

# Advisory Committee on Genetic Privacy and Research

## Meeting Minutes — December 1, 2004

### Attendees

Emily Harris (Co-Chairperson), Gayle Woods, Nan Newell, Bob Nystrom, Margo Neufeld, Kerry Silvey, Kiley Ariail, Kara Manning, Bob Koler, Jon Zonana, Andrea Meyer, Michael Becker, Patricia Backlar, Laura Zukowski

### Introduction and Announcements

- Welcome and Introductions — Everyone introduced himself or herself.
- Review of Draft Minutes from Last Meeting (November 3, 2004) — Draft minutes from November 3, 2004, had been circulated in the e-mail prior to this meeting. Nan Newell requested clarification of the recommendation regarding the Insurance Division's *Oregon Standard Health Statement*. In addition to the Insurance Division's plan to post a notice on the form itself and on their website, the committee recommended that the DHS Genetic Program's website should carry a notice that applicants are not required to report genetic testing, genetic information, or genetic counseling on the *Oregon Standard Health Statement*. Both websites should link to each and carry the notice.

***Outcome:*** *Co-Chair Emily Harris directed that the minutes of November 3 were approved with the above correction. Contact Laura Zukowski ([laura.a.zukowski@state.or.us](mailto:laura.a.zukowski@state.or.us) or 503-731-4021) if you would like to request additional changes.*

- Gayle Woods announced that Jann Goodpaster has left state service for a job in the private sector, and so will be unable to continue representing the Department of Consumer and Business Services as an alternate member of this committee.

***Outcome:*** *Gayle will contact Kiley Ariail to recommend a replacement for Jann Goodpaster. Kiley will follow up with the recommended replacement and will request appointment through the Assistant Director of DHS Health Services.*

- Appointment of a Pharmaceutical Industry Representative member is needed.

***Outcome:*** *Kiley Ariail will contact Desiree Hollemon to confirm her acceptance of an appointment.*

### Legislative Procedures

There was a brief discussion of the legislative report and the process for introducing new legislation. If there is not full consensus on a recommendation or opinion stated in the legislative report, there will be opportunity to include one or more minority reports.

If the committee decides to proceed with one or more of the anti-discrimination concepts and/or one or more of the proposed research changes, DHS staff may not engage in the legislative process. DHS staff will be asked to comment on and make recommendations

on the concepts in writing, and may be asked to testify. Because these concepts are not sponsored by DHS, however, staff may not represent or publicly support the concepts. It is permissible for DHS staff members to work on these legislative pieces as part of their support of this committee.

It is possible that the Legislative Committee could choose to combine any or all of the amendments as one piece of legislation.

### **Research: Recommendations**

Emily Harris led a discussion of proposed changes to current Oregon genetic privacy statutes. She and Kara Manning presented a draft of suggested changes to the statutes, which govern genetic research, including consent, opt-out provisions, and retention of specimens or information. The following bulleted list summarizes discussion of each suggested change. Please note that statute citations correspond to the draft document. In some instances, the draft document renumbers the original statutes.

- Draft ORS 192.537(7) — Emily identified this change as the one she believed would be the least controversial and expressed surprise at the amount of discussion it generated. At issue in this section is whether research subjects may inspect their research records, or whether CLIA regulations would prohibit research subjects from examining any test results from laboratories that are not CLIA certified. Members were not in agreement over what the actual CLIA regulation is, how commonly research tests are performed by labs that are not CLIA certified, and whether CLIA or Oregon law would prevail if challenged.

Emily had suggested adding the word “medical” in front of “records of the individual” (last sentence in section 7). Another member suggested using the term “clinical” instead of “medical”; yet another member suggested adding (only) the phrase, “except as prohibited by law” at the end of the section.

- Draft ORS 192.547(5)(c)(A) — The suggested change would add language to an existing section to allow individual identifiers in coded research when a research subject consented to the use of his/her individual identifiers. The purpose of this change would be to enable research studies, such as multi-site cancer treatment trials, to use individual identifiers for quality control when delivering protocols or study results to a subject. (An example is use of an acrostic to identify each research subject.) A second purpose would be to ease requirements in order to avoid exclusion of Oregon residents from national research studies, especially drug trials.
- Draft ORS 192.547(5)(e) — Emily identified this change as a “quality control issue.” The proposed change is insertion of the phrase, “When there is no documented consent for genetic research:” in front of the existing language about use of limited data sets. Emily stated that current law inadvertently encourages the use of identified data over coded data. The original intent of the section was to allow for the use of historical samples for which there is no documented consent. There is concern that the

current language sets requirements for information from all coded research (and not just information for which there is no documented consent). Arguments were made that the section offers no additional protection, creates the burden of additional paperwork, discourages coded research while encouraging identified research, and is confusing for IRBs to apply to specific studies/samples.

