonin, PhD**  
**NCBI, NLM**



**Bruce J. Tromberg, PhD**  
**NIBIB**



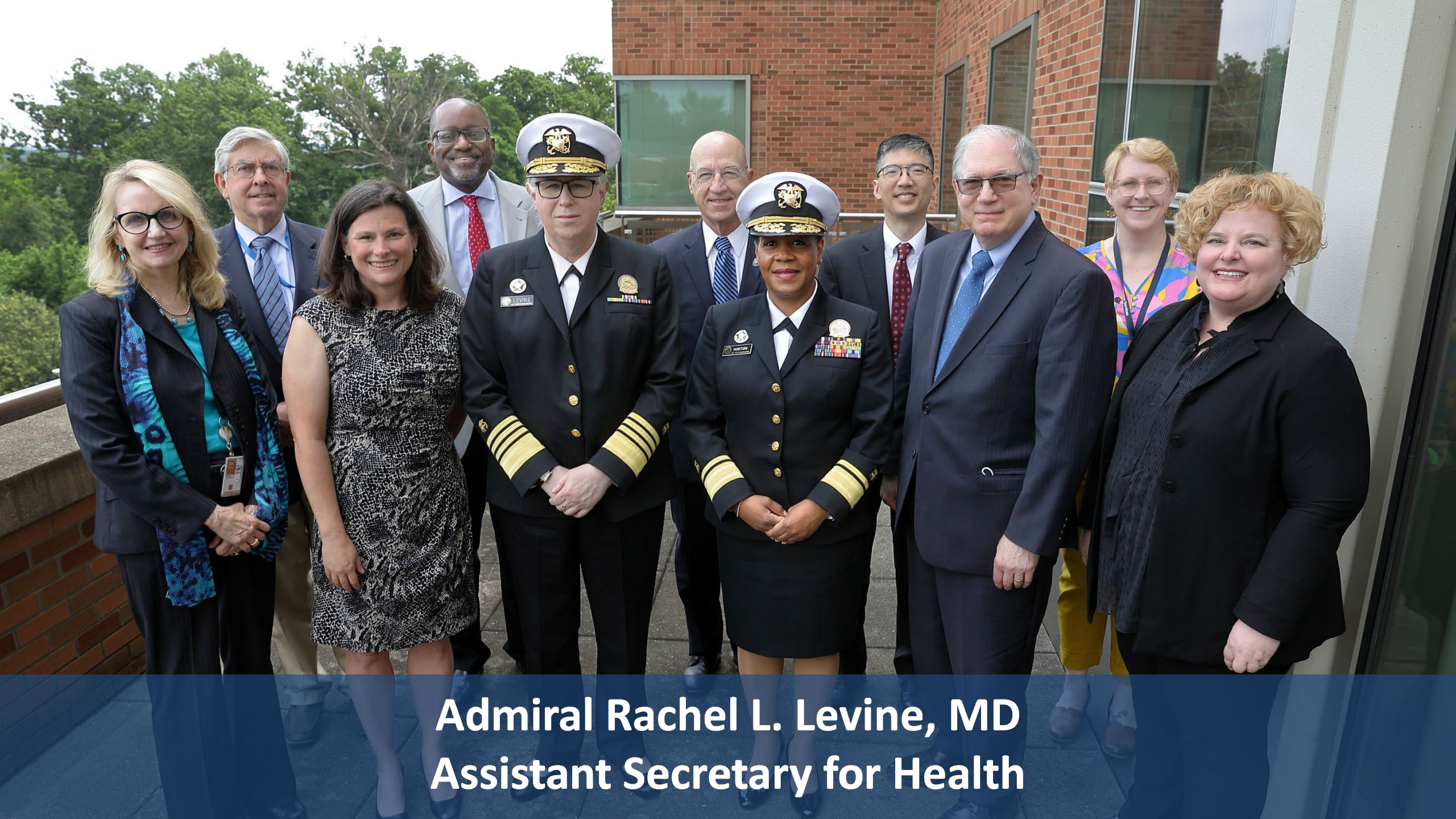
**Jennifer Webster-  
Cyriaque, DDS, PhD**  
**NIDCR, NIAID**

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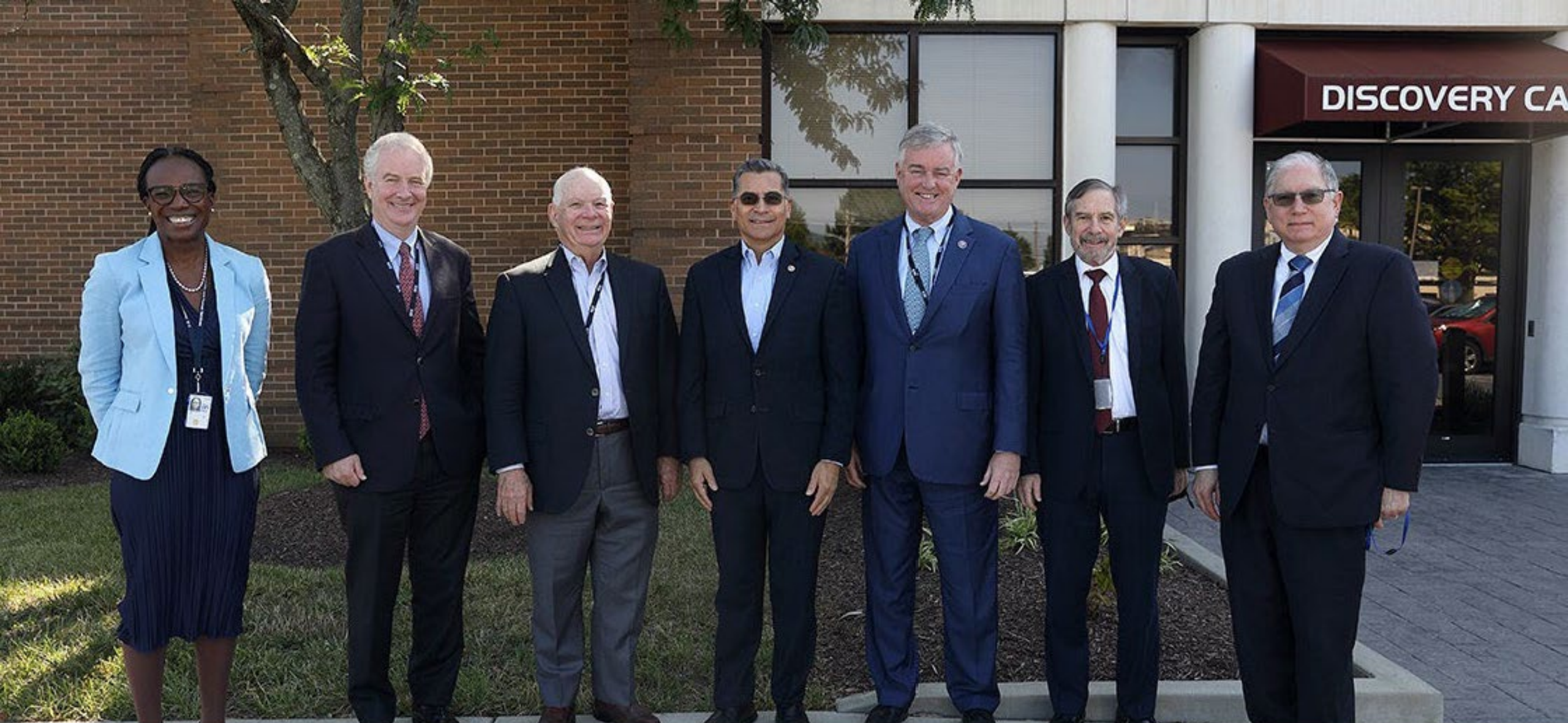
**Admiral Rachel L. Levine, MD  
Assistant Secretary for Health**





