

March 2007

Report to the 2007 Legislative Assembly

Advisory Committee on Genetic
Privacy and Research



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Executive Summary

The Advisory Committee on Genetic Privacy and Research (ACGPR), created in its current form by the Oregon legislature in 2001, studies the effect of Oregon's regulation of the use and disclosure of genetic information. In this report, the ACGPR:

- Recommends that one legislative change be adopted that will make current Oregon law more consistent with recently instituted federal medical information privacy statutes.
- Reviews a strategy for educating the public about genetic discrimination.
- Discusses initial impressions of the bill, SB 1025, enacted in the 2005 Legislature that requires all Oregon patients be notified of their right to opt out of coded or anonymous genetic research.
- Discusses education of the research community as it relates to SB 1025.
- Proposes a review of the policy basis for Oregon's genetic privacy statutes.

In addition, the report reviews ACGPR's plans to continue the following activities during the next biennium:

- Monitoring the effect of Oregon genetic privacy laws on medical research, access to health care, and health care providers' management of health care information.
- Monitoring and collaborating with other agencies at the state and national levels working on policy issues in genetic and health care privacy.

Introduction

The 2001 Oregon Legislature appointed the Advisory Committee on Genetic Privacy and Research (ACGPR). The committee is charged to report to the Legislature biennially on the use and disclosure of genetic information as regulated by Oregon law and make recommendations for change when appropriate. Other tasks assigned to the ACGPR include advising the Oregon Department of Human Services on the content and implementation of administrative rules, creating opportunities for public education, and eliciting public input on the issues of genetic privacy and research.

The committee is composed of fifteen volunteer members and alternates appointed by the Senate President, Speaker of the House, and the Department of Human Services. Members serve renewable two-year terms. Composition of the ACGPR represents the diversity of stakeholders in genetic privacy and research in Oregon.

The Committee recommended four legislative actions to the 2005 Legislature. The recommendation to modify informed consent requirements for research under certain limited conditions was adopted¹. A recommendation to exempt routine disclosures of genetic information by providers and health insurers was withdrawn by the ACGPR and has been modified into a new recommendation for legislative action in 2007. Recommendations for two statutory changes to Oregon's anti-discrimination protections were withdrawn after initial hearings. The ACGPR has decided to table these recommendations pending potential action at the federal level regarding anti-discrimination protections relating to the use of genetic information.

The following pages detail the ACGPR's recommendations to the 2007 Legislature and describe its proposed activities in preparation for the 2009 Legislative Assembly.

¹ ORS 192.537

1. Routine Disclosures of Genetic Information (Proposed Statute)

Existing Oregon law prohibiting disclosure of genetic information without authorization was passed prior to the Federal Health Insurance Portability and Accountability Act (HIPAA) going into effect. While a statute specifically protecting genetic information was important when the Oregon Genetic Privacy law was passed, since the advent of health information protections contained in HIPAA, it is now unduly burdensome. SB 759 will harmonize Oregon genetic privacy statutes with state and federal law related to medical record privacy in general.

SB 759 will allow, as does HIPAA, disclosure of genetic information for purposes of treatment, payment, and health care operations without special authorization. These routine disclosures are necessary for the proper care of the patient. Oregon law prohibiting discriminatory use of genetic information remains in effect. Additionally, the proposed legislation continues to forbid health insurers from using genetic information for underwriting purposes.

The Committee believes that this proposed legislative adjustment will improve health care for Oregonians and reduce the burden of additional paperwork on physicians. Please see Appendix IV for text of SB 759.

2. Public Concerns About Discrimination – A Public Education Strategy

Over the past two years, the Committee has observed that genetic discrimination remains a concern for Oregon citizens despite protections offered by the state Genetic Privacy Act. Consumer fear of discrimination in insurance and employment is reported in the scientific literature². Consumers associate media reports of lost personal information and identity theft with a high likelihood of misuse in any circumstance where information is disclosed, thus increasing concerns about the misuse of genetic information.

Lack of knowledge of the protections provided by state and federal privacy statutes explains in part why Oregonians are concerned. In response to these concerns, the Committee is increasing its public education efforts. The first step is to create a brochure that summarizes Oregon's genetic discrimination protections (see Appendix II for draft). After testing the content of the brochure with consumers, genetic counselors, and other healthcare professionals, the brochure will be translated into several languages and distributed through multiple channels. Additional methods to educate the public about the Oregon Genetic Privacy Act will be explored.

² Hall M et al Concerns in a primary care population about genetic discrimination by insurers. *Genetics in Medicine* 2005;7(5):331-315

3. Follow-up on Senate Bill 1025 - General Notification of Opt-out Rights Related to Certain Forms of Genetic Research

Federal regulations permit research to be conducted on blood and tissue samples without consent if the identity of the subject of the research is unknown to the researcher and could not be connected, even indirectly, to the subject. The 2001 Oregon Legislature passed a statute specifically focused on *genetic* research that is more restrictive than federal regulations. Oregonians have the right to opt out of ever being involved in anonymous or coded *genetic* research that might otherwise be conducted without their consent. The new law, SB 1025, passed by the 2005 Legislature created a way for patients to exercise this right. Providers now must notify their patients of this right to opt out of anonymous, unconsented genetic research and keep a record showing that a patient has chosen to opt out of such research. Scientists wishing to conduct genetic research on coded or anonymous samples³ in Oregon, must exclude any patients who have opted out of any and all unconsented coded or anonymous genetic research.

