

HeLa Genome Data Access Working Group

Report to the
Advisory Committee to the Director

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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

Lisa A. Cooper, M.D., M.P.H.

James F. Fries Professor of Medicine and Director, Johns Hopkins Center to Eliminate Cardiovascular Health Disparities

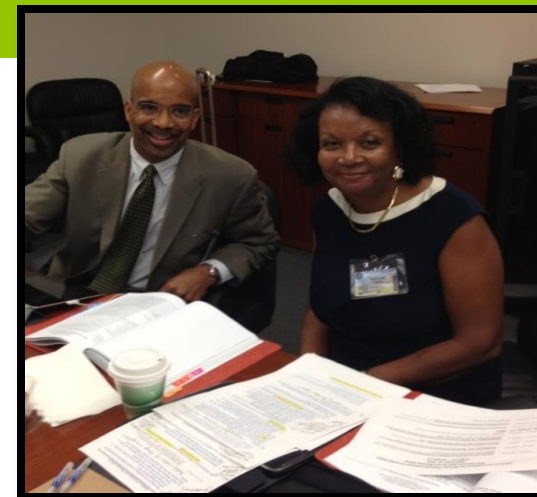
Johns Hopkins University School of Medicine
Baltimore, MD

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?

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)

Update on HeLa Access Requests

- 30 Data Access Requests evaluated by the Working Group

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

- 13 approved requestors have downloaded the data
- 5 annual reports from data users have been received and administratively approved by NIH staff
- 1 pending request to be reported today

Working Group Findings: Evaluation of Access Request

Since the last ACD meeting, the Working Group has evaluated one Data Access Request consistent with the HeLa Data Use Agreement

Project Title	Requestor's Name and Affiliation	Project Overview	Working Group Findings: Consistent with Data Use Agreement?
HeLa Cells: Repetitive Elements	Robert Schneider Institut de Genetique et de Biologie Moleculaire et Cellulaire, Illkirch, France	<ul style="list-style-type: none"> The requestor plans on comparing retrotransposon, sometimes called "jumping genes," insertion locations in the genomes in several human cell lines including HeLa cell lines, with the aim of gaining insight regarding the mechanisms by which these elements are regulated by cells. 	<i>Conditional (will be approved pending receipt of satisfactory non-technical summary)</i>

ACD Discussion, Vote, and Recommendation
