

# Advisory Committee on Genetic Privacy and Research Meeting Minutes — Mar. 7, 2007

**FINAL**

## Attendees:

Mike Garland, Mary Pat Bland, John Anderson, Mark Loveless, Marc Marenco, Bob Nystrom, Kara Manning Drolet, Theodore Falk, Allison Naleway, Steve Nemirow, Gregory Fowler, Terry Crandall, Patricia Backlar, Gwen Dayton

## February Agenda overview:

1. Agenda approval
2. Approval of Minutes for Feb 2006
3. Meeting time will be 1:30 – 3 on a trial basis.
4. Update on SB 759  
-Gwen Dayton
5. 2007 ACGPR Activities
  - a. Genetic Exceptionalism plan of action
  - b. Monitoring the impact of Oregon's Genetic Privacy Laws
  - c. Education Subcommittee Update
6. Discussion of genetic discrimination articles: Kass et al and L. Goslin.
7. Adjourn

## 1, 2, 3 - Outcome:

- The agenda was approved, and the minutes were approved. Time for meetings is set to 1:30 – 3 pm on a trial basis.

## 4 – Update on SB 759 – Gwen Dayton

The bill is out of legislative council, and seems to be drafted ok. The sponsor is the Committee on Rules. Need a rep from the insurance industry to assist in working with/educating the legislators re:SB 759. Maybe Gayle Woods could assist? Or Bart ?McMell or John Powell or Art ?Bedit? Gwen and Betsy Earl (KP lobbyist) spoke with Senator Burdick (Judiciary Committee Chair) about SB 759.

It is possible that an early amendment is needed to address the following issue: modification of the definition of “genetic test” to include “metabolite” and remove “proteins” (see below).

“**Genetic test**” means a test for determining the presence or absence of genetic characteristics in an individual or the individual’s blood relatives, including tests of nucleic acids such as DNA[,] **and** RNA [*and mitochondrial DNA*], chromosomes or [*proteins*] **metabolites** in order to diagnose or determine a genetic characteristic." Matter in **boldfaced** type is new. Matter in *italic* and [brackets] is to be omitted.

Members of the committee uncertain why this language change was made back in the previous version of SB 759 (2005 legislative session-SB 99). Seems likely that modification was put forward to have definition of genetic test be more inclusive and account for testing done to diagnosis genetic conditions via individual amnio acids etc (e.g. testing for PKU). Some individuals have raised concerns that the inclusion of “metabolites” in the definition of “genetic test” could have serious, unintended consequences (e.g definition of genetic test would be expanded to include many common

diagnostic lab tests for disorders which are almost always biochemical rather than genetic in nature (e.g., diabetes, kidney disease, liver disease, etc.)). Committee will try to identify who suggested wording and determine if it is prudent to continue to include this updated definition of “genetic test” or if amendment to SB 759 should be put forward to return definition of genetic test to that currently in law (see below).

“**Genetic test**” means a test for determining the presence or absence of genetic characteristics in an individual or the individual’s blood relatives, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.

Somewhat related to this issue, Gwen noted would be very helpful for hospitals and providers if guidance around “what is a genetic test” and “what is not a genetic test” could be created. It was determined this is best done by DHS providing a guidance document instead of changing administrative rules. DHS Genetics program will work on a draft. Mike Garland will assist as this ties in nicely to work he has been doing to provide guidance to researchers/IRBs around this issue.

**4 - Outcome:**

- Gwen will let ACGPR members know once SB 759 has been assigned to a committee and a hearing has been scheduled. Keep in mind she will be counting on ACGPR members to ask with moving this legislation forward.
- DHS Genetics program will draft guidance document providing examples of *what is* and *what is not* a genetic test as defined by Oregon Genetic Privacy law. Mike Garland will assist by reviewing document.

**5 – 2007 ACGPR Activities**

**a. Genetic Exceptionalism plan of action**

Co-chairs discussed how best to approach this topic in 2007. Proposal was made to first systematically review the Oregon Genetic Privacy law vs federal statutes from a research, clinical, and consumer/genetic discrimination perspective. After better understanding protections that exist on a federal level with those in place via the Oregon Genetic Privacy law, committee can decide next step in reviewing topic of genetic exceptionalism.

All committee members are encouraged to review their materials to see what summaries they may have that compare/contrast Oregon Genetic Privacy laws with federal statutes (HIPAA, Federal Common Rule, ADA). Ted Falk offered that there is a long Oregon Bar document summarizing HIPAA. Review on genetic exceptionalism by Summer Street will also be sent around to the committee and reviewed again. Suggestion was made to try to form grid for classifying legislation:

research			
clinical			
discrimination			
	obtaining	retaining	disclosing

Patricia noted that the committee must be clear about genetic exceptionalism...are we for or against in regards to access to health care and how information is treated?

It is possible that the role of the committee and its charge has been unclear: what are the underlying assumptions, and have they been challenged? Do we really need the Oregon Genetic Privacy laws? Example was given that AIDS has changed from being a case of exceptionalism to not being a case of exceptionalism.

**b. Monitoring the impact of Oregon’s Genetic Privacy Laws**

This is one of the goals of ACGPR for 2007-2009. Several methods of gathering this feedback were discussed (e.g. regular emails to key representatives from various viewpoints asking for feedback on OR Genetic Privacy law, hosting a open hearing at PSOB or with Oregon Health Forum for the public, providers, labs etc where various groups can come and provide feedback in-person or via email etc). It was mentioned that soliciting input is likely more reliable a way of truly monitoring the impact of laws vs passively collecting information that filters back to ACGPR. Passive approach is biased towards collecting negative experiences with OR Genetic Privacy law. ACGPR will continue to consider how best to monitor impact of OGP laws.

**c. Education Subcommittee Update**

Subcommittee has struggled with finding the right level for pamphlet for consumers/patients and providers that reviews federal and state genetic discrimination protections. Suggestion made by the committee back in November to simply draft fact sheet. Some now feel revised version is too simple. Mary Pat will send around both versions of pamphlet. Please email genetics program with feedback by 3/21/07.

**5 - Outcome:**

- Committee will review existing resources and provide summary of Oregon Genetic Privacy law vs federal statutes. Kara to review this from research perspective. Ron Marcum to review from clinical perspective. Mary Pat to review from perspective of patients/genetic discrimination. Once summaries have been reviewed and discussed by the committee, plan to determine next steps/committees position on genetic exceptionalism will be determined.
- Committee will continue to determine how best to gather feedback from diverse sources re: impact of Oregon Genetic Privacy legislation.
- Two versions of fact sheet on federal and state genetic discrimination protections will be sent around to all committee members. Please provide feedback by 3/21/07.

**6 – Discussion of genetic discrimination articles: Kass et al, “Access to health insurance: experiences and attitudes of those with genetic versus non-genetic medical conditions.” And L.Goslin “Genetic Privacy”. – Patricia Backlar**

The Kass article is in a sense a “measurement of worry”, since individuals are self-reporting from the group insured sector of the market. The variations in demographics could show a greater variation in care than anything seen between genetic and non-genetic diseases.

Gostin article documents reviews the arguments for not treating genetic information any differently than other medical information.

Copies of both articles can be obtained by contacting the DHS Genetics Program.

**6 - Outcome:**

- Kass article points to the fact that it is very difficult to truly understand the frequency of genetic discrimination. Article does clearly document public's concern around this issue.
- Gostin provides a solid review of topic of genetic exceptionalism.

**7 - Adjourned**

**Next Meeting:**

**May 2, 2007**

**1:30 p.m. to 3:00 p.m.**

**800 NE Oregon room 130**

**Portland, OR 97232**

**Upcoming meetings**

**June 6, 2007**

**1:30 p.m. to 3:00 p.m.**

**800 NE Oregon room 130**

**Portland, OR 97232**

**August 1, 2007**

**1:30 p.m. to 3:00 p.m.**

**800 NE Oregon room 130**

**Portland, OR 97232**