

# 2013 Report to the Oregon Legislature

## Advisory Committee on Genetic Privacy and Research

March 2013



## Executive summary

---

The Advisory Committee on Genetic Privacy and Research (ACGPR), created in its current form by the Oregon Legislature in 2001 (Senate Bill 114), studies the effect of Oregon's regulation of the use and disclosure of genetic information and the rights of individuals regarding their DNA samples and genetic information. The ACGPR also creates opportunities for public education on scientific, legal and ethical developments within the fields of genetic privacy and research and elicits public input on these matters.

In this report, the ACGPR:

- Reviews the structure and intent of the committee.
- Discusses four recent major events in national genetic research and privacy as they relate to Oregon genetic privacy and research.
- Summarizes the committee activities during the 2011 biennium (July 1, 2011 – June 30, 2013).
- Describes the reasons why the committee is unable to fully achieve the duties mandated by Oregon law (ORS 192.549).

In addition, this report highlights recommended activities for the 2013 biennium (July 1, 2013 – June 30, 2015):

- Monitor the landscape of national legislation as it affects the Oregon Genetic Privacy Law (OGPL); especially

changes to the Common Rule and any emerging interpretation or challenge of Genetic Information Nondiscrimination Act of 2008 (GINA) or other federal laws relating to the use or disclosure of genetic information.

- Solicit stakeholder input to determine if the OGPL is understood and whether stakeholder understanding affects compliance with the law and allows for adequate protection of the genetic privacy of Oregonians.
- Assess and formulate solutions to the identified problems with current legislation, including other laws that apply to use and retention of tissue samples or test results.
- Monitor major events in national genetic privacy and research, including developments in direct-to-consumer testing, implementation of student sickle cell trait testing, and the development of health information exchanges

At this time, the committee does not recommend changes to Oregon's current genetic privacy statutes. However, it does recommend that the legislature make funding available to the Oregon Health Authority to staff the ACGPR.

## About the Advisory Committee on Genetic Privacy and Research (ACGPR)

The 2001 Oregon Legislature established the Advisory Committee on Genetic Privacy and Research (ACGPR).

Composition of the ACGPR represents the diversity of Oregon stakeholders in genetic privacy and research. The committee is required by statute to report to the Oregon Legislature biennially on the use and disclosure of genetic information as regulated by Oregon law (ORS 192.549) and make recommendations for change when appropriate. Other tasks assigned to the ACGPR include creating opportunities for public education on the scientific, legal and ethical development within the fields of genetic privacy and research and eliciting public input on these matters.

During the 2011 biennium:

- The committee was composed of 21 volunteer members and alternates, serving two-year terms.
- The President of the Senate appointed Senator Elizabeth Steiner Hayward to the committee.
- No representative of the House was appointed.
- Whenever possible, the Oregon Health Authority appointed a member and alternates from the following 13 categories:
  - a. Academic institutions involved in genetic research;

- b. Physicians licensed under ORS chapter 677;
  - c. Voluntary organizations involved in the development of public policy on issues related to genetic privacy;
  - d. Hospitals;
  - e. The Department of Human Services;<sup>1</sup>
  - f. The Department of Consumer and Business Services;
  - g. Health care service contractors involved in genetic and health services research;
  - h. The biosciences industry;
  - i. The pharmaceutical industry;
  - j. Health care consumers;
  - k. Organizations advocating for privacy of medical information;
  - l. Public members of institutional review boards; and
  - m. Organizations or individuals promoting public education about genetic research and genetic privacy and public involvement in policymaking related to genetic research and genetic privacy.
- Representation from the biosciences and pharmaceutical industries remained unfilled.

---

<sup>1</sup> During the 2009-2011 biennium, the Oregon Health Authority (OHA) was established, and the Public Health Division, formerly a part of the Department of Human Services (DHS), became a part of OHA.

## **Recent major events in national genetic privacy and research**

### **Direct-to-Consumer Genetic Testing**

Advances in genetic research and genetic privacy issues continue to frequent the headlines. In addition, the availability and affordability of direct-to-consumer genetic tests, including whole genome sequencing, genetic profiling and pharmacogenetics is becoming more accessible to the general public. However, the analytic validity, clinical validity, clinical utility and associated ethical, legal and social implications of many available genetic tests have not been fully evaluated, leaving consumers at risk of harm. One company that offers genetic testing currently has three Oregon locations. This provides an opportunity to educate both direct-to-consumer companies and the general public about the Oregon genetic privacy law and genetic privacy issues. The ACGPR will continue to follow both the national discourse regarding direct-to-consumer genetic testing and the availability of such tests in Oregon.

### **Changing Federal Landscape**

Significant changes to the Common Rule (45 CFR part 46) are currently under consideration. Some of the proposed changes would require written consent for research use of biological specimens, including de-identified specimens. This change, although similar to Oregon's opt-out provision for anonymous and coded genetic research, offers broader protection by covering biological specimens and requiring opt-in of participants. If these or similar changes to the Common

Rule go into effect, some of the research provisions of the Oregon Genetic Privacy Law may become redundant. In addition, interpretations of the Federal Genetic Information Nondiscrimination Act (GINA) rules are expected to continue. The ACGPR will continue to monitor Federal rules and their interpretation, and evaluate any impact to or redundancy of the Oregon Genetic Privacy Laws.

### **U.S. Supreme Court Reviews Human Gene Patents**

On November 30, 2012, the U.S. Supreme Court agreed to hear arguments about whether human genes are patentable. Specifically, the lawsuit is against a molecular diagnostic company, Myriad, which has a patent on isolated DNA of the genes BRCA1 and BRCA2. The case largely revolves around the idea that research, testing and treatment are inhibited through the patenting of genes. The impact of the Supreme Court's decision of the OGPR and Federal laws will be monitored and assessed.

### **Sickle Cell Trait Testing**

In April 2010, the National Collegiate Athletic Association (NCAA) adopted the requirement for all Division 1 institutions to include, as part of the medical examination required for all incoming student-athletes before athletics participation, a sickle cell solubility test or documentation of results of a prior test or a signed waiver declining the test. News of this policy swept across the country, raising concern that testing may be unnecessary and could lead to unintentional discrimination and breaches

to genetic privacy. Unanswered questions arose during the ACGPR discussions about whether the tests were medically necessary, if genetic counseling would be provided with the testing, and whether the testing would occur in a way that was compliant with Oregon's notification policy and genetic privacy law. Additional unanswered questions related to the genetic testing of minors, who would access the genetic test results, and whether follow-up action based on the test results would be compliant with the Americans with Disabilities Act.

The committee decided to follow up with the four Division I universities in Oregon (Portland State University, Oregon State University, University of Oregon and University of Portland) to learn whether sickle cell trait testing is being conducted by each institution. Please see page 8 for details.

The NCAA sickle cell trait testing requirement was adopted for Division II schools in January 2012, and will be under consideration for Division III schools in January 2013. The ACGPR continues to follow developments around sickle cell trait testing and look for opportunities for public education about the issue. The committee will also remain aware of other genetic related tests, such as heart disease panels, that may become required for student athlete participation.

### **Health Care Reform**

Health care reform is taking shape in states nationwide. In Oregon, the development of a Health Information Exchange (HIE) will

significantly restructure how health care information is collected and used. During the summer of 2011, HIE became a topic of interest to the committee and further information was sought. In October 2011, a subcommittee of the ACGPR met to discuss their experience with and understanding of HIE in Oregon. In conclusion, the subcommittee decided that genetic information is currently being protected the same as other health information within the HIE and therefore no action was recommended. The ACGPR will continue to monitor Oregon HIE development as well as any other impacts of changes resulting from the implementation of the Patient Protection and Affordable Care Act.

In the 2013 biennium, the ACGPR will continue to monitor the national landscape as it relates to their work of assuring Oregonians genetic privacy, preventing misuse of genetic information, and keeping the legal environment amenable for genetic research and genetic health services in the state.

## Follow-up from the 2011 Report to the Oregon Legislature

In the last report, the ACGPR proposed ongoing work in four areas. In this section, a summary of activities follows each recommended area:

1. *The committee recommends that the Legislature pass legislation that directs Legislative Counsel to reconcile GINA, federal and state HIPAA, and OGPL. Based on the reconciliation, changes to Oregon's genetic privacy statutes may be necessary.*

During the 2011 biennium, the Oregon Health Authority (OHA) provided funds for the committee to move forward with efforts to reconcile Genetic Information Non-discrimination Law (GINA), federal and state Health Insurance Portability and Accountability Acts (HIPAA) and Oregon Genetic Privacy Law (OGPL).

With this goal in mind, the Oregon Genetics Program asked Shannon O'Fallon, JD, Senior Assistant Attorney General, to review the OGPL in reference to GINA and HIPAA. Draft legislation for a reconciliation of the OGPL to these other laws and draft legislation for a selective repeal of the OGPL were both considered. Please see Appendix 1 for a summary report from Shannon O'Fallon including draft legislation.

Through this work, the committee recognized problems in the current legislation, but could not achieve an adequate reconciliation of the OGPL with the Federal laws through consensus. The committee decided

to not move forward with either draft of the legislation options for the 2013 legislative session but preferred to look further into the areas of the law that were highlighted as most confusing during the committee discussions on the reconciliation effort, as described in Area 2 below.

2. *Continue to monitor the effect of the Oregon genetic privacy statutes on medical research, access to genetic services, and health care providers' management of medical information.*

During the reconciliation process described above, committee members recognized how the desire to provide additional protection to genetic information has largely shaped the current Oregon law. The committee will continue to be mindful as they recommend future action of the varying positions on the relationship between genetic information and other biological information.

The committee intends to assess the understanding and interpretations of the current legislation with various stakeholders, concentrating on specific problems identified within the current legislation including but not limited to:

- Uncertainty about definitions such as 'DNA sample' and 'biological specimen';
- The lack of clarity between distinguishing characteristics of clinical and research tests;
- The lack of clear separation between

clinical, research, insurance and employment requirements;

- Differing interpretations of how to carry out the requirement of notification in practice;
- Overlap with other laws that apply to the use and retention of samples and information obtained in clinical settings.

Further complicating these efforts are anticipated changes at the federal level to the Common Rule (45 CFR part 46), and interpretations of GINA.

Together, these committee discussions helped us determine where the ACGPR should focus our next efforts. During the end of the current biennium, or in the next biennium, the committee plans to conduct a survey of healthcare system and research staff in order to get a robust response to the questions: ‘Do stakeholders understand the Oregon Genetic Privacy Law?’, and ‘Does stakeholder understanding affect their ability to comply with the law and adequately protect the genetic privacy of Oregonians?’. The committee will also continue to assess the identified problems with current legislation as time and resources allow.

3. *Continue to look for opportunities to participate in educational efforts and elicit public input representative of the diversity of opinions through collaborations with other organizations and community partners, as staff and volunteer time allows.*

### **Sickle Cell Trait Testing of Student Athletes**

After discussion of the NCAA requirement for all Division 1 institutions to test student-athletes for sickle cell trait, the committee decided to follow up with the four Division I universities in Oregon (Portland State University, Oregon State University, University of Oregon and University of Portland) to learn how sickle cell trait testing is being conducted by each institution. Oregon Genetics Program staff, at the direction of the committee, sent the athletic director of each school the following 2 questions:

1. Is your athletic department testing student athletes for the sickle cell trait?
2. If so, what is your testing policy, including how you test for the trait, uses of the information, and the informed consent process (please send a copy).

Through this inquiry, we learned in March 2011, that both Oregon State University and the University of Oregon were testing student athletes for the sickle cell trait, while the University of Portland was not. Portland State University did not respond to our request for information.

In July, 2011, after discussion of the universities’ responses, the ACGPR sent information to each university Athletic Director to help assure that each university’s genetic testing practices follow state law. The information sent included a memo from the ACGPR describing the Oregon Genetic Privacy Law and a copy of the Oregon

Administrative Rules pertaining to genetic information and privacy. The requirement to obtain informed consent prior to performing a genetic test on an individual to collect and retain genetic information, a sample consent form and a copy of the ORS 192.522 Authorization form were emphasized. Please see Appendix 2 for the communications sent to the university Athletic Directors regarding sickle cell trait testing.

To date, the Oregon Genetics Program has not received responses regarding the educational packets. In the spring of 2013, the committee intends to follow up with the universities previously contacted.

### **Population-Based Survey Regarding Genetic Testing**

In 2010, the Oregon Genetics Program surveyed the general Oregon population using the Oregon Behavioral Risk Factor Surveillance System. The data was analyzed during the 2011 biennium and revealed that almost half of Oregonians are very or somewhat interested in “having a genetic test that could tell them about their chance of developing a disease”. Yet a substantial majority of Oregonians are very or somewhat concerned “that life insurance companies might use genetic test results to determine life insurance coverage and costs”. In addition, while a large

majority of Oregonians think it is very or somewhat important “to have laws that prevent genetic test results from being used to determine life insurance coverage and costs”, less than 20% of Oregonians have heard about “laws that prevent genetic test results from being used to determine health insurance coverage and costs, such as GINA, the Genetic Information Non-discrimination Act”. These findings support our understanding that Oregonians are interested in having genetic tests, but are also concerned about discrimination.

4. *Continue to evaluate whether the charge of the committee is being adequately met through volunteer and non-funded OHA capacity.*

As set forth in ORS 192.549(5), the Oregon Health Authority<sup>2</sup>, through the Oregon Genetics Program, provides non-funded staff for the advisory committee, while members and alternates on the committee volunteer their time and personal resources to serve on the committee. The committee feels that their work is worthwhile, yet it is clear that the full charge of the committee is not adequately met through volunteer and non-funded OHA capacity. Due to the broad scope of genetic privacy and research issues and the limited resources of the committee, we are not able to conduct thorough and scientifically

---

<sup>2</sup> During the 2009-2011 biennium, the Oregon Health Authority (OHA) was established, and the Public Health Division, formerly a part of the Department of Human Services (DHS), became a part of OHA.

based surveys, create and implement educational efforts that could reach broadly, nor monitor the effect of the OGPL in depth. The committee recommends that the legislature make funding available to the Oregon Health Authority to support the ACGPR and its planned activities.

### **Recommended focus of ACGPR activity for the 2013 biennium**

As we move into the next biennium, the committee recommends four focus areas for their future work.

- Monitor the landscape of national legislation as it affects the OGPL, especially changes to the Common Rule and any emerging interpretation or challenge of GINA or other federal laws relating to the use or disclosure of genetic information.
- Solicit stakeholder input to determine if the OGPL is understood and whether understanding affects compliance with the law and allows for adequate protection of the genetic privacy of Oregonians.
- Assess and formulate solutions to the identified problems with current legislation, including other laws that apply to use and retention of tissue samples or test results.
- Monitor major events in national genetic privacy & research, including developments in direct-to-consumer testing, implementation of student sickle cell trait testing, and the development of health information exchanges.

