

# Director's Update

Francis S. Collins, M.D., Ph.D.  
Director, National Institutes of Health  
**Council of Councils Meeting**  
**September 6, 2019**



# Changes in Leadership

## ■ Retirements

- Paul A. Sieving, M.D., Ph.D., Director of the National Eye Institute (7/29/19)
- Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S., Director of the National Institute of Environmental Health Sciences (10/3/19)



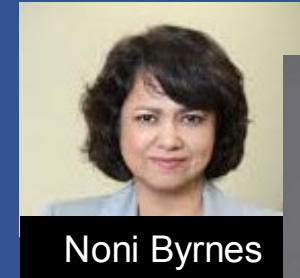
Paul Sieving



Linda Birnbaum

## ■ New Hires

- Noni Byrnes, Ph.D., Director, Center for Scientific Review (2/27/19)
- Debara L. Tucci, M.D., M.S., M.B.A., Director, National Institute on Deafness and Other Communication Disorders (9/3/19)



Noni Byrnes



Debara Tucci

## ■ New Positions

- Tara A. Schwetz, Ph.D., Associate Deputy Director, NIH (1/7/19)



Tara Schwetz



## GOVERNMENT HALL OF FAME

# 2019 Inaugural Inductees



APOLLO 11 ASTRONAUTS:  
EDWIN "BUZZ" ALDRIN, NEIL ARMSTRONG  
AND MICHAEL COLLINS



DWIGHT INK



ELLIOT RICHARDSON



ANTHONY FAUCI

Fauci is an immunologist who helped pioneer treatment and vaccine for AIDS. Since 1984, he has headed the National Institute of Allergy and Infectious Diseases, where he administers key research into sexually transmitted infections, influenza, tuberculosis, malaria and illnesses from potential agents of bioterrorism. He has advised five presidents on global HIV/AIDS issues.



GRACE HOPPER



COLIN POWELL



PAUL VOLCKER



ALICE RIVLIN



THEODORE ROOSEVELT

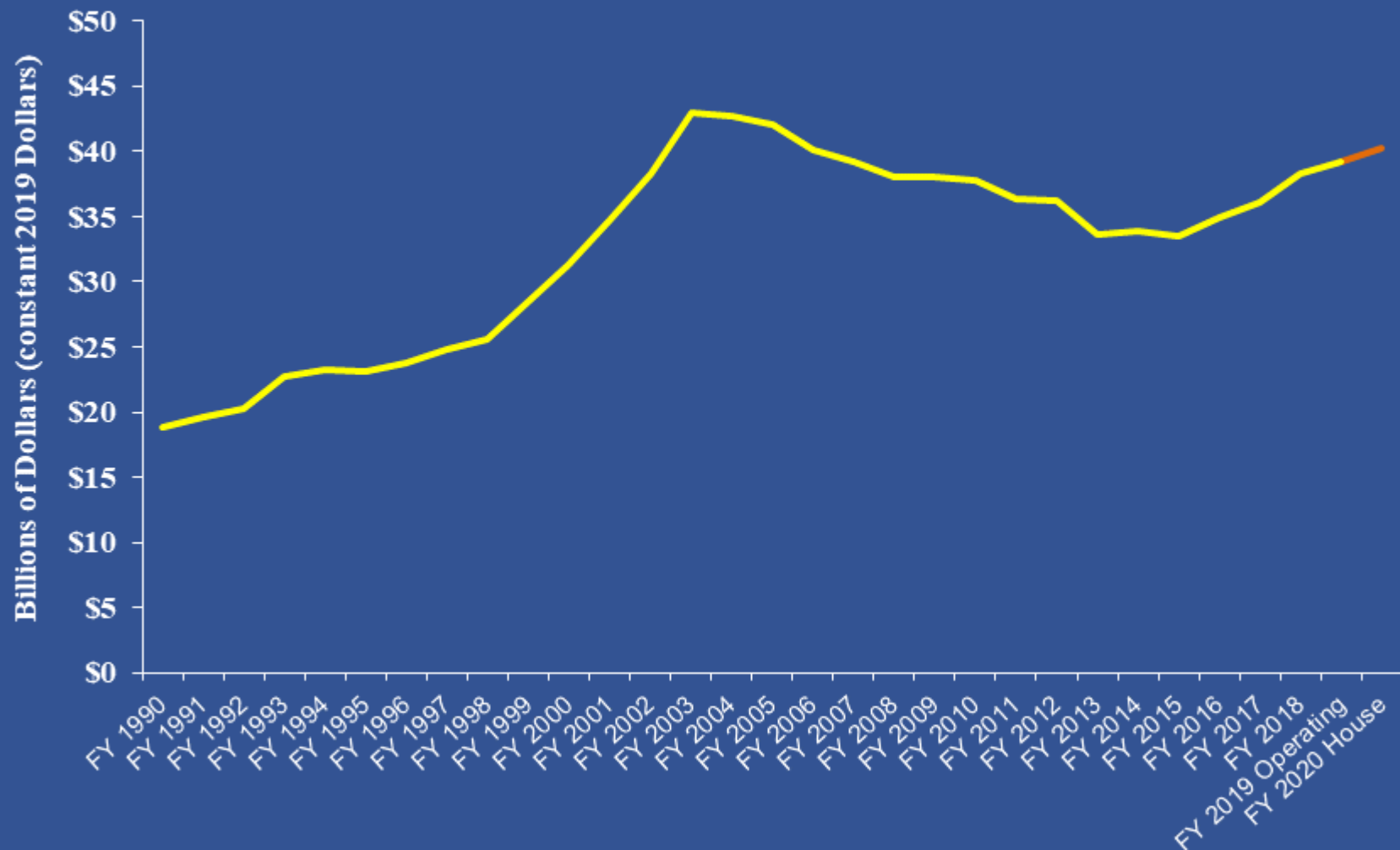


DONNA SHALALA



SUSAN SOLOMON

# National Institutes of Health Funding 1990-2020



Note: Dollar values are adjusted to 2019 dollars using the Biomedical Research and Development Price Index (BRDPI), <http://officeofbudget.od.nih.gov/gbiPriceIndexes.html>

Source: NIH Office of Extramural Research and Office of Budget source data (January 2019).

