

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

FINAL

Attendees:

Mike Garland, Mary Pat Bland, John Anderson, Mark Loveless, Marc Marengo, Nan Newell, Bob Nystrom, Kara Manning Drolet, Theodore Falk, Allison Naleway, John Zonana, Ron Marcum, Steve Nemirow, June Olson, Casey Bush, Ann Smith Sehdev, Paul Dorsey, Keith Hanson, Anne Greer, Janice Olson

February Agenda overview:

1. Agenda approval
2. Approval of Minutes for December 2006
3. Introductions and announcements – upcoming events
Location of future ACGPR meetings
4. Election of Committee Chair 2007-08
Michael Garland, Jon Zonana, and Mary Pat Bland
5. Inherited vs. Acquired...Oregon Genetic Privacy Law Clinical Challenges
(1:30pm)
Anne Greer, June Olson, M.D., Janice Olson, M.D., Keith Hanson, M.D., Paul B. Dorsey, M.S., Ronald G. Marcum M.D., Jason Davis, Ann Smith-Sehdev, M.D.
6. Update on SB XX
Gwen Dayton
7. Updated Background Documents on Oregon's Genetic Privacy Laws
Mary Pat Bland
8. Conference report – Personal Exchange: Ensuring the Portability and Privacy of Oregonian's Health Information
TBD
9. Update: IRB genetic Research Educational Guide Project
Michael Garland
10. Adjourn

1 - Outcome:

- The agenda was approved

2 - Outcome:

- The December minutes were approved with revisions. January minutes were not reviewed, as there was no January meeting.

3 - Introductions and Announcements

- ACGPR Future Meeting Location: OMA new facility is in far SW PDX. Could consider having meetings at PSOB (NE) and parking validation would be provided. Group agreed to NE PSOB location.
- Genetic Information Nondiscrimination Act (GINA): This piece of federal legislation is moving along in the House. Pres. Bush states he will support. If it passes as written, both individual, group, and SSI supplemental healthcare coverage would be addressed. Bill does NOT distinguish between heritable and acquired genetic tests. TF notes it would behoove ACGPR to pay attention to final legislative language and wording as this may greatly help us as we re-examine Oregon Genetic Privacy statutes.
- Hopkins Genetics and Public Policy Project: Project aims to assess the public opinion about future large US population based studies examining the roles of genes and environment and human health. Group will be visiting Portland in Spring to conduct 3 focus groups with target populations. Group is open to providing a talk to discuss the project for those interested. DHS-Genetics program will work with Hopkins team to arrange and keep ACGPR members posted.

3 - Outcome:

- Group agreed to meet at NE PSOB location for future ACGPR meetings.

4 - Election of Committee Chair 2007-08

4 - Outcome:

- Committee co-chairs were unanimously elected (Patricia Backlar and Kara Manning-Drolet)

5 - Inherited vs. Acquired...Oregon Genetic Privacy Law Clinical Challenges

In the process of drafting and implementing policy, a local health system was prompted to review again some of the details of OR genetic privacy law that make the operationalization of the statute difficult. Two key issues with the existing genetic privacy statutes include 1) the need to get informed consent from patients undergoing any type of genetic testing (which health system is doing using written consent form) and 2) need for consent for retention or disclosure of genetic information. It is also concerning that family genetic history is not protected the OR genetic privacy law.

A provider presented the number of consents he has to provide to patients undergoing BM biopsy. The sheer number of consents to review is burdensome. The question is how to alleviate paperwork burden. Possible solutions vary. If the two main challenges

of the OR genetic privacy laws highlighted in the paragraph above were addressed, MD would still have multiple consents to review with patients (only 1-2 consents would be eliminated). Providers noted that every little bit of paperwork that can be eliminated helps greatly in limiting patients' skepticism of the medical system when faced with multiple consents for a procedure.

The question was raised: Was the intent of the law to address all DNA testing or just that that is heritable (vs acquired)? Genetic tests that are being performed in the BM biopsy example are often ordered multiple times to track disease status/treatment (or "noninherited" or "acquired" genetic changes). Consenting for these tests each time the test is ordered is incredibly burdensome. The parallel between genetic testing for acquired genetic changes and checking for HIV was noted.

Legislation to be proposed (formerly know as SB99) was discussed. While proposed legislation will be helpful, there are some disclosures permitted by HIPAA not included in legislation to be proposed that still could present a problem.

Health system group would like ACGPR to consider defining constitutional state vs. acquired genetic test in OR genetic privacy law. Could administrative rules define/include an exception for non-heritable conditions? Question was raised: would change from acquired vs inherited truly address the main burden Legacy is facing (i.e. multiple consents). Also, ACGPR's decision to review topic of genetic exceptionalism may address many of these issues. Point was also made that it would be very important to understand all of implications of rewording definitions etc as in the past, Committee has been forced to modify legislation on multiple occasions due to unforeseen consequences of a seemingly benign change to the Oregon Genetic Privacy laws.

Provider group also noted that family history SHOULD be included in OR Genetic Privacy law and currently isn't. Members discussed the fact that this issue was brought to the legislature before and did not pass.

Overall, ACGPR members appreciated the challenges with lack of definition of "inherited" in the current Oregon Genetic Privacy Statutes. Researchers and clinicians from the Committee have struggled with this issue on multiple occasions.

At this time, it is too late to ask legislative council to remold legislation being drafted (formerly SB99). On the other hand, having a good definition of genetic tests and inherited vs. acquired is important. On the issue of number of consent forms, ACGPR cannot help with this exclusively but could possibly collaborate with others to try to address this issue. At this point, interested providers/health systems would need to obtain a sponsor lobbyist or legislative aid.

5 - Outcome:

ACGPR members were understanding and very interested in the issues raised by the healthcare providers and system staff. Unfortunately, it is too late in the legislative process to modify legislation that will be proposed by Committee. Also, time is needed to clearly understand all the implications of definition changes. At this point,

5 – Outcome (cont):

providers/health systems interested in requesting a modification to the Oregon Genetic Privacy statutes would need to obtain a sponsor lobbyist or legislative aid. ACGPR members all agreed that issues raised in this presentation should be considered as the Committee works to address the issue of genetic exceptionalism/systematically review OR genetic privacy law in this next year.

6 - Update on SB XX

Gwen would like assistance on this effort. Mike Garland volunteered to be co-lead. Ron Marcum will also assist. Suggestion was also made to check with Brian Bohinger (OHSU lobbyist) and KP lobbyist given it is in their interest to have bill pass. Bill is still in legislative council. Gwen is checking on status of things. She has a meeting scheduled with Senator Burdick, chair of the judiciary committee to discuss SB XX.

6 - Outcome:

- Mike Garland and Ron Marcum will assist Gwen with SB XX.

7 - Updated Background Documents on Oregon’s Genetic Privacy Laws

DHS Genetics Program is in the process of updating our website, including section on genetic privacy and research. Two background documents 1- History of Oregon Genetic Privacy Laws, and 2- listing of key Oregon Genetic Privacy Laws will be sent to ACGPR members for review. Please submit comments.

7 - Outcome:

- Submit edits to john.a.anderson@state.or.us or marypat.bland@state.or.us

8 - Conference report – Personal Exchange: Ensuring the Portability and Privacy of Oregonian’s Health Information

Conference occurred on bad snow day so no Committee members were able to attend.

8 - Outcome:

PowerPoint slides from Conference can be found at <http://cpd.ogi.edu/Seminars07/PersonalExchange.htm>

9 - Update: IRB genetic Research Educational Guide Project

Mike G would like to continue this work (with David Holt, Kara Manning Drolet, Charlotte Shupert, Allison, and Casey Bush). There was a bit of discussion about whether or not guidance can occur as the main problem for researcher seems to be better defining what is genetic information/what is a genetic test. ACGPR would not be able to give

advice without providing interpretation (which we would not be able to do). One member noted that Committee has focus for quite a long time on IRBs and really ACGPR needs to turn back focus to clinical care. Clinical care issues should be prioritized over further IRB work.

9 - Outcome:

- Mike Garland to determine how best to proceed with this item.

10 – Adjourned

Next Meeting:

March 7, 2007

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

800 NE Oregon room 130

Portland, OR 97232

Upcoming meetings:

April 4, 2007

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

800 NE Oregon room 130

Portland, OR 97232

May 2, 2007

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

800 NE Oregon room 130

Portland, OR 97232