STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
1102 SE Quince Street • PO Box 47990
Olympia, Washington 98504-7990

October 9, 2002

Honorable Members of the Washington State Legislature

Dear Ladies and Gentlemen:

The Washington State Board of Health (SBOH) respectfully submits the enclosed report to the Legislature, *Genetic Privacy, Discrimination, and Research in Washington State: Findings, Conclusions, and Recommendations of the Washington State Board of Health Genetics Task Force.*

The Board convened the Washington State Genetics Task Force (GTF) in response to a proviso in ESSB 6153 Sect. 220.8. The GTF comprised 22 members, including some of our state's and nation's top genetics scientists, representatives from ACLU, the business community, the biotechnology industry, the ethics community, and citizens affected by developments in genetics. The GTF convened five meetings over nine months and considered an extensive volume of information from a variety of experts.

Pursuant to the charge set forth by the Legislature, the Task Force examined existing Washington State policies that may address genetic privacy and discrimination and considered remedies to compensate individuals for the misuse of their genetic information. In general, GTF members agreed that identifiable genetic information is personal information and the privacy of personal information is paramount regardless of who holds the information. Furthermore, the GTF found that existing laws provide some protection against privacy violations and discrimination based on genetic information. It concluded that these laws provide the greatest protection for genetic information obtained, used, or stored within the health and medical care systems.

The Task Force, however, identified gaps and ambiguities in existing protection for genetic information collected or held outside of the health and medical care systems. These insufficiencies make it possible for privacy and civil rights violations to occur. With respect to incentives for further research and development in the use of DNA to promote public health, safety, and welfare, the GTF concluded that incentives might include policies that address perceived risks of discrimination or privacy violations. These would help reassure potential research subjects who might otherwise be dissuaded from participating in research studies.

The enclosed report summarizes the wide range of background information received by the GTF. The information contained therein provides the basis and justification for the following recommendations to improve privacy and circumstances surrounding the possibility of discrimination based on genetic information in Washington State.

Incidence of discriminatory actions based upon genetic information

1.1 Reports of genetic testing should remain in medical records and receive the same protection as other sensitive medical information.

1.2 Support and authorize funding where necessary for efforts to educate consumers, research subjects, researchers, health care providers, employers, and insurers about how genetic information derived from genetic testing, as part of medical information, can be used, the concepts and consequences of anonymity in research, and the reporting and other mechanisms available to those who believe they have been discriminated against. These efforts should include: 1) providing information to consumers, research subjects, researchers, health care providers, employers, and insurers about existing laws and penalties for violations regarding the privacy and appropriate use of genetic information; 2) establishing a graduate program in genetic counseling at the University of Washington to address the current and future needs of the state's population.

1.3 Change the Washington State Law Against Discrimination (Chapter 49.60 RCW) to explicitly include "genetic information" in the list of characteristics that receive protection under the law. The GTF recommends that "genetic information" be defined as, "Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination."

Strategies to safeguard civil rights and privacy related to genetic information

2.1 Adopt in rule the existing administrative policies protecting the privacy of newborn screening specimens and other tissue samples held by the state.

2.2 Create policy to make all research in the State of Washington involving genetic information obtained from human subjects subject to the standards that are in place for federally funded and/or regulated human subjects research.

2.3 Where current law permits the collection or use of genetic information by employers or insurers, state law should require informed consent from the individual for collection, storage, disclosure, and any use of such information. Uses of such information should be restricted to those purposes for which it is collected or purposes required by law. The individual providing the information shall receive the results of any tests conducted by or for the recipient of the information.

2.4 Revise Chapter 26.04 RCW to remove the ban on first cousin marriage.

Remedies to compensate individuals for inappropriate use of genetic information

3.1 Designate a centralized agency to receive and act upon reports of discrimination based upon genetic information or violations of privacy involving genetic information.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

4.1 Given the limited nature of the data provided by testing conducted for the criminal DNA database, incentives for research using this resource are not warranted.

4.2 Ensure that state policy requires that in all research involving genetic information from individuals, explicit voluntary consent or assent be obtained or waived as detailed in applicable law and regulations.

4.3 Invite all stakeholders to participate in any process to create policies addressing the use of genetic information in research.

Sincerely,

Linda Lake, Chair
Washington State Board of Health

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Executive Summary

The Washington State Legislature recognized a need to evaluate state policies regarding genetic privacy and discrimination, and to assess the potential effect of new policies on privacy, civil rights, and research and development into the use of deoxyribonucleic acid (DNA) to promote public health, safety, and welfare. This recognition led to the inclusion of language in the state's biennial budget—Engrossed Substitute Senate Bill (ESSB) 6153, Section 220.8—directing the State Board of Health (SBOH) to convene a broad-based task force charged with reviewing "the available information on the potential risks and benefits to public and personal health and safety, and to individual privacy, of emerging technologies involving human DNA."

Pursuant to this mandate, the Board established the Genetics Task Force (GTF) in October 2001. The 22-member volunteer GTF, which comprised representatives from a variety of professional, consumer, and public organizations, held five public meetings between January 2002 and September 2002. During this time the Task Force received and evaluated information pertaining to four areas identified by the Legislature:

a) the incidence of discriminatory actions based upon genetic information;

b) strategies to safeguard civil rights and privacy related to genetic information;

c) remedies to compensate individuals for inappropriate use of genetic information; and

d) incentives for further research and development in the use of DNA to promote public health, safety, and welfare.

The findings of the Task Force reflect the complexity of the issues surrounding genetic privacy and discrimination based on genetic information. Overall, the Task Force recognized that research and development into new DNA-based technologies is proceeding at a rapid pace, and it is providing knowledge and many potentially beneficial tools to medicine and public health. These technologies are also creating opportunities for researchers, insurers, and employers to use genetic information in ways previously unavailable.

The Task Force examined existing Washington State policies that may address genetic privacy and discrimination. The GTF sought to determine if the policies adequately protect privacy and civil rights and provide sufficient incentives to promote the progress of potentially beneficial research and development. The GTF discovered that there are many facets to this question including, but not limited to, the debate over genetic exceptionalism and the absence of significant quantitative data regarding privacy violations and discriminatory actions associated with the use of genetic information.

In general, Task Force members agreed that identifiable genetic information is personal information and the privacy of personal information is paramount regardless of who holds the information. Furthermore, the absence of quantitative data on the incidence of privacy violations or discriminatory actions does not necessarily mean that these acts do not occur. The Task Force cannot determine the extent to which this finding may be an indication that: 1) victims or witnesses of discrimination do not report such incidents out of fear, embarrassment, or ignorance of wrongdoing; 2) authorities do not recognize such incidents because of a lack of active surveillance, oversight, or enforcement of program policies or existing anti-discrimination laws; 3) the public, health care providers, and researchers lack knowledge of existing reporting mechanisms and appropriate avenues for recourse; and/or 4) these events have not occurred in Washington State.

The Task Force also agreed that existing laws provide some protection against privacy violations and discrimination based on genetic information. The members concluded that these laws provide the greatest protection for genetic information obtained, used, or stored within the health and medical care systems. However, the Task Force identified gaps and ambiguities in existing laws that leave open the opportunity for privacy and civil rights violations to occur by not providing sufficient protection for genetic information collected or held outside of the health and medical care systems.

In addition, the Task Force considered remedies to compensate individuals for the misuse of their genetic information. The GTF found that recourse and remedies for privacy or civil rights violations consist of reporting violations to administrative or

oversight agencies and pursuing actions against perpetrators in court. Most laws reviewed by the GTF that are aimed at protecting an individual's civil rights and privacy provide for civil or criminal penalties in cases of wrongdoing. However, the Task Force noted that there is a dearth of case law specific to the misuse of genetic information on which it might draw conclusions about remedies individuals claiming privacy violations or discrimination based on genetic information may receive. In contrast, case law provides examples of remedies for wrongdoing by health care providers, employers, or insurance companies in matters related to the broad issues of privacy and civil rights. Therefore, the GTF found that avenues for obtaining compensation or punishing violators exist within the current legal tort system, but they may not explicitly apply to instances of privacy violations or discrimination involving genetic information.

Finally, the GTF evaluated incentives for further research and development in the use of DNA to promote public health, safety, and welfare. Incentives may include policies that address perceived risks of discrimination or privacy violations to assure that potential research subjects are not dissuaded from participating in research studies. Overall the Task Force found that incentives to continue genetic research and development exist in the form of funding and opportunities created by industry, academic, and government research agendas.

Based on the findings and conclusions outlined in this report, the GTF developed the following recommendations for the Washington State Legislature regarding genetic privacy and discrimination and incentives to promote further research and development in the use of DNA to promote public health, safety, and welfare. Some of these recommendations call for new legislation.[1] Nineteen members of the 22-member GTF endorsed this report; the remaining three members did not issue position statements regarding the content presented herein. However, at least two of them were very active participants throughout the entire process and are believed to be generally supportive of this report.

Incidence of discriminatory actions based upon genetic information

Recommendations[2]

1.1 Reports of genetic testing should remain in medical records and receive the same protection as other sensitive medical information.

1.2 Support and authorize funding as needed for efforts to educate consumers, research subjects, researchers, health care providers, employers, and insurers about how genetic information derived from genetic testing, as part of medical information, can be used, the concepts and consequences of anonymity in research, and the reporting and other mechanisms available to those who believe they have been discriminated against. These efforts should include: 1) providing information to consumers, research subjects, researchers, health care providers, employers, and insurers about existing laws and penalties for violations regarding the privacy and appropriate use of genetic information; 2) establishing a graduate program in genetic counseling at the University of Washington to address the current and future needs of the population.[3]

1.3 Change the Washington State Law Against Discrimination (Chapter 49.60 RCW) to explicitly include "genetic information" in the list of characteristics that receive protection under the law. The GTF recommends that

[1] Discussions of the GTF's conclusions and logic that supports these recommendations can be found in the "Conclusions and Recommendations" section of the report, beginning on page 23.

[2] Minority Recommendation: Prof. Philip Bereano proposed that the state create a policy to destroy the tissue samples in the forensic database after the DNA profiling is complete.

[3] Robin Bennett and Dr. Wylie Burke recommended that this effort include education for health care providers and genetic testing laboratories regarding the professional ethic against presymptomatic testing of children under age 18 years for untreatable adult onset disorders, including such children being placed for adoption. Julie Sanford Hanna stated that the onus of making the decision to conduct presymptomatic genetic testing on children under age 18 years should be primarily on health care providers and not on laboratory personnel because health care providers order tests and are more likely to develop a relationship with patients and their families. Thus, she suggested that the educational and policy efforts in this area should focus on health care providers.

"genetic information" be defined as "Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination."[4]

Strategies to safeguard civil rights and privacy related to genetic information

Recommendations[5]

2.1 Adopt in rule the existing administrative policies protecting the privacy of newborn screening specimens and other tissue samples held by the state.

2.2 Create policy to make all research in the State of Washington involving genetic information obtained from human subjects subject to the standards that are in place for federally funded and/or regulated human subjects research.[6]

2.3 Where current law permits the collection or use of genetic information by employers or insurers, state law should require informed consent from the individual for collection, storage, disclosure, and any use of such information. Uses of such information should be restricted to those purposes for which it is collected or purposes required by law. The individual providing the information shall receive the results of any tests conducted by or for the recipient of the information.

2.4 Revise Chapter 26.04 RCW to remove the ban on first cousin marriage.

Remedies to compensate individuals for inappropriate use of genetic information

Recommendations[7]

3.1 Designate a centralized agency to receive and act upon reports of discrimination based upon genetic information or violations of privacy involving genetic information.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Recommendations

4.1 Given the limited nature of the data provided by testing conducted for the criminal DNA database, incentives for research using this resource are not warranted.

4.2 Ensure that state policy requires that in all research involving genetic information from individuals, explicit voluntary consent or assent be obtained or waived as detailed in applicable law and regulations.[8]

4.3 Invite all stakeholders to participate in any process to create policies addressing the use of genetic information in research.

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[4] Mellani Hughes, JD dissented from this recommendation on the grounds that WSHRC and EEOC both interpret the WLAD and the ADA to be applicable in cases of employment or other discrimination based on genetic information, rendering additional language in Chapter 49.60 RCW unnecessary, particularly when there is little evidence of such discrimination. Dr. Peter Byers also dissented from this recommendation on the grounds that current statute and codes appear to provide the same protection, existing policies restrict access to genetic information, and this change may lead to unanticipated problems. In addition, Dr. Nancy Fisher and Dr. Peter Byers felt that the proposed definition of genetic information is too broad to have power and value in the context of the statute.

[5] Minority Recommendation: Prof. Philip Bereano and Ty Thorsen recommended that the state enact legislation that explicitly defines genetic discrimination, genetic information, and privacy rights of individuals with respect to genetic information.

[6] Dissent: Mellani Hughes, JD dissented from this recommendation on the grounds that insufficient evidence was received about whom this type of policy would affect.

[7] Minority Recommendation: Prof. Philip Bereano and Ty Thorsen recommended that the state pass legislation that protects the privacy of genetic information, defines and outlaws genetic discrimination, and provides avenues for redress when violations are proven.

[8] See also recommendation number 2.2 under "Strategies to safeguard civil rights and privacy related to genetic information." If all research conducted in the state were subject to federal law this concern would be addressed.

Introduction

The 2001–03 Washington State biennial operating budget, enacted as Engrossed Substitute Senate Bill 6153 in June 2001, included a proviso (Sect. 220.8) for the State Board of Health (SBOH) to convene a broad-based task force to "review the available information on the potential risks and benefits to public and personal health and safety, and to individual privacy, of emerging technologies involving human DNA." The proviso directed the task force to report its findings, conclusions, and recommendations no later than October 2002.

The mandate required the task force to consider evidence brought to it on the following four issues:

1) the incidence of discriminatory actions based upon genetic information;

2) strategies to safeguard civil rights and privacy related to genetic information;

3) remedies to compensate individuals for inappropriate use of genetic information; and

4) incentives for further research and development in the use of DNA to promote public health, safety and welfare.