# Topics for Today

- NIH HEAL (Helping to End Addiction Long-term<sup>SM</sup>) Initiative
  - HEALing Communities Study
- Artificial Intelligence: ACD WG Update
- Human Genome Editing – Exciting Promise for Cures, Need for Moratorium on Germline
- Addressing Foreign Influence on Research ... and Harassment in the Research Workplace





# NIH HEAL Initiative<sup>SM</sup>

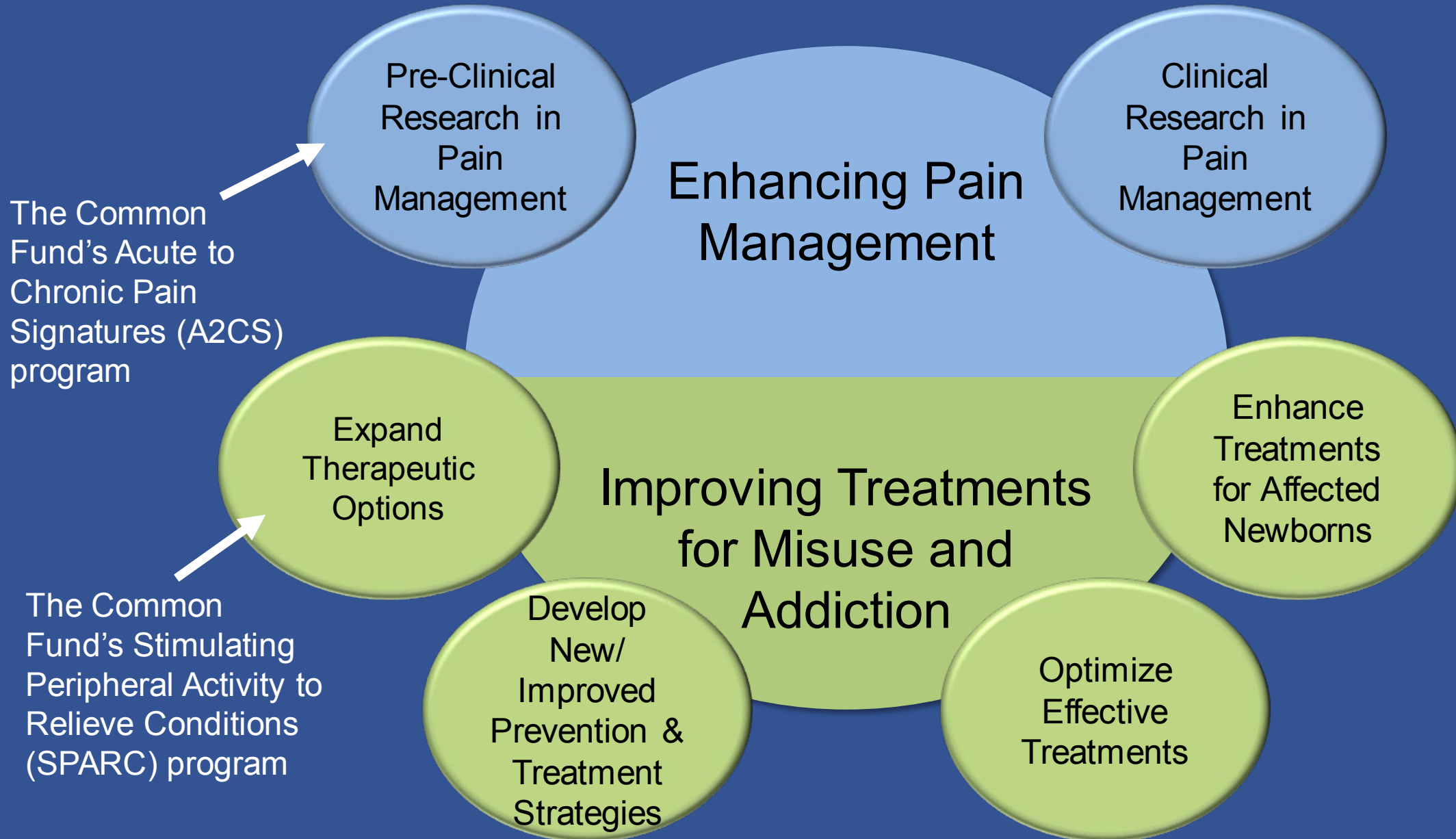
- Trans-NIH research initiative to:
  - Improve prevention and treatment strategies for opioid misuse and addiction
  - Enhance pain management
- Goals are scientific solutions to the opioid crisis
- Coordinating with the HHS Secretary, Surgeon General, federal partners, local government officials and communities



# NIH HEAL Initiative: At a Glance

- \$500M/year
  - Will spend \$930M in FY2019
- 12 NIH Institute and Centers leading 26 HEAL research projects
  - Over 20 collaborating Institutes, Centers, and Offices
  - From prevention research, basic and translational research, clinical trials, to implementation science
  - Multiple projects integrating research into new settings
- Released 40+ funding announcements for FY2019
  - HEAL Multi-Disciplinary Working Group met Aug 22-23 and final allocating decisions for FY2019 were made