## **Appendices**

1. Summary report from Shannon O'Fallon including draft legislation
2. Communications regarding sickle cell trait testing

At this time, the committee does not recommend changes to Oregon's current genetic privacy statutes. However, it does recommend that the legislature make funding available to the Oregon Health Authority to staff the ACGPR.

# Appendix 1

## Genetic privacy



**DEPARTMENT OF JUSTICE**  
GENERAL COUNSEL DIVISION

**MEMORANDUM**

DATE: July 11, 2012

TO: Kara Manning Drolet, PhD, Co-Chair  
Advisory Committee on Genetic Privacy and Research

Patricia Backlar, PhD, Co-Chair  
Advisory Committee on Genetic Privacy and Research

Robert Nystrom, MA, Manager  
Adolescent Health Section & Genetics Program  
Oregon Public Health Division

FROM: Shannon K. O'Fallon, Senior Assistant Attorney General  
Health and Human Services Section

SUBJECT: Reconciling Oregon Genetic Privacy Law with Federal Law - Summary Report

In July of 2011 you requested that I provide recommendations to the Oregon Health Authority and the Advisory Committee on Genetic Privacy and Research (ACGPR) for legislation needed to reconcile Oregon law with the federal law titled the Genetic Information Non-Discrimination Act (GINA) that was passed by Congress in 2008.<sup>1</sup> My approach to this project was to: (1) Draft legislation that retains Oregon's genetic privacy laws, with some reorganization, but that reconciles any conflict with GINA; and (2) Draft legislation that repeals the portions of Oregon's genetic privacy laws that are unnecessary (arguably) because the federal law is just as or more protective than state law.

In undertaking this project I reviewed GINA and its federal implementing regulations, the Health Insurance Portability and Accountability Act (HIPAA) and applicable state laws.<sup>2</sup> GINA generally prohibits discrimination based on an individual's genetic information with respect to health insurance coverage and employment. The Notice of Proposed rulemaking issued by the Department of Health and Human Services (DHHS) describes GINA as follows:

---

<sup>1</sup> Public Law 110 – 233.

<sup>2</sup> See 74 Fed. Reg. 51698 (October 7, 2009); 74 Fed. Reg. 51664 (October 7, 2009); 75 Fed. Reg. 68912 (November 9, 2010); ORS 192.531 – 192.581; ORS 746.135, 659A.300 – 659A.303.

In particular, with respect to health coverage, Title I of GINA generally prohibits discrimination in group premiums based on genetic information, proscribes the use of genetic information as a basis for determining eligibility or setting premiums in the individual and Medicare supplemental policy (Medigap) insurance markets, and limits the ability of group health plans, health insurance issuers, and Medigap issuers to collect genetic information or to request or require that individuals undergo genetic testing. Title II of GINA generally prohibits use of genetic information in the employment context, restricts acquisition of genetic information by employers and other entities covered by Title II,<sup>3</sup> and strictly limits such entities from disclosing genetic information. The Departments of Labor (Employee Benefits Security Administration), Treasury (Internal Revenue Service), and HHS (Centers for Medicare & Medicaid Services) are responsible for administering and enforcing the GINA Title I nondiscrimination provisions, and the Equal Employment Opportunity Commission (EEOC) is responsible for administering and enforcing the GINA Title II nondiscrimination provisions.

In addition to these nondiscrimination provisions, Title I of GINA contains certain new privacy protections for genetic information. In particular, section 105 of GINA, entitled ‘‘Privacy and Confidentiality,’’ amends Part C of Title XI of the Social Security Act by adding section 1180 to address the application of the HIPAA Privacy Rule to genetic information. Section 1180 requires the Secretary of HHS to revise the Privacy Rule to clarify that genetic information is health information and to prohibit group health plans, health insurance issuers (including HMOs), and issuers of Medicare supplemental policies from using or disclosing genetic information for underwriting purposes.<sup>4</sup>

As a general matter I determined that state law does not conflict with GINA in any significant way in part because Oregon law covers matters that GINA does not. For example, Oregon uses different definitions for some of the same terms that GINA defines but to the extent these definitions apply to Oregon laws governing genetic research there is no conflict because GINA does not address research. Oregon law is stricter than GINA in some instances which is permissible under GINA but, depending on your point of view, unnecessary given the extent to which HIPAA protects PHI (protected health information) and the extent to which GINA prohibits certain entities from asking for or using genetic information. Since Oregon genetic privacy laws were adopted there are many protections in federal law that prohibit discrimination based on genetic information and that protect genetic information but the federal laws are on the whole not as protective as state law.

That said, it is also true, in my view, that Oregon’s genetic privacy law is poorly organized, confusing, and in places legally inconsistent. Some of what I tried to do, which is

---

<sup>3</sup> An employer that employs 15 or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year is subject to GINA. 29 CFR 1635.2(c) and (d).

<sup>4</sup> 74 Fed Reg, No. 193 (October 7, 2009).

apparent in the attached drafts, is to better organize the provisions and make the entire law more comprehensible.

I drafted two separate versions of Oregon's genetic privacy laws, one titled the "reconciliation" draft and one titled the "selective repeal" draft. The high points of each draft are below:

The reconciliation draft:

- Inserts the GINA definitions and removes state definitions that are in conflict.
- Keeps the informed consent section in ORS 192.535 intact, generally, with the amendments intended to bring clarity.
- Reorganizes ORS 192.539 and parts of ORS 192.537 to have sections that relate to each other, closer in proximity so that the overall genetic privacy statutes make more sense.
- Like the selective repeal draft, puts all the research provisions together but has different edits because ORS 192.535 is not proposed for repeal.
- Like the selective repeal draft, makes edits to ORS 192.547 to put all of OHA's rule making requirements together and deletes the research provisions that have been moved.
- Retains ORS 659A.303 related to employment discrimination so that it can be enforced by the state.
- Like the selective repeal draft, retains ORS 746.135 that protects against discrimination in insurance because Oregon law is protective, but uses GINA's definitions.
- Suggests certain changes to ORS 192.539 because certain provisions are in conflict with HIPAA – the disclosure of genetic information, whether or not that disclosure is in good faith or is corrected before being discovered is still a violation of HIPAA and is still a disclosure under HIPAA.

The (selective) repeal draft:

- Generally speaking this draft preserves those parts of state law that deal with genetic research and the related notice and opt-out and the insurance discrimination provisions because state law is more restrictive than federal law.
- Keeps state definitions because the provisions that remain, with the exception of the insurance provision, are not preempted or in conflict with GINA.
- Proposes to repeal the informed consent section, ORS 192.535, because health care professionals have their own standards for informed consent for testing and HIPAA and other state laws protect PHI which includes genetic information, from unauthorized disclosure.
- Places all requirements with regard to research in ORS 192.537.
- Proposes to repeal ORS 192.539 because HIPAA and other state laws protect against the unauthorized disclosure.
- Proposes to repeal ORS 192.543, criminal penalties for violations of the law since the genetic privacy law if amended as proposed in this draft would only deal with notice, the opt out, and research.

- Repeals the employment discrimination statute in ORS 659A.303 because GINA adequately protects against discrimination in employment related to genetic information.
- Suggests certain changes to ORS 192.539 because certain provisions are in conflict with HIPAA – the disclosure of genetic information, whether or not that disclosure is in good faith or is corrected before being discovered is still a violation of HIPAA and is still a disclosure under HIPAA.

For the most part the suggested changes in the selective repeal draft are not legally necessary and policy decisions need to be made about whether genetic information should be treated in a manner distinct from other medical information.

\* Language in brackets and italicized is proposed to be deleted.

\*\* Underlined language is proposed to be added.

## GENETIC PRIVACY – Reconciliation Draft

**192.531 Definitions for ORS 192.531 to 192.549.** 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.]*
3. [(4)] “Clinical” means relating to or obtained through the actual observation, diagnosis or treatment of patients and not through research.
4. [(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]* family member. A coded DNA sample or genetic information is supplied by a repository to an investigator with a system of encryption.
5. [(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]* family member, 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 July 17, 2007.
6. [(7)] “Disclose” means to release, publish or otherwise make known to a third party a DNA sample or genetic information.
7. [(8)] “DNA” means deoxyribonucleic acid.

8. [(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.
9. “Family member” means with respect to any individual:
- (a). A person who is a dependent of that individual as the result of marriage, birth, adoption, or placement for adoption; or
  - (b). A first-degree, second-degree, third-degree, or fourth-degree relative of the individual, or of a dependent of the individual as defined in § 1635.3(a)(1).
    - A. First-degree relatives include an individual’s parents, siblings, and children.
    - B. Second-degree relatives include an individual’s grandparents, grandchildren, uncles, aunts, nephews, nieces, and half-siblings.
    - C. Third-degree relatives include an individual’s great-grandparents, great grandchildren, great uncles/aunts, and first cousins.
    - D. Fourth-degree relatives include an individual’s great-great-grandparents, great-great-grandchildren, and first cousins once-removed (i.e., the children of the individual’s first cousins).
10. “Family medical history” means information about the manifestation of disease or disorder in family members of the individual.
11. [(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*] family member. “Genetic characteristic” does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than through a genetic test.
12. (a) [(11)] “Genetic information” means information about:[*an individual or the individual’s blood relatives obtained from a genetic test.*]
- A. An individual’s genetic tests;
  - B. The genetic tests of that individual’s family members;
  - C. The manifestation of disease or disorder in family members of the individual (family medical history);
  - D. An individual’s request for, or receipt of, genetic services, or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or

E. The genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology.

(b) Genetic information does not include information about the sex or age of the individual, the sex or age of family members, or information about the race or ethnicity of the individual or family members that is not derived from a genetic test.

13. [(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.

14. [(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, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.*]

15. (a) “Genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.

(b) Genetic tests include, but are not limited to:

A. A test to determine whether someone has the BRCA1 or BRCA2 variant evidencing a predisposition to breast cancer, a test to determine whether someone has a genetic variant associated with hereditary nonpolyposis colon cancer, and a test for a genetic variant for Huntington’s Disease;

B. Carrier screening for adults using genetic analysis to determine the risk of conditions such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome in future offspring;

C. Amniocentesis and other evaluations used to determine the presence of genetic abnormalities in a fetus during pregnancy;

D. Newborn screening analysis that uses DNA, RNA, protein, or metabolite analysis to detect or indicate genotypes, mutations, or chromosomal changes, such as a test for PKU performed so that treatment can begin before a disease manifests;

E. Preimplantation genetic diagnosis performed on embryos created using invitro fertilization;

- F. Pharmacogenetic tests that detect genotypes, mutations, or chromosomal changes that indicate how an individual will react to a drug or a particular dosage of a drug;
  - G. DNA testing to detect genetic markers that are associated with information about ancestry; and
  - H. DNA testing that reveals family relationships, such as paternity.
- (c) The following are examples of tests or procedures that are not genetic tests:
- A. An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes;
  - B. A medical examination that tests for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins, or metabolites;
  - C. A test for infectious and communicable diseases that may be transmitted through food handling;
  - D. Complete blood counts, cholesterol tests, and liver-function tests.
- (d) Alcohol and Drug Testing—
- A. A test for the presence of alcohol or illegal drugs is not a genetic test.
  - B. A test to determine whether an individual has a genetic predisposition for alcoholism or drug use is a genetic test.
16. [(15)] “Health care provider” has the meaning given that term in ORS 192.519.
17. [(16)] “Identifiable” means capable of being linked to the individual or a [*blood relative*] family member of the individual from whom the DNA sample or genetic information was obtained.
18. [(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*] family member of the individual from whom the sample or information was obtained.
19. [(18)] “Identifier” means data elements that directly link a DNA sample or genetic information to the individual or a [*blood relative*] family member 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.
20. [(19)] “Individually identifiable health information” has the meaning given that term in ORS 192.519.

21. “Manifestation or manifested” means with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this part, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.
22. [(20)] “Obtain genetic information” means performing or getting the results of a genetic test.
23. [(21)] “Person” has the meaning given in ORS 433.045.
24. [(22)] “Research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.
25. [(23)] “Retain a DNA sample” means the act of storing the DNA sample.
26. [(24)] “Retain genetic information” means making a record of the genetic information.
27. [(25)] “Unidentified” means deidentified or not identifiable.

### **192.533 Legislative findings; purposes.**

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 relative*] family members. 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 relative*] family members, 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 relative*] family members 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.

2. The purposes of the genetic privacy statutes are as follows:

- (a) To define the rights of individuals whose genetic information is collected, retained or disclosed and the rights of the individuals' [*blood relative*] family members.
- (b) To define the circumstances under which an individual may be subjected to genetic testing.
- (c) To define the circumstances under which an individual's genetic information may be collected, retained or disclosed.
- (d) To protect against discrimination by an insurer or employer based upon an individual's genetic characteristics.
- (e) To define the circumstances under which a DNA sample or genetic information may be used for research.

## **INFORMED CONSENT/CONFIDENTIALITY/GENERAL**

### **192.535 Informed consent for obtaining genetic information.**

- 1. A person may not obtain or retain genetic information from an individual, or from an individual's DNA sample, without first obtaining informed consent of the individual or the individual's representative in accordance with subsection (2) or (3) of this section, except:
  - (a) As authorized by ORS 181.085 or comparable provisions of federal criminal law relating to the identification of persons, or for the purpose of establishing the identity of a person in the course of an investigation conducted by a law enforcement agency, a district attorney, a medical examiner or the Criminal Justice Division of the Department of Justice;
  - (b) For anonymous research or coded research conducted under conditions described in ORS 192.537(2), after notification pursuant to ORS 192.538 or pursuant to ORS 192.547(7)(b);

- (c) As permitted by rules of the Oregon Health Authority for identification of deceased individuals;
  - (d) As permitted by rules of the Oregon Health Authority for newborn screening procedures;
  - (e) As authorized by statute for the purpose of establishing paternity; *[or]*
  - (f) For the purpose of furnishing genetic information relating to a decedent for medical diagnosis of *[blood relative]* family members of the decedent; *or*
  - (g) As permitted by the Genetic Information Nondiscrimination Act of 2008, 29 CFR 1635.8(b).
2. *[Except as provided in subsection (3) of this section, a]* A physician licensed under ORS chapter 677 shall seek the informed consent of the individual or the individual's representative prior to obtaining genetic information from the individual or from the individual's DNA sample *[for the purposes of subsection (1) of this section]* in the manner provided by ORS 677.097. *[Except as provided in subsection (3) of this section, any other]*
  3. A licensed health care provider other than a physician or a health care facility must seek the informed consent of the individual or the individual's representative prior to obtaining genetic information from the individual or from the individual's DNA sample *[for the purposes of subsection (1) of this section]* in a manner substantially similar to that provided by ORS 677.097 for physicians.
  4. *[(3)]* A person conducting research shall seek the informed consent of the individual or the individual's representative prior to obtaining genetic information from the individual or from the individual's DNA sample *[for the purposes of subsection (1) of this section]* in the manner provided by ORS 192.547.
  5. *[(4) Except as provided in ORS 746.135 (1), any]* Any person not described in subsection (2) or (3) of this section must seek the informed consent of the individual or the individual's representative prior to obtaining genetic information from the individual or from the individual's DNA sample *[for the purposes of subsection (1) of this section]* in the manner provided by rules adopted by the Oregon Health Authority.
  6. *[(5)]* The Oregon Health Authority may not adopt rules under subsection (1)(d) of this section that would require the providing of a DNA sample for the purpose of obtaining complete genetic information used to screen all newborns.

