

Advisory Committee on Genetic Privacy and Research Meeting Minutes — August 2, 2006

Attendees:

Mike Garland (co-chair), Jon Zonana (co-chair), Robert Nystrom, Mary Pat Bland, Gayle Woods, Steven J Nemirow, Amy Thomas, Allison Naleway, Andrea Meyer, Terry Crandall, Ted Falk, Gwen Dayton, Nan Newell, Kara Manning-Drolet, Sn Richard Devlin, Mark Loveless, Patricia Backlar, Casey Bush (guest), Robb Moses

Announcements and introductions:

Introduction of two new ACGPR participants: Steve Nemirow, Director of the Kartini Clinic for Disordered Eating. Steve will be representing “Public Members of IRBs” on ACGPR. Mary Pat Bland, the new Genetics Program Coordinator w/DHS, was also introduced. Guest Casey Bush was in attendance to share Legacy’s experience with Opt-Out Notification.

Minutes from June’s meeting were not available for approval. The July ACGPR meeting was canceled due to the July 4th holiday.

Outcome:

June 7th’s minutes will be proposed for review in September along with August’s minutes.

Candidates are being interviewed for the Administrative Specialist 1 (AS1) support position with the DHS Genetics program.

Outcome:

Bob will keep the committee posted as things develop in this area.

Update on New Member Recruitment

Nan Newell mentioned she was contacted via email by a person from the biosciences industry that indicated that they might be interested in participating in ACGPR. Unfortunately, the individual’s contact information was lost & although Nan has made various attempts to locate this person, it has not been possible. Hopefully this individual will recontact Nan soon.

Outcome:

Mike Garland will continue to work on committee recruitment.

Education Material Update: Researcher and IRB Fact Sheet

Educational fact sheets for consumers & providers have been completed and are posted on DHS Genetics Program Website (www.oregongenetics.org). DHS has received positive comments from several sources on the helpfulness of these materials.

Draft of Fact Sheet for Researchers & IRB was created by Kara Drolet. A copy of this document was sent to the committee with deadline for comments set for August 4. Thus far, only 1 committee member has responded with suggestions. Two issues were discussed: 1) how to better define what constitutes a genetic test & 2) the possibility of providing an algorithm to researchers/IRBs that more clearly delineates the steps necessary for the particular type of genetic research being conducted. After some discussion, it was decided that it is better to complete & post the Researcher/IRB Fact Sheet ASAP rather than significantly modifying the document to address the previously mentioned concerns. Additional resources for researchers may be created (such as a document that uses specific case examples & more clearly defines what follow up steps need to be taken for the various types of genetic research (e.g. coded/anonymous studies vs open studies)).

Outcome:

New deadline for comments on Fact Sheet for Researchers & IRBs is August 11th. Unless major concerns are raised by a committee member upon review of this document, minor changes will be incorporated into fact sheet & final version will be sent to committee members & posted on DHS-Genetics Program website shortly after August 11th.

DHS-Genetics Program will continue to work on a checklist for healthcare providers & institutions reviewing the basic steps necessary to comply with SB1025.

Discussion: Response to Opt-out Notification

Kara Drolet provided insight into OHSU's experience w/opt-out notification. The percentage of patients that are choosing to opt-out will be greater as staff at OHSU Integrity Office have not yet processed all of the opt-out letters received. ~198 K opt-out notification letters were sent to pts & Integrity office has received ~7100 "opt-outs" (~3-4%). Kara noted most callers she has spoken with were unaware of the fact that anonymous & coded research normally occurs in medical settings prior to receiving opt-out notification. Most callers were also unaware of Oregon's genetic privacy statute prior to receiving an opt-out letter.

Senator Devlin noted that one would hope consumers would appreciate the fact that they are now being given a choice that they previously had not been given. The Senator also noted that consumers are accustomed to having to "opt-out" vs having to "opt-in" for most other elective programs.

Terry Crandall noted that laboratories in the state have been struggling with logistics re:SB1025. Terry has received phone calls from 12 different labs with various questions about implementation (e.g. what specimen types does opt-out apply to, what to do if a specimen is split & ½ is sent to an outside reference laboratory etc). Some issues were clarified: opt-out provision applies to any biological specimen (NOT just blood samples submitted for genetic testing).

Gwen Dayton noted that she has heard anecdotally that the vast majority of individuals are opting-out in rural communities. She noted that hospitals are wondering if this is due to the fact that often the genetic research opt-out form is provided to patients at the time they are signing multiple documents for pending in-patient care (e.g. surgery). These patients may be automatically signing the opt-out form without thoroughly reading it over.

