



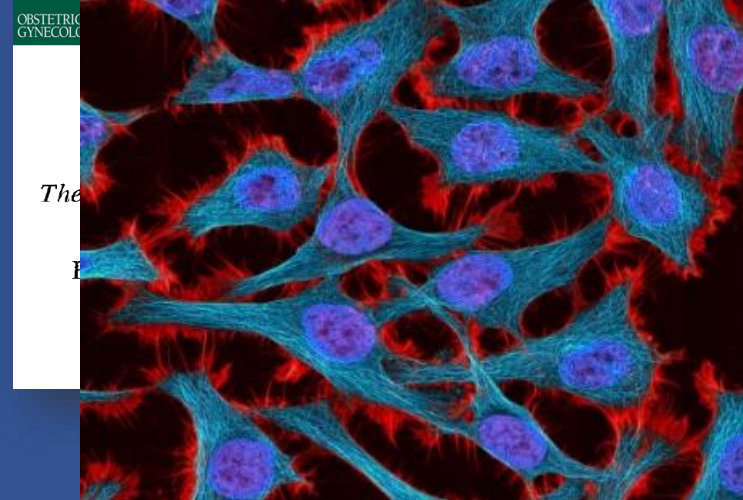


# HeLa Cells and the Lacks Family

- 1951: doctors in Baltimore took biopsy from 31-year-old African American woman with aggressive cervical cancer
  - Patient, **Henrietta Lacks**, died 8 months later
- Cells soon found to be “immortal” – invaluable to research
  - Named **HeLa** – used without Lacks’ knowledge, consent
- 1971: Henrietta’s identity made public
  - Start of challenges for Lacks family
- 2010: Rebecca Skloot’s book brought wide attention to Henrietta, Lacks family, HeLa cells
- 1951 to now: HeLa cells hard at work....



