

Advisory Committee on Genetic Privacy and Research

Work Session Minutes — May 7, 2003

Attendees

Ted Falk (Co-Chairperson), Astrid Newell (Co-Chairperson), Bob Koler, Greg Fowler, Kara Manning, Patricia Backlar, Kerry Silvey, Emily L. Harris, Michael Garland, Andrea Meyer, Gwen Dayton, Laura Zukowski

Megan Hill (Guest)

Welcome/Introductions

Megan Hill, Willamette University intern, joined the meeting. She helped staff the DNA Day table in the State Capitol in April and has also helped recruit participants for the Salem public outreach session later this month.

General Announcements

- A legislative staffperson contacted Ted Falk for guidance in drafting a genetic privacy law for the State of California. The staffperson was surprised that Oregon had repealed its genetic property clause. Ted sent the person some reports.
- Andrea Meyer reported that the Oregon Legislative Session is expected to continue into August. It is likely that the budget sessions will be lengthy.

Review of Minutes

Outcome: Meeting and work session minutes from January 8, February 5, March 5, and April 2 were approved with the agreement that corrections are still allowable. Please contact Laura Zukowski with requests for changes, (503) 731-4021 or laura.a.zukowski@state.or.us.

Updates

- Legislation—Senate Bill 618 was approved by the Senate Judiciary Committee and on the Senate Floor. Senator Avel Gordly cast the only dissenting vote. The committee may request feedback on what issues in the legislation were of concern to Senator Gordly. ACGPR could address these issues in a future meeting.

SB 618 A-Engrossed was scheduled for another hearing in the House Judiciary Committee today, but this was postponed until Monday, May 12, to enable this committee to review a proposed amendment and decide whether to send it forward. (This amendment was discussed later in the meeting under the section, “New Items.”)

Ted Falk and Astrid Newell presented ACGPR's 2003 Legislative Report to the Senate Judiciary Committee at the start of the session. Due to time constraints, it is unlikely that they will be able to present this report to the House Judiciary Committee.

- Education and Outreach—Subcommittee Chair Michael Garland updated the group on plans for the community forums and “focused or guided conversations.” (The group has stopped using the misnomer “focus groups” for these sessions.) He brought copies of a draft script of the conversations for the group to review and also clarified methodology for these sessions.

For each of the three focused conversations, organizers have recruited around twelve participants with the expectation that eight to twelve of them will attend. Michael Garland and Barry Anderson will facilitate each session. Participants will sit in a u-shape, where they will be able to see one another and some large poster sheets where Barry will record responses. One sheet will hold ideas that don't seem to fit within the three topic areas (genetic exceptionalism, protections around the seeking of genetic counseling, and insurance issues). Each group will edit responses on the poster sheets as they are being created and again during a review at the end of each session.

Each topical segment will open with some (brief) background context, which will be followed by a probe as to whether any respondents have considered the issue, and then an open-ended trigger question. At some point in the meetings, participants will be asked to answer a brief demographic survey about themselves. Attendees of this meeting suggested asking each participant for occupation, gender, age group, education level, and race/ethnicity.

There will be a general forum at each site, also. The forum will consist of a panel session and audience, a viewing of a portion of one of the Fred Friendly seminars, and a slide show that will be adapted from the PowerPoint presentation that was shown to the legislature.

As a separate outreach activity, Greg Fowler, Megan Hill, and other volunteers organized a DNA Day information table in the Capitol Lobby on April 23. They passed out double helix cookies, engaged in lots of conversations with passerbys, and showed a short film. The film may be posted on the Geneforum.org website.

Outcome 1: Feedback on any aspect of the community forums or focused conversations should be addressed to Michael Garland, mdgar@teleport.com, before Tuesday, May 13. He is especially interested in suggestions for phrases or expressions to use, shortening questions, and asking questions with less background or setup.

Outcome 2: Kerry Silvey will remove contact information for ACGPR members and interested parties that appears on the PacNoRGG genetics website.

Outcome 3: Greg Fowler will set a link to the PacNoRGG website on the Geneforum website.

