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….
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.

Credit: NIH Library on behalf of the HeLa Genome Data Access Working Group
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
Genetic Code of Human Life Is Cracked by Scientists

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 ...

BASEPAIRS

Rungs between the strands of the double helix.

BASES

Adenine

Cytosine

Guanine

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.

Science Times

A special issue

- Putting the genome to work
- Some information has already paid research dividends.
- Two research methods, two results.
- Four million so far to genome.
- More articles, charts and photos of the genome effort.

Section F

Decoding the Book of Life

A New Stone for Humanity

The New York Times
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….
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
- **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
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

<table>
<thead>
<tr>
<th>No. Requests</th>
<th>Status</th>
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<tbody>
<tr>
<td>78</td>
<td>Evaluated by the HeLa Genome Data Access Working Group</td>
</tr>
<tr>
<td>72 (92% approval)</td>
<td>Approved by NIH Director</td>
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- 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
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.

SECTION I. 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

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

Gender and Ethnic Diversity in NIMH-funded Clinical Trials: Review of a Decade of Published Research
Winnie W. S. Mak - Rita W. Law - Jennifer Alvarez - Elmo J. Perez-Stable

Race, Medical Researcher Distrust, Perceived Harm, and Willingness to Participate in Cardiovascular Prevention Trials
Noelle S. Sherber, MD, Steven P. Schulman, MD, Eric L. Ding, ScD, and Neil R. Powe, MD, MPH, MBA

Cancer
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 Enhanced Diversity in Cancer Trials
Moon S. Chun, Jr, PhD MHA,Jr, Primo N. Nouri, MD

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

Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled
Sam S. Oh,1, Joshua Galanter,2,3, Neeta Thakur,1, María Pino-Yanes,1,2,4, Nicolas E. Barceló,1, Marquita J. White,1, Danielle M. de Bruin,3, Ruth M. Greenblatt,1,5, Kirsten Bibbins-Domingo,1,6, Alan H. B. Wu,1, Luisa N. Borrelli,2, Chris Gunter3,10, Neil R. Powe,1,4, Esteban G. Burchard1,2,4,6
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

**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
- Surveys
- Baseline Measurements
- Electronic Health Records
- Enroll & Consent

HEALTH CARE PROVIDER ORGANIZATIONS
- Apps, Phones & Wearables
- Bio-Samples (Blood/Urine)

Bio-Samples (Blood/Urine)
Earning Participants’ Trust

To advance medicine’s future, the NIH tries to win the trust of communities mistreated in the past.
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
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
Debt to the Lacks Family

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.