

**Advisory Committee on Genetic Privacy and Research
FINAL Minutes**

March 7th, 2012
1:30 – 3:00 pm

Room 368
Portland State Office Building
800 NE Oregon Street, Portland, OR 97232

Attendees

Members: Patricia Backlar, Hillary Booth, Kara Drolet, Ken Gatter (phone), Stuart Kaplan, Steve Nemirow (phone), Gayle Woods (phone), Laura Zukowski

Alternates: Karen E. Cooper, Beth Crane

Staff: Summer Cox, Robert Nystrom, Shannon O'Fallon, Bridget Roemmich

Guests: John Atkins (phone), Peter Jacky, Bob Shoemaker, Becky Straus

Members Not Present

Members: Anne Greer, Jenny Franks, Katrina Goddard

Alternates: Allison Naleway, Eran Klein, Gregory Fowler, John Sorensen, Paul B. Dorsey, Rhonda I. Saunders-Ricks, Terry Crandall

1. Introduction of attendees, including guests.
 - a. John Atkins, Policy Analyst, Oregon Insurance Division;
 - a. Peter Jacky, Kaiser Director of Molecular and Chromosome Diagnostic Lab, an author of the original Oregon genetic privacy law (OGPL);
 - b. Bob Shoemaker, former state senator, chair of Senate Committee on Healthcare and Bioethics 1989-1994, worked with Multnomah County Medical Society to draft, lobby and enact original OGPL;
 - c. Becky Straus, ACLU Legislative Director.
2. Review and approval, with edits (detail below), of minutes for February 2012.
 - a. Add to section on 2nd ACLU concern (bottom of pg 3), paragraph starting with "Another part of the reason". As there are certain situations where employers can still ask for genetic information, such as working with toxic substances, etc, add, "with certain exceptions" to "GINA prohibits employers from asking for genetic information".
 - b. Add to minutes that GINA is a national law.
 - c. Page 5, conclusion to section 3, change "ACLU supports the removal" to "ACLU does not oppose the removal".
3. Review of February discussion and remaining member concerns, committee agreed to postpone vote until all concerns are discussed.

Keep the legislative findings (192.533) in their entirety.

a. Section 1 (of March minutes): Committee members briefly reviewed the tentative decision to keep the legislative findings in their entirety (192.533); no concerns were raised.

Leave in the informed consent sections (192.535).

b. Section 2: Committee members briefly reviewed the tentative decision to leave in the informed consent sections (192.535); no concerns were raised.

- The committee does not expect this to change current clinical practice.
- The committee recognized that there might be additional work in the future to more clearly organize statutes that affect research, clinical practice and employment.

Continue efforts to more clearly organize statutes that affect research, clinical practice and employment.

- The committee recognized that the legislature has recently made changes to laws relating to HIV testing. Please see SB 1507: (<http://www.leg.state.or.us/12reg/measpdf/sb1500.dir/sb1507.en.pdf>). This bill removed the informed consent requirement for HIV testing and replaced it with the requirement that providers give notice and provide the patient with an opportunity to decline testing. These two things can be provided written or verbally and, if written, can be included in a general medical consent form. ORS 192.566 provides a sample authorization-to-disclose form that a health care provider may use that contains provisions in accordance with ORS 192.558 and that references release of both HIV and genetic information. See <http://www.leg.state.or.us/ors/192.html>. This sample authorization may need to be re-evaluated.

Recommend changes to OAR and ORS if decide to move forward with legislative concept.

- The rules regarding consent forms for obtaining genetic information (OAR 333-025-0140) and an example consent form (OAR 333-025-0140, Appendix 1), can be found at: <http://66.241.70.117/files/sb1025final.pdf>
- The committee agreed that it was their intent to recommend revisions to both the Oregon Administrative Rules (OAR) and the Oregon Revised Statutes (ORS) if they decide to move forward with the legislative concept.

c. Section 3: Committee members reviewed the tentative decision to remove the disclosure of genetic information section (192.539), and ultimately upheld their tentative decision to remove the section.