Development of Administrative Rules

The new statute required the Department of Human Services to enact administrative rules by January 1st, 2006. The ACGPR gave advice and feedback on the process and content of the new rules. Rules regarding the requirement that health care providers create an opportunity for individuals to request that their information or biologic specimens not be disclosed or retained for anonymous research were to be operationalized by July 1st, 2006.

Information for providers, consumers, and researchers

The statute and administrative³ rules created a complex set of arrangements effecting researchers, providers, and patients. As a result, the ACGPR recommended that the DHS Oregon Genetics Program staff create three informational fact sheets to improve compliance with the law. The fact sheets, approved by the ACGPR, are posted on the Oregon Genetics Program web site (www.oregongenetics.org). Please see Appendix III for copies of:

- Fact Sheet for Consumers
- Fact Sheet for Health Care Providers
- Fact Sheet for IRBs and Researchers
- Example Opt Out Form

Because the ACGPR is charged to monitor the effects of genetic privacy legislation, it sought preliminary information about the impact of SB 1025 on health care organizations, providers, consumers and clinical laboratories. Although data were

³ Definition of anonymous research – no connection between the records and the patient.
Definition of coded research – patient records are coded and code is not shared with the researcher

gathered from several sources, only a few months have passed since the law became operational. Below are some initial impressions the Committee gathered.

a) Senate Bill 1025 – Consumer experiences

No survey has yet been done to objectively gather consumer perspectives on SB 1025. However, anecdotal comments from different consumer sources show varied opinions. Some individuals indicated they are pleased to have the chance to potentially contribute to genetic research in Oregon. Others indicated frustration with this legislation. The most common concern voiced by consumers is that SB 1025 requires Oregonians to take an *active* role in letting their provider know that they do *not* wish to have their health information or blood samples used in IRB-approved coded or anonymous research.

This issue highlights a gap in consumer knowledge about medical research in general. Many consumers are not aware that their health information or biological specimens can be used (without their consent) in Oregon, as in other states, for non-genetic IRB-approved coded or anonymous research studies under the Federal Common Rule. Consumers are unaware that, as a result of the Oregon Genetic Privacy Act, they are actually being given *more* protection and choice regarding genetic research than is provided in other states. The Committee will continue to create educational resources for the public in an effort to address the observed gaps in consumer knowledge regarding medical research.

b) Senate Bill 1025 – Health care provider and medical clinic experiences

SB 1025 requires health care providers to provide patients, at least once, the opportunity to opt out of any future anonymous or coded genetic research studies. Thus far, one challenge highlighted by SB 1025 is the difficulty in notifying all Oregon healthcare providers of legislative changes. Although the Oregon Association of Hospitals and Health Systems and Oregon Medical Association were instrumental in notifying and assisting all their members with the implementation, several healthcare providers contacted DHS after July 2006 indicating they were not aware of SB 1025. Clinicians operating private practices and those serving in rural communities seem most challenging to reach.

Anecdotal information gathered from several large medical centers shows a wide variation in the number of patients choosing to “opt out,” with some settings reporting as low as a 4%, while others report rates ~45%. It is not known why there appears to be such a diversity of responses. One factor that might influence a consumer’s likelihood of opting out is the method used to inform patients of their choice. Some healthcare systems sent all members written information and an opt out form while other centers discuss the choice with each member at the time of medical visits.

As with any legislative change, it can be challenging for health care providers and medical clinics to adapt their systems and procedures to new laws. Although some initial observations are available, more time is needed to truly understand the experiences of medical clinics and providers with SB 1025.

c) Senate Bill 1025 – Clinical laboratory experiences

Some information was gathered from Oregon clinical laboratories about their experience with SB 1025. Since clinical laboratories work with and store biological specimens, it is necessary for Oregon labs to develop a system of tracking which individuals chose not to have their samples used for certain genetic research studies. The Committee learned that monitoring patient opt out requests is a challenge for some laboratories, especially since samples may be sent from one laboratory to another. In order to address this challenge, some health systems have notified their laboratories that *all* patient samples are to be treated as if the patient has “opted out”. Beyond this approach, it is anticipated that tracking a patient’s opt out status will get easier as lab systems are created to address this need.

d) Senate Bill 1025 – Researcher experiences

SB 1025 was intended to enhance the work of those engaged in genetic research in Oregon; their work has a strong influence on the well being of Oregonians. Given so little time has passed since the operationalization of SB 1025, it is not surprising that there is very limited information on the magnitude of benefit of SB 1025 to researchers. The Committee will continue to monitor the impact of SB 1025 on genetic research.

4. Education of the Genetic Research Community

In response to a request from ACGPR, the research compliance staff at the Oregon Health and Sciences University organized a forum for IRB members and researchers to review and discuss the changes in genetic privacy and research created by the passage of SB 1025. As a consequence of the forum, the Oregon Genetics Program will post a guide for Oregon researchers and IRBs to identify when research fits the definition of genetic research.