# Roy Blunt Center for Alzheimer's Disease and Related Dementias Research





**Xavier Becerra  
HHS Secretary**

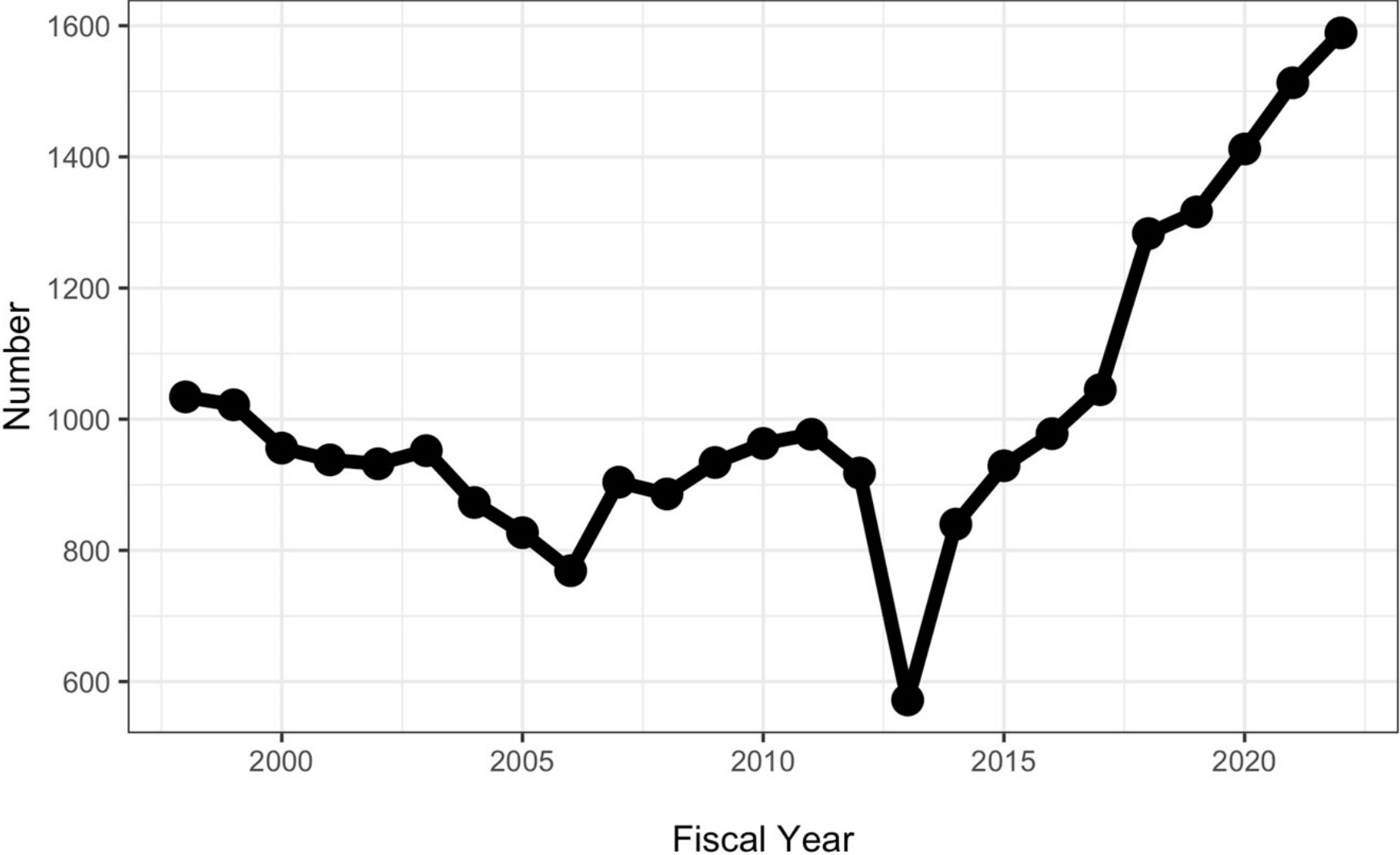


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# Early Stage Investigators (ESI) Funded on First R01-Equivalents



- NIH's goal is to fund 1100 ESI per year
- In 2022, NIH funded a record **1589 ESI applicants**



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# Improving Quality of Public Information about R&D Contracts

- R&D contract awards represent ~8% of the NIH budget
- Current public data on R&D contracts lacks the richness of grants data
- Later this year, NIH will begin requiring extramural R&D contract awardees to upload information about the science being done into eRA Commons
- The new process will:
  - Allow contract awardee to accurately characterizes contracts
  - Improve transparency into contract data, commensurate to grants
  - Replace manual process of uploading information by NIH staff



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**Objective 1: Grow and Sustain DEIA through Structural and Cultural Change**