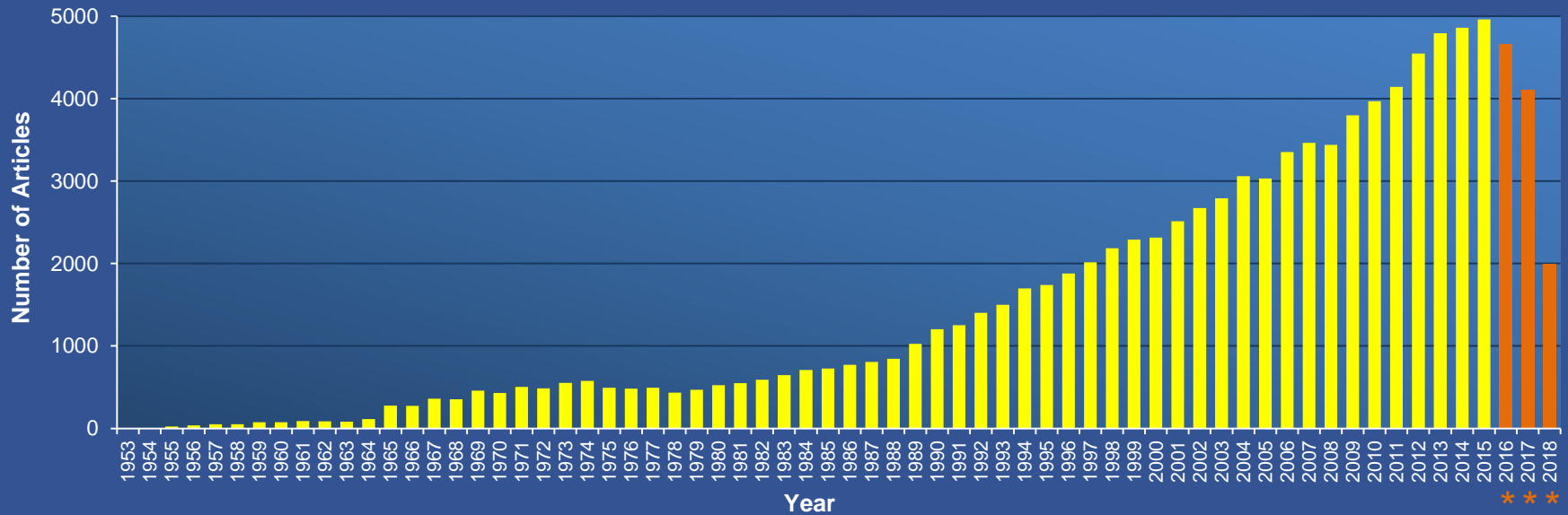
Lacks family/ITV/Rex Features



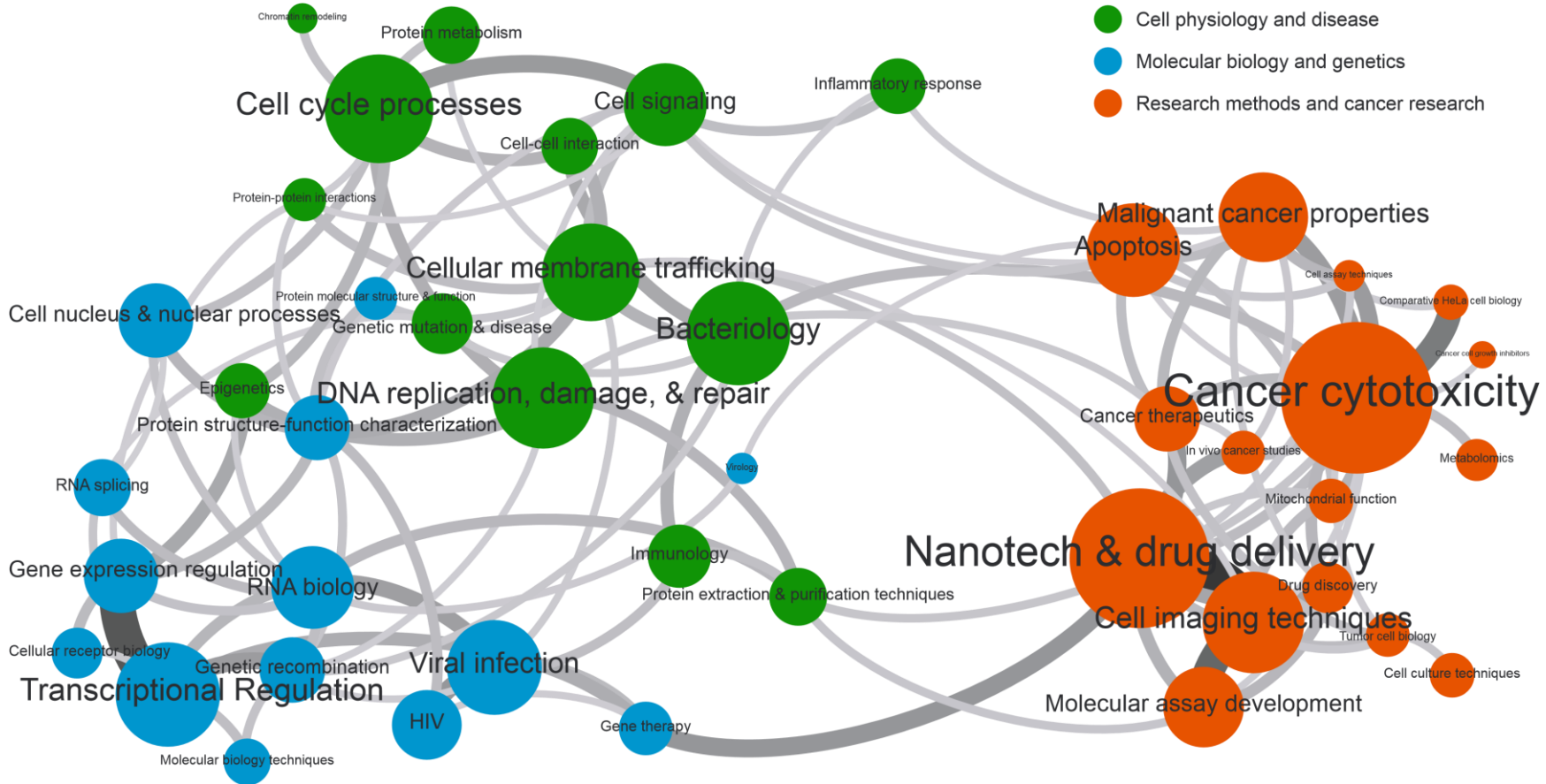
# The Contribution of HeLa Cells to Biomedical Research

*Over 100,000 publications resulting from research using HeLa Cells*

- >142 countries
- Three Nobel Prizes (telomerase, HPV and cancer, and nanoscale imaging)



\* 2016-2018 papers have not yet been fully indexed. "HeLa" appeared in title or abstract. 2018 data is still being populated.



