

The Enduring Legacy of Henrietta Lacks

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

Henrietta Lacks Memorial Lecture

October 6, 2018



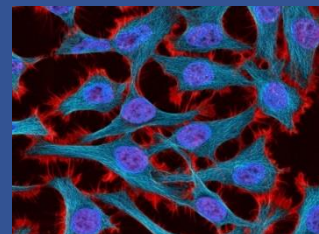
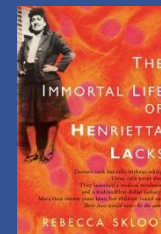
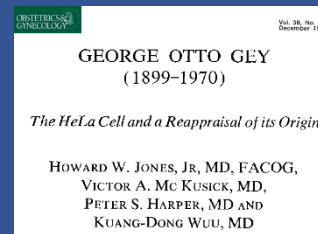
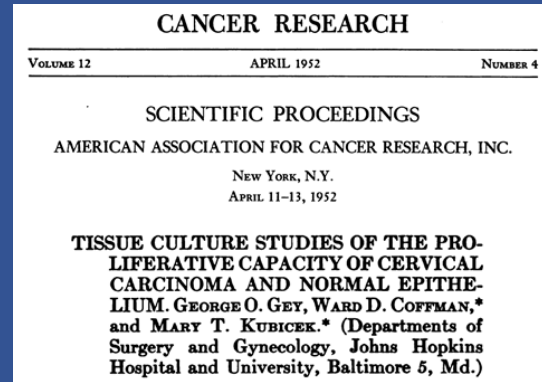


HeLa Cells and the Lacks Family

- 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....



