

HeLa Genome Data Access Working Group

Report to the Advisory Committee to the Director

December 10, 2021

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Acting Associate Director for Science Policy
Acting Director of the Office of Science Policy
National Institutes of Health

Spero M. Manson, Ph.D.

Distinguished Professor of Public Health and Psychiatry
Director, Centers for American Indian and Alaska Native Health
The Colorado Trust Chair in American Indian Health
Associate Dean for Research at the Colorado School of Public
Health
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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

HeLa Genome Data Access Working Group Roster

Spero M. Mason, Ph.D. (Co-Chair)

Distinguished Professor of Public Health and Psychiatry
Director, Centers for American Indian and Alaska Native Health
The Colorado Trust Chair in American Indian Health
Associate Dean for Research at the Colorado School of Public Health
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Lyric Jorgenson, Ph.D. (Co-Chair)

Acting Associate Director for Science Policy
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Ruth Faden, Ph.D., M.P.H.

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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

Robert L. 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?

Status of Data Access Requests

Number of Requests	Status
94	Evaluated by the HeLa Genome Data Access Working Group
86	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 New Requests	Status
2	Being reported to ACD today

Working Group Findings: Evaluation of Access Requests

Since the last ACD meeting, the Working Group found 3 requests to be consistent with the HeLa Genome Data Use Agreement

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
Non-coding and coding alterations in cancer	Goteborg University	<ul style="list-style-type: none"><li data-bbox="672 508 1534 768">• The investigator proposes to research DNA sequences that do not produce proteins. These sequences that do not produce proteins are known as non-coding RNAs and recent evidence has uncovered a role of non-coding RNAs in cancer progression.<li data-bbox="672 822 1456 1039">• The investigator proposes to use the HeLa Cell Genome Sequencing Studies as a reference to identify non-coding RNA sequences in cancer sequences that may contribute to cancer.	CONSISTENT WITH DATA USE AGREEMENT

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Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
Detection of loss of heterozygosity in RNAseq data	University of Washington	<ul style="list-style-type: none"><li data-bbox="606 496 1561 986">• The investigator wishes to determine the lineage of individual cells by detecting genetic mutations, or changes. The investigator has developed a technical approach to detect genetic changes in individual cells using RNA, a copy of DNA. One genetic change the investigator detected is “loss of heterozygosity” or LOH – when one of two copies of a gene is deleted. The investigator used this technical approach to identify genetic regions of LOH throughout the mammalian genome.<li data-bbox="606 1033 1522 1205">• The investigator proposes to use the HeLa cell genome sequence to validate that their approach can detect LOH in regions of the human genome.	CONSISTENT WITH DATA USE AGREEMENT

ACD Discussion, Recommendation and Votes