Patient Privacy and Public Trust:

How Health Surveillance Systems Are Undermining Both

Newborn Genetic Testing and Surveillance Systems

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

ALABAMA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
AL	STATUTE: Code of Alabama, Title 1, Article 8 RULE: A.A.C., Chapter 420-10-1	**Section 22-20-3 — Neonatal testing for certain diseases; rules and regulations for treatment thereof.** **(a)** It shall be the duty of the administrative officer or other persons in charge of each institution caring for infants 28 days or less of age, or the physician attending a newborn child or the person attending a newborn child that was not attended by a physician to cause to have administered to every such infant or child in his care a reliable test for hypothyroidism and a reliable test for phenylketonuria (PKU), such as the Guthrie test, or any other test considered equally reliable by the State Board of Health and a reliable test for sickle cell anemia, sickle cell trait, and/or abnormal hemoglobin and ***such other tests relating to mental retardation or other heritable diseases and conditions as are designated by the Board of Health***.	**Section 22-20-3** **(a)** … *provided,* that no such initial screening or confirmatory tests shall be given to any child whose parents object thereto on the grounds that such tests conflict with their religious tenets and practices. In the event a test is not given to a child on account of such objections by the parents, then no physician, nurse, laboratory technician, person administering tests, hospital, institution or other health care provider shall be liable for failure to administer the test. ***NOTE: The Department's Rule does not mention the right of parents to object to the testing or provide a method for parents to secure that exemption.***	NONE FOUND	NO	YES

		Provided, however, that the Board of Health shall designate only conditions that are detectable by mass screening of newborn infants. Initial mass screening tests and the recording of results shall be performed by the Public Health Laboratory at such times and in such manner as may be prescribed by the State Board of Health; confirmatory tests shall be undertaken by such laboratory facilities as are designated by the attending physician or parent; … *[emphasis added]* **(b)** The State Board of Health shall promulgate such rules and regulations as it considers necessary to provide for the care and treatment of those newborn infants whose tests are determined positive, including but not limited to, advising dietary treatment for such infants. The State Board of Health shall promulgate any other rules and regulations necessary to effectuate the provisions of this section including the collection of a reasonable fee for the newborn child screening program.				

		420-10-.04 Reporting and Notification **(1)** The Alabama Department of Public Health shall report all results of …testing to the submitting health care provider… **(2)** The submitting health care provider shall report all results, including positives, suspected positive results, and unsatisfactory specimens, to the physician of record… **(3)** The Department of Public Health may release results of newborn screening tests, including hearing screening results, to any physician registered with the Alabama Voice Response System under the terms and conditions of the system without a signed release form the parent or guardian.				

ALASKA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
AK	STATUTE: A.S., Title 18, Article 02, Chapter 18.15, Sec. 18.15.200 and Sections 18.15.355 – 18.15.395 RULE: 7 AAC 27.530 and 27.570	**18.15.200. Screening for phenylketonuria.** **(a)** A physician who attends a newborn child shall cause this child to be tested for phenylketonuria (PKU). If the mother is delivered in the absence of a physician, the nurse who first visits the child shall cause this test to be performed. **(b)** The department shall adopt regulations regarding the method used and the time or times of testing as accepted medical practice indicates.	**18.15.200. Screening for phenylketonuria** **(f)** A licensed physician or licensed nurse attending a newborn or infant who violates this section is guilty of a misdemeanor and, upon conviction, is punishable by a fine of not more than $500. However, a person attending a newborn or infant whose request for appropriate specimens from the newborn or infant is ***denied by the parent*** or guardian is not guilty of a misdemeanor.	**Sec. 18.15.355. Prevention and control of conditions of public health importance.** (a) The department may use the powers and provisions set out in AS 18.15.355 - 18.15.395 to prevent, control, or ameliorate conditions of public health importance or accomplish other ***essential public health services and functions***. **(b)** In performing its duties under AS 18.15.355 - 18.15.395, the department may **(1)** establish standards **(A)** for the prevention, control, or amelioration of conditions of public health importance; **(B)** to accomplish other essential public health services and functions; and **(2)** adopt regulations to implement and interpret AS 18.15.355 - 18.15.395.	NO	YES

Updated September 2013. 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.

		(c) The necessary laboratory tests and the test materials, reporting forms, and mailing cartons shall be provided by the department. **(d)** All tests considered positive by the screening method shall be reported by the screening laboratory to the physician and to the department. The department shall provide services for the performance of a quantitative blood phenylalanine test or its equivalent for diagnostic purposes. A confirmed diagnosis of phenylketonuria shall be reported to the physician and to the department. The department shall provide services for treatment and clinical follow-up of any diagnosed case.	The fact that a child has not been subjected to the test because a request for appropriate specimens has been denied by the parents or guardian shall be reported to the department. *[emphasis added]* **7 AAC 27.530. Collection of blood specimen; refusal of collection**…**(d)** A parent or guardian of a newborn child who ***refuses to permit collection*** of a specimen should affirm that refusal by signing the "refusal for testing statement" on the back of the newborn child screening card provided by the department or on a copy of the card with complete information provided.	**Sec. 18.15.360. Data collection.** **(a)** The department is authorized to collect, analyze, and maintain databases of information related to **(1)** risk factors identified for conditions of public health importance; **(2)** morbidity and mortality rates for conditions of public health importance; **(3)** community indicators relevant to conditions of public health importance; and **(4)** longitudinal data on traumatic or acquired brain injury from the registry established under AS 47.80.500 (c)(1); and (5) any other data needed to accomplish or further the mission or goals of public health or provide essential public health services and functions. **(b)** … The department is authorized to obtain information from federal, state, and local governmental agencies, Alaska Native organizations, health care providers, pre-hospital emergency medical services, or other private and public organizations operating in the state.		

		(e) When presumptive positive screening tests have been reported to the department, it shall provide, on request, either the true blood phenylalanine test or subsidize the performance of this test at an approved laboratory… **Sec. 18.15.210. Testing for certain other heritable diseases.** The department shall administer and provide services for testing for other heritable diseases that lead to mental retardation and physical disabilities as screening programs accepted by current medical practice and as developed.	The information on the front of the card must be completed by the medical facility or service and the card sent to the designated laboratory. *[emphasis added]* From, "***State of Alaska FY 2005 Governor's Operating Budget***," Department of Health and Social Services Medical Assistance Administration Component Budget Summary, 12/15/03: "**Newborn Metabolic Screening Program (NBMS).** NBMS tests all Alaska newborns for congenital metabolic disorders as well as endocrine disorders…	The department may also use information available from other governmental and private sources, reports of hospital discharge data, information included in death certificates, other vital statistics, environmental data, and public information. The department may request information from and inspect health care records maintained by health care providers that identify individuals or characteristics of individuals with reportable diseases or other conditions of public health importance. … **Sec. 18.15.375. Epidemiological investigation. (a)** The department may investigate conditions of public health importance in the state through methods of epidemiological investigation. The department may also ascertain the existence of cases of illness or other conditions of public health importance, investigate potential sources of exposure or infection and ensure that they are subject to proper control measures, and		

		7 AAC 27.570. Annual review and report. The department will appoint a committee to annually review the results of the newborn child metabolic disorder screening program, consider addition or deletion of tests based on experience in this state and on newly developed tests recommended by the American Academy of Pediatrics, Committee on Genetics, and report to health care providers and the public on these matters.	Parents are allowed to refuse the test on religious grounds under what it [sic] entitled 'Informed Dissent'. The back of the form is signed, forwarded to the Oregon Public Health Laboratory, and then on to the NBMS program manager where it is entered into a ***refusal database.*** *[emphasis added]*	determine the extent of the disease outbreak, epidemic, risk to health and safety, or disaster**.** **Sec. 18.15.395. Definitions.** …**(10)** ***"essential public health services and functions" mean services and functions to*** **(A)** monitor health status to identify and solve community health problems; **(B)** investigate and diagnose health problems and health hazards in the community; **(C)** inform and educate individuals about and empower them to deal with health issues; **(D)** mobilize public and private sector collaboration and action to identify and solve health problems; **(E)** develop policies, plans, and programs that support individual and community health efforts; **(F)** enforce statutes and regulations of this state that protect health and ensure safety; **(G)** link individuals to needed health services and facilitate the provision of health care when otherwise unavailable;		

				(H) ensure a competent public health workforce; **(I)** evaluate effectiveness, accessibility, and quality of personal and population-based health services; or **(J)** ***research for new insights and innovative solutions to health problems;…*** *[emphasis added]*		

ARIZONA

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
AZ	STATUTE: ARS, Title 36, Article 5 RULE: AAC, Title 9, Chapter 13, Article 2	**A.R.S. §36-694. Report of blood tests; newborn screening program; committee; fee; definitions** …**B.** When a birth is reported the attending physician or person who is required to make a report on the birth shall order or cause to be ordered tests for certain congenital disorders. The results of tests for these disorders must be reported to the department of health services... **D.** The director of the department of health services shall establish a newborn screening program within the department to assure that the testing for congenital disorders and the reporting of hearing test results required by this section are conducted in an effective and efficient manner. The newborn screening program shall include an education program for the general public, the medical community, parents and professional groups. The director shall designate the state laboratory as the only testing facility for the program.	NONE FOUND	**R9-13-206. Reporting Requirements for Specimens**… D. Bloodspot test results are confidential subject to the disclosure provisions of 9 A.A.C. 1, Article 3 [R9-1-302 &R9-1-303 - Disclosure of Medical Records, Payment Records, and Public Health Records], and A.R.S. §§ 12-2801 and 12-2802.[Genetic Testing] **§12-2802. Confidentiality of genetic testing results; disclosure.** **A.** *Except as otherwise provided in this article*, genetic testing and information derived from genetic testing are confidential and considered privileged to the person tested and shall be *released only to*:…	NO	NO

Updated September 2013. 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.

		E. The newborn screening program shall establish and maintain a central database of newborns and infants who are tested for hearing loss and congenital disorders that includes information required in rule… **G.** The director shall establish a committee to provide recommendations and advice to the department on at least an annual basis regarding tests that the committee believes should be included in the newborn screening program. **ARTICLE 2. NEWBORN AND INFANT SCREENING** **R9-13-203. General Requirements for Newborn and Infant Bloodspot Tests A.** When a bloodspot test is ordered for a newborn or an infant, a health care facility's designee, a health care provider, or the health care provider's designee shall: 1. Only use a specimen collection kit supplied by the Department; 2. Collect a blood sample from the newborn or infant on a specimen collection kit; 3. ***Complete the following information on the specimen collection kit:*** *[emphasis added]*		**4.** A researcher for medical research or public health purposes only if the research is conducted pursuant to applicable federal or state laws and regulations governing clinical and biological research or if the identity of the individual providing the … ***9. The authorized agent of a federal, state or county health department to conduct activities specifically authorized pursuant to the laws of this state for the birth defects registry, children's rehabilitative services, newborn screening and sickle cell diagnosis and treatment programs and chronic, environmentally provoked and infectious disease programs.*** *[emphasis added]*		

		a. The newborn's or infant's name, gender, race, ethnicity, medical record number, and if applicable, AHCCCS identification number; b. The newborn's or infant's type of food or food source; c. Whether the newborn or infant is from a single or multiple birth; d. If the newborn or infant is from a multiple birth, the birth order of the newborn or infant; e. Whether the newborn or infant has a medical condition that may affect the bloodspot test results; f. Whether the newborn or infant received antibiotics or a blood transfusion and, if applicable, the date of the last blood transfusion; g. The method of blood sample collection; h. The date and time of birth, and the newborn's or infant's weight at birth; i. The date and time of blood sample collection, and the newborn's or infant's weight when the blood sample is collected; j. The name and identification code of the health care facility or health care provider submitting the specimen collection kit;		**R9-1-302. Medical Records or Payment Records Disclosure. A.** Except as provided in subsection (B), an employee or volunteer shall not disclose to a third person medical records or payment records containing individually identifiable health information that the employee or volunteer obtained or accessed as a result of the employment or volunteering. **B.** Unless otherwise prohibited by law, an employee or volunteer may disclose to a third person medical records or payment records containing individually identifiable health information:… **6.** At the direction of the Human Subjects Review Board, if the medical records or payment records are sought for research and the disclosure meets the requirements of 45 CFR 164.512(i)(2) [federal HIPAA rule research access provision]…		

		k. The name, identification code, and address of the health care provider responsible for the management of medical services provided to the newborn or infant; l. Except as provided in subsection (A)(3)(m), the mother's first and last names, date of birth, name before first marriage, mailing address, phone number, and if applicable, AHCCCS identification number; and m. If the newborn's or infant's mother does not have physical custody of the newborn or infant, the first and last names, mailing address, and phone number of the person who has physical custody of the newborn or infant.		**R9-1-303. Public Health Records Disclosure.** **A.** A.R.S. Title 39, Chapter 1, Article 2 governs the Department's disclosure of public health records, except for:… **3**. At the direction of the Human Subjects Review Board, disclosure of public health records that are not de-identified when: **a.** The public health records are sought for research, and **b.** The disclosure meets the requirements of 45 CFR 164.512(i)(2).		

ARKANSAS

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
AR	STATUTE: A.C.A., Title 20, Subtitle 2, Chapter 15, Subchapter 3 RULE: AAC, 007.16.07-001	**20-15-301. Injunction.** The State Board of Health shall have the power to enforce this subchapter by appropriate action for injunction in the circuit courts of this state. **20-15-302.Testing of newborns.** **(a)(1)(A)**All newborn infants shall be tested for phenylketonuria, hypothyroidism, galactosemia, cystic fibrosis, and sickle-cell anemia. **(B)**In addition, if reliable and efficient testing techniques are available, all newborn infants shall be tested for other genetic disorders of metabolism by employing procedures approved by the State Board of Health… **(b)**All positive test results shall be sent immediately to the Division of Health of the Department of Health and Human Services.	**20-15-302. (e)** The provisions of this section shall not apply if the parents or legal guardian of a newborn infant object to the testing on medical, religious, or philosophical grounds **20-15-303. Exception.** This subchapter shall not apply to any child whose parents or guardian	**20-15-302 Testing of newborns.**… **(c)(2)(A)** Information on newborn infants and their families compiled under this section may be used by the division and persons or public or private entities designated by the division. **(B)** Information used under subdivision (c)(2)(A) of this section may not refer to or disclose the identity of any person. **(c)(3)**All materials, data, and information received by the division are confidential and are not subject to examination or disclosure as public information under the Freedom of Information Act of 1967, § 25-19-101 et seq….	NO	YES

Updated September 2013. 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.

		(c)(1)The division shall establish and maintain a program of reviewing and following up on positive cases so that measures may be taken to prevent mental retardation or other permanent disabilities. **007.16.07-001. Section I. Purpose.** The purpose of this regulation is to assure that all infants born in Arkansas have the opportunity to be screened for genetic metabolic illnesses…	objects thereto on the grounds that it conflicts with the tenets and practices of a recognized church or religious faith of which the parent or guardian is an adherent or member.	**20-35-103. Nondisclosure.** **(b)(1)** ***All stored tissues, including blood, that arise from surgery, other diagnostic or therapeutic steps, or autopsy may be disclosed for genetic or other research studies, if:*** **(A)** The patient's name or social security number is not attached to or included with the specimen; or **(B)** The patient's name or social security number is attached to or included with the specimen and the patient has given informed written consent to the disclosure. **(2)** Informed written consent shall not be included in a section of the consent for treatment, admission to a hospital or clinic, or permission for an autopsy.		

		Section VI. **ARKANSAS DEPARTMENT OF HEALTH ROLE IN TREATMENT AND MONITORING** …**B. Registry 1.** For Phenylketonuria (PKU), Congenital Hypthyroidism (CH), Galactosemia, Sicke Cell Disease (SS) and other hemoglobinopathies, Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, or Organic Acid Disorders, the ***Department shall maintain a registry to record laboratory results and diagnoses of all tested infants, and to track referral*** for those infants in whom abnormal findings were noted during the screening process. *[emphasis added]*		**(c)(1)** It shall be permissible to publish or otherwise use the results of genetic research studies for research or educational purposes if no individual subject is identified. **(2)** If specific informed consent from the individual has been obtained in writing, the individual may be identified.		

