

HeLa Genome Data Access Working Group

Report to the Advisory Committee to the Director

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Charge to the HeLa Genome Data Access Working Group

- Evaluate 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
 - ACD makes recommendations to NIH Director about whether a request should be approved or disapproved
- Make recommendations to the ACD on changes to the terms specified in the HeLa Genome Data Use Agreement

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

Working Group Evaluation Criteria

To evaluate whether an Access Request is consistent with the HeLa Genome Data Use Agreement, the Working Group uses the following questions as a guide:

- 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 IP or developing commercial products or services?
 - Does the requestor foresee that IP or commercial products may arise 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?

Through special instructions, the requestor is advised to address these items in their Research Use Statement, in addition to describing the objectives, design, and analysis plan of the proposed research and providing a statement explaining why the HeLa cell genome sequence data is valuable for the proposed research. Plans for IP or commercialization of a product or service is not used by the Working Group to make a final evaluation; this information is obtained for disclosure purposes only.

Types of Findings Reported by the Working Group

In evaluating an Access Request, the Working Group will report a finding as:

- Consistent with the Data Use Agreement
- Not consistent with the Data Use Agreement

The Working Group may ask Requestors to respond to additional questions before a final evaluation is made. If so, the Working Group may initially report a finding as:

- Conditional (will be consistent with the Data Use Agreement if additional satisfactory information is obtained from the Requestor)
- Pending (will require a re-evaluation from the Working group once additional information is obtained from the Requestor)

Updates on Previous Data Access Requests

To date, the Working Group has evaluated 18 data access requests, of which:

- The NIH Director has approved eight of the data access requests recommended for approval by the ACD
- The findings on nine requests are being reported to the ACD at this meeting
- One request is pending an evaluation by the Working Group; the evaluation will be made once the requestor responds to follow-up questions

Working Group Findings: Evaluation of Access Requests

Since the last ACD meeting, the Working Group has found 1 request not consistent and 8 requests consistent with the HeLa Genome Data Use Agreement:

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
Mining Exome Sequencing and Array Based Genome Wide Association Studies for Disease Target and Biomarker Discovery	Bristol-Myers Squibb Company	<ul style="list-style-type: none"> The aim of the project is to study how changes in the sequence of the HeLa genome affect gene activity. HeLa cell genome sequencing data will be used for control purposes while looking for biomarkers in other genomic datasets. 	<p><u>NOT</u> CONSISTENT WITH DATA USE AGREEMENT</p> <p>Reason:</p> <ul style="list-style-type: none"> Requestor has no intention to disseminate findings Requestor did not indicate how HeLa cell genome sequence data are valuable for the proposed research
TargetInfectX-Multi-Pronged Perturbation of Pathogen Infection in Human Cells	University of Basel; Zurich University; ETH Zurich	<ul style="list-style-type: none"> The aim of the project is to design genome analysis tools that will enable identification of the parts of the cell that allow viruses to enter the cell. HeLa cell genome sequencing data will provide the gene sequence information required to properly design the tools. This work may lead to an improved understanding of infection and ways to fight it. 	<p>CONSISTENT WITH DATA USE AGREEMENT</p>
Identifying Allele-specific Biases in HeLa Transcript Processing	University of North Carolina, Chapel Hill	<ul style="list-style-type: none"> HeLa cell gene activity will be examined by comparing HeLa cell genome sequencing data to existing HeLa gene activity data. Results from this work will provide clues as to when genetic changes begin to cause disease, such as chronic obstructive pulmonary disease. 	<p>CONSISTENT WITH DATA USE AGREEMENT</p>

Working Group Findings: Evaluation of Access Requests Continued

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
Allele-specific Analyses in the HeLa Genome	Yale University	<ul style="list-style-type: none"> The aim of the project is to further develop a genome analysis software tool called AlleleSeq.1, which is used with non-cancer genomes to detect changes in a gene that can alter gene activity. HeLa genome cell sequencing data will be used to modify the software to analyze cancer genomes, which are more complex than non-cancer genomes. 	CONSISTENT WITH DATA USE AGREEMENT
Genomic Engineering in Alzheimer's Disease	Flanders Interuniversity Institute for Biotechnology	<ul style="list-style-type: none"> The aim of the project is to design tools for genomic engineering that will allow researchers to alter the sequence of genes in HeLa cell lines. HeLa cell genome sequencing data will provide the gene sequence information required to design the tools. These tools will enable the project team to assess the function of genes that are involved in neurodegenerative diseases such as Parkinson's disease. 	CONSISTENT WITH DATA USE AGREEMENT
Allele-specific Gene Regulation	Uppsala University	<ul style="list-style-type: none"> The aim of the project is to study how genetic variations found in the HeLa genome affect gene activity. Genetic variations found by comparing HeLa gene activity data generated in previous experiments to HeLa cell genome sequencing data will provide clues into the cause of diseases involving cervical cell defects. 	CONSISTENT WITH DATA USE AGREEMENT

Working Group Findings: Evaluation of Access Requests Continued

Project Title	Requestor's Affiliation	Project Overview	Working Group Findings
Use of HeLa Cells to Study Assembly of HIV-1	Rockefeller University	<ul style="list-style-type: none"> The aim of the project is to understand how HIV activity could be disrupted by identifying and studying key cell proteins involved in the virus formation process. The project team will use HeLa cell genome sequencing data to further studies of how HIV develops into a mature and active virus in HeLa cells. 	<i>CONSISTENT WITH DATA USE AGREEMENT</i>
Compare HeLa Genome with SH-SY5Y Neuroblastoma Cell Line	University of Luxembourg	<ul style="list-style-type: none"> The aim of the project is to determine which human cell lines are suitable for studying neurodegenerative diseases, such as Parkinson's disease. A comparative analysis will be conducted using genome data from a neuroblastoma cell line and the HeLa cell genome sequencing data and the results will help guide the selection of genetically optimal cell lines for use in disease research. 	<i>CONSISTENT WITH DATA USE AGREEMENT</i>
Genome Editing of HeLa Cells to Study Endocytosis	Medical Research Council	<ul style="list-style-type: none"> The aim of the project is to design molecular tools that will allow researchers to alter the sequence of genes in HeLa cells. These methods will be used to alter the sequence of specific genes that play a role in a basic cellular process called endocytosis where cells engulf and absorb various molecules that are outside the cell. 	<i>CONSISTENT WITH DATA USE AGREEMENT</i>

HeLa Genome Data Access Working Group Roster

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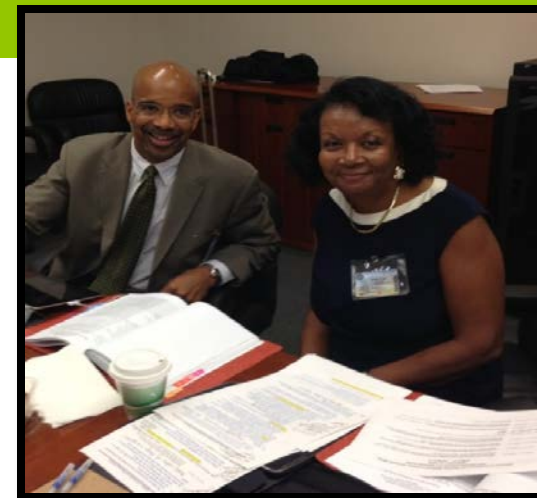
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