

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

February 1st, 2012
1:30 – 3:00 pm

Room 1B
Portland State Office Building
800 NE Oregon Street, Portland, OR 97232

Attendees

Members: Anne Greer, Kara Drolet, Ken Gatter, Laura Zukowski, Patricia Backlar, Stuart Kaplan

Alternates: Beth Crane

Genetics: Bridget Roemmich, Summer Cox

Guests: Shannon O'Fallon, Peter Jacky, Bob Shoemaker

Members Not Present

Members: Gayle Woods, Hillary Booth, Jenny Franks, Katrina Goddard, Steve Nemirow

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

1. Review and approval, with edits, of minutes for January 2012
2. Introduction of attendees, guests:
 - a. Shannon O'Fallon, Assistant Attorney General;
 - b. Peter Jacky, geneticist with Kaiser, Director of Molecular and Chromosome Diagnostic Lab, one of the authors of the original Oregon genetic privacy law (OGPL);
 - c. 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.
3. Discussion of select repeal draft and member concerns.

Background discussion: The federal Genetic Information Nondiscrimination Act of 2008 (GINA) is based on a non-discrimination model and is mostly concerned with genetic information, and protecting people from any discriminatory use of the information. HIPAA has adopted the GINA language and genetic information is protected as protected health information (PHI) under HIPAA. Neither GINA nor HIPAA cover obtainment of information with the same breadth as the Oregon law, but instead govern the use of the information once it is held. Our state law is

primarily a consent model with some non-discrimination features and focused on genetic privacy. The state law regulates the obtainment of genetic information, the “how” one comes into possession of the genetic information.

We are trying to resolve the inconsistencies and potential conflicts between GINA, HIPAA and state law. Many of the conflicts are because of the different definitions. The difficulty for those who are subject to both the federal and state law is in determining how to comply with both when the definitions around what is genetic information are different. Members agreed the main goals were to 1) evaluate what sections of the OGPL were still necessary given current federal laws, and 2) simplify law were possible so that people can more easily follow it.

Shannon described the current draft repeal legislation. In this draft, she has marked where sections were moved to or from and provided reasoning behind suggested changes. Changes in draft repeal version may look larger than they actually are, as Shannon tried to take out anything that was adequately covered by federal law. For example, where GINA is adequately protective in the sense of prohibiting discrimination, Shannon suggests taking out similar provisions in state law. And where there are adequate provisions in GINA and HIPAA governing confidentiality, Shannon suggests taking those out of state law. The current draft legislation maintains the research provisions, notice, opt-out and insurance provisions. Though Shannon has brought all of the research related legislation scattered throughout statute into one section (192.537).

In terms of changes from the existing state law, the changes may not be substantive in practice. For example, there are a couple of places state law talks about “no person” disclosing genetic information, whereas HIPAA governs covered entities and GINA covers employers with 15 or more employees and insurers underwriting group insurance. If we removed the OGPL provision, we would lose the broad protection offered by the “no person” language of the current statute. However, the question is: Who else out there has the genetic information that we are concerned about them disclosing? Especially since discrimination is prohibited in insurance and employment. This is a policy decision that the committee needs to make. It was noted that smaller employers (less than 15 employees) are not covered by GINA and their employees might lose protections if the Oregon statutes were repealed.

The ACLU identified five areas of concern.

1) Legislative findings should remain in their entirety.

Shannon had suggested that some be taken out, as they may no longer reflect the current thinking of the committee, such as genetic privacy being inadequately protected. However, the legislative findings have no legal significance and can be left unaltered. The ACLU voiced the importance of maintaining the original articulation of legislative intent, even though we now have federal laws that overlap with the OGPL.

- Committee members informally agreed (no vote was taken) to keep the legislative findings in their entirety.

2) **192.535 (informed consent to obtain genetic information from an individual) should explicitly address the protection of informed consent to obtain genetic information.**

There is a concern that if we take this out, we are losing the positive protection that exists in state law and that also is supported by a private right of action if someone was to violate the law. This is another policy decision that the committee needs to make. Currently, statute 192.535 lists exceptions, refers to other statutes that govern physicians and other healthcare professionals, and refers to OHA obligation to supply a sample informed consent form. Current law allows delegation of obtaining informed consent, the only gap in protection if this is repealed is with unlicensed providers or facilities.

If informed consent for testing is a matter of standard practice, common law and statute for physicians and other healthcare providers, do we need this section of the law? If obtaining genetic information by insurers and employers is prohibited and if discrimination is prohibited, then what are we protecting against? Especially if the committee is moving away from the idea of genetic exceptionalism and genetic information should be treated like other medical information, this section of the law may not be necessary.

ACLU voiced doubt that the verdict about genetic exceptionalism has been officially decided by the committee and that the debate had been mainly philosophical. Because of this they request that disagreement with the idea behind genetic exceptionalism not be used as a premise to recommend repeal of the informed consent sections of the legislation.

In a healthcare setting, physicians and other health care providers are covered by ORS 677.097. Federal law does not tell practitioners in states how to obtain informed consent. Informed consent is state regulated, but the OGPL didn't add anything for obtaining a genetic test in a health care setting because it referred to the previously existing state law about informed consent. So in the healthcare setting, we lose nothing by deleting the provision. Informed consent in a research setting is covered in another statute as well. So who else is obtaining genetic information? Who are we regulating? What about universities that test for Sickle Cell trait? What about Direct to Consumer testing?