Topics of HeLa Cell Research

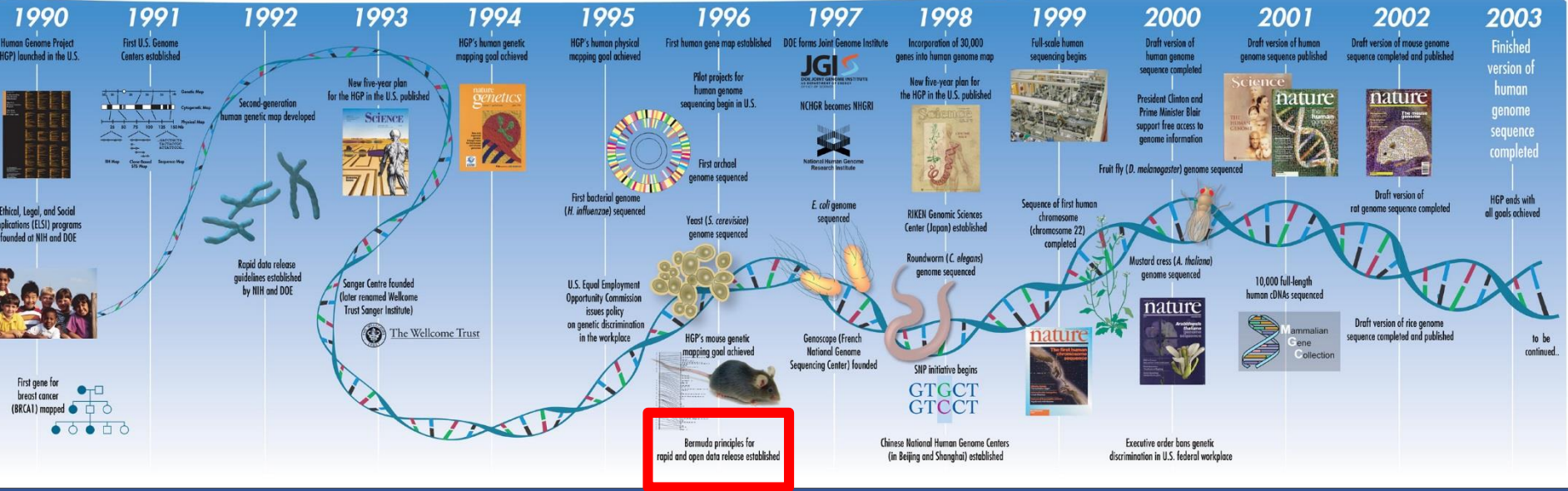
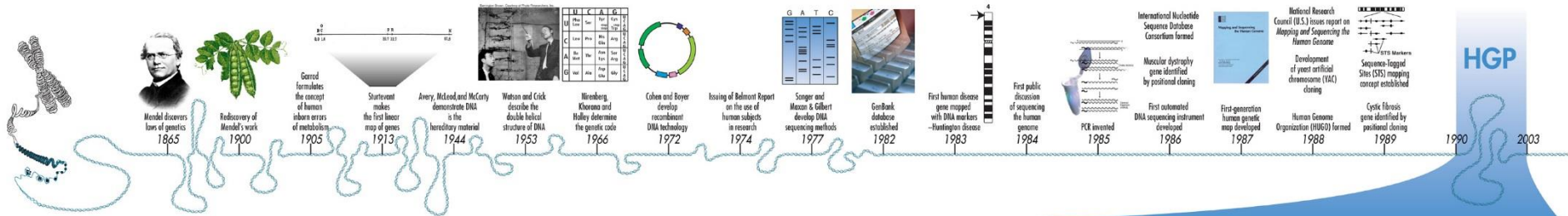
# NIH: Steward of Medical and Behavioral Research for the United States



“Science in pursuit of **fundamental knowledge** about the nature and behavior of living systems ... and the **application of that knowledge** to extend healthy life and reduce illness and disability.”