The guide will be posted on the Oregon Genetics Program website in the next six months.

Three components will be presented:

- A decision guide for determining when research meets the statutory definition of “genetic research”
- Clarification of the status of materials coming into Oregon from laboratories and institutions outside of Oregon
- Several case studies to provide concrete examples of the issues that Oregon IRBs need to be able to resolve in approving or rejecting research protocols

5. Proposed Review of the Basis for Genetic Privacy Laws

Oregon's genetic privacy statutes were originally developed in 1995, based on the following legislative findings now in ORS 192.533(1):

The Legislative Assembly finds that:

- (a) The DNA molecule contains information about the probable medical future of an individual and the individual's blood relatives. This information is written in a code that is rapidly being broken.
- (b) Genetic information is uniquely private and personal information that generally should not be collected, retained or disclosed without the individual's authorization.
- (c) The improper collection, retention or disclosure of genetic information can lead to significant harm to an individual and the individual's blood relatives, including stigmatization and discrimination in areas such as employment, education, health care and insurance.
- (d) An analysis of an individual's DNA provides information not only about the individual, but also about blood relatives of the individual, with the potential for impacting family privacy, including reproductive decisions.
- (e) Current legal protections for medical information, tissue samples and DNA samples are inadequate to protect genetic privacy.
- (f) Laws for the collection, storage and use of identifiable DNA samples and private genetic information obtained from those samples are needed both to protect individual and family privacy and to permit and encourage legitimate scientific and medical research.

These findings embody the premise that genetic information and testing differ from other medical information and testing in ways that deserve special protection. (This is sometimes called "genetic exceptionalism.") The operative provisions of Oregon's genetic privacy law are based on these findings.

Under ORS 192.549(7), "[t]he advisory committee shall study the use and disclosure of genetic information and shall develop and refine a legal framework that defines the rights of individuals whose DNA samples and genetic information are collected, stored, analyzed and disclosed."

In order to fulfill its legislative charge, ACGPR believes it should reexamine the legislative findings. ACGPR began this study in 2005-07 but discovered that the questions involved raise more complicated problems than it was able to examine within the time frame of Committee's 2006 agenda. Consequently, we propose making a reexamination of the legislative premises as the major focus of the ACGPR work plan for the coming biennial period to prepare for the 2009 legislative session.

This reexamination is prompted by important legal and scholarly changes since 1995, including the following:

1. Health Information Privacy Protection. The HIPAA Privacy Regulations and their Oregon counterparts are now in effect. These broad legal protections for health information include protecting genetic information as it falls within health information. ACGPR is currently recommending removing special protection for genetic information when it is protected by HIPAA, since the specific genetic protection is no longer needed.
2. Evolving Scholarship. A vigorous debate among academic commentators has questioned whether genetic information should be handled in special ways.
3. Confusing Definitions. Experience in Oregon and nationally has shown that the definitions of what makes information and samples “genetic” are not easily drawn. The Oregon definitions can confuse researchers, clinicians, and others who must work with the law.
4. Discrimination. Although fears of genetic discrimination persist—particularly as to employment, insurance, and medical research—it is not known how widespread such discrimination may be. We are still in the early stages of genetic testing, and it is unclear how much of an issue genetic discrimination may become as technology advances and testing becomes more widespread. Oregon’s law could be streamlined while leaving in place the current strong protections against discrimination in employment and insurance and the protections of human subjects in genetic research.
5. Benefits and Costs. The benefits of Oregon’s genetic privacy law are significant. The law protects Oregonians from discrimination by prohibiting health insurance underwriting based on genetic test results and barring the use of genetic test results in employment practices. Moreover the law protects Oregonians’ privacy by regulating how genetic information may be obtained, retained, used, and disclosed. Prior to 2005 the costs of compliance were probably nominal, except for extra steps required for approval of genetic research protocols. As a result of changes in the law, significant costs were imposed in the health care sector in the form of notices to consumers. The costs of compliance need to be balanced against the benefits.

These changes have not undercut many of the reasons for Oregon’s law, but we propose to reexamine those reasons in the context of the above developments.

6. Recommended focus of ACGPR activity for 2007-2009

The Committee’s proposed ongoing work in the next biennium, 2007-2009, includes:

1. 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.

2. 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.
3. 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.
4. Monitor and collaborate with other agencies at the state and national levels working on policy issues in genetic and health care privacy.
5. 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.

