Analysis of state laws on informed consent for clinical genetic testing in the era of genomic sequencing

(Informed consent for clinical genetic testing)

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ABSTRACT

This article assesses the adequacy of informed consent to clinical genetic testing laws based on an examination of 15 states with institutions that had been involved in a National Institutes of Health-supported Clinical Sequencing Exploratory Research Consortium project. We identified relevant statutory provisions through a legal search engine and included statutes that describe the informed consent requirements for clinical genetic testing and/or the protections for genetic material, information, or data. We found that statutory definitions were often limited in problematic ways, such as focusing only on variants known to be associated with disease or negative health effects or associated with asymptomatic disease. Some statutes required complex levels of detail if applied to genomic technologies and set confusing disclosure standards for current use and future access. Others had exceptions from informed consent requirements for future research use, limited requirements for the destruction of specimens as opposed to derived data, or linked key definitional components to the evolving concept of "identifiability." Further reform and research are needed to ensure that state law protections advance as rapidly as the science they aspire to enable.

Key Words: Law, informed consent, policy, identifiability, genetic counseling

INTRODUCTION

The informed consent process is the main mechanism through which we protect and enable patients' decision-making. Many states have recognized informed consent for clinical genetic testing as an area warranting special protections, but such laws were generally conceptualized in an era when genetic tests involved targeted analysis for disease and provided specific and limited information about a single variant. Since that time, fundamental advances in genetic technologies—including approaches such as whole genome or exome sequencing, microarrays, and other technologies that allow simultaneous analysis of many genes—have transformed clinical genetic testing. It is therefore critical for genetic counselors, who are often involved in obtaining consent from patients for genetic testing, to ask how best to counsel patients in making good health care decisions for themselves going forward. Part of addressing that question involves considering whether these laws are adequately tailored toward enabling such conversations.

In general, most of the original clinical genetic testing laws paired requirements for informed consent with protections against non-consensual use of genetic information. This was motivated by the goal of restricting insurers (especially health insurers) or employers from using genetic information against customer or employee interests (Yesley, 1997). Given the sweeping changes in the science of genomic testing, this article seeks to assess the adequacy of current genetic-specific state laws on informed consent based on an examination of 15 states. We undertook this analysis as a subgroup of the Informed Consent and Governance Working Group of the first stage of the Clinical Sequencing Exploratory Research (CSER1) Consortium,

which explored challenges to integrating genetic sequencing into clinical settings (Green et al., 2016).

Past summaries and critiques of state genetic testing laws have focused on a specific type or context of genetic testing—e.g., whole genome sequencing, health insurance, employment, research—or were completed prior to the development of the most recent genomic technologies (PCSBI, 2012; Hall & Rich, 2000; Rothenberg, 1995; Rothenberg et al., 1997; Hakimian, Taube, Bledsoe, & Aamodt, 2004; McEwen & Reilly, 1992). Here we focus on the current intersection of the law with a wide array of modern testing technologies and conclude that in many states, informed consent laws for clinical genetic testing as currently written pose significant challenges for clinicians and are not suited to address modern technologies. Although genetic counselors must work within the confines of current law, we recommend that when in gray zones or areas of conflict, they should focus on information that aligns with stated patient values and comports with the spirit of the law: helping patients make better-informed decisions for themselves and their families. Finally, we recognize that genetic counselors will have an important role to play as advocates for improved statutes.

MATERIALS AND METHODS

We examined state laws specific to informed consent for genetic testing from fifteen states where institutions that had been involved in a CSER1 Consortium project were located (AL, CA, MD, MA, MI, MN, MO, NY, NC, OH, OR, PA, TN, TX, WA). Although CSER is a research program, it focuses on the integration of genome sequencing in clinical care. Thus, these states are among those most likely to have the laboratories, geneticists, and technologies available for

rapid introduction of advanced genetic technologies into clinical care—making them appropriate targets for an examination of laws related to informed consent.