CALIFORNIA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
CA	STATUTE: Health and Safety Code Sections: 12500 – 125002 124975 – 124996 (Hereditary Disorders Act) RULE: CA Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 9, Group 3, Article 2 §6501 – 6507.1	**125000. (a)** It is the policy of the State of California to make every effort to detect, as early as possible, phenylketonuria and other preventable heritable or congenital disorders leading to mental retardation or physical defects. The department shall ***establish a genetic disease unit*** that shall coordinate all programs of the department in the area of genetic disease. The unit shall promote a statewide program of information, testing, and counseling services and shall have the responsibility of designating tests and regulations to be used in	**125000.** … **(d)** This section shall not apply if a parent or guardian of the newborn child objects to a test on the ground that the test conflicts with his or her religious beliefs or practices. **§ 6501. Scope of Newborn Testing.** Each newborn born in California shall be tested for galactosemia, hereditary hemoglobinopathies, phenylketonuria and primary congenital hypothyroidism in accordance with procedures in this Group.	**125002. (a)** In order to align closely related programs and in order to facilitate research into the causes of, and treatment for, birth defects, the Birth Defects Monitoring Program provided for pursuant to Chapter 1 (commencing with Section 103825) of Part 2 of Division 102 shall become part of the Maternal, Child, and Adolescent Health program provided for in Article 1 (commencing with Section 123225) of Chapter 1 of Part 2 of Division 106.	NO	YES

		executing this program. *[emphasis added]* The information, tests, and counseling for children shall be in accordance with accepted medical practices and shall be administered to each child born in California once the department has established appropriate regulations and testing methods. The information, tests, and counseling for pregnant women shall be in accordance with accepted medical practices and shall be offered to each pregnant woman in California once the department has established appropriate regulations and testing methods. These regulations shall follow the standards and principles specified in Section 124980. The department may provide laboratory testing	**§ 6501.2 Religious Objection.** **(a)** The provisions of Section 6501 shall not apply if a parent or legally appointed guardian objects to a test on the ground that it conflicts with his or her religious beliefs or practices. If the parent or legal guardian refuses to allow the collection of a blood specimen, such refusal shall be: **(1)** made in writing, **(2)** signed by a parent or legally appointed guardian, and **(3)** included in the newborn's medical or hospital record. **(b)** Birth attendants or physicians shall provide to parent(s) or legally appointed guardian(s) who object to the test on the basis it is in conflict with their religious beliefs or practices, a refusal form approved by the Department and shall obtain the appropriate signature(s) upon the form. If the parent(s) or legally appointed guardian(s) is unable to read such material, it shall be translated or read to such person(s) in a language understood by such persons.	**(b)** It is the intent of the Legislature that pregnancy blood samples, taken for prenatal screening, shall be stored and made available to any researcher who is approved by the department for the following purposes: **(1)** ***Research to identify risk factors for children's and women's diseases***. **(2)** Research to develop and evaluate screening tests. **(3)** Research to develop and evaluate prevention strategies. **(4)** Research to develop and evaluate treatments. *[emphasis added]* **(c)** Before any pregnancy blood samples are released for research purposes, all of the following conditions must be met:		

		facilities or contract with any laboratory that it deems qualified to conduct tests required under this section. However, notwithstanding Section 125005, provision of laboratory testing facilities by the department shall be contingent upon the provision of funding therefore by specific appropriation to the ***Genetic Disease Testing Fund*** enacted by the Legislature. If moneys appropriated for purposes of this section are not authorized for expenditure to provide laboratory facilities, the department may nevertheless contract to provide laboratory testing services pursuant to this section and shall perform laboratory services, including, but not limited to, quality control, confirmatory, and	**124975.** The Legislature hereby finds and declares that: … **(j)** Participation of persons in hereditary disorders programs in the State of California should be wholly voluntary, except for initial screening for phenylketonuria (PKU) and other genetic disorders treatable through the California newborn screening program. All information obtained from persons involved in hereditary disorders programs in the state should be held strictly confidential.	**(1)** Individual consent at the time the sample is drawn to allow confidential use of the sample for research purposes by the department or the department's approved researchers. **(2)** Protocol review for scientific merit by the department or another entity authorized by the department. **(3)** Protocol review by the State Committee for the Protection of Human Subjects.		

		emergency testing, necessary to ensure the objectives of this program… *[emphasis added]* …**(h)** The department may appoint experts in the area of genetic **screening**, including, but not limited to, cytogenetics, molecular biology, prenatal, specimen collection, and ultrasound to provide expert advice and opinion on the interpretation and enforcement of regulations adopted pursuant to this section.	**124980.** The director shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety. Standards shall include licensure of master level genetic counselors and doctoral level geneticists. Regulations adopted shall implement the principles established in this section. These principles shall include, but not be limited to, the following: …	**(d)** Since the pregnancy blood samples described in this section **will be stored** by the California Birth Defects Monitoring Program or another entity authorized by the State Department of Public Health, Section 103850, pertaining to confidentiality of information, is applicable. *[emphasis added]*		

		These experts shall be designated agents of the state with respect to their assignments. These experts shall receive no salary, but shall be reimbursed for expenses associated with the purposes of this section. All expenses of the experts for the purposes of this section shall be paid from the Genetic Disease Testing Fund. *[emphasis added]*	**(f)** No testing, ***except initial screening for phenylketonuria (PKU) and other diseases that may be added to the newborn screening program, shall require mandatory participation***, and no testing programs shall require restriction of childbearing, and participation in a testing program shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or to participate in, any other program, except where necessary to determine eligibility for further programs of diagnoses of or therapy for hereditary conditions. *[emphasis added]* …			

			(h) All participants in programs on hereditary disorders shall be protected from undue physical and mental harm, and ***except for initial screening for phenylketonuria (PKU) and other diseases that may be added to newborn screening programs,*** shall be informed of the nature of risks involved in participation in the programs, and those determined to be affected with genetic disease shall be informed of the nature, and where possible the cost, of available therapies or maintenance programs, and shall be informed of the possible benefits and risks associated with these therapies and programs. *[emphasis added]*			

COLORADO

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
CO	STATUTES: Title 25, Article 4 CRS 24-4-25-4-801 – 804 CRS 1001 – 1006 CRS 25-1-122 RULE: 5 CCR 1005-4	**25-4-802. Tests for metabolic defects.** **(1)** It is the duty of either the chief medical staff officer or other person in charge of each institution caring for newborn infants… to cause to be obtained from every such infant a specimen of the type designated by the state board of health, which specimen shall be forwarded to the department of public health and environment or other laboratory approved by it for testing for phenylketonuria and testing for such other metabolic defects which may be prescribed from time to time by the state board of health to be conducted with respect to such specimen.	**25-4-1002. Legislative declaration.** **(1)** The general assembly hereby finds and declares that: **(a)** State policy regarding newborn screening and genetic counseling and education should be made with full public knowledge, in light of expert opinion, and should be constantly reviewed to consider changing medical knowledge and ensure full public protection;	**25-4-1003. (2)(e)** All information gathered by the department of public health and environment, or by other agencies, entities, and individuals conducting programs and projects on newborn screening and genetic counseling and education, other than statistical information and information which the individual allows to be released through his informed consent, shall be confidential. Public and private access to individual patient data shall be limited to data compiled without the individual's name;	NO	YES

Updated September 2013. 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.

		25-4-803. Rules and regulations. **(1)** The state board of health shall promulgate rules and regulations concerning the obtaining of samples or specimens from newborn infants required for the tests prescribed by the state board of health for the handling and delivery of the same and for the testing and examination thereof to detect phenylketonuria or other metabolic disorders found likely to cause mental retardation.	**(b)** Participation of persons in genetic counseling programs in this state should be ***wholly voluntary*** and that all information obtained from persons involved in such programs or in newborn screening programs in the state should be held strictly confidential. *[emphasis added]*	**10-3-1104.7. Genetic testing - legislative declaration - definitions - limitations on disclosure of information – liability**. **(5)** …any research facility may use the information derived from genetic testing for scientific research purposes so long as the identity of any individual to whom the information pertains is not disclosed to any third party; except that the individual's identity may be disclosed to the individual's physician if the individual consents to such disclosure in writing.		

		(2) The department of public health and environment shall furnish all physicians, public health nurses, hospitals, maternity homes, county departments of social services, and the state department of human services available medical information concerning the nature and effects of phenylketonuria and other metabolic disorders and defects found likely to cause mental retardation. **25-4-1001. Short title.** This part 10 shall be known and may be cited as the "Newborn Screening and Genetic Counseling and Education Act."	**25-4-804. Exceptions.** Nothing in the provisions of this part 8 shall be construed to require the testing or medical treatment for the minor child of any person who is a member of a well-recognized church or religious denomination and whose religious convictions in accordance with the tenets or principles of his church or religious denomination are against medical treatment for disease or physical defects.	**25-1-122. Named reporting of certain diseases and conditions - access to medical records - confidentiality of reports and records.** **(1)** With respect to investigations of epidemic and communicable diseases, morbidity and mortality, cancer in connection with the statewide cancer registry, environmental and chronic diseases, sexually transmitted infections, tuberculosis, and rabies and mammal bites, the board has the authority to require reporting, without patient consent, of occurrences of those diseases and conditions by any person… **(3)** Any report or disclosure made in good faith pursuant to subsection (1) or (2) of this section shall not constitute libel or slander or a violation of any right of privacy or privileged communication.		

Updated September 2013. 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.

		25-4-1003. Powers and duties of executive director - newborn screening programs - genetic counseling and education programs – rules. **(b)** Promulgate rules, regulations, and standards for the provision of newborn screening programs and genetic counseling and education programs; **25-4-1004. Newborn screening.** …**(b)** On or after April 1, 1989, all infants born in the state of Colorado shall be tested for the following conditions: Phenylketonuria, hypothyroidism, abnormal hemoglobins, galactosemia, cystic fibrosis, biotinidase deficiency, and such other conditions as the board of health may determine meet the criteria set forth in paragraph **(c)** of this subsection **(1)**. Appropriate specimens for such testing shall be forwarded by the hospital in which the child is	**25-4-1005. Exceptions.** Nothing in the provisions of this part 10 shall be construed to require the testing or medical treatment for the minor child of any person or of any person who is a member of a well-recognized church or religious denomination and whose religious convictions in accordance with the tenets or principles of his church or religious denomination are against medical treatment for disease or physical defects or has a personal objection to the administration of such tests or treatment.	**(4)** … Such reports and records shall not be released, shared with any agency or institution, or made public, upon subpoena, search warrant, discovery proceedings, or otherwise, except under any of the following circumstances: **(a)** Release may be made of medical and epidemiological information in a manner such that no individual person can be identified; **(b)** Release may be made of medical and epidemiological information to the extent necessary for the treatment, control, investigation, and prevention of diseases and conditions dangerous to the public health; except that every effort shall be made to limit disclosure of personal identifying information to the minimal amount necessary to accomplish the public health purpose;…		

		born to the laboratory operated or designated by the department of public health and environment for such purposes….The results of the testing shall be forwarded directly to the physician or other primary health care provider for the provision of such information to the parent or parents of the child. ***The results of any testing or follow-up testing pursuant to section 25-4-1004.5 may be sent to the immunization tracking system authorized by section 25-4-2403 and accessed by the physician or other primary health care provider.*** *[emphasis added]* **(c)** The board of health shall…determine whether or not to test infants for conditions which are not specifically enumerated in this subsection.				

		25-4-1006. Cash funds.…**(2)** Notwithstanding any provision of this section to the contrary, for the fiscal year beginning July 1, 1988, the state treasurer shall transfer to the general fund out of any unappropriated moneys in the newborn screening and genetic counseling cash funds the sum of five hundred thousand dollars. **5 CCR 1005-4…1.4 Testing and Reporting:…**The [Colorado Department of Public Health and Environment] Laboratory shall report as follows:…1.4.4 The submitting agency that originated the specimen shall forward the Newborn Screening results to the health care provider responsible for the newborn's care…				

CONNECTICUT

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
CT	STATUTE: Title 19a Chapter 368a RULE: Public Health Code Section 19-13-D41 (under revision)	**19a-55. Newborn infant health screening. Tests Required. Fees. Regulations**. **(a)** The administrative officer or other person in charge of each institution caring for newborn infants shall cause to have administered to every such infant in its care an HIV-related test, as defined in section 19a-581, a test for phenylketonuria and other metabolic diseases, hypothyroidism, galactosemia, sickle cell disease, maple syrup urine disease, homocystinuria, biotinidase deficiency, congenital adrenal hyperplasia and such other tests for inborn errors of metabolism as shall be prescribed by the Department of Public Health. The tests shall be administered as soon after birth as is medically appropriate… The Commissioner of Public Health shall	**19a-55. Newborn infant health screening.** … **(c)** The provisions of this section shall not apply to any infant whose parents object to the test or treatment as being in conflict with their religious tenets and practice.	**19a-25-3. Disclosure of identifiable health data** **(a)** The department shall not disclose identifiable health data unless:… **(2)** The disclosure is to health care providers, the local director of health, the department, another state or public health agency, including those in other states and the federal government, or other persons when deemed necessary by the department in its sole discretion for disease prevention and control pursuant to section 19a-215 of the Connecticut General Statutes or for the purpose of reducing morbidity and mortality from any cause or condition, except that every effort shall be made to limit the disclosure of identifiable	NO	YES

		(1) administer the newborn screening program, **(2)** direct persons identified through the screening program to appropriate specialty centers for treatments, consistent with any applicable confidentiality requirements, and **(3)** set the fees to be charged to institutions to cover all expenses of the comprehensive screening program including testing, tracking and treatment. ...The commissioner shall adopt regulations, in accordance with chapter 54, to implement the provisions of this section.	**Sec. 19-13-D42. Objection of parents to test** If the parents of an infant object in writing to a test for phenylketonuria and other inborn errors of metabolism, as being in conflict with their religious tenets and practice, such fact shall be reported to the state department of health and a statement on a form provided by the state department of health signed by the parents shall be made a part of the infant's hospital record.	health data to the minimal amount necessary to accomplish the public health purpose; **(3)** The disclosure is to an individual, organization, governmental entity in this or another state or to the federal government, provided the department determines that: (A) Based upon a written application and such other information as required by the department to be submitted by the requesting individual, organization or governmental entity the data will be used solely for bona fide medical and scientific research; (B) The disclosure of data to the requesting individual, organization or governmental entity is required for the medical or scientific research proposed;		

		Sec. 19-13-D41. (UNDER REVISION) Tests of infants for phenylketonuria and metabolic errors. Unless the parents object, the administrator or other person in charge of any institution providing medical care of infants twenty-eight days or less of age shall cause to be taken from each such infant a blood specimen or specimens satisfactory for tests for phenylketonuria and other inborn errors of metabolism, subject to the following conditions: **(a)** Materials for the collection of specimens shall be of a type furnished by or acceptable to the state department of health; **(b)** Specimens shall not be collected until at least twenty-four hours after the first milk feeding of the infant unless discharged sooner, in which case specimens shall be taken not earlier than three hours before discharge;		(C) The requesting individual, organization, or governmental entity has entered into a written agreement satisfactory to the department agreeing to protect such data in accordance with the requirements of this section and not permit disclosure without prior approval of the department; and (D) The requesting individual, organization or governmental entity, upon request of the department or after a specified date or event, returns or destroys all identifiable health data provided by the department and copies thereof in any form.		

		(c) Specimens shall be submitted to the laboratory division of the state department of health, or to a laboratory approved for the purpose by the state department of health, within forty-eight hours after collection; **(d)** Laboratory tests shall be made according to methods approved by the state department of health; **(e)** Information accompanying each specimen shall be sufficient to identify for future reference the infant from whom taken; **(f)** Results of tests shall be transmitted to the state department of public health within twenty-four hours after test on forms provided for the purpose; **(g)** Records of tests shall clearly indicate the tests performed and the results thereof and shall be maintained for a period of five years.				

DELAWARE

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance	Exemption	Research Authority	Consent Required?	Dissent Allowed?
DE	16 D.C. §122 (1) and 16 DC §122(3)(h) **RULE:** D.A.C. 4107	**§ 122. Powers and duties of the Department of Health and Social Services.** The Department shall have the following general powers and duties: **(1)** Supervision of all matters relating to the preservation of the life and health of the people of the State… **(3)** Adopt, promulgate, amend, and repeal regulations consistent with law, which regulations shall not extend, modify or conflict with any law of this State or the reasonable implications thereof, and which shall be enforced by all state	**4107. 10.0 Religious Exemption From Testing: …10.2** In the event a religious exemption is claimed from the requirements for testing for Hereditary Disorders, the person otherwise responsible for submitting the specimen for testing shall be responsible for submitting a completed affidavit to the Delaware Newborn Screening Program Office, signed by the infant's parent or legal guardian, using the following language: 1. (I) (We) (am) (are) the (parent(s)) (legal guardian(s)) of (name of child) 2. (I) (We) hereby (swear) (affirm) that (I) (we) subscribe to a belief in a relation to a Supreme Being involving duties superior to those arising from any human relation.	**4107. …8.0 Confidentiality Of Records …8.1** The Newborn Screening Program shall maintain and treat as confidential all newborn screening communications with institutions, families and health care providers. The Newborn Screening Program shall maintain and treat as confidential a record of every newborn in	NO	YES-religious

Updated September 2013. 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.

		and local public health officials, to:… **h.** Control the practice of non-nurse midwives including the issuance of permits and protect and promote the health of all mothers and children… **4107. Testing of Newborn Infants For Metabolic, Hematologic and Endocrinologic Disorders.** Under the authority granted to the Department of Health and Social Services, Division of Public Health under 16 **Del.C.** §122(1), 16 **Del.C.** §122(3)(h)**,** and 29 **Del.C.** §7904 the Department of Health and Social Services, Division of Public Health, State of Delaware adopts the following regulations pertaining to the testing of newborns for various	3. (I) (We) further (swear) (affirm) that our belief is sincere and meaningful and occupies a place in (my) (our) life parallel to that filled by the orthodox belief in God. 4. This belief is not a political, sociological or philosophical view of a merely personal moral code. 5. This belief causes (me) (us) to request an exemption from the requirements for testing for Hereditary Disorders by the Delaware Newborn Screening Program for _____ (name of child). **4107. 10.3** The Newborn Screening Refusal Form will be provided through the Newborn Screening Program Office.	whom a diagnosis of one or more of the various metabolic, hematologic, or endocrinologic disorders is confirmed. **8.2** Information may be disclosed by the Newborn Screening Program in summary forms, which do not identify individuals. Individuals or institutions requesting summary data must submit a proposal to the Newborn Screening Program and to the Institutional Review Board of the Division of Public Health.		

		disorders. **PURPOSE:** …Each newborn delivered in the state must be provided a panel of screening tests to identify certain metabolic, hematologic and endocrinologic disorders that may result in developmental delay, mental retardation, serious medical conditions, or death.				