- Draft ORS 192.547(10) — This change would insert a new section into the statute to allow next of kin to consent to inclusion of a deceased person’s genetic sample in a research study and to allow (when next of kin is “unavailable”) the use of a deceased person’s sample if the researcher follows requirements for anonymous or coded research. The rationale for this change is the difficulty that researchers have in locating and identifying who is the next of kin. In situations with sudden or violent deaths, researchers also are reluctant to contact next of kin. Other arguments in favor of this change are that the Common Rule does not apply to research involving decedents. Rather, the Common Rule applies only to research involving “human subjects”, who are defined as “living” individuals. Thus, the proposed revision is not in conflict with federal human subjects protections. . Additionally, it is desirable for a researcher to work with a “representative sample” of tissues. As individual samples are excluded from the set of potential tissue samples, the ultimate study sample can end up skewed, which can compromise the quality of a study and ultimately affect the other study participants, especially in drug trials.

Arguments against adopting this section included respect for cultures that prohibit the removal of body parts (for religious/spiritual reasons) and recognition that some deceased persons would never have consented to participate in genetic research while alive.

- Draft 192.547(11) — This change would insert a new section in the statute to allow clinical samples to be used in coded genetic research without specific consent. Emily cited the need for assessing methods of care delivery for particular conditions or assessing behavioral outcomes of genetic testing as rationales for this change. She stated that it’s “nearly impossible” to obtain consent for use of clinical samples in genetic research when consent is not obtained prior to collection.
- Draft 192.537(2)(a)(C) — This change would add language to an existing section to allow an individual to consent to anonymous genetic research in general, rather than per specimen. The reasoning behind this suggested change is to simplify tracking of consent by researchers.

During the discussion, one participant used the example of a pregnant woman’s consenting to cystic fibrosis carrier screening. The woman would give consent for the test itself, her doctor would record the test and result in her chart. She would also be given the front-end choice (at the time of consent) to opt out of any future genetic research. If she chose to keep her sample in the “genetic research stream,” researchers would be able to track her health status in future years.

***Outcome 1:*** *The committee will continue this discussion at the next meeting (January 5).*

***Outcome 2:*** *Emily Harris will ask Ted Falk to clarify whether CLIA regulations or Oregon law would prevail in situations where a research subject requests inspection of their research records, and the records contain test results obtained from a laboratory that is not CLIA certified. Either Emily or Ted will report to the committee about this issue at the January 5 meeting.*

***Outcome 3:*** *Kara Manning and Kiley Ariail will locate and share the specific CLIA regulations that govern the release to research subjects of laboratory test results conducted under a research protocol.*

***Outcome 4:*** *Kara Manning will ask the attorneys at her worksite to clarify for the committee whether a researcher at OHSU would have to comply when a research subject requested his or her own records from a particular research study.*

***Outcome 5:*** *Emily Harris will clarify with Ted Falk what Oregon law requires for consent to use a deceased person's genetic sample or genetic information in a research study. One of them will report to the committee at the January 5 meeting.*

***Outcome 6:*** *Emily Harris will report (at the January 5 meeting) on HIPAA and Oregon requirements for consent for genetic research with clinically generated samples.*

### **Insurance and Employment**

Emily Harris reported that members voted unanimously to proceed with the two legislative concepts to add protections against discrimination in employment and health insurance, which is based on family medical history or the seeking of genetic services. The vote on the third issue was split (whether to proceed with legislation to protect against discrimination in employment and health insurance, which is based on the medical history of non-blood family members). Six members voted in favor of the concept, five voted against, and four members abstained.

There was some discussion of the third concept, but there was no agreement on whether or not to proceed with it. Some people present said they were confused by the issue and suspected that others may have voted for and against the concept without fully understanding it.

***Outcome 1:*** *Emily Harris will ask Gwen Dayton and Ted Falk if they would draft language for legislative concepts that would protect against discrimination in employment and insurance based on family medical history and whether an individual has sought genetic counseling or services.*

***Outcome 2:*** *Jon Zonana will e-mail the committee an explanation of a third legislative concept that would prohibit discrimination in employment and insurance that is based on medical history of non-blood family members.*

**2005 Legislative Report: Who Is Doing What?**

***Outcome:*** *Due to lack of time, this agenda item will be addressed through e-mail. Emily Harris, Gwen Dayton, and/or Kiley Ariail will assign writers to various sections of the legislative report and communicate their plan by e-mail.*

**2005 Meeting Schedule**

January 5	July 6
February 2	August 3
March 2	September 7
April 6	October 5
May 4	November 2
June 1	December 7

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