In response, SBOH formed the Genetics Task Force (GTF). It comprised 22 members and met five times over nine months between January and September 2002. During this period, it received and deliberated over information from experts and interested parties on privacy, discrimination, and research with respect to genetic information.

Information received by the GTF included analyses of state and federal legislation and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rules, the Americans with Disabilities Act (ADA), the Uniform Health Care Information Act (Chapter 70.02 RCW), the Washington Law Against Discrimination (WLAD) (Chapter 49.60 RCW), and Office of the Insurance Commissioner (OIC) rules. The GTF also received presentations regarding Washington State's newborn screening program and related privacy policies, the history of genetics-related legislation in Washington State, the historical practices of eugenics, legislative efforts in other states, and the potential effect of privacy and anti-discrimination policies on ongoing and future genetic research endeavors in Washington.

This report summarizes the findings, conclusions and recommendations of the GTF.

Background

Legislative History

The Washington State Legislature considered 25 different drafts of various genetics-related legislation from January 1998 to March 2002. (A summary of legislation considered during this period is available by request from SBOH.) The scope of the proposed legislation varied significantly and included topics such as criminal DNA databases, health insurance practices, informed consent requirements, prohibitions against the misuse of genetic information, statutory definitions of terms such as "genetic information" or "health care information," the formation of review committees and/or task forces, and genetic testing practices. During this time period, few of the proposed bills related to genetic privacy and discrimination issues passed out of the Legislature.

The debates surrounding proposed privacy and anti-discrimination legislation predominantly focused on two areas: 1) the need to protect the privacy rights of individuals and to prevent the use of genetic information to adversely discriminate against individuals in insurance or employment; and 2) the effect of such legislation on genetic research and development and the biotechnology industry in Washington. One effort to reach a resolution to these debates was the establishment of the Joint Select Committee on DNA Identification in 1999. This Committee included four members each from the House and Senate. The Committee expired in July 2000 without agreeing upon recommendations for further legislative action.

Subsequent legislative activity aimed at collecting information regarding the need for and impact of genetic privacy and anti-discrimination legislation included Section 220(8) of the 2001–03 Washington State biennial operating budget described previously.

ESSB 5207, passed in March 2002, is the most recent legislative action taken by the Washington State Legislature with respect to genetic privacy. ESSB 5207 amended the Uniform Health Care Information Act (Chapter 70.02 RCW) to include a person's deoxyribonucleic acid (DNA) and identified sequence of chemical base pairs in the definition of "health care information."

Defining Scope and Membership

In response to the directive in ESSB 6153, SBOH approved a work plan for the GTF in October 2001.[9] The plan defined the scope of the GTF consistent with the budget proviso. The Board asked the GTF to consider the potential of genetic information to advance scientific knowledge and improve health care practice in the context of privacy and discrimination concerns and to consider possible regulations regarding the use of and access to genetic information. The work plan included consideration of the collection, storage, and sharing of genetic information within the health and medical care systems as well as the use of genetic information in the context of health, life, and disability insurance and employment as balanced against the risk of harm to scientific research and development. The scope of the GTF excluded issues related to stem cell research and cloning.

SBOH invited experts and interested persons from the following interests to serve on the GTF: state and local public health, public and private purchasers of medical care, health insurance carriers, primary care physicians, pathologists and laboratorians, genetic counselors, hospitals, genetic ethicists, institutional review boards, research geneticists, trial attorneys, medical research institutions, civil rights advocates, privacy advocates, citizens who have undergone genetic testing, parents whose children have been helped by genetic testing, the biotechnology industry, and experts in privacy laws. Some invitees were presently or previously involved with existing SBOH or Washington State Department of Health (DOH) genetics committees such as the Newborn Screening Advisory Committee, the Prenatal Screening Advisory Committee, and the Genetic Services Advisory Committee. Others represented relevant professional societies and associations (see Table 1).[10]

[9] Available at http://www.doh.wa.gov/SBOH/Priorities/Genetics/genetics.htm.

[10] Robert Miyamoto expressed a concern that GTF membership represented a bias toward health and related issues. He felt the time required to participate fully excluded individuals not professionally involved in the issues . Members who were professionally involved, he stated, were able to influence the process more than those who had to take time from work to devote time to the issues. He believes that this dynamic affected the outcome of the report.

Table 1: GTF Members

Robin Bennett, MS, CGC
University of Washington, Medical Genetics
Representing: Genetic Counselors

Mellani Hughes, JD
Governmental Affairs Counsel, Association of Washington Business
Representing: Private Purchasers of Medical Care

Philip L. Bereano, JD
Professor, University of Washington College of Engineering, Department of Technical Communication; Founding Board Member, Council for Responsible Genetics; Vice-President, Washington Biotechnology Action Council
Representing: The American Civil Liberties Union

Linda Lake, MBA, Chair
Chair, Washington State Board of Health
Representing: Washington State Board of Health

Wylie Burke, MD, PhD
Professor and Chair, University of Washington, Department of History and Medical Ethics
Representing: Genetics and Medical Ethics

Helen McGough
Director, Human Subjects Division, University of Washington
Representing: Institutional Review Boards

Peter Byers, MD
Professor, University of Washington, Department of Medicine, Department of Pathology
Representing: Research Geneticists

Robert Miyamoto
Associate Director for Applied Research and Technology, University of Washington Applied Physics Laboratory
Representing: Parents of children helped by genetic testing

Maureen Callaghan, MD
The Middleton Foundation, Inc.
Representing: Washington State Medical Association

Suzanne Plemmons, RN, MN, CS
Family and Community Health Director, Bremerton-Kitsap Health
Representing: Local Public Health

Howard Coleman
Chairman, CEO, and Chief Development Officer, Genelex Corporation
Representing: Biotechnology Industry

Ree Sailors
Executive Policy Advisor, Office of the Governor
Representing: Public Purchasers of Medical Care

Amanda DuBois, JD
Washington State Trial Lawyers Association
Representing: Trial Attorneys

Julie Sando
Representing: Citizens who have undergone genetic testing

Joe Finkbonner, RPh, MHA
Member, Washington State Board of Health
Representing: Washington State Board of Health

Julie Sanford-Hanna, PhD
President, Department of Health Genetic Advisory Committee; Director, Clinical Cytogenetics, Sacred Heart Medical Center, Department of Lab Medicine
Representing: Pathologists or Laboratory Medicine

Nancy Fisher, MD, MPH, RN
Medical Director, Regence Blue Shield
Representing: Health Insurance Carriers

C. Ronald Scott, MD
Professor, University of Washington, Department of Pediatrics
Representing: Medical Research Institutions

Maxine Hayes, MD, MPH
State Health Officer, Department of Health
Representing: State Public Health

Brenda Suiter
Director, Rural and Public Health Policy, Washington State Hospital Association
Representing: Hospitals

Vicki Hohner, MBA
Senior Consultant, Fox Systems, Inc.
Representing: HIPAA Privacy Experts

Ty Thorsen
Product Development Manager, Cisco Systems
Board Member, American Civil Liberties Union—Washington
Representing: Privacy Advocates, ACLU-WA

Methods

The GTF met five times over nine months in 2002: January 3, February 25, April 12, June 25, and September 4. All meetings were open to the public. Three meetings served as opportunities to hear from experts or interested parties on specific topics. Table 2 summarizes the topics covered. GTF staff supplemented information received at these meetings with literature and legislative research, and with consultation with legal advisors. Staff presented research summaries in the forms of the Genetic Privacy and Genetic Discrimination Matrix for Washington State and the Genetics Task Force Working Glossary (Appendices B and C) and meeting summaries, (available at www.doh.wa.gov/SBOH/Priorities/Genetics/genetics.htm).

The GTF reviewed the charge in the budget proviso and the scope of work detailed in the work plan at its January 3 meeting. State Senator Rosa Franklin and Representative Al O'Brien spoke about the Legislature's intentions when drafting the charge. Their comments provided a context in which the GTF could place the legislative mandate and helped to narrow its focus to specific areas of legislative interest. Additional information received at that meeting included: an overview of previously proposed genetics-related legislation the state; an introduction to the fundamentals of genomic science and the potential ethical, legal, and social implications of scientific advancements related to human genetics; an introduction to federal and state privacy laws and regulations such as HIPAA, the Uniform Health Care Information Act (Chapter 70.02 RCW), the Governor's Executive Order on Privacy (EO 00-03), and the Patient's Bill of Rights (SB 6199); an introduction to the Washington Newborn Screening Program; and an overview of Institutional Review Board (IRB) practices and policies.

The GTF convened its second meeting on February 25. Prior to the meeting, the GTF published a notice of its intent to receive information about evidence of privacy violations concerning the unauthorized release or misuse of genetic information. It issued press releases, held public hearings, solicited testimony on the SBOH Web site, and provided several avenues for the public to submit oral, written, or electronic testimony. Representatives from the Office of the Insurance Commissioner (OIC) and the Washington State Human Rights Commission (WSHRC) reviewed regulations they administered and explained how existing regulations may pertain to genetic discrimination in insurance and employment. OIC and WSHRC also provided information on the reported incidences of genetic discrimination. Other presentations included overviews of historical eugenics practices, potential misuses of genetic information, the practices and policies of health insurers, and genetic privacy and antidiscrimination legislation in other states.

The third GTF meeting occurred April 12 in conjunction with the Henry Art Gallery's Gene(sis) exhibit. The GTF heard from three panels of researchers on academic/basic science research, public health research, and industry-sponsored research. The panelists provided perspectives on the multitude of uses for genetic information in research and the development of genetic technologies to promote public health, safety, and welfare. Panelists also addressed oversight by local and federal agencies including requirements to protect human subjects through informed consent procedures, monitoring, and the maintenance of data security. After hearing from the panels, GTF members developed a strategy for drafting conclusions and recommendations based on findings from the previous meetings and formed four subcommittees to draft reports from the perspective of different circumstances for obtaining and/or using genetic information (see Table 3).

The GTF reviewed a draft of the final report and received comments on it from four community advocacy groups at the September 4 meeting. Significant changes to the conclusions and recommendations resulted from this discussion. Collectively, GTF members revised several of the conclusions and recommendations in the subcommittee reports and added some new recommendations. Subsequently, staff revised the report and provided a second draft to members for review. Nineteen members endorsed the revised report; some endorsements were contingent on the inclusion of minor changes or additional statements reflecting their opinions (see Appendix A for a summary of comments). Three members did not submit position statements.

Table 2: Meeting Topics and Presenters, January 2002-April 2002

January 3, 2002

Topic	Presenters
Overview of Work Plan	Roberta Wines
Review of legislative history	Joan Mell, JD
Legislative context for charge to the GTF	Senator Franklin, Representative O'Brien
Introduction to genomics	Dave Eaton, PhD, Wylie Burke, MD, PhD
Newborn Screening Program	Debra Lochner-Doyle
HIPAA and genetic privacy	Vicki Hohner
Washington State Health Care Information Act	Joan Mell, JD
Institutional Review Board policies and guidelines	Helen McGough

February 25, 2002

Topic	Presenters
Overview of pertinent insurance laws and policies	Jon Hedegard, Office of the Insurance Commissioner
Overview of genetic privacy and genetic discrimination	Philip Bereano, JD
Historical perspectives on eugenics	Nancy Fisher, MD
Introduction to health insurance practices and policies	Nancy Fisher, MD
Review of genetics related privacy and discrimination legislation in other states	Mary Ferguson, PhD
Overview of the effects of genetics privacy legislation on research in Oregon	Roberta Wines
Evidence of genetic discrimination and privacy violations in Washington State	Mary Clogston, Washington State Human Rights Commission

April 12, 2002

Topic	Presenters
Academic/Basic Science Panel	Kenneth Thummel, PhD, Jonathan Tait, MD, PhD
Public Health Panel	Karen Edwards, PhD, Maxine Hayes, MD, MPH, Amy Klein, MPH
Biotechnology Industry Panel	Eric Earling, Steve Gilbert, PhD, Bruce Montgomery, MD

Table 3: Genetics Task Force Subcommittees

SC1: The use of genetic information for health care including the diagnosis of symptomatic patients, reproductive decision-making, and predictive genetic testing for low penetrant genetic disorders	C. Ronald Scott, M.D. (Chair), Robin Bennett, M.S.,C.G.C., Julie Sanford-Hanna, Ph.D., Robert Miyamoto, Ph.D., Maureen Callaghan, M.D.
SC2: State mandated DNA collection and testing	Maxine Hayes, M.D., M.P.H. (Chair), Philip Bereano J.D., Brenda Suiter, Howard Coleman, Suzanne Plemmons, R.N., M.N., C.S.
SC3: The use of genetic information for research purposes	Peter Byers, M.D. (Chair), Helen McGough, Philip Bereano, J.D., Amanda DuBois, J.D., Vicki Hohner
SC4: The use of genetic information for social purposes such as insurance and employment	Mellani Hughes, J.D. (Chair), Ty Thorsen, Wylie Burke, M.D., Ph.D., Nancy Fisher M.D., M.P.H., R.N., Joe Finkbonner

The Subcommittees

The GTF organized into four subcommittees to clearly delineate some of the different circumstances in which an individual's genetic information may be obtained and used:

1) The use of genetic information for health care including:
    a) the diagnosis of symptomatic patients;
    b) reproductive decision-making; and
    c) predictive genetic testing for low penetrant genetic disorders;
2) State mandated DNA collection and testing including:
    a) newborn screening; and
    b) criminal DNA databases;
3) The use of genetic information for research purposes; and
4) The use of genetic information for social purposes such as health, life, and disability insurance and employment.

Reports from the Subcommittees are available by contacting SBOH or visiting its Web site. Following is a brief description of the approach taken by each Subcommittee and the issues considered by the members.

