### South Carolina

**Newborn Genetic Testing & Surveillance System**

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<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Genetic Testing and Surveillance System</th>
<th>Exemption</th>
<th>Research Authority</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
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<tr>
<td>SC</td>
<td>STATUTE: SCCL, Title 44, Chapter 37 RULE: Chapter 61-80, Sections A to I, and Appendices A to C</td>
<td>SECTION 44-37-30 Neonatal testing of children; storage and availability of blood samples for future tests; confidentiality; religious exemption; violation and penalties. (A) A child born in this State, except a child born of a parent who objects on religious grounds and indicates this objection before testing on a form promulgated in regulation by the Department of Health and Environmental Control, shall have neonatal testing to detect inborn metabolic errors and hemoglobinopathies. (B) Information obtained as a result of the tests</td>
<td>44-37-30: (A) A child born in this State, except a child born of a parent who objects on religious grounds and indicates this objection before testing on a form promulgated in regulation by the Department of Health and Environmental Control,.. (E)(1) A blood sample that has not been stored at minus 20° centigrade before the effective date of this section must be destroyed in a scientifically acceptable manner six months from the effective date of this section unless a parent or legal guardian of a child from whom a blood sample was obtained, or</td>
<td>44-37-30: (D)(2) A blood sample released for confidential, anonymous study pursuant to this section must not contain information which may be used to determine the identity of the donor. A blood sample released pursuant to this section may contain demographic or other statistical information. If scientific study identifies genetic information that may benefit the child, the department may notify confidentially the parent or legal guardian, or the child if eighteen years of age or older, of this information.</td>
<td>NO</td>
<td>YES</td>
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<td><strong>Section D - Collection of Specimen.</strong></td>
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<td><strong>2...c.</strong> A specimen shall be collected from every child born in the hospital prior to release from the hospital (except when the parents object due to religious convictions) in accordance with the parent or legal guardian of the child from whom a blood sample was obtained directs the department at the time of testing or at any time after that on a form promulgated in regulation by the department.</td>
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<td><strong>(D)(1)</strong> Unless otherwise directed pursuant to this subsection, a blood sample obtained pursuant to this section must be conducted pursuant to this section is confidential and may be released only to a parent or legal guardian of the child, the child’s physician, and the child when eighteen years of age or older when requested on a form promulgated in regulation by the department.</td>
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<td><strong>(C)</strong> A blood sample obtained pursuant to this section is confidential and may be released only as the parent or legal guardian of the child from whom a blood sample was obtained, or the child when eighteen years of age or older, directs the department at the time of testing or at any time after that on a form promulgated in regulation by the department.</td>
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<td><strong>(E)(2)</strong> A blood sample stored at minus 20° centigrade pursuant to this section before the effective date of this section must be retained as prescribed in subsection (D) unless directed by the parent or legal guardian of the child from whom a blood sample was obtained to destroy or return the blood sample.</td>
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Laboratory shall store all specimens at minus 20° Centigrade and may release specimens for purposes of confidential, anonymous scientific study unless prohibited by the parents, legal guardians, or children from whom the specimens were obtained when the children are eighteen years of age or older.

4. Hospital staff or other persons who collect these specimens shall ensure that the parent's or legal guardian's storage choice is documented on the Blood Sample Storage Options form if the parent or legal guardian does not agree to have their child's blood specimen stored and potentially released for confidential, anonymous scientific study. In these instances, the Laboratory shall maintain all such specimens based upon the storage option chosen by the parent or legal guardian as documented on the Blood Sample Storage Options.
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<th>stored by the department at minus 20° centigrade and may be released for purposes of confidential, anonymous scientific study. The release of a blood sample must conform with regulations promulgated by the department. At the time of testing or at any time after that, on a form promulgated in regulation by the department, the parent or legal guardian of the child from whom a blood sample was obtained, or the child when eighteen years of age or older, may direct the department to: <strong>(a)</strong> return a blood sample in its entirety and any test results not less than two years after the date of testing; <strong>(b)</strong> destroy a blood sample in a scientifically acceptable manner not less than two years after the date of the testing; or procedure specified in the Official Departmental Instructions. If the parent objects to the screening on the basis of religious convictions, the parent shall complete the procedure specified in the Official Departmental Instructions.</th>
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<td>61-80 Section H-Forms</td>
<td><strong>1. Religious Objection Form:</strong> The Religious Objection Form, Appendix A of this regulation, shall be completed if the parents refuse newborn screening for inborn metabolic errors and hemoglobinopathies for their child based upon religious convictions. <strong>2. Information Release Form:</strong> The Information Release Form, Appendix B of this regulation, may be completed as needed for release of information form.</td>
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**Section G-Use of Stored Specimen**