Informed consent rules are derived from a complex intersection of state and federal case law, statutes, and regulations (e.g., state laws on general clinical informed consent and relevant federal anti-discrimination legislation such as the Americans with Disabilities Act (ADA) and the Genetic Information Nondiscrimination Act (GINA)). Our research here focuses on *state statutes* addressing informed consent for clinical genetic testing. These statutes arguably play the greatest role in shaping day-to-day informed consent disclosures but also create variability for providers across the country. We identified relevant state statutory provisions through the legal search engine LexisNexis Academic, using search terms "genetic OR genomic AND test OR testing," as well as "'genetic information' AND consent OR authorization." We narrowed these findings by including only those that related to genetic material, information, or data. We excluded statutes that only included discrimination protections or "opt-outs" as well as those that did not focus on informed consent to clinical genetic testing. Ten of the 15 CSER states (CA, MD, MA, MI, MN, MO, NY, OR, TN, TX) had laws that met our inclusion criteria (**Supplement**).

Prior to data collection, the authors identified categories of information to be collected. Initially, two authors (KSB, AP) collected data from six pilot states for review. The research team then iteratively organized information into categories based on previous state reviews. Two authors (KSB, AP) then undertook statute identification and data collection. Through a series of group discussions, the team identified areas on which to focus our analysis, relevant critiques, and conclusions.

RESULTS

Here we focus on three areas that we hypothesized would be of most relevance to genetic counselors affected by modern advances in genetic science and technology: (1) the definitional scope of informed consent protections, (2) the content of informed consent disclosures, and (3) possible future research use of specimens collected in the clinical context. We also present and analyze the state statutes relating to these areas while highlighting potential issues for practicing clinicians.

Scope of protections

First we examine the definitions (i.e., "genetic characteristic," "genetic information," or "genetic test") that set the scope of subsequent informed consent protections in light of new genomic technologies—including protections for testing, use, retention, disclosure, and future research use of clinical specimens or data (e.g., Mass. Ann. Laws ch. 111 § 70G(c)(1), 2016; Mich. Comp. Laws § 500.3829a(7), 2016; Minn. Ann. Stat. § 13.386(Subd. 3)(a)(3), 2016; Cal. Insurance Code § 742.407(b), 2016; MD. Code Ann., Ins. § 27-909(d), 2016). We found these definitions to be limited in several problematic ways for genetic counselors seeking to explain them in the consent process, including that they focus only on variants *known to be associated* with disease or *negative* health effects or variants associated with asymptomatic disease—whereas a genetic counselor's actual practice often goes beyond such limits (**Table 1**).

In six of the states surveyed (CA, MD, MI, MN, TX) the definition of genetic characteristic, test, or predisposition was limited to variants that are known, determined, or scientifically or medically accepted or believed to be associated with disease or disorder (Cal. Health & Safety Code § 1374.7(d), 2012 (incorporated by reference in Cal. Civil Code § 56.17(h), 2017); Cal. Insurance Code § 10147, 2000; MD. Code Ann., Ins. § 27-909(5), 2016; MD. Code

Ann., Ins. § 27-909(a)(3), 2016; Mich. Comp. Laws § 333.17020(8)(b); Mich. Comp. Laws § 333.17520(8)(b), 2016; Minn. Ann. Stat. § 72A.139(Subd. 2)(b), 2016; Tex. Insurance Code Ann. § 546.001(2, 4); Tex. Labor Code Ann. § 21.401(3,5), 2016; Tex. Occupational Code Ann. § 58.001(3, 5), 2016). Limiting variants to those medically accepted as associated with disease is inadequate for the scope and scale of results that genetic counselors might return in clinical care, and provides no guidance on other types of information. For example, the clinical genetics community has established the following range of classifications for genetic variants: benign, likely benign, variants of uncertain significance, likely pathogenic, and pathogenic (Richards et al., 2015). But what do the legal definitions mean when taken in conjunction with these classifications? Are variants that are "likely pathogenic" or "pathogenic" "medically accepted" while the others are not? The answer is unclear.

