HeLa Genome Data Access Working Group

Report to the Advisory Committee to the Director

December 11, 2020

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Acting Chief of Staff
Associate Director for Science Policy
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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
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The Colorado Trust Chair in American Indian Health
Associate Dean for Research at the Colorado School of Public Health
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Carrie D. Wolinetz, Ph.D. (Co-Chair)
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Russ B. Altman, M.D., Ph.D.
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Director, Johns Hopkins Berman Institute of Bioethics
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
92	Evaluated by the HeLa Genome Data Access Working Group
83	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**
3	Being reported to ACD today

Working Group Findings: Evaluation of Access Requests

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

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
Detecting mutations contributing to resistance to cancer treatment	**The Bioinformatics CRO**	• **The investigator is studying how drug treatment of cancer cells can change the cancer cell's genomic sequence (e.g., mutate) to cause drug resistance, or an inability of cancer cells to respond to drug treatment** • **In order to identify which genetic sequences changed, or mutated, as a result of drug resistance, the investigator proposes to compare the genome of drug-treated, drug resistant cancer cells to the untreated cancer cell genomes from the HeLa Cell Genome Sequencing Studies.**	**CONSISTENT WITH DATA USE AGREEMENT**
Nascent transcription at CTCF boundaries regulates insulation and promoter transcription	**National Centre For Biological Sciences**	• **The investigator proposes to use the HeLa Cell Genome Sequencing Studies to understand the regulation of a specific area in the genome that is highly transcribed, or turned on, in HeLa cells.**	**CONSISTENT WITH DATA USE AGREEMENT**

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Identify split reads from whole genome sequencing data of HeLa cell line	H. Lee Moffitt Cancer Center and Research Institution	• The investigator predicts that in HeLa cells, single stranded DNA uses U-turn like molecules to duplicate into double stranded DNA. The investigator proposes to use the HeLa Cell Genome Sequencing Studies to analyze if these U-turn like molecules play a role in DNA duplication by comparing the HeLa genome sequences to previously published duplication sequences. • The comparison between the two pair of alignments may uncover the use of U-turn like molecules in DNA duplication in HeLa cells.	CONSISTENT WITH DATA USE AGREEMENT

ACD Discussion, Recommendation and Votes