

Advisory Committee on Genetic Privacy and Research

Meeting Minutes — July 6, 2005

Attendees

Emily Harris (co-chair), Gwen Dayton (co-chair), Stuart Kaplan, Kiley Ariail, Jon Zonana, Bob Nystrom, Ted Falk, Nanette Newell, Kara Manning, Summer Street (guest), and Naomi Adams

Introduction and Announcements

- Summer Street, the new intern for the Oregon Genetics Program, introduced herself. Summer is a University of Oregon Graduate and has a bachelor's degree in Biology. Currently she is completing the Masters of Public Administration Degree at the Portland State University (Health Administration and Policy Track). Summer intends to be with the Genetics Program through the end of November 2005, possibly longer.
- Everyone introduced himself or herself.
- Reviewed draft minutes from last meeting on June 1, 2005. Stuart Kaplan suggested some alternate wording in one of the paragraphs for the sake of clarity.
- Kiley Ariail announced her November maternity leave.

<p><u>Outcome:</u> Naomi will update the minutes as per Stuart Kaplan's suggestions. Contact Naomi Adams (naomi.adams@state.or.us or 971-673-0242) if you would like to request further changes.</p>
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Update on A-engrossed SB-1025

On 07/05/06 the House Committee on State and Federal Affairs passed the –4 amended version of SB-1025 with no nays and none excused. The bill was sent to the floor with a “do pass” recommendation. No opposition was expressed by either Providence or the Oregon Medical Association. Emily pointed out that Kaiser had some concerns, but was looking for the ACLU to agree that the language should be flexible. Kaiser representatives felt that David Fidanque's testimony helped ease concern about implementation.

Gwen explained the –4 amendments. As a whole, the changes in the –4 version were made for clarity. For instance:

- Section 6 subsection 7(c) clarifies that if the opt-out process is completed, additional informed consent is not needed for anonymous or coded research.

Specific components of the A-engrossed version of the bill were discussed. Section 5 sub (3) refers to opting out with a check-off or “mark”. Gwen explained

that the statute is intentionally not specific on this point. In practice, how an institution chooses to demonstrate an opt-out is up to the institution.

A variety of related issues were discussed, including how labs will confirm that samples were acquired with full notification of right to opt-out of future research. The process will not be specified in the law or rules. Ted Falk explained that to some extent the labs that have contact with researchers and hospitals will control the process. Kaiser and OHSU will likely create repositories of samples known to have been collected in compliance with the law. Researchers using samples from these repositories will know that labs have gone through the steps to ensure compliance.

Ted Falk pointed out that this bill regulates only the beginning and end point of specimen use. There is no requirement for a lab to keep notification and opt-out records. However, a lab that provides specimens for researcher should know that specimens are coming from physicians who have been following correct procedure. The law provides civil liability for doctors and researchers who fail to get proper notice or consent, so researchers should find out where the specimens are coming from and this shouldn't be terribly difficult for larger institutions.

The effective date of this law is July 1, 2006, at which point providers will be required to begin giving notice. Samples taken before this date will be subject to the present version of the law. The basic rule, which went into effect in 1995, remains true. The exceptions for anonymous coded research went into effect in 2001.

The group agreed that a timeline be created to clarify which version of the Genetic Privacy Law applies to samples taken at various points in time. Ted reminded the group that there is such a matrix in the 2001 Legislative report that could simply be updated

New Legislative Members Needed as Committee Members

Current membership terms expire at the end of the calendar year. Kiley Ariail asked the group to begin considering potential legislative members to recruit as committee members. The group also needs to consider a new chair and co-chair.

The Intern

Summer Street is working through November as an intern for the Genetics Program. Her project will consist of a research project exploring genetic exceptionalism, including a written report and presentation of her findings to the group. Major components will include:

- Defining and understanding the concept of genetic exceptionalism
- The history of genetic exceptionalism
- How genetic exceptionalism has been conceptualized by other states, national and international entities

- How it's been applied in Oregon specifically.
- Emerging trends in thinking on genetic exceptionalism in
 - Law
 - Ethics
 - Policy
 - Lay press

Discussion followed about relevant research questions and approaches. A number of fundamental questions were offered, which Kiley and Emily noted for project planning. Proposed questions included clarifying the similarities and distinctions between genetic information and other types of medical information, exploring whether genetic information is special in a way that requires special protections (like HIV and psychiatric information), and whether genetic issues reveal broader issues that need to be addressed, like whether the familial character of genetic information allows for the individual to be the proper unit of privacy protection. Genetic information is inherently familial and raises issues about how well privacy can really be protected.

Stuart suggested periodic progress reports to the committee. Kiley noted that some committee members would be asked for more input individually.

Outcome

Summer will put together a bibliography for the group to look at.

The Administrative Rules Process

By statute, the deadline for instituting administrative rules for SB 1025 is January 2, 2006. Kiley Ariail explained that DHS initiates and facilitates the process, but the task of actually writing the rules will fall to the committee.

The DHS rules coordinator is Christina Hartman. She will help map out a schedule for completion of the rules. Kiley will support the committee by drafting the rules as decided by the committee. Naomi Adams will assist with updates and revisions as needed.

Bob Nystrom suggested making the last 4 meetings of 2005 work group meetings to make sure the rules are completed on time. Emily agreed and suggested starting with an information session for the providers who will be affected by the new rules as well as members of the Kaiser hospital association group that may have an interest in this process and may be able to make suggestions. Gwen thought it would be better to establish what would be in the rules before bringing in outside entities.

Adjourned.

Next Meeting August 3, 2005

**First Wednesday of each month
1:00 to 3:00 p.m.
Oregon Medical Association
5210 S.W. Corbett Avenue in Portland**