National Institutes of Health
Advisory Committee to the Director
HeLa Genome Data Access Working Group

CHARGE

HeLa is a human epithelial adenocarcinoma cell line that was derived from biopsy specimens of a 31-year old patient named Henrietta Lacks who was being treated for cervical cancer at The Johns Hopkins University Hospital in 1951. The specimens were obtained without her knowledge or consent not long before her death, and the cell line was established shortly thereafter. HeLa cells were the first type of human cells to be stably cultured for research, and the HeLa cell line is the world's most commonly used human cell line. It has advanced our understanding of fundamental biological processes, and it has been used for testing the polio vaccine, establishing basic techniques for cloning and in vitro fertilization, identifying the cause of cervical cancer (HPV), and advancing the development of anti-cancer drugs.

In spring 2013, a research team in Germany posted the full genome sequence of a HeLa cell line on a public database. The posting of the data triggered strong reactions from researchers, patient advocates, and bioethicists who were concerned that it violated the privacy of the Lacks family, whose identities are widely known as a result of the bestselling book "The Immortal Life of Henrietta Lacks." When the Lacks family expressed concerns about what these data might reveal about their disease risk, the data were removed from public view. At the same time, a second HeLa genome sequence paper was under consideration for publication in *Nature*.

In response to this situation the National Institutes of Health (NIH) worked with the scientific community and the Lacks family to establish a special process for making HeLa cell sequence data available for biomedical research. NIH-funded researchers who sequence HeLa cell lines will be expected to deposit their data into NIH's database of Genotypes and Phenotypes (dbGaP) and requests for access to the data will be subject to a special review and approval process involving the HeLa Genome Data Access Working Group of the Advisory Committee to the Director (ACD). NIH has taken this extraordinary step because full sequence data can reveal certain heritable aspects of Henrietta Lacks' germline DNA, and can thus be used to draw inferences of possible, if uncertain, significance about her descendants. This process was developed in consultation with the Lacks family, who wish to see the HeLa genomic sequence data used for the advancement of biomedical research while having a role in how the sequence data are used.[1]

The ACD HeLa Genome Data Access Working Group is charged with reviewing requests from the research community for access to HeLa cell line sequence data in dbGaP and assessing whether the requests align with the terms of use defined in the HeLa Genome Data Use Agreement, http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000640.v1.p1. The Working Group's findings will be reported to the ACD, and the ACD will make recommendations to the NIH Director about whether a request

[1] Further background information can be found in Hudson KL and Collins FS. Family matters. Nature. Vol. 500, pages 141-142 (August 8, 2013).

should be approved or disapproved. The NIH Director will decide whether access to the data will be granted. As needed, the Working Group may make recommendations to the ACD on changes to the terms of use spelled out in the HeLa Genome Data Use Agreement.

The Working Group will be composed of two members of the Henrietta Lacks family and a number of relevant scientific experts. In carrying out its charge, the Working Group may consult other experts as needed.

Meetings of the ACD HeLa Genome Data Access Working Group will be held on an as needed basis. The Working Group may also confer between meetings via electronic, oral, and written communications.

The operations of the ACD HeLa Genome Data Access Working Group will be managed by the Office of Science Policy (OSP), Office of the Director, NIH. In addition to organizing meetings, preparing and distributing meeting materials to Working Group members, OSP staff will be responsible for communicating with investigators, maintaining records, and preparing meeting summaries.