

Privacy Issues in the Sharing of Genetic Information

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Introduction

Scientific breakthroughs and technological advancements have led to the emergence of personalized medicine – a practice based on the use of an individual's genetic profile to guide health care decisions made about the prevention, diagnosis, and treatment of disease.

Genomic DNA sequencing, the technology that launched the biomedical revolution, has accelerated rapidly and the costs of sequencing continue to decrease. It took \$1 billion and 13 years to sequence the first draft of the human genome.¹ In January 2014, Illumina introduced technology that can sequence a human genome for \$1,000.² Now that the sequencing of human genomes is getting faster and less expensive, the health care industry is coming closer to realizing the promise of personalized medicine.

By integrating gene sequencing and historical treatment from a patient's electronic health record, big data analytics have built upon the advances in genomic sequencing to facilitate research on more effective treatments for diseases, such as cancer. Such efforts, however, offer just one example of the multitude of initiatives by government and industry in the areas of genomic research, clinical decision making, and consumer health tracking with data generated by wearable devices, smartphones and low-cost diagnostic kits, including genetic data. All of these initiatives depend to some degree on the ability of organizations to aggregate, integrate, and use genetic information. They also depend on and the permissible uses of genetic information as governed by state and federal privacy laws.

This white paper describes key issues in privacy law related to genetic information³ that should be

considered in the use and dissemination of genetic information for secondary uses, including research and other data sharing initiatives.



Federal Privacy Law

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule was amended in 2013 by the Omnibus Final Rule to address genetic information.

The Omnibus Final Rule expressly defines genetic information as health information protected by the HIPAA Privacy Rule.⁴ Like other health information, to be protected by HIPAA, genetic information must meet the definition of protected health information (PHI). In other words, it must be individually identifiable and maintained by a covered entity or a business associate.⁵ It is important to remember that the HIPAA Privacy Rule only directly applies to persons or entities that are defined as “covered entities,” including health plans, health care clearinghouses, and any health care provider that electronically transmits health information in connection with a transaction – such as billing a health plan for reimbursement for services – for which there is a HIPAA standard transaction and code set. Covered providers include physicians, genetic testing laboratories, genetic counselors, and other organizations.

In addition, the Omnibus Final Rule incorporated the ban on use and disclosure of genetic information for underwriting purposes by health plans and insurers, including employer-sponsored health plans, as set forth in the Genetic Information Nondiscrimination Act. (GINA). Health plans and insurers are prohibited from using genetic information when determining eligibility and measuring premiums, contributions, cost sharing, or benefit, but, as will be discussed below, disclosures of genetic information may be made consistent with the rules governing PHI generally.⁶

In general, the HIPAA Privacy Rule limits the uses and disclosures of PHI (including genetic information) without individual authorization. Concerning the use

and disclosure of PHI, there are no special restrictions on the use and disclosure of sensitive information, such as genetic information. All PHI is protected according to essentially the same standards. Covered entities are permitted to use and disclose PHI (with exceptions for psychotherapy notes) for treatment, payment, and health care operations.⁷

The Privacy Rule also permits a covered entity to use and disclose PHI for research purposes⁸, without an individual’s authorization, under certain conditions.⁹ The Omnibus Final Rule expanded the use of PHI for research and harmonized HIPAA with the Common Rule¹⁰ by allowing covered entities to obtain individual authorization for the uses and disclosures of PHI for future research purposes, so long as the authorization adequately describes the future research such that it would be reasonable for the individual to expect that his or her PHI could be used or disclosed for future research purposes. The revised Privacy Rule provides considerable flexibility regarding 1) description of the PHI to be used, and 2) description of the recipients of the PHI (which may be unknown) for the future research.¹¹

The Privacy Rule provides several key “pathways” that permit use of PHI to create research databases for future research purposes:

- » **Pursuant to an Institutional Review Board (IRB) or privacy board waiver of authorization.** An IRB operating under a federal-wide assurance or a privacy board that functions under the Privacy Rule may grant a waiver or alteration of written authorization if the proposed use or disclosure will pose minimal risk to participants’ privacy, the research could not practicably be conducted without the waiver or alteration of authorization and cannot be conducted using de-identified information, and other specified criteria are met.