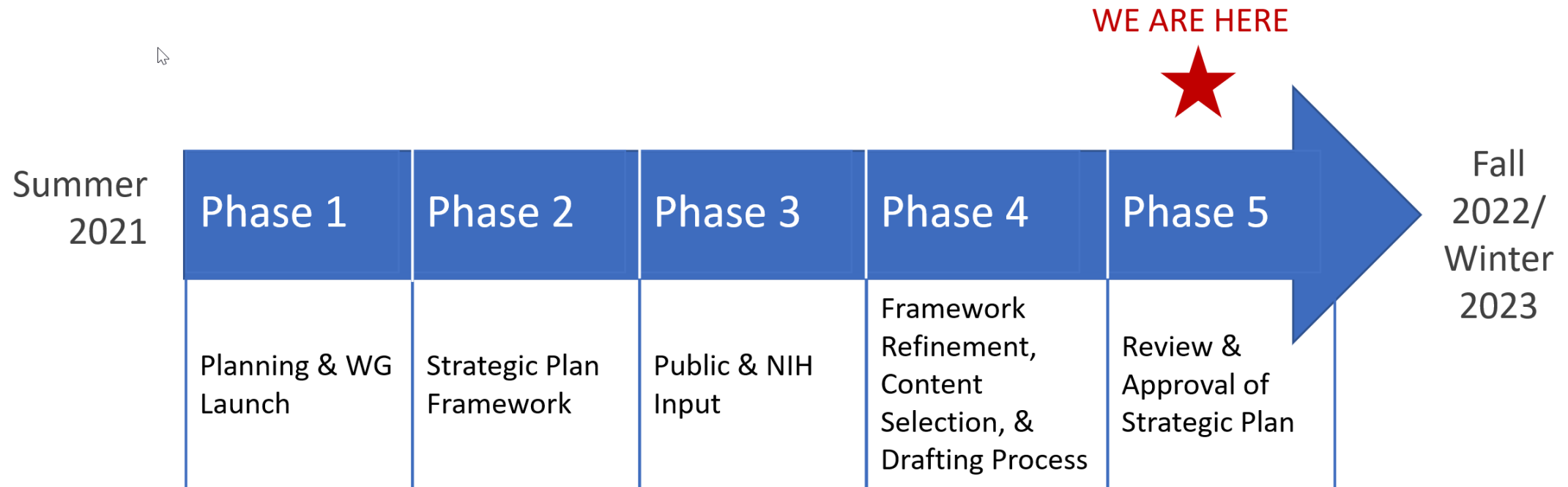
**Objective 2: Implement Organizational Practices to Center and Prioritize DEIA in the Workforce**



**Objective 3: Advance DEIA through Research**

DEIA  
Strategic  
Plan  
Framework

# Process & Timeline



# Current Status



## Community Input

Internal NIH  
External community



## Review and Approval Process

Pending final sign-off by NIH Leadership



## Plan Implementation

Comprehensive, inclusive, and intentional approach to implementation



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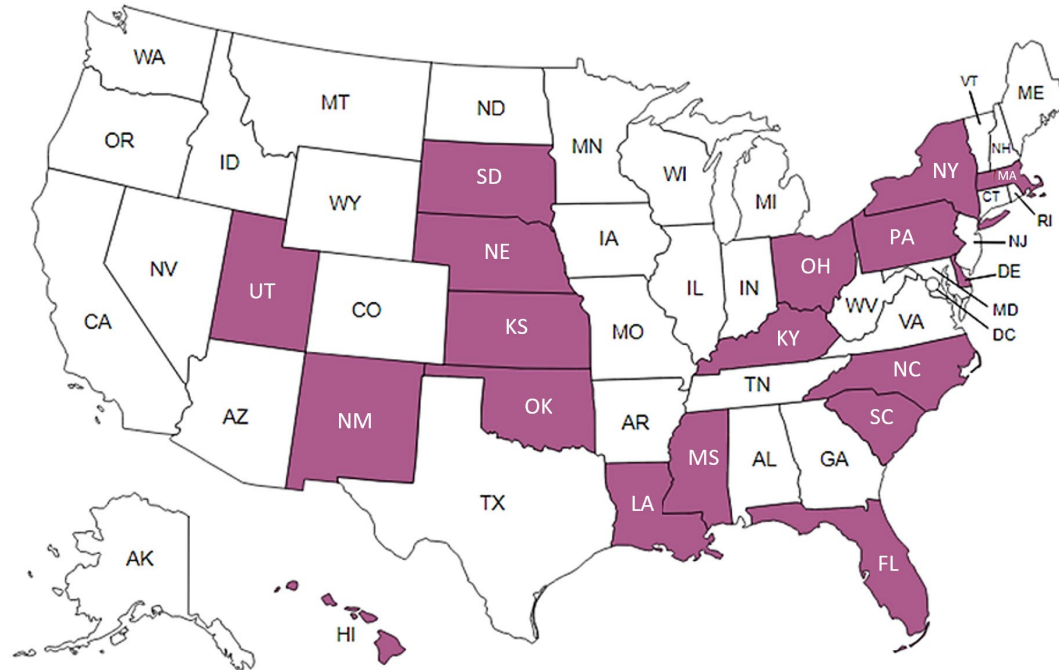


**NIH**  
**HEAL**  
**INITIATIVE**

**NIH** Eunice Kennedy Shriver National Institute  
of Child Health and Human Development  
**NEONATAL RESEARCH NETWORK**

**NIH** National Institutes of Health  
Environmental influences on Child Health Outcomes (ECHO)  
**IDEA States Pediatric Network**

# Eating, Sleeping and Consoling for Neonatal Opioid Withdrawal A Randomized Controlled Trial



# Background and Objective

- Neonatal opioid withdrawal syndrome (NOWS) follows *in utero* opioid exposure
  - Opioid epidemic → high incidence of NOWS
  - Newborns are irritable, do not eat or sleep well, spend many days in hospital
  - If symptomatic enough, clinicians traditionally treat with replacement opioids
- Substantial variation in management of NOWS
  - No evidence-based standard of care
- Objective: Effectiveness and safety of new approach vs. usual care
  - Simpler assessment—Eat, Sleep, Console
  - Prioritize non-pharmacologic care, e.g., holding, swaddling, rocking
  - Caretaker involvement

# Study Design

- Collaboration across 2 NIH pediatric clinical trial networks
  - Office of the Director and NICHD
- Stepped wedge cluster randomized trial
  - Randomly allocated 26 hospitals to transition from usual care to Eat, Sleep, Console care at designated time
- Whole of practice change
  - Trained ~5000 nurses
- Led by 3 Early Stage Investigators

NIH  
**HEAL**  
INITIATIVE

NIH Eunice Kennedy Shriver National Institute  
of Child Health and Human Development  
NEONATAL RESEARCH NETWORK

NIH National Institutes of Health  
Environmental influences on Child Health Outcomes (ECHO)  
**IDeA States Pediatric Network**



# Results, Conclusions, Next Steps

- Eat, Sleep, Console care approach
  - Substantially decreased time until infants medically ready for discharge from hospital
  - Substantially decreased pharmacologic treatment
  - Did not affect safety outcomes through 3 months of age
  - Provides strong support for standard care for NOWS
- Presented at national meeting December 5, 2022
- Manuscript under review
- Next
  - 2-year follow-up for family wellbeing, child neurodevelopment

# About the Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD)



Partnerships

Research

Infrastructure

Training

## Goals:

- to enhance the **participation** and **representation** of researchers and communities currently underrepresented in the development of artificial intelligence and machine learning (AI/ML) models
- to address health disparities and inequities using AI/ML
- to improve the capabilities of this emerging technology, beginning with the use of electronic health record (EHR) and extending to other diverse data

