

Advisory Committee on Genetic Privacy and Research

November 6, 2002

Attendees

Astrid Newell (Co-Chairperson), Ted Falk (Co-Chairperson), Bob Koler, Emily Harris, Kara Manning, Katy King, Kathy Walsh, Andrea Meyer, Michael J. Garland, Victor Leo, Peter Jacky, Patricia Backlar, Laura Zukowski

Welcome and Introductions

Everyone present introduced himself or herself. Katy King, Intergovernmental Relations Liaison for the Oregon Department of Human Services, joined the meeting as a guest.

Review of Meeting Minutes from October 2, 2002

Laura Zukowski forgot to bring copies of the minutes for review.

Outcome: *Laura Zukowski will e-mail the draft of minutes from the meeting on October 2. Please review the draft minutes and send corrections to Laura directly, either through e-mail (laura.a.zukowski@state.or.us), or by fax (503-731-4091).*

Updates/Announcements

1. Fred Friendly Seminars/*Our Genes, Our Choices* — Michael Garland reported that Morgan Holm of Oregon Public Broadcasting (OPB) submitted the proposal for the \$10,000 outreach grant to the Fred Friendly Seminars. Morgan has not heard back from them yet. If the proposal is funded, Geneforum will begin development of website pages to coordinate with the Fred Friendly Seminars. OPB has not finalized the exact dates of the three January broadcasts.

The (Oregon) Genetics Plan Advisory Council is interested in the broadcasts and may participate in some fashion.

2. Marc Marengo was involved in the Ecumenical Ministries' workshops on the ethics of stem cell research. The committee would like to tie in to this outreach effort to the faith community.
3. Gene patent expert Bill Noonan (William D. Noonan, M.D.) gave his annual lecture to medical students at Oregon Health and Science University in late October. Both Astrid Newell and Ted Falk attended the talk. Dr. Noonan discussed the patenting of genes under the stricter laws currently in effect and reported that fewer patents are being issued.

4. Katy King, DHS Intergovernmental Relations Liaison, outlined the process the committee and DHS will follow for submission of the Legislative Report.
 - Once the committee finalizes the report, there will be a briefing with the remaining legislators on this committee (Representative Lane Shetterly and Senator Peter Courtney), Katy King, and one to two ACGPR members. An executive summary would be useful for the briefing, but it is not required. The legislators should be alerted to any dissension on recommendations.
 - Then, there will be a 15-20 minute briefing with the Judiciary Chairperson, along with one to two ACGPR members, and Katy King. The chairperson should be told about any dissension on recommendations.

The committee could choose to develop a DHS legislative background information sheet, but this is optional.

In response to a question about how to introduce draft legislation, Katy shared the following information.

- Any introduction of a draft bill would be separate from this committee's legislative report process.
- Committee members could ask any legislator to sponsor a draft bill.
- Committee members could have an ACGPR legislator introduce a draft bill.
- No DHS employee may support a draft bill without approval from the governor. A DHS employee may provide information about a draft bill, but cannot lobby or take a position. (A DHS employee may be involved in the legislative process as a private citizen, but not in an official capacity without permission.)

***Outcome:* Katy King will set the two briefing appointments. Katy King, Astrid Newell, and Ted Falk will attend both briefings.**

Review of Draft Legislative Report

The group reviewed more than half of the draft legislative report by going through it page by page. The following is a brief listing of corrections requested and the major discussions that occurred.

- Page 3/I.C. Committee Structure and Function — First sentence should say that the committee met monthly over a time period of twelve months, not for twelve months.
- Page 5/II.A.1.a) Confidentiality — The Advisory Committee on Privacy of Medical Information and Records is proposing legislation to resolve some small, very technical issues resulting from HIPAA. ACGPR member Gwen Dayton also serves on this committee.

***Outcome 1:* Andrea Meyer will forward some web links and contacts to Astrid Newell, which describe some issues that will result when HIPAA goes into effect and pre-empts Oregon's genetic privacy law.**

Outcome 2: The Legislative Report will include a letter summarizing the recommendations of the Advisory Committee on Privacy of Medical Information and Records.

