

Advisory Committee on Genetic Privacy and Research

Report to the 2003 Legislature

January 30, 2003

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January 30, 2003

Executive Summary

The Advisory Committee on Genetic Privacy and Research was appointed by Oregon's 2001 Legislature to study the use and disclosure of genetic information and make any needed recommendations for change. Based on our year-long study, we recommend the following.

The Oregon Legislature should enact a bill in 2003 that will:

- Clarify the definition of anonymous genetic research and specify how the notification requirement for anonymous genetic research is satisfied. Enact new standards regulating coded research. Permit the use in anonymous or coded research of genetic materials obtained without notification or consent before the effective date of the 2003 law.
- Add a transitional clause, assuring that genetic research approved by an institutional review board (IRB) is governed by the law in effect when the IRB approves the study.
- Add a membership category to the Committee to represent the public.
- Eliminate any federal preemption problems in Oregon's genetic privacy law and conform its terminology to the federal health information privacy law (HIPAA).
- Be effective upon enactment.

This Committee, in addition to its existing assignments for 2003-05, should:

- Seek funding for policy research into the role Oregon should play in gene patenting and for public outreach and education.
- Seek effective ways to apply the principle of informed consent to obtaining, retaining, and disclosing DNA samples and genetic information.
- Study the impact of federal law on privacy of genetic information and consider streamlining Oregon's law in light of federal law.
- Study the definition of "genetic information," including whether family history, clinical diagnosis of a genetic condition, and somatic genetic changes should be included.
- Monitor discrimination from an individual's seeking genetic counseling or genetic testing.

The Oregon Department of Human Services, Health Services, should:

- Promulgate guidelines recommending that IRBs permit genetic research involving coded identifiers only if a series of requirements are met.
- Complete an initial IRB registry and use it for educating IRBs.
- Adopt administrative rules implementing this Committee's previous recommendations. (This has already been accomplished.)
- Continue to support this Committee's work.

Recommendations

The Advisory Committee on Genetic Privacy and Research makes the following recommendations to the 2003 Legislature. Page references in each recommendation refer to the full report.

Recommendation 1: HIPAA Preemption. We recommend that the Legislature eliminate any HIPAA preemption problems in Oregon’s genetic privacy law and conform the terminology of the law to HIPAA.¹ (Page 4)

Recommendation 2: Informed Consent. We recommend that this Committee continue to examine how the principle and definition of informed consent apply to obtaining, retaining, and disclosing DNA samples and genetic information. The Committee should address issues of consent and assent for minors and persons lacking competency. (Page 5)

Recommendation 3: Simplification. We recommend that this Committee continue to study the impact of HIPAA on privacy of genetic information. Once HIPAA has stabilized, the special provisions of Oregon law protecting privacy of genetic health information should be revisited, and consideration should be given to streamlining Oregon’s law in light of HIPAA. (Page 7)

Recommendation 4: Review of Research. We recommend that the Committee examine the procedures for protecting subjects of genetic research. (Page 8)

Recommendation 5: Genetic Information. We recommend that this Committee be charged with continuing to study the issues related to the definition of genetic information and whether family history and clinical diagnosis of a genetic condition should constitute “genetic information” for the purposes of the law. (Page 9)

Recommendation 6: Genetic Counseling. We recommend that this Committee continue to monitor discrimination issues surrounding an individual’s seeking genetic counseling or genetic testing. (Page 10)

Recommendation 7: Somatic Changes. We recommend that this Committee continue to study whether somatic genetic changes should constitute “genetic information” for the purposes of the law. (Page 11)

Recommendation 8: Guidelines for Coded Research. We recommend that, as soon as feasible, the Department of Human Services, Health Services, promulgate guidelines for IRBs recommending that genetic research involving coded materials be permissible only if all the following requirements are met.

- a. The subject has granted either informed consent for the particular research project or permission for genetic research generally. This requirement does not apply to use in research of genetic information or DNA specimens obtained before the effective date of the guidelines.
- b. The research has been approved by an appropriate IRB review after disclosure by the researcher to the IRB of risks associated with the coding.

¹ “HIPAA” refers to the federal health information privacy law.

- c. The data used by the researcher are coded so that no personal identifiers are directly linked to the genetic information or specimen.
- d. The code that identifies the information or specimen is not derived from personal identifiers.
- e. Data are stored securely (e.g., password protected electronic files) with access limited to necessary personnel.
- f. The code to link personal identifiers to study identifiers is kept securely and separately from genetic information or specimens and is not accessible to the researcher unless specifically approved by the IRB.
- g. The dataset is limited to elements required for analysis.
- h. The dataset meets HIPAA criteria for a “limited data set,” and the researcher has a data use agreement as provided by HIPAA. (Page 16)

Recommendation 9: Statute for Coded Research. We recommend that the statute governing genetic research be amended in 2003 to permit coded research only if all the guidelines described in Recommendation 8 are met. (The date in guideline “a” should become the effective date of the 2003 law.) (Page 16)

Recommendation 10: Anonymous Genetic Research. We recommend that the statute regarding anonymous genetic research be amended in 2003 as follows.

- a. Consider the notification requirement to be satisfied if an individual has given general permission for the sample to be used in genetic research. Accordingly, a DNA sample or genetic information obtained after the effective date of the 2003 law may be used for anonymous genetic research if the subject (a) has granted informed consent for the specific anonymous research project, (b) has granted consent for genetic research generally, or (c) has been notified the sample or genetic information may be used for anonymous genetic research and did not, at the time of notification, request that the sample not be used for anonymous genetic research.
- b. Change the effective date of this provision to the effective date of the 2003 law.
- c. Add to the statutory definition of “anonymous research” a stipulation that research is anonymous if (a) it uses only data that are deidentified within the meaning of HIPAA, and (b) it is unlinked (not coded). (Page 18)

Recommendation 11: Recontact. We recommended the adoption of an administrative rule for recontacting research participants. The rule we recommended is now in effect and provides that:

- a. Recontact of a research subject should not occur unless the subject was informed during the initial consent process that recontact may occur under specified circumstances.
- b. If recontact of subjects is contemplated to inform them of information developed in the course of research (e.g., new genetic information about the subject), the researcher must provide research protocols to the IRB describing the circumstances that might lead to recontact, as well as a plan for managing the process.
- c. In order to consider recontact in a situation where recontact was not contemplated and therefore not addressed in research protocols, a researcher must seek approval from the IRB for recontact and must assure the following conditions exist: a) the findings are scientifically

valid and confirmed; b) the findings have significant implications for the subject's or the public's health; and c) a course of action to ameliorate or treat the subject's or the public's health concerns is readily available.

- d. The researcher shall determine and adhere to the expressed wishes and desires of the research subject in relation to disclosure of genetic information to that individual.
- e. When information developed in the course of a research study is disclosed to a subject, appropriate medical advice and referral must be provided.
- f. A decision to recontact research subjects must have prior approval of the IRB. (Page 19)

Recommendation 12: IRB Registry. We recommended that information obtained through the federal Office of Human Research Protection's registry be used as a starting point for Oregon's registry and that the initial registry be completed by DHS/HS by December 1, 2002. (This has been done.) (Page 20)

Recommendation 13: Education of IRBs. We recommend that the registry be used for transmitting:

- a. the guidelines on coded research, as recommended above (Recommendation 8);
- b. education and guidance, such as a fact sheet regarding types of consent required and a practical and usable summary of the HIPAA rules for deidentification or limited data sets;
- c. this report; and
- d. Oregon's statute and rules governing genetic research. (Page 20)

Recommendation 14: Transitional Clause. We recommend adding a transitional clause to the statute, assuring that genetic research approved by an IRB shall be governed by the law in effect at the time the IRB approves the study. (Page 21)

Recommendation 15: Gene Patenting. We recommend that this Committee seek funding for expertise outside of the Committee for support of policy research into the role Oregon should play in gene patenting. We further recommend that the charge to this Committee regarding this issue be carried over to the next biennium. (Page 22)

Recommendation 16: Effective Date. We recommend that the statutory changes for 2003 be adopted with an emergency clause. (Page 22)

Recommendation 17: Public Input. We recommend that this Committee seek funding for support of activities that will elicit public input on issues related to privacy and research involving genetic information. These funds should also support ongoing review of opportunities for education of the public on scientific, legal, and ethical developments within the fields of genetic privacy and research. (Page 27)

Recommendation 18: Committee Membership. We recommend that a fifteenth membership category be added officially to the Committee to represent organizations that promote public awareness of genetics and public involvement in policy. (Page 27)

I. Overview

A. Background and History

As genetic science and technology have evolved rapidly over the past decade, concern has grown about the potential for discrimination in employment, insurance, health care, education, and society based on personal genetic information. This concern prompted discussion and eventual introduction of legislation aimed at protecting the genetic privacy of individuals and families in Oregon. In 1995, Oregon's main genetic privacy statute was enacted. The intent of the law is to protect genetic privacy and prevent any citizen in Oregon from experiencing discrimination on the basis of medically indicated genetic testing². Oregon was the first state in the country with a comprehensive law protecting genetic privacy, and because we were first we knew that modifications to the law would be necessary as the technology developed and as the law was tried in practice.

Since 1995, Oregonians have deliberated about the best way to protect genetic privacy without unduly limiting research. Genetic research may improve health through advances in medical diagnosis and treatment and is important to Oregon's biotechnology and biomedical research industry. Efforts to strike a balance between privacy and research led the 2001 Legislature to pass SB 114, which was signed into law on June 25, 2001.³ (See Exhibit A for more information on the history of genetic privacy legislation in Oregon.)

B. Charge to the Advisory Committee

In addition to modifying the 1995 genetic privacy legislation, 2001 SB 114 established the Advisory Committee on Genetic Privacy and Research to guide state discussion on genetic privacy and research issues. The legislature charged the committee to:

- Consult with the Department of Human Services/Health Services (DHS/HS) on administrative rules and on guidelines for genetic research;
- Report biennially to the legislature and recommend legislative changes or other actions;
- Study the use and disclosure of genetic information;
- Develop and refine a legal framework that defines the rights of individuals whose DNA samples or genetic information are collected, stored, analyzed and disclosed; and
- Create opportunities for public education on scientific, legal, ethical developments in genetic privacy and research and elicit public input on these issues.

The following report summarizes the advisory committee's 2001-2003 activities, sets forth its recommendations to the 2003 Legislature, and describes its activities planned for 2003-2005.

² ORS 192.533.

³ Chapter 588, Oregon Laws 2001. The statute is codified at ORS 659A.300 to 659A.303, 192.531 to 192.549, and 746.135.

C. Committee Structure and Function

SB 114 mandates an Advisory Committee on Genetic Privacy and Research whose 14 members and alternates are appointed by the Senate President, House Speaker, and the Assistant Director of the Department of Human Services/Health Services (DHS/HS) for a two-year term that may be renewed.⁴ The committee must include representatives from the Oregon Legislature (House and Senate), licensed physicians, voluntary organizations involved in the development of public policy on genetic privacy, hospitals, DHS/HS, Department of Consumer and Business Services, health care service contractors, biosciences industry, pharmaceutical industry, health care consumers, organizations advocating for privacy of medical information, and public members of institutional review boards. A list of potential non-legislative members was derived from the roster of the Genetic Research Advisory Committee, the similar committee established by the 1999 Legislature. The final committee roster was approved by Barry Kast, Assistant Director of DHS/HS, and is set forth in Exhibit B.

We met during a twelve-month period, from December 2001 through December 2002. Ted Falk, J.D., Ph.D. (representing the Oregon Genetic Privacy Advisory Committee) and Astrid Newell, M.D. (representing DHS/HS) were elected co-chairs of the committee. DHS/HS staff facilitated our meetings, minutes, and correspondence. A listserv and email group were set up to facilitate communication. We chose to operate primarily under a consensus model. Although votes are to be taken on issues for which consensus is not possible and minority reports were encouraged if views diverged, there were no dissenting votes or minority positions on this report.

The Committee members and alternates are volunteers who invested many uncompensated hours in the research and writing that led to this report. The Committee has successfully supported private organizations' grant funding for expanded activities and expects to continue to seek outside funding for 2003-05.

D. Administrative Rules Process

Our first task was to assist DHS/HS in creating administrative rules implementing SB 114. The process for rules development included several smaller workgroup meetings from December through February, review by the full committee and state attorney general, and review and refinement of the rules from March through August. A rules hearing was held on June 21, 2002. Testimony was received, and minor changes to the rules were incorporated. Rules were filed with the Secretary of State on September 27, 2002, and became effective on that date. The full text of the rules is set forth in Exhibit C below. This report will discuss the major issues in preparing the rules.

E. Subcommittees and Tasks

We divided into three smaller task-oriented subcommittees, which are described below.

- **Public Education and Outreach:** charged with creating opportunities for public education and input about genetic privacy and other genetic policy issues.
- **Clinical Issues:** charged with addressing issues related to clinical care, namely privacy of genetic information obtained through means other than through a genetic test, privacy of persons seeking genetic services, and whether to make modifications of the opt-out

⁴ ORS 192.549.

provision for anonymous research. This subcommittee examined the impact of federal privacy law on these issues.

- **Research Issues:** charged with addressing issues related to informed consent for genetic research, guidelines for coded research, and recontact of research subjects.

Each subcommittee presented a summary of activities, findings, and recommendations to the full committee for consideration and integration into this report.

II. Analysis of Statutory Assignments

The advisory committee may make any recommendations for legislative changes deemed necessary by the advisory committee.⁵

We have a general assignment from the Legislature to recommend legislative changes we deem necessary. In addition, the Legislature gave us a number of assignments on specific topics quoted below. In this section of the report, we set forth our findings and recommendations regarding each issue assigned to us. Recommendations are numbered and set off in frames, and are collected at the beginning of the report (page v).

A. Genetic Privacy

1. Legal Framework

The advisory committee shall study the use and disclosure of genetic information and shall develop and refine a legal framework that defines the rights of individuals whose DNA samples and genetic information are collected, stored, analyzed and disclosed.⁶

The legal framework for Oregon's genetic privacy law is based on four key principles:

- a) **Confidentiality**, *i.e.*, duties to control the flow of genetic information;
- b) **Informed consent**, *i.e.*, procedures for obtaining, retaining, and using DNA samples;
- c) **Special protections for genetic materials**, *i.e.*, the idea that DNA samples and genetic information present special issues and should be regulated by special laws beyond those for medical information and samples generally; and
- d) **Independent review of research**, *i.e.*, the procedure of prior review by an institutional review board or similar independent ethics committee of the impact of genetic research on human subjects.

a) Confidentiality

With the 2001 amendments to Oregon's genetic privacy law, confidentiality replaced property as the foundational principle of the law. The concept of property emphasized the rights of the individual to own products of his or her body. By contrast, the concept of confidentiality emphasizes the obligations of the person who possesses genetic information. The law defines these obligations with respect to the three major activities of obtaining, retaining, or disclosing confidential genetic information.

⁵ ORS 192.549(6).

⁶ ORS 192.549(7).

Up until now, Oregon could define its own confidentiality requirements without paying much attention to federal confidentiality laws, because there were few of any importance for genetic privacy. With the adoption of final health information privacy rules under the federal law known as “HIPAA,”⁷ to be effective April 13, 2003, this has changed in three ways.

First, HIPAA generally furnishes a level of privacy below which no state may go and preempts inconsistent state laws. Thus, Oregon’s genetic privacy law must avoid preemption by HIPAA. The Legislature has established the Advisory Committee on Privacy of Medical Information and Records, under SB 104,⁸ as responsible for conforming Oregon’s laws to HIPAA. We have submitted to that Committee an analysis of the preemption issues in the current genetic privacy law, and we defer to that Committee’s expertise in choosing which changes to make in order to conform to HIPAA. Fortunately, the HIPAA preemption problems for the genetic privacy law are relatively minor and technical. Because HIPAA leaves states free to adopt more stringent protections, nearly all of the provisions of Oregon’s genetic privacy law will be unaffected when HIPAA goes into effect.

Second, HIPAA furnishes a detailed legal framework for many issues of health information privacy. While Oregon is legally free to enact genetic privacy protections beyond those of HIPAA, all future changes in Oregon’s confidentiality requirement should analyze HIPAA first to determine the background law. This is discussed further in section c) below.

Third, HIPAA introduced new terminology, which has become standard in the law of health information privacy. We expect the Advisory Committee on Privacy of Medical Information and Records will make recommendations about terminological improvements in Oregon’s statutes, including the genetic privacy statute.

The protections of Oregon’s genetic privacy law turn on when genetic materials are individually identifiable, but our law does not define this concept. We believe it is appropriate for Oregon to adopt a definition based on HIPAA terminology:

Genetic information or a DNA sample is *individually identifiable* if it identifies the individual, or if there is a reasonable basis to believe it can identify the individual.⁹

For example, a name, social security number, or patient number identifies an individual, while there is a reasonable basis to believe an address can identify the individual; therefore, name, social security number, patient number, and address are each examples of identifiers that make genetic materials individually identifiable.

Recommendation 1: HIPAA Preemption. We recommend that the Legislature eliminate any HIPAA preemption problems in Oregon’s genetic privacy law and conform the terminology of the law to HIPAA.

⁷ The federal statute called the Health Insurance Portability and Accountability Act has several titles. The title relevant here pertains to privacy of health information and was implemented through administrative rules found at 45 CFR parts 160 and 164. The acronym “HIPAA” here refers to those federal privacy rules.

⁸ Chapter 314, Oregon Laws 2001.

⁹ 45 CFR § 160.102 (definition of “individually identifiable health information”).

b) Informed Consent

“Informed consent” is the legal principle that a competent adult has a right to consent to medical treatment or other procedures, based on information necessary to make an informed decision. Correspondingly, the physician has a duty to provide the patient with information about the proposed treatment, with its alternatives and risks, before obtaining the patient’s consent.¹⁰

This principle is also fundamental to biomedical research, which can proceed only with the informed consent of the research subject. Federal rules, discussed in d) below, dictate the informed consent procedures a research study may use.

Oregon’s genetic privacy law uses the terminology of informed consent, but departs from the standard usage in several ways. First, the term “informed consent” is used for settings outside clinical health care, such as genetic testing for employment, in which the term has no established meaning.¹¹ Oregon law designates four separate legal contexts for consent: clinical health care, research, insurance, and other (including employment). Second, while traditional informed consent conveys information to the patient about the expected biological consequences of the treatment,¹² informed consent to genetic testing focuses more on social and financial consequences in realms of insurance and employment.¹³ Third, the legal doctrine of informed consent was created to protect against invasions of the body and does not readily translate into protections for genetic information and DNA samples that have been removed or extracted from the patient’s body. Finally, while informed consent traditionally was between only the physician and a single patient, in the realm of genetics the effects on family members and even populations are inherent. Attached as Exhibit D below is Professor Patricia Backlar’s working paper, prepared for this Committee, which delves further into the difficulties with the concept of informed consent.

We raised concerns about the concept of informed consent for genetic testing or genetic research in relation to minors and persons lacking competency. Further study and guidelines are needed to address these important issues.

Recommendation 2: Informed Consent. We recommend that this Committee continue to examine how the principle and definition of informed consent apply to obtaining, retaining, and disclosing DNA samples and genetic information. The Committee should address issues of consent and assent for minors and persons lacking competency.

c) Special Protections for Genetic Materials

Genetic information can differ significantly from other medical information in being predictive of future medical conditions, in tracing heritable conditions, in uniquely and comprehensively identifying the individual, and in furnishing a molecular explanation of medical phenomena. This unique status of genetic information has led Oregon, followed by many other states, to conclude that genetic information deserves special protections under the law. The debate over this conclusion continues, and some believe that the best way to protect genetic privacy is to

¹⁰ See “Principles of Consent to Health Care,” Chapter 1 of *Oregon Health Law Manual*, Vol. 1 (T. Falk, ed., Oregon State Bar Continuing Legal Education, 1997 and revised version forthcoming 2003), § 1.4.

¹¹ ORS 192.535(4). 659A.300(5).

¹² “Principles of Consent to Health Care,” note 10 *supra*, § 1.67.

¹³ OAR 333-025-0095, Appendix 1.

strengthen privacy of all medical materials. Oregon, however, has based its current law on the idea that the distinctive attributes of genetic information, mentioned above, require special legal protection that background medical privacy law does not provide.

Oregon's original 1995 genetic privacy law had provisions in the areas of health care, insurance, and employment. The 2001 amendments added provisions in a fourth area, biomedical research. In the words of the statute:

“Current legal protections for medical information, tissue samples and DNA samples are inadequate to protect genetic privacy.

“Laws for the collection, storage and use of identifiable DNA samples and private genetic information obtained from those samples are needed both to protect individual and family privacy and to permit and encourage legitimate scientific and medical research.”¹⁴

While the background laws protecting general health information have not provided adequate privacy protections for genetic information up until now (and special genetic privacy protections have been needed), this may not be the case in the near future. The emergence of HIPAA significantly changes the environment of health information privacy.

Once HIPAA becomes a stable feature of the legal landscape, it may make sense to rely on HIPAA within its scope of regulation, rather than adopting special laws at the state level. HIPAA will protect the privacy of genetic health information, and in many respects will do so better than Oregon's law. HIPAA is not restricted by the Oregon state jurisdictional boundaries that restrict Oregon's law and create confusion about whether information and samples in interstate commerce are subject to Oregon's law. The HIPAA rules are far more comprehensive and detailed than would have been either practical or politically feasible for Oregon's genetic privacy law. HIPAA has benefited from intense national debate and scrutiny by interest groups, bureaucratic agencies, and the public. Vast amounts of money and energy are being spent on educating organizations about, and creating systems that will support, compliance with HIPAA.

At the same time, HIPAA is restricted to regulating specifically covered persons, basically health care providers and health plans. Even after HIPAA goes into effect, there will be areas that state law will continue to regulate, such as insurance and employment.

In the future, we may consider simplifying Oregon's genetic privacy law in light of the more comprehensive and detailed protection that HIPAA provides. It is too soon to consider this sort of simplification of Oregon's law, however, for several reasons:

- HIPAA rules do not go into effect until April 2003 and thus have not yet been examined in practice;
- Efforts can be directed towards aligning Oregon's genetic privacy law with HIPAA, minimizing the practical problems arising from having to follow both sets of laws;
- We expect that 2003 Oregon law changes motivated by HIPAA will focus primarily on avoiding preemption, rather than on repealing or simplifying Oregon laws that are redundant with HIPAA;

¹⁴ ORS 192.533(1)(e) and (f).

- The relevant HIPAA provisions are administrative rules, which the federal administration could change at any time;
- A number of HIPAA issues have become political footballs, and pleas for relief from this regulation or for stiffening it, are still being heard in both the executive and legislative branches in Washington, D.C.

Recommendation 3: Simplification. We recommend that this Committee continue to study the impact of HIPAA on privacy of genetic information. Once HIPAA has stabilized, the special provisions of Oregon law protecting privacy of genetic health information should be revisited, and consideration should be given to streamlining Oregon’s law in light of HIPAA.

d) Independent Review of Research

Research on human subjects is generally regulated by the Federal Policy for the Protection of Human Subjects, better known as the Common Rule. Under the Common Rule, a local committee known as an Institutional Review Board (IRB) reviews proposed research protocols to assure that the human subjects involved are protected.¹⁵

The Common Rule is not preemptive, and any additional state protections must be followed.¹⁶ Oregon adds specific protections for scientific research in its law governing genetic privacy. Building on the Common Rule, Oregon’s 2001 amendments to its genetic privacy law add protections for blood relatives and specify certain procedures for IRBs that review genetic research. These amendments, together with administrative rules subsequently adopted to interpret the law, resolved many of the concerns of the research community while adding new protections for human subjects of genetic research.

Oregon’s genetic privacy law governing research follows the substantive and procedural approach of the Common Rule. Substantively, informed consent and confidentiality are required. Procedurally, research subjects are protected through independent prospective review of the ethics of the research project by an IRB.¹⁷ By design, the IRB review is local, autonomous, and final. This local autonomy can lead to inconsistent protection of the public, however.¹⁸ Further examination is required to determine the appropriateness of how study designs undergo prior

¹⁵ The Federal Policy for the Protection of Human Subjects, originally adopted in 1966, is now generally known as the “Common Rule,” because substantially identical versions of the administrative rule have been adopted in common by all the federal agencies that fund medical and scientific research. The Common Rule was originally adopted in 1991 and governs the federal agencies listed in OAR 333-025-0025(8).

The Office for Human Research Protections of the Department of Health and Human Services is the lead agency for coordinating federal enforcement and development of the Common Rule. <http://ohrp.osophs.dhhs.gov/>. The DHHS portion of the Common Rule, 45 CFR part 46, is customarily used to stand for the Common Rule as a whole.

¹⁶ 45 CFR §§ 46.101(f), 46.116(e).

¹⁷ 45 CFR § 46.102(g); ORS 192.547(1)(b); OAR 333-025-0025(13).

¹⁸ Institute of Medicine, *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs* (2001).

review, how risk-to-benefit ratios are calculated, and the ways that historical data are used in genetic research.

The approach Oregon has taken to improving IRB review of genetic research is educational rather than regulatory. IRBs that review Oregon research must register with the Department of Human Services.¹⁹ The purpose of this state registry is to allow communication with IRBs, for example to send information and suggested guidelines.²⁰

Recommendation 4: Review of Research. We recommend that the Committee examine the procedures for protecting subjects of genetic research.

2. Information Obtained Other Than through a Genetic Test

*The report [to the 2003 Legislature] shall include recommendations relating to privacy of information about genetic conditions obtained other than through a genetic test.*²¹

The current statute defines “genetic information” to mean information about an individual or the individual’s blood relatives obtained from a genetic test.²² We considered whether family history or clinical diagnosis of a genetic condition would or should be considered genetic information.

a) Family History

Oregon’s definition of genetic information does not include information about genetic conditions obtained other than through a genetic test.²³ Although information about family history may reveal genetic traits, Oregon’s genetic privacy law furnishes protection only when blood relatives have had a genetic test. For example, insurance applicants may not be asked if a blood relative tested positively for the gene that causes Huntington’s disease, yet may be asked if a blood relative was diagnosed with Huntington’s disease.

Given the purposes of Oregon’s law, this way of drawing the boundary around protected genetic information is puzzling. For example, if the concern is potential discrimination in insurance and employment from a family member’s genetic diagnosis that foretells a future disease, the discrimination seems just as unfair whether or not the particular diagnosis was made using a genetic test.

Despite these problems, we have found no viable way to extend the protection of the law to family history without expanding the genetic privacy law far beyond its special focus and getting into general issues of health information privacy. HIPAA will furnish additional protections here, and this subject should be revisited after HIPAA goes into effect.

b) Clinical Diagnosis of Genetic Condition

Currently, the genetic privacy law leaves ambiguity about whether a diagnosis of a genetic condition or other clinical information related to a particular genetic condition is included in the

¹⁹ ORS 192.547(3); OAR 333-025-0070.

²⁰ This section of the report draws upon Theodore C. Falk, “Review of Scientific Research,” in *Oregon Health Law Manual*, vol. 1 (Oregon State Bar Continuing Legal Education, forthcoming 2003).

²¹ 2001 Senate Bill 114, § 8(1)(c), reprinted after ORS 192.549.

²² ORS 192.531(9).

²³ ORS 192.531(8), (9) and (11).

definition of “genetic information.” In some cases, a diagnosis of a particular genetic condition is made only through a genetic test (and therefore would be protected under the law), while in many other instances the diagnosis (e.g., cystic fibrosis) may be made through a health history and physical exam (not covered by the law) or a genetic test (covered under the law). When a particular diagnosis may be based either on a genetic test or on clinical information, a researcher or healthcare provider cannot know from the diagnosis alone whether the protections of the law apply.

Arguments can be made both to include and to exclude a “clinical genetic diagnosis” from the definition of genetic information. As we learn more about genetics, it is increasingly clear that many, if not all, conditions have at least some genetic component. Because of the complexities of the issue and unknown ramifications of either narrowing or expanding the definition, it is prudent at this time to leave the definition as is and continue to study the issue.

Recommendation 5: Genetic Information. We recommend that this Committee be charged with continuing to study the issues related to the definition of genetic information and whether family history and clinical diagnosis of a genetic condition should constitute “genetic information” for the purposes of the law.

3. Persons Who Seek Clinical Genetic Evaluation, Counseling, or Testing

*The report [to the 2003 Legislature] shall include recommendations relating to privacy of persons who seek genetic counseling or genetic testing.*²⁴

Oregon’s current law protects the privacy of the outcome of a genetic test, but not the fact that an individual sought genetic counseling or testing. Yet the very act of seeking genetic counseling or testing may be based on perceived risks that may be as revealing about the individual’s medical future as the results themselves. For example, if a genetic test to determine one’s susceptibility to breast cancer is only available to those patients who have a strong family history of breast cancer (i.e., with multiple affected family members), then the fact that an individual has sought and undergone testing in and of itself indicates that the individual is at higher risk for developing the condition than the general population. This could lead to discrimination based on perceived risk, even if the results of the test indicated that the “breast cancer gene” was not present.²⁵

Similar reasoning caused Oregon’s 1987 law regarding privacy of HIV information to protect the identity of individuals who seek HIV testing as well as the results of the test. The reasoning was that public health authorities recommended HIV testing only for individuals known to be at risk of HIV transmission (through intravenous drug use, homosexual sex, etc.), and so the fact of HIV testing was tantamount to an admission of risk for the disease. Although Oregon’s 1995 law on genetic privacy was in many respects based upon the earlier HIV testing law, not included in the later law was the language protecting the identity of the person who elects to be tested.

²⁴ 2001 Senate Bill 114, § 8(1)(d), reprinted after ORS 192.459.

²⁵ One member of the Committee described an Oregon case of an individual who was denied life insurance because of a referral for genetic counseling. Although this would not necessarily be illegal under current Oregon law, which permits genetic underwriting for life insurance, this case does illustrate the inferences that may be drawn from a referral for genetic counseling.

On the other hand, creating special protections should be used sparingly in areas where abuses are not known. We are concerned that any attempt to protect the privacy of those seeking genetic counseling could interfere with the normal process of referral to genetic counseling. HIPAA will protect referrals and genetic counseling from unauthorized disclosure. In addition, genetic counseling and evaluation occur for a variety of reasons that may have little to do with risk factors, such as broad-based prenatal counseling based on no more than the mother's age, and counseling of ethnic minorities. If being referred for or having an appointment for a genetic evaluation or genetic counseling does not mean the person has a diagnosis that could impact job performance or health insurance costs, the potential for discrimination may be small though real. Perhaps this potential for discrimination could be solved by adding sections to the employment and insurance statutes prohibiting use of the fact that a person was referred for or had an appointment for a genetic evaluation or genetic counseling to make insurance or employment decisions.

Recommendation 6: Genetic Counseling. We recommend that this Committee continue to monitor discrimination issues surrounding an individual's seeking genetic counseling or genetic testing.

4. Somatic Genetic Changes

"Somatic" genetic changes are changes or mutations within a cell or group of cells (e.g., in tumor cells) that are not inherited or passed on to the next generation. The cells derived from the cell with the original mutation will have the change. Other cells in the body will not. Only genetic changes in germline cells (eggs and sperm) are passed on to the next generation.

A person may be a genetic "mosaic"⁷ some cells have a change, while others do not. A common example of this is non-inherited changes in the DNA that cause a cell to become cancerous. All of the "daughter cells" of that cell will have the changes and be cancerous, but all of the other cells of the body not derived from that cell will not.

Oregon's genetic privacy law defines "genetic information" as information obtained from a genetic test, which in turn is defined as a test for a genetic characteristic.²⁶ The definition of "genetic characteristic" does not distinguish between somatic and inherited genes. "Genetic test" is defined by the substances within a cell that are tested, i.e., "DNA, RNA, and mitochondrial DNA, chromosomes or proteins," and the purpose of the test.

We discussed whether somatic changes should be considered genetic information under the law. Considering the rationale for special protections for genetic material (Section A.1.c.), information from somatic changes may be predictive of future medical conditions or furnish a molecular explanation of medical phenomena. In these ways somatic and heritable genetic information are similar.

On the other hand, somatic changes differ from heritable changes in important ways. Unlike heritable genetic information, information about somatic changes is not useful in tracing heritable conditions and does not pose a risk to blood relatives. Nor do somatic changes uniquely and comprehensively identify the individual. Moreover, as a practical matter, somatic genetic changes are often identified only after a disease has already been diagnosed.

²⁶ ORS 192.531(8), (9) and (11).

Therefore, somatic changes raise some but not all of the same concerns as heritable genetic information. Whether to exclude somatic changes from the definition of genetic information requires further consideration, taking into account impacts on clinical care and research.

Recommendation 7: Somatic Changes. We recommend that this Committee continue to study whether somatic genetic changes should constitute “genetic information” for the purposes of the law.

B. Genetic Research

For most genetic research, we believe Oregon’s law provides a satisfactory set of requirements, building on and extending the federal Common Rule. The current law²⁷ generally strikes a sophisticated balance between the privacy rights of research subjects and the needs of researchers and the community for scientific progress. Nonetheless, the new law requires adjustment in several respects discussed below.

1. Informed Consent for Genetic Research

*The report [to the 2003 Legislature] shall include recommendations relating to whether to modify or expand current statutory provisions requiring informed consent for genetic research.*²⁸

The permission that must be obtained from the research subject depends upon the extent to which the research information is identified with known individuals. The National Bioethics Advisory Commission has developed a schema to describe the character of the personal information associated with particular samples of human biological materials as they exist in the hands of researchers.²⁹ We have found it useful to apply this schema to genetic materials (i.e., genetic information and DNA samples), as follows.

- **Unidentified materials:** These materials are supplied to investigators from a repository collection of unidentified materials. Materials in a repository collection are unidentified if individually identifiable information was not collected or, if collected, was not maintained and cannot be retrieved by the repository.
- **Unlinked materials:** Sometimes termed “anonymized” or “deidentified,” these materials lack identifiers or codes that can link a particular material to an identified individual. These materials may be from a repository collection where the materials were identified but have been furnished to the investigator with identifiers and codes removed. Neither the investigator nor the repository can reconstruct the individual identity of the materials in the hands of investigators.
- **Coded materials:** Sometimes termed “linked,” these materials are supplied by repositories to investigators from identified materials with a code or encryption rather

²⁷ ORS 192.547, with related changes at ORS 192.531, 192.535(3) and 192.537(2).

²⁸ 2001 Senate Bill 114, § 8(1)(e), reprinted after ORS 192.459.

²⁹ National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethics Issues and Policy Guidance* (1999), available at <http://www.georgetown.edu/research/nrcbl/nbac/pubs.html> (“NBAC Report”). The schema is on pp. i and 16-17.

than with individually identifying information. The repository (or an agent holding the code or encryption key under security precautions) retains the ability to link the materials with individual identities, but the investigator cannot do so.

- **Identified materials:** These materials are supplied by repositories from identified specimens with individual identifiers that actually identify the subject or that could reasonably allow the researcher to link the materials directly to the individual from whom the material was obtained.

“Anonymous research” as defined by Oregon law can be done with either unidentified or unlinked materials. Oregon does not currently distinguish between coded and identified research.

The following matrix summarizes the existing Oregon law governing the permissibility of various types of research studies depending on two parameters: the form of permission obtained from research subject, and the identifiability of the research materials using the categories defined above:

Is a Genetic Research Study Permitted under Existing Oregon Law?

Form of Permission Obtained from Research Subject	Identifiability of Research Materials			
	Unidentified	Unlinked (Deidentified)	Coded	Identified
Informed consent to the particular genetic research project (only for the purpose stated in the consent)	Yes	Yes	Yes	Yes
Permission for genetic research generally	Yes	Yes	No, unless materials obtained before June 25, 2001	No, unless materials obtained before June 25, 2001
Permission for research, not specifically mentioning genetic research	Yes	Yes	No, unless materials obtained before June 25, 2001	No, unless materials obtained before June 25, 2001
Notification that anonymous research may be performed, and subject did not take opportunity to opt out	Yes	Yes	No	No
No known permission or notification	No, unless material obtained before January 1, 2002	No, unless material obtained before January 1, 2002	No	No

In this table and the one on the following page, “no” means the research is prohibited, while “yes” means the research may be permitted (as long as other laws are followed and the IRB approves it).

We propose changing whether various types of research studies are permitted. The studies we recommend be permitted are outlined in the matrix below.

**Will a Research Study Be Permitted under Oregon Law
 with Recommended 2003 Legislative Changes?**

Form of Permission Obtained from Research Subject	Identifiability of Research Materials			
	Unidentified	Unlinked (Deidentified)	Coded	Identified
Informed consent to the particular genetic research project (only for the purpose stated in the consent)	Yes	Yes	Yes	Yes
Permission for genetic research generally	Yes	Yes	<i>Yes</i>	No, unless material obtained before June 25, 2001
Permission for research, not specifically mentioning genetic research	<i>No, unless material obtained before effective date of 2003 law</i>	<i>No, unless material obtained before effective date of 2003 law</i>	No, unless material obtained before <i>effective date of 2003 law</i>	No, unless material obtained before June 25, 2001
Notification that anonymous research may be performed, and subject did not take opportunity to opt out	Yes	Yes	No, unless material obtained before <i>effective date of 2003 law</i>	No
No known permission or notification	No, unless material obtained before <i>effective date of 2003 law</i>	No, unless material obtained before <i>effective date of 2003 law</i>	No, unless material obtained before <i>effective date of 2003 law</i>	No

“2003 law” refers to Oregon legislation we recommend be enacted in 2003. Proposed changes are italicized. As can be seen, we propose changes for genetic research that is either coded or is anonymous (unidentified or unlinked). These two areas are discussed below.

a) Coded Genetic Research

In consultation with the Advisory Committee on Genetic Privacy and Research, the Department of Human Services shall promulgate guidelines for genetic research in which the identity of the

*individual providing a DNA sample is protected by an encryption or coding system. The department shall base the guidelines on recommendations of credible national and state organizations.*³⁰

If genetic materials are coded, then the research is not anonymous. No matter how securely privacy may be protected by the coding, the possibility of revealing identities through opening the code means that identities can be determined and hence are not anonymous. Therefore, coded research must undergo IRB review and is not exempt from review as anonymous.

The 2001 legislative changes pertaining to genetic research³¹ were based in part on two premises that on subsequent inquiry have proved faulty. First, it was assumed that consent to research had generally been obtained for stored materials. Further investigation reveals that often either no consent was obtained, none can be documented currently, or the consent was obtained for the procedure itself rather than to obtain or retain the materials.

Second, it was assumed that anonymous research would be an adequate alternative when consent requirements could not be met. Further investigation reveals that, for many genetic research studies, anonymous or anonymized research is methodologically inadequate. By contrast, coded research allows the investigator to verify data and add data elements without having the subject's personal identification be part of the research study.

The current law requires administrative guidelines for research involving coded genetic materials. The current law, however, effectively prohibits research on banks of genetic materials collected and stored before the effective date of the law if no known consent or notification occurred. This type of research appears ethically legitimate as long as there are sufficient protections of patient privacy.

Coded research on previously obtained genetic materials can be appropriately restricted to protect patient privacy. Thus, while informed consent should remain the general rule, the guidelines we propose should clarify what kind of coded research can be done without full-dress informed consent.

A research subject can, of course, give informed consent to a coded research study. In that case the terms of the consent, under conditions approved by the IRB, govern the standards for coding that the research project will follow.

More frequently, however, researchers desire to use coded research, because obtaining consent is not practical, and knowing the identity of the person contributing the sample is not necessary to answer the research question. In that case, the legal environment should furnish standards for the coded research.

Per our charge, we considered the recommendations of credible authorities, such as the National Bioethics Advisory Commission³² and the Centers of Medicare and Medicaid Services.³³ The guidelines we propose below are based on our review. For example, we recommend that such

³⁰ ORS 192.547(5).

³¹ See footnote 27.

³² See footnote 29.

³³ The federal Centers of Medicare and Medicaid Services promulgate the HIPAA privacy rules.

research be permitted only so long as it meets the standards under the HIPAA privacy rules for a limited data set.³⁴

We propose that these guidelines be adopted into law by legislative action. Meanwhile, the administrative guidelines called for under the 2001 law can help fill the gap until the 2003 legislature acts. Moreover, issuance of guidelines can put researchers on notice of the actions they will need to take when legislative changes occur in 2003.

Recommendation 8: Guidelines for Coded Research. We recommend that, as soon as feasible, the Department of Human Services, Health Services, promulgate guidelines for IRBs recommending that genetic research involving coded materials be permissible only if all the following requirements are met.

- a. The subject has granted either informed consent for the particular research project or permission for genetic research generally. This requirement does not apply to use in research of genetic information or DNA specimens obtained before the effective date of the guidelines.
- b. The research has been approved by an appropriate IRB review after disclosure by the researcher to the IRB of risks associated with the coding.
- c. The data used by the researcher are coded so that no personal identifiers are directly linked to the genetic information or specimen.
- d. The code that identifies the information or specimen is not derived from personal identifiers.
- e. Data are stored securely (e.g., password protected electronic files) with access limited to necessary personnel.
- f. The code to link personal identifiers to study identifiers is kept securely and separately from genetic information or specimens and is not accessible to the researcher unless specifically approved by the IRB.
- g. The dataset is limited to elements required for analysis.
- h. The dataset meets HIPAA criteria for a “limited data set,” and the researcher has a data use agreement as provided by HIPAA.

Recommendation 9: Statute for Coded Research. We recommend that the statute governing genetic research be amended in 2003 to permit coded research only if all the guidelines described in Recommendation 8 are met. (The date in guideline “a” should become the effective date of the 2003 law.)

b) Anonymous Genetic Research

The report [to the 2003 Legislature] shall include recommendations relating to whether to modify the notification requirement of ORS [192.537 (2)] for anonymous research.³⁵

³⁴ Limited data sets are defined at 45 CFR § 164.514(e). The full analysis of this issue is set forth in Exhibit E.

³⁵ 2001 Senate Bill 114, § 8(1)(f), reprinted after ORS 192.459.

The 2001 law requires a notification and opportunity for opt-out if an individual's genetic materials are to be used in anonymous genetic research. Upon our advice, the administrative rules require notification in written form at least once (but not necessarily every time) a biological sample is obtained.³⁶

Two interpretive issues arose. First, though the presumed intent of the notification statute was for individuals to be notified that their samples might be used in anonymous **genetic** research, the statute refers only to notification for "anonymous research." This should be clarified in the statute. Second, it is unclear whether samples from individuals who had actually given consent for research could be used in anonymous genetic research without additional notification and opt-out provision. If the individual had given consent for genetic research in general, then one could assume that they had received adequate notification and opportunity to opt out (by not signing or not giving consent). However, if an individual has given consent only for a specific project using identifiable information, then they would also need to be notified that their sample could be used in the future for anonymous genetic research and given the opportunity to opt out. This interpretation of the statute should be codified, also.

As discussed more fully on page 23 below, we were able to benefit from a survey conducted by Geneforum on our behalf. The survey results show surprisingly strong popular support for the right of an individual to have an element of control over use of his or her genetic materials in anonymous research. Accordingly, weakening or repealing the notification provision would be unwise.

However, there are reasons to delay the effective date of this provision to the effective date of a 2003 law. Although the notification provision of the existing statute was legally effective January 1, 2002, in practice researchers awaited the issuance of the administrative rules, which became effective September 27, 2002. Moreover, until the education of the IRBs on the registry occurs (see discussion on page 19), many researchers are unaware of the requirements of the law.

In addition, the definition of "anonymous research" should be clarified. The statute defines "anonymous research" to mean research where "the identity of an individual who has provided a sample, or the identity of an individual from whom genetic information has been obtained, or the identity of the individual's blood relatives, cannot be determined."³⁷ This definition, accurate as far as it goes, does not provide much concrete guidance. The fact that genetic material could be subject to analysis, matching it with the DNA of an identified individual, as commonly occurs in criminal and paternity cases, does not by itself eliminate the possibility of anonymous research. The main concern of the law is the use of identifiers associated with the genetic material. Nonetheless, the possibility of additional genetic testing must be kept in mind when determining whether genetic material is anonymous.

Whether identities can be determined from a given piece of genetic material is a complex statistical question that depends on such factors as the sample size, the number and character of identifiers, and the rarity of the genetic traits involved. Some legal experts fear that because genetic information itself (e.g., a rare chromosome abnormality) could be a unique (or nearly unique) identifying characteristic, this would effectively prohibit anonymous research. Oregon's law does not have either criteria or a safe harbor test for determining whether given genetic

³⁶ OAR 333-025-0120(4).

³⁷ ORS 192.531(1).

materials are in fact anonymous. HIPAA rules do furnish specific criteria for data that are “de-identified” that Oregon may adopt in order to qualify the research as anonymous.³⁸ The practical problems with using linked materials could be resolved by adding a statutory safe harbor that research using only data that are deidentified within the meaning of HIPAA is anonymous.

Recommendation 10: Anonymous Genetic Research. We recommend that the statute regarding anonymous genetic research be amended in 2003 as follows.

- a. Consider the notification requirement to be satisfied if an individual has given general permission for the sample to be used in genetic research. Accordingly, a DNA sample or genetic information obtained after the effective date of the 2003 law may be used for anonymous genetic research if the subject (a) has granted informed consent for the specific anonymous research project, (b) has granted consent for genetic research generally, or (c) has been notified the sample or genetic information may be used for anonymous genetic research and did not, at the time of notification, request that the sample not be used for anonymous genetic research.
- b. Change the effective date of this provision to the effective date of the 2003 law.
- c. Add to the statutory definition of “anonymous research” a stipulation that research is anonymous if (a) it uses only data that are deidentified within the meaning of HIPAA, and (b) it is unlinked (not coded).

2. Recontact of Research Subjects

*The report [to the 2003 Legislature] shall include recommendations relating to standards for recontacting patients who have provided samples for genetic research.*³⁹

As required by the statute, the Department of Human Services adopted criteria for recontacting an individual or an individual’s physician if DNA samples or genetic information are used in research with personal identifiers. In adopting the criteria, the Department considered the recommendations of national organizations, such as those created by executive order by the President of the United States, and the recommendations of our Committee.⁴⁰ Upon our recommendation, these guidelines for recontact of research subjects were incorporated into an administrative rule.⁴¹

³⁸ De-identification is defined at 42 CFR §§ 164.502(d), and 164.514(a)-(c). The full analysis of this issue is set forth in Exhibit E.

³⁹ 2001 Senate Bill 114, § 8(1)(b), reprinted after ORS 192.459.

⁴⁰ ORS 192.547(8).

⁴¹ OAR 333-025-0130.

Recommendation 11: Recontact. We recommended the adoption of an administrative rule for recontacting research participants. The rule we recommended is now in effect and provides that:

- a. Recontact of a research subject should not occur unless the subject was informed during the initial consent process that recontact may occur under specified circumstances.
- b. If recontact of subjects is contemplated to inform them of information developed in the course of research (e.g., new genetic information about the subject), the researcher must provide research protocols to the IRB describing the circumstances that might lead to recontact, as well as a plan for managing the process.
- c. In order to consider recontact in a situation where recontact was not contemplated and therefore not addressed in research protocols, a researcher must seek approval from the IRB for recontact and must assure the following conditions exist: a) the findings are scientifically valid and confirmed; b) the findings have significant implications for the subject's or the public's health; and c) a course of action to ameliorate or treat the subject's or the public's health concerns is readily available.
- d. The researcher shall determine and adhere to the expressed wishes and desires of the research subject in relation to disclosure of genetic information to that individual.
- e. When information developed in the course of a research study is disclosed to a subject, appropriate medical advice and referral must be provided.
- f. A decision to recontact research subjects must have prior approval of the IRB.

a) IRB Registry

*The Department of Human Services shall adopt rules requiring that all institutional review boards register with the department. The Department shall consult with the Advisory Committee on Genetic Privacy and Research before adopting the rules.*⁴²

DHS/HS has recently established a registry of IRBs that review research, which is conducted in Oregon or which involves research subjects living in Oregon. The purpose of this registry is to have a contact list of IRBs to provide information about laws, rules, guidelines, and recommendations for review and approval of genetic research, as well as to collect information about IRB practices and procedures. The purpose is not for DHS to have a regulatory role over IRBs.

DHS/HS has completed the first stage of creating the registry, namely collecting IRB registrations on file with the federal government. Included are the name of the IRB and its associated institution, contact person, address, phone number, and whether it is registered with the federal Office of Human Research Protection. DHS/HS will develop a form for registration of those IRBs, hopefully few, that are not federally registered.

⁴² ORS 192.547 (3) and (4). As appropriate, we were consulted before the administrative rules on the IRB registry were adopted.

We have mentioned the importance of educating IRBs about Oregon's genetic privacy law and have recommended the content for guidelines that IRBs should follow in reviewing coded research. IRBs should also be given the background information and guidance that will encourage them to review genetic research carefully under Oregon's law.

Recommendation 12: IRB Registry. We recommended that information obtained through the federal Office of Human Research Protection's registry be used as a starting point for Oregon's registry and that the initial registry be completed by DHS/HS by December 1, 2002. (This has been done.)

Recommendation 13: Education of IRBs. We recommend that the registry be used for transmitting:

- a. the guidelines on coded research, as recommended above in Recommendation 8 on page v;
- b. education and guidance, such as a fact sheet regarding types of consent required and a practical and usable summary of the HIPAA rules for deidentification or limited data sets;
- c. this report; and
- d. Oregon's statute and rules governing genetic research.

b) Rules for IRB Approval of Research

*The Department of Human Services shall adopt rules for conducting research using DNA samples, genetic testing and genetic information. Rules establishing minimum research standards shall conform to the Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46, that is current at the time the rules are adopted. The Department shall consult with the Advisory Committee on Genetic Privacy and Research before adopting the rules, including rules identifying those parts of the Federal Policy for the Protection of Human Subjects that are applicable.*⁴³

As required, DHS/HS consulted with us and adopted Oregon Administrative Rules clarifying the applicability of the Common Rule to research in Oregon.⁴⁴

Certain issues remain unresolved in the administrative rules. For example, we considered but were unable to agree upon jurisdictional standards for determining whether research that has some contact with Oregon is subject to Oregon's law, e.g., studies conducted by researchers in other states that include subjects residing in Oregon.

Another issue that needs to be clarified is a researcher's responsibility for responding to changes in the genetic privacy act that become effective after the IRB has approved the study. (The Common Rule requires IRBs to review all research projects annually, even if a research project spans more than one year.) The issue may be addressed by adding a transitional clause, stating that the statute in effect at the time an IRB approves (or reapproves) a study will govern the study.

⁴³ ORS 192.547 (1)(a) and (4).

⁴⁴ OAR 333-025-0105 to 333-025-0130.

Recommendation 14: Transitional Clause. We recommend adding a transitional clause to the statute, assuring that genetic research approved by an IRB shall be governed by the law in effect at the time the IRB approves the study.

3. Gene Patenting

*The report [to the 2003 Legislature] shall include recommendations relating to patenting of human genes.*⁴⁵

Contrary to what many people expect, it is quite possible to patent a gene. For a number of years, the United States Patent and Trademark Office issued such patents under its general rules. Recently, that Office has issued guidelines to clarify and restrict the circumstances under which gene patents may be issued.⁴⁶

Gene patents have been roiled in controversy for a number of reasons. Opponents of gene patenting assert that gene patents interfere with research, allow unfair licensing fees to be charged for genetic tests whose invention predated the patent, impair patient access to genetic tests, and create unknown risks for testing genes whose patent applications are pending. Proponents of the current system assert that gene patents are no different from patents on other chemical compounds isolated from nature that have been granted for years and are the best way to reward innovation and research. (See bibliography in Exhibit F below.)

We faced two difficulties in coming to a policy recommendation on gene patenting. First, patenting is a federal matter, and it is unclear what if any role states may play with regard to patent policy. Expert legal assistance is needed to resolve this conundrum. Bills have been introduced in the U.S. Congress to reform the law of gene patenting. While Oregon has expert patent lawyers, we expect that assistance from a scholar from outside the Northwest, such as Professor Rebecca Eisenberg of the University of Michigan Law School, will be needed in order to clarify the interplay of federalism and patent policy.

Second, we did not have the time to evaluate and resolve the competing policy arguments pro and con. Resolution of these issues needs to take into account broader issues of the biotechnology industry in Oregon. Considerable effort has gone into reconciling Oregon's commitment to genetic privacy with its commitment to be an environment hospitable to scientific research. A similar effort will be required to assure that any Oregon policies on gene patenting balance protecting the individual with fostering a nascent biotechnology industry. Gene patents are also at stake in the public investments that are being made in the growing stream of technology transfer from research universities like OHSU to commercial biotechnology companies, so any state policy on gene patenting becomes part of our higher education framework.

Because of the amount of legal and policy expertise that would be required to address this issue adequately, we were unable to complete our study of gene patenting issues this biennium.

⁴⁵ 2001 Senate Bill 114, § 8(1)(a), reprinted after ORS 192.459.

⁴⁶ United States Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (1/5/01), <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>.

Recommendation 15: Gene Patenting. We recommend that this Committee seek funding for expertise outside of the Committee for support of policy research into the role Oregon should play in gene patenting. We further recommend that the charge to this Committee regarding this issue be carried over to the next biennium.

4. Effective Date

Recommendation 16: Effective Date. We recommend that the statutory changes for 2003 be adopted with an emergency clause.

C. Public Education and Public Input

The advisory committee shall create opportunities for public education on the scientific, legal and ethical development within the fields of genetic privacy and research. The advisory committee shall also elicit public input on these matters. The advisory committee shall make reasonable efforts to obtain public input that is representative of the diversity of opinion on this subject. The advisory committee's recommendations to the Legislative Assembly shall take into consideration public concerns and values related to these matters.⁴⁷

We sought to inform ourselves about public values by reviewing existing qualitative data gathered in public consultation activities and by planning and commissioning new opinion polls. We also worked to identify and build on existing opportunities to enhance public awareness and knowledge about genetics issues.

1. Public Input Data

We reviewed several sources of public input seeking ideas relevant to the questions assigned to us.

a) Geneforum Data

Valuable information relevant to our work comes from Geneforum, an Oregon-based organization that seeks to promote dialogue and educate people about genome science and its impact on their lives through innovative and interactive strategies. Geneforum has obtained input from the public and selected stakeholders/constituencies by a variety of means, including its website [<http://www.geneforum.org/>], a series of focus groups around Oregon, a series of radio call-in shows in collaboration with Oregon Public Broadcasting, a survey of Oregon health-care opinion leaders, and an analysis of “Informed Consent in the Gene Age” by the *Oregon Ethics Commons*, an Oregon leadership salon. Summarized below are the significant findings generated by these communication strategies.

- Closely related family members and descendants are included, along with the patient and society, as stakeholders in decisions about genetic testing and research participation.

⁴⁷ ORS 192.547(8).

- People understand the value and benefits of health research, including genetic research, but are also concerned about personal privacy (particularly in relation to insurance and employment).
- The information about one's person contained in genetic material is seen to be more important than the material itself.
- Genetic material itself has value to many, because "it is mine."
- Confidentiality is not seen as an adequate substitute for informed consent related to genetic testing and research.
- Deliberate violations of confidentiality (e.g., unauthorized disclosure of genetic information) are seen as equivalent in seriousness to felonies.
- As part of the basis for making an informed decision about participation in genetic testing or research, many would like to know more about the mechanism for ensuring confidentiality, including monitoring bodies and sanctions for violations.
- As part of the basis for informed decision-making and consent, many would like to know something about the uses to which their genetic material would be put. Would it go to a medical organization or some other organization? A for-profit or a non-profit organization? Would it be used for somatic line or germline research? If the latter, additional information may be desired.
- The context of the informed consent decision should be arranged to maximize the rationality of the decision. Use of a general informed consent form, completed in advance of going to a health care provider or researcher, should be considered, as well as making available genetic counselors, seminars, and an educational website where more information can be obtained.

b) Interviews Conducted for State Genetics Assessment and Planning

Over the past two years, the Oregon Department of Human Services, the Child Development and Rehabilitation Center at Oregon Health & Science University and a broad-based advisory committee have been actively involved in a collaborative statewide needs assessment and planning project related to genetics and the public's health. The result of this planning project was a document entitled: Oregon's Strategic Plan for Genetics and Public Health. (See Exhibit G.)

As part of the assessment process, public input was sought on a number of issues, including perceptions and values related to genetics issues. A total of 22 qualitative assessment activities were conducted, including interviews and surveys of key informants from diverse cultural backgrounds, consumers of genetic services, health care providers, and genetic service providers. Assuring individual and family choice in regards to genetic testing and genetic research, as well as maintaining the privacy of personal genetic information, emerged as core public values.

c) Public Opinion Survey (June 2002)

In June 2002 our Committee, with funding from Geneforum, added two questions to a general survey being conducted by Davis, Hibbits & McCaig (DHM). The two questions focused on

consent for genetic research, including anonymous research. The following summary is drawn from an analysis provided by the polling firm. The complete analysis is in Exhibit H.

Using a telephone-based protocol, 500 adults (randomly selected from the state's general population) were surveyed. After being presented with a brief scenario, each participant was asked questions related to the use of blood or tissue samples in genetic research. The questions addressed whether it was important to the participant to be notified that his or her blood or tissue sample might be used in research (including anonymous research) and whether it was important for the participant to be able to refuse permission for use of material in genetic research.

The survey findings demonstrate the importance the public places on knowing about the possible use of their blood or tissue sample for genetic research. More than two-thirds of respondents (69%) thought it important to be able to refuse permission, even if there were no way to identify the blood or tissue sample came from them. Nearly three-quarters of all respondents wanted some kind of notification that their blood sample might be used in research, even where information was coded so the researcher could not identify them. A majority of respondents (57%) wanted the opportunity to consent or refuse for each project.

These responses suggest a fairly strong level of agreement among the general public in Oregon for consent to use a blood or tissue sample for genetic research. These opinions generally are held across all demographic groups. The results of this survey are relevant to two questions assigned to us: 1) whether to alter the existing policy on informed consent; and 2) whether to alter the requirement about notification prior to use of samples in anonymous research. Given the survey findings, it would be advisable to use strict consent guidelines and to continue to require an opportunity for control by potential subjects of anonymous research.

d) Follow-Up Survey

To explore more deeply the values behind the responses to the June survey, we supported the efforts by Geneforum, a Portland-based nonprofit educational organization, to develop a follow-up opinion survey about consent and notification. The further value exploration would offer more nuanced guidance for us in constructing recommendations for the Legislature. Working with the Committee, Geneforum will conduct a population survey to determine how a random and representative sample of Oregonians feels about consent in the context of genetic research and privacy. Geneforum has obtained \$35,000 grant funding from the Rose Tucker Charitable Trust, the Collins Medical Trust, and the Jackson Foundation for this purpose. Geneforum has contracted with the market and public opinion research firm of Davis, Hibbits & McCaig, Inc. (who performed the June 2002 survey described in the previous section) to conduct the survey. The results will enable us to take the core values of citizens into account in making policy recommendations to the State Legislature regarding consent for the acquisition, storage, and/or use of tissue and DNA sample collections for genetic research.

This survey would examine two issues: the importance of informed consent and the possibilities for general consent to future anonymous research. From the public input obtained through a follow-up survey, this Committee, and in turn the Legislature, would get three kinds of information on public values relevant to informed consent:

- A list of values relevant to the specific issues;
- Quantification of the relative importance of these values in contributing to the importance of informed consent;

- Quantification of the acceptability of anonymous research with prior notification.

The list of values can serve as a checklist when evaluating the desirability of any policy alternative regarding informed consent, and the quantification can provide guidance as to how much importance to attach to each. This information can also be used to stimulate and guide thought about creative alternatives to policy options currently under consideration. The quantification of the relative desirability of various forms of blanket informed consent can stimulate and guide thought in the design of acceptable forms of blanket informed consent.

e) Outreach to African-American Faith Communities

The Pacific Institute for Ethics and Social Policy (<http://pacinst.pacificu.edu>) has just completed a pilot public education/outreach program for two African American communities with the help of a grant from the Northwest Health Foundation. Forty-five people from Bethel African Methodist Episcopal Church and Allen Temple Methodist Episcopal Church met over a period of two months to discuss case studies and questions developed for this project by the Pacific Institute. Five areas of potential concern were covered: 1) Genetic Information; 2) Genetic Research; 3) Genetic Manipulation; 4) Genetic Justice; and 5) Genetic Self-Understanding. Two group leaders worked with Marc Marengo (philosopher), Lisa Sardinia (geneticist and attorney), and Kate Crow (genetic counselor) to develop a method for doing effective education, which addresses the real questions these communities had and provides useful qualitative research, which could be used in the development of public policy. The process used was driven largely by case study. Participants learned some basic genetic science using sickle cell anemia as an example. A case study involving sickle cell was then used to ask basic questions about the *implications* of the science for ethics, law, and social policy. Each case would take participants more deeply into the science and more deeply into the complex social, moral, and religious questions that the science raises.

At the time of this report the program has just ended, so no detailed analysis of the data is available. However, a few general remarks are worth making.

- The details of the science of genetics are important. People were genuinely curious about what is known about genes: how they work; how they combine through reproduction; how they go awry and create medical problems. Any program which bypasses the science, however basic, misses an important part of the public education imperative.
- Average people with only a basic education can still understand the fundamental vocabulary and concepts of genetics. Within three weeks' time, these participants were familiar with and could meaningfully use terms, such as "gene," "allele," "mutation," "base pair," "homozygous," "heterozygous," "dominant," "recessive," etc.
- Public input without minimal public education is often misleading. The initial conversations in this program were quite different than the conversations toward the end. For good historical reasons, minority communities are especially suspicious of genetic research, genetic databases, stem cell research, and so on. The tension between wanting to understand the science and deeply fearing the technology was palpable. Only through sustained conversations in an environment of trust could differences of opinion between members of these groups emerge.

- Being a member of the African American community *and* a member of a faith community deeply informs the self-understanding out of which participants approached the phenomenon of genetic technology. Participants were sufficiently stimulated by the conversations that some of them went away and developed quasi-formal responses using authoritative texts within the community. The basic expression of this self-understanding came in the form of two persistent beliefs: 1) we lack the wisdom to responsibly use genetic knowledge, and 2) people of faith have an obligation to become informed and actively participate in policy decision-making.
- There is no static, easily predictable attitude that flows from being African American or a member of a faith community. Again, it took some time to observe this as the barriers to trust are so great. Some felt that genetic screening, for example, was usurping the wisdom of God, as in God will give us what he desires to give us. Others felt that God has given us the knowledge and the power to do something with the knowledge, and so we should seek wisdom and act. Both of these perspectives were described as coming from a posture of faith.
- People respond when they believe someone in a position of influence is listening. The project director's membership on the advisory board was significant to the participants. While maintaining a somewhat skeptical attitude throughout the series, participants nonetheless would often say, "make sure you get this in your report," or "if you can make them understand *that* we'd be satisfied!" This would reinforce our recommendation that we include a bioethicist (preferably with strong public education skills) on the advisory board.
- Once people understand the basics of genetic science and the technologies that are emerging and the social/ethical/policy questions that are now pressing in around us, they universally agree that public education programs such as this are both necessary and urgent.

We hope that more programs such as this will be possible. They are necessary to assure that our conversations, which lead to recommendations for the Oregon Legislature, are fully informed by sustained vigorous public education and an effective process for listening to public opinion. Surveys are only as good as the understanding of those surveyed. In the area of genetics, there is a clear and well-articulated need for basic public education commensurate with the decision-making process. Using the Northwest Health Foundation/Pacific Institute pilot program as one model for public education and outreach would help us generate the kind of rational and ethical approach to genetic policy making that Oregon urgently needs.

2. Educational Outreach: Fred Friendly Broadcasts

In addition to work on obtaining public input, we have made plans to educate the general public about the ethical and legal issues associated with genetics. In partnership with Oregon Public Broadcasting, we stimulated an educational outreach project involving Oregon Health Decisions, GeneForum, the Oregon Ethics Commons, the Oregon State Genetics Program, and the OHSU School of Nursing. With our support, Oregon Public Broadcasting was awarded a \$10,000 grant from the Fred Friendly Seminars to support educational outreach in association with the broadcast of *Our Genes, Our Choices*. The Fred Friendly group has developed for Public Television three segments dealing with social, ethical, and legal implications of the new genetics. OPB is broadcasting the segments in January 2003.

We seized the opportunity to connect our work with these broadcasts. The educational outreach will stimulate viewers to watch the series, explore the issues more deeply, and make their views

known through internet-based interactive scenarios created by Geneforum⁴⁸ These three scenarios were designed to coordinate with the three Fred Friendly Seminars and with our report to the Legislature. We will use public input gathered at the Geneforum website to help design a future scientific survey of Oregonians about values and concerns relevant to our continuing work.

The outreach project includes plans for several community-based discussions in association with the statewide campuses of the OHSU School of Nursing. These meetings will engage invited members of the public in the issues raised by the broadcasts and our work. The results of these meetings will also be used to guide the public opinion survey described above.

Recommendation 17: Public Input. We recommend that this Committee seek funding for support of activities that will elicit public input on issues related to privacy and research involving genetic information. These funds should also support ongoing review of opportunities for education of the public on scientific, legal, and ethical developments within the fields of genetic privacy and research.

3. Advisory Committee Membership

In addition to the fourteen statutorily mandated categories for membership in the Committee, we have several alternate members who have contributed greatly to this report and whose backgrounds are in public involvement in health policy.

Recommendation 18: Committee Membership. We recommend that a fifteenth membership category be added officially to the Committee to represent organizations that promote public awareness of genetics and public involvement in policy.

D. Future Tasks for the Committee

We have been asked to “make recommendations to the [2005] Legislative Assembly on genetic testing and use of genetic information by insurers.” We understand this to mean there should be separate charges on genetic testing and on insurance. Some of the issues are as follows.

Genetic testing is not regulated by any government agency at present when done at home, outside the federally regulated context of a medical laboratory. Until recently the FDA was moving towards action to regulate home genetic testing, but it now appears that no federal regulation will be forthcoming for the time being.⁴⁹ The Committee should examine this issue for potential regulation at the state level.

Use of genetic information by insurers has been controversial since the law’s inception. The insurance provision was the only part of the 1995 bill to be debated actively before the Legislature, and the compromise was to prohibit use of genetic information for underwriting health insurance while permitting such use in other lines of insurance, e.g., life and disability insurance. This debate was revived in 2001 with the proposal of HB 2519, which would have banned all uses of genetic information in insurance, but in fact the only substantive change the Legislature made in the insurance provision in 2001 was to prohibit insurance underwriting

⁴⁸ <http://www.geneforum.org>.

⁴⁹ “HHS Seeks Science Advice to Match Bush Views,” Washington Post, September 17, 2002, Page A1.

based on genetic information about a blood relative.⁵⁰ One intermediate option that we will consider in our future deliberations is further regulation of genetic testing for insurance and of questions about genetic information.⁵¹ In addition to these tasks already assigned, our recommendations above include several additional charges for the Committee.

⁵⁰ Oregon Laws 2001, chapter 588, § 8(2).

⁵¹ This is the approach Oregon has taken for HIV testing for insurance. See OAR 836-050-0200 to -0255.

Exhibit A. History of Oregon's Genetic Privacy Law

The 1995 Legislature Enacts a Comprehensive Genetic Privacy Act

The seed for Oregon's genetic privacy law was planted at meetings convened in 1994 by the Multnomah County Medical Society (now called the Medical Society of Metropolitan Portland) to examine medical privacy in Oregon. The group decided to tackle one specific area, genetic privacy, whose rapid change and explosive growth posed great potential for discrimination to compromise access to medical care. A cross-disciplinary workgroup was formed to prepare a bill for the 1995 legislature.

The bill was drafted with the realization that the primary distinguishing feature between genetic and all other medical testing is the unique ability of a genetic test result to predict a person's future health. These so called predictive genetic tests can accurately predict a person's future health prior to the individual experiencing any symptoms that might be diagnosed by any other available medical diagnostic procedure.

Prior to the introduction of this legislation, individuals in Oregon had no existing state or federal protection for genetic privacy and very unclear protection from insurance discrimination that could result from genetic testing. Oregon's only law specifically relating to genetic privacy was a provision enacted in 1993 to prohibit certain kinds of discrimination in employment based on genetic information.⁵² The workgroup proposed to expand this to a comprehensive approach protecting the privacy of DNA testing and genetic information in all settings, including insurance and health care as well as employment.

The Medical Society's bill was enacted in 1995 with the declared goal of protecting the privacy of genetic samples and protecting individuals from employment and insurance discrimination on the basis of genetic test results. The bill was sponsored by Senator Neil Bryant and was known as Senate Bill 276. The bill represented a consensus of all major interest groups, and the only area in which the bill was modified in response to concerns was in the area of insurance.⁵³ Most elements of the 1995 law remain in force.⁵⁴

The intent of the law, as set forth in ORS 192.533, is to protect genetic privacy and prevent any citizen in Oregon from experiencing insurance or employment discrimination on the basis of a medically indicated genetic testing. Oregon was the first state in the country with a comprehensive law protecting genetic privacy, and because we were the first we knew that modifications to the law would be necessary as the technology developed and as the law was tried in practice.

SB 276 created privacy protection for three kinds of activities: obtaining, retaining, and disclosing genetic material. Both genetic information and DNA samples are protected. The bill did not have any express enforcement or remedial provisions.

SB 276 defined genetic information as the "property" of the individual from whom it was derived. This property provision was an attempt to solve several legal problems: providing guidance to the courts as to the nature of a person's rights in genetic information, allowing family

⁵² ORS 659A.303.

⁵³ 1995 Oregon Laws ch. 680.

⁵⁴ ORS 659A.300 to 659A.303, 192.531 to 192.549, and 746.135

ownership of genetic information, and implying a remedy for a blood relative of an individual who suffers discrimination. As described below, however, the property clause became controversial and has now been repealed.

In 1996, the Health Division adopted administrative rules in the specific areas called for by the 1995 statute. These include consent forms for genetic testing for insurance and other non-medical contexts. Although additional rules were adopted in 2001, the 1996 rules remain in force with little change.

The 1997 Legislature Considers Impacts on Research

Effects on biomedical research were not considered when the 1995 bill was enacted. During the 1997 legislative session a bill sponsored by the Smith Kline Beecham pharmaceutical company sought to repeal the property provision, which the company said was having a negative impact on research. The concerns were that a subject of research might later assert a claim to own the fruits of research and that a transfer of those rights to a researcher might be unenforceable.

The 1997 Legislature enacted one amendment to the genetic privacy law in order to mitigate the impacts on research. The law explicitly exempted anonymous research from the privacy act, since research done anonymously could not conceivably result in discrimination.⁵⁵ The property provision was maintained, however.

The 1999 Legislature Debates Property and Creates an Advisory Committee

Concerns over the property clause continued, particularly among the biomedical research community. Several proposals were introduced to eliminate or modify it and were vigorously debated. In the outcome, the competing, complicated proposals stalemated and the legislation actually adopted did only two things.

First, research reviewed by an institutional review board (IRB) was exempted from the genetic privacy law under a provision having a two-year sunset.⁵⁶ Second, a Genetic Research Advisory Committee (GRAC) was created under the Office for Oregon Health Plan Policy and Research. The Committee was charged to “study the use and disclosure of genetic information and shall develop a legal framework that defines the rights of individuals whose DNA samples and genetic information are collected, stored, analyzed and disclosed.”⁵⁷

The Advisory Committee met during year 2000 and addressed its charge through a broad series of recommendations for change. After much debate and study, the Committee unanimously recommended replacing the property clause with a confidentiality clause and enacting several remedial and family-rights provisions to replace the various dimensions of the property clause. The Committee’s Report, *Assuring Genetic Privacy in Oregon*, was published in November 2000.⁵⁸ The report made recommendations in five areas—remedy for violations, family issues, informed consent, property, and continued oversight—and included a draft bill.

⁵⁵ 1997 Oregon Laws ch. 780.

⁵⁶ 1999 Oregon Laws ch. 921, §§ 1-3.

⁵⁷ 1999 Oregon Laws ch. 921, § 4.

⁵⁸ http://www.ohppr.state.or.us/genetic/GRAC_final.pdf.

The 2001 Legislature Overhauls the Genetic Privacy Law

The 2001 Legislature adopted all of the Advisory Committee's recommendations and enacted Senate Bill 114.⁵⁹ The Legislature also adopted a suggestion by the Oregon ACLU that patients be notified if their DNA sample or genetic information is to be used in anonymous research and have an opportunity to opt out of such use.⁶⁰

The 2001 legislation includes the following provisions:⁶¹

- **Legal Framework.** Specifies that genetic information and DNA sample are private and that an individual has a right to protection of that privacy. Deletes provision providing that genetic information and DNA sample are the "property" of the individual.
- **Remedy For Violations.** Establishes a civil cause of action to enforce the individual's privacy interest by an individual, an individual's blood relative, estate, or the Attorney General. Establishes minimum damages for specified violations from \$0 for inadvertent disclosure that is corrected to \$250,000 for a disclosure with the intent to use for commercial advantage. Creates criminal penalty for intentional violations.
- **Research.** Requires the Health Division to adopt rules consistent with Federal Policy for the Protection of Human Subjects (Common Rule), to establish minimum standards for genetic research, and to create a registry of institutional review boards. Requires review by an institutional review board of all proposed anonymous research. Delegates authority to Health Division to promulgate guidelines for genetic research in which the identity of the individual is encrypted. Requires Health Division to establish criteria for recontact of individuals when using research information with personal identifiers. Requires persons conducting research to obtain informed consent of the individual except where the individual's identity is anonymous or encrypted. Limits the use of a blanket informed consent for further research. Requires notification to individual that individual's DNA sample or genetic information may be used for anonymous research before any sample may be used for anonymous research.
- **Family Issues.** Adds privacy protections for blood relatives of the subject of genetic testing.
- **Continued Oversight.** Establishes and specifies composition of Advisory Committee on Genetic Privacy and Research and specifies issues for report to legislature.

⁵⁹ 2001 Oregon Laws ch. 588.

⁶⁰ ORS 192.537(2).

⁶¹ This outline is based on the House Staff Measure summary for SB 114A (June 6, 2001), <http://www.leg.state.or.us/comm/sms/sms01/sb0114ahjud06-06-2001.pdf>.

Exhibit B. Advisory Committee Roster

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Exhibit C. Administrative Rules

Chapter 333, Division 25: Genetic Information And Privacy

333-025-0100 Definitions

As used in these rules:

(1) “Anonymous research” means scientific or medical research conducted in such a manner that the identity of an individual who has provided a sample, or the identity of an individual from whom genetic information has been obtained or the identity of the individual’s blood relatives, cannot be determined. “Anonymous research” does not include research conducted in such a manner that the identity of such an individual, or the identity of the individual’s blood relatives, can be determined by use of a code, encryption key or other means of linking the information to a specific individual.

(2) “Blanket informed consent” means that the individual has consented to the use of that individual’s DNA sample or health information for any future research, but has not been provided with a description of or consented to the use of the sample in genetic research or any specific genetic research project.

(3) “Blood relative” means a person who is:

(a) Related by blood to an individual; and

(b) A parent, sibling, son, daughter, grandparent, grandchild, aunt, uncle, first cousin, niece or nephew of the individual.

(4) “Clinical” means relating to or obtained through the actual observation, diagnosis, or treatment of patients and not through research.

(5) “Disclose” means to release, publish, or otherwise make known to a third party a DNA sample or genetic information.

(6) “DNA” means deoxyribonucleic acid.

(7) “DNA sample” means any human biological specimen that is obtained or retained for the purpose of extracting and analyzing the individual’s DNA to perform a genetic test. “DNA sample” includes DNA extracted from the specimen.

(8) “Federal Common Rule” means the Federal Policy for the Protection of Human Subjects, as adopted by the following federal agencies and as revised through 11/13/2001:

7 CFR Part 1c, Department of Agriculture

10 CFR Part 745, Department of Energy

14 CFR Part 1230, National Aeronautics and Space Administration

15 CFR Part 27, Department of Commerce

16 CFR Part 1028, Consumer Product Safety Commission

21 CFR Parts 50 and 56, Food and Drug Administration

22 CFR Part 225, International Development Cooperation Agency, Agency for International Development

24 CFR Part 60, Department of Housing and Urban Development

28 CFR Part 46, Department of Justice
32 CFR Part 219, Department of Defense
34 CFR Part 97, Department of Education
38 CFR Part 16, Department of Veterans Affairs
40 CFR Part 26, Environmental Protection Agency
45 CFR Part 690, National Science Foundation
45 CFR Part 46, Department of Health and Human Services
49 CFR Part 11, Department of Transportation

In the case of research not subject to federal regulation under one of these provisions, “Federal Common Rule” means 45 CFR Part 46.

(9) “Genetic characteristic” includes a gene, chromosome or alteration thereof that may be tested to determine the existence or risk of a disease, disorder, trait, propensity or syndrome or to identify an individual or a blood relative. “Genetic characteristic” does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than through a genetic test.

(10) “Genetic information” means information about an individual or the individual’s blood relatives obtained from a genetic test.

(11) “Genetic research” means research using human DNA samples, genetic testing or genetic information.

(12) “Genetic test” means a test for determining the presence or absence of genetic characteristics in a human individual or the individual’s blood relatives, including tests of nucleic acids such as DNA, RNA, and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.

(13) “Institutional Review Board” or “IRB” means an Institutional Review Board established in accord with and for the purposes expressed in the Federal Common Rule.

(14) “IRB approval” means the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and Federal and State requirements.

(15) “Obtain genetic information” means performing or getting the results of a genetic test.

(16) “Person” includes but is not limited to any health care provider, health care facility, clinical laboratory, blood or sperm bank, insurer, insurance agent, insurance-support organization, as defined in ORS 746.600, government agency, employer, research organization or agent of any of them.

(17) “Recontact” means disclosure of genetic research findings to a research subject or the subject’s physician through use of personal identifiers.

(18) “Research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

(19) “Retain a DNA sample” means the act of storing the DNA sample.

(20) “Retain genetic information” means making a record of the genetic information.

(21) “Specific informed consent for genetic research” means the individual or the individual’s representative has consented to the use of that individual’s DNA sample or genetic information for genetic research or for a specified genetic research project.

Research Involving Human Genetic Materials

333-025-0105 Scope

- (1) OAR 333-025-0105 to 0130 apply to all genetic research subject to the law of the State of Oregon.
- (2) All genetic research must comply with the applicable standards set forth in the Federal Common Rule. Additional protections for subjects of research are authorized by ORS 192.531 et seq. and these rules.

333-025-0110 Institutional Review Boards (IRBs) and Approval for Research

- (1) An IRB must conform to the organizational and operational standards contained in the Federal Common Rule.
- (2) All proposed genetic research, including anonymous research, or research otherwise exempt from IRB approval, must first be submitted to an IRB for explicit prior approval or an explicit determination that the research is anonymous or otherwise exempt.
- (3) A researcher must disclose to the IRB the intended use of human DNA samples, genetic tests or other genetic information for every proposed research project, including anonymous or otherwise exempt research.
- (4) A researcher must follow the informed consent requirements of OAR 333-025-0115 and provide assurances to the IRB that these requirements have been met.

333-025-0115 Informed Consent for Non-Exempt Genetic Research

- (1) A researcher may use a human biological sample or genetic information obtained after June 25, 2001 only with specific informed consent.
- (2) A researcher may use a human biological sample or genetic information obtained prior to June 25, 2001 with blanket informed consent or specific informed consent.

333-025-0120 Anonymous or Exempt Genetic Research

- (1) Any person proposing to conduct genetic research that is thought to be anonymous shall obtain from an IRB, prior to conducting such research, a determination that the research is anonymous. The person shall furnish the IRB with assurances that the criteria in 3) below are met.
- (2) Any person proposing to conduct research that is thought to be exempt from review shall obtain an IRB determination that the research is exempt from review under 45 CFR 46.101(b) or other applicable exemption from the Federal Common Rule.
- (3) A human biological sample or genetic information obtained on or after January 1, 2002, may be used in anonymous genetic research only if prior to the time the research is conducted, the subject was notified that anonymous research may take place in the future, and at the time

notification took place the subject did not request that the sample or information be withheld from anonymous research.

(4) For purposes of paragraph (3) of this rule, "notification" means the providing of a written statement in plain language and in the subject's own language to a subject from whom one or more biological samples or genetic information has been obtained, or from whom such samples or information are expected to be obtained, that biological samples or genetic information obtained from the subject may be used for anonymous research. Notification must be provided at least once prior to the time the person conducts research using the subject's samples or information. Notification may be provided more often as necessary to ensure effective notification to the subject or effective implementation of the subject's intent. The statement must include, but need not be limited to:

(a) A general description of the type of biological samples or genetic information that the person providing the notification intends to use in anonymous research;

(b) A general explanation of the meaning of anonymous research and

(c) An opportunity for the subject to request that the subject's sample or genetic information be withheld from anonymous research.

333-025-0125 IRB Registry

(1) The Department of Human Services/Health Services shall establish and maintain a registry of IRBs that review research conducted in Oregon or that involves research subjects living in Oregon.

(2) By October 1, 2002, each existing IRB must register with the Department of Human Services/Health Services on registration forms provided by the Department.

(3) The Department will update its registry annually. IRBs will be required to renew its registration each year, or sooner if there exists material changes in the terms of registration.

333-025-0130 Recontact

(1) Recontact of a research subject should not occur unless the subject was informed during the initial consent process that recontact may occur under specified circumstances and with this understanding, the research subject consented to participate in the study.

(2) If recontact of subjects is contemplated, the researcher must provide research protocols to the IRB describing the circumstances that might lead to recontact, as well as a plan for managing the process. If a subject declines the possibility of recontact, the researcher may not recontact the subject.

(3) Notwithstanding 1) above, in order to consider recontact in a situation where recontact was not contemplated and therefore not addressed in research protocols a researcher must seek approval from the IRB for re-contact and must assure the following conditions exist:

(i) The findings are scientifically valid and confirmed;

(ii) The findings have significant implications for the subject's or the public's health; and

(iii) A course of action to ameliorate or treat the subject's or the public's health concerns is readily available.

(4) Under conditions described in 3), the researcher shall determine and adhere to the expressed wishes and desires of the research subject in relation to disclosure of genetic information to that individual.

(5) When research results are disclosed to a subject, appropriate medical advice and referral must be provided.

(6) In all cases, a decision to recontact research subjects must have prior approval of the IRB.

333-025-0135 Information Concerning Deceased Individuals

(1) (a) Anyone permitted by Oregon law to dispose of the body of a deceased individual or who is authorized by ORS 146.113-117 to submit the DNA sample of an unidentified deceased individual to a DNA diagnostic laboratory may obtain or retain genetic information only for the purpose of identification of the deceased. After identification, relevant information concerning the death shall be submitted into the permanent medical record of the deceased.

(b) A DNA sample of or genetic information about a deceased individual may be used for medical diagnosis of blood relatives of the individual and for no other purpose except as otherwise authorized by law. A request to use a sample or information for such purpose may be made by (A) a representative designated by the decedent to act on the individual's behalf after death; (B) the closest surviving blood relative of the decedent; or (C) if there is more than one surviving blood relative of the same degree of relationship to the decedent, by the majority of the surviving closest blood relatives of the decedent.

(2) A DNA sample sent to a diagnostic laboratory for testing under (1)(a) or (b) above must be accompanied by an affidavit stating that the specific purpose for obtaining the DNA sample is to identify the deceased individual or is for medical diagnosis of blood relatives of the decedent, and for no other purpose.

Informed Consent for Obtaining Genetic Information

333-025-0140 Informed Consent Procedures

(1) Unless exempted by ORS 192.535 (1)(a)-(f), all persons collecting genetic information must conform to standards of informed consent as follows:

(a) Physicians licensed under ORS chapter 677, and any other licensed health care providers or facilities, shall obtain informed consent according to ORS 677.097.

(b) A person conducting research shall obtain informed consent according to the procedure given in OAR 333-025-0115.

(c) If genetic information is collected in connection with an insurance transaction governed by ORS 746.135, informed consent will be conducted in the manner described by the Department of Consumer and Business Services under authority of ORS 746.135(1).

(2) For persons not described in (1) above, informed consent must be obtained using the form and process contained in Appendix 1 of these rules or a form which is substantially similar.

(3) Elements to be contained in a consent form for obtaining genetic information include:

(a) The name of the individual whose DNA sample is to be tested.

(b) The name of the individual, company, or organization requesting the genetic test for the purpose of obtaining genetic information.

(c) A statement signed by the individual whose DNA sample is to be tested indicating that he/she authorizes the genetic test.

(d) A statement that specifies the purpose of the test and the genetic characteristic for which the DNA sample will be tested.

(4) Process for obtaining informed consent using the form contained in Appendix 1 or a form that is substantively similar:

(a) Explain that the genetic test is voluntary; inform the individual that he/she may choose not to have his/her DNA sample tested; and inform the individual that he/she has the option of withdrawing consent at any time.

(b) Explain the risks and benefits of having the genetic test, including a description of the provisions of Oregon law pertaining to individual rights with regard to genetic information and the confidential nature of the genetic information; a statement of potential consequences with regard to insurability, employability, and social discrimination if the genetic test results or genetic information become known to others; the implications of both positive and negative test results; and the availability of support services, including genetic counseling.

(c) Inform the individual that it may be in his/her best interest to retain his/her DNA sample for future diagnostic testing, but that he/she has the right to have his/her DNA sample promptly destroyed after completion of the specific genetic test which was authorized.

(d) Inform the individual about the implications, including potential insurability, of authorizing disclosure to a third party payer that the genetic test was performed, and that he/she has the option of paying the cost of the genetic test out of pocket rather than filing an insurance claim.

(e) Ask the individual whether he/she has any further questions, and if so, provide the individual with the opportunity to ask questions and receive answers from either a genetic counselor or another person who is sufficiently knowledgeable to give accurate, understandable and complete answers to his/her questions.

(f) Request that the individual read, complete, sign and date the consent form.

(g) Provide the individual with a copy of the completed form for his/her personal records.

Retention of Genetic Information

333-025-0145 Retention for the Purpose of Identification of Deceased Individuals

(1) Any person who is permitted by Oregon law to dispose of the body of a deceased individual, or anyone who is authorized by ORS 146.113-117 may retain the genetic information obtained from an unidentified deceased individual's DNA sample without specific authorization for the purpose of identification of the deceased individual.

(2) Upon identification of the deceased individual, persons so authorized in Section (1) shall convey the deceased individual's genetic information to his/her permanent medical record.

333-025-0150 Retention for the Purpose of Testing to Benefit Blood Relatives of Deceased Individuals

Any person may retain the genetic information of a deceased individual indefinitely for the sole purpose of benefiting blood relatives of the deceased individual without specific authorization.

333-025-0155 Retention for the Purpose of Newborn Screening Procedures

The Department of Human Services may retain the blood samples of newborns collected for the control of metabolic diseases, as provided in ORS 433.285, for up to one year.

Disclosure of Genetic Information

333-025-0160 Procedure for Authorization of Disclosure by the Tested Individual or the Tested Individual's Representative

Any person, other than those excepted in ORS 192.539, shall be required to obtain specific authorization from the individual on whose sample a genetic test was conducted, or an individual's representative, to disclose genetic information, by completing the consent form specified in Appendix 2 or a form that is substantively similar and by using the following procedure:

- (1) Request that the tested individual, or his/her representative, read, sign and date the prescribed consent form; and
- (2) Read, sign, and date the prescribed consent form on behalf of the individual or organization requesting the release of genetic information; and
- (3) Provide the tested individual, or his/her representative, with a copy of the completed consent form for his/her personal records.

OAR 333-025-0140 Appendix 1: Sample Consent Form, Obtaining Genetic Information

Section 1

AUTHORIZED PERSON:

The individual's DNA sample will be tested solely for the genetic characteristic below:

PROCESS TO FOLLOW PRIOR TO OBTAINING GENETIC INFORMATION:

After each of the points below have been clearly explained to the individual to be tested, or the individual's representative, please initial in the space provided to ensure that the informed consent procedure has been followed.

_____I have informed the individual that this genetic test is completely voluntary; that he/she has the option of withdrawing consent to the genetic test at any time.

_____I have explained to the individual the risks and benefits of having a genetic test, including:
a description of the provisions of Oregon law pertaining to the confidentiality of genetic information;
a statement of the potential consequences regarding insurability, employability, and social discrimination if the genetic test results become known to others;
a statement explaining the implications of positive and negative test results, and the availability of support services, including genetic counseling.

_____I have informed the individual that it may be in his/her best interest to retain the DNA sample for future diagnostic testing, but also of his/her right to have the DNA sample promptly destroyed after the specific purpose for which it was tested (unless retention of the sample is otherwise authorized by law).

_____I have informed the individual that it may be in his/her best interest to retain the DNA sample for future diagnostic testing, but also of his/her right to have the DNA sample promptly destroyed after the specific purpose for which it was tested (unless retention of the sample is otherwise authorized by law).

_____I have informed the individual about the meaning and purpose of the authorization form for disclosure of procedure to a third party payer, including:
an explanation of the potential risks of disclosure to third-party payers that a genetic test has been performed;
an explanation of the individual's option to pay out-of-pocket for the cost of the genetic testing procedure.

_____ I have asked the individual whether he/she has any further questions; and if so, I have provided the individual with an opportunity to ask questions and receive answers from either a genetic counselor, or a person who is sufficiently knowledgeable to give accurate and understandable answers about genetic testing and its implications.

_____ I have asked the individual to read, complete, sign and date this consent form; and provided the individual a copy of this completed form for his/her personal records.

The above referenced information was explained by me, to the individual, and the individual signed this consent form in my presence.

Name of authorized person

Signature of authorized person

Date

Section 2

AUTHORIZATION FOR DISCLOSURE OF PROCEDURE TO THIRD PARTY PAYER

Please check one box and sign:

I authorize disclosure to my **health insurance company (or other third party payer responsible for payment of my medical bills)**, pursuant to normal billing procedures that my genetic information was obtained. I understand that by authorizing this disclosure, I am not authorizing access to the test results.

Health Insurance Company or Third Party Payer

Signature of individual authorizing disclosure

Date

Signature of individual's representative

Relation to individual

Date

I agree to pay out-of-pocket for the cost of the genetic testing procedure. I understand that by accepting financial responsibility, no information in my medical record relating to this procedure will be disclosed to a third party payer without my prior permission.

Signature of individual

Date

Signature of individual's representative

Relation to individual

Date

Section 3

INFORMED CONSENT

It has been explained to me that the procedure to be undertaken is a test of my DNA sample to obtain genetic information solely for the purpose(s) listed below. It has also been explained that consent to this procedure is completely voluntary. I have been told that there are risks and potential consequences regarding employability, insurability and social discrimination that may result from the collection of my genetic information.

Please check one box:

- I have been asked if I want a more detailed explanation of the risks and benefits of genetic testing. I am satisfied with the explanation provided to me and do not need any more information.
- I have requested and received further explanation for the proposed genetic test and more information about the potential risks and consequences for the test for me and my family. I am satisfied with the additional information provided to me and do not need any more information.
- I have requested further explanation of the proposed genetic test and more information about the potential risks and consequences for the test for me and my family, and do not consent to the collection of my genetic information at this time.

I consent to the collection of my genetic information for the purpose of:

and acknowledge that the results of this test or procedure will be recorded in my confidential medical record.

Name of individual consenting to test or procedure

Signature of individual consenting to test or representative	Relation to individual	Date
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Signature of individual's representative	Relation to individual	Date
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Name of individual/Facility/Agency ordering collection of genetic information

OAR 333-025-0160 Appendix 2: Consent Form, Disclosure Of Genetic Information

SPECIFIC AUTHORIZATION:

I authorize the disclosure of my genetic information only to the individual/facility/agency and SOLELY for the purpose(s) listed below. I understand that I may revoke this authorization at any time, except to the extent action has already been taken on the authorization.

I HEREBY AUTHORIZE:

_____ ()
Individual/Facility/Agency

Street Address

City State Zip

TO PROVIDE GENETIC INFORMATION ABOUT ME TO:

Individual/Facility/Agency

Street Address

City State Zip

Exhibit D. “Informed Consent”: A Limited Protection

Prepared for the Committee by Patricia Backlar

(Patricia Backlar is Professor of Bioethics at Portland State University.
She was a member of the National Bioethics Advisory Commission.)

It was some 10 years ago or more that I had the following dream: I am walking down the hall, and as the director of transplant services is bustling by, he invites me to their party. I ask him what they are celebrating, and he tells me they have just performed a medical breakthrough: they have successfully completed the first appendix transplant in history. I argue with him: “But what is the point of transplanting an appendix? We take out an appendix, we don’t put one back! That’s not ethical.” He responds: What do you mean, ‘it’s not ethical? We had the patient’s consent.’ (Freedman, 1996, p. 319)

“The self-determination ideal is, of course, much celebrated in our political tradition: it was the guiding ideal in this country for our War of Independence from Great Britain” (Burt, 1966, p. 30). Society’s formal regard for informed consent processes in both clinical treatment and human subject research, and the conventional prominence in which we place it, provide evidence of our continuing esteem for this concept. The informed consent process, in which each individual is adequately informed, accurately understands and appreciates the information, and voluntarily consents or refuses, is the means through which the principle of respect for an individual’s liberty to make choices that directly affect his or her person may be sustained. Yet, the act of making those choices (the act itself presupposing self-determination and control) may not be sufficient to achieve the desired protection.

Genesis of “Informed Consent”

The 1950s U.S. legal doctrine of *informed* consent has its genesis in English common law, which proscribed unauthorized touching (unwanted physical contact) with another person (Faden & Beauchamp, 1986). Customarily if a physician was derelict in negotiating a proper consent from a patient, it would have been considered a cause for battery action at law. “Whether or not harm befalls the person is irrelevant; it is the ‘unconsented to touching’ that is wrong” (Levine, 1986, p. 97). Nowadays, malpractice cases are more likely to be based on negligence rather than battery, but whichever holds, negligence or battery, the consent becomes invalid if any pertinent information germane to the decision to consent is not disclosed (Appelbaum, Lidz, & Meisel, 1987).

The legal and enforcement mechanisms for informed consent for treatment or research are different and have evolved quite discretely. For the most part the mechanism of consent to treatment has been formed by case law, whereas that of consent to research has been regulated by professional codes, statutes, and administrative regulations, with litigation being a less significant factor (Appelbaum, Lidz, & Meisel, 1987). Despite these differences, both consent practices have the following aims: one, to make sure that persons with decision-making capacity are able to effect their own determinations and protect their self interest, and two, to protect individuals who lack decision-making capacity from making decisions that may be harmful to their persons (Backlar, 1996, 1998a).

Indeed, in clinical treatment and biomedical research, much critical attention has been paid to the obstacles involved in obtaining consent from individuals who, for a variety of reasons, lack capacity for decision-making. On the other hand, it has become common practice to assume that informed consent procedures adequately protect the self-interests of competent adult patients. In part, this presumption may have been little questioned, because the exercise of self-determination—i.e., the particular act of consent/refusal—in itself inculcates an impression of being in control not only in the present but also in the future. Yet, actual control over any future event is unlikely, perhaps even more so when individuals make complicated health care treatment or research decisions in which the consequences of their choices are unclear.

Understanding the limitations inherent in informed consent does not diminish its importance. Patients and potential research subjects are “not merely human; they are social, moral, legal, and political entities with rights, to whom obligations are due” (Cassel, 2000, p. 16). The informed consent procedures remain valuable; deference to personal choice involved in the informed consent/refusal processes signifies an essential respect for persons. Without question, informed consent procedures are necessary, because they protect individuals against “unconsented to touching.” Notwithstanding the importance of respect for a person’s self-determination, it may not be sufficient—cannot be relied upon—to protect a patient’s future best interests.

“Informed Consent” and its Limitations

Informed Consent to Clinical Treatment

Informed consent processes have become central to our opinions of how best to protect patients and human research subjects. Yet, as anyone who has been a patient is likely to have experienced, there are “practical limits to all informed consent requirements . . . medical information is complex, professional time is scarce and expensive, and perhaps most [individuals] when feeling ill are less than perfect at eliciting and assimilating information that can be complex and upsetting.” (O’Neil, 2002, p. 44)

In reality, although informed consent procedures are an important protection against coerced treatment, the type of protection obtained may be limited to a proscription against ‘unauthorized touching.’ As O’Neil (2002, p. 26) and other commentators have observed, the patient is “only going to be allowed to accept or refuse treatment proposed by professionals . . . what is mistakenly spoken of as ‘patient autonomy’ masks the fact that the patient’s role is only to say ‘yes’ or do without treatment.” In the United States, the right to refuse treatment appears to be fundamental, yet the right to demand treatment is not similarly protected. In effect, in most cases where the patient is faced with an ultimatum (e.g., sign the consent form or not have the procedure), the “voluntariness” of the patient’s consent is cast in doubt.

Informed Consent to Human Subject Research

In human subject research, as in clinical treatment, respect for persons requires that informed consent be obtained; the potential research participant must have the opportunity for self-determination, made possible through the mechanism of voluntary and informed consent processes. This requirement was described in the first international document to address research ethics, the Nuremberg Code (Trials of War Criminals . . . , 1949), in response to the cruel research by Nazi doctors on prisoners who, because of their circumstance, were not in a position to give their consent, whether or not they were competent. The first principle of the Nuremberg Code makes clear that “the voluntary consent of the human subject is absolutely necessary.” However, the subsequent principles are equally important for adequate human subject protection,

e.g., experiments must yield “fruitful results for the good of society”; scrupulous attention must be paid to research design; experiments should be so conducted to avoid all unnecessary physical and mental suffering and injury; the “degree of risk should never exceed that determined by the humanitarian importance of the problem to be solved . . .” Informed consent procedures depend on a wider set of moral requirements, which determine obligations, responsibilities and rights, if they are to provide more than the fundamental protection against unwanted touching.

To be sure, if researchers do not receive the potential subject’s voluntary informed consent, they may not enlist that subject. However, the right of the potential subject to refuse to participate in research became for many the only moral constraint worthy of attention, even though this issue should not be addressed until other prior important issues have been resolved. (Childress, 1990, p. 16).

Informed Consent to Genetic Research with Human Biological Materials

“For research in which individuals provide human biological materials⁶² . . . if the research is not otherwise exempt from federal regulations, all human subjects research generally requires informed consent of subjects” (NBAC, 1999, p. 30). Yet, if the characteristic attribute of the “informed consent procedures” lies only in its power to thwart unwanted touching, what protection can such procedures offer when tissue is no longer connected to an individual?

The notorious case of John Moore v. The Regents of the University of California (1990)⁶³ is an example of how unsatisfactory it may be for persons to rely only on “informed consent procedures” to control the future uses and research of their human biological materials. The court rejected the idea that Mr. Moore’s tissue was property of the type a person could “own” (in part, the court was concerned that to grant such rights would complicate and slow down research unduly). Thus, the California Supreme Court’s majority view circumvented the hard questions raised by Moore’s attorneys and left, in the eyes of some commentators, “the protection of social values and the continued development of the social meaning of the body and health to the marketplace” (Andrews & Nelkin, 1997, p.211). Nevertheless, the court did offer the plaintiff a remedy: Moore was allowed to collect for breach of fiduciary duty if the physician/researcher had failed to inform him about the prospective research and potential financial interest in

⁶² “[T]he term ‘human biological materials’ is defined to encompass the full range of specimens, from subcellular structures such as DNA, to cells, tissues (e.g., blood, bone, muscle, connective tissue, and skin), organs (e.g., liver, bladder, heart, kidney, and placenta, gametes (i.e., sperm and ova), embryos, fetal tissues, and waste (e.g., hair nail clippings, urine, feces, and sweat, which often contains shed skin cells)” (NBAC, 1999, pp. 1-2).

⁶³ Mr. Moore was a patient at UCLA Medical School. His attending physician, Dr. David Golde, confirmed a diagnosis of hairy-cell leukemia after withdrawing blood, bone marrow aspirate, and other bodily substances. John Moore’s physician proposed to remove his spleen in order to slow the progress of his disease. Based on the information he received from his physician, Mr. Moore signed a consent form consenting to the splenectomy. However, Dr. Golde did not inform Mr. Moore that certain of his blood products and blood components were of great value in research and that access to a patient whose blood contained these substances would potentially provide scientific, competitive and commercial advantages. Without Mr. Moore’s knowledge, or consent, Dr. Golde patented certain chemicals in Moore’s blood and sold the rights to develop the cells to a pharmaceutical company for \$15 million. Indeed, for seven years, Mr. Moore traveled from his home in Seattle to the UCLA Medical Center, where under the guise of the ongoing patient-physician relationship, Dr. Golde continued research on Moore’s cells and withdrew additional samples of blood, blood serum, skin, bone marrow aspirate and sperm. Moore sued the doctor for malpractice and property theft.

Moore's tissue. In other words, the court held that Moore should have been asked for his consent for the use of his tissue.

In general, in clinical treatment and human subject research, the act of voluntary informed consent or refusal (authorizing or declining to authorize) may successfully protect an individual against unauthorized touching. When John Moore's physician recommended that Mr. Moore's spleen be removed, Moore signed a form consenting to the procedure. If Moore had refused, it is highly unlikely that the physician would have proceeded with the splenectomy. Patients' individual choices about whether their "intact" person may, or may not, be touched appear to be well respected. Thus the issue, in the Moore case, was not about "unconsented to physical touching" of his person. The point in question, was the unauthorized *use of* and *research with* his tissue *after* it was removed from his person.

Despite the court's ruling in the Moore case, it remains uncertain how an individual's "act of consent" to removal of tissue will provide adequate protection against particular harms and wrongs when the tissue is no longer connected to that person. Clinicians, researchers, and hospitals, when collecting tissues, may make a good faith attempt to inform patients before seeking their consent. Yet, because human biological materials can be acquired in diverse ways and used for multiple purposes, the collectors of tissue may not know for what or how the tissue samples may be used in the future.

Tissue may be taken₇ for a variety of reasons₇ in the course of diagnosis or treatment (as was the case with Moore). In other circumstances, individuals may donate blood, organs, and sell sperm or eggs. Human tissues may be removed after an individual's death (in which case, consent for the *removal* of tissue after death must be obtained from the individual prior to death or from relatives, the exception being, the coroner's authority to determine the cause of death). Information about an individual in the form of deoxyribonucleic acid (DNA), the molecular basis of genes, can be harvested directly from patient samples soon after their receipt. Alternatively, DNA can be prepared from stored tissues, blood, serum, cytological preparations, and pathology specimens. Because DNA is an informational molecule, the information or sequence of DNA stored in a computer is subject to the same considerations as DNA itself.

"Genetic information is one form of biological or medical information. Like other types of medical information, genetic analyses can reveal sensitive information about a person" (NBAC, 1999, p. 3). Yet, much genetic information is not precisely private. Personal genetic information is similar to, yet differs from, routine medical information about a single individual. It is alike, inasmuch as, the information may correspond with particular diseases, yet can differ because personal genetic information can also be familial. DNA information taken from one individual may have serious and unexpected ramifications not only for that particular individual, but also for the individual's relatives and others. Indeed, some commentators have proposed that informed consent procedures relevant to genetic tests should include family members (when applicable) as well as the individual person.

In general, however, considerations pertinent to personal medical information are also germane to genetic information. Personal medical histories may be difficult to hide (or, as is the case with applications for health or life insurance, are improper to conceal). A condition relevant for members in a family (e.g., inherited diseases like diabetes or heart disease) or a community (e.g., contagious diseases like tuberculosis and sexually transmitted diseases, or environmental hazards like West Nile virus) may be revealed from medical data belonging to a single member of that

family or community. In such cases, we are hesitant to deviate from individual consent procedures. Indeed, we remain reluctant to compel individuals who are living together (whether or not they are related) to share information about their medical history.

For the most part, genetic technologies are considered the purview of biomedical research and clinical genetics—i.e., for diagnosis, confirmation of diagnosis, information relevant to reproductive decisions, use in epidemiological studies, use in development of genetically targeted medicines (pharmacogenetics), functional genomics, etc.⁶⁴ Genetic information obtained from such procedures is *medical* information,⁶⁵ and when that is the case, informed consent and personal choice can still provide patients and potential research subjects a protection against unwanted touching.⁶⁶ However, there are serious implications hidden in the Moore court's remedy (the ruling that his physicians had a duty, in advance, to disclose all pertinent information and ask for his consent for the *use* of his tissue), which could have far reaching and complicated effects. Namely (and ironically given the court's ruling), the consent process could still curb the advancement of science, but not address the protections that a patient might have had in mind. For example, a research team may have the right to use blood samples taken with consent for one epidemiological study, but not for another more fruitful study, which had not been contemplated at the time of the original research project. On the other hand, patients also may not consider what protections may be important to them at a future time. People are not always prescient about their future needs. Not only do circumstances change, but what appears to be essential at one point in time, may not be required at another time (Backlar, 1998b).

There is, however, one protection that patients and research subjects rarely relinquish. In the practice of medicine, the patient's claim to privacy and the physician's promise to maintain confidentiality form the cornerstone of the physician-patient relationship. Patients trust their physicians and permit them to hold enormous power; in exchange, they expect physicians to be loyal and to act solely in their best interests (Backlar, 2001; Rodwin, 1993). Relevant to medical confidentiality, in research with human biological materials, e.g., where permanent cell lines can be created from tissue (as was done with Moore's discarded spleen), there may be numerous consequences to genetic research with human tissue involving not only financial and social issues, but also a compelling interest to access the information by other researchers, third parties, family members, and even the patients themselves. It is not reasonable to presume that the provision of individual informed consent alone—i.e., the choice to participate or not—will be

⁶⁴ Non-clinical applications of genetic technologies may involve genetic profiling. DNA evidence may be used for establishment of paternity (child support) or non-paternity, and for criminal prosecutions. In England, forensic scientists are developing a technique that uses DNA evidence to create a genetic 'photo-profile' of criminals. Forensic uses of genetic information are not intended to reveal medical information. In the U.S., researchers can request certificates of confidentiality in order to protect result from subpoena.

⁶⁵ "At the international level, the general ethical and legal requirements for medical research . . . constitute a *sine qua non* for genetic research, and exceptions are limited to overriding considerations or specific situations" (Knoppers *et al.*, 1998).

⁶⁶ Because some firms market medical genetic tests to the public directly, often through the internet, informed consent may not provide even this protection. Such genetic tests may be purchased without any medical and clinical oversight, or genetic counseling. Individuals can swab a few cells from inside their cheek and mail them to a company for genetic analysis. They could intentionally, and as easily, substitute someone else's DNA for their own.

adequate to secure medical privacy.⁶⁷ Indeed, in the words of Bartha Knoppers and colleagues (1997), “Ultimately . . . in order to respect autonomy and privacy, the problem is neither that of status or consent, nor of the confidentiality and security of samples and information but rather of the locus of that respect and the tool(s) to achieve it within society, human rights being both individual, collective and above all procedural in their realization.”

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⁶⁷ Some observers believe that multi-purpose genetic databases raise serious ethical questions relevant to consent, privacy, and commercialization. For example, Iceland’s Health Records Database, which contains “‘nonpersonally identifiable health data’ from the medical records of Icelandic citizens... [I]nformation included in this central database will come from a variety of sources, including health records, genealogical records, and genetic information from biological samples collected with informed consent . . .” (NBAC, 1999, p. 22).

In general, when information in a particular database is designated ‘not personally identifiable,’ it may be presumed that personal privacy is protected. However, in the case of *genetic* data, Gostin (1995) believes otherwise:

Genomic data that are not linked to identifiable individuals can significantly reduce, but not eliminate, privacy concerns. Genomic data are qualitatively different from other health data because they are inherently linked to one person. While non-genetic descriptions of any given patient’s disease and treatment could apply to many individuals, genomic data are unique. But, although the ability to identify named individual in a large population simply from genetic material is unlikely, the capacity of computers to search multiple databases provides a potential for linking genomic information to that person. It follows that nonlinked genomic data do not assure anonymity and that privacy and security safeguards must attach to any form of genetic material (p. 179).

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Exhibit E. HIPAA Privacy Rules: Anonymous and Coded Research

We have recommended that coded research be required to meet the standards for a limited data set under the HIPAA privacy rules.⁶⁸ We have also recommended that information, which has been deidentified within the meaning of HIPAA, qualify for anonymous research (page vi). This exhibit explains the HIPAA concepts of limited data set and de-identification.⁶⁹

Like Oregon's genetic privacy law and the Common Rule, HIPAA regulates individually identifiable health information. HIPAA defines information as individually identifiable if it identifies the individual, or if there is a reasonable basis to believe it can identify the individual.⁷⁰ We have recommended including this definition in the privacy law.⁷¹

HIPAA rules furnish two ways to reduce or eliminate the risk that an individual may be identified through research on information about the individual: de-identification and limited data sets. These are described below.

1. De-Identification

HIPAA rules exempt what they call "de-identified information,"⁷² i.e., information from which the possibility of individual identification has been stripped. If the material has been coded, then disclosure of the code is regulated by HIPAA, as is de-identified material that has subsequently been reidentified.

HIPAA rules offer two alternative ways to de-identify protected information:

- A statistical and scientific expert determines that the risk of identification is very small, and the disclosing entity documents the results of this analysis (the "expert test");⁷³ or
- Eighteen enumerated identifiers are stripped from the information, and the entity furnishing the information has no actual knowledge that the information could be re-identified (the "safe harbor").⁷⁴ The safe harbor does not require expert judgment.

⁶⁸ Recommendations 8(h) and 9, page vi.

⁶⁹ Recommendation 10(c), page vi.

⁷⁰ 45 CFR § 160.102 (definition of "individually identifiable health information").

⁷¹ Chapter 314, Oregon Laws 2001.

⁷² 45 CFR §§ 164.502(d), 164.514(a).

⁷³ "A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

"(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

"(ii) Documents the methods and results of the analysis that justify such determination" 45 CFR § 164.514(b)(1).

⁷⁴ "(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed [see list on page 59]; and

HIPAA rules also impose two standards on any code for re-identification of records:

- The code is not derived from individually identifiable information; and
- The code and the mechanism for re-identification are not disclosed.⁷⁵

The expert test is based on published guidance on how experts determine the risk of disclosing records.⁷⁶ This guidance discusses techniques an expert should consider in reducing the two main sources of risk: records with very unusual characteristics and the existence of external records that can be matched.

With respect to the safe harbor, the preamble to the HIPAA rules rejected the suggestion that stripping off only direct identifiers (e.g., name and social security number) would be sufficient to protect privacy. On the contrary, the preamble demonstrated that even age over 90 years or a 3-digit zip code could be an identifier in some cases.

2. Limited Data Sets

The latest amendments to the HIPAA rules permit an alternative approach under which records would be stripped of only a more limited set of direct identifiers, if the purpose of the disclosure is research, public health, or health care operations.⁷⁷

A limited data set resembles the second, safe harbor method of de-identification, in that specified personal identifiers are stripped from data in order to liberate users of the data from most HIPAA restrictions. The list of identifiers that a limited data set must omit is somewhat shorter and simpler than the list for de-identification.⁷⁸ Because this creates some risk of being “hacked” open to reveal identities, a limited data set may be used only pursuant to an express data use agreement with a business associate.⁷⁹ Research is a use to which a limited data set may be put.⁸⁰

“(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information” 45 CFR § 164.514(b)(2).

⁷⁵ “A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

“(1) Derivation. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

“(2) Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification” 45 CFR § 164.514(c).

⁷⁶ The preamble of the HIPAA rules (65 Fed Reg at 82709) cited: (1) *Statistical Policy Working Paper 22* Report on Statistical Disclosure Limitation Methodology

(<http://www.fcs.gov/working-papers/wp22.html>) (prepared by the Subcommittee on Disclosure Limitation Methodology, Federal Committee on Statistical Methodology, Office of Management and Budget); and (2) the *Checklist on Disclosure Potential of Proposed Data Releases*

(http://www.fcs.gov/docs/checklist_799.doc) (prepared by the Confidentiality and Data Access Committee, Federal Committee on Statistical Methodology, Office of Management and Budget).

⁷⁷ 45 CFR § 164.514(e).

⁷⁸ 45 CFR § 164.514(e)(2).

⁷⁹ 45 CFR § 164.514(e)(4).

⁸⁰ 45 CFR § 164.514(e)(3).

Unlike data de-identified by the safe harbor method, a limited data set may include five-digit zip codes and dates related to the individual. Also, to de-identify data completely under the safe harbor, in addition to removing 17 specific identifiers, one must satisfy a catch-all requirement for removal of, “any other unique identifying number, characteristic or code,”⁸¹ No comparable catch-all requirement applies to the limited data set, which accordingly is a more mechanical method to implement.

Below is a comparison of the requirements for de-identification and for limited data sets:

	De-Identification	Limited Data Set
Names	Exclude	Exclude
Postal addresses	Three-digit zip codes with 20,000 people permitted	City, state, and five-digit zip codes permitted
Dates	Exclude except for year and ages under 90 years	Permitted
Telephone numbers	Exclude	Exclude
Fax numbers	Exclude	Exclude
Electronic mail addresses	Exclude	Exclude
Social security numbers	Exclude	Exclude
Medical record numbers	Exclude	Exclude
Health plan beneficiary numbers	Exclude	Exclude
Account numbers	Exclude	Exclude
Certificate/license numbers	Exclude	Exclude
Vehicle identifiers and serial numbers, including license plate numbers	Exclude	Exclude
Device identifiers and serial numbers	Exclude	Exclude
Web Universal Resource Locators (URLs)	Exclude	Exclude
Internet Protocol (IP) address numbers	Exclude	Exclude
Biometric identifiers, including finger and voice prints	Exclude	Exclude
Full face photographic images and any comparable images and	Exclude	Exclude

⁸¹ 45 CFR § 164.514 (b)(2)(i)(R).

	De-Identification	Limited Data Set
Any other unique identifying number, characteristic, or code	Exclude	Permitted
Additional requirements	Code not derived from individually identifiable information	Data use and business associate agreements
Citations	45 CFR § 164.514(b)(2)	45 CFR § 164.514(e)

Exhibit F. Gene Patenting Bibliography

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Exhibit G. Oregon's Strategic Plan for Genetics and Public Health November 2002⁸²

Introduction to Oregon's Strategic Plan for Genetics and Public Health

Acknowledgements

We would like to thank those who gave their time, energy, and insights into Oregon's Genetics Assessment and Planning Project. A special thanks to:

- The individuals, families and community groups who participated in our assessment and planning activities;
- The students and their faculty members who so competently assisted in conducting assessment activities;
- The Oregon Department of Human Services;
- The Child Development and Rehabilitation Center at Oregon Health & Science University;
- The Genetics Steering Committee & Genetics Plan Advisory Council;
- Oregon's genetic service providers (e.g., geneticists, genetic counselors, laboratory professionals);
- Colleagues from other state genetic programs; and
- The Maternal and Child Health Bureau within the Health Resources and Services Administration (HRSA) for funding and technical assistance that made this project possible.

Overview

Rapid technological advances in the field of genetics and the potential impact of these advances on individual and population health make this area a high priority for public health consideration and planning. It is envisioned that as the role of genetics in many, if not most health processes, is further delineated, there will be marked changes in the scope and nature of genetics services as well as genetic information and policy needs. Though Oregon has had a number of excellent programs and resources to serve individuals and families impacted by inherited conditions and other special health needs, a comprehensive and coordinated effort addressing genetics and public health was needed.

⁸² Supported by a grant from the Maternal and Child Health Bureau
Grant # 4 H46 MC 00172-02-1.

Recognizing the emerging importance of genetics for public health, the Oregon Department of Human Services, Office of Family Health and the Child Development and Rehabilitation Center at Oregon Health & Science University applied for and received a two-year federal grant from the HRSA Maternal and Child Health Bureau to conduct an assessment of Oregon's genetic health care system and develop a state public health plan to improve existing or develop new genetic health services and resources. The assessment and planning process began in June 2000 and was carried out by state Genetics Program staff with guidance from the Genetics Plan Advisory Council, a broad-based group of state and community partners. Program staff used the "ten essential services of public health" as a framework for the assessment process. Issues such as health data collection and analysis, public information and education, health care workforce competency, health services access and quality, health policy development, research and partnerships were all addressed from a "genetics" perspective. The assessment included a comprehensive inventory of current genetic health services and resources as well as an array of community assessment activities (e.g., interviews, surveys, focus groups and other group processes) with diverse stakeholders. Using assessment findings, a strategic plan was developed to guide the activities of the State Genetics Program and its partners over the next 3-5 years.

Key assessment findings included:

- An identified need to increase public health capacity (e.g., trained public health staff and resources) to address current and emerging genetic health issues
- A need to collect more data about genetics and health (e.g., genetic conditions, birth defects, genetic health services) to guide public health planning and system improvement
- A need to enhance public understanding of genetics and the impact of genetics on health, with significant community interest in learning about these topics
- A recognition on the part of health care providers and consumers that genetic concepts are not generally incorporated into routine health care practice and a desire for additional training and technical assistance resources to make this happen
- A need identified on the part of individuals with inherited conditions, particularly adults, for more comprehensive and coordinated primary care services
- A recognition that Oregon has a cadre of skilled genetics professionals and an array of quality genetic services (e.g., genetic counseling, genetic testing, newborn screening), but that there remain a number of barriers to accessing services, including lack of awareness about the services, cost and insurance reimbursement for services, lack of services outside of the metropolitan areas and cultural barriers
- A general desire to expand and enhance population-based services (e.g., newborn screening) to benefit larger segments of the population, as long as personal choice is not compromised
- An identified need to inform public policy makers about the implications of genetic advances and to continue efforts to address community concern about issues such as genetic privacy and discrimination

- A need to assure involvement of diverse stakeholders, including multicultural groups and consumers, in genetic public policy decisions

Structure of the plan:

Oregon's Strategic Plan for Genetics and Public Health includes the following components: mission (our purpose for being); vision (our view of an ideal world); broad-based goals (what we want to happen as a result of our efforts), strategies (how we will work toward our goals), strategic objectives (our priority areas of focus over the next 3-5 years), tactics (things that we will do to address our priority areas), partners and resources (people, agencies, etc. that we will work with to meet our goals and address our priorities), timeline (target dates for initiation of activities in particular areas), and outcomes that may be impacted by strategies (measurable outcomes that we can monitor to track progress towards our goals).

Specific details about activities and dates will be incorporated into a Genetics Program work plan. Some of the specifics will depend largely on available resources and funding. The strategic plan will provide direction as we seek out these resources. A detailed evaluation plan will also be developed.

The strategic plan is meant to be a fluid document, one that can and will change with new findings and new priorities. Comments and suggestions are always welcome as we strive to make this a living, working document.

Notes on language and wording:

Throughout the plan we strove to use language that is inclusive and positive. In general, we chose the term "inherited conditions," rather than genetic conditions to reflect the broad scope of conditions that are either primarily or partially genetic in nature. As more is learned about the interrelationship of genetics and health, it becomes increasingly clear that most if not all health conditions have a genetic component. Birth defects, referring primarily to congenital anomalies, were included in the plan intentionally. In practice, the needs of individuals and families that are impacted by birth defects and genetic conditions are similar.

The term "genetic services" is used throughout the document. This term refers to clinical health services that focus on the genetic or inherited components of health and disease. Genetic services may either be "primary level" services, provided by a primary care provider such as a family physician, or "specialty" services provided by trained genetics professionals such as genetic counselors or medical geneticists. In general, the use of the term "genetic services" in the plan reflects the "specialty" level of service unless otherwise noted.

Individual health services refer to services that are provided in the context of personal health care and are directed at meeting the needs of a particular individual or family. Population-based services refer to services such as newborn screening that are carried out on a population level (e.g., all newborns).

For questions or comments, please contact us at:

The Genetics Program

(A joint program of the Oregon Department of Human Services, Office of Family Health and the Oregon Health & Science University, Child Development and Rehabilitation Center)

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Glossary of Abbreviations and Acronyms

ASTHO ᵀ Association of State and Territorial Health Officials

ACGPR ᵀ Advisory Committee on Genetic Privacy and Research (statutory committee formed in 2001 to advise legislature on genetic policy issues)

CDC ᵀ Centers for Disease Control and Prevention (federal agency)

DHS/HS ᵀ Oregon Department of Human Services/Health Services (formerly Oregon Health Division)

DHS/HS/OFH ᵀ Office of Family Health (Oregon's state Title V agency)

HRSA ᵀ Health Resources and Services Administration (federal agency within the U.S. Department of Health and Human Services)

OHSU/CDRC ᵀ Oregon Health & Science University/Child Development and Rehabilitation Center (Oregon's Title V agency for children with special health needs)

Oregon's Strategic Plan for Genetics and Public Health (updated November 2002)

Mission

To improve the health and well-being of people living in Oregon who are impacted by inherited conditions and birth defects

Vision

We envision a world where genetics is viewed as an integral component of health and health care, where human genetic variation is celebrated, and where all people benefit from advances in genetic science and technology while privacy and personal choice are maintained.

Goals

- Reduce morbidity and mortality from inherited conditions and birth defects
- Improve quality of life for individuals and families impacted by inherited conditions and birth defects
- Empower people to make informed decisions about genetics and health

Strategies

I. Build public health infrastructure needed to address current and emerging issues in genetics and health

- a. Increase state genetics program capacity and ensure sustainability*
- b. Ensure that state genetics program content is up-to-date and consistent with national, state and community priorities
- c. Enhance genetics content and competency of other public health programs and services

II. Improve availability and quality of data about inherited conditions, birth defects, and genetic services for public health planning and system improvement

- a. Increase availability of accurate, up-to-date information about incidence, prevalence and health outcomes for inherited conditions and birth defects
- b. Increase availability of information about utilization, access and quality of genetic services

III. Educate the public about genetics and health

- a. Increase public awareness of genetic services and resources in Oregon*
- b. Increase public understanding of basic genetic principles and health issues, including ethical, legal and social implications of genetic advances
- c. Increase public awareness and practice of healthy behaviors to reduce risk of birth defects

IV. Promote integration of genetics into health care practice

- a. Increase health care provider understanding of genetic concepts and how they relate to health and health care*
- b. Strengthen primary care provider capacity to provide “primary level genetic services” across the lifespan
- c. Increase health care provider promotion of healthy behaviors to reduce risk of birth defects
- d. Increase health care provider awareness and use of genetic services and resources

V. Improve availability and access to individual and population-based genetic services

- a. Increase insurance coverage and reimbursement for genetic services and supports*
- b. Increase availability of genetic services outside of the Portland metro area*
- c. Decrease cultural barriers to genetic services*
- d. Expand/enhance newborn screening services for inherited and congenital conditions that are amenable to early identification and intervention

VI. Promote the development of public policy that protects individual and family health and privacy while supporting advancements in genetic science and technology

- a. Increase policy maker understanding of the ethical, legal and social implications of genetics and genetic technology*
- b. Address concerns about genetic privacy and discrimination
- c. Ensure diverse input into public policy decisions about genetics

*Denotes priority objectives as identified by the Genetics Plan Advisory Council

I. Build public health infrastructure needed to address current and emerging issues in genetics and health

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
Increase the state genetics program capacity and ensure sustainability	Identify program staffing and resource needs	DHS/HS-Office of Family Health OHSU/CDRC	In progress (July 2002)
	Secure short and long term funding for program staff and activities	DHS/HS-Office of Family Health, Office of Medical Assistance Programs Federal partners (HRSA, CDC) Other funders (e.g., NW Health Foundation)	Ongoing
	Centralize educational information, resources and technical assistance within the state genetics program	DHS/HS-Office of Family Health OHSU/CDRC	Ongoing
	Develop and maintain an accessible genetics program website	DHS/HS-Office of Family Health OHSU/CDRC	Initial target-September 2002 Revised target-January 2003

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Market the genetics program and its resources to the general public, health care providers, and key public health and other state policy leaders	DHS/HS-Administration OHSU/CDRC-Administration	January 2003
Ensure that the state genetics program content is up-to-date and consistent with national, state and community priorities	Convene an expert advisory body to guide program direction and provide input into policies	Consumers/family advocacy Genetic service providers Health professionals/systems Ethicists/academicians	In progress (September 2002)
	Create opportunities for public dialogue and input from diverse communities into program activities and decisions	Multicultural, faith, business, academic communities DHS/HS-Office of Multicultural Health Geneforum.org Pacific University (Marc Marenco)	January 2003 and ongoing
	Monitor state and national genetics and health policy issues and activities and incorporate into genetics program planning and activities	Federal partners (ASTHO, CDC, HRSA)	Ongoing

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Develop an ongoing evaluation process for the state genetics program and the strategic plan	Genetics advisory committee	Initial target-July 2002 (and annually) Revised target-December 2002
Enhance genetics content and competency of other public health programs and services	Create a cross-program work group to identify opportunities for incorporating genetics into existing programs and services	DHS/HS- maternal and child health, chronic disease prevention/health promotion, environmental health programs OHSU/CDRC Local health departments	January 2003
	Develop educational opportunities in genetics for state and local public health program staff	DHS/HS-Offices Local health departments	Initial target-January 2003 Revised target-July 2003

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Assure that genetics program staff and genetics professionals participate in work groups or activities that address conditions or topics of public health concern Newborn hearing screening Newborn metabolic screening Birth Defects Cardiovascular health Asthma Obesity Diabetes Cancer Racial and Ethnic Health Disparities Others	DHS/HS-Offices OHSU/CDRC Genetic service providers	Ongoing

Outcomes that this strategy may impact:

- Increase proportion of public health program staff who have attended a genetics educational event
- Identify and increase the proportion of public health program staff who demonstrate understanding of basic genetic principles and applicability to public health
- Increase the proportion of public health program materials that include genetics information

II. Improve availability and quality of data about inherited conditions, birth defects, and genetic services for public health planning and system improvement

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
<p>Increase availability of accurate, up-to-date information about incidence, prevalence and health outcomes for selected inherited conditions and birth defects</p>	<p>Participate in the development of a module within the consolidated child and family health information system (FamilyNET) that supports identification and follow-up of children with special health needs, including those with inherited conditions and birth defects</p>	<p>DHS/HS-Office of Family Health, Office of Disease Prevention and Epidemiology (Vital Statistics), Public Health Lab OHSU/CDRC (HRSA Community Integration Grant) Oregon Commission on Children and Families Oregon Dept of Education</p>	<p>In progress</p>
	<p>Link newborn metabolic and hearing screening data with birth certificates to improve case finding</p>	<p>DHS/HS-Office of Family Health, Office of Disease Prevention and Epidemiology (Vital Statistics), Public Health Lab</p>	<p>In progress</p>
	<p>Support efforts to improve the accuracy of information about inherited conditions and congenital anomalies that is collected on birth certificates</p>	<p>DHS/HS-Office of Disease Prevention and Epidemiology (Vital Statistics) Birthing facilities</p>	<p>Ongoing</p>

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Support research studies to evaluate interventions and health outcomes for specific inherited conditions or birth defects	DHS/HS-Public Health Lab (Newborn Screening Program) OHSU/CDRC- Genetics and Birth Defects Clinics Other genetic service providers (Kaiser, Legacy, Providence)	In progress (September 2002)
	Explore the development and implementation of a state birth defects surveillance system	DHS/HS-Office of Family Health (Genetics), Office of Disease Prevention and Epidemiology OHSU/CDRC March of Dimes Hospitals/birthing facilities Federal partners (HRSA, CDC)	In progress (September 2002)
	Determine feasibility/desirability of increasing genetic or family history information in existing disease registries and surveillance systems Cancer Registry Diabetes Surveillance Asthma Surveillance	DHS/HS-Office of Disease Prevention and Epidemiology (Chronic Disease)	July 2003

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Develop and implement targeted data collection methodologies that are inclusive of people of color to help identify and mitigate disparities related to inherited conditions and birth defects	Office of Multicultural Health African American Health Coalition Other Community Partners	January 2004
Increase availability of information about utilization, access and quality of genetic services	Use existing population surveys to obtain information about access to and utilization of genetic services Pregnancy Risk Assess and Monitor System (PRAMS) Oregon Healthy Teens Survey Behavioral Risk Factor Surveillance System (BRFSS)	DHS/HS- Office of Family Health; Office of Disease Prevention and Epidemiology	Initial target-July 2003 Revised target-Janaury 2004
	Explore the feasibility of standardized collection of core genetic services data from Oregon providers	Genetic service providers	July 2004
	Conduct surveys or other activities to further delineate health care provider practices related to genetics	OHSU (Genetics Dept -S. Hayflick)	July 2003

Outcomes that this strategy may impact:

- Identify incidence and prevalence of common birth defects/congenital anomalies (e.g., neural tube defects, cleft lip/palate, Down syndrome, congenital hearing loss) and document disparities
- Identify referral and utilization patterns for various genetic services and document disparities (e.g., multiple marker screening for pregnant women, prenatal cystic fibrosis carrier screening, genetic evaluation for congenital hearing loss)

III. Educate the public about genetics and health

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
Increase public awareness of genetic services and resources in Oregon (high priority)	Create and disseminate materials about how to access Oregon genetic services and other genetics-related resources	OHSU/CDRC Pacific Northwest Regional Genetics Group (PacNoRGG) Genetic service providers Support groups	Initial target-July 2002 Revised target-September 2002 In Progress
	Create and disseminate consumer-oriented information about Oregon's Genetic Privacy Act	Advisory Committee on Genetic Privacy and Research	Initial target-September 2002 Revised target-January 2003
Increase public understanding of basic genetic principles and health issues, including ethical, legal and social implications of genetic advances	Advocate for enhancements to the state K-12 science and health benchmarks and curriculum related to genetics	Oregon Dept. of Education Schools of Education (teacher training)	July 2003
	Improve quantity and accuracy of genetics information published in Oregon-based media	Newspapers (Oregonian, Eugene Register Guard, Salem Statesman) TV/Radio (Oregon Public Broadcasting and others)	In progress (September 2002)

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Identify opportunities to bring genetics-related information to interested community groups (e.g., incorporating genetics information into presentations about health topics that are relevant to a particular community or population)	Key informant interview contacts Multicultural communities Faith community Business community	Initial target-January 2003 Revised target-January 2004
Increase public awareness and practice of healthy behaviors to reduce risk of birth defects	Participate in the development of a social marketing campaign to increase use of multivitamins with folic acid by women of reproductive age	March of Dimes DHS-Folic Acid Committee (Perinatal and Child Health, Adolescent Health, Women's and Reproductive Health, WIC)	Initial target-September 2002 Revised target-January 2003
	Create (or) compile and disseminate educational materials related to birth defects prevention and avoidance of known teratogens	March of Dimes National Birth Defects Prevention Network CDC Center for Birth Defects and Developmental Disability	January 2003

Outcomes that this strategy may impact:

- Identify and increase the proportion of K-12 students having coursework in genetics that covers basic principles as well as ethical, legal and social implications of genetic advances
- Identify and increase the proportion of K-12 students who demonstrate understanding of basic genetic principles
- Increase the proportion of pregnancies initiated with optimal folic acid use
- Decrease the incidence of neural tube defects (e.g., spina bifida)

IV. Promote integration of genetics into Oregon health care practice

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
<p>Increase health care provider understanding of genetic concepts and how they relate to health and health care (high priority)</p>	<p>Advocate for the addition or enhancement of case-based, experiential genetics content in Oregon health professional training programs, including:</p> <ul style="list-style-type: none"> Nursing Allied Health Mental Health/Social Work Public Health Medicine 	<p>Public Health Training Programs (OHSU, PSU, OSU)</p> <p>Nursing Schools (OHSU, Univ. of Portland, Linfield College)</p> <p>Allied Health Training Programs (OT, PT, Speech, Audiology, PA)</p> <p>Social Work/Mental Health Training Programs</p> <p>Medical Training Programs (OHSU)</p>	<p>July 2003</p>
	<p>Incorporate practical genetics education into existing continuing health professional education activities (or) develop new continuing education programs</p>	<p>Professional medical organizations (Oregon Academy of Family Physicians, Oregon Pediatric Society, American College of Obstetrics and Gynecology-Oregon chapter, Oregon Nurses Association, mental health professionals, others)</p>	<p>April 2003</p>
	<p>Create and disseminate informational materials for health care providers about implementation of Oregon's Genetic Privacy Act</p>	<p>Advisory Committee on Genetic Privacy and Research</p>	<p>Initial target-September 2002</p> <p>Revised target-January 2003</p>

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
<p>Strengthen primary care provider capacity to provide “primary level genetic services” across the lifespan</p>	<p>Disseminate professional standards and guidelines to primary care providers</p> <p>General standards and guidelines for incorporating genetics into primary care (e.g., taking family history, identifying and evaluating risk)</p> <p>Guidelines for management of specific diseases or conditions across the lifespan (e.g., managing an adult with Down syndrome, a pregnant woman with PKU)</p>	<p>National professional organizations (American College of Medical Genetics, American Academy of Pediatrics)</p> <p>Genetic service providers</p>	<p>Ongoing</p>
	<p>Develop or create links to tools (e.g., web-based) for primary care providers to have timely access to accurate information about diagnosis and management of specific inherited conditions or genetic risks</p>	<p>GeneReviews web page</p> <p>Genetic service providers</p>	<p>January 2004</p>

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Support the development of ongoing technical assistance/mentorship to primary care providers by genetic service providers (e.g., consider development of a provider hotline)	Genetic service providers	January 2004
Increase health care provider promotion of healthy behaviors to reduce risk of birth defects	Participate in the development of an educational campaign to increase health care provider promotion of multivitamins with folic acid for all women of reproductive age	March of Dimes DHS/HS-Folic Acid Committee	Initial target-September 2002 Revised target-July 2003
	Participate in the development of an educational campaign to increase health care provider recognition and early intervention for alcohol and other drug use during pregnancy	DHS/HS-Office of Family Health; Office of Mental Health and Addiction Services Northwest Indian Tribes Health professional organizations March of Dimes	September 2003
Increase health care provider awareness and use of genetic services and resources	Create opportunities for networking between health care providers and genetic services providers	Genetic service providers Health professional organizations	September 2003

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Create and disseminate informational materials targeted at health care providers about accessing genetic services in Oregon	PacNoRGG Genetic service providers	In progress (September 2002)

Outcomes that this strategy may impact:

- Increase proportion of health professional training programs that include genetics throughout training curriculum
- Increase proportion of physicians who have received specific training in the use and interpretation of genetic tests
- Increase proportion of physicians who routinely complete a comprehensive three-generation family history with their patients
- Increase proportion of individuals, especially adults, who have special needs due to inherited or congenital conditions who have a “medical home” (comprehensive, coordinated primary care)
- Increase proportion of primary care providers who routinely recommend multivitamins with folic acid to all women of reproductive age
- Increase proportion of primary care and prenatal care providers who routinely ask women about alcohol use and provide education about the effects of alcohol on pregnancy outcomes
- Increase the frequency of medically indicated referrals to genetic specialty services

V. Improve availability and access to individual and population-based genetic health services

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
Increase insurance coverage and reimbursement for genetic services and supports (high priority)	Develop educational presentations for health plan administrators about the role and value of genetic services in prevention and health promotion	DHS/HS-Office of Medical Assistance Programs Health plans/insurers	Initial target-September 2002 Revised target-January 2003
	Advocate for health plan quality assurance and improvement measures related to genetic services (primary and specialty level services) as an incentive to assure service coverage	Health plans/insurers	January 2003
	Identify and support genetic service provider billing practices that optimize reimbursement	American College of Medical Genetics resources Genetic service providers Health plans	Initial target-September 2002 Revised target-July 2003
	Identify and secure funding for genetic services for uninsured and underinsured Multiple marker screening during pregnancy	DHS/HS-Office of Medical Assistance Programs	January 2004

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Explore feasibility & desirability of promoting legislation to mandate: licensure of genetic counselors and insurance reimbursement for genetic counseling	Genetic service providers Health plans Dept of Consumer and Business Affairs (Insurance Division)	In progress (September 2002)
Increase availability of genetic services outside of the Portland metro area (high priority)	Develop and implement plan for delivering genetic services in rural and outlying areas using nontraditional methods (e.g., telemedicine)	Oregon Health & Science University Other genetic service providers	July 2003
	Support the development of ongoing technical assistance/mentorship from genetic service providers in Portland to health care providers in rural areas	Genetic service providers Primary care professional organizations (family medicine, internal medicine, pediatrics, obstetrics)	January 2004
Decrease cultural barriers to genetic services (high priority)	Create and disseminate culturally sensitive educational materials about genetic health services, including development of materials in multiple languages	HRSA-Tandem Mass Spectrometry: Financial, Ethical, Legal, Social Issues SPRANS grant partners (HI, ID, WA, CA, AK)	In progress

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Create educational opportunities for genetic service providers and other health providers to learn about cultural issues that impact perceptions about genetics and health practices	DHS/HS-Office of Multicultural Health Genetic service providers Health professional organizations Multicultural community groups	July 2003
	Create educational opportunities for medical interpreters to improve their skills related to genetic service visits	Medical interpreters Genetic service providers	Initial target-July 2003 Revised target-July 2004
Expand/enhance newborn screening services for inherited and congenital conditions that are amenable to early identification and intervention	Implement tandem mass spectrometry technology and screening protocols for Medium Chain Acyl CoA-Dehydrogenase Deficiency (MCADD) and other inherited metabolic disorders	DHS/HS-Public Health Lab (Newborn Screening Program)	Initial target-August 2002 Revised target-October 2002 (completed)
	Update endocrine testing technology to screen for congenital hypothyroidism and congenital adrenal hyperplasia	DHS/HS-Public Health Lab (Newborn Screening Program)	April 2003

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Convene newborn metabolic screening program advisory body to provide guidance on policies such as selection of additional conditions for screening	DHS/HS-Public Health Lab (Newborn Screening Program)	January 2003
	Create and disseminate culturally competent information about expanded newborn screening services to health care providers and expectant/new parents	DHS/HS-Public Health Lab (Newborn Screening Program) HRSA Tandem Mass Spectrometry: SPRANS Grant Prenatal care providers/birthing facilities	In progress

Outcomes that this strategy may impact:

- Increase proportion of health plans that cover genetic services for at-risk individuals and their family members
- Increase proportion of genetic service claims that are reimbursed at fair market value
- Increase proportion of uninsured/underinsured individuals who receive medically indicated genetic services (e.g., multiple marker screening, genetic counseling for undocumented pregnant women)
- Increase proportion of state population with access to genetic services within 50 miles
- Increase proportion of medical interpreters who have received basic genetics education
- Increase proportion of expectant/new parents who are aware of the newborn metabolic screening program purpose and process
- Increase the number of children with Medium Chain Acyl CoA-Dehydrogenase Deficiency (MCADD) who are identified within the first two weeks of life
- Increase the number of children with Congenital Adrenal Hyperplasia (CAH) are identified within the first two weeks of life

VI. Promote the development of public policy that protects individual and family health and privacy while supporting advancements in genetic science and technology

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
Increase policy maker understanding of the ethical, legal and social implications of genetics and genetic technology (high priority)	Develop educational materials and presentations for legislators, their staffs, and other policy makers about the policy implications of advances in genetics	DHS/HS-Legislative affairs Legislators Advisory Committee on Genetic Privacy and Research	January 2003
Address concerns about genetic privacy and discrimination	Convene and facilitate state Advisory Committee on Genetic Privacy and Research (ACGPR)	ACGPR committee members: Consumers Biotechnology/ pharmaceutical industry Academic/Research institutions Health professionals/ clinicians Bioethics American Civil Liberties Union (ACLU)	In progress
	Promulgate and implement administrative rules corresponding to Oregon Genetic Privacy Act	ACGPR committee members	In progress (September 2002)
	Create opportunities for public dialogue and input into public policy decisions related to genetic privacy and discrimination issues	ACGPR committee members Geneforum.org (public opinion survey)	Initiated July 2002 and ongoing

Strategic Objectives	Tactics	Partners/Resources	Timeline (target initiation)
	Study and develop policy recommendations related to: Genetic discrimination in insurance and employment settings Adoption issues (privacy of genetic information about biological parents) Reproductive technologies (privacy of genetic information about egg and sperm donors)	ACGPR committee members	July 2003
Ensure diverse input into public policy decisions about genetics	Maintain advisory bodies that represent the cultural, professional, geographic, gender and age diversity of the state	Advisory Committees (ACGPR, Newborn Screening Advisory Committee, Genetics Advisory Committee)	Ongoing
	Develop an ongoing review process to assure that opportunities for public input are accessible to individuals from diverse backgrounds	DHS/HS-Office of Multicultural Health	Ongoing

Outcomes that this strategy may impact:

- Identify and decrease occurrence of violations of state genetic privacy rules and regulations
- Increase proportion of Oregon legislators who have participated in an educational session on genetics and public policy

Exhibit H. Geneforum Public Input Survey Report



July 9, 2002

To: Greg Fowler, Geneforum

From: Adam Davis, Davis, Hibbitts & McCaig, Inc.

Re: Geneforum Survey Questions

I. Introduction

Davis, Hibbitts & McCaig, Inc. (DHM) is pleased to present the results of a statewide telephone survey conducted during June to assist Geneforum in assessing public attitudes regarding genetic privacy. The survey findings will assist Geneforum to provide public input to the deliberations of the Advisory Committee on Genetic Privacy and Research.

The sample size for the survey was 500. Respondents were age 18 and over and randomly drawn from the state's general population. This memo will highlight key findings and note significant subgroup variations for gender, age, years of residence, and area of residence. For additional information, please see the accompanying set of data tables.

Statement of Limitations. In gathering the responses, DHM employed quality control measures which included questionnaire pretesting, callbacks, and verification.

Any sampling of opinions or attitudes is subject to a margin of error, which represents the difference between a sample of a given population and the total population (here, Oregon's general population age 18 plus). For a sample size of 500, if the respondents answered a particular question in the proportion of 90% one way and 10% the other, the margin of error would be +/- 2.63%. If they answered 50% each way, the margin would be +/- 4.38%. The reason for the difference lies in the fact that when response categories are relatively even in size, each is numerically smaller and thus slightly less able - on a statistical basis - to approximate the larger population.

These plus-minus error margins represent differences between the sample and total population at a confidence interval, or probability, calculated to be 95%. This means that there is a 95% probability that the sample taken for this study would fall within the stated margins of error if compared with the results achieved from surveying the entire target population.

II. Results

Respondents were given a brief statement about genetic research:

"In genetic research, scientists examine the genes in samples of material from human beings, like blood samples. I have two questions about how you think scientists should be able to use blood samples taken from your body as part of your health care."

Based on this set-up, they were first asked:

"Suppose the scientist will conduct the genetic research in a way that makes it impossible for anyone to identify the blood sample as coming from you. How important is it to you to have the opportunity to refuse permission for your blood sample to be used in genetic research?"

Over half (53%) chose *very* important, 16% said somewhat important, 12% said not too important, 16% chose not at all important, and 2% were unsure or did not respond (Table 1). Fully 69% chose important, compared to 28% choosing not important. Although strictly speaking this is not a true scaled variable, it might be of interest to note that, if very important=1 and not at all important=4, the mean of 1.91 (S.D. = 1.15, n=488) fell on the important side of the scale.

Respondents were then asked:

“Suppose the blood sample was taken from you several years ago and stored, and you were not told it might be used in genetic research. Today, a scientist wants to use your blood sample in genetic research and the information that identifies you is coded so the researcher does not know who you are. What sort of notification would you require from the genetic researcher before your stored blood sample is used in genetic research?”

A quarter (24%) said they would not require any notification, 16% would require notification only once, 57% wanted the opportunity to consent or refuse for each project, and 3% were unsure or did not respond (Table 2). If we combine the two response categories which required some sort of notification, almost three-fourths (73%) wanted notification before use.

This question was significant by age. The two younger age groups (18-34 and 35-54), compared to older respondents, wanted the consent or refuse option for each project (64%, 60%, compared to 50%). Older respondents (age 55+), compared to other respondents, were more likely to choose the not required option (16%, 20%, compared to 33%). Percents requiring notification only once did not vary by age (18%, 17%, 12%).

III. Conclusion

The survey findings clearly demonstrate the importance the public places on knowing about the possible use of their blood sample for genetic research. More than two-thirds (69%) thought it important to be able to refuse permission, even if there were no way to identify the blood sample came from them.

Nearly three-quarters of all respondents wanted some kind of notification that their blood sample might be used in research, even where information was coded so the researcher could not identify them. A majority (57%) wanted the opportunity to consent or refuse for *each* project.

These responses lead us to conclude there is a fairly strong level of agreement among the general public in Oregon for consent to use a blood sample for genetic research. There were no significant subgroup variations for the first question, and only one for the second, meaning these opinions generally are held across all demographic groups. Given these findings, it would be advisable for any public policy decisions regarding genetic research to take them into account.