



Fact Sheet for Health Care Providers

2005 Legislative Changes in Oregon's Genetic Privacy Law

What is the new law?

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

What are the new administrative rules?

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

How do the changes affect me?

- Starting July 1, 2006, most Oregon health care providers must notify the patients they see or whose specimens they collect that they may "opt out" of having their health information or biological specimens used for coded or anonymous genetic research.
- You or your staff may be asked questions about the new law by your patients.
- If a patient notifies you by completing an opt-out form that she/he does not want her/his specimen or health information used for coded or anonymous genetic

research you must inform any indirect provider you send the patient's specimens or health information to of the patient's wishes. Also, you cannot use the patient's health information or specimens for such research yourself unless you obtain specific informed consent and IRB approval.

What do I need to do?

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

Where can I get more information?

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

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

-
- 1 "Anonymous" means that the no one can identify the individual from whom the biological specimen or health information was obtained.
 - 2 "Coded" means that the individual from whom a biological specimen or health information was obtained cannot be identified without using a code or other encryption that is kept separately from the specimen or information. Researchers do not have access to the individual identifiers without special permission from an IRB.
 - 3 An Institutional Review Board (IRB) is an independent group of scientists and non-scientists that is charged with protecting the rights and safety of research participants. In Oregon, any research study that includes genetic information must be approved by a Federally-qualified IRB before the study begins.
-

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