

# HeLa Genome Data Access Working Group

Report to the  
Advisory Committee to the Director

September 5, 2014

**Renee Jenkins, MD**

*Professor and Chair Emeritus, Department  
of Pediatrics and Child Health  
Howard University*

# Presentation Overview

- Background on the HeLa Genome Data Access Working Group
  - Revisions to the Special Instructions for Preparing a Research Use Statement for Requesting Access to HeLa Cell Genome Sequence Data in dbGaP
- HeLa Genome Data Access Requests
- Workshop on Scientific and Ethical Issues Related to Open-Access HeLa Genomic Data
- ACD Discussion, Vote, and Recommendations

# The HeLa Genome Data Use Agreement

Per the agreement between NIH and the Lacks family, NIH requests that *all researchers*:

- Apply for access to HeLa whole genome sequence in the database of Genotype and Phenotype (dbGaP)
- Abide by terms outlined in the HeLa Genome Data Use Agreement, such as:
  - Data can only be used for biomedical research only; this does not include the study of population origins or ancestry
  - Requestors are not to make contact with the Lacks family
  - Requestors are to disclose any commercial plans
  - Requestors are to include an acknowledgment in publications and presentations
- Deposit future whole genome sequence data into dbGaP

# Role of HeLa Genome Data Access Working Group

- Evaluate requests to access HeLa cell genome data in dbGaP for consistency with the terms of the HeLa Genome Data Use Agreement
- Report findings to the Advisory Committee to the Director
- Make recommendations to the ACD on changes to the terms specified in the HeLa Genome Data Use Agreement

# HeLa Genome Data Access Working Group Roster

## **Renee Jenkins, M.D. (Chair)**

Professor and Chair Emeritus

Department of Pediatrics and Child Health  
Howard University

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

Professor, Bioengineering, Genetics, & Medicine  
Director, Biomedical Informatics Training Program  
Stanford University

## **Ruth Faden, Ph.D., M.P.H.**

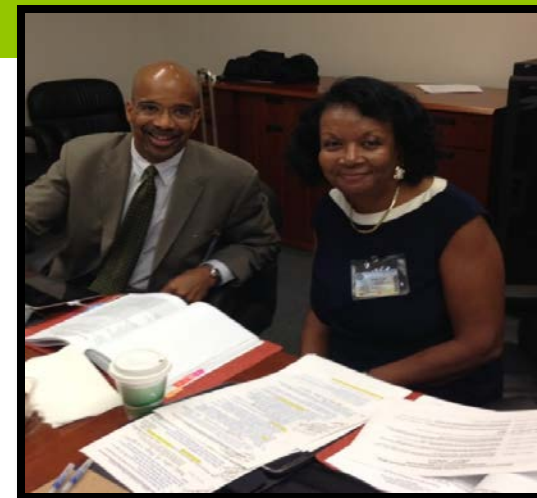
Philip Franklin Wagley Professor in Biomedical Ethics  
Director, Johns Hopkins Berman Institute of Bioethics  
Johns Hopkins University

## **Kathy Hudson, Ph.D.**

Deputy Director for Science, Outreach, and Policy  
National Institutes of Health

## **David Lacks Jr.**

Representative, Henrietta Lacks Family  
Baltimore, MD



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

President, Director and Faculty Investigator  
HudsonAlpha Institute

## **Robert Nussbaum, M.D.**

Professor of Medicine  
Chief of Division of Genomic Medicine  
University of California, San Francisco

## **Veronica Spencer**

Representative, Henrietta Lacks Family  
Baltimore, MD

## **Clyde W. Yancy, M.D.**

Professor in Medicine-Cardiology and Medical Social Sciences  
Chief, Division of Medicine-Cardiology  
Northwestern University  
Feinberg School of Medicine

# Working Group Evaluation Criteria

- Is the proposed research focused on health, medical, or biomedical research objectives?
  - Is the proposed research related to determining the ancestry or population origins of HeLa cells?
- Are there any plans to develop intellectual property?  
Specifically:
  - Does the requestor anticipate or foresee IP or developing commercial products or services from the proposed research?
  - Has the requestor agreed to notify NIH if their plans for IP or commercial products change?
- Are there any plans to publish or present findings?

