

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

December 7th, 2011
1:30 – 3:00 pm

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

Attendees

Members: Anne Greer, Jenny Franks, Kara Drolet, Katrina Goddard (phone), Ken Gatter, Patricia Backlar, Steve Nemirow (phone), Stuart Kaplan

Alternates: Beth Crane, Eran Klein

Genetics: Bob Nystrom, Bridget Roemmich, Summer Cox

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

Members Not Present

Members: Gayle Woods, Hillary Booth, Laura Zukowski

Alternates: Allison Naleway, 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 June 2011
3. Brief overview of history of Genetic Privacy Laws and current situation
 - a. Redundancy and potential conflict between language in GINA/HIPAA and the OGPL
 - b. Meeting objective - to make a decision on whether to move forward with a legislative concept, four options to consider:
 - Select repeal of some OGPL sections (draft legislation)
 - Reconciliation of OGPL to federal laws (draft legislation)
 - Repeal of OGPL in its entirety (use federal protections only)
 - Take no action at this time (see how Common Rule changes)
4. Review & discussion of reconciliation and select repeal draft legislation, led by Shannon O'Fallon
 - a. Please see draft legislation documents for detail of individual comments from Shannon

- Reconciliation is largely an issue of clarifying definitions and rewording/reorganizing to clarify some sections
- Select repeal removes redundancy, leaves the informed consent requirement for research, private right of action, and advisory committee sections. Also keeps the “retention” language versus only collection/disclosure.

5. Other discussion points included:

- a. HHS recently announced an advance notice of proposed rulemaking (ANPRM) to the Common Rule, with significant changes designed to strengthen protections for human research subjects, including an opt-out for anonymous/coded research involving biospecimens that is similar to Oregon’s protection.
 - Proposed changes may make the research part of OGPL redundant
 - Comment period is now closed, next proposed rules will be created and a comment period will open, uncertain of timeframe for final rules
- b. OGPL is broader than federal law in some areas of insurance
 - Insurance protections are more specific and allow for enforcement and regulation
 - may cover more insurance entities than HIPAA (unclear to us what entities are covered by federal laws)
- c. Although HIPAA generally does not require authorization for treatment, payment, and health care operations, the OGPL currently defaults to regular medical practice for consenting by physicians as part of genetic testing for medical care
- d. Bob Nystrom reported that in order for this to be on the 2013 legislative session, the committee would need to make a decision by March 2012.

6. Next Steps

- a. Check within your organizations and with stakeholders to gather opinions on this matter
- b. Consider how GINA is being implemented in other states and possible unintended consequences of changes to OGPL
 - Particularly looking at how affects research conducted by insurance orgs: ‘Additional’ protections afforded by only partial repeal of the OGPL may only affect research at non-insurance organizations, since organizations, such as Kaiser, must follow a notification rule based on federal law (GINA).

Depending on how the notification rule is interpreted, this may mean that organizations such as Kaiser must implement an opt-out consent for research based on GINA, and the OGPL is redundant, at least for these organizations. This is the current interpretation of GINA by Kaiser for non-Oregon regions that we must have a notification with opt-out consent. The additional protections by the OGPL may then become relevant only to research at non-insurance organizations. Perhaps this needs to be made more clear in the language, especially if we go with reconciliation or partial repeal.

c. Committee to meet on January 4th to continue discussion

7. Adjourn

<p>Next Meeting January 4, 2012 1:30 – 3:00</p>
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