

NATIONAL CANCER INSTITUTE CANCER DIAGNOSIS PROGRAM

50-State Survey of Laws Regulating the Collection, Storage, and Use of Human Tissue Specimens and Associated Data for Research

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Introduction

State laws regulating the conduct of research using human tissue specimens and associated data exist in nearly every one of the fifty states. States have enacted laws that restrict the uses and disclosures of medical information, the conduct of genetic tests, and the use of genetic information, and that impose additional requirements for review of research and informed consent when human beings are involved as subjects of research. State statutes often overlap with the federal rules governing the conduct of human subjects research, but the scope, definitions, and standards of protection differ among the states.

This report presents an overview of the state laws that affect the uses of tissue and associated data in research. It includes a chart showing the requirements for the conduct of tissue research state by state and a table compiling state statutes, and addresses the following questions when tissue specimens and data are obtained:

- How do state laws protecting the confidentiality of medical information and individual privacy affect the use of tissue samples and associated data?
- How do state laws on human subject protection affect the uses of tissue samples and data for research?
- How do state statutes that define and regulate the conduct of “genetic tests” or the acquisition of “genetic information” affect the conduct of research on tissue samples and associated data?

The Resources Development Branch of the Cancer Diagnosis Program at the National Cancer Institute has prepared this survey and analysis to serve as a guide to researchers interested in the state legal and regulatory requirements for research and to examine the potential consequences of a system that incorporates divergent (and sometimes not well known) standards. The survey reflects the status of state laws as of November 2004. It is not intended as legal advice, but as an outline of the legal and regulatory requirements for tissue research. For further information on specific state law requirements, please consult an attorney.

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Federal Regulation of Tissue Research

Research on human tissue has led to significant improvements in medical treatment and in understanding the etiology of disease.¹ Breakthroughs in molecular science now permit the study of the causes and pathways of disease, reinforcing hopes of earlier and more accurate diagnoses and allowing the possibility of developing individually tailored treatments and therapies. In parallel with scientific advances, extensive public discussion is under way among scientists, privacy advocates, patient groups, and ethicists over the collection, storage, and use of human tissue samples for research.

Tissue research involves a range of activities including the collection, storage, analysis, or transfer of tissue samples and data. A research study might collect samples and data in one state, transfer those samples and data to a central repository in another state, and then disclose the data to researchers in a third state. Molecular analysis of a tissue sample might be defined as a “use” of a sample or a “genetic test,” while sending the sample or research data to a collaborator in another state might constitute a disclosure of medical or genetic information. A routine research activity undertaken on a daily basis across the states could potentially involve laws governing informed consent, confidentiality of medical information, restrictions on the retention of genetic information, and human subject protections, using divergent standards in multiple states.

The questions surrounding the control and use of excised tissue and associated data focus on ways to facilitate important scientific research while upholding the key legal and ethical principles of individual autonomy and privacy. Specific issues include the conditions necessary for the disclosure of private medical information; whether each new use of human tissue specimens requires individual consent; the scope and specificity of that consent; and when deidentified or anonymous specimens and associated data² may be used for research.

Research that is conducted or supported by the federal government, including research using human tissue specimens, residual diagnostic specimens, or medical information that is not otherwise exempt, is governed by the “Federal Policy for the Protection of Human Subjects”³ set forth in the Code of Federal Regulations. The Department of Health and Human Services (HHS) has codified the federal policy at 45 C.F.R. part 46, Subpart A (known as the “Common Rule”), that applies to HHS-funded research⁴ that is not otherwise exempt, and in 21 C.F.R. parts 50 and 56, which similarly govern research on products regulated by the Food and Drug Administration (FDA). According to HHS regulations at 45 C.F.R. 46.101(b)(4), the study or collection of “existing data” (including stored samples, records, pathological specimens, or diagnostic specimens) is deemed exempt from the requirements of the Common Rule, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers linked to subjects.

Federal regulations covering protection of human subjects offer little overt direction regarding the use of human tissue for research. According to HHS regulations, tissue research is deemed human subjects research subject to federal regulations when identifiable private information is obtained about a living individual or when an investigator obtains data through interaction or intervention with an individual.⁵ The FDA regulations apply when research is conducted for an application that will be submitted to the FDA.

The substantive requirements under both sets of regulations are similar:⁶ The proposed research activity must be submitted to an institutional review board for scientific and ethical review (unless the activity is classified as exempt), and informed consent of the subject must be obtained or waived. FDA regulations do not permit waiver of informed consent for human subjects research, except under certain emergency circumstances. Certain types of research are eligible for expedited review according to the Office for Human Research Protections (OHRP) and FDA guidance,⁷ including the prospective collection of biological specimens by noninvasive means when taken for research purposes.⁸

Federal policy directs Institutional Review Boards (IRBs) to weigh the potential risks of the research, which may include risks to the privacy of the individual if personal information is disclosed. Federal policy for protection of human subjects explicitly does not preempt applicable state laws or local laws or regulations that provide additional protections for human research subjects.⁹

A new federal regulation, the “Privacy Rule,” established under the authority of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and implemented in April 2003,¹⁰ imposes additional limitations on the research uses and disclosures of identifiable patient information. While the Privacy Rule does not cover tissue specimens per se, the data associated with tissue specimens may be considered protected health information and therefore may be subject to restrictions on use and disclosure. In general, HIPAA requires patient authorization for specific uses of protected health information, although certain exceptions apply.¹¹ HIPAA does not preempt state laws that impose more stringent protection on individually identifiable health information, but rather defers to the higher standard of privacy protection.¹²

The federal regulations for protection of human research subjects and the federal Privacy Rule explicitly state that they do not affect state or local laws or regulations which otherwise apply and which provide additional protections.¹³ As a result, when conducting research activities in certain states, researchers need to be aware of state laws that impose additional requirements beyond those set forth in the federal regulations. This survey will review the laws that impose additional requirements in each state and will provide an explanation of the purpose of these laws and their protections.

State Regulation of Tissue Research

State laws affecting the use of tissue and associated data in scientific research are found in a variety of sources, including medical records laws, privacy and health privacy laws, genetic testing/genetic information laws, and laws on human subject protection. State laws may require researchers to obtain prior written informed consent from individuals for specific research uses of tissue or data, to notify individuals prior to the conduct of a “genetic test,” to limit the length of time permitted for retention of tissue samples when genetic information is obtained, or to remove identifiers prior to release of patient information.

Most states require that “medical” or “health” information, or information collected in the course of clinical care (which often includes tissue specimens and associated data), be kept confidential. Many states that otherwise restrict the disclosure of medical or health information permit disclosure for research purposes when protections for the subjects exist (e.g., anonymization of the record, approval by an IRB, explicit consent of the individual, etc.). Those state laws that permit the disclosure of medical or health information for research purposes generally specify that one or more of the following conditions must be met: (1) IRB review and approval of the research, (2) conduct of research according to federal regulations for the protection of human subjects, or (3) use of “anonymous” information that does not identify the research subject.

Some states impose supplemental restrictions on genetic testing and the collection of genetic information, usually in the context of clinical genetic tests, in order to prohibit “genetic discrimination” in the provision of insurance and employment. A few states extend the duties of the federal regulations to privately sponsored research, or to research not otherwise covered by federal regulations, while others impose supplemental requirements on the process of obtaining informed consent.

The laws are often inconsistent from state to state and even differ within the states depending on the source. Regulations differ with regard to the scope of protection and the types of limits imposed on uses of and access to tissue specimens and associated data. Since much scientific research involves collaboration across state lines, researchers who study human tissue should be aware of their rights and duties under their states’ laws with respect to the control and use of tissue specimens for research. The differences in the requirements of various states, and the difficulty in comparing the conditions required for the conduct of research in different states, have led to uncertainty about the actions required by researchers to comply with state laws when human tissue is used in research. As noted by the National Bioethics Advisory Commission, with respect to the use of information in medical records, “the variability of state law protections has been cited as a problem in and of itself.”¹⁴

Analysis of State Laws

I. Health and Medical Information

Preserving the privacy and confidentiality of an individual's medical or health information is a legal obligation in most states.¹⁵ The limits on the use of patient information vary widely among states, but health providers, employers, and insurers who obtain an individual's health information are generally required to restrict its release.¹⁶

Research on human tissue samples and associated data requires that researchers comply with state laws governing access to and use of medical information, since tissue specimens are usually considered "health care information" or "patient information." This is true even though specimens (like X rays, radiographic films, tracings, etc.) were not traditionally considered part of the medical record. In certain states, the definition of health care information specifically references tissue samples as part of health information. For example, North Dakota has one of the broadest definitions of protected health information, including the following definition of identifiable medical, genetic, or demographic information:

"Any fluid or tissue samples collected from an individual, diagnostic and test results, whether oral or recorded in any form or medium, which...relates to the past, present, or future physical or mental health or condition of an individual, including individual cells and their components; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (2) (a) Identifies an individual; or (b) With respect to which there is a reasonable basis to believe that the information can be used to identify an individual."

While state laws often restrict the use of medical or health information, exceptions to the rules against disclosure are commonly made for releases of information to law enforcement authorities for determination of paternity, or to scientists for research purposes. These "research exceptions" often permit disclosures of health information, and even genetic information,¹⁷ without the requirement to obtain individual permission when the data are anonymous, when the patient is not identified, or when an IRB has approved the research.

The exceptions are common, but they are not identical or uniform. More than half of the states have research exceptions in their medical records laws permitting disclosures to scientific researchers without specific individual consent under certain conditions.¹⁸ The conditions differ from state to state; however, they all reflect the underlying notion that if individual privacy is protected, the use of tissue samples by researchers is valid and ethical.¹⁹

Alaska uses a common method of prohibiting most disclosures of health information, while permitting disclosures for research when patient privacy is protected:

“For research that is subject to federal law and regulations protecting the rights and welfare of research participants; or (B) using health information that protects the confidentiality of participants by coding or encryption of information that would otherwise identify the patient.”

At the other end of the spectrum, a few states (e.g., Vermont), have enacted patients’ rights laws requiring informed consent and notice when hospital patients are also subjects of human research studies. Others, like Maryland,²⁰ Oregon,²¹ and Minnesota,²² specify the form and content of the patient authorization required for disclosure of health information. Minnesota imposes perhaps the strictest restrictions on disclosures, establishing an elaborate mechanism for releases of patient information, even for research purposes. Minnesota law states that health records may be released to an external researcher solely for purposes of medical or scientific research, and only as follows:

“(1) Health records generated before January 1, 1997, may be released if the patient has not objected or does not elect to object after that date; (2) for health records generated on or after January 1, 1997, the provider must: (i) disclose in writing to patients currently being treated by the provider that health records, regardless of when generated, may be released and that the patient may object, in which case the records will not be released; and (ii) use reasonable efforts to obtain the patient’s written general authorization that describes the release of records in item (i), which does not expire but may be revoked or limited in writing at any time by the patient or the patient’s authorized representative.”²³

Connecticut passed a highly detailed statute pertaining to veterans’ health information and access to clinical health care information that specifies the process for requesting, providing, examining, and retaining tissue slides and pathology blocks. Connecticut law requires that patients or their designated health provider have the right to examine slides with their retained tissue, and specifies procedures for requesting, safeguarding, cutting, and returning tissue slides.²⁴

II. Genetic Information

In addition to the restrictions on uses of “medical information” that can affect research on tissue specimens and data, many states²⁰ have placed specific restrictions on “genetic tests” and the collection or disclosure of “genetic information.”²⁵ These statutes can affect tissue research activities depending on the specificity of the definitions of “genetic test” or “genetic information,” and whether the definitions include analysis of the components of a gene (even for molecular testing in which hereditary conditions are not being studied), in addition to the

more commonly understood description of a genetic test as referring to a test that involves familial or hereditary conditions.

Among the states that regulate the conduct of genetic tests or the acquisition of genetic information, twenty-one allow research uses of genetic information under specified conditions, usually when patient identities are protected.²⁶ This approach distinguishes the clinical and research uses of tissue and data, freeing research activities from certain limits on usage as long as protections exist.

Delaware, Nevada, New Jersey, New York, and Oregon have laws requiring researchers to obtain individual informed consent in order to retain “genetic information.” If this informed consent is not obtained, or if an individual directs that the specimen be destroyed, this might conflict with the need to retain specimens for quality-assurance purposes.

One example of a statute that distinguishes between research and clinical data is in the Massachusetts statute describing “genetic information” as information that is gathered from a clinical or diagnostic test of DNA, RNA, or other genetic components:

“The term genetic information shall not include any information about an identifiable person that is taken: (1) as a biopsy, autopsy, or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins.²⁷”

Many statutes contain language similar to that found in a Nebraska law which excludes from the definition of “genetic test” regulated by the statute any activities undertaken as part of biomedical research:

“Genetic test does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome. Genetic test does not include a procedure performed as a component of biomedical research that is conducted pursuant to the federal Common Rule under 21 C.F.R. Parts 50 and 56 and 45 C.F.R. Part 46 as such regulations existed on September 1, 2001.²⁸”

Conversely, some states use broad definitions of “genetic test” that do not exclude research from their scope. Louisiana, New Hampshire, New Mexico, Oregon, and Iowa all use broad definitions of “genetic test,” similar to the definition in the following Louisiana statute, which may restrict the ability of researchers to use tissue samples:

“Genetic test means any test for determining the presence or absence of genetic characteristics in an individual, including tests of nucleic acids, such as DNA, RNA, and mitochondrial DNA, chromosomes, or proteins in order to diagnose or identify a genetic characteristic.²⁹”

New York law protects the confidentiality of records of genetic tests. “Biological samples” are described as “any material part of the human body or of discharge therefrom known to contain DNA, including but not limited to tissue specimens, blood, or urine.”³⁰ This law imposes very strict requirements for informed consent and retention of samples for limited periods, but the law permits the conduct of research on anonymous samples, pursuant to a research protocol approved by an IRB, when the identity of the individuals is protected. Arkansas and Oklahoma utilize similar statutes that permit the use of excess surgical and diagnostic tissue (and blood) for genetic research or other research studies as long as patient privacy is assured.³¹

Michigan and Nebraska have identical statutes for the conduct of genetic tests, which impose a strict requirement to obtain informed consent from individuals that incorporates a statement of future uses of the sample, who will have access to the sample, etc.³² Both states permit research without informed consent when research is conducted pursuant to federal regulations. South Carolina similarly imposes strict limits on the conduct of genetic tests for clinical purposes, but permits the use of samples and information for research purposes when patient identities are not disclosed.³³ South Dakota demands that informed consent documents include specific provisions including who will have access to the samples.³⁴ South Dakota does not permit releases of information for research without informed consent.

New Jersey imposes some of the strictest limits on the use of samples for research purposes in its Genetic Privacy Act.³⁵ Among other things, the Act requires the destruction of samples used in genetic research upon completion of the project, unless individual informed consent is obtained. However, the Act also states that this section only applies to information that can be tied to an individual or his family, implying that it only applies to identifiable information. Similarly, Texas does not allow indefinite retention of samples taken for clinical tests, but does allow their retention for research purposes.³⁶

In some states, different definitions of “genetic test” are found in several laws in the same state. For example, Arizona addresses genetic testing in two separate state statutes: one that covers genetic tests in general (in the statutes governing Courts and Civil Proceedings),³⁷ and another in the laws regulating the provision of insurance,³⁸ using a different definition of “genetic test” in each statute. The definition of “genetic test” in the insurance statute is more restrictive, limiting the use of information from clinical tests.

To date, state statutes have not addressed ownership of tissue samples. However, individual ownership of “genetic information” has been declared by four states: Colorado,³⁹ Florida,⁴⁰ Georgia,⁴¹ and Louisiana.⁴² These statutes have not been tested to examine their validity or scope,⁴³ but they reflect the effort to exert individual control over one’s genetic material in the face of insurers, employers, and commercial entities that seek to obtain genetic information.

For the purposes of research using tissue, the statutes addressing ownership could prove problematic if interpreted literally since such an interpretation would restrict the ability of researchers to use the “personal property” of another. However, note that of the four states that deem genetic information to be “owned” by the individual, three of them (Colorado, Georgia, and Louisiana) permit the use of “genetic information” for research purposes when the identity of the individual is not disclosed. Thus, while these provisions appear restrictive, they permit the use and retention of genetic information for research purposes when the data are anonymous.

III. State Laws on Human Subject Protection

New York, Virginia, California, and (most recently) Maryland impose additional requirements on the conduct of human subjects research beyond those set forth in federal regulations.

Maryland⁴⁴ and Virginia⁴⁵ extend the provisions of the Common Rule requiring informed consent from subjects (or a waiver of the requirement to obtain informed consent) and independent ethical review by an IRB or other qualified entity to all human subjects research, regardless of the funding source. In addition, the Maryland law provides for public access to the minutes of IRB meetings, with confidential information redacted if necessary. California mandates that informed consent be obtained from participants in research; however, no independent scientific review is required.

New York state public health statutes include an explicit requirement to obtain informed consent and to review research for studies not otherwise covered by the federal regulations.⁴⁶ New York’s law on human subject protection exempts from the definition of human research “biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice, or for epidemiological investigations.” By explicitly exempting tissue taken exclusively for research purposes, and excess surgical or diagnostic tissue, New York permits the use of tissue samples in research without the attendant requirements for specific informed consent and review of the research.

Many states have enacted some form of a patients’ bill of rights,⁴⁷ some of which require that written informed consent be obtained to participate in research, or that informed consent be documented.⁴⁸ Of these, only New York explicitly excludes tissue research from the restrictions of the statute.

Case Studies

The following hypothetical situations are presented as a basis for the discussion of the practical implications resulting from the different state laws and conditions imposed on the use of specimens for research. The state laws presented cover various research activities including collection, storage, analysis, and distribution of tissue specimens and associated patient data. HIPAA is not specifically addressed.

I. State Law Requirements and Informed Consent

The ABC Repository has been accruing specimens for decades. The Repository has vast collections of archived tissue and data, most of which were collected using general surgical consent forms.

Surgical and diagnostic specimens are received, logged, and coded, with the following patient information retained: date of diagnosis, date of surgery, age of patient at diagnosis. ABC also collects specimens prospectively to meet the needs of researchers. Collection sites use general surgical consent forms for use of tissue and data following waiver of the need for specific informed consent by the IRBs. When specimens are sent to researchers, patient names are removed from the specimens and associated data to protect patient identity, a code is assigned, and a link is retained for quality control. The ABC Repository recently received samples of prostate tissue from medical centers in the following states: Washington, Minnesota, Texas, California, and Pennsylvania.

The ABC Repository adheres to federal policy for human subjects research. ABC's IRB has reviewed and approved the Repository's operating procedures that stipulate that requests to use ABC's tissue samples and data must comply with the Common Rule. Since links to patient identity are retained by ABC (although not disclosed to researchers), ABC considers use of its specimens to be human subjects research.⁴⁹ In order to obtain specimens from ABC, researchers must provide documentation of IRB review and approval.

Recently, ABC staff met with researchers at several collection sites and decided to review whether their procedures meet the requirements of state law with respect to privacy of medical information and informed consent. Since the Repository depends both on collection of samples and data from various sites and on distribution of samples and data to researchers in multiple states, the staff began with a review of the pertinent laws in the five states that provided the most recent specimens of prostate cancer.