# Revision to the “Special Instructions”

- A non-technical summary (lay language summary) of the proposed research is to be included in each data access request
  - The non-technical summaries provided by many of the requestors have been inadequate, and the Working Group relies on them to understand the request.
- Because of this, the Working Group has developed clarifying language in the “Special Instructions” regarding expectations for the Non-Technical Summary:

“In addition to the Research Use Statement, a requestor is required to also provide a **Non-Technical Research Summary**. The non-technical summary should describe the purpose and objectives of the proposed research in terms that are understandable to a lay reader. In addition to informing the HeLa Genome Data Access Working Group, which is composed of a multi-disciplinary scientific and clinical experts as well as members of the public, the non-technical summary is posted on the public portion of the dbGaP HeLa Cell Genome Sequencing Studies webpage.”

# Types of Findings Reported by the Working Group

In evaluating a Data Access Request, the Working Group will report a finding as:

- **Consistent** with the Data Use Agreement
- **Inconsistent** with the Data Use Agreement
- **Conditional** (will be consistent with the Data Use Agreement if NIH staff find that additional information obtained from the Requestor is satisfactory)
- **Pending** (will require a re-evaluation from the Working group once additional information is obtained from the Requestor)



# HeLa Data Access Requests

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# Update on HeLa Data Access Requests

- 30 Data Access Requests evaluated by the Working Group

Number of Requests	Status
21	Approved by NIH Director
1	Disapproved by NIH Director
4	Pending (require re-evaluation by the Working Group)
4	Being reported today

- 10 approved requestors have downloaded the data

# Working Group Findings: Evaluation of Access Requests

Since the last ACD meeting, the Working Group has found four Data Access Requests consistent with the HeLa Data Use Agreement

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings: Consistent with Data Use Agreement?
Analysis of Gene Expression, Splicing Regulation, and mRNA Degradation in Human Cells	University of California Berkeley	<ul style="list-style-type: none"> <li>The requestor plans to evaluate the effects of variations in the HeLa genome with that seen in other human cell lines, in order to learn more about gene regulation, structure and function.</li> </ul>	<b>Yes</b>
Development of Methods to Infer the 3D Structure of the Genome	University of Washington	<ul style="list-style-type: none"> <li>The overall goal of the project is to use the HeLa genome dataset to test hypotheses about three-dimensional folding of chromosomes, which is important for cellular function.</li> </ul>	<b>Yes</b>
Searching for Infectious Cancer Agents	University of Pittsburgh	<ul style="list-style-type: none"> <li>The requestor would like to search the genomic sequence of various tumors to potentially discover new types of viral infections that cause cancer.</li> </ul>	<b>Yes</b>
Polymorphisms in the shifted self peptidome following viral infection	Vanderbilt University; University of Texas, El Paso	<ul style="list-style-type: none"> <li>The requestor plans to study how the set of proteins found on the surface of cells change after a viral infection and how these vary among the population.</li> </ul>	<b>Yes</b>

# Workshop on Scientific and Ethical Issues Related to Open-Access HeLa Genomic Data

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# Background

- The current HeLa policy applies to whole genome data only
- Other HeLa genomic data types are currently in open-access and include, for example, epigenetic or RNAseq data
- Need to evaluate whether the Policy should apply prospectively to other HeLa genome data types
- Workshop on Scientific And Ethical Issues Related to Open-Access HeLa Genomic Data was held on May 14

