

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 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., MSc (co-chair)

Professor in Medicine-Cardiology and Medical Social Sciences
Chief, Division of Medicine-Cardiology
Northwestern University
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Kathy Hudson, Ph.D. (co-chair)

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Director, Johns Hopkins Berman Institute of Bioethics
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David Lacks Jr.

Representative, Henrietta Lacks Family

Richard Myers, Ph.D.

President, Director and Faculty Investigator
HudsonAlpha Institute

Robert Nussbaum, M.D.

Chief Medical Officer
Invitae Corporation

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
55	Evaluated by the HeLa Genome Data Access Working Group
46	Approved by NIH Director
1	Disapproved by NIH Director
7	Disapproved by NIH staff (requestors did not respond to requests for clarifications regarding publication plans, IP, and/or the non-technical summary)
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
Chromatin Dynamics Related to its Structure	European Molecular Biology Laboratory	<ul style="list-style-type: none"> • The research team has used time-lapse microscopy methods to identify chromatin movements in HeLa cells in an effort to better understand genomic function and regulation • The research team will compare its microscopy data with sequencing-based structural information obtained from the HeLa data in dbGaP, to better understand how structure and dynamics of the genome influence genes and cellular functions 	CONSISTENT WITH DATA USE AGREEMENT

ACD Discussion, Vote, and Recommendations

Working Group Finding: Evaluation of Access Request

Project Title	Requestor's Affiliation	Working Group Findings
Chromatin Dynamics Related to its Structure	European Molecular Biology Laboratory	CONSISTENT WITH DATA USE AGREEMENT