HeLa Genome Data Access Working Group

Report to the
Advisory Committee to the Director

September 17 2015

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

Clyde Yancy, M.D.
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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:

  o Data can only be used for biomedical research only; this does not include the study of population origins or ancestry

  o Requestors are not to make contact with the Lacks family

  o Requestors are to disclose any commercial plans

  o 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
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Kathy Hudson, Ph.D. (co-chair)
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Russ Altman, M.D., Ph.D.
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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?

  o Is the proposed research related to determining the ancestry or population origins of HeLa cells?

- Are there any plans to develop intellectual property? Specifically:

  o Does the requestor anticipate or foresee IP or developing commercial products or services from the proposed research?

  o 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
43	Evaluated by the HeLa Genome Data Access Working Group
35	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**
24	Approved requestors have downloaded the data
Number of Annual Reports	**Status**
20 (Renewal Requests)	Approved administratively by NIH staff
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 has found 3 requests to be consistent with the HeLa Genome Data Use Agreement:

Project Title	Requestor's Affiliation	Working Group Findings
Human Spliceosome Structure and Function	University of California Santa Cruz	CONSISTENT WITH DATA USE AGREEMENT
Gene Copy Number at Naturally-Variant Loci in HeLa	University of Arizona, Tucson	CONSISTENT WITH DATA USE AGREEMENT
Integrating Epigenetic Data with Hi-C to Infer 3D Models of Genomes	University of Oslo, Norway	CONSISTENT WITH DATA USE AGREEMENT

ACD Discussion, Vote, and Recommendations

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Additional Information

Working Group Findings: Evaluation of Access Requests

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

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
Human Spliceosome Structure and Function	University of California Santa Cruz	• The genome is naturally edited through a process called splicing. Errors in this editing process are often associated with genetic diseases and cancers. • The research proposed in this request aims to use the HeLa genome sequence as a reference in designing genome editing experiments to test the effects of different splicing patterns and their influence on gene expression. • The research also hopes to examine factors that alter HeLa cell growth and structure.	CONSISTENT WITH DATA USE AGREEMENT
Gene Copy Number at Naturally-Variant Loci in HeLa	University of Arizona, Tucson	• The HeLa dataset will be compared to other dbGaP cancer data to identify and characterize genomic changes, such as the number of copies of a gene or genomic mutations, and to understand the role of such changes in the development of cancer.	CONSISTENT WITH DATA USE AGREEMENT
Integrating Epigenetic Data with Hi-C to Infer 3D Models of Genomes	University of Oslo, Norway	• The main goal of this research is to understand how the genome is folded into a three-dimensional structure and factors that affect this process, which could lead to diseases such as cancer. • This study aims to compare existing epigenomic data from HeLa cells with structural data to generate a HeLa 3D genome to evaluate the relationship between genomic structure and function.	CONSISTENT WITH DATA USE AGREEMENT