# NIH HEAL Initiative: Research Overview



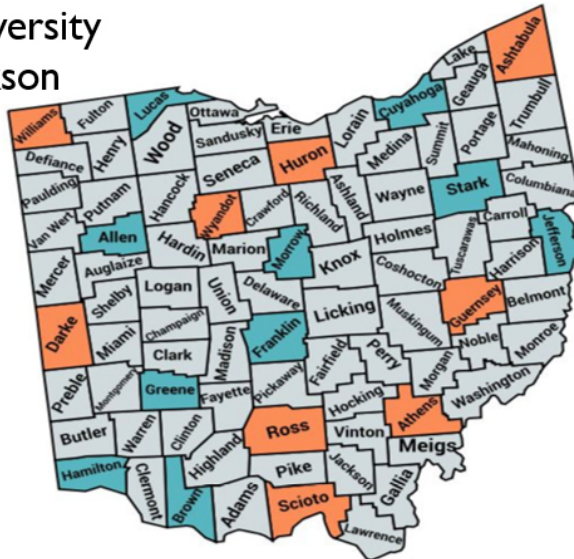


# The HEALing Communities Study: Primary Goal and Key Outcomes

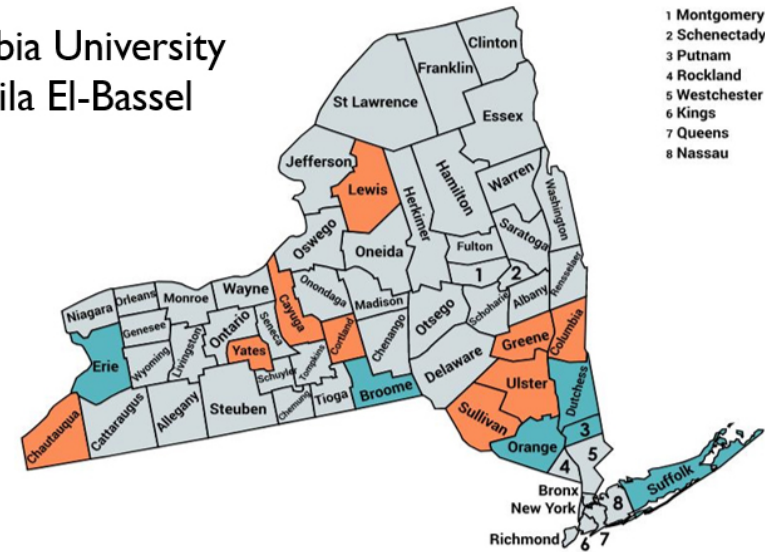
- Primary Goal: develop an evidence-based, integrated, comprehensive strategy that reduces opioid-related overdose fatalities by 40% in 3 years across communities highly affected by the opioid crisis
- Key Outcomes:
  - Reduce overdose fatalities and events
  - Increase naloxone access
  - Decrease incidence of OUD
  - Increase the number of individuals:
    - Receiving medication and behavioral treatment
    - Retained in treatment beyond 6 months
    - Receiving recovery support services

# The HEALing Communities Study: Research Sites

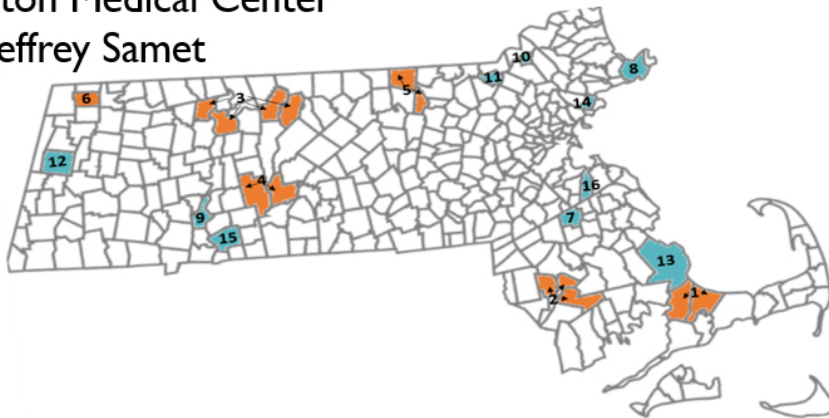
Ohio State University  
PI: Rebecca Jackson



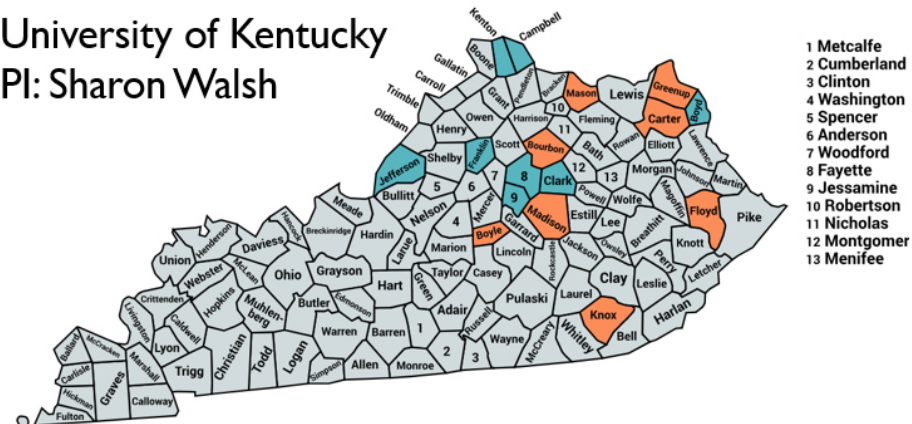
Columbia University  
PI: Nabila El-Bassel