FLORIDA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
FL	STATUTE: F.S. Title XXIX, Chapter 383 RULE: 64C-7	**383.14. Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.** **(1)** SCREENING REQUIREMENTS.--To help ensure access to the maternal and child health care system, the Department of Health shall promote the screening of all newborns born in Florida for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, as screening programs accepted by current medical practice become available and practical in the judgment of the department. The department shall also promote the identification and screening of all newborns in this state and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention,	**383.14.** … **(4)** OBJECTIONS OF PARENT OR GUARDIAN.--The provisions of this section shall not apply when the parent or guardian of the child objects thereto. A written statement of such objection shall be presented to the physician or other person whose duty it is to administer and report tests and screenings under this section.	**381.0032 Epidemiological research. (1)** The [health] department may conduct studies concerning the epidemiology of diseases of public health significance, such as acquired immune deficiency syndrome and other diseases in Florida. These studies may not duplicate national studies but shall be designed to provide special insight and understanding into Florida-specific problems given this state's unique climate and geography, demographic mix, and high rate of immigration.	NO	NO

		remediation, and prevention services, including, but not limited to, parent support and training programs, home visitation, and case management. Identification, perinatal screening, and intervention efforts shall begin prior to and immediately following the birth of the child by the attending health care provider. Such efforts shall be conducted in hospitals, perinatal centers, county health departments, school health programs that provide prenatal care, and birthing centers, and reported to the Office of Vital Statistics. **(1)…(b)** Postnatal screening.--A risk factor analysis using the department's designated risk assessment instrument shall also be conducted as part of the medical screening process upon the birth of a child and submitted to the department's Office of Vital Statistics for recording and other purposes provided for in this chapter. The department's screening process for risk assessment shall include a scoring mechanism and procedures that establish thresholds for notification, further assessment, referral, and eligibility for services by professionals or paraprofessionals consistent with the	**64C-7.008 Objection to Prenatal and Infant (Postnatal) Risk Screening.** **(1)** The provider shall request any pregnant woman who objects to ***prenatal risk screening***, after the purpose of the screening has been fully explained, to indicate her objection in writing on the screening instrument, and to sign the instrument. The screening instrument to be used is the Healthy Start Prenatal Risk Screening Instrument, DOH Form 3134, 2/01 (English version),	**(2)** Epidemiological studies designed by the department shall emphasize practical applications and utility in the control of diseases of public health significance, such as acute or chronic diseases caused by infectious agents, host factors, or toxic substances. These studies shall, to the maximum extent possible, use state and local public health workers as field teams, study design team members, reviewers, and co-authors. Epidemiological studies conducted pursuant to this section shall be directed by the State Health Officer or his or her designee.		

		level of risk. Procedures for developing and using the screening instrument, notification, referral, and care coordination services, reporting requirements, management information, and maintenance of a ***computer-driven registry*** in the Office of Vital Statistics which ensures privacy safeguards must be consistent with the provisions and plans established under chapter 411, Pub. L. No. 99-457, and this chapter. Procedures for developing and using the screening instrument, notification, referral, and care coordination services, reporting requirements, management information, and maintenance of a ***computer-driven registry*** in the Office of Vital Statistics which ensures privacy safeguards must be consistent with the provisions and plans established under chapter 411, Pub. L. No. 99-457, and this chapter. Procedures established for reporting information and maintaining a confidential registry must include a mechanism for ***a centralized information depository*** at the state and county levels. The department shall coordinate with existing risk assessment systems and information registries. The department must ensure,	or DOH Form 3134 H, 2/01 (Creole version), or DOH Form 3134 S, 2/01 (Spanish version), which are incorporated by reference. Copies of the Healthy Start Prenatal Risk Screening Instrument can be obtained by writing to: the Office of Maternal and Child Health, Bin A-13 (HSFFM), 4052 Bald Cypress Way, Tallahassee, FL 32399-1723. If the woman refuses to sign the instrument, this refusal shall be indicated on the patient's signature line. The provider is to complete the	**(3)** The department shall work with the various universities and colleges in this state, including, but not limited to, the College of Public Health at the University of South Florida, when it deems it appropriate and necessary in carrying out such studies. **381.86 Institutional Review Board. (1)** The Institutional Review Board is created within the Department of Health in order to satisfy federal requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an institutional review board review all biomedical and behavioral research on human subjects which is funded or supported in any manner by the department.		

		to the maximum extent possible, that the screening information registry is integrated with the department's automated data systems, including the Florida On-line Recipient Integrated Data Access (FLORIDA) system… *[emphasis added]* **(2)** RULES.--After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state shall, prior to becoming 1 week of age, be subjected to a test for phenylketonuria and, at the appropriate age, be tested for such other metabolic diseases and hereditary or congenital disorders as the department may deem necessary from time to time. After consultation with the Office of Early Learning, the department shall also ***adopt and enforce rules requiring every newborn in this state to be screened for environmental risk factors that place children and their families at risk for increased morbidity, mortality, and other negative outcomes.***	demographic items (name, address, phone number and type of provider) in the provider section and sign and date the form. *[emphasis added]* **(2)** The provider shall request any parent or guardian who objects ***to infant (postnatal) risk screening*** of their child or ward, after the purpose of the screening has been fully explained, to indicate the objection in writing on the screening instrument, and to sign the instrument. The screening instrument to be used is the			

		(3)…(d) Maintain a confidential registry of cases, including information of importance for the purpose of follow-up services to prevent mental retardation, to correct or ameliorate physical handicaps, and for epidemiologic studies, if indicated. ***Such registry shall be exempt from the provisions of s. 119.07(1)*** [public access to records held by public agencies]. **64C-7.006 Newborn Screening Records. (1)** The State Public Health Laboratory and Children's Medical Services shall maintain records of the results of all screening and follow up testing for these conditions in accordance with department records management procedures. **(2)** The department shall maintain a confidential newborn screening registry of all abnormal screening results, for the purpose of service delivery and program administration and the registry will be maintained in accordance with the department's confidentiality requirements as stated in Rule 64F-10.008, F.A.C.	Healthy Start Infant (Postnatal) Risk Screening Instrument, DOH Form 3135, 2/01 (English version), or DOH Form 3135 H, 2/01 (Creole version), or DOH Form 3135 S, 2/01 (Spanish version), which are incorporated by reference. Copies of the Healthy Start Infant (Postnatal) Risk Screening Instrument can be obtained by writing to: the Office of Maternal and Child Health, Bin A-13 (HSFFM), 4052 Bald Cypress Way, Tallahassee, FL 32399-1723. If the parent or guardian refuses			

		64C-7.010 Prenatal and Infant (Postnatal) Risk Screening Records. **(1)** Prenatal Risk Screening Records **(a)** The health care provider shall maintain a completed copy of the Healthy Start Prenatal Risk Screening Instrument in the pregnant women's medical record. **(b)** The provider of care coordination shall initiate documentation on every Healthy Start pregnant woman. That documentation shall contain, at a minimum, a scored prenatal risk screening instrument and record of case disposition, except for participants who are referred based on other factors subsequent to the initial screen. For those participants, documentation in the record shall include documentation of the participant's risk factors and the record of case disposition. **(c)** ***The department shall maintain a confidential registry of the risk screening results on all pregnant women received from health care providers.*** *[emphasis added]*	to sign the instrument, this refusal shall be indicated on the patient's signature line. The provider is to complete the demographic items (name, address, phone number and type of provider) in the provider section and sign and date the form. *[emphasis added]* **(3)** Prenatal and infant (postnatal) risk screening shall not be conducted if the affected pregnant woman, parent, or guardian objects to the screening.			

		(2) Infant (Postnatal) Risk Screening Records **(a)** The health care provider shall assure that a completed copy of the Healthy Start Infant (Postnatal) Risk Screening Instrument is placed in the infant's medical record. **(b)** The provider of care coordination shall initiate documentation on every Healthy Start infant. That documentation shall contain, at a minimum, a scored infant (postnatal) risk screening instrument and record of case disposition, except for participants who are referred based on other factors subsequent to the initial screen. For those participants, documentation in the record shall include documentation of the participant's risk factors and the record of case disposition. **(c)** ***The department shall maintain a confidential registry of the risk screening results on all infants received from the health care providers.*** *[all emphasis added]*				

GEORGIA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
GA	STATUTE: Title 31 Chapter 1 Title 31 Chapter 2 Title 31 Chapter 12 Title 33 Chapter 54 RULE: 290-5-.02 and 290-5-24	**§ 31-1-3.1. Reporting disabled newborn persons; referral to treatment and rehabilitative services.** **(a)** It is the intent of the General Assembly to ensure the registration by the department of disabled newborn persons in order that all such persons might obtain referral and other services provided by existing state agencies, departments, other organizations, and individuals. **(b)** As used in this Code section, the term "disabled newborn person" means a person less than 12 months old who is deaf, blind, or has a serious congenital defect as defined by the department.	**§31-12-6:** **(i)** The requirements of this Code section with regard to screening, retrieval, and diagnosis shall not apply to any infant whose parents object in writing thereto on the grounds that such tests and treatment conflict with their religious tenets and practices.	**§ 31-12-1. Power to conduct research and studies** The Department of Public Health and county boards of health are empowered to conduct studies, research, and training appropriate to the prevention of diseases and accidents, the use and control of toxic materials, and the prevention of environmental conditions which, if permitted to develop or continue, would likely endanger the health of individuals or communities.	NO	YES - religious

Updated September 2013. 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.

		§31-12-6 System for prevention of serious illness, severe physical or developmental disability, and death resulting from inherited metabolic and genetic disorders **(a)** The department shall promulgate rules and regulations creating a system for the prevention of serious illness, severe physical or developmental disability, and death caused by genetic conditions, such as phenylketonuria, galactosemia, homocystinuria, maple syrup urine disease, hypothyroidism, congenital adrenal hyperplasia, and such ***other inherited metabolic and genetic disorders as may be identified in the future*** to result in serious illness, severe physical or developmental disability, and death if undiagnosed and untreated. The system shall have five components: screening newborns for the disorders; retrieving potentially affected screenees back into the health care system; accomplishing specific diagnoses; initiating and continuing therapy; and assessing the program…	**§31-12-7 Rules and regulations regarding tests for sickle cell anemia, sickle cell trait, and other metabolic and genetic disorders; counseling; fees.** **(a)** …provided, however, that this Code section shall not apply to any infant whose parents object thereto on the grounds that such tests and treatment conflict with their religious tenets and practices.	**Chapter 54, Genetic Testing:** **§ 33-54-6. Use of information for scientific research purposes authorized.** Notwithstanding the provisions of Code Sections 33-54-3 and 33-54-4, ***any research facility may conduct genetic testing and may use the information derived from genetic testing for scientific research purposes*** so long as the identity of any individual tested is not disclosed to any third party, except that the individual's identity may be disclosed to the individual's physician with the consent of the individual. (enacted by Ga. L. 1995) *[emphasis added]*		

		(c) The department shall be responsible for the screening of all newborns for the disorders enumerated and in a manner determined by the department pursuant to rules and regulations and shall be responsible for assessment of the program. **§ 31-12-7. Rules and regulations regarding tests for sickle cell anemia, sickle cell trait, and other metabolic and genetic disorders; counseling; fees: (a)** In coordination and association with the system established by the department for the screening, retrieval, and diagnosis of certain metabolic and genetic disorders pursuant to Code Section 31-12-6, the department, or its successor agency or department, shall adopt and promulgate appropriate rules and regulations governing tests for sickle cell anemia, sickle cell trait, and other metabolic and genetic disorders as enumerated by the department pursuant to rules and regulations so that as nearly as possible all newborn infants who are susceptible or likely to have sickle cell anemia, sickle cell trait, or other metabolic and genetic disorders shall receive a test for sickle	**290-5-24-.02 Provisions. (1)** Every live born infant shall have an adequate blood test for all disorders defined in Rule 290-5-24-.01 unless its parents or legal guardians for religious reasons object in writing to such testing.	**§ 31-12-5. State-wide network for medical genetics services** **(a)** The department and appropriate medical centers shall cooperate in the development of a state-wide network for medical genetics. **(b)** The network shall be available state-wide and will be responsible for training of personnel in genetics, researching inborn errors of metabolism, and quality control of laboratory services for genetics. This system shall also provide counseling regarding genetically caused disorders.		

		cell anemia, sickle cell trait, or other metabolic and genetic disorders or all of such conditions as soon after birth as successful testing and treatment therefor may be initiated;… **290-5-24-.02 Provisions**. …**(5)** Approved laboratories performing mandated newborn screening tests for the purpose of satisfying the legal requirements for testing newborns shall report all such test results to the attending physician and the hospital where the birth occurred; the results shall be made a part of the clinical record Such laboratories shall report all results to the Genetic Newborn Screening Program of the Department on the day the testing is completed and this report shall include the patient's required information.				

		…**(10)** In determining which disorders are to be added or deleted from the newborn screening panel, the Director, Division of Public Health will seek the advice and guidance of the Newborn Screening Advisory Committee…**(b)** Upon consideration of these criteria, the Director will recommend adding or deleting a specific disorder to the Board. Upon approval by the Board, the disorder will be added to or deleted form the newborn screening panel. ***["Board" not defined]***				

Updated September 2013. 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.

HAWAII

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
HI	STATUTE: H.R.S Title 19, Chapter 321, Part XXII RULE: Title 11, Chapter 143	**§321-291. Tests for phenylketonuria, hypothyroidism, and other metabolic diseases. (a)** The department of health may specify diseases to be screened for in newborn infants and methods to be employed to best prevent mortality and morbidity within the population of the State. **(b)** The person in charge of each institution caring for newborn infants and the responsible physician attending the birth of a newborn or the person assisting the birth of a child not attended by a physician, shall ensure that every infant in the person's care be tested for phenylketonuria, hypothyroidism, and any other disease that may be specified by the department of health;…	**§321-291**…**(b)**…provided that this section shall not apply if the parents, guardians, or other persons having custody or control of the child object thereto on the grounds that the tests conflict with their religious tenets and beliefs and written objection is made a part of the infant's medical record.	**§11-143-12 Confidentiality**. All information, including records, correspondence, and documents, specific to individual newborns, shall be confidential and shall be used solely for the purposes of medical intervention, counseling, scientific research, or reporting. The infant's name shall be kept confidential.	NO	YES – but rules violate the law because refusal is only for repeat or confirmatory testing.

Updated September 2013. 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.

		§321-363 Rules. The department shall adopt rules, pursuant to chapter 91, necessary for the purposes of this part, including but not limited to administration and quality of newborn hearing screening; retention of records and related data; reporting of positive screening results; diagnostic evaluation and intervention for infants with hearing impairment; informing parents about the purpose of screening; and maintaining the confidentiality of affected families. **11-143-5…(f)** The hospital shall keep record summaries of infants born or transferred by month of birth, as to whether the newborn screening tests were done, the test results, and actions taken based on test results or missing results. These summaries shall be compiled monthly and sent to the department not later than thirty days after the end of the month….	**§11-143-7 Parental notification and refusal**. **(a)** Copies of the parent information brochure shall be available to parents, guardians, other persons having custody or control of the child, hospitals, physicians, birth attendants, birth registrars, nurses, and childbirth educators. **(b)** The parent, guardian, or other person having custody or control of the child shall be notified by the department of the need for ***repeat or confirmatory testing*** when the department is not able to obtain follow-up information from the physician.			

Updated September 2013. 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.

			(c) The parent, guardian, or other person having custody or control of the child may refuse the newborn screening tests for their infant on the grounds that the newborn screening tests conflict with the religious tenets and beliefs of the parent, guardian, or other person having custody or control of the child. The medical implications of that refusal shall be included on a special refusal form provided by the department. The refusal form shall be signed by the parent, guardian, or other person having custody or control of the child. **(d)** A copy of the refusal form shall be retained in the newborn's medical record and a copy shall be sent to the department.			

