Senate Bill 1025

Sponsored by COMMITTEE ON RULES

SUMMARY

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

Modifies requirements for use, retention and disclosure of genetic information and DNA samples. Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to genetic privacy; creating new provisions; amending ORS 192.531 and 192.547; and declaring an emergency.

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

SECTION 1. ORS 192.531 is amended to read:

192.531. As used in ORS 192.531 to 192.549:

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

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

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

(a) Related by blood to an individual; and

(b) A parent, sibling, son, daughter, grandparent, grandchild, aunt, uncle, first cousin, niece or nephew of the individual.

(4) "Clinical" means relating to or obtained through the actual observation, diagnosis or treatment of patients and not through research.

(5) "Coded" means identifiable only through the use of a system of encryption that links a DNA sample or genetic information to an individual or the individual's blood relative. A coded DNA sample or genetic information is supplied by a repository to an investigator with a system of encryption.

(6) "Covered entity" has the meaning given that term in ORS 192.519.

[*(6)*] **(7)** "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).

[*(7)*] **(8)** "Disclose" means to release, publish or otherwise make known to a third party a DNA sample or genetic information.

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

[*(8)*] **(9)** "DNA" means deoxyribonucleic acid.

[*(9)*] **(10)** "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)*] **(11)** "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)*] **(12)** "Genetic information" means information about an individual or the individual's blood relatives obtained from a genetic test.

[*(12)*] **(13)** "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)*] **(14)** "Genetic research" means research using DNA samples, genetic testing or genetic information.

[*(14)*] **(15)** "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)*] **(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.

[*(16)*] **(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.

[*(17)*] **(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.

[*(18)*] **(19)** "Obtain genetic information" means performing or getting the results of a genetic test.

[*(19)*] **(20)** "Person" has the meaning given in ORS 433.045.

[*(20)*] **(21)** "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

[*(21)*] **(22)** "Retain a DNA sample" means the act of storing the DNA sample.

[*(22)*] **(23)** "Retain genetic information" means making a record of the genetic information.

[*(23)*] **(24)** "Unidentified" means deidentified or not identifiable.

SECTION 2. Section 3 of this 2005 Act is added to and made a part of ORS 192.531 to 192.549.

SECTION 3. (1) Notwithstanding ORS 192.537 (3), a covered entity may retain genetic information of an individual without obtaining authorization from the individual or the individual's representative if:

(a) The covered entity conducts scientific or medical genetic research;

(b) The genetic information is being retained pursuant to the authorization requirements for research under the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164;

(c) The covered entity is using the genetic information for anonymous research and the use of the genetic information complied with ORS 192.537 (2); and

(d) The covered entity is conducting research in compliance with the rules adopted by the Department of Human Services under ORS 192.547.

(2) Notwithstanding ORS 192.539 (1), a covered entity may disclose genetic information of an individual without obtaining authorization from the individual or the individual's representative if:

(a) The covered entity conducts scientific or medical genetic research;

(b) The genetic information is being disclosed pursuant to the authorization requirements for research under the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164;

(c) The covered entity is using the genetic information for anonymous research and the use of the genetic information complied with ORS 192.537 (2); and

(d) The covered entity is conducting research in compliance with the rules adopted by the Department of Human Services under ORS 192.547.

SECTION 4. ORS 192.547 is amended to read:

192.547. (1)(a) The Department of Human Services 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 Department of Human Services 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 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, must disclose to the institutional review board the proposed use of DNA samples, genetic testing or genetic information.

(3) The Department of Human Services 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 Department of Human Services 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) The subject has granted informed consent for the specific research project or has consented

to genetic research generally.

(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)** [*In cases in which informed consent is required by either ORS 192.535 or the Federal Policy for the Protection of Human Subjects, samples collected before June 25, 2001, with blanket informed consent for research may be used for genetic research without specific informed consent, but samples obtained after June 25, 2001, must have specific informed consent from the individual for genetic research.*] **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 for genetic research if an institutional review board operating under subsection (1)(b) of this section waives or alters the consent requirements pursuant to rules adopted by the department under subsection (1)(a) of this section.

(c) Except as provided in paragraph (b) of this subsection, a person must have specific informed consent from an individual to use a DNA sample or the individual's genetic information obtained on or after June 25, 2001, for genetic research.

(8) Except as otherwise allowed by rule of the Department of Human Services, 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 Department of Human Services 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.

SECTION 5. This 2005 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2005 Act takes effect on its passage.