- » **With authorization from an individual to create the research repository.** According to the Department of Health and Human Services (HHS), the development of research repositories and databases for future research purposes is itself a “research activity,” thereby requiring authorization or waiver of authorization (discussed just above) to the extent PHI would be involved.
- » **Collection and use of a limited data set (which may include geographic information other than street address, all elements of dates and ages, and certain other unique identifying characteristics or codes).** A Covered entity may release a limited data set if the researcher signs a data use agreement (DUA), which assures the Covered entity that the recipient will protect the limited data set and will not make any effort to re-identify individuals using the data set.
- » **Collection and use of de-identified data.** Under HIPAA, data that is de-identified is not considered PHI and thus is not subject to HIPAA protections. HIPAA provides two methods through which data may be de-identified: 1) the Safe Harbor Method, which requires the removal of identifiers and an absence of actual knowledge that the remaining information could be used to identify the individual, and 2) the Expert Determination Method, which involves a formal determination by a qualified expert.¹²

The HIPAA requirement to obtain informed consent for future research uses, intended to harmonize the standard with the Common Rule, is also consistent with the National Institutes of Health (NIH) policy announced in August of 2014 on future research using genomic data. NIH expects scientists to seek informed consent for the genomic data they collect to allow for future research use and broad sharing to the “greatest extent possible,” under its final Genomic Data Sharing Policy (GDS policy). The final GDS policy applies to all NIH-funded, large-scale human and non-human projects that generate genomic data, starting with funding applications submitted for a January 25, 2015 receipt date.¹³

It is important to note, however, that not all health information or genetic information is subject to the HIPAA Privacy Rule. Among other exceptions, PHI does

not include health information maintained in employment records. The Privacy Rule also does not apply to information maintained in certain personal health records (PHR) or information gathered through certain online applications. In general, a PHR is an electronic record of an individual’s health information by which the individual controls access to the information and may have the ability to manage, track, and participate in his or her own health care. HHS clarifies that the HIPAA Privacy Rule applies solely to PHRs that are offered by health plans or health care providers that are covered by the HIPAA Privacy Rule, but not to those offered by employers (separate from the employer’s group health plan) or by PHR vendors directly to an individual. PHR vendors are governed by the privacy policies of the entity that offers them, and subject to the jurisdiction of the Federal Trade Commission (FTC). FTC regulations have established health breach reporting obligations and applied these requirements to PHR vendors, PHR-related entities that offer products through the vendor’s Web site, or access or send information to a PHR (such as Web-based applications that allow patients to upload a reading from a blood pressure pedometer into a PHR), or third-party service providers to vendors of PHRs. The FTC treats a violation of the breach reporting regulation as an unfair or deceptive act or practice.¹⁴ Under the existing legal framework, organizations that are not covered entities have fewer restrictions regarding the research and other secondary uses of data. However, as will be discussed below, because state law generally imposes additional restrictions on genetic information, state law privacy issues are paramount in any consideration of use and sharing of genetic information.



State-Specific Restrictions on the Use and Disclosure of Genetic Information

GENERAL RESTRICTIONS ON THE USE AND DISCLOSURE OF GENETIC INFORMATION

Although data may be shared for treatment, payment, health care operations, and research under HIPAA, the sharing of genetic information may also be subject to state-specific restrictions. Most states have genetic privacy laws, and those laws that generally more stringent than HIPAA are not preempted. State genetic privacy laws typically require an individual's specific written consent for the collection, retention, use, or disclosure of genetic information about an individual, with certain exceptions, (*i.e.*, when the use or disclosure of genetic information is necessary to a criminal investigation, necessary to comply with a court order, or in connection with anonymous medical research). In most cases, the state laws governing use and disclosure of genetic information apply to anyone who handles genetic information, although in some states, the law applies only to health care providers and health care facilities.

In all, 35 states have laws that specifically restrict disclosure of genetic information.¹⁵ The vast majority of these states require written consent from the subject of the information prior to the disclosure of genetic information. For example, Massachusetts law prevents health care providers and facilities from identifying the person being tested or disclosing the results of a genetic test to any person other than the subject of the test without first obtaining the informed written consent from the subject, with certain exceptions for confidential research information.¹⁶

In 20 of these states, the restrictions on disclosures without consent apply to any person or to genetic information generally, rather than to health care

providers or insurers.¹⁷ Therefore, not only health care providers, but any entity that obtains genetic information requires consent for the re-disclosure of such information.

