

2011 Report to the Oregon Legislature

Advisory Committee on Genetic Privacy and Research

March 2011

Executive summary

The Advisory Committee on Genetic Privacy and Research (ACGPR), created in its current form by the Oregon Legislature in 2001 (Senate Bill 114), studies the effect of Oregon's regulation of the use and disclosure of genetic information. In this report, the ACGPR:

- Reviews discussion on reconciling the federal Genetic Information Nondiscrimination Act (GINA), the Health Insurance Portability and Accountability Act (HIPAA), and the Oregon Genetic Privacy Law (OGPL).
- Reviews a study done for the committee on the past and continuing financial impact on health care systems to implement the changes to the law in 2005 (SB 1025).
- Summarizes other major topics of discussion during the biennium.
- Reviews progress on work proposed in the report to the 2009 Oregon Legislature.

In the 2011-2013 biennium, ACGPR will continue to monitor the effect of OGPL on medical research, access to health care, and health care providers' management of health care information and review national and international genetic privacy issues as they relate to OGPL. However,

ACGPR does not have the resources to achieve some of its recommended and mandated activities, including:

- Conducting a detailed examination of any changes needed to Oregon's genetic privacy statutes in light of the passage of the federal GINA and adopted rules governing GINA and HIPAA.
- Fulfilling the ACGPR's charge of educating the public and eliciting public input representative of the diversity of opinions on the scientific, legal and ethical development within the fields of genetic privacy and research.
- Taking the lead on any legislative changes that the committee proposes.

The ACGPR concluded at the end of the 2009-2011 biennium that the committee's charge is not being adequately met through volunteer and non-funded Oregon Health Authority (OHA)¹ staff capacity.

At this time, the committee does not recommend changes to Oregon's current genetic privacy statutes. However, it does recommend that the Legislature pass legislation that directs Legislative Counsel to reconcile GINA and federal HIPAA with OGPL and state HIPAA.

¹ During the 2009-2011 biennium, the Oregon Health Authority (OHA) was established, and the Public Health Division, formerly a part of the Department of Human Services (DHS), became a part of OHA.

About the Advisory Committee on Genetic Privacy and Research (ACGPR)

The 2001 Oregon Legislature established the Advisory Committee on Genetic Privacy and Research (ACGPR). The committee is required to report to the Oregon Legislature biennially on the use and disclosure of genetic information as regulated by Oregon law and make recommendations for change when appropriate. Other tasks assigned to the ACGPR include advising OHA on the content and implementation of administrative rules, creating opportunities for public education, and eliciting public input on the issues of genetic privacy and research.

The committee is composed of 22 volunteer members and alternates appointed by the Oregon Senate president, speaker of the House of Representatives, and the Oregon Health Authority. Members serve renewable two-year terms. Composition of the ACGPR represents the diversity of Oregon stakeholders in genetic privacy and research.

Recent major events in national genetic privacy

Over the past biennium, genetic research and genetic privacy issues have frequented the headlines. Rules were proposed and finalized for the federal Genetic Information Nondiscrimination Act (GINA) that was passed in 2008.

GINA provides individuals with federal protections against genetic discrimination in health insurance and employment. Because GINA had just been passed, and rules had not been written, ACGPR did not propose legislative changes to OGPL in the last Legislative Report. The rules are now written, but the complexity of the new rules caused ACGPR to conclude that it was not able to determine how GINA and OGPL could be reconciled without a substantial study. Details of the committee's conversations and analysis for the past biennium are on p. 4.

The increasing popularity of direct-to-consumer (DTC) genetic testing caused ACGPR to study how federal regulations and the Oregon law might be applied to this testing. Details of this study are on p. 6 and in Appendix 1.

In the past biennium, samples derived from newborn screening have been discussed for use in anonymized research projects, because they represent such a rich source of population-wide genetic diversity.²

Newborn screening consists of analyzing blood taken from virtually all newborns in the United States for a number of metabolic deficiencies. The newborn blood is spotted onto absorbent paper in advance of the laboratory testing, and after testing, these blood spots are stored, in some states, for a number of years. Nationally, controversy arose as to whether these studies were ethical because parents

² For more information, see "Considerations and Recommendations for a National Policy Regarding the Retention and Use of Dried Blood Spot Specimens after Newborn Screening," Advisory Committee on Heritable Disorders in Newborns' and Children's Work Group. September 2009. www.resourcerepository.org/documents/1681/briefingpaper:considerationsandrecommendationsforanationalpolicyregardingtheretentionanduseofdriedbloodspotspecimensafternewborns/#

did not originally consent to genetic research on their child, and the blood used in research is often from children who have not reached the age of consent. In Oregon, no newborn screening blood spots are available for anonymized or coded research, and all blood spots are destroyed after one year, so this issue does not affect Oregonians. However, the ACGPR will continue to follow the national discourse.

After a long legal battle, the Havasupai Indians won their case against Arizona State University in April 2010 for violation of informed consent for genetic research. Because of the high prevalence of diabetes, the Havasupai had agreed to give ASU blood samples for diabetes genetic research. However, the ASU researchers additionally used the blood for other genetic research for which they had not consented. One difficulty with informed consent is the uncertainty of what genetic information can tell us about disease and other traits, and how this information can be used or misused, now and in the future. Discussion continues in the research community for better ways to consent participants in genetic research.

Follow-up from the 2009 Report to the Oregon Legislature

In the last report, the ACGPR proposed ongoing work in five areas. A summary of progress in these areas follows:

1. *Assess the possible conflicts and redundancies between the Oregon genetic privacy and HIPAA statutes, GINA and HIPAA, as well as other previously existing laws that protect genetic information.*

The Oregon Genetic Privacy Law (OGPL) was enacted in 1995 and has been amended several times since. On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), the first federal law comparable to Oregon's, was enacted. GINA prohibits genetic discrimination in employment and health insurance, and its rules were written into the federal HIPAA rules. The federal law is not preemptive, so the provisions of Oregon law remain in place and unaffected. While broadly similar, the Oregon law and GINA differ in many particulars, including key definitions and the "opt-out" provision in OGPL. In its 2009 report to the Legislature, ACGPR proposed conducting an analysis of Oregon law by comparison with GINA and making recommendations to the 2011 Oregon Legislature. During the past biennium, the effect of the passage of GINA and incorporation of GINA definitions into HIPAA were debated extensively at committee meetings, and the conclusion was reached that an even deeper analysis than first suggested two years ago would need to be done to determine how to reconcile the laws and propose legislation. The Health Law Committee of the Oregon Bar Association was approached, but its priority is the new federal health care law. Other health attorneys were approached, but no one wanted to take on this magnitude of a project as a volunteer. Because of lack of funding for staffing of the ACGPR and relying on only the volunteer capacity of the

committee members, the analysis was not done. The committee continues to think that it is important to conduct such an analysis. Now that the federal rules have been published, the timing is right to proceed on this project. When an analysis is completed, it is likely that new or revised legislation will need to be written.

2. *Assess the cost of the implementation of the notification and opt-out requirements of SB 1025, passed by the 2005 Oregon Legislature.*

Summary of the opt-out provision of 2005 legislation (SB 1025)

The Oregon Legislature passed SB 1025 in 2005 and revised it in 2007. The statute requires all health care providers who obtain blood, tissue, or other biologic specimens or clinical individually identifiable health information to provide a notice concerning the potential use of their genetic information in anonymous or coded research to the patient at the first clinical visit. This notice gives patients the opportunity to opt out of allowing their specimens or health information to be used for this research for any reason, including privacy concerns. This required notice applies whether or not the sample or health information was originally obtained for a genetic purpose. If the patient does not opt out, it is assumed that the patient has opted in and, therefore, will allow use of his or her biologic sample or health information for anonymous or

coded genetic research at sometime in the future. The opt-out provision is a one-time requirement, although the patient may change his or her mind and opt out anytime later. The 2009 Legislative Report reviewed the effect of SB 1025 on various stakeholders (www.oregon.gov/DHS/ph/genetics/docs/ACGPR2009LegReport.pdf). This report reviews the cost of implementation of the law.

Cost of SB 1025 to clinics and hospitals

A student group contacted the committee and volunteered to conduct a survey of hospitals and clinics to assess their estimates of how much it costs to implement and maintain the opt-out requirement. Their findings ranged widely among provider institutions, depending on the procedures used for giving notice to patients and educating them about the statute. While the information from this study was useful for committee discussion purposes, several concerns were raised about the quality of the methodology used. The committee concluded that more research would be needed before any definitive statements about the cost of the opt-out provision might be made. The preliminary findings useful for committee discussions include the following:

- Four hospitals (46 percent of statewide market share) and two large clinics (one in Portland, one statewide) participated.

- All institutions independently assessed the new law and determined their compliance policy.
- Provider institutions reported that implementation and ongoing compliance has been expensive.
- Whether the institution benefited from the law depended on whether or not the institution does genetic research.