## **192.XXX Disclosure of genetic information; retention; exceptions.**

1. Regardless of the manner of receipt or the source of genetic information, including information received from an individual or a family member of the individual, a person may not disclose or be compelled, by subpoena or any other means, to disclose the identity of an individual upon whom a genetic test has been performed or the identity of a family member of the individual, or to disclose genetic information about the individual or a family member of the individual in a manner that permits identification of the individual, unless disclosure is:
  - (a) Authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest, or a child fatality review by a county multidisciplinary child abuse team;
  - (b) Required by specific court order entered pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;
  - (c) Authorized by statute for the purpose of establishing paternity;
  - (d) Specifically authorized by the tested individual or the tested individual's representative by signing a consent form prescribed by rules of the Oregon Health Authority;
  - (e) For the purpose of furnishing genetic information relating to a decedent for medical diagnosis of family members of the decedent; or
  - (f) For the purpose of identifying bodies.
2. A person to whom genetic information or the identity of an individual upon whom a genetic test has been performed has been lawfully disclosed may not redisclose such information without complying with the provisions in this rule.
3. A person may not retain another individual's genetic information or DNA sample without first obtaining authorization from the individual or the individual's representative, unless retention is authorized:
  - (a) By ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a county multidisciplinary child abuse team;
  - (b) By specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;

- (c) Is permitted by rules of the Oregon Health Authority for identification of, or testing to benefit family members of, deceased individuals;
  - (d) Is permitted by rules of the authority for newborn screening procedures; or
  - (e) Is for anonymous research or coded research conducted after notification or with consent pursuant to subsection \_\_\_\_\_ of this section or ORS 192.538.
4. The DNA sample of an individual from which genetic information has been obtained shall be destroyed promptly upon the specific request of that individual or the individual's representative, unless retention is:
- (a) Authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a county multidisciplinary child abuse team;
  - (b) Authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions; or
  - (c) For anonymous research or coded research conducted after notification or with consent pursuant to subsection \_\_\_\_\_ of this section or ORS 192.538.

**192.XXX. Right to obtain genetic information.**

- 1. An individual or an individual's representative, promptly upon request, may inspect, request correction of and obtain genetic information from the records of the individual.

**192.XXX. Use of genetic information for medical purposes.**

Subject to the provisions of ORS 192.531 to 192.549, and to policies adopted by the person in possession of a DNA sample, an individual or the individual's representative may request that the individual's DNA sample be made available for additional genetic testing for medical diagnostic purposes. If the individual is deceased and has not designated a representative to act on behalf of the individual after death, a request under this subsection may be made by the closest surviving family member of the decedent or, if there is more than one surviving family member of the same degree of relationship to the decedent, by the majority of the surviving closest family members of the decedent.

## **RESEARCH**

### **192.537 Use of genetic information for anonymous or coded research.**

**[Individual's rights in genetic information; retention of information; destruction of information.]**

1. *[Subject to the provisions of ORS 192.531 to 192.549, 659A.303 and 746.135, an individual's genetic information and DNA sample are private and must be protected, and an individual has a right to the protection of that privacy. Any person authorized by law or by an individual or an individual's representative to obtain, retain or use an individual's genetic information or any DNA sample must maintain the confidentiality of the information or sample and protect the information or sample from unauthorized disclosure or misuse.*
- 2.] (a) A person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research only if the individual:
  - A. Has granted informed consent for the specific anonymous research or coded research project;
  - B. Has granted consent for genetic research generally;
  - C. Was notified in accordance with ORS 192.538 that the individual's biological specimen or clinical individually identifiable health information may be used for anonymous research or coded research and the individual did not, at the time of notification, request that the biological specimen or clinical individually identifiable health information not be used for anonymous research or coded research; or
  - D. Was not notified, due to emergency circumstances, in accordance with ORS 192.538 that the individual's biological specimen or clinical individually identifiable health information may be used for anonymous research or coded research and the individual died before receiving the notice.
- (b) Paragraph (a) of this subsection does not apply to biological specimens or clinical individually identifiable health information obtained before July 29, 2005, if an institutional review board operating under ORS 192.547(1) (b) meets the requirements described in subsection \_\_\_\_ of this section [ORS 192.547(7)(b)].

*[(3) A person may not retain another individual's genetic information or DNA sample without first obtaining authorization from the individual or the individual's representative, unless:*

- A. *Retention is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a county multidisciplinary child abuse team;*
- B. *Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;*
- C. *Retention is permitted by rules of the Oregon Health Authority for identification of, or testing to benefit blood relatives of, deceased individuals;*
- D. *Retention is permitted by rules of the authority for newborn screening procedures; or*
- E. *Retention is for anonymous research or coded research conducted after notification or with consent pursuant to subsection (2) of this section or ORS 192.538.]*

*(4) The DNA sample of an individual from which genetic information has been obtained shall be destroyed promptly upon the specific request of that individual or the individual's representative, unless:*

- a. *Retention is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a county multidisciplinary child abuse team;*
- b. *Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions; or*
- c. *Retention is for anonymous research or coded research conducted after notification or with consent pursuant to subsection (2) of this section or ORS 192.538.]*

3. [(5)] A DNA sample from an individual that is the subject of a research project, other than an anonymous research project, shall be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first, unless the individual or the individual's representative directs otherwise by informed consent.

*[(6) A DNA sample from an individual for insurance or employment purposes shall be destroyed promptly after the purpose for which the sample was obtained has been accomplished unless retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil, criminal and juvenile proceedings.*

*(7) An individual or an individual's representative, promptly upon request, may inspect, request correction of and obtain genetic information from the records of the individual.*

*(8) Subject to the provisions of ORS 192.531 to 192.549, and to policies adopted by the person in possession of a DNA sample, an individual or the individual's representative may request that the individual's DNA sample be made available for additional genetic testing for medical diagnostic purposes. If the individual is deceased and has not designated a representative to act on behalf of the individual after death, a request under this subsection may be made by the closest surviving blood relative of the decedent or, if there is more than one surviving blood relative of the same degree of relationship to the decedent, by the majority of the surviving closest blood relatives of the decedent.*

*(9) The Oregon Health Authority shall coordinate the implementation of this section.*

*(10) Subsections (3) to (8) of this section apply only to a DNA sample or genetic information that is coded, identified or identifiable.*

*(11) This section does not apply to any law, contract or other arrangement that determines a person's rights to compensation relating to substances or information derived from an individual's DNA sample.]*

4. Genetic research in which the DNA sample or genetic information is coded shall satisfy the following requirements:

(a)

- A. The subject has granted informed consent for the specific research project;
- B. The subject has consented to genetic research generally; or
- C. The DNA sample or genetic information is derived from a biological specimen or from clinical individually identifiable health information that was obtained or retained in compliance with ORS 192.537 (2).

(b) The research has been approved by an institutional review board after disclosure by the investigator to the board of risks associated with the coding.

(c) The code is:

- A. Not derived from individual identifiers;
- B. Kept securely and separately from the DNA samples and genetic information; and
- C. Not accessible to the investigator unless specifically approved by the institutional review board.

(d) Data is stored securely in password protected electronic files or by other means with access limited to necessary personnel.

- (e) The data is limited to elements required for analysis and meets the criteria in 45 C.F.R 164.514(e) for a limited data set.
- (f) The investigator is a party to the data use agreement as provided by 45 C.F.R. 164.514(e) for limited data set recipients.
- 5. Persons proposing to conduct anonymous research, coded research or genetic research that is otherwise thought to be exempt from review must obtain from an institutional review board prior to conducting such research a determination that the proposed research is exempt from review.
- 6. A person proposing to conduct research including anonymous research or coded research, must disclose to the institutional review board the proposed use of DNA samples, genetic testing or genetic information.
- 7. Research conducted in accordance with this section is rebuttably presumed to comply with ORS 192.535 and 192.539.
- 8. (a) Notwithstanding ORS 192.535, a person may use a DNA sample or genetic information obtained, with blanket informed consent, before June 25, 2001, for genetic research.  
  
(b) Notwithstanding ORS 192.535, a person may use a DNA sample or genetic information obtained without specific informed consent and derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research if an institutional review board operating under ORS 192.547(1)(b):
  - A. Waives or alters the consent requirements pursuant to the Federal Policy for the Protection of Human Subjects; and
  - B. Waives authorization pursuant to the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164.(c) Except as provided in subsection \_\_\_\_\_ of this section or paragraph (b) of this subsection, a person must have specific informed consent from an individual to use a DNA sample or genetic information of the individual obtained on or after June 25, 2001, for genetic research.
- 9. Except as otherwise allowed by rule of the Oregon Health Authority, if DNA samples or genetic information obtained for either clinical or research purposes is used in research, a person may not recontact the individual or the individual's physician by using research information that is identifiable or coded.
- 10. The requirements for consent to, or notification of, obtaining a DNA sample or genetic information for genetic research are governed by the provisions of

ORS 192.531 to 192.549 and the administrative rules that were in effect on the effective date of the institutional review board's most recent approval of the study.

11. Subsections ( ) to ( ) of this section apply only to a DNA sample or genetic information that is coded, identified or identifiable
12. This section does not apply to any law, contract or other arrangement that determines a person's rights to compensation relating to substances or information derived from an individual's DNA sample.

### **192.538 Notice by health care provider regarding anonymous or coded research.**

1. A health care provider that is a covered entity as defined in ORS 192.519 (2) (c) and that obtains an individual's biological specimen or clinical individually identifiable health information shall notify the individual that the biological specimen or clinical individually identifiable health information may be disclosed or retained by the provider for anonymous research or coded research.
2. A health care provider that is not a covered entity as defined in ORS 192.519 (2) (c) and that obtains an individual's biological specimen or clinical individually identifiable health information may notify the individual that the biological specimen or clinical individually identifiable health information may be disclosed or retained by the provider for anonymous research or coded research.
3. A health care provider described in subsection (1) of this section shall provide a notice to the individual describing how the biological specimen or clinical individually identifiable health information may be used and allowing the individual to request that the specimen or information not be disclosed or retained for anonymous research or coded research. The notice must contain a place where the individual may mark the individual's request that the specimen or information not be disclosed or retained for anonymous research or coded research before returning the notice to the health care provider.
4. The notice described in subsection (3) of this section:
  - (a) Must be given no later than when the provider obtains an individual's biological specimen or clinical individually identifiable health information; and
  - (b) May be given at the same time and in the same manner as the notice of privacy practices required under the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164.

**[192.539 Disclosure of genetic information; exceptions.**

1. *Regardless of the manner of receipt or the source of genetic information, including information received from an individual or a blood relative of the individual, a person may not disclose or be compelled, by subpoena or any other means, to disclose the identity of an individual upon whom a genetic test has been performed or the identity of a blood relative of the individual, or to disclose genetic information about the individual or a blood relative of the individual in a manner that permits identification of the individual, unless:*
  - (a) *Disclosure is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest, or a child fatality review by a county multidisciplinary child abuse team;*
  - (b) *Disclosure is required by specific court order entered pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;*
  - (c) *Disclosure is authorized by statute for the purpose of establishing paternity;*
  - (d) *Disclosure is specifically authorized by the tested individual or the tested individual's representative by signing a consent form prescribed by rules of the Oregon Health Authority;*
  - (e) *Disclosure is for the purpose of furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent; or*
  - (f) *Disclosure is for the purpose of identifying bodies.*
2. *The prohibitions of this section apply to any redisclosure by any person after another person has disclosed genetic information or the identity of an individual upon whom a genetic test has been performed, or has disclosed genetic information or the identity of a blood relative of the individual.*
3. *A release or publication is not a disclosure if:*
  - (a) *It involves a good faith belief by the person who caused the release or publication that the person was not in violation of this section;*
  - (b) *It is not due to willful neglect;*
  - (c) *It is corrected in the manner described in ORS 192.541 (4);*
  - (d) *The correction with respect to genetic information is completed before the information is read or heard by a third party; and*
  - (e) *The correction with respect to DNA samples is completed before the sample is retained or genetically tested by a third party.]*

**192.540 Use of deceased individual's DNA sample or genetic information for research.**

Notwithstanding ORS 192.535 and 192.537(2), a person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research if the individual was deceased when the individual's biological specimen or clinical individually identifiable health information was obtained.

**192.541 Private right of action; remedies; affirmative defense; attorney fees.**

1. An individual or an individual's [*blood relative*] family member, representative or estate may bring a civil action against any person who violates ORS 192.535, 192.537, 192.539 or 192.547.
2. For a violation of ORS 192.537 or 192.547, the court shall award the greater of actual damages or:
  - (a) \$100, for an inadvertent violation that does not arise out of the negligence of the defendant;
  - (b) \$500, for a negligent violation;
  - (c) \$10,000, for a knowing or reckless violation;
  - (d) \$15,000, for a knowing violation based on a fraudulent misrepresentation; or
  - (e) \$25,000, for a knowing violation committed with intent to sell, transfer or use for commercial advantage, personal gain or malicious harm.
3. For a violation of ORS 192.535 or 192.539, the court shall award the greater of actual damages or:
  - (a) \$1,000, for an inadvertent violation that does not arise out of the negligence of the defendant;
  - (b) \$5,000, for a negligent violation;
  - (c) \$100,000, for a knowing or reckless violation;
  - (d) \$150,000, for a knowing violation based on a fraudulent misrepresentation; or
  - (e) \$250,000, for a knowing violation committed with intent to sell, transfer or use for commercial advantage, personal gain or malicious harm.
4. It is an affirmative defense to an action described in subsection (2)(a) or (b) or (3)(a) or (b) of this section that the defendant corrected the violation through

destruction of illegally retained or obtained samples or information, or took other action to correct the violation, if the correction was completed within 120 days after the defendant knew or should have known that the violation occurred.

5. The court may provide such equitable relief as it deems necessary or proper.
6. (a) The court may award attorney fees to a defendant only if the court finds that the plaintiff had no objectively reasonable basis for asserting a claim or for appealing an adverse decision of the trial court.  
  