A second related issue is that even variants that are not medically accepted as being associated with a disorder may be strongly suspected of being pathogenic or may be associated with conditions or behaviors that—while not constituting illnesses—are nevertheless stigmatizing (e.g., the association of the *MAOA-L* variant with impulsive and antisocial behavior (Fergusson, Boden, Horwood, Miller, & Kennedy, 2011)). Also, evolving scientific knowledge creates the possibility that the legal status of certain test results might be reclassified in the future (Mahon, 2015). This is problematic when genetic counselors need to know prospectively which tests are covered by genetic-specific informed consent statutes.

In six states (CA, MD, MI, MN, NY, TX) the definition of genetic characteristic, information, test, or predisposition was limited to a test or variant associated with a *negative* health effect (Cal. Insurance Code § 10147(b,e), 2000; MD. Code Ann., Ins. § 27-909(5), 2016;

MD. Code Ann., Ins. § 27-909(a)(3), 2016; Mich. Comp. Laws § 333.17020(8)(c), 2016; Mich. Comp. Laws § 333.17520(8)(c), 2016; Minn. Ann. Stat. § 62A.31(Subd. 8)(j), 2016; Minn. Ann. Stat. § 72A.139(Subd. 2)(b), 2016; N.Y. Civil Rights Law § 79-l(1)(a-b), 2016; N.Y. Human Rights Law § 292(21-a), 2016; Tex. Occupational Code Ann. § 58.001(3), 2016). This means that genetic-specific clinical informed consent may not be required by the statutes for variants associated with *positive* health effects (e.g., A673T in the *APP* gene, which helps protect against Alzheimer's disease (Jonsson et al., 2012)). But current genetic technologies frequently yield data about several categories of findings, e.g., positive and negative associations with diseases, drug metabolism, non-disease associated traits, ancestry, and variants of uncertain significance (VUS) or associated with more than one phenotypic condition. Statutes that limit their scope to disease-associated findings might therefore be difficult to apply when access to or release of the entire data set is in question.

Another limitation of note is that in five states (CA, MD, MA, MN, TX) definitions were limited to genetic characteristics, information, or tests "presently not associated" with symptoms (i.e. protections were limited to persons who were asymptomatic or presymptomatic) or not related to manifest disease (Cal. Health & Safety Code § 1374.7(d), 2012 (incorporated by reference in Cal. Civil Code § 56.17(h), 2017); Cal. Insurance Code § 10147(b), 2000; MD. Code Ann., Ins. § 27-909(a)(3), 2016; Mass. Ann. Laws ch. 111 § 70G(a), 2016; Minn. Ann. Stat. § 62A.31(Subd. 8)(j), 2016; Tex. Insurance Code Ann. § 546.001(4); Tex. Labor Code Ann. § 21.401(5), 2016; Tex. Occupational Code Ann. § 58.001(5), 2016). The clinical genetic informed consent protections in these states thus do not cover testing done *after* the onset of symptoms. Granted, these definitions generally arose in the context of concern about

discrimination against asymptomatic individuals and other anti-discrimination laws, such as the ADA, might protect patients once symptomatic. However, in 2001 the New York Task Force on Life and the Law (the "Task Force") recommended that such definitions be expanded to cover *all* genetic information (Carroll & Coleman, 2001). But not only has this definitional problem yet to be resolved, it has been exacerbated by the advent of genetic technologies employed as diagnostic tools when symptoms already exist, but are of unknown etiology (Saunders et al., 2012).

Required disclosures for informed consent

A second area of particular interest is the information that is required to be *disclosed* during the informed consent process, such as discussion of the nature and purpose of the genetic test (which all states with disclosure requirements mandate). But notably, only four of the states we examined delineate specific disclosure requirements: CA (whose statute uses the term "written authorization," has content similar to other states' informed consent laws and thus was included in our analysis), MA, MI, and NY (Cal. Civil Code § 56.17(e), 2017; Cal. Insurance Code § 742.407(g), 2016; Cal. Insurance Code § 10123.35(g), 2017; Cal. Insurance Code § 10140.1(g), 2017; Cal. Insurance Code § 10148(a), 2000; Cal. Insurance Code § 10149.1(g), 2000; Mass. Ann. Laws ch. 111 § 70G(a), 2016; Mich. Comp. Laws § 333.17020(2), 2016; Mich. Comp. Laws § 333.17520(2), 2016; N.Y. Civil Rights Law § 79-l(2)(b), 2016; N.Y. Insurance Law § 2615(b), 2015). Overall, we found that these statutes require disclosure of complex levels of detail, often require descriptions of options for destruction of biospecimens while ignoring the resulting data, and set confusing standards for disclosure regarding authorized parties and future access (**Table 2**). However, we note that they also might require

provision of written information identifying a geneticist or genetic counselor as an added resource (Mass. Ann. Laws ch. 111 § 70G(a) (2016)).

