HeLa Genome Data Access Working Group

Report to the Advisory Committee to the Director

March 28, 2017

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Associate Director for Science Policy
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Bloomberg Distinguished Professor
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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
  - Evaluation not based on scientific merit
- 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

Lisa A. Cooper, M.D., M.P.H., FACP (Co-Chair)
Bloomberg Distinguished Professor,
James F. Fries Professor of Medicine and Director, Johns Hopkins Center to Eliminate Cardiovascular Health Disparities
Johns Hopkins University School of Medicine

Carrie D. Wolinetz, Ph.D. (Co-Chair)
Associate Director for Science Policy
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Russ Altman, M.D., Ph.D.
Professor, Bioengineering, Genetics, & Medicine
Director, Biomedical Informatics Training Program
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Ruth Faden, Ph.D., M.P.H.
Philip Franklin Wagley Professor in Biomedical Ethics
Director, Johns Hopkins Berman Institute of Bioethics
Bloomberg School of Public Health
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.
Chief Medical Officer
Invitae Corporation

Veronica Spencer
Representative, Henrietta Lacks Family

HeLa Whole Genome Sequence Data in dbGaP

Principle Investigator	Institution	Project Title	Submission Year
Andrew Adey	Oregon Health and Science University	Construction of thousands of single cell genome sequencing libraries using combinatorial indexing	2017
Jay Shendure	University of Washington	Massively multiplex single-cell Hi-C	2016
Xun Xu	BGI-Shenzhen, China	Full-length single-cell RNA-seq applied to a viral human cancer: Applications to HPV expression and splicing analysis in HeLa S3 cells	2016
Erez Aiden	Baylor College of Medicine	A 3D Map of the Human Genome at Kilobase Resolution Reveals Principles of Chromatin Looping	2016
Jay Shendure	University of Washington	Chromosome-scale scaffolding of de novo genome assemblies based on chromatin interactions	2014
Jay Shendure	University of Washington	The haplotype-resolved genome and epigenome of the aneuploid HeLa cancer cell line	2013
Lars Steinmetz	European Molecular Biology Laboratory	The Genomic and Transcriptomic Landscape of a HeLa Cell Line	2013

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
63	Evaluated by the HeLa Genome Data Access Working Group
53	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**
2	Being reported to ACD today

Working Group Findings: Evaluation of Access Requests

Since the last ACD meeting, the Working Group has found 2 requests to be consistent with the HeLa Genome Data Use Agreement:

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
Studies of L1-Mediated Pseudogene Formation in Human HeLa Cells	University of Michigan	• Long Interspersed Element-1 (L1) retrotransposons are also known as "jumping genes" due to their ability to move about the genome. Much of what is known about L1 "jumping genes" come from using HeLa cells. • The investigator wishes to use the HeLa whole genome sequence data in dbGaP as a reference and to validate how L1 or 'jumping genes' move about the genome to impact its structure and function and contribute to human genetic variation and in some cases, disease.	CONSISTENT WITH DATA USE AGREEMENT
Predicting 3D Regulatory Interactions	J. David Gladstone Institutes	• The investigator previously published a method, TargetFinder, which predicts 3D interactions between genomic regions from basic genomic data. • The investigator requests to use HeLa whole genome sequence data to validate their method, TargetFinder, in different cell lines.	CONSISTENT WITH DATA USE AGREEMENT (all three requests)

ACD Discussion, Vote, and Recommendations

Working Group Findings: Evaluation of Access Requests

Project Title	Requestor's Affiliation	Working Group Findings
Studies of L1-Mediated Pseudogene Formation in Human HeLa Cells	University of Michigan	CONSISTENT WITH DATA USE AGREEMENT
Predicting 3D Regulatory Interactions	J. David Gladstone Institutes	CONSISTENT WITH DATA USE AGREEMENT (all three requests)