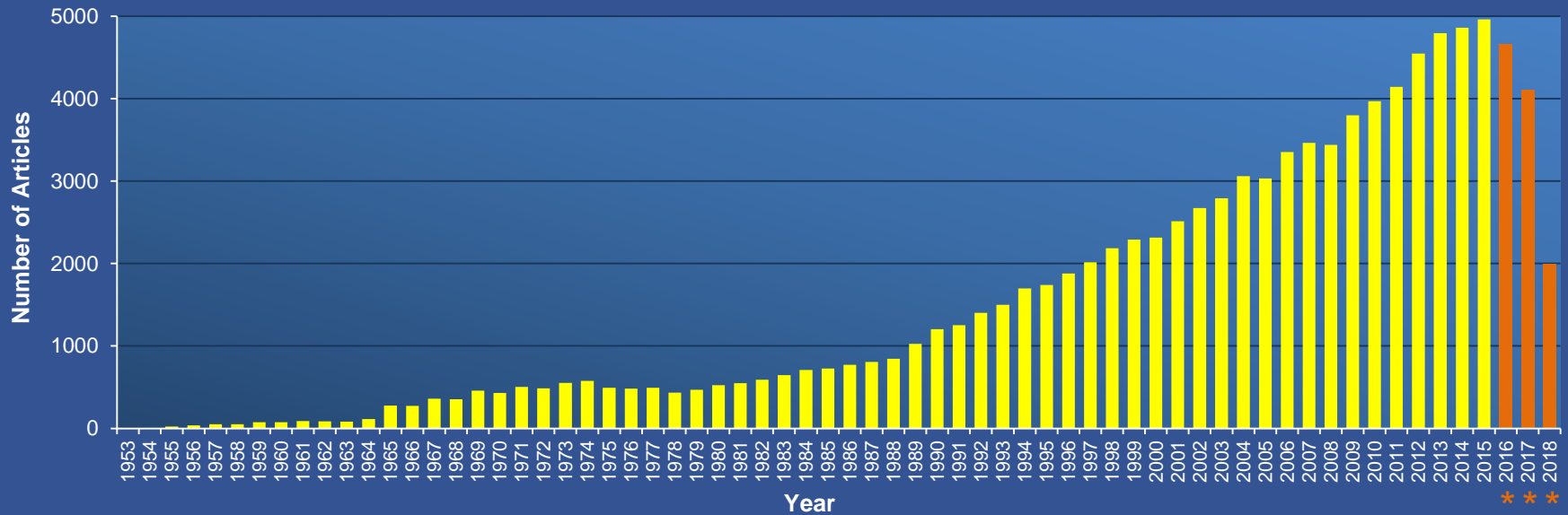
Lacks family/ITV/Rex Features



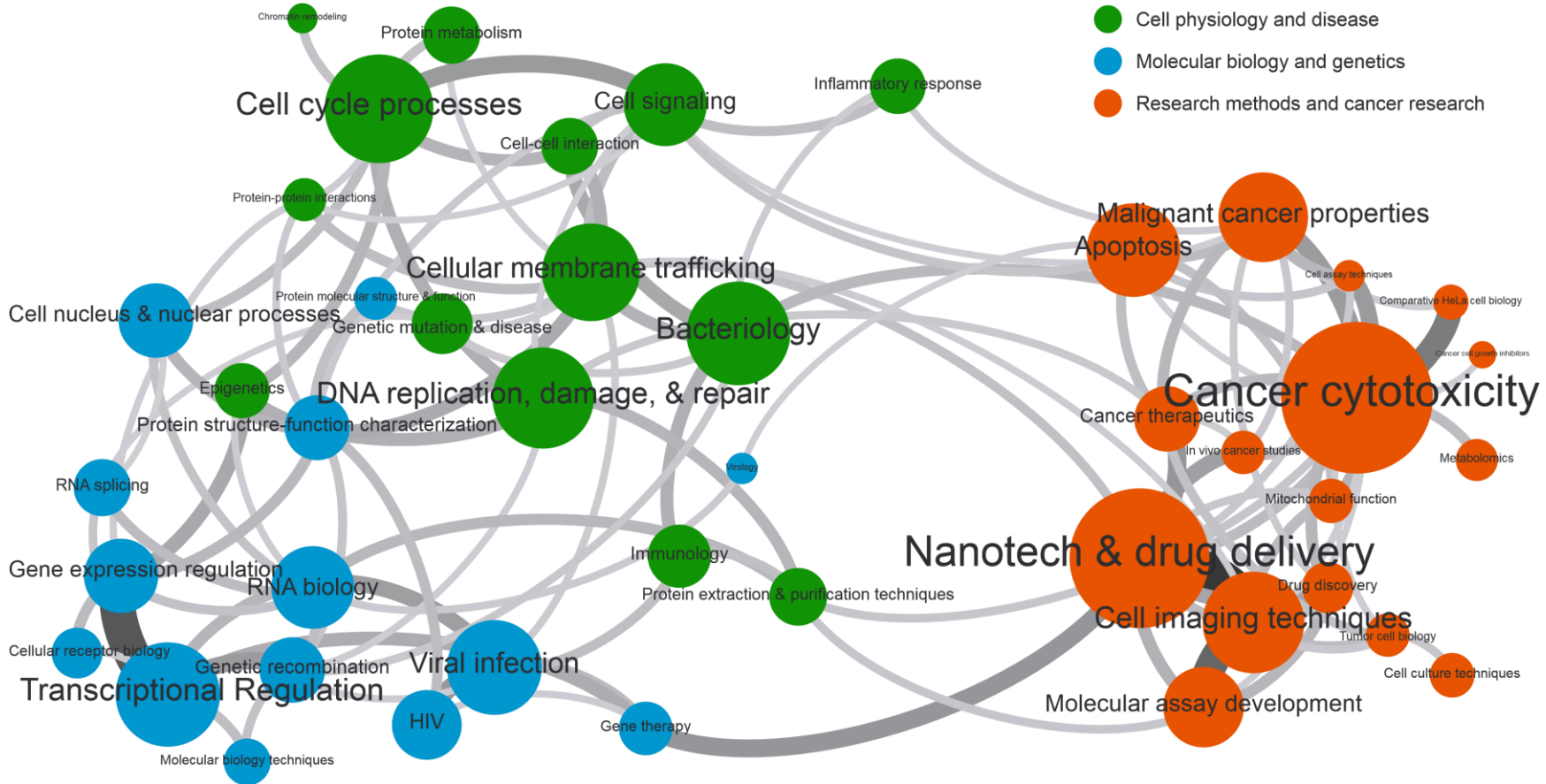
The Contribution of HeLa Cells to Biomedical Research