Do ABC Repository activities comply with state laws?

Discussion of Case Study #1

State laws generally govern activities that take place within the geographic limits of a state or that affect the citizens of a state. In the case of tissue research, the laws of the state where a collection takes place must be followed with respect to confidentiality of the medical information and informed consent. Virtually all states protect the confidentiality of medical records, but the rules governing informed consent for uses of medical information differ from state to state. Since tissue samples and data will likely be included in the definition of medical “information,” restrictions on disclosures of “medical” or “health” information must be followed. Some state statutes have research exceptions permitting the use of medical information without explicit patient consent when patient identities are protected.

All collection sites should review their state laws to ensure that they are permitted to collect specimens and data and handle the data in a manner that protects confidentiality. They should also determine whether special conditions apply for “disclosure” of the data to the ABC Repository without explicit patient consent. For further information, see OHRP’s recent guidance document “Research Involving Coded Private Information or Biological Specimens.” The guidance document describes the circumstances where research using coded private information or biological specimens will not be considered human subjects research, and therefore not subject to HHS regulations for protection of human research subjects (see <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>).

Washington

ABC and the researchers in Washington State need to check whether the general surgical consents used by the collection sites comport with Washington State law that strictly protects disclosures of medical information.

Washington state permits releases of information to researchers without the specific consent of the individual when an IRB has determined that the research project “(i) is of sufficient importance to outweigh the intrusion into the privacy of the patient that would result from the disclosure; (ii) Is impracticable without the use or disclosure of the health care information in individually identifiable form; (iii) Contains reasonable safeguards to protect the information from redisclosure; (iv) Contains reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research project; and (v) Contains procedures to remove or destroy at the earliest opportunity, consistent with the purposes of the project, information that would enable the patient to be identified, unless an institutional review board authorizes retention of identifying information for purposes of another research project.”⁵⁰

Therefore, the research team in Washington may send the samples and data to the ABC Repository as long as an IRB has reviewed the research protocol and is satisfied that the collection site can comply with the rules. According to the statute, the researchers in Washington may not release any individually identifiable information since they are relying on permission obtained from general (surgical) consent forms, rather than express individual consent to the research.

Minnesota

Minnesota has one of the most restrictive laws on disclosures of medical information among the 50 states. Minnesota law permits the release of health information to researchers for medical or scientific research,⁵¹ but only under very limited circumstances. Health records generated prior to January 1, 1997, may be released if the patient has not objected.

For records created after January 1, 1997, providers must advise patients in writing that their records may be released, and if the patient objects, the records may not be released. Providers are required to use reasonable efforts to obtain a patient's written general authorization for release of records. The authorization is not required to expire but may be revoked or limited by the patient at any time. Finally, upon the request of the patient, providers are required to provide information on how the patient may contact an external researcher to whom the health record was released and the date it was released.

The statute includes further obligations that the provider make reasonable efforts to determine (1) that the use or disclosure does not violate any limitations under which the record was collected; (2) that the use or disclosure in individually identifiable form is necessary to accomplish the research or statistical purpose for which the use or disclosure is to be made; (3) that the recipient has established and maintains adequate safeguards to protect the records from unauthorized disclosure, including a procedure for removal or destruction of information that identifies the patient; and (4) that further use or release of the records in individually identifiable form to anyone (other than the patient) without the patient's consent is prohibited.

In the facts presented in this Case Study, the samples and data may be transferred freely if they were collected prior to January 1, 1997, and if the patient has not objected (or does not object). For samples and data that were accrued after January 1, 1997, the researchers in Minnesota must ensure that they have complied with the rules set out above. Only samples of patients that have received proper notification and an opportunity to object may be used. The authorizations for release of patient medical information must include the required elements under state law and should be checked to ensure that they have not expired.

Texas

Texas Medical Records Privacy Act requires written authorization for disclosures of medical information unless an exception applies. For research purposes, disclosures of patient health information by hospitals are permitted without written authorization if the research is conducted according to federal regulations for the conduct of human subjects research (45 C.F.R. 46 or 21 C.F.R. 50/56), where an IRB has approved the research.⁵² If the research is not subject to the federal rules, then researchers must obtain the express written authorization of the individual.

The privacy Texas law (similar to HIPAA) requires documentation of the waiver of informed consent prior to releases of information where there is no express written authorization.

If the research activity that takes place in Texas (in this scenario, the collection of specimens is a research activity) is conducted in accordance with the federal regulations governing human subjects research, and an IRB approves, the research team at the collection site may obtain a waiver of the requirement of individual informed consent in order to send the data and samples to the ABC Repository.

In order to comply with Medical Records Privacy law, the researchers in Texas must document the waiver given by the IRB. If so, then there is no need for individual consent prior to sending the samples and data to the Repository. If the research is not subject to the federal regulations, then the researchers must obtain the express consent of the individual participants for the use of their samples and data.

California

California's "Confidentiality of Medical Information Act" regulates disclosures of medical information and genetic information. The Act mandates the confidentiality of medical records when acquired, stored, and used and includes specific criteria for a valid authorization. Medical information is defined as "any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, or contractor regarding a patient's medical history, mental or physical condition, or treatment. 'Individually identifiable' means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity."⁵³ The Act includes a research exception permitting disclosures without patient authorization for "bona fide" research where the identity of participants is protected.⁵⁴

California has also enacted a law called the Protection of Human Subjects in Medical Experimentation Act.⁵⁵ The Act requires that informed consent of participants be obtained for all medical experiments, defined as:

“... (a) the severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject. (b) The investigational use of a drug or device as provided in Sections 111590 and 111595. (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.”

The Medical Experimentation law exempts research at institutions that hold a valid Assurance of Compliance⁵⁶ pursuant to Part 46 of Title 45 of the Code of Federal Regulations and that obtain informed consent in the method and manner required by such regulations.

The research team in California may release the specimens and data to ABC under the following conditions: (1) in order to comply with the Confidentiality of Medical Information Act, if the research is “bona fide” research (presumably, bona fide research is conducted by an institution holding an Assurance of Compliance) and participant identities are protected; and (2) in order to comply with the Medical Experimentation Law, if the recipient institutions are operating according to the terms of an Assurance of Compliance with federal regulations; or (3) if the consent/authorization of the individual is obtained.

Under facts presented in Case Study #1, since the ABC Repository operates according to the federal regulations, research activities will qualify as “bona fide” research. If patient identities are not disclosed to the Repository (even if links are retained), the samples and data may be sent to ABC without individual consent.

Pennsylvania

Pennsylvania law has no specific provision allowing the release of information from medical records for research purposes. Therefore, if the institutions collecting the information consider general consent forms adequate to protect patient information, and do not require consent to specific uses by patients, the site may release the information to ABC Repository.

II. State Law Requirements and Genetic Testing

Researchers have proposed a multi-site study of somatic gene mutations to evaluate a potential link between XYZ environmental toxin and uterine cancer.

Patients undergoing surgical procedures for uterine cancer were asked to sign a separate informed consent form for research. The informed consent form used for the collection described the intended use of the tissue and data for research into uterine cancer, including possibly for genetic research, the necessity of voluntary participation, and the measures undertaken to protect individual identity. Samples and data were stored at a central repository and then sent to various medical centers for molecular analysis.

Codes were assigned to protect individual identities. Investigators at the local sites maintained access to the links, but no patient names or links to the code were sent to researchers at the various sites. In addition to tissue samples, the investigators require the following patient information: diagnosis, date of diagnosis, exposure history, and age of patient at diagnosis.⁵⁷

The study has been funded by the NCI, and samples and data are to be sent as cases for molecular analysis to researchers in four states: Arizona, Alabama, New York, and Oregon.

The IRBs at each recipient institution approved the research and the informed consent forms according to the requirements of the federal regulations (45 C.F.R. 46). Nevertheless, the principal investigator is concerned about complying with state laws on genetic testing in the various states.

Discussion of Case Study #2

The state laws that impose special requirements for genetic testing are triggered when activities that fall within the definition of “genetic test” occur within a particular state, or when “genetic information” is gathered in a state with a statute imposing conditions on genetic tests. This will usually require a careful reading of the statutory language and the definitions of “genetic test,” “genetic information,” and “medical information.”

Arizona

Arizona law defines genetic test as:⁵⁸

“a) A test of a person’s genes, genetic sequence, gene products, or chromosomes for abnormalities or deficiencies, including carrier status, that: (i) Are linked to physical or mental disorders or impairments. (ii) Indicate a susceptibility to any illness, disease, impairment, or other disorder, whether physical or mental. (iii) Demonstrate genetic or chromosomal damage due to any environmental factor.”

Arizona explicitly carves out biomedical research from other activities by statute, stating that the definition of genetic test in the statute does not include “Tests given for use in biomedical research that is conducted to generate scientific knowledge about genes or to learn about the genetic basis of disease or for developing pharmaceutical and other treatment of disease.”

The proposed activity falls within the exemption for “biomedical research.” Thus the conditions for conducting a genetic test do not apply and the researchers in Arizona are not required to comply with any additional state law provisions.

Alabama

Alabama prohibits health plans from requiring genetic tests showing predisposition to cancer or from using genetic information to determine eligibility for coverage.⁵⁹ No other prohibitions on uses of genetic information apply, and the definition of genetic test used in the insurance statutes is careful to reference clinical genetic tests. Therefore, the statute does not affect researchers using biological material.

The research at this site may proceed as proposed by the investigators.

New York

New York State has laws on medical privacy, genetic privacy, and human subject protection, making it among the more restrictive states for the conduct of research.

New York prohibits the conduct of “genetic tests” without the prior written informed consent of the individual. A genetic test is defined as:

“... Any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual’s offspring; such term shall also include DNA profile analysis. ‘Genetic test’ shall not be deemed to include any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation, unless conducted purposely to identify such genetic variation.”⁶⁰

According to the statute, prior to a genetic test, individuals must be notified, individual authorization must be obtained, and specific elements must be incorporated into the informed consent form including: a general description of each specific disease or condition tested for, the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease, the name of the person or categories of persons or organizations to whom the test results may be disclosed, and a statement that no tests other than those authorized shall be performed on the biological sample.

For clinical genetic tests, the informed consent must state 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. New York law requires individual authorization for sample retention for up to ten years if no genetic testing is performed; however, informed consent must be obtained prior to the conduct of genetic tests. Retention of a DNA sample past a period of ten years requires explicit consent for a longer or indefinite period of retention.

Nevertheless, for research (rather than for clinical purposes), New York law provides that samples may be used without individual informed consent when IRB approval of the research protocol is given, as long as the identity of the individual has been removed, the results are not linked to the person, and no information relating to the identity of the individual is disclosed.

Therefore, for the purposes of compliance with the New York law on “Confidentiality of Records of Genetic Tests,” the samples and data may be used as proposed, as long as IRB approval is obtained, and the information regarding individual identities is protected.

New York State has a separate statute governing the conduct of human subjects research by all researchers—public and private—in the state of New York.⁶¹ The law extends the requirements of the federal regulations for informed consent (the elements are identified) and review by a human research review committee for all human subjects research. The law explicitly references use of tissue in research and exempts research using excess surgical and diagnostic tissue as follows:

“Human research shall not, however, be construed to mean the conduct of biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice, or to include epidemiological investigations.”

Since the samples were collected during surgical procedures, the human subjects law should not prevent the conduct of the study.

Oregon

Oregon has strict laws protecting the confidentiality of the patient’s medical records,⁶² and requires specific conditions for the use and disclosure of genetic information.

Oregon’s Privacy Act requires stringent consent for use of tissue samples and data, and includes language describing the uniquely private and personal nature of genetic information to individuals and to their family members. The Act defines a genetic test expansively as: “a test for determining the presence or absence of genetic characteristics in an 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.”⁶³

The proposed analysis of tissue and data falls within the definition of genetic test and might be subject to the limits on use, disclosure, and redisclosure. However, Oregon law provides a research exception permitting use of genetic information without individual informed consent for “anonymous research.”⁶⁴ This may occur if the individual was notified the sample or genetic information may be used for anonymous research, but not if the individual, after being notified of the intended use, requested that the sample not be used for anonymous research.

Oregon researchers must maintain the confidentiality of the information or sample and protect the information or sample from unauthorized disclosure or misuse.

III. Individual Ownership of Excised Tissue Samples

Ms. Smith entered the Garden City Medical Center for surgery to remove a lung tumor. Dr. Jones, the treating physician, noted Ms. Smith’s unique response to therapy and embarked on a research project to study Ms. Smith’s blood and cells without informing her. Ms. Smith was asked to come to the medical center for regular blood draws and medical procedures, and, additionally, Dr. Jones used her excised cells to create a cell line for research purposes, all unknown to Ms. Smith.

Dr. Jones and Garden City Medical Center developed a unique diagnostic test used to detect the presence of lung tumors using a simple blood test. They obtained a patent on this test and have sold the test to other health care providers.

Can Ms. Smith obtain a portion of the revenues from the patented blood test developed using her blood and tissue?

Discussion of Case Study #3

In the 1990 case of *Moore v. Regents of the University of California*,⁶⁵ the California Supreme Court found that individuals did not retain rights of ownership in excised tissue when tissue was used for research purposes. The court also held that even if human cells initially belonged to an individual, these excised cells were legally and factually distinct from the resulting research product.

George Moore signed a consent form agreeing to the removal of his spleen for the treatment for hairy cell leukemia. Moore was asked to come to the medical center for regular blood draws and medical procedures, and, additionally, the treating physician used Moore’s excised cells to create a cell line for research purposes, all unknown to Moore. Moore sued the physician, claiming “conversion” (or deprivation of a property interest), breach of the duty to obtain informed consent, and breach of fiduciary duty for using the excised cells without the patient’s consent to the research use.

On the matter of ownership of the removed cells, the court found that individuals did not retain rights of ownership in excised tissue. However, the Court did find that

the physician had breached his duty to obtain informed consent for the research conducted on George Moore, ruling that in the context of a therapeutic relationship, a physician has a duty to disclose and to obtain informed consent from a patient who is the subject of research. The court also found a breach of a fiduciary relationship and violation of informed consent since, under California law, physicians must disclose all personal interests that may affect medical judgment.

Since this case is only binding in the state of California, the question of individual ownership of excised tissue is still uncertain in most states. Nevertheless, this decision has been influential, and there is a presumption that researchers are entitled to use tissue specimens for further study as long as such use complied with existing regulations and laws.

In a more recent case decided in May 2003, in *Greenberg et al. v. Miami Children's Hospital*,⁶⁶ a group of families of children with Canavan's disease, along with several not-for-profit institutions, sued the Miami Children's Hospital and Dr. Reuben Matalon, the researcher who had developed the prenatal genetic test for Canavan's disease, after a patent for the test was obtained. Canavan's disease is a rare, autosomal neurodegenerative disorder characterized by degeneration of CNS white matter and specific CNS pathological findings. Canavan's disease always results in early death in children and infants, depending on the type inherited, and no treatment is available. Diagnostic tests were not available to detect the disorder in utero until Dr. Matalon successfully isolated the gene responsible for Canavan's disease in 1993.

The individual plaintiffs sued on behalf of their children who had donated blood and tissue samples to Dr. Matalon while he was working to isolate the gene.⁶⁷ Other plaintiffs joined the suit to pursue a public policy claim protesting the enforcement of the patent, including collection of royalties and licensing fees for restrictive licensing arrangements. When the plaintiffs learned that a patent had been obtained and was being enforced to restrict the availability of the prenatal test, they sued.

According to the plaintiffs, their collaboration in the process was based on the "understanding and expectations that such samples and information would be used for the specific purpose of researching Canavan's disease and identifying mutations in the Canavan's disease gene which could lead to carrier detection within their families and benefit the population at large." Plaintiffs further alleged that it was their "understanding that any carrier and prenatal testing developed in connection with the research for which they were providing essential support would be provided on an affordable and accessible basis, and that Matalon's research would remain in the public domain to promote the discovery of more effective prevention techniques and treatments and, eventually, to effectuate a cure for Canavan's disease."

The judge dismissed all claims against the defendants except the claim of unjust enrichment (Ballentine's Legal Dictionary defines unjust enrichment as the circumstances which give rise to the obligation of restitution, or the receiving and retention of property, money, or benefits which in justice and equity belong to another), for failing to share the financial benefit that accrued from licensing fees and royalties for the prenatal test.⁶⁹ While the case eventually settled, the judge held that an individual does not retain a continuing interest in tissue and blood "donated" for research purposes.

While this case is helpful in understanding some rights that researchers may have to use tissue specimens, it is uncertain whether this ruling will apply to all circumstances since the case involved specific facts where the individuals were fully informed of the research purpose and gave their explicit prior consent.

Conclusion

While few states specifically address research uses of tissue samples, numerous laws that regulate medical information, genetic testing, and the conduct of human subjects research affect the ability of researchers to collect, store, access, distribute, or analyze tissue samples and associated data. A review reveals that most of these laws focus on protecting individual privacy and confidentiality to minimize risks of harm. Some potential risks to subjects whose specimens and data are used in research could result from releases of private medical information. These risks might include loss of insurance or loss of employment. Other risks that have been identified are not necessarily related to inappropriate releases of information, such as loss of dignity or autonomy, or infringement on privacy.

The laws in various states differ widely in scope, definitions used, and applications for research. The rules also differ depending on whether the source is public health statutes, insurance statutes, privacy laws, or laws protecting research subjects. As a result, the application of many statutes to research uses of tissue and data is unclear, with vague and conflicting definitions leading to variable interpretations and implementation.

Statutes that permit uses of tissue and data for research may state that "anonymous" research is allowed, without defining "anonymous." Other statutes may intend to allow research uses of data where confidentiality is "protected" or "ensured" without providing an explanation of the standard. Various states define the terms "genetic test" and "genetic information" differently, affecting their scope and the type of scientific activity covered. As a result, some scientific research activity could be limited, depending on a state's definitions of "genetic test" or "genetic information," even when the legislative intent seems to be regulation of the conduct of clinical genetic tests. For example, research that studies certain hereditary characteristics

(such as hair color, eye color, etc.) could be defined broadly as “genetic” research and become subject to additional restrictions, even though the research is unlikely to create increased risk to subjects.

The difficulty in applying the limits on uses of medical information or genetic information to research on tissue samples and data is further complicated when the provisions of one state law diverge from those of another. If interpreting the rules for research in any single state is difficult, adhering to the rules when multiple state statutes apply is exponentially more complicated. This may present challenges for multi-site collaborative research involving the collection, distribution, and use of specimens and data if these sites are located in different states.

Research depends on a timely and smooth flow of scientific information. Research depends equally on the trust of the public that participates in and supports the conduct of research. Maintaining that trust requires protecting research subjects from risks by ensuring the integrity and confidentiality of information and individual privacy, dignity, and autonomy. Since state laws are designed to incorporate a balance of societal and individual interests, adopting clear standards and definitions is critical to supporting valuable scientific research that is reliant on a smooth flow of data, while ensuring adequate protections for the rights of individuals.

