

# Advisory Committee on Genetic Privacy and Research Meeting Minutes — September 7, 2005

## Attendees:

Emily Harris (**co-chair**), Gwen Dayton (**co-chair**), Michael Garland, Ted Falk, Mark Loveless, Marc Marenco, Kara Manning, Gayle Woods, Stewart Kaplan, Patricia Backlar, Bob Duemig, Robert Nystrom, Kiley Ariail, Summer L. Street, and Naomi Adams.

## Welcome and Introductions

- Everyone introduced himself or herself.
- Reviewed draft minutes from last meeting of August 3, 2005

## Outcome:

**Co-Chair Gwen Dayton directed that the minutes of August 3, 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 August minutes.**

The draft administrative rules are due at DHS on October 7. The rules draft should be done and sent out by end of September so that members can review and comment by the October meeting. There will be a hearing on the rules but the committee should come to an agreement on the content of the rules before then. After the draft rules are distributed, the committee will be asked to review the rules and share their thoughts with the rest of the group as soon as possible.

Notification and opt out rules will be discussed in the 9-08-05 rules working meeting from noon until 2 pm at DHS. This working group has already been provided with a first draft. A complete draft will be sent out prior to the next ACGPR meeting on October 5<sup>th</sup>. Kiley will also send out a progress note email after the meeting on 9-8.

## **Draft Research Rules**

Ted Falk explained the rationale behind the draft administrative rules relating to research. In contrast to the notification rules, which will be new, the research rules are a modification of existing rules. He then asked the group to refer to a marked up version of the draft research rules that was distributed via email and provided during the meeting and reviewed the research rules page by page.

Page 1 – definition of biological sample

Page 2 – augmented the existing definition of “deidentified” with more detail from the Federal Privacy rule

Page 4 -- definition of Federal Privacy rule

Page 5 -- Definition of Limited Data Set taken from the Federal Privacy rule.

Page 6 – Adds clarification that the Oregon Rules set standards that augment the standards set forth in federal law.

Page 7 -- Technical changes

Page 8 -- Two substantive provisions deleted because they were altered by 1025.

Major content changes are on page 8, in 333-025-0120 Section 3. The word “or” will be added to the end of each subsection a-g on pages 8 and 9 to add clarity. Ted explained the meaning of each sentence (a-g). He felt that this was all very important to understand, as these were the heart of the changes to the research rules. This section might take some reflection to fully understand and anyone who has questions should feel free to ask him for clarification.

Page 12 -- use of specimens from the deceased.

Page 16 -- conforming language.

Concern was voiced about how the link between opt-out statements and researchers will be made. According to 333-025-0120, researchers are currently required to submit research plans to an IRB for confirmation that the IRB agrees that the conditions for anonymity are met. Researchers will bear the responsibility of confirming that anonymous or coded samples are available for research and not subject to opt-out statements. How this will be done is not stipulated in the rules but will be left to institutions to determine. Mark Loveless suggested clarifying or defining the term “subject” as used in 333-025-0120 subsection a, b, and e. Gwen will try to add this in the notice rules.

Education for IRBs and/or researchers will be needed when the law takes effect. The DHS genetics program has done this type of education in the past and intends to do so again in 2006. The committee will also consider creating materials specifically for providers as well.

The draft rules deadline for the internal DHS rulemaking process is October 7. The public hearing will likely take place in December. Committee members may comment on the rules before the October 7 deadline, and at the public hearing, but not in the interim. The group should be motivated to complete review and comment as quickly as possible because a newly passed bill relating to the creation of administrative rules will require some additional work if the rules deadline is not met. Any questions about the rules should be sent to the entire group. Questions should be submitted within a week of this discussion.

### **Summer Street's Discussion of Genetic Exceptionalism Research**

Summer will send an annotated bibliography to those who request it. She is making progress on her reading and discussed the evolution of genetic exceptionalism and explained that many people have changed their positions over time. Summer agreed to look into the issue of family information and how it becomes relevant when someone is dead.

#### **Outcomes:**

- **The goal is to have the rules draft done by the end of the month of September.**
- **Committee members should send questions about rules to the entire group with the next week.**
- **Kiley will circulate the complete draft rules to the committee as a whole.**
- **The notification committee will meet at least twice, as currently scheduled**
- **Kiley will send out a progress note email after the work group meetings**
- **The word "or" will be added to the end of each sentence in section "3", on pages 8 and 9 to add clarity.**
- **The committee will try to draft in the meaning of the word "subject" as per Mark Loveless' suggestion. He was referring to page 8, where the word "subject" was used in subsection a, b, and e.**
- **Summer will send an annotated bibliography to those who request one.**
- **Summer will continue researching theories for and against genetic exceptionalism to share with the group.**

**Next Meeting October 5th, 2005**

**1:00 to 3:00 p.m.**

**Oregon Medical Association**

**5210 S.W. Corbett Avenue in Portland**