

Advisory Committee on Genetic Privacy and Research

Meeting Minutes — July 2, 2003

Attendees

(Co-Chairpersons) Ted Falk and Astrid Newell, Bob Koler, Kara Manning, Emily Harris, Barry Anderson, Greg Fowler, Gwen Dayton, Laura Zukowski

(Guests) Diane Lund, Kate Crow

Welcome/Introductions

Guests Kate Crow, from Kaiser Permanente Northwest, and Diane Lund, from Oregon Health Forum, joined the meeting.

Announcements/Updates

- Governor Kulongoski signed Senate Bill 618, which went into effect immediately. This committee will develop Administrative Rules for this legislation in the coming months.
- In a routine review of Senate Bill 618, the Assistant Attorney General raised the question whether something that had unique bio-identifiers could be de-identified. This committee has raised that question in the past and will continue to revisit the issue.
- The Centers for Disease Control and Prevention has awarded a five-year grant of \$1.25 million to the DHS Office of Family Health for genomic program development and coordination. The purpose and goals of the grant include education of the public health workforce around genetics, and integration of that knowledge into all areas of public health, especially disease prevention. The genomics program will cover some of the key components of “Oregon’s Strategic Plan for Genetics and Public Health.” Some of ACGPR’s current members and alternates helped develop that plan. The grant period began on July 1 and is projected to run through June 30, 2008.
- DHS staff continue to work on development of website pages on genetics. Astrid Newell will announce when everything is uploaded. PACNORGG’s extensive website of Oregon public health documents relating to genetics can be accessed at <http://www.oregongenetics.org>. This site contains many documents from both this committee’s work and the Oregon public health genetics needs assessment and planning process.
- Astrid Newell announced that she recently completed work with a genomics advisory committee of the Association of State and Territorial Health Officials. One of the main projects of the ASTHO Genomics Program was to develop a tool kit for development of public health genetic programs. These toolkits are now available in hard copy and online at www.genomicstoolkit.org. She has copies of this tool kit and

will loan them out to anyone who is interested. Her e-mail address is astrid.marie.newell@state.or.us.

Public Input

- Review of Focused Conversations — Greg Fowler and Barry Anderson shared copies of a draft report and executive summary about the three focused conversations that Geneforum and Oregon Public Broadcasting sponsored this past May. The events were in Bend, Salem, and LaGrande. Barry commented that he was struck by the articulateness of the respondents. The groups were not representative of the state's larger population.

Outcome 1: Address comments and edits to Barry Anderson (andersonb@pdx.edu), Greg Fowler (gflower@geneforum.org), and/or Michael Garland (mgarland@teleport.com).

Outcome 2: Barry and Greg will look into burning a CD of photographs to create an electronic scrapbook of the focused conversations.

Outcome 3: Barry and Greg will consider removing the initial word, "only," from the summary statements in the boxes on pages 5, 6, and 7. They will correct the year from 2003 to 2004 at the start of both full report and the executive summary.

- Public Input Survey Greg Fowler and Barry Anderson updated everyone on plans for the random phone survey on genetic privacy. They hope to have the survey fielded by a market research firm in October. There will be 1,000 respondents contacted by phone, who will be demographically representative of the state's population. The cost for the survey will be covered by \$25,000 in grant funds.

Outcome: The group will start to build the public input survey from "ground zero" again. The questions will be written last after issues are developed.

Work Plan 2003-05

- timeline
- sketch of survey (at least topic areas)
- simultaneous development of public input survey and the work plan
- subcommittee/work group structure

Astrid Newell and Ted Falk passed around a list of the committee's charges for the 2003-05 fiscal year. They suggested that the committee needed to begin work on these charges, by breaking into smaller workgroups, and that the public opinion survey topic areas could be developed simultaneously.

Several people suggested different groupings for the topic areas, and suggested including input from a broader group of participants, including representatives from regulatory, billing, and clinical operations. Various suggestions for groupings included Insurance, Technology and Research, Clinical Issues, Education, Public Input; Protections, The Law and What It Covers, Patenting, Insurance; the addition of Jurisdiction (i.e., who's

protected, Oregon law and patenting, Oregon subjects studied by out-of-state researchers, use of out-of-state subjects by Oregon researchers, use of samples brought into Oregon from out of state). Based on feedback from the focused conversation participants, suggestions for additional topic areas included the need for more genetic counselors and the issue of designer babies or eugenics.

Outcome 1: *Gwen Dayton volunteered that she has contacts for experts on issues d, e, g, h (informed consent; HIPAA and Oregon law; whether family history, clinical diagnosis, or somatic changes should be included in the definition of genetic information; and discrimination based on the seeking of genetic counseling or evaluation).*

Outcome 2: *The committee will develop a list of concepts by the September meeting, so that the group may wordsmith the actual questions (with the help of the market research firm).*

Outcome 3: *Astrid Newell and Ted Falk will e-mail the entire group to ask everyone to choose at least one issue, contemplate it, and work up some thoughtful comments about it. The group will do this in place of subcommittee meetings. While considering each issue, individuals should consider what they would like to know and what types or responses they would expect.*

Senate Bill 618 Issues and Administrative Rules

- **Department of Justice Issues Related to SB 618**
Astrid Newell reported that she did submit her request for review and clarification of SB 618 by the Attorney General's office. Rhea Kessler, who helped with questions about the last set of administrative rules this group developed, has forwarded Astrid's letter on to Mary Campbell, who is assigned to review issues within the Health Services area of DHS.

Outcome: *Gwen Dayton volunteered to be available to Mary Campbell in case she has any questions regarding HIPAA.*

- **Consent and Disclosure Forms**
The consent and disclosure forms that are currently in statute are out of compliance with HIPAA and must be revised. The committee needs to review SB 618 to decide specifically which areas administrative rules will address. One area for work is the issue of whether anonymous genetic research is compliant with federal law, both from a research and legal standpoint.

Outcome 1: *The group agreed to request opening the Administrative Rules just once to address implementation of SB 618 and to clean up the consent and disclosure forms.*

Outcome 2: *Gwen Dayton will write up the question of whether Oregon's allowing anonymous research on DNA samples is in violation of HIPAA requirements for creating a limited data set, and then circulate the issue among her national colleagues with a request for responses. (The issue is whether information from a*

DNA sample can be included in a “limited data set,” which under HIPAA regulations must have all “biometric identifiers” stripped away from sample.)

Education

Discussion continued about outreach and education to IRBs around genetic privacy issues and changes in both Oregon and federal laws. The committee decided at last month’s meeting to convene a group of representatives from IRBs to work on issues.

Outcome 1: DHS and OHSU will sponsor a meeting of representatives from IRBs. The purpose of the meeting will be to generate questions and practical issues around implementation/interpretation of the genetic privacy statute, identify gaps in the law, and receive input from the major institutions in the state.

Outcome 2: Kara Manning will send some suggestions for meeting dates for the meeting in coordination with schedules of some staff members at OHSU.

Outcome 3: Astrid Newell will check with Mellony Bernal at DHS to try to locate an e-mail group of contacts from IRBs that registered with the federal government for State of Oregon research.

Outcome 4: Astrid Newell will send out a save-the-date announcement for the joint DHS/OHSU meeting by July 15. A packet of materials will be sent to contacts to review before the meeting.

Next Meeting

Wednesday, September 3
1:00 to 4:00 p.m.
Oregon Medical Association
5210 S.W. Corbett Avenue

Future Full Committee Meetings

Wednesday, November 5

1:00 to 4:00 p.m.
Oregon Medical Association
5210 S.W. Corbett Avenue