NATIONAL CANCER INSTITUTE CANCER DIAGNOSIS PROGRAM

50-State Survey of Laws Regulating the Collection, Storage, and Use of Human Tissue Specimens and Associated Data for Research

Appendix A

Summary of State Laws

This summary of state laws does not include full citations for statutes that prohibit discrimination in employment or insurance on the basis of genetic testing or genetic information. There are other comprehensive collections of state laws addressing genetic nondiscrimination in employment and insurance. Therefore, there are complete references only where the statute is relevant for the conduct of research using tissue specimens.

ALABAMA

Confidentiality of Health Information

Patient medical records must be kept confidential, regardless of the state where the medical records of any Alabama patient are maintained [Code of Alabama Section 34-24-504].

Conditions Imposed on Genetic Testing/Use of Genetic information

Conditions are imposed on the conduct of clinical genetic tests for cancer [Code of Alabama Section 27-53-1 et seq.].

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

“Genetic Characteristics.” A scientifically or medically identifiable gene or chromosome, or alteration thereof, that is known to be a cause of a disease or disorder, or determined to be associated with a statistically increased risk of development of a disease or disorder.

“Genetic Test.” A presymptomatic laboratory test which is generally accepted in the scientific and medical communities for the determination of the presence or absence of the genetic characteristics that cause or are associated with risk of a disease or disorder. [Code of Alabama Section 27-53-1]

ALASKA

Confidentiality of Health Information

- HMOs may not release medical information without individual consent (oral, electronic, or written), except for research that is conducted according to the Common Rule, or where the identity of participants is coded. [Alaska Statutes 21.86.280]
- Medical and public health records are not open to public inspection. [Alaska Statutes 09.25.120]
- Information held by insurance organizations must be kept confidential.
- Data and records that identify an individual are confidential, and may not be disclosed or copied [Alaska Statutes 18.05.042].

Conditions Imposed on Genetic Testing/Use of Genetic information

Rules imposed on genetic testing and genetic privacy. Written informed consent is required to collect DNA samples, perform DNA analysis, retain DNA samples or disclose the results of a DNA analysis. [Alaska Statutes 18.13.010]

Permitted Releases of Health Information or Genetic Information for Research

Managed care entities may disclose medical information without the individual's consent for research that is either: 1) subject to federal law and regulations protecting the rights and welfare of research participants, or 2) protects the confidentiality of the participants in the study through coding or encryption of identifying information. [Alaska Statutes 21.07.040]

Definition of Genetic Test/Genetic Information

DNA means deoxyribonucleic acid, including mitochondrial DNA, complementary DNA, and DNA derived from ribonucleic acid. [Alaska Statutes 18.13.100]

DNA Analysis means DNA or genetic typing and testing to determine the presence or absence of genetic characteristics in an individual, including tests of nucleic acids or chromosomes in order to diagnose or identify a genetic characteristic; DNA analysis does not include a routine physical measurement, a test for drugs, alcohol, cholesterol, or the human immunodeficiency virus, a chemical, blood, or urine analysis, or any other diagnostic test that is widely accepted and in use in clinical practice; (3) genetic characteristic includes a gene, chromosome, or alterations of a gene or chromosome 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. [Alaska Statutes 18.13.100]

ARIZONA

Confidentiality of Health Information

- All medical records and the information in them are privileged and confidential and may not be disclosed by physicians, hospitals, and other health care providers. [Arizona Revised Statutes 12.2292]
- Medical records are defined as all communications that are recorded in any form or medium and that are maintained for purposes of patient treatment, including reports, notes and orders, test results, diagnoses, treatments, photographs, videotapes, X rays, billing records and the results of independent medical examinations that describe patient care. Medical records include psychological records and all medical records held by a health care provider, including medical records that are prepared by other providers [Arizona Revised Statutes 12.2291 and 12.2292]

Conditions Imposed on Genetic Testing/Use of Genetic information

Conditions imposed on clinical genetic testing.

Permitted Releases of Health Information or Genetic Information for Research

- Genetic testing and information derived from genetic testing are confidential and considered privileged to the person tested, except they may be released to researchers for medical research or public health purposes if the research is conducted pursuant to applicable federal or state laws and regulations governing clinical and biological research or if the identity of the individual providing the sample is not disclosed to the person collecting and conducting the research. [Arizona Revised Statutes 12-2802]
- Medical information may not be released by insurance companies, however, releases of information for research purposes without individual consent are permitted when the subject is not identified [Arizona Revised Statutes 20-2113].

Definition of Genetic Test/Genetic Information

“Genetic test” or “genetic testing”: (a) means a test of a person’s genes, genetic sequence, gene products or chromosomes for abnormalities or deficiencies, including carrier status, that: (i) Are linked to physical or mental disorders or impairments. (ii) Indicate a susceptibility to any illness, disease, impairment, or other disorder, whether physical or mental. (ii) Demonstrate genetic or chromosomal damage due to any environmental factor. (b) Does not include:....(v) Tests given for use in biomedical research that is conducted to generate scientific knowledge about genes or to learn about the genetic basis of disease or for developing pharmaceutical and other treatment of disease.

[Arizona Revised Statutes, Title 12, Chapter 19, Genetic Testing, Section 12-2801. Definitions]

“Gene products” means gene fragments, nucleic acids, or proteins derived from deoxyribonucleic acids that would be a reflection of or indicate DNA sequence information.

“Genetic test” means an analysis of an individual’s DNA, gene products or chromosomes that indicates a propensity for or susceptibility to illness, disease, impairment or other disorders, whether physical or mental, or that demonstrates genetic or chromosomal damage due to environmental factors, or carrier status for disease or disorder.

[Arizona Revised Statutes, Title 20, Insurance, Section 20-448.02, Genetic testing; informed consent; definitions]

ARKANSAS

Confidentiality of Health Information

- HMOs may not disclose any personal medical information without an applicant’s consent [Arkansas Code Annotated 23-76-129]
- Records are defined as “hospital records or medical records and includes an admitting form, discharge summary, history and physical, progress notes, physicians’ orders, reports of operations, recovery room records, lab reports, consultation reports, medication records, nurses’ notes, and other reports catalogued and maintained by the hospital’s medical record department. ”Records” does not include X-rays, electrocardiograms, and similar graphic matter.” [Arkansas Code Annotated 16-46-301]
- The use of medical records for research is permitted when the identity of the participant is protected. [Arkansas Code Annotated 20-09-304]

Conditions Imposed on Genetic Testing/Use of Genetic information

Research records of individual subjects in genetic research studies may not be subject to subpoena or disclosed to employers or health insurers without the informed, written consent of the individual. [Arkansas Code Annotated, Genetic Research Studies Nondisclosure Act. Section 20-35-103]

Permitted Releases of Health Information or Genetic Information for Research

All stored tissues, including blood, that arise from surgery, other diagnostic or therapeutic steps, or autopsy may be disclosed for genetic or other research studies, if: (A) The patient’s name or social security number is not attached to or included with the specimen; or (B) The patient’s name or social security number

is attached to or included with the specimen and the patient has given informed written consent to the disclosure. Informed written consent shall not be included in a section of the consent for treatment, admission to a hospital or clinic, or permission for an autopsy. (C) (1) It shall be permissible to publish or otherwise use the results of genetic research studies for research or educational purposes if no individual subject is identified. (2) If specific informed consent from the individual has been obtained in writing, the individual may be identified.

[Arkansas Code Annotated, Genetic Research Studies Nondisclosure Act. Section 20-35-103]

Results of genetic research studies may be published or otherwise used if individual subjects are not identified. If written informed consent is obtained, the individual may be identified.

[Arkansas Code Annotated, Genetic Research Studies Nondisclosure Act. Section 20-35-103.]

Definition of Genetic Test/Genetic Information

Genetic research studies are defined as genetic research studies approved by an institutional review board as defined in 21 C.F.R., Act 50, as it existed on January 1, 2001, or conducted subject to the requirements of the federal Common Rule at 21 C.F.R., Act 50 and Act 56, and 45 C.F.R., Act 46, as existed on January 1, 2001. [Arkansas Code Annotated, Genetic Research Studies Nondisclosure Act 20-35-102]

“Genetic test” means a laboratory test of the DNA, RNA, or chromosomes of an individual for the purpose of identifying the presence or absence of inherited alterations in the DNA, RNA, or chromosomes that cause a predisposition for a clinically recognized disease or disorder.

[Arkansas Code Annotated, Genetic Information in the Workplace Act and Genetic Nondiscrimination in Insurance Act (Arkansas Code Annotated 11-5-403 and 23-66-230)]

Confidentiality of Health Information

- The “Confidentiality of Medical Information Act” requires health care providers, employers, and insurers to obtain written authorization from patients prior to disclosure of identifiable information. The Act regulates both medical information and genetic information. It grants patients access to healthcare information and protects the confidentiality of the information. [Annotated California Civil Code Section 56.10, 56.104, 56.20]
- Patients whose medical information is disclosed in violation of the Act may recover compensatory or punitive damages [Annotated California Civil Code Section 56.35]
- Medical information is defined as “any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, or contractor regarding a patient’s medical history, mental or physical condition, or treatment. ‘Individually identifiable’ means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient’s name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual’s identity.” [Annotated California Civil Code, 56.05(f)].
- California enacted the “Human Experimentation: Experimental Subject’s Bill of Rights” [Annotated California Civil Code, 24172] requiring the informed consent of human participants in medical research.

Conditions Imposed on Genetic Testing/Use of Genetic information

Legal restrictions on the use of genetic information and clinical genetic testing by health care service plans. Penalties are imposed for unauthorized or negligent disclosures of results of clinical genetic tests. [Annotated California Civil Code, 56.17]

Permitted Releases of Health Information or Genetic Information for Research

The Confidentiality of Medical Information Act permits disclosures without patient authorization to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed may be redisclosed by the recipient in any way that would disclose the identity of any patient. [Annotated California Civil Code 56.10(c) (7)]

Medical information may not be sold, intentionally shared, or otherwise used for any purpose not necessary to provide health care services to the patient, unless authorized by the patient or specifically permitted by the CMIA. [Annotated California Civil Code 56.10(d)]

Definition of Genetic Test/Genetic Information

“Genetic characteristics” means 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, and that is presently not associated with any symptoms of any disease or disorder.

“Test of a person’s genetic characteristics” means a laboratory test which is generally accepted in the scientific and medical communities for the determination of the presence or absence of genetic characteristics.

[Annotated California Civil Code, Section 10147 and Section 102331.1]

“Genetic characteristics” as used in this section means either of the following:

- (1) Any scientifically or medically identifiable gene or chromosome, or combination or alteration thereof, that is known to be a cause of a disease or disorder in a person or his or her offspring, or that is determined to be associated with a statistically increased risk of development of a disease or disorder, and that is presently not associated with any symptoms of any disease or disorder.
- (2) Inherited characteristics that may derive from the individual or family member, that are known to be a cause of a disease or disorder in a person or his or her offspring, or that are determined to be associated with a statistically increased risk of development of a disease or disorder, and that are presently not associated with any symptoms of any disease or disorder.

[Annotated California Civil Code Section 56.17 uses the definition of “Genetic Characteristic” found in the Health and Safety Code Section 1374.7(d)]

State Law Covering Human Research Subjects

California has adopted the Protection of Human Subjects in Medical Experimentation Act. The Act requires informed consent to be obtained from participants in research; however, no independent scientific review is required.

“Experimental subject’s bill of rights,” means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in Section 24175, this list shall include, but not be limited to the subject’s right to: (a) be informed of the nature and purpose of the

experiment. (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized. (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment. (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable. (e) Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits. (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise. (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved. (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice. (i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178. (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

24175. (a) Except as otherwise provided in this section, no person shall be subjected to any medical experiment unless the informed consent of such person is obtained.

24178. Except for this section and the requirements set forth in Sections 24172 and 24176, this chapter shall not apply to any person who is conducting a medical experiment as an investigator within an institution which holds an assurance with the Department of Health, Education and Welfare pursuant to Part 46 of Title 45 of the Code of Federal Regulations and who obtains informed consent in the method and manner required by such regulations.

[Annotated California Code, Section 24072]

COLORADO

Confidentiality of Health Information

- Medical records and health information must be kept confidential [Colorado Revised Statutes Annotated 25-1-1201].

Conditions Imposed on Genetic Testing/Use of Genetic information

- Genetic information is considered the unique property of the individual to whom the information pertains; Any information concerning an individual obtained through the use of genetic techniques may be subject to abuses if disclosed to unauthorized third parties without the willing consent of the individual to whom the information pertains. [Colorado Revised Statutes Annotated 10-3-1104.7]
- Information derived from genetic testing must be kept confidential and privileged. Releases of genetic testing information that identifies the person tested for purposes other than diagnosis, treatment, or therapy, requires specific written consent by the person tested. [Colorado Revised Statutes Annotated 10-3-1104.7]
- Entities that receives information derived from genetic testing may not seek, use, or keep the information for any nontherapeutic purpose or for any underwriting purpose connected with the provision of health care insurance, group disability insurance, or long-term care insurance coverage. [Colorado Revised Statutes Annotated 10-3-1104.7]

Authors' note: Of the four states (Florida, Colorado, Georgia, and Louisiana) that state that an individual is the "owner" of his or genetic information, three of them, Colorado, Georgia, and Louisiana permit the use of "genetic information" for research purposes when the identity of the individual is not disclosed.

Permitted Releases of Health Information or Genetic Information for Research

Research facilities may use the information derived from genetic testing for scientific research purposes so long as the identity of any individual to whom the information pertains is not disclosed to any third party; except that the individual's identity may be disclosed to the individual's physician if the individual consents to such disclosure in writing. [Colorado Revised Statutes Annotated 6-18-103]

Definition of Genetic Test/Genetic Information

"Genetic testing" means any laboratory test of human DNA, RNA, or chromosomes that is used to identify the presence or absence of alterations in genetic material which are associated with disease or illness. "Genetic testing"

includes only such tests as are direct measures of such alterations rather than indirect manifestations thereof. [Colorado Revised Statutes Annotated 10-3-1104.7]

CONNECTICUT

Confidentiality of Health Information

- Managed Care organizations may not disclose medical information without the patient's written consent. [Connecticut General Statutes 38A-478]
- Insurers and employers may not disclose individually identifiable information.
- Sales of individually identifiable medical record information prohibited. Disclosures for marketing of individually identifiable medical record information are prohibited without the prior written consent of the individual to whom the individually identifiable medical record information pertains or, in the case of a minor, of the minor's parent or guardian. [Connecticut General Statutes Section 38a-988a.] The Health Care Records Act defines the health care record as: bills, x-rays, copies of lab reports, contact lens specifications, records of prescriptions and other technical information used in assessing the patient's health condition. [Connecticut General Statutes 20-7c.]
- Connecticut addresses access to tissue slides and blocks in the context of obtaining veteran's information. The law states that patients (or their designated health provider) have the right to examine slides that include their tissue. [Connecticut General Statutes Section 19a-490b]

Conditions Imposed on Genetic Testing/Use of Genetic information

Restrictions on the use of genetic information for provision of insurance or employment purposes.

Permitted Releases of Health Information or Genetic Information for Research

Health care providers may transfer individual identifiable medical record information for the purposes of clinical research, utilization review, quality review, performance improvement, billing for services or other functions performed by health care providers or their agents in support of direct patient care, provided (A) in the case of clinical research, no individually identifiable medical record information may be disclosed by the clinical researcher, unless the disclosure would otherwise be permitted, and (B) the entity to whom the information is transferred agrees not to disclose the information unless the disclosure would otherwise be permitted if made by the transferor. [Connecticut General Statutes Section 38a-988a.]

Definition of Genetic Test/Genetic Information

None.

State Law Pertaining to Use of Tissue Specimens

Authors' note: Connecticut passed a highly detailed statute pertaining to veterans' health information and access to clinical health care information that specifies the process for requesting, providing, examining, and retaining tissue slides and pathology blocks. Title 19a "Public Health and Well-being" mandates that patients or their designated health provider have the right to examine slides with their retained tissue, and specifies procedures for requesting, safeguarding, cutting, and returning tissue slides.

Furnishing of health records and veterans' information. Access to tissue slides or blocks.

(a) Upon the written request of a patient or the patient's attorney or authorized representative, or pursuant to a written authorization, an institution licensed pursuant to this chapter shall furnish to the person making such request a copy of the patient's health record including but not limited to, copies of bills, laboratory reports, prescriptions and other technical information used in assessing the patient's health condition. In addition, an institution shall provide the patient or the patient's designated health care provider with a reasonable opportunity to examine retained tissue slides and retained pathology tissue blocks. Upon the written request of the patient, the patient's attorney or the patient's designated health care provider, an institution shall send the original retained tissue slide or original retained tissue block directly to the patient's designated licensed institution, laboratory or physician. If the original slide or block is not available or if a new section cut of the original slide or block is a fair representation of the original slide or block, then the institution may send the new section cut, which is clearly labeled as a new section cut, to the patient's designated health care provider. Any patient or the patient's attorney or authorized representative who is provided with an original retained slide, tissue block or a new section under the provisions of this subsection shall be solely responsible for safeguarding and returning the slide, block or new section to the institution. Any institution or laboratory that has released an original slide, an original tissue block or new section pursuant to the provisions of this subsection shall not be subject to any liability arising out of releasing or not retaining the slide, block or new section and no cause of action for damages shall arise against any such institution for releasing or not retaining the slide, block or new section. No such institution shall charge more than sixty-five cents per page, including any research fees, clerical fees, handling fees or related costs, and the cost of first class postage, if applicable, for furnishing or providing access to a health record pursuant to this subsection, except such

an institution may charge the amount necessary to cover its cost of materials for furnishing a copy of an x-ray or for furnishing an original retained slide, an original tissue block or a new section cut from a retained pathology tissue block. For purposes of this subsection, “health care provider” means an institution or laboratory licensed under this chapter or licensed in the state where located or a physician licensed under chapter 370 or licensed in the state where located. [Connecticut General Statutes Section 19a-490b]

DELAWARE

Confidentiality of Health Information

HMOs may not disclose health information without the patient’s express consent [Delaware Code Annotated, Title 16, 9102/9113].

Conditions Imposed on Genetic Testing/Use of Genetic information

Conditions are imposed on the collection and use of genetic information regarding carrier status, information regarding an increased likelihood of future disease or increased sensitivity to any substance, information derived from laboratory tests that identify mutations in specific genes or chromosomes, requests for genetic services or counseling, tests of gene products and direct analysis of genes or chromosomes. Informed consent must be obtained (with explicit terms set forth in the statute) in order to obtain genetic information, to retain genetic information, and to release genetic information to third parties. [Delaware Code Annotated 16-1220].

Permitted Releases of Health Information or Genetic Information for Research

- Genetic information may be obtained only with the informed consent of the individual, except that informed consent is not required to obtain genetic information for anonymous research where the identity of the subject will not be released.
- Genetic information may not be retained without the informed consent of the individual, except when the retention of information is for anonymous research where the identity of the subject will not be released.
- Individual tissue samples from which genetic information has been obtained shall be destroyed promptly unless retention is authorized by the individual; or retention is for anonymous research where the identity of the subject will not be released.