1. Stored blood specimens may be released for the purposes of confidential, anonymous scientific study unless prohibited by the parent, legal guardian, or child from whom the specimen was obtained when he/she is eighteen years of age or older.

2. The Department's Institutional Review Board shall approve all scientific studies that use stored blood specimens before the specimens are released.

3. Blood specimens released for scientific study shall not contain information that may be used to determine the identity of the children from whom they were obtained by the person(s) to whom the specimens are released. The Department shall code the
(c) store a blood sample at minus 20° centigrade but not release the blood sample for confidential, anonymous scientific study.

(2) A blood sample released for confidential, anonymous study pursuant to this section must not contain information which may be used to determine the identity of the donor. A blood sample released pursuant to this section may contain demographic or other statistical information. If scientific study identifies genetic information that may benefit the child, the department may notify confidentially the parent or legal guardian, or the child if eighteen years of age or older, of this information.

(E)(1) A blood sample that has not been stored at minus 20° centigrade before the effective date regarding newborn screening for inborn metabolic errors and hemoglobinopathies to persons other than those specified elsewhere in this regulation.

3. Blood Sample Storage Options Form: The Blood Sample Storage Options Form, Appendix C of this regulation, shall be completed if the parents or legal guardians do not agree to have their child’s specimen stored and potentially released for confidential, anonymous scientific study.

APPENDIX A: Religious Objection Form: DHEC 1804, Newborn Screening Program, Parental Statement of Religious Objection

I am the parent or legal guardian of __________, a child born __________ in South Carolina. I

specimens before releasing them so that the Department can identify the children from whom the blood specimens were obtained if necessary.

4. If any such scientific study identifies genetic or other information that may benefit the children from whom the specimens were obtained, the Department may confidentially provide this information to the parents, legal guardians or children from whom the specimens were obtained when the children are eighteen years of age or older.

Section 38-93-40. Confidentiality; disclosure restrictions and exceptions.

(A) All genetic information obtained before or after the effective date of this chapter must be 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
| Section 38-93-50. | Informed consent required for genetic test; exceptions. It is unlawful to perform a genetic test on an individual without first obtaining specific informed consent to the test from the individual, or a person legally authorized to consent on behalf of the individual, unless the test is performed: … (4) pursuant to a statute or court order specifically requiring that the test be performed. (5) for diagnosis or treatment of the individual if performed by a clinical laboratory that has received a specimen referral from the individual's treating physician or another clinical

(2) A blood sample stored at minus 20° centigrade pursuant to this section before the effective date of this section must be retained as prescribed in subsection (D) unless directed by the parent or legal guardian of the child from whom a blood sample was obtained to destroy or return the blood sample. (F) The department shall promulgate regulations necessary for the implementation of this section must be destroyed in a scientifically acceptable manner six months from the effective date of this section unless a parent or legal guardian of a child from whom a blood sample was obtained, or the child if eighteen years of age or older, requests return of the blood sample on a form provided by the department.

(5) for diagnosis or treatment of the individual if performed by a clinical laboratory that has received a specimen referral from the individual's treating physician or another clinical

(6) as specifically authorized or required by a state or federal statute. [emphasis added]

I understand that my child may suffer brain damage, other bodily harm or death if a disease that can be detected by blood spot screening is not diagnosed. I understand that such harm can be lessened or prevented by early diagnosis and treatment. I understand that these diseases are usually silent, and may be present in a child that looks healthy. I understand that the blood spot screening test is the

request that my child not be tested by blood spot screening in order to detect silent, deadly metabolic diseases and hemoglobinopathies. I certify that this refusal is based on religious grounds. Religious grounds are the only permitted reason for refusal under South Carolina law, Section 44-37-30 (C).

