

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

Child's complete legal name: _____

Child's date of birth: _____

Parent or legal guardian's complete name: _____

Parent or legal guardian's complete address: _____

South Carolina law requires the Department of Health and Environmental Control to store your child's blood sample in a manner required by law. The blood sample is collected on a special piece of filter paper. This is called "newborn screening." The blood is tested to see if your child has one of the "newborn screening" diseases that can cause mental retardation, abnormal growth or even death. After the tests are done, the filter paper is stored in a freezer at the state laboratory. This storage is highly protected, and each sample is held under strict confidentiality.

A child's blood sample can only be released for approved research, without any identifying information, to learn new information about diseases. The law allows you to choose one of the options below, if you do not want your child's blood sample handled this way. **However, you are not required to check one of the boxes below.**

- I want my child's blood sample stored by the South Carolina Department of Health and Environmental Control, but I do not want my child's blood sample to be used for research.
- I want my child's blood sample destroyed by the South Carolina Department of Health and Environmental Control two years after the date of testing.
- I want my child's blood sample to be returned to me two years after the date of testing. I understand that it is my responsibility to notify the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC, 29201, of address or name changes.

I have been given the brochure produced by the South Carolina Department of Health and Environmental Control that describes the conditions for which testing is currently available and explains the benefits of testing and blood sample storage.

Parent: _____ Date: _____

I have given the brochure produced by the South Carolina Department of Health and Environmental Control to the parent/legal guardian of the child named above.

Name: _____ Date: _____

DHEC can store your baby's blood sample for special study. Studies help DHEC find out new information about diseases. If a study finds something in your child's blood sample that can help your child, DHEC can confidentially notify you (or your child if he/she is 18 years or older).

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 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

Section F - Storage of Specimens

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 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.
3. The 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 form.

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 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 H - Forms

1. **Religious Objection Form:** 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.
2. **Information Release Form:** The Information Release Form, Appendix B of this regulation, may be completed as needed for release of information 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.

Section I - Enforcement Provision

1. Constitutionality

If any part or provision of these regulations is legally declared unconstitutional or if the application thereof to any persons or circumstances is held invalid, the validity and constitutionality of the remainder of these regulations shall not be affected thereby.

2. Penalties

Violation of these regulations shall be punishable in accordance with Section 44-37-30 of the Code of Laws of South Carolina, 1976, as amended.