Appendix I: ACGPR Member Roster

Advisory Committee on Genetic Privacy and Research Member Roster 2006-2008

Senate President's Representatives

Senator Richard Devlin
Senator Alan Bates (Alternate)

Speaker of the House's Representatives

Representative Kevin Cameron
Representative Vicki Berger (Alternate)

Academic Institutions Involved In Genetic Research

Robb Moses, MD
Kara Manning Drolet, PhD (Alternate)

Licensed Physicians

Jonathan Zonana, MD
George Anadiotis, DO (Alternate)

Voluntary Organizations: Genetic Privacy Policy Development

Marc Marengo, PhD
Theodore Falk, JD (Alternate)

Hospitals

Gwen Dayton, JD

Department of Human Services, Health Services

Nan Newell, PhD
Terry Crandall, BS, MT (ASCLS) (Alternate)

Department of Consumer and Business Services

Gayle Woods
Lewis Littlehales (Alternate)

Health Care Services Contractors: Genetic and Health Services Research

Allison Naleway, PhD
David Holt (Alternate)

Biosciences Industry

vacant

Pharmaceutical Industry

Mark Loveless, MD

Health Care Consumers

Amy Thomas
Marilyn Hartzell, Med (Alternate)

Organizations Advocating for Privacy of Medical Information

Stuart Kaplan, PhD
Andrea Meyer (Alternate)

Public Members of Institutional Review Boards

Steven J Nemirow, Esq

Education and Ethics

Mike Garland, PhD
Patricia Backlar, PhD (1st Alternate)
Gregory Fowler, PhD (2nd Alternate)

Interested Parties

Mary L Durham, PhD
Peter Jacky, PhD
Ronald G Markum, MD
Lisa Sardinia, PhD, JD
Kerry Silvey, MA, CGC
Bob Shoemaker, JD

DHS Staff

Mary Pat Bland, MS, CGC
Bob Nystrom, MA
John Anderson

Oregon Genetic Discrimination Protections

A review of laws that protect Oregonians from health insurance and job discrimination

With the completion of the Human Genome Project in 2003, much is being learned about genes and their role in disease. Over time, more and more Oregonians will have their doctors or genetic specialists recommend genetic testing for medical care. Some of these individuals will not have testing because of fear of genetic discrimination. This fact sheet addresses some of the concerns voiced by patients about discrimination.

What is “genetic testing”? Who might have genetic testing? Genetic testing is the process of testing a person’s DNA or genetic material for a specific disease or risk for disease. Examples include chromosome, DNA, and RNA studies. There are many reasons a person might have genetic testing. Some examples include: a child with developmental delay, a person with a strong family history of cancer, and a person with clinical symptoms suggestive of a genetic condition.

What is “genetic discrimination” and why are some people concerned about it? Genetic discrimination is the act of treating an individual with a genetic condition or positive genetic test unfairly because of this information. Some people are concerned that if they have a genetic test, they may be not able to get health, disability or life insurance or might be at risk of losing their job. People are also concerned if they have a genetic test, this could make it more difficult for their family members to obtain insurance.

How common is genetic discrimination? Several studies have noted the public’s widespread concern about genetic discrimination. Although to date, there appear to have been few cases, without adequate protections, the public’s concern is justified. Fortunately, many of these concerns are being addressed by federal and state laws.

How do national and Oregon state laws protect me? How do they protect my family? There are national and state laws in place to protect Oregonians from genetic discrimination. These laws are briefly reviewed below. Please see the resources at the end of this brochure for more detailed information.

Health insurance
The Health Insurance Portability and Accountability Act (HIPAA) is a national law that prevents a health plan from excluding, denying, canceling, or increasing the cost for a person or his/her dependent’s coverage based on a genetic test result and/or a genetic diagnosis. Under HIPAA, genetic information cannot be viewed as a pre-existing condition. One of the limitations to HIPAA is that it does not apply to plans purchased by an individual (vs. group plans purchased through/provided by an employer). HIPAA also does not prevent the increase of rates or denial of coverage of an entire group based on the health status of an individual member.

Oregon state law prevents the use of genetic test results from an individual or blood relative to reject, deny, limit, cancel, refuse to renew, increase rates of, or otherwise affect any health insurance policy. In contrast to HIPAA, Oregon’s genetic privacy statutes cover individual and group insurance plans. (ORS 192.531-192.549*)

The Oregon Genetic Privacy statutes do not apply to individuals with clinical symptoms of a genetic condition and/or a family history of a genetic disease. These individuals may have protections under HIPAA & the Americans with Disabilities Act (noted below).

Life and Disability insurance
Currently there are no federal laws in place that provide protections against life or disability insurance discrimination.

In Oregon, it is unlawful to use a blood relative’s genetic test results to deny or alter a person’s life or disability insurance policy (ORS 731.162, 746.135*).

Oregon laws do not restrict companies from using a person's genetic test result, diagnosis, or family history to affect disability or life insurance.

Laws providing job protection

Many experts feel the Americans with Disabilities Act (ADA) provides employment protections to individuals with genetic conditions regardless if a condition was diagnosed by genetic test or medical symptoms. Other sources question if genetic discrimination in the work place is covered by the ADA.

Federal employees have additional employment protections.

In Oregon, it is unlawful for an employer to use a genetic test result from an employee, prospective employee, or blood relative of an employee/prospective employee in hiring, terminating, or restricting benefits to this individual (ORS 659A.303*).

Who should I contact if I feel I have been a victim of genetic discrimination? Note: the time window for filing complaints may be limited.