Another part of the reason to remove the informed consent section is that it does not add protections beyond those already provided elsewhere in the healthcare and research settings. It does, however, remove the requirements for informed consent in any other (non healthcare, non research) setting. GINA prohibits employers from asking for genetic information, with certain exceptions. A healthcare provider is the only one that can order a test from a lab, and they have other statutes that require

informed consent. HIPAA governs the use and disclosure of information by covered entities.

This provision addresses something broader than the federal provisions, as neither HIPAA nor GINA speak to informed consent. 192.535 refers to anyone obtaining genetic information from an individual.

Member question: What would be the downside of leaving the informed consent provision as it now stands? General answer: the provision doesn't change anything in the healthcare setting, but makes the law harder to comply with because of the added complexity.

Many physicians are frustrated by the broad definitions of genetic information and the different definitions used by state and federal laws. The original idea in focusing on the repeal draft was that if we could take out the sections that were covered by GINA, we would be simplifying the law by not having the differing definitions covering the same protections. Since the federal law does not cover the informed consent piece, we are not really addressing that concern in this case. With this remaining in the state law, we may have federal law defining genetic information more narrowly (committee not sure), while the state law covers informed consent with a broader definition of genetic information (so we have not achieved our goal of simplifying the law and making it easier to follow). However, the confusion is more likely to occur in the retention and disclosure sections, than in the informed consent section.

What about this unknown group of people who may be obtaining genetic information that are not licensed healthcare providers? Do we need to protect against them? Ultimately, we are balancing a small amount of additional protection offered by this informed consent provision with the cost of having a less clear law. The ACLU of Oregon's position is that the benefit of more comprehensive privacy protection outweighs possible benefits from simplifying the wording of the law. It should be noted that the "reconciliation" version that we discussed did keep this informed consent provision. Furthermore, case law supporting informed consent existed prior to the passage of OGPL, yet the Legislature felt that it was still beneficial to have a specific informed consent provision for genetic information. ACLU feels it is important to keep this in the law, to assure full protection and not assume protections are provided by common law and other provisions.

- Committee members informally agreed (no vote was taken) to leave in the informed consent sections.

3) 192.539 (disclosure of genetic information) should remain in so that employers are regulated by disclosure laws.

Removal of this provision has been suggested because HIPAA and ORS 192.520 (Oregon HIPAA) are thought to adequately protect genetic

information. However, the current provision applies to anyone, not just a HIPAA covered entity or a GINA covered entity. GINA requires covered entities (employer, employing office, employment agency, labor organization or joint labor management committee) to treat genetic information about an employee or member as confidential. Even under the ADA the employer would be liable for disclosing genetic information about an employee. It was noted that there is still a subset of employers with less than 15 employees, who are not covered (under GINA). The ADA may also have a employer size clause.

This is the section that would continue the confusion and conflict in definitions because 192.529 we refer to Oregon HIPAA (192.520) and HIPAA uses GINA definitions. This leaves open confusion about when and what kind of information one can disclose without authorization. Members strongly expressed support of removal of this section.

- ACLU does not oppose the removal of this section, committee members informally agreed (no vote was taken) to remove this section.

4) In repealing 659A.303 (state employment provision), we might lose the state private right of action.

659A.303 is proposed to be repealed because GINA has broader protections. This section of the state law allows private right of action, and one concern was that in repeal we would lose this along with the state enforcement provisions. Shannon is still trying to get an answer to this, but it appears that under the federal rules there is a private right of action through the civil rights act. There are provisions that allow for recovery of damages, including punitive damages. It may be, though, that you have to jump through some hoops with the federal EEOC before you could try to enforce this law on your own, rather than having a federal agency do it for you. To date, we do not know of any litigation or enforcement of this provision. If we keep this section, we will need to use the GINA definitions of genetic information.

- Members did not express strong feeling around the repeal of this section, other than the repeal might simplify the law. ACLU will discuss this further, committee members agreed to defer this decision to the next meeting.

5) Add provisions to 192.535 that cover obtaining and retaining genetic information.

Though legally possible, this would change current practice, requiring consent to obtain and consent to retain. 192.529 addresses retention and disclosure and refers to HIPAA, which has GINA definitions. Having a statute that requires consent to retain information implies that a patient can refuse consent and the information would have to be removed from the patient record. However, it is not technologically or ethically possible to

remove information from the medical file. The provider has to enter and retain information all information gathered about their patients, the information is protected through GINA and HIPAA. Adding obtaining and retaining provisions to 192.535 could be done legally, but could not be done in practice. Part of the issue as that we have deferred to another set of statutes that govern how physicians gain the patients informed consent.

- Committee members informally agreed (no vote was taken) that there is not a practical way to make sure that authorization to retain is part of the informed consent to obtain disclosure. The ACLU will need to discuss this matter further.

4. Decision on legislative concept – final decision postponed until next meeting

- Legislative concept for the 2013 legislative session needs to be completed by March 2012. The full legislative concept needs to include direction and clear detail of suggested changes to the law, along with reasoning for changes. We do not need final language at that time.

5. Next Steps – ACLU will continue discussion and communicate with Shannon and Oregon Genetics Program; Summer will send pertinent ACLU communications out to the entire committee; Summer will send out the 192.529 language.

6. Adjourn

**Next Meeting
March 7, 2012
1:30 – 3:00**