

# **Advisory Committee on Genetic Privacy and Research Meeting Minutes — June 1, 2005**

## **Attendees:**

Emily Harris (co-chair), Gwen Dayton (co-chair), Stuart Kaplan, Michael Garland, Gayle Woods, Bob Koler, Ted Falk, Kara Manning, Patricia Backlar, Nan Newell, Mark Loveless, Naomi Adams

## **Announcements:**

Draft minutes from the last meeting on February 2, 2005 were reviewed. Stuart Kaplan announced that in last month's meeting, he had misunderstood The ACLU position on opt-out vs. opt-in, and had apologized to Gwen for the misunderstanding.

Patricia Backlar distributed a copy of an article discussing a study which found that people are concerned about genetic discrimination and future insurance coverage. The May 22, 2005 article discusses some of the potentially negative consequences that being able to predict illnesses will introduce as the science of bioinformatics and knowledge of the human genome advances. The article found that there is a real potential for discrimination if confidential health information is released and falls into the hands of insurers who could use the information to deny coverage. However, the author argues that this danger could lead to a great breakthrough: the movement toward a universal healthcare system.

Emily talked about the May 20, 2005 OMPH Symposium, sponsored by the Oregon Genetics Program at DHS, in which Muin Khoury and Larry Gostin were guest speakers. At the symposium, Emily and Kiley met an MPH (student Health Policy & Management track) with a strong background in genetics who is seeking a summer internship experience. She may work with the Kiley, Emily, and the ACGPR to research the genetic exceptionalism issue, provide a summary report, and give a presentation on the issue. Kiley and Emily plan to meet with her later in the month of June.

Stuart Kaplan felt that it would be helpful to know whether the potential intern has strong writing skills in order to write reviews of essays with an ability to weigh the strength of arguments, etc. Ted Falk felt that the appendix to the 2001 committee, which was trying to provide assumed principals of genetic exceptionalism, would be a good starting place. He added that she should be capable of reading legal journals, as that's where much of the discussion on genetic privacy began.

Mike Garland also agreed saying that this is a good achievable goal and is a reasonable expectation, as she has to write a masters thesis for her program.

She should perhaps be guided a little bit to look at the legal and philosophic literature as well as keep her from being overwhelmed with articles about HIPAA.

**Outcome:**

**Co-Chair Emily Harris directed that the minutes of May 4, 2005 were approved with the provision that they were still correctable. Contact Naomi Adams ([naomi.adams@state.or.us](mailto:naomi.adams@state.or.us) or 971-673-0271) if you would like to request corrections to the May minutes.**

**Kiley Ariail and Emily Harris will follow-up with the MPH student to discuss a potential internship project.**

**The Future of Genetic Privacy**

A general discussion of the future of genetic privacy followed. Mike Garland noted that in the future, the Committee should be clear that proposing changes to genetic privacy laws is not intended to diminish the importance of genetic privacy protections. Perhaps this wasn't clear to the Senate Judiciary Committee, and as a result the ACGPR-sponsored legislation faced opposition. Trish agreed, noting that it is important for people to understand that we still want to offer people protections, but existing protections may become obsolete and we may need to find new ways to protect people. Ted Falk added that it was important to realize that privacy is very much an evolving concept and it is rapidly evolving in the law and ethics.

The group followed with a discussion of the theory behind privacy and confidentiality, and just what kinds of things the intern will be expected to do including reading legal journals.

**SB 1025**

The group turned to a discussion of the status of SB 1025. Ted Falk explained to the group that SB 1025 as currently drafted has a trade-off allowing research to be done as long as there is a notice and opt-out for anonymous AND coded research.

The potential passage of SB 1025 was recognized as an opportunity for public education. Discussion followed on the content and method of delivery, particularly on whether notice will be given along with HIPAA notice of privacy practices, or independently. It was also acknowledged that the Committee needs to think carefully about defining the goals of an educational effort, the appropriate target audience, the appropriate content, and a method of delivering a useful message. One option is to create a fact sheet for electronic availability on the

DHS Genetics website. This discussion will resume after the outcome of SB1025 is known.

### **SB1025-3 Amendments**

Gwen explained that the Senate Judiciary Committee adopted the –3 amendments, and sent the bill to the Senate floor with a “do pass” recommendation. Ted Falk then explained the existing law and what the differences are, and the compromise that was made that affects the scope of the changes approved by the ACGPR.

The purpose of the 2001 (existing) law is to notify people that their biological specimens might be used for anonymous genetic research and give them the opportunity to opt out. The -3 amendments were created in compromise with the ACLU, and expand opt-out to include coded research. In addition, IRBs would have the authority to waive or alter informed consent as sought in the original SB 1025.

Further discussion addressed Emily’s concern that physicians will have the responsibility to inform patients, track whether the samples have gone through notice and opt out, and flag them accordingly. Ted explained that if a researcher finds a sample that has no indication if notice has been served, then the sample couldn’t be used. Physicians will need to create the notice and opt out opportunity; research would be unlawful unless notice and opt out had been given (page 11, Subsection G, line 21).

Gwen suggested that this policy be enforced by rule so that it is clear in the law that if a specimen has no indication of notice and opt out, then it can’t be used. The rules should also state that a researcher who uses a specimen in reliance on physicians’ action would not be held liable.

Mike Garland then questioned Section 5 subsection 1 (page 8 line 18), asking what the provider as defined in subsection 2 has to do in order to comply with this law. Gwen answered that they would comply with subsection 3 and agreed to fix the language in order to make this clearer.

Kara Manning asked Ted and Gwen about transition periods: what happens to samples obtained before the effective date of this legislation? Ted explained that there is a series of transition rules on pages 11-13. The most important is in section 9, page 13, line 7-9, specifying that the law becomes operative July 1, 2006. Page 6, lines 7-11, are also very important in that regard, as is section 7.

Emily voiced concern the language in section 5 subsection 3. She is concerned that it could be confusing and possibly change the meaning of the law. Gwen and Ted agreed to review.

Gwen also has concerns about the language in Section 5. It should be made clear that this law creates a one-time notice and that specimens may be used for research if one does not opt out. People will not be required to opt out each time they submit a specimen.

**OUTCOME:**

**Gwen and Ted will review Mike Garland's and Emily Harris' concerns about the clarity and meaning of the language in Section 5 subsection 1.**

**The Cost of Implementing SB1025**

Discussion ensued about the cost of implementing the new law. Will the cost be minimal or very expensive? What is the cost/benefit? Concern was voiced about the potential high cost of implementation. Ted noted that it is not really possible to quantify the cost.

The ACGPR has a whole has not had an opportunity to express its position on the 1025-3 amendments. While the Committee supported the original SB 1025, the amendments change the bill considerably. Concerns have been voiced about various components of the 1025-3. Ted suggested that the Committee consider whether they support proceeding with the bill, overlooking the technicalities of the language for now. He argued that if the ACGPR does not support the law, it should be abandoned.

**OUTCOME:**

**Once it becomes available, the engrossed version of SB 1025 incorporating -3 amendments will be circulated. The new opt-out provision will be explained, and an e-mail vote will be taken on whether the ACGPR continues to support this bill.**

**Adjourned.**

Next Meeting July 6<sup>th</sup>, 2005  
First Wednesday of each month  
1:00 to 3:00 p.m.  
Oregon Medical Association  
5210 S.W. Corbett Avenue in Portland