Department of Health and Human Services (HIPAA/health insurance discrimination)
<http://www.hhs.gov/ocr/hipaa/> or 1-866-627-7748

Equal Employment Opportunity Commission (ADA/Executive Order 13145/employment discrimination) www.eeoc.gov
Regional Field Office 206-220-6883

Oregon Bureau of Labor Industries (employment discrimination) <http://www.oregon.gov/BOLI> or 971-673-0761

State of Oregon Insurance Division at Department of Consumer and Business Services (health, disability, & life insurance discrimination)
<http://www.oregoninsurance.org> or 1-888-877-4894

Where can I get more information?

FORCE: Facing Our Risk of Cancer Empowered www.facingourrisk.org or 1-866-288-7475.
Organization has a very helpful brochure that provides more information about national anti-discrimination laws.

State of Oregon Genetics Program:
www.oregongenetics.org

Genetic Alliance www.geneticalliance.org
202-966-5557

Genetics and the Law-A Project by the Council on for Responsible Genetics
<http://www.genelaw.info/>
National Conference of State Legislatures
www.ncsl.org/programs/health/genetics/charts.htm

National Society of Genetic Counselors "Find A Counselor" www.nsgc.org

* ORS=Oregon Revised Statutes. See <http://www.leg.state.or.us/ors/home.htm>

This fact sheet is provided by the Department of Human Services, Health Services to help consumers and health care providers better understand existing genetic anti-discrimination protections. Laws noted contain many details that are not included in this fact sheet. You are encouraged to obtain legal consultation if you require more precise interpretation.

Last updated: 11/22/06

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Appendix III: Education Resources Related to Opt-out Rights

- Fact Sheet for Health Care Consumers - Genetic Privacy and Research
- Fact Sheet for Health Care Providers - 2005 Legislative Changes in Oregon's Genetic Privacy Law
- Fact Sheet for Researchers and IRBs – Legislative Changes in Oregon's Genetic Privacy Law
- Example Notification and Patient Opt-Out Form



Fact Sheet for Health Care Consumers **Genetic Privacy & Research**

Oregon's first genetic privacy laws were passed in 1995 with a goal of trying to help protect your genetic information and prevent possible employment or insurance discrimination to health care consumers like yourself.

In 2005, a few changes were made in Oregon laws about when results of a genetic test, specimens collected (such as blood or tissue), or health care information may be available for certain types of genetic research. You will be asked to make decisions about this starting in 2006.

What is the same?

- If genetic test results, specimens collected or health care information can be linked to you (for example if it includes your name or address or birth date) the researcher must still get your permission before using this information for genetic research.

What is new?

- If genetic test results, specimens collected or other health care information does not include any information that can be linked to you (or there is only a code and the key to the code is kept separately) the new law allows researchers to access these and ask permission of an independent review board (called an IRB) to use the test results, specimens collected or health care information for what is called "anonymous" or "coded" genetic research.
- The new law requires you to make a decision regarding use of your health information in anonymous or coded genetic research.
- As a result, starting July 1, 2006, the new law requires that your doctor or health care provider give you notice and asks you to complete a form at least once and mark if you DO NOT want any of your specimens or health care information available for anonymous or coded genetic research. This is often called an "opt-out" form.

Why was the change made?

- Many people want to keep their health care information, including their genetic information, private. Many people also recognize that medical and genetic research can help develop new information that allows both patients and doctors to learn more about diseases, make good health care decisions, and discover new treatments.
- The new law tries to balance the interests of those who want to keep their genetic information private by allowing them to make a decision to “opt-out” while allowing researchers to do genetic research needed to make good health care decisions by you and your health care providers.

What do I need to do?

- You will need to make a personal decision on whether your genetic test results, specimens collected or health care information will be available for anonymous or coded genetic research.
- If you DO NOT want your results of a genetic test, specimens collected or health care information available for anonymous or coded genetic research you must mark that place on the form provided by your doctor or health care provider
- If you DO want the results of a genetic test, specimens collected, or your health care information available for anonymous or coded genetic research, you don't need to do anything.
- In either case, your health care provider is responsible for providing a notice and form for you to mark. This only needs to happen once, not at every visit.
- If you change your mind in the future, it is YOUR responsibility to inform your health care provider and it would only affect results of genetic tests, specimens collected or health care information from that date forward.

Where can I get more information?

Talk to your doctor or health care provider.

The Oregon Genetics Program – (971) 673-0271 or www.oregongenetics.org.



Fact Sheet for Health Care Providers 2005 Legislative Changes in Oregon's Genetic Privacy Law

What is the new law?

- Senate Bill 1025 was passed by the 2005 Oregon Legislature and modifies requirements for use, retention and disclosure of genetic information and DNA samples. New administrative rules became effective January 1, 2006, and all requirements must be operative by July 1, 2006.
- The new law changes the types of research that can be done without informed consent using an individual's (a) biological specimen, or (b) identifiable health information.
- The changes apply to all research that includes genetic information, termed "genetic research" under Oregon's law.
- Beginning July 1, 2006, health care providers who are "covered entities" must notify their patients that any specimens or health information collected will be available for anonymous¹ or coded² genetic research unless the person "opts out." Other health care providers are encouraged to do the same.
- A person "opts out" by completing an opt-out form in writing notifying the health care provider that she/he does not want her/his specimen or information available for coded or anonymous genetic research.
- If an individual does not "opt out," her/his specimen or information can only then be used for anonymous or coded genetic research if the research study is approved by a Federally-qualified Institutional Review Board (IRB)³.