New Items for Discussion

- **Recent Research Study Concerns**—Bob Koler brought a question to the group concerning consent requirements for a research study on sudden unexplained death that involves genetic and pathology testing of blood and/or tissue samples. In this study, emergency medical technicians have been drawing blood from patients when they place venous lines during resuscitation attempts. The protocol has been to hold the blood and/or tissue samples until consent can be obtained from a living relative or patient (if he or she recovers from the episode.) Medical records and autopsy reports are also obtained once consent is given. The purpose of the study is to identify genetic mutations that may correlate to sudden unexplained death.

The study has expanded recently to include more sites. OHSU is one of the new proposed sites; the OHSU IRB has not yet approved the study, because of apparent conflicts between the study protocol provisions and Oregon’s genetic privacy law related to consent. Ted Falk drafted an amendment for SB 618A that could exempt research on decedents from consent requirements when a waiver of authorization for research is obtained. He also submitted a memorandum (“HIPAA and Genetic Research,” dated May 5) to the group in advance of this meeting that discusses the issue in more detail.

Objections to submitting this amendment included the lack of time for a fuller discussion and the possibility that the new proposed amendment could hold up the entire bill, which was discussed in detail and approved by the group.

Outcome 1: The draft amendment will not be introduced.

Outcome 2: This issue will be set aside for future discussion. Ted’s memo will be used as a starting point for the discussion.

- **Handling Requests for Interpretation of Genetic Privacy Act: ACGPR, DHS Roles and Responsibilities**—Astrid Newell reported at the April 2 meeting that she has received multiple requests from staff at hospitals and health systems who are looking for guidance on how to implement genetic privacy laws. The questions have dealt with a range of issues related to the clinical setting, including consent procedures for genetic testing, billing practices, and release of information for referral of laboratory specimens. Depending on the issue, Astrid has referred people back to their organization’s own legal counsel or brought questions to this committee; on occasion she has answered some of the more straightforward questions, also, but always with the warning that she is not a lawyer.

Outcome 1: Gwen Dayton volunteered to host an advisory group of representatives from various hospitals/health systems, which will include clinicians and genetic providers. She will announce the formation of this group at the OAHHS HIPAA

Task Force meeting tomorrow. This group will examine implementation issues; one agenda item will be to make recommendations for the sample consent forms for obtaining and disclosing genetic information, which are referenced in the administrative rules.

Outcome 2: *Review of the consent forms will be added to the agenda for the June 4 work session.*

- Helping Others Understand the Law: Developing Fact Sheets and Primers for General Public, Clinicians, and Researchers—Astrid Newell circulated a draft fact sheet on genetic privacy for the group to review. She drafted it at the request of the DHS HIPAA Coordinator after a child protective services worker requested a release-of-information form to look at the medical records of a potential adoptive parent with a genetic condition. The fact sheet is intended to be a general reference for patients, researchers, people who need to implement the law, the general public, or anyone with questions.

Specific edits to the draft fact sheet included:

- change the title to “Genetic Privacy Fact Sheet: Overview of Oregon Law”;
- delete the second paragraph;
- elaborate on the second from last final bulleted item on page 1.

More general suggestions for the fact sheet included:

- add a section on recontact of research subjects;
- consider adding in items from the OHSU primer;
- consider organizing the fact sheet around the subjects headings of obtaining, retaining, and disclosing genetic information;
- develop a list of who is likely to seek guidance around interpreting Oregon’s privacy law and under what circumstances;
- develop a chart that compares Oregon’s law and HIPAA requirements, which would include any past questions;
- create separate documents (with one consistent format) for different audiences, i.e., researchers, clinicians, social services providers (including prison workers), general consumers;
- post the various fact sheets on the DHS website and include some background information under a heading titled, “How to Comply?”

Outcome 1: *Astrid and Ted will add the development of these fact sheets to the agenda for the June work session.*

Outcome 2: *Invite medical records administrators from local hospitals to the June work session.*

Next Meeting—Work Session

Wednesday, June 4

1:00 to 4:00 p.m.

Oregon Medical Association

5210 S.W. Corbett Avenue

Agenda: Conforming Consent Forms to HIPAA; Development of Fact Sheets

Future Full Committee Meetings

Wednesday, July 2

Wednesday, September 3

Wednesday, October 1

Wednesday, November 5

Wednesday, December 3

1:00 to 4:00 p.m.

Oregon Medical Association

5210 S.W. Corbett Avenue