(b) The court shall award attorney fees to a plaintiff if the court finds that the defendant committed a violation described in subsection (2)(c), (d) or (e) or (3) (c), (d) or (e) of this section.
7. An action authorized by subsection (1) of this section must be commenced within three years after the date the plaintiff knew or should have known of the violation, but in no instance more than 10 years after the date of the violation.
8. A plaintiff may recover damages provided by subsections (2) and (3) of this section for each violation by a defendant.
9. ORS 31.725, 31.730, 31.735 and 31.740 do not apply to amounts awarded in actions under this section.

#### **192.543 Criminal penalty.**

1. A person commits the crime of unlawfully obtaining, retaining or disclosing genetic information if the person knowingly, recklessly or with criminal negligence, as those terms are defined in ORS 161.085, obtains, retains or discloses genetic information in violation of ORS 192.531 to 192.549.
2. Unlawfully obtaining, retaining or disclosing genetic information is a Class A misdemeanor.

#### **192.545 Enforcement; Attorney General or district attorney; intervention.**

1. The Attorney General or a district attorney may bring an action against a person who violates ORS 192.535, 192.537, 192.539 or 192.547. In addition to remedies otherwise provided in ORS 192.541, the court shall award to the Attorney General or district attorney the costs of the investigation.
2. The Attorney General may intervene in a civil action brought under ORS 192.541 if the Attorney General certifies that, in the opinion of the Attorney General, the action is of general public importance. In the action, the Attorney

General shall be entitled to the same relief as if the Attorney General instituted the action under this section.

### **192.547 Oregon Health Authority rules; procedures.**

1. (a) The Oregon Health Authority shall adopt rules for conducting research using DNA samples, genetic testing and genetic information. Rules establishing minimum research standards shall conform to the Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46, that is current at the time the rules are adopted. [*The rules may be changed from time to time as may be necessary.*]
- (b) The rules adopted by the Oregon Health Authority shall address the operation and appointment of institutional review boards. The rules shall conform to the compositional and operational standards for such boards contained in the Federal Policy for the Protection of Human Subjects that is current at the time the rules are adopted. The rules must [*require*]:
  - A. Require that research conducted under paragraph (a) of this subsection be conducted with the approval of the institutional review board;
  - B. Require that all institutional review boards operating under subsection (1)(b) of this section register with the Authority; and
  - C. Establish criteria for recontacting an individual or an individual's physician, taking into consideration the recommendations of national organizations such as those created by executive order by the President of the United States.

*[(c) Persons proposing to conduct anonymous research, coded research or genetic research that is otherwise thought to be exempt from review must obtain from an institutional review board prior to conducting such research a determination that the proposed research is exempt from review*

2. *A person proposing to conduct research under subsection (1) of this section, including anonymous research or coded research, must disclose to the institutional review board the proposed use of DNA samples, genetic testing or genetic information.*
3. *The Oregon Health Authority shall adopt rules requiring that all institutional review boards operating under subsection (1)(b) of this section register with the department. The Advisory Committee on Genetic Privacy and Research shall use the registry to educate institutional review boards about the purposes and requirements of the genetic privacy statutes and administrative rules relating to genetic research.]*

4. The Oregon Health Authority shall consult with the Advisory Committee on Genetic Privacy and Research before adopting the rules required under subsections (1) and (3) of this section, including rules identifying those parts of the Federal Policy for the Protection of Human Subjects that are applicable to this section.
5. [*Genetic research in which the DNA sample or genetic information is coded shall satisfy the following requirements:*
  - (a)
    - A. *The subject has granted informed consent for the specific research project;*
    - B. *The subject has consented to genetic research generally; or*
    - C. *The DNA sample or genetic information is derived from a biological specimen or from clinical individually identifiable health information that was obtained or retained in compliance with ORS 192.537 (2).*
  - (b) *The research has been approved by an institutional review board after disclosure by the investigator to the board of risks associated with the coding.*
  - (c) *The code is:*
    - A. *Not derived from individual identifiers;*
    - B. *Kept securely and separately from the DNA samples and genetic information; and*
    - C. *Not accessible to the investigator unless specifically approved by the institutional review board.*
  - (d) *Data is stored securely in password protected electronic files or by other means with access limited to necessary personnel.*
  - (e) *The data is limited to elements required for analysis and meets the criteria in 45 C.F.R 164.514(e) for a limited data set.*
  - (f) *The investigator is a party to the data use agreement as provided by 45 C.F.R. 164.514(e) for limited data set recipients.*
6. *Research conducted in accordance with this section is rebuttably presumed to comply with ORS 192.535 and 192.539.*
7. (a) *Notwithstanding ORS 192.535, a person may use a DNA sample or genetic information obtained, with blanket informed consent, before June 25, 2001, for genetic research.*

- (b) Notwithstanding ORS 192.535, a person may use a DNA sample or genetic information obtained without specific informed consent and derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research if an institutional review board operating under subsection (1)(b) of this section:*
- A. Waives or alters the consent requirements pursuant to the Federal Policy for the Protection of Human Subjects; and*
  - B. Waives authorization pursuant to the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164.*
- (c) Except as provided in subsection (5)(a) of this section or paragraph (b) of this subsection, a person must have specific informed consent from an individual to use a DNA sample or genetic information of the individual obtained on or after June 25, 2001, for genetic research.*
- 8. Except as otherwise allowed by rule of the Oregon Health Authority, if DNA samples or genetic information obtained for either clinical or research purposes is used in research, a person may not recontact the individual or the individual's physician by using research information that is identifiable or coded. The Oregon Health Authority shall adopt by rule criteria for recontacting an individual or an individual's physician. In adopting the criteria, the department shall consider the recommendations of national organizations such as those created by executive order by the President of the United States and the recommendations of the Advisory Committee on Genetic Privacy and Research.*
- 9. The requirements for consent to, or notification of, obtaining a DNA sample or genetic information for genetic research are governed by the provisions of ORS 192.531 to 192.549 and the administrative rules that were in effect on the effective date of the institutional review board's most recent approval of the study.]*

### **192.549 Advisory Committee on Genetic Privacy and Research.**

1. The Advisory Committee on Genetic Privacy and Research is established consisting of 15 members. The President of the Senate and the Speaker of the House of Representatives shall each appoint one member and one alternate. The Director of the Oregon Health Authority shall appoint one representative and one alternate from each of the following categories:
  - (a). Academic institutions involved in genetic research;
  - (b). Physicians licensed under ORS chapter 677;

- (c). Voluntary organizations involved in the development of public policy on issues related to genetic privacy;
  - (d). Hospitals;
  - (e). The Department of Consumer and Business Services;
  - (f). The Oregon Health Authority;
  - (g). Health care service contractors involved in genetic and health services research;
  - (h). The biosciences industry;
  - (i). The pharmaceutical industry;
  - (j). Health care consumers;
  - (k). Organizations advocating for privacy of medical information;
  - (l). Public members of institutional review boards; and
  - (m). Organizations or individuals promoting public education about genetic research and genetic privacy and public involvement in policymaking related to genetic research and genetic privacy.
2. Organizations and individuals representing the categories listed in subsection (1) of this section may recommend nominees for membership on the advisory committee to the President, the Speaker and the director.
  3. Members and alternate members of the advisory committee serve two-year terms and may be reappointed.
  4. Members and alternate members of the advisory committee serve at the pleasure of the appointing entity.
  5. The Oregon Health Authority shall provide staff for the advisory committee.
  6. The advisory committee shall:
    - (a) [*report*] Report biennially to the Legislative Assembly in the manner provided by ORS 192.245. The report shall include the activities and the results of any studies conducted by the advisory committee. The advisory committee may make any recommendations for legislative changes deemed necessary by the advisory committee.
    - (b) [(7) *The advisory committee shall study*] 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.

- (c) [(8) *The advisory committee shall create*] Create opportunities for public education on the scientific, legal and ethical development within the fields of genetic privacy and research. The advisory committee shall also elicit public input on these matters. The advisory committee shall make reasonable efforts to obtain public input that is representative of the diversity of opinion on this subject. The advisory committee's recommendations to the Legislative Assembly shall take into consideration public concerns and values related to these matters.
- (d) Use the institutional review board registry maintained by the Authority to educate institutional review boards about the purposes and requirements of the genetic privacy statutes and administrative rules relating to genetic research.

### **659A.303 Employer prohibited from obtaining, seeking to obtain or using genetic information; remedies.**

1. It is an unlawful employment practice for an employer to seek to obtain, to obtain or to use genetic information of an employee or a prospective employee, or of a [*blood relative*] family member of the employee or prospective employee, to distinguish between or discriminate against or restrict any right or benefit otherwise due or available to an employee or a prospective employee.
2. An employee or prospective employee may bring a civil action under ORS 659A.885 for a violation of this section.
3. For purposes of this section, [*“blood relative”*], “family member”, “genetic information” and “obtain genetic information” have the meanings given those terms in ORS 192.531.

### **746.135 Genetic tests and information; rules.**

1. If a person asks an applicant for insurance to take a genetic test in connection with an application for insurance, the use of the test shall be revealed to the applicant and the person shall obtain the specific authorization of the applicant using a form adopted by the Director of the Department of Consumer and Business Services by rule.

2. A person may not use favorable genetic information to induce the purchase of insurance.
3. A person may not use genetic information to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy for hospital or medical expenses.
4. A person may not use genetic information about a [*blood relative*] family member to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy of insurance.
5. For purposes of this section, [*blood relative,*] “genetic information” and “genetic test” have the meanings given those terms in ORS 192.531.
6. For purposes of this section “family member” means, with respect to an individual:
  - (a) A dependent of such individual; and
  - (b) Any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of an individual described in subsection (a).

**659A.300 Requiring breathalyzer, polygraph, psychological stress or brainwave test or genetic test prohibited; exceptions.**

1. Except as provided in this section, it is an unlawful employment practice for any employer to subject, directly or indirectly, any employee or prospective employee to any breathalyzer test, polygraph examination, psychological stress test, genetic test or brain-wave test.
2. As used in this section:
  - (a) “Breathalyzer test” means a test to detect the presence of alcohol in the body through the use of instrumentation or mechanical devices.
  - (b) “Genetic test” has the meaning given in ORS 192.531.
  - (c) “Polygraph examination or psychological stress test” means a test to detect deception or to verify the truth of statements through the use of instrumentation or mechanical devices.
  - (d) An individual is “under the influence of intoxicating liquor” when the individual’s blood alcohol content exceeds the amount prescribed in a collective bargaining agreement or the amount prescribed in the employer’s work rules if there is no applicable collective bargaining provision.

3. Nothing in subsection (1) of this section shall be construed to prohibit the administration of a polygraph examination to an individual, if the individual consents to the examination, during the course of criminal or civil judicial proceedings in which the individual is a party or witness or during the course of a criminal investigation conducted by a law enforcement agency, as defined in ORS 181.010, a district attorney or the Attorney General.
4. Nothing in subsection (1) of this section shall be construed to prohibit the administration of a breathalyzer test to an individual if the individual consents to the test. If the employer has reasonable grounds to believe that the individual is under the influence of intoxicating liquor, the employer may require, as a condition for employment or continuation of employment, the administration of a blood alcohol content test by a third party or a breathalyzer test. The employer shall not require the employee to pay the cost of administering any such test.
5. Subsection (1) of this section does not prohibit the administration of a genetic test to an individual if the individual or the individual's representative grants informed consent in the manner provided by ORS 192.535, and the genetic test is administered solely to determine a bona fide occupational qualification.

**\* Language in brackets and italicized is proposed to be deleted.**

**\*\* Underlined language is proposed to be added.**

## **GENETIC PRIVACY – Selected Repeal Draft**

### **192.531 Definitions for ORS 192.531 to 192.549.**

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 July 17, 2007.
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, RNA and mitochondrial DNA, chromosomes or proteins 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.

### **192.533 Legislative findings; purposes.**

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.*]
2. The purposes of the genetic privacy statutes are [as follows:
- (a) *To define the rights of individuals whose genetic information is collected, retained or disclosed and the rights of the individuals' blood relatives.*
  - (b) *To define the circumstances under which an individual may be subjected to genetic testing.*
  - (c) *To define the circumstances under which an individual's genetic information may be collected, retained or disclosed.*
  - (d) *To protect against discrimination by an insurer or employer based upon an individual's genetic characteristics.*
  - (e) To] to *define the circumstances under which a DNA sample or genetic information may be used for research.*

**[192.535 Informed consent for obtaining genetic information.**

1. *A person may not obtain genetic information from an individual, or from an individual's DNA sample, without first obtaining informed consent of the individual or the individual's representative, except:*
  - (a) *As authorized by ORS 181.085 or comparable provisions of federal criminal law relating to the identification of persons, or for the purpose of establishing the identity of a person in the course of an investigation conducted by a law enforcement agency, a district attorney, a medical examiner or the Criminal Justice Division of the Department of Justice;*

- (b) *For anonymous research or coded research conducted under conditions described in ORS 192.537 (2), after notification pursuant to ORS 192.538 or pursuant to ORS 192.547 (7)(b);*
  - (c) *As permitted by rules of the Oregon Health Authority for identification of deceased individuals;*
  - (d) *As permitted by rules of the Oregon Health Authority for newborn screening procedures;*
  - (e) *As authorized by statute for the purpose of establishing paternity; or*
  - (f) *For the purpose of furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent.*
2. *Except as provided in subsection (3) of this section, a physician licensed under ORS chapter 677 shall seek the informed consent of the individual or the individual's representative for the purposes of subsection (1) of this section in the manner provided by ORS 677.097. Except as provided in subsection (3) of this section, any other licensed health care provider or facility must seek the informed consent of the individual or the individual's representative for the purposes of subsection (1) of this section in a manner substantially similar to that provided by ORS 677.097 for physicians.*
  3. *A person conducting research shall seek the informed consent of the individual or the individual's representative for the purposes of subsection (1) of this section in the manner provided by ORS 192.547.*
  4. *Except as provided in ORS 746.135 (1), any person not described in subsection (2) or (3) of this section must seek the informed consent of the individual or the individual's representative for the purposes of subsection (1) of this section in the manner provided by rules adopted by the Oregon Health Authority.*
  5. *The Oregon Health Authority may not adopt rules under subsection (1)(d) of this section that would require the providing of a DNA sample for the purpose of obtaining complete genetic information used to screen all newborns.]*

**192.537 Use of genetic information for anonymous or coded research.**

**[Individual's rights in genetic information; retention of information; destruction of information].**

1. *[Subject to the provisions of ORS 192.531 to 192.549, 659A.303 and 746.135, an individual's genetic information and DNA sample are private and must be protected, and an individual has a right to the protection of that privacy. Any person authorized by law or by an individual or an individual's representative to obtain, retain or use an individual's*

*genetic information or any DNA sample must maintain the confidentiality of the information or sample and protect the information or sample from unauthorized disclosure or misuse.*

- 2.] (a) A person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research only if the individual:
- A. Has granted informed consent for the specific anonymous research or coded research project;
  - B. Has granted consent for genetic research generally;
  - C. Was notified in accordance with ORS 192.538 that the individual's biological specimen or clinical individually identifiable health information may be used for anonymous research or coded research and the individual did not, at the time of notification, request that the biological specimen or clinical individually identifiable health information not be used for anonymous research or coded research; or
  - D. Was not notified, due to emergency circumstances, in accordance with ORS 192.538 that the individual's biological specimen or clinical individually identifiable health information may be used for anonymous research or coded research and the individual died before receiving the notice.
- (b) Paragraph (a) of this subsection does not apply to biological specimens or clinical individually identifiable health information obtained before July 29, 2005, if an institutional review board operating under ORS 192.547(1) (b) meets the requirements described in subsection (b) of this section [ORS 192.547 (7)(b)].

