

# Advisory Committee on Genetic Privacy and Research

## Meeting Minutes - Nov 7th, 2007

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### Attendees:

Andrea Meyer, Nan Newell, Steve Nemirow, Terry Crandall (alternate), Ron Marcum (alternate), Gayle Woods, Kara Manning Drolet, Bob Nystrom (DHS), John Anderson (DHS)

### September Agenda overview:

1. Agenda approval
2. Approval of Minutes for October 2007
3. Announcements
4. Continued Genetic Exceptionalism Discussion – walk through two examples of tests. How are they currently protected?
  - a. HepC
  - b. Huntingtons
5. Plans for obtaining input on Oregon Genetic Privacy law.
  - Dec. 5 meeting: input from lab managers
6. Adjourn

### 1, 2 - Outcome:

- Agenda was approved, with item 5 moved into item 3. Minutes were approved, with the following corrections:

KMD – Predictability and the ability to perform interventions are important considerations in relation to discrimination in insurance, as opposed to considering only whether or not a test is genetic. The hypothetical situation is a patient who has no symptoms, does not have a genetic condition, but has undergone a predictive test.

KMD – What does Oregon law do that other laws don't? Mainly, some additional minimal protections. If GENA passed, there would be some minimal additional protections in the areas of life and disability insurance. Otherwise the laws are duplicative.

- Future corrections to minutes can be directed to [john.a.anderson@state.or.us](mailto:john.a.anderson@state.or.us).

### 3. Announcements, and Plans for obtaining input on Oregon Genetic Privacy law:

#### Oregon Genetics Program Births

October 30<sup>th</sup> - Addison Anne Farley born to Mary Pat Bland. >9lbs.

Nov. 5 - Leor Noam Poris born to Amy Zlot. >7lbs.

Congratulations!

They will both be back in January...Kerry Silvey will be filling in halftime.

## Plans for Obtaining Input

The committee is renewing the request for people to attend. Terry Crandall has found several people...he hopes also to get Rogue Valley and Salem Hospital.

Some groups of specific types of people to attend meetings would be:

- Researchers
- Genetic counselors
- Diagnostic lab techs
- Consumers
- Hospital administrators/medical records personnel

Lab managers will attend the Dec. 5<sup>th</sup> meeting. Jim MacLoury is also a source of other names, and Paul Dorsey has volunteered to be a point person.

Keep an eye open for additional names...the committee will see how it goes on Dec. 5<sup>th</sup>.

### **3 - Outcome:**

- An email by Kara Manning Drolet will be sent to the entire list on the subject of obtaining input.

## **4. Continued Genetic Exceptionalism Discussion**

The committee continues to walk through the comparison documents with the HepC/Huntingtons example.

KMD – The greatest difference between the Genetic Privacy Act/HIPAA/Common Rule is that the GPA has the opt out/notification requirement/opt out tracking if consent is waived.

The headache here is the broad definition of genetic testing, genetic research, and the opt out requirement (particularly when the researcher may not agree that it is genetic research). For the example of HepC/Huntingtons:

### HepC

obtain liver samples  
de-identify sample  
look for HepC in sample  
waiver of consent is ok, because it's not genetic

### Huntingtons

obtain blood sample  
de-identify sample  
subject can opt out, because it's genetic

Why is this the case?

AM – Because it's the law...should I defend the law? If anything this argues for an expansion of the law.

NN – If it's anonymous what's the problem?

AM – Nothing is truly anonymous, due to the genetic characteristics.

KMD – There are no identifiers...the sample can't be matched to a person.

AM – That may not be true...research should not be conducted on people who don't give consent. Consent is a key right.

NN – There are two arguments here...the last one, and that DNA itself is a personal identifier. The law doesn't agree with that.

AM – The ACLU instituted policy change, and it didn't happen quite as expected. The law is still important in principle, in spite of the resistance to opt out.

KMD – The charts are a way to compare the laws, due to the large amount of information.

AM – What is the definition of a genetic test? Why are there discrepancies between different things? Why not expand protections to all?

RM – Both the common rule and HIPAA say that once the sample is de-identified, it can be used in research. Oregon law adds the opt out option and notice to patient for genetic testing. We are exceptional in that regard.

AM – The rights of an individual are another protection.

RM – We didn't want to duplicate effort. If Oregon law adds reasonable protections, we may keep it in spite of federal law.

KMD – Looking ahead, this exercise could help us answer questions like “should we keep this law?” and “can we make these definitions more clear?” The comparisons could help us work out what to protect, and help us see if we care about changes that are not inherited.

SN – If a debacle happens and the DNA is de-identified...“de-identified” as a convention within the law suddenly becomes less convincing, possibly.

NN – For 911 people stepped up...

RM – The law spells out explicitly that you don't make an effort to find the other part of the info.

AM – Human error, bribery and thievery exist. Clearly, genetic info about me is also about my family. A broken nail doesn't tell about my family, but DNA does.

RM – A broken nail, or bone could tell certain things...

AM – But it is not a code that I and my family carry. It's more concrete than the broken nail example. We want to empower people with the info to make decisions.

SN – This is really an argument against genetic exceptionalism.

AM – No...

SN – The HepC/Huntingtons example...there is no reason to treat them differently.

AM – Once it becomes genetic, you get more information vs. the more speculative.

SN – So we think genetic info is loaded...but this is the fad of the moment. We now know that HepC is genetically influenced. We should be respectful of all information...

AM – Still, genetic information is exceptional.

RM – We can still draw together several pieces of information and learn a lot, without genetic info.

AM – Data mining. Do we need additional protections for all information, is a question.

NN – To expand the conversation...knowing that research contributes economic value...are we ok giving up a certain amount of research? It's another piece of the puzzle.

AM – I would want better information on that.

NN – Since the law was passed in 1995, research is down. Is Oregon willing to give up research preeminence?

SN – It presumes that you can show the law caused that, not competition between research centers.

NN – I don't have the data, but is this an issue?

AM – We need more information to determine if it should be a part of our discussion. It would be very challenging for us to determine what data and factors would go into an analysis to support a statement that research is down in Oregon, including many factors beyond the Oregon law, and I think this would go beyond the scope of our work.

KMD – Has the notification requirement harmed research? We need more time to determine the impact.

NN – It's worth considering looking at.

SN – We have the opt out figures...they're higher than you might have thought.

AM – Ask people if they feel they got something in return for opt out vs. research.

SN – Researchers may provide their view about that.

AM – If we have a conversation, let's be careful about conclusions.

KMD – Other parts as applied to research are not as unique to HIPAA...the laws are more similar. Both HIPAA and the Common Rule waive consent in certain circumstances. With GPA you have the right to have your sample destroyed.

RM – Info captured in good faith does not have to be retrieved.

KMD – In practice...the clinic would return the sample.

AM – Some law enforcement situations are outrageous.

RM – The question about DNA destruction...if it impacts research, does it matter? (for example, if the sample is taken halfway through)

KMD – No, it doesn't take that into account.

AM – It depends on the agreement signed. Have samples been withdrawn?

RM – There has been revocation of authorization. You can destroy the sample and still have the code, the analysis and work product.

NN – Does Oregon cover law enforcement?

KMD – Yes, some parts.

RM – You can refuse to give blood to the police.

SN – Yes, but there is a presumption.

AM – There could be research in prison.

NN – The Common Rule has protections.

BN – And law enforcement has to seek a court order.

AM – Not always...for example a National Security Letter.

KMD – A researcher can't give results except from a CLIA-approved lab.

AM – It's unique but not exceptional.

NN – What does private right of action mean?

AM – It means I can't sue, but I can hope the Attorney General will take action.

BN – Is a class action a bundle of private rights of action?

AM – Yes.

SN – A civil penalty, a fee the court imposes.

KMD – The next step is to go back and look at the definitions as part two to the discussion. For example, a genetic test could tell you things about your family.

SN – For example, if your family history predicts 60%, what about the other 40%?

NN – There are about 4000 single gene diseases. You're only tested if it's in your family.

RM – This is just the threshold of understanding the breadth of this.

NN – The single-gene diseases are rare compared with what is coming down the pike.

KMD – The speakers can talk about what is or isn't a genetic test.

AM – That's been a discussion over the past 3-4 years, and the question is do we take it to the legislature?

NN – We need to learn where medicine is going.

KMD – Maybe we're ready to tackle looking at the definitions, and making improvements.

RM – One of our charges is making recommendations of improvements to legislature.

KMD – One provider complained of hardship regarding compliance with the law for cancer treatment.

Am – We need more members and more legislators.

NN – Another path is "all tests are genetic", and do you want to opt in/opt out of everything.

SN – It's part of what we are considering.

NN – The first thing the doctor does is take a family history.

SN – The heritable and not genetic example (environment starvation) is something we could look at.

**4 - Outcome:**

- The speakers will provide further input.
- We will start to look at definitions, and the possibility of modifying them.

**6. Adjourn**