Subcommittee One: The use of genetic information for health care including: a) the diagnosis of symptomatic patients; b) reproductive decision-making; and c) predictive genetic testing for low-penetrant genetic disorders

Subcommittee One analyzed the information presented to the GTF from the perspective of the health and medical care system. For the purposes of their deliberations, the members of Subcommittee One adopted the following definition of "genetic test": the analysis of DNA, RNA, chromosomes, proteins, or other gene products to detect disease-related genotypes, mutations or karyotypes for clinical purposes or phenotype prediction.

Genetic information is used in a variety of ways within the health and medical care system. For example, physicians use it for the medical diagnosis of symptomatic patients. This generally occurs through either chromosome or DNA analysis conducted in licensed medical laboratories. Physicians may request DNA analysis of blood samples from children with mental retardation who are suspected of having Fragile X syndrome, from males with symptoms of Duchenne muscular dystrophy, from persons with a clotting disorder, or from adults with muscle and neurologic changes suggestive of a genetic condition. The introduction of DNA testing has simplified the medical diagnosis of these and many other conditions that in the past may have involved anesthesia, muscle biopsies, or expensive and laborious testing by other means.

DNA technology is a very powerful tool in reproductive medicine and physicians and counselors use genetic information to assist people with reproductive decisions. In general, the technology is used for this purpose in two ways: 1) identification of asymptomatic pregnant couples at risk for having a newborn with a severe genetic disease; and 2) utilization of DNA technology in subsequent pregnancies in families that have previously given birth to a child with a genetic disorder. Both situations offer parents and health care providers the opportunity to prevent or prepare for the birth of a child affected by a genetic disorder.

A third way that health care providers use genetic information is for the predictive identification of genetic risk factors associated with late-onset diseases. In certain instances, DNA testing can identify genetic predisposition to a disease prior to the onset of clinical symptoms. This type of testing may be used in three different situations. First, young children at high risk for developing a serious disorder for which intervention may be available can be tested for a genetic predisposition to the disorder before symptoms arise. Predictive genetic testing may be offered to infants who have a sibling with cystic fibrosis, male children in families with Duchenne muscular dystrophy, or children born into a family at high risk for a genetic disease for which therapy is available.

The second category of predictive genetic testing is more complicated. A number of disorders exist in which clinical symptoms do not present until adulthood. DNA technology has the potential to identify individuals at risk for some of these conditions

at any age prior to the onset of symptoms. Genetic testing can predict some of these disorders with a finite probability prior to the onset of symptoms if an individual carries a particular form of a gene associated with the disorder. Examples include the predilection for breast cancer in individuals who carry an abnormality of the BRCA1 or BRCA2 genes, or the predilection for neurological degeneration around the age of 40 in individuals with an abnormality of the Huntington disease gene. In the case of a woman with a strong family history of breast cancer, it may be appropriate to screen that woman using DNA testing to determine her genetic risk of developing breast cancer. Screening allows for early detection or prevention of breast cancer in a woman with mutations in BRCA1 or BRCA2. In the case of Huntington disease, an autosomal dominant condition, children of an affected individual are at 50 percent risk for developing the condition in adulthood, but there exist no medical strategies for treatment or cure. In this case, DNA testing may be appropriate for medical information and for personal decision-making on lifestyle changes.

A third use of predictive genetic testing is the testing of children under 18 years of age for medical conditions that may present in adulthood; again the examples of testing for susceptibility to breast cancer or Huntington disease is relevant. Many health care providers consider it unethical to test children for adult onset disorders prior to the age when they can give informed consent. This opinion applies to children born into families who are at increased risk for adult onset diseases or children being placed for adoption with no known prior risk factors.

Subcommittee Two: State-mandated DNA collection and testing including: a) newborn screening; and b) criminal DNA databases

The report presented by Subcommittee Two is based on two instances of state law that require the collection and testing of an individual's DNA. First, the subcommittee considered Chapter 70.83 RCW and Chapter 246-560 WAC concerning the State's Newborn Screening Program. Chapter 70.83 RCW requires "… screening tests of all newborn infants before they are discharged from the hospital for the detection of phenylketonuria and other heritable or metabolic disorders leading to mental retardation or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices." Other disorders for which testing is done include congenital hypothyroidism, congenital adrenal hyperplasia, and hemoglobinopathies. SBOH regulations (Chapter 246-650 WAC) adopted pursuant to this statute direct hospitals to obtain blood specimens from infants and send them to the State Public Health Laboratory for testing. Specimens consist of a few drops of blood that are absorbed and dried onto a filter paper form.

The second instance concerns collection of DNA from felons and certain other criminals and the maintenance of the information gleaned from the sample. The recently amended state DNA Data Base law (Chapter 43.43 RCW) requires that "Every adult or juvenile individual convicted of a felony, stalking … harassment … or communicating with a minor for immoral purposes … must have a biological sample collected for purposes of DNA identification analysis …." These samples are tested according to specifications outlined in federal law and retained by the Forensic Services Bureau of the Washington State Patrol (WSP). The statute restricts uses to "… identification analysis and prosecution of a criminal offense or for the identification of human remains or missing persons" or "… improving the operation of the [DNA identification] system." The statute allows WSP to submit DNA test results to the FBI Combined DNA index system (CODIS), which is authorized under the DNA Identification Act of 1994 (42 U.S.C.A§14132).

Subcommittee Three: The use of genetic information for research purposes

Subcommittee Three examined the collection and use of genetic information for research purposes. Research in human genetics has become one of the most exciting areas of study in the last decade, bringing with it both promise and concern. The technological innovations that accompanied the thrust to provide the genetic map and sequences of the human genomes have been increasingly applied to the examination of human variation. Variation is being studied from several perspectives: individual identification for forensic purposes; identification of known disease-causing mutations; and discovery of DNA sequences that may be associated with susceptibility to common diseases such as heart disease, hypertension, diabetes, stroke, and mental illness, among others.

The interest in studies of human genetics exists for several reasons. First, humans have an intense curiosity about who we are and how we came to be. The analysis of the origins of modern humans and their migrations has provided a picture of the relationships among all humans that emphasizes common features. Second, the identification of the more than 30,000 genes that encode proteins and regulatory molecules has provided the substrate for understanding the intricacies of human development in both health and disease. Technological advances have made it possible to work with more than one gene at a time and to define how genetic "systems" work. The area of greatest interest to most researchers is the detailed analysis of the genes that are involved in promoting health and disease.

This type of research occurs in several settings including the academic research community, where it is often supported by federal or other charitable funds, and private industry, where it is usually supported by funds from private enterprises such as pharmaceutical companies. The activities in this domain are significant in a clinical setting for the diagnosis and confirmation of specific genetic disorders.

These research activities warrant consideration as they raise questions about the manner in which research findings are used and the extent to which findings about individuals that emanate from research done in publicly versus privately funded environments are subject to the same types of regulation. There is already a complex network of regulatory provisions for research funded or regulated through federal sources that contain explicit guidelines on the protection of subjects and the protection of the information that results from these studies. Issues such as how these data could be treated and how they form part of the medical information about an individual can arise with the publication of the these data and the release to individuals of information from the studies.

Subcommittee Four: The use of genetic information for social purposes such as health, life and disability insurance and employment

Subcommittee Four considered the use of genetic information for social purposes. The members of this subcommittee evaluated the potential for employers and insurance companies to use an individual's genetic information. Issues considered by this subcommittee included whether employers could obtain and use genetic information to make employment decisions and what constitutes appropriate use of genetic information in life, health, and disability insurance.

Findings

The GTF adopted the following findings related to the four areas specified in the legislative mandate:

Incidence of discriminatory actions based upon genetic information in Washington State

The GTF solicited testimony from the Washington State Human Rights Commission (WSHRC), the Office of the Insurance Commissioner (OIC), and the DOH Genetic Services Section (GSS) regarding evidence of discriminatory actions based upon the use of genetic information. Representatives from OIC and WSHRC testified that neither agency has received reports or complaints from citizens of Washington State with respect to adverse discriminatory actions resulting from an employer's or insurance company's knowledge of an individual's genetic information. A representative from the DOH GSS provided a log of 38 inquiries and complaints received between November 20, 1991 and November 16, 2001. The Task Force found that three of these incidents represented cases in which family history or genetic status may have been used to adversely discriminate against an individual. The rest of the complaints were based on the need for additional education or genetic counseling resources.

The GTF received no additional information about documented cases of adverse discriminatory actions based on genetic information obtained or used for diagnostic genetic testing, reproductive decision-making, predictive genetic testing, newborn screening, criminal DNA databases, or research. However, members agreed that the possibility of discrimination based on genetic testing, and predictive genetic testing in particular, exists. In addition, fear of discrimination may prevent individuals from participating in research, seeking clinical genetic tests, or disclosing genetic information. With regard to the use of DNA technology for prenatal or preconception testing, the Task Force found that there is little, if any, risk of discrimination because testing is always voluntary, done with informed consent and test results are maintained within the patient's private medical record. Task Force members reaffirmed the right of individuals to seek genetic counseling and appropriate genetic testing when they are at risk for transmitting a serious genetic disorder and the rights of children born with genetic conditions or at risk for developing genetic conditions to be free from discrimination because of any immediate or future disability.

Other findings related to the incidence of discriminatory actions based on genetic information are based on a review of the legislation, policies, and procedures associated with the Newborn Screening Program, the criminal DNA database, research activities, insurance industry policies and practices, and employment practices. The GTF found that no active surveillance systems are in place to proactively monitor the use of genetic information created and stored within the state's Newborn Screening Program or the criminal DNA database or for insurance or employment purposes. In contrast, the GTF found that formal reporting and monitoring systems are in place for research activities. Reporting systems allow research subjects to report perceived abuses that occur during a research study to the principal investigator, IRB, or a federal oversight agency such as the Food and Drug Administration. Internal and federal oversight agencies actively monitor researchers and IRBs; however, research that is not regulated by federal human subjects standards such as 45 CFR 46 (the Common Rule) and 21 CFR 50 may not have such monitoring systems in place.

The risk of discrimination based on predictive genetic information led the GTF to consider the possibility of discrimination based on information from DNA research studies regarding predispositions to disease. In some cases, this information might be disclosed to research subjects. The GTF found that individuals may be protected from some forms of misuse of this information by WAC 284.43.720, which prohibits health plans from treating genetic information as a health condition in the absence of a diagnosis of the related condition.

With respect to the incidence of discrimination based on genetic information used for social purposes such as insurance and employment, the GTF found that state agencies do not systematically survey people or make proactive efforts to collect information regarding such discrimination; however, agencies such as DOH, OIC, and WSHRC have passive reporting systems in place for receiving complaints.

In addition, the GTF examined the potential risks of adverse discrimination based upon genetic information in insurance and employment and found that statistical tables used by life insurance companies are based on estimates of life expectancy at a given age. These estimates account for the population-based occurrence of genetic conditions that may affect life expectancy. Furthermore, information about an individual's family history is a common and allowable request for some types of insurance coverage and broader definitions of genetic information may include family history. The GTF also found that health, life, and disability insurers view genetic information as a category of health care or medical information and that some state laws and industry practice disallow the use of health information (including genetic information) to set rates for, cancel, or not renew a consumer of health insurance. Specifically, RCW 48.18.480 prohibits unfair discrimination in insurance matters and WAC 284-43-720 states that "health carriers may not reject health plan applicants and may not limit or exclude plan coverage for any reason associated with health risk or perceived health risk except for the imposition of a preexisting condition exclusion as permitted in this chapter." Disability and life insurance may use health information to underwrite a policy but state law and/or industry practice prohibits the use of health information to cancel or not renew an existing consumer of these policies. Table 4 and the Genetic Privacy and Genetic Discrimination Matrix for Washington State in Appendix B summarize some of the laws and policies governing insurance practices in Washington State.

Table 4: Specific insurance policies and practices in Washington

Issue	Summary
Health insurance (preexisting conditions)	Individual, small-, and large-group health insurance plans may contain a waiting period of up to nine months for coverage of preexisting conditions,[11] but genetic information cannot be considered a health condition unless it is accompanied by a diagnosis of the condition.[12]
Long-term care, Medicaid supplemental, and disability insurance (preexisting conditions)	Preexisting condition limitations vary for long-term care, Medicare supplemental, individual or group disability insurance. The use of genetic information to define a preexisting condition may not be prohibited by law for some long-term care, Medicare supplemental, individual, or group disability insurance plans.[13]
Life insurance	In general, life insurance companies can use health care information, including genetic information, to deny coverage or to set initial rates; there are no laws preventing the use of preexisting conditions in life insurance underwriting. However, regulations do prohibit cancellation of a policy because of health conditions that emerge after issuance. Life insurance rates are term-based and policies may be periodically re-classified.
Property and casualty insurance	Property and casualty insurance plans generally do not consider health care information when enrolling clients, however the use of health care information for these plans is not specifically prohibited. An insurer using health care information to deny, cancel, or set rates must justify the action.[14]

[11] RCW 48.43.012; RCW 48.43.025(1); RCW 48.43.025(2)
[12] WAC 284-43-720(3)
[13] WAC 284.54.200; 284.66.063; WAC 284.50.320
[14] Robert Miyamoto suggested similar uses of health care information by life insurance companies should also require justification.

Regarding the risk of adverse discrimination in employment based on genetic information, the GTF found that the WSHRC and the Federal Equal Employment Opportunities Commission (EEOC) interpret the WLAD (Chapter 49.60 RCW) and the ADA to be applicable in cases of employment or other discrimination based on genetic information. However, the scope and interpretation of these laws with respect to genetic information has not been tested in the courts.

WSHRC writes rules and oversees the implementation of the WLAD. A representative from WSHRC testified to the GTF that WSHRC rules are broad enough to allow the agency to investigate and take action against claims of discrimination based on genetic information if they arise. WLAD prohibits employers from refusing to hire, discharging or barring, or discriminating against any person in compensation based on any sensory, mental, or physical handicap.[15] The scope of the WLAD also includes real estate, public accommodation, credit, and insurance practices.