Because of other commitments, the students declined to do any more work on the project.

3. *Continue to monitor the effect of the Oregon genetic privacy statutes on medical research, access to genetic services, and health care providers' management of medical information.*

Direct-to-Consumer (DTC) Genetic Testing

In the 2009-2011 biennium, the genetic privacy issue that arose in the national media was DTC genetic testing. DTC testing is done mostly on the Internet by companies that, for a price, take a small amount of a consumer's saliva and analyze the genetic material in it for ancestor information and predisposition to several diseases. It is generally accepted in the scientific literature that these tests provide no health value. The companies have little federal regulation or oversight, and their policies vary on privacy, informed consent, and disposition of genetic information. ACGPR requested review of these issues from the Public Health

Genetics Program, and two white papers were written, one concerning regulation and one concerning privacy and genetic information. These papers can be found in Appendix 1.

The committee concluded, because of the scientific controversy around DTC genetic testing and because there is no consensus yet among states or the federal government about how to best monitor and regulate this testing, that it would not propose any changes to Oregon law at this time, but will continue to monitor the national conversation.

4. *Continue to look for opportunities to participate in educational efforts and elicit public input representative of the diversity of opinions through collaborations with other organizations and community partners.*

- The Genetics Program maintains an up-to-date website, **www.oregongenetics.org**, including resources for the public.
- The committee wrote a “sidebar” for the Association of State and Territorial Health Officers’ “The 2010 State Public Health Genomics Resource Guide” about the implementation and history of Oregon’s Genetic Privacy Law (Appendix 2).
- Pacific University’s Institute for Ethics and Social Policy shared with the committee an overview of its “Genetic Science, Ethics, and Policy” forum materials. We discussed ways to work together.

- The committee was a partner in a grant proposal to the Robert Wood Johnson Foundation Public Health Law program on Genetic Privacy Laws and their Effect on Population Health (Appendix 3). This proposal was submitted twice but not selected for funding.
5. *Evaluate whether the charge of the committee is being adequately met through volunteer and non-funded Oregon Health Authority staff capacity.*

The committee agrees that there is important work to be done and will continue to do as much as possible with volunteer and committee member time. The committee continues to be staffed by the Public Health Genetics Program but receives no General Funds (GF) to administer the committee or to conduct activities related to the committee's charge.

Recommended focus of ACGPR activity for 2011-2013

As we move into the next biennium, the committee recommends four focus areas.

1. The committee recommends that the Legislature pass legislation that directs Legislative Counsel to reconcile GINA, federal and state HIPAA, and OGPL. Based on the reconciliation, changes to Oregon's genetic privacy statutes may be necessary.
2. Continue to monitor the effect of the Oregon genetic privacy statutes on medical research, access to genetic services, and health care providers' management of medical information.

3. Continue to look for opportunities to participate in educational efforts and elicit public input representative of the diversity of opinions through collaborations with other organizations and community partners, as staff and volunteer time allow.
4. Continue to evaluate whether the charge of the committee is being adequately met through volunteer and non-funded OHA capacity.

Appendices

1. Direct-to-consumer genetic testing
2. "Up Close: Oregon's Genetic Privacy Policy and Health Agency Response," The 2010 State Public Health Genomics Resource Guide, Association of State and Territorial Health Officers
3. Robert Wood Johnson Foundation Public Health Law: background and proposal

Appendix 1

Direct-to-consumer genetic testing – White papers

Regulation of Direct-to-Consumer (DTC) Genetic Tests

Provided for the Oregon Advisory Committee on Genetic Privacy and Research
1/27/2010

Regulation of DTC genetic testing is limited and confusing. The Secretary's Advisory Committee on Genetics, Health & Society and others have identified significant gaps in the U.S., Canada, and Europe in the oversight and enforcement of genetic testing, particularly DTC genetic tests (Hogarth, et al., 2008; Magnus et al., 2009). Additionally, the current scientific literature shows limited predictive value of these tests for consumers, although this is likely to change in the future (Janssens, et al., 2008; Caulfield, et al., 2009). The lack of laboratory and clinical validity for these tests and potentially misleading advertising has let some to call for regulation of DTC genetic testing. This summary explores the background for this regulation. For the purpose of this summary, "DTC genetic tests" refers to those genetic tests that are both advertised and sold to the consumer, either in a store or on the Internet (where the large majority are sold), without a physician's involvement (Hogarth, et al., 2008).

Current Regulatory Framework

Federal regulation of genetic tests is minimal and mostly confined to:

- Food and Drug Administration's (FDA) regulation of commercial test kits, and
- Centers for Medicare and Medicaid Services' regulation of quality control of laboratories performing tests intended "to assess patient health and inform medical decisions" through the Clinical Laboratory Improvement Amendments (CLIA).

Many commercially available genetic tests are not test kits but are instead freestanding tests and do not fall under the FDA regulatory purview. These tests, or "home brews" as referred to by the FDA, are designed, manufactured, assembled, and validated by a single lab for use in that lab (Frosst and Wattendorf, 2006; Hogarth, et al., 2008). CLIA standards for quality, accuracy, and reliability must be met, but it nor FDA regulates the clinical validity (accuracy with which a test predicts a clinical outcome) or

utility (likelihood that using the test result will lead to a beneficial outcome) of these tests. Additionally, CLIA proficiency testing does not include standards specific to DNA-based genetic tests (Magnus, et al., 2009), thus also not regulating the analytic validity (accuracy with which a test identifies the particular genetic variant). Federal regulations under the CLIA amendments leave the permissibility of DTC tests to the discretion of individual states. CLIA does require laboratories to have a “written or electronic request for patient testing from an authorized person,” although states can define for themselves who is an “authorized person” (Genetics and Public Policy Center, 2007). While most medical tests, including genetic tests, are not approved for sale DTC, a few tests for various conditions, such as pregnancy and blood glucose levels, are approved for DTC sales in several states (Genetic and Public Policy Center, 2007). Specifically for DTC genetic tests, there is an absence of federal regulatory leadership.

DTC advertising for medical tests and interventions is regulated by the Federal Trade Commission (FTC). However, the regulation of advertising for DTC genetic tests may be more difficult than, say, prescription drugs, because advertising for genetics tests is not subject to same degree of federal oversight, and Internet advertising is more difficult to regulate (Matloff and Caplan, 2008).

What Are other States Doing?

Laboratory Regulations

In 2007, the Genetics & Public Policy Center published a comparison of state laws for DTC testing, using surveys of state statutes and telephone interviews with state government officials. It is important to note that this survey addressed the broader topic of DTC testing and did not specifically address DTC *genetic* testing. The results of this survey indicated that 13 states prohibit DTC testing, while 12 permit it only for specified categories of tests, which tend to exclude genetic tests. The other remaining state laws are silent on the issue of DTC testing. Even states that prohibit DTC testing may still not be able to limit cross-border sales, which is common because of the Internet-based nature of DTC genetic testing. The information from this survey is only somewhat useful because DTC genetic testing was not specifically addressed in this survey and a

significant amount of the data was gathered from “state government officials” and is not necessarily documented in state law.

For the purpose of this summary, the Oregon Genetics Program looked specifically at the regulation of DTC testing in California, New York, and Washington State, because California and New York have particularly stringent regulation, and New York and Washington have non-CLIA regulatory systems.

In California, DTC testing is permitted only for specified tests: “pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test kit,” as well as HIV tests. The question of DTC Internet sales is not addressed specifically in California state law. The California Department of Public Health recently sent ‘cease and desist’ letters to 13 genetic testing companies (not all in California) to stop the sale of personal genomics tests to California residents because state law requires a medical license to order and give results of clinical laboratory tests, including genetic tests, to patients (Pollack, 2008). On the other hand, these companies argue that they are in compliance with the law because (Magnus, et al., 2009):

- They do not think that the information that they provide is medical, but rather personal genetic information;
- They do their testing in laboratories that are licensed by the state in which they reside;
- They have a physician on staff who is said to be involved in the ordering of these DTC genetic tests.

All these arguments have been refuted by the other genetic and medical professionals (Pollack, 2008).

New York arguably has the most conservative laboratory testing regulations in the country. New York is one of two states that have opted out of CLIA requirements in exchange for their own more restrictive state-run laboratory quality assurance program. All testing performed on specimens derived from the human body and collected in New York must be approved by and performed in a laboratory holding a permit from the New York State Department of Health, whether the laboratory is in New York or not. Because

the New York law dates from the 1960s, it does not specifically address sales over the Internet. However, DTC test sales are only allowed for test kits that have been approved by the FDA for direct, over-the-counter sale to consumers (Willey, 2009).

Similar to California, tests may be ordered only by New York licensed physicians “or other persons authorized by law to use the findings of laboratory examinations in their practice or the performance of their official duties,” which does not include consumers. And laboratories must report the results of the test only to the person who ordered it. Laboratories may communicate with the tested person only with the written authorization of the ordering person, and then only to repeat the test results.