2. Genetic research in which the DNA sample or genetic information is coded shall, in addition to complying with subsection (1) of this section, ensure that:

- (a)
- A. The subject has granted informed consent for the specific research project;
  - B. The subject has consented to genetic research generally; or
  - C. The DNA sample or genetic information is derived from a biological specimen or from clinical individually identifiable health information that was obtained or retained in compliance with subsection (1) of this section.
- (b) The research has been approved by an institutional review board after disclosure by the investigator to the board of risks associated with the coding.

- (c) The code is:
  - A. Not derived from individual identifiers;
  - B. Kept securely and separately from the DNA samples and genetic information; and
  - C. Not accessible to the investigator unless specifically approved by the institutional review board.
- (d) Data is stored securely in password protected electronic files or by other means with access limited to necessary personnel.
- (e) The data is limited to elements required for analysis and meets the criteria in 45 C.F.R 164.514(e) for a limited data set.
- (f) The investigator is a party to the data use agreement as provided by 45 C.F.R. 164.514(e) for limited data set recipients, if a data use agreement is required.
- 3. A person may use a DNA sample or genetic information obtained:
  - (a) With blanket informed consent, before June 25, 2001, for genetic research.
  - (b) Without specific informed consent and derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research if an institutional review board:
    - A. Waives or alters the consent requirements pursuant to the Federal Policy for the Protection of Human Subjects; and
    - B. Waives authorization pursuant to the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164.
- 4. Except as provided in subsection (2)(a) of this section or paragraph (b) of this subsection, a person must have specific informed consent from an individual to use a DNA sample or genetic information of the individual obtained on or after June 25, 2001, for genetic research.
- 5. Except as otherwise allowed by rule of the Oregon Health Authority, if DNA samples or genetic information obtained for either clinical or research purposes is used in research, a person may not recontact the individual or the individual's physician by using research information that is identifiable or coded. The Oregon Health Authority shall adopt by rule criteria for recontacting an individual or an individual's physician. In adopting the criteria, the department shall consider the recommendations of national organizations such as those created by executive order by the President of the United States and the recommendations of the Advisory Committee on Genetic Privacy and Research.

6. The requirements for consent to, or notification of, obtaining a DNA sample or genetic information for genetic research are governed by the provisions of ORS 192.531 to 192.549 and the administrative rules that were in effect on the effective date of the institutional review board's most recent approval of the study.
7. Notwithstanding ORS 192.537(2), a person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research if the individual was deceased when the individual's biological specimen or clinical individually identifiable health information was obtained.

[3] *A person may not retain another individual's genetic information or DNA sample without first obtaining authorization from the individual or the individual's representative, unless:*

- (a) *Retention is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a county multidisciplinary child abuse team;*
- (b) *Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;*
- (c) *Retention is permitted by rules of the Oregon Health Authority for identification of, or testing to benefit blood relatives of, deceased individuals;*
- (d) *Retention is permitted by rules of the authority for newborn screening procedures; or*
- (e) *Retention is for anonymous research or coded research conducted after notification or with consent pursuant to subsection (2) of this section or ORS 192.538.*

4. *The DNA sample of an individual from which genetic information has been obtained shall be destroyed promptly upon the specific request of that individual or the individual's representative, unless:*

- (a) *Retention is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a county multidisciplinary child abuse team;*
- (b) *Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions; or*
- (c) *Retention is for anonymous research or coded research conducted after notification or with consent pursuant to subsection (2) of this section or ORS 192.538.*

5. *A DNA sample from an individual that is the subject of a research project, other than an anonymous research project, shall be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first, unless the individual or the individual's representative directs otherwise by informed consent.*
6. *A DNA sample from an individual for insurance or employment purposes shall be destroyed promptly after the purpose for which the sample was obtained has been accomplished unless retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil, criminal and juvenile proceedings*
7. *An individual or an individual's representative, promptly upon request, may inspect, request correction of and obtain genetic information from the records of the individual.*
8. *Subject to the provisions of ORS 192.531 to 192.549, and to policies adopted by the person in possession of a DNA sample, an individual or the individual's representative may request that the individual's DNA sample be made available for additional genetic testing for medical diagnostic purposes. If the individual is deceased and has not designated a representative to act on behalf of the individual after death, a request under this subsection may be made by the closest surviving blood relative of the decedent or, if there is more than one surviving blood relative of the same degree of relationship to the decedent, by the majority of the surviving closest blood relatives of the decedent.*
9. *The Oregon Health Authority shall coordinate the implementation of this section.*
10. *Subsections (3) to (8) of this section apply only to a DNA sample or genetic information that is coded, identified or identifiable.*
11. *This section does not apply to any law, contract or other arrangement that determines a person's rights to compensation relating to substances or information derived from an individual's DNA sample.]*

**192.538 Notice by health care provider regarding anonymous or coded research.**

1. A health care provider that is a covered entity as defined in ORS 192.519 (2) (c) and that obtains an individual's biological specimen or clinical individually identifiable health information shall notify the individual that the biological specimen or clinical individually identifiable health information may be disclosed or retained by the provider for anonymous research or coded research.
2. A health care provider that is not a covered entity as defined in ORS 192.519 (2) (c) and that obtains an individual's biological specimen or clinical individually identifiable health information may notify the individual that the biological specimen or clinical individually identifiable health information may be disclosed or retained by the provider for anonymous research or coded research.

3. A health care provider described in subsection (1) of this section shall provide a notice to the individual describing how the biological specimen or clinical individually identifiable health information may be used and allowing the individual to request that the specimen or information not be disclosed or retained for anonymous research or coded research. The notice must contain a place where the individual may mark the individual's request that the specimen or information not be disclosed or retained for anonymous research or coded research before returning the notice to the health care provider.
4. The notice described in subsection (3) of this section:
  - (a) Must be given no later than when the provider obtains an individual's biological specimen or clinical individually identifiable health information; and
  - (b) May be given at the same time and in the same manner as the notice of privacy practices required under the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164.

**[192.539 Disclosure of genetic information; exceptions.**

1. *Regardless of the manner of receipt or the source of genetic information, including information received from an individual or a blood relative of the individual, a person may not disclose or be compelled, by subpoena or any other means, to disclose the identity of an individual upon whom a genetic test has been performed or the identity of a blood relative of the individual, or to disclose genetic information about the individual or a blood relative of the individual in a manner that permits identification of the individual, unless:*
  - (a) *Disclosure is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest, or a child fatality review by a county multidisciplinary child abuse team;*
  - (b) *Disclosure is required by specific court order entered pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;*
  - (c) *Disclosure is authorized by statute for the purpose of establishing paternity;*
  - (d) *Disclosure is specifically authorized by the tested individual or the tested individual's representative by signing a consent form prescribed by rules of the Oregon Health Authority;*
  - (e) *Disclosure is for the purpose of furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent; or*

- (f) *Disclosure is for the purpose of identifying bodies.*
2. *The prohibitions of this section apply to any redisclosure by any person after another person has disclosed genetic information or the identity of an individual upon whom a genetic test has been performed, or has disclosed genetic information or the identity of a blood relative of the individual.*
  3. *A release or publication is not a disclosure if:*
    - (a) *It involves a good faith belief by the person who caused the release or publication that the person was not in violation of this section;*
    - (b) *It is not due to willful neglect;*
    - (c) *It is corrected in the manner described in ORS 192.541 (4);*
    - (d) *The correction with respect to genetic information is completed before the information is read or heard by a third party; and*
    - (e) *The correction with respect to DNA samples is completed before the sample is retained or genetically tested by a third party.]*

**[192.540 Use of deceased individual's DNA sample or genetic information for research.**

*Notwithstanding ORS 192.535 and 192.537 (2), a person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research if the individual was deceased when the individual's biological specimen or clinical individually identifiable health information was obtained.]*

**192.541 Private right of action; remedies; affirmative defense; attorney fees.**

1. An individual or an individual's blood relative, representative or estate may bring a civil action against any person who violates ORS [192.535,] 192.537, [192.539 or 192.547]
2. For a violation of ORS 192.537 [or 192.547,] the court shall award the greater of actual damages or:
  - (a) \$100, for an inadvertent violation that does not arise out of the negligence of the defendant;
  - (b) \$500, for a negligent violation;

- (c) \$10,000, for a knowing or reckless violation;
  - (d) \$15,000, for a knowing violation based on a fraudulent misrepresentation; or
  - (e) \$25,000, for a knowing violation committed with intent to sell, transfer or use for commercial advantage, personal gain or malicious harm.
3. *[For a violation of ORS 192.535 or 192.539, the court shall award the greater of actual damages or:*
- (a) \$1,000, for an inadvertent violation that does not arise out of the negligence of the defendant;*
  - (b) \$5,000, for a negligent violation;*
  - (c) \$100,000, for a knowing or reckless violation;*
  - (d) \$150,000, for a knowing violation based on a fraudulent misrepresentation; or*
  - (e) \$250,000, for a knowing violation committed with intent to sell, transfer or use for commercial advantage, personal gain or malicious harm.]*
4. It is an affirmative defense to an action described in subsection (2)(a) or (b) *[or (3)(a) or (b)]* of this section that the defendant corrected the violation through destruction of illegally retained or obtained samples or information, or took other action to correct the violation, if the correction was completed within 120 days after the defendant knew or should have known that the violation occurred.
- [5.] **(4)** The court may provide such equitable relief as it deems necessary or proper.
- [6.] **(5)(a)** The court may award attorney fees to a defendant only if the court finds that the plaintiff had no objectively reasonable basis for asserting a claim or for appealing an adverse decision of the trial court.
- (b) The court shall award attorney fees to a plaintiff if the court finds that the defendant committed a violation described in subsection (2)(c), (d) or (e) *[or (3)(c), (d) or (e)]* of this section.
- [7.] **(6)** An action authorized by subsection (1) of this section must be commenced within three years after the date the plaintiff knew or should have known of the violation, but in no instance more than 10 years after the date of the violation.
- [8.] **(7)** A plaintiff may recover damages provided by subsection[s] (2) *[and (3)]* of this section for each violation by a defendant.
- [9.] **(8)** ORS 31.725, 31.730, 31.735 and 31.740 do not apply to amounts awarded in actions under this section.

**[192.543 Criminal penalty.**

1. *A person commits the crime of unlawfully obtaining, retaining or disclosing genetic information if the person knowingly, recklessly or with criminal negligence, as those terms are defined in ORS 161.085, obtains, retains or discloses genetic information in violation of ORS 192.531 to 192.549.*
2. *Unlawfully obtaining, retaining or disclosing genetic information is a Class A misdemeanor.]*

**192.545 Enforcement; Attorney General or district attorney; intervention.**

1. The Attorney General or a district attorney may bring an action against a person who violates ORS [192.535], 192.537, [192.539] or 192.547. In addition to remedies otherwise provided in ORS 192.541, the court shall award to the Attorney General or district attorney the costs of the investigation.
2. The Attorney General may intervene in a civil action brought under ORS 192.541 if the Attorney General certifies that, in the opinion of the Attorney General, the action is of general public importance. In the action, the Attorney General shall be entitled to the same relief as if the Attorney General instituted the action under this section.

**192.547 Oregon Health Authority rules; procedures.**

1. (a) The Oregon Health Authority shall adopt rules for conducting research using DNA samples, genetic testing and genetic information. Rules establishing minimum research standards shall conform to the Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46, that is current at the time the rules are adopted. The rules may be changed from time to time as may be necessary.
- (b) The rules adopted by the Oregon Health Authority shall address the operation and appointment of institutional review boards. The rules shall conform to the compositional and operational standards for such boards contained in the Federal Policy for the Protection of Human Subjects that is current at the time the rules are adopted. The rules must require that research conducted under paragraph (a) of this subsection be conducted with the approval of the institutional review board.
- (c) Persons proposing to conduct anonymous research, coded research or genetic research that is otherwise thought to be exempt from review must obtain

from an institutional review board prior to conducting such research a determination that the proposed research is exempt from review.

2. A person proposing to conduct research under subsection (1) of this section, including anonymous research or coded research, must disclose to the institutional review board the proposed use of DNA samples, genetic testing or genetic information.
3. The Oregon Health Authority shall adopt rules requiring that all institutional review boards operating under subsection (1)(b) of this section register with the department. The Advisory Committee on Genetic Privacy and Research shall use the registry to educate institutional review boards about the purposes and requirements of the genetic privacy statutes and administrative rules relating to genetic research.
4. The Oregon Health Authority shall consult with the Advisory Committee on Genetic Privacy and Research before adopting the rules required under subsections (1) and (3) of this section, including rules identifying those parts of the Federal Policy for the Protection of Human Subjects that are applicable to this section.
- [5. *Genetic research in which the DNA sample or genetic information is coded shall satisfy the following requirements:*
  - (a)
    - A. *The subject has granted informed consent for the specific research project;*
    - B. *The subject has consented to genetic research generally; or*
    - C. *The DNA sample or genetic information is derived from a biological specimen or from clinical individually identifiable health information that was obtained or retained in compliance with ORS 192.537 (2).*
  - (b) *The research has been approved by an institutional review board after disclosure by the investigator to the board of risks associated with the coding.*
  - (c) *The code is:*
    - A. *Not derived from individual identifiers;*
    - B. *Kept securely and separately from the DNA samples and genetic information; and*
    - C. *Not accessible to the investigator unless specifically approved by the institutional review board.*
  - (d) *Data is stored securely in password protected electronic files or by other means with access limited to necessary personnel.*



## **192.549 Advisory Committee on Genetic Privacy and Research.**

1. The Advisory Committee on Genetic Privacy and Research is established consisting of 15 members. The President of the Senate and the Speaker of the House of Representatives shall each appoint one member and one alternate. The Director of the Oregon Health Authority shall appoint one representative and one alternate from each of the following categories:
  - (a) Academic institutions involved in genetic research;
  - (b) Physicians licensed under ORS chapter 677;
  - (c) Voluntary organizations involved in the development of public policy on issues related to genetic privacy;
  - (d) Hospitals;
  - (e) The Department of Consumer and Business Services;
  - (f) The Oregon Health Authority;
  - (g) Health care service contractors involved in genetic and health services research;
  - (h) The biosciences industry;
  - (i) The pharmaceutical industry;
  - (j) Health care consumers;
  - (k) Organizations advocating for privacy of medical information;
  - (l) Public members of institutional review boards; and
  - (m) Organizations or individuals promoting public education about genetic research and genetic privacy and public involvement in policymaking related to genetic research and genetic privacy.
2. Organizations and individuals representing the categories listed in subsection (1) of this section may recommend nominees for membership on the advisory committee to the President, the Speaker and the director.
3. Members and alternate members of the advisory committee serve two-year terms and may be reappointed.
4. Members and alternate members of the advisory committee serve at the pleasure of the appointing entity.
5. The Oregon Health Authority shall provide staff for the advisory committee.

6. The advisory committee shall report biennially to the Legislative Assembly in the manner provided by ORS 192.245. The report shall include the activities and the results of any studies conducted by the advisory committee. The advisory committee may make any recommendations for legislative changes deemed necessary by the advisory committee.
7. The 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.
8. The advisory committee shall create opportunities for public education on the scientific, legal and ethical development within the fields of genetic privacy and research. The advisory committee shall also elicit public input on these matters. The advisory committee shall make reasonable efforts to obtain public input that is representative of the diversity of opinion on this subject. The advisory committee's recommendations to the Legislative Assembly shall take into consideration public concerns and values related to these matters.

**[659A.303 Employer prohibited from obtaining, seeking to obtain or using genetic information; remedies.**

1. *It is an unlawful employment practice for an employer to seek to obtain, to obtain or to use genetic information of an employee or a prospective employee, or of a blood relative of the employee or prospective employee, to distinguish between or discriminate against or restrict any right or benefit otherwise due or available to an employee or a prospective employee.*
2. *An employee or prospective employee may bring a civil action under ORS 659A.885 for a violation of this section.*
3. *For purposes of this section, "blood relative," "genetic information" and "obtain genetic information" have the meanings given those terms in ORS 192.531.]*

**746.135 Genetic tests and information; rules.**

1. If a person asks an applicant for insurance to take a genetic test in connection with an application for insurance, the use of the test shall be revealed to the applicant and the person shall obtain the specific authorization of the applicant using a form adopted by the Director of the Department of Consumer and Business Services by rule..

2. A person may not use favorable genetic information to induce the purchase of insurance.
3. A person may not use genetic information to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy for hospital or medical expenses.
4. A person may not use genetic information about a **family member** [*blood relative*] to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy of insurance.
5. For purposes of this section: [*“blood relative,” “genetic information” and “genetic test” have the meanings given those terms in ORS 192.531*] **“family member,” “genetic information” and “genetic test” have the meanings given those terms in 29 CFR 1635.3.**

**[659A.300 Requiring breathalyzer, polygraph, psychological stress or brain-wave test or genetic test prohibited; exceptions.**

1. *Except as provided in this section, it is an unlawful employment practice for any employer to subject, directly or indirectly, any employee or prospective employee to any breathalyzer test, polygraph examination, psychological stress test, genetic test or brain-wave test.*
2. *As used in this section:*
  - (a) *“Breathalyzer test” means a test to detect the presence of alcohol in the body through the use of instrumentation or mechanical devices.*
  - (b) *“Genetic test” has the meaning given in ORS 192.531.*
  - (c) *“Polygraph examination or psychological stress test” means a test to detect deception or to verify the truth of statements through the use of instrumentation or mechanical devices.*
  - (d) *An individual is “under the influence of intoxicating liquor” when the individual’s blood alcohol content exceeds the amount prescribed in a collective bargaining agreement or the amount prescribed in the employer’s work rules if there is no applicable collective bargaining provision.*
3. *Nothing in subsection (1) of this section shall be construed to prohibit the administration of a polygraph examination to an individual, if the individual consents to the examination, during the course of criminal or civil judicial proceedings in which the individual is a party or witness or during the course of a criminal investigation conducted by a law enforcement agency, as defined in ORS 181.010, a district attorney or the Attorney General.*

4. *Nothing in subsection (1) of this section shall be construed to prohibit the administration of a breathalyzer test to an individual if the individual consents to the test. If the employer has reasonable grounds to believe that the individual is under the influence of intoxicating liquor, the employer may require, as a condition for employment or continuation of employment, the administration of a blood alcohol content test by a third party or a breathalyzer test. The employer shall not require the employee to pay the cost of administering any such test.*
5. *Subsection (1) of this section does not prohibit the administration of a genetic test to an individual if the individual or the individual's representative grants informed consent in the manner provided by ORS 192.535, and the genetic test is administered solely to determine a bona fide occupational qualification.]*



## Appendix 2

### Communications regarding sickle cell trait testing

There are four NCAA Division 1 schools in Oregon: University of Oregon, Oregon State University, University of Portland and Portland State University.

<http://web1.ncaa.org/memberLinks/links.jsp>

University of Oregon

Robert "Rob" A Mullens  
Dir Intercollegiate Athletics  
Casanova Athletic Center  
2727 Leo Harris Pkwy  
Eugene, OR 97403-8835  
[athleticdirector@uoregon.edu](mailto:athleticdirector@uoregon.edu)

Portland State University

Torre Chisholm  
Director of Athletics  
PO Box 751  
Portland, OR 97207  
Phone: (503) 725-4000  
[chisholm@pdx.edu](mailto:chisholm@pdx.edu)

Oregon State University

Bob De Carolis  
Director of Athletics  
Corvallis, OR 97331  
541-737-7373  
[Bob.DeCarolis@oregonstate.edu](mailto:Bob.DeCarolis@oregonstate.edu)

University of Portland

Larry Williams  
Athletic Director  
5000 N. Willamette Blvd.  
Portland, OR 97203-5798  
Phone: 503-943-7117  
[williams@up.edu](mailto:williams@up.edu)

March 1, 2011

Dear Recipient Name (Athletic Director),

The Advisory Committee on Genetic Privacy and Research (ACGPR) was established by the Oregon Legislature in 2001 to provide ongoing review and guidance on genetic privacy and research issues (<http://www.oregon.gov/DHS/ph/genetics/research.shtml>).

Recently, a committee member brought the new NCAA policy of testing for sickle cell trait to the committee's attention, and none of us knew what the Oregon universities were doing with respect to the policy. (Please see the attached NCAA Fact Sheet for further information).

We are surveying the Oregon universities for information only about your implementation of sickle cell trait testing of NCAA Division 1 athletes (we are not involved in regulation or enforcement). This information will be used only by the committee to keep up-to-date on genetics issues in Oregon.

Please let us know whether or not your athletic department is testing student athletes for the sickle cell trait and, if so, please send us a copy of your testing policy, including how you test for the trait, uses of the information, and the informed consent process.

Thank you for your time and attention to this matter. Please do not hesitate to contact me if you have any questions.

Kind Regards,

Summer L. Cox, MPH  
Genetics Analyst, Oregon Genetics Program  
Office of Family Health, Oregon Public Health Division  
800 NE Oregon St. Ste. 805  
Portland, Oregon 97232  
PH: 971-673-0273 / FAX: 971-673-0250  
Email: [summer.l.cox@state.or.us](mailto:summer.l.cox@state.or.us)

Appendix 2: Communications regarding sickle cell trait testing

Athletic Director's Full Name  
University Name  
Address 1  
Address 2  
City, OR Zip

July 11, 2011

Re: Informed Consent in Sickle Cell Trait Testing of Student Athletes

Dear First Name Last Name (Athletic Director),

I am writing you on behalf of the Advisory Committee on Genetic Privacy and Research (ACGPR) regarding your university's practices relating to genetic testing of NCAA Division 1 athletes. The ACGPR is charged by the Oregon State legislature to study the use and disclosure of genetic information and to educate the public on the legal requirements and ethical developments in genetic privacy and research. The ACGPR recently surveyed Oregon universities about their implementation of sickle cell trait testing of NCAA Division 1 athletes. We would like to help ensure that your university's genetic testing practices follow state law.

Oregon's Genetic Privacy Law has been in effect since 1995. The Oregon law (ORS 192.529 to 192.549) includes the requirement to obtain informed consent prior to performing a genetic test on an individual for the purpose of collecting and retaining genetic information. There are a number of points that must be clearly contained within an informed consent form, as described in the Oregon Administrative Rules under Section 333-025-0140. In addition, any disclosure of health information (e.g., to your institution, including coaches or trainers) must be in accordance with ORS 192.522.

Enclosed you will find a copy of the Oregon Administrative Rules pertaining to genetic information and privacy, including a sample consent form in Appendix 1, and a copy of the ORS 192.522 Authorization form. We invite you to review the enclosed information and use it to ensure that you are following Oregon state law regarding genetic testing. In addition, you may want to consult your legal counsel or compliance department. Please do not hesitate to contact me or the Oregon Genetics Program if you have any questions.

Most sincerely,

Kara Manning Drolet, PhD  
Co-Chair, Advisory Committee on Genetic Privacy and Research

Oregon Genetics Program  
800 NE Oregon St, Suite 805  
Portland, OR 97232  
971-673-0273  
<http://www.oregongenetics.org>

# OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION

## DIVISION 25

### GENETIC INFORMATION AND PRIVACY

333-025-0100

#### Definitions

As used in these rules:

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. “Anonymous research” does not include research conducted in such a manner that the identity of such an individual, or the identity of the individual’s blood relatives, can be determined by use of a code, encryption key or other means of linking the information to a specific individual.
2. “Biological sample” means any human biological specimen that may be used as a DNA sample.
3. “Blanket informed consent” means that the individual has consented to the use of that 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.
4. “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.
5. “Clinical” means relating to or obtained through the actual observation, diagnosis, or treatment of patients and not through research.
6. “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.
7. “Covered entity,” as applied to a health care provider, means a health care provider that transmits any health information in electronic form to carry out financial or administrative activities in connection with a transaction covered by ORS 192.518 to 192.524.

8. “Deidentified” means lacking, or having had removed, the identifiers or system of encryption that would make it possible for a person to link a biological sample or health 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. DNA samples and genetic information will be considered deidentified only if they meet the following standards provided in the Federal Privacy Rule:
  - (a) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
    - A. Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
    - B. Documents the methods and results of the analysis that justify such determination; or
  - (b) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
    - A. Names;
    - B. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
      - i. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
      - ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
    - C. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
    - D. Telephone numbers;
    - E. Fax numbers;
    - F. Electronic mail addresses;

- G. Social security numbers;
  - H. Medical record numbers;
  - I. Health plan beneficiary numbers;
  - J. Account numbers;
  - K. Certificate/license numbers;
  - L. Vehicle identifiers and serial numbers, including license plate numbers;
  - M. Device identifiers and serial numbers;
  - N. Web Universal Resource Locators (URLs);
  - O. Internet Protocol (IP) address numbers;
  - P. Biometric identifiers, including finger and voice prints;
  - Q. Full face photographic images and any comparable images; and
  - R. Any other unique identifying number, characteristic, or code; and
- (c) The investigator and repository do not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.
9. “Direct provider” means a health care provider that is not an indirect treatment provider.
  10. “Disclose” means to release, publish, or otherwise make known to a third party a biological sample or health information.
  11. “DNA” means deoxyribonucleic acid.
  12. “DNA sample” means any human biological specimen that is obtained or retained for the purpose of extracting and analyzing the individual’s DNA to perform a genetic test. “DNA sample” includes DNA extracted from the specimen.
  13. “Federal Common Rule” means the Federal Policy for the Protection of Human Subjects, as adopted by the following federal agencies and as revised through November 13, 2001: 7 CFR Part 1c, Department of Agriculture; 10 CFR Part 745, Department of Energy; 14 CFR Part 1230, National Aeronautics and Space Administration; 15 CFR Part 27, Department of Commerce; 16 CFR Part 1028, Consumer Product Safety Commission; 21 CFR Parts 50 and 56, Food and Drug Administration; 22 CFR Part 225, International Development Cooperation Agency, Agency for International Development; 24 CFR Part 60, Department

of Housing and Urban Development; 28 CFR Part 46, Department of Justice; 32 CFR Part 219, Department of Defense; 34 CFR Part 97, Department of Education; 38 CFR Part 16, Department of Veterans Affairs; 40 CFR Part 26, Environmental Protection Agency; 45 CFR Part 690, National Science Foundation; 45 CFR Part 46, Department of Health and Human Services; 49 CFR Part 11, Department of Transportation. In the case of research not subject to federal regulation under one of these provisions, “Federal Common Rule” means 45 CFR Part 46.

14. “Federal Privacy Rule” means the federal regulations under the Health Insurance Portability and Accountability Act, 45 CFR parts 160 and 164.
15. “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.
16. “Genetic information” means information about an individual or the individual’s blood relatives obtained from a genetic test.
17. “Genetic research” means research using human DNA samples, genetic testing or genetic information.
18. “Genetic test” means 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.
19. “Health care facility” means a hospital, long term care facility, an ambulatory surgical center, a freestanding birthing center or an outpatient dialysis center. “Health care facility” does not mean:
  - (a) An establishment furnishing residential care or treatment not meeting federal intermediate care standards, not following a primarily medical model of treatment, prohibited from admitting persons requiring 24-hour nursing care and licensed or approved under the rules of the Department of Human Services or the Department of Corrections; or
  - (b) An establishment furnishing primarily domiciliary care.
20. “Health care provider” has the meaning given in ORS 192.519(5).
21. “Health information” means any information in any form or medium that:
  - (a) Is created or received by a health care provider, a state health plan, a health

insurer, a healthcare clearinghouse, a public health authority, an employer, a life insurer, a school, or a university; and

(b) Relates to:

- A. The past, present or future physical or mental health or condition of an individual;
- B. The provision of health care to an individual; or
- C. The past, present or future payment for the provision of health care to an individual.

- 22. “Human biological specimen” means any material derived from human subjects, such as blood, urine, tissues, organs, hair, nail clippings, or any other cells or fluids, whether collected for research purposes or as residual specimens from diagnostic, therapeutic, or surgical procedures.
- 23. “Identifiable” or “Individually identifiable” means capable of being linked to the individual or a blood relative of the individual from whom the biological sample or health information was obtained, including demographic information that identifies the individual, or for which there is a reasonable basis to believe the information can be used to identify an individual.
- 24. “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.
- 25. “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.
- 26. “Indirect provider” means a health care provider having a relationship with an individual in which:
  - (a) The health care provider delivers health care to the individual based on the orders of another health care provider; and
  - (b) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.
- 27. “Institutional Review Board” or “IRB” means an Institutional Review Board

established in accord with and for the purposes expressed in the Federal Common Rule.

28. “IRB approval” means the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and Federal and State requirements.
29. “Limited data set” means protected health information that, in accordance with the Federal Privacy Rule, excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
  - (a) Names;
  - (b) Postal address information, other than town or city, state, and zip code;
  - (c) Telephone numbers;
  - (d) Fax numbers;
  - (e) Electronic mail addresses;
  - (f) Social security numbers;
  - (g) Medical record numbers;
  - (h) Health plan beneficiary numbers;
  - (i) Account numbers;
  - (j) Certificate/license numbers;
  - (k) Vehicle identifiers and serial numbers, including license plate numbers;
  - (l) Device identifiers and serial numbers;
  - (m) Web Universal Resource Locators (URLs);
  - (n) Internet Protocol (IP) address numbers;
  - (o) Biometric identifiers, including finger and voice prints; and
  - (p) Full face photographic images and any comparable images.
30. “Obtain genetic information” means performing or getting the results of a genetic test.
31. “Opt-out statement” means a written expression of an individual’s desire to withhold his or her own biological specimen or clinical individually identifiable health information from use and disclosure for the purpose of anonymous research or coded research.

32. “Person” includes but is not limited to any health care provider, health care facility, clinical laboratory, blood or sperm bank, insurer, insurance agent, insurance-support organization, as defined in ORS 746.600, government agency, employer, research organization or agent of any of them.
33. “Personal representative” includes but is not limited to:
  - (a) A person appointed as a guardian under ORS 125.305, 419B.370, 419C.481 or 419C.555 with authority to make medical and health care decisions;
  - (b) A person appointed as a health care representative under ORS 127.505 to 127.660 or a representative under ORS 127.700 to 127.737 to make health care decisions or mental health treatment decisions; and
  - (c) A person appointed as a personal representative under ORS Chapter 113.
34. “Recontact” means disclosure of genetic research findings to a research subject or the subject’s physician through use of personal identifiers.
35. “Research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.
36. “Retain a DNA sample” means the act of storing the DNA sample.
37. “Retain genetic information” means making a record of the genetic information.
38. “Specific informed consent for genetic research” means the individual or the individual’s representative has consented to the use of that individual’s DNA sample or genetic information for genetic research or for a specified genetic research project.
39. “Unidentified” means deidentified or not identifiable.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 192.531

Stats. Implemented: ORS 192.531

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04;

PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

## Research Involving Human Genetic Materials

333-025-0105

### Scope

1. OAR 333-025-0100 to 0165 apply to all genetic research subject to the law of the State of Oregon.
2. All genetic research must comply with the applicable standards set forth in the Federal Common Rule. Additional protections for subjects of research are authorized by ORS 192.531 et seq. and these rules. These rules set state standards that are in addition to, and not intended to alter, any requirements under the Federal Common Rule or the Federal Privacy Rule.

Stat. Auth.: ORS 192.531-192.549

Stats. Implemented: ORS 192.531-192.549

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04;

PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0110

### Institutional Review Boards (IRBs) and Approval for Research

1. An IRB must conform to the organizational and operational standards contained in the Federal Common Rule.
2. All proposed genetic research, including anonymous research, or research otherwise exempt from IRB approval, must first be submitted to an IRB for explicit prior approval or an explicit determination that the research is anonymous or otherwise exempt.
3. A researcher must disclose to the IRB the intended use of human DNA samples, genetic tests or other genetic information for every proposed research project, including anonymous or otherwise exempt research.
4. A researcher must follow the requirements of OAR 333-025-0115 and 333-025-0120 and provide assurances to the IRB that these requirements have been met.

Stat. Auth.: ORS 192.547

Stats. Implemented: ORS 192.533 & 192.547

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04;  
PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0115

### **Informed Consent for Non-Exempt Genetic Research**

1. Except as provided in OAR 333-025-0120, a researcher may use an identified human biological sample or genetic information obtained on or after June 25, 2001, for genetic research only with specific informed consent for genetic research.
2. Except as provided in OAR 333-025-0120, a researcher may use an identified human biological sample or genetic information obtained prior to June 25, 2001, for genetic research with blanket informed consent or specific informed consent for genetic research.

Stat. Auth.: ORS 192.535 & 192.547

Stats. Implemented: ORS 192.535 & 192.547

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04;  
PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0120

### **Anonymous, Coded, or Exempt Genetic Research**

1. Any person proposing to conduct genetic research that is thought to be anonymous shall obtain from an IRB, prior to conducting such research, a determination that the research is anonymous. The person shall furnish the IRB with assurances that the criteria in (3) below are met.
2. Any person proposing to conduct research that is thought to be exempt from review shall obtain an IRB determination that the research is exempt from review under 45 CFR 46.101(b) or other applicable exemption from the Federal Common Rule.
3. 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:

- (a) The subject has granted informed consent for the specific anonymous or coded research project; or
  - (b) The subject has granted consent for genetic research generally; or
  - (c) The subject was notified in accordance with OAR 333-025-0165 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
  - (d) The subject was not notified, due to emergency circumstances, in accordance with OAR 333-025- 0165, 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
  - (e) The subject has granted blanket informed consent and the sample or information was obtained before June 25, 2001; or
  - (f) The subject was deceased when the sample or information was obtained; or
  - (g) An Institutional Review Board:
    - A. Waives or alters the consent requirements pursuant to the Federal Common Rule; and
    - B. Waives authorization pursuant to the Federal Privacy Rule.
4. In addition to the requirements of section (3) of this rule, genetic research in which the DNA sample or genetic information is coded shall satisfy the following requirements:
- (a) The research has been approved by an Institutional Review Board after disclosure by the investigator to the board of risks associated with the coding;
  - (b) The code is:
    - A. Not derived from individual identifiers;
    - B. Kept securely and separately from the DNA samples and genetic information; and
    - C. Not accessible to the investigator unless specifically approved by the Institutional Review Board.
  - (c) Data is stored securely in password protected electronic files or by other means with access limited to necessary personnel;

- (d) The data is limited to elements required for analysis and is a limited data set; and
- (e) The investigator is a party to a data use agreement with any limited data set recipient. The data use agreement must:
  - A. Establish the permitted uses and disclosures of such information by the limited data set recipient, limited to research uses. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of the Federal Privacy Rule, if done by the investigator;
  - B. Establish who is permitted to use or receive the limited data set; and
  - C. Provide that the limited data set recipient will:
    - i. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
    - ii. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
    - iii. Report to the investigator any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
    - iv. Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
    - v. Not identify the information or contact the individuals.

Stat. Auth.: ORS 192.537 & 192.547

Stats. Implemented: ORS 192.535, 192.537 & 192.547

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04;

PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0125

### **IRB Registry**

1. The Department of Human Services/Health Services shall establish and maintain a registry of IRBs that review research conducted in Oregon or that involves research subjects living in Oregon.
2. By October 1, 2002, each existing IRB must register with the Department of Human Services/Health Services on registration forms provided by the Department.
3. The Department will update its registry annually. Each IRB will be required to renew its registration each year, or sooner if there exists material changes in the terms of registration.

Stat. Auth.: ORS 192.547

Stats. Implemented: ORS 192.547

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04;

PH 9-2004, f. & cert. ef 3-23-04

333-025-0130

### **Recontact**

1. Recontact of a research subject should not occur unless the subject was informed during the initial consent process that recontact may occur under specified circumstances and with this understanding, the research subject consented to participate in the study.
2. If recontact of subjects is contemplated, the researcher must provide research protocols to the IRB describing the circumstances that might lead to recontact, as well as a plan for managing the process. If a subject declines the possibility of recontact, the researcher may not recontact the subject.
3. Notwithstanding (1) above, in order to consider recontact in a situation where recontact was not contemplated and therefore not addressed in research protocols a researcher must seek approval from the IRB for re-contact and must assure the following conditions exist:
  - (a) The findings are scientifically valid and confirmed;

- (b) The findings have significant implications for the subject's or the public's health; and
  - (c) A course of action to ameliorate or treat the subject's or the public's health concerns is readily available.
4. Under conditions described in (3), the researcher shall determine and adhere to the expressed wishes and desires of the research subject in relation to disclosure of genetic information to that individual.
  5. When research results are disclosed to a subject, appropriate medical advice and referral must be provided.
  6. In all cases, a decision to recontact research subjects must have prior approval of the IRB.

Stat. Auth.: ORS 192.547

Stats. Implemented: ORS 192.547

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04;

PH 9-2004, f. & cert. ef 3-23-04

## **Obtaining Genetic Information for Identification of Deceased Individuals**

333-025-0135

### **Information Concerning Deceased Individuals**

1. Anyone permitted by Oregon law to dispose of the body of a deceased individual or who is authorized by ORS 146.113 to 146.117 to submit the DNA sample of an unidentified deceased individual to a DNA diagnostic laboratory may obtain or retain genetic information for the purpose of identification of the deceased. After identification, relevant information concerning the death shall be submitted into the permanent medical record of the deceased.
2. A DNA sample of or genetic information about a deceased individual may be used for medical diagnosis of blood relatives of the individual and for no other purpose except as otherwise authorized by law. A request to use a sample or information for such purpose may be made by:
  - (a) A representative designated by the decedent to act on the individual's behalf after death;
  - (b) The closest surviving blood relative of the decedent; or

- (c) If there is more than one surviving blood relative of the same degree of relationship to the decedent, by the majority of the surviving closest blood relatives of the decedent.
- 3. A DNA sample sent to a diagnostic laboratory for testing under Section (1) or (2) of this rule must be accompanied by an affidavit stating that the specific purpose for obtaining the DNA sample is to identify the deceased individual or is for medical diagnosis of blood relatives of the decedent, and for no other purpose.
- 4. A person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research, if the individual was deceased when the individual's biological specimen or clinical individually identifiable health information was obtained (OAR 333-025-0120).

Stat. Auth.: ORS 192.535, 192.537 & 192.539

Stats. Implemented: ORS 192.535, 192.537 & 192.539

Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0500 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0500 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0500 by PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

## **Informed Consent for Obtaining Genetic Information**

333-025-0140

### **Informed Consent Procedures**

- 1. Unless exempted by ORS 192.535(1)(a)-(f), all persons collecting genetic information must conform to standards of informed consent as follows:
  - (a) Physicians licensed under ORS Chapter 677, and any other licensed health care providers or facilities, shall obtain informed consent according to ORS 677.097;
  - (b) Except as provided in OAR 333-025-0120, a person conducting research shall obtain informed consent according to the procedure given in OAR 333-025-0115; and
  - (c) If genetic information is collected in connection with an insurance transaction governed by ORS 746.135, informed consent will be conducted in the manner

described by the Department of Consumer and Business Services under authority of ORS 746.135(1).

2. For persons not described in (1) above, informed consent must be obtained using the form and process contained in Appendix 1 of these rules or a form which is substantively similar.
3. Elements to be contained in a consent form for obtaining genetic information include:
  - (a) The name of the individual whose DNA sample is to be tested;
  - (b) The name of the individual, company, or organization requesting the genetic test for the purpose of obtaining genetic information;
  - (c) A statement signed by the individual whose DNA sample is to be tested indicating that he/she authorizes the genetic test; and
  - (d) A statement that specifies the purpose of the test and the genetic characteristic for which the DNA sample will be tested.
4. Process for obtaining informed consent using the form contained in Appendix 1 or a form that is substantively similar:
  - (a) Explain that the genetic test is voluntary;
  - (b) Inform the individual that he/she may choose not to have his/her DNA sample tested;
  - (c) Inform the individual that he/she has the option of withdrawing consent at any time;
  - (d) Explain the risks and benefits of having the genetic test, including:
    - A. A description of the provisions of Oregon law pertaining to individual rights with regard to genetic information and the confidential nature of the genetic information;
    - B. A statement of potential consequences with regard to insurability, employability, and social discrimination if the genetic test results or genetic information become known to others;
    - C. The implications of both positive and negative test results; and
    - D. The availability of support services, including genetic counseling.
  - (e) Inform the individual that it may be in his/her best interest to retain his/her DNA sample for future diagnostic testing, but that he/she has the right to

have his/her DNA sample promptly destroyed after completion of the specific genetic test which was authorized;

- (f) Inform the individual about the implications, including potential insurability, of authorizing disclosure to a third party payer that the genetic test was performed, and that he/she has the option of paying the cost of the genetic test out of pocket rather than filing an insurance claim;
- (g) Ask the individual whether he/she has any further questions, and if so, provide the individual with the opportunity to ask questions and receive answers from either a genetic counselor or another person who is sufficiently knowledgeable to give accurate, understandable and complete answers to his/her questions;
- (h) Request that the individual read, complete, sign and date the consent form; and
- (i) Provide the individual with a copy of the completed form for his/her personal records.

[Forms and Appendices referenced are available from the agency.]

Stat. Auth.: ORS 192.535

Stats. Implemented: ORS 192.535

Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0510 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0510 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0510 by PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

## **Retention of Genetic Information**

333-025-0145

### **Retention for the Purpose of Identification of Deceased Individuals**

1. Any person who is permitted by Oregon law to dispose of the body of a deceased individual, or anyone who is authorized by ORS 146.113-117 may retain the genetic information obtained from an unidentified deceased individual's DNA sample without specific authorization for the purpose of identification of the deceased individual.
2. Upon identification of the deceased individual, persons so authorized in Section (1) shall convey the deceased individual's genetic information to his/her permanent medical record.

Stat. Auth.: ORS 192.537 & 192.539

Stats. Implemented: ORS 192.537 & 192.539

Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0520 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0520 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0520 by PH 9-2004, f. & cert. ef 3-23-04

333-025-0150

### **Retention for the Purpose of Testing to Benefit Blood Relatives of Deceased Individuals**

Any person may retain the genetic information of a deceased individual indefinitely for the sole purpose of benefiting blood relatives of the deceased individual without specific authorization.

Stat. Auth.: ORS 192.535 & 192.537

Stats. Implemented: ORS 192.535 & 192.537

Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0530 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0530 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0530 by PH 9-2004, f. & cert. ef 3-23-04

333-025-0155

### **Retention for the Purpose of Newborn Screening Procedures**

The Department of Human Services may retain the blood samples of newborns collected for the control of metabolic diseases, as provided in ORS 433.285, for up to one year.

Stat. Auth.: ORS 433.285, 192.535 & 192.537

Stats. Implemented: ORS 192.535 & 192.537

Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0540 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0540 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0540 by PH 9-2004, f. & cert. ef 3-23-04

## Disclosure of Genetic Information

333-025-0160

### **Procedure for Authorization of Disclosure by the Tested Individual or the Tested Individual's Representative**

Except as provided in ORS 192.539, and except for research disclosures authorized by an Institutional Review Board in accordance with these rules, any person shall be required to obtain specific authorization from the individual on whose sample a genetic test was conducted, or an individual's representative, to disclose genetic information, by completing the consent form specified in ORS 192.522, or a form that is substantively similar and by using the following procedure:

1. Request that the tested individual, or his/her representative, read, sign and date the prescribed consent form; and
2. Read, sign, and date the prescribed consent form on behalf of the individual or organization requesting the release of genetic information; and
3. Provide the tested individual, or his/her representative, with a copy of the completed consent form for his/her personal records.

Stat. Auth.: ORS 192.539

Stats. Implemented: ORS 192.539

Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0550 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0550 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0550 by PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0165

### **Provider Notification and Opt Out**

1. A direct provider that is a covered entity and who obtains a biological specimen or clinical individually identifiable health information from an individual must:
  - (a) Notify the individual or his/her personal representative, in accordance with this rule, that the individual's biological specimen or clinical individually identifiable health information may be used or disclosed for anonymous or coded research; and
  - (b) Give the individual the opportunity to make an opt-out statement.

2. Any health care provider that is not described in Section (1) of this rule may, but is not required to, furnish the notification and opportunity for an opt-out statement described in Section (1) of this rule.
3. A health care provider described in Section (1) of this rule must provide notification no later than the time required for federal privacy notices by the Federal Privacy Rule for services rendered on or after July 1, 2006 (see 45 CFR 164.520).
4. If a health care provider is required to provide notification pursuant to Section (1) of this rule, the health care provider must provide notification at least once per individual, regardless of how many times the provider obtains the individual's biological specimen or clinical individually identifiable health information.
5. If a health care facility provides the notice pursuant to Section (1) of this rule, a health care provider providing care to patients in the health care facility is not required to provide an additional notice with respect to services provided in the facility.
6. Notification may be delivered in a manner determined by the health care provider within the requirements of this rule, including but not limited to any manner permitted for the provision of the notice of privacy practices required under the Federal Privacy Rule.
7. Notification must include:
  - (a) A place where the individual may mark to indicate the individual's opt-out statement;
  - (b) A general explanation of the meaning of anonymous and coded research;
  - (c) A statement describing that the biological specimen or clinical individually identifiable health information may be used at some undetermined point in the future without further notice to the individual;
  - (d) A statement that a refusal to allow use of biological specimens or clinical individually identifiable health information will not affect access to or provision of health care by the provider originally providing notice;
  - (e) A statement specifying that the individual retains the right to make or revoke an opt-out statement by submitting in writing such a request to the health care provider originally providing notice;
  - (f) A statement indicating that an opt-out statement will be valid from the date received by the health care provider;
  - (g) A prominent heading indicating the purpose of the notice; and

- (h) The name, or title, and telephone number or other contact information of a person or office to contact for further information.
8. If a health care provider is required to provide notification pursuant to Section (1) of this rule, notification may be, but is not required to be, provided using the form contained in Appendix 2 of these rules.
  9. Any health care provider described by Section (1) of this rule that receives an opt-out statement of an individual must, at the time of disclosure of a biological specimen or clinical individually identifiable health information, inform the indirect provider that is the intended recipient that the individual's biological specimen or clinical individually identifiable health information is subject to an opt out statement.
    - (a) Methods to inform the indirect provider may include, but shall not be limited to, marking or noting the biological specimen container or clinical individually identifiable health information as subject to an opt-out statement. The mark or notation may be in any form that can be understood by the intended recipient.
    - (b) If an opt-out statement is received after the completion of the first service delivery and within the first fourteen (14) days from the completion of the first service delivery, a health care provider is encouraged, but is not required, to make a good faith effort to inform the indirect health care provider of the opt-out statement.
    - (c) Any recipient of an individual's biological specimen or clinical individually identifiable health information from a health care provider described by Section (1) of this rule that is not informed of the individual's opt-out statement within fourteen (14) calendar days of receipt may presume that the individual has not made an opt-out statement.
  10. Any health care provider subject to Section (1) of this rule must have a process in place to demonstrate compliance with this rule.

[ED. NOTE: Forms and appendices referenced are available from the agency.]

Stat. Auth.: ORS 192.547

Stats. Implemented: ORS 192.531 - 192.549

Hist.: PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

*Directions: This form consists of two sections. Section 1 to be completed by the individual ordering the genetic test. Section 2 to be completed by the individual being tested.*

**Section 1: Checklist to be completed by individual ordering a genetic test**

The individual's DNA sample will be tested solely for the genetic characteristic below:

---

(Name of genetic characteristic)

**PROCESS TO FOLLOW PRIOR TO OBTAINING GENETIC INFORMATION:**

*After each of the points below have been clearly explained to the individual to be tested, or the individual's personal representative, please initial in the space provided to ensure that the informed consent procedure has been followed.*

- I have informed the individual that this genetic test is completely voluntary; that he/she has the option of withdrawing consent to the genetic test at any time.
- I have explained to the individual the risks and benefits of having a genetic test, including:
  - a description of the provisions of Oregon law pertaining to the confidentiality of genetic information;
  - a statement of the potential consequences regarding insurability, employability, and social discrimination if the genetic test results become known to others;
  - a statement explaining the implications of positive and negative test results, and the availability of support services, including genetic counseling.
- I have informed the individual that it may be in his/her best interest to retain the DNA sample for future diagnostic testing, but also of his/her right to have the DNA sample promptly destroyed after the specific purpose for which it was tested (unless retention of the sample is otherwise authorized by law).
- I have informed the individual that it may be in his/her best interest to retain the DNA sample for future diagnostic testing, but also of his/her right to have the DNA sample promptly destroyed after the specific purpose for which it was tested (unless retention of the sample is otherwise authorized by law).

EXAMPLE Consent Form, Obtaining Genetic Information

(Other forms may be developed and used that meet requirements)

- I have informed the individual about the meaning and purpose of the authorization form for disclosure of procedure to a third party payer, including:
  - an explanation of the potential risks of disclosure to third-party payers that a genetic test has been performed;
  - an explanation of the individual’s option to pay out-of-pocket for the cost of the genetic testing procedure.
- I have asked the individual whether he/she has any further questions; and if so, I have provided the individual with an opportunity to ask questions and receive answers from either a genetic counselor, or a person who is sufficiently knowledgeable to give accurate and understandable answers about genetic testing and its implications.
- I have asked the individual to read, complete, sign and date this consent form; and provided the individual a copy of this completed form for his/her personal records.

The above referenced information was explained by me, to the individual being tested, and the individual being tested signed this consent form in my presence.

---

Name of individual ordering genetic test

---

Signature of individual ordering genetic test Date

**Section 2: Model Informed Consent Form:**

*To be completed by individual being tested or the individual's personal representative.*

It has been explained to me that the procedure to be undertaken is a test of my DNA sample to obtain genetic information solely for the purpose(s) listed below. It has also been explained that consent to this procedure is completely voluntary. I have been told that there are risks and potential consequences regarding employability, insurability and social discrimination that may result from the collection of my genetic information.

**Please check one:**

- I have been asked if I want a more detailed explanation of the risks and benefits of genetic testing. I am satisfied with the explanation provided to me and do not need any more information.
- I have requested and received further explanation for the proposed genetic test and more information about the potential risks and consequences for the test for me and my family.
- I am satisfied with the additional information provided to me and do not need any more information.
- I have requested further explanation of the proposed genetic test and more information about the potential risks and consequences for the test for me and my family, and do not consent to the collection of my genetic information at this time.
- I consent to the collection of my genetic information for the purpose of:

---

and acknowledge that the results of this test or procedure will be recorded in my confidential medical record.

---

Name of individual ordering genetic test

---

Signature of individual ordering genetic test

Date

OAR 333-025-0140, Appendix 1  
EXAMPLE Consent Form, Obtaining Genetic Information  
(Other forms may be developed and used that meet requirements)

**OR**

---

Name of personal representative of individual consenting to test or procedure

---

Relation to individual consenting to test or procedure

---

Signature of personal representative of  
individual consenting to test or procedure

Date

**192.522 Authorization form.** A health care provider may use an authorization that contains the following provisions in accordance with ORS 192.520:

**AUTHORIZATION  
TO USE AND DISCLOSE PROTECTED  
HEALTH INFORMATION**

I authorize: \_\_\_\_\_ (Name of person/entity disclosing information) to use and disclose a copy of the specific health information described below regarding:

\_\_\_\_\_  
(Name of individual)

consisting of: (Describe information to be used/disclosed)

to: \_\_\_\_\_ (Name and address of recipient or recipients)

\_\_\_\_\_  
for the purpose of: (Describe each purpose of disclosure or indicate that the disclosure is at the request of the individual)

If the information to be disclosed contains any of the types of records or information listed below, additional laws relating to the use and disclosure of the information may apply. I understand and agree that this information will be disclosed if I place my initials in the applicable space next to the type of information.

\_\_\_\_\_ HIV/AIDS information

\_\_\_\_\_ Genetic testing information

\_\_\_\_\_ Mental health information

\_\_\_\_\_ Drug/alcohol diagnosis, treatment, or referral information.

I understand that the information used or disclosed pursuant to this authorization may be subject to redisclosure and no longer be protected under federal law. However, I also understand that federal or

state law may restrict redisclosure of HIV/AIDS information, mental health information, genetic testing information and drug/alcohol diagnosis, treatment or referral information.

## **PROVIDER INFORMATION**

You do not need to sign this authorization. Refusal to sign the authorization will not adversely affect your ability to receive health care services or reimbursement for services. The only circumstance when refusal to sign means you will not receive health care services is if the health care services are solely for the purpose of providing health information to someone else and the authorization is necessary to make that disclosure.

You may revoke this authorization in writing at any time. If you revoke your authorization, the information described above may no longer be used or disclosed for the purposes described in this written authorization. The only exception is when a covered entity has taken action in reliance on the authorization or the authorization was obtained as a condition of obtaining insurance coverage.

To revoke this authorization, please send a written statement to \_\_\_\_\_ (contact person) at \_\_\_\_\_ (address of person/entity disclosing information) and state that you are revoking this authorization.

## **SIGNATURE**

I have read this authorization and I understand it. Unless revoked, this authorization expires \_\_\_\_\_

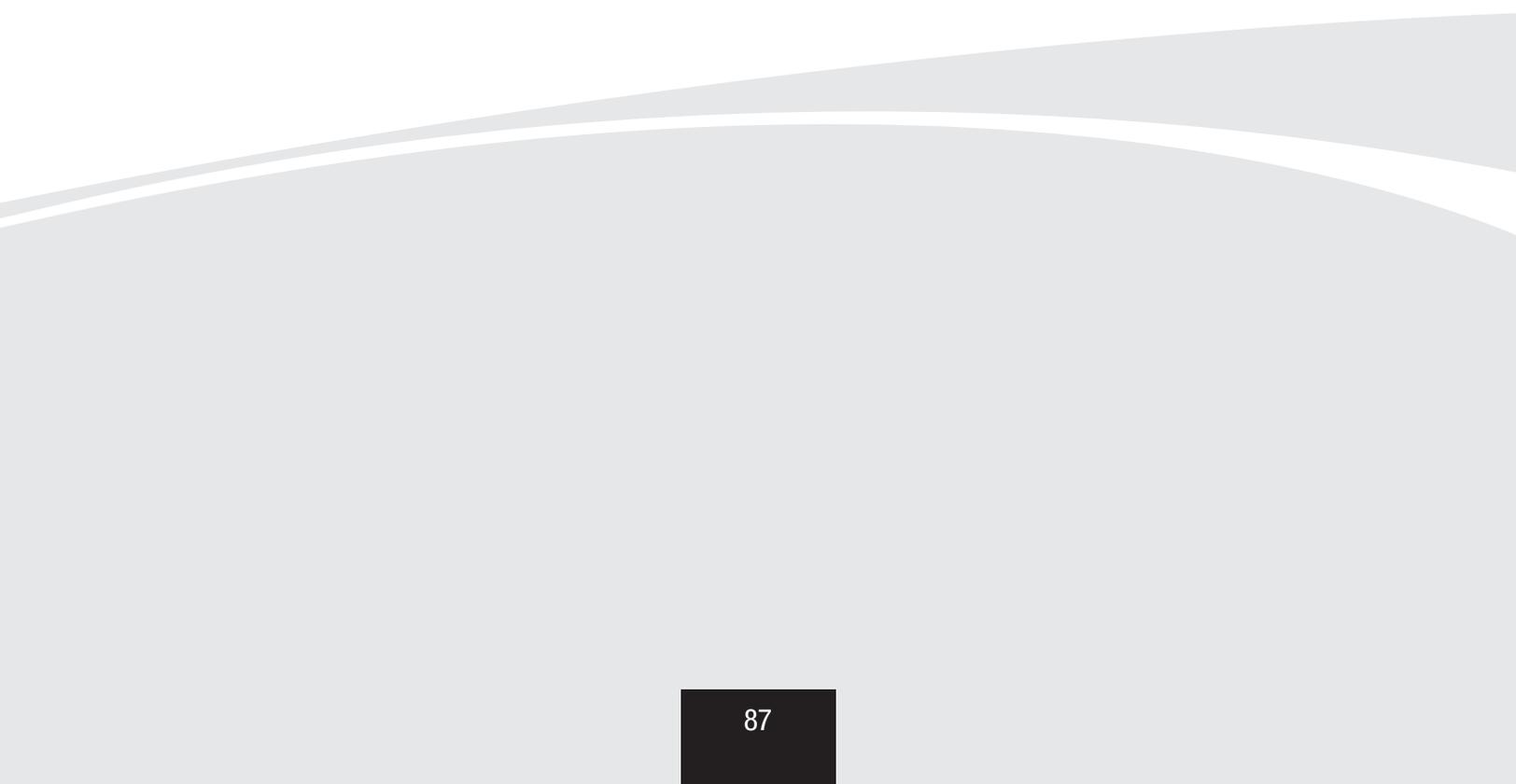
(insert either applicable date or event).

By: \_\_\_\_\_

(individual or personal representative)

Date: \_\_\_\_\_

Description of personal representative's authority:



# **2013 Report to the Oregon Legislature Advisory Committee on Genetic Privacy and Research**



**PUBLIC HEALTH DIVISION**  
Center for Prevention & Health Promotion

This document can be provided upon request in alternative formats for individuals with disabilities. Other formats may include (but are not limited to) large print, Braille, audio recordings, Web-based communications and other electronic formats. E-mail [derek.mills@state.or.us](mailto:derek.mills@state.or.us), or call 971-673-0249 (voice) or 971-673-0372 (TTY) to arrange for the alternative format that will work best for you.