Other disclosure categories include risks and benefits; reliability, effectiveness, or level of certainty of results; or whether any other tests will be performed on the sample (Mich. Comp. Laws § 333.17020(2), 2016; Mich. Comp. Laws § 333.17520(2), 2016; Mass. Ann. Laws ch. 111 § 70G(a), 2016; Mich. Comp. Laws § 333.17020(2), 2016; Mich. Comp. Laws § 333.17520(2), 2016; N.Y. Civil Rights Law § 79-l(2)(b), 2016; N.Y. Insurance Law § 2615(b), 2015; N.Y. Civil Rights Law § 79-l(2)(b), 2016; N.Y. Insurance Law § 2615(b), 2015). But again, current genomic technologies may identify variants associated with a large number of conditions; having to disclose specific risks, benefits, and implications for all of them is challenging, if not impossible. New York requires that "the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease" be disclosed, although it acknowledges that if "no level of certainty has been established" that requirement may be disregarded (N.Y. Civil Rights Law § 79-l(2)(b), 2016; N.Y. Insurance Law § 2615(b), 2015). But, the predictive validity of genomic analyses may depend on the variant in question.

New York also addresses duration of authorization or length of retention of a sample. The sample needs to be destroyed "not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized…" (N.Y. Civil Rights Law § 79-l(2)(b), 2016; N.Y. Insurance Law § 2615(b), 2015). However, as discussed further below, it is more often the data (not the sample) that could be transferred to a biorepository and stored indefinitely for secondary research or other purposes, potentially generating privacy concerns for an individual that are relevant to the informed consent discussion.

All of the states require disclosure of which persons or entities would have access to the information or sample. While access to human biospecimens is an area heavily regulated by other federal and state laws, access to the information or data generated by a genetic test remains an important aspect of patient privacy and the informed consent process. Massachusetts and New York address access by describing the persons or entities who may be told the results, Michigan describes the persons who have access to the sample and information, and California describes those authorized to disclose information (Mass. Ann. Laws ch. 111 § 70G(a), 2016; N.Y. Civil Rights Law § 79-l(2)(b), 2016; N.Y. Insurance Law § 2615(b), 2015; Mich. Comp. Laws § 333.17020(2), 2016; Mich. Comp. Laws § 333.17520(2) ,2016; Cal. Civil Code § 56.17(g), 2017; Cal. Insurance Code § 742.407(g), 2016; Cal. Insurance Code § 10123.35(g), 2017; Cal. Insurance Code § 10140.1(g), 2017; Cal. Insurance Code § 10149.1(g), 2000). Addressing not only who has access to the *sample,* but also who has access to the *information generated* from the sample is critical in light of new technologies as the amount of data that can be generated from a single sample has grown exponentially. The resultant information implicates informed consent discussions not just about privacy risks, but also about benefits as information might be useful to family members, and—through secondary research—could potentially yield family-specific variant discovery.

Research use and identifiability

The last area we queried is secondary research use of biospecimens and genetic data and information generated in the clinical context. Potential research use is relevant to the genetic counselor's informed consent process because a patient's clinical test results, data, or samples may be used for future research in some circumstances, and could even be of direct

relevance to patients and families *if* those results are returned. In addition, the clinician and researcher may be the same person. If specimens or data remain identifiable, then research with that material is often governed by the federal Common Rule; but if the materials cannot readily be re-identified, it is generally not considered human subjects research (45 C.F.R. § 46, 2009). However, the potential for future research use may still raise disclosure concerns for clinicians. Many of the state laws we analyzed had limitations related to exceptions from informed consent for future research use or destruction requirements targeting specimens as opposed to derived data, or rested their requirements on the data's "identifiability"—a rapidly evolving concept (**Table 3**).

