

Advisory Committee on Genetic Privacy and Research Meeting Minutes — October 5, 2005

Attendees:

Ted Falk (**sitting in as chair for Emily Harris and Gwen Dayton**), Senator Richard Devlin, Margo Neufeld, Rob Moses, Bob Nystrom, Julie Koch, David Findanque, Staci Coy, Charles Sinsel, Gayle Woods, Jon Zonana, Kara Manning, Kiley Ariail, Bob Duehmig, Summer Street, Mike Garland, Jane Alm, Stuart Kaplan, Betsy Earls, Trish Backlar, Naomi Adams,

Welcome and Introductions

- Everyone introduced himself or herself.
- Reviewed draft minutes from last meeting of September 7, 2005

Outcome:

Ted Falk directed that the minutes of September 7, 2005 were approved with the provision that they were still correctable. Contact Naomi Adams (naomi.adams@state.or.us or 971-673-0271) if you would like to request corrections to the September minutes.

The entire meeting was devoted to review and discussion of the draft administrative rules for implementation of SB1025. Several points of concern were addressed, including:

- The apparent lack of specific rule language to describe the transaction between health care providers and researchers. Mike Garland expressed the concern that researchers and IRBs will need to be able to say where the materials and specimens they use come from and that the processes that they have in place are adequate and will not result in mix-ups. Several related concerns were voiced, including a concern about keeping opt-out specimens out of the research stream, the role of the IRB in assuring compliance, and the responsibility of the researcher to assure that no opt-out specimens are used in research. Several members of the notification and opt-out working committee explained that the terms of compliance for transaction between providers and researchers was intentionally not defined. There was wide agreement within this group that because of the complexity and inherent differences in the internal operations of health systems and health providers, it is best to state the statutory requirements in general terms and leave design and implementation to the individual health system or provider.
- The apparent lack of a specific provision for monitoring compliance. In response to this concern, the group was reminded that an oversight role is not written into the statute (SB1025), and that DHS can only write rules to implement the terms of the statute. The statute is written in such a way so that voluntary compliance is called for. The penalty for a person or provider not having a process in place is a civil penalty or private right of action. The penalty ranges from \$100 to \$250,000 depending on whether the provider was being negligent or willfully reckless. An individual patient who found that their information had been used

could sue the researcher. Civil enforcement, though rarely imposed in practice, has an effective “in terrorem” effect on the people that might be affected by them.

- Educational efforts needed for both researchers/IRBs and health care providers. DHS reports that there is a statewide IRB registry now in place. The purpose of the registry is not regulatory, but educational. The DHS Genetics Program plans to implement educational activities for IRBs and researchers in the first half of 2006, similar to the IRB Forums that followed the passage of the 2003 bill. The Genetics Program will also work with health care providers and health systems on provider education activities.

After a lengthy discussion of the concerns noted above, Ted Falk led the group through each section of the rules beginning with 333-025-0160, addressing notification and opt-out. Several technical comments were made and noted for final revisions. Additional comments were made regarding circumstances in which a person is not competent or doesn't have a personal representative. Individual organizations will choose how to treat that information, however the law doesn't directly address not having the capacity to opt out.

Dave Fidanque introduced a model Notification and Opt-out form. The original Model Notification and Opt-Out was drafted by Emily Harris and has gone through several rounds of review. The current version reflects the most recent revisions by the ACLU. Several suggestions for improvement were made. Julie Koch suggested changing the header to “Genetic Research” instead of just “Research”. Mike Garland suggested including the words “genetic” and “future” in the heading. The model notification and opt-out form will be sent to an editor at Kaiser Permanente for final revision and submitted with the draft rules.

<p>Outcome: Final revisions will be made and the rules will be submitted to DHS by the October 7 deadline. The Model Notification and Opt-out form will be edited for language appropriate for a lay audience by the editor at Kaiser Permanente and will be submitted with the draft rules. Committee members and other interested parties will have the opportunity to provide written or oral testimony at the public hearing, to be scheduled for November or December.</p>

Adjourned

Next Meeting November 2, 2005

1:00 to 3:00 p.m.

Oregon Medical Association

5210 S.W. Corbett Avenue in Portland