## North Carolina

### Newborn Genetic Testing & Surveillance System

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<th>State</th>
<th>Statute/Rule</th>
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<tr>
<td>NC</td>
<td>STATUTE: NCGS Chapter 130A, Article 5 Part 1, and Article 15 (Center for Health Statistics) 10A NCAC 42H.0314</td>
<td>§130A-125. Screening of newborns for metabolic and other hereditary and congenital disorders. (a) The Department shall establish and administer a Newborn Screening Program. The program shall include, but shall not be limited to: (1) Development and distribution of educational materials regarding the availability and benefits of newborn screening. (2) Provision of laboratory testing.</td>
<td>§130A-125 … (b) The Commission shall adopt rules necessary to implement the Newborn Screening Program. The rules shall include, but shall not be limited to, the conditions for which screening shall be required, provided that screening shall not be required when the parents or the guardian of the infant object to such screening. If the parents or guardian object to the screening, the objection shall be presented in writing.</td>
<td>From North Carolina Birth Defects Monitoring Program Surveillance Report, July 2000: “A birth defect, as defined by the March of Dimes, is an abnormality of structure, function, or body metabolism that is present at birth and results in physical or mental disability...This report is designed to provide information concerning birth defects in North Carolina, particularly neural tube defects, orofacial clefts, cardiovascular defects, and chromosomal disorders. [emphasis added]</td>
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Consent Required? | Dissent Allowed? |
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<td>NO</td>
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(3) Development of follow-up protocols to assure early treatment for identified children, and the provision of genetic counseling and support services for the families of identified children.

(4) Provision of necessary dietary treatment products or medications for identified children as medically indicated and when not otherwise available.

(5) For each newborn, provision of physiological screening in each ear for the presence of permanent hearing loss…. to the physician or other person responsible for administering the test, who shall place the written objection in the infant's medical record.

10A NCAC 43H.0314 SUBMISSION OF BLOOD SPECIMENS FOR SCREENING OF NEWBORNS.

(a) The attending physician shall draw a blood specimen for each infant born in North Carolina and shall submit such specimens to the North Carolina State Laboratory for Public Health for testing for the following metabolic and other hereditary and congenital disorders:

(1) phenylketonuria (PKU); (2) galactosemia; (3) congenital primary hypothyroidism; (4) congenital adrenal hyperplasia (21-hydroxylase deficiency); and (5) sickle cell disease.

**10A NCAC 43H.0314 SUBMISSION OF BLOOD SPEIMENS FOR SCREENING OF NEWBORN...**

... (b) Notwithstanding Paragraph (a) of this Rule, parents or guardians may object to screening in accordance with G.S. 130A-125(b).

**From the North Carolina State Center for Health Statistics website: Special Projects within the Birth Defects Monitoring Program:**

“The North Carolina Birth Defects Monitoring Program is involved in university-based collaborative research projects. These include:

1. North Carolina Center for Birth Defects Research and Prevention (NCCBDRP). The NCCBDRP is a joint effort between the University of North Carolina, School of Public Health at Chapel Hill and the N.C. Birth Defects Monitoring Program. The Center’s mission is to conduct epidemiologic research into the causes of birth defects, and to promote the use of research findings to enhance public health education and prevention efforts. The North Carolina Center is one of eight such centers in the U.S. that are currently funded by the Centers for Disease Control. All of the centers participate in the National Birth Defects Prevention Study, an ongoing case-control study aimed at understanding the causes of birth defects and possible methods for prevention...”
Chapter 130A, Article 15 – State Center for Health Statistics.
§ 130A-371. State Center for Health Statistics established. A State Center for Health Statistics is established within the Department. (1983, c. 891, s. 2.)

§ 130A-373. Authority and duties.
(a) The State Center for Health Statistics is authorized to: (1) Collect, maintain and analyze health data on:…and (2) Undertake and support research, demonstrations and evaluations respecting new or improved methods for obtaining data.
(b) The State Center for Health Statistics may collect health data on behalf of other governmental or nonprofit organizations.
(c) The State Center for Health Statistics shall collect data only on a voluntary basis except when there is specific legal authority to compel mandatory reporting of the health data. In collecting health data on a voluntary basis, the State Center for Health Statistics shall give the person a statement in writing:
(1) That the data is being collected on a voluntary basis and that the person is not required to respond; and
(2) The purposes for which the health data is being collected. [emphasis added]

(d) Subject to the provisions of G.S. 130A-374, the State Center for Health Statistics may share health data with other persons, agencies and organizations.

(e) The State Center for Health Statistics shall:
(1) Take necessary action to assure that statistics developed under this Article are of high quality, timely and comprehensive, as well as specific and adequately analyzed and indexed; and
(2) Publish, make available and disseminate statistics on as wide a basis as practical.

(f) The State Center for Health Statistics shall coordinate health data activities within the State in order to eliminate unnecessary duplication of data collection and to maximize the usefulness of data collected by:
(1) Participating with State and local agencies in the design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the State and local levels; and

(2) Undertaking and supporting research, development, demonstration and evaluation respecting the cooperative system.

130A-374. Security of health data.

(a) Medical records of individual patients shall be confidential and shall not be public records open to inspection. The State Center for Health Statistics may disclose medical records of individual patients which identify the individual described in the record only if:

(1) The individual described in the medical record has authorized the disclosure; or

(2) The disclosure is for bona fide research purposes. The Commission shall adopt rules providing for the use of the medical records for research purposes. [emphasis added]
CCHF REPORT 2013: Patient Privacy and Public Trust: How Health Surveillance Systems Are Undermining Both

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Updated August 2012. All state statutes and department rules originally accessed online July/Aug 2008. Statute/Rule data not inclusive. For comprehensive or updated language, access complete statute and rules online, at local library or through the state legislature.

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