

History of Oregon’s Genetic Privacy Law

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The 1995 Legislature Enacts a Comprehensive Genetic Privacy Act

The seed for Oregon’s genetic privacy law was planted at meetings convened in 1994 by the Multnomah County Medical Society (now called the Medical Society of Metropolitan Portland) to examine medical privacy in Oregon. The group decided to tackle one specific area, genetic privacy, whose rapid change and explosive growth posed great potential for discrimination to compromise access to medical care. A cross-disciplinary workgroup was formed to prepare a bill for the 1995 legislature.

The bill was drafted with the realization that the primary distinguishing feature between genetic and all other medical testing is the unique ability of a genetic test result to predict a person’s future health. These so-called predictive genetic tests can accurately predict a person’s future health prior to the individual experiencing any symptoms that might be diagnosed by any other available medical diagnostic procedure.

Prior to the introduction of this legislation, individuals in Oregon had no existing state or federal protection for genetic privacy and very unclear protection from insurance discrimination that could result from genetic testing. Oregon’s only law specifically relating to genetic privacy was a provision enacted in 1993 to prohibit certain kinds of discrimination in employment based on genetic information.¹ The workgroup proposed to expand this to a comprehensive approach protecting the privacy of DNA testing and genetic information in all settings, including insurance and health care as well as employment.

The Medical Society’s bill was enacted in 1995 with the declared goal of protecting the privacy of genetic samples and protecting individuals from employment and insurance discrimination on the basis of genetic test results. The bill was sponsored by Senator Neil Bryant and was known as Senate Bill 276. The bill represented a consensus of all major interest groups, and the only area in which the bill was modified in response to concerns was in the area of insurance.² Most elements of the 1995 law remain in force.³

¹ ORS 659A.303.

² 1995 Oregon Laws ch. 680.

³ ORS 659A.300 to 659A.303, 192.531 to 192.549, and 746.135

The intent of the law, as set forth in ORS 192.533, is to protect genetic privacy and prevent any citizen in Oregon from experiencing health insurance or employment discrimination on the basis of a medically indicated genetic test. Oregon was the first state in the country with a comprehensive law protecting genetic privacy, and because we were the first we knew that modifications to the law would be necessary as the technology developed and as the law was tried in practice.

SB 276 created privacy protection for three kinds of activities: obtaining, retaining, and disclosing genetic material. Both genetic information and DNA samples are protected. The bill did not have any express enforcement or remedial provisions.

SB 276 defined genetic information as the “property” of the individual from whom it was derived. This property provision was an attempt to solve several legal problems: providing guidance to the courts as to the nature of a person’s rights to genetic information, allowing family ownership of genetic information, and implying a remedy for a blood relative of an individual who suffers discrimination. As described below, however, the property clause became controversial and has now been repealed.

In 1996, the Health Division adopted administrative rules in the specific areas called for by the 1995 statute. These include consent forms for genetic testing for insurance and other non-medical contexts. Administrative rules have been updated as necessary based on changes to genetic privacy law.

The 1997 Legislature Considers Impacts on Research

Effects on biomedical research were not considered when the 1995 bill was enacted. During the 1997 legislative session a bill sponsored by the Smith Kline Beecham pharmaceutical company sought to repeal the property provision, which the company said was having a negative impact on research. The concerns were that a subject of research might later assert a claim to own the fruits of research and that a transfer of those rights to a researcher might be unenforceable.

The 1997 Legislature enacted one amendment to the genetic privacy law in order to mitigate the impacts on research. The law explicitly exempted anonymous research from the privacy act, since research done anonymously could not conceivably result in discrimination.⁴ The property provision was maintained, however.

The 1999 Legislature Debates Property and Creates an Advisory Committee

Concerns over the property clause continued, particularly among the biomedical research community. Several proposals were introduced to eliminate or modify it and were vigorously debated. In the outcome, the competing, complicated proposals stalemated and the legislation actually adopted did only two things.

First, research review by an institutional review board (IRB) was exempted from the genetic privacy law under a provision having a two-year sunset.⁵ Second, a Genetic Research Advisory Committee (GRAC) was created under the Office for Oregon Health Plan Policy and Research. The Committee was charged to “study the use and disclosure of genetic information and shall develop a legal

⁴ 1997 Oregon Laws ch. 780.

⁵ 1999 Oregon Laws ch. 921, §§ 1-3.

framework that defines the rights of individuals whose DNA samples and genetic information are collected, stored, analyzed and disclosed.”⁶

The Advisory Committee met during year 2000 and addressed its charge through a broad series of recommendations for change. After much debate and study, the Committee unanimously recommended replacing the property clause with a confidentiality clause and enacting several remedial and family-rights provisions to replace the various dimensions of the property clause. The Committee’s Report, *Assuring Genetic Privacy in Oregon*, was published in November 2000.⁷ The report made recommendations in five areas – remedy for violations, family issues, informed consent, property, and continued oversight – and included a draft bill.

