

Advisory Committee on Genetic Privacy and Research Meeting Minutes—May 8, 2002

Attendees

Astrid Newell, Ted Falk, Kiley Ariail, Peter Jacky, Marc Marengo, Sean Stevens, Gwen Dayton, Kathleen Walsh, Marilyn Hartzell, Kerry Silvey, Emily Harris, Robert Koler, Greg Fowler, Margaret Everett, Mike Garland, Patricia Backlar, Cara Manning, Barry Anderson, Laura Zukowski

I. Welcome/Introductions

Cara Manning, the Assistant Compliance Officer from OHSU, was introduced by Robert Koler. She will be translating the genetics rules and regulations onto the OHSU website.

Marilyn Hartzell, from the Child Development and Rehabilitation Center at OHSU, introduced herself as the alternate health care consumer member.

II. Public Outreach and Education Subcommittee

Mike Garland led the group in a brainstorming session on defining the public input survey. He began with the assumption that the survey would not question all respondents about all eight subject areas, that is, that the survey would be tailored somewhat for different respondent groups. He also emphasized that the survey would provide information in addition to an existing body of research.

The group addressed each of the eight statutory topics listed in Section 8 of SB 114 individually, what segments of "public" the group thought should be surveyed, and whether the group thought the survey should be quantitative, semi-quantitative, or qualitative. Marc Marengo assisted Mike by collecting detailed notes on all of the feedback.

A brief summary of the feedback follows after each of the italicized statutory topics. The group was asked whether the "general public" should be asked questions about:

1) *Patenting of human genes*—The group seemed split on this issue. Those opposed mentioned that the subject is too complicated for the general public. Those in favor of inclusion believe that this issue is a huge concern for the general public and that there is a lot of anger around this issue. Other comments included: the survey could be educational if scenarios were used; asking if someone is for or against gene patenting would not be useful, but that targeting questions about patenting to individuals or families who are facing genetic problems might yield useful information.

2) *Standards for recontacting patients who have provided samples for genetic research*—Most of the group appeared to be in favor of asking consumers, professional society members, specific target groups, and the unaffected general public. Comments included: Oregon should develop standards and values around this issue and not leave these types of recontact decisions open to practitioners; there's a disconnect between the general public's beliefs and the beliefs of professional working in the field of genetics; recontact touches on informed consent and so should be asked of all respondents; the limits of time and energy would favor not asking the general public about this topic.

3) *Privacy of information about genetic conditions obtained other than through a genetic test*—(An example of this would be information gleaned through a family history.) More comments seemed to be in favor of inclusion on the survey for the general public. Those in favor commented that: it would help correct the common misbelief that medical information privacy laws apply to family history; family history is no different than medical information; it's an easily understood concept that affects the broad public; existing protections under HIPAA should be included on the survey. A comment in opposition was that there's not a difference between medical information and genetic information.

4) *Privacy of persons who seek genetic counseling or genetic testing*—Those in favor of inclusion for the general public said: the fact that a person had sought counseling, not just any results of testing, should be protected; genetic testing could be compared to HIV testing, because the act of seeking these types of tests is revealing in itself. A comment in opposition was that seeking genetic testing or counseling was not specific enough information to warrant special treatment.

5) *Whether to modify or expand current statutory provisions requiring informed consent for genetic research*—More comments were opposed to inclusion for all groups, because of the timing of the new law that will be going into effect and a reluctance to tinker with them more until they actually play out in real life. One comment in favor was that there are specimens in storage now, and that it's important for the public to know the future uses for any of these specimens.

6) *Whether to modify the notification requirement of ORS 659.715(2) for anonymous research*—("opt-out" clause) Responses from the group varied between "yes," "no," and "maybe." One person referred to the ACLU's claim that a majority of the public cares even if the research is anonymous. Another person reported being curious enough to consider including the topic for the general public, but was ambivalent. A third person was clearly in favor.

7) *(For 2005 report) Genetic testing and use of genetic information by insurers*—Responses varied: one emphatic "yes" vote for the general public; one "yes" vote for asking insurance carriers how they are using genetic information and for excluding this topic from the general survey; one "no" vote, because the answers seem predictable and public sentiment can be examined through existing research; one vote either to ask both the general public and insurance carriers or to ask neither group.

