

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

January 4th, 2012
1:30 – 3:00 pm

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

Attendees

Members: Anne Greer (phone), Hillary Booth, Kara Drolet, Katrina Goddard, Ken Gatter, Laura Zukowski, Patricia Backlar, Steve Nemirow (phone), Stuart Kaplan

Alternates: Beth Crane

Genetics: Bob Nystrom, Bridget Roemmich, Summer Cox

Guests: Becky Straus, John Atkins, Shannon O'Fallon

Members Not Present

Members: Gayle Woods, Jenny Franks

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

1. Introduction of attendees
 - a. Guests: Shannon O'Fallon, Assistant Attorney General; Becky Straus, ACLU; John Atkins, Oregon Insurance Division
2. Review and approval of minutes for December 2011
3. Kara Drolet provided a brief background for our discussion
 - a. Introduction of the Common Rule and the advanced notice of public rulemaking (see handout for detail); comment period now closed.
 - b. Issue 2 (of handout) is the most relevant to our discussion. Proposed changes would require written consent for research use of bio-specimens (even de-identified), and is similar, though more broad (protects all bio-specimens, not only genetic), to Oregon's opt-out for genetic research. The proposal is currently more similar to an opt-in process. If/when such changes go into effect, the research section of the Oregon Genetic Privacy Law (OGPL) will

be redundant.

- c. Since these are not yet drafted rules, the timing and wording of final rules are unknown, but a significant overhaul of the Common Rule is a likely outcome in the next few years.
4. Feedback from members about discussions within their organizations and with stakeholders:
- a. Kara – reconciliation will likely take more effort to identify potential impact to institutions; Common Rule changes are likely to happen at some point and might make research protections of OGPL redundant; selective repeal that leaves the research protections unchanged is more feasible.
 - b. Anne – stakeholders at the recent hospital association compliance meeting were uniformly supportive of repeal or selective repeal that included the research opt-out; agreement that existing federal and state laws (other than OGPL) would provide the necessary protections.
 - c. Ken – physicians supported any efforts to simplify the current language and reduce conflicts with other state and federal laws; overall there was a preference for repeal or selected repeal to reconciliation; there is an obvious need to make research easier to conduct within the state and between states, the law should be simplified and re-evaluated at the very least.
 - d. Katrina – researchers expressed that the federal laws provide sufficient protections and are in favor of a complete repeal of the OGPL.
 - e. Stuart/Becky – ACLU does not support a full repeal of the OGPL at this point; would like more information before weighing in on a selected repeal; there is concern that if GINA changes, or if rules are adopted that are different than we anticipate, Oregonians might lose current protections (if OGPL is not fully in place); enforcement mechanisms need to be maintained, if not strengthened.
 - f. Beth – voiced support for GINA's broader definition of family member (vs. blood relative), and would like to see the adoption of GINA language, which feels more respectful and egalitarian, in the OGPL.
 - g. Trish – strongly supports a complete repeal of the OGPL, and

believes that we can rely on current federal law to provide the necessary protections. Oregon needs to be able to easily conduct research and collaboration with those outside the state. Federal legislation provides sufficient to protections and will not inhibit research and the dollars that will follow.

5. Revisited expense of opt-out and student project (flawed)
 - a. Expense of opt-out was affected by each system's interpretation and implementation of the requirements.
 - b. Requirement of ANY covered entity (not just hospitals); varied levels of awareness and compliance.
 - c. Great misunderstanding of notice requirements and who should be making the decision (patients vs. providers).
6. Current draft of selected repeal keeps criminal penalties; keeps private right of action; and keeps research opt-out requirement.
7. Retention discussed
 - a. Retention not covered by GINA; members unsure if retention is directly addressed by HIPAA
 - b. From the hospital/clinic perspective, the OGPL retention requirement may not affect how an entity handles, discloses and uses genetic information. There is no benefit to consumer, nor a burden on the entity. Samples are retained in accordance with state law requirements, while information is retained in the medical record.
 - c. The research authorization covers how long a sample will be kept or when it will be disposed of. If a sample is obtained for research purposes, the patient can request destruction of the specimen; though information derived from the specimen will be maintained.
8. Shannon offered the possibility of drafting legislation that provides broad rulemaking authority to OHA, so that we can create rules to maintain the current opt-out requirements, but would allow us to change the rules more easily in the future if changes to the Common Rule make the research protections redundant (vs. going back to the legislature to make statute changes).
 - a. Move the opt-out piece of OGPL into a rule making process
 - b. Provide statutory rulemaking authority to OHA

9. Bob reminded us that the legislative concept placeholder is for the 2013 legislative session; we will need to have a full legislative concept (direction and clear detail of changes and reasoning) by March 2012, but do not need final language at that time.
10. Katrina Goddard spoke about the interpretation of GINA notification rule by insurance organizations such as Kaiser. Kaiser interprets GINA to require opt-out similar to OGPL. Currently, NW Kaiser sends form explaining OGPL out to all new members, which they can sign and send back if they want to “opt-out”. (Originally had a mass mailing of all members). Hawaii Kaiser has started to send out a similar letter to patients in order to be compliant with current federal law (because they are an insurer).
11. Review of options regarding the Oregon Genetic Privacy Law
 - a. Selective repeal
 - Many members spoke in support of continuing discussion
 - Benefits of aligning OGPL with GINA now include: federal time line in uncertain (e.g. when will the Common Rule changes happen); need to have legislation that is clear and easily implemented; can revisit these issues in future, as federal rules change.
 - b. Complete repeal
 - Many members expressed concern that complete repeal at this time is premature; there was concern that federal laws do not yet provide adequate protection, including use of genetic samples & information in research, lack of criminal penalties, and lack of state private right of action.
 - GINA does not cover use of tissues, only information.
 - This option should be re-evaluated when Common Rule changes or any change to federal law or rules change.
 - c. Reconciliation
 - no members spoke in support of this option
 - d. Take no action
 - no members spoke in support of this option
12. Next Steps
 - a. Shannon will revise the selective repeal draft and provide

information about the differences between the selective repeal and reconciliation versions.

- b. Members will review revised selective repeal and identify specific concerns they have with the selective repeal
 - Please let Shannon know in advance about questions regarding how or why a specific change to the law was suggested.
- c. Members will invite stakeholders to join our next meeting
 - Anne will invite Gwen Dayton and/or others
 - Becky/Stuart will ask Dave Fidanque to weigh in
 - Trish had some stakeholders to invite or speak with (Alex Capron (USC) and someone from the FDA)
- d. We do not necessarily need unanimous agreement from committee members. However, we want general consensus before we present anything to the legislature. Dissenting members can write a minority report or speak at legislative hearings.

13. Adjourn

<p style="text-align: center;">Next Meeting February 1, 2012 1:30 – 3:00</p>