What are the new administrative rules?

- Administrative Rules describe how statutes should be implemented. SB1025 directed the Oregon Department of Human Services to develop and write the new rules by January 1, 2006.
- The Administrative Rules related to Oregon's Genetic Privacy Law describe how patients must be notified and what content is required.
- A sample notification form that complies with the Administrative Rules is available on the www.oregongenetics.org/ web site.

How do the changes affect me?

- Starting July 1, 2006, most Oregon health care providers must notify the patients they see or whose specimens they collect that they may "opt out"

of having their health information or biological specimens used for coded or anonymous genetic research.

- You or your staff may be asked questions about the new law by your patients. If a patient notifies you by completing an opt-out form that she/he does not want her/his specimen or health information used for coded or anonymous genetic research you must inform any indirect provider you send the patient's specimens or health information to of the patient's wishes. Also, you cannot use the patient's health information or specimens for such research yourself unless you obtain specific informed consent and IRB approval.

What do I need to do?

- Starting July 1, 2006, notify all individuals whose biological specimen or individually identifiable health information you obtain that unless they "opt out," their specimen or information will be available for anonymous or coded genetic research.
- Each patient must be notified at least once.
- Give your patients the opportunity to complete an "opt out" form.
- Keep track of which patients have completed an "opt out" form.
- An "opt out" form becomes effective when it is received by the health care provider. It applies to all specimens and health information collected after the "opt out" statement is received.
- If an "opt out" form is received within 14 days of the first date of service, you are encouraged to notify all recipients that you had sent specimens or health information to that the individual does not want their specimens or health information used for coded or anonymous genetic research.

Where can I get more information?

- The Oregon Genetics Program website, www.oregongenetics.org/ includes:
 - Oregon's Genetic Privacy Statutes
 - Oregon's Administrative Rules pertaining to the Genetic Privacy Statutes
 - A sample opt-out form
 - Fact sheets for patients, IRB's and Researchers
 - Other information on genetic privacy, genetics, and genomics

¹ "Anonymous" means that no one can identify the individual from whom the biological specimen or health information was obtained.

² "Coded" means that the individual from whom a biological specimen or health information was obtained cannot be identified without using a code or other encryption that is kept separately from the specimen or information. Researchers do not have access to the individual identifiers without special permission from an IRB.

³ An Institutional Review Board (IRB) is an independent group of scientists and non-scientists that is charged with protecting the rights and safety of research participants. In Oregon, any research study that includes genetic information must be approved by a Federally-qualified IRB before the study begins.

This fact sheet is provided by the Department of Human Services, Health Services to help health care providers comply with Oregon's Genetic Privacy Laws and related Administrative Rules. The law and rules contain many details that are not included in this fact sheet. You are encouraged to obtain legal consultation if you require more precise interpretation.



Fact Sheet for Researchers and Institutional Review Boards

Legislative Changes in Oregon's Genetic Privacy Law

What is the new law?

- Senate Bill 1025 was passed by the 2005 Oregon Legislature and modifies requirements for use, retention and disclosure of genetic information and DNA samples. New administrative rules became effective January 1, 2006, and all requirements must be operative by July 1, 2006.
- The new law allows a waiver of consent for anonymous and coded genetic research if certain requirements are met as outlined below.
- Beginning July 1, 2006, health care providers who are "covered entities" must notify their patients that any specimens or health information collected will be available for anonymous¹ or coded² genetic research unless the person "opts out" by completing an opt-out form notifying the health care provider that she/he does not want her/his specimen or information available for coded or anonymous genetic research. Providers must also have a process in place to demonstrate compliance with this opt-out requirement.
- If an individual does not "opt out," her/his specimen or information can only then be used for anonymous or coded genetic research if the research study is approved by a federally-qualified Institutional Review Board (IRB).

How is genetic research defined in the law?

- Research using human DNA samples, genetic testing or genetic information.
 - Genetic information is any information about an individual or the individual's blood relatives obtained from a genetic test.
 - A genetic test is a test for determining the presence or absence of genetic characteristics in a human individual or the individual's blood relatives, including tests of nucleic acids such as DNA, RNA, and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.
 - A genetic characteristic includes a gene, chromosome or alteration thereof that may be tested to determine the existence or risk of a disease, disorder, trait, propensity or syndrome or to identify an individual or a blood relative. Genetic characteristic does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than through a genetic test.

How do the changes affect genetic research in Oregon?

- The requirements for anonymous and coded genetic research have changed. A researcher proposing to conduct anonymous or coded genetic research must provide assurances to the IRB that the criteria below are met.

