HeLa Genome Data Access Working Group:

Report to the Advisory Committee to the Director

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HeLa Genome Data Access Working Group: Charge

Working Group Charge:

- Review requests to access HeLa cell genome data in dbGaP and assess whether they align with the HeLa Genome Data Use Agreement

HeLa Genome Data Access Working Group:

- The Working Group will review and, as needed, may suggest changes to the Data Use Agreement or the working group charge
- The Working Group may consult experts as needed
  - rigorous review of scientific merit is not within the purview of the WG but the working group will consider the science in order to fairly adjudicate how well the application meets the review criteria
- The Working Group findings will be reported to the ACD
  - The ACD will make recommendations to the NIH Director about specific data access requests
  - The NIH Director will decide whether access will be granted

Criteria for Review of Access Requests

Working Group members are to ensure that:

- 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 these cells
- The applicant discloses plans to develop intellectual property or commercial products or services based on the findings
- The applicant discloses plans to publish or present the findings
- The applicant agrees not to contact any member of the Lacks family directly but may work through the WG for any high priority queries
  - Designated Lacks family members remain available for public speaking and community events

Overview of Data Access Request Review

- **Six** Data Access Requests were reviewed
  - **One** was approved
  - **Three** were conditionally approved on 9/12/13; the necessary follow-up questions were immediately answered to the satisfaction of the Working Group on 9/13/13 and these three requests have been **approved**.
  - **Two** are pending Working Group decision following receipt of additional information

Overview of Data Access Request Review

- Based on this first review, the Working Group identified a number of issues to consider in future meetings

Overview of Data Access Request Review

- Discussion of how to streamline application process so that applicants provide responses to specific access criteria
- Need responsive statements from applicants that address the following questions about IP/commercialization:
    1. *Do you anticipate IP or developing commercial products or services?*
    2. *Is it foreseeable that IP or commercial products or services may arise from your research with HeLa cells?*
    3. *If IP or commercial plans or expectations change, will you agree to notify the NIH under the terms of this data use agreement?*
- Need information about why HeLa cells are uniquely valuable for the proposed research
- Need information about whether the research will use other HeLa genomic data and the source of these data
- Will consider how to ensure that the non-technical summary achieves the necessary clarity and appropriateness for the general public

Working Group Findings: *Review of Access Requests*

Project Title	**Working Group Findings**	**Follow up questions**
Computations Methods for Integrative Analysis of Omics Datasets	***APPROVED***	No follow up
Use of Haplotype Resolved HeLa Genome Sequence to Map Ribo-seq Reads for Inference of Allele-specific mRNA Translation Rates	***APPROVED***	IP
The Role of Cohesin and the Cohesin Loading Factor NIPBL in Transcriptional Regulation of HeLa Cells	***APPROVED***	IP
Cancer Haplomics: Computation of Haplotypes in the Presence of Polyploidy and Variable Copy Number	***APPROVED***	IP and publication plans
Development of Methods to Detect Cancer-causing Driver Mutations	Pending decision	IP and source of other datasets
The Effects of Human Papillomavirus 18 Integration Into the Haplotype-resolved Genome of HeLa Cell Line	Pending decision	IP, publication plans, IT

Next Steps and Items for Further Discussion

- Develop a Working Group standard operating procedures document
- Develop a defined process to best coordinate review with ACD proceedings in a timely manner
- Review data types subject to the HeLa Genome Data Use Agreement
- Understand how best to manage *submission* of any new HeLa genome datasets
- Acquire insight in the management of intellectual property under this data use agreement

Acknowledgement

Henrietta Lacks, and the HeLa cell line that was established from her tumor cells without her knowledge or consent in 1951, have made significant contributions to scientific progress and advances in human health. We are grateful to Henrietta Lacks, now deceased, and to her surviving family members for their contributions to biomedical research.

ACD Discussion on Working Group Findings

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