

# Accessing your own genomic data is a civil right but requires strategies to manage safety

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The Genetic Information Nondiscrimination Act of 2008, or GINA, expanded individuals' access to genetic information by forcing changes to the Health Insurance Portability and Accountability Act (HIPAA)

Privacy Rule. These amendments, finalized in 2013 and 2014, gave Americans a civil right to obtain copies of their own genetic test results stored at HIPAA-regulated laboratories. In a commentary published January 4 in the *American Journal of Human Genetics*, Barbara J. Evans, Alumnae College Professor of Law and Professor of Electrical and Computer Engineering at the University of Houston, describes how civil rights and safety concerns collided after these changes and offers strategies to reconcile the two.

GINA celebrates its tenth anniversary this year amid ongoing controversy, says Evans. "Scholars poke fun at GINA for 'solving' a problem that, as far as the evidence shows, never actually existed: genetic discrimination in employment and health insurance," she says. "Meanwhile, GINA declined to tackle problems that cause real headaches for people who are about to undergo genetic testing, such as whether the results might make it impossible to buy long-term care insurance."

The individual access right GINA created is also a source of heated controversy. Lawmakers foresaw that Americans need a right of access, for example, to protect themselves from being wrongly linked to a crime based on a genetic test mix-up or to help them assess how much hackers stole from a research lab that was storing their genomic data. But GINA created that right by amending the HIPAA Privacy Rule, which left some loose ends.

"You only have an access right if the party that stores your data happens to be HIPAA-regulated. Most direct-to-consumer testing and cloud data storage services are not HIPAA-regulated, so you may not have an access right if your data are there, says Evans. Also, the new access right was not successfully integrated with other regulations. "You have one regulator telling research labs to provide access, to protect [civil rights](#). Other regulators try to block access, citing safety concerns. Labs are

caught in the middle and many Americans are being deprived of a federally protected civil right to see their data."

The source of the dispute is that many research laboratories are HIPAA regulated and subject to the new access right. Giving people access to data from research laboratories is controversial because the genomic data they produce do not always contain clinically relevant information (only about 200 gene sequences have known clinical significance). Someone could misinterpret the data to pursue needless medical treatment or waste healthcare resources to clarify findings that they misunderstand.

Because of concerns that research data could be misused, bioethicists and medical professionals, as well as safety regulators like the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services, which regulates clinical labs, at times, have taken stances that cause research labs to block people's new access right. "The good news is that we aren't forced to choose between having safety or having civil rights," Evans adds, "We can have both, but it requires regulators to be smart and think outside their usual boxes."

In her commentary, Evans says that safety regulators have many tools to address safety risks without blocking access, such as requiring warnings and disclosures and sending informational letters to physicians. She also recommends publishing reliability scores for organizations that provide genomic interpretation services. Congress may also need to authorize funds to help research laboratories deal with the cost of providing access after research grants end.

"Having access to your own genomic data also lets you exercise important constitutional rights, such as your First Amendment rights to assemble and petition the government. You can go on social media and assemble groups of people with genes like yours and lobby Congress to

spend more research dollars studying how those genes affect your health," says Evans. "Like the right to vote, [access](#) to one's own [genomic data](#) is a foundational civil right that empowers people to protect all their other civil rights."

**More information:** *American Journal of Human Genetics*, Evans BJ.: "HIPAA's individual right of access to genomic data: reconciling safety and civil rights" [www.cell.com/ajhg/fulltext/S0002-9297\(17\)30493-7](http://www.cell.com/ajhg/fulltext/S0002-9297(17)30493-7) , DOI: [10.1016/j.ajhg.2017.12.004](https://doi.org/10.1016/j.ajhg.2017.12.004)

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