Also in 2008, New York sent letters to 31 DTC genetic testing companies saying that they need licenses to solicit DNA specimens from state residents (Pollack, 2008). The companies responded with similar responses to those received by the California Department of Public Health. However, some DTC genetic testing laboratories have chosen not to provide services to New York residents or have attempted to obtain New York State laboratory permits because of these limitations (Langreth and Herper, 2008).

Washington has also opted out of CLIA regulation for state regulation through the Office of Laboratory Quality Assurance at the Washington State Department of Health. Washington conducts biennial on-site surveys of their medical test sites to examine quality control. Neither DTC testing nor DTC genetic testing is mentioned specifically in Washington law or on their website for the Office of Laboratory Quality Assurance.

In Washington, test requisitions must include the name and address of the authorized person ordering the test. An “authorized person” is defined as any individual allowed by Washington law or rule to order tests or receive test results, and according to an “official” with the Washington State Department of Health this can include consumers (Genetics and Public Policy Center, 2007). Test results may only be released to the authorized person or designees. The same “official” at the Washington State Department of Health indicated that there is nothing in Washington law that prohibits DTC testing.

For background and comparison, in Oregon, a clinical laboratory can test specimens “only at the request of a physician, dentist, or other person authorized by law to use the findings of laboratory examinations.” This phrase “other person authorized” has been interpreted by several practitioner boards to include different types of licensed

practitioners, but not consumers. DTC testing is permitted for certain specified tests including substance abuse testing, hemoglobin, glucose, fecal occult blood, pregnancy, and cholesterol, and it is unclear whether this includes tests that can be ordered over the Internet. DTC genetic testing is not specifically mentioned in state statute. (Genetics and Public Policy Center, 2007)

False Advertising Laws

In 2009, the Genetics & Public Policy Center published a second survey, this time looking at state false advertising laws and their potential impact on DTC genetic testing. There have been concerns that some DTC testing companies make claims about their tests that are false or misleading. Federal law prohibits companies from using unfair, deceptive, or fraudulent trade practices, including making false or misleading advertising claims. Although several complaints have been filed and are pending with the FTC regarding specific DTC genetic testing companies, the FTC has not taken direct action against any of them (ASHG Statement, 2007; Pollack, 2008). The FTC issued a broad consumer alert warning that “some of these [DTC genetic] tests lack scientific validity, and others provide medical results that are meaningful only in the context of a full medical evaluation” (Federal Trade Commission, 2006). At least one professional society has called for the FTC to oversee advertising claims made by genetic test manufacturers (Robson, et al., 2010).

The 2009 survey by the Genetics and Public Policy Center also included a review of state laws to determine whether any states have legislation specific to the advertising of genetic tests. None were found. The survey also examined false advertising laws to determine whether they were applicable to companies marketing genetic tests. The results of this survey showed that while all states have general consumer protection statutes, none of them have laws that directly address genetic testing, and that the application of these laws may be challenging because of the complexity of DTC genetic testing products and services.

What Are Other Countries Doing?

Several countries have issued reports cautioning against the use of DTC genetic testing, and several European countries have banned or are considering banning it entirely (Clark, 2009). In April 2009, the German Parliament approved what is arguably the most restrictive and paternalistic extreme of regulation of genetic information and services. This regulation, the Human Genetic Examination Act, requires that “diagnostic” or “predictive” genetic examinations be ordered and interpreted by medical doctors having appropriate training and conducted only by institutions having the appropriate accreditation. Presumably, Germans would not be able to provide DTC genetic tests unless they are claimed to be “educational or information products, not clinical or medical services.” (Clark, 2009). It is unclear whether this would limit a German individual from ordering and receiving information from a genetic test online from another country. On the other hand, the UK House of Lords recently advised that the DTC genetic testing industry adopt a voluntary code of conduct (Clark, 2009), and Gurwitz and Bregman-Eschet (2009) also suggested that a self-regulated worldwide industry with best practice guidelines would make DTC genetic testing generally more acceptable.

Conclusion

Although ensuring adequate information, high-quality laboratories, and accurate claims and interpretation of test results is important for all genetic tests, including those that are provided DTC (ASHG Statement, 2007), it is difficult to determine an effective approach to the regulation of DTC genetic tests. This is because these tests range from those used to predict risk of future disease to those providing information about lifestyle choices such as diet, which may be seen as a more “recreational” use of DTC genetic tests (ASHG Statement, 2007). After reviewing the current literature and limited information regarding regulation of DTC genetic tests, it is evident that more discussions both at the state and federal level are necessary before policies regarding regulation of DTC genetic tests should be established.

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Links to specific state legislation regarding DTC testing:

CA- <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=bpc&group=01001-02000&file=1240-1246.5>

NY- <http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS>

OR- <http://www.leg.state.or.us/ors/438.html>
http://arcweb.sos.state.or.us/rules/OARs_300/OAR_333/333_024.html

WA- <http://apps.leg.wa.gov/WAC/default.aspx?cite=246-338-010>
<http://apps.leg.wa.gov/WAC/default.aspx?cite=246-338-070>

Direct to Consumer Genetic Tests Overview of Informed Consent and Privacy at Four Major Companies

**Dr. Nicoleta Voian - Oregon Public Health Genetics Program
May 5th, 2010**

Conclusion: Of the four major direct to consumer (DTC) genetic testing companies, all meet Oregon's required informed consent and genetic privacy standards. All of the companies state that the results of genetic testing have limited medical value and should not be used for changing health behaviors.

Many states have laws to safeguard genetic information beyond the protection provided for other types of health information. Oregon is one of the states with genetic privacy laws and requires informed consent to obtain/access one's genetic information, retain the genetic information, and disclose the genetic information with certain exceptions. Also, genetic information and DNA samples must be kept confidential and protected from disclosure. Oregon's Genetic Privacy Law (OGPL) also stipulates the private right for action and specific penalties for genetic privacy violations.

I analyzed the four major DTC genetic testing companies: 23andMe, DeCodeMe, DNA Direct and Navigenics, to assess their compliance with OGPL and with the 2003 American Society of Clinical Oncology basic elements for informed consent for cancer susceptibility genetic testing.¹

I found that searching websites for privacy and consent information is not an easy task, even for a person with medical background. The informed consent documents were not written clearly, nor were they easily accessible to the customer. The relevant information was often spread among different documents, including informed consent, privacy policy, and terms and conditions, and other less obvious document titles.

DNA Direct's informed consent is not accessible without registering. I made several attempts to obtain a copy of their informed consent through e-mail and phone, without success so far.

Regarding compliance with state laws, three companies only have vague mentions about state laws, and it is expected that the customer should know about his/her state of residence requirements and be in compliance with them. On the other hand, Navigenics references all state genetics' laws and offers phone support for understanding the informed consent document.

Three of the four companies offer complimentary genetic counseling for customers, and the fourth (23 and Me) provides a link to a link to the National Society of Genetic Counselors.

Two of the companies (23 and Me and Navigenics) state that they will use your genetic and personal health information in anonymous research, and 23 and Me and DeCode state that they will contact you for consent for individually identifiable additional research.

Attached is a summary of whether each company meets OGPL and ASCO standards. Also attached is background material, mostly informed consent forms and privacy policies, from the four companies.

¹<http://www.asco.org/ASCOv2/Public+Policy/Policy+Issues/Genetic+Nondiscrimination/ASCO's+Position>

Direct to Consumer (DTC) Genetic Testing Companies

Details on whether DTC companies' documents meet Oregon Genetic Privacy Law

	23andMe	DeCodeMe	DNA Direct	Navigenics
Informed consent required to obtain/access genetic information	Yes (IC)	Yes (IC)	IC not available without registration	Yes (IC)
Informed consent required to retain genetic information	Yes (IC)	Yes (IC) If customer does not cancel, data will be retained indefinitely	IC not available without registration	Yes (IC)
Informed consent required to disclose genetic information	Yes (IC)	Yes (IC)	IC not available without registration	Yes (IC)
Maintain confidentiality and protect from disclosure	Yes (Privacy Policy and IC)	Yes (Privacy Policy and IC)	Yes ("Company Standards" and Privacy Policy)	Yes (Privacy Policy and IC)
DNA sample destroyed upon request, upon project completion, and upon consumer withdrawal from project	Yes (IC) Saliva and DNA will be destroyed after analysis.	Yes (IC) Saliva and DNA will be destroyed after analysis.	??	Yes (IC) They keep saliva for 1 year. No other tests will be done without separate written consent, except that the sample could be use for internal quality control
Private right of action	California - Any claims to be made within 1 year	Iceland - Any claims to be made within 1 year	??	California

IC – Informed consent

**Basic Elements of Informed Consent for Cancer Genetic Susceptibility Testing
(American Society of Clinical Oncology, 2003)**

