

§ 79-1. Confidentiality of records of genetic tests. 1. As used in this section, the following terms shall have the following meanings:

(a) "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.

(b) "genetic predisposition" shall mean the presence of a variation in the composition of the genes of an individual or an individual's family member which is scientifically or medically identifiable and which is determined to be associated with an increased statistical risk of being expressed as either a physical or mental disease or disability in the individual or having offspring with a genetically influenced disease, but which has not resulted in any symptoms of such disease or disorder.

(c) "biological sample" shall mean any material part of the human body or of discharge therefrom known to contain DNA, including but not limited to tissue specimen, blood, or urine.

(d) "institutional review board" shall mean a human research review committee established and approved under the provisions of article twenty-four-A of the public health law, or an institutional review board established and approved under the provisions of 45 CFR part 46 or 42 USC 30 V-1, for the purpose of reviewing and monitoring research involving human subjects.

2. (a) No person shall perform a genetic test on a biological sample taken from an individual without the prior written informed consent of such individual as provided in paragraph (b) of this subdivision, except as otherwise provided in paragraph (c) of subdivision two and by subdivision nine of this section.

(b) Written informed consent to a genetic test shall consist of written authorization that is dated and signed and includes at least the following:

(1) a general description of the test;

(2) a statement of the purpose of the test;

2-a. a statement indicating that the individual may wish to obtain professional genetic counseling prior to signing the informed consent.

(3) a statement that a positive test result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult their physician or pursue genetic counseling;

(4) a general description of each specific disease or condition tested for;

(5) the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease. If no level of certainty has been established, this subparagraph may be disregarded;

(6) the name of the person or categories of persons or organizations to whom the test results may be disclosed;

(7) a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent; and

(8) the signature of the individual subject of the test or, if that individual lacks the capacity to consent, the signature of the person authorized to consent for such individual.

(c) A general waiver, wherein consent is secured for genetic testing without compliance with paragraph (b) of this subdivision, shall not constitute informed consent. Notwithstanding the provisions of this section, for purposes of research conducted in accordance with the provisions of subdivision nine of this section, a general waiver for the use of samples for research may be granted which would authorize the use of samples for these research purposes.

(d) Any further disclosure of genetic test results to persons or organizations not named on the informed consent shall require the further informed consent of the subject of the test.

(e) Written consent by an individual for tests to be conducted on a biological sample and to the lawful possession and ownership of such sample by a laboratory shall not be deemed written informed consent for the performance of any genetic test on that sample, except as further

provided in subdivision four of this section.

(f) 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. The requirements of subparagraphs three, four and five of paragraph (b) of this subdivision may be modified by the institutional review board in case the research protocol does not permit such degree of specificity.

3. (a) All records, findings and results of any genetic test performed on any person shall be deemed confidential and shall not be disclosed without the written informed consent of the person to whom such genetic test relates. This information shall not be released to any person or organization not specifically authorized by the individual subject of the test. Unauthorized solicitation or possession of such information shall be unlawful, except for the unintentional possession of such information as part of a health record created prior to the effective date of this section and provided no action adverse to the interests of the subject are taken as a result of such possession. Nothing in this section shall preclude the release of such information, with the subject's consent, to a health insurer or health maintenance organization of any information reasonably required for purposes of claims administration, provided, however, that further distribution within the insurer or to other recipients shall require the subject's informed consent in each case.

(b) No person who lawfully possesses information derived from a genetic test on a biological sample from an individual shall incorporate such information into the records of a non-consenting individual who may be genetically related to the tested individual; nor shall any inferences be drawn, used, or communicated regarding the possible genetic status of the non-consenting individual.

4. (a) Notwithstanding the provisions of subdivision two of this section, genetic tests may be performed on anonymous samples for research or statistical purposes, pursuant to a research protocol approved by an institutional review board which assures the anonymity of the sources of the samples.

(b) Notwithstanding the provisions of subdivision two of this section, genetic tests may be performed without the consent of the person who is the subject of the tests pursuant to an order of a court of competent jurisdiction or as provided pursuant to article forty-nine-B of the executive law or as provided by section twenty-five hundred-a of the public health law.

(c) Notwithstanding the provisions of paragraph (a) of subdivision three of this section, the results of a genetic test may be disclosed to specified individuals without the consent of the subject of the test as provided in an order of a court of competent jurisdiction or as provided pursuant to article forty-nine-B of the executive law or section twenty-five hundred-a of the public health law.

