

Advisory Committee on Genetic Privacy and Research

Meeting Minutes- June 6th, 2007

FINAL

Attendees:

Allison Naleway, Mark Bonanno, Ted Falk, Mark Loveless, Stuart Kaplan, Ron Marcum, Steve Nemirow, Kara Manning Drolet, Mary Pat Bland

June Agenda overview:

1. Agenda approval
2. Approval of Minutes for May 2007
3. Announcements
4. Discussion of Guidance on What Is and What is Not a Genetic Test - Mary Pat Bland
5. Genetic Exceptionalism 2007 Plan of Action: Discussion of key questions - Kara Drolet
6. Adjourn

1, 2 - Outcome:

- Agenda & minutes were approved. Future corrections to minutes can be directed to: john.a.anderson@state.or.us.

3. Announcements:

* Upcoming Portland Privacy Summit: Kara Manning Drolet, Michael Garland, and Carol Pratt will be speaking at the upcoming Confidentiality Issues Unique to Human Subjects Research Privacy Summit sponsored by the The Northwest Association for Biomedical Research (NWABR). Conference summary: NWABR invites you to join your peers in a discussion-based workshop about protecting the privacy of human subjects in protocols using tissue and data repositories and electronic medical records for research purposes. Learn and discuss the fundamental elements of HIPAA that impact these areas of research, understand the operational questions IRBs must ask to determine if/when the Oregon Genetic Privacy Act applies, develop functional definitions for some key terms, and work with your peers to identify best practices. Share your ideas about refining the Oregon Genetic Privacy Act with members of the state Advisory Committee on Genetic Privacy & Research. What is the future of this law? Where should it go?

Kara will share feedback received at the summit re: the Oregon Genetic Privacy laws with ACGPR.

3 - Outcome:

- Portland Privacy Conference is scheduled for Thursday Aug 23rd from 8 am- noon. To register go to: www.portlandprivacysummit.kintera.org or contact Laurie Hassell at 206-465-4691.

4. Discussion of Guidance on What Is and What is Not a Genetic Test

During the March meeting, a request was put forward that DHS draft a guidance document that lists examples of what is/what is not a genetic test as defined by the Oregon Genetic Privacy law. After discussion at the May ACGPR meeting, draft document was sent to ACGPR members for further comments/suggestions. Members were also asked to evaluate if guidance document was still useful given it will not be possible to categorize somatic/non-inherited genetic tests as anything other than a genetic test (somatic/non-inherited genetic tests are the primary area of tests presenting challenges to clinicians in Oregon based on current state genetic privacy law). Committee agreed today that document would still be useful. Additional tests to be added to guidance are: HLA typing, HPV testing. Also consider addressing sex and age testing (both noted to NOT be genetic tests in current version of federal GINA bill).

4 - Outcome:

- ACGPR members to submit any additional tests they would like included in guidance ASAP to Mary Pat Bland (marypat.bland@state.or.us). DHS will review guidance document with legal resource.

5. Genetic Exceptionalism 2007 Plan of Action: Discussion of key questions

To start off the committee's discussion on genetic exceptionalism and the need for possible changes to the Oregon Genetic Privacy law, it was requested that all members consider the following questions and be prepared to share their thoughts at the June meeting:

- * What protections for health information/biological samples are necessary that are NOT ALREADY PROTECTED under the other federal laws/proposed laws (HIPAA, GINA, etc)?
- * What types of health information and biological samples should be covered under these protections? When thinking about "protection" think about research and clinical practice requirements and discrimination protections that already exist in the Oregon Genetic Privacy law. Which of the protections under the current Oregon law should be kept? Why?

The following thoughts were shared:

* Ted Falk: It is important to consider that even the seemingly simplest modifications to Oregon Genetic Privacy law have proven to have unforeseen complicated implications. If we want to consider changing Oregon Genetic Privacy law, it is important to consider what can be consolidated and what is truly important. The passage or non-passage of the federal Genetic Information Non-Discrimination Act (GINA) will be key in determining if/what potential updates to Oregon Genetic Privacy law are necessary. Should GINA pass, it would be quite logical to reapproach the OR legislator with updates to the OR Genetic Privacy law to align state and federal laws without redundancies. If GINA does NOT pass, ACGPR would need to consider if modifying the law is truly necessary as legislation may be difficult to pass given the multiple modifications that have been necessary to date. For now, it seems appropriate to wait and see if GINA is passes.