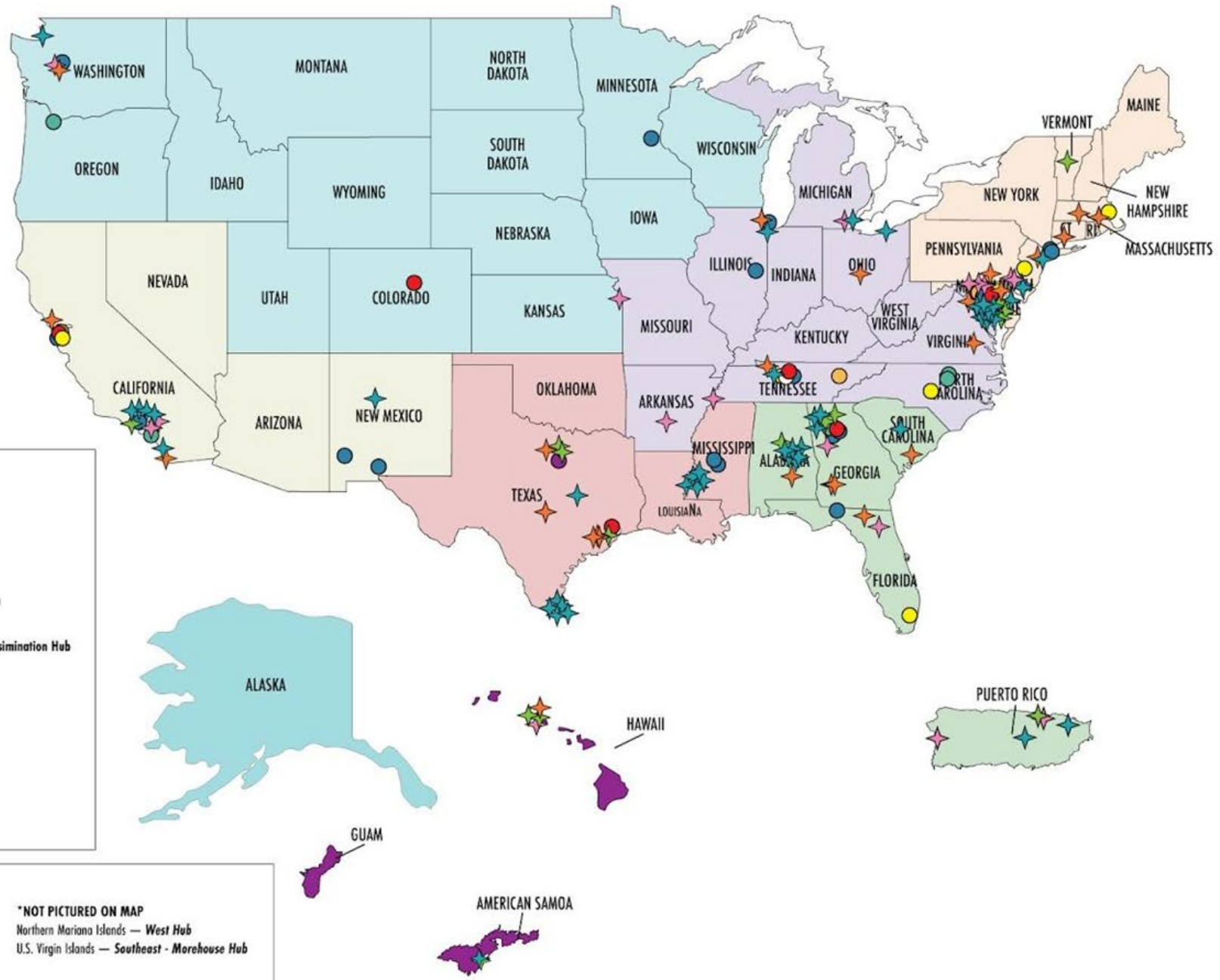
<https://aim-ahead.net/>

<https://datascience.nih.gov/artificial-intelligence/aim-ahead>

# AIM-AHEAD Accomplishments

- 22 [Research Fellowships](#) awarded in 2022, engaging early-career researchers from under-represented populations in biomedical research that involves the use of AI/ML methodologies on Electronic Health Record Data.
- 25 [Leadership Fellowships](#) awarded in 2022, preparing a diverse leaders to champion the use of AI/ML in addressing persistent health disparities
- 27 [PRIME training practicum](#) awards made in 2022, enhancing technical competencies in AI/ML for graduate students from MSIs.
- 46 [Professional Development awards](#) made in 2022 to underrepresented health care workers to enhance awareness and understanding of AI and health equity.
- 22 **Pilot research projects** awarded in 2022, to test new paradigms of research, data analysis, and the new ways for underrepresented groups to derive value from their own health data.
- [AIM-AHEAD connect](#) platform launched as virtual hub for research at the intersection of AI/ML and health equity.
- Numerous [webinars](#) and symposia, including AI for Health Equity ([AIEHS 2022](#))





**Core**

- Data Research Core
- Data Science Training Core
- Infrastructure Core
- L/A Core
- Primary LAC Institution
- Central Hub
- Communications & Dissemination Hub

**Hubs**

- North and Midwest Hub
- Northeast Hub
- South Central Hub
- Southeast - Meharry Hub
- Southeast - Morehouse Hub
- West Hub

**Awards**

- ◆ Pilot Project
- ◆ Leadership Fellow
- ◆ Research Fellow
- ◆ DSTC Pilot Program

**\*NOT PICTURED ON MAP**  
 Northern Mariana Islands — West Hub  
 U.S. Virgin Islands — Southeast - Morehouse Hub

# Consortium Development Pilot Projects

The AIM-AHEAD Coordinating Center supports a range of pilot projects deemed to address high priority opportunities in AI/ML and health equity.