# The Human Genome Project



# Laying the Foundation for Open Access: *Bermuda Principles*



Bermuda principles for rapid and open data release established

HUMAN GENOMIC SEQUENCE GENERATED BY LARGE SCALE CENTRES

## RELEASE

- Automatic release of sequence assemblies >1k's (preferably daily)
- Immediate submission of finished annotated sequence

and in the public domain

- Aim to have all sequence freely available for both research and development, in order to maximise its benefit to society.

## POLICY

- The funding agencies are urged to foster these policies



# The New York Times

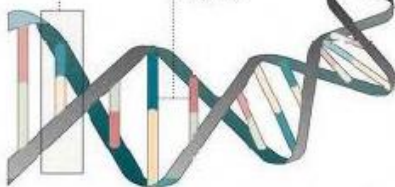
NEW YORK, TUESDAY, JUNE 27, 2000

## Genetic Code of Human Life Is Cracked by Scientists

### The Book of Life

The three billion  
base pairs ...

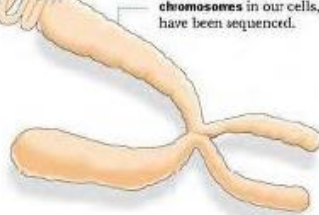
BASE PAIRS  
Rungs between  
the strands of  
the double helix



BASES  
A adenine  
C cytosine  
G guanine  
T thymine

... of the intertwining  
double helix of DNA ...

... that make up the set of  
chromosomes in our cells,  
have been sequenced.



By ordering the base units, scientists hope to  
locate the genes and determine their functions.

The New York Times

### Science Times

A special issue

- Putting the genome to work.
- Some information has already paid research dividends.
- Two research methods, two results.
- From Mendel to helix to genome.
- More articles, charts and photos of the genome effort.

Section F





## The Human Genome Project: 1990–2003



2,500 scientists  
20 research institutions  
6 different countries  
Data released every 24 hours



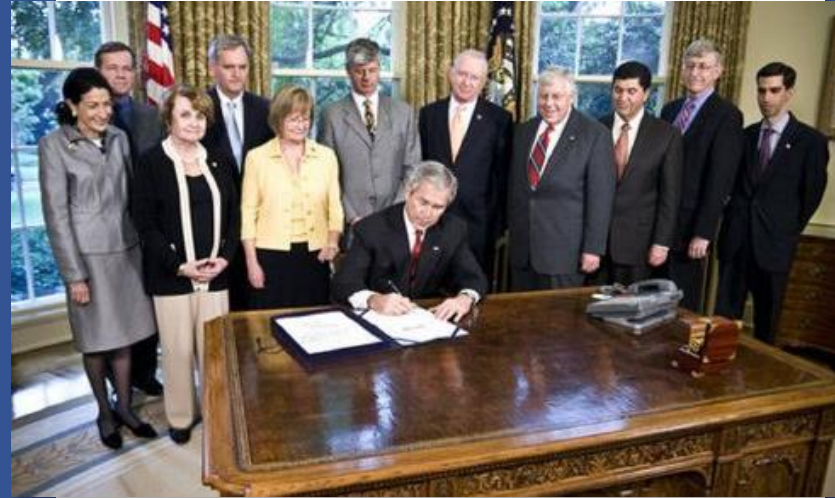
# Protecting Against Genetic Discrimination

- Early recognition: as more data is available, individual protections must expand
- 2008: passage of the Genetic Information Nondiscrimination Act (GINA)
- But much remained to be done – as NIH's interactions with the Lacks family would show....