Boston Medical Center  
PI: Jeffrey Samet



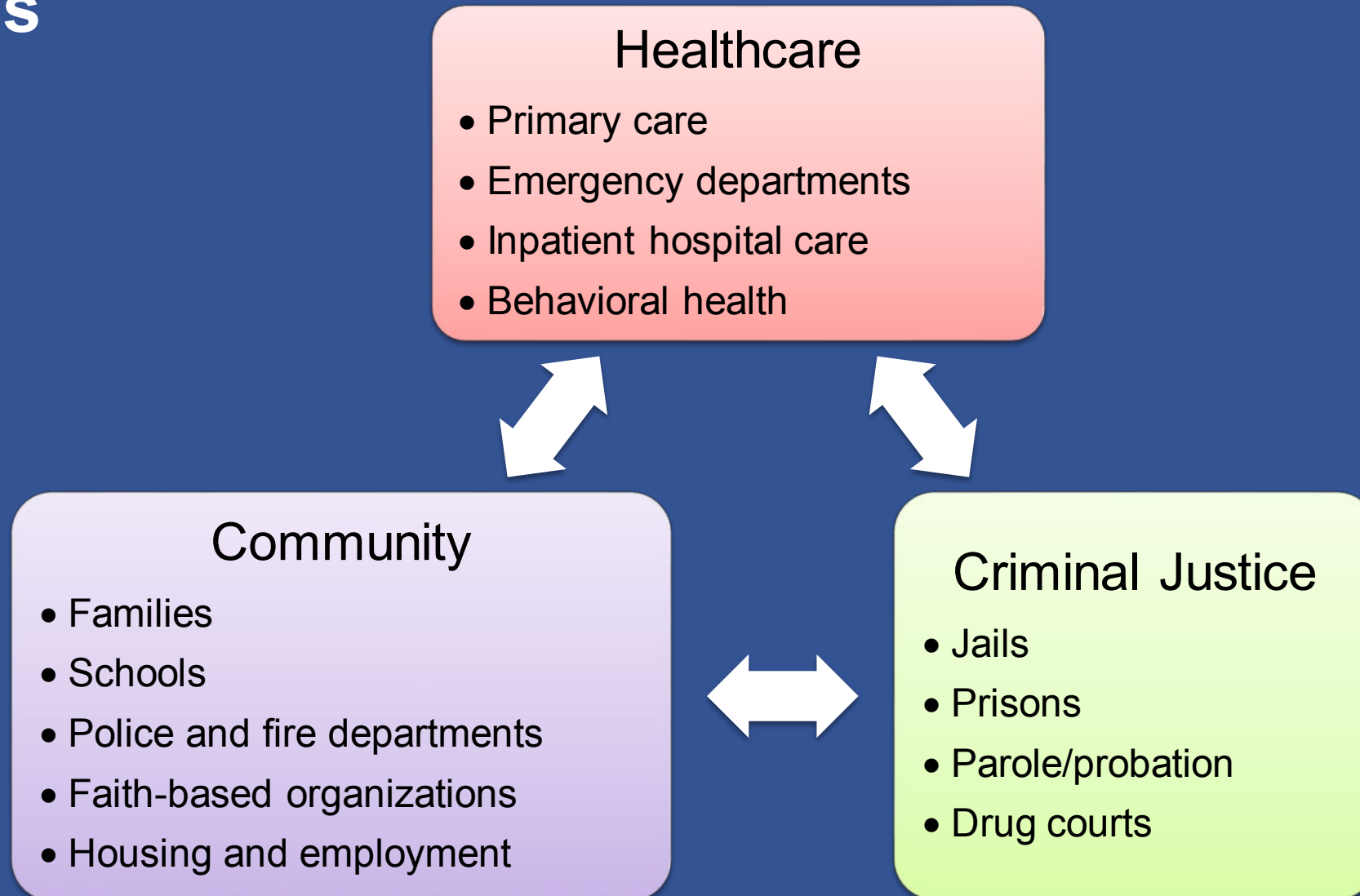
University of Kentucky  
PI: Sharon Walsh



■ Rural Communities

■ Urban Communities

# The HEALing Communities Study: Settings



## NIH HEAL INITIATIVE

### HEAL Initiative

Research

Governance and Guidance

Funding Opportunities

Events

News and Announcements

Resources

## HEALing Communities Study



### Overview

The HEALing Communities Study will generate evidence about how tools for preventing and treating opioid addiction are most effective at the local level. The National Institutes of Health, together with the Substance Abuse and Mental Health Services Administration (SAMHSA), has launched this multisite implementation research study to test the impact of an integrated set of evidence-based interventions across healthcare, behavioral health, justice, and other community-based settings. The goal is to prevent and treat opioid misuse and opioid use disorder (OUD) within highly affected communities in four states and reduce opioid related deaths by 40 percent over three years. Each site is partnering with at least 15 communities to measure the impact of these efforts.

Follow along with the HEALing  
Communities Study

### Email Updates

Sign up to receive email updates about the HEAL Initiative.

[Sign up for updates](#)

### Contact Us

Please send email to  
[HEALquestion@od.nih.gov](mailto:HEALquestion@od.nih.gov)



# Topics for Today

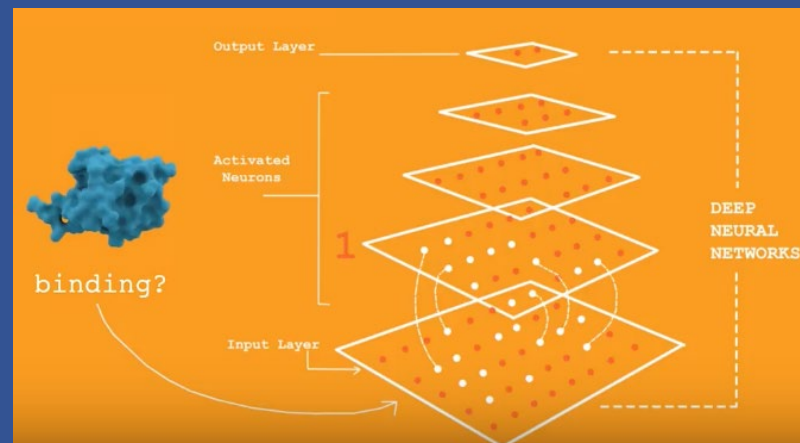
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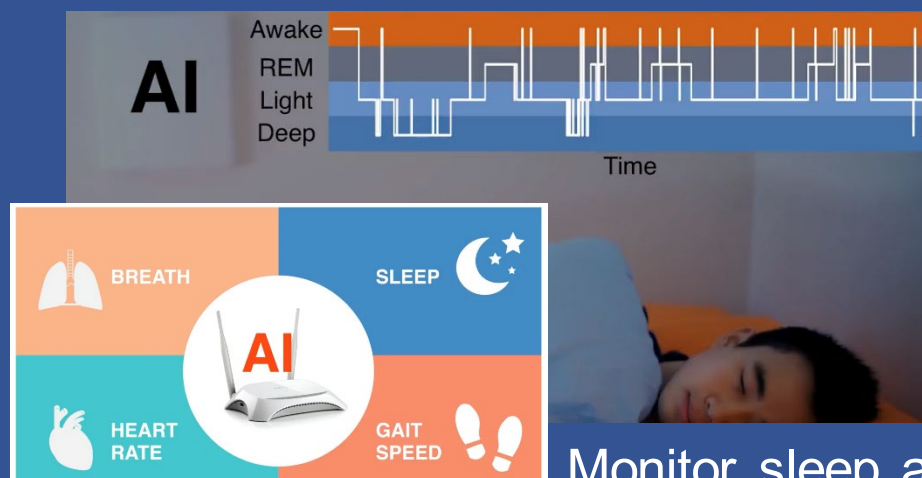
# Artificial Intelligence (AI) in Biomedicine



Extract medical information from text in EMRs/EHRs



Interpret genomic sequence data to understand impact of mutations on protein function



Monitor sleep and vitals from home to send to doctors



**Input**  
Chest X-Ray Image

**CheXNet**  
121-layer CNN

**Output**  
Pneumonia Positive (85%)



Read medical images to help make a diagnosis



# NIH/ACD AI Working Group

*Charged, December 2018; Interim Report, June 2019*



Rediet Abebe  
Cornell University



Greg Corrado  
Google



Kate Crawford  
AI Now Institute



Barbara Engelhardt  
Princeton University



David Glazer  
Verily (Co-Chair)