- Concern was raised that repeal of the existing Oregon law would leave the employees of small employers (less than 15 employees) without protection, where they do have protections under the existing law. It was voiced that removing this protection would be a great disservice to a large number of Oregonians.
 - Committee considered discussing use and disclosure of genetic information by employers and inviting employment specialists to inform our conversation.
 - The idea that this section is “the heart of the matter” in resolving conflicting definitions between OGPL, HIPAA and GINA was raised.
 - The committee considered the option of “divvying up” the text in

Repeal the disclosure of genetic information statute (192.539) in its entirety.

the statutes to remove the clinical piece, which seems to create the confusion around state and federal definitions, but leaving in the employer and research restrictions.

- Members thought that Oregon had quite a few “small” employers; though we were unsure about what instances this part of the law might protect people from.
- Shannon O’Fallon mentioned that leaving in section 659A.303 (state employment provision) would protect employees from disclosure by any size employee and also allow for private right of action. There may also be protections provided by the ADA.

- Committee members reaffirmed their decision to remove section 192.539.

- Also mentioned in this conversation:

- Disclosure coverage would still exist in HIPAA, GINA, and the ADA.
- GINA only covers group insurance plans.
- Statute 192.529, which refers to Oregon HIPAA (192.520), and thereby using GINA definitions, has been renumbered to 192.581.
- Disclosure of paternity results is excluded from the OGPL.

d. Section 4: Committee members continued the discussion around repealing the state employment provision (659A.303).

- Shannon O’Fallon stated that there appears to be a process in the federal law to sue for employment discrimination, but there may be some “hoops” that have to be jumped through with the EEOC.
- If we keep the state employment provision in the Oregon law, then we will retain the ability to pursue private right of action.
- We would still have enforcement authority for violations of the insurance code.
- We could use GINA definitions in this statute to eliminate possible confusion between state and federal law.
- The ACLU is in favor of retaining the state private right of action.
- If take out 192.539, do the state right of actions in 659A.303 retain meaning? HIPAA permits the state attorney general to enforce violations, so the state right of action would be upheld in that way. For employment, there may be federal right of action for enforcement of GINA through the civil rights act.
- Shannon O’Fallon mentioned the possibility of putting in “cannot disclose” language as well, so that even if employers somehow obtain genetic information, it cannot be disclosed or passed on.
- Small group insurance for small employers is “guarantee issue”, so there

Keep statute 659A.303 and add in wording to protect against disclosure if inadvertent obtainment of information.

Repeal the disclosure of genetic information statute (192.539) in its entirety.

would not be a denial of coverage. Though the insurer would look at aggregate claims data that can influence the rates to a certain degree, no specific information is provided to the employer about what led to the rate offered. This would not indicate people with a genetic condition (or a chronic health condition).

- Not all employers are benevolent, which argues that we should keep protections for groups of all sizes.
- Keeping 659A.303 would address all of these concerns.

❖ Members expressed support of 1) keeping the 659A.303 statute, 2) adding in “disclosure” wording to the 659A.303 statute in order to protect against disclosure in the case of inadvertent obtainment of genetic information, 3) removing the disclosure of genetic information section (192.539).

- e. Section 5: Committee members continued the discussion about adding provisions to 192.535 that cover obtaining and retaining genetic information.
- Members revisited the difficulties this would cause to current clinical practice and the technological and ethical issues that would arise from removing information from a patient’s medical file.
 - ACLU queried the handling of a biological sample and asked if the repeals suggested in 192.537 would take away the informed consent of the patient to retain their biological sample.
 - 192.551 (formerly 192.529) only speaks to genetic information (not biological sample).

192.581 Allowed retention or disclosure of genetic information. (1) Notwithstanding ORS 192.537 (3), a health care provider may retain genetic information of an individual without obtaining an authorization from the individual or a personal representative of the individual if the retention is for treatment, payment or health care operations by the provider.