- Page 6/II.A.1.b) Informed Consent — Remove a few words from the boxed recommendation so that it reads, “We recommend that this Committee continue to seek ways to improve upon the principle of informed consent as applied to obtaining, retaining, and disclosing DNA samples and genetic information.”
- Page 7/II.A.1.c) Genetic Exceptionalism — Move the description of the Common Rule that appears in the middle of page 20 to page 7, where it is first mentioned in the report.
- Page 9/II.A.2.a) Family History — Define the term “secondary research subject,” so that it is clearer to a reader that this term refers to someone who is not recruited for a research study but potentially impacted or harmed by a study. Also, define the acronym “IRB.” Lastly, box the final paragraph of this section, so that it is marked as a recommendation, and include it in the list of recommendations in the executive summary.
- Page 10/II.A.2.b) Clinical Diagnosis of a Genetic Condition — There was a long discussion about whether the definition of “genetic information” should include or exclude clinical diagnoses of genetic conditions (that are not based on genetic tests). The current statute defines genetic information as, “information about an individual or the individual’s blood relatives obtained from a genetic test.” The draft recommendation is to: 1) alter the statute to clarify that clinical diagnoses are not genetic information unless specifically obtained from genetic tests; 2) request that the committee be charged to continue to study the issue of whether genetic information should include clinical diagnoses that are not based on a genetic tests and family histories.

Objections to the recommendations related to researchers’ being unable to determine how a genetic diagnosis had been obtained (when extracting information from a medical record), the lack of a conclusive list of which genetic conditions have a genetic test, the “moving target” nature of “genetic” versus “non-genetic” as researchers discover more about the underlying genetics of various conditions, the illogic of having differing levels of protection for conditions like Parkinson’s Disease (no genetic test available) and Huntington’s Chorea (genetic test available but diagnosis often made through clinical observation), possibly hindering “non-genetic” research that encompasses information that is genetic in nature (such as studying the efficacy of vaccines among high-risk groups that are defined by having asthma, which is linked to genetics, or various hemoglobinopathies linked to ethnic bloodlines).

Outcome 1: Insert the phrase “of genetic information” after the phrase “the statutory definition.”

Outcome 2: This discussion was tabled due to concerns about addressing other parts of the report. At the end of the meeting, the group will consider whether to schedule a special work session.

- Page 11/ II.A.3. Privacy of Person Who Seek Clinical Genetic Evaluation, Counseling or Testing — Amend the recommendation at the top of page 11 to read, “We recommend no change in the law in this area. We further recommend that this Committee continue to monitor discrimination issues around genetic counseling and genetic testing.”

- Pages 15-16/II.B.e) Conclusion — There was a long discussion of the table on page 15 that summarizes the permissibility of research in situations where subjects have granted different types of consent. Many edits were suggested and accepted. The core disagreement concerned whether coded research required consent from subjects, rather than just notification.

Outcome 1: Separate the middle column (called “Coded or Anonymous”) into two separate columns entitled “Coded” and “Anonymous.” Results under “Coded” column will read Yes, Yes, No, No, No. Results under “Anonymous” column will read (downwards) Yes, Yes, No or possibly Yes (to be determined), Yes, No.

Outcome 2: Add a header over four columns to the right and call it “Form of Research.”

Outcome 3: After every use of the term “anonymous,” add the word “unidentifiable.”

Outcome 4: Reword the first form of consent listed to read, “Informed consent to one particular research project.”

Outcome 5: Reference every “Yes” in the first text row to a footnote that says, “Only for types of uses stated in consent.”

Outcome 6: There will be an extra working session on November 20, from 1:00 to 4:00 p.m., to continue editing the draft legislative report.

- Page 16/Recommendation box’s item 3.e. — Drop the final phrase, “and is not accessible to the researcher.” It is impossible to keep the code key inaccessible to a researcher in situations where the researcher is also the clinician.

Issues to Discuss at Working Session on November 20

- Page 22/II.B.7.b) Transitional (“Grandfather”) Clause for Studies Already Approved by an IRB — The committee will discuss the boxed recommendation about adding a transitional clause to the current statute that would allow research already approved by an IRB when the current statute took effect to be governed by the law in effect at the time of approval. Disagreement centers around the final phrase, “not to exceed one year.” There is concern about how this clause would affect research that studies somatic changes in tissues.

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Upcoming Meetings

Oregon Medical Association

5210 S.W. Corbett Avenue

- Additional Working Session
Wednesday, November 20, 2002
1:00 to 4:00 p.m.
- Wednesday, December 4, 2002
1:00 to 4:00 p.m.
- Wednesday, January 8, 2003 (second Wednesday due to New Year holiday)
1:00 to 4:00 p.m.