The EEOC writes rules pertaining to and oversees the implementation of the ADA. The EEOC rules address the retention, storage, and use of employees' health information. The EEOC considers the scope of the ADA to include genetic tests and genetic information and believes that employers who discriminate against employees on the basis of predictive genetic tests "regard" the employees as having a disabling impairment and are therefore acting in violation of the ADA.[16] The ADA states that before making an offer of employment, an employer may not ask job applicants about the existence, nature, or severity of a disability; applicants may be asked about their ability to perform job functions. Under the ADA, a job offer may be conditioned on the results of a medical examination, but only if the examination is required for all entering employees in the same job category and the medical examination is job-related and consistent with business necessity.

The GTF notes that neither the WSHRC interpretation of the WLAD or the EEOC interpretation of the ADA with respect to the applicability of these statutes to cases involving discrimination based upon genetic information have been tested in court. Furthermore, the GTF found that recent Supreme Court decisions suggest a more narrow scope and interpretation of the ADA.[17]

Overall, the Task Force agreed that receiving very few reported cases of adverse discriminatory actions based on genetic information does not prove such incidents do not occur more frequently. Furthermore, the few documented cases of potential discrimination received by the GTF may not represent all such cases. The GTF found the lack of evidence of reported cases does not necessarily indicate that there is no risk of adverse discrimination based up genetic information. Some argue the perceived risk of discrimination may explain the low numbers of reported cases of discrimination and represent a need for education about how genetic information can be legally obtained, used, or disclosed, and how abuses can be reported.

Strategies to safeguard civil rights and privacy related to genetic information

The GTF received information about several state and federal strategies that may protect individuals' civil rights and privacy with respect to their genetic information. The Task Force found that these existing laws, regulations and policies provide substantive protection with respect to an individual's privacy and civil rights relating to his or her genetic information especially if that information is held within a medical record or is considered health care information. However, the GTF identified some ambiguities and/or weaknesses in existing legislation and noted specific gaps and/or lack of protection against certain privacy or civil rights violations with regard to genetic information held outside of the health and medical care system.

[15] Additional state legislation regarding protection from discrimination in employment includes Chapter 49.44.010 RCW, which prohibits "blacklisting" by employers. This statute prohibits an employer from willfully or maliciously making a statement with the intention of preventing a person from securing employment.

[16] EEOC Compliance Manual, section 902.8, available online at http://www.eeoc.gov/docs/902cm.html.

[17] Board of Trustees of the University of Alabama v. Garrett, 531 U.S. 356 (2001); Albertson's, Inc. v. Kirkingburg, 527 U.S. 555 (1999); Sutton v. United Airlines, 527 U.S. 471 (1999); Murphy v. United Parcel Service, 527 U.S. 516 (1999); Toyota Motor Manufacturing, Kentucky, Inc. v. Williams, 122 S.Ct. 681 (2002).

Strategies at the state level include the Uniform Health Care Information Act (Chapter 70.02 RCW), the Patient's Bill of Rights (SB 6199), Release of Records for Research (Chapter 42.48 RCW), the Governor's Executive Order on Privacy (EO 00-03), and various legislation including WAC 284-04-500, WAC 246-320-205 (2) (5), RCW 43.105.310, and RCW 51.28.070 that regulate the privacy of health care information held by health insurers, hospitals, and state agencies. Specifically, the Task Force found that state and federal laws protect the privacy of medical records. For example, the Washington State Legislature recently amended the definition of "health care information" in the Uniform Health Care Information Act (Chapter 70.02 RCW) by passing ESSB 5207 in March 2002. The statutory definition of "health care information" now includes DNA. Furthermore, the GTF received evidence indicating that newborn blood spots obtained and used in the Newborn Screening Program and the data associated with these spots fit within the definition of health care information and fall under the purview of this state law. In addition, the Task Force reviewed a draft of the DOH Newborn Screening Specimen Policy that sets specific privacy standards for the newborn blood spots collected and stored by the state. (A summary of this policy and the draft document are available from SBOH).

In addition, the Uniform Health Care Information Act prohibits the unauthorized disclosure of identifiable health care information by a health care provider for research purposes unless such disclosure meets IRB approval (RCW 70.02.050 1(g)). To the extent that genetic information generated in the course of research is considered health care information, the Uniform Health Care Information Act also protects the privacy of this information. GTF members noted, however, that there is a question as to whether some research data is considered health care information. The Uniform Health Care Information Act does not protect the privacy of health care information held outside of the health care system.

Other state laws address the privacy and civil rights of research subjects and individuals seeking or holding an insurance policy. For example, the Release of Records for Research statute (Chapter 42.48 RCW) provides parameters under which a state agency may disclose individually identifiable personal information for research purposes and under which researchers may further disclose such information. Additionally, the Patient's Bill of Rights (SB 6199) and WAC 284-04-500 mandate that health carriers and insurers adopt policies and procedures that conform administrative, business, and operational practices to protect an enrollee's right to privacy or right to confidential health care services granted under state or federal laws. Another strategy adopted by Washington State is the Governor's Executive Order on Privacy (EO 00-03), which protects the privacy of all readily identifiable personal information held by a state agency or contractor. EO 00-03 prohibits state agencies, employees or contractors from disclosing identifiable personal information to any party without legal authority. Finally, various pieces of legislation such as WAC 246-320-205(2)(5), RCW 43.105.310, and RCW 51.28.070 mandate that hospitals and state agencies such as the Department of Labor and Industry maintain specific standards of privacy.

In addition to protections afforded to health information, the Task Force noted that existing safeguards exist to protect the privacy of genetic information collected and stored as part of the criminal DNA database system.[18] Uses for this information are restricted in both state and federal law. Furthermore, the segments of DNA tested in this program are not associated with any known medical condition or disease.

Federal laws that aim to protect an individual's privacy and civil rights with respect to their genetic information include the HIPAA Privacy Rules, EEOC Rules and the ADA, and the Protection of Human Subjects (45 CFR 46 and 21 CFR 50) regulations. The HIPAA Privacy Rules, to which covered entities must comply by April 2003, apply to health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically. Health care information is defined within HIPAA as "any informa-

[18] Prof. Bereano noted that additional safeguards may be warranted in order to adequately protect genetic information in the tissue samples collected for the criminal DNA database system.

tion, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual or the provisions of health care to an individual or the past, present, or future payment for the provision of health care to an individual." A report published by the National Conference of State Legislatures (NCSL) states, "this definition includes currently manifested diseases of genetic origin as well as genetic information, since such information "relates to" a possible future medical condition."[19]

The HIPAA Privacy Rules grant patients specific control over the release and use of their health information. A previous version of the Rules required physicians to obtain the consent of patients before releasing private health information for purposes related to treatment, payment and health care operations. Under these rules, providers were not required to provide care if the patient did not consent to the release of information for these purposes.[20] However, in August 2002 the Department of Health and Human Services (HHS) revised this rule. Under the revised rule, a patient's consent is no longer required for the release of health information for the purposes of treating patients, paying bills and carrying out various health care operations. Disclosures for other purposes require patient authorization but a physician cannot deny a patient care in the absence of such authorization.[21] With respect to research, the new HIPAA Privacy Rules allow researchers to use a single combined form to obtain informed consent for participation in research and authorization to use or disclose protected health information for such research. The new rules also specify requirements relating to a researcher obtaining an IRB waiver of authorization by streamlining waiver criteria to more closely follow the requirement of the "Common Rule" (45 CFR 46), which governs federally funded research.

HIPAA does not apply to individual or small-group (defined as fewer than 50 individuals) health plans and the regulations do not apply to entities outside of the health care system other than contractors who obtain identifiable information as part of their responsibilities to the health plan or health care provider. Furthermore, no active surveillance or monitoring system ensures compliance with these regulations. More restrictive state laws preempt the HIPAA Privacy Rules and separate privacy mandates exist at the state and national level that protect information held by the criminal justice system, schools, public health agencies, mental health and substance abuse providers, and other entities.

Other federal laws such as the ADA, 45 CFR 46 and 21 CFR 50/56 protect individuals from unauthorized disclosure or use of their health information by employers and researchers. The ADA and rules adopted by the EEOC define the type of information an employer can request and use in making employment decisions. Federal regulations such as 45 CFR 46 and 21 CFR 50/56 regulate the conduct of research involving human subjects. 45 CFR 46 applies to all research involving human subjects that is conducted, supported, or otherwise subject to regulation by any federal department or agency including research conducted outside the United States. This regulation also requires that research that is neither conducted nor supported by a federal department or agency, but is subject to regulation as defined in Sec 46.102(e) must be reviewed and approved by an IRB.[22] In addition, some private funding sources may require that researchers comply with 45 CFR 46. Still other privately funded researchers may voluntarily abide by 45 CFR 46 regardless of their funding or regulatory source. The Task Force noted that genetic research activities conducted without federal financial support, in facilities that have not voluntarily adopted the federal protections, and that do not involve FDA-regulated test articles are not required to conform to and follow legal requirements and standards established for the involvement of human subjects in research.

[19] NCSL "Genetics Policy and Law: A Report for Policy Makers," September 2001
[20] Ibid
[21] Ibid
[22] 45 CFR 46 Sec 46.101 (a) and Sec 46.101 (a)(2)

Research regulated by the Food and Drug Administration (FDA) is subject to the purview of 21 CFR 50 and 21 CFR 56, which specify requirements for the protection of human subjects in research and the circumstances under which IRB review is required. Researchers and IRBs undergo routine inspections to verify compliance with these federal regulations; they also have extensive reporting responsibilities to parent agencies. In addition, researchers, IRBs and federal oversight agencies accept and investigate complaints from research subjects regarding violations of these regulations.

According to 45 CFR 46, different research study designs require different levels of informed consent. For example, research using "anonymized" biological samples from which all information that could identify the individuals from whom they were obtained has been removed may not require the informed consent of the individuals. However, research that involves samples linked to information from which the donor can be identified almost always requires the consent of the individual who originally provided the information or biological sample. Certificates of confidentiality[23] constitute another level of protection available to research subjects. Researchers may apply for a federal certificate of confidentiality to protect research data from court-ordered disclosures under most circumstances.

With respect to strategies to safeguard individual privacy and civil rights in matters outside of the health care system or research arena, the Task Force examined Washington's law on domestic relations (RCW 26.04.020), which prohibits marriage between persons closer in kin than second cousins. GTF members presumed that the law was based in part on the previously widely held belief that the probability of related individuals bearing children with congenital defects due to genetic abnormalities was high. Recent scientific studies, however show that the risk of such harm is low and therefore, the GTF found that there is little biological basis for these restrictions.[24] It is legal to marry a first cousin in many other states and the 79th National Conference of Commissioners on Uniform State Laws and Proceedings (1970) recommended striking cousin marriage restrictions. Therefore, it appears to GTF members that from a scientific perspective, the law banning marriage between first cousins is unnecessary.

Based on this information, the Task Force found that at present the scope and interpretation of existing laws provide substantive protection of an individual's privacy and civil rights regarding genetic information. The Task Force noted, however, that the extent to which these laws encompass genetic information varies, and in some situations may be poorly defined and untested. Furthermore, the scope and interpretation of some of these laws may change over time and with increasing demands on the legal system to apply these laws to situations in which the central issue is the use or disclosure of genetic information. GTF members noted that the privacy of health care information and medical records seem to be well protected by existing legislation; however, gaps and ambiguities in existing laws leave open the opportunity for privacy and civil rights violations to occur in areas outside of the health and medical care systems.

Remedies to compensate individuals for inappropriate use of genetic information

The Task Force found that avenues for obtaining compensation or punishing those who engage in genetic discrimination or the invasion of genetic privacy exist within the current legal tort system. Many strategies reviewed in the previous section include clauses pertaining to compensation or legal action in cases where inappropriate use of genetic information occurs. In most circumstances, claims of privacy or civil rights violations must be reported to an oversight agency and/or brought before a court of law. Specifically, the Task Force found that state and federal agencies such as WSHRC, OIC, the Office of Civil Rights (OCR), and the EEOC have authority to investigate claims and levy fines against violators. Table 5 summarizes the provisions that may allow for compensation for victims and/or legal action against those who inappropriately use genetic information.

[23] For more information about Federal Certificates of Confidentiality see: http://grants1.nih.gov/grants/policy/coc/
[24] Bennett, R. et al., Journal of Genetic Counseling, 2002;11:97-119

Table 5: Summary of legislation providing penalties and/or remedies to compensate individuals for inappropriate use of genetic information

Law	Allowable Remedies
Uniform Health Care Information Act (Chapter 70.02 RCW)	Action can be brought against violators. Relief is limited to actual damages and attorney fees and other expenses of bringing the action. The individual must state the claim within two years after the cause of action is discovered.
Release of Records for Research (Chapter 42.48.050 RCW)	Unauthorized disclosure of personally identifiable information by a researcher who obtained the information from a state agency is a gross misdemeanor subject to fines up to $10,000 for each violation.
Washington Law Against Discrimination (Chapter 49.60 RCW)	This statute does not provide for specific compensation, however, the WSHRC receives and investigates complaints and may hold hearings and subpoena witnesses. If WSHRC efforts fail to remedy the problem, the matter may be sent to the Attorney General for litigation before the Administrative Law Judge. In addition, individuals may sue for discrimination under this statute.
Patient's Bill of Rights (ESSB 6199)	Individuals may sue violators and the parties involved may request an independent review process.
HIPAA Privacy Rules	The Health and Human Services Office for Civil Rights (OCR) relies on reports and formal complaints regarding violations and investigates claims of violations and seeks informal resolutions. If an informal resolution cannot be achieved, OCR may apply civil monetary fines or work with the Justice Department to seek criminal prosecution. Civil monetary penalties are $100 per violation and capped at $25,000 per year. Criminal fines range from $50,000 to $250,000 and prison terms range from one to 10 years.
Americans with Disabilities Act	The EEOC relies on individuals to report violations, as there is no active monitoring system. Reported violations are investigated and in cases of wrongdoing, the EEOC may sue violators in court. Individuals may also file suit against those in violation of the ADA.[25]
The Protection of Human Subjects regulations (45 CFR 46 and 21 CFR 50)	IRBs monitor compliance with federal and local regulations. Federal oversight agencies may also conduct periodic inspections. IRBs rely on internal and external reviews and inspections of research proposals and reporting of violations by research subjects or others. The FDA inspects entities regulated by the FDA for compliance with FDA regulations. Penalties include fines, suspension of research activities and suspension of federal funding for research involving humans. In addition, victims of violations may sue researchers and institutions that house research.
The federal DNA Identification Act (1994)	Establishes criminal penalties for individuals who knowingly violate privacy protection standards and provides that access to the federal system is subject to cancellation if privacy requirements are not met. The Act does not provide individuals with specific remedies for the inappropriate use of their genetic information.

