

**Oregon Department of Human Services
Advisory Committee on Genetic Privacy and Research**

Meeting Minutes — December 5, 2001

Member Attendees

Ken Burry, Hal Hart, Margaret Everett, Andrea Meyer, Greg Fowler, Gwen Dayton, Marc Marengo, Lori Long, Jann Goodpaster, Jeff Lipps, Patricia Backlar, Cheryl Hermerath, Jim Anderson, Ted Falk, Victor Leo, Representative Lane Shetterly (via phone), Emily Harris, Robb Moses, Mike Skeels, Jim Gardner, Jim Anderson (representing Scott Gallant/OMA),

Guest Attendees

Peter Jacky, Bob Shoemaker, Sean Stevens

DHS Staff Attendees

Astrid Newell, Damiana Merryweather, Kiley Ariail, Kerry Silvey (with DHS and CDRC), Rachel Shapiro, Laura Zukowski

Introductions

Background

Astrid Newell, Medical Consultant and Acting Perinatal and Child Health Manager with the Department of Human Services, gave a brief overview of genetic privacy activities in Oregon over the last several years.

The Genetic Privacy Act of 1995 aimed to protect the privacy of individuals in the context of genetic research diagnostics, by addressing who can collect, retain, and disclose genetic information. The act was the first legislation of its type in the country and included a property clause that stipulated that, "an individual's genetic information and DNA sample are the property of the individual except when the information or sample is used in anonymous research." Concerns about the property clause's being unenforceable in court, or perhaps inhibiting genetic research or the biotech industry prompted the 1999 legislature to convene the Genetic Research Advisory Committee (GRAC), which ultimately determined the property clause was not essential to protect privacy and recommended criminal and civil penalties for violation of genetic privacy along with other recommendations. Senate Bill 114 (SB 114) is based on the recommendations of GRAC and brought about these changes as of June 25, 2001:

- ◆ imposed civil and criminal penalties for violation of genetic privacy;
- ◆ removed the property clause from earlier legislation;
- ◆ mandated a 14-member advisory board, the Advisory Committee on Genetic Privacy and Research (ACGPR), to work with the Oregon Department of Human Services, Health Services (DHS/HS).

The Advisory Committee on Genetic Privacy and Research (ACGPR) was charged by the legislature to:

- ◆ consult with DHS/HS on administrative rules;
- ◆ consult with DHS/HS on creation of guidelines for genetic research;
- ◆ report biennially to the legislature and recommend legislative changes/actions;
- ◆ study the use and disclosure of genetic information;
- ◆ develop and refine the legal framework to define the rights of individuals whose DNA samples/genetic information are collected, stored, analyzed and disclosed;
- ◆ create opportunities for public education on scientific, legal, and ethical developments in genetic privacy and research.

Committee members should expect to begin working immediately on draft administrative rules for SB 114, which was signed into law on June 25, 2001.

Business

Kiley Ariail, a recent MPH graduate from the University of Washington who is working part time with DHS/HS and part time as a research coordinator in the Public Health and Preventive Medicine program at OHSU, made various announcements about practical details related to the committee.

1. All references to Department of Human Services, Oregon Health Division are now obsolete. The division has been reorganized and is now called Department of Human Services, Health Services.
2. Kiley will be facilitating the committee's writing of the draft rules, but will be leaving the committee toward the end of January when her employment agreement with DHS/HS ends.
3. Members updated and corrected their entries on the roster, which was circulated around the room.
4. The immediate focus of the committee will be the draft administrative rules. Some decisions and arrangements, such as elections, will be delayed until the third meeting. Until that time, the rules established under GRAC will apply. One of these rules is that there is one vote per represented group.
5. The legislature did not allocate any money for this committee to help pay for parking or refreshments.
6. Here are three basic reference documents that are posted on the internet:
 - a) National Bioethics Advisory Commission: Ethical and Policy Issues in Research Involving Human Participants, August 2001.
Volume 1 (full report) available at:
<http://bioethics.georgetown.edu/nbac/human/overvol1.pdf>
Volume 2 (commissioned papers) available at:
<http://bioethics.georgetown.edu/nbac/human/overvol2.html>
 - b) Federal Common Rule (Policies for Conducting Human Subjects Research): 45 CFR 46 - Protection of Human Subjects.
Available at: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

- c) Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1976)
available at:
<http://www.med.umich.edu/irbmed/ethics/belmont/BELMONTR.HTM>

Administrative Rules

Damiana Merryweather, Legislative Liaison with DHS/HS, described the administrative rules process and proposed timeline to the group. With the exception of the Notification Clause, which doesn't go into effect until January 1, 2002, SB 114 is in effect already. Members who serve on this committee should be aware that they are charged with representing their own interests, the interests of the group they represent, and the interests of the State of Oregon. They are constrained and obligated by the statutory language that SB 114 established.