			§11-143-3 Definitions. As used in this chapter: "Confirmatory specimen" means a specimen collected for the purpose of performing a confirmatory test. "Confirmatory test" means a test performed on a specimen to determine the validity of a ***previou***s positive test.			

IDAHO

State	Statute/Rule	Language Specific to Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
ID	I.S. Title 39, Chapter 9 IDAPA 16, Title 02, Chapter 12 (16.02.12)	**39-909. TESTS FOR PHENYLKETONURIA AND PREVENTABLE DISEASES IN NEWBORN INFANTS**. It shall be the duty of the administrative officer or other person in charge of each hospital or other institution caring for newborn infants and the person responsible for the registration of the birth of such infant under section 39-256, Idaho Code, to cause to have administered to every newborn infant in its or his care a test for phenylketonuria and such other tests for preventable diseases as prescribed by the state board of health and welfare. The person administering such tests shall make such reports of the results thereof as required by the state board of health and welfare.	**39-912. EXEMPTION BECAUSE OF RELIGIOUS BELIEF**. The provisions of this act shall not apply to any child whose parent or guardian objects thereto on the grounds that it conflicts with the tenets or practices of a recognized church or religious denomination of which said parent or guardian is an adherent or member.	NO	NO	YES religious

		39-910. DUTIES OF DIRECTOR IN ENFORCING ACT. It shall be the duty of the director of the department of health and welfare: **1.** To enforce the provisions of this act. **2.** To prescribe what tests shall be made for preventable diseases in addition to the test for phenylketonuria. **3.** To publish rules of the board prescribing the time and manner of administering tests required by this act. **4.** To furnish copies of this act and the rules promulgated hereunder to physicians, hospitals or other institutions or persons required by this act to have tests administered to newborn infants. **5.** ***To maintain a record of all infants found to have phenylketonuria or other preventable diseases and to supervise local health agencies in the treatment and cure of such infants.*** 6. To disseminate information and advice to the public concerning the dangers and effects of phenylketonuria and other preventable diseases and their detection and treatment.				

ILLINOIS

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
IL	STATUTE: 410 ILCS 240 RULES: JCAR Title 77, Ch. I, Sub Cp.t I, Part 661, Section 661.50, 661.60, 840.200 and 840.30	**410 ILCS 240 Sec. 0.01 Short title.** This Act may be cited as the Newborn Metabolic Screening Act. **410 ILCS 240 Sec. 1** The Illinois Department of Public Health shall promulgate and enforce rules and regulations requiring that every newborn be subjected to tests for phenylketonuria, hypothyroidism, galactosemia and such other metabolic diseases as the Department may deem necessary from time to time. The Department is empowered to promulgate such additional rules and regulations as are found necessary for the administration of this Act, including mandatory reporting of the results of all tests for these conditions to the Illinois Department of Public Health.	**410 ILCS 240 Sec. 3** The provisions of this Act shall not apply when parent or guardian of the child objects thereto on the grounds that such test conflicts with his religious tenets and practices. A written statement of such objection shall be presented to the physician or other person whose duty it is to administer and report such tests under the provisions of this Act.	**JCAR 77 - Section 840.200 Adverse Pregnancy Outcome** An adverse pregnancy outcome for an infant consists of one or more of the following case criterion: …**(e) (3)** Endocrine, metabolic or immune disorder: **(A)** Hypothyroidism (ICD-9-CM 243); **(B)** Adrenogenital syndrome (ICD-9-CM 255.2); ***(C) Inborn errors of metabolism (ICD-9-CM 270-273, 275-276);*** **(D)** Cystic fibrosis (ICD-9-CM 277.0); or	NO	YES religious

Updated September 2013. 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.

		410 ILCS 240 Sec. 2 The Department of Public Health shall… **(a6)** In accordance with the timetable specified in this subsection, provide all newborns with expanded screening tests for the presence of certain Lysosomal Storage Disorders known as Krabbe, Pompe, Gaucher, Fabry, and Niemann−Pick… **(b)** maintain a **registry of cases** including information of importance for the purpose of follow-up services to prevent mental retardation… **(e)** Require that all specimens collected pursuant to this Act or the rules and regulations promulgated hereunder be submitted for testing to the nearest Department of Public Health laboratory designated to perform such tests…	**JCAR 77 - Section 661.60 Exemption**. Whenever a newborn screening test is not performed because a parent or guardian presents a written statement of objection on the basis of religious tenets and practices, documentation shall be maintained by the facility of birth or by the primary health care provider. ***Objection based on religious tenets and practices is the only ground for exemption.*** The Department shall be notified in writing.	**(E)** Immune deficiency disorder (ICD-9-CM 279)…. **JCAR 77 - Section 840.30 Availability of [Health and Hazardous Substances] Registry Information:** … **(b)** All requests by medical or epidemiologic researchers for confidential Registry data must be submitted in writing to the Department… **(d)(1)** The Department will enter into research agreements for all approved research requests…		

		JCAR 77 - Section 661.50 Diagnosis and Treatment. The Department shall also maintain a ***registry*** to record the results of diagnosis and treatment for all diagnosed cases identified. It is imperative to perform ongoing evaluation of the newborn screening program. This process includes outcome evaluation of children diagnosed through newborn screening. The Department shall request, from the medical specialist or primary care provider, updated information annually, concerning developmental milestones, for each child diagnosed with a disorder for which the Department screens.		**(k)** Every reporting facility shall provide access to diagnostic, treatment, follow-up and survival information regarding specified patients or other patients specified through rapid case ascertainment for research studies conducted by the Department. **410 ILCS 240 Sec. 2** … **(e)**… Nothing in this Act shall be construed to prohibit any licensed medical facility from collecting additional specimens for testing for metabolic or neonatal diseases or any other diseases or conditions, as it deems fit.		

INDIANA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
IN	STATUTE: Title 13 Article 38 (Health Registries) and Title 16, Article 41 (PKU et.al) RULE: 410 IAC Article 3 Rule 3	**IC 16-38-1-1. Newborn screening registry; development Sec. 1.** The state department shall develop the newborn screening registry under IC 16-41-17-10. **IC 16-41-17-10. Follow-up programs; newborn screening fees; waste blood specimen confidentiality Sec. 10. (a)** The state department shall develop the following: **(1)** A registry for tracking and follow-up of all newborns and individuals for screening. **(2)** A centralized program that provides follow-up, diagnosis, management, and family counseling and support…	**IC 16-41-17-2. Examinations; religious exemption** **(d)** If a parent of an infant objects in writing, for reasons pertaining to religious beliefs only, the infant is exempt from the examinations required by this chapter.	**IC 16-41-17-1.Waste blood specimen Sec. 1.** As used in this chapter, "waste blood specimen" means a blood sample or a solid, liquid, or semiliquid blood product that**:** **(1)** has served the intended purpose under section 4 of this chapter; or **(2)** has served the natural, biological, medical, or intended purpose and has been discarded or accumulated for discard from a use other than as provided under section 10(a)(5) of this chapter.	NO	YES

Updated September 2013. 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.

		IC 16-41-17-2. Examinations; religious exemption Sec. 2. …[E]very infant shall be given examinations at the earliest feasible time for the detection of the following disorders: **(1)** Phenylketonuria**.** **(2)** Hypothyroidism **(3)** Hemoglobinopathies, including sickle cell anemia. **(4)** Galactosemia. **(5**) Maple Syrup urine disease. **(6)** Homocystinuria. **(7)** Inborn errors of metabolism that result in mental retardation and that are designated by the state department. **(8)** Congenital adrenal hyperplasia. **(9)** Biotinidase deficiency. **(10)** Disorders detected by tandem mass spectrometry or other technologies with the same or greater detection capabilities as tandem mass spectrometry… **(b)** Subject to subsection (d), every infant shall be given a physiologic hearing screening examination….	**410 IAC 3-3-2. Provision of testing information; religious objection.** **(b)** Any parent or guardian who objects to the testing for reasons pertaining to religious beliefs only shall so indicate by signing a statement of informed refusal. Such objection shall become part of the medical record and the infant shall be exempted from the testing.	**IC 16-41-17-10. Sec. 10**… **(5)** A system for using, for epidemiological survey and research purposes, any waste blood specimen generated under this chapter. **(f)** Waste blood specimens used for the purpose of implementing the system described under subsection (a)(5) may not include the name or other identifying characteristics that would identify the individual submitting the specimen.		

		Rule 3. Examination of Infants for Disorders **410 IAC 3-3-7. Follow-up of positive results…** **(g)** The board shall maintain a **tracking system** for follow-up of newborn screening results, and shall maintain a **confidential registry** of every infant born for whom the diagnosis of phenylketonuria, hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, or hemoglobinopathy has been confirmed. These records shall be utilized only for the purpose of service delivery and program administration and shall be managed in accordance with the procedures described in 410 IAC 1-2-2.				

IOWA

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
IA	STATUTE: Title IV, Subtitle 2, Chapter 136A RULE: IAC 641—4.1 to 4.7(6)	**136A.1 PURPOSE** To reduce and avoid adverse health conditions of inhabitants of the state, the Iowa department of public health shall initiate, conduct, and supervise screening and health care programs in order to detect and predict congenital or inherited disorders. The department shall assist in the translation and integration of genetic and genomic advances into public health services to improve health outcomes throughout the life span of the inhabitants of the state.	**136A.5 NEWBORN METABOLIC TESTING…3.** This section does not apply if a parent objects to the screening. If a parent objects to the screening of a newborn, the attending health care provider shall document the refusal in the newborn's medical record and shall obtain a written refusal from the parent and report the refusal to the	**641-4.3(7) Sharing of information and confidentiality.** …**(b.)** The program shall not release confidential information except to the following persons an entities, under the following conditions:… **(4)** A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department and the state board of health.	NO	YES

		641-4.3(1) Newborn screening policy….**c.** The center may monitor individuals identified as having a genetic or metabolic disorder for the purpose of conducting public health surveillance or intervention and for determining whether early detection, treatment, and counseling lead to the amelioration or avoidance of the adverse outcomes of the disorder. Birthing hospitals or birth centers and health care providers shall provide patient data and records to the center upon request to facilitate the monitoring. Any identifying information provided to the center shall remain confidential pursuant to Iowa Code section 22.7(2). **136A.3 ESTABLISHMENT OF CENTER FOR CONGENITAL AND INHERITED DISORDERS -- DUTIES.** A center for congenital and inherited disorders is established within the department. The center shall do all of the following: **1.** Initiate, conduct, and supervise statewide screening programs for congenital and inherited disorders amenable to population screening.	department as provided by rule of the department. **641-4.3 (2) Neonatal metabolic screening procedure for facilitators and providers.** **a.** *Educating parent or guardian*. Before a specimen from an infant is obtained, a parent or guardian shall be informed of the type of specimen, how it is obtained, the nature of the disorders for which the infant is being screened, the consequences of treatment	**641-4.7(6) Access to information in the IRCID.** The IRCID and the department shall not release confidential information except to the following, under the following conditions: **(e.)** Researchers, in accordance with the following: **(1)** All proposals for research using the IRCID data to be conducted by persons other than program staff shall first be submitted to and accepted by the researcher's institutional review board. Proposals shall then be reviewed and approved by the department and the IRCID's internal advisory committee before research can commence.		

		2. Initiate, conduct, and supervise statewide health care programs to aid in the early detection, treatment, prevention, education, and provision of supportive care related to congenital and inherited disorders. **3.** Develop specifications for and designate a central laboratory in which tests conducted pursuant to the screening programs provided for in subsection 1 will be performed. **4.** Gather, evaluate, and maintain information related to causes, severity, prevention, and methods of treatment for congenital and inherited disorders in conjunction with ***a central registry,*** screening programs, genetic health care programs, and ongoing scientific investigations and surveys.	and nontreatment, and the retention, use and disposition of residual specimens. **b.** *Waiver.* Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record. The birthing hospital, birth center, or attending health care provider shall notify the central laboratory of the waiver within six days of the refusal.	**(2)** The IRCID shall submit to the IRCID's internal advisory committee for approval a protocol describing any research conducted by the IRCID in which the IRCID deems it necessary to contact case subjects and controls. **641-4.7(5) Confidentiality and disclosure of information.** Reports, records, and other information collected by or provided to the IRCID relating to a person known to have or suspected of having a congenital or inherited disorder are confidential records pursuant to Iowa Code sections 22.7 and 136A.7…		

		5. Perform surveillance and monitoring of congenital and inherited disorders to determine the occurrence and trends of the disorders, to conduct thorough and complete epidemiological surveys, to assist in the planning for and provision of services to children with congenital and inherited disorders and their families, and to identify environmental and genetic risk factors for congenital and inherited disorders. **6.** Provide information related to severity, causes, prevention, and methods of treatment for congenital and inherited disorders to the public, medical and scientific communities, and health science disciplines. **7.** Implement public education programs, continuing education programs for health practitioners, and education programs for trainees of the health science disciplines related to genetics, congenital disorders, and inheritable disorders.		**641-4.3(8) Retention, use and disposition of residual neonatal metabolic screening specimens.** **a.** A neonatal metabolic screening specimen collection form consists of a filter paper containing the dried blood spots (DBS) specimen and the attached requisition that contains information about the infant and birthing hospital, birth center, or drawing laboratory. The DBS specimen can be separated from the information contained in the requisition form. **(1)** The residual DBS specimen shall be held for five years in a locked area at the UHL [University Hygienic Laboratory]. **(2)** The residual DBS specimen ~~forms~~ shall be stored for the first year at -70 degrees C.		

		8. Participate in policy development to assure the appropriate use and confidentiality of genetic information and technologies to improve health and prevent disease. **9.** Collaborate with state and local health agencies and other public and private organizations to provide education, intervention, and treatment for congenital and inherited disorders and to integrate genetics and genomics advances into public health activities and policies. **136A.5 NEWBORN METABOLIC TESTING.** **1.** All newborns born in this state shall be screened for congenital and inherited disorders in accordance with rules adopted by the department. **2.** An attending health care provider shall ensure that every newborn under the provider's care is screened for congenital and inherited disorders in accordance with rules adopted by the department…		**(3)** After one year, the residual DBS specimen shall be archived for four additional years at room temperature. **(4)** The residual DBS specimen shall be incinerated after completion of the retention period. ***b. Research use.*** **(1)** Investigators shall submit proposals to use residual DBS specimens to the center. Any intent to utilize information associated with the requested specimens as part of the research study must be clearly delineated in the proposal. **(2)** Before research can commence, proposals shall be approved by the researcher's institutional review board, the congenital and inherited disorders advisory committee, and the department.		

		136A.6 CENTRAL REGISTRY. The center for congenital and inherited disorders shall maintain a central registry, or shall establish an agreement with a designated contractor to maintain a central registry, to compile, evaluate, retain, and disseminate information on the occurrence, prevalence, causes, treatment, and prevention of congenital disorders. Congenital disorders shall be considered reportable conditions in accordance with rules adopted by the department and shall be abstracted and maintained by the registry. **641-4.7. Iowa registry for congenital and inherited disorders. [IRCID]** The central registry provides active statewide surveillance for selected congenital and inherited disorders…		**(3)** Personally identifiable residual specimens or records shall not be disclosed without documentation of informed parental consent obtained by the researcher. **(4)** Research on anonymized or identifiable residual specimens shall be allowed in instances where research would further: neonatal metabolic screening activities; the health of an infant or child for whom no other specimens are available or readily attainable; or general medical knowledge for existing public health surveillance activities.		

		641-4.7(3) Central registry activities. a. The center shall establish an agreement with the University of Iowa to implement the activities of the central registry….**c.** The central registry staff shall review hospital records, clinical charts, physician's records, vital records and prenatal records pursuant to 641-1.3 (139A) and any other information that the central registry deems necessary and appropriate for birth defects surveillance. **641-4.1 Program explanation.** The center for congenital and inherited disorders within the department of public health provides administrative oversight to the following: Iowa neonatal metabolic screening program, expanded maternal serum alphafetoprotein screening program, regional genetic consultation service, neuromuscular and related genetic disease program ***and Iowa registry for congenital and inherited disorders.*** *[emphasis added]*		**641-4.2 Definitions….** "*Anonymized specimen*" means a specimen that cannot be traced back to or linked with the particular infant from whom the specimen was obtained. Specimens shall be anonymized by removing the dried blood spot portion from the infant information portion of the specimen collection form…		

KANSAS

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
KS	STATUTE: Chapter 65, Article 1, K.S.A. 65-180 to 65-183 RULE: K.A.R. 28-4-501 to 513	**Statute 65-180. …[R]egistry of cases; …newborn screening programs.** The secretary of health and environment shall: … **(b)** Provide recognized screening tests… **(d)** Maintain a registry of cases… **65-181. Same; tests in accordance with rules and regulations of secretary.** The administrative officer or other person in charge of each institution or the attending physician, caring for infants 28 days of age or younger shall have administered to every such infant or child in its or such physician's care, tests for congenital hypothyroidism, galactosemia, phenylketonuria and other genetic diseases which may be detected with the *same specimen*…	**65-182. Same; provisions inapplicable where parents object on religious grounds.** The provisions of this section shall not apply to any infant whose parents object thereto on the grounds that such tests and treatment conflict with their religious tenets and practices. **65-180. (c)** Provide a follow-up program by providing test results and other information to identified physicians; locate infants with abnormal newborn screening test results; **with parental consent**, monitor infants to assure appropriate testing to either confirm or not confirm the disease suggested by the screening test results; **with parental consent**, monitor therapy and treatment for infants with confirmed diagnosis…		NO	YES

Updated September 2013. 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.