#	Institutions/Organization	Description
1	University of Puerto Rico	Identify reference intervals of cardiometabolic related laboratory tests for Hispanic populations using Machine Learning Methods (MLM)
2	Kula no na Po'e Hawaii o Papak0. .0.olea, Kewalo, Kalawahine University of Hawaii at Manoa Hawaii Pacific University Ulu Hi-Tech	Ka Malu a Moananui: Bridging the cardiometabolic diseases gap in the US Affiliated Pacific Islands (USA-PI) by providing AI/ML tools to Community Health Workers
3	University of Hawaii at Manoa	Leveraging AI and Machine Learning to address intersex under-diagnosis/under-recognition
4	Medical Decision Logic, Inc. Nah Tah Wahsh Hannaville High School Michigan Department of Education Prince George's County Public Schools	Establishing student project capabilities to improve suicide prevention (PROTECT): Rich data access, ML algorithm optimization, translation to practice
5	Houston Methodist Research Institute University of Houston	Using Artificial Intelligence to improve cardiometabolic health: Validating a kidney transplant derailers index to predict transplant drop-out risk for African American and Hispanic patients
6	University of Florida College of Medicine - Jacksonville	Conducting research leveraging AIM-AHEAD centralized patient-level data resource - Outpatient Opioid use and consequences
7	Acclinate	Culturally tailored participatory action research (CURATOR) to identify AI/ML applicable health disparities approach
8	Alexandria City Public Schools George Washington University	AI-for-You: Data mining to improve mental health through shared decision-making in minority adolescents and their parents
9	Emory University	Radiology AI/ML to address disparities in cardiometabolic diseases and cancer research through the AIM-AHEAD Consortium
10	University of Miami Florida Atlantic University Caridad Center	Developing a precise, localized, community focused, population health framework in an FQHC to tackle chronic disease disparities through EHR data
11	Vibrent Health Association of Community Cancer Centers Loyal Jones Appalachian Center at Berea College Bluefield State University Marshall University Bon Secours - Southside Regional Medical Center St. Elizabeth Healthcare	Stratifying health care biases and determinants of high cancer death rates in rural Appalachia by AI/ML-facilitated HER data Analytics
12	Providence	Leveraging the Center for Kidney Disease Research, Education, and Hope (CURE-CKD) Registry as a toll to reduce cardiometabolic disparities
13	Baylor College of Medicine	Building AI/ML algorithm to predict and prevent cancer treatment complications in underserved and minority patients in a metropolitan catchment area
14	University of North Texas	Evaluating bias in predictive and explainable ML algorithms among older adults with cancer
15	University of Colorado Denver University of California, Irvine	Cardiometabolic risk prediction among American Indian and Alaska Native (AI/AN) adult using machine learning (ML) approaches and electronic health record (EHR) data
16	Norwich University	Modeling exposure to gun violence and trajectory of behavioral health outcomes
17	University of Miami Florida Memorial University Miami Dade College	Creating an educational AI/ML-based infrastructure and job readiness (CAIR) program to increase workforce diversity and professional development amongst URM faculty and students
18	MedCognetics, Inc.	Racially unbiased Artificial Intelligence (AI) algorithms for breast cancer detection
19	American Samoa Community Cancer Coalition University of Hawaii Cancer Center	A pilot study assessing AI/ML models to increase colorectal cancer detection for indigenous American Samoa adults
20	University of Hawaii at Manoa	Machine learning (ML)-based approaches to understand lung cancer health disparities by integrating genomics and health record data
21	University of Georgia	Improving prediction of beneficiary-level medical costs by incorporating social determinants of health indicators in risk adjustment models to address health disparities: A machine learning approach

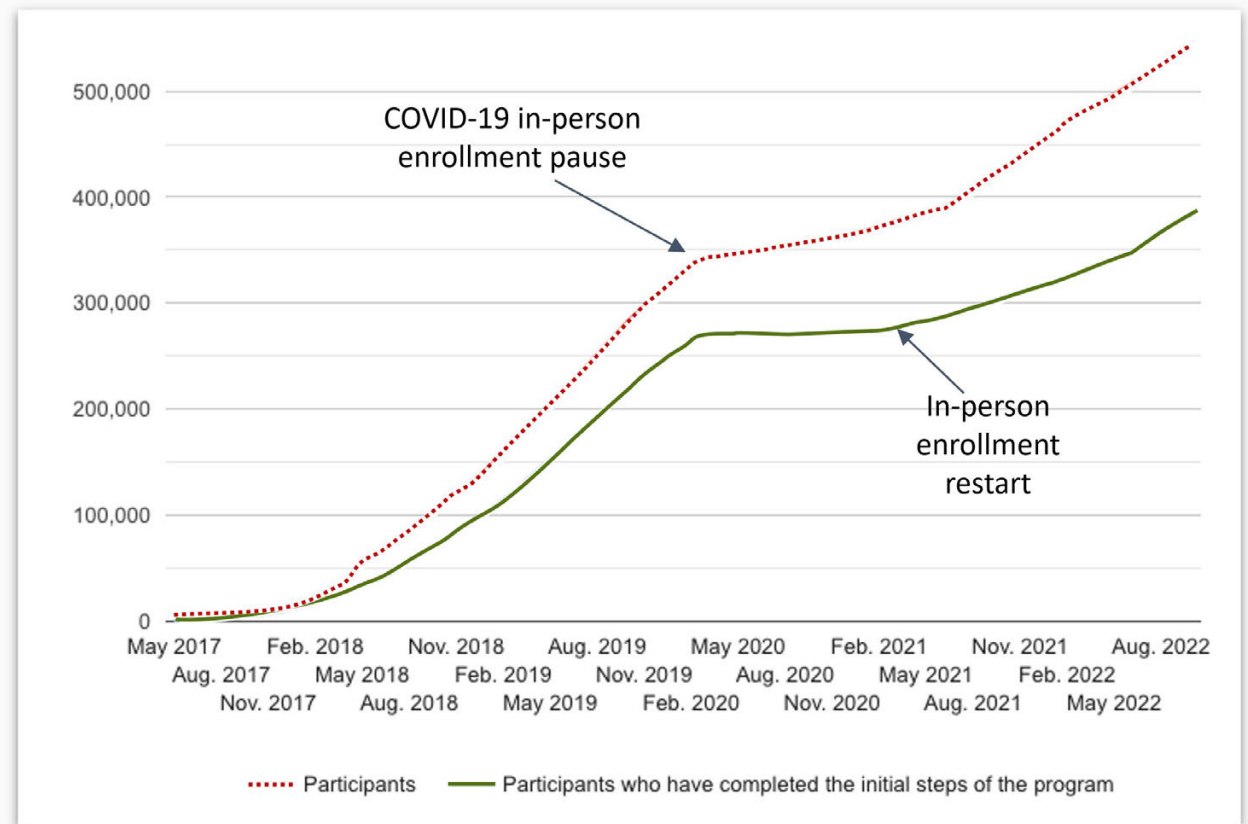
# All of Us Enrollment Update as of December 5, 2022

**559,000+**  
Participants

**339,000+**  
Electronic Health  
Records

**393,000+**  
Participants who have  
completed initial steps  
of the program

**411,000+**  
Biosamples



## Diversity

Includes racial and ethnic minorities as well as sexual and gender minorities, people with low income or limited education and other groups.

**50%+** Racial and Ethnic Minorities

**80%+** Underrepresented in Biomedical Research




# Genomic Health-Related Return of Results in Pilot Testing

**All of Us**  
RESEARCH PROGRAM

JANE DOE  
DOB: May 25, 1977  
ID: 123456

Specimen: Blood  
Barcode: 223 234234 2343  
Collected: September 15, 2018  
Report date: October 2, 2018

RESEARCH RESULT - Your doctor will need to confirm this result with a clinical test before using it in your care.



## Medicine and your DNA

Our **genes** affect how we respond to medicine.

**Genes affect how we respond to medicine in many different ways**

Some genes help move medicines to the right part of your body. Some genes help break down medicines in your body. Some genes even change the way medicines work into a form that makes them work properly.

This test looked at a few of the genes in your DNA that affect how medicines are used by your body. The medical term for this kind of information is "pharmacogenomics".

**What is this kind of information used for?**

Doctors and pharmacists use this kind of information when they consider why medicines work differently for different people.

**But doctors and pharmacists don't make decisions based on just DNA.** Some other important considerations include age, weight, health, diet, and other medicines you are taking at the same time.

**IMPORTANT!**

**Share this report with your doctor.**

- If your doctor has prescribed medicine for you, **keep taking it.** It can be dangerous to stop taking a medicine, or to change the dose or timing of a medicine, without first asking your doctor.
- This report comes from a research program so it is a **research result.** That means that neither you nor your doctor should use it to make any changes to your medicines. Your doctor would need a separate clinical test if they wanted to use the information.

Genome Center: XXXXX, CLIA #XXXXXXXXX  
Laboratory Director: XXXXXX

Hereditary Disease Risk Report: DNA and the risk for some diseases

RESEARCH RESULT - Your doctor will need to confirm this result with a clinical test before using it in your care.

**All of Us**  
RESEARCH PROGRAM

JANE DOE  
DOB: May 25, 1977  
ID: 123456

Specimen: Blood  
Barcode: 223 234234 2343  
Collected: September 15, 2018  
Report date: October 2, 2018



## Your Result:

Something very important for your health was found in your **BRCA1** gene.

**What does this mean?**

- This result means that you are more likely than other people to get certain types of cancer.
- It does **not** mean that you have certain types of cancer.
- It does **not** mean that you will definitely get certain types of cancer.
- This result is important** and should not be ignored.

**IMPORTANT!**

**Share this report with your doctor.**

- This report comes from a research program so it is a **research result.** Your doctor will need to confirm these results with a clinical genetics test before using them in your care.
- Do not change your medical care** before this result is confirmed by your doctor.
- Results provided are from an investigational device.** An "investigational device" is a device that is the subject of a clinical study.

**The BRCA1 gene**

Women and men who have this result in the **BRCA1** gene have a higher chance of developing certain cancers in their lifetime compared to someone without this result. Women are at higher risk for breast cancer and ovarian cancer. They may also have a higher risk of pancreatic cancer. Men are at higher risk for male breast cancer and pancreatic cancer. They may also have a higher risk of prostate cancer.

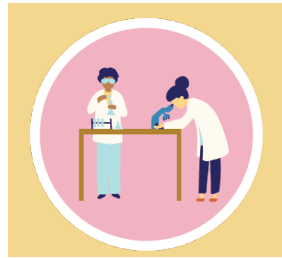
Genome Center: XXXXX, CLIA #XXXXXXXXX  
Laboratory Director: XXXXXX

Hereditary Disease Risk Report: DNA and the risk for some diseases

- **Hereditary disease risk** (starting with ACMG59) and **medicine and your DNA** (pharmacogenomics)
- Participants can choose results they want
- Interpretation begins at Clinical Validation Laboratories
- All results supported by Genetic Counselors
- Participants can obtain clinical results available for ACMG59 at no cost

# All of Us Researcher Workbench Usage and Diversity

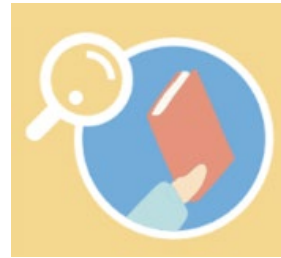
## Research on the Researcher Workbench



**3,600+**  
Registered  
Researchers



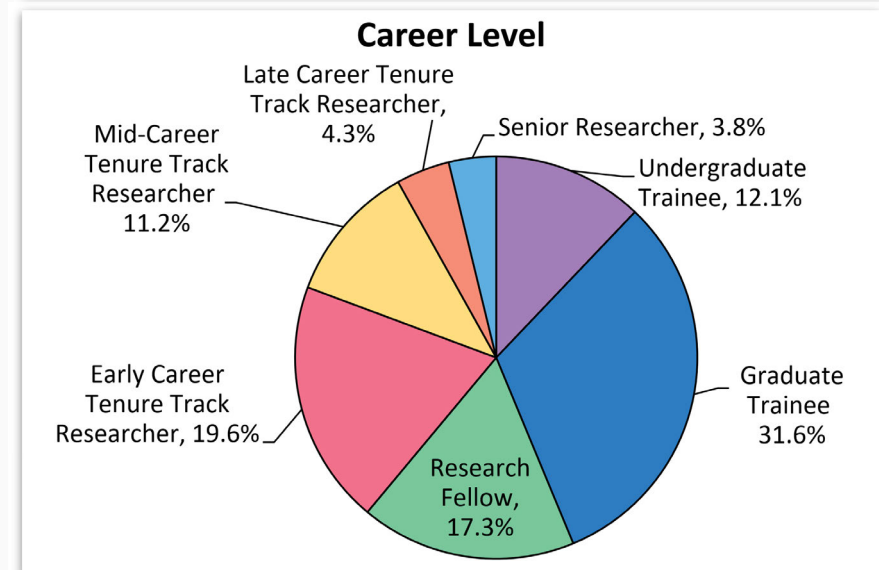
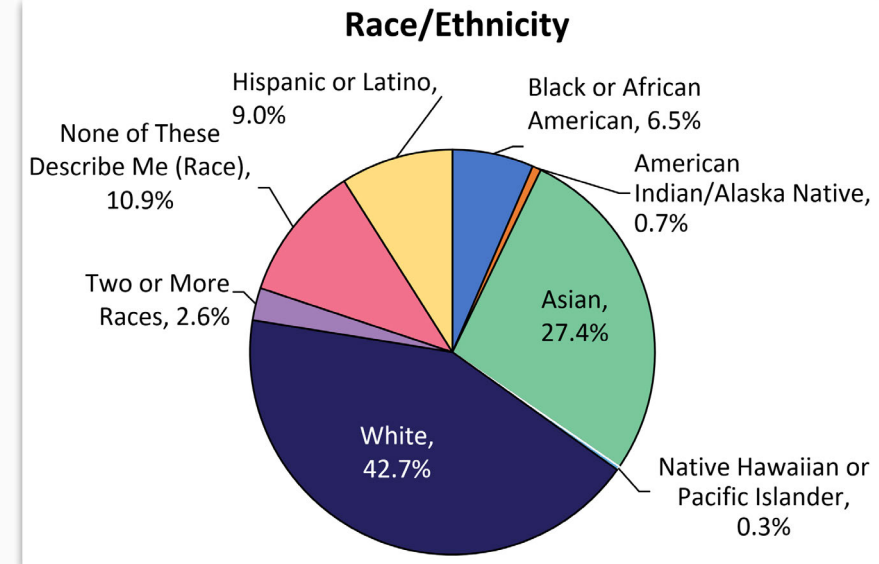
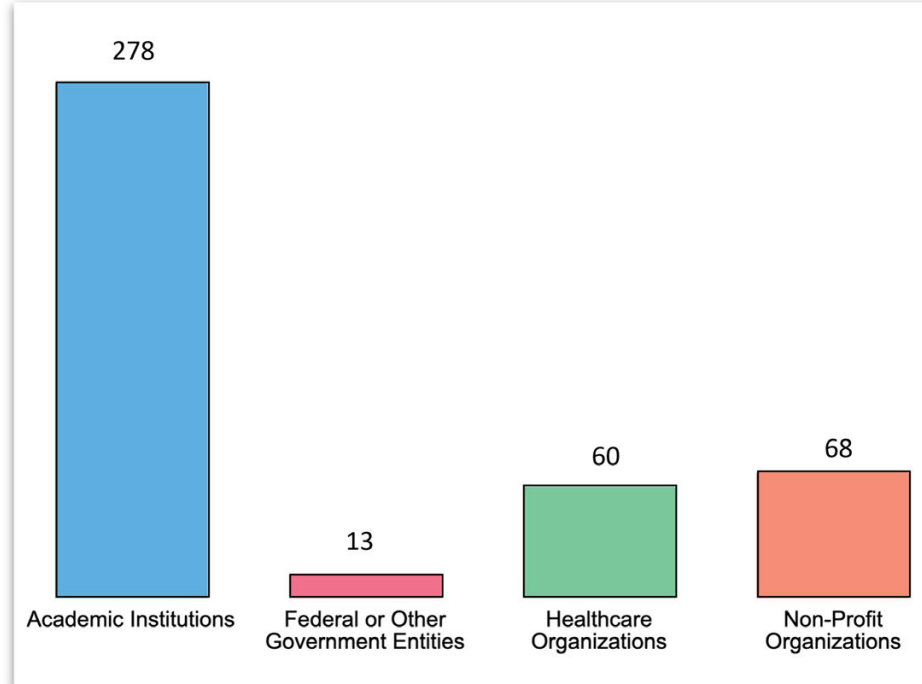
**3,099+**  
Active  
Projects



**100+**  
Publications  
using *All of Us*  
data

### 435+ Organizations:

- 28 Historically Black Colleges & Universities
- 36 Hispanic Serving Institutions



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# Budget Update

**NIH Director's Report to the Advisory  
Committee to the Director  
December 8, 2022**

**Neil K. Shapiro  
Associate Director for Budget, NIH**



## FY 2023 So Far

- Currently under a Continuing Resolution
  - First through December 16, 2022.
  - Second expected, into at least early January.
  - Funding level is FY 2022 enacted, prorated for the time period.
- Congress is working on an omnibus, which may include both annual and supplemental appropriations.
- Type 1 Diabetes mandatory funding is already appropriated for FY 2023 but reduced by 5.7 percent (from \$150 to \$141.45 million) due to sequestration.

# Appropriations Action: House

- FY 2023 bill was approved by Subcommittee on June 23 and full Committee on June 30. It was not included in a consolidated bill that passed the House in July.
- Includes a \$2.5 billion increase over FY 2022 for NIH Institutes and Centers.
- Across-the-board increase of at least 3.2 percent, as well as targeted increases for several research areas.
- ARPA-H is funded at \$2.75 billion, a \$1.75 billion increase over FY 2022, but in HHS without authority to transfer to NIH.



# Appropriations Action: Senate

- FY 2023 bill recommended by the Subcommittee Chair was released on July 28.
- Funding level for NIH is \$2 billion above FY 2022.
- Across-the-board increase of at least 3.1 percent, as well as targeted increases for several research areas.
- ARPA-H is funded at \$1 billion, the same level as FY 2022, within NIH.
- Includes \$16 billion of emergency supplemental funding to HHS for COVID-19, including development of next-generation vaccines.

# FY 2023 Comparison

<b>\$ in billions</b>	<b>FY 2022 Enacted</b>	<b>FY 2023 PB</b>	<b>FY 2023 House</b>	<b>FY 2023 Senate</b>
Program Level*	45.18	45.45	47.68	47.18
+/- FY 2022		+0.27	+2.50	+2.00
ARPA-H	1.00	5.00	2.75	1.00
<i>*less ARPA-H and the Pandemic Preparedness mandatory proposal</i>				

- The Pandemic Preparedness proposal (\$12.05 billion) has not advanced in Congress, but more emergency supplemental funding has been requested for HHS to respond to COVID-19, including Long COVID.

# FY 2023 Targeted Increases

<b>\$ in millions</b>	<b>FY 2023 PB</b>	<b>FY 2023 House</b>	<b>FY 2023 Senate</b>
Opioids/pain (inc. HEAL)	552	98	140
Health disparities	350	100	100
Alzheimer's disease	--	200	--
Buildings & Facilities	50	50	100
Nutrition Science	96	39	24

- Several of the NIH priorities with initiative funding in the President's Budget received support from both House and Senate.





# Legislative Update

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Adrienne Hallett

Associate Director for Legislative Policy & Analysis

December 8, 2022

# Lame Duck Legislation

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FY 2023 Appropriations - government funding expires December 16, 2022



National Defense Authorization Act (NDAA)



Other Health Provisions - FDA technical fixes; Pandemic Preparedness; ARPA-H authorization



Debt limit?



# 2022 Midterm Election Outcomes

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Voters Sought Stability and Incumbents Won

## Senators

100 % of  
incumbents won

51D – 49R

## House

97 % of  
incumbents won

219R – 212D

\*Races still pending  
Majority = 218

## Governors

98 % of  
incumbents won

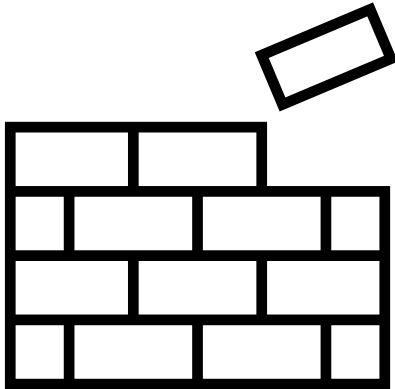
26R – 24D



# 118<sup>th</sup> Congress

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- Convenes on January 3, 2023
- Each Congress rebuilds itself – new rules and orders are made
  - Leadership elections
  - Committee assignments and leaders determined
- New Majority in the House – rules to watch:
  - Remote and proxy voting debate
  - Term limits debate for committee chairs and ranking members
  - Debate on whether and how to allow earmarks
  - Debate on rule change for removing the Speaker





# Majority Size Matters

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- Narrow margins of control in both Chambers.
- House – 1-vote majority empowers caucuses
  - Freedom Caucus ~50 members
  - Republican Governance (Tuesday Group) ~45 members
  - Problem Solvers ~50 bipartisan members
  - Blue Dog Democrats ~20 members
  - Progressive Caucus ~100 members
- Senate Majority – Democrats gained 1 seat
  - Determines Committee power structure and subpoena power.