Of these states, 12 also specifically restrict the re-disclosure of genetic information without consent. For example, Delaware law restricts the disclosure of genetic information regardless of the manner of receipt or the source of genetic information, including information received from an individual.¹⁸ Therefore, if a PHR vendor receives genetic information from an individual, it is prohibited from re-disclosing such information without the individual's consent.

Finally, some states have specific requirements for the consent of the authorization. In some states, the specific elements of written "informed consent" are established in the statutes.¹⁹

The consequence of the unlawful disclosure of genetic information varies among the states. Many states impose civil liability, criminal punishment, or both for violation of the applicable statute, and some provide equitable relief for violations of the statute.²⁰ One statute authorizes monetary penalties up to \$250,000,²¹ and others authorize jail time for up to one year.²² Some states adopt a different approach, treating unlawful disclosure as an unfair trade practice.²³

In summary, if an organization operates nationally or across multiple states, consent for the disclosure and/or redisclosure of genetic information is likely required. Such consent should comply with the most stringent requirements of the applicable states.



Table 1, included at the end of this document, catalogues the various state statutes and regulations that limit disclosure, retention, and re-disclosure of genetic information.

PROPERTY RIGHTS

In addition to the restrictions on the use or disclosure of genetic information, several states have passed laws intending to protect genetic data of individuals as property, asserting that an individual is the “owner” of his or her genetic information. Under Alaska law, a DNA sample and the results of a DNA analysis performed on the sample are the “exclusive property” of the person sampled or analyzed.²⁴ A Florida statute provides that the results of DNA analysis are the “exclusive property of the person tested” and may not be disclosed without the consent of the person tested.²⁵ In Colorado, with respect to the state’s regulation of insurers, Colorado law similarly provides that “genetic information is the unique property of the individual to whom the information pertains.”²⁶ Georgia’s provisions on the ownership of genetic data also pertain to insurers and states that genetic information is the “unique property” of the individual tested.²⁷ While courts have yet to fully explore the meaning of exclusivity or uniqueness as it pertains to an individual’s ownership of genetic data under these state statutes, it is possible to interpret the qualifications “exclusive” or “unique” as emphasizing the prohibition of the use of another individual’s genetic data absent some waiver of the individual’s property rights.²⁸

In contrast to the “exclusive” and “unique” property rights provided by some states, Louisiana law describes the property rights of individuals in more general terms. With respect to insurers, the Louisiana Insurance Code provides that an “insured’s or enrollee’s genetic information is the property of the insured or enrollee.”²⁹ Notably, Louisiana broadly defines “genetic information” not just to include DNA analyses, but to include “all information about genes, gene products, inherited characteristics, or family history/pedigree that is expressed in common language.”³⁰ This definition even includes information regarding the “manifestation of a disease or disorder in family members of an individual.”³¹ Particularly for

states with broad definitions of genetic information, such as Louisiana, applicable members of industry dealing with medical information of individuals (not just DNA samples or analyses) should take steps to facilitate compliance with the state laws on handling genetic information. For instance, a physician that maintains patient medical history information may be subject to state laws on ownership of genetic data, even if the records do not contain information on patient DNA. Prior to making certain uses or disclosures of such medical history information, the physician should consider whether authorization and a waiver of property rights is required for any proposed secondary uses of genetic information.

Courts in some states have issued rulings further delineating the property rights held by an individual relating to that individual’s genetic data. In *Moore v. Regents of the University of California*, the California Supreme Court rejected the plaintiff’s claim of property in his bio specimens, reasoning that the plaintiff had no property rights in the particular cellular material at issue.³² In *Moore*, the court noted that the pertinent genetic code in the cellular material was “no more unique to [the plaintiff] than the number of vertebrae in the spine or the chemical formula of hemoglobin.”³³ In comparison with *Moore*, a Florida state court distinguished between rights an individual may have in bodily tissues versus genetic material, reasoning that even if Florida law grants an individual a property right in *genetic material* donated for medical research purposes, “the property right in blood and tissue samples . . . evaporates once the sample is voluntarily given to a third party.”³⁴

Although such genetic property right statutes have not been fully tested in court, they suggest that any consent for collection of genetic information from individuals should expressly clarify the rights of the parties to use and profit from discoveries based on such information. Such waivers, however, cannot be used if the data may be used for research governed by the federal Food and Drug Administration (FDA) or subject to the Common Rule. According to the FDA, informed consent documents cannot contain exculpatory language that requires subjects to



relinquish any of their legal rights.³⁵ Likewise, federal guidance for researchers governed by the Common Rule indicates that statements that the subject “donate,” “give up all claim,” or “give up property rights in tissue or data” are not acceptable for an informed consent document. It is acceptable, however, for such consent form to say that there are no plans to compensate the subject and the subject authorizes use of tissue samples or information for research purposes.³⁶