	23andMe	DeCodeMe	DNA direct	Navigenics
Information on the specific genetic mutation(s) or genomic variants being tested	Yes ("Health reports-Disease risk")	Yes (IC)	Yes (personalized report)	No mutation or variant information
Implications of a positive and negative result	Yes ("Health report")	Yes	??	Yes ("What we offer"- Comprehensive genetic analysis at no charge genetic counselor will analyze the result)
Possibility that the test will not be informative	Yes (IC)	Yes (IC)	Yes ("Customer Guidelines")	Yes (IC)
Options for risk estimation without genetic or genomic testing	No	No	Yes	No
Risk of passing a genetic variant to children	No	No	Yes	Yes ("Genetics and health-DNA-FAQ Family conversations") With counselor advice at no charge
Technical accuracy of the test including, where required by law, licensure of the testing laboratory	Yes (IC)	Yes (IC)	Yes ("Our Standards")	Yes (IC)
Fees involved in testing and counseling, and for DTC genetic testing, whether the counselor is	Fees stated. No genetic counseling offered. They have a link to National Society of	Fees stated. Genetic counseling at no charge (FAQ)	Fees stated. Genetic counseling at no charge; pre test and post	Fees stated. Genetic counseling at no charge (IC); pre test and post test counseling;

	23andMe	DeCodeMe	DNA direct	Navigenics
employed by the testing company	Genetic Counselors		test counseling	help with informed consent process
Psychological implications of the test results	Yes (IC)	No	Yes (“Customer Guidelines”)	Yes (IC)
Risk of and protection against genetic discrimination by employers or insurers	Yes (IC) Statement about GINA “the protection it will provide against discrimination by employers and health insurance companies for employment and coverage issues has not been clearly established.”	No	Yes (“Customer Guidelines”)	Yes (IC)
Confidentiality issues, including for DTC genetic testing companies, policies related to privacy and data security	Yes (Privacy Policy and IC)	Yes (Privacy Policy and IC)	Yes (“Company Standards” and Privacy Policy)	Yes (Privacy Policy and IC)
Possible use of DNA sample in future research	Yes (IC) Internal research (anonymous) w/o additional contact; collaborative research (non-profit and commercial) including individual PHI with new consent and IRB approval; aggregated data w/o additional contact.	Yes (IC) Consumer will be contacted for any research study	No statement	Yes (IC) Internal research (anonymous) w/o additional contact; can consent to “contribute your genetic information to science” and anonymous information will be shared with non-profit organizations
Options and limitations of medical	Yes (IC)	Yes (IC)	Yes (“Customer Guidelines”)	Yes (IC)

	23andMe	DeCodeMe	DNA direct	Navigenics
surveillance and strategies for prevention after genetic or genomic testing	“You should not change your health behaviors on the basis of this information”			
Importance of sharing genetic and genomic test results with at-risk relatives	No (IC) “Genetic information that you share with family, friends or employers may be used against your interest.”	No	Yes (“Genetic consultation services- Personalized reports”)	Yes (“Genetics and Health-DNA FAQ- Family conversations”) Counseling available
Plans for follow up after testing	No	No	Yes (“Genetic consultation services- Personalized reports”)	Yes (“Genetics and Health-DNA FAQ Next steps”) counseling available

Other information

	23 and me	DeCodeMe	DNA Direct	Navigenics
Service for children	>13 with parent/guardian consent	Not specified	>13 with parent/guardian	>18
Genetic information used for potential commercial products	No	No “the information generated from the Genetic Scan will not be used for any business or commercial enterprise”	No, but the company does make the statement “Provide transparency regarding funding sources and commercial partnerships, as appropriate.”	No, any research results are in the public interest.

Appendix 2

“Up Close: Oregon’s Genetic Privacy Policy
and Health Agency Response”

The 2010 State Public Health Genomics
Resource Guide

Association of State and Territorial Health
Officers

Up Close: Oregon's Genetic Privacy Policy and Health Agency Response

In 1995, the Oregon legislature enacted comprehensive genetic privacy legislation to protect individuals from employment and insurance discrimination based on genetic test results. The law broadly prohibits disclosure of genetic information, and contains several provisions related to patient privacy, including a recent requirement that healthcare providers and health systems give patients an opportunity to opt-out of anonymous or coded genetic research. Anonymous research is defined in statute as "scientific or medical genetic research conducted in such a manner that any DNA sample or genetic information used in the research is unidentified."

Policymakers have revisited the law several times over the years, as shown in Table 14. The creation of a Genetic Research Advisory Committee in 1999, changed to the Advisory Committee on Genetic Privacy and Research in 2001, formalized a process for revisiting and revising state law. The Committee is required to report every two years to the Oregon Legislature on the use and disclosure of genetic information and make recommendations for changing the law, if needed. In addition to monitoring the state policy environment, the Committee also addresses the implications of federal privacy laws, including the Health Insurance Portability and Accountability Act of 1996 and the Genetic Information Nondiscrimination Act of 2008, on the state's existing requirements. Other Committee tasks include advising the Oregon Department of Human Services on administrative rules (e.g., informed consent policies), creating opportunities for public education, and obtaining public input on genetic privacy and research issues.

Oregon's experience illustrates the fluid nature of genomics policy development, as well as the ongoing role for state health officials. Implementing the 2005 opt-out requirement proved challenging for stakeholders, especially hospitals, providers and laboratories who were required to develop new procedures and invest resources to comply with the requirements. The dynamic nature of Oregon's privacy legislation impacts other stakeholders, including state health agency staff, who are responsible for informing the public about privacy protections, overseeing institutional review boards that review genetic research, and developing and implementing policies (e.g., informed consent processes).

Additionally, the Legislature has never appropriated any funding for any of these activities. The legislative process demonstrates that enhancing the public good while providing privacy protections is a complex and ongoing process, best achieved by allowing for changes based on stakeholder feedback and objective research and analysis.

Table 14. Oregon Legislative Timeline

1995	<ul style="list-style-type: none"> Legislature enacted the Comprehensive Genetic Privacy Act to protect the privacy of genetic samples and protect individuals from employment and insurance discrimination based on test results. The law created privacy protections for obtaining, retaining and disclosing genetic material. The law defined genetic information as the “property” of the individual. As directed in statute, in 1996 the Oregon Health Division adopted administrative rules for consent forms for genetic testing.
1997	<ul style="list-style-type: none"> In response to charges that the property clause was having negative effects on research, the Legislature amended the statute to exempt anonymous research from the privacy act because anonymous research could not result in discrimination.
1999	<ul style="list-style-type: none"> The Legislature created a Genetic Research Advisory Committee to “study the use and disclosure of genetic information and...develop a legal framework that defines the rights of individuals whose DNA samples and genetic information are collected, stored, analyzed and disclosed.”
2000	<ul style="list-style-type: none"> The Advisory Committee recommended that the Legislature replace the controversial property provision with a confidentiality clause. The Advisory Committee published the report, Assuring Genetic Privacy in Oregon, which made recommendations for the remedy of violations, family issues, informed consent, property and continued oversight.
2001	<ul style="list-style-type: none"> The Legislature deleted the property provision and specified that genetic information and DNA samples are private and that individuals and their families have a right to protection of that privacy. The law contained several other changes, such as requiring researchers to obtain informed consent except when the person’s identity is anonymous or encrypted. It also created penalties for intentional violations.
2003	<ul style="list-style-type: none"> The Legislature added some provisions to the statute, including new definitions (e.g., anonymous research) and new standards for regulating coded research.
2005	<ul style="list-style-type: none"> The Advisory Committee made several recommendations in their 2005 report to the Legislature, including: <ul style="list-style-type: none"> - Exempt routine disclosures of genetic information by providers and health insurers from special protections. - Prohibit use of family members’ medical history for health insurance and employment decisions. - Prohibit employers and health insurers from using information concerning whether a person sought genetic counseling. - Modify informed consent requirements for research. The Legislature modified informed consent requirements for research under certain limited conditions and required health care providers and health systems to inform patients about their right to “opt-out” of anonymous or coded IRB-approved research.
2007	<ul style="list-style-type: none"> The Legislature amended the statute to align the Oregon statute with federal HIPAA requirements.

Source: Oregon Department of Human Services, Genetics Program, History of Oregon’s Genetic Privacy Law, <http://www.oregon.gov/DHS/ph/genetics/docs/HistoryofOrego021408.pdf>.

Informational Resources on Oregon's Privacy Laws

History of Oregon’s Genetic Privacy Law
<http://www.oregon.gov/DHS/ph/genetics/docs/HistoryofOrego021408.pdf>.