[Delaware Code: 16-1221/1222]

Definition of Genetic Test/Genetic Information

“Genetic information” means information about inherited genes or chromosomes, and of alterations thereof, whether obtained from an individual or family member, that is scientifically or medically believed to predispose an individual to disease, disorder or syndrome or believed to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome. [Delaware Code 16-1220]

“Genetic test” means a test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids such as DNA, RNA, and mitochondrial DNA, chromosomes or proteins in order to identify a predisposing genetic characteristic associated with disease, disorder or syndrome. [Delaware Code 16-1220]

“Genetic information” means information about inherited genes or chromosomes, and of alterations thereof, whether obtained from an individual or family member, that is scientifically or medically believed to predispose an individual to disease, disorder or syndrome, or believed to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome. This includes, but is not limited to, information regarding carrier status, information regarding an increased likelihood of future disease or increased sensitivity to any substance, information derived from laboratory tests that identify mutations in specific genes or chromosomes, requests for genetic services or counseling, tests of gene products, and direct analysis of genes or chromosomes.

[Delaware Code, Title 18–Insurance Code: 2317 Genetics Based Discrimination]

FLORIDA

Confidentiality of Health Information

- Florida imposes rules for ownership and control of patient records [Florida Statutes Annotated 456.057].
- The sale of medical information is prohibited [Florida Statutes Annotated, 456.057] “Absent a specific written release or authorization permitting utilization of patient information for solicitation or marketing the sale of goods or services, any use of that information for those purposes is prohibited.”

Conditions Imposed on Genetic Testing/Use of Genetic information

- DNA analysis may be performed only with the consent of the individual being tested.
- The results of DNA tests are the personal property of the individual.
- The results of DNA tests may not be disclosed without permission.
- Anyone performing DNA analysis must provide notice to the individual whose DNA is being tested.

[Florida Statutes Annotated 760.40]

Permitted Releases of Health Information or Genetic Information for Research

Florida law specifies strict duties and procedures for “records owners” but allows research uses of data with the informed consent of the individual patient or when the data are unidentified (“For statistical and scientific research, provided the information is abstracted in such a way as to protect the identity of the patient or provided written permission is received from the patient or the patient’s legal representative.”) The records owner is defined as “any health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legal drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner.” [Florida Statutes Annotated 456.057]

Definition of Genetic Test/Genetic Information

“Genetic information” means information derived from genetic testing to determine the presence or absence of variations or mutations, including carrier status, in an individual’s genetic material or genes that are scientifically or medically believed to cause a disease, disorder, or syndrome, or are associated with a statistically increased risk of developing a disease, disorder, or syndrome, which is asymptomatic at the time of testing. Such testing does not include

routine physical examinations or chemical, blood, or urine analysis, unless conducted purposefully to obtain genetic information, or questions regarding family history.

[Florida Statutes Annotated, Title XXXVII, 627.4301 Genetic information for insurance purposes]

“As used in this section, the term “DNA analysis” means the medical and biological examination and analysis of a person to identify the presence and composition of genes in that person’s body. The term includes DNA typing and genetic testing. (2) (a) Except for purposes of criminal prosecution, except for purposes of determining paternity as provided in s. 742.12(1), and except for purposes of acquiring specimens from persons convicted of certain offenses or as otherwise provided in s. 943.325, DNA analysis may be performed only with the informed consent of the person to be tested, and the results of such DNA analysis, whether held by a public or private entity, are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested. Such information held by a public entity is exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.” [Florida Statutes Annotated, Title XLIV, 760.40 Genetic testing; informed consent; confidentiality]

GEORGIA

Confidentiality of Health Information

Medical information held by HMOs must be kept confidential. [Georgia Code Annotated 33-21-23)

Conditions Imposed on Genetic Testing/Use of Genetic information

Genetic information is considered the “unique property of the individual tested.” Restrictions are imposed on access to and use of genetic information by insurers, HMOs, managed care organizations, and other payors. [Georgia Code Annotated 33-54-1 and 33-54-6]

Permitted Releases of Health Information or Genetic Information for Research

- Research facilities may conduct 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, except that the individuals’ identify may not only be disclosed with the consent of the individual. [Georgia Code Annotated 33-54-6].

Definition of Genetic Test/Genetic Information

“Genetic testing” means laboratory tests of human DNA or chromosomes for the purpose of identifying the presence or absence of inherited alterations in genetic material or genes which are associated with a disease or illness that is asymptomatic at the time of testing and that arises solely as a result of such abnormality in genes or genetic material. For purposes of this chapter, genetic testing shall not include routine physical measurements; chemical, blood, and urine analysis; tests for abuse of drugs; and tests for the presence of the human immunodeficiency virus. [Georgia Code Annotated 33-54-2]

HAWAII

Confidentiality of Health Information

Hawaii repealed its state statute regarding privacy of health care information following the passage of HIPAA.

Conditions Imposed on Genetic Testing/Use of Genetic information

Hawaii prohibits discrimination in insurance and employment on the basis of genetic information.

Permitted Releases of Health Information or Genetic Information for Research

Permitted for certain types of research

Definition of Genetic Test/Genetic Information

“Genetic information” means information about genes, gene products, hereditary susceptibility to disease, or inherited characteristics that may derive from the individual or family member. [Hawaii Revised Statutes Annotated 432D-26]

“Genetic test” means a laboratory test which is generally accepted in scientific and medical communities for the determination of the presence or absence of genetic information. [Hawaii Revised Statutes Annotated 378-1].

IDAHO

Confidentiality of Health Information

Patient information must be kept confidential. [Idaho Code 54-1727].

Conditions Imposed on Genetic Testing/Use of Genetic information

Legal restrictions are imposed on the use of genetic information for insurance purposes.

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

None.

ILLINOIS

Confidentiality of Health Information

- Medical records and medical information kept by hospitals must be protected and kept confidential [Illinois Compiled Statutes Annotated, Chapter 210 85/6.17].
- The Illinois' Medical Patient Rights Act establishes a right to privacy and confidentiality in health care and restricts the disclosure of medical information maintained by physicians, hospitals, and insurers unless individual patient authorization is obtained. [Illinois Compiled Statutes Annotated, Chapter 410, 50/3(d)]

Conditions Imposed on Genetic Testing/Use of Genetic information

The Illinois “Genetic Information Privacy Act” requires that the results of genetic tests be kept confidential, and the fact that an individual has undergone genetic testing be kept confidential. Employers and insurers may not use genetic information appropriately and may not release it except under certain specified conditions. Confidential information may be released only to the individual tested and to persons specifically authorized in writing by that individual to receive the information. [Illinois Compiled Statutes Annotated, Chapter 410, 513/15-30]

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

“Genetic testing” means a test of a person’s genes, gene products, or chromosomes for abnormalities or deficiencies, including carrier status, that (i) are linked to physical or mental disorders or Impairments, (ii) indicate a susceptibility to illness, disease, impairment, or other disorders, whether physical or mental, or (iii) demonstrate genetic or chromosomal damage due to environmental factors. Genetic testing does not include routine physical measurements; chemical, blood and urine analyses that are widely accepted and in use in clinical practice; tests for use of drugs; and tests for the presence of the human immunodeficiency virus. [Illinois Compiled Statutes Annotated Chapter 410 513/10]

Patients’ Rights Act (Experimental Procedures)

Illinois has passed a patients’ rights act requiring certain minimal rights for patients. Patient is defined as “any person who has received or is receiving medical care, treatment, or services from an individual or institution licensed to provide medical care or treatment in this State.” [Illinois Compiled Statutes Annotated 410 50/2.01]

“Any patient who is the subject of a research program or an experimental procedure, as defined under the rules and regulations of the Hospital Licensing Act, shall have, at a minimum, the right to receive an explanation of the nature and possible consequences of such research or experiment before the research or experiment is conducted, and to consent to or reject it. No physician may conduct any research program or experimental procedure on a patient without the prior informed consent of the patient or, if the patient is unable to consent, the patient’s guardian, spouse, parent, or authorized agent. The Act does not apply to research programs or medical experimental procedure for patients subject to a life-threatening emergency that is conducted in accordance with Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code of Federal Regulations.” [Illinois Compiled Statutes Annotated 410 50/3.1]

INDIANA

Confidentiality of Health Information

- Health care providers must protect the confidentiality of the health records, but may disclose a patient's identity when it is essential. The provider may disclose a health record to another provider or to a nonprofit medical research organization for scientific, statistical, or educational projects [Annotated Indiana Code 16-18-2-295; 16-39-5-3]
- Health care record is defined as written, electronic, or printed information possessed by a provider concerning any diagnosis, treatment, or prognosis of the patient. [Annotated Indiana Code 16-18-2-168]
- Health care records may be used without the specific written authorization of the patient for scientific, statistical, and educational purposes among other reasons, provided that each party that receives the information protects its confidentiality. [Annotated Indiana Code 16-18-2-295 and 16-39-5-3.]
- HMOs must maintain the confidentiality of medical information. [Annotated Indiana Code 27-13-31-1]

Conditions Imposed on Genetic Testing/Use of Genetic information

Legal restrictions imposed on the use of genetic information in the provision of insurance.

Permitted Releases of Health Information or Genetic Information for Research

Providers may disclose a health record to another provider or to a nonprofit medical research organization for scientific, statistical, or educational projects provided that each party that receives the information protects its confidentiality. [Annotated Indiana Code Section 16-39-5-3.]

Definition of Genetic Test/Genetic Information

As used in this chapter, "genetic screening or testing" means a laboratory test:

- 1) of an individual's genes or chromosomes for abnormalities, defects, or deficiencies, including changes in the number, structure, or integrity of an individual's chromosomes or carrier status, that: (A) are linked to physical or mental disorders or impairments; (B) indicate a susceptibility to illness, disease, or other disorders, whether physical or mental; or (C) demonstrate genetic or chromosomal damage due to environmental factors; and (2) that is a direct test for abnormalities, defects, or deficiencies in an individual's genes or chromosomes. (b) The term does not include the detection of a genetic disorder through the manifestation of the genetic disorder.

[Annotated Indiana Code 27-8-26-2]

IOWA

Confidentiality of Health Information

- Medical records are confidential and are not open to public inspection unless ordered by a court [Iowa Code Annotated 22.7]
- Iowa law prohibits the release, sales, or use of medical information for the purpose of sales or marketing of services or products. Persons are prohibited from using medical information that is released, sold, or otherwise obtained in violation of this section for sales or marketing of services or products. [Iowa Code Annotated, 144D.3]

Conditions Imposed on Genetic Testing/Use of Genetic information

Legal restrictions imposed on the use of genetic information in the provision of insurance. Discrimination in employment on the basis of genetic information is prohibited.

Permitted Releases of Health Information or Genetic Information for Research

Mpme

Definition of Genetic Test/Genetic Information

“Genetic testing” means a test of a person’s genes, gene products, or chromosomes, for abnormalities or deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicate a susceptibility to illness, disease, impairment, or other disorders, whether physical or mental, or that demonstrate genetic or chromosomal damage due to environmental factors. [Iowa Code Annotated, 729.6 Genetic testing (c)]

KANSAS

Confidentiality of Health Information

HMOs may not disclose personal health information without the individual’s express consent. [Kansas Statutes Annotated 40-3226(a)]

Conditions Imposed on Genetic Testing/Use of Genetic information

Restricts the use of genetic information in the provision of insurance or employment.

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

Genetic screening or testing means a laboratory test of a person's genes or chromosomes for abnormalities, defects or deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicate a susceptibility to illness, disease or other disorders, whether physical or mental, which test is a direct test for abnormalities, defects or deficiencies, and not an indirect manifestation of genetic disorders.

[Kansas Statutes Annotated 40-2259. Genetic screening or testing; prohibiting the use of; exceptions.]

KENTUCKY

Confidentiality of Health Information

Health plan utilization agents may not disclose personal health information except as permitted under HIPAA. [Kentucky Revised Statutes Annotated 422.317].

Conditions Imposed on Genetic Testing/Use of Genetic information

Restricts the use of genetic information for provision of insurance.

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

None.

LOUISIANA

Confidentiality of Health Information

HMOs must protect the confidentiality of medical information [Louisiana Statutes Annotated - Revised Statutes 22:2020].

Conditions Imposed on Genetic Testing/Use of Genetic information

- Genetic information must be kept confidential. Disclosure is subject to specific conditions. [Louisiana Statutes Annotated - Revised Statutes 213.7].
- Genetic discrimination in the workplace is prohibited. Employers may not disclose genetic information about employees.
- Louisiana restricts use of genetic information by insurers. According to insurance statutes, “An insured’s or enrollee’s genetic information is the property of the insured or enrollee” 22:213.7(E).
- A general authorization for the release of medical records does not serve as an authorization for the disclosure of genetic information. [Louisiana Revised Statutes Annotated Section 22:213.7 C(5).]
- Authorization for disclosure of genetic information must be written, and adhere to the format specified by statute, including describing the specific genetic information to be disclosed and stating the date upon which the authorization will expire, which may not be more than sixty days from the date of authorization. [Louisiana Revised Statutes Annotated Section 22:213.7 C(2).]

Permitted Releases of Health Information or Genetic Information for Research

- Louisiana law permits releases of genetic information “anonymous research where the identity of the individual will not be released.” [Louisiana Revised Statutes Annotated Section 22:213.7 D.]
- Louisiana law which state that an insured’s or enrollee’s genetic information is the property of the insured or enrollee do not apply to genetic information obtained for anonymous research where the identity of the subject will not be released. [Louisiana Revised Statutes Annotated Section 22:213.7 D.]
- A general authorization for the release of medical records does not serve as an authorization for the disclosure of genetic information. [Louisiana Revised Statutes Annotated Section 22:213.7 C(5).]
- The authorization for disclosure of genetic information must be in writing, and adhere to the format specified by statute, including describing the specific genetic information to be disclosed and stating the date upon which

the authorization will expire, which may not be more than sixty days from the date of authorization. [Louisiana Revised Statutes Annotated Section 22:213.7 C(2).]

Definition of Genetic Test/Genetic Information

“Genetic analysis” means the process of characterizing genetic information from a human tissue sample.

“Genetic information” means all information about genes, gene products, inherited characteristics, or family history/pedigree that is expressed in common language.

“Genetic test” means any test for determining the presence or absence of genetic characteristics in an individual, including tests of nucleic acids, such as DNA, RNA, and mitochondrial DNA, chromosomes, or proteins in order to diagnose or identify a genetic characteristic.

“Individual” means the source of a human tissue sample from which a DNA sample is extracted or genetic information is characterized.

“Individual identifier” means a name, address, social security number, health insurance identification number, or similar information by which the identity of an individual can be determined with reasonable accuracy, either directly or by reference to other available information. Such term does not include characters, numbers, or codes assigned to an individual or a DNA sample that cannot singly be used to identify an individual.

[Louisiana Statutes Annotated – Revised Statutes Section 213.7.]

MAINE

Confidentiality of Health Information

- Health care information is confidential and may not be disclosed by health facilities without the written consent of the individual. “Health care” means preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, services, treatment, procedures or counseling, including appropriate assistance with disease or symptom management and maintenance, that affects an individual’s physical, mental or behavioral condition, including individual cells or their components or genetic information, or the structure or function of the human body or any part of the human body. Health care includes prescribing, dispensing or furnishing to an individual drugs, biologicals, medical devices or health care equipment and supplies; providing hospice services to an individual; and the banking of blood, sperm, organs or any other tissue. [Maine Revised Statutes Annotated, Title 22, Section 1711-C]
- Maine prohibits the sale or marketing of medical information by a health care practitioner or facility without written or oral authorization for the disclosure. [Maine Revised Statutes Annotated, Title 22: Section 1711-C]

State Law Prohibiting Sales of Medical Information

Maryland prohibits “persons” from disclosing by sale, rental, or barter any medical record.

[Annotated Code of Maryland, 4-304]

Conditions Imposed on Genetic Testing/Use of Genetic information

All DNA records are confidential and access to records is limited to governmental criminal justice and law enforcement agencies. Nonidentifying information may be released to advance DNA analysis methods and support statistical interpretation of DNA analysis. [Maine Revised Statutes Annotated, Title 25, Section 1577]

Permitted Releases of Health Information or Genetic Information for Research

Maine’s statute requiring that health care information be kept confidential and requires informed consent for disclosures excludes information that “Protect(s) the anonymity of the individual by means of encryption or encoding of individual identifiers or information pertaining to or derived from federally sponsored, authorized or regulated research governed by 21 Code of Federal Regulations, Parts 50 and 56 and 45 Code of Federal Regulations, Part 46, to the extent that such information is used in a manner that protects the identification of individuals.” [Maine Revised Statutes Annotated, Title 22, Section 1711-C]

Definition of Genetic Test/Genetic Information

As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

- A. “Genetic characteristic” means any inherited gene or chromosome, or alteration of a gene or chromosome that is scientifically or medically believed to predispose an individual to a disease, disorder or syndrome or to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome.
- B. “Genetic information” means the information concerning genes, gene products, or inherited characteristics that may be obtained from an individual or family member. C. “Genetic test” means a test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids, such as deoxyribonucleic acid, or DNA, ribonucleic acid, or RNA, or mitochondrial DNA, and tests of chromosomes or proteins in order to identify a predisposing genetic characteristic.
- C. “Genetic test” means a test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids, such as deoxyribonucleic acid, or DNA, ribonucleic acid, or RNA, or mitochondrial DNA, and tests of chromosomes or proteins in order to identify a predisposing genetic characteristic.

[Maine Revised Statutes Annotated, Title 5 Section 19301 and Title 24A Section 2159-C (use of genetic information for insurance and employment respectively)]

Authors’ note: Maine’s health care information statute covers genetic information because “health care information” is defined broadly. Health care information means information that directly identifies the individual and relates to that individual’s health care, which includes services and treatment that involve individual cells or their components or genetic information. [Maine Revised Statute, Title 22, Section 1711-C and 1999 Maine Laws 512.]

MARYLAND

Confidentiality of Health Information

- Patient medical records must be kept confidential. Information may be disclosed only with patient consent. [Annotated Code of Maryland 4-302]
- HMOs must establish a medical records system that assures maximum confidentiality. [Annotated Code of Maryland Code 19-710(n)]

Conditions Imposed on Genetic Testing/Use of Genetic information

- Maryland law restricts the use and disclosure of genetic information by insurers, nonprofit health service plans, and HMOs. An authorization must be obtained for each disclosure and must meet certain statutory requirements. [Annotated Code of Maryland, Section 27-909]
- Discrimination by employers or insurers on the basis of genetic testing is prohibited. [Annotated Code of Maryland, Article 49B and 27-909]

Permitted Releases of Health Information or Genetic Information for Research

- Insurers are permitted to disclose health information for research purposes “to a researcher, on request, for medical and health care research in accordance with a protocol approved by an institutional review board.” [Annotated Code of Maryland 14-138]
- Health care providers are permitted to disclose information without the authorization of the person in interest in numerous situations, including to persons needing the information for educational or research purposes, subject to the applicable requirements of an institutional review board if the person given access to the medical record signs an acknowledgment of the duty under this Act not to redisclose any patient identifying information [Annotated Code of Maryland 4-305].

Definition of Genetic Test/Genetic Information

“Gene product” means the biochemical material, either RNA or protein, made by a gene.