A human biological sample or clinical individually identifiable health information may be used in anonymous or coded genetic research only if prior to the time the research is conducted:

1. The subject has granted informed consent for the specific anonymous or coded research project as part of an IRB approved study; or
2. The subject has granted consent for genetic research generally; or
3. The subject was notified that the individual's sample or information may be used for anonymous or coded research, and before the sample or information was obtained, the subject did not request that the sample or information be withheld from anonymous or coded research; or
4. The subject was not notified, due to emergency circumstances that the individual's sample or information may be used for anonymous research or coded research, and the individual died before receiving the notice; or
5. The subject has granted blanket informed consent and the sample or information was obtained before June 25, 2001; or
6. The subject was deceased when the sample or information was obtained

What do Researchers and IRBs need to do as a result of these changes?

- If a researcher proposes to conduct anonymous or coded genetic research without seeking informed consent:
 1. IRBs must review the research project to determine if consent and authorization can be waived under the Federal Common Rule and the Federal Privacy Rule.
 2. IRBs must determine whether the researcher has provided appropriate assurances regarding subject notification (if required), and exclusion of individuals who have opted out.

Where can I get more information?

The Oregon Genetics Program website, www.oregongenetics.org includes:

- Oregon's Genetic Privacy Statutes
- Oregon's Administrative Rules pertaining to the Genetic Privacy Statutes
- A sample opt-out form
- Fact sheets for health care consumers and providers
- Other information on genetic privacy, genetics, and genomics

-
- 1 "Anonymous" means that no one can identify the individual from whom the biological specimen or health information was obtained.
 - 2 "Coded" means that the individual from whom a biological specimen or health information was obtained cannot be identified without using a code or other encryption that is kept separately from the specimen or information. Researchers do not have access to the individual identifiers without special permission from an IRB.

This fact sheet is provided by the Department of Human Services, Health Services to help health care providers comply with Oregon's Genetic Privacy Laws and related Administrative Rules (ORS 192.531 through 192.549. OAR 333-025-0100 through 333-025-0165). The law and rules contain many details that are not included in this fact sheet. You are encouraged to obtain legal consultation if you require more precise interpretation.

(Other statements and formats may be developed and used that meet requirements)

[Name of Entity]

Notice of Your Right to Decline Participation in Future Anonymous or Coded Genetic Research

The State of Oregon has laws to protect the genetic privacy of individuals. These laws give you the right to decline to have your health information or biological samples used for research. A biological sample may include a blood sample, urine sample, or other materials collected from your body. You can decide whether to allow your health information or biological samples to be available for genetic research. Your decision will not affect the care you receive from your health care provider or your health insurance coverage.

Research is important because it gives us valuable information on how to improve health, such as ways to prevent or improve treatment for heart disease, diabetes, and cancer. Under Oregon law, a special team reviews all genetic research before it begins. This team makes sure that the benefits of the research are greater than any risks to participants.

In anonymous research, personal information that could be used to identify you, like your name or medical record number, cannot be linked to your health information or biological sample. In coded research, personal information that could be used to identify you is kept separate from your health information or biological sample so it would be very difficult for someone to link your personal information to your health information or biological sample. Your identity is protected in both types of research.

If you want to allow your health information and biological sample to be available for anonymous or coded genetic research, **you don't have to do anything**. If you make this choice, your health information or biological sample may be used for anonymous or coded genetic research without further notice to you.

If you want to decline to have your health information and biological sample available for anonymous or coded genetic research, **you must tell your health care provider** by:
[Fill in relevant options below]

- Completing this form and giving it to your health care provider
- Completing this form and mailing it to the address provided
- Going to [Website] and completing the form provided

Your decision is effective on the date your health care provider receives this form.

If you have any questions or concerns about this notice, please contact [Fill in name or title of a person or office] at [Fill in phone number or other contact information].

No matter what you decide now, you can always change your mind later. If you change your mind, tell your health care provider your decision in writing by [sending a letter,

(Other statements and formats may be developed and used that meet requirements)

include mailing address] [sending an e-mail to **] [going to **website address**]. If you change your mind, the new decision will apply only to health information or biological samples collected after your health care provider receives written notice of your new decision.

I decline to have my health information and biological samples available for anonymous or coded genetic research.

Printed Name

[Add other identifying information as relevant (e.g., birthdate, medical record number, address) and necessary to make sure the statement is recorded for the correct person]

Appendix IV: Senate Bill 759

74th OREGON LEGISLATIVE ASSEMBLY--2007 Regular Session

NOTE: Matter within { + braces and plus signs + } in an amended section is new. Matter within { - braces and minus signs - } is existing law to be omitted. New sections are within { + braces and plus signs + } .

LC 1970

Senate Bill 759

Sponsored by COMMITTEE ON RULES

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure as introduced.

Modifies requirements for retention and disclosure of genetic information.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to genetic information; creating new provisions; amending ORS 192.531; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. { + Section 2 of this 2007 Act is added to and made a part of ORS 192.518 to 192.526. + }

SECTION 2. { + (1) Notwithstanding ORS 192.537 (3), a health care provider may retain genetic information of an individual without obtaining an authorization from the individual or a personal representative of the individual if the retention is for treatment, payment or health care operations by the provider.

(2) Notwithstanding ORS 192.539 (1), a health care provider may disclose genetic information of an individual without obtaining an authorization from the individual or a personal representative of the individual if the provider discloses the genetic information in accordance with ORS 192.520 (3).

