

HeLa Genome Data Access Working Group

Report to the Advisory Committee to the Director

Renee Jenkins, MD

*Professor and Chair Emeritus, Department
of Pediatrics and Child Health
Howard University*

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 defined by the Lacks family
 - Biomedical research only
 - No contact with family
 - Disclosure of commercial plans
 - Include acknowledgment in publications and presentations
- Deposit future whole genome sequence data into dbGaP

HeLa Genome Data Access Working Group: Charge

- Assess requests to access HeLa cell genome data in dbGaP for consistency with the HeLa Genome Data Use Agreement
- Report findings to the Advisory Committee to the Director

HeLa Genome Data Access Working Group Roster

Renee Jenkins, M.D. (Chair)

Professor and Chair Emeritus

Department of Pediatrics and Child Health
Howard University

Russ B. Altman, M.D., Ph.D.

Professor, Bioengineering, Genetics, & Medicine
Director, Biomedical Informatics Training Program
Stanford University

Ruth Faden, Ph.D., M.P.H.

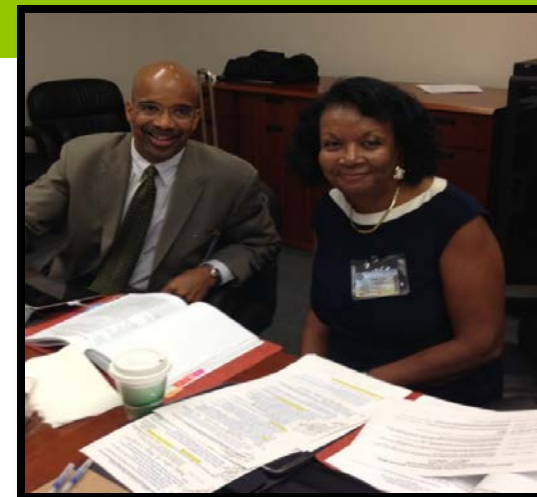
Philip Franklin Wagley Professor in Biomedical Ethics
Director, Johns Hopkins Berman Institute of Bioethics
Johns Hopkins University

***Kathy Hudson, Ph.D.**

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

David Lacks Jr.

Representative, Henrietta Lacks Family
Baltimore, MD



***Richard M. 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
Baltimore, MD

Clyde W. Yancy, M.D.

Professor in Medicine-Cardiology and Medical Social Sciences
Chief, Division of Medicine-Cardiology
Northwestern University
Feinberg School of Medicine

*Indicates new members

Standard Operating Procedures

The Working Group will meet on a monthly basis

- Requests received up to two days in advance of the meeting will be assessed
- The Working Group meeting schedule may be modified based on the volume of requests received
- Working Group reports will be coordinated with ACD meetings

All Working Group members will review all requests

Criteria for Assessment of Access Requests

Working Group members are to assess whether:

- The proposed research is focused on health, medical, or biomedical objectives
- The proposed research is not related to determining the ancestry or population origins of the HeLa cells
- The requestor discloses plans to develop intellectual property or commercial products or services based on the findings
- The requestor discloses plans to publish or present the findings

Options for Review Outcomes

After assessing a request, the Working Group has several options for classifying the request:

- The proposed research is consistent with the Data Use Agreement (“Consistent”)
- The proposed research is consistent with the Data Use Agreement, provided that satisfactory answers to follow-up questions are received (“Conditional”)
- The proposed research cannot be found consistent with the Data Use Agreement until additional information is received (“Pending”)
- The proposed research is inconsistent with the Data Use Agreement (“Inconsistent”)

Working Group Assessment of Intellectual Property in Disclosed in Requests

- NIH is limited in the actions it can take regarding the filing of Intellectual Property by requestors
- The Data Use Agreement does not provide for denying a request on the basis of Intellectual Property alone
- A request can be denied if a requestor does not provide requested information about his or her plans for Intellectual Property or commercialization
 - Requests can also be denied if requestors do not agree to notify NIH in the event that their plans for Intellectual Property or commercialization change

Updates on Previous Data Access Requests

Since the last meeting of the ACD on September 16:

- Dr. Collins approved all four of the data access requests recommended for approval by the ACD
 - Data has been downloaded for two of these four requests
- Working Group requested additional information on two data access requests
 - Responses have been received for one of these pending requests

Working Group Findings: Assessment of Access Requests

Since the last ACD meeting, the Working Group has found 4 requests consistent with the Data Use Agreement:

Project Title	Working Group Findings	Follow up questions
Development of Methods to Detect Cancer-causing Driver Mutations	CONSISTENT (formerly pending)	IP and source of other datasets (response received)
Identifying Genomic Alterations in the HeLa Cell Genome	CONSISTENT	Role of the IT Director (clarification received)
Epigenomics of HeLa	CONSISTENT	No follow up
Chromosome-scale scaffolding of de novo genome assemblies based on chromatin interactions	CONSISTENT <ul style="list-style-type: none">▪ Approved by NIH Director	No follow up

Overview of Data Access Request Approved on November 2, 2013

NIH learned that an investigator who had submitted data to dbGaP planned to publish a paper on November 3, 2013

- When developing the HeLa policy, NIH did not consider the need to assess the initial use of data by investigators who generate or submit HeLa cell whole genome data
- The investigator agreed to submit a request for use of their own data to be assessed by the HeLa Working Group; the ACD was consulted and the NIH Director approved the request

New Approach to HeLa Genome Sequencers

NIH plans to issue a revised policy and ask data submitters to request access to the data they generated

- NIH will discuss revised policy with extant HeLa sequence producers
- Future requests will be assessed by the Working Group for consistency with the HeLa Genome Data Use Agreement
- NIH will request leading journals to assist in ensuring that submitted manuscripts follow the HeLa policy

ACD Discussion on Working Group Findings

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