“Genetic information” means information: 1. about chromosomes, genes, gene products, or inherited characteristics that may derive from an individual or a family member; 2. obtained for diagnostic and therapeutic purposes; and 3. obtained at a time when the individual to whom the information relates is asymptomatic for the disease. (ii) “Genetic information” does not include: 1. routine physical measurements; 2. chemical, blood, and urine analyses that are widely accepted and in use in clinical practice; 3. tests for use of drugs; or 4. tests for the presence of the human immunodeficiency virus.

“Genetic services” means health services that are provided to obtain, assess, and interpret genetic information for diagnostic and therapeutic purposes and for genetic education and counseling.

“Genetic test” means a laboratory test of human chromosomes, genes, or gene products that is used to identify the presence or absence of inherited or congenital alterations in genetic material that are associated with disease or illness.

[Annotated Code of Maryland, Section 27-909]

State Law Covering Human Research Subjects

A person may not conduct research using a human subject unless the person conducts the research in accordance with the federal regulations on the protection of human subjects.

[Annotated Code of Maryland, Human Subject Research, Section 13-2002]

Authors’ note: Maryland and Virginia extend the provisions of the Common Rule requiring informed consent from subjects (or waiver), and independent ethical review (by an IRB or other qualified entity), to all human subjects research, regardless of whether the funding source is federal or private. In addition, the Maryland law provides for public access to the minutes of IRB meetings, with confidential information redacted if necessary.

MASSACHUSETTS

Confidentiality of Health Information

- Patients have a right to confidentiality of all records and communication.

[Massachusetts General Laws Annotated Chapter 111, 70E].

- Individuals have a general right of privacy [Massachusetts General Laws Annotated Chapter 214, 1(B)]. This privacy right also covers the confidentiality of medical information.

Conditions Imposed on Genetic Testing/Use of Genetic information

- Prior written informed consent is required for genetic testing. Genetic information and reports are protected as private information; prior written consent is required for genetic testing. Records pertaining to genetic information shall be kept confidential except that research information may be used for epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease. [Massachusetts General Laws Annotated Title 16, Chapter 22, Section 70G. Genetic information and reports protected as private information; prior written consent for genetic testing]
- Massachusetts prohibits discrimination based on genetic information.

Permitted Releases of Health Information or Genetic Information for Research

- Physicians and others may disclose information under certain circumstances, including for research [Massachusetts General Laws Annotated, Chapter 112 12G).
- Massachusetts permits the use of genetic information for research. Confidential research information is defined as any results of a genetic test maintained pursuant to pharmacological and clinical research protocols which are subject to and conducted in accordance with the review and approval of an Institutional Review Board established pursuant to the provisions of 45 CFR 46 and 21 CFR 50 and 56 and that protects the confidentiality of the individual who is the subject of the genetic test either by encryption, encoding or other means consistent with the requirements of said federal regulations, or where the identity of the individual is unknown or protected from disclosure by encrypting or encoding, or by other means consistent with the requirements of said federal regulations. [Massachusetts General Laws Annotated, Title 16, Chapter 111, Section 70G].

Definition of Genetic Test/Genetic Information

Authors' note: Two definitions are used in two different sections of the law.

“Genetic test,” a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying genes, inherited or acquired genetic

abnormalities, or the presence or absence of inherited or acquired characteristics in genetic material. For the purposes of this section, the term genetic test shall not include tests given for drugs, alcohol, cholesterol, or HIV; or any test for the purpose of diagnosing or detecting an existing disease, illness, impairment or disorder. [Massachusetts General Laws Annotated, Title 16, Chapter 111]

“Genetic test,” a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying the genes, or genetic abnormalities, or the presence or absence of inherited or acquired characteristics in genetic material. [Massachusetts General Laws Annotated, Title 22, Chapter 176A]

MICHIGAN

Confidentiality of Health Information

- Patients can refuse the release of medical records to individuals outside the health care facility, except when transferring or as required by law. [Michigan Compiled Laws 333.20201.]
- Nonprofit health care corporations may not disclose (or redisclose) personal data, including records relating to a member’s medical history, care, treatment or service, without the prior, written, specific, informed consent of the member. [Michigan Compiled Laws Section 550.1105 (defining health care corporation); 550.1107 (defining personal data); and 550.1406]

Conditions Imposed on Genetic Testing/Use of Genetic information

Michigan requires physicians or other individuals performing presymptomatic or predictive genetic test to first obtain the written, informed consent of the test subject. The informed consent must be a signed writing executed by the test subject or the legally authorized representative of the test subject that confirms that the physician or the individual acting under the delegatory authority of the physician has explained, and the test subject or the legally authorized representative of the test subject understands, at a minimum, all of the following: (a) The nature and purpose of the presymptomatic or predictive genetic test. (b) The effectiveness and limitations of the presymptomatic or predictive genetic test. (c) The implications of taking the presymptomatic or predictive genetic test, including, but not limited to, the medical risks and benefits. (d) The future uses of the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test. (e) The meaning of the presymptomatic or predictive genetic test results and the procedure for providing notice of the results to the test subject. (f) Who will have access to the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the

information obtained from the presymptomatic or predictive genetic test, and the test subject's right to confidential treatment of the sample and the information. [Michigan Compiled Laws 333.17520).

Information regarding clinical genetic tests may not be disclosed [Michigan Compiled Laws 712.13].

Permitted Releases of Health Information or Genetic Information for Research

Medical information

A person participating in a designated medical research project may not disclose the information obtained except in strict conformity with that project.

Information may be provided to medical research projects and is not considered to be the willful betrayal of a professional secret or the violation of a confidential relationship. [Michigan Compiled Laws Annotated, Section 333.2633]

Definition of Genetic Test/Genetic Information

“Genetic information” means information about a gene, gene product, or inherited characteristics of an individual derived from the individual's family history or a genetic test. [Michigan Compiled Laws Annotated, Section 37.1201]

“Genetic test” means the analysis of human DNA, RNA, chromosomes, and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including, but not limited to, a chemical analysis, of body fluids, unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome (c) “Predictive genetic test” means a genetic test performed for the purpose of predicting the future probability that the test subject will develop a genetically related disease or disability. (d) “Presymptomatic genetic test” means a genetic test performed before the onset of clinical symptoms or indications of disease. (9) For purposes of subsection (8) (b), the term “genetic test” does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal Common Rule under 21 C.F.R. Parts 50 and 56 and 45 C.F.R. Part 46. [Michigan Compiled Laws Annotated, 37.1201 and 333.17520 and 500.3407b]

MINNESOTA

Confidentiality of Health Information

- Health care providers may not disclose confidential health information without the patient’s signed and dated consent, unless specifically authorized by law. The consent is valid for one year, unless the patient specifically authorizes a consent that does not expire. [Minnesota Statutes Annotated 144.335].
- Health records generated prior to January 1, 1997, may be released if the patient hasn’t objected. However, in order to release records generated after January 1, 1997, the provider must first advise the patient in writing that his records may be released. If the patient objects, the records may not be released. Authorization for release may also be established by a patient’s nonresponse to a mailed notice that his records may be released if he does not object. The statute describes the patient health record as follows: “including but not limited to laboratory reports, x-rays, prescriptions, and other technical information used in assessing the patient’s health condition.” [Minnesota Statutes Annotated 144.335].

Conditions Imposed on Genetic Testing/Use of Genetic information

Minnesota’s Genetic Discrimination Act prohibits health plans from inquiring whether an individual has undergone a genetic test or from requiring, requesting, or inquiring if an individual has a genetic testing history. An individual who has undergone a genetic test has “the right to confidential treatment of the results.” [Minnesota Statutes Annotated, Section: 72A.139 72A.139]

Employers may condition employment on genetic information and may not administer genetic test. [Minnesota Statutes Annotated 181.974]

Permitted Releases of Health Information or Genetic Information for Research

Health records may be released to an external researcher solely for purposes of medical or scientific research only as follows:

- (1) health records generated before January 1, 1997, may be released if the patient has not objected or does not elect to object after that date;
- (2) for health records generated on or after January 1, 1997, the provider must:
 - (i) disclose in writing to patients currently being treated by the provider that health records, regardless of when generated, may be released and that the patient may object, in which case the records will not be released; and
 - (ii) use reasonable efforts to obtain the patient’s written general authorization that describes the release of records in item (i), which does not expire but may be revoked or limited in writing at any time by the patient or the patient’s authorized representative;
- (3) authorization may be established if an authorization is mailed at least two

times to the patient’s last known address with a postage prepaid return envelope and a conspicuous notice that the patient’s medical records may be released if the patient does not object, and at least 60 days have expired since the second notice was sent; and the provider must advise the patient of the rights specified in clause (4); and

(4) the provider must, at the request of the patient, provide information on how the patient may contact an external researcher to whom the health record was released and the date it was released. In making a release for research purposes the provider shall make a reasonable effort to determine that: (i) the use or disclosure does not violate any limitations under which the record was collected; (ii) the use or disclosure in individually identifiable form is necessary to accomplish the research or statistical purpose for which the use or disclosure is to be made; (iii) the recipient has established and maintains adequate safeguards to protect the records from unauthorized disclosure, including a procedure for removal or destruction of information that identifies the patient; and (iv) further use or release of the records in individually identifiable form to a person other than the patient without the patient’s consent is prohibited.

[Minnesota Statutes Annotated 144.335]

Definition of Genetic Test/Genetic Information

Genetic test means the analysis of human DNA, RNA, chromosomes, proteins, or certain metals in order to detect disease –related genotypes or mutations. Tests for metabolites fall within the definition of a test when an excess or deficiency of the metabolites indicates the presence of a mutation. Administration of metabolic tests by an employer or employment agency that are not intended to reveal the presence of a mutation not violate this section, regardless of the results of the tests. Test results revealing a mutation are, however, subject to this section.

[Minnesota Statutes Annotated 181.974 “Genetic Testing in Employment”]

A “genetic test” means 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. “Genetic test” does not include a cholesterol test or other test not conducted for the purpose of determining the presence or absence of a person’s gene or genes.”

[Minnesota Statutes Annotated 72A.139 “Genetic Discrimination Act”]

Confidentiality of Health Information

Hospital records must be kept confidential [Annotated Mississippi Code, 41-9-67].

Conditions Imposed on Genetic Testing/Use of Genetic information

None.

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

None.

MISSOURI

Confidentiality of Health Information

HMOs must maintain the confidentiality of health information and health records. [Vernon's Annotated Missouri Statutes 354.515]

Conditions Imposed on Genetic Testing/Use of Genetic information

Employers may not use genetic information or genetic test results. [Vernon's Annotated Missouri Statutes 375.1306]

Genetic information must be treated as a confidential medical record and may not be disclosed without the written authorization of the individual, except for the purposes of medical research. [Vernon's Annotated Missouri Statutes 191.317]

Permitted Releases of Health Information or Genetic Information for Research

Disclosure of medical information without the subject's consent is permitted for purposes of health research conducted in accordance with the provisions of the federal regulations (45 CFR 46 or 21 CFR 50 and 56) ; or to health research using archives or databases in which the identity of individuals is protected from disclosure by coding or encryption or by removing all identities [Vernon's Annotated Missouri Statutes 375.1309]

All testing results and personal information obtained from any individual, or from specimens from any individual shall be held confidential and be considered a confidential medical records, except for such information that an individual, parent or guardian consents to be released; but the individual must first be fully informed of the information to be released, of the risks, benefits and purposes for such release, and of the identify of those to whom the information will be released. Statistical data compiled without reference to the identity of any

individual shall not be declared confidential. [Vernon's Annotated Missouri Statutes 191.317]

Definition of Genetic Test/Genetic Information

“Genetic test,” a laboratory test of human deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) used to identify the presence or absence of inherited alterations in the DNA or RNA which cause predisposition to disease or illness. The term does not include routine physical measurements and examinations, routine tests performed as a part of a physical examination, chemical, blood or urine analysis, cholesterol tests, tests for the presence of the human immunodeficiency virus, a test for drugs, or tests commonly accepted in clinical practice at the time. [Vernon's Annotated Missouri Statutes 375.1300]

MONTANA

Confidentiality of Health Information

- Health care providers may not disclose health care information about a patient to any other person without the patient's written authorization. [Montana Code Annotated, 50-16-525]
- HMOs must keep medical information confidential. [Montana Code Annotated, 33-31-113]

Conditions Imposed on Genetic Testing/Use of Genetic information

Restricts the use or attempt to obtain genetic information for non-therapeutic purposes (insurance, employment, etc.).

Insurers may not seek genetic information about an individual for a purpose that is: (a) unrelated to assessing or managing the individual's current health; (b) inappropriate in an asymptomatic individual; or (c) unrelated to research.

Permitted Releases of Health Information or Genetic Information for Research

Disclosures by health care providers are permitted without patient authorization “for use in a research project that an institutional review board has determined: (a) is of sufficient importance to outweigh the intrusion into the privacy of the patient that would result from the disclosure; (b) is impracticable without the use or disclosure of the health care information in individually identifiable form; (c) contains reasonable safeguards to protect the information from improper disclosure; (d) contains reasonable safeguards to protect against directly or indirectly identifying any patient in any report of the research project; and (e) contains procedures to remove or destroy at the earliest opportunity, consistent

with the purposes of the project, information that would enable the patient to be identified, unless an institutional review board authorizes retention of identifying information for purposes of another research project.” [Montana Code Annotated 50-16-529]

Definition of Genetic Test/Genetic Information

“Genetic information” means information derived from genetic testing or medical evaluation to determine the presence or absence of variations or mutations, including carrier status, in an individual’s genetic material or genes that are scientifically or medically believed to cause a disease, disorder, or syndrome or are associated with a statistically increased risk of developing a disease, disorder, or syndrome that is asymptomatic at the time of testing.

“Genetic testing” or “genetic test” means a test used to diagnose a presymptomatic genetic factor, including analysis of human deoxyribonucleic acid or ribonucleic acid, chromosomes, proteins, or metabolites. The term does not include a routine physical examination or a chemical, blood, or urine analysis, unless conducted or analyzed purposefully or knowingly to obtain genetic information, or a family history.

“Genetic trait” means any medically or scientifically identified genetic factor, known or presumed to be present in the individual or a biological relative but not presently associated with any manifestations of the disorder in the individual, that could cause a disorder or be statistically associated with an increased risk of development of a disorder.

[Montana Code Annotated 33-18-901]

NEBRASKA

Confidentiality of Health Information

- HMOs must maintain the confidentiality of health information. [Nebraska Revised Statutes 44-43,172]
- Nonpublic consumer health information must not be disclosed by insurers. The Consumer Health Information Act defines “Nonpublic personal health information” as health information that identifies an individual or with respect to which there is a reasonable basis to believe that the information could be used to identify an individual. [Nebraska Revised Statutes Section 44-903(21) “Health information” is any information (except age or gender), recorded in any form, that was created by or derived from a health care provider or the consumer that relates to the past, present or future physical, mental or behavioral health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care. Entities that comply with HIPAA are exempt from the requirements of the Act. [Nebraska Revised Statute Section 44-903(15)].

Conditions Imposed on Genetic Testing/Use of Genetic information

Physicians are required to obtain the written informed consent of the patient prior to perform a presymptomatic or predictive genetic test .The informed consent document must explain the following: (a) The nature and purpose of the presymptomatic or predictive genetic test; (b) The effectiveness and limitations of the presymptomatic or predictive genetic test; (c) The implications of taking the presymptomatic or predictive genetic test, including the medical risks and benefits; (d) The future uses of the sample taken to conduct the presymptomatic or predictive genetic test and the genetic information obtained from the presymptomatic or predictive genetic test; (e) The meaning of the presymptomatic or predictive genetic test results and the procedure for providing notice of the results to the patient; and (f) Who will have access to the sample taken to conduct the presymptomatic or predictive genetic test and the genetic information obtained from the presymptomatic or predictive genetic test, and the patient’s right to confidential treatment of the sample and the genetic information. [Nevada Revised Statutes, Physician; genetic tests; written informed consent; 71-1,104.01].

Permitted Releases of Health Information or Genetic Information for Research

Genetic information means information about a gene, gene product, or inherited characteristic derived from a genetic test; (b) Genetic test means the analysis of human DNA, RNA, and chromosomes and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical

communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome. Genetic test does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal Common Rule under 21 C.F.R. Parts 50 and 56 and 45 C.F.R. Part 46, as such regulations existed on September 1, 2001.”

[Nebraska Revised Statutes, Requirements for Genetic Tests, Physicians, 71-1,104.01]

Research that is conducted pursuant to federal Common Rule under 21 C.F.R. Parts 50 and 56 and 45 C.F.R. Part 46, as such regulations existed on September 1, 2001 is not subject to the restrictions imposed on “genetic tests.” [Nebraska Revised Statutes 77-5519, Genetic test, defined]

The Consumer Health Information Act permits disclosures without the authorization of the individual for the performance of several defined activities, including “scientific, medical or public policy research.” [Nebraska Revised Statutes Section 44-903(15)].

Definition of Genetic Test/Genetic Information

Genetic test means the analysis of human DNA, RNA, and chromosomes and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome. Genetic test does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal Common Rule under 21 C.F.R. Parts 50 and 56 and 45 C.F.R. Part 46, as such regulations existed on September 1, 2001. [Nebraska Revised Statutes 77-5519, Genetic test, defined]

Genetic information means information about a gene, gene product, or inherited characteristic derived from a genetic test. [Nebraska Revised Statutes, Genetic test, defined 77-5518]

Genetic test means the analysis of human DNA, RNA, and chromosomes and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be

generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome. [Nebraska Revised Statutes 48-236 Employment and Genetic Testing]

NEVADA

Confidentiality of Health Information

- Nevada prohibits the release of laboratory results to third parties: A licensed laboratory may release the results of tests performed at the laboratory regarding a patient of a rural hospital only to the patient, the physician who ordered the tests and a health care provider currently treating or providing assistance in the treatment of the patient. [Nevada Revised Statutes Section 652.193.]
- “Health care records” defined. “Health care records” means any reports, notes, orders, Photographs, X-rays or other recorded data or information whether maintained in written, electronic or other form which is received or produced by a provider of health care, or any person employed by him, and contains information relating to the medical history, examination, diagnosis or treatment of the patient. [Nevada Revised Statutes 629.021]

Conditions Imposed on Genetic Testing/Use of Genetic information

Conditions are imposed on the use, retention, and collection of genetic information. [Nevada Revised Statutes Annotated 629.161]

A person who has authorized another person to retain his genetic information may request that person to destroy the genetic information. The information must be destroyed unless it is necessary to conduct a criminal investigation or for a medical facility to maintain a medical record of the person, authorized by a court order, or required by law. [Nevada Revised Statutes Annotated 629.161]

It is unlawful to disclose or to compel a person to disclose the identity of a person who was the subject of a genetic test or to disclose genetic information of that person in an identifying manner without first obtaining the informed consent of that person his legal guardian (exceptions apply). [Nevada Revised Statutes Annotated 629.171]

The law includes several exceptions permitting retention and use, including for research purposes “where the identities of the persons from whom the genetic

information is obtained are not disclosed to the person conducting the study.” [Nevada Revised Statutes Annotated 629.121(4)].

HMOs may not require enrollees to take genetic tests. [Nevada Revised Statutes Annotated 695C.207].

