

Advisory Committee on Genetic Privacy and Research

Meeting Minutes — January 8, 2003

Attendees

Ted Falk (Co-Chairperson), Astrid Newell (Co-Chairperson), Emily Harris, Bob Koler, Kara Manning, Nicole Rymarchyk, Astrid Newell, Robb Moses, Andrea Meyer, Michael Garland, Margaret Everett, Ted Falk, Patricia Backlar, Victor Leo, Laura Zukowski

Special Thanks

The Committee acknowledged the large contribution that Ted Falk has made to the Legislative Report. Everyone thanked Ted for his “intellectual contribution and time.”

Introductions

Everyone introduced himself or herself.

Review of Minutes

Laura Zukowski e-mailed corrected minutes for the meetings on November 6 and 20, 2002.

Outcome: *Andrea Meyer moved to accept the latest draft minutes from meetings on November 6, November 20, and December 4. Michael Garland seconded the motion. Minutes from these three meetings were approved.*

Announcement

The Pacific Northwest Regional Genetics Group (PACNORGG) has begun posting this committee’s minutes and other documents on a website dedicated to genetics in Oregon. The website is sponsored by the Maternal and Child Health Bureau of the federal agency Health Resources and Services Administration.

Outcome 1: *Astrid Newell will e-mail the address to the PACNORGG website. (Note website address: <http://mchneighborhood.ichp.edu/pacnorgg/oregon/index.htm>).*

Outcome 2: *DHS staff will send PACNORGG this committee’s legislative report after it is finalized, so that it can be posted on their website.*

Outcome 3: *Geneforum will add a link on their website to the legislative report (at the PACNORGG website).*

Agenda Review

Astrid Newell requested that the committee discuss the frequency of meetings as an item under “Other Business” at the end of the meeting.

General Updates

- Astrid Newell shared that she and Kerry Silvey gave the OHSU Genetics Grand Rounds on December 19. They presented information about the Oregon Genetics Plan, recent history of genetics-related legislation in the state, and existing privacy laws and administrative rules in Oregon.
- Greg Fowler resubmitted the Collins Medical Trust grant application, along with the same letter of support from this committee that was submitted the first time. The grant would fund a field survey in the spring of 2003.

Public Outreach/Education — Fred Friendly Follow-Up

The first broadcast of the Fred Friendly Seminar *Our Genes/Our Choices* aired on January 2 on OPB. Many of the people present at this meeting had watched it. Comments were favorable and included the observations that the show was fast paced, provocative, and did a good job of pointing out concerns and barriers for an average individual. The topic concerned the privacy of genetic information and was called, “Who Gets to Know?” The next broadcast will address reproductive genetic issues and selection of genetic traits. It will be shown on Thursday, January 9, at 10 p.m. The third and final part of the series will be shown on January 16 and will address “challenging questions about the social, ethical, and legal quandaries surrounding genetic research, and about the limits of personal responsibility.”

Michael Garland updated the group on plans to connect public outreach to these broadcasts. The late hour of the broadcasts has made it impossible to plan public meetings to coincide with any of the broadcasts. The original plan included these three components:

- OPB promotional support
- local outreach through Oregon Health Decisions—approximately 1,000 postcards
- OHSU School of Nursing community meetings (5-6 sites)

The OHSU School of Nursing community meetings have been problematic and are being redesigned/reconsidered. The late hour of the broadcasts, the lack of advance notice of the broadcast dates, and the stipulation that only half of the grant award is released upfront have handicapped efforts to develop the community meetings. Michael will keep the group informed about future developments. Having three small gatherings in La Grande, Ashland, and Portland, where small groups would view a videotaped broadcast and then discuss it afterwards, is under consideration.

Ongoing efforts at outreach include:

- Geneforum’s interactive website surveys (www.geneforum.org)
- an offer from the ACLU to disseminate information
- Nicole Rymarchyk’s circulation of website link among providers at OHSU’s Cancer Institute

Recommendation: *At some point in the future, Geneforum may wish to de-link their interactive surveys from the Fred Friendly Seminar genetics broadcasts.*

Outcome: *At Andrea Meyer’s request, Michael Garland will send Andrea a short blurb to use for an ACLU website link to the Geneforum surveys. Andrea will submit a request to the ACLU to have the link posted on its website.*

Legislative Report

The committee reviewed the draft legislative report that was e-mailed on December 23. The following is a brief summary of edits, discussions, and agreements that occurred during the meeting. After the report is finalized, committee members and interested parties will receive electronic copies of the report; legislators will receive hard copies. There will be very few hard copies created, due to cost. There will be a link to the document in pdf format on the PACNORGG website.