Narrow margins  
empower factions



# Congressional Leadership - Democrats

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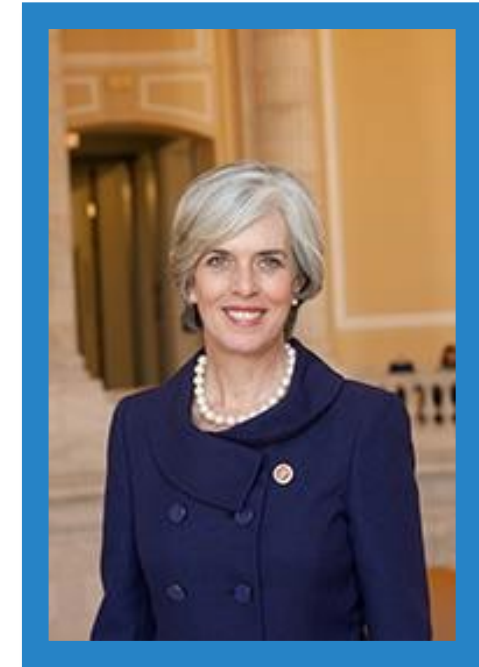
Generational shift for House Democrats.



Rep. Pete Aguilar  
Democratic Caucus Chair



Rep. Hakeem Jeffries  
Minority Leader



Rep. Katherine Clark  
Minority Whip

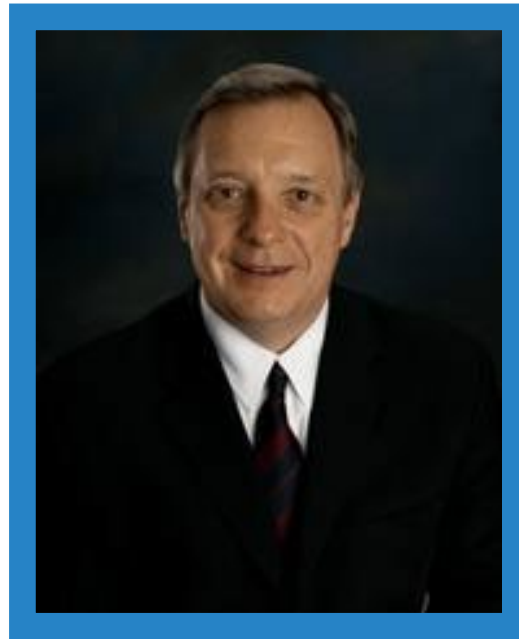
# Congressional Leadership - Democrats

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Pressure on the Senate to follow suit...



Sen. Chuck Schumer  
Majority Leader



Sen. Dick Durbin  
Majority Whip



Sen. Patty Murray  
President Pro Tempore

# Congressional Leadership - Republicans

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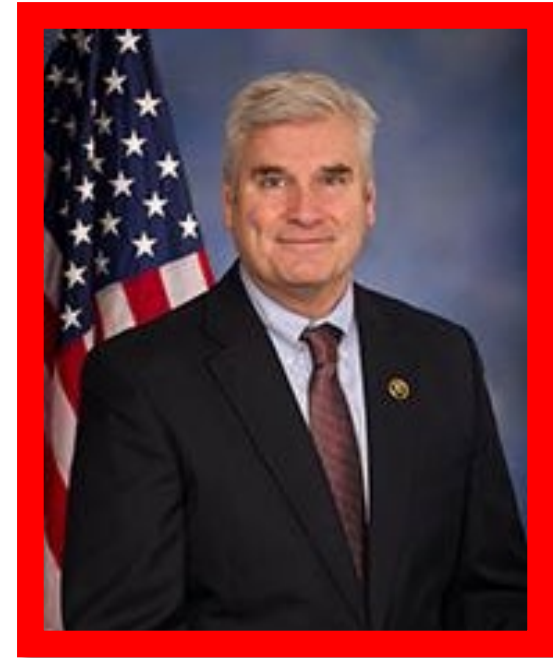
Election for the new Speaker of the House in January.



Rep. Kevin McCarthy  
Speaker?



Rep. Steve Scalise  
Majority Leader



Rep. Tom Emmer  
Majority Whip



# Congressional Leadership - Republicans

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Senate.



Sen. Mitch McConnell  
Minority Leader



Sen. John Thune  
Minority Whip



Sen. John Barrasso  
Republican Conference Chair

# New Leadership of Health Policy Panel

## New Priorities

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“...will focus on universal health care, lowering the cost of prescription drugs, increasing access to higher education, and protecting workers’ right on the job”

Senator Bernie Sanders  
(expected Chairman of HELP)

“HELP passed the Surprise Medical Billing bill. The administration has not implemented it well. I’d like to have oversight over surprise medical billing.”

Senator Bill Cassidy  
(expected Ranking Member of HELP)



# House Leaders Proclaiming a Renewed Focus on Oversight

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“The American people deserve the facts. Part of our constitutional duty, when I take the oath of office on January 3 in a new Congress...is to do those investigations, do the oversight so the people, we the people, get the facts, get the truth.”

Representative Jim Jordan (expected Chairman of House Judiciary )

“We believe that there have been hundreds of billions, if not trillions of dollars wasted over the past three years, so that spans two administrations, in the name of COVID. We want to have hearings on that.”

Representative James Comer  
(expected Chairman of House Oversight)



# House Leaders Proclaiming a Renewed Focus on Oversight

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“How the pandemic started, that’s probably the most important public health question that needs to be answered.”

Representative Cathy McMorris Rodgers (expected Chairwoman of House Energy & Commerce)

## Stated Priorities

1. Afghanistan
2. Hunter Biden
3. COVID-19 Response and Origins



# NIH Priorities for the 118<sup>th</sup> Congress

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1

- Introducing NIH broadly
  - Record number of retirements the last 3 election cycles.
  - Newer Members only know NIH from COVID and controversy

2

- Develop champions for programs and policies
  - General support for scientific and public health priorities
  - Additional knowledge for sensitive topics, such as:
    - animal research, genomic data sharing, international collaboration.

3

- NIH Director nominee?

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Questions?

# Topics for Today

- Appointments and Departures
- Awards and Honorees
- Special Events
- ESI Update
- eRA Update
- DEIA Strategic Plan Update
- Initiatives Updates
- Budget and Legislative Updates
- **Reflection: Leading Through Turbulent Times**







# NIH...

# Turning Discovery Into Health

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