

Advisory Committee on Genetic Privacy and Research

Meeting Minutes - Dec 5th, 2007

Phone Attendees:

Ken with Interfab, Rich with the Eastburn Clinic in Corvallis, Steve Joyce with Rogue Valley, Harlan Acres with Good Samaritan Hospital, Vivian Benfield with Oregon Medical Laboratories, Matt with Quest Diagnostics, Anna, Ted with Quest Diagnostics, Kelly with Lab/Cor, Rebecca,

Terry Crandall, Ted Falk, Bob Nystrom, John Anderson, Kara Manning Drolet, Andrea Meyer, Ron Marcum, Jim MacLowry (OHSU), Stuart Kaplan

December Agenda overview:

1. Agenda approval
2. Approval of Minutes for November 2007
3. Announcements
4. Input on Oregon Genetic Privacy Law – discussion with lab managers
5. Begin discussion on definitions
6. Adjourn

1, 2 - Outcome:

- Agenda was approved
- Minutes were approved, with typos corrected and Andrea's changes.
- Future corrections to minutes can be directed to gwen.trieu@state.or.us.

3. Announcements:

The January meeting is cancelled.

Susan Hayfield, OHSU, Casey Bush and Pierre LeChance and possibilities for the February meeting.

3 - Outcome:

- More info on guests for the February meeting later.

4. Input of Oregon Genetic Privacy Law – discussion with lab managers

Matt, Quest – A summary of how we handled this: we reviewed the law, and based on the law and its broadness and definitions we have taken the position that samples are precluded from being used for anything besides the ordered test. To manage the intent of the law, opt-out patients are tracked with excel.

TC – What is your position?

Matt, Quest – Compliance officer, NW Business Unit.

TF – Have there been problems with compliance, pre opt-out?

Matt, Quest – There were no challenges to the law prior to opt-out, by clients or providers.

Rebecca, Anna – We agree.

Vivian Benfield, Oregon Medical Laboratory – There's no genetic research here, we ignore opt out info. We don't forward info and the law doesn't say what to do with the info. We may send a blanket letter, once we decide that we need to.

TF – Any compliance issues prior to opt-out?

Vivian Benfield, Oregon Medical Laboratory – Only once...a particular physician didn't want any patients to have genetic research.

BN – How often are you approached for genetic research?

Vivian Benfield, Oregon Medical Laboratory – Never.

KMD – Researchers would approach hospitals, not labs.

Rich, Eastburn Clinic – We send a blanket letter...only the ordered test, nothing else. There's no option to opt-out: everyone is opted out automatically.

BN – So it's a risk management system?

AM – The intent was ease in the sense of allowing patients to opt-out and still have research.

Steve Joyce, Rogue Valley – We considered the blanket letter to labs. The burden is tracking the info and informing patients of opt-out rights.

AM – What do you do?

Steve Joyce, Rogue Valley – Give the opt-out info to patients and then record that. We get a form that can go with the sample to the reference lab.

AM – Orally or written?

Steve Joyce, Rogue Valley – I don't know. If we get a form we record that.

AM – Is it part of the materials given to patients?

Steve Joyce, Rogue Valley – Yes. The problem is the volume of samples taken. The responsibility falls on the physician.

Harlan Acres, Good Samaritan – Physicians have the opt-out forms. There are two types of specimens here...not many opt out anyway.

Southern Oregon – We have a lot of people here who want to opt out.

Kelly, Lab/Cor – We are the same as Quest. We only do the test, not research, and the sample is thrown away. We point out that it's the direct providers responsibility. We image any opt-out we get.

RM – Do you keep test results on site?

Kelly, Lab/Cor – Yes...we are required by CLIA to keep them for seven years.

BN – Are you approached for research?

Kelly, Lab/Cor – No.

Jim MacLowry, OHSU – We do many things on specimens. We do a blanket letter to reference labs...no research. All patients coming to OHSU have the opportunity to opt-out. When OHSU is approached for research, we review the opt-outs. Genetic and non-genetic are treated the same way. Any specimens that go to consultants are marked not for research.

Labs need to review all materials with the same seriousness...genetic or non-genetic.

AM – So you treat non-genetic as opted out?

Jim MacLowry, OHSU – Yes.

KMD – The labs are indicating that the tracking procedures are complex and so they are doing blanket opt-outs, since the burden is on the primary provider anyway.

AM – The opt-out should be honored, regardless of breaks of obligation.

RM – Labs of direct providers have an obligation to pass on data.

TF – The labs have made adjustments to simplify their lives and comply with the law.

AM – As long as it never gets to research, that's fine. The issue is a third party lab that is not notified of the opt-out.

RM – We get outside samples with no indication, we default to opt-out. This is what the labs are doing as a blanket policy.

AM – The spirit if the law is that the intent of the opt-out is carried through.

Jim MacLowry, OHSU – When they don't do research, it doesn't come up. And OHSU defaults to opt-out. For very high-interest samples, the chain is followed back to determine opt-out status.

AM – Is there still a possibility that it can go to a research lab?

Vivian Benfield, Oregon Medical Laboratory – The letter of the law doesn't require us to forward opt-outs.

TF – As a note, the committee does recommendations and advisory work for policymakers, not enforcement.

KMD – Mary Pat Bland may be able to provide guidelines for indirect providers.

BN – The committee exists to inform the legislature in terms of how the law is serving the community and providers. We need to hear what you are actually doing.

TF – Since we have you on the phone...just looking at clinical testing, do you have problems or issues with consent to genetic vs. non-genetic? That is, certain consents are required, even clinically for genetic tests.

Harlan Acres, Good Samaritan – Not at Good Sam.

Jim MacLowry, OHSU – What form do you mean?

TF – Not a form, just a generic requirement for consent for a genetic test.

Jim MacLowry, OHSU – Diagnostic appropriateness is the only requirement.

TF – It's not a special form, no.

RM – Do you believe that the definition of genetic test applies only to testing, or also the results of a test?

Steve Joyce, Rogue Valley – We understood there was additional info, but as a community hospital we were not directly involved.

Matt, Quest – Policies are that we don't release info or use it for other purposes. The info only goes to the clinician and the patient report.

RM – The test AND the info are subject to this law, in the opinion of OHSU.

KMD – Any other comments?

Jim MacLowry, OHSU – For our lab, some types of specimens, reports, tests, and samples can be used for calibration etc. We don't consider it research. It's QC. I imagine other labs do this.

AM – The ACLU is not concerned about this.

KMD – It's not addressed in the law.

BN – Quest mentioned that they exclude samples from QA.

Matt, Quest – Patient challenges were a part of our conservative approach.

TF – This has been permitted from the beginning, I think...validation of a lab process is not research. CLIA had specifics on validation of lab samples.

Matt, Quest – A FAQ to the lab community would help.

Jim MacLowry, OHSU – Although we would have to defer to DC, not Salem.

Kelly, Lab/Cor – The statute includes DNA, RNA, mitochondria...what about chlamydia and gonorrhea?

Jim MacLowry, OHSU – If you search for the genetics of the organism and not the patient it's not a genetic test.

KMD – Thank you, this was very helpful, we will look into a FAQ for labs.

4 - Outcome:

- The committee will investigate producing a FAQ about opt-out and genetic testing for the lab community.

5 Begin discussion on definitions

Genetic exceptionalism can apply to both family members and future (currently asymptomatic) diseases. A narrower definition for genetic testing will include conditions known to be heritable, and asymptomatic individuals. The SACGHS report has helpful information.

TF – They don't think that the distinction makes sense, but why are so many states adopting exceptionalist ideas? Is it a neutral group?

KMD – I imagine most are genetics specialists.

BN – It's broad-based, as per the front of the report.

TF – It would be good to know who's report this is, before we go too far down the road.

AM – Are they privacy experts?

BN – I don't have a list of individuals.

KMD – It's oversight, not about exceptionalism.

SK – Page 28 asks what's the big deal? There are two responses: get rid of rules for genetics tests, or improve rules for all tests.

KMD – We worked with the comparison document last time, research in particular. We might have trouble putting genetic tests in a box, vs. treating EVERYTHING as genetic. But this doesn't address the real concerns about genetics. So what kinds of genetics tests becomes the issue.

SK – Have been here for most of the genetics exceptionalism conversation, wondering about the utility of that direction

AM – We shouldn't just look at consistency.

KMD – We could just leave the laws as they are. Just wondering if the conclusions we have made are correct, and if we should that in law.

JM – Genetic vs. non-genetic is problematic given the advancing knowledge in medicine. We could get into a hopeless morass of what is and isn't a genetic test. There is no way genetic info can be specifically protected in relation to the other info, in terms of theft etc.

AM – HIPAA and the pharmacy database for schedules 2, 3 and 4...law enforcement can subpoena it. Why does this not violate HIPAA?

JM – From a lab standpoint, there are many constraints on releasing data.

AM – Given this example, I'm wary of lowering the bar elsewhere.

JM – If there is a lab data problem, work on that in terms of genetic testing.

AM – Some say we don't need the Oregon law, since we have HIPAA. But look at the pharmacy database.

JM – What does HIPAA say about the pharmacy database?

KMD – This question will come up again on the agenda in February.

5 - Outcome:

- The definitions discussion will continue in February.

6. Adjourn