SCIENCE

VOL. 270 • 20 OCTOBER 1995

■ POLICY FORUMS



Karen Rothenberg,\* Barbara Fuller, Mark Rothstein, Troy Duster, Mary Jo Ellis Kahn, Rita Cunningham, Beth Fine, Kathy Hudson, Mary-Claire King, Patricia Murphy, Gary Swergold, Francis Collins

# Two Tours of Duty at NIH

*National Human Genome Research Institute, 1993 to 2008;  
Returned in 2009 as NIH Director*



# HeLa Whole Genome Sequence Made Public 2013

- *March*: German researchers posted HeLa genome sequence
  - Lacks family asked that sequence be removed; data was removed
  - But 2<sup>nd</sup> publication was per
- *April–July*: NIH, Lacks family
  - Three meetings of core par

nature International weekly journal of science

News & Comment News 2018 September Article

The New York Times

**Sunday Review** | The Opinion Pages

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH SPORTS OPINION

OPINION

## The Immortal Life of Henrietta Lacks, the Sequel

By REBECCA SKLOOT

Published: March 23, 2013 | 125 Comments

LAST week, scientists sequenced the genome of cells taken without consent from a woman named Henrietta Lacks. She was a black tobacco farmer and mother of five, and though she died in 1951, her cells, code-named HeLa, live on. They were used to help develop our most important vaccines and cancer medications, in vitro fertilization, gene mapping, cloning. Now they may finally help create laws to protect her family's privacy — and yours.



nature International weekly journal of science

News & Comment News

NATURE | NEWS

## HeLa publication

Genome of controversial cell

Ewen Callaway

27 March 2013



# NIH-Lacks Family Agreement Announced August 7, 2013

**The New York Times**

## A Family Consents to a Medical Gift, 62 Years

By CARL ZIMMER



Jeri Lacks Whye, center, one of Henrietta Lacks's grandchildren, with her own daughters, Jabrea, left, and Aiyana Rogers.

Henrietta Lacks was only 31 when she died of cervical cancer in

**USA TODAY**

## NIH makes privacy agreement with Henrietta Lacks' family

Dan Vergano, USA TODAY

**BMJ**

NEWS

BMJ 2013;347:f5041 doi: 10.1136/bmj.f5041 (Published 9 August 2013)

## NIH and family of Henrietta Lacks reach agreement on access to HeLa genome

**npr**


shots HEALTH NEWS FROM NPR

## Decades After Henrietta Lacks' Family Gets A Say On

August 7, 2013 - 1:40 PM ET

Morning Edition talks with NIH's Dr. Francis Collins

**CBS NEWS**



By DANIELLE ELLIOT | CBS NEWS | August 8, 2013, 8:00 AM

## Lacks family, NIH reach agreement on genome data

On Jan. 29, 1951, a poor black woman from Johns Hopkins Hospital, complaining of pain in her abdomen for a year, but, unbeknownst to her family, cells from the cancerous tumor that ended her life continued to live on in research labs around the world.

**NBC NEWS**

## NIH finally makes good on Lacks' family – and it's an ethicist says

by ART CAPLAN, PH.D.



Cells taken from Henrietta Lacks, shown in the 1940s, eventually led to the creation of HeLa cells. But neither she nor her family gave consent.

**SCIENTIFIC AMERICAN**

HEALTH

## Deal Reached with NIH over Henrietta Lacks' Cell Line

The family of the woman whose cells have helped advance a great deal of biological research has agreed to a case-by-case release of her genomic data

By Ferra Callaway, Nature magazine on August 7, 2013

**The Washington Post**

Health & Science

## NIH, family of Henrietta Lacks reach deal on access to DNA code

By MALCOLM RITTER and — Associated Press  
August 7, 2013

NEW YORK — Some 60 years ago, a doctor in Baltimore removed cancer cells from a poor black patient named Henrietta Lacks without her knowledge or consent. Those cells eventually helped lead to a multitude of medical treatments and laid the groundwork for the multibillion-dollar biotech industry.