Permitted Releases of Health Information or Genetic Information for Research

Genetic information may be retained and uses for research purposes where the identities of the persons from whom the genetic information is obtained are not disclosed to the person conducting the study. [Nevada Revised Statute 629.121 (4)]

Definition of Genetic Test/Genetic Information

“Genetic test” defined. “Genetic test” means a test, including a laboratory test that uses deoxyribonucleic acid extracted from the cells of a person or a diagnostic test, to determine the presence of abnormalities or deficiencies, including carrier status, that:

1. Are linked to physical or mental disorders or impairments; or
2. Indicate a susceptibility to illness, disease, impairment, or any other disorder, whether physical or mental.

[Nevada Revised Statutes Annotated 629.121]

“Genetic information” means any information that is obtained from a genetic test. [Nevada Revised Statutes Annotated 629.121]

NEW HAMPSHIRE

Confidentiality of Health Information

- Medical information contained in the medical records in the possession of any health care provider is deemed to be the property of the patient. [New Hampshire Revised Statutes, 332: I-1]
- Health care facilities must ensure confidential treatment of a patient's medical records and written consent is required for releases of information. [New Hampshire Revised Statutes 151.21X]
- Medical and scientific research information must be kept confidential and used only for medical or scientific purposes [New Hampshire Revised Statutes, 126 A:11]
- Health care providers are expressly prohibited from releasing or using patient-identifiable medical information for the purpose of sales or marketing of services or products unless they have obtained the patient's written authorization. [New Hampshire Revised Statutes 332-I:1.]
- Insurer must maintain the confidentiality of health information. [New Hampshire Revised Statutes 420-J:10]
- The release or use of patient identifiable medical information for the purpose of sales or marketing is prohibited without written authorization. [New Hampshire Revised Statutes 332-I:1]

Conditions Imposed on Genetic Testing/Use of Genetic information

Conditions imposed on the use of genetic testing for insurance and employment.

Genetic information may not be disclosed without consent [New Hampshire Revised Statutes Section 141-H:2]

Permitted Releases of Health Information or Genetic Information for Research

Disclosures of information without individual authorization are permitted for research purposes [New Hampshire Administrative Code Revised Annotated, 3005.01.].

Definition of Genetic Test/Genetic Information

“Genetic testing” means a test, examination, or analysis which is generally accepted in the scientific and medical communities for the purpose of identifying the presence, absence, or alteration of any gene or chromosome, and any report, interpretation, or evaluation of such a test, examination, or analysis, but excludes any otherwise lawful test, examination, or analysis that is undertaken for the purpose of determining whether an individual meets reasonable functional standards for a specific job or task. [New Hampshire Revised Statutes 141-H:1]

NEW JERSEY

Confidentiality of Health Information

Hospital patients have a right to privacy, and patients' medical records must be kept confidential. [New Jersey Statutes Annotated 26:2H-12.8]

Authors' note: Many states have enacted some form of a patients' bill of rights (Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Maryland, Massachusetts, Minnesota, Mississippi, Montana, Nevada, North Carolina, New Hampshire, New Jersey, North Dakota, Oregon, Rhode Island, Tennessee, Texas, Vermont) some of which require informed consent to participate in research or that consent be documented (Delaware, Hawaii, Maryland, Massachusetts, Minnesota, Montana, North Carolina). Of these, only New York explicitly excludes the research uses of tissue research from the restrictions of the statute.

Conditions Imposed on Genetic Testing/Use of Genetic information

The "Genetic Privacy Act" establishes rules for the collection, storage, and use of identifiable DNA samples and private genetic information obtained from those samples. The Act requires informed consent from an individual prior to obtaining genetic information. The Act includes provisions for notifying individuals that a genetic test will be requested or required, and a prohibition on disclosure without consent. [New Jersey Statutes Annotated 10:5-48]

New Jersey law prohibits discrimination in the provision of insurance on the basis of genetic information or genetic testing. [New Jersey Statutes Annotated 17B:30-12]

Permitted Releases of Health Information or Genetic Information for Research

The requirement to obtain informed consent when obtaining genetic information does not apply for anonymous research where the identity of the subject will not be released. [New Jersey Statutes Annotated 10:5-45]

Definition of Genetic Test/Genetic Information

"Genetic characteristic" means any inherited gene or chromosome, or alteration thereof, that is scientifically or medically believed to predispose an individual to a disease, disorder or syndrome, or to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome.

"Genetic information" means the information about genes, gene products or inherited characteristics that may derive from an individual or family member.

"Genetic test" means a test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to identify a predisposing genetic characteristic.

[New Jersey Statutes Annotated 10:5-5]

Genetic information means the information about genes, gene products or inherited characteristics that derive from an individual or family member.

Genetic test means a test for determining the presence or absence of an inherited genetic characteristic of an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes in order to identify a predisposing genetic characteristic.

[New Jersey Statutes Annotated 17B:30-12].

NEW MEXICO

Confidentiality of Health Information

- Health information must be maintained in a confidential manner. All patient-identifying health information is strictly confidential. [West's New Mexico Statutes Annotated 14-6-1]
- HMOs must protect the confidentiality of medical information. [West's New Mexico Statutes Annotated 59A-46-27]

Conditions Imposed on Genetic Testing/Use of Genetic information

- The Genetic Information Informed Privacy Act requires written consent prior to obtaining genetic information or samples for genetic analysis from a person. [West's New Mexico Statutes Annotated 24-21-2/3]
- Retention of genetic information, gene products or samples for genetic analysis is only permitted under limited circumstances, including where the retention is authorized under a research protocol approved by an IRB pursuant to federal law or a "medical registry or repository authorized by state or federal law". A person's genetic information or samples for genetic analysis shall be destroyed promptly upon the specific request by that person or that person's authorized representative unless retention is authorized under a research protocol approved by an institution review board pursuant to federal law or a medical registry or repository authorized by state or federal law. [West's New Mexico Statutes Annotated 24-21-5]

Permitted Releases of Health Information or Genetic Information for Research

A person's DNA, genetic information or the results of genetic analysis may be obtained, retained, transmitted or used without the person's written and informed consent for the purpose of medical or scientific research and education, including retention of gene products, genetic information or genetic analysis if the identity of the person or person's family members is not disclosed. [West's New Mexico Statutes Annotated, 24-21-3.]

Definition of Genetic Test/Genetic Information

"DNA" means deoxyribonucleic acid, including mitochondrial DNA, complementary DNA and DNA derived from ribonucleic acid.

"Gene products" means gene fragments, ribonucleic acids or proteins derived from DNA that would be a reflection of or indicate DNA sequence information.

"Genetic analysis" means a test of a person's DNA, gene products or chromosomes that indicates a propensity for or susceptibility to illness, disease, impairment or other disorders, whether physical or mental; that demonstrates genetic or chromosomal damage due to environmental factors; or that indicates carrier status for disease or disorder; excluded, however, are routine physical measurements, chemical, blood and urine analysis, tests for drugs, and tests for the presence of HIV virus and any other tests or analyses commonly accepted in clinical practice at the time ordered.

"Genetic information" means information about the genetic makeup of a person or members of a person's family, including information resulting from genetic analysis, DNA composition, participation in genetic research or use of genetic services.

[West's New Mexico Statutes Annotated, 24-21-2]

NEW YORK

Confidentiality of Health Information

- HMOs must keep patient information confidential. [McKinney’s Consolidated Laws of New York Annotated 4410]
- Health care providers may disclose patient information to someone other than the subject of the information pursuant to a patient authorization or when otherwise authorized by law. [New York Public Health Law, Section 18(6)]

Conditions Imposed on Genetic Testing/Use of Genetic information

According to the New York law, genetic tests generally cannot be performed on a biological sample taken from an individual without the prior written informed consent of the individual. An informed consent must contain, among other things, the name of the person or categories of persons or organizations to whom the test results may be disclosed. Genetic testing may be performed on specimens from deceased persons if informed consent is provided by the next of kin. The statute defines “biological samples” as “any material part of the human body or of discharge therefrom known to contain DNA, including but not limited to tissue specimens, blood, or urine.”

[McKinney’s Consolidated Laws of New York Annotated, Section 79-1]

Authors’ note: Arkansas and Oklahoma utilize similar statutes that permit the use of excess surgical and diagnostic tissue (and blood) for genetic research or other research studies as long as patient privacy is assured.

Insurers must obtain informed consent prior to performing genetic testing. [McKinney’s Consolidated Laws of New York Annotated, Section 2612].

Permitted Releases of Health Information or Genetic Information for Research

- New York law allows access to information “to qualified researchers.” [McKinney’s Consolidated Laws of New York Annotated, Public Health, Title II, Section 18).
- Disclosure is permitted for medical research purposes, with the approval of an institutional review board and the written informed consent of the subject, samples may be kept for longer than sixty days and utilized for scientific research. [McKinney’s Consolidated Laws of New York Annotated Section 79-1. Confidentiality of records of genetic tests]

Definition of Genetic Test/Genetic Information

“Genetic test” shall mean any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual’s offspring; such term shall also include DNA profile analysis. “Genetic test” shall not be deemed to include any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation, unless conducted purposely to identify such genetic variation.

[McKinney’s Consolidated Laws of New York Annotated, Section 79-1].

State Law Covering Human Research Subjects

New York state public health statutes include an explicit requirement to obtain informed consent and to review research for studies not otherwise covered by the federal regulations. New York’s law on human subject protection exempts from the definition of human research “biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice, or for epidemiological investigations.” By carving out tissue taken exclusively for research purposes, or excess surgical or diagnostic tissue, New York permits the use of tissue samples in research, without the attendant requirements for specific informed consent and review of the research. [McKinney’s Public Health Law 2440]

The New York state human subject legislation addresses tissue research, stating that some tissue research is not considered to be human subject research. [McKinney’s Public Health Law 2441]

“Human research” means any medical experiments, research, or scientific or psychological investigation, which utilizes human subjects and which involves physical or psychological intervention by the researcher upon the body of the subject and which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject. Human research shall not, however, be construed to mean the conduct of biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice, or to include epidemiological investigations. “Fluid” means a normal body excretion or any fluid formed by normal or pathological body processes obtained during diagnostic or therapeutic procedures conducted for the benefit of the human subject. “Tissue” means part or all of any organ of a human subject removed during a diagnostic or therapeutic procedure conducted for the benefit of the human subject. [McKinney’s Public Health Law 2440]

NORTH CAROLINA

Confidentiality of Health Information

- Medical records maintained in healthcare facilities and hospitals must be kept confidential. [West's North Carolina General Statutes Annotated, 131E-97].
- HMOs must keep medical information confidential. [West's North Carolina General Statutes Annotated, 58-67-180].

Conditions Imposed on Genetic Testing/Use of Genetic information

Restricts the use of genetic information for provision of insurance. Prohibits discrimination on the basis of genetic testing or genetic information in employment. [West's North Carolina General Statutes Annotated, 95-28.1A]

Permitted Releases of Health Information or Genetic Information for Research

All scientific research proposed to be conducted by persons other than authorized Program staff using the information from the Program, shall first be reviewed and approved by the Director of the State Center for Health and Environmental Statistics and an appropriate committee for the protection of human subjects which is approved by the United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations. Satisfaction of the terms of the Commission's rules for data access shall entitle the researcher to obtain information from the Program and, if part of the research protocol, to contact case subjects.

[West's North Carolina General Statutes Annotated, Section 130A-131.17. Confidentiality of information; research]

Definition of Genetic Test/Genetic Information

“Genetic information” means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member. “Genetic information” does not include the results of routine physical measurements, blood chemistries, blood counts, urine analyses, tests for abuse of drugs, and tests for the presence of human immunodeficiency virus.

[West's North Carolina General Statutes Annotated, Section 58-3-215. Health Insurance: Definition of Genetic information]

As used in this section, the term “genetic test” means a test for determining the presence or absence of genetic characteristics in an individual or a member of the individual's family in order to diagnose a genetic condition or characteristic or ascertain susceptibility to a genetic condition. [West's North Carolina General Statutes Annotated, Section 95-28.1A. Discrimination against persons based on genetic testing or genetic information prohibited.]

NORTH DAKOTA

Confidentiality of Health Information

- Health information is considered confidential information and must be protected except under certain circumstances according to the Health Information Protection Act. [North Dakota Century Code, Chapter 23-01.3]
- The Health Information Protection Act references tissue and cells specifically in the definition of confidential information: “Protected health information” means any information, including genetic information, demographic information, and fluid or tissue samples collected from an individual, diagnostic and test results, whether oral or recorded in any form or medium, which: a. Is created or received by a health care provider, health researcher, health plan, health oversight authority, public health authority, employer, health or life insurer, school or university; and b. (1) Relates to the past, present, or future physical or mental health or condition of an individual, including individual cells and their components; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (2) (a) Identifies an individual; or (b) With respect to which there is a reasonable basis to believe that the information can be used to identify an individual. [North Dakota Century Code, Chapter 23-01.3-01]
- HMOs and insurers are prohibited from disclosed confidential medical information. [North Dakota Century Code 26.1-36-12.4 and 26.1-18.1-23]

Conditions Imposed on Genetic Testing/Use of Genetic information

Prohibits discrimination in the provision of insurance or employment.

Permitted Releases of Health Information or Genetic Information for Research

- North Dakota law protecting health information permits releases of medical information for use in biomedical research approved by an IRB, or for public health research where the identity of the patient is protected through coding or encryption. [North Dakota Century Code, Chapter 23-01.3]
- The definition of protected health information includes information (and genetic information) created or received by a variety of entities, including “health researchers” when the identity of an individual is known, or when there is a reasonable basis to believe that the information could be used to identify an individual.

Definition of Genetic Test/Use of Genetic Information

“Protected health information” means any information, including genetic information [North Dakota Century Code, Chapter 23-01.3-01]

OHIO

Confidentiality of Health Information

Personal patient information, including medical record information and information collected or received by insurers must be kept confidential by health providers and by insurers. [Baldwin’s Ohio Revised Code Annotated, Section 3904.01 and 3904.13].

Conditions Imposed on Genetic Testing/Use of Genetic information

Restricts the use of genetic information in the provision of insurance.

Permitted Releases of Health Information or Genetic Information for Research

Releases of information are permitted for research as follows: When personal or privileged information may be disclosed. (I) Made for the purpose of conducting actuarial or research studies, provided the following conditions are met: (1) No individual may be identified in any actuarial or research report; (2) Materials allowing the individual to be identified are returned or destroyed as soon as they are no longer needed; (3) The actuarial or research organization agrees not to disclose the information unless the disclosure would otherwise be permitted by this section if made by an insurance institution, agent, or insurance support organization. [Baldwin’s Ohio Revised Code Annotated Section 3904.13]

Definition of Genetic Test/Genetic Information

“Genetic screening or testing” means a laboratory test of a person’s genes or chromosomes for abnormalities, defects, or deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicate a susceptibility to illness, disease, or other disorders, whether physical or mental, which test is a direct test for abnormalities, defects, or deficiencies, and not an indirect manifestation of genetic disorders.

[Baldwin’s Ohio Revised Code Annotated Section 1751.64 Genetic screening or testing]

OKLAHOMA

Confidentiality of Health Information

Conditions Imposed on Genetic Testing/Use of Genetic information

Oklahoma has passed a “Genetic Research Studies Nondisclosure Act” which imposes restrictions on the use and disclosure of genetic information.

[Oklahoma Statutes Annotated, Section 36-3614.4]

The Act addresses the use of stored tissue, stating that it may be used when informed consent is obtained. [Oklahoma Statutes Annotated, Section 36-3614.4]

Oklahoma law prohibits genetic discrimination in employment and in insurance.

Permitted Releases of Health Information or Genetic Information for Research

Oklahoma allows the use of results of genetic research studies for research or educational purposes if the subjects are not identified (if the subjects are to be identified then specific informed consent is required). The Genetic Research Studies Nondisclosure Act states as follows: “All stored tissues, including blood, that arise from surgery, other diagnostic or therapeutic steps, or autopsy may be disclosed for genetic or other research studies if informed consent has been obtained. Informed consent may be included in a section of the consent for treatment, admission to a hospital or clinic, or permission for an autopsy and no other consent shall be required. It shall be permissible to publish or otherwise use the results of genetic research studies for research or educational purposes if no individual subject is identified. If specific informed consent from the individual has been obtained, the individual may be identified. [Oklahoma Statutes Annotated, Section 3614.4]

Definition of Genetic Test/Genetic Information

Authors’ note: Genetic information is regulated by three separate statutes: the Genetic Research Studies Nondiscrimination Act [36-3614.4], the Genetic Nondiscrimination in Insurance Act [36-3614.1], and the Genetic Nondiscrimination in Employment Act [36-3614.2] The “Genetic Nondiscrimination in Employment Act” Section 36-3614.2 and the Genetic Nondiscrimination in Insurance Act Section 36-3614.1] use identical definitions of Genetic Test and Genetic Information.

“Genetic information” means information derived from the results of a genetic test. Genetic information shall not include family history, the results of a routine physical examination or test, the results of a chemical, blood or urine analysis, the results of a test to determine drug use, the results of a test for the presence of the human immunodeficiency virus, or the results of any other test commonly accepted in clinical practice at the time it is ordered by the insurer; (4.) “Genetic

test” means a laboratory test of the DNA, RNA, or chromosomes of an individual for the purpose of identifying the presence or absence of inherited alterations in the DNA, RNA, or chromosomes that cause a predisposition for a clinically recognized disease or disorder. “Genetic test” shall not include: a. a routine physical examination or a routine test performed as a part of a physical examination, b. a chemical, blood, or urine analysis, c. a test to determine drug use, d. a test for the presence of the human immunodeficiency virus, or e. any other test commonly accepted in clinical practice at the time it is ordered by the insurer.

OREGON

Confidentiality of Health Information

- Insurers, public health care providers and public health care facilities must use or disclose protected medical information according to individual authorization or in a manner consistent with individual authorization. [Oregon Revised Statutes Annotated 192.520]

Conditions Imposed on Genetic Testing/Use of Genetic information

According to Oregon law, an individual's genetic information and DNA sample are private and must be protected, and an individual has a right to the protection of that privacy. Any person authorized by law or by an individual or an individual's representative to obtain, retain or use an individual's genetic information or any DNA sample must maintain the confidentiality of the information or sample and protect the information or sample from unauthorized disclosure or misuse.

A person may use an individual's DNA sample or genetic information for anonymous research only if the individual:

- (A) Has granted informed consent for the specific anonymous research project;
 - (B) Has granted consent for genetic research generally; or
 - (C) Was notified the sample or genetic information may be used for anonymous research and the individual did not, at the time of notification, request that the sample not be used for anonymous research.
- (b) The Department of Human Services shall adopt rules to implement paragraph (a) of this subsection after considering similar federal regulations.
- (3) A person may not retain another individual's genetic information or DNA sample without first obtaining authorization from the individual or the individual's representative, unless:

(a) Retention is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a multidisciplinary child abuse team; (b) Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions; (c) Retention is permitted by rules of the Department of Human Services for identification of, or testing to benefit blood relatives of, deceased individuals; (d) Retention is permitted by rules of the Department of Human Services for newborn screening procedures; or (e) Retention is for anonymous research conducted after notification or with consent pursuant to subsection (2) of this section.

