

# Genetic Research Privacy Protection Act

*Senators Elizabeth Warren (D-Mass.) and Mike Enzi (R-Wyo.)*

Researchers today generate large amounts of genetic data and federal agencies, as well as research institutions, maintain large databases of genetic information. This presents important privacy concerns, as it is now possible to identify an individual, and information about that person's health and the health of his or her family members, using genetic information. Genetic information collected through research is not typically protected under the Health Insurance Portability and Accountability Act (HIPAA), and courts have not uniformly viewed genetic information as private. Given the expansion of genetic research, rapidly evolving science, and the launch of the Precision Medicine Initiative, it is critical to protect the privacy of research participants.

## ***Significant concerns exist about access to genetic information.***

- To promote data-sharing and to harness the statistical power of large datasets, genetic data generated from NIH-funded research is shared with consent in an NIH repository. While federally-held genetic data are stripped of traditional identifiers like Social Security numbers and birthdates, a person's complete genome is unique to that individual and therefore cannot truly be de-identified. A recent study showed that it is possible to determine the identity of a research subject using genetic sequence data and publicly searchable online databases of genealogy and address information.<sup>1,2</sup> Privacy concerns about unauthorized access to and misuse of genetic data have been raised, including by the Presidential Commission for the Study of Bioethical Issues.<sup>3,4</sup>

## ***Existing genetic privacy protections under federal law are limited.***

- *FOIA*: The NIH has denied FOIA requests and appeals for information related to the "HeLa" cell line,<sup>5,6</sup> but it is unclear if information from a genetic database will qualify for a FOIA exemption if a challenge is brought in court. There is legal precedent that genetic information is not always private.<sup>7</sup>
- *Certificates of Confidentiality (CoCs)*: CoCs are issued by the NIH to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects of a research project, during civil, criminal, administrative, legislative, or other proceedings. CoCs are currently not mandatory, nor do they prevent the information from being volunteered by the researcher.

## ***The bipartisan Genetic Research Privacy Protection Act would:***

- Adds a specific FOIA exemption for all identifiable information, including genetic information, in the Public Health Service Act (PHSA).
- Requires the NIH to issue CoCs to all federally funded researchers who collect identifiable information, and strengthens CoCs so that identifiable information must be kept private. Important exceptions to CoCs allow for research data sharing, protection of health and safety, and research participants to access their own data.
- Protects any information that is identifiable from FOIA requests and, through enhanced CoCs, ensures that research participants are protected currently and into the future.

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<sup>1</sup> "Identifying personal genomes by surname inference." Gymrek *et al.* *Science*. January 18, 2013.

<sup>2</sup> "The Complexities of Genomic Identifiability." Rodriguez *et al.* *Science*. January 18, 2013.

<sup>3</sup> "Privacy and Progress in Whole Genome Sequencing." The President's Commission for the Study of Bioethical Issues, 2012.

<sup>4</sup> "Anonymity in Genetic Research Can Be Fleeting." Veronique Lacapra, National Public Radio, January 17, 2013.

<sup>5</sup> "DNA and insurance, Fate and Risk." A collection of op-eds by leading experts and advocates, *New York Times*, April 14, 2014.

<sup>6</sup> The story of the HeLa cell line was highly publicized in a best-selling book, which brought notoriety to Ms. Lacks and her family. "The Immortal Life of Henrietta Lacks" by Rebecca Skloot, 2010.

<sup>7</sup> <http://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf>

<sup>7</sup> A Conceptual Framework for Genetic Policy: Comparing the Medical, Public Health and Fundamental Rights Models." Lori B. Andrews, *Washington University Law Review*, Vol 79 Issue 1 (2001).