



## Fact Sheet for Researchers and Institutional Review Boards Legislative Changes in Oregon's Genetic Privacy Law

### **What is the new law?**

- Senate Bill 1025 was passed by the 2005 Oregon Legislature and modifies requirements for use, retention and disclosure of genetic information and DNA samples. New administrative rules became effective January 1, 2006, and all requirements must be operative by July 1, 2006.
- The new law allows a waiver of consent for anonymous and coded genetic research if certain requirements are met as outlined below.
- Beginning July 1, 2006, health care providers who are “covered entities” must notify their patients that any specimens or health information collected will be available for anonymous<sup>1</sup> or coded<sup>2</sup> genetic research unless the person “opts out” by completing an opt-out form notifying the health care provider that she/he does not want her/his specimen or information available for coded or anonymous genetic research. Providers must also have a process in place to demonstrate compliance with this opt-out requirement.
- If an individual does not “opt out,” her/his specimen or information can only then be used for anonymous or coded genetic research if the research study is approved by a federally-qualified Institutional Review Board (IRB).

### **How is genetic research defined in the law?**

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

### **How do the changes affect genetic research in Oregon?**

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

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

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

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

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

### ***Where can I get more information?***

The Oregon Genetics Program website, [www.healthoregon.org/genetics](http://www.healthoregon.org/genetics) includes:

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

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- 1 "Anonymous" means that no one can identify the individual from whom the biological specimen or health information was obtained.
  - 2 "Coded" means that the individual from whom a biological specimen or health information was obtained cannot be identified without using a code or other encryption that is kept separately from the specimen or information. Researchers do not have access to the individual identifiers without special permission from an IRB.
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This fact sheet is provided by the Department of Human Services, Health Services to help health care providers comply with Oregon's Genetic Privacy Laws and related Administrative Rules (ORS 192.531 through 192.549. OAR 333-025-0100 through 333-025-0165). The law and rules contain many details that are not included in this fact sheet. You are encouraged to obtain legal consultation if you require more precise interpretation.