David Haussler  
USCS



Dina Katabi  
MIT Computer  
Science & AI Lab



Daphne Koller  
Insitro



Anshul Kundaje  
Stanford University



Eric Lander  
Broad Institute



Jennifer Listgarten  
UC Berkeley



Michael McManus  
Intel



Lawrence Tabak  
NIH (Co-Chair)



Serena Yeung  
Harvard

# AI WG Recommendations (June 2019)

*Note: All Classified as “Do Now”*

- More AI-ready data:
  - Begin cataloging existing data sets and tracking attributes relevant for AI readiness
- More multilingual researchers (with *experience* in both biomedicine & computer science; and with *expertise* in at least one):
  - Co-sponsor workshop on *Learning Meaningful Representations of Life* at the NeurIPS (Neural Information Processing Systems) conference in December 2019
  - Allocate at least one third of this year’s fellows to AI projects
- Important areas to *apply* to AI:
  - Create a “top 10” catalog of success stories to inspire future investment and creativity



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# Advances in Gene Editing

- Powerful tools rapidly becoming ubiquitous
- Ease, precision of technology makes feasible experiments too difficult to conduct using older techniques
- Multiple Applications
  - Basic Science
  - Gene Drives – the end of malaria?
  - Somatic Cell Gene Therapy – **non-heritable**





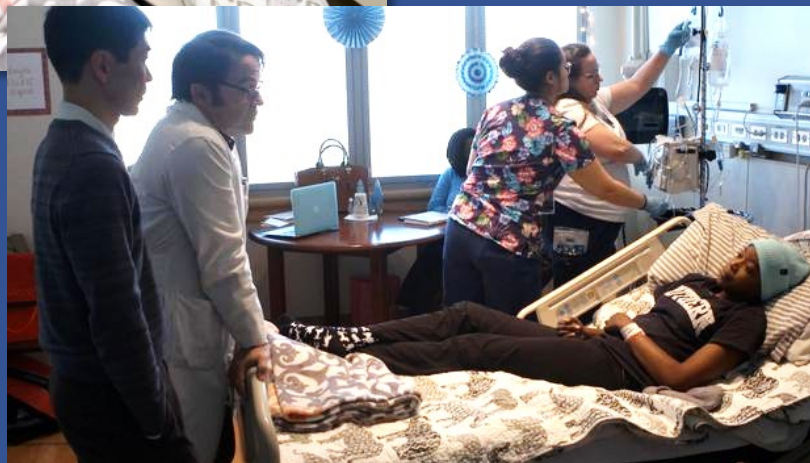
60 MINUTES

# COULD GENE THERAPY CURE SICKLE CELL ANEMIA?

*An NIH clinical trial is ushering in a genetic revolution as an innovative type of gene therapy is used to attempt to cure sickle cell anemia.*

2019  
MAR 10

CORRESPONDENT  
JONATHAN LAPOOK

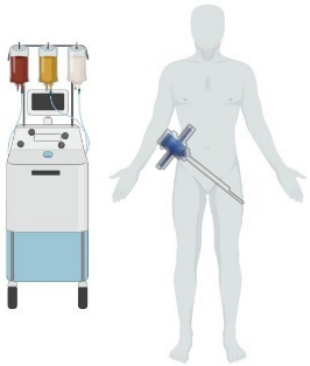




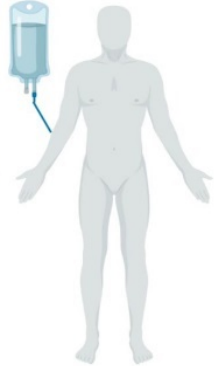
# Gene Therapy for Sickle Cell Disease

*John Tisdale, NIH in Collaboration with Bluebird Bio*

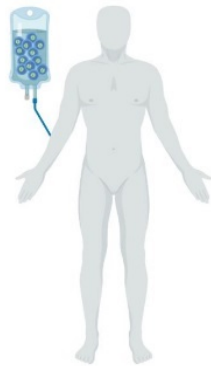
Hematopoietic stem cell (HSC) collection



Bone marrow conditioning



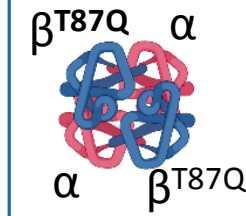
Gene-modified HSCs infusion



Modified HSCs reconstitute blood with functional red blood cells (RBCs)



Modified RBCs express gene therapy-derived HbA<sup>T87Q</sup>



2-yr follow-up  
↓  
Long-Term Follow-Up Study

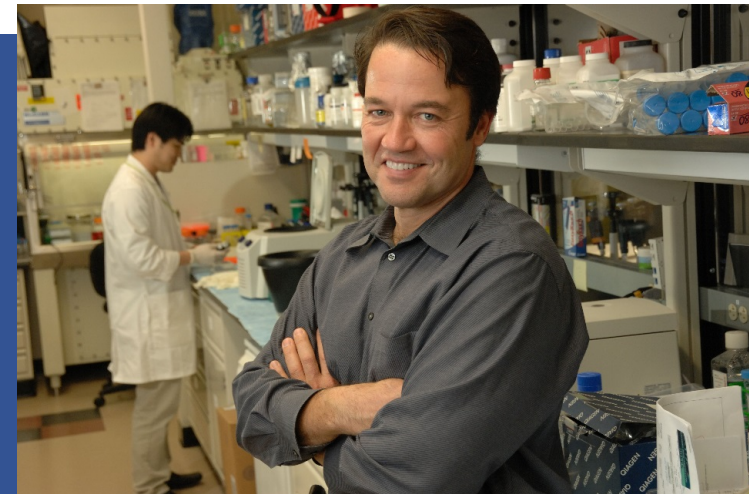
Making the Gene Therapy Product



Select specific HSCs (CD34+)

Introduce lentiviral vector (HbA<sup>T87Q</sup>)

Cryopreserve and test gene-modified HSCs





# First US Trial of Gene Editing for SCD Has Begun

*Ex vivo* treatment of hematopoietic stem cells – knockout BCL11A enhancer



Source: CRISPR Therapeutics AG

January 04, 2019 07:00 ET

**CRISPR Therapeutics and Vertex  
FDA Fast Track Designation for  
Treatment of Sickle Cell Disease**



WAMU 88.5  
AMERICAN UNIVERSITY RADIO

TREATMENTS

## In A 1st, Doctors In U.S. Use CRISPR Tool To Treat Patient With Genetic Disorder

July 29, 2019 · 5:18 AM ET  
Heard on Morning Edition



ROB STEIN



Victoria Gray, 34, of Forest, Miss., volunteered for one of the most anticipated medical experiments in decades: the first attempt to use the gene-editing technique CRISPR to treat a genetic disorder in the U.S.  
Meredith Rizzo/NPR

Subjects With Severe Sickle Cell Disease

study in up to 12 subjects 18 to 35 years of age with  
and efficacy of autologous CRISPR-Cas9 Modified  
s) using CTX001.

