

# Advisory Committee on Genetic Privacy and Research Meeting Minutes — May 2nd, 2007

**FINAL**

## Attendees:

Nan Newell, Kara Manning Drolet, Gwen Dayton, Mary Pat Bland, John Anderson, Ron Marcum, Steven Nemirow, Stuart Kaplan, Patricia Backlar, Gayle Woods, Alison Naleway.

## May Agenda overview:

1. Agenda approval
2. Approval of Minutes for March 2007
3. Alternative for “Licensed MD” ACGPR representative  
Jon Zonana, Mary Pat Bland
4. Update on SB 759  
Gwen Dayton
5. Genetic Exceptionalism 2007 Plan of Action: Review of OGPA vs. Federal Statutes Summaries
  - a. Research/laboratory implications – Kara Drolet
  - b. Genetic discrimination protections – Mary Pat Bland
  - c. Clinicians/hospitals implications – Ron Marcum
6. Guidance on What Is and What Is Not a Genetic Test
7. Adjourn

### 1, 2 - Outcome:

- The agenda was approved, and the minutes were approved with the indicated corrections. Direct correction information to [john.a.anderson@state.or.us](mailto:john.a.anderson@state.or.us).

### 3 – Alternate for Jon Zonana

The committee discussed the option of appointing Paul Dorsey, who is a genetic counselor (not an MD), as an alternate for Jon Zonana. The make up of ACGPR is noted in ORS 192.549 as follows “DHS shall appoint one representative and one alternate from the following categories.....physician licensed under ORS chapter 677...”. DHS has looked for a geneticist (MD) who is able to attend meetings in place of Jon Zonana for over a year but has been unable to find one who was able to serve. In light of Mr. Dorsey’s experience as a genetic counselor working with multiple patients with genetic testing issues, the decision was made to include him as a voting alternate for Jon. Some members expressed reservations about accepting a candidate who did not strictly meet the credentialing requirements noted by ORS 192.549. Others felt that his genetic counseling experience met the intention of the “physician” category noted. After it was determined that a quorum was present, a motion was made to accept Paul Dorsey as a voting member and official alternate. Motion was made, seconded and passed. 5 in favor, 2 opposed, 1 abstain

### 3 - Outcome:

- Genetic counselor Paul Dorsey will serve as an alternate for Jon Zonana.

#### **4 – Update on SB759**

The public hearing for SB759 took place on 4/19/07. Testifying were Gwen Dayton, Oregon Association of Hospitals and Health Systems, Ron Marcum, OHSU, Katherine Bradley, DHS, Andrea Meyer, ACLU, Tim Martinez, OMA, Carl Lundberg, Consumer Business Services, and Bruce Fitzwater, Christian Science. A needed subsequent work session was not scheduled prior to the April 30<sup>th</sup> deadline. As a result, the bill cannot move forward.

There are two options for reactivating the bill. The first is rewriting SB759 into an existing bill that has a compatible relating clause. The second is using Sen. Burdick’s priority bill, which she has generously offered to the committee.

#### **4 - Outcome:**

- Since a needed work session was not scheduled by the April 30<sup>th</sup> deadline, work needs to be done if concepts in SB 759 are to move forward. SB 759 can either be incorporated into an existing bill with a similar relating clause or Sen. Burdick’s priority bill could be used to move SB 759 along. Gwen Dayton will keep the committee informed of developments by email.

#### **5 – Genetic Exceptionalism 2007 Plan of Action**

The work of the committee is based largely on the idea that genetic information has unique qualities in relation to privacy and discrimination that require specific legal remedies. The legislative findings of the Oregon Genetic Privacy Act, ORS 192.533 as written in the 2003 statute, are largely based on the concept of genetic exceptionalism. Of primary concern was: 1) the private and personal nature of genetic information, 2) the potential for genetic information to reveal the probable medical future of an individual, 3) the potential for genetic information to reveal the probable medical future of an individual's blood relatives, and 4) the potential for significant harm when genetic information is revealed.

The four of the main arguments against genetic exceptionalism include: 1) the lack of qualitative differences between genetic and nongenetic information, 2) the complexity of disease etiology does not fit easily within the concept of genetic exceptionalism, 3) the idea that it is unethical to treat genetic and nongenetic information differently, and 4) the fact that genetic exceptionalism may actively cause harm.

The Genetic Exceptionalism 2007 Plan of Action seeks to start Committee discussions on the topic of Genetic Exceptionalism by comparing existing and proposed federal genetic legislation to the Oregon genetic privacy statutes. The purpose of this is to determine whether or not legislation grounded in exceptionalism is indeed required to provide acceptable levels of privacy and discrimination protection to Oregonians.

**a. Kara Drolet – research/laboratory implications of a comparison between Common Rule Requirements 45 CFR 46, HIPAA Requirements 45 CFR 160, 162, and 164 and Oregon Genetic Privacy Act Requirements ORS 192.531-549, OAR 333-025**

Categories were selected for the matrix document based on relevant legislative features. Note that HIPAA has many proscriptive areas, such as identity, need-to-know, and limited circumstances. It also contains the right to revoke authorization. HIPAA puts an emphasis on the protection of information by researchers and covered entities, using the “need to know” approach. These aspects of the legislation are listed in more detail in the matrix. The Oregon Genetic Privacy Act is more inline with the Federal Common Rule in the area of Waiver of Consent. Anonymous research is a main difference between these two. Overall, the Oregon legislation provides more research requirements (subject protections) than the Common Rule.

Please review the document...your feedback is desired on these comparisons between legislative features. To go forward with bigger decisions, this review of existing law is needed.

**b. Mary Pat Bland – discrimination comparison between Genetic Information Nondiscrimination Act (H.R. 493), Americans with Disabilities Act, Executive Order 13145, Civil Rights Act – Title VII, Oregon Genetic Privacy Act, and HIPAA**

Comparisons between the different pieces of legislation were made in the areas of employment discrimination, health care/health insurance discrimination, and disability/life insurance discrimination.

In the area of health care discrimination, GINA seems to have just as many protections as Oregon law (note: Mary Pat noted the disclaimer that comparison has NOT been reviewed by a legal expert. It would be especially helpful if ACGPR members with a legal background provide feedback.). One noted difference between Oregon law and GINA is: Oregon permits insurance companies to require an applicant to undergo genetic testing but notes conditional requirements. GINA as written prohibits insurance companies from requiring patients to undergo genetic testing. Another significant difference between GINA as currently written and Oregon law is that family history and pursuit of genetic services are included in protections provided by GINA and NOT included in Oregon law.

For disability/life insurance, there seem to be no federal protections. Oregon has protections against using blood relative information to deny disability/life insurance coverage.

For employment discrimination, GINA and Oregon law both provide protection from discrimination based on genetic information. Again, employment discriminations provided by GINA are broader than those provided by employment discrimination protections noted in Oregon Genetic Privacy law as family history and pursuit of genetic services are covered under GINA.

**c. Ron Marcum – comparison of HIPAA vs OGPA from clinical perspective**

Ron compared HIPAA requirements to Oregon Genetic Privacy Act requirements.

For treatment, HIPAA is broad and has extensive parameters, that is, many specific areas of health care listed explicitly. Oregon excludes research info, which under HIPAA is included in the designated record set.

The definition of disclosure is equivalent in HIPAA and Oregon. (However, circumstances in which info can be disclosed differs between HIPAA and Oregon law).

For Health Information, HIPAA considers genetic information to be health information. Oregon calls out genetic information with some sub definitions.

For De-identified information, HIPAA is specific and proscriptive. Oregon uses HIPAA parameters. For informed consent, optional under HIPAA, required by Oregon.

For protection of genetic information, HIPAA applies protections to all PHI. Oregon protection is general.

For retention and use of genetic information, HIPAA applies standard use and disclosure rules. Oregon requires authorization. (Committee has attempted to align Oregon law with HIPAA in this area with SB 759).

For inspection, amendment, access: HIPAA has specific parameters, Oregon is very general with no implementation guidance.

For use of genetic information of deceased individuals, HIPAA is equivalent to Oregon.

For notice required re:privacy practices, HIPAA requires notice at first provision of care, Oregon requires a similar notice regarding genetic information.

For use and disclosure restriction, patients may request restriction under HIPAA but a covered entity is not required to agree, Oregon requires acceptance of restriction (“opting out”) for anonymous or coded genetic research.

One key difference between Oregon law and HIPAA is the need to obtain informed consent when obtaining “genetic information” from a patient. This presents an issue to clinics asking family history/previous medical history questions that pertain to genetic info AND to clinicians ordering genetic testing for patients.

#### **5 - Outcome:**

- Committee members thought that reviews were useful. Suggestion was made that eventually, committee might consider also creating a version of the matrices that convey the same information but in a higher-level/simpler manner. This could be a useful background educational tool when working with members of the community and legislators.
- DHS will email around summaries
- All ACGPR members should review, email author with suggestions, and be prepared to continue discussion based on this background in future meetings.

#### **6 – Guidance on What Is and What Is Not a Genetic Test**

During the March meeting, a request was put forward that DHS draft a guidance document that lists examples of what is/what is not a genetic test as defined by the Oregon Genetic Privacy law. Genetics program worked to attempt to do this and consulted several ACGPR members. After careful consideration it became clear that it did not appear possible to include somatic/non-heritable genetic

tests (e.g. chromosome FISH testing for the BCR-ABL rearrangement associated with a certain form of leukemia) in the list of what is not a genetic test based on the current definition of a "genetic test" in Oregon law. Previously, the Genetics Program understood that it was this group of tests (the somatic/non-heritable genetic tests) that were the most problematic for the individuals that requested the guidance document and therefore the document may now not be necessary.

Several committee members concurred that based on the current definitions of a "genetic test" and "genetic information" in Oregon law, it appears somatic genetic testing IS covered by the law. Suggestion was made to ask for examples of tests in the "grey" area that clinicians/hospitals may have been struggling with, compile this list, discuss at an upcoming ACGPR meeting, and then if deemed appropriate, Genetic program will discuss tests in the "grey" area with legal resource.

**6 - Outcome:**

- DHS will send an email with a list of potential "tricky" or "grey area" genetic tests. ACGPR members will let the DHS Genetic Program know if they have additional tests to add. The list will be reviewed at the next ACGPR meeting. If it seems that guidance would be particularly helpful to hospitals/providers for the list generated, the Genetics Program will work with legal sources to clarify if the test is a "genetic test" or not and will issue a guidance document.

**7 – Adjourned**

**Next Meeting:**

**June 6, 2007**

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

**800 NE Oregon room 130**

**Portland, OR 97232**

**Upcoming meetings:**

**August 1, 2007**

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

**800 NE Oregon room 130**

**Portland, OR 97232**

**September 5, 2007**

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

**800 NE Oregon room 130**

**Portland, OR 97232**