(2) Notwithstanding ORS 192.539 (1), a health care provider may disclose genetic information of an individual without obtaining an authorization from the individual or a personal representative of the individual if the provider discloses the genetic information in accordance with ORS 192.558 [formerly 192.520] (3).

(3) As used in this section, “retain genetic information” has the meaning given that term in ORS 192.531. [Formerly 192.529]

- ACLU repeated concern about repeals to 192.537, especially around subsection (3), (4), and (5), which might result in taking away protections related to retention of a biological sample.
- Healthcare providers are required to retain samples under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as part of their quality control and is not dependent on patient consent. To give out clinical information, laboratories have to be CLIA compliant and CLIA approved.
- ACLU queried that if national laws require the retention of biological

samples for clinical purposes, why do we have 192.537(4) in the current statutes (note: in the repeal version, original subsections 3 – 9 are suggested to be removed, original subsection four is located on page 6).

- Members discussed that this section may have been largely intended for research when the original legislation was created.
- This is an example of how confusing these statutes can be, making it difficult for clinicians and researchers to follow the law.
 - Our original purpose of reviewing the OGPL was to see if we could clean up or simplify the confusing and conflicting sections while retaining the research, employment and insurance provisions that protect Oregonians from misuse of genetic information and genetic samples.
- Shannon suggested that the retention and destruction aspects of the OGPL might conflict with a variety of other laws.
- In the clinical setting, 192.538(1) currently requires covered entities to give notice that describes the extent to which they are going to retain or disclose the sample and information for anonymous or coded research (vs any/all retention). This provides the notice and the opportunity for people to opt-out. This section is proposed to be retained.
- Samples are retained for research reasons AND clinical reasons (e.g., to test when have new technology that impacts treatment) and we need to leave room for both activities.
 - Research needs to retain the option to opt-out of research, but clinical practice needs to be able to follow federal oversight laws and retain purposes for auditing and diagnostic purposes. The OGPL needs to more distinctly separate research and clinical requirements.
- ACLU voiced remaining concerns about removing the original 192.537 (5), (6), (7), (8) (page 6 of draft repeal version).
 - Covered in other laws or already covered in consent and notification process
 - HIPAA only covers genetic information (not samples)
- Members discussed the ACLU suggestion to retain 192.537(5) in order to address concerns with destruction of genetic samples after research has ended, and supported the idea but emphasized that the genetic information gained from the samples must be retained.
- General support for efforts to more clearly identify the statutes that regulate the three areas of research, clinical practice, and insurance was reiterated.

ACLU requests more time to discuss these matters.

❖ ACLU requests more time to discuss these matters further, but members

generally expressed support of 1) NOT adding provisions to 192.535 that cover obtaining and retaining genetic information, and 2) retention of 192.537(5).

4. Summary, Updates and Next Steps.

- a. It was the general sense of the committee that we have made a lot of progress and that these discussions are moving towards our original goal of consolidating the research pieces and removing or clarifying some clinical pieces in order to harmonize with HIPAA. We anticipate being able to resolve the details and language of the proposed selective repeal legislation in the near future
- b. Written draft of proposed changes to the Common Rule is expected to be posted in June 2012.
- c. Per Katy King, legislative concepts are going to be returned to in April, which is an important timeline to keep in mind if we are expecting that OHA would carry the legislative concept to the legislature.
 - Currently the legislative concept is represented as a technical fix, but it must be acknowledged that not all members agree that the current selective repeal draft is a purely technical fix and feel that we should avoid such misleading terminology.
 - OHA wants to bring very few legislative concepts to the legislature.
- d. Another (preferred) option would be to have our ACGPR legislative representative bring the legislative concept forward.
 - This option would allow us more time, but we would need to file pre-session, by August 2012 at the latest.
 - Oregon Genetics Program will work with Katie King to identify ACGPR legislative appointments (Elizabeth Steiner suggested).

5. Adjourn

Next Meeting
April 4th, 2012
1:30 – 3:00