# The Agreement: Details

## *HeLa Whole Genome Sequence in NIH Database of Genotypes and Phenotypes (dbGaP)*

- Researchers apply for access; criteria include
  - Using data only for health, medical, or biomedical research objectives
    - No studies of population origins or ancestry
  - Make no contact with Lacks family regarding proposed research
  - Disclose any commercial plans
  - Acknowledge family in publications, presentations
  - Share results
  - Deposit future HeLa whole genome sequence data into dbGaP
- Genome Data Access Working Group evaluates all requests



# HeLa Genome Data Access Working Group (2014)

- Evaluate requests to access HeLa genome sequence data
  - Consist with HeLa Genome Data Use Agreement?
- Report, make recommendations to NIH Advisory Committee to the Director





# HeLa Genome Data Access Working Group

## *(Today)*

### **Carrie D. Wolinetz, Ph.D. (Co-Chair)**

Acting Chief of Staff and Associate Director for Science Policy, Office of the Director – *NIH*

### **Spero Manson, Ph.D. (Co-Chair)**

Distinguished Professor of Public Health and Psychiatry and Director, Centers for American Indian and Alaska Native Health; Colorado Trust Chair in American Indian Health, and Associate Dean for Research – *Colorado School of Public Health*

### **Russ B. Altman, M.D., Ph.D.**

Professor, Bioengineering, Genetics, and Medicine and Director, Biomedical Informatics Training Program – *Stanford University*

### **Ruth Faden, PhD., M.P.H.**

Philip Franklin Wagley Professor in Biomedical Ethics and Director, Johns Hopkins Berman Institute of Bioethics Bloomberg School of Public Health – *Johns Hopkins University*

### **David Lacks, Jr.**

Representative, Henrietta Lacks Family

### **Jeri Lacks-Whye**

Representative, Henrietta Lacks Family

### **Richard M. Myers, Ph.D.**

President, Director and Faculty Investigator – *HudsonAlpha Institute for Biotechnology*

### **Veronica Spencer**

Representative, Henrietta Lacks Family

# Status of Requests to Access HeLa Genomic Data 2013-Present

No. Requests	Status
78	Evaluated by the HeLa Genome Data Access Working Group
72 (92% approval)	Approved by NIH Director

- Investigators from 19 countries have requested access to data
- Approved uses, outcomes (e.g., publications, IP) publicly available on the HeLa Cell Genome Sequencing Studies study page
- Rejections for incomplete applications; unwillingness to share data



# Getting the Word Out: Special NIH Event for Scientists, Trainees

- NIH-Lacks Family Partnership: overview; current status
- Personal reflections: agreement development; discussions about partnership
- Q&A session



## Given a Voice: An Update on the NIH-Lacks Family Partnership



Friday, July 21, 2017

1:30-2:30 pm

National Institutes of Health  
Masur Auditorium, Building 10

### Speakers:

Jeri Lacks-Whye, granddaughter of Henrietta Lacks  
David Lacks, Jr., grandson of Henrietta Lacks  
Dina Paltoo, Ph.D., M.P.H., Office of Science Policy, NIH  
Francis Collins, M.D., Ph.D., Director, NIH

# NIH: Steward of Medical and Behavioral Research for the United States



“Science in pursuit of **fundamental knowledge** about the nature and behavior of living systems ... and the **application of that knowledge** to extend healthy life and reduce illness and disability.”



# Turning Discovery into Health: Enhancing Diversity Among Clinical Research Participants

## One Hundred Third Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday,  
the fifth day of January, one thousand nine hundred and ninety-three

### An Act

To amend the Public Health Service Act to revise and extend the programs of  
the National Institutes of Health, and for other purposes.

Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “National  
Institutes of Health Revitalization Act of 1993”.

### Subtitle B—Clinical Research Equity Regarding Women and Minorities

Adm Policy Ment Health (2007) 34:497–503  
DOI 10.1007/s10488-007-0133-z

ORIGINAL PAPER

### Gender and Ethnic Diversity in NIMH-funded Clinical Trials: Review of a Decade of Published Research

Winnie W. S. Mak · Rita W. Law · Jennifer Alvidrez ·  
Eliseo J. Pérez-Stable

Medicine

January 2008

### Race, Medical Researcher Distrust, Perceived Harm, and Willingness to Participate in Cardiovascular Prevention Trials

Noëlle S. Sherber, MD, Steven P. Schulman, MD, Eric L. Ding, ScD,  
and Neil R. Powe, MD, MPH, MBA

### Cancer

April 1, 2014

### Twenty Years Post-NIH Revitalization Act: Enhancing Minority Participation in Clinical Trials (EMPACT): Laying the Groundwork for Improving Minority Clinical Trial Accrual

Renewing the Case for Enhancing

Moon S. Chen, Jr, PhD MPH<sup>1,2</sup>; Primo N. L.

