

HeLa Genome Data Access Working Group

Report to the Advisory Committee to the Director

December 10, 2015

Kathy Hudson, Ph.D.

Deputy Director for Science, Outreach, and
Policy

National Institutes of Health

Clyde Yancy, M.D.

Professor in Medicine-Cardiology and Medical
Social Sciences

Chief, Division of Medicine-Cardiology

Northwestern University

Feinberg School of Medicine

The HeLa Genome Data Use Agreement

Per the agreement between NIH and the Lacks family, NIH is requesting 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

Clyde Yancy, M.D. (co-chair)

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

Kathy Hudson, Ph.D. (co-chair)

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

Russ Altman, M.D., Ph.D.

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

Lisa 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



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

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

David Lacks Jr.

Representative, Henrietta Lacks Family

Richard 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

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)

Status of Data Access Requests

Number of Requests	Status
44	Evaluated by the HeLa Genome Data Access Working Group
38	Approved by NIH Director
1	Disapproved by NIH Director
5	Disapproved by NIH staff (requestors did not respond to requests for clarifications regarding publication plans, IP, and/or the non-technical summary)
Number of Data Downloads	Status
29	Approved requestors have downloaded the data
Number of Annual Reports	Status
25 (Renewal Requests)	Approved administratively by NIH staff
Number of New Requests	Status
1	Being reported to ACD today

Working Group Finding: Evaluation of Access Request

Since the last ACD meeting, the Working Group has found 1 request to be consistent with the HeLa Genome Data Use Agreement:

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
tRNA Nucleotide Analysis	ANY LANGUAGE COMMUNICATIONS, INC.	<ul style="list-style-type: none"> • Transport ribonucleic acid (tRNA) functions to decode the RNA sequence into a protein. Mutations in tRNA have been shown to affect gene expression. • This investigator proposes to analyze the tRNA sequence from the HeLa genome for novel variations that may be involved in cancer gene expression. 	CONSISTENT WITH DATA USE AGREEMENT

ACD Discussion, Vote, and Recommendations

Working Group Finding: Evaluation of Access Request

Since the last ACD meeting, the Working Group has found 1 request to be consistent with the HeLa Genome Data Use Agreement:

Project Title	Requestor's Affiliation	Working Group Finding
tRNA Nucleotide Analysis	ANY LANGUAGE COMMUNICATIONS, INC.	CONSISTENT WITH DATA USE AGREEMENT