(d) In authorizing a genetic test or the disclosure of genetic test results to specified individuals, the court shall consider the privacy interests of the individual subject of the genetic test and of close relatives of such individual, the public interest, and, in the case of medical or anthropological research, the ethical appropriateness of the research. Disclosure shall be permitted only to individuals or agencies expressly named in court orders.

5. Penalties. (a) Any person who violates the provisions of subdivision two or three of this section shall be guilty of a violation punishable by a civil fine of not more than one thousand dollars.

(b) Any person who willfully violates the provisions of subdivision two or three of this section shall be guilty of a misdemeanor punishable by a fine of not more than five thousand dollars or by imprisonment for not more than ninety days or by both such fine and imprisonment.

6. Nothing in this section shall be applicable to an authorized insurer, as defined in paragraph ten of subsection (a) of section one hundred seven of the insurance law, or a person acting on behalf of an authorized insurer who is in compliance with section twenty-six hundred twelve of the insurance law nor shall anything in this section be deemed to prohibit or limit an authorized insurer from obtaining information pursuant to section twenty-six hundred twelve of the insurance law.

7. Notwithstanding the provisions of subdivision two of this section,

genetic testing of newborn infants may be performed as provided pursuant to article twenty-five and section forty-one hundred thirty-five-b of the public health law.

8. Notwithstanding the provisions of subparagraph seven of paragraph (b) of subdivision two of this section, additional genetic testing may be performed on a given sample without additional consent of the person tested provided such testing is necessary and required to demonstrate the integrity of the sample tested or to resolve the analysis of a test with a previously indeterminate result.

9. (a) Notwithstanding the provisions of subdivisions two and ten of this section, samples may be used for tests other than those for which specific consent has been obtained, for purposes of research conducted in accordance with applicable law and regulation and pursuant to a research protocol approved by an institutional review board, provided that the individuals who provided the samples have given prior written informed consent for the use of their sample for general research purposes and did not specify time limits or other factors that would restrict use of the sample for the test, and (1) the samples have been permanently stripped of identifying information; or (2) a coding system has been established to protect the identity of the individuals who provided the samples, and an institutional review board has reviewed and approved the procedures for the coding system.

(b) If consent to storage of the tissue sample is withdrawn at any time, the entity storing the sample shall promptly destroy the sample or portions thereof that have not already been used for research purposes.

(c) In no event shall family members of an individual who provided a stored tissue sample be contacted for clinical, research, or other purposes without consent from the individual who provided the tissue sample with respect to the specific family members who will be contacted and the specific purpose of the contact.

(d) In no event shall any information about an individual derived from genetic tests performed on stored human tissue or information linking an individual with specific results of genetic tests be released to any organization or person without the explicit written consent of the individual who donated the stored tissue to release of the information

for the purposes set forth in the written consent document.

(e) Written informed consent for use of stored human tissue for general research purposes shall consist of written authorization that includes at least the following:

(1) a statement that the sample will be used for future genetic tests;

(2) the time period during which the tissue will be stored, or if no time limit is specified, a statement that the tissue will be stored for as long as deemed useful for research purposes;

(3) a description of the policies and procedures to protect patient confidentiality;

(4) a statement of the right to withdraw consent to use of the tissue for future use at any time and the name of the organization that should be contacted to withdraw consent;

(5) a statement allowing individuals to consent to future contact for any or all purposes, including the following: (i) research purposes; (ii) provision of general information about research findings; and (iii) information about the test on their sample that may benefit them or their family members in relation to their choices regarding preventive or clinical care; and

(6) a statement explaining the benefits and risks of consenting to future contact for the purposes set forth in subparagraph five of this paragraph. In no event shall information about specific test results on stored human tissue donated for general research purposes be disclosed to an individual without obtaining informed consent for the disclosure as required by paragraph (b) of subdivision two of this section.

10. Notwithstanding the provisions of subdivision two of this section, DNA samples may be stored for up to ten years in the absence of genetic testing, if authorized in writing by the subject. Prior to the performance of any genetic test upon stored samples, informed consent must be obtained as provided in subdivision two of this section. Retention of a DNA sample past a period of ten years requires explicit consent for a longer or indefinite period of retention.

11. Genetic testing may be performed on specimens from deceased persons if informed consent is provided by the next-of-kin as specified in subdivision two of this section.