RESPIRATORY AND  
CRITICAL CARE MEDICINE<sup>®</sup>

March 1 2015

### Moving toward True Inclusion of Racial/Ethnic Minorities in Federally Funded Studies

A Key Step for Achieving Respiratory Health Equality in the United States

Celedón<sup>4</sup>

nature

18 SEPTEMBER 2014

## Missing patients

Effective clinical studies must consider all  
ethnicities – exclusion can endanger populations,  
says Esteban G. Burchard.

PLOS MEDICINE

POLICY FORUM

December 15, 2015

### Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled

Sam S. Oh<sup>1</sup>, Joshua Galanter<sup>1,2</sup>, Neeta Thakur<sup>1</sup>, Maria Pino-Yanes<sup>1,3,4</sup>, Nicolas E. Barcelo<sup>1</sup>,  
Marquitta J. White<sup>1</sup>, Danielle M. de Bruin<sup>1</sup>, Ruth M. Greenblatt<sup>1,5</sup>, Kirsten Bibbins-  
Domingo<sup>1,6</sup>, Alan H. B. Wu<sup>7</sup>, Luisa N. Borrell<sup>8</sup>, Chris Gunter<sup>9,10</sup>, Neil R. Powe<sup>1,6</sup>, Esteban  
G. Burchard<sup>1,2</sup>

# Biomedical Research and Participant Diversity: Ongoing Challenge; Many Causes....

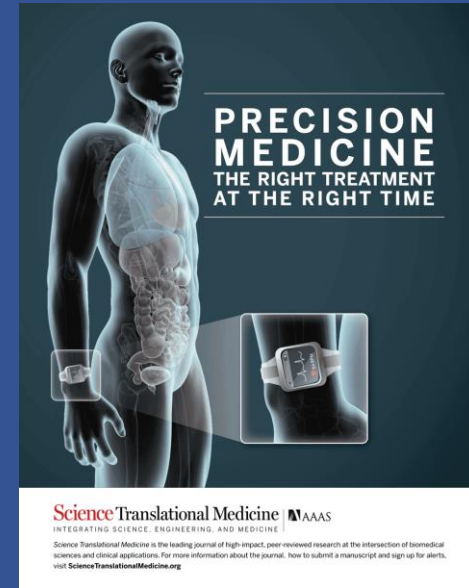
Legacy of Tuskegee casts a long shadow

- 1932: U.S. Public Health Service recruited “colored people” with “bad blood”
  - No mention of syphilis – no informed consent
- 1945-47: new drug, Penicillin, now standard treatment
  - Never offered to participants
- 1972: article exposes study; study ends
  - 1974: \$10M out-of-court settlement reached
- 1997: President Bill Clinton offers formal apology on behalf of U.S.



# Bringing More *Precision* to Medicine

- Emerging approach to disease prevention and treatment that transforms mostly one-size-fits-all approach of Western medicine
- Tailors medical care to fit our unique medical selves
  - Considers individual variability in lifestyle, environment, genes
- Based on an old premise – think prescription glasses
  - But needing new insights, technologies, science to advance
  - Diversity is essential



# Working With the Lacks Family to Broaden Our Understanding of “Research Participants”

U. of Illinois Cancer Center event: *Advancing Trust in Medical Research*

- NIH-supported researcher Dr. Robert Winn engaged four generations of Lacks family, >500 community members, to discuss
  - How to increase diversity among participants in clinical trials
  - How historical mistrust affects precision health





# The *All of Us* Research Program

**All of Us**  
RESEARCH PROGRAM | The  
Future of  
Health Begins  
With You

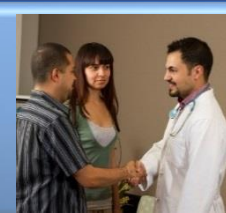
**Description:** a historic, longitudinal effort to gather data from **one million or more** people living in the US ... that takes into account individual differences in lifestyle, socioeconomics, environment, and biology