(3) As used in this section, 'retain genetic information ' has the meaning given that term in ORS 192.531. + }

SECTION 3. ORS 192.531 is amended to read:

192.531. As used in ORS 192.531 to 192.549:

(1) 'Anonymous research' means scientific or medical genetic research conducted in such a manner that any DNA sample or genetic information used in the research is unidentified.

(2) 'Blanket informed consent' means that the individual has consented to the use of the individual's DNA sample or health information for any future research, but has not been provided with a description of or consented to the use of the sample in genetic research or any specific genetic research project.

(3) 'Blood relative' means a person who is:

- (a) Related by blood to an individual; and
- (b) A parent, sibling, son, daughter, grandparent, grandchild, aunt, uncle, first cousin, niece or nephew of the individual.
- (4) 'Clinical' means relating to or obtained through the actual observation, diagnosis or treatment of patients and not through research.
- (5) 'Coded' means identifiable only through the use of a system of encryption that links a DNA sample or genetic information to an individual or the individual's blood relative. A coded DNA sample or genetic information is supplied by a repository to an investigator with a system of encryption.
- (6) 'Deidentified' means lacking, or having had removed, the identifiers or system of encryption that would make it possible for a person to link a DNA sample or genetic information to an individual or the individual's blood relative, and neither the investigator nor the repository can reconstruct the identity of the individual from whom the sample or information was obtained. Deidentified DNA samples and genetic information must meet the standards provided in 45 C.F.R. 164.502(d) and 164.514(a) to (c) { + , as in effect on the effective date of this 2007 Act + }.
- (7) 'Disclose' means to release, publish or otherwise make known to a third party a DNA sample or genetic information.
- (8) 'DNA' means deoxyribonucleic acid.
- (9) 'DNA sample' means any human biological specimen that is obtained or retained for the purpose of extracting and analyzing DNA to perform a genetic test. 'DNA sample' includes DNA extracted from the specimen.
- (10) 'Genetic characteristic' includes a gene, chromosome or alteration thereof that may be tested to determine the existence or risk of a disease, disorder, trait, propensity or syndrome, or to identify an individual or a blood relative. 'Genetic characteristic' does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than through a genetic test.
- (11) 'Genetic information' means information about an individual or the individual's blood relatives obtained from a genetic test.
- (12) 'Genetic privacy statutes' means ORS 192.531 to 192.549, 659A.303 and 746.135 and the provisions of ORS 659A.300 relating to genetic testing.
- (13) 'Genetic research' means research using DNA samples, genetic testing or genetic information.
- (14) 'Genetic test' means a test for determining the presence or absence of genetic characteristics in an individual or the individual's blood relatives, including tests of nucleic acids such as DNA { - , - } { + and + } RNA { - and mitochondrial DNA - } , chromosomes or { - proteins - } { + metabolites + } in order to diagnose or determine a genetic characteristic.
- (15) 'Health care provider' has the meaning given that term in ORS 192.519.
- (16) 'Identifiable' means capable of being linked to the individual or a blood relative of the individual from whom the DNA sample or genetic information was obtained.
- (17) 'Identified' means having an identifier that links, or that could readily allow the recipient to link, a DNA sample or

genetic information directly to the individual or a blood relative of the individual from whom the sample or information was obtained.

(18) 'Identifier' means data elements that directly link a DNA sample or genetic information to the individual or a blood relative of the individual from whom the sample or information was obtained. Identifiers include, but are not limited to, names, telephone numbers, electronic mail addresses, Social Security numbers, driver license numbers and fingerprints.

(19) 'Individually identifiable health information' has the meaning given that term in ORS 192.519.

(20) 'Obtain genetic information' means performing or getting the results of a genetic test.

(21) 'Person' has the meaning given in ORS 433.045.

(22) 'Research' means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

(23) 'Retain a DNA sample' means the act of storing the DNA sample.

(24) 'Retain genetic information' means making a record of the genetic information.

(25) 'Unidentified' means deidentified or not identifiable.

SECTION 4. { + Section 5 of this 2007 Act is added to and made a part of ORS 746.600 to 746.690. + }

SECTION 5. { + (1) Notwithstanding ORS 192.537 (3), a health insurer may retain genetic information of an individual without obtaining an authorization from the individual or a personal representative of the individual if the retention is for treatment, payment or health care operations by the insurer.

(2) Notwithstanding ORS 192.539 (1), a health insurer may disclose genetic information of an individual without obtaining an authorization from the individual or a personal representative of the individual if the insurer discloses the genetic information in accordance with ORS 746.607 (3).

(3) As used in this section, 'retain genetic information ' has the meaning given that term in ORS 192.531.

(4) As used in this section, 'health care operations' does not include underwriting activities.

(5) Nothing in this section shall be construed to interfere with or limit the requirements of ORS 746.135. + }

SECTION 6. { + Sections 2 and 5 of this 2007 Act apply to genetic information obtained before, on or after the effective date of this 2007 Act. + }

SECTION 7. { + This 2007 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2007 Act takes effect on its passage. + }