Casey Bush provided information on Legacy health system's experience with genetic research opt-outs. Legacy has hospital personnel review their opt-out form with patients. Review time is taking between 5-40 minutes (when pt is seeking treatment review times tend to be shorter). Out of the 1st 10K patients that were informed of their opt-out option, 37% have decided to "opt-out". In general, it seems the longer information is reviewed with patients, the more likely they are to "opt-out".

Discussion of why SB1025 set up to have pt's "opt-in" if they do nothing vs "opt-out". Recollection was that a default of "opt-in" provides a greater benefit to researchers. The option of having BOTH opt-out & opt-in boxes on a form is allowed by SB1025. This is what is done on Providence form.

Allison Naleway reviewed Kaiser experience thus far w/opt-outs. Letters were sent to all members. Kaiser also has backlog of requests for opt-out status. So far ~480K letters have been sent to members & ~29-30K individuals have decided to "opt out" (~6%). Allison mentioned her sense, like Kara, is that individuals are now aware of the fact that IRB approved anonymous & coded research is done in other areas of medicine w/out their consent.

Outcome:

Sub-committee of Jason Davis from OHSU (davisjas@ohsu.edu), Casey Bush from Legacy (CBush@LHS.ORG) & Steve Nemirow (chair) will monitor experiences of various medical centers w/genetic research opt-out implementation. Information will be compiled & included in 2007 ACGPR Legislative Report.

Discussion: SB99 future plans and Health Information, Privacy and Security Collaborative

The core concept of the original bill was reviewed (improving HIPPA conformity and reducing barriers to information exchange related to healthcare treatment, payment and operations). Gwen & Ted drafted a simplified SB99 concept (hardcopy was provided to

ACGPR members). Two items were added-Section 5, subsection 4 & 5-wording was added to address concerns raised when SB99 presented to Judiciary Committee in 2005 re: health insurers using health info for discrimination.

The 2 SB99 amendments that were proposed in 2005 were discussed (hardcopies provided to committee members). “-1” or the “anti-discrimination” SB99 amendment was proposed to clarify the restrictions on health insurers when using genetic information. The “-2” or SB99 amendment “limiting use of genetic info” proposed to restrict the use of family medical history and the use of information about the act of seeking genetic counseling, in insurance or employment decisions. Committee discussed whether or not ACGPR should consider “-1” or “-2” amendments.

Senator Devlin encouraged ACGPR members to meet w/members of 2007 Judiciary Committee for a substantive amount of time if the decision is made to reintroduce SB99. Bill should be presented simply with concrete examples for the legislators.

Jon Zonana noted that a federal anti-discrimination law has been proposed & passed by the Senate. Although the law has multiple sponsors in the House, it has been stalled. Despite bipartisan support, it is unlikely legislation will be passed this session. IF statute were to pass, there may be no need for SB99. Should committee defer working on proposing SB99 until we know more about federal legislation?

Outcome:

- Committee voted to move forward with SB99. ACGPR subcommittee that will lead this effort includes: Gwen Dayton (chair), Andrea Meyer, Amy Thomas, and Brian Boehringer (OHSU).
- Committee also felt consumer informational pamphlet summarizing existing anti-discrimination legislation would be useful. DHS & Jon Zonana to work on this project.

Presentation by Jodi Pettit, MD and Summer Boslaugh, MBA,MPH from Oregon Health Care Quality Corporation on the Health Information, Privacy, & Security Collaborative Project:

Project works to optimize healthcare systems sharing/managing health information efficiently & confidentially through a process of reviewing legislation & best practices as they apply to a variety of complex clinical case scenarios. Group is looking for participants & would welcome involvement from a member of ACGPR. More information can be found at: <http://www.q-corp.org/q-corp/default.asp?id=33>

If ACGPR members are interested in working on the Health Information Security & Privacy Collaboration project, contact Dr. Jodi Pettit at 503-706-2208.
jody.pettit@state.or.us

Continued Discussion of Special Status of Genetic Information as Basis for Public Policy:

Mike Garland, Patricia Backlar, & other subcommittee members will continue this discussion with the goal of bring information back to ACGPR by the October meeting.

Adjourned

Next Meeting Sept 6, 2006

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

Oregon Medical Association

5210 S.W. Corbett Avenue in Portland