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

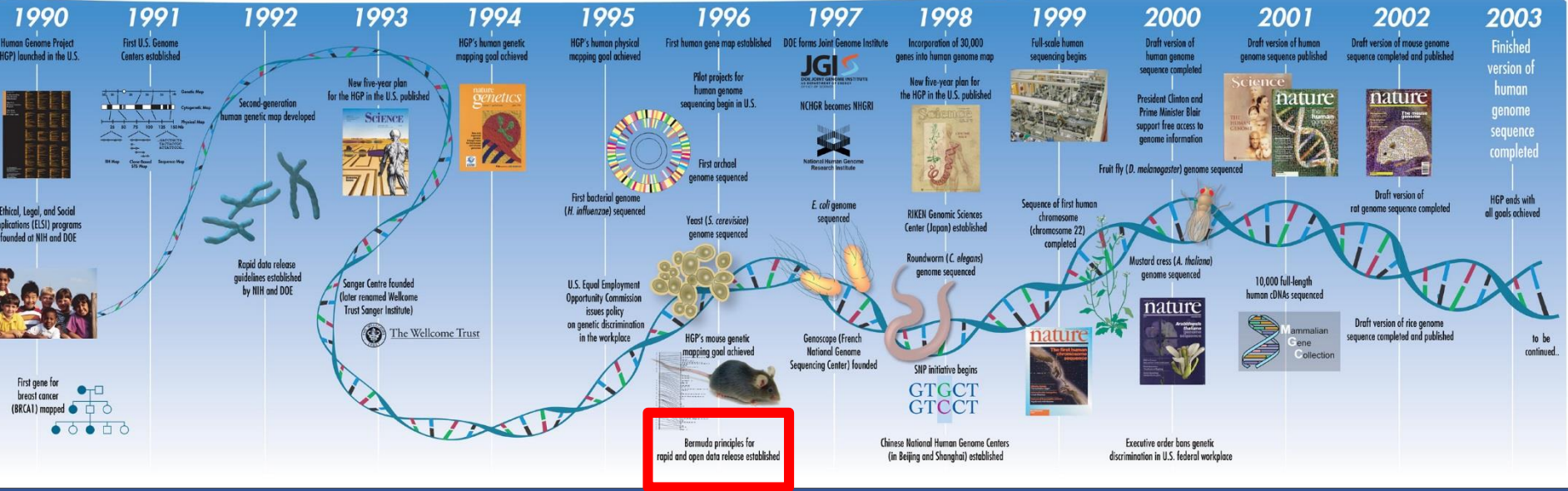
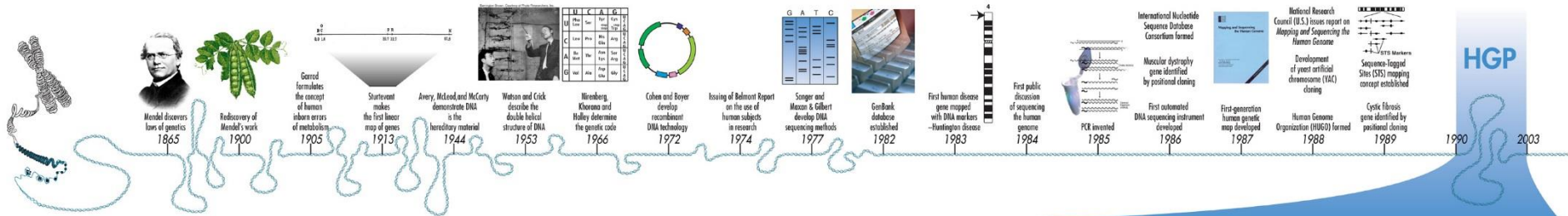
NIH: Steward of Medical and Behavioral Research for the United States



“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 >1kb (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

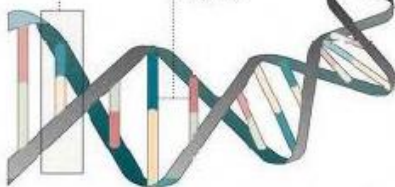
NEW YORK, TUESDAY, JUNE 27, 2000

Genetic Code of Human Life Is Cracked by Scientists

The Book of Life

The three billion
base pairs ...