(4) The DNA sample of an individual from which genetic information has been obtained shall be destroyed promptly upon the specific request of that individual or the individual's representative, unless: (a) Retention is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a multidisciplinary child abuse team; (b) Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions; or (c) retention is for anonymous research conducted after notification or with consent pursuant to subsection (2) of this section.

A DNA sample from an individual that is the subject of a research project, other than an anonymous research project, shall be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first, unless the individual or the individual's representative directs otherwise by informed consent.

A DNA sample from an individual for insurance or employment purposes shall be destroyed promptly after the purpose for which the sample was obtained has been accomplished unless retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil, criminal and juvenile proceedings.

An individual or an individual's representative, promptly upon request, may inspect, request correction of and obtain genetic information from the records of the individual.

An individual or the individual's representative may request that the individual's DNA sample be made available for additional genetic testing for medical diagnostic purposes. If the individual is deceased and has not designated a representative to act on behalf of the individual after death, a request under this subsection may be made by the closest surviving blood relative of the decedent

or, 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.

This section applies only to a DNA sample or genetic information that is coded, identified or identifiable. This section does not apply to any law, contract or other arrangement that determines a person's rights to compensation relating to substances or information derived from an individual's DNA sample.

[Oregon Revised Statutes Annotated 192.537]

Permitted Releases of Health Information or Genetic Information for Research

An individual's DNA sample or genetic information may be used for anonymous research only if the individual was notified the sample or genetic information may be used for anonymous research and the individual did not, at the time of notification, request that the sample not be used for anonymous research.

"Anonymous research" means scientific or medical genetic research conducted in such a manner that any DNA sample or genetic information used in the research is unidentified. "Blanket informed consent" means that the individual has consented to the use of the 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.

[West's Oregon Revised Statutes Annotated 192.531]

Definition of Genetic Test/Genetic Information

"Genetic test" means a test for determining the presence or absence of genetic characteristics in an 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. [West's Oregon Revised Statutes Annotated 192.531 Definitions]

PENNSYLVANIA

Confidentiality of Health Information

The right to privacy under the search and seizure provision of the Pennsylvania Constitution extends to medical records of patients.

Conditions Imposed on Genetic Testing/Use of Genetic information

None (except for forensics and paternity testing).

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

None.

RHODE ISLAND

Confidentiality of Health Information

- Health care information may not be released or transferred without written consent except as provided by law. [General Laws of Rhode Island Annotated, “Confidentiality of Health Care Communications and Information Act” 5-37.3].
- Patients in health care facilities have the right to privacy and confidentiality of all records pertaining to treatment except as provided by law. [General Laws of Rhode Island Annotated 23-17-19.1(6)]

Conditions Imposed on Genetic Testing/Use of Genetic information

- Rhode Island’s Confidentiality of Health Care Communications and Information Act states that confidential health care information may not be given, sold, transferred, or in any way relayed to any other person not specified in the consent form without first obtaining the subject’s additional consent. [General Law of Rhode Island Annotated 5-37.3-4(d).]
- Selling the genetic test of a current or prospective employee or licensee for an employer, employment agency, or licensing agency is prohibited. [General Laws of Rhode Island Annotated 28-6.7-1.]
- Conditions imposed on clinical genetic testing.
- Disclosures of genetic information by HMOs or insurers is prohibited.
- The use of genetic information in employment is prohibited.

Permitted Releases of Health Information or Genetic Information for Research

- Disclosures of information are permitted for to qualified personnel for the purpose of conducting scientific research, provided that personnel shall not identify, directly or indirectly, any individual patient in any report of that research, audit, or evaluation, or otherwise disclose patient identities in any manner [Rhode Island General Laws Section 5-37.3].
- Insurance administrators, health plans and providers may not release genetic information without prior written authorization of the individual except for those participating in research settings governed by the Federal Policy for the Protection of Human Research Subjects (also known as “The Common Rule”). Tests conducted purely for research are excluded from the definition of genetic tests, as are tests for somatic (as opposed to heritable) mutations, and testing for forensic purposes. [Rhode Island General Laws Section 27-19-44 Section 27-19-44]

Definition of Genetic Test/Genetic Information

“Genetic testing” is the analysis of an individual’s DNA, RNA, chromosomes, proteins and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn and carrier screening, as well as testing in high risk families may be included provided there is an approved release by a parent or guardian. Tests for metabolites are covered only when they are undertaken with high probability that an excess of deficiency of the metabolite indicates the presence of heritable mutations in single genes. “Genetic testing” does not mean routine physical measurement, a routine chemical, blood, or urine analysis or a test for drugs or for HIV infections. [Rhode Island General Laws Section 28-6.7-2.1 and 27-19-44]

SOUTH CAROLINA

Confidentiality of Health Information

- Physicians may not release records without patient consent unless authorized by law [Code of Laws of South Carolina Section 44-115-20.]
- HMOs may not release health information without patient's consent. [Code of Laws of South Carolina Section 38-33-260]

Conditions Imposed on Genetic Testing/Use of Genetic information

- South Carolina's "Privacy of Genetic Information Act" requires that all genetic information is generally confidential and must not be disclosed to a third party in a manner that allows identification of the individual tested without first obtaining the written informed consent of that individual. [Code of Laws of South Carolina Section 38-93-10]
- The Genetic Privacy Act imposes specific requirements for informed consent for clinical genetic tests. Genetic discrimination is prohibited.

[Code of Laws of South Carolina Section 38-93-30]

Permitted Releases of Health Information or Genetic Information for Research

Genetic information may be released for use in research studies in which the identities of the persons from whom the genetic information is obtained are not disclosed to the person conducting the study. [Code of Laws of South Carolina Section 38-93-40]

Definition of Genetic Test/Genetic Information

"Genetic test" means a laboratory test or other scientifically or medically accepted procedure for determining the presence or absence of genetic characteristics in an individual.

"Genetic characteristic" means any scientifically or medically identifiable gene or chromosome, or alteration thereof, which is known to be a cause of disease or disorder, or determined to be associated with a statistically increased risk of development of a disease or disorder and which is asymptomatic of any disease or disorder.

"Genetic information" means information about genes, gene products, or genetic characteristics derived from an individual or a family member of the individual.

"Gene product" is a scientific term that means messenger RNA and translated protein. For purposes of this chapter, genetic information shall not include routine physical measurements; chemical, blood, and urine analysis, unless

conducted purposely to diagnose a genetic characteristic; tests for abuse of drugs; and tests for the presence of the human immunodeficiency virus.

[Code of Laws of South Carolina Section 38-93-10]

SOUTH DAKOTA

Confidentiality of Health Information

- Patient records are confidential [South Dakota Codified Laws 47-11F-17].
- HMOs must maintain the confidentiality of medical records [South Dakota Codified Laws 58-41-74]
- Information obtained in medical studies is deemed confidential and is to be used exclusively for medical research. [South Dakota Codified Laws 34-14]

Conditions Imposed on Genetic Testing/Use of Genetic information

South Dakota imposes strict restrictions on the conduct of clinical genetic tests, require obtaining prior written informed consent and a description of: 1. The nature and purpose of the predictive genetic test; 2. The effectiveness and limitations of the predictive genetic test; 3. The implications of taking the predictive genetic test, including, the medical risks and benefits; 4. The future uses of the sample taken from the person tested in order to conduct the predictive genetic test and the information obtained from the predictive genetic test; 5. The meaning of the predictive genetic test results and the procedure for providing notice of the results to the person tested; and 6. A listing of who will have access to the sample taken from the person tested in order to conduct the predictive genetic test and the information obtained from the predictive genetic test, and the person's right to confidential treatment of the sample and the information.

[South Dakota Codified Laws 34-14-22]

South Carolina imposes special restriction on the use of cells or tissues obtained from human embryos. Non-therapeutic research using human embryos is prohibited. "Nontherapeutic research" means research that is not intended to help preserve the life and health of the particular embryo subjected to risk. It does not include in vitro fertilization and accompanying embryo transfer to a woman's body or any diagnostic test which may assist in the future care of a child subjected to such tests. [South Dakota Codified Laws 34-14-18]

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

“Genetic information,” information derived from a genetic test about a gene, gene product, or inherited characteristic;

“Genetic test,” a test of human DNA, RNA, chromosomes, or genes performed in order to identify the presence or absence of an inherited variation, alteration, or mutation which is associated with predisposition to disease, illness, impairment, or other disorder. Genetic test does not mean a routine physical measurement; a chemical, blood, or urine analysis; a test for drugs or HIV infection; any test commonly accepted in clinical practice; or any test performed due to the presence of signs, symptoms, or other manifestations of a disease, illness, impairment, or other disorder;

“Predictive genetic test,” a genetic test performed for the purpose of predicting the future probability that the person tested will develop a genetically related disease or disability.

[South Dakota Codified Laws 34-14-21]

Genetic information is information about genes, gene products, and inherited characteristics that may derive from the individual or a family member. This includes information regarding carrier status and information derived from laboratory tests that identify mutations in specific genes or chromosomes, physical medical examinations, family histories, and direct analysis of genes or chromosomes. [South Dakota Codified Laws 58-1-24 and 60-2-21 prohibition on discrimination in employment and insurance]

TENNESSEE

Confidentiality of Health Information

- Health care providers must maintain the confidentiality of patient medical records. Medical records are defined as all medical histories, records, reports and summaries, diagnoses, prognoses of treatment and medication ordered and given, X-ray and radiology interpretations, physical therapy notes and lab reports. [West's Tennessee Code Annotated 63-2-101]
- Insurers may not release identifiable information regarding the physical or mental health of the patient. [West's Tennessee Code Annotated 56-51-150]
- Patients in health care facilities have a right to privacy. Patient identifying information may not be divulged except as specified. [West's Tennessee Code Annotated Section 68-11-1502]. Patient identifying information may not be sold.
- Individuals have the right to receive all pertinent medical information from their medical file gathered during the course of sponsored research. [West's Tennessee Code Annotated Section 49-7-120]

Conditions Imposed on Genetic Testing/Use of Genetic information

Insurers may not disclose genetic information or discriminate on the basis of genetic information.

Permitted Releases of Health Information or Genetic Information for Research

Health information that does not readily identify the patient may be disclosed with the written authorization of the patient, or if the disclosure is made for bona fide research or audit purposes. [West's Tennessee Code Annotated Section 56-7-124]

Definition of Genetic Test/Genetic Information

“Genetic information” means information derived from genetic testing to determine the presence or absence of variations or mutations, including carrier status, in an individual’s genetic material or genes that are scientifically or medically believed to cause a disease, disorder or syndrome, or are associated with a statistically increased risk of developing a disease, disorder or syndrome, which is asymptomatic at the time of testing. Such testing does not include either routine physical examinations or chemical, blood, or urine analysis unless conducted purposefully to obtain genetic information or questions regarding family history.

[West's Tennessee Code Annotated Section 56-7-2702]

TEXAS

Confidentiality of Health Information

- Physicians must maintain the confidentiality of patient records and patient communication. [Vernon’s Texas Statutes and Codes Annotated 159.002]
- The Privacy of Health Information Act requires that identifiable health information be kept private. The Privacy of Health Information Act does not apply to covered entities required to comply with HIPAA. [Vernon’s Texas Statutes and Codes Annotated 602.002]

Conditions Imposed on Genetic Testing/Use of Genetic information

Texas regulates clinical genetic testing, requiring limits on collection, use and retention of samples. [Vernon’s Texas Statutes and Codes Annotated 58.001]

A person who undergoes a genetic test has the right to know the results of the test. [Vernon’s Texas Statutes and Codes Annotated 546.101]

Genetic information may not be used for insurance purposes or for employment purposes. Genetic information obtained by insurers or employers may not be released without specific authorization. [Vernon’s Texas Statutes and Codes Annotated 546.102 and 58.102]

Permitted Releases of Health Information or Genetic Information for Research

Nonpublic personal health information may be disclosed without written authorization by covered entities to the extent the disclosure is necessary for actuarial, scientific, medical or public policy research. [Vernon’s Texas Statutes and Codes Annotated 602.053]

Samples of genetic information must be destroyed unless (1) the individual authorizes retention of the sample or (2) if the use is for treatment or research. For samples obtained for research purposes, retention is permitted if the research has been “cleared” by an institutional review board, the sample is retained under the requirements that the institutional review board imposes on a specific research for a project, or as authorized by the research participant with institutional review board approval under federal law.

[Vernon’s Texas Statutes and Codes Annotated 58.051]

Insurers may disclose genetic information for actuarial or research studies if a tested individual may not be identified in any actuarial or research report; and any materials that identify a tested individual are returned or destroyed as soon as reasonably practicable.

[Vernon’s Texas Statutes and Codes Annotated 21.73]

Definition of Genetic Test/Genetic Information

“DNA” means deoxyribonucleic acid.

“Family health history” means a history taken by a physician or genetic professional to ascertain genetic or medical information about an individual’s family.

“Genetic characteristic” means a scientifically or medically identifiable genetic or chromosomal variation, composition, or alteration that: A. is scientifically or medically believed to: i. predispose an individual to a disease, disorder, or syndrome; or ii. be associated with a statistically significant increased risk of development of a disease, disorder, or syndrome; and B. may or may not be associated with any symptom of an ongoing disease, disorder, or syndrome affecting an individual on the date that genetic information is obtained regarding that individual.

“Genetic information” means information that is: A. obtained from or based on a scientific or medical determination of the presence or absence in an individual of a genetic characteristic; or B. derived from the results of a genetic test performed on, or a family health history obtained from, that individual.

“Genetic test” means a presymptomatic laboratory test of an individual’s genes, gene products, or chromosomes that analyzes the individual’s DNA, RNA, proteins, or chromosomes; and is performed to identify any genetic variation, compositions, or alterations that are associated with an individual’s having a statistically increased risk or developing a clinically recognized disease, disorder, or syndrome; or to be a carrier of such a disease, disorder, or syndrome. The term does not include a blood test, cholesterol test, urine test, or other physical test used for a purpose other than determining a genetic or chromosomal variation, composition, or alteration in a specific individual.

[Vernon’s Texas Statutes and Codes Annotated 546.001 and 58.001 and 21.401]

UTAH

Confidentiality of Health Information

- HMOs must maintain the confidentiality of patient medical records. [West’s Utah Code Annotated 31A-8-405]
- The Utah Health Data Authority Act authorizes the collection of health data. Health Data collected pursuant to the Act must be kept confidential. [West’s Utah Code Annotated 26-33]

Conditions Imposed on Genetic Testing/Use of Genetic information

- The Genetic Testing Privacy Act restricts the ability of insurers and employers to require genetic tests and obtain genetic information. [West’s Utah Code Annotated 26-45-103/104]
- Utah imposes condition on clinical genetic testing.

Permitted Releases of Health Information or Genetic Information for Research

The Health Data Authority Act permits disclosures of identifiable health data when the individual has consented to the disclosure; or if the disclosure is to any organization that has an institutional review board, for a specified period, solely for bona fide research and statistical purposes, determined in accordance with department rules, and the department determines that the data is required for the research and statistical purposes proposed and the requesting individual or organization enters into a written agreement satisfactory to the department to protect the data in accordance with this chapter or other applicable law and not permit further disclosure without prior approval of the department. Any health data disclosed shall be identified by control number only. [West’s Utah Code Annotated 26-33a-109]

Definition of Genetic Test/Genetic Information

“DNA” means deoxyribonucleic acid, ribonucleic acid, and chromosomes, which may be analyzed to detect heritable diseases or conditions, including the identification of carriers, predicting risk of disease, or establishing a clinical diagnosis.

“DNA sample” means any human biological specimen from which DNA can be extracted, or DNA extracted from such specimen.

“Genetic analysis” or “genetic test” means the testing or analysis of an identifiable individual’s DNA that results in information that is derived from the presence, absence, alteration, or mutation of an inherited gene or genes, or the presence or absence of a specific DNA marker or markers.

“Genetic analysis” or “genetic test” does not mean: (i) a routine physical examination; (ii) a routine chemical, blood, or urine analysis; (iii) a test to identify the presence of drugs or HIV infection; or (iv) a test performed due to the presence of signs, symptoms, or other manifestations of a disease, illness, impairment, or other disorder.

[West’s Utah Code Annotated 26-45-102]

VERMONT

Confidentiality of Health Information

Patients have the right to privacy during their treatment according to the Bill of Rights for Hospital Patients. The Bill of Rights requires that medical information must be kept confidential, that patients must be informed of research, that research shall be voluntary, and that patients have the right to refuse to participate in research projects. The Bill of Rights also requires permission to release information for research without written authorization. [Vermont Statutes Annotated, Title 18, Section 1852]

Conditions Imposed on Genetic Testing/Use of Genetic information

Individuals cannot be required to undergo genetic test except under certain circumstances (paternity, forensics, or certain insurance transactions). The results of genetic tests or the fact that a test has been conducted are protected from disclosure without the written authorization of the individual. [Vermont Statutes Annotated, Title 18, Section 9331-9334]

Discrimination in employment or insurance on the basis of genetic testing is forbidden.

[Vermont Statutes Annotated, Title 18, Section 9331-9334]

Permitted Releases of Health Information or Genetic Information for Research

Genetic testing may not be performed on individuals or body parts of any individual nor shall any bodily materials be released for purposes of genetic testing without the prior written authorization and informed consent of the individual to be tested except for medical research where the identity of the subject is unknown or, if the research shall be conducted with anonymized medical information where individual identifiers are encrypted or encoded and the identity of the individual is not disclosed, or if the identity of the individual is known, where standards of protection are equal to those contained in regulations promulgated by the federal Office for Protection from Research Risk (OPRR). [Vermont Statutes Annotated, Title 18, Section 9332]

Definition of Genetic Test/Genetic Information

“Genetic information” means the results of “genetic testing” contained in any report, interpretation, evaluation, or other record thereof.

“Genetic testing” means a test, examination or analysis that is diagnostic or predictive of a particular heritable disease or disorder and is of: (i) a human chromosome or gene; (ii) human DNA or RNA; or (iii) a human genetically encoded protein.

The test for human genetically encoded protein referred to in subdivision (A) (iii) of this subdivision shall be generally accepted in the scientific and medical communities as being specifically determinative for the presence or absence of a mutation, alteration, or deletion of a gene or chromosome.

For the purposes of sections 9332 and 9333 of this title, as they apply to insurers, section 9334 of this title, and section 4727 of Title 8, and notwithstanding any language in this section to the contrary, “genetic testing” does not include: (i) a test, examination or analysis which reports on an individual’s current condition unless such a test, examination or analysis is designed or intended to be specifically determinative for the presence or absence of a mutation, alteration, or deletion of a gene or chromosome; or (ii) a test, examination or analysis of a human chromosome or gene, of human DNA or RNA, or of a human genetically encoded protein that is diagnostic or predictive of a particular heritable disease or disorder, if, in accordance with generally accepted standards in the medical community, the potential presence or absence of a mutation, alteration or deletion of a gene or chromosome has already manifested itself by causing a disease, disorder or medical condition or by symptoms highly predictive of the disease, disorder or medical condition.

[Vermont Statutes Annotated, Title 18, Section 9331]

VIRGINIA

Confidentiality of Health Information

- Patient health records must be kept private [West's Annotated Code of Virginia, 32.1-127.1:03]
- Statute on human subjects in research imposes requirements on the conduct of human research regardless of the source of funding, requiring obtaining informed consent from participants and review by human research review committees. [West's Annotated Code of Virginia, 32.1-162.16]

Conditions Imposed on Genetic Testing/Use of Genetic information

Genetic information must be kept private [West's Annotated Code of Virginia, 38.2-508.4]

Employers and insurers may not require individuals to undergo genetic tests.

Permitted Releases of Health Information or Genetic Information for Research

Disclosures of health information for research purposes are permitted as follows: (i) any provider who receives records from another provider from making subsequent disclosures as permitted under this section or (ii) any provider from furnishing records and aggregate or other data, from which patient-identifying prescription information has been removed, encoded or encrypted, to qualified researchers, including, but not limited to, pharmaceutical manufacturers and their agents or contractors, for purposes of clinical, pharmaco-epidemiological, pharmaco-economic, or other health services research. [Virginia Code Annotated, Section 32.1-127.1:03]

Definition of Genetic Test/Genetic Information

Genetic test means a test for determining the presence or absence of genetic characteristics in an individual in order to diagnose a genetic characteristic. [Virginia Code Annotated, Section 38.2-508.4]

State Law Covering Human Research Subjects

Virginia requires informed consent of subjects prior to participation in research and imposes other specific requirements on the conduct of human subjects research. [Virginia Code Annotated, Section 32.1-162.18]

WASHINGTON

Confidentiality of Health Information

Health care information maintained by providers must be kept confidential and disclosures are restricted. [West's Revised Code of Washington 70.02.005 et seq.]

Conditions Imposed on Genetic Testing/Use of Genetic information

Genetic information may not be used for employment purposes.

Permitted Releases of Health Information or Genetic Information for Research

A health care provider may disclose health care information about a patient without the patient's authorization to the extent a recipient needs to know the information, if the disclosure is for use in a research project that an institutional review board has determined: (i) Is of sufficient importance to outweigh the intrusion into the privacy of the patient that would result from the disclosure; (ii) Is impracticable without the use or disclosure of the health care information in individually identifiable form; (iii) Contains reasonable safeguards to protect the information from redisclosure; (iv) Contains reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research project; and (v) Contains procedures to remove or destroy at the earliest opportunity, consistent with the purposes of the project, information that would enable the patient to be identified, unless an institutional review board authorizes retention of identifying information for purposes of another research project.

[West's Revised Code of Washington, 70.02.050]

Definition of Genetic Test/Genetic Information

Genetic information is information about inherited characteristics that are derived from a DNA-based or other laboratory test, family history, or medical examination. Genetic information does not include routine physical measurements, including chemical and urine analysis, unless conducted purposefully to diagnose genetic or inherited characteristics. [West's Revised Code of Washington Annotated 49.44.180]

WEST VIRGINIA

Confidentiality of Health Information

HMOs must maintain the confidentiality of medical information. [West's Annotated Code of West Virginia, 33-25A-26]

Insurers must maintain the confidentiality of medical information. [West's Annotated Code of West Virginia, 33-25D-28]

Conditions Imposed on Genetic Testing/Use of Genetic information

Insurers may not use genetic information to determine eligibility.

Permitted Releases of Health Information or Genetic Information for Research

None.

Definition of Genetic Test/Genetic Information

None.

WISCONSIN

Confidentiality of Health Information

Patient health records must be kept confidential. Health care records may not be disclosed without the informed consent of the patient, except under certain specified circumstances. [West's Wisconsin Statutes Annotated Section 146.82]

Personal medical information may not be disclosed by insurers. [West's Wisconsin Statutes Annotated Section 610.70]

Conditions Imposed on Genetic Testing/Use of Genetic information

Restricts the use of genetic information in the employment and insurance.

Permitted Releases of Health Information or Genetic Information for Research

The law permits releases of information without informed consent, if the researcher is affiliated with the health care provider and provides written assurances to the custodian of the patient health care records that the information will be used only for the purposes for which it is provided to the researcher, the information will not be released to a person not connected with the study, and the final product of the research will not reveal information that may serve to identify the patient whose records are being released under this paragraph without the informed consent of the patient. [West's Wisconsin Statutes Annotated Section 146.82]

Definition of Genetic Test/Genetic Information

Authors' note: Wisconsin law has different definitions of genetic test depending on whether the conduct of such tests is addressed in the context of insurance or employment.

“Genetic test” means a test using deoxyribonucleic acid extracted from an individual’s cells in order to determine the presence of a genetic disease or disorder or the individual’s predisposition for a particular genetic disease or disorder. [West’s Wisconsin Statutes Annotated Section 631.89(1)]

“Genetic test” means a test of a person’s genes, gene products or chromosomes for abnormalities or deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicate a susceptibility to illness, disease, impairment or other disorders, whether physical or mental, or that demonstrate genetic or chromosomal damage due to environmental factors. [West’s Wisconsin Statutes Annotated Section 942.07]

WYOMING

Confidentiality of Health Information

Hospitals and health care facilities may not disclose health care information without patient authorization except under certain circumstances. [Wyoming Statutes, 35-2-609]

Insurers must maintain the confidentiality of medical information. [Wyoming Statutes, 26-34-130]

Conditions Imposed on Genetic Testing/Use of Genetic information

Wyoming requires that the results of genetic testing be confidential. Testing on identifiable genetic material submitted for the purposes of determining paternity must be confidential and used solely for the purposes of determining paternity unless individual identifiers are removed. Restricts the use of genetic information in the provision of insurance. [Wyoming Statutes, 14-2-710]

Permitted Releases of Health Information or Genetic Information for Research

Wyoming permits disclosures of health information for research purposes for use in a research project that an institutional review board has determined is of sufficient importance to outweigh the intrusion into the privacy of the patient that would result from the disclosure; is impracticable without the use or

disclosure of the health care information in individually identifiable form; contains reasonable safeguards to protect the information from redisclosure; contains reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research project; and contains procedures to remove or destroy at the earliest possible opportunity, consistent with the purposes. [Wyoming Statutes, 35-2-609]

Definition of Genetic Test/Genetic Information

Genetic information means any information about genes, gene products or inherited characteristics that may derive from an individual or a family member, including but not limited to information regarding carrier status, regarding an increased likelihood of future disease or increased sensitivity to any substance, derived from laboratory tests that identify mutations in specific genes, chromosomes, physical medical examination, family histories, request for genetic services or counseling, tests of gene products and direct analysis of genes and chromosomes. [Wyoming Statutes, 14-2-710]

**NATIONAL CANCER INSTITUTE
CANCER DIAGNOSIS PROGRAM**

**50-State Survey of Laws
Regulating the Collection, Storage,
and Use of Human Tissue Specimens
and Associated Data for Research**

Appendix B

Table of State Law Requirements

Table of State Law Requirements

| STATE | Disclosures of Medical Information Permitted for Research | | State Laws for Human Subjects Protection | Conditions Imposed on Genetic Testing/ Genetic Information | Genetic Information Defined as Personal Property |
|---------------|---|---|--|---|--|
| | For Anonymous Data (or Identity Protected) | With IRB Approval or When Federal Rules Apply | | | |
| ALABAMA | | | | × | |
| ALASKA | × | × | | × | |
| ARIZONA | × | × | | × | |
| ARKANSAS | × | | | × | |
| CALIFORNIA | × | × | × | × | |
| COLORADO | × | × | | × | × |
| CONNECTICUT | × | × | | × | |
| DELAWARE | × | | | × | |
| FLORIDA | × | | | × | × |
| GEORGIA | × | | | × | × |
| HAWAII | × | × | | × | |
| IDAHO | | | | × | |
| ILLINOIS | | | | × | |
| INDIANA | × | × | | × | |
| IOWA | | | | × | |
| KANSAS | | | | × | |
| KENTUCKY | | | | × | |
| LOUISIANA | × | | | × | × |
| MAINE | × | × | | × | |
| MARYLAND | × | × | × | × | |
| MASSACHUSETTS | | | | × | |
| MICHIGAN | | × | | × | |
| MINNESOTA | | | | × | |
| MISSISSIPPI | | | | | |
| MISSOURI | × | × | | × | |

| STATE | Disclosures of Medical Information Permitted for Research | | State Laws for Human Subjects Protection | Conditions Imposed on Genetic Testing/ Genetic Information | Genetic Information Defined as Personal Property |
|----------------|---|---|--|---|--|
| | For Anonymous Data (or Identity Protected) | With IRB Approval or When Federal Rules Apply | | | |
| MONTANA | | × | | × | |
| NEBRASKA | | × | | × | |
| NEVADA | × | | | × | |
| NEW HAMPSHIRE | | × | | × | |
| NEW JERSEY | × | | | × | |
| NEW MEXICO | × | | | × | |
| NEW YORK | | × | × | × | |
| NORTH CAROLINA | | × | | × | |
| NORTH DAKOTA | × | × | | × | |
| OHIO | × | × | | × | |
| OKLAHOMA | × | | | × | |
| OREGON | × | | | × | |
| PENNSYLVANIA | | | | | |
| RHODE ISLAND | × | × | | × | |
| SOUTH CAROLINA | × | | | × | |
| SOUTH DAKOTA | | | | × | |
| TENNESSEE | × | | | × | |
| TEXAS | × | × | | × | |
| UTAH | × | | | × | |
| VERMONT | × | × | | × | |
| VIRGINIA | × | × | × | × | |
| WASHINGTON | × | × | | × | |
| WEST VIRGINIA | | | | × | |
| WISCONSIN | × | | | × | |
| WYOMING | × | × | | × | |

References

- 1 National Bioethics Advisory Commission, “Research Involving Human Biological Materials: Ethical Issues and Policy Guidance” (1999), Chapter 3: Current Guidance on the Use of Human Biological Materials in Research, page 56.
- 2 The term “patient data” is used in this survey to represent all medical and health information derived from human tissue samples, regardless of whether such information is obtained in a clinical or research setting and regardless of whether such information is taken from healthy individuals or “patients.” Use of the term “patient data” parallels many state statutes that refer to information in the patient medical record, but the intention here is to cover information beyond that which is included in the medical record. When reference is made to individually identifiable data, this will be specified.
- 3 While the Common Rule only applies to human subjects research that is federally funded or conducted, many research institutions have agreed to subject all of their research activities to its requirements.
- 4 45 C.F.R. 46.101(a) establishes the scope of the Federal Policy for Protection of Human Subjects. Seventeen federal agencies have adopted Subpart A as their policy for protection of human research subjects in research that is federally funded or conducted.
- 5 45 C.F.R. 46.102.
- 6 More information about the federal regulations for human subjects protection can be found at:
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm> and
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=50.3>
- 7 Office for Human Research Protections, DHHS, Guidance on the Use of Expedited Review Procedures (2003),
<http://www.hhs.gov/ohrp/humansubjects/guidance/exprev.htm>
- 8 More information about the specifics of OHRP’s policy on Expedited Review of Research Protocols can be found at:
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm>.
- 9 Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law No. 104-191, Section 264 (1996); Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Section 160 (2002), 45 C.F.R. Section 164 subparts A, E (2002).
- 10 Health Insurance Portability and Accountability Act of 1996.

- 11 This report does not address the details of HIPAA implementation and compliance, but further information can be obtained from: <http://privacyrule-andresearch.nih.gov>. To view the complete final Privacy Rule, see: <http://www.hhs.gov/ocr/hipaa/finalreg.html>.
- 12 Section 160.203(b). A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if the provision of state law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.
- 13 45 C.F.R. 46.101(f).
- 14 National Bioethics Advisory Commission, “Research Involving Human Biological Materials: Ethical Issues and Policy Guidance” (1999), Chapter 3: Current Guidance on the Use of Human Biological Materials in Research, page 56.
- 15 North Dakota Century Code, Chapter 23-01.3, Health Information Protection Act.
- 16 These laws are often aimed at preventing the use of personal medical information to deny insurance coverage or employment and to prevent discrimination or stigmatization. A handful of states directly addressed the issue of commercial use of genetic information, often stating that medical information and/or genetic information may not be sold.
- 17 See Colorado.
- 18 Alaska Statutes 21.07.040(b) (2) (A) (B).
- 19 Vermont Statutes Annotated, Title 18, Section 1852(10). The patient has the right to be advised if the hospital proposes to engage in or perform human experimentation affecting the patient’s care or treatment. Participation by patients in clinical training programs or in the gathering of data for research purposes shall be voluntary. The patient has the right to refuse to participate in such research projects.
- 20 Annotated Code of Maryland Code; 4-303; 4-304(a).
- 21 Oregon Revised Statutes Annotated, Medical Records, 192.525.
- 22 Minnesota Statutes Annotated, Section 144.335 subd. 3a(d).
- 23 Minnesota Statute Annotated, Section 144.335 subd. 3a(d).
- 24 Connecticut General Statutes, Section 19A-490B.
- 25 As of April 2003, over 30 states have enacted some form of legislation governing the use and disclosure of genetic information. Sixteen states

require informed consent to perform or require a genetic test or in order to obtain genetic information about an individual. Twenty-five states require informed consent to disclose genetic information, and some of these specify the type of written authorization required to disclose genetic information. Six states require individual permission to retain genetic information.

- 26 Arizona, Arkansas, Colorado, Delaware, Georgia, Louisiana, Maryland, Massachusetts, Missouri, Nebraska, New Jersey, New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, Texas, Vermont, and Virginia permit research uses of genetic information under certain specified conditions.
- 27 Massachusetts General Laws Annotated, Section 70g. Genetic Information and Reports Protected As Private Information; Prior Written Consent for Genetic Testing.
- 28 Nebraska Revised Statutes 77-5519, Genetic test, defined.
- 29 Louisiana Revised Statutes Annotated, 22: 213.7.
- 30 McKinney's Consolidated Laws of New York Annotated, Section 79-1(2).
- 31 Arkansas Code Annotated 20-35-103: All stored tissues, including blood, that arise from surgery, other diagnostic or therapeutic steps, or autopsy may be disclosed for genetic or other research studies, if: (A) The patient's name or social security number is not attached to or included with the specimen; or (B) The patient's name or social security number is attached to or included with the specimen and the patient has given informed written consent to the disclosure. Oklahoma Statutes, Title 36, Chapter 1, Article 36, Section 3614.4–Genetic Research Studies Nondisclosure Act: All stored tissues, including blood, that arise from surgery, other diagnostic or therapeutic steps, or autopsy may be disclosed for genetic or other research studies if informed consent has been obtained. (“Informed consent may be included in a section of the consent for treatment, admission to a hospital or clinic, or permission for an autopsy and no other consent shall be required.”)
- 32 Michigan Compiled Laws Annotated, Genetic Test–Informed Consent 333.17520; Nebraska Revised Statute 71-1,104.01.
- 33 Code of Laws of South Carolina “Privacy of Genetic Information Act,” Section 38-93-10.
- 34 South Dakota Codified Laws 34-14-22.
- 35 New Jersey Statutes Annotated 10:5-43.
- 36 Vernon's Texas Statutes and Codes Annotated, Article 9032, Prohibited Use of Genetic Information.

- 37 Arizona Revised Statutes, 12-2802.
- 38 Arizona Revised Statutes, 20-448.02.
- 39 Colorado Revised Statutes Annotated, 10-3-1104.7.
- 40 Florida Statutes Annotated, Title XLIV, 760.40. Genetic testing; informed consent; confidentiality.
- 41 Georgia Code Annotated, Sections 33-54-1 and 33-54-6.
- 42 Louisiana Revised Statutes Annotated, 22:213.7(E).
- 43 In the recent decision by a federal court in Florida, the judge decided that this statute addressing ownership of the results of DNA analysis did not mean that individuals who voluntarily contributed blood and tissue samples for research purposes retained an ownership interest in the sample or in the resulting patented research product. Daniel Greenberg, Fern Kupfer, Frieda Eisen, David Green, Canavan Foundation, Dor Yeshorim, And National Tay-Sachs And Allied Diseases Association, Inc., Plaintiffs, v. Miami Children's Hospital Research Institute, Inc., Variety Children's Hospital, Inc. D/B/A Miami Children's Hospital, And Reuben Matalon, Defendants. Case Number: 02-22244-Civ-Moreno, United States District Court For The Southern District Of Florida, Miami Division, 2003 U.S. District, Lexis 8959, May 29, 2003.
- 44 Annotated Code of Maryland, Human Subject Research,13-2002.
- 45 West's Annotated Code of Virginia, Section 32.1-162.16.
- 46 McKinney's Public Health Law, Section 2440-6.
- 47 Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Maryland, Massachusetts, Minnesota, Mississippi, Montana, Nevada, North Carolina, New Hampshire, New Jersey, North Dakota, Oregon, Rhode Island, Tennessee, Texas, Vermont.
- 48 Delaware, Hawaii, Maryland, Massachusetts, Minnesota, Montana, North Carolina.
- 49 45 C.F.R. 46.102(f).
- 50 West's Revised Code of Washington 70.02.050(g).
- 51 Minnesota Statutes Annotated, 144.335.
- 52 Vernon's Texas Statutes and Codes Annotated, 602.053.
- 53 Annotated California Civil Code, Section 56-56.05(f).
- 54 Annotated California Civil Code, Section 56.10(d).
- 55 Annotated California Civil Code 24170.

- ⁵⁶ According to Department of Health and Human Services (HHS) human subjects regulations at 45 C.F.R. 46.103, every institution engaged in human subjects research supported or conducted by DHHS must obtain an Assurance of Compliance approved by the Office for Human Research Protections (OHRP). Historically, OHRP has approved three basic types of assurances: Multiple Project Assurance (MPA), Cooperative Project Assurance (CPA), and Single Project Assurance (SPA). All MPAs approved by OHRP were designated for federalwide use.
- ⁵⁷ The data will comprise a limited data set under HIPAA.
- ⁵⁸ Arizona Revised Statutes, Title 12, Chapter 19, Genetic Testing, 12-2801, Definitions.
- ⁵⁹ Code of Alabama, Insurance Code Sections 27-53-2 and 27-53-1-4.
- ⁶⁰ McKinney's Consolidated Laws of New York Annotated, Section 79-1.
- ⁶¹ McKinney's Public Health Law, Protection Of Human Subjects, Section 2440-2446.
- ⁶² Oregon Revised Statutes Annotated, Medical Records, 192.525.
- ⁶³ Oregon Revised Statutes Annotated, Genetic Privacy Act, 192.533.
- ⁶⁴ Oregon Revised Statutes Annotated, 192.537
- ⁶⁵ *Moore v. Regents of the University of California, et.al.*, 499 U.S. 936, 111 S. Ct. 1388, 113 L.Ed. 2d 444, (1991).
- ⁶⁶ Daniel Greenberg, Fern Kupfer, Frieda Eisen, David Green, Canavan Foundation, Dor Yeshorim, And National Tay-Sachs And Allied Diseases Association, Inc., Plaintiffs, v. Miami Children's Hospital Research Institute, Inc., Variety Children's Hospital, Inc. D/B/A Miami Children's Hospital, And Reuben Matalon, Defendants. 264 F.Supp.2d, 1064 (May 29, 2003).



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