RESEARCH

States are somewhat split on whether and how they restrict the further uses and disclosures of genetic information for research. Some states that grant protection to genetic data exempt certain kinds of anonymous data from state genetic data protections.³⁷ For instance, Georgia’s law on genetic testing provides that with limited exceptions, “any research facility may conduct genetic testing and may use the information derived from genetic testing for scientific research purposes so long as the identity of any individual tested is not disclosed to any third party.”³⁸ Colorado’s law granting protections to genetic data has substantially similar exemptions to Georgia’s law with respect to the sharing of anonymized genetic data.³⁹ Other states, such as Massachusetts (described above), exempt from the consent requirements disclosure for confidential research for epidemiological research or research on the effectiveness of treatment for a particular disease. Other states, such as Oregon, allow an individual to opt out of research uses of data generally, even if such data is anonymized or coded. Specifically, Oregon law requires a health care provider that obtains an individual’s clinical individually identifiable health information to notify the individual that the information may be disclosed or retained by the provider for anonymous research or coded research, and allow the individual to request that the specimen or information not be disclosed or retained for anonymous research or coded research.⁴⁰

Another issue with the use of anonymized data for research is whether genetic data can be truly anonymized. For data to be anonymized, all the connections between an individual and the individual’s

record must be irreversibly broken, making it impossible to identify the person. Some hold that data may be anonymized by completely removing identifiers, by aggregating data into groups and ranges and not reporting individuals’ identities, or by micro-aggregating the data into pseudocases representative of the real population.⁴¹ Although de-identification and anonymization are closely linked in the literature regarding genetic ownership and disclosure, the two terms are distinct and should not be used interchangeably. De-identification means that the personal identifiers in a record have been removed, and while it would be difficult to re-identify the subject of the information, it would not be impossible to do so. In contrast, the anonymization of genetic data, at least in theory, makes it impossible to identify the individual person to whom the data pertains. Many analysts have argued that due to the degree of information encoded in DNA, it is not possible to truly anonymize the data.⁴²



Conclusion

Federal privacy laws, such as HIPAA, may apply to genetic information, provided that it is collected, maintained, or received from covered entities. Therefore, any arrangement that involves the secondary use or sharing of genetic information should take into consideration the applicability of HIPAA.

For future research uses of genetic information, the informed consent requirements under the Common Rule and the NIH GDS are also key guidance.

State privacy laws provide greater challenges than federal privacy laws with respect to the sharing and dissemination of genetic information. In consideration of the state law restrictions, entities that intend to share genetic information for any secondary use should be attentive to a few key issues. Organizations will generally be required to obtain express consent (or informed consent) from individuals for the retention or use of genetic information in a form that includes the elements specified in state law. Moreover, to the extent that genetic information is collected from individuals in states where the individual has a property right in his or her genetic information, organizations should consider requesting a waiver of property rights in genetic information to facilitate the retention and further use and disclosure of such information. If the genetic information is to be used for future research, such waivers should be limited to an authorization for the use of information and a waiver of compensation, if applicable. Finally, given the challenges associated with anonymization of genetic information, organizations that are disclosing genetic information under an exception for anonymized data should consider engaging statistical experts to establish the methodology for anonymizing genetic information,

rather than relying on more simplistic methods such as the removal of identifiers.

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¹ Personalized Medicine Coalition, *The Case for Personalized Medicine*, 4th Ed. (2014), p. 18.

² Vance, Ashlee, *Illumina's DNA Supercomputer Ushers in the \$1,000 Human Genome*, *Businessweek* (Jan. 14, 2014).

³ This paper does not address DNA samples and the additional issues associated with the collection and use of tissues.

⁴ Department of Health and Human Services, *Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule*, 78 Fed. Reg. 5566 (Jan. 25, 2013).; Genetic information includes information about the genetic tests of an individual and his or her family members, the medical history of those family members, and any request for genetic services (including genetic testing, counseling, or education) or participation in clinical research. A family member includes any dependent or relation to the fourth degree (e.g., great-



great-grandparents or grandchildren, children of first cousins) or closer, without reference to the existence of biological ties. The protections under HIPAA extend to all genetic information, whether the information originated before or after the compliance date for the final regulations.

⁵ 45 C.F.R. § 160.103 and § 164.501.

⁶ 45 C.F.R. § 164.502(a)(5).

⁷ 45 C.F.R. § 164.506. Treatment is the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another. Payment encompasses activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish or obtain reimbursement for health care delivered to an individual and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual. Health care operations are any of the following activities: (a) quality assessment and improvement activities, including case management and care coordination; (b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation; (c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk; (e) business planning, development, management, and administration; and (f) business management and general administrative activities of the entity, including but not limited to: de-identifying PHI, creating a limited data set, and certain fundraising for the benefit of the covered entity.

⁸ 45 C.F.R. § 164.512(i); “Research” is defined as any systematic investigation designed to develop or contribute to generalizable knowledge.

⁹ The covered entity must either obtain: (1) documentation that an alteration or waiver of individuals’ authorization for the use or disclosure of PHI about them for research purposes has been approved by an Institutional Review Board or Privacy Board; (2) representations from the researcher that the use or disclosure of the PHI is solely to prepare a research protocol or for similar purpose preparatory to research, that the researcher will not remove any PHI from the covered entity, and that PHI for which access is sought is necessary for the research; or (3) representations from the researcher that the use or disclosure sought is solely for research on the PHI of decedents, that the protected health information sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is sought. There are certain other options for limited data sets and de-identified data.

¹⁰ Another important source of regulation for research stems from the Common Rule at 45 C.F.R. Part 46. The Common Rule applies to all research involving human subjects that is supported or regulated by any federal department or agency. Any research involving genetic information that falls under the Common Rule must first be approved by the Institutional Review Board and, where

applicable, informed consent is required by subjects of research studies.

¹¹ 78 Fed. Reg. at 5611 – 5615.

¹² 45 C.F.R. § 164.514(a)-(b)

¹³ National Institutes of Health, Final NIH Genomic Data Sharing Policy, 79 Fed. Reg. 51345 (Aug. 28, 2014).

¹⁴ Office for Civil Rights, Personal Health Records and the HIPAA Privacy Rule, available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthis/phrs.pdf>.

¹⁵ See Table 1, Summary of State Genetic Information Disclosure Laws.

¹⁶ Mass. Gen. Laws ch. 111, § 70G. . .

¹⁷ See, e.g., Alaska Stat. § 18.13.010(a)(1) (2013).

¹⁸ Del. Code Ann., tit. 16, §§ 1205.

¹⁹ See Table 1, Summary of State Genetic Information Disclosure Laws.

²⁰ E.g., Iowa Code § 729.6.8.a. (2013).

²¹ Or. Rev. Stat. § 192.541.3.e. (2013).

²² See, e.g., Vt. Stat. Ann. tit. 18, § 9335 (2013).

²³ See, e.g., Ga. Code Ann. § 33-54-8 (2013).

²⁴ Alaska Stat. § 18.13.010(a)(2).

²⁵ Fla. Stat. § 760.40(2)(a).

²⁶ C.R.S. § 10-3-1104.7(1)(a).

²⁷ O.C.G.A. § 33-54-1(1).

²⁸ Cf. *Gibbons v. Ogden*, 22 U.S. 1 (1824) (“If anyone has a right to property, such right is a perfect and exclusive right. But, that word, exclusive, is more frequently applied to express, that others have been excluded or shut out from the participation of what they were previously entitled, or would, but for that exclusion, be entitled to enjoy and use.” (citations and internal quotation marks omitted)).

²⁹ La. R.S. 22:1023(E).

³⁰ La. R.S. 22:1023(A)(8)(a).

³¹ La. R.S. 22:1023(A)(8)(a).

³² *Moore v. Regents of University of California*, 793 P.2d. 479 (Cal. 1990).

³³ *Moore v. Regents of University of California*, 793 P.2d. 479 (Cal. 1990).

³⁴ *Greenberg v. Miami Children’s Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1075 (S.D. Fla. 2003).

³⁵ 21 C.F.R. § 50.20.

³⁶ HHS Office for Human Research Protections, Exculpatory Language in Informed Consent, available at <http://www.hhs.gov/ohrp/policy/exculp.html>.

³⁷ Prince, *supra* note 1 at 207.

³⁸ O.C.G.A. § 33-54-6.

³⁹ See C.R.S. § 10-3-1104.7(5).

⁴⁰ O.R.S. § 192.538(1), (3).

⁴¹ Anya E. R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy or Property Models May Not Fit All*, 79 Brooklyn L. Rev. 175, 206-07 (2013).

⁴² Anya E. R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy or Property Models May Not Fit All*, 79 Brooklyn L. Rev. 175, 207 (2013).



Table 1: Summary of State Genetic Information Disclosure Laws

Below is a summary of state statutes and regulations specifically relating to the disclosure of genetic information and genetic tests.¹ This information is current as of September 3, 2014.

State	Applicable Statute and Regulations	Scope of Applicability of Statute/Regulation	Is Consent Required to Disclose Genetic Information?	Are There Specific Restrictions on the Retention and/or Re-disclosure of Genetic Information?	Are There Specific Statutory Penalties for Unlawful Disclosure of Genetic Information?	Comments
Alabama	n/a	n/a	n/a	n/a	n/a	n/a
Alaska	Alaska Stat. §§ 18.13.010 – 18.13.100.	Applies to “persons.”	Yes. Informed written consent is required for certain disclosures.	Yes. Consent to retain, collect, analyze or disclose genetic information is required.	Yes. Unlawful DNA collection, analysis, retention, or disclosure is a misdemeanor.	A general authorization for the release of medical records or medical information is not sufficient for the disclosure of genetic information.
Arizona	Ariz. Rev. Stat. § 20-448.02.	Applies to “persons.”	Yes.	No.	No.	Contains specific written consent requirements.
Arkansas	Ark. Code Ann. § 20-35-101 to 103.	Applies to genetic information used for research purposes.	Yes. Written consent is required for certain disclosures.	No.	No.	Contains specific written consent requirements.
California	Cal. Ins. Code § 10149.1; 10 Cal. Code Regs. § 2218.20.	Applies to “persons” regulated under the Insurance Code.	Yes. Written consent is required for certain disclosures.	No.	Yes. Civil penalties may be imposed (fines up to \$10,000) for negligent or wilful disclosure of identifiable genetic test results.	This statute applies to the disclosure of the results of a test for a genetic characteristic.



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Colorado	Colo. Rev. Stat. § 10-3-1104.7.	Applies to "entities."	Yes. Written consent is required for certain disclosures.	Yes. Any entity that receives information derived from genetic testing may not seek, use, or keep the information for any nontherapeutic purpose. Re-disclosure for research purposes may be allowed in certain circumstances.	Yes. Penalties for violations include equitable relief, and the greater of actual damages or \$10,000 per violation.	Contains specific written consent requirements.
Connecticut	n/a	n/a	n/a	n/a	n/a	n/a
Delaware	Del. Code Ann., tit. 16, §§ 1202; 1203, 1205, 1206, 1208.	Applies to a "person."	Yes.	Yes. Consent to retain genetic information is required. Authorization is required for subsequent disclosures of genetic information.	Yes. Wilful violations are subject to fines up to \$50,000, and all actual damages.	None.
District of Columbia	n/a	n/a	n/a	n/a	n/a	n/a
Florida	Fla. Stat. § 760.40.	Applies to a "person."	Yes.	No.	Yes. Violations are considered a misdemeanor.	None.
Georgia	Ga Code Ann. § 33-54-1 et seq.	Applies to "persons," with additional restrictions on insurers and researchers.	Yes. Written consent is required for certain disclosures.	No.	Yes. Violation of the statute is considered an unfair trade practice.	None.



State	Applicable Statute and Regulations	Scope of Applicability of Statute/Regulation	Is Consent Required to Disclose Genetic Information?	Are There Specific Restrictions on the Retention and/or Re-disclosure of Genetic Information?	Are There Specific Statutory Penalties for Unlawful Disclosure of Genetic Information?	Comments
Hawaii	Haw. Rev. Stat. § 431:10A-118.	Applies to insurers.	Yes. Written consent is required for certain disclosures.	No.	No.	None.
Idaho	Idaho Code Ann. § 39-8301 to 8304.	Applies to employers.	Yes.	No.	Yes. The Attorney General may bring an action against employers for violations of the statute.	None.
Illinois	410 Ill. Comp. Stat. 513/15, 30, 35, 40.	Applies to "persons."	Yes. Written consent is required for certain disclosures.	Yes. Authorization is required for subsequent disclosures of genetic information.	Yes. Negligent, intentional, and reckless violations are punishable with fines up to \$15,000 or actual damages, whichever is greater.	Contains specific written consent requirements.
Indiana	n/a	n/a	n/a	n/a	n/a	n/a
Iowa	Iowa Code § 729.6.	Applies to "persons."	Yes. Written consent is required for certain disclosures.	No.	Yes. Violations may result in civil penalties and availability of equitable relief.	None.
Kansas	n/a	n/a	n/a	n/a	n/a	n/a
Kentucky	n/a	n/a	n/a	n/a	n/a	n/a
Louisiana	La. Rev. Stat. Ann. § 22:242, 1023, 40:1299.6. L.A. Admin. Code tit. 37, § 4501 et seq.	Applies to insurers.	Yes. Written consent is required for certain disclosures.	Yes. Consent to retain genetic information is generally required.	Yes. Negligent violations may result in civil penalties up to treble damages. Willful violations may result in civil penalties up to \$100,000.	A general authorization for the release of medical records or medical information is not sufficient for the disclosure of genetic information. Contains specific written consent requirements.
Maine	n/a	n/a	n/a	n/a	n/a	n/a
Maryland	Md. Ins. Code § 27-909.	Applies to insurers, nonprofit health service plans, and health maintenance organizations.	Yes. Written consent is required for certain disclosures.	No.	Yes. Insurance companies may be denied business certificates or be subject to a cease and desist order, among other potential penalties.	None.



State	Applicable Statute and Regulations	Scope of Applicability of Statute/Regulation	Is Consent Required to Disclose Genetic Information?	Are There Specific Restrictions on the Retention and/or Re-disclosure of Genetic Information?	Are There Specific Statutory Penalties for Unlawful Disclosure of Genetic Information?	Comments
Massachusetts	Mass. Gen. Laws ch. 111, § 70G.	Applies to facilities, physicians, and health care providers, with some exceptions.	Yes. Written consent is required for certain disclosures.	No.	Yes. Violations may result in a civil action for injunctive relief.	Contains specific written consent requirements.
Michigan	n/a	n/a	n/a	n/a	n/a	None.
Minnesota	Minn. Stat. § 13.386.	Applies to government entities and "other persons."	Yes. Written consent is required for certain disclosures.	Yes. Written consent is required for the retention of genetic information. Re-disclosure of genetic information is restricted.	n/a	None.
Mississippi	n/a	n/a	n/a	n/a	n/a	n/a
Missouri	Mo. Rev. Stat. § 375.1309.	Applies to "any person."	Yes. Written consent is required for certain disclosures.	Yes. Written consent may be required for certain re-disclosures.	Yes. Violations may result in a civil action.	None.
Montana	n/a	n/a	n/a	n/a	n/a	n/a
Nebraska	n/a	n/a	n/a	n/a	n/a	None.
Nevada	Nev. Rev. Stat. Ann § 629.101 to 201.	Applies to "any person."	Yes.	Yes. Consent to retain genetic information is required.	Yes. Violations may be considered a misdemeanor, and civil remedies may also be available.	None.
New Hampshire	N.H. Rev. Stat. Ann. § 141-H:2.	Applies to "any person."	Yes. Written consent is required for certain disclosures.	No.	No.	None.



State	Applicable Statute and Regulations	Scope of Applicability of Statute/Regulation	Is Consent Required to Disclose Genetic Information?	Are There Specific Restrictions on the Retention and/or Re-disclosure of Genetic Information?	Are There Specific Statutory Penalties for Unlawful Disclosure of Genetic Information?	Comments
New Jersey	N.J. Stat. § 10:5-43 to 49.	Applies to “any person.”	Yes. Written consent is required for certain disclosures.	Yes. Consent to retain genetic information is required. There are restrictions on re-disclosure of genetic information.	Yes. Penalties range from a \$1,000 to \$5,000 fine and/or 6 months to 1 year in jail plus actual damages.	Contains specific written consent requirements.
New Mexico	N.M. Stat. Ann. § 24-21-1 to 7.	Applies to “any person.”	Yes. Written consent is required for certain disclosures.	Yes. Consent to retain genetic information is required.	Yes. Penalties may result in a civil action by the Attorney General and/or victim may bring an action for damages or other relief.	None.
New York	NY CLS Civ R § 79-L.	Applies to “any person.”	Yes. Written consent is required for certain disclosures.	Yes. Any re-disclosure of genetic test results requires informed consent.	Yes. Penalties range from a \$1,000 - \$5,000, a misdemeanor conviction and/or 90 days in jail.	A general authorization for the release of medical information is not sufficient.
North Carolina	n/a	n/a	n/a	n/a	n/a	None.
North Dakota	N.D. Cent. Code, § 23-01.3-01 et seq.	Applies mainly to public health authorities.	Yes.	Yes. Re-disclosure of individually identifiable genetic information is restricted.	No.	Genetic information is protected under general state privacy law.
Ohio	n/a	n/a	n/a	n/a	n/a	None.
Oklahoma	Okla. Stat. tit. 36 §§ 3614.3, 36143.4.	Applies to persons, except insurers.	Yes.	No.	No.	None.
Oregon	Or. Rev. Stat. § 192.531 to 549; Or. Admin. R. 333-025-0100 et seq.	Applies to a “person.”	Yes.	Yes. There are restrictions on re-disclosure of genetic information. Consent to retain genetic information is required.	Yes. Penalties for violations include the imposition of actual damages, fines up to \$250,000; equitable relief, Attorney General can bring an action, and may also be considered a crime.	None.
Pennsylvania	n/a	n/a	n/a	n/a	n/a	n/a



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Rhode Island	R.I. Gen. Laws §§ 27-18-52, 52.1, 19-44, 44.1, 20-39, 39.1, 41-53, 53.1.	Applies to insurance administrators, health plans, and providers.	Yes. Written consent is required for certain disclosures.	Yes. Authorization is required for certain re-disclosures.	No.	Contains specific written consent requirements.
South Carolina	S.C. Code Ann. § 38-93-10 <i>et seq.</i>	Applies to persons or entities that obtain genetic information.	Yes. Written consent is required for certain disclosures.	No.	No.	None.
South Dakota	S.D. Codified Laws §§ 34-14-21 – 34-14-25.	Applies to “persons.”	n/a	n/a	n/a	This statute requires informed written consent from patients before conducting a genetic test.
Tennessee	Tenn. Code Ann. § 56-7-2704.	Applies to insurance providers.	Yes. Written consent is required for certain disclosures.	No.	No.	Contains specific written consent requirements.
Texas	Tex. Ins. Code § 546.001 <i>et seq.</i> ; Tex. Lab. Code §§ 21.403 – 405; ; Tex. Occ. Code § 58.102.	Applies to certain health benefit plans and “persons.”	Yes. Written consent is required for certain disclosures.	Yes. There are restrictions on re-disclosure of genetic information.	Yes. Violations may result in a civil penalty up to \$10,000, and the Attorney General may also bring an action.	Contains specific written consent requirements.
Utah	Utah Code Ann. § 26-45-101 <i>et seq.</i>	Applies to employers and health care insurers.	No.	Yes. There are restrictions on re-disclosure of genetic information by insurers. Insurers may only retain genetic information in accordance with HIPAA.	Yes. An individual may recover damages and be granted equitable relief in a civil action. An insurance company or employer may be liable for actual damages, up to \$100,000 if the violation is a result of an intentional act, and punitive damages if the violation is the result of a malicious act, and reasonable attorneys’ fees.	Employers and insurers may not access genetic information in connection with certain employment decisions.



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Vermont	18 V.S.A. § 9331 to 9335.	Applies to employers and insurers.	Yes. Written consent is required for certain disclosures.	No.	Yes. Violations may be considered an unfair business practice.	None.
Virginia	Va. Stat. Ann. § 38.2-508.4.	Applies to insurers.	Yes.	No.	No.	None.
Washington	n/a	n/a	n/a	n/a	n/a	n/a
West Virginia	n/a	n/a	n/a	n/a	n/a	n/a
Wisconsin	n/a	n/a	n/a	n/a	n/a	n/a
Wyoming	n/a	n/a	n/a	n/a	n/a	n/a

¹ These statutes and regulations are in addition to state statutes and regulations that generally apply to the disclosure of health information. This chart does not address the informed consent requirements for conducting genetic testing, or the scope of practice or licensing requirements for genetic counselors. The research does not extend to case law or Attorney General opinions with respect to the disclosure of genetic information.