2009 Report to the Oregon Legislature from the Advisory Committee on Genetic Privacy and Research
<http://www.oregon.gov/DHS/ph/genetics/docs/ACGPR2009LegReport.pdf>

Oregon Genetic Privacy Laws
http://www.oregon.gov/DHS/ph/genetics/docs/Oregon_Genetic_Privacy_Statutes_07.pdf

Appendix 3

“Genetic Privacy Laws and their Effect of Population Health”

Proposal for Robert Wood Johnson Foundation
Public Health Law grant program

**RWJF Public Health Law Research
Brief Proposal Narrative**

Genetic Privacy Laws and Their Effect on Population Health

April 6, 2010

Organization: Genetics Program, Oregon Public Health Division, Department of Human Services, State of Oregon

Summary:

While the role of genetic testing in medicine is well established, genetic privacy issues are an ongoing concern. People generally do not want their genetic information to be made widely available, especially to employers and insurance companies, and this concern may keep people from having genetic testing or caused them to pay testing costs out-of-pocket to keep the results out of their medical records.

This project proposes the first systematic study to determine whether promulgation of genetic privacy laws can be associated with a higher likelihood of using of genetic testing. Positive genetic tests can lead to various health behaviors that can improve quality of life, extend life, and help people with reproductive decisions. Peoples' differing perceptions of their level of legal "protectedness" may have a measurable association with their willingness to have a genetic test.

Oregon passed the U.S.'s first genetic privacy and non-discrimination law in 1995. In 2008, the federal Genetic Information Nondiscrimination Act was signed into law. This project proposes to analyze the privacy and non-discrimination provisions in these laws and compare them with other legal and regulatory schemes (e.g., HIPAA, ADA) intended for non-genetic personal medical and non-medical information.

Data for the project will be gathered in three ways – a statewide population-based quantitative survey, qualitative focus groups, and legal analysis. The analysis of these data will be used to draw conclusions on the usefulness of genetic privacy laws in directing health behavior. The outcomes of the study will help determine if current laws are coincident with public perception and if they have an intermediate effect of increasing the use of appropriate genetic tests, which will lead to the long term effect of improving health.

Background and Significance:

Although genetic privacy has led to contentious discussions in both the public and professional press for several decades (1), there have been to date no systematic studies to determine whether promulgation of genetic privacy laws can be associated with an increased use of genetic testing, a first step to possibly establishing a causal link with increased healthy behaviors. Peoples' differing perceptions of their level of legal "protectedness" may have a measurable association with their willingness to submit to genetic testing. This project will use qualitative and quantitative tools to determine if Oregonians believe genetic privacy laws are truly protective

and, if so, whether there is an association with their likelihood of seeking genetic testing. It will also explore any association with healthy lifestyle changes, screening and prophylactic measures.

Genetic testing has an important role in community health care. Genetic testing is most commonly used right after a baby is born. Blood is taken and tested for up to 50 different genetic diseases, allowing early intervention in the baby's life and helping ensure a relatively normal life. Without these tests, afflicted babies often have multiple physical and developmental disabilities and some die in the first few years of life. Newborn screening is required in all US states (2). When a couple have a baby with a genetic disease, they will often use prenatal genetic testing in subsequent pregnancies to determine the genetic status of the fetus (3). Their relatives may also choose to get genetic testing to see if they carry the disease gene if they are planning a family.

Genetic tests can also be used to see if a person has a susceptibility to a particular disease, usually after that person or a family member has been diagnosed and the family history examined. If a genetic susceptibility is found, doctors may suggest increased health surveillance, prophylactic procedures, and lifestyle changes to moderate the effects of a person's genetic makeup (4). Additionally, non-affected family members can be advised of their possible increased risk for that disease, and if they choose to be tested and are found to be susceptible, they can also make appropriate health care and lifestyle choices.

While the role of genetic testing in medicine is well established, genetic privacy issues are an ongoing concern. Generally, it is believed that people do not want their genetic information to be made widely available, especially to employers and insurance companies, and this concern may have kept people from having genetic testing done or caused them to pay costs out-of-pocket and keep the results from their doctors (5).

Many state and federal laws have been passed concerning genetic privacy and genetic discrimination (6). However, few of these laws are extensive, for instance including long term care or life insurance, and state and federal laws have inconsistencies, some of them significant (7).

Oregon passed the U.S.'s first genetic privacy and non-discrimination law in 1995 (8). Since that time, it has been revised several times, in part because of unforeseen advances affecting practicing medicine and performing research. In 2008, the federal Genetic Information Nondiscrimination Act (GINA) was signed into law.

This project will help us understand how OGPL and GINA may affect the uptake of genetic testing. Data for the project will be gathered in three ways – a statewide quantitative survey, selected qualitative focus groups, and legal analysis.

Methods, Measures, and Analysis:

Survey of Oregonians:

Using the Behavioral Risk Factor Surveillance Survey (BRFSS) (9), the Oregon population will be surveyed to assess how health behavior is influenced by genetic privacy laws. The Oregon

Genetics Program will add 5-6 questions related to genetic privacy and health behavior to the 2011 BRFSS. Specifically, these questions will provide information on:

- Oregonians' knowledge of how genetic testing can impact their health.
- Oregonians' awareness of genetic privacy laws, both state and national.
- Oregonians' perceived risk of their genetic information being inadvertently disclosed by their health care provider.
- Oregonians' perceived risk of being discriminated against in employment and health, life, and long term care insurance based on their genetic makeup.
- Oregonians' privacy concerns with respect to genetic and other types of personal information.

BRFSS, the largest on-going telephone health survey in the world, is a state-based, random-digit dialed telephone survey exploring health conditions and risk behaviors of U.S. adults (9).

Using the results of the BRFSS, a number of qualitative **focus groups** will be held around the state, ensuring that age, race, and gender are appropriately represented, to understand genetic privacy issues and health behavior in more depth. These focus groups will specifically address:

- Understanding of the usefulness of genetic tests.
- Age stratification regarding privacy issues. It has been theorized that younger people who use the Internet more frequently have fewer issues with privacy in general. Is there an age difference in expressed concern over genetic privacy?
- Gender differences. Women use health care services more than men. Thus, it is possible that women may feel differently about the use of genetics in their health care. Do women and men feel more or less strongly about the risk of genetic information being used for medical good or discrimination?
- Rural/urban issues. Are there differences in how urban and rural populations view genetic privacy issues and why?
- Subjective views of legal protections relating to both genetic and other personal information. Do perceptions of the effectiveness of legal protections of genetic information and other types of personal information differ depending on the type of information and to what extent?

The research group will identify areas of agreement and disagreement among interviewees and discern important themes.

The project proposes to **analyze several current laws** and compare provisions of OGPL and GINA with privacy and confidentiality provisions of other law and statutory and regulatory schemes [e.g., HIPAA(10)] that control treatment of non-genetic personal medical and non-medical information. The analysis will compare federal and state anti-discrimination approaches relating to non-genetic medical conditions (e.g., Americans with Disabilities Act) with GINA and OGPL protections of genetic conditions. If people think that their legal protection against employment discrimination for a mostly non-genetic condition (e.g., tuberculosis) is more or less robust than their protection against discrimination for a condition with a larger genetic component (e.g., some mental illnesses), does that translate into a different degree of willingness to be tested?

Legal analysis will be conducted by a private attorney specializing in health care law. Comparisons will be made of the genetic privacy laws identified above and others identified in the course of the study. This comparison will be presented in an easy-to-understand format to allow provision-by-provision comparisons between HIPAA, GINA, OGPL, and other genetic privacy laws. A comparison will also be made between non-genetic anti-discrimination laws (e.g., ADA) and the laws mentioned above. These two analyses will be widely reviewed by other legal practitioners to assure a fair assessment.

Legal and Public Health Collaboration:

We propose a collaboration among the Oregon Public Health Genetics Program, the Oregon Advisory Committee on Genetic Privacy and Research (ACGPR) (the legislatively mandated committee that oversees OGPL), the Oregon Department of Justice, and a Portland-based private health care law attorney (yet to be determined).

The Principal Investigator will be Dr. Nan Newell, Oregon Public Health Genetics Program Coordinator. Dr. Newell will help with the overall design of the study and oversee the day-to-day management of the project. She brings public health and scientific expertise to the team. Her program is well-versed in planning, analysis, and evaluation of quantitative and qualitative study results.

The project will be overseen by the ACGPR, which has debated and published on genetic privacy issues since the original OGPL was passed and the Committee formed in 1995 (11). The membership includes two state senators, two state representatives, six lawyers, and several doctors, scientists, insurance and corporate representatives, an ethicist, and community members. This Committee has a long history of collaboration, and the questions being asked in this application are ones the Committee has been interested in for some time.

Two people on ACGPR will advise this project:

- Stuart Kaplan, Professor, Lewis and Clark College and Board Member, ACLU of Oregon. Dr. Kaplan will help with the overall design and management of the study and will bring the ACLU's perspective, which emphasizes personal privacy.
- Steven J Nemirow, Director, Kartini Clinic for Disordered Eating, a hospital research IRB member, and a practicing attorney working in delivery of health care. Mr. Nemirow will help with the overall design and management of the study and advise on legal issues.