In our review, seven states (CA, MA, MI, MO, NY, OR, TX) had some exceptions to the requirements for clinical informed consent for future research use (Cal. Health & Safety Code § 124980(j), 2017; Mass. Ann. Laws ch. 111 § 70G(b), 2016; Mass. Ann. Laws ch. 111 § 70G(c)(2), 2016; Mich. Comp. Laws § 333.17020(9), 2016; Mich. Comp. Laws § 333.17520(9), 2016; MO. Ann. Stat. § 375.1309, 2017; N.Y. Civil Rights Law § 79-l(4)(a), 2016; OR. Rev. Stat. § 192.535(1), 2015; OR. Rev. Stat. § 192.540(d), 2015; OR. Rev. Stat. § 192.547(7)(b), 2015; Tex. Insurance Code Ann. § 546.054, 2016; Tex. Labor Code Ann. § 21.4031(b), 2016; Tex. Occupational Code Ann. § 58.103(b), 2016). Previous 50-state surveys have confirmed this finding—more than half of states have such research exceptions (Hakimian et al., 2004). As noted above, federal research regulations might offer some protection, but with limits (45 C.F.R. § 46, 2009). When research is exempted from consent requirements, persons who would decline to have their samples used for particular kinds of research are unable to do so *and* such laws might incentivize de-identified research to begin with. Therefore, not only do state laws offer

inadequate protections that are too limited for the informed consent concerns of some patients, but—in light of less burdensome requirements for de-identified secondary research—they can unintentionally create barriers for return of research results that might be beneficial for participants and their families.

Three of these seven states (NY, OR, TX) also specifically discuss destruction of a biological specimen (N.Y. Civil Rights Law § 79-l(9)(b), 2016; OR. Rev. Stat. § 192.537(4, 5), 2015; Tex. Insurance Code Ann. § 546.054, 2016). For example, under New York's *Civil Rights Law*, anonymous samples may be used for IRB-approved research without specific consent if the donor had consented to general secondary research use. But if that consent to storage is withdrawn, the sample (or portions that have not already been used for research) must be promptly destroyed (N.Y. Civil Rights Law § 79-l(9)(b), 2016). However, these statutes focus on destruction of the *specimens* themselves, rather than the data derived from them—a major limitation given the breadth and value of genomic data once generated (Annas, 2001).

A final area of focus is the use of the term "identifiability." The scope of identifiability is addressed by several different federal statutory schemes that have been analyzed elsewhere (Majumder, Guerrini, Bollinger, Cook-Deegan, & McGuire, 2017). In our review, seven states (CA, MD, MA, MN, NY, OR, TX) have at least one statute that is founded on the identifiability of a contributor from their specimen, information, or data (Cal. Civil Code § 56.17(b), 2017; Cal. Insurance Code § 742.407(b), 2016; MD. Code Ann., Ins. § 27-909(c)(3), 2016; Mass. Ann. Laws ch. 111 § 70G(a), 2016; Minn. Ann. Stat. § 144.192(Subd. 1)(b), 2016; N.Y. Civil Rights Law § 79-l(9)(a), 2016; OR. Rev. Stat. § 192.537(2), 2015; Tex. Insurance Code Ann. § 546.103(b), 2016). For example, in California, anyone who willfully discloses a genetic result that "identifies or

provides identifying characteristics of the person" without written authorization from that person will be assessed a civil penalty (Cal. Insurance Code § 742.407(d), 2016). In Massachusetts, the very definition of "genetic information" is limited to an "individually identifiable result" of a genetic test, leading George Annas in 2001 to observe that it "seeks both to protect individual privacy and to promote genetic research. It accomplishes the latter, but only at the expense of the former..." (Mass. Ann. Laws ch. 111 § 70G(a), 2016; Annas, 2001). But technologies have advanced to the point that identification of a single person's data from an aggregate data set might be possible (Gymrek, McGuire, Golan, Halperin & Erlich, 2013). While re-identification is highly unlikely, this possibility at least challenges the widely-held conception of binary categories of "identifiable" and "de-identified."

DISCUSSION

Our research focused on three areas of informed consent that are of particular relevance to genetic counselors employing modern genetic testing technologies. We found several areas where these laws—specifically tailored to protecting patients during informed consent to clinical genetic testing—are profoundly limited or confusing when applied to the current realities of this advancing technology.

Many state laws do not cover the return of test results that fall outside the scope of disease-causing variants, thus oddly limiting informed consent requirements for the growing body of results that patients and families might seek (e.g., disease-protective results, uncertain results, results related to asymptomatic conditions). Retaining these distinct genetic testing laws will require periodic updates to ensure they do not improperly exclude subsets of results, and that disclosure requirements are tailored to modern genetic and genomic testing

technologies. In addition, clinical genetic testing legislation should consider the porous flow of resulting specimens and information to secondary contexts such as research, learning health systems, or quality improvement initiatives (Spector-Bagdady & Jagsi, 2018 (In Press)). The ongoing impulse to protect privacy, motivating de-identification of biospecimens and related data for research, may unduly restrict return of relevant results that could be of benefit to patients and families. As such, the overall inadequacy of state laws presents potential challenges for genetic counselors as they seek to inform and support patients and families in making testing decisions. These discrepancies and complications often leave genetic professionals in the position of focusing on enabling good decision-making for their patients and their families according to their best professional judgment—yet unsure where this practice situates them vis-à-vis existing state law.

From a future advocacy standpoint, clinicians—especially genetic counselors—along with affected families, have much at stake and offer a critical perspective on how state laws can provide relevant protections that simultaneously facilitate realizing the potential benefits of disclosing genetic information. There is recent precedent for effective advocacy from the clinical and research communities on the topic of clinical genetic testing: leading, for example, to intensive media coverage of the American Society of Human Genetics' letter regarding the "Preserving Employee Wellness Programs Act," and the veto of Wyoming's recent Genetic Information Privacy law due to concerns that an amendment "could be interpreted to prohibit genetic testing facilities, research facilities and even universities from using a third party to store or back up" data (Sun, 2017; Mead, 2017). Genetic counselors can act as a critical resource for state legislatures, as well as within their institutions, by clarifying how such laws

impact patients and families on a daily basis and the complex obligations (e.g., selecting a laboratory, selecting a test, disclosing risks and benefits of that test) that clinicians face.

In conjunction with specific advocacy efforts, uniformity across jurisdictions would also be desirable for clinicians practicing, and specimens traveling, across state lines. But it is unclear whether state legislatures have the bandwidth or expertise to formulate and maintain such updated policies. Incorporation of specific provisions into regulations, rather than embodying them in statutory language—with an appropriate state health agency charged with updating them as needed—may be a more reasonable approach.

Our study had several limitations—most notably that we confined our review to 15 states, all of which have major institutions that conduct genomic research such that they might not be representative of all U.S. states. We have also highlighted what we identified as major issues across these states; other problems may exist within these individual states' laws that we did not review here. We also limited our search terms to focus on clinical genetic testing or information and therefore might have excluded some statutes of potential interest. Also, informed consent is governed by a complex intersection of statutes, regulations, and case law; here we focused our review to state statutes requiring explicit informed consent to clinical genetic testing. Despite these limitations, this review provides a valuable perspective on the complexities that can arise in the context of genetic-specific consent laws and rapidly advancing genomic technologies.

While genomic technologies are changing the nature of testing, the goals of clinical informed consent have generally stayed the same: to inform patients of the potential benefits, risks, implications, and use of tests and data being generated. Science often advances more

rapidly than the laws that govern it; genetic-specific clinical informed consent laws must strike a balance between adequate specificity to protect patients and enough flexibility to ensure those continued protections in the context of advancing technology. Too often these laws, theoretically enacted specifically to support the process of informed consent to genetic testing, constrain and confound as much as clarify. We must aim to protect scientific progress for our patients, as well as to promote the biospecimen and data donations that will enable better health decision-making and outcomes for our future patients. Reform efforts and further research are needed to ensure that state law protections advance as rapidly as the science they aspire to enable.

SUPPLEMENTARY MATERIAL

Supplementary material is attached.

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DISCLOSURE

The authors declare no conflicts of interest.

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Table 1. Examples of state statutory definitions of "genetic test" or "characteristic."

Statutory Example	Limitation
Genetic characteristic: "any scientifically or medically identifiable gene or chromosome, or alteration thereof, that is known to be a cause of a disease or disorder, or that is determined to be associated with a statistically increased risk of development of a disease or disorder..."[a]	To variants known or associated with disease or disorder
Genetic test: "a laboratory test…used to identify the presence or absence of inherited or congenital alterations in genetic material that are associated with disease or illness."[b]	To tests associated with negative health effects
Genetic test: "…a presymptomatic test of a person's genes, gene products, or chromosomes for the purpose of determining the presence or absence of a gene or genes that exhibit abnormalities, defects, or deficiencies, including carrier status, that are known to be the cause of a disease or disorder, or are determined to be associated with a statistically increased risk of development of a disease or disorder."[c]	To a presymptomatic test

[a]CAL. INSURANCE CODE § 10147(b) (2000)
[b]MD. CODE ANN., INS. § 27-909(5) (2016)
[c]MINN. ANN. STAT. § 72A.139(2)(B) (2016).

Table 2: Examples of state statutory provisions on written consent and authorization.

Statutory Example	Informed Consent Disclosures
Prior written consent: "…shall include: (1) a statement of the purpose of the test; (2) a statement that prior to signing the consent form, the consenting person discussed with the medical practitioner ordering the test the reliability of positive or negative test results and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease; (3) a statement that the consenting person was informed about the availability and importance of genetic counseling and provided with written information identifying a genetic counselor or medical geneticist from whom the consenting person might obtain such counseling; (4) a general description of each specific disease or condition tested for; and (5) the person or persons to whom the test results may be disclosed."[a]	Nature and purpose
Written informed consent: "…includes…a statement that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent…"[b]	Period of retention
Written authorization: "…Specifies the types of persons authorized to disclose information about the individual…[and] states the name or functions of the persons or entities authorized to receive the information..."[c]	Nature of access

[a]MASS. ANN. LAWS ch. 111 § 70G(a) (2016).
[b]N.Y. CIVIL RIGHTS LAW § 79-l(2)(b) (2016).
[c]CAL. CIVIL CODE § 56.17(g) (2017).

Table 3: Examples of state statutory exemption provisions on research use and identifiability.

Exceptions	Statutory Example
Research exception	"A person may not obtain genetic information from an individual, or from an individual's DNA sample, without first obtaining informed consent of the individual or the individual's representative, except…for anonymous research or coded research conducted under conditions described in ORS 192.537(2) [e.g., they have granted specific consent, broad consent, or have been notified that their specimen or information may be deidentified and used for research], after notification pursuant to ORS 192.538 (Notification by health care provider regarding anonymous or coded research) or pursuant to ORS 192.547 (7)(b)[the appropriate operation and appointment of IRBs][among other exceptions]…"[a]
Exceptions from destruction of sample in research context	"A sample of genetic material obtained from an individual for a genetic test shall be destroyed promptly after the purpose for which the sample was obtained is accomplished unless…the individual authorizes retention of the sample for medical treatment or scientific research [or] the sample was obtained for research that is cleared by an institutional review board and retention of the sample is: (A) under a requirement the institutional review board imposes on a specific research project; or (B) authorized by the research participant with institutional review board approval under federal law…"[b]
Exceptions to redisclosure rules if not identifiable	"A health benefit plan issuer may redisclose genetic information without an authorization…for actuarial or research studies if…a tested individual could not be identified in any actuarial or research report..."[c]

[a] OR. REV. STAT. § 192.535(1) (2015).
[b] TEX. INSURANCE CODE ANN. § 546.054 (2016).
[c] TEX. INSURANCE CODE ANN. § 546.103(b) (2016).