* Stuart Kaplan: Concurr with Ted Falk. Passage vs non-passage of GINA will be key in determining committee's direction.

* Kara Manning Drolet: It may be useful to note that there are a few areas where Oregon Genetic Privacy law differs from genetic discrimination protections provided by GINA (based on the current legislative language of GINA) – no protections in the current federal law for life or disability insurance. Oregon Genetic Privacy law provides very limited protection (it is unlawful to use *blood relative's* genetic test results to deny insurance). Should GINA pass, committee would need to decide how strongly we feel about the need for this limited area of life insurance/disability genetic discrimination protection.

* Mark Loveless: Caution should be taken when considering future modifications to law...there could be potential unforeseen implications of legislative language changes. It would be important to focus on not doing major harm (e.g. to researchers, consumers, clinicians) if modifications made. Gathering feedback from clinicians and researchers about the functionality of OGP law is crucial. It would be useful for the committee to consider ways to gather more input from the groups impacted by OGP law. Law should be balanced – provide benefits of privacy protections without causing significantly hampering research or clinician practices.

Steve Nemirow: There seems to be a shift and definition of what is considered genetic research is now broadening. It is important to consider the impact of immovable law on research in this ever evolving

setting. (NOTE: In contrast to the Oregon Genetic Privacy Law, the federal GINA bill does NOT address genetic research issues.)

Allison Naleway: Oregon Genetic Privacy Law is very complex and is quite unwieldy for researchers. Many well-intentioned researchers find it difficult to follow/understand the Oregon law. For now, it seems important for the committee to wait and see if GINA passes.

Bob Nystrom: Because the foundation for Oregon Genetic Privacy Law was laid prior to HIPAA, modifications made over the years have resulted in a law that has become very complex, cumbersome, and challenging for people to understand. It seems useful to consider creating a “kinder & gentler” law that is easier for consumers, hospitals, clinicians, and researchers to follow. It also seems the fundamental premise behind the law (genetic exceptionalism) has not been intensely studied by the committee.

Ron Marcum: Agrees at this point ACGPR should wait to see if the federal law (GINA) is passed. If so, ACGPR could consider approaching the legislature with a simplified law. Genetic exceptionalism is essentially a matter of philosophy: does genetic material deserve special protections and if so, what exactly needs to be protected? It seems appropriate for ACGPR to not work on legislative fixes to the law until it is clear what will happen with GINA. The small/minor fixes that have been made to Oregon Genetic Privacy law can be taxing to clinicians, hospitals, and researchers. If committee feels in the future changes are needed, it would be important to consider a more significant overhaul of the law.

Stuart Kaplan: It may not be possible to come to a clear conclusion as a committee about genetic exceptionalism. There are likely to be many different perspectives. A discussion around this topic could still be useful but it is important to realize it may be unrealistic to expect a unified perspective on the topic.

Ted Falk: The question of genetic exceptionalism will be answered for ACGPR should GINA pass.

Committee agreed on the importance of gathering more feedback from those impacted by Oregon Genetic Privacy law. Kara will be asking participants at the upcoming IRB/Research Genetic Privacy meeting in August about their thoughts on Oregon Genetic Privacy law. Committee discussed ways to actively gather feedback from other sources. Suggestion was made to have genetic counselors in the state participate at a ACGPR meeting and provide feedback on how law is functioning for them/their patients. Suggestion was also made to send out question about Oregon Genetic Privacy law to clinical labs in the state via mailing (Terry Crandell could help coordinate) requesting input. Co-chairs and DHS to discuss and propose more formal plan to ACGPR.

July meeting will be canceled (on July 4th). During August meeting, committee can address genetic exceptionalism question further...given her background in ethics, Trish Backlar would be the natural person to lead this discussion.

5 - Outcome:

- Committee will not discuss potential legislative updates to Oregon Genetic Privacy law until status of federal Genetic Information Non-Discrimination Act (GINA) is clear. Committee will discuss concept of genetic exceptionalism further. Committee will also consider ways to more actively gather feedback from those impacted by Oregon Genetic Privacy Law (labs, researchers, genetic counselors, consumers).

6. Adjourn