Two other key team members are:

- Shannon O'Fallon, Senior Assistant Attorney General, Oregon Department of Justice. Ms. O'Fallon is the state attorney for the Public Health Division. She brings an intimate knowledge of Oregon's public health laws to the team.
- A private health care law attorney (yet to be determined). There are several excellent health care attorneys in the area with whom the ACGPR has relationships. If requested to write a full proposal, we will supply more information on their expertise.

The results of the survey, focus groups, and legal analysis will be brought together to draw conclusions on the usefulness of genetic privacy laws in directing health behavior. The outcome

of the study will guide future conversations about genetic privacy and help determine if current laws are coincident with public perception and if they have an intermediate effect of getting more people to consider appropriate genetic tests, which will lead to the long term effect of improving health. The ACLU and the Oregon Public Health Division will consider using the results in the context of their public education and legislative agendas. These conclusions also will be presented nationally and published in a peer-reviewed journal.

Research Team:

Dr. Nanette Newell is the Oregon Public Health Genetics Program Coordinator. She oversees the Program's CDC Cancer Genomics Surveillance Grant and the legislatively-mandated Advisory Committee on Genetic Privacy and Research (ACGPR), which makes policy proposals to the legislature to ensure the genetic privacy of Oregonians while promoting the use of genetics in the clinic and in research. She has represented Oregon's Department of Human Services on the ACGPR for 7 years. Prior to her public health career, she worked in the biotechnology industry for over 20 years specializing in market analysis, strategic planning, fund raising, Internet privacy, and ethics. She has her Ph.D. in molecular biology from the Johns Hopkins School of Medicine and her MBA from the University of North Carolina, Chapel Hill.

Shannon O'Fallon is a Senior Assistant Attorney General with the Oregon Department of Justice, and is the lead attorney for the Oregon Public Health Division. Ms. O'Fallon earned her J.D. from the University of Oregon School of Law, and before that graduated from the University of Washington with a B.A. After law school Ms. O'Fallon worked in the Alaska Attorney General's Office in the Human Services Section and Natural Resources Section for seven years, and has worked for the Oregon Department of Justice since 2002.

Dr. Stuart Kaplan is Associate Professor of Communication and Department Chair at Lewis and Clark College in Portland, Oregon. He received his Ph.D. from the University of Oregon. He has published articles on information privacy, communication policy, and Internet free speech in *Communication Monographs*, *Journalism Quarterly*, *Critical Studies in Mass Communication*, and *Idaho Law Review*. Dr. Kaplan is a 15 year member of the Oregon ACLU and has served as its President for the most recent three years. He was also Oregon's ACLU representative to the ACLU's Nations Board for 7 years.

Steve Nemirow is an attorney and the director of the Kartini Clinic for Disordered Eating and founder and chair of the Kartini Foundation, dedicated to supporting families of children suffering from pediatric eating disorders. He brings years of experience as an advocate for the pediatric community and an analytical and creative perspective on pediatric issues. He is a member of the Legacy Emanuel Hospital IRB.

References and Endnotes:

1. For instance, see:
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2. Crowe, S. (2008) A Brief History of Newborn Screening in the United States, Staff Discussion Paper, The President's Council on Bioethics. Downloaded March 22, 2010 from http://www.bioethics.gov/background/newborn_screening_crowe.html.
 3. For background on the uses of genetic testing, see National Human Genome Research Institute (NHGRI) (Mar. 19, 2010) Frequently Asked Questions about Genetic Testing. Downloaded on March 22, 2010 from <http://www.genome.gov/19516567>.
 4. For instance, for breast and ovarian cancer susceptibility interventions, see National Institute of Cancer (Feb. 24, 2010) Genetics of Breast and Ovarian Cancer. Downloaded March 22, 2010 from http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/healthprofessional/allpages/print#Section_575.
 5. Hall, M. A., et al. (2005) Concerns in a primary care population about genetic discrimination by insurers. *Genetics in Medicine* 7(5): 311-316.

National Library of Medicine, Genetics Home Reference (Mar. 21, 2010) Will health insurance cover the costs of genetic testing? Downloaded on March 22, 2010 from <http://ghr.nlm.nih.gov/handbook/testing/insurancecoverage>.

6. The federal Genetic Information Nondiscrimination Act (GINA) of 2008 (HR 493) is an example (for a summary, see Coalition for Genetic Fairness (2008) What does GINA mean? A guide to the Genetic Information Nondiscrimination Act. <http://www.geneticfairness.org>). Several states also have similar statutes in place (National Conference of State Legislatures (Jan. 2008) Genetic Privacy Laws. Downloaded on Mar. 16, 2010 from <http://www.ncsl.org/default.aspx?tabid=14287>).
7. For instance, putting the GINA rules into federal HIPAA rules makes it extremely difficult for states to separate genetic privacy concerns from genetic discrimination.
8. 1995 Oregon Laws Chapter 680.
9. <http://www.cdc.gov/brfss/>
10. For background, see <http://www.hhs.gov/ocr/privacy/index.html>
11. For a roster of the members and their associations, see <http://www.oregon.gov/DHS/ph/genetics/docs/ACGPRroster2009-2011.pdf>

**OREGON DEPARTMENT OF HUMAN SERVICES
GENETIC PRIVACY LAWS AND POPULATION HEALTH
PRELIMINARY BUDGET AND NARRATIVE - 18 MONTHS
6-Apr-10**

		Grant Budget	Category Sum
PERSONNEL			\$42,443
Genetics Program Coordinator - Nan Newell, \$87,978/year. Dr. Newell will assure coordination with legal partners and collaborators and will help with the overall design of the study. She will lead and oversee the overall implementation of the program and timely reports, as required.	.2 FTE	\$26,393	
Genetics Epidemiologist - Amy Zlot \$69,439/year. Ms. Zlot will provide analysis and interpretation of the BRFSS results.	.10 FTE	\$10,416	
Administrative Specialist - Gwen Trieu \$37,557/year. Ms. Trieu will provide essential support for the project including meeting coordination, word processing, and correspondence.	.10 FTE	\$5,634	
FRINGE BENEFITS			\$21,349
Benefits are estimated at 50.3% of salary. They include: FICA, retirement, worker's compensation insurance, and health and dental insurances. Contributions are negotiated in collective bargaining.			
TOTAL PERSONNEL & FRINGE BENEFITS			\$63,792
SUPPLIES			\$882
General office supplies will be used by project staff to carryout daily activities of the program.			
Office supplies (stationary, paper, pens, diskettes) \$20/month x 18 months		\$360	
Mailing \$10/month x 18 months		\$180	
Duplicating/Printing \$19/month x 18 months		\$342	

**OREGON DEPARTMENT OF HUMAN SERVICES
GENETIC PRIVACY LAWS AND POPULATION HEALTH
PRELIMINARY BUDGET AND NARRATIVE - 18 MONTHS
6-Apr-10**

	Grant Budget	Category Sum
CONTRACTS (purchased services)		\$58,000
Health Care Law Attorney-to be determined. This person will perform the legal analysis, attend all the focus groups, and help with the final synthesis of the information. \$250/hour for 150 hours.	\$37,500	
Focus Groups: Interviewer \$1,200/day for 10 days, three people travel to five focus group sites around the state \$3,000, transcription of conversations \$2,000, incentives \$500, analysis \$3,000.	\$20,500	
OTHER		\$14,670
Phone line, long distance, and FAX charges (\$35/month x 18 months)	\$630	
Questions for 2010 BRFSS	\$9,000	
Department of Justice review of materials \$126/hour for 40 hours	\$5,040	
Total Direct Costs		\$137,344
OVERHEAD - NON PURCHASED SERVICES - 12%		\$9,521
OVERHEAD - PURCHASED SERVICES - 4%		\$2,320
TOTAL		\$149,185

	In kind amount
IN KIND BUDGET	
ACGPR advisors - Dr. Stuart Kaplan (\$150/hr), Mr. Steve Nemirow (\$250/hr). These advisors will donate their time (40 hours each) to the project.	\$16,000
TOTAL IN KIND	\$16,000



Robert Wood Johnson Foundation

Public Health Law Research

Making the Case for Laws
That Improve Health



2010 Call for Proposals—Round 2

Brief Proposal Deadline

April 14, 2010

Program Overview

(Please refer to specific sections for complete details.)

Purpose (See The Program on page 3.)

The Robert Wood Johnson Foundation® (RWJF) seeks to build the evidence for and strengthen the use of regulatory, legal and policy solutions to improve public health. RWJF is equally interested in identifying and ameliorating laws and legal practices that unintentionally harm health. As public health practitioners, policy-makers and others consider how laws influence the public's health, they need evidence to inform questions such as: How does law influence health and health behavior? Which laws have the greatest impact? Can current laws be made more effective through better enforcement, or do they require amendment? The purpose of RWJF's *Public Health Law Research* program is to answer such questions by building a field of research and practice in public health law.

Eligibility Criteria (page 10)

Preference will be given to those applicant organizations that are either public entities or nonprofit organizations that are tax-exempt under Section 501(c)(3) of the Internal Revenue Code or a tribal group recognized by the U.S. federal government, or affiliated with a tribal group. Applicant organizations must be based in the United States or its territories. The focus of this program is the United States; studies involving other countries will be considered only to the extent they may directly inform U.S. law and policy.

Selection Criteria (page 10)

Complete selection criteria can be found starting on page 10.

Total Awards

- *Short-term studies:* Up to 18-month awards of up to \$150,000 each.
- *Complex and comprehensive studies:* Up to 30-month awards of up to \$450,000 each.
- Up to \$3.5 million will be available under this call for proposals (CFP) for research studies.

Key Dates and Deadlines

- **February 10, 2010**—CFP released and online application becomes available.
- **March 17, 2010**—Web conference for interested applicants. Registration is required.
- **April 14, 2010 (3 p.m. ET)**—Deadline for receipt of brief proposals.
- **Early June**—Applicants notified if invited to submit full proposals.
- **June 17, 2010**—Web conference for full proposal applicants. Registration is required.
- **July 21, 2010 (3 p.m. ET)**—Deadline for receipt of full proposals.
- **September 30, 2010**—Finalists notified.
- **November 15, 2010**—Funding initiated.

How to Apply (page 12)

Applications for this solicitation must be submitted electronically. Visit www.rwjf.org/cfp/phlr and use the Apply link for this solicitation. You will be required to register at MyRWJF before you begin the application process.

www.publichealthlawresearch.org

The Program

Public health law research is *the scientific study of the relation of law and legal practices to population health*. Laws have improved the public's health by influencing individual behavior (e.g., seatbelt use and immunizations) and the physical and social environment in which people live (e.g., regulating exposure to lead, mandating smoke-free workplaces, limiting sales of hazardous products). Laws not designed as health measures also influence public health for better or worse (e.g., criminal law enforcement by police). Rigorous, credible research can inform and guide the crafting and implementation of laws that promote public health.

Public Health Law Research is a five-year, \$17.3 million RWJF national program. The goal of this program is to build the evidence for and increase the use of effective regulatory, legal and policy solutions—whether statutes, regulations, case law or other policies—to protect and improve population health and the public health system.

This program includes three primary activities:

- Funding research and evaluation related to public health laws and their impact.
- Providing technical assistance to and coordination for those engaging in this type of research, analysis, evaluation and/or integration into practice.
- Supporting communication, translation and outreach efforts.

Total Awards

Up to \$3.5 million is available in this round. There are two categories of funding. Both require the integration of legal analysis and empirical research to determine effects of laws and policies on the health of the public. We encourage applicants to carefully consider their proposed research questions and scope of work to determine the appropriate level of funding to pursue. The selection process will focus on both the adequacy of funding to complete an individual

project, and the selection of a set of projects that most efficiently advances the program's goal of supporting rigorous research that will help to pave the way for public health laws and policies that improve health in communities around the country.

1. **Short-term studies.** This category includes qualitative or quantitative studies of the development, implementation, and/or mechanism(s) of action or health effects of specific laws or regulations. These grants will be up to \$150,000 each for up to 18 months.
2. **Complex and comprehensive studies.** This category includes multistate, time-series analyses and other in-depth evaluations of laws implemented across a variety of jurisdictions and fields, analyses of effective and ineffective components of laws and regulations, and analyses of implementation and enforcement challenges. These grants will be up to \$450,000 each for up to 30 months.

Overall Study Guidelines

Studies funded through this program will be at the intersection of law and public health. Studies may draw upon a range of other disciplines, including medicine, economics, sociology, psychology and public policy and administration, but the primary focus of the study should be a law or policy and its influence on public health.

The program seeks to support innovative theoretical approaches to assessing how laws influence public health. We encourage creativity and innovation in selecting and blending research methods. Innovative methods include experimental designs and simulations, the use of biological markers as outcome variables, mixed qualitative-quantitative studies, and the application of cutting-edge econometric and time-series models.

Research teams must demonstrate expertise in both law and public health. Research teams that combine legal expertise with advanced research design and statistical competence are strongly encouraged. Successful proposals will normally demonstrate that the research team includes investigators with practice experience, and/or that the research plan is closely informed by practice. Cooperation with health officials and other public health and governmental practitioners will usually enhance theoretical significance, methodological rigor and practical relevance.

Please note: Studies that focus primarily on substance abuse (i.e., alcohol, tobacco and drugs), the health care system and health care delivery and preventing childhood obesity will not be candidates for funding under this round. Please visit the Foundation's Web site (www.rwjf.org) for information about those areas.

Key Proposal Elements

Regardless of topic or academic discipline, proposals should convey essential information about the proposed study. Recognizing the space limitations of the brief proposal format, we expect applicants to ensure that:

- The proposal presents a theory or conceptual framework that clearly guides the design of and/or motivation for the empirical research.
- The proposal demonstrates the topic's relevance to and significance for public health, and explains how the results of the study will be useful to practitioners and policy-makers.
- The study design is systematic and rigorous. For example, for interview studies, the application addresses sampling, recruitment, interview topics, and methods for conducting the interviews and analyzing the data.
- The methods description is clear and appropriate to the research question(s) posed.

- The design, methods and measures draw, where appropriate, on theory and empirical research in law and regulation as well as epidemiology or other disciplines in public health.
- The measures are appropriate: variables for outcomes, mechanisms of action and other data accurately represent the underlying constructs or populations of interest.

Applicants selected to submit full proposals will be asked to address these study elements in greater detail. General guidance on PHLR design criteria can be found on the project website at www.publichealthlawresearch.org.

Topics for Research

This call for proposals focuses on three topics:

1. The impact of laws and legal practices on population health outcomes.
2. The use of innovative policies or regulatory techniques to promote healthier individual or organizational behavior.
3. The development, implementation and/or effectiveness of ordinances, executive orders and other legal tools used by local governments to improve public health.

The first two topics above are not specific to any jurisdictional level. Topic 3 is confined to the study of *local* laws and enforcement practices. *The examples of studies are for illustrative purposes only; they do not indicate a preference for studies of these specific topics.*

Topic Area 1: The impact of laws and legal practices on population health outcomes

Studies in this topic area will examine how laws or the activities of legal institutions and agents influence health outcomes, behaviors, or environmental conditions that are reasonably (and demonstrably) proximal to a health outcome. These *intervention studies* empirically assess the intended or unintended

effect of law on public health. They may involve the design and implementation of a new legal intervention or the observation and assessment of an existing law or regulatory tool. The evaluation of the intervention may include a quantitative assessment of changes in the relevant health outcomes, process evaluations of how the law has been implemented or both. Study methods may include case studies, controlled experiments, exploitation of natural experiments and quasi-experimental designs. The development of interventions by themselves without a public health application or assessment of potential health effects will not be funded.

Illustrative examples of studies that may contribute to improved understanding of the impact of law and legal practices on population health outcomes include:

- studies exploring how compulsory vaccination laws influence vaccination coverage rates or incidence of vaccine-preventable diseases;
- studies of the effect on death and injury of laws restricting cell phone use or similar behaviors while driving;
- studies of the impact of civil rights laws and policies in improving health outcomes;
- studies of the effects of clean water laws and enforcement on the safety of drinking water.

Topic Area 2: The use of innovative policies or regulatory techniques to promote healthier individual or organizational behavior

Studies in this topic area will assess innovative uses of regulatory authority to promote public health. Governments are using legal authority in new ways to effectively leverage other forms of control. Agencies have tackled complex regulatory challenges by creating partnerships and networks across government and with the private sector. Instead of issuing and enforcing rules, some agencies have enlisted regulated entities in setting industry standards of behavior,

drawn on the public to help monitor compliance, used market forces to shape behavior, and have emphasized incentives rather than punishments. For example, legal preparedness for disasters has entailed the creation of a legal infrastructure for cross-agency and inter-jurisdictional cooperation. Efforts to keep our food supply safe depend on government regulations and inspections and also industry codes of practice and accreditation programs. Voluntary accreditation and other quality improvement strategies are being used to improve the performance of public health agencies.

Illustrative examples of studies that may contribute to improved understanding of innovative public health regulation would include:

- a study of governance mechanisms—health impact assessments, advisory boards, participatory planning—used by health agencies to increase community participation in the public health regulatory process;
- a study of innovative laws and law enforcement practices to reduce the harmful community health effects related to crime, policing and incarceration;
- qualitative analysis of the role of private organizations in the regulatory process, such as the involvement of the food industry in developing, implementing and evaluating food safety policies;
- a study of health authorities’ use of environmental design, “default rules” and other “soft-law” mechanisms to promote healthier behavior in place of overt regulation.