		65-183. Same; report by physicians to secretary. Every physician having knowledge of a case of congenital hypothyroidism, galactosemia or phenylketonuria and other genetic diseases as may be detected with tests given pursuant to this act in one of such physician's own patients shall report the case … **KAR 28-4-509 Registry.** **(a)** The registry shall be a computerized data system that includes the diagnosed individuals' name, birth-date, unique identification number, diagnosis, address including telephone number, parental names and addresses, guardian, nuclear family size and health status. **(b)** Persons or guardians of minor children with a confirmed diagnosis of phenylketonuria, hypothyroidism or galactosemia shall forward to the newborn screening coordinator any address □and health status changes within three months of the change. (Authorized by K.S.A. 65-101; implementing K.S.A. 65-180;…)	**KAR 28-4-512 Parental education. (a)** Providers of prenatal health care shall discuss and distribute written material describing the newborn screening program as a component of the prenatal care to pregnant women. **(b)** Prior to obtaining the specimen for newborn screening, the person responsible for obtaining the specimen shall inform the parent or parents about the newborn screening program, including how the test can be refused. **28-4-511 Test refusal.** Refusal to take part in the testing procedure shall be documented in the child's record at the institution or physician's office or both.			

KENTUCKY

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority?	Consent Required?	Dissent Allowed?
KY	STATUTE: KRS 214.155 RULE: KAR 902	**214.155 Screening and tests for heritable disorders for newborns and infants -- Information provided to parent or guardian -- Application for federal grants -- Section cited as James William Lazzaro and Madison Leigh Heflin Newborn Screening Act.** **(1)** The Cabinet for Health and Family Services shall operate a newborn screening program for heritable disorders that includes but is not limited to procedures for conducting initial newborn screening tests on infants twenty-eight (28) days or less of age and definitive diagnostic evaluations provided by a state university-based specialty clinic for infants whose initial screening tests resulted in a positive test… **(2)**…The listing of tests for heritable disorders to be performed shall include all conditions consistent with the recommendations of the American College of Medical Genetics	**214.155 (4)** Nothing in this section shall be construed to require the testing of any child whose parents are members of a nationally recognized and established church or religious denomination, the teachings of which are opposed to medical tests, and who object in writing to the testing of his or her child on that ground.	**Title XVII, Chapter 194A Cabinet for Health and Family Services: 194A.060 Confidentiality of records and reports. (1)** The secretary shall develop and promulgate administrative regulations that protect the confidential nature of all records and reports of the cabinet that directly or indirectly identify a client or patient or former client or patient of the cabinet and that insure that these records are not	NO	YES

		(3) Each health care provider of newborn care shall provide an infant's parent or guardian with information about the newborn screening tests required under subsection (2) of this section. The institution or health care provider shall arrange for appropriate and timely follow-ups to the newborn screening tests, including but not limited to additional diagnoses, evaluation, and treatment when indicated… **(6)** A parent or guardian shall be provided information by the institution or health care provider of newborn care about the availability and costs of screening tests not specified in subsection (2) of this section. The parent or guardian shall be responsible for costs relating to additional screening tests performed under this subsection… **902 KAR 4:030. Newborn Screening Program. …Section 4. Specimen Collection. (1)** Capillary blood specimens required in Section 3 of this administrative regulation shall be obtained by a heel stick. Blood from the heel stick shall be applied directly to filter paper specimen card. All circles shall be saturated completely using a drop of blood per circle on a filter paper specimen card. The specimen collector shall provide, on the filter paper specimen card, information requested by the laboratory.	**902 KAR 4:030. Newborn Screening Program** **(e)** Hospitals or facilities shall report all written refusals, in accordance with RS 214.155(4), to the program within seven (7) days.	disclosed to or by any person except as, and insofar as: **(a)** The person identified or the guardian, if any, shall give consent; or **(b)** Disclosure may be permitted under state or federal law. **(2)** The cabinet shall share pertinent information from within the agency's records on clients, current and former clients, recipients, and patients as may be permitted by federal and state confidentiality statutes and regulations governing release of data with other public, quasi-public, and private agencies involved in providing services to current or former		

		(2) The capillary blood specimen shall be air dried for three (3) hours and then shall be mailed or sent to the laboratory within twenty-four (24) hours of collection of the specimen or the next business day in which mail or delivery service is available. **(3)** Submitters send submit blood specimens to the Cabinet for Health and Family Services, Department for Public Health, Division of Laboratory Services, P.O. Box 2010, Frankfort, Kentucky 40602. **(4)** Specimens processed or tracked under the newborn screening program shall be limited to specimens on infants less than six (6) months of age.		clients or patients subject to confidentially agreements as permitted by federal and state law if those agencies demonstrate a direct, tangible, an legitimate interest in the records. In all instance, the individual's right to privacy is to be respected.		

LOUISIANA

State	Statute/ Rule	Language Specific to Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
LA	STATUTE: RS 40:1299 Part XV RULE: LAC 48: V.6303	**PART XV. GENETIC CONDITIONS AND NEWBORNS: §1299. Programs for combating phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, biotinidase deficiency, and other genetic conditions A.** The Department of Health and Hospitals is hereby authorized and directed to establish, maintain, and carry out programs designed to reduce mortality and morbidity from sickle cell disease and to prevent central nervous system damage in children with phenylketonuria, congenital hypothyroidism, biotinidase deficiency, and genetic conditions tested under the authority of R.S. 40:1299.1(B). **§1299.1. Tests. A. (1)** The physician attending a newborn child, or the person attending a newborn child who was not attended by a physician, shall cause the child to be subjected to tests…	**§1299.1. Tests A. (1)** The physician attending a newborn child, or the person attending a newborn child who was not attended by a physician, shall cause the child to be subjected to tests for phenylketonuria … and other genetic conditions that have been approved by the Department of Health and Hospitals;	**§1299.** …**B.(1)** The Department of Health and Hospitals shall establish and maintain a diagnostic laboratory for each of the following purposes:	NO	YES

Updated September 2013. 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.

		(2) If any of the tests are positive, the attending physician or person shall notify the Department of Health and Hospitals. **(3)** The department shall follow up all positive tests with the attending physician who notified the department thereof and with the parents of the newborn child… **LAC 48: V 6303 (G)**….**8.** Mandatory Reporting of Positive Test Results Indicating Disease…**10.** ***Reporting requirements of private laboratories to the Genetic Diseases Program Office for public health surveillance and quality assurance purposes.*** **a.** The laboratory must submit quarterly statistical reports to the Genetic Disease Program Office that indicate the number of specimens screened by method, the number of specimens unsatisfactory for testing, the number normal and positive, and for screening of hemoglobinopathies, the number by phenotype…	however, no such tests shall be given to any child whose parents object thereto. **§1299.1. Tests.** …**B.** The Department of Health and Hospitals shall, after consultation with medical geneticists from each of the state's medical schools and by rule adopted in accordance with the Administrative Procedure Act, add to the genetic conditions tested for in Subsection A of this Section;	**(a)** Conducting experiments, projects, and other undertakings as may be necessary to develop tests for the early detection of phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, biotinidase deficiency, and other genetic conditions. **(b)** Developing ways or discovering methods to be used for the prevention and treatment of these diseases.		

		b. The laboratory must electronically report newborn screening results on all Louisiana newborns screened to the Genetic Diseases Program Office on a monthly basis. The file format and data layout will be determined by the Genetic Diseases Program. Essential patient data is the following and is required to be reported unless "optional" is indicated: **i.** child's first name; **ii.** child's last name; **iii.** mother's first name; **iv.** mother's last name; **v.** mother's maiden name (optional); **vi.** child's street address; **vii.** child's city; **viii.** child's state; **ix.** child's zip code; **x.** child's parish (optional); **xi.** child's date of birth (format: mm/dd/yyyy); **xii.** child's sex; **xiii.** child's race (format: (W)hite, (B)lack, Native America, Asian, other, Hispanic); **xiv.** mother's social security number (format: 999-99-9999). **xv.** Child's test results.	however, no approved test for any genetic condition added shall be given to any child whose parents object thereto.	**(c)** Such other purposes as may be deemed necessary by the department to carry out any program adopted under the authority of this Part, including conducting experiments, projects, and other undertakings as may be necessary to develop tests for genetic conditions made part of the battery of tests by the Department of Health and Hospitals under R.S. 40:1299.1(B).		

MAINE

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
ME	STATUTE: Title 22, Subtitle 2, Part 3, Chapter 261-A M.R.S. §1532 to 1533 RULE: 10-144, Chapter 283	**§1532. Detection of serious conditions.** The department shall require hospitals, birthing centers and other birthing services to test newborn infants, or to cause them to be tested, by means of blood spot screening for the presence of treatable congenital, genetic or metabolic conditions that may be expected to result in subsequent cognitive disabilities, serious illness or death. The department shall adopt rules to define this requirement and the approved testing methods, materials, procedure and testing sequences. Reports and records of those making these tests may be required to be submitted to the department in accordance with departmental rules. The department may, on request, offer consultation, training and evaluation services to those testing facilities. The department shall adopt rules according to which it shall in a timely fashion refer	**§1532. …**The requirement in this section that a newborn infant be tested for the presence of treatable congenital, genetic or metabolic conditions that may be expected to result in subsequent cognitive disability does not apply to a child if the parents of that child object on the grounds that the test conflicts with their religious tenets and practices.	**Chapter 283: 12.0 FILTER PAPER STORAGE AND USE** **12.2** After testing is completed, leftover filter paper specimens will be stored indefinitely…	NO	YES

Updated September 2013. 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.

		newborn infants with confirmed treatable congenital, genetic or metabolic conditions to the Child Development Services System as defined in Title 20-A, section 7001, subsection 1-A. The department shall also adopt rules according to which it shall in a timely fashion refer a newborn infant to the Child Development Services System if at least 6 months have passed since an initial positive test result of a treatable congenital, genetic or metabolic condition without the specific nature of the condition having been confirmed. The department and the Department of Education shall execute an interagency agreement to facilitate all referrals in this section. In accordance with the interagency agreement, the Department of Education shall offer a single point of contact for the Department of Health and Human Services to use in making referrals. Also in accordance with the interagency agreement, the Child Development Services System may make direct contact with the families who are referred. The referrals may take	**Chapter 283:** **9.0 PARENTAL REFUSAL OF THE SCREENING TESTS** **9.1** In the instance of parental refusal of the screening tests on religious grounds, the parental refusal shall be stated in writing and made a part of the infant's medical record. **9.2** The administrator of hospitals and birthing centers, and principal birthing attendants shall ensure that the Maine Newborn Screening Program, Maine Department of Health and Human Services is notified in writing of the parental refusal within 5 days of the infant's birth.	**12.5** The information…is used to identify infants at risk of birth defects in order to develop programs to prevent and detect such defects. **12.6** Unless the person or his/her legal authorized representative ***specifically prohibits such use in writing***, the blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research…		

		place electronically. For purposes of quality assurance and improvement, the Child Development Services System shall supply to the department aggregate data at least annually on the number of children referred to the Child Development Services System under this section who are found eligible for early intervention services and on the number of children found not eligible for early intervention services. In addition, the department shall supply data at least annually to the Child Development Services System on how many children in the newborn blood spot screening program as established by rule of the department under section 1533, subsection 2, paragraph G were screened and how many were found to have a disorder…		**12.7** Filter paper specimens may be released for research or testing with identifiers intact with specific written request or consent of a parent/guardian; for anonymous research without consent as approved by the Department with input from the program advisory committee; or for program evaluation or planning without consent.		

MARYLAND

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
MD	STATUTE: M.C. Title 13, Subtitle 1. RULE: 10.52.12.00 to 10.52.12.12	**§ 13-111 Statewide system for screening newborns (a)** Establishment. – The Department shall establish a coordinated statewide system for screening all newborn infants in the State for certain hereditary and congenital disorders associated with severe problems of health or development, except when the parent or guardian of the newborn infant objects.	**§ 13-109. …(e) Minimum Standards - Restrictions on participation.-** The rules, regulations, and standards of the Department shall: **(1)** Require that, before an individual participates in a hereditary and congenital disorders program, the person who conducts the program shall inform the individual or, if the individual is a minor or disabled person, a parent or guardian of the person of the requirement that participation in the program be wholly voluntary and of any risk that is involved in participation;	**10.10.13.15 Test Specimens – Use, Research, Storage, and Retention.** **A. Use.** A permittee may use a newborn infant blood-spot from a newborn infant to test for only the conditions listed in Regulation .12C of this chapter.	YES	YES

Updated September 2013. 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.

		(b) Department of Public Health laboratory to perform tests. – Except as provided in § 13-112 of this subtitle, the Department's ***public health laboratory is the sole laboratory authorized to perform test*** on specimens from newborn infants collected to screen for hereditary and congenital disorders as determined under subsection (d)(2) of this section. *[emphasis added]*	**(2)** Prohibit the testing of an individual for a hereditary or congenital disorder unless the individual or, if the individual is a minor or disabled person, a parent or guardian of the person: **(i)** Is informed fully of the purpose of the test and the nature and consequences of being affected by a hereditary or congenital disorder or being a carrier of a hereditary disorder; **(ii)** Is given a reasonable opportunity to object, and **(iii)** Does not object to the test; and **(3)** Require unambiguous diagnostic results to be made available through a physician or other source of health care to the individual or, if the individual is a minor or disabled person, to a parent or guardian of the person.	**B. Research.** A researcher may not use a Maryland newborn infant's blood-spot or test results for research purposes unless the: (1) Research is approved in writing by the Department's: (a) Newborn screening Program; and (b) Institutional Review Board; and (2) The researcher acknowledges in writing that the researcher will return all untested blood-spots to the Department's public health laboratory within 6 months of completing the approved research. **C. Storage**. A permittee or researcher shall store a newborn infant blood-spot in a sealed, moisture-proof container at between 2 [degrees] and 23 [degrees] C.		

		10.52.12.03 Definitions. …(10 Hereditary Disorders. (a) "Hereditary disorder" means a disorder that: (i) Is transmissible through the genetic material deoxyribonucleic acid (DNA); or (ii) Arises through the improper processing of information in the genetic material. (b) "Hereditary disorder" includes: (i) Hemoglobin disorders; (ii) Metabolic disorders; and (iii) Endocrine disorders. (11) Metabolic disorder" means a disorder caused by a genetic alteration that results in a defect in the function of a specific enzyme, hormone, or protein, which can be detected by:	**(f) Minimum Standards - Program participation requirements and childbearing restrictions** *prohibited*.- The rules, regulations, and standards of the Department shall provide that a hereditary and congenital disorders program may not: **(1)** Require participation in the program; **(2)** Require restriction of childbearing; or **(3)** Be prerequisite for eligibility for any service or other program. **g) Minimum Standards - Protection of program participants.-** The rules, regulations, and standards of the Department shall provide that: **(1)** Each participant in a hereditary and congenital disorders program shall be:	**D. Retention.** A permittee shall: (1) Retain a newborn infant's: (a) Gel, produced when testing for hemoglobin disorders, for at least 90 days after testing is complete; and (b) Blood-spot for 25 years after the blood-sp0t is received for screening, supplemental, or diagnostic testing; and (Return to the State's public health laboratory all untested blood-spots received from the Department's public health laboratory for supplemental of diagnostic testing within 90 days after testing is completed by the permittee.		