Kiley proposed a timeline for adoption of the administrative rules, which would entail having the draft administrative rules reviewed and signed off on by DHS by January 14, filing for publication of Notice of Proposed Rulemaking in the Oregon Bulletin by January 15 in order to have the draft rules published on February 1, holding a rulemaking public hearing during the week of February 15 through 21, and having the adopted administrative rules go into effect around February 22. If the group does not meet the January 15 deadline, the entire schedule will move back one month exactly, with February 15 being the next deadline for filing of publication of the draft rules and March 22 being the next earliest possible date for the administrative rules to go into effect. Members expressed concerns about the disruption of upcoming holidays and vacations, the requirement to involve the public, losing Kiley's input when her employment ends in late January, the enforceability and workability of the statute that SB 114 changed, the lack of time for the committee to complete future assignments, and the sensitive nature of some of the issues around genetics policy.

Outcome: In the final vote, there were no objections to the committee's moving their deadlines back one month. February 14 is now the target date to have the draft administrative rules revised and signed off on by DHS. Dates for publishing the draft rules, holding public hearings, etc., are all moved back one month. The first possible date the rules could go into effect is now March 22. Rules can be reopened and amended if the need arises.

In an effort to break the task down into smaller units, Kiley passed out a list of draft rules and proposed grouping the rules into four topic areas and addressing the rules by topic. The topics would be organizational rules; rules for conducting research with genetic materials; IRB function and structure; informed consent. The group would begin to address the first topic of organizational rules today, and smaller working groups would address the other three topic areas between now and February 14. Members discussed advantages and disadvantages of this strategy. Some members expressed discomfort about the artificial constraints of breaking up the rules by topic; others were concerned

about the lack of guidance to researchers and organizations that face questions around interpretation of the law daily and the fact that most of the law's provisions are already in effect.

Outcome 1: The committee will begin to address what Kiley assumed would be the simplest sections of the statute today (Sections A, K, L). The other topics will be addressed in upcoming meetings. DHS will announce the meetings and topics, and anyone interested in being part of the various discussions will attend the meeting.

Outcome 2: DHS will set up a list serve to facilitate discussion around the topics. Anyone not attending a working group meeting can have input through list serve discussions.

Discussion and Revision of Draft Sections A, K, L

The group began discussing Section A/Scope, but did not have time to address Sections K or L.

Members did not reach agreement around issues of the scope of the law. Discussion revolved around these points:

- ◆ What constitutes “publicly available”?
- ◆ Does the site of sampling (where the tissue was collected) affect Oregon’s requirements, that is, would samples collected outside Oregon be treated differently?
- ◆ Does the subject’s residence affect Oregon’s requirements?
- ◆ If genetic samples are sent out of state, could the original Oregon collection site be sued if the sample were not protected under the laws of Oregon?
- ◆ Could researchers evade Oregon laws by collecting samples or testing samples outside the state to avoid Oregon’s stricter laws?
- ◆ Would researchers in Oregon be unable to use samples collected outside the state if other states’ legal consent requirements were less stringent?
- ◆ What are the requirements and liability for researchers who send results to another state for analysis (“disclosure”)?

Outcome: Trish Backlar will fax Astrid Newell a document that includes recommendations from the National Bioethics Advisory Commission to distribute to meeting attendees.

Upcoming Meetings

1. Working Group Meeting on the IRB registry and other IRB issues
(Section H, and Sections B, C, D, E as time allows)

Tuesday, December 18, 2001

1:00 to 3:00 p.m.

Portland State Office Building

800 NE Oregon Street

Room 120-B (first floor)

2. Full Committee Meeting

Wednesday, January 23, 2002

1:00 to 4:00 p.m.

Oregon Medical Association (location to be confirmed)

5210 SW Corbett Avenue

Portland, Oregon 97201

(503) 226-1555

In general, the full committee will meet on Wednesday afternoons. Working group meetings will be scheduled separately.