## New York

### Newborn Genetic Testing & Surveillance System

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/ Rule</th>
<th>Language Specific to Genetic Testing &amp; Surveillance System</th>
<th>Exemption</th>
<th>Research Authority</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
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<tbody>
<tr>
<td>NY</td>
<td>STATUTE: Public Health Law, Article 25, §2500-G, Title 1 Civil Rights Law, Article 7, § 79-l 10 NYCRR 69-6.1</td>
<td>§ 2500. Maternal and child health; duties of commissioner. 1. The commissioner shall act in an advisory and supervisory capacity, in matters pertaining to the safeguarding of motherhood, the prevention of maternal, perinatal, infant and child mortality, the prevention of diseases, low birth weight, and defects of childhood and the promotion of maternal, prenatal and child health, including care in hospitals, and shall administer such services bearing on the health of mothers and children for which funds</td>
<td>§ 2500-a. ...(b) The provisions of this section shall not apply in the case of any infant or child whose parent or guardian is a member of a recognized religious organization whose teachings and tenets are contrary to the testing herein required and who notifies the person charged with</td>
<td>79-l. Confidentiality of records of genetic tests.  ...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</td>
<td>NO</td>
<td>YES</td>
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§ 2500-a. Test for phenylketonuria and other diseases and conditions. (a) It shall be the duty of the administrative officer or other person in charge of each institution caring for infants twenty-eight days or less of age and the person required in pursuance of the provisions of section forty-one hundred thirty of this chapter to register the birth of a child, to cause to have administered to every such infant or child in its or his care a test for phenylketonuria, homozygous sickle cell disease, hypothyroidism, branched-chain ketonuria, galactosemia, homocystinuria and having such test administered of his objection thereto.

Section 69-1.3. Responsibilities of the chief executive officer…The chief executive officer shall ensure that…(a) The infant's parent is informed of the purpose and need for newborn screening, and given newborn screening educational materials provided by the testing laboratory.

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
| Section 69-1.3 | Responsibilities of the chief executive officer | Specimen collection forms are properly stored in a cool and dry environment prior to use. Such forms shall be legibly and fully completed, and shall include all information required by the testing laboratory for processing specimens,| 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 research purposes.  

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… [emphasis added]  

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... |
and conducting tracking and follow-up activities, including, but not limited to, information identifying:
(1) the infant's name; sex; whether single birth or, if twin birth, sequence of birth; ethnicity; date of birth; birth weight; medical record number; and whether premature and/or transfused, with transfusion date;
(2) the specimen, including identification number, the date collected, infant's age in hours at time of collection; and whether initial or repeat specimen;
(3) the mother's name, address, county of residence, telephone number, social security number, age in years and test result for hepatitis B surface antigen (HBs Ag); and conducting tracking and follow-up activities, including, but not limited to, information identifying:
(1) the infant's name; sex; whether single birth or, if twin birth, sequence of birth; ethnicity; date of birth; birth weight; medical record number; and whether premature and/or transfused, with transfusion date;
(2) the specimen, including identification number, the date collected, infant's age in hours at time of collection; and whether initial or repeat specimen;
(3) the mother's name, address, county of residence, telephone number, social security number, age in years and test result for hepatitis B surface antigen (HBs Ag); 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.

(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: [emphasis added]

(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
(4) the hospital or responsible institution's name and city; permanent facility identifier (PFI) code; and whether hospital of birth, or home birth; and (5) the responsible physician's name, address, telephone number and license number.

(c) The above information shall also be submitted to the department in an electronic format which is consistent with the technical specifications established by the department.

Section 69-1.8. Follow-up review, tracking and educational activities. The testing laboratory shall:

(a) record requested diagnoses and case follow-up information submitted by health care providers and specialty

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<td>(3) a description of the policies and procedures to protect patient confidentiality;</td>
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<td>(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;</td>
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<td>(5) a statement allowing individuals to consent to future contact for any or all purposes, including the following:</td>
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<td>(i) research purposes;</td>
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<td>(ii) provision of general information about research findings; and</td>
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<td>(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</td>
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| (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
| care centers; (b) maintain tracking records on identified cases; and (c) provide educational activities and materials. | 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... [emphasis added] |