The 2001 Legislature Overhauls the Genetic Privacy Law

The 2001 Legislature adopted all of the Genetic Research Advisory Committee’s recommendations and enacted Senate Bill 114.⁸ The Legislature also adopted a suggestion by the Oregon ACLU that patients be notified if their DNA sample or genetic information is to be used in anonymous research and have an opportunity to opt out of such use.⁹ The 2001 legislation includes the following provisions:¹⁰

- **Legal Framework.** Specifies that genetic information and DNA samples are private and that an individual has a right to protection of that privacy. Deletes provision providing that genetic information and DNA sample are the “property” of the individual.
- **Remedy For Violations.** Establishes a civil cause of action to enforce the individual’s privacy interest by an individual, an individual’s blood relative, estate, or the Attorney General. Establishes minimum damages for specified violations from \$0 for inadvertent disclosure that is corrected to \$250,000 for a disclosure with the intent to use for commercial advantage. Creates criminal penalty for intentional violations.
- **Research.** Requires the Health Division to adopt rules consistent with Federal Policy for the Protection of Human Subjects (Common Rule), to establish minimum standards for genetic research, and to create a registry of institutional review boards. Requires review by an institutional review board of all proposed anonymous research. Delegates authority to Health Division to promulgate guidelines for genetic research in which the identity of the individual is encrypted. Requires Health Division to establish criteria for recontact of individuals when using research information with personal identifiers. Requires persons conducting research to obtain informed consent of the individual except where the individual’s identity is anonymous or encrypted. Limits the use of a blanket informed consent for further research. Requires notification to individual that individual’s DNA sample or genetic information may be used for anonymous research before any sample may be used for anonymous research.
- **Family Issues.** Adds privacy protections for blood relatives of the subject of genetic testing.

⁶ 1999 Oregon Laws ch. 921, § 4.

⁷ <http://egov.oregon.gov/DHS/ph/genetics/docs/gracrpt.pdf>

⁸ 2001 Oregon Laws ch. 588.

⁹ ORS 192.537(2).

¹⁰ This outline is based on the House Staff Measure summary for SB 114A (June 6, 2001), <http://www.leg.state.or.us/comm/sms/sms01/sb0114ahjud06-06-2001.pdf>

- **Continued Oversight.** Establishes and specifies composition of Advisory Committee on Genetic Privacy and Research and specifies issues for report to legislature.

The 2003 Legislature Fine Tunes Genetic Research Provisions

The Advisory Committee on Genetic Privacy and Research submitted a report to the 2003 Legislature based on its two years of studying the use and disclosure of genetic information.¹¹ To carry out the Advisory Committee's legislative recommendations, the Legislature enacted Senate Bill 618, effective June 12, 2003. This bill has the following provisions:

- **Terminology.** Defines new terms (coded, deidentified, identified, identifiable, and unidentified) derived from National Bioethics Advisory Commission.
- **Anonymous Research.** Clarifies the definition of anonymous genetic research. Specifies how the consent or notification requirement for anonymous genetic research is satisfied.
- **Coded Research.** Enacts new standards regulating coded research.
- **Tissue Banks.** Permits the use in anonymous or coded research of genetic materials obtained without notification or consent before the effective date of the 2003 law.
- **Institutional Review Boards.** Adds a transitional clause, assuring that genetic research approved by an institutional review board (IRB) is governed by the law in effect when the IRB approves the study. Advisory Committee to educate institutional review boards about genetic privacy law.
- **Advisory Committee.** Adds a membership category to the Committee to represent public education about genetics and public involvement in policy. Augments charge of Advisory Committee (see below)

The 2005 Legislature Balances Benefits of Genetic Research with Patient Privacy

The Advisory Committee recommended four additional legislative actions in 2005 as outlined in their report to the Legislature¹². The recommendations addressed several aspects of genetic research and privacy, and would:

- Exempt routine disclosures of genetic information by providers and health insurers from special protections.
- Prohibit use of blood relatives' medical history for health insurance and employment decisions.
- Prohibit use of information concerning whether a person has sought genetic counseling for health insurance and employment decisions.
- Modify informed consent requirements for research under certain limited circumstances.

¹¹ <http://egov.oregon.gov/DHS/ph/genetics/docs/acgprprt.pdf>

¹² <http://egov.oregon.gov/DHS/ph/genetics/docs/ACGPR2005LegReport.pdf>

The recommendation to modify informed consent requirements for research under certain limited conditions was adopted in SB 1025. The ACLU requested a notation be included in SB 1025 that requires healthcare providers/health systems to provide patients with notice of their right to “opt out” of anonymous or coded IRB-approved research studies. DHS wrote the Administrative Rules¹³ with guidance from ACGPR.

After initially being presented in SB 99, the recommendation to exempt routine disclosures of genetic information by providers and health insurers however was withdrawn. Also, recommendations for the two statutory changes to Oregon’s anti-discrimination protections were withdrawn after initial hearings. The ACGPR decided to table these recommendations pending potential action at the federal level regarding anti-discrimination protections relating to the use of genetic information.

The 2007 Legislature Streamlines Oregon Genetic Privacy Law

In 2007 the Committee recommended one legislative change that better aligns Oregon genetic privacy statutes with federal medical information privacy statutes in Senate Bill 759. This legislation amended existing law to allow disclosure of genetic information for purposes of treatment, payment and health care operations without specific authorization. HIPAA restrictions will remain, and Oregon law prohibiting discriminatory use of genetic information remains in effect. Details of this legislation are reviewed in the 2007 ACGPR Report to the Legislative Assembly¹⁴.

The Committee’s proposed activities for the 2007-2009 biennium are:

- Examine the scholarly basis for special and additional privacy protections for genetic information. Determine whether significant changes in the structure and content of Oregon’s genetic privacy legislation are called for given advances in genetic science and scholarly opinion about whether genetic information deserves any special consideration.
- Continue to monitor the effect of Oregon’s genetic privacy laws, especially SB 1025, on medical research, access to health care, and health care providers’ management of medical information.
- Educate the general public about the discrimination protections in the Oregon Genetic Privacy Law. Continue to monitor federal genetic anti-discrimination legislation to determine if there is a need for further state discrimination legislation.
- Monitor and collaborate with other agencies at the state and national levels working on policy issues in genetic and health care privacy.
- Participate and support community partners in efforts to continue to educate the general public and health care providers about the ethical and legal issues associated with genetics.

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¹³ OAR 333-025-0100 through 333-025-0165

¹⁴ See www.oregongenetics.org