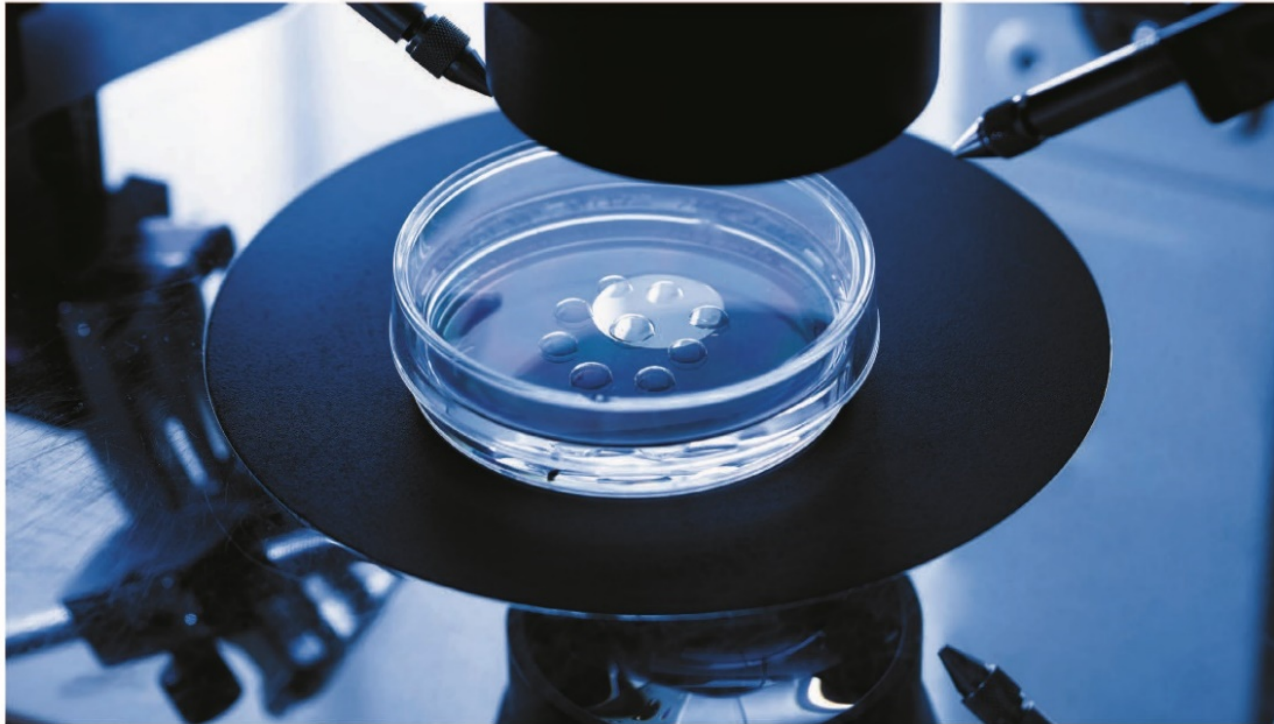
# Advances in Gene Editing

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- Multiple Applications
  - Basic Science
  - Gene Drives – the end of malaria?
  - Somatic Cell Gene Therapy – **non-heritable**
  - Human Germline Modification – **heritable**





# COMMENT



Embryos cultured as part of *in vitro* fertilization can be screened for genetic diseases.

## Adopt a moratorium on heritable genome editing

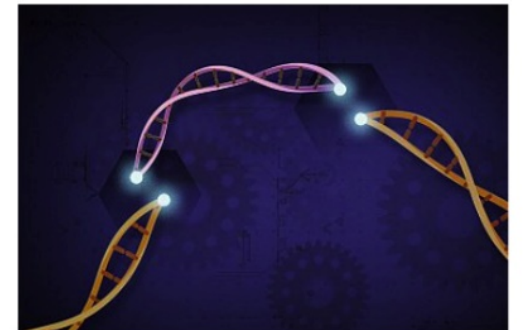
Eric Lander, Françoise Baylis, Feng Zhang, Emmanuelle Charpentier, Paul Berg and specialists from seven countries call for an international governance framework.

### THE NIH DIRECTOR

March 13, 2019

## NIH supports international moratorium on clinical application of germline editing

Today, leading scientists and ethicists from seven countries have [called for an international moratorium](#) on the use of genetic editing to modify the human germline for clinical purposes. The call comes in the wake of irresponsible and unethical research in China, in which twins were born after alterations to their DNA before implantation. This unexpected and unwelcome revelation roiled the scientific community and the general public, and crystallized the need for guiding international principles. Research on the potential to alter the very biological essence of humanity raises profound safety, ethical, and philosophical issues. I expressed [NIH's position on the incident in November 2018](#).



CRISPR-Cas9 is a customizable tool that lets scientists cut and insert small pieces of DNA at precise areas along a DNA strand. This lets scientists study our genes in a specific, targeted way. *Ernesto del Aguila III, NHGRI.*

# Future Release of a Moratorium?

## *Considerations for a Path Forward*

- Safety: risk of unintended mutations (“off-target edits”)
- Medical: are there needs that *only* germline editing could meet?
  - Currently editing would require use of *in vitro* fertilization
  - Genetic diagnosis of embryos would then be needed
  - Why not just implant the unaffected embryos?
  - Mitochondrial diseases are in a different category
- Societal, ethical, moral issues
  - Consent
  - Justice/equity
  - Philosophical
  - Theological





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# Addressing Foreign Influence on Research



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

August 20, 2018

Dear Colleagues:

For many decades, the National Institutes of Health (NIH) has participated in productive partnerships with universities and academic medical centers, leading to many discoveries that have led to dramatic improvements in human health. NIH is proud to help support our diverse perspectives and backgrounds.

