

Advisory Committee on Genetic Privacy and Research

Meeting Minutes — March 3, 2004

Attendees

Emily Harris (Co-Chairperson), Gwen Dayton (Co-Chairperson), Bob Koler, Kara Manning, Nan Newell, Patricia Backlar, Kerry Silvey, Astrid Newell, Kiley Ariail, Carol Pratt, Michael Garland, Marc Marengo, Barry Anderson, Greg Fowler, Laura Zukowski

Welcome and Introductions

Everyone introduced himself or herself.

Minutes from February 4, 2004, had been circulated by e-mail prior to the meeting. No one present had any requests for corrections or additions.

Outcome: Minutes from the meeting on February 4, 2004, were approved with the provision that edits could be made to them by contacting Laura Zukowski, laura.a.zukowski@state.or.us.

Meeting Schedule

Results of the informal survey on meeting day/time preference showed a strong preference for Wednesday meetings that ended earlier than 4:00 p.m.

Outcome: The committee will meet the first Wednesday of every month, from 1:00 to 3:00 p.m., for the rest of 2004. Laura Zukowski will try to schedule these meetings in the same room at the Oregon Medical Association. If she is unable to schedule this location for any of the meetings, she will contact the co-chairs. Gwen Dayton or Emily Harris may be able to schedule (free) conference rooms at their worksites.

Public Input Survey

Michael Garland, Education Subcommittee Chair, presented a reworked survey to the group. This version has an emphasis on privacy and exceptionalism instead of informed consent, which has been dropped. General discussion brought up questions about whether to include any questions about HIPAA, the suggestion to drop Section 4: Trade-Offs among Values, and a suggestion to find out if the public has any concerns about official and unofficial tissue banks. Another idea was to include questions to gauge trust, such as asking, “How likely is it that my family will benefit from genetic research?” or “How likely is it that my insurance company will use my genetic information against me?” These two questions, in addition to including race in the demographic section, could help measure differences in trust levels among different ethnic groups.

Outcome: Direct all feedback about the public input survey to Michael Garland, mdgar@teleport.com by March 10 (one week from today).

Current Status of Protection

There were several brief presentations:

- Astrid Newell presented information on the history and current status of Oregon's genetic privacy statutes.
- Kiley Ariail shared some background information about recent legislation in Washington that addresses genetic privacy and discrimination prevention.
- Gwen Dayton gave an overview of (federal) HIPAA privacy regulations.

Highlights of information about Oregon information included:

- The lines between what is and what is not genetic information are becoming increasingly blurred as genetic information is integrated into health care.
- Feedback from researchers at the IRB Forum last summer was that the definition of "genetic research" is subject to interpretation.
- Employers may perform genetic tests if an employee or prospective employee consents, but the employer cannot require the tests or restrict rights or benefits on the basis of genetic test results.

Highlights of Kiley's update included:

- (Washington) Senate Bill 5207 (2002) defines a "patient's [DNA] and identified sequence of chemical base pairs" as "health care information." This is a novel approach not found in any other state's laws.
- (Washington's) Senate Bill 6153 convened a Genetics Task Force that later recommended that: genetic test information should remain in medical records and receive the same protections as other medical information; the anti-discrimination law should explicitly include genetic information (including family history); all research involving genetic information should be subject to federal human subjects research protections; insurers and employers should be required to have informed consent before being able to use genetic information.
- There are four additional bills current under consideration that would: 1) include genetic information as a protected category in the state's anti-discrimination law; 2) define "genetic information" as information about inherited characteristics which can be derived from a DNA-based or other laboratory test, family history, or medical examination; 3) require informed consent before an employer or insurer uses genetic information; 4) prohibit the use of genetic information in employment decisions; 5) exclude family history from the definition of genetic information.

Gwen Dayton gave an overview of (federal) HIPAA privacy regulations that included the following points.

- HIPAA covers the use, retention, and disclosure of personal health information by health care providers, health plans, and clearinghouses. It has nothing to do with informed consent and does not cover the actions of employers or life insurers.

- Personal health information includes all health information (past, present, and future) and individual identifiers such as social security number, address, demographics, etc.
- Authorization to use, retain, or disclose personal health information is required, except for routine treatment, payment, and health care operations. Disclosures of personal health information should be the minimum necessary.
- Oregon House Bill 2305 (adopted in 2003 Regular Session) defines when a covered health care entity is required to obtain authorization and when it is not.
- Researchers are required to have authorization for use, retention, and disclosure of genetic information except when they receive a waiver from an IRB or the federal government.
- HIPAA does not carve out HIV, mental health, or substance abuse information.
- Individual states may choose to adopt stricter laws than HIPAA.
- Oregon law may still need to address discrimination based on genetic information derived from clinical care versus information derived from genetic testing.

Outcome: *Read the document that summarizes Oregon’s genetic privacy regulations (genpriv_statutes.pdf or “Oregon Genetic Privacy Statutes or <http://www.dhs.state.or.us/publichealth/genetics/docs/03law.pdf>).*

Break

Next Steps Discussion

There was general discussion about what genetic privacy would look like in Oregon if HIPAA were the only law in effect. Initial discussion identified the following potential gaps and areas of concern.

- HIPAA addresses primary disclosures, but does not address redisclosure of information by entities that are not covered by HIPAA.
- HIPAA does not treat information about mental health, HIV status, or substance abuse treatment any differently than it does other health care information.
- HIPAA would not require an IRB to review authorization for a research study. Federal law would require an IRB to review consent and authorization for a research study involving humans.
- Some of the requirements around authorization and consent under current Oregon law are administrative burdens for some entities, including tissue banks and hospitals.
- HIPAA does not address genetic discrimination by insurers or employers.
- Smaller community hospitals, private sponsors of research, and physicians doing research who have never been trained in research are of special concern. These entities are not always informed about legal requirements for proper procedures, informed consent, and documentation of authorization.
- Personal autonomy; privacy; potential discrimination against individuals, families, ethnic groups, and genders are all concerns.

Outcome 1: *At the April 7 meeting, Carol Pratt will compare genetic research under HIPAA regulations versus genetic research under current Oregon law.*

Outcome 2: Emily Harris will follow up with Jon Zonana to invite him to co-present with her and Gwen Dayton on April 7. This group will provide information about genetic testing in a clinical care setting under HIPAA regulations versus under current Oregon law.

Outcome 3: Kiley Ariail will present information about protections against discrimination based on genetic information, including the Americans with Disabilities Act and proposed federal legislation.

Other Business

This item is deferred until the next meeting due to lack of time.

2004 Meeting Schedule (First Wednesday of Each Month)

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

1:00 to 4:00 p.m.
Oregon Medical Association
5210 SW Corbett Avenue in Portland