[25] Prof. Bereano noted that it is unlikely that employees would be aware of the misuse of their genetic information and therefore unlikely to report violations.

Task Force members found that legal avenues available to victims of the misuse of genetic information consist of reporting violations to administrative or oversight agencies and pursuing actions in court. Most of the laws reviewed by the GTF that are aimed at protecting individual civil rights and privacy provide for civil or criminal penalties in cases of wrongdoing.

Incentives for further research and development in the use of DNA to promote public health, safety and welfare

Representatives from academic/basic science research, public health, and the biotechnology industry appeared before the GTF and discussed the current and future contributions of genetic research to public health, safety and welfare and the regulations, practices, and methods pertaining to different types of genetic research. The panelists informed the Task Force that the potential benefits of genetic research and emerging genetic technology include: achieving a better understanding of many aspects of human biology; the development of tools for medical care including: disease prevention, diagnosis, and treatment; expansion of genetic testing as an aid for the reproductive health of mothers and fetuses; and the development of genetic tests that will identify individuals at risk for developing adult onset diseases for which interventions may be available such as diabetes, hypertension, renal disease, and cardiovascular disease. Previous and ongoing research has resulted in the development of numerous genetic tests. However, the full benefits and clinical applicability of some of these tests may not yet be realized because knowledge about the significance of test results with respect to outcomes and other consequences is lacking for many of them. Ongoing and future genetic research such as studies aimed at associating genotypes with phenotypic profiles may be important to medical and public health knowledge in this area as well as to the development of screening programs, education and intervention programs, and therapies. The Task Force noted, however, that the issuing of patents for specific DNA sequences may interfere with basic research and the useful development of genetic tests for clinical purposes by barring other researchers from certain areas of inquiry and by elevating the prices charged for genetic tests.

Access to research subjects and biological material is important for studies investigating the relationship between genotype and phenotype and the continued development of genetic tests, technology and pharmaceuticals. Under current policies, research involving human subjects may be subject to different oversight requirements depending on the source of funding and/or regulation or level of anonymity involved in the data collection process. For some study designs, anonymous research samples, for which informed consent may not be required, are adequate. Other studies require the use of identifiers to match clinical data with genotype data. The latter type of research most often requires informed consent from, and therefore access to, the individuals from whom the samples and clinical data were derived. Several presenters noted that fear of discrimination is a reason that people may choose not to participate in genetic studies.

Regarding incentives for further research and development in the use of DNA to promote public health, safety and welfare, representatives from the biotechnology industry commented that their research and business endeavors are sensitive to changes in policy that may affect their ability to conduct research. The Task Force found from other testimony that academic/basic science, public health and biotechnology researchers receive adequate incentives to conduct genetic research. Adequate incentives exist within the medical community for researching and developing uses of DNA to promote predictive testing of late onset diseases. For example, there is funding available for and ongoing research on predicting individuals at risk for developing diabetes, hypertension, renal disease, and cardiovascular disease. In addition, government and private funds exist to expand the use of genetic testing in reproductive medicine. Incentives at the state level include the availability of newborn screening specimens for research as long as appropriate safeguards are followed. The Task Force found that, overall, incentives to continue genetic research and development exist in the form of funding and opportunities created by industry, academic, and government research agendas but policies that address the perceived risk of discrimination may provide an additional incentive.

Conclusions and Recommendations

The following conclusions and recommendations reflect the opinions of the Genetics Task Force regarding Washington State policies related to individuals' civil rights and privacy with respect to their genetic information. These conclusions and recommendations are based on the GTF's findings and specific conclusions and recommendations proposed by the four subcommittees. In some cases, the Task Force adopted the conclusions and recommendations brought forth by each subcommittee; however, some conclusions and recommendations changed after discussion among the whole group.

Incidence of discriminatory actions based upon genetic information

With respect to the incidence of discriminatory actions based on genetic information, the Task Force reached several conclusions. First, based on reports from the Office of the Insurance Commissioner (OIC), the Washington State Human Rights Commission (WSHRC), and the DOH Genetic Services Section (GSS), it concluded that very few documented cases of discrimination have been reported in Washington State. Evidence presented to the Task Force by the OIC, WSHRC, and DOH GSS did not indicate that there is a widespread problem regarding the use of genetic information for social purposes such as employment or health, life, or disability insurance. However, reported incidents may not represent all such events and while the reported rate of discrimination appears low, the risk of discrimination based upon genetic information may still exist. For example, genetic testing may place individuals at risk for genetic discrimination should such information exceed the bounds of the medical care system. In addition, gaps in protection exist that may leave research subjects vulnerable to the misuse of genetic information obtained in research if that information would have to be reported by the subject to insurers, employers, or others who may make decisions on the basis of that information and use it in an adverse fashion against the individual. In contrast, genetic information that remains part of an individual's private medical record and is limited in its use by third parties presents little risk of discrimination.

Second, fear of discrimination may prevent individuals from pursuing medically indicated genetic testing, participating in research studies, and disclosing relevant genetic information when appropriate. Given the potential benefit of genetic testing to an individual's health and the contributions of genetic research to improving public health, safety, and welfare, the GTF concluded that reducing the impact of this fear is important. Increased awareness of the meaning of specific genetic information and of both the appropriate uses and the means for reporting inappropriate uses of genetic information may encourage people to utilize genetic technology.

Lastly, the GTF concluded that regulatory interpretations of existing state and federal laws as well as industry practices and policies, provide some protection against discrimination in health, life, and disability insurance and may provide protection against employment discrimination or other privacy and civil rights violations. However, if the language in the law on which the regulation is based does not explicitly refer to genetic information, the interpretation is left open to challenge in court and could potentially be overturned.

Recommendations[26]

1.1 Reports of genetic testing should remain in medical records and receive the same protection as other sensitive medical information.

1.2 Support and authorize funding where necessary for efforts to educate consumers, research subjects, researchers, health care providers, employers, and insurers about how genetic information derived from genetic testing, as part of medical information, can be used, the concepts and consequences of anonymity in research, and the reporting and other mechanisms available to those who believe they have been discriminated against. These efforts

[26]Minority Recommendation: Prof. Philip Bereano proposed that the state create a policy to destroy the tissue samples in the forensic database after the DNA profiling is complete.

should include: 1) providing information to consumers, research subjects, researchers, health care providers, employers, and insurers about existing laws and penalties for violations regarding the privacy and appropriate use of genetic information; 2) establishing a graduate program in genetic counseling at the University of Washington to address the current and future needs of the state's population.[27]

1.3 Change the Washington State Law Against Discrimination (Chapter 49.60 RCW) to explicitly include "genetic information" in the list of characteristics that receive protection under the law. The GTF recommends that "genetic information" be defined as "Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination."[28]

Strategies to safeguard civil rights and privacy related to genetic information

In general the Task Force felt that the protection of individuals' civil rights and privacy with respect to their genetic information is paramount. The members recognized that many of the benefits of DNA technology depend on the exchange of personal, sensitive information between an individual and a health care provider, researcher, or even an insurer. This exchange must be uninhibited by fears of privacy violations or unfair discrimination; individuals must be assured that their information, once voluntarily shared, will be kept confidential and not be misused.[29]

Based on its examination of existing strategies to safeguard civil rights and privacy related to genetic information, the GTF concluded that existing strategies aimed at protecting the privacy of health care information substantively protect genetic information as long as it remains in the health or medical care system. Many of the laws regulating the privacy of health or medical records are unambiguous and they appropriately prohibit the misuse of health care information including genetic information. One area of the health care system that may need additional safeguards is the protection of newborn screening specimens and other biological samples collected and stored by Washington State. The GTF noted that this program, along with the criminal DNA database, represent two instances of state-mandated DNA collection and testing; the members caution that any infringement on an individual's rights to free choice regarding their DNA/genetic information is perilous and to be avoided in all but the most specific and compelling circumstances found in these two programs. Furthermore, because the state mandates testing of all newborns, it must protect the privacy of the samples it collects and stores.

The GTF also concluded that adequate safeguards exist at the federal level to protect information collected, used, or generated in the course of federally funded or regulated research. However, the federal standards for human subjects research may not apply to all genetic research. For example these standards may not apply to research that is not federally funded or regulated. Therefore, appropriate monitoring or oversight systems may be lacking in some settings.

Under some circumstances insurers and employers may request or obtain specific health care

[27] Robin Bennett and Dr. Wylie Burke recommended that this effort include education for health care providers and genetic testing laboratories regarding the professional ethic against presymptomatic testing of children under age 18 years for untreatable adult onset disorders, including such children being placed for adoption. Julie Sanford Hanna stated that the onus of making the decision to conduct presymptomatic genetic testing on children under age 18 years should be primarily on health care providers and not on laboratory personnel because health care providers order tests and are more likely to develop a relationship with patients and their families. Thus, she suggested that the educational and policy efforts in this area should focus on health care providers.

[28] Mellani Hughes, JD dissented from this recommendation on the grounds that WSHRC and EEOC both interpret the WLAD and the ADA to be applicable in cases of employment or other discrimination based on genetic information, rendering additional language in Chapter 49.60 RCW unnecessary, particularly when there is little evidence of such discrimination. Dr. Peter Byers also dissented from this recommendation on the grounds that current statute and codes appear to provide the same protection, existing policies restrict access to genetic information, and this change may lead to unanticipated problems. In addition, Dr. Nancy Fisher and Dr. Peter Byers felt that the proposed definition of genetic information is too broad to have power and value in the context of the statute.

[29] HIPAA Privacy Rule, Standards for Privacy of Individually Identifiable Health Information, Federal Register, December 28, 2000.

information about an individual. The GTF concluded that in these circumstances, the individual providing the information may not be informed of the reasons for collecting, testing, storing, or further disclosing such information. Uninformed collection, use, or disclosure of personal health information is a violation of the individual's right to privacy.

Finally, with respect to privacy and civil rights related to genetic information, the GTF concluded that the Washington State law prohibiting the marriage of first cousins (RCW 26.04.020) may not be justified on a scientific basis and restriction of marriage between cousins can be construed as genetic discrimination.

Recommendations[30]

2.1 Adopt in rule existing administrative policies protecting the privacy of newborn screening specimens and other tissue samples held by the state.

2.2 Create policy to make all research in the State of Washington involving genetic information obtained from human subjects subject to the standards that are in place for federally funded and/or regulated human subjects research.[31]

2.3 Where current law permits the collection or use of genetic information by employers or insurers, state law should require informed consent from the individual for collection, storage, disclosure, and any use of such information. Uses of such information should be restricted to those purposes for which it is collected or purposes required by law. The individual providing the information shall receive the results of any tests conducted by or for the recipient of the information.

2.4 Revise Chapter 26.04 RCW to remove the ban on first cousin marriage.

Remedies to compensate individuals for inappropriate use of genetic information

The GTF concluded that the existing tort system provides an avenue to compensate individuals for inappropriate use of genetic information. For example, the current legal tort system provides sufficient remedies if genetic information, including newborn screening specimens or data is misused in a health care setting or by a health care provider. With respect to genetic information that is collected and maintained for the criminal DNA database, federal law provides penalties for inappropriate use, but neither federal nor state law provide specific remedies to individuals beyond the current tort system. Furthermore, existing penalties for the violation of laws protecting the privacy and civil rights of individuals who provide genetic information for research purposes are adequate. However, in some cases, a specific oversight or regulatory agency charged with monitoring adherence to existing laws or receiving complaints about violations is lacking.

Recommendations[32]

3.1 Designate a centralized agency to receive and act upon reports of discrimination based upon genetic information or violations of privacy involving genetic information.

[30] Minority Recommendation: Prof. Philip Bereano and Ty Thorsen recommended that the state enact legislation that explicitly defines genetic discrimination, genetic information, and privacy rights of individuals with respect to genetic information.

[31] Dissent: Mellani Hughes, JD dissented from this recommendation on the grounds that insufficient evidence was received about whom this type of policy would affect.

[32] Minority Recommendation: Prof. Philip Bereano and Ty Thorsen recommended that the state pass legislation that protects the privacy of genetic information, defines and outlaws genetic discrimination, and provides avenues for redress when violations are proven.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

The Task Force considered evidence presented to it regarding DNA research in Washington State and came to several conclusions. First, as genetic technologies improve through research, genetic testing will be introduced into the public health system as an adjunct to newborn screening for treatable genetic diseases to promote and assist the safety and welfare of young children detected with treatable disorders. Second, the development of testing for risk factors associated with multifactorial common diseases such as diabetes, hypertension, renal disease, and cardiovascular disorders may have a beneficial effect on public health policy and the welfare and safety of the population and therefore this research should be encouraged as a means of improving the health of the population. Third, at present, the development of genetic tests far outpaces the availability of information and personnel to interpret and apply the test results in a health care setting and the costs for making genetic testing available, as a result of costly research and development studies, may impede equitable availability of such resources to all segments of the population.

Regarding incentives for further research and development on the use of DNA to promote public health safety and welfare the GTF concluded that cooperation from state programs may be important aspects of successful research programs, however some data retained by the state, such as data held within the criminal DNA database, is not appropriate for research.

The GTF also concluded that Washington law must be such that biotechnology companies and other researchers want to locate or continue to remain and operate within the state. Policies that address the perception of the risk of discrimination associated with participating in a genetic research study may encourage research participation and provide an incentive for continued research and development. For example, protections provided by DOH policy, DSHS/DOH Human Subject Research Review Board policy, and the Release of Records for Research statute appear to be adequate to protect individuals without unnecessarily impeding research; requiring that all research comply with similar requirements such as informed consent may increase subject participation in research. Participation from all interested parties is essential for successful policy development.

Recommendations

4.1 Given the limited nature of the data provided by testing conducted for the criminal DNA database, incentives for research using this resource are not warranted.

4.2 Ensure that state policy requires that in all research involving genetic information from individuals, explicit voluntary consent or assent be obtained or waived as detailed in applicable law and regulations.[33]

4.3 Invite all stakeholders to participate in any process to create policies addressing the use of genetic information in research

[33] See also recommendation number 2.2 under "Strategies to safeguard civil rights and privacy related to genetic information." If all research conducted in the state were subject to federal law this concern would be addressed.

Appendix A

GTF Members' Responses to Report (September 17 Draft)

Name	Comments	Action Taken	Endorsement
Robin Bennett	Added comment to one recommendation; technical comments	Inserted comment as a footnote; made corrections as indicated	Yes
Phil Bereano	Several technical comments; submitted 2-page document titled "Separate Views," see below	Made many changes as indicated; unable to make other changes without significantly changing the existing content	Yes
Wylie Burke	Suggested change in the language of one recommendation	Made change as suggested	Yes
Peter Byers	Dissented from one recommendation; submitted text for section on Subcommittee Three; one technical comment	Inserted dissent as a footnote; incorporated text into appropriate section; made change as suggested	Yes
Maureen Callaghan	No response		——
Howard Coleman	No comments on content		Yes
Amanda DuBois	No comments on content		Yes
Joe Finkbonner	No comments on content		Yes
Nancy Fisher	Added comment to one recommendation	Inserted comment as footnote	Yes
Maxine Hayes	No comments on content		Yes
Vicki Hohner	No response		——
Mellani Hughes	Dissented from one recommendation; technical comments	Inserted dissent as a footnote, made changes/corrections as suggested	Yes
Linda Lake	No comment on content		Yes
Helen McGough	Provided a reference; suggested change in the language of one recommendation	Inserted reference; made change as suggested	Yes
Robert Miyamoto	Added comments to methods and findings	Inserted comments as footnotes	Yes
Suzanne Plemmons	Technical comments	Made changes and corrections as suggested	Yes
Ree Sailors	No response		——
Julie Sando	No comments on content		Yes
Julie Sanford-Hanna	Added comment to one recommendation	Inserted comment as a footnote	Yes
C. Ron Scott	Commented on missing language from recommendations	Issue addressed in different section of report	Yes
Brenda Suiter	Technical comments	Made changes/corrections as suggested	Yes
Ty Thorsen	Technical comments	Made changes/corrections as suggested	Yes

Separate Views

Professor Philip L. Bereano

The documentation in the peer-reviewed literature of over 200 cases of genetic discrimination a number of years ago, the passage of legislation on this topic by over 40 states in the last decade, two recent and well-publicized cases (Burlington Northern and Lawrence Labs), and an enormous literature—both scholarly and popular—testify to the reality of genetic privacy and discrimination as proper subjects of public policy. I am pleased that the Task Force is recommending some statutory amendments to address some of these issues.

These remarks are designed to explain the several footnotes indicating that, in my view, these recommendations do not go far enough. I believe that new legislation on this subject, which clearly covers employment and life insurance, as well as the health area, is necessary. I also feel that the Task Force has inadequately addressed the privacy issues inherent in the initial taking and storing of biological samples.

Currently, residents of this state are at higher risk of having their genetic data misused than are residents elsewhere. There is no reason to believe that genetic discrimination has NOT occurred here, especially since there are essentially no independent systems for reporting it (and protecting the victim) so as to provide monitoring of the situation. Since we don't look, we don't find; but that is not evidence that the problem doesn't locally exist.

Research and Healthcare Activities

There is no justification for excluding research activities from the arenas where individuals ought to be able to determine what is done with information about them. None of us exists for the purpose of providing interesting data for the furtherance of someone else's career or profit margin. No studies were provided to us indicating that respecting the genetic privacy of research subjects by requiring voluntary informed consent for the collection and use of their genetic information has inhibited research; indeed, I do not believe that there are any such studies at all.

The Task Force's approach is based on a paradigm ("the altruistic researcher") that is increasingly shown to be at variance with reality. Given the current ties between researchers—even academic researchers—and the corporate sector (via patent holdings, stock options, contracts, directorships, etc.), many researchers have a decided interest in the use of their research data that goes well beyond preparing a paper that will pass peer review. "All policymakers must be vigilant to the possibility of research data being manipulated by corporate bodies and of scientific colleagues being seduced by the material charms of industry. Trust is no defense against an aggressively deceptive corporate sector." (*The Lancet*, April 2000)

The US Office of Research Integrity, a national monitoring agency, reported that 2001 had the highest number of misconduct cases in 25 years. (*British Medical Journal* 2002; 325:182; 27 July). Violations of patient confidentiality are on the front page of the *New York Times* (see, for example, "Free Prozac in Junk Mail Draws a Lawsuit," July 6, 2002). Even prestigious local institutions such as the Fred Hutchinson Cancer Research Center have bent ethical boundaries (see, for example, "Judge: Hutch didn't reveal study's risk to patient", *Seattle Times*, Aug. 9, 2002), and researchers have left the University of Washington for completely private work rather than submit even to minimal restrictions. Furthermore, this summer, the Administration has significantly weakened the proposed HIPPA data privacy rules by eliminating critical aspects of patient control.

I strongly agree with the view stated by the Task Force that genetic information should be protected in order to bolster peoples' confidence in the health care system, assuring that individuals have no hesitation about getting the diagnoses and treatments they may need, and also minimizing barriers to their participation in bioresearch. One-third of recent survey respondents feared that genetic testing might endanger their health insurance, and thus some refused to participate in research activities; these fears lead many to decline genetic counseling (Rothenberg and Terry, *Science*, 12 July 2002).

Forensics

I cannot subscribe to the position that tissue samples taken from individuals to create an ID database should not be destroyed after the DNA code is obtained. This view flies in the face of virtually all of the literature on the subject, even literature that is not very sensitive to civil liberties concerns (see, for example, Williamson and Duncan, "DNA Testing for All," *Nature*, 418, 585-6, 2002). These samples contain a great deal of biological information over and above anything that is germane to the DNA bank. Our recommendations, in my view, ought to be more consistent with the position of the Nation's Founders who were clearly skeptical of the use of power by forces of government, and advocated many practical ways to limit government as a result. Especially at this time, when the FBI and its parent agency the Justice Department are establishing sweeping new surveillance operations with hardly a nod to civil liberties, our Task Force ought to be less trusting. Colleagues who work with the CODIS system assure me that it is under no practical oversight. The government always claims that acknowledging civil liberties makes it less efficient; but ours was never designed to be the most efficient form of governance, only the most democratic. We should recommend that the tissue samples be destroyed after the purpose for taking them (getting the unique DNA code) has been satisfied.

Note: *Ty Thorsen supports the above comments drafted by Phil Bereano.*

Appendix C: Genetic Privacy and Genetic Discrimination Matrix in Washington State

Note: The Meeting Summaries prepared after the first three GTF meetings may be helpful cross-references for many topics. These are available at http://www.doh.wa.gov/SBOH/Priorities/Genetics/genetics.htm.

	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**Americans with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Encompasses/Defines Genetic Information	Yes: 'Health information' is defined broadly and is generally interpreted to encompass genetic information. No: It does not specifically define *genetic information* separate from health information.	Yes: "Health care information" includes an individual's deoxyribonucleic acid and identified sequence of chemical base pairs. No: Does not specifically define "genetic information" separate from health care information.	Yes: It uses the same definition of "health care information" as RCW 70.02. No: Does not specifically define "genetic information" separate from health care information.	Yes: It protects all readily identifiable personal information. No: It does not specifically define "genetic information" separately from other types of personal information.	Yes: **45 CFR 46** applies to all personally identifiable information used for research. **21 CFR 50/56** apply to all research regulated by the FDA. No: Do not specifically define "genetic information."	Yes: The EEOC interprets the ADA "regarded as" clause to encompass existing and pre-symptomatic genetic disorders. No: Does not specifically define "genetic information."	Yes: WAC 284-43-720 genetic information is not a pre-existing condition without a diagnosis of the condition. No: Does not specifically define "genetic information."	Yes: Disability is broadly defined and is interpreted to encompass genetic disorders. WAC 162.22.020 No: Does not specifically define "genetic information" separate from disability.
	Health Information Portability and Accountability Act (HIPAA)*	**Washington Stat Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**Americans with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Requires Authorization for the Release of Genetic Information to Third Parties Within the Health Care System	No: The revised Rule does not require that health care providers obtain a patient's consent/authorization for the release of health information for 'routine purposes' such as treatment, health care operations, and payment. Yes: Specific authorization is required for all other releases. Exceptions exist for public health, research, law enforcement, and other uses required by law.	Yes: Under RCW 70.02.020, a health care provider is required to obtain written authorization from an individual for the release of any health care information to any other person. (EXCEPT as outlined in RCW 70.02.050)	Yes: Patient consent is required for the disclosure of health care information.	Yes: It prevents state agencies, employees and contractors from selling or disclosing personal identifying information.	Yes: **45 CFR 46** requires authorization to release identifiable information, except as required by law. To obtain additional protections against compelled disclosure, researchers may apply for a federal certificate of confidentiality. **21 CFR 50** requires notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	N/A	Yes: Requires insurers to protect patients' privacy according to existing state and federal laws.	N/A

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	Americans with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Requires Authorization to Release Genetic Information to Entities Outside of the Health Care System (banks, schools, loan agencies, etc)	Yes: It requires specific authorization for disclosure (if the disclosures is for purposes other than treatment, payment, or health care operations) but HIPAA does not protect the information once it leaves the health care system if the information is released to an entity not covered by HIPAA. There are some exceptions and other laws may govern privacy in other areas.	Yes: It requires specific authorization for disclosure but it does not protect the information once it leaves the health care system. There are some exceptions and other laws may govern privacy in other areas.	Yes: It requires specific authorization for disclosure of health care information.	Yes: It prohibits state agencies, employees or contractors from disclosing personal information to any party without legal authority.	Yes: **45 CFR 46** requires authorization to release identifiable information to all entities except when required by law. **21 CFR 50** requires notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	N/A	Yes, requires insurers to protect patients' privacy according to existing state and federal laws.	N/A
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**Americans with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Includes Specific Informed Consent Requirements for the Disclosure or Use of Genetic Information	No: Neither specific authorization nor informed consent is required to disclose or use health information for routine purposes such as treatment, payment, health care operations, and for selected other uses by law or for the public good. Yes: Patients must authorize all other disclosures or uses and be informed about what information will be released and for what purposes.	Yes: It requires specific authorization for all disclosures except to third party payers and other exceptions as outlined in 70.02.050. Patients must be informed about what information will be released and for what purposes.	Yes: It mandates the same authorization/consent requirements as 70.02	N/A	Yes: **45 CFR 46** Requires consent for disclosure of any identifiable information, but does not specify genetic information. **21 CFR 50** requires informed consent for participating in research including notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	N/A	No	N/A

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	Americans with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Protects Human Biological Material (tissue, cells or serum) **from Unauthorized Release or Use**	No: It defines health information as oral, written or electronic; does not imply or specify biological material. The assumption is that material is not health information until it is translated into oral, written, or electronic form.	No: It does not explicitly refer to biological material, but does cover "any information whether oral or recorded in any form or medium", which could theoretically encompass biological material.	N/A	N/A	Yes: **45 CFR 46** considers human biological samples from living humans stored with links to identifiers as research involving human subjects. **21 CFR 50** requires an explanation of the procedures to be followed including use of biological materials.	N/A	N/A	N/A
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**Americans with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Regulates Access to Genetic Information by Blood or Legal Relatives	Yes: Release of health information is permitted with the individual's consent (if the individual is present) and/or if the covered entity reasonably infers consent based on medical judgment or lack of objection. Health care providers must notify patients that they have the right to agree or object to disclosure practices such as disclosure to family. (Sect. 164.510)	Yes: 70.02.050 1(e) Health care providers may orally relate an individual's health care information to family members and others with a close personal relationship to the individual without the individual's consent unless the individual has instructed the health care provider in writing not to disclose the information. RCW 70.02.130 A person authorized to consent to health care for another may also exercise the right to access and authorize disclosure of the information.	Maybe: Health carriers and insurers are required to adopt policies and procedures that conform administrative, business, and operational practices to protect an enrollee's right to privacy or right to confidential health care services granted under state or federal laws. (SB 6199 Section 5). State and federal laws allow relatives to have access to health care information.	Maybe: State agencies are required to "provide reasonable assurances that those [records] containing confidential personal information are properly safeguarded". This may protect information from release to related third parties, but it may not. No: No specific mention is made about release of or access to information to family members or related third parties.	Yes: **46.116 (a) (5) and 21 CFR 50** require that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained. This is interpreted to include information about to whom information may be given and under what circumstances. No: There are no specific limits or guidelines regarding the release of information.	N/A	N/A	N/A

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	Americans with Disabilities Act (ADA	Office of Insurance Commissioner RCW Title 48 WAC 284.43	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulates the Use of Genetic Information by Health Insurance Companies for Determining Eligibility or Setting Rates	Yes: The portability component states that genetic information may not be considered a pre-existing condition unless a patient has a diagnosis. It also provides that insurers cannot use genetic information to apply different eligibility requirements or rates to individuals within a group plan. No: It does not regulate what information an insurance company may ask for.	No: It does not generally apply to insurers. However, 70.02.045 does prohibit third party payers from releasing health care information. See next column re SB6199.	Yes: It makes insurers subject to the provisions of the UHCIA in regards to disclosure and protection of health care information, although exemptions are broader with respect to insurers activity. No: It does not regulate how the insurer can use the information in practice.	No: Only applies to state governments agencies, employees and contractors.	N/A	N/A	Yes: Insofar as defining a pre-existing condition is concerned and insofar as the rules disallow "high-risk" rate setting based on health status by health plans. (WAC 284-43-720) (RCW 48.44.23). See RCW 48.43.005 for list of exceptions to "health plan"	Yes: Addresses issues related to discrimination based on status in a protected class (e.g., disabled)
	Heal Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**Americans with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Regulates the Use of Genetic Information by Life Insurance Companies for Determining Eligibility or Setting Rates	No: It only applies to health insurance.	No: It only applies to health insurance.	No: It only applies to health insurance.	No: It only applies to state governments agencies, employees and contractors.	N/A	N/A	Yes: May allow use of genetic information to deny a life insurance policy but prohibits the cancellation of a policy based on new information obtained after the policy was issued. Allows the use of genetic information to set rates but not change them. WAC 284.84.100	Yes: Addresses issues related to discrimination based on status in a protected class (e.g. disabled)

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulates Use of Genetic Information by Other Entities (e.g. banking, housing, schools) for Determining Eligibility or Setting Rates	No, does not apply to genetic information outside of the health care system or its contractors.	No.	No, it only applies to health insurance.	No, only applies to state governments agencies, employees and contractors.	N/A.	N/A	N/A	Yes, addresses issues related to discrimination based on status in a protected class (e.g. if someone with a genetic predisposition was perceived as or treated as disabled, they would be protected)
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Regulates Use of Genetic Information by Employers for Determining Employment Status or Health Insurance Benefits Eligibility	Yes, insofar as an employer cannot deny an employee health care benefits offered to other employees based on genetic information. No, it does not specifically regulate the use of genetic information for employment decisions.	N/A.	N/A.	No it does not specifically regulate use, it does regulate the collection and release of readily identifiable information if the employer is a state agency or contractor. It does not regulate use of genetic information for employment decisions.	N/A.	Yes, requires employers to make reasonable accommodations for person with disabilities and disallows them from requiring medical/genetic testing that is not job-related or consistent with business necessity.	No.	Yes, addresses issues related to discrimination based on status in a protected class (e.g. if someone with a genetic predisposition was perceived as or treated as disabled, they would be protected)

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	Americans with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Protects Asymptomatic People with a Genetic Susceptibility from Unauthorized Disclosure of Genetic Information and/or Discrimination Based on Genetic Status	Yes: Individuals with a record of a genetic susceptibility are protected from the disclosure of that information for non-routine purposes. Yes: It protects an individual from health insurance discrimination as described above. No: It does not protect from employment or other discrimination.	Yes: Individuals with a record of a genetic susceptibility are protected from the disclosure of that information if it is part of their health care/medical record; except as outlined in 70.02.050. No: It does not protect against employment or other discrimination.	No: It does not regulate health insurance eligibility requirements, however it mandates that those requirements be disclosed prior to enrollment. (pre-existing conditions are defined and regulated elsewhere)	Maybe: It limits "the collection of personal information to that reasonably necessary for purposes of program implementation, authentication of identity, security, and other legally appropriate agency operations." No: It does not protect against employment or other discrimination.	Yes: **46.116 (a) (5)** and **21 CFR 50** requires that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained. This is interpreted to include information about to whom information may be given and under what circumstances. No: There are no specific limits or guidelines regarding the release of information.	Yes: The EEOC interprets the "regarded as" clause to be protective of persons with pre-symptomatic genetic conditions.	Yes: By limiting the use of genetic information without a diagnosis in the determination of a pre-existing condition. (WAC 284-43-720)	Yes: Definition of disability includes conditions that are perceived to exist whether or not they exist in fact.
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**Americans with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Protects Symptomatic People with a Genetic Disorder from Unauthorized Disclosure of Genetic Information and/or Discrimination Based on Genetic Status	Yes: Individuals with a record of a genetic susceptibility are protected from the disclosure of that information for non-routine purposes. Yes: It protects an individual from health insurance discrimination as described above. No: It does not against employment or other discrimination.	Yes: Individuals with a record of a genetic susceptibility are protected from the disclosure of that information if it is part of their health care/medical record; except as outlined in RCW 70.02.050. No: It does not protect against employment or other discrimination.	No: It does not regulate health insurance eligibility requirements, however it mandates that those requirements are disclosed prior to enrollment. (pre-existing conditions are defined and regulated elsewhere)	Maybe: It limits "the collection of personal information to that reasonably necessary for purposes of program implementation, authentication of identity, security, and other legally appropriate agency operations. No: It does not protect against employment or other discrimination.	Yes: **46.116 (a) (5)** and **21 CFR 50** requires that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained including information about to whom information may be given and under what circumstances. No: There are no specific limits or guidelines regarding the release of information. N/A to discrimination issues.	Yes: An individual with a disability under the ADA is "a person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment."	Yes, to the extent that the disease is not classifiable as a pre-existing condition. (WAC 284-43-720)	Yes: Definition of disability includes conditions that are perceived to exist whether or not they exist in fact.

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	Americans with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulates the Genetic Testing of Minor Children	No: HIPAA provides for state laws to control minors' rights where applicable.	N/A Other: RCW13.64.060 gives emancipated minors the right to give informed consent for health care services.	N/A	N/A	Yes: **45 CFR46** and **title 21** contain special provisions for research involving children. No: Do not refer directly to genetic testing.	N/A	Other: The Regence Group laboratory policy (9/15/99) regarding genetic testing: genetic testing in children to confirm symptoms or predict adult onset diseases is not medically necessary unless direct medical benefit is contingent upon the test result.	N/A
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**Americans with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Regulates Use and or Disclosure of Genetic Information under Circumstances Related to Adoption	No: There are no restrictions placed on the use of health information in adoption. The only reference made to adoption limits an insurers ability to impose pre-existing condition exclusions on adopted children.	No: There are no provisions in this law regarding the use of genetic information in the adoption process. Other: RCW 26.33.350 mandates that all persons, firms, societies, associations, corporations and state agencies involved in an adoption disclose all known and available medical information to the adoptive parents.	N/A	Maybe: Requires state agencies to provide reasonable assurances that confidential personal information is properly safeguarded. State agencies dealing with adoptions fall under the purview of this EO. No: There is no mention of the adoption process.	N/A	N/A	N/A	N/A

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	Americans with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulates Release of and Access to Genetic Information Held by Entities Outside of the Health Care System	No: Does not address the protection of health information pursuant to its release to uncovered entities (health oversight agencies, courts, law enforcement, etc). Other federal laws exist in some areas that may apply to these entities, e.g. FERPA regulates privacy of educational records in K-12 schools.	No: Does not pertain to the use or disclosure of health care information once it has been disclosed by a health care provider to a third party outside the health care system (law enforcement, courts, public health agencies, etc. Yes: This law addresses the parameters for the release of information in research and by third party payors.	No: Has the same limitations as RCW 70.02	Yes: A state agency, before contracting with an outside entity, must ascertain that the contractor has protections in place and will not allow or make unauthorized disclosures of the information. However, it does not provide specific protections that follow the information upon its release to any other entity.	Yes: **46.116 (a) (5)** requires all agencies receiving federal funds or regulated by a federal agency for research to use informed consent procedures that include an explanation of the extent to which confidentiality of identifiable records will be maintained. No: There are no specific limits or guidelines regarding the release of information.	N/A	N/A	N/A
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**Americans with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Includes Exceptions for Research	Yes: 164.512 (i) allows disclosure of health information for research with appropriate waiver and IRB or other oversight board approval. 164.502 (d) provides guidelines for de-identifying protected health information	Yes: 70.02.050 1(g) allows disclosure of health care information for research without consent if approved by an IRB.	N/A	N/A	Yes: Some research may be exempt from IRB review. For example, privately funded research that is not regulated by a federal agency is not required by federal law to follow federal rules and guidelines. Also, some federally funded research may be exempt if it meets specific criteria. (See the April 12 meeting summary for more detail)	N/A	N/A	N/A

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	Americans with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulatory Oversight and/or Enforcement and Penalties for Violations	Yes: The Health and Human Services Office for Civil Rights (OCR) enforces the HIPAA privacy rules. OCR relies on reports and formal complaints regarding violations; a formal enforcement rule is pending. OCR investigates claims of violations and seeks 'informal' resolutions of noncompliance. If an informal resolution cannot be found, OCR may apply civil monetary fines or work with the Justice Department to seek criminal prosecution. Civil monetary penalties are $100 per violation and capped at $25,000 per year. Criminal fines range from $50.000 - $250,000 and prison terms range from 1 to 10 years.	Yes: Provides for civil remedies for non-compliance to RCW 70.02. There is no oversight/regulatory body; claims of violations must be tried in court. The court may order actual damages but not incidental or consequential damages. Other: RCW 42.48.050 unauthorized disclosure of personally identifiable information by a researcher who obtained the information from a state agency is a gross misdemeanor subject to fines up to $10,000 for each violation.	Yes: Permits individuals to sue violators; an independent review process may be requested.	Yes: Each state agency appoints a designee to receive and process citizen complaints regarding privacy violations. A representative from the governor's office oversees this EO and handles complaints not addressed to specific agencies.	Yes: Institutional Review Boards monitor compliance with federal and local regulations. IRBs rely on internal and external review and inspection of research proposals and reporting of violations by research subjects or others. Penalties include fines, suspension of research activities and suspension of federal funding for research involving humans. The FDA inspects entities regulated by the FDA for compliance with FDA regulations.	Yes: The Equal Employment Opportunities Commission is the regulatory body for the ADA. The EEOC relies on employees or others to report violations. The EEOC investigates reported violations and may sue violators in court.	Yes: The OIC receives and investigates reports of violations and can levy fines on violators.	Yes: The WA State Human Rights Commission is the regulatory body for RCW 49.60. The WSHRC receives and investigates complaints. The WSHRC may hold hearings and subpoena witnesses. If WSHRC efforts fail to remedy the problem, the matter may be sent to the Attorney General for litigation before the Administrative Law Judge.

*Other resources: 1) Health Information Administration "HIPAA Policy Guide Matrix" at http://depts.washington.edu/hia under the "more information" section. 2) Comparative Health Privacy Law Matrix, a draft is available in the GTF meeting materials for February 25, 2002.

Appendix C: GTF Glossary

This glossary lists terms that are either used in the Genetics Task Force (GTF) Report or may be useful in understanding some of the issues discussed in the report. Where applicable, the first definition listed under a term is the definition adopted by the GTF and the definition used throughout the report. Subsequent definitions for each term are provided as a supplemental resource.

Anonymous

1) Unidentified/unidentifiable.

2) The National Bioethics Advisory Committee describes anonymous biological material as "*Unidentified specimens:* For these specimens, identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved by the repository." And "*Unidentified samples:* Sometimes termed "anonymous," these samples are supplied by repositories to investigators from a collection of unidentified human biological specimens."[34]

Anonymized

1) Identifying information has been removed and is no longer associated with the information.

2) The National Bioethics Advisory Committee describes anonymized biological material as "*Unlinked samples:* Sometimes termed "anonymized," these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being."[35]

Confidentiality

1) This term is sometimes confused with "privacy"; however "confidentiality" is not the same thing as "privacy." "Confidentiality" is characterized by an organizational or professional *responsibility* to protect private information; e.g., a physician has a responsibility to keep a patient's personal health information confidential. "Privacy" is an individuals' *right* to have information remain secret; e.g. a patient has a right to keep personal health information from being disclosed to others or made public.

2) Black's Law Dictionary Definition: Entrusted with the confidence of another or with his secret affairs or purposes; intended to be held in confidence or kept secret.

3) Limited access to or limited disclosure of certain information. Access or disclosure is governed by statute, rule, or case law.

De-Identified

1) HIPAA regulations stipulate that 18 individual identifiers must be removed from health information to 'de-identify' it. These include: name of patient, relatives, or employer; address; all elements of dates (except year) for dates directly related to an individual including birth date, admission date, discharge date, date of death and all ages over 89; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate or license numbers; vehicle identifiers and serial numbers, including license numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including voice and fingerprints, full-face photographic images and comparable images; any other unique identifying number, characteristic, or code.[36]

[34] http://bioethics.georgetown.edu/nbac/pubs.html "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance", accessed 3/26/02.
[35] Ibid
[36] From: Smith, K./Murphy, G., HIPAA policy development guide, University of Washington Health Information Administration, 2001; http://depts.washington.edu/hia.

Deoxyribonucleic Acid (DNA)

1) A nucleic acid that constitutes the genetic material of all cellular organisms and the DNA viruses; DNA replicates and controls through messenger RNA the inheritable characteristics of all organisms. A molecule of DNA is made up of two parallel twisted chains of alternating units of phosphoric acid and deoxyribose, linked by crosspieces of the purine bases and the pyrimidine bases, resulting in a right-handed helical structure, that carries genetic information encoded in the sequence of the bases.[37]

Disability

1) The Washington State Human Rights Commission (162 WAC) defines "disability" as "the presence of any sensory, mental, or physical disability" and "the presence of any sensory, mental, or physical disability" includes, but is not limited to, "circumstances where a sensory, mental or physical condition: a) is medically cognizable; b) exists as a record or history; c) is perceived to exist whether or not it exists in fact.

2) The Americans with Disabilities Act (ADA) defines "a person with a disability" as an individual who:
   - Has a physical or mental impairment that substantially limits one or more major life activities;
   - Has a record of such an impairment; or
   - Is regarded as having such an impairment

   A major life activity includes: functions such as caring for oneself; performing manual tasks; walking; seeing; hearing; speaking; breathing; learning; and working.

Discrimination

1) Black's Law Dictionary: ...A failure to treat all alike under substantially similar conditions

Emancipated Minor

1) RCW 13.64 010 states that "any minor who is sixteen years of age or older and who is a resident of this state may petition in the superior court for a declaration of emancipation." RCW 13.64.060 defines the power and capacity of emancipated minor in the following way:

   (1) An emancipated minor shall be considered to have the power and capacity of an adult, except as provided in subsection (2) of this section. A minor shall be considered emancipated for the purposes of, but not limited to:

   (a) The termination of parental obligations of financial support, care, supervision, and any other obligation the parent may have by virtue of the parent-child relationship, including obligations imposed because of marital dissolution;

   (b) The right to sue or be sued in his or her own name;

   (c) The right to retain his or her own earnings;

   (d) The right to establish a separate residence or domicile;

   (e) The right to enter into nonvoidable contracts;

   (f) The right to act autonomously, and with the power and capacity of an adult, in all business relationships, including but not limited to property transactions;

   (g) The right to work, and earn a living, subject only to the health and safety regulations designed to protect those under age of majority regardless of their legal status; and

[37] http://www.academicpress.com/inscight/04221999/DNA1.htm, accessed 3/26/02

(h) The right to give informed consent for receiving health care services.

(2) An emancipated minor shall not be considered an adult for: (a) The purposes of the adult criminal laws of the state unless the decline of jurisdiction procedures contained in RCW 13.40.110 are used or the minor is tried in criminal court pursuant to *RCW 13.04.030(1)(e)(iv); (b) the criminal laws of the state when the emancipated minor is a victim and the age of the victim is an element of the offense; or (c) those specific constitutional and statutory age requirements regarding voting, use of alcoholic beverages, possession of firearms, and other health and safety regulations relevant to the minor because of the minor's age.

Genetic Characteristic

1) The GTF did not adopt a specific definition for this term. Several state laws offer different definitions of the term "genetic characteristic." For example:

• **South Carolina law** (S 535) defines "Genetic characteristic": Any scientifically or medically identifiable gene or chromosome, or alteration thereof, which is known to be a cause of disease or disorder or determined to be associated with a statistically increased risk of development of a disease or disorder and which is asymptomatic of any disease or disorder.

• **California law** (SB 654) defines "Genetic characteristic": any scientifically or medically identifiable gene or chromosome, or combination or alteration thereof, that is known to be a cause of a disease or disorder in a person or his or her offspring, or is determined to be associated with a statistically increased risk of development of a disease or disorder, or inherited characteristics that may derive from the individual or family member, that is presently not associated with any symptoms of any disease or disorder."

Genetic Discrimination

1) Differential treatment of an individual or class of individuals based on genetic information. Generally used to refer to adverse or unfair discrimination in employment or health, life and disability insurance.

Genetic Information

1) Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination.[38]

2) Both HIPAA (29 USC Sec. 1181(b)) and WAC 284-43-720 state that "genetic information" shall not be treated as a pre-existing condition in the absence of a diagnosis of the condition related to such information.

3) Previously proposed legislation in Washington State included the following definitions for "genetic information":

• **1998 SB 5298:** Information about genes, gene products, or inherited characteristics.

• **2001 SB 5282 & 5283:** This legislation included no use of the term "genetic information" instead its focus narrowed to discuss DNA specifically; e.g., it used the language "screen a person's DNA" in which "screening" meant to obtain a person's DNA and identify a sequence of chemical base pairs or interpret data from DNA analysis.

[38] This definition is based on the definition of "genetic information" in SB 6663 proposed in 1998. The GTF replaced the term "genetic test" with "DNA-based or other laboratory test."

• **2001 SB 5665:** Information about genes, gene products, or inherited characteristics, that may derive from an individual or family member of such individual and includes but is not limited to information derived from genetic tests and information about a request for or the receipt of genetic services by such individual or family member of such individual. "Genetic information" also includes information about the occurrence of a disease or disorder in family members.

4) Other state's definitions and case law definitions include:

• **Oregon's definition:** "Genetic information" means information about an individual or an individual's blood relatives obtained from a genetic test.

• **South Carolina's definition:** "Genetic information" means information about genes, gene products, or genetic characteristics derived from an individual or a family member of the individual. 'Gene product' is a scientific term that means messenger RNA and translated protein. For purposes of this chapter, 'genetic information' shall not include routine physical measurements: chemical, blood, and urine analysis, unless conducted purposely to diagnose a genetic characteristic; tests for abuse of drugs; and tests for the presence of HIV".

• **Case law:** This appeal involves the question of whether a clerical or administrative worker who undergoes a general employee health examination may, without his knowledge, be tested for highly private and sensitive medical and genetic information such as syphilis, sickle cell trait, and pregnancy.[39]

Genetic Test

1) The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn and carrier screening, as well as testing in high-risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes. Tests conducted purely for research are excluded from the definition, as are tests for somatic (as opposed to heritable) mutations, and testing for forensic purposes.[40]

2) The analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect disease-related genotypes or mutations. Tests for metabolites fall within the definition of "genetic tests" when an excess or deficiency of the metabolites indicates the presence of a mutation or mutations. The conducting of metabolic tests by a department or agency that are not intended to reveal the presence of a mutation shall not be considered a violation of this order, regardless of the results of the tests. Test results revealing a mutation shall, however, be subject to the provisions of this order.[41]

[39] Norman-Bloodsaw v. Lawrence Berkeley Laboratory 135 F.3d 1260 C.A.9 (Cal.), 1998.
[40] NIH Task Force on Genetic Testing
[41] President Clinton's Executive Order To Prohibit Discrimination in Federal Employment Based on Genetic Information

3) The analysis of chromosomes, genes, and/or gene products to determine whether a mutation is present that is causing or will cause a certain disease or condition. It does not involve treatment for disease, such as gene therapy, although test results can sometimes suggest treatment options." The report also defines *gene testing* as "examination of body fluid or tissue for the presence of altered or abnormal amounts of a protein, chemical, chromosome, or gene that indicate the presence or absence of genetic disease." A definition of *predictive gene tests* is also provided: "Predictive gene tests: tests to identify gene abnormalities in a healthy person that may make them susceptible to certain diseases or disorders.[42]

4) A laboratory test or other scientifically or medically accepted procedure for determining the presence or absence of genetic characteristics in an individual.[43]

Genomics

1) The study of genes and their function. Recent advances in genomics are bringing about a revolution in our understanding of the molecular mechanisms of disease, including the complex interplay of genetic and environmental factors. Genomics is also stimulating the discovery of breakthrough healthcare products by revealing thousands of new biological targets for the development of drugs, and by giving scientists innovative ways to design new drugs, vaccines and DNA diagnostics. Genomics-based therapeutics include "traditional" small chemical drugs, protein drugs, and potentially gene therapy.[44]

2) Genomics is operationally defined as investigations into the structure and function of very large numbers of genes undertaken in a simultaneous fashion. There are three types of genomics: structural, functional and comparative.[45]

Health Care Information

1) Any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs. The term includes any record of disclosures of health care information.[46]

Health Information

1) Any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual or the provisions of health care to an individual or the past, present, or future payment for the provision of health care to an individual.[47]

[42] The Secretary's Advisory Committee on Genetic Testing; http://www4.od.nih.gov/oba/sacgt/gtdocuments.html, Public Consultation on Oversight of Genetic Tests, accessed 3/26/02
[43] South Carolina law (S 535)
[44] http://genomics.phrma.org/lexicon/g.html and http://www.ornl.gov/TechResources/Human_Genome/glossary/glossary_g.html
[45] http://genomics.ucdavis.edu/what.html
[46] Washington State Uniform Health Care Information Act RCW 70.02
[47] Health Information Portability and Accountability Act (HIPAA)

Human Subject

1) Two federal regulations define "human subject":

   • An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.[48]

   • A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.[49]

Informed Consent (Health Care)

1) If a patient while legally competent, or his representative if he is not competent, signs a consent form which sets forth the following, the signed consent form shall constitute prima facie evidence that the patient gave his informed consent to the treatment administered and the patient has the burden of rebutting this by a preponderance of the evidence:

   (1) A description, in language the patient could reasonably be expected to understand, of:

   (a) The nature and character of the proposed treatment;

   (b) The anticipated results of the proposed treatment;

   (c) The recognized possible alternative forms of treatment; and

   (d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment;

   (2) Or as an alternative, a statement that the patient elects not to be informed of the elements set forth in subsection (1) of this section.

   Failure to use a form shall not be admissible as evidence of failure to obtain informed consent.[50]

Informed Consent (Research)

1) Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

   (a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

[48] 21 CFR 50 Sec. 50.3
[49] 45 CFR 46
[50] RCW 7.70.060

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.[50]

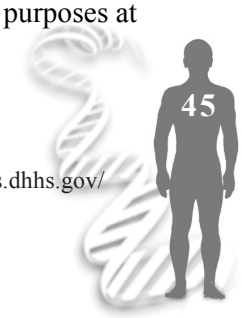
Law

1) A rule of conduct or action prescribed or formally recognized as binding or enforced by a controlling authority: a) A command or provision enacted by a legislature, also statute; b) Something (as a judicial decision or administrative rule) authoritatively accorded binding or controlling effect in the administration of justice.[52]

2) Includes statutes, regulations, constitutions, common law and judge-made law (judicial opinions). Black's Law Dictionary defines law as: "That which is laid down, ordained, or established. That which must be obeyed and followed by citizens, subject to sanctions or legal consequences."

Minor

1) RCW Title 26 Domestic Relations Chapter 26.28 defines "age of majority." 26.28.010 reads: "Except as otherwise specifically provided by law, all persons shall be deemed and taken to be of full age for all purposes at the age of eighteen years."



[51] Section 46.116 of the 45 CFR 46 describes general requirements of informed consent in research. http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

[52] http://www.lawyers.com/lawyers-com/content/glossary/glossary.html accessed 3/26/02

Privacy

1) This term is sometimes confused with the term "confidentiality." "Privacy" is an individual's *right* to have information remain secret, e.g. a patient has a right to keep personal health information from being disclosed to others or made public. "Confidentiality" is characterized by an organizational or professional *responsibility* to protect private information, e.g. a physician has a responsibility to keep a patient's personal health information confidential. Privacy, unlike confidentiality, is constitutionally based.

2) A constitutional or common law right to protect information that would be highly offensive to a reasonable person if it were disclosed. Courts have broadly characterized the right to privacy as a right to confidentiality and autonomy-the right to be let alone.

3) Black's Law Dictionary Definition: Right to privacy: The right to be let alone, the right of a person to be free from unwarranted publicity.

4) A person's right to keep information about him/herself from being disclosed to others.

Regulation/Rule

A general term, meaning a provision adopted by a governmental entity under the authority granted to the entity by the legislature in statute or the constitution. In Washington State, these are called the Washington Administrative Code (WACs). At the Federal level the term is Code of Federal Regulations (CFRs). An example is HIPAA. HIPAA is a federal legislative act, which is codified in statute. Under the statutory authority of HIPAA, the Department of Health and Human Services promulgated a series of Rules, one of which is the Privacy Rule. A rule is enforceable law, however its legal effect may be challenged on a variety of grounds, both procedural and substantive. Black's Law Dictionary definition of rule is: "An established standard, guide, or regulation."

Appendix D: Links to Electronic Resources

Washington State Legislation

- Uniform Health Care Information Act
  Chapter 70.02 RCW
  http://www.leg.wa.gov/rcw/index.cfm?fuseaction=chapter&chapter=70.02&RequestTimeout=500
  Engrossed Subsitute Senate Bill 5207
  http://www.leg.wa.gov/wsladm/billinfo/dspBillSummary.cfm?billnumber=5207
- Washington State Law Against Discrimination
  Chapter 49.60 RCW
  http://www.leg.wa.gov/rcw/index.cfm?fuseaction=chapter&chapter=49.60&RequestTimeout=500
  Title 162 WAC
  http://www.leg.wa.gov/wac/index.cfm?fuseaction=title&title=162
- Insurance Commissioner Rules
  WAC 284-43-720
  http://www.leg.wa.gov/wac/index.cfm?fuseaction=Section&Section=284-43-720
  WAC 284-84-100
  http://www.leg.wa.gov/wac/index.cfm?fuseaction=Section&Section=284-84-100
  RCW 48.44.023
  http://www.leg.wa.gov/RCW/index.cfm?fuseaction=section&section=48.44.023
  RCW 48.43.005
  http://www.leg.wa.gov/RCW/index.cfm?fuseaction=section&section=48.43.005
- Public Officers and Agencies, Release of Records for Research (Chapter 42.48 RCW)
  http://www.leg.wa.gov/rcw/index.cfm?fuseaction=chapter&chapter=42.48&RequestTimeout=500
- Governor's Executive Order EO 00-03
  http://www.governor.wa.gov/eo/eo_00-03.htm
- Patient's Bill of Rights (SB 6199)
  http://www.leg.wa.gov/pub/billinfo/1999-00/senate/6175-6199/6199-s2_sl_03152000.txt

Federal Legislation/Regulations

- HIPAA (Available in several electronic formats, choose the one you want to download)–
  http://aspe.hhs.gov/admnsimp/bannerps.htm
- 45 CFR 46–http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html
- 21 CFR 50–http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr50_00.html
- 21 CFR 56–http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr56_00.html
- ADA–http://www.usdoj.gov/crt/ada/pubs/ada.txt
- Executive Order on Genetic Discrimination–http://usgovinfo.about.com/library/neo020800.htm

Other Resources

- NCSL Genetics Legislation Tables
  http://www.ncsl.org/programs/health/genetics/charts.htm
- HIPAA Policy Guide Matrix
  http://depts.washington.edu/hia (can be found under the "more information" section)
- Federal Policy and Legislative Activities
  http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/fedlegis.html#ppolicy
- Association of State and Territorial Health Officials (ASTHO) Genetics Activities
  http://www.astho.org/index.php?template=pubs.php
- California Health Care Foundation Report on Genetics and Privacy
  http://www.chcf.org/topics/view.cfm?itemID=19759

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