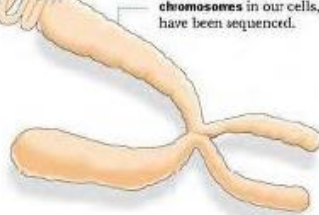
BASE PAIRS
Rungs between
the strands of
the double helix



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

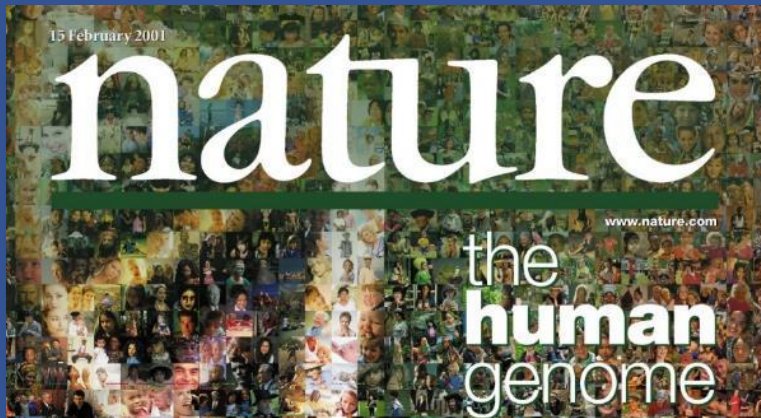
Science Times

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





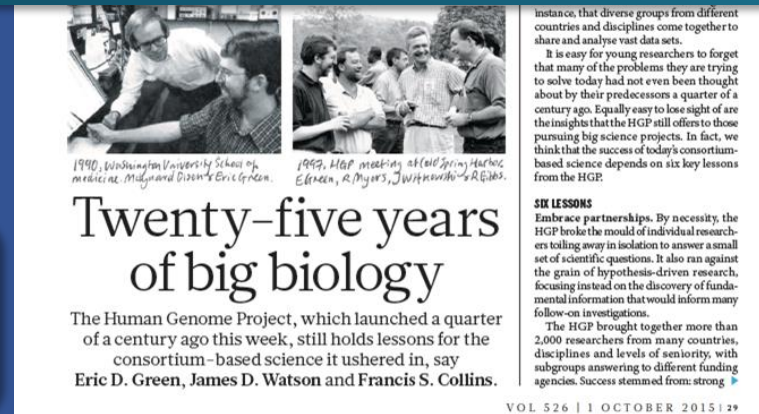
The Human Genome Project: 1990–2003



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

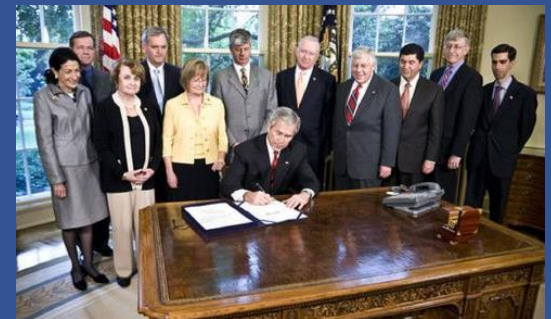


“The HGP changed the norms around data sharing in biomedical research.”



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....



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 2nd publication was pending – and public, media attention was growing
- *April–July:* NIH, Lacks family met to craft long-term solution
 - Three meetings of core participants
 - Lacks Family: 6 to 10 family members attended each session
 - NIH: Francis Collins, Kathy Hudson
 - JHU: Daniel Ford, Ruth Faden
 - Rebecca Skloot
 - Discussed complex issues, challenges – sought an agreement



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

npr



shots HEALTH NEWS FROM NPR

PUBLIC HEALTH

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

USA TODAY

NIH makes privacy agreement with Henrietta Lacks' family

Dan Vergano, USA TODAY

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 Baltimore, Md., died in Johns Hopkins Hospital, complaining of pain in her abdomen. She was 31 years old. Her life continued to live on in research labs around the world.

