

Advisory Committee on Genetic Privacy and Research Meeting Minutes — February 6, 2002

Attendees

Astrid Newell, Ted Falk, Jeff Lipps, Robb Moses, Sean Stevens, Margaret Everett, Kiley Ariail, Daniel Field, Bob Koler, Mike Garland, Marc Marenco, Kerry Silvey, Scott Gallant, Laura Zukowski

Welcome and Introductions

Everyone introduced himself/herself. Daniel Field, from Kaiser Permanente Center for Health Research, attended as the alternate for Emily Harris.

Review of Minutes from January 23, 2002

There was one correction and one addition.

1. In the section where attendees are listed, Barry Anderson should be listed as a guest, not a member.
2. In the section, "Public Input and Education Mandated by SB 114," Mike Garland, Marc Marenco, Trish Backlar, Kerry Silvey, Barry Anderson, and Kiley Ariail should be listed as interested in participating in an education subcommittee.

Outcome: Minutes were approved with the above two changes. Laura Zukowski will make the requested changes.

Administrative Rules

Astrid Newell distributed the latest draft of the proposed administrative rules and summarized edits. Changes made since the committee last reviewed the document (January 23) are shown in red and blue ink, with the most recent changes shown in blue. The following points were discussed:

1. Recontact, pages 4-5:

No IRB permission is required for recontact if front-end consent was given by the subject, that is, if recontact was part of the original approved project design and the subject gave consent for recontact. If permission for recontact was not given by the subject in the initial consent process, then IRB permission is required for any recontact of subjects. Permission to recontact a subject does not give a researcher permission to contact a subject's physician with information.

Recontact with relatives is not addressed in this section, although the group did touch upon the issue as it relates to the privacy rights of deceased individuals. In Oregon, privacy rights expire at death (with the exception of information that relates to HIV status of the deceased.)

The word "clinical" should be struck from both places where it occurs in the first sentence of the section.

2. Procedure to Follow to Obtain Informed Consent, page 6:

Number 1(c): insert a rule number after the reference to the Department of Consumer and Business Services.

Re-number Rule 2 to be Rule 4.

Re-number Rule 3 to be Rule 5.

3. Retention for the Purpose of Testing to Benefit Blood Relatives of Deceased Individuals, page 9:

In the title of the section, insert the word "Medically" in front of the word "Benefit."

In the first sentence of the section, insert "medical" in the first sentence, so that it reads, ". . . for the sole purpose of medically benefitting blood relatives . . ."

Outcome 1: A motion to approve the draft administrative rules (with the changes discussed today.) There were no dissenting votes. DHS will still be able to change the rules after the public hearings.

Outcome 2: Astrid will write a "best draft" that includes the above changes and submit it by February 14, so that the rules can be placed on the schedule for a public hearing in March.

Leadership

At the meeting on January 23, members elected Astrid Newell and Ted Falk as co-chairs of this committee, with the understanding that the election could be reopened at today's meeting if members requested it.

Outcome: A motion to close the nomination was made and seconded. Astrid and Ted were elected to co-chair this committee with no dissenting votes.

Gene Patenting Proposal

Astrid Newell reported that she and Ted Falk have been developing a timeline for the committee's work. There is a legislative report due early in 2003, which will need to be written during November and December. The committee is charged with addressing several issues in this report. Most of these issues fit within the following three subcommittees. Each committee's assigned areas are listed briefly, also.

1. Education — providing opportunities for public education and eliciting public input on genetics issues

2. Research Issues — developing standards for recontacting patients who have provided samples for genetic research, recommending whether to modify or expand current statutory provisions requiring informed consent for genetic research, developing guidelines for encrypted research
3. Clinical Issues — addressing privacy of information about genetic conditions obtained other than through a genetic test, privacy of persons who seek genetic counseling or genetic testing, recommending whether or not to modify the notification requirement of ORS 659.715 (2) for anonymous research

The charge by the legislature to make recommendations around gene patenting will not be assigned to any of the above subcommittees. Due to the complexity of this issue and the scarcity of expertise on the subject among members, this issue will receive special treatment and be addressed by the full committee.

Various suggestions were made for accessing outside experts' help:

1. Plan a conference or forum (possibly in September) to explore gene patenting. Invite experts, such as Rebecca Eisenberg (gene patent lawyer/expert) or Bill Noonan.
2. Do a "reality check" on any recommendations the committee develops. This would involve contacting a business that patents genes and asking whether the business would consider patenting under the laws/rules the committee has developed.
3. Explore whether any of the classes that are part of the bioethics program at PSU would be interested in taking part in the process. Patricia Backlar would be the logical person to contact first.
4. Check in with Todd Shearer at the Office of Technology Transfer at OHSU for more input on any recommendations or guidelines around gene patenting.

Outcome 1: Addressing the insurance reporting requirement is deferred for the time being. The advisory committee does not need to report back to the legislature on this issue until early 2005.

Outcome 2: Ted Falk will contact one of the professors at the Lewis and Clark School of Law and ask whether it would be possible to have one of the law classes "define a set of constraints" or set a framework around the issues of gene patenting.

Outcome 3: The conference/forum will be used to explore policy once the framework is developed (possibly with the input of law students.)

Subcommittees (Education, Clinical Issues, Research Issues)

Members signed up for their choice(s) of subcommittee. The Education Subcommittee met immediately following this (full committee) meeting. The group began mapping out a plan/timeline for their work.

Results of Sign-Up:

Education—Mike Garland, Kerry Silvey, Marc Marenco, Greg Fowler, Trish Backlar, Barry Anderson

Clinical Issues—Gwen Dayton, Kathy Walsh, Sean Stevens

Research Issues—Jeff Lipps, Emily Harris, Margaret Everett, Scott Gallant, Kiley Ariail, Bob Koler

Other/Miscellaneous

The group discussed setting a standing meeting time for the full committee.

Outcome 1: The full committee will meet the first Wednesday of each month from 1-4 p.m., with the exception of July when the committee will meet on the second Wednesday. (See list of dates that follow this section.)

Outcome 2: Laura Zukowski will try to schedule a room at the OMA for each of these dates.

First Wednesdays in 2002

March 6

April 3

May 1

***June 5

July 10 (NOTE: this is the second Wednesday)

August 7

September 4

October 2

November 6

December 4

All of the above meetings are scheduled for the Oregon Medical Association except the June 5th meeting.

***On June 5, the committee will meet at the Portland State Office Building, 800 NE Oregon Street, Room 120-B.