Topic Area 3: The development, implementation and/or effectiveness of ordinances, executive orders and other legal tools used by local governments to improve public health

Studies funded in this topic area will add to the evidence base for effective use of law at the local level by exploring the implementation and effectiveness of local ordinances, codes, orders, and other legal tools.

Towns, cities and counties are vested with authority over a range of activities, such as food safety, land use, disease control and prevention, and law enforcement. Through that authority they can powerfully influence behaviors and the environment in which decisions that influence health are made. Using their legal authority, towns, cities and counties can also enhance the impact of or fill gaps in state and national regulations. In the past, local governments have offered important early leadership in areas such as tobacco control, harm reduction and the prevention of unintentional injuries. Local governments have often been innovators in public health law, developing new measures like menu labeling, bans on trans fats, clean indoor air laws and health-oriented zoning codes.

Illustrative examples of studies that may add to the evidence base on local public health law include:

- multi-city comparative assessment of zoning and land use regimes and how they affect individual health behavior, the community health environment, and health outcomes;
- identification of factors supporting effective diffusion of beneficial local public health law innovations to other jurisdictions;
- a study of how, why and to what extent local governments make use of their legal authority to achieve local public health goals;
- a study of the health impact of a city-level anti-violence initiative;
- studies of the health effects of legal measures undertaken by transportation, economic development, housing, and other “non-health” agencies.

Eligibility Criteria

Preference will be given to those applicants that are either public entities or nonprofit organizations that are tax-exempt under Section 501(c)(3) of the Internal Revenue Code or a tribal group recognized by the U.S. federal government, or affiliated with a tribal group. Applicant organizations must be based in the United States or its territories. The focus of this program is the United States; studies involving other countries will be considered only to the extent they may directly inform U.S. law and policy.

Selection Criteria

All proposals will be screened for eligibility and then assessed by a committee composed of RWJF staff, national program office (NPO) staff, a national advisory committee and other expert reviewers. The following criteria will be used to assess proposals:

- Significance of the public health problem addressed;
- Effective collaboration between public health and legal researchers and practitioners;
- Inclusion of investigators who are new to the field;
- Potential impact of study results on the development, crafting and implementation of laws and policies that positively influence population health;
- Plan for translation of research findings to the practice community and policy-makers;
- Efficient use of available funds within individual proposals and across the set of funded proposals;
- Ability of the study to advance methods in public health law research in general;
- Adequacy of personnel and resources to complete the proposed project.

Further guidance on PHLR research can be found on our Web site, www.publichealthlawresearch.org.

This program has a National Advisory Committee that makes funding recommendations to the Foundation. All final funding decisions are made by RWJF.

Grantees are expected to participate in the program's annual meeting, specifically, the Principle Investigator and Co-Principle Investigator. The National Program Office will pay for up to two senior project personnel to attend the meeting. In addition, grantees are encouraged to take advantage of opportunities to communicate grant results including but not limited to conferences, policy briefings, media interviews and other forms of communications.

Evaluation and Monitoring

An independent research group selected and funded by RWJF will conduct an evaluation of the program. As a condition of accepting RWJF funds, grantees will be required to participate in the evaluation.

Grantees are expected to meet RWJF requirements for the submission of narrative and financial reports, as well as periodic information needed for overall project performance monitoring and management. We may ask principle investigators to participate in periodic meetings and give progress reports on their grants. At the close of each grant, the lead agency is expected to provide a written report on the project and its findings, suitable for wide dissemination.

Use of Grant Funds

Grant funds may be used for project staff salaries, consultant fees, data collection and analysis, meetings, supplies, project-related travel and other direct project expenses, including a limited amount of equipment essential to the project. In keeping with RWJF policy, grant funds may *not* be used to subsidize individuals for the costs of their health care, to support clinical trials of unapproved drugs or devices, to construct or renovate facilities, for lobbying or as a substitute for funds currently being used to support similar activities.

How to Apply

Applications for this solicitation must be submitted electronically. Visit www.rwjf.org/cfp/phlr and use the Apply link for this solicitation. You will be required to register at MyRWJF before you begin the application process.

There are two stages in the competitive proposal process: (1) applicants submit a brief proposal that describes the project and, if invited (2) applicants then submit a full proposal and line-item budget for a grant.

Stage 1: Brief Proposals

Applicants must submit a brief proposal that describes the project and include a one-page preliminary budget. These should total no more than five pages in length.

Stage 2: Full Proposals

Selected Stage 1 applicants will be invited by letter or e-mail to submit a full proposal accompanied by a budget and budget narrative. Applicants invited to submit a full proposal will be expected to elaborate on the brief proposal, including a discussion of the study's significance, theoretical foundation, design, methods of data collection and analysis, and dissemination of findings. Further description and information will be provided at that stage to successful applicants.

For more information on the program and application requirements please contact the *Public Health Law Research* Grant Solicitation Helpdesk at (215) 204-2134 or phlr@temple.edu.

Helpdesk is available during the application process 9 a.m. to 5 p.m. ET, Monday–Friday, with the exception of May 31, July 2, and September 6, 2010.

Program Direction

Direction and technical assistance for this program are provided by the *Public Health Law Research* national program office located at:

Center for Health Law, Policy and Practice,
Temple University Beasley School of Law
1719 N. Broad St.
Philadelphia, PA 19122
www.publichealthlawresearch.org

Responsible staff members at the NPO at Temple University and other institutions are:

- Scott Burris, J.D., *program director*
- Heidi Grunwald, Ph.D., *deputy director*
- Jennifer Ibrahim, Ph.D., M.P.H., M.A., *associate director*
- Alexander Wagenaar, Ph.D., M.S.W., *associate director, University of Florida*
- Sharon Barkley-Samuels, *office manager*
- Evan Anderson, J.D., *legal fellow*
- Marek Sulzynski, M.P.A., *research and policy network coordinator*
- Michelle Mello, Ph.D., J.D., M.Phil., *methods core member, Harvard University*
- Jeffrey Swanson, Ph.D., M.A., M.Phil., *methods core member, Duke University*
- Jennifer Wood, Ph.D., M.A., *methods core member*
- Prabhu Ponkshe, M.A., L.L.B., *communications consultant, Health Matrix, Inc.*

Responsible representatives at RWJF are:

- Angela McGowan, J.D., M.P.H., *senior program officer*
- Michelle Larkin, J.D., M.S., R.N., *team director and senior program officer*
- Tom Andruszewski, *senior grants administrator*

Other Grant Opportunities

RWJF's *New Connections* initiative, in collaboration with *Public Health Law Research* will release a new CFP in early 2010. It will support research consistent with the *Public Health Law Research* mission by investigators from underrepresented groups. Announcements of the CFP will be available at www.publichealthlawresearch.org and www.rwjf-newconnections.org.

Timetable

- **February 10, 2010**

CFP released and online application becomes available.

- **March 17, 2010 (2:30–3:30 p.m. ET)**

Informational Web conference call. Registration is required.

- **April 14, 2010 (3 p.m. ET)**

Deadline for receipt of brief proposals.

- **Early June**

Applicants notified if invited to submit a full proposal.

- **June 17, 2010 (2:30–3:30 p.m. ET)**

Informational Web conference call for full proposal applicants. Registration is required.

- **July 21, 2010 (3 p.m. ET)**

Deadline for receipt of full proposals.

- **September 30, 2010**

Finalists notified.

- **November 15, 2010**

Funding initiated.

Applications for this solicitation must be submitted electronically. Visit www.rwjf.org/cfp/phlr and use the Apply link for this solicitation. You will be required to register at MyRWJF before you begin the application process.

Program staff may not be able to assist all applicants in the final 24 hours before the submission deadline. In fairness to all applicants, the program will not accept late applications.

About the Robert Wood Johnson Foundation

The Robert Wood Johnson Foundation focuses on the pressing health and health care issues facing our country. As the nation's largest philanthropy devoted exclusively to improving the health and health care of all Americans, we work with a diverse group of organizations and individuals to identify solutions and achieve comprehensive, meaningful and timely change.

For more than 35 years we've brought experience, commitment and a rigorous, balanced approach to the problems that affect the health and health care of those we serve. When it comes to helping Americans lead healthier lives and get the care they need, we expect to make a difference in your lifetime.

For more information visit www.rwjf.org.

Sign up to receive e-mail alerts on upcoming calls for proposals at www.rwjf.org/services.



Robert Wood Johnson
Foundation

Route 1 and College Road East
P.O. Box 2316
Princeton, NJ 08543-2316

February 2010

2011 Report to the Oregon Legislature Advisory Committee on Genetic Privacy and Research



**PUBLIC HEALTH DIVISION
Office of Family Health**

This document can be provided upon request in alternative formats for individuals with disabilities. Other formats may include (but are not limited to) large print, Braille, audio recordings, Web-based communications and other electronic formats. E-mail derek.mills@state.or.us, or call 971-673-0249 (voice) or 971-673-0372 (TTY) to arrange for the alternative format that will work best for you.

(03/01/2011)