Outcome 1: *The PACNORGG website will link to the report in several pieces—the Executive Summary, Recommendations, main body of the report, and each individual exhibit. The document sections will be in pdf format and available to the public.*

Outcome 2: *Any additional requests for changes to the draft report are due to Ted Falk or Astrid Newell by the end of day, Monday, January 13.*

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- Page 1/Overview, middle of second paragraph

Outcome: *The word “budding” (in front of the phrase, “biotechnology and biomedical research industry”) is deleted.*

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- Page 4/II.A.1.a) Confidentiality, first sentence in last paragraph on page

Outcome: *Delete both mentions of birth date, because birth date is not mentioned in proposed HIPAA regulations and is not unique.*

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- Page 9/II.A.3. Persons Who Seek Clinical Genetics Evaluation, Counseling . . . There was a discussion about how to clarify the first paragraph in this section.

Outcome: *Astrid Newell will rewrite this section and circulate it through the e-mail.*

- ***Page 10/II.4. Somatic Genetic Changes***

The committee reviewed and discussed a rewrite of this section, which Emily Harris proposed to explain the controversy of including versus excluding somatic genetic changes from the law’s protection. There was no disagreement that the committee should recommend further study the issue; however, there were objections to the body of this rewrite. Specific objections included: length of section is too long; the final three paragraphs don’t appear to support the preceding paragraphs; the rewrite is not balanced enough, i.e., it favors excluding somatic genetic changes; the rewrite raises more questions and is not simpler than the earlier versions; the rewrite does not offer any help toward “shaping the conceptual box of ‘special status.’”

Outcome: Astrid Newell, Ted Falk, and Emily Harris will continue the discussion outside of the meeting and will circulate another version of the section to allow for comment from the rest of the committee.

- Page 14/II.B.1., table with recommended changes

Outcome: In the “No known permission” row, under the column “Coded,” the result will be corrected to read, “No, unless material obtained before the effective date of 2003 law.”

- Page 14/II.B.1.a) Coded Genetic Research, recommendation box

Outcome: There was unanimous agreement to change the language of the final sentence in recommendation 8.a. to match the language used in the matrices. The sentence now reads, “This requirement does not apply to use in research of genetic information or DNA specimens obtained before the effective date of 2003 law.”

- Pages 20-21/Rules for IRB Approval of Research

There was more discussion about how changes in genetic privacy laws could affect a project that was approved prior to new laws’ going into effect. One researcher had concerns that the annual review process could halt a project midstream if a law changed. The majority of people present did not believe this would be problem, because samples collected prior to the laws would be governed under the earlier laws and samples collected after the law would be governed under the new law. The suggestion that IRBs could use more guidance on interpreting new laws resurfaced again, as it has at other recent committee meetings.

Outcome 1: This section (and recommendation 14) will stand as written. The law in effect at the time an IRB approves a project will govern it until the next review.

Outcome 2: Emily Harris will review earlier versions of this section and may choose to make a recommendation to Ted Falk for additional changes.

Legislative Session Issues/Next Steps

The Legislative Subcommittee will track legislation related to genetic privacy and research during the session. Katy King, DHS Intergovernmental Liaison, will set meetings with each of the remaining legislators on this committee (Senators Nelson and Courtney, Representative Shetterly) and this committee’s co-chairs. The meetings will be used to brief the legislators on the legislative report and recommendations.

Additional steps will include the following.

- Ted Falk will draft a legislative concept from the committee’s recommended changes. He will mark up the existing statute. By having Ted draft the concept, rather than waiting for Legislative Counsel to do it, the committee hopes to speed up the process and preserve the intent of the recommendations. Legislative Counsel will review and rework the draft.

- Once the draft concept is returned from Legislative Counsel, informational packets will go out to groups who might be interested in this legislation. Groups will have a chance to propose amendments to the draft.
- Next, the House or Senate Judiciary Committee will review the legislative concept.
- Committee members will request that potential key partners review the draft concept. Recommendations of people to contact included OHSU's legislative liaison (Brian Boehringer), Barney Speight of Kaiser Permanente, Bruce Bishop of the Oregon Association of Hospitals and Health Systems, Jim Gardner of the Pharmaceutical Research and Manufacturers of America, Jeff Lipps of Oregon Biosciences Association, and Scott Gallant of the Oregon Medical Association.

Other Business

Due to the committee's completion of administrative rules and near completion of its legislative report, Astrid Newell asked members to consider having the full committee meet less frequently for the next several months and/or possibly shortening the meetings to two hours. The committee will need to begin working on new agenda items (insurance, etc.) in September.

Outcome: The committee will begin meeting every other month until next fall. Full committee meetings will be in March, May, July, and September. A conference room has been scheduled in the OMA building for each month of 2003, and so subcommittees or working groups will be free to use the room during the months when the full committee does not meet.

Request: A member requested minutes be written for subcommittee meetings.

Working Group Session

Wednesday, February 5, 2003

1:00 to 4:00 p.m.

Oregon Medical Association

5210 S.W. Corbett Avenue

Future Full Committee Meetings

First Wednesdays —

March 5

May 7

July 2

September 3

October 1

November 5

December 3

1:00 to 4:00 p.m.

Oregon Medical Association

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