The NIH-funded biomedical enterprise, to be successful, must be fair, transparent, and

NIH Advisory Committee to the Director (ACD)

## ACD Working Group for Foreign Influences on Research Integrity

December 2018 Report

# Science



The main campus of the Baylor College of Medicine in Houston, Texas BAYLOR COLLEGE OF MEDICINE

## U.S. universities reassess collaborations with foreign scientists in wake of NIH letters

By **Jeffrey Mervis** | Apr. 26, 2019, 11:40 AM

## AAMCNEWS

Tuesday, May 28, 2019 | by Ken Budd, special to AAMCNews

## Combatting undue foreign influence at U.S. research institutions

Academic research labs across the country are taking steps to protect their intellectual property after the NIH warned of data breaches and shadow labs. Here's what you need to know.



At the University of Texas MD Anderson Cancer Center in Houston, Texas, the USB ports on researchers' computers have been disabled. Flash drives? They're gone, too. MD Anderson is at the forefront of efforts to prevent the theft of U.S. research, and the steps have ranged from data security to dismissals. In April



# Addressing Harassment in the Research Workplace

EDITORIALS **THIS WEEK**  
24 OCTOBER 2013 | VOL 502 |

## End harassment

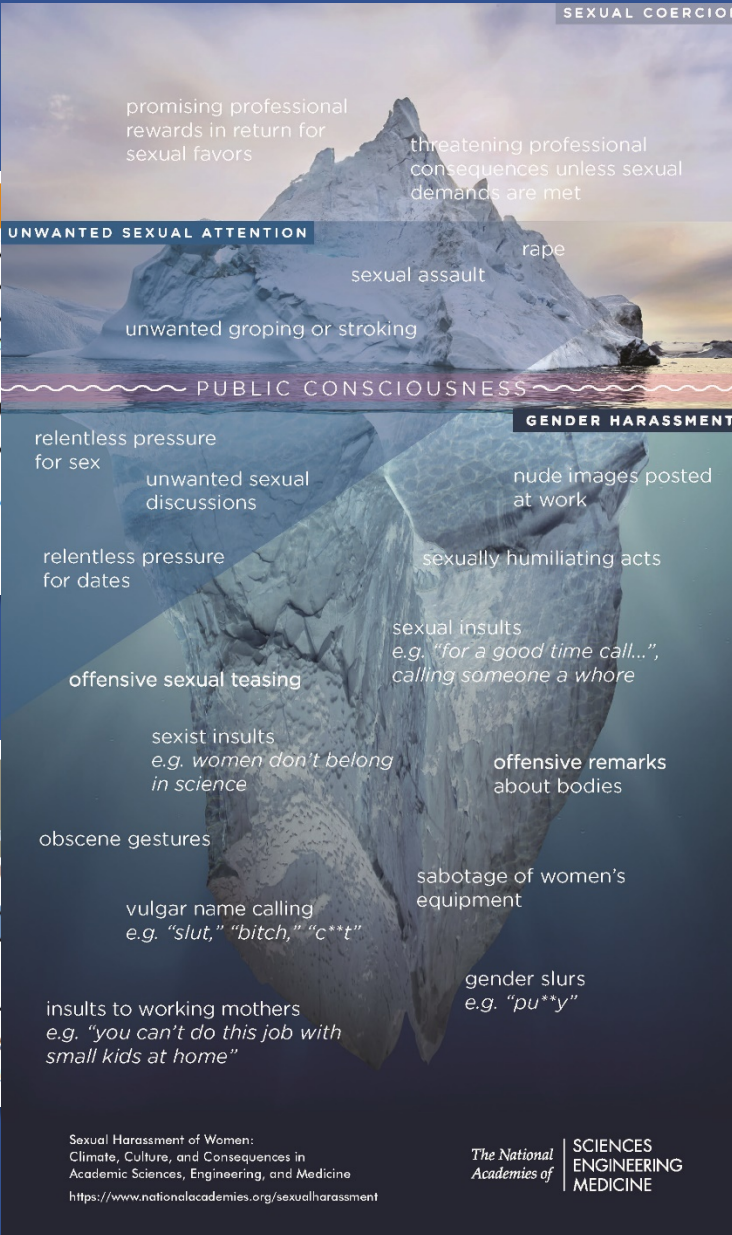
*Sexual harassment is a stain on science. We must all take a stand against it.*

**WORLD VIEW** *A personal take on events*  
21 JAN



## Sexual harassment not be kept un

*A female scientist who was harassed by a... by the system that is supposed to protect h*



SEXUAL COERCION

promising professional rewards in return for sexual favors

threatening professional consequences unless sexual demands are met

UNWANTED SEXUAL ATTENTION

sexual assault

rape

unwanted groping or stroking

PUBLIC CONSCIOUSNESS

GENDER HARASSMENT

relentless pressure for sex

unwanted sexual discussions

relentless pressure for dates

sexually humiliating acts

sexual insults  
e.g. "for a good time call...,"  
calling someone a whore

offensive sexual teasing

sexist insults  
e.g. women don't belong  
in science

offensive remarks  
about bodies

obscene gestures

vulgar name calling  
e.g. "slut," "bitch," "c\*\*t"

insults to working mothers  
e.g. "you can't do this job with  
small kids at home"

sabotage of women's  
equipment

gender slurs  
e.g. "pu\*\*y"

Sexual Harassment of Women:  
Climate, Culture, and Consequences in  
Academic Sciences, Engineering, and Medicine  
<https://www.nationalacademies.org/sexualharassment>