NBC NEWS

NIH finally makes good on promise to Lacks' family – and it's a relief, ethicist says

by ART CAPLAN, PH.D.



Cells taken from Henrietta Lacks, shown in the 1940s, eventually helped lead to a multitude of medical treatments. But neither she nor her family gave consent.

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

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^{1,2}; Primo N. L.

RESPIRATORY AND
CRITICAL CARE MEDICINE[®]

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

Celedón⁴

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. Oh¹, Joshua Galanter^{1,2}, Neeta Thakur¹, Maria Pino-Yanes^{1,3,4}, Nicolas E. Barcelo¹,
Marquitta J. White¹, Danielle M. de Bruin¹, Ruth M. Greenblatt^{1,5}, Kirsten Bibbins-
Domingo^{1,6}, Alan H. B. Wu⁷, Luisa N. Borrell⁸, Chris Gunter^{9,10}, Neil R. Powe^{1,6}, Esteban
G. Burchard^{1,2}

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

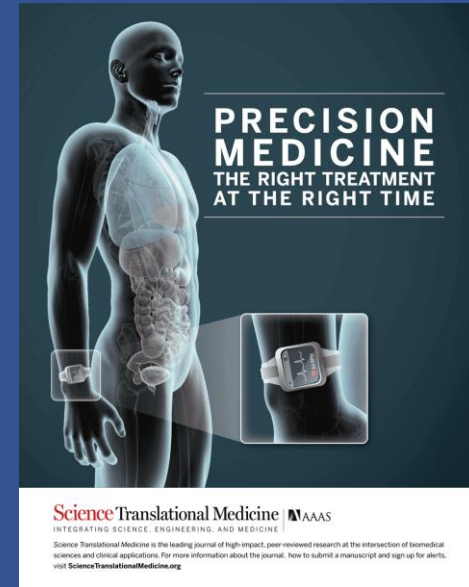
Legacy of Tuskegee casts a long shadow

- 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

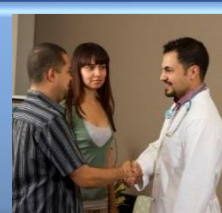
Description: a historic, longitudinal effort to gather data from **one million or more** people living in the US ... that takes into account individual differences in lifestyle, socioeconomics, environment, and biology

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



Sign up at Joinallofus.org

All of Us
RESEARCH PROGRAM

[ABOUT](#)

[HOW TO JOIN](#)

[NEWS & EVENTS](#)

[COMMUNITY](#)

[LOG IN](#)



[Español](#)

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](#)



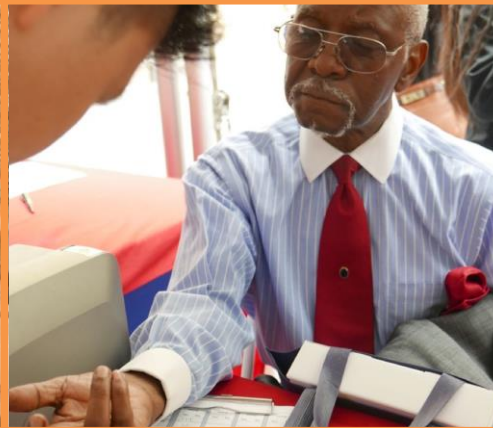
Importance of Diversity video

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*

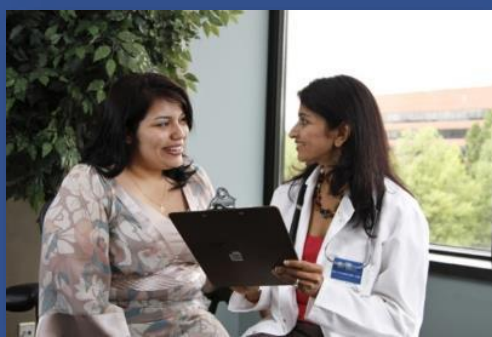




The main goal was science and being part of the conversation.

David Lacks Jr.





NIH... *Turning Discovery Into Health*

www.nih.gov/hope

directorsblog.nih.gov

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