(2) A blood sample stored at minus 20° centigrade pursuant to this section before the effective date of this section must be retained as prescribed in subsection (D) unless directed by the parent or legal guardian of the child from whom a blood sample was obtained to destroy or return the blood sample. (F) The department shall promulgate regulations necessary for the implementation of this

of that individual or a person legally authorized to consent on behalf of the individual, except that genetic information may be disclosed without consent:

of that individual or a person legally authorized to consent on behalf of the individual, except that genetic information may be disclosed without consent:
section. All forms must include information concerning the benefits of neonatal testing and storage of a blood sample. **(G)** A person who violates this section or the regulations promulgated pursuant to this section or who provides or obtains or otherwise tampers with a blood sample collected pursuant to this section is guilty of a misdemeanor and, upon conviction, may be fined not more than fifty thousand dollars or imprisoned for not more than three years.

**61-80. Neonatal Screening For Inborn Metabolic Errors and Hemoglobinopathies…**

**S**ection **D- Collection of Specimen**…e. The Hospital shall review the patient record for each child born in the hospital no later than ten (10) days after delivery to ensure that a specimen was

best way to detect these disorders early, and that testing is routinely done for every child. I understand that this testing is quick, easy and that the results are confidential. I understand that this testing has been the standard of care for all children born in South Carolina and the rest of the United States for many years.

I have been fully informed of, and fully understand, the possible devastating consequences to my child’s health if blood spot screening is not done. I have been fully informed of, and fully understand the benefits of testing and blood specimen storage. I have been given the brochure produced by the South Carolina Department of Health and Environmental Control that describes the conditions for which laboratory. Nothing in this item may be construed so as to waive the requirement that the treating physician obtain specific informed consent in accordance with the provisions of this section. [emphasis added]

**APPENDIX C: Blood Sample Storage Options Form: DHEC 1812, Blood Sample Storage Options, Screening for Inborn Metabolic Errors and Hemoglobinopathies…**

…” IF THIS FORM IS NOT SIGNED BY A PARENT/LEGAL GUARDIAN AND/OR NONE OF THE ABOVE BOXES ARE CHECKED, THE BLOOD SAMPLE WILL BE STORED AS REQUIRED BY SC CODE ANN. SECTION 44-37-30 AT -20 DEGREES CENTIGRADE AND MAY
collected and submitted to the Laboratory.

61-80. Section F-Storage of Specimen
1. Hospital staff or other persons who collect blood specimens for the purpose of screening for inborn metabolic errors and hemoglobinopathies shall inform each child's parent or legal guardian of the blood specimen storage options.

2. Hospital staff or other persons who collect these blood specimens shall give the brochure produced by the Department that explains newborn screening for inborn metabolic errors and hemoglobinopathies to the parent or legal guardian as a means of informing them of the benefits of screening and blood specimen storage. Hospital staff or other persons who collect these testing is currently available and explains the benefits of testing and blood specimen storage. I also understand that my child would have been tested for these conditions except for my objection. I have been given the opportunity to ask questions concerning this testing and these conditions, and all of my questions have been fully answered to my satisfaction.

I release and hold harmless the South Carolina Department of Health and Environmental Control, the hospital or other facility at which the birth occurred, the person(s) responsible for the collection of the blood spots, and any other person or entity relying on this objection, for any injury, illness and/or consequences, including the death of my child,

BE RELEASED ONLY FOR CONFIDENTIAL, ANONYMOUS SCIENTIFIC STUDY.

NOTE TO PROVIDERS: The parent or legal guardian is not required to sign this form. However, the person who gives the brochure that explains neonatal testing and blood sample storage to the parent or legal guardian must sign this form.
blood specimens shall indicate that the brochure was given to the parent or legal guardian by documenting in the appropriate space on the Blood Sample Storage Options Form… which may result to my child as the result of my refusal of blood spot screening.

Parent: __________
Date: __________
Witness: __________