**Mission:** accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care – for all of us



# All of Us: Objectives

- Nurture enduring relationships with participant partners
  - Who reflect the nation's diversity – across ages, races/ethnicities, genders, geographies, backgrounds...
- Build richest, largest-ever biomedical resource
  - Dataset that's as easy, safe, and free to access as possible
- Catalyze a robust biomedical research ecosystem
  - Engaging a wide array of researchers, funders



# Participant Engagement

DIRECT VOLUNTEERS



HEALTH CARE PROVIDER ORGANIZATIONS



Enroll & Consent



Surveys



Baseline Measurements



Electronic Health Records



Apps, Phones & Wearables



Bio-Samples (Blood/Urine)



# Earning Participants' Trust

STAT

To advance medicine's future, the NIH tries to win the trust of communities mistreated in the past

By LEV FACHER @levfacher / SEPTEMBER 22, 2017



# The future of health begins with you.

The *All of Us* Research Program has a simple mission. We want to speed up health research breakthroughs. To do this, we're asking one million people to share health information. In the future, researchers can use this to conduct thousands of health studies.



[JOIN NOW](#)

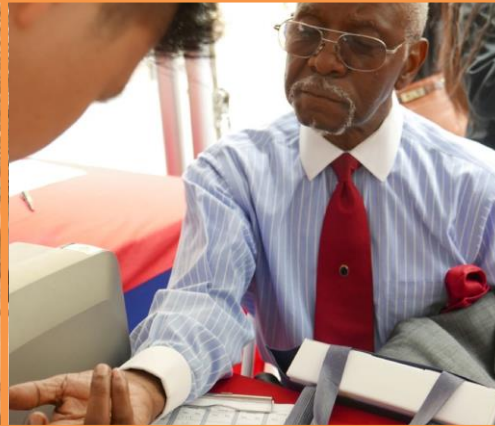
[JoinAllOfUs.org](https://JoinAllOfUs.org)

# All of Us

RESEARCH PROGRAM

# Launch Highlights

## May 6, 2018



Birmingham, AL

Chicago, IL

Detroit, MI

Kansas City, MO



Nashville, TN

New York, NY

Pasco, WA

*I realized that All of Us was about my family's story.*

*It was about your family's story.*

*It's about what we face every day.*

*~Veronica Robinson  
All of Us Launch, Chicago  
May 6, 2018*



*Photo by Rob Karlic*

# Debt to the Lacks Family

**All of Us**  
RESEARCH PROGRAM | The  
Future of  
Health Begins  
With You

*We are so grateful for the input and support of Henrietta Lacks' family; their feedback and experiences helped shape our program's values and protocol and we hope to continue to partner with them for years to come.*

**Eric Dishman**  
Director, *All of Us*





# Debt to the Lacks Family

*It was such an incredible honor to share the stage with members of the Henrietta Lacks family. Despite their own unfortunate personal experience with research, it was abundantly clear that they are committed to leveraging their experience, altruism, knowledge and trust as Ambassadors in underrepresented communities to convey the many compelling reasons why diversity in research is vitally important to the health of our nation.*

**Dara Richardson-Heron, M.D.**  
Chief Engagement Officer, *All of Us*

**All of Us**  
RESEARCH PROGRAM | The  
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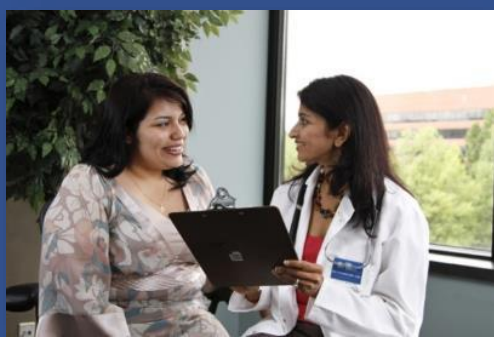




*The main goal was science and being part of the conversation.*

**David Lacks Jr.**





**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) 

