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Background Brief on …

Genetic Privacy

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Our DNA molecules contain genetic information that can be used to benefit or harm us. Oregon, like many other states, has adopted genetic privacy laws to protect the public from the abusive use of genetic information (ORS 192.531 to 192.549). Oregon's genetic privacy statute was created prior to the federal Health Insurance Portability and Accountability Act **(HIPAA)** law that provides basic disclosure protections to any form of health information, including genetic information.

In Oregon, it is a Class A misdemeanor to unlawfully obtain, retain, or disclose genetic information (ORS 192.543). Oregon law also creates a civil cause of action against anyone who unlawfully obtains or discloses genetic information, with the right to obtain the greater of actual damages or set statutory damages that range from $100 for negligent violations up to $250,000 for knowing violations committed with the intent to sell or use a person's DNA for commercial purposes (ORS 192.541).

Oregon law allows the use of DNA without an individual's consent for:

- Identification of deceased individuals
- Paternity
- Newborn screening
- Genetic information from a decedent for medical diagnoses of blood relatives
- Court order
- Anonymous or coded research conducted after proper notification

Oregon law requires the Department of Human Services **(DHS)** Health Division to adopt rules establishing minimum research standards for the collecting and testing of genetic information. The law also requires that individuals be given the option to request their biological sample or health information not be used for anonymous or coded genetic research.

Oregon law requires DHS to establish institutional review boards that review and approve a researcher's request to conduct anonymous or coded genetic research. A researcher cannot conduct genetic research in Oregon without approval by an institutional review board.

Oregon law prohibits an employer from obtaining or using genetic information to discriminate against the employee or prospective

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employee or a blood relative of the employee or prospective employee. The law also prohibits an insurance company from using genetic information to encourage an individual to obtain insurance, or from using the results to reject an application or to increase the rates of a life or health insurance policy (ORS 746.135).

History

The 1995 Legislative Assembly enacted Oregon's first genetic privacy law over concerns that the improper collection, retention, or disclosure of genetic information could lead to significant harm to the individual, including stigmatization and discrimination in employment, education, health care and insurance. The 1995 law established genetic information as the property of the individual and, as such, required law enforcement, district attorneys, and researchers to obtain informed consent before obtaining genetic information from an individual. This particular provision caused problems for both the law enforcement and medical research community.

The 1999 Legislative Assembly modified Oregon's then-existing genetic privacy laws with the goal of balancing the protection of patient confidentiality with the continuation of vital medical research in Oregon. Also, at the urging of Oregon Health & Science University **(OHSU)**, the pharmaceutical research industry, and the Oregon Medical Association, the Legislative Assembly created the Genetic Research Advisory Committee **(GRAC)** to study the use and disclosure of genetic information and to report back to the 2001 Legislative Assembly.

Following the GRAC review, the 2001 Legislative Assembly enacted Senate Bill 114. The most significant change contained in Senate Bill 114 was that it declared DNA to be the property of the individual and granted a privacy right. In addition, Senate Bill 114 continued GRAC, renaming it the Advisory Committee on Genetic Privacy and Research **(ACGPR)**, and charging it to study the use and disclosure of genetic information and to develop and refine a legal framework that defines the rights of individuals whose DNA samples are collected, stored, analyzed, and disclosed. Senate Bill 114 also imposed upon ACGPR the duty to report biennially to the Legislature.

Changes affecting the standards for coded and anonymous genetic research were made to the Oregon genetic privacy law during the 2003 Legislative Session through Senate Bill 618.

In 2005, ACGPR once again reported back to the Legislative Assembly and, at the urging of ACGPR, the Legislative Assembly enacted Senate Bill 1025 that established a set of limited conditions under which researchers could conduct anonymous or coded genetic research studies without seeking the written consent of the subjects. A key component of this legislation was the need for a one-time notification of patients by health care providers. Patients must be informed of their right to decline the use of their health information or specimens in these types of genetic research studies.

Federal Law

The federal government regulates research involving human subjects conducted, supported, or otherwise regulated by any federal department or agency (56 FR 28003, revised November 13, 2001). These regulations, known as the Common Rule because 15 federal agencies adopted them simultaneously, reach genetic testing involving humans. These regulations do not affect state laws or regulations that provide additional protections for human subjects. In fact, as part of Senate Bill 114, the Legislative Assembly made the Common Rule applicable to nonfederal research conducted in Oregon.

HIPAA establishes a basic threshold for the protection of health care data. Health care data includes the genetic information of individual patients. These regulations set limitations on the release of health records and provide individuals with more control over their personal health information.

Recent Legislation

Senate Bill 244 (2007) allows a health care provider to retain genetic information of an individual without authorization if the retention is for treatment, payment or health care operations. It also allows a health care provider to disclose genetic information of an individual without authorization if the provider discloses information consistent with ORS 192.520(3) or with ORS 746.607(3) (regarding disclosure to another health care entity with a relationship to the individual for certain purposes including but not limited to treatment).

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