# Workshop Participants

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

Stanford University

**Dixie B. Baker, Ph.D.**

Genetic Alliance

**Barbara Bowles Biesecker, Ph.D., MS, CGC**

National Institutes of Health

**Vence L. Bonham, J.D.**

National Institutes of Health

**Lawrence C. Brody, Ph.D.**

National Institutes of Health

**John D. Carpten, Ph.D.**

Translational Genomics Research Institute

**Stephen J. Chanock, M.D.**

National Institutes of Health

**Giselle Corbie-Smith, M.D., M.Sc.**

University of North Carolina School of Medicine

**Yaniv Erlich, Ph.D.**

Whitehead Institute

**Ruth R. Faden, Ph.D., M.P.H.**

Johns Hopkins University

**Paul Flicek, Ph.D.**

European Bioinformatics Institute

**Nanibaa' Garrison, Ph.D.**

Vanderbilt University

**Aaron Goldenberg, Ph.D., M.P.H.**

Case Western Reserve University

**Laurie Goodman, Ph.D.**

*GigaScience*

**Hank Greely, J.D.**

Stanford University

**Eric Green, M.D., Ph.D.**

National Institutes of Health

**Kathy L. Hudson, Ph.D.**

National Institutes of Health

**Chanita Hughes-Halbert, Ph.D.**

Medical University of South Carolina

**Renee R. Jenkins, M.D.**

Howard University

**Lynn B. Jorde, Ph.D.**

University of Utah

**Rick Kittles, Ph.D.**

University of Illinois at Chicago

**David Lacks, Jr.**

Representative, Henrietta Lacks Family

**Kimberley Lacks**

Representative, Henrietta Lacks

**Shirley Lacks**

Representative, Henrietta Lacks

**Sandra Soo-Jin Lee, Ph.D.**

Stanford School of Medicine

**Daniel MacArthur, Ph.D.**

Broad Institute of MIT and Harvard

**Pilar Ossorio, J.D., Ph.D.**

University of Wisconsin

**Jim Ostell, Ph.D.**

National Institutes of Health

**Laura Lyman Rodriguez, Ph.D.**

National Institutes of Health

**Charles Rotimi, Ph.D.**

National Institutes of Health

**Charmaine D. M. Royal, Ph.D.**

Duke University

**Jay Shendure, M.D., Ph.D.**

University of Washington

**Veronica Spencer**

Representative, Henrietta Lacks Family

**Lars Steinmetz, Ph.D.**

European Molecular Biology Laboratory

**Susan M. Wolf, J.D.**

University of Minnesota

**Clyde W. Yancy, M.D.**

Northwestern University Feinberg School of  
Medicine

**Ma'n Zawati, LL.B., LL.M.**

McGill University

# Workshop Agenda Overview

- HeLa genomic data currently in open access and future considerations
- Scientific value of HeLa genomic data
- The information revealed by and the privacy risks of different types of open-access HeLa genomic data
- Ethical implications of open versus controlled data access
- Applying the NIH HeLa Genomic Data Policy to other HeLa genomic data types

# Preferences of Participating Lacks Family Members

- Desire that scientists have efficient and effective access to HeLa genomic data
- Concerned about delaying or halting the progress of science with HeLa cells
- Want to be informed about scientific developments with the use of HeLa cells



# Preliminary Workshop Outcomes

- HeLa Genome Data Use Agreement
  - Not much enthusiasm for expanding policy
- Open vs Controlled Access to HeLa Genomic Data
  - HeLa genomic data, beyond whole genome sequences, do not need to be kept in controlled access
- HeLa Cell Research Collection
- HeLa Cell Research Symposia
- Information sharing with the Lacks family
  - Periodic summary of how HeLa cells and sequences are being used in research

# Working Group Findings

- Privacy considerations are not significant enough to outweigh the scientific and public health benefits of maintaining the other types of genomic data in unrestricted databases and, as such, the NIH HeLa genome data policy need not change.
- A periodic symposium in association with an extant national scientific meeting (e.g., AAAS, ASCB, ASHG) would be the most useful, comprehensive, and feasible approach to capture and disseminate information on HeLa cell research.

# Next Steps

- ACD to make a recommendation to the NIH Director
- NIH to consult with the Lacks family
- NIH Director will make a final decision on how to move forward

# ACD Discussion, Vote, and Recommendations

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# Working Group Findings on Four Data Access Requests

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# Working Group Findings on the Workshop

- No change to the NIH HeLa genome data policy.
- NIH should hold a periodic, special session at a national scientific meeting (e.g., AAAS, ASCB, ASHG) that would focus on revolutionary research utilizing HeLa cells.