

# Advisory Committee on Genetic Privacy and Research

## Meeting Minutes — January 5, 2005

### Attendees

Emily Harris (Co-Chairperson), Stuart Kaplan, Ted Falk, Michael Garland, Bob Koler, Kara Manning, Kiley Ariail, Jon Zonana, Kerry Silvey, Bob Nystrom, Nan Newell, Carol Pratt, Patricia Backlar, Laura Zukowski

### Introduction and Announcements

- Welcome and Introductions — Everyone introduced himself or herself.
- Review of Draft Minutes from Last Meeting (December 1, 2004) — Draft minutes from December 1, 2004, had been circulated by e-mail prior to this meeting.  
***Outcome: Co-Chair Emily Harris directed that the minutes of December 1 were approved with the provision that they were still correctable. Contact Laura Zukowski ([laura.a.zukowski@state.or.us](mailto:laura.a.zukowski@state.or.us) or 503-731-4021) if you would like to request changes to the December minutes.***
- There have been changes in committee membership. DHS Administrator Barry Kast has made the following new appointments: Stuart Kaplan has replaced Andrea Meyer as the member representative for organizations advocating for privacy of medical information, and Andrea Meyer has moved to the alternate member position (and replaced David Fidanque, who resigned); Lewis Littlehales has replaced Jann Goodpaster as the alternate member representative from the Oregon Department of Consumer and Business Services. DHS staff is looking for a replacement for the pharmaceutical representative member, Desiree Hollemon, who has changed jobs within her company and is spending a large portion of her time outside the country, and for consumer member Margaret Everett, who also resigned, effective upon her replacement.  
***Outcome: Michael Garland will follow up with Kiley Ariail to suggest a pharmaceutical industry representative.***

### Employment and Health Insurance: Continuing Discussion

The committee continued to discuss proposed amendments that would protect against genetic discrimination in employment and health insurance. Results of the committee's e-mail vote last November showed unanimous support for prohibitions against discrimination based on an individual's family medical history and the seeking of genetic counseling. Votes over the amendment to redefine "family member" to include non-blood relatives were split, with six members in favor, five against, and four refraining.

Jon Zonana and Kerry Silvey questioned whether members voted against redefining "family member," because they did not understand the concept. Members expressed an

unwillingness to open this issue with the Legislature, because they were unconvinced that a compelling reason exists for the change.

***Outcome 1:*** Ted Falk, Jon Zonana, and Gwen Dayton will draft language for a legislative concept that would create changes to statutes relating to employment and health insurance. The draft will incorporate prohibitions against discrimination based on an individual's medical family history and the seeking of genetic counseling, but will not redefine family member to include non-blood relatives.

***Outcome 2:*** Laura Zukowski will send out draft minutes as soon as they are written. She will not wait for the next meeting's agenda before sending out draft minutes.

#### **Legislative Report: Status Update**

Emily Harris reported that she, Gwen Dayton, and Kiley Ariail have begun writing the legislative report and hope to have e-mailed a draft to the committee before the next meeting. The report will be shorter than the one prepared for the 2003 Legislature and will contain a summary and recommendations.

***Outcome 1:*** Michael Garland will draft a section on the activities of the Public Input Subcommittee.

***Outcome 2:*** The chairpersons and Kiley Ariail will try to circulate a draft of the legislative report through e-mail before the next meeting on February 2.

***Outcome 3:*** The committee will discuss how it wishes to introduce the legislative report and whether the introduction of the report should be bundled with a legislative hearing.

***Outcome 4:*** The DHS-sponsored legislation (SB 99, formerly LC 298) will remain separate from other proposed genetic privacy legislation.

#### **Research: Continuing Discussion of Recommendations**

Emily Harris thanked Carol Pratt, Kara Manning, and Kiley Ariail for their time and work on the proposed legislative concepts regarding genetic research. She brought a summary handout to help guide the discussion of the Research Subcommittee's recommendations for changes to genetic research requirements. Emily also brought a separate handout, which addresses a former recommendation from the subcommittee that was discussed at the last meeting. The Research Subcommittee has decided to drop this recommendation about CLIA regulations and release of research test results to research subjects.

The committee did not reach consensus on the policy decision of whether or not to pursue changes to research sections of Oregon's genetic privacy law. Justification for changes is based on researchers' being unable to access clinically generated genetic samples and information (both historical samples and future samples) and to publish results of studies out in the world, the desirability of Oregonians' having the opportunity to participate in all possible national studies (especially drug trials), and the desire to simplify how Oregon's privacy laws and HIPAA regulations interface with one another.

The discussion revealed opposing opinions about numerous issues, including whether or not any changes to research statutes are needed. Some members believe research is hampered by current Oregon protections and believe HIPAA alone or HIPAA plus a few additional (state) protections would offer sufficient protection for research subjects. Some members appeared ready to make more extensive changes to the research statutes, to bring it closer in line with HIPAA definitions, etc. There was also disagreement over how feasible it is at this point in time to introduce more legislation, how extensive changes should be this session (minor changes or a complete overhaul), how receptive legislators would be to proposed changes, and what sorts of justifications would be effective in convincing legislators of the necessity of research changes.

During the discussion, committee members mentioned various approaches for changes to Oregon law, which included the following.

- The committee could rewrite the statute's definitions of the various types of data, in order to make Oregon law more consistent with HIPAA. (Oregon law mirrors definitions used by the National Bioethics Advisory Committee, with a few later changes influenced by HIPAA.) An advantage to this approach would be simplicity. Several members have expressed opinions that Oregon law is unenforceable, difficult to understand in relation to HIPAA, and creates cynicism. Lawyers for various research institutions and clinical/research institutions have interpreted the laws differently.
- Oregon legislation could change state law to govern only those research entities that are exempt from HIPAA and to let HIPAA alone govern non-exempt researchers.
- Oregon legislation could define "covered entity" to be all genetic researchers, regardless of whether the researchers were privately or publicly funded or transmit data electronically. This approach would allow Oregon's privacy law to continue to govern entities such as prisons, which do not transmit personal health information electronically and are therefore exempt from HIPAA regulations.
- The committee could add state requirements for the use of written agreements between genetic researchers and data sources, which would state that under no circumstances would investigators ever be given the key to code(s).
- One observer stated that Oregon law should protect tissue samples in addition to the genetic information that is generated from sample analysis. HIPAA does not protect tissue samples, just the information that results from the analysis of samples.
- The committee could submit legislation to create a few simple changes in this session and then add the issue to the list of the committee's charges for next session, in order to do a more global overhaul in the future.

***Outcome: Ted Falk, Gwen Dayton, and anyone else who is interested will draft a few statements that summarize the two proposed research changes. These changes would affect consent requirements for coded genetic research that uses information generated as part of clinical care and consent/opt-out requirements for coded or anonymous genetic research that uses specimens or information from deceased individuals when next of kin cannot be located or contacted. At the February 2 meeting, the committee***

*will vote on the policy issue of whether to pursue legislation in this legislative session, plan to pursue it in a future legislative session, or not to pursue these changes.*

**Adjournment**

**Meeting Schedule**

February 2	August 3
March 2	September 7
April 6	October 5
May 4	November 2
June 1	December 7
July 6	

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First Wednesday of each month  
1:00 to 3:00 p.m.  
Oregon Medical Association  
5210 S.W. Corbett Avenue in Portland