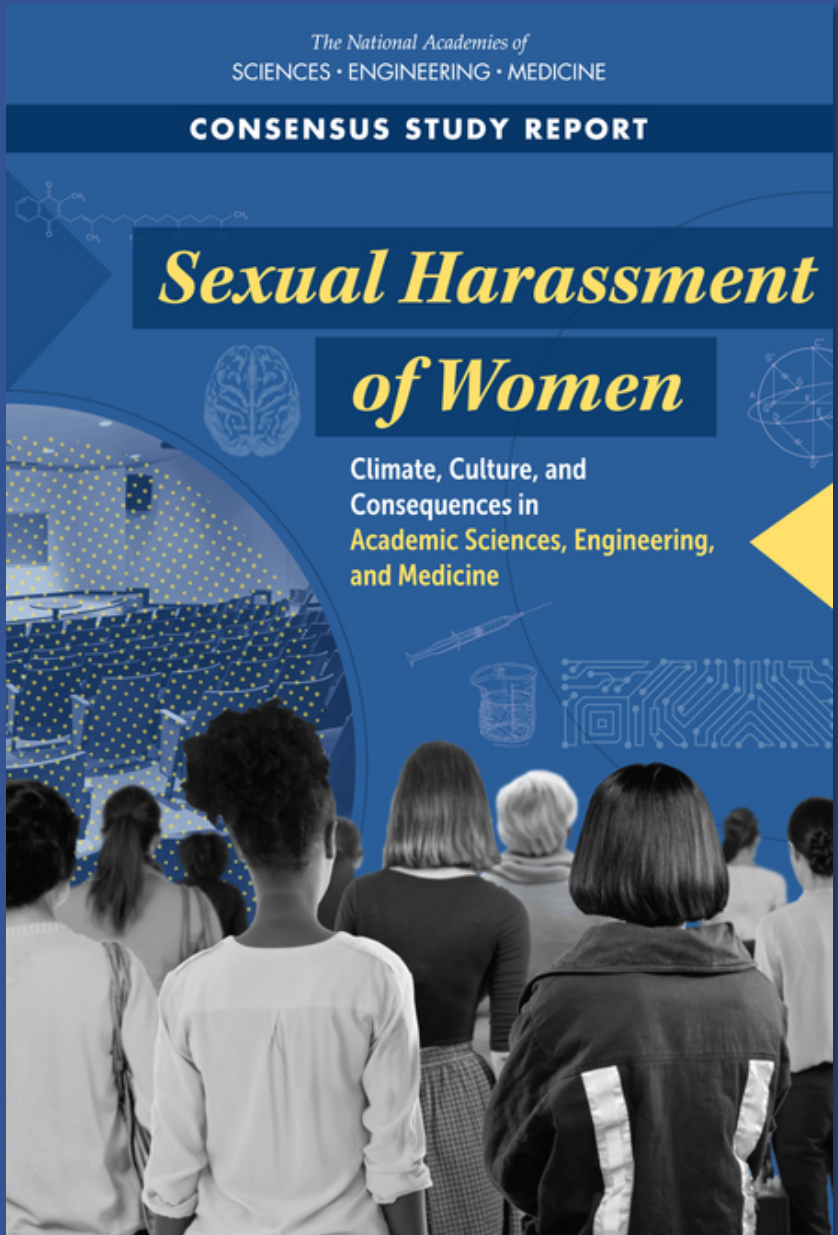
The National Academies of  
SCIENCES  
ENGINEERING  
MEDICINE

The National Academies of  
SCIENCES • ENGINEERING • MEDICINE

## CONSENSUS STUDY REPORT

# Sexual Harassment of Women

Climate, Culture, and  
Consequences in  
Academic Sciences, Engineering,  
and Medicine





# NIH Efforts to Address Sexual Harassment in Science (2019)

- Issued statement on commitment to address the issue
- Sent letter to NIH-funded Institutions
  - Clarifying expectations of institutions and investigators
  - Stressing our intent to take action when necessary
- Established mechanisms to report concerns about NIH-funded institutions
- Launched anti-harassment websites and communications campaign
- Administered “Workplace Climate and Harassment Survey” to NIH staff

# ACD WG on Changing the Culture to End Sexual Harassment – Interim Recommendations (June 2019)

- Treat professional misconduct, including sexual harassment, as seriously as research misconduct
- Require all PIs to attest, when submitting NIH grant applications and progress reports, that they have not violated and will not violate their institutional code of conduct
- Establish mechanisms for restorative justice for survivors and to recapture lost talent
- Develop novel approaches to address investigator independence from their mentors

# THE NIH DIRECTOR

June 12, 2019

## Time to End the Manel Tradition

Government  
Executive

June 13, 2019

CNN

The NIH director is tired of all-male panels at scientific conventions. So he's doing something about it



By Doug Criss, CNN

Updated 10:25 AM ET, Thu June 13, 2019

FORTUNE

HEALTH • BRAINSTORM HEALTH

### The NIH Chief Wants to End the 'Manel'— Brainstorm Health

By Sy Mukherjee June 12, 2019



Francis Collins, director of the National Institutes of Health, says, "Too often, women and members of other groups underrepresented in science are conspicuously missing" from the lineup at key events. AP FILE PHOTO

Management

### It's Time to End the 'Manel' Tradition of All-Male Speaking Panels

Forbes

### NIH Director: No More 'Manels', How To Make Panels More Diverse



Jun 15, 2019

Bruce Y. Lee Contributor @  
Healthcare

TIME

HEALTH • SCIENCE

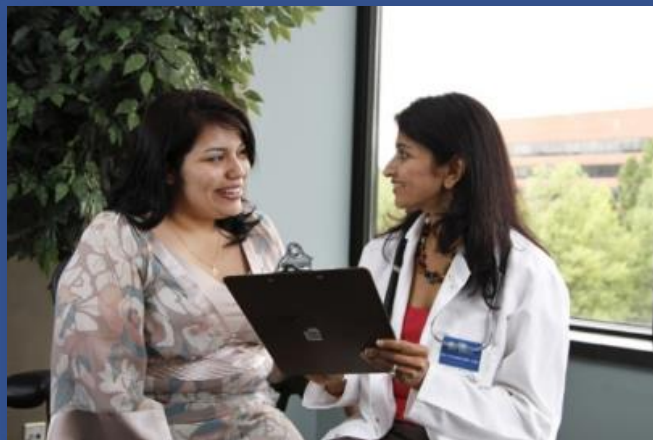
### NIH Director Francis Collins Has a Plan to Help Eliminate "Manels"

BY ALICE PARK

JUNE 24, 2019

ice to equality; leaders must  
rough their actions," says Dr.  
National Institutes of Health.





**NIH...** *Turning Discovery Into Health*

[www.nih.gov/hope](http://www.nih.gov/hope)

[directorsblog.nih.gov](http://directorsblog.nih.gov)

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