8) *Guidelines for encryption*—The group was not in agreement. One person commented that that encryption is so technical that a detailed explanation would need to preface the question and that this would bias responses too much to be meaningful. Another person commented that no explanation was needed (beyond the probability of failure and the consequences or risks) and that the general survey should include this topic.

Outcome 1: *Marc Marenco will compile more detailed notes, and these will be distributed to the group.*

Outcome 2: *Please direct any other ideas or comments to Mike Garland directly. (Phone (503) 494-2554; Fax (503) 494-4981; E-mail garlandm@ohsu.edu)*

III. Administrative Rules Update

Astrid Newell reported that Barry Kast, DHS Administrator, signed the April 15 version of the draft administrative rules. They are ready now for public comment. A hearing is scheduled for Friday, June 21, from 1:00 to 3:00 p.m. in the Portland State Office Building, 800 NE Oregon Street, Room 120-C. DHS staff will tape all comments at the hearing. Anyone who prefers may submit their testimony in writing, also. After the hearing, the Attorney General will comment. If the rules are accepted, Barry Kast will re-sign them, and they will go into effect.

An announcement will appear in the Bulletin, which goes to all public libraries, and also to an internal DHS contact list of interested parties.

Outcome: Gwen Dayton will circulate a matrix she is still developing that compares HIPAA regulations to Oregon laws around the issues of consent to obtain and authorization to use or disclose. She is using the framework of "obtaining, retaining, and disclosing."

IV. Additional Subcommittee Updates

- A. Research Issues**—Emily Harris reported that there is nothing to share with the group.
- B. Clinical Issues**—Kathy Walsh reported that there is nothing to share with the group.

V. DHS/CDRC Public Health Genetics Strategic Plan Update

Astrid Newell and Kerry Silvey reported on progress of the Genetics Plan Advisory Council, which has been meeting for over one year to develop the Oregon Public Health Genetics Strategic Plan. This plan will direct DHS and CDRC on their priorities for addressing genetic issues over the next five years. The group came together for a full-day summit on April 4 to pull together their goals and objectives. The draft plan went out to members of that advisory council on May 7. They will be meeting again on May 10 to discuss the draft.

Outcome: Astrid Newell will e-mail the draft plan to this group after the Genetics Plan Advisory Council has had a chance to edit the document more. This group will have a chance to comment on the plan.

VI. Discussion of Coded/Encoded Research Document

Ted Falk opened a discussion on coded/encoded research, which the Research Issues Subcommittee will continue to study in more depth and will eventually bring back to the full committee. He e-mailed the committee a document on this topic to begin the discussion.

The new HIPAA regulations are scheduled to go into effect on April 14, 2003. This federal legislation will regulate identifiable medical information and defines a road map on how to "de-identify" information:

- 1) a statistician may declare the low possibility of identifying an individual's information through specific requirements, which are spelled out in the act;
- 2) a researcher may remove certain information, such as a subject's name, social security number, phone number, fax information, geographic information, etc.

HIPAA forbids coding that embeds information. (An example of this would be an insurance policy number that contains information about the policy of the holder of the policy.) A researcher would need to use a key to crack the code. Where a key is stored and who has access to the key is crucial. Oregon law addresses inadvertent or non-malicious versus malicious disclosures.

VII. Discussion of Gene Patenting Issues

Last week, Ted Falk sent a list of links to websites that address gene patenting issues. He noted that this committee is not charged with writing a biotechnology policy for Oregon, although it is one of the subjects that the groups is mandated to address in the legislative report.

Outcome: The committee should examine the websites that Ted listed in his e-mail of last week. At the next meeting (June 5), Ted would like the group to begin discussing what is distinctive about genetic biotechnology and identifying what concerns a public policy should address.

VIII. Announcements

Kerry Silvey announced that Georgetown University is sponsoring a conference on genetics and privacy. She will e-mail the committee a link to a website that describes the event.

Astrid Newell announced that there will be a symposium on genetic privacy on June 13-15 in Rochester, New York. She will e-mail the committee a link to a website that describes the event.

Next Meeting

Wednesday, June 5, 2002

1:00—4:00 p.m.

Portland State Office Building

800 N.E. Oregon Street

Room 120-B (first floor next to the cafeteria in the main lobby)

If you park in the Liberty Centre garage (north side of NE Oregon Street between 6th and 7th Avenues), DHS can validate your parking stub.