

HOUSE AMENDMENTS TO A-ENGROSSED SENATE BILL 1025

By COMMITTEE ON STATE AND FEDERAL AFFAIRS

July 10

1 On page 5 of the printed A-engrossed bill, delete lines 43 through 45 and insert:

2 “**SECTION 6.** ORS 192.547 is amended to read:

3 “192.547. (1)(a) The Department of Human Services shall adopt rules for conducting research
4 using DNA samples, genetic testing and genetic information. Rules establishing minimum research
5 standards shall conform to the Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46,
6 that is current at the time the rules are adopted. The rules may be changed from time to time as
7 may be necessary.

8 “(b) The rules adopted by the Department of Human Services shall address the operation and
9 appointment of institutional review boards. The rules shall conform to the compositional and oper-
10 ational standards for such boards contained in the Federal Policy for the Protection of Human
11 Subjects that is current at the time the rules are adopted. The rules must require that research
12 conducted under paragraph (a) of this subsection be conducted with the approval of the institutional
13 review board.

14 “(c) Persons proposing to conduct anonymous research, **coded research** or genetic research
15 that is otherwise thought to be exempt from review must obtain from an institutional review board
16 prior to conducting such research a determination that the proposed research is exempt from re-
17 view.

18 “(2) A person proposing to conduct research under subsection (1) of this section, including
19 anonymous research **or coded research**, must disclose to the institutional review board the pro-
20 posed use of DNA samples, genetic testing or genetic information.

21 “(3) The Department of Human Services shall adopt rules requiring that all institutional review
22 boards operating under subsection (1)(b) of this section register with the department. The Advisory
23 Committee on Genetic Privacy and Research shall use the registry to educate institutional review
24 boards about the purposes and requirements of the genetic privacy statutes and administrative rules
25 relating to genetic research.

26 “(4) The Department of Human Services shall consult with the Advisory Committee on Genetic
27 Privacy and Research before adopting the rules required under subsections (1) and (3) of this sec-
28 tion, including rules identifying those parts of the Federal Policy for the Protection of Human Sub-
29 jects that are applicable to this section.

30 “(5) Genetic research in which the DNA sample or genetic information is coded shall satisfy the
31 following requirements:

32 “(a)(A) The subject has granted informed consent for the specific research project; [*or*]

33 “(B) **The subject** has consented to genetic research generally[.]; **or**

34 “(C) **The DNA sample or genetic information is derived from a biological specimen or**
35 **from clinical individually identifiable health information that was obtained or retained in**

1 **compliance with ORS 192.537 (2).**

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

4 “(c) The code is:

5 “(A) Not derived from individual identifiers;

6 “(B) Kept securely and separately from the DNA samples and genetic information; and

7 “(C) Not accessible to the investigator unless specifically approved by the institutional review
8 board.

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

11 “(e) The data is limited to elements required for analysis and meets the criteria in 45 C.F.R.
12 164.514(e) for a limited data set.

13 “(f) The investigator is a party to the data use agreement as provided by 45 C.F.R. 164.514(e) for
14 limited data set recipients.

15 “(6) Research conducted in accordance with this section is rebuttably presumed to comply with
16 ORS 192.535 and 192.539.

17 “[*(7) In cases in which informed consent is required by either ORS 192.535 or the Federal Policy*
18 *for the Protection of Human Subjects, samples collected before June 25, 2001, with blanket informed*
19 *consent for research may be used for genetic research without specific informed consent, but samples*
20 *obtained after June 25, 2001, must have specific informed consent from the individual for genetic re-*
21 *search.*.]

22 “**(7)(a) Notwithstanding ORS 192.535, a person may use a DNA sample or genetic infor-**
23 **mation obtained, with blanket informed consent, before June 25, 2001, for genetic research.**

24 “**(b) Notwithstanding ORS 192.535, a person may use a DNA sample or genetic informa-**
25 **tion obtained without specific informed consent and derived from a biological specimen or**
26 **clinical individually identifiable health information for anonymous research or coded re-**
27 **search if an institutional review board operating under subsection (1)(b) of this section:**

28 “**(A) Waives or alters the consent requirements pursuant to the Federal Policy for the**
29 **Protection of Human Subjects; and**

30 “**(B) Waives authorization pursuant to the federal Health Insurance Portability and Ac-**
31 **countability Act privacy regulations, 45 C.F.R. parts 160 and 164.**

32 “**(c) Except as provided in subsection (5)(a) of this section or paragraph (b) of this sub-**
33 **section, a person must have specific informed consent from an individual to use a DNA**
34 **sample or genetic information of the individual obtained on or after June 25, 2001, for genetic**
35 **research.**

36 “(8) Except as otherwise allowed by rule of the Department of Human Services, if DNA samples
37 or genetic information obtained for either clinical or research purposes is used in research, a person
38 may not recontact the individual or the individual’s physician by using research information that is
39 identifiable or coded. The Department of Human Services shall adopt by rule criteria for recon-
40 tacting an individual or an individual’s physician. In adopting the criteria, the department shall
41 consider the recommendations of national organizations such as those created by executive order
42 by the President of the United States and the recommendations of the Advisory Committee on Ge-
43 netic Privacy and Research.

44 “(9) The requirements for consent to, or notification of, obtaining a DNA sample or genetic in-
45 formation for genetic research are governed by the provisions of ORS 192.531 to 192.549 and the

1 administrative rules that were in effect on the effective date of the institutional review board's most
2 recent approval of the study.”

3 Delete page 6.

4 On page 7, delete lines 1 through 31.

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