		(a) Direct analysis of the enzyme, hormone, or protein; or (b) Testing for a substance whose metabolism is altered as a result of the defect. … **10.52.12.15 Records.** A. The screening of newborn infants pursuant to this chapter is a population based public health surveillance program. …	**(i)** Protected from undue physical or mental harm; and **(ii)** Informed of the nature, cost, benefits, and risks of any therapy or maintenance program available for an individual affected by a hereditary or congenital disorder; and **2)** Each participant in a screening program for a hereditary or congenital disorder shall have available counseling services that: **(i)** Are nondirective; **(ii)** Emphasize informing the individual; and **(iii)** Do not require restriction of childbearing.	**10.10.13.13 Screening Test Specimens – Collection and Test Requisition.** …*B. Blood-Spot Collection Test Requisition Card Information.* A person shall record the following information as specified on the Department-supplied blood-spot collection test requisition card: *(1) Newborn infant information,* including: (a) Name; (b) Date of birth; (c) Time of birth; (d) Current weight; (e) Gender; (f) Race; (g) Gestational age; (h) Birthing facility identification, including the: (i) Facility name; (ii) Facility street address, city, state, and zip code; and (iii) Newborn infant's medical record or chart number; (i) Date and time of first feeding; (j) Type of feeding, such as: (i) Breast; (ii) Lactose-containing formula; 0r (iii) Formula containing no		

		§13-102 Findings The General Assembly finds that: **(1)** Everyone in this State is entitled to the highest level of health care attainable and protection from inadequate health services; **(2)** Hereditary and congenital disorders are often costly and tragic and sometimes deadly burdens to the health and well-being of the citizens of this State; **(3)** Detection through screening for hereditary and congenital disorders can: (i) Lead to alleviation of the disability of some hereditary and congenital disorders; and	**10.52.12.06 Pre-Test Information**. Before a specimen is sent for newborn screening, a health care provider shall provide to the newborn infant's parent or guardian an explanation of newborn screening that includes: **A.** Reason for newborn screening, including the: **(1)** Purpose of the testing; and **(2)** Nature and consequences of being affected by a hereditary or congenital disorder or being a carrier of a hereditary or congenital disorder; and	lactose; (k) Transfusion history, including transfusion date and time; (l) General health status of the newborn infant; and (m) The total protein and calorie intake for any newborn infant in a neonatal intensive care setting*; (2) Blood-spot specimen information*, including: (a) Date of collection; (b) Time of collection; and (c) initials or other identifier of the individual who collected the specimen*; (3) Mother or guardian information*, including: (a) Name; (b) Street address, city, state and zip code; and (c) Telephone number where the mother or guardian may be reached; *(4) Information on the pediatrician or attending physician* who will be following the newborn infant, including the physician's: (a) Name; (b) Street address, city, state, and zip code; and (c)		

		(ii) Further the understanding of and accumulation of medical knowledge about other hereditary and congenital disorders that may lead to their eventual alleviation or cure; **(4)** Hereditary and congenital disorders differ in severity, in that: (i) Some have little effect on the normal functioning of an individual; and (ii) Some may be alleviated, wholly or partly, through medical intervention and treatment; **(5)** Most if not all, individual are carriers of some hereditary disorder and are substantially unaffected by that fact;	**B**. A parent or guardian's right to object to having the testing performed, including: **(1)** Stating that newborn screening is wholly voluntary; **(2)** Explaining any risk involved in having newborn screening performed; and **(3)** Providing a reasonable opportunity to object to screening. **10.52.12.07 Births in a Birthing Facility A.** Specimen Collection and Screening. If the parent or guardian of the newborn infant does not object to newborn screening, the individual in charge of a birthing facility or the individual's designated representative shall:	Telephone number; and *(5) Other information* that can affect the test results or the interpretation of the test results when applicable, such as that antibiotics were administered to the: (a) Mother; or (b) Newborn infant. **10.52.12.03 Definitions**. … **(20)** "Supplemental test" means a test performed on a specimen collected from a newborn infant that is: **(a)** Used to detect a hereditary or congenital disorder not specified in Regulation .05 of this chapter; or **(b)** Not required to be performed by the Department's public health laboratory under this chapter or COMAR 10.10.13.		

		(6) A carrier of a hereditary disorder should not be discriminated against or stigmatized; **(7)** Medical knowledge of the discovery, diagnosis, treatment, and cure of hereditary and congenital disorders is expanding rapidly and often at an uneven rate, so that hereditary and congenital disorders are discovered long before their treatment or cure can be found; **(8)** Legislation designed to alleviate the problems associated with specific hereditary and congenital disorders may tend to be inflexible in the face of rapidly expanding medical knowledge;	**(1)** Collect a blood specimen: **(a)** As set forth in: **(i)** §§C and D of this regulation; and **(ii)** COMAR 10.10.13.13; and **(b)** Pursuant to the procedures established in COMAR 10.10.13.14A; and **(2)** Submit the collected blood specimen to the Department's public health laboratory. **B. Parental Objection.** When a parent or guardian objects to newborn screening, the individual in charge of a birthing facility or the individual's designated representative shall: **(1)** Have the parent or guardian sign a form that states the parent or guardian objects to newborn screening; and	**10.52.12.05 Selection of Disorders for Screening.** **A.** The Department, with the advice of the Council, shall select the disorders for which screening is required by the Newborn Screening Program: … **C. Supplemental Tests.** The State's Newborn Screening Program may not request or perform a supplemental test until the public health laboratory has confirmed there is sufficient specimen to test for the required panel of disorders set forth in §B of this regulation.		

		(9) The policy of this State on hereditary and congenital disorders should be: (i) Made with full public knowledge, in light of expert opinion; and (ii) Reviewed constantly to consider changing medical knowledge and ensure full public protection; **(10)** Participation in a hereditary and congenital disorders program should be wholly voluntary, and all information obtained about any individual in a hereditary and congenital disorders program should be kept confidential; and **(11)** A commission is needed: (1) To ensure that the policies and programs of this State for hereditary and congenital disorders comply with the principles established in this subtitle; and	**(2)** Inform the Department's Follow-Up Unit by telephone, fax, or email of the objection within 12 hours after the objection. **10.52.12.08 Births Outside a Birthing Facility** …**A.** **(1)** Provide to a parent or guardian the information that a health care provider is required to provide to a parent or guardian under Regulation .06 of this chapter; **(2)** Have the parent or guardian sign a form that state the parent or guardian object to newborn screening if the parent or guardian objects; **(3)** Inform the Department's Follow-Up Unit by telephone, fax, or email of the objection within 12 hours after the objection; …			

		(ii) To preserve and protect the freedom, health, and well-being of the citizens of this State from improper treatment or advice, discrimination, violation of privacy, or undue anxiety that results from any hereditary and congenital disorders program. **§ 13-108. Advisory Council - Specific powers as to hereditary and congenital disorder.** To preserve and protect the health and welfare of the citizens of this State, the Advisory Council may:… **(4)** Advise the Secretary as to the need for rules, regulations, and standards for the detection and management of hereditary and congenital disorders…				

		§ 13-109. Advisory Council - Rules, regulations, and standards. **(a)** *In general.*- Subject to the requirements of this section, the Department may adopt rules, regulations, and standards for the detection and management of hereditary and congenital disorders. **(b)** *Consultations and consideration* **(1)** Before the Department adopts a rule, regulation, or standard, the Department shall consult: **(i)** The public, especially communities and groups who particularly are affected by hereditary and congenital disorders programs;				

		(ii) Where appropriate, experts in the medical, psychological, ethical, social, and economic effects of programs for the detection and management of hereditary and congenital disorders; and **(iii)** The Advisory Council… **c) Minimum standards - Access to information.** **(1)** The rules, regulations, and standards of the Department shall require the Department and each person who conducts a hereditary and congenital disorders program to keep in code and treat as a confidential medical record all information that is gathered in the program and identifies an individual.				

		However, this requirement does not prevent the disclosure of information if the individual or, if the individual is a minor or disabled person, a parent or guardian of the person: **(i)** Is informed of the scope of information to be released and the purpose of the release; and **(ii)** Consents to the release… **10.52.12.14 Counseling.** Upon request, the Department's Newborn Screening Follow-Up Unit shall make available to any parent or guardian of a newborn infant tested pursuant to this chapter, counseling services that: **A.** Are nondirective; **B.** Emphasize informing the parent or guardian; and **C**. Do not require the restriction of childbearing.				

MASSACHUSETTS

State	Statute/ Rule	Language Specific to Database	Exemption	Research Authority	Consent Required?	Dissent Authorized?
MA	STATUTE: Title XVI, Chapter 111, Sections 110A and 70G RULE: 105 CMR	**Chapter 111: Section 110A. Tests of newborn children for treatable disorders or diseases.** The physician attending a newborn child shall cause said child to be subjected to tests for phenylketonuria, cretinism and such other specifically treatable genetic or biochemical disorders or treatable infectious diseases which may be determined by testing as specified by the commissioner. The commissioner may convene an advisory committee on newborn screening to assist him in determining which tests are necessary. The department shall make such rules pertaining to such tests as accepted medical practice shall indicate…	**Section 110A.** …The provisions of this section shall not apply if the parents of such child object thereto on the grounds that such test conflicts with their religious tenets and practices.	**Chapter 111: Section 70G. Genetic information and reports protected as private information; prior written consent for genetic testing.** **a)**…For purposes of this section, ***the term genetic information shall <u>not</u> include*** any information about an identifiable person that is taken :…**(3)** as a newborn screening pursuant to section 110A:… *[emphasis added]* **(c)** No facility, as defined in section 70E, and no physician or health care provider shall: **(1)** test any person for genetic information without first obtaining the prior written consent;	NO	YES

Updated September 2013. 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.

		105 CMR 300.000 REPORTABLE DISEASES, SURVEILLANCE AND ISOLATION AND QUARANTINE REQUIREMENTS. …300.020: Definitions….Disease. An abnormal condition or functional impairment resulting from infection, metabolic abnormalities, physical or physiological injury or other cause, marked by subjective complaints, associated with a specific history, and clinical signs and symptoms, and/or laboratory or radiographic findings… **Illness.** An abnormal condition or functional impairment resulting from infection, metabolic abnormalities, physical or physiological injury or other cause, marketed by subjective complaints and clinical signs.		**(2)** disclose the results of a genetic test to any person other than the subject thereof without first obtaining the informed written consent except where the results disclosed will be used only as is confidential research information for use in epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease; or identify the person being tested to any other person without first obtaining informed written consent or upon proper judicial order.		

		105 CMR 300.191: Access to Medical Records and Other Information. (A) The Department and local boards of health are authorized to obtain, upon request, from health care providers and other persons subject to the provisions of 105 CMR 300.000 et seq., medical records and other information that the Department or the local board of health deems necessary to carry out its responsibilities to investigate, monitor, prevent and control diseases dangerous to the public health…		Organizations conducting pharmoco-economic studies in systematic research to determine the cost benefits of specific treatment for genetic based disease shall be exempted from the need to re-obtain informed written consent.		

MICHIGAN

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
MI	STATUTE: MI Public Health Code, Act 368 of 1978 RULE: "R325.1471 et seq. Michigan Administrative Code." (unable to find)	**Section 333.5431 Testing newborn infant for certain condition; reporting positive test results to parents, guardian, or person in loco parentis; compliance; fee; "Detroit consumer price index" defined; violation as misdemeanor; hardship waiver; conduct of department regarding blood specimens; pamphlet; additional blood specimen for future identification.** Sec. 5431. (1) A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant shall administer or cause to be administered to the infant a test for each of the following: (a) Phenylketonuria. (b) Galactosemia.	If parents object to NBS, they should be asked to sign a document that indicates that they have been informed of the risk to their newborn if screening is not done. Each hospital should develop its own document that meets the legal department's specifications. A sample form is included in Appendix 9.	**333.2611 Coordination of activities; establishment of policy; interests to be considered; establishment, purpose, and powers of nonprofit corporation.** **(1)** The department shall coordinate the health services research, evaluation, an demonstration and health statistical activities undertaken or supported by the department. **(2)** The department shall establish policy consistent with this part to administer health services research evaluation, an demonstration and health statistical activities undertaken or supported by the department. …	NO	YES

		(c) Hypothyroidism. (d) Maple syrup urine disease. (e) Biotinidase deficiency. (f) Sickle cell anemia. (g) Congenital adrenal hyperplasia. (h) Medium-chain acyl-coenzyme A dehydrogenase deficiency. (i) Other treatable but otherwise disabling conditions as designated by the department. (2) **The informed consent requirement of sections 17020 and 17520 do not apply** to the tests required under subsection (a)… (7) The department shall do all of the following in regard to the blood specimens taken for purposes of conducting the tests required under subsection (1). (a) By April 1, 2000, develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed. The schedule shall meet at least all of the following requirements:	A copy of the signed document should be forwarded to the NBS follow- up program. Parents whose only objection is that their child's specimen will be stored indefinitely by the state can choose to have the newborn screen done and then have the bloodspots destroyed by filling out the form Directive to Destroy Residual Newborn Screening Blood Specimen. See Appendix 11." (Source: "Newborn Screening Guide," Michigan Department of Community Health, July 2013, http://www.michigan.gov/documents/mdch/MI_NBS_Guide_368636_7.pdf, accessed 9/12/13)	**(3)** The department may establish a nonprofit corporation pursuant to the nonprofit corporation act, Act No. 162 of the Public Acts of 1982, begin sections 450.2101 to 450-3192 of the Michigan Compiled Laws. The purpose of the corporation shall be to plan, promote, and coordinate health services research with a public university or a consortium of public universities within the state. The corporation may research, evaluate, and demonstrate all of the following: (a) The cause, effects, extent, and nature of illness and disability among all or a particular group of the people of this state…		

		(i) Be consistent with nationally recognized standards for laboratory accreditation and federal law. (ii) Require that the disposal be conducted in compliance with section 13811. (iii) Require that the disposal be conducted in the presence of a witness. For the purposes of this subparagraph, the witness may be an individual involved in the disposal or any other individual. (iv) Require that a written record of the disposal be made and kept, and that the witness required under subparagraph (iii) signs the record. (b) Allow the blood specimens to be used for medical research during the retention period established under subdivision (a), as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of subchapter A of title 45 of the code of federal		"**Material Transfer Agreement** means a contract governing the transfer of tangible research materials between two organizations and recipient's intentions are for use in research purposes. The DCH has adopted the definitions, terms, and conditions for the Uniform Biological Material Transfer Agreement ("UMBTA") published in the Federal Register, vol, 60, March 8, 1995, page 12771 et seq. with the following exception. MDCH has added additional terms and conditions that apply only to the transfer of newborn screening specimens for research.		

		regulations. (8) The department shall rewrite its pamphlet…[which]…shall include at least all of the following information… (a) The nature and purpose of the testing program… (b) The purpose and value of the infant's parent, guardian, or person in loco parentis retaining a blood specimen obtained under subsection (9) in a safe place. (c) The department's schedule for retaining and disposing of blood specimens developed under subsection (7)(a).. (d) That the blood specimens taken for purposes of conducting the tests required under subsection (a) may be used for medical research pursuant to subsection (7)(b). (9) In addition to the requirements of subsection (1), the health professional described in subsection (1) or the hospital or other facility…may offer to draw an additional blood specimen		**Michigan BioTrust for Health** means the initiative by the DCH to make extra DBS from newborn screening more available for medical and public health research by storing these DBS in optimal conditions and promoting their availability to researchers. **BioTrust Scientific Advisory Board** means a board of scientist established consistent with the requirements of AD. Rule 325.9055 and appointed by the Director for participation on scientific advisory panels that review proposed research covered by this policy for scientific merit. **BioTrust Scientific**		

		from the infant….The health professional or hospital or other facility employee making the offer shall explain…that the additional blood specimen can be used for future identification purposes and should be kept in a safe place. **105 CMR 300.000 REPORTABLE DISEASES AND ISOLATION AND QUARANTINE REQUIREMENTS.** **…300.020:** **Definitions….Disease.** An abnormal condition or functional impairment resulting from infection, metabolic abnormalities, physical or physiological injury or other cause, marked by subjective complaints, associated with a specific history, and clinical signs and symptoms, and/or laboratory or radiographic findings… **Illness.** An abnormal condition or functional impairment resulting from infection,		**Review Panel** means a panel of at least three members selected from the BioTrust Scientific Advisory Board to review a specific research proposal." - "Policies for Research Use of Dried Blood Spots," POLICY AND PROCEDURE MANUAL, Department of Community Health, State of Michigan, November 19, 2010 – accessed August 17, 2012.		

		metabolic abnormalities, physical or physiological injury or other cause, marketed by subjective complaints and clinical signs. **105 CMR 300.191: Access to Medical Records and Other Information. (A)** The Department and local boards of health are authorized to obtain, upon request, from health care providers and other persons subject to the provisions of 105 CMR 300.000 et seq., medical records and other information that the Department or the local board of health deems necessary to carry out its responsibilities to investigate, monitor, prevent and control diseases dangerous to the public health…				

		R 325.9041 Chronic disease prevention and control list. Rule 1. In addition to the diseases listed in section 5411 of Act No. 368 of the Public Acts of 1978, as amended, being S333.5411 of the Michigan Compiled Laws, Alzheimer's disease and other chronic dementias are designated by the department as chronic diseases pursuant to the provisions of section 5439 of Act No. 368 of the Public Acts of 1978, as amended, being S333.5439 of				

		the Michigan Compiled Laws.				

MINNESOTA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
MN	STATUTE: M.S. 144.125 – 144.128 RULE: M.R. 4615	**144.125 TESTS OF INFANTS FOR HERITABLE AND CONGENITAL DISORDERS. Subdivision 1. Duty to perform testing.** It is the	**144.125. Subd. 3. Information provided to parents.** **(a)** The department shall make	**M.S. 144.125. Subd. 5. Newborn screening program operations**….(b) No research, public health studies, or development of new newborn screening tests shall be conducted under this subdivision.	YES	YES

		duty of **(1)** the administrative officer or other person in charge of each institution caring for infants 28 days or less of age, **(2)** the person required in pursuance of the provisions of section 144.215, to register the birth of a child, or **(3)** the nurse midwife or midwife in attendance at the birth, to arrange to have administered to every infant or child in its care tests for heritable and congenital disorders according to subdivision 2 and rules prescribed by the state commissioner of health. Testing and the recording and reporting of test results shall be performed at the times and in the manner prescribed by the commissioner of health. The commissioner shall charge a fee so that the total of fees	information and forms available to health care providers who provide prenatal care describing the newborn screening program and the provisions of this section to be used in a discussion with expectant parents and parents of newborns using electronic and other means. **(b)** Prior to collecting a sample, persons with a duty to perform testing under subdivision 1 must: **(1)** provide parents or legal guardians of infants with a document that	**Subd. 6. Standard retention period for samples and test results.** The standard retention period for blood samples with a negative test result is up to 71 days from the date of receipt of the sample. The standard retention period for blood samples with a positive test result is up to 24 months from the last date of reporting…During the standard retention period, the Department of Health may use blood samples and test results for newborn screening program operations in accordance with subdivision 5. **Subd. 7. Parental options for extended storage and use.** (a) The parent or legal guardian of an infant otherwise subject to testing under this section may authorize that the infant's blood sample and test results be retained and used by the Department of Health beyond the standard retention periods provided in subdivision 6 or the purposes described in subdivision 9. (b) The Department of Health must provide a consent form, with		

		collected will approximate the costs of conducting the tests and implementing and maintaining a system to follow-up infants with heritable or congenital disorders…	provides the following information: (i) the benefits of newborn screening; (ii) that the blood sample will be used to test for heritable and congenital disorders, as determined under subdivision 2;	an attached Tennessen warning pursuant to section 13.04, subdivision 2. The consent form must provide the following: (1) information as to the personal identification and use of samples and test results for studies, including studies used to develop new tests; (2) information as to the personal identification and use of samples and test results for public health studies or research not related to newborn screening;		
		144.128 COMMISSIONER'S DUTIES. The commissioner shall:… (a) **(3)** maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services; **(4)** prepare a separate form for use by parents or by adults who were tested as minors to direct	(iii) the data that will be collected as part of the testing; (iv) the standard retention periods for blood samples and test results as provided in subdivision 6; (v) that blood samples and test results will be	(3) information that explains that the Department of Health will not store a blood sample or test result for longer than 18 years from an infant's birth date; (4) information that explains that, upon approval by the Department of Health's Institutional Review Board, blood samples and test results may be shared with external parties for public health studies or research; (5) information that explains that blood samples contain various components, including		

		that blood samples and test results be destroyed; **(5)** comply with a destruction request as described in section 144.125; **(6)** notify individuals who request destruction of samples and test results that the samples and test results have been destroyed and the date of destruction; and .. **(**b) Nothing in section 144.125 to 144.128 shall exempt the commissioner from the requirement of the genetic privacy act in section 13.386 or from the penalties for violation of the geneti privacy act as provided in chapter 13. **4615.0750 PURPOSE AND SCOPE.** The purpose and scope of parts 4615.0750 to 4615.0760 is	used for program operations during the standard retention period in accordance with subdivision 5; (vi) the Department of Health's Web site address where more information and forms may be obtained; and (vii) that ***parents have a right to elect not to have newborn screening performed and a right to secure private testing;*** **(2)** upon request, provide parents or legal guardians of infants with	deoxyribonucleic acid (DNA); and (6) the benefits and risks associated with the department's storage of a child's blood sample and test results. **Subd. 8. Extended storage and use of samples and test results.** When authorized in writing by a parent or legal guardian under subdivision 7, the Department of Health may store blood samples and test results for a time period not to exceed 18 years from the infant's birth date, and may use the blood samples and test results in accordance with subdivision 9. **Subd. 9. Written informed consent for other use of samples and test results.** With the written, informed consent of a parent or legal guardian, the Department of Health may: (1) use blood samples and test results for studies related to newborn screening, including studies used to develop new tests; and (2) use blood samples and test results for public health studies or		

		to describe the responsibilities of the Minnesota Department of Health to assure that persons diagnosed as having hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia will: **(1)** have access to approved laboratory treatment control tests when available; **(2)** have necessary financial assistance for treatment of diagnosed cases when indicated; and **(3)** be included in a registry of cases for the purpose of coordinating follow-up	forms necessary to request the infant not have blood collected for testing; and (3) record in the infant's medical record that a parent or legal guardian of the infant has received the information provided pursuant to this subdivision and has had an opportunity to ask questions.	research not related to newborn screening, and upon approval by the Department of Health's Institutional Review Board, share samples and test results with external parties for public health studies or research. Subd. 10. **Revoking consent for storage and use.** A parent or legal guardian may revoke approval for extended storage or use of blood samples or test results at any time by providing a signed and dated form requesting destruction of the blood samples or test results. The Department of Health shall make necessary forms available on the department's Web site. Blood samples must be destroyed within one week of receipt of a request or within one week of the standard retention period for blood samples		

		services. **4615.0755 DEFINITIONS.** **Subp. 8. Registry.** "Registry" means a permanent record maintained by the department on each patient diagnosed by a physician and reported to the department as having hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia. **4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.** … **Subp. 4. Registry of cases.** The department shall maintain a registry of all diagnosed cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal	(c)Nothing in this section prohibits a parent or legal guardian of an infant from having newborn screening performed by a private entity. **Subd. 4. Parental options.** (a) The parent or legal guardian of an infant otherwise subject to testing under this section may elect not to have newborn screening performed.	provided in subdivision 6, whichever is later. Test results must be destroyed within one month of receipt of a request or within one month of the standard retention period for test results provided in subdivision 6, whichever is later. **13.386** Subd. 3. **Collection, storage, use, and dissemination of genetic information.** Unless otherwise expressly provided by law, genetic information about an individual: **(1)** may be collected by a government entity, as defined in section 13.02, subdivision 7a, or any other person only with the written informed consent of the individual; **(2)** may be used only for purposes to which the individual has given written informed		

		hyperplasia reported to the department. The registry shall be updated not more often than annually by direct contact with the patient to determine their address and their need for medical treatment services, educational materials, and counseling related to their metabolic disease. The registry shall include the following minimum data on each patient: **A.** name of patient; **B.** gender; **C.** date of birth; **D.** place of birth; **E.** parents' names; **F.** current address of patient; **G.** diagnosis; **H.** name and address of physician; and **I.** other data the commissioner deems necessary for follow-up	(b) If a parent or legal guardian elects not to have newborn screening performed, then the election shall be recorded on a form that is signed by the parent or legal guardian…A written election to decline testing exempts persons with a duty to perform testing and the Department of Health from the requirements of this section and section 144.128.	consent; **(3)** may be stored only for a period of time to which the individual has given written informed consent; and **(4)** may be disseminated only: **(i)** with the individual's written informed consent… Consent to disseminate genetic information under item (i) must be signed and dated.		

		services.				

MISSISSIPPI

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
MS	STATUTE: Title 41, Chapter 21 RULE: Title 15, Part IV, Subpart 01,	**§ 41-21-201. Newborn screening program.** **(1)** The State Department of Health shall establish, maintain and carry out a comprehensive newborn screening program designed to detect hypothyroidism, phenylketonuria (PKU), hemoglobinopathy, congenital adrenal hyperplasia (CAH), galactosemia, and such other conditions as specified by the State Board of Health and as	**§ 41-21-203 Testing of newborn children for certain conditions. (1):** All newborn	**Chapter 38, Section IV…41 Laboratory Requirements: 41.07 Record Retention:** Records of standardization,	NO	YES

	Chapter 38	recommended by the American Academy of Pediatrics. The State Board of Health shall adopt any rules and regulations necessary to accomplish the program. **(2)** The State Board of Health shall determine and specify the conditions that will be included in the comprehensive newborn screening program in addition to those conditions named in subsection (1) of this section, upon the advice and recommendations of a genetics advisory committee and in accordance with the recommendations of the American Academy of Pediatrics. The advisory committee shall be appointed by the Executive Director of the State Department of Health, and shall include at least two (2) pediatricians and one (1) consumer representative from a family that has experience with a newborn infant with an abnormal screening test. The State Department of Health shall maintain a list of each of the conditions included in the comprehensive newborn screening program, which shall be made available to physicians and other health care providers who are required to provide for newborn screening testing under Section 41-21-203. **(3)** The State Department of Health shall develop information materials about newborn screening tests that are available, which may be used by physicians and other health care providers to inform	infants shall be screened… However, no such tests shall be given to any child whose parents object thereto on the grounds that the test conflicts with his religious practices or tenets.	quality control, and patient values must be kept for at least two years. It is advisable for laboratories to retain these records until the statute of limitations regarding medical malpractice actions expires as stipulated by Mississippi state law. **41.08 Specimen Retention:** Specimen must be retained for at least 365 days. ***Under no circumstances will the retained specimen be used for research or purposes other***		

		pregnant women and parents. **§ 41-21-203. Testing of newborn children for certain conditions.** **(1)** All newborn infants shall be screened by the physician or other health care provider attending the infant, using tests that have been approved by the State Board of Health, to detect those conditions listed in Section 41-21-201 and the other conditions specified by the State Board of Health for the comprehensive newborn screening program….The tests provided under the comprehensive newborn screening program shall be evaluated in laboratories located in the United States. The State Department of Health shall follow up all positive tests with the attending physician or other health care provider who notified the department thereof, and with the parents of the newborn child. The services and facilities of the State Department of Health and those of other state boards, departments and agencies cooperating with the State Department of Health in carrying out the comprehensive newborn screening program shall be made available to all newborn infants with abnormal screening tests. **(2)** The State Department of Health shall provide ongoing epidemiologic surveillance of the comprehensive newborn screening program to determine the efficacy and cost effectiveness of screening newborn infants.		***than confirmation of previous test results.*** *[emphasis added]*		

MISSOURI

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
MO	STATUTE: M.R.S. Title XII, Chapter 191 RULE:	**Genetics program to be established by department--rules authorized--procedure. 191.315. 1.** The department is hereby designated as administrator of a	**191.331. 4.** The provisions of this section shall not apply if the parents of such child object to the tests or examinations provided in this section on the grounds that such tests or examinations conflict with their religious tenets	**191.323**. The department may… **(3)** Conduct or support scientific research concerning the	NO	YES

Updated September 2013. 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.

	Title 19, Division 25,	comprehensive genetics program which will provide genetic diagnosis, counseling, treatment, education and research… **Genetic diagnostic and counseling services to be established --outreach centers, duties--referral for abortion, procedure, requirements.** **191.320**. The department may contract with tertiary genetic centers to … initiate and conduct investigations of the causes, mortality, methods of treatment, prevention and cure of genetic disorders and related birth defects. **Powers and duties of department of health and senior services in prevention and treatment of genetic diseases and birth defects.** **191.323.** The department may:…**(4)** Maintain a central registry to collect and store data to facilitate	and practices. **5.** As provided in subsection 4 of this section, the parents of any child who fail to have such test or examination administered after notice of the requirement for such test or examination shall be required to document in writing such refusal. All physicians, certified nurse midwives, public health nurses and administrators of ambulatory surgical centers or hospitals shall provide to the parents or guardians a written packet of educational information developed and supplied by the department of health and senior services describing the type of specimen, how it is obtained, the nature of diseases being screened, and the consequences of treatment and nontreatment. The attending physician, certified nurse midwife, public health facility, ambulatory surgical center or hospital shall obtain the written refusal and make such refusal part of the medical record of the infant. **25-36.010 Testing for Metabolic and Disorders**…**(4)** Parents who	causes, mortality, methods of treatment, prevention and cure of genetic diseases which are considered to be of major importance to the problems of genetic disease and birth defects in Missouri, in cooperation with other public and private agencies, except as provided in section 188.037, RSMo; **191.331…. 9.** The department shall have authority over the use, retention, and disposal of biological specimens and all related information collected in		

		the compiling of statistical information on the causes, treatment, prevention and cure of genetic diseases. Identifying information shall remain confidential pursuant to the provisions of section 191.315. Information will be reported to the Missouri board of health and other health care agencies so that it may be used for the prevention and treatment of genetic diseases and birth defects;…	object to testing on religious grounds shall state those objections in writing. The written objection shall be filed with the attending physician, certified nurse midwife, public health facility, ambulatory surgical center or hospital. Upon receipt, the attending physician, certified nurse midwife, public health facility, ambulatory surgical center or hospital shall send a copy of the written objection to the Department of Health and Senior Services, Bureau of Genetics and Healthy Childhood, PO Box 570, Jefferson City, MO 65102-0570	connection with newborn screening tests conducted under subsection 1 of this section. The use of such specimens and related information shall only be made for public health purposes and shall comply with all applicable provisions of federal law. The department may charge a reasonable fee for the use of such specimens for public health research and preparing and supplying specimens for research proposals approved by the department.		
		Infants to be tested for metabolic and genetic diseases--reports -- exceptions--refusal to test--fee for screening test, department may impose by rule, use of fees--formula provided by department, when--assistance available, when. **191.331. 1.** Every infant who is born in this state shall be tested for phenylketonuria and such	**191.317 1.** All testing results and personal information obtained from any individual, or from specimens from any individual, shall be held confidential and be considered a confidential medical record, except for such information as the individual, parent or guardian consents to be released; but the individual must first be fully informed of the scope of the information requests to be released, of the risks, benefits and purposes for such			

		other metabolic or genetic diseases as are prescribed by the department. The test used by the department shall be dictated by accepted medical practice and such tests shall be of the types approved by the department. All newborn screening tests required by the department shall be performed by the department of health and senior services laboratories…	release, and of the identity of those to whom the information will be released. Statistical data compiled without reference to the identity of any individual shall not be declared confidential. Notwithstanding any other provision of law to the contrary the department may release the results of newborn screening tests to a child's health care professional.			
		2. All physicians, certified nurse midwives, public health nurses and administrators of ambulatory surgical centers or hospitals shall report to the department all diagnosed cases of phenylketonuria and other metabolic or genetic diseases as designated by the department. The department shall prescribe and furnish all necessary	**191.317. …2** … At the time of collection, the parent or legal guardian of the child from whom a biological specimen was obtained may direct the department to: **(1)** Return a biological specimen that remains after all screening tests have been performed; **(2)** Destroy a biological specimen in a scientifically acceptable manner after all screening tests required under section 191.331 or rule promulgated thereunder have	**191.317** 2**.** The specimen shall be retained for five years after initial submission to the department. After five years, the specimen shall be destroyed. Unless otherwise directed under this section, a biological specimen may be		

		reporting forms…	been performed; or **(3)** Store a biological specimen but not release the biological specimen for anonymous scientific study.	released for purposes of anonymous scientific study… **3**. A biological specimen released for anonymous study under this section shall not contain information that may be used to determine the identity of the donor.		

MONTANA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption Language	Research Authority	Consent Required?	Dissent Allowed?
MT	STATUTE: M.C.A Title 50 RULE: A.R.M. 37.57.301 to 321	**50-19-203. Newborn screening and follow-up for metabolic and genetic disorders. (1)** A person in charge of a facility in which a child is born or a facility in which a newborn is provided care or a person responsible for the registration of the birth of a newborn shall ensure that each newborn is administered tests designed to detect inborn metabolic and genetic disorders as required under rules adopted by the department. **(2)** The tests must be done by an approved laboratory. An approved laboratory must be the laboratory of the	NONE FOUND "There is no provision in the A.R.M. that allow parents to refuse mandatory	NOT FOUND	NO	NO

		department or a laboratory approved by the department. **(3)** The department shall contract with one or more providers qualified to provide follow-up services, including counseling and education, for children and parents of children identified with metabolic or genetic disorders to ensure the availability of follow-up services. **50-19-211. Statewide genetics program established. (1)** A combined, comprehensive statewide genetics program is established in the department… *FROM: "State Title V Block Grant Narrative, State: Montana. Application Year: 2009," (https://perfdata.hrsa.gov/mchb/mchreports/documents/2009/Narratives/MT-Narratives.htm)*: "Hearing and mandated genetic screening also occur for the majority of Montana's children, regardless of whether they are Medicaid enrollees or not. Efforts to increase the percent of infants screened are ongoing through the development of new partnerships, support of current relationships and exploration of new legislation or guidelines to support screenings…" "Montana's "heel-stick" newborn screening follow up has been	newborn screening. In statute (M.C.A. Title 50 Chapter 19), "A person in charge of a facility wherein a child is born or wherein a newborn infant is cared for or a person responsible for the registration of birth of an infant shall ensure each infant is administered tests designed to detect inborn metabolic errors as shall be required to be administered under rules adopted by the department."			

		housed in the FCHB since 1995 and is a part of the MCHDM section. Follow up efforts continue to be a partnership between medical providers and hospitals, the public health laboratory, parents, the FCHB and the CSHCN program. Montana presently screens for four department-required blood tests for PKU, galactosemia, congenital hypothyroidism, and hemoglobinopathies. Interest in adding additional tests has been expressed by the medical community, but in light of fiscal constraints and resistance to increases in existing lab charges, no additional lab screenings have been mandated in the last few years. Montana is monitoring national efforts to recommend additional screening tests in the future. At present, our state lab, which conducts newborn screening for the state, lacks mass spectrometry equipment, which will be necessary for inclusion of some of the additional tests. The lab presently works with out of state labs to facilitate provider requests for additional testing."	FROM: "Montana Dept. of Public Health and Human Services "Newborn Screening Guide to Test Collection"			

NEBRASKA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
NE	STATUTE: NRS Chapter 71, Sections 71-519 to 524 NRS Title 181,	**Section 71-519. Screening test; duties; disease management; duties; fees authorized; immunity from liability**. (1) All infants born in the State of Nebraska shall be screened for phenylketonuria, primary	**NO** **71-524. Enforcement; procedure.** In addition to any other remedies which may be available by law, a civil	**Section 71-522. Central data registry; department; duties; use of data.** ...The department shall also use reported data to evaluate the quality of the statewide system of newborn screening and develop procedures for quality assurance. Reported data in anonymous or statistical form may be made available by the department for	NO	NO

	Chapter 2 NAC Title 181, Chapter 5 (exempt from genetic privacy law)	hypothyroidism, biotinidase deficiency, galactosemia, hemoglobinopathies, medium-chain acyl co-a dehydrogenase (MCAD) deficiency and such other metabolic diseases as the Department of Health and Human Services may from time to time specify. **71-521. Tests and reports; department; duties.** The Department of Health and Human Services shall prescribe the tests, the test methods and techniques, and such reports and reporting procedures as are necessary to implement sections 71-519 to 71-524. **71-522**. **Central data registry; department;**	proceeding to enforce section 71-519 may be brought in the district court of the county where the infant is domiciled or found. The attending physician, the hospital or other birthing facility, the Attorney General, or the county attorney of the county where the infant is domiciled or found may institute such proceedings as are necessary to enforce such section. It shall be the duty of the Attorney General or the county	purposes of research. **71-519. (c)** The department shall adopt and promulgate rules and regulations relating to the use of such specimens and related information. Such use shall only be made for public health purposes and shall comply with all applicable provisions of federal law. The department may charge a reasonable fee for evaluating proposals relating to the use of such specimens for public health research and for preparing and supplying specimens for research proposals approved by the department. **2-007.08A Use of Residual Dried Blood**		

		duties; use of data. The Department of Health and Human Services shall establish and maintain a central data registry for the collection and storage of reported data concerning metabolic diseases. The department shall use reported data to ensure that all infants born in the State of Nebraska are tested for diseases set forth in section 71-519 or by rule and regulation… **71-519. (4)(a)** The department shall have authority over the use, retention, and disposal of blood specimens and all related information collected in connection with metabolic disease testing conducted under subsection (1) of this section. **(b)** The department shall adopt and promulgate rules and regulations relating to the retention and disposal of such specimens…	attorney to whom the Department of Health and Human Services reports a violation to cause appropriate proceedings to be initiated without delay. A hearing on any action brought pursuant to this section shall be held within seventy-two hours of the filing of such action, and a decision shall be rendered by the court within twenty-four hours of the close of the hearing. **Title 181**	**Spots**: Residual dried blood spots may be used for public health research only when: **1.** The Chief Medical Officer and the Newborn Screening Advisory Committee or its proxy sub-committee have reviewed and approved the application for research containing but not limited to the following information: **a.** The full report of the review and approval of the research by a Human Subjects Review or Institutional Review Board; **b.** The qualifications of the applicant and of the principal investigator, if other than the applicant, including education, experience, prior publications, and recommendations of professional colleagues who have knowledge and experience of scientific or medical research; **c.** The purpose of the research project, a summary of the project, and the anticipated time of completion of the project; **d.** The location where the research project will be conducted and the equipment, personnel, and other resources available to		

		2-007.02F. Blood Spot Storage, Use and Disposal Records: The testing laboratory must maintain for 25 years an index or catalog of the residual dried blood spots processed in the laboratory that includes the following information: **1.** The serial number or unique identifier of each specimen processed; **2.** The test results of each specimen processed; **3.** Verification of disposal of specimens not released for research or diagnostic purposes. This information may be batched by test completion date so long as each serial	**SPECIAL HEALTH PROGRAMS, CHAPTER 5 CONSENT FOR PREDICTIVE GENETIC TESTING** **5-003.03** Required newborn screening tests are exempted from the requirement for written informed consent, but the attending physician must inform the parent about the required tests.	the applicant to carry out the project; **e.** The identity of the individual or entity funding the research project, a description of the availability of funds for the research project, and any conditions on the receipt or continuation of the funding; **f.** The specific data or biological sample information requested and a description of the use to be made of it and, if subject-identifying data is requested, a substantiation of the need for access to the subject-identifying data; **g.** A description of the measures to be taken to secure the data and biological sample information and to maintain the confidentiality of such during the research project, for disposal of the data and biological sample upon completion of the study, and to assure that the results of the study will not divulge or make public, information that will disclose the identity of any individual subject; **h.** A description of the process that will be used for obtaining written consent from the legally responsible parent or guardian of the individuals whose specimens will be		

		number or unique identifier can be linked with its test completion date; **4.** Date of disposal; **5.** Location of disposal if other than the laboratory; **6.** For specimens released for research, documentation as required at 181 NAC 2-007.08; and **7.** Signature of the person who released, disposed of, or witnessed the disposal of the specimen; or for specimens disposed of by a contractor, written evidence that the contract for disposal of residual dried blood spots requires disposal be done in accordance with 181 NAC 2-007.02F, 3, 4, and 5.		requested; **i** If contact with a subject or subject's parent or legal guardian is planned or expected beyond obtaining consent as required under 181 NAC 2-007.08A1h, substantiation of the need for the contact and a description of the method to be used to obtain permission from the subject or subject's parent or legal guardian for the contact; and; **j.** Such additional information as the Department determines to be necessary to assure that release of data to the applicant is appropriate and consistent with these regulations, Title 181 NAC 2. **2.** For every specimen released for research, with or without patient identifying information, the laboratory must document: **a.** Who had access to the specimen; **b.** To whom the specimen was released; **c.** The amount of specimen released; and **d.** Evidence from the research entity that written consents were obtained from the legally responsible parent or guardian of the individuals whose specimens were released.		

		2-07.07 Storage of Residual Dried Blood Spots: The testing laboratory must store the residual dried blood spots for 90 days. Specimens must be refrigerated in sealed bags of low gas permeability. **2-007.10 Disposal of Residual Dried Blood Spots:** Residual dried blood spots not released under 181 NAC 2-007.08 must be disposed of within 30 days of the end of the 90-day storage time. Destruction of the specimens, by incineration, by autoclaving and shredding, or by some other reasonable and prudent means, must ensure that identifying		**3.** The blood spot is not released for public health research until after the 90-day storage time. During the 90-day storage time, it must be available for clinical purposes for the patient. **4.** Records required at 181 NAC 2-007.08A, items 1 and 2, must be retained for ***25 years.*** 2-**007.08C Residual dried blood spots may be used for public health purposes as follows**. 1. They may be used for quality assurance and improvement of newborn screening practices subject to the following: **a.** Only dried blood spots deemed unsatisfactory for testing may be released to the submitting hospital to use as examples of poor specimen quality; **b**. The filter paper portion of the CARE form containing the dried blood spots must be detached from the written patient		

		information cannot be linked to the residual dried blood spots.		identification part of the form prior to release; **c.** The bar code and filter paper serial number linking the dried blood spot to the patient identification information must be removed from the residual dried blood spot prior to release; and **d.** Requests for return of unsatisfactory specimens must be made by the submitting facility through the NNSP. 2. They may be used for other public health purposes when: **a.** The Chief Medical Officer has determined there is a valid public health purpose; **b..** The Chief Medical Officer has informed the Newborn Screening Advisory Committee about the public health use of the residual dried blood spots; **c.** Patient information linking the specimen to the patient will be protected; **d..** There are assurances that all applicable provisions of federal law will be complied with; and		

				e. The blood spot is not released or used for the public health purpose until after the 90-day storage time. During the 90-day storage time it must be available for clinical or identification purposes for the patient, unless a public health emergency is declared.		

NEVADA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
NV	STATUTE: Title 40, Chapter 442 RULE: NAC Chapter 442	**NRS 442.008 Examination of infants: Regulations; duties of physician, midwife, nurse, obstetric center or hospital; exemption.** **1.** The State Board of Health, upon the recommendation of the State Health Officer, shall adopt regulations governing examinations and tests required for the discovery in infants of preventable or	**YES** **NRS 442.008.** …**4.** An infant is exempt from examination and testing if either parent files a written objection with the person or	*Unclear* **NRS 439.240 State Hygienic Laboratory.** **1.** The University of Nevada School of Medicine shall maintain	NO	YES

		inheritable disorders, including tests for the presence of sickle cell anemia. **2.** Any physician, midwife, nurse, obstetric center or hospital of any nature attending or assisting in any way any infant, or the mother of any infant, at childbirth shall make or cause to be made an examination of the infant, including standard tests, to the extent required by regulations of the State Board of Health as is necessary for the discovery of conditions indicating such disorders. **3.** If the examination and tests reveal the existence of such conditions in an infant, the physician, midwife, nurse, obstetric center or hospital attending or assisting at the birth of the infant shall immediately: **(a)** Report the condition to the State Health Officer or his representative, the local health officer of the county or city within which the infant or the mother of the infant resides, and the local health officer of the county or city in which the child is born; and **(b)** Discuss the condition with the parent, parents or other persons responsible for the care of the infant and	institution responsible for making the examination or tests. *[NOTE: The RULE does not mention exemption or a process to follow for objecting parents.]*	the State Public Health Laboratory, and may establish or maintain such branch laboratories as may be necessary. **2.** The purpose of the State Public Health Laboratory is: **(a)** To make available, at such charges as may be established, to health officials, the State Dairy Commission and licensed physicians of the State, proper laboratory facilities for the prompt diagnosis of communicable diseases.		

		inform them of the treatment necessary for the amelioration of the condition. **NAC 442.030 Taking of blood sample required. (**NRS 442.008**)** **1.** Except as otherwise provided in NAC 442.035, every hospital or obstetric center in which an infant is born must take an appropriate blood sample from the infant before he is discharged from the hospital or obstetric center. The sample must be taken not later than the seventh day of the infant's life regardless of the feeding status of the infant. If an infant is discharged before he is 48 hours of age, the hospital or obstetric center must take an appropriate blood sample as close as possible to the time of the infant's discharge from the hospital or		**(b)** To make necessary examinations and analyses of water, natural ice, sewage, milk, food and clinical material. ***(c) To conduct research into the nature, cause, diagnosis and control of diseases.*** **(d)** To undertake such other technical and laboratory duties as are in the interest of the health of the general public. **3.** The person in charge of the State Public Health Laboratory, or his designee, must be a skilled		

		obstetric center. **2.** The sample must be placed in a kit supplied by the Health Division and must be mailed to the address indicated on the kit within 24 hours after the sample is taken. **3.** If an infant is not born in a hospital or obstetric center, the person who is legally responsible for registering the birth of the child must have a physician, hospital, public health nurse or the ***State Hygienic Laboratory*** take the first blood sample between the 3rd and 7th day and the second blood sample between the 15th and 56th day of the infant's life. *[emphasis added]*		bacteriologist. **4.** The person in charge of the State Public Health Laboratory may have such technical assistants as that person, in cooperation with the University of Nevada School of Medicine, considers necessary. **5.** Reports of investigations conducted at the State Public Health Laboratory may be published from time to time in bulletins and circulars. *[emphasis added]*		

NEW HAMPSHIRE

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed ?
NH	STATUTE: Title X, Chapter 132:10-a to c RULE: Chapter He-P	**132:10-a Newborn Screening Tests Required; Newborn Screening Advisory Committee. –** **I.** The physician, hospital, nurse midwife,	**132:10-c Exception. –** The provisions of RSA 132:10-a and 10-b shall not apply if the parents of such child object thereto. **He-P 3008.03 Definitions.** …**(e)** "Dried blood spot (DBS)"	**132:10-a. III-a.** The department shall ensure that the laboratory analyzing tests authorized under paragraph I	NO	YES

Updated September 2013. 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.

	3000	midwife, or other health care provider attending a newborn child shall test a newborn child for metabolic disorders. Such tests shall include, but not be limited to, phenylketonuria, galactosemia, homocystinuria, maple syrup urine disease, and hypothyroidism. Additional disorders shall be added to the newborn screening panel based upon, but not limited to, the following considerations: **(a)** The disorder is well-defined with a known incidence. **(b)** The disorder is associated with significant morbidity and/or mortality. **(c)** The disorder can be detected with a screening test that is ethical, safe, accurate, and cost-effective. **(d)** Effective treatment exists for the disorder, and that early treatment,	means a specimen of blood obtained from an infant through the heel stick procedure, which is then applied to a filter paper and dried… **(j)** "Informed dissent" means the written refusal by an infant's parent or guardian to participate in newborn screening as defined in this rule. **(k)** "Laboratory" means the testing facility authorized by the state of New Hampshire to conduct DBS testing on its behalf…. **(n)** "Newborn screening program (NSP)" means the department program, which has responsibility for managing all aspects of infant screening pursuant to RSA 132:10-a. **He-P 3008.04 Newborn Screening.** **(a)** Newborn screening shall be required for all infants born in the state of New Hampshire, in accordance with RSA 132:10-a,	destroys any samples no later than 6 months following the completion of testing. Any samples taken for newborn screening shall only be used for tests require under this section. No such samples may be used for other research or DNA testing purposes unless authorized by the parent or guardian. **He-P 3008.11 Requests for DBS or Related Records**. Residual DBS and related records may be retrieved for other purposes		

		meaning before the onset of symptoms, is more effective in improving health outcomes than later treatment… **III.** The department of health and human services shall establish a newborn screening advisory committee which shall include a member of the oversight committee on health and human services, established in RSA 126-A:13, and representation from health care subspecialties, as determined by the	unless the parent(s) or guardian(s) object. **(c)** If the infant's parent or guardian objects to the performance of DBS testing, he or she shall provide ***informed dissent*** to the infant's healthcare provider or designee, subject to the following: *[emphasis added]* **(1)** A statement of dissent for testing shall be signed and dated by the infant's parent or guardian; **(2)** The statement of dissent shall be included in the infant's medical record; **(3)** The infant's healthcare provider or designee shall submit a copy of the statement of dissent to the NSP; and **(4)** A copy of the statement of dissent shall be provided to the parent or guardian. **(d)** Newborn screening tests shall be conducted as follows: **(1)** The DBS shall be collected from the infant through the heel stick procedure and applied to the	only with the written authorization of the parent-or guardian.		

		department. **He-P 3008.18 Quality Assurance**. … **(e)** The NSP [Newborn Screening Program]…shall compare the data sets of infants screened with New Hampshire birth certificate files…	filter paper obtained from the NSP; and **(2)** If the newborn screening tests are performed by a laboratory other than that used by the NSP, the infant's healthcare provider shall request all tests required by the NSP and provide a copy of these test results to the NSP.			
		He-P 3008.10 Disposal of DBS Residual. **(a)** The testing laboratory shall store DBS specimens in sealed bags of low gas permeability containing a desiccant and humidity indicator at –20 degrees Celsius. **(b)** The testing laboratory shall destroy DBS specimens six months after	**He-P 3008.18 Quality Assurance**. …**(c)** The NSP shall provide upon request: **(1)** Information regarding acceptable procedures for the collection, handling, short-term storage and transport of a DBS; **(2)** Information regarding newborn screening that shall be given to and reviewed with the parent or guardian of each infant prior to testing; and			

		the collection date, in a manner consistent with applicable federal requirements relating to the disposal of human blood and body fluids per OSHA regulations 29 CFR 1910.1030. **(c)** If the storage environment of any DBS is found to have deviated from the required conditions described in (a) above, such that the stability of the specimen is likely to have been affected, the testing laboratory shall first notify the NSP and shall then destroy the DBS specimen.	**(3)** Text to be used in statements of dissent…			

		He-P 3008.11 Requests for DBS or Related Records. Residual DBS specimens and related records may be retrieved for other purposes only with the written authorization of a parent or guardian.				

NEW JERSEY

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
NJ	STATUTE: NJPS, Title 26, Chapter 2 RULE: NJAC Title	**26:2-111. Testing of infants for biochemical disorders.** All infants born in this State shall be tested for hypothyroidism, galactosemia and phenylketonuria. The Commissioner of Health shall issue regulations to assure that newborns are so tested in a manner	**26:2-111. …**The provisions of this section shall not apply if the parents of a newborn infant object to the	**§ 8:18-1.14 Provision of notice of availability of supplemental newborn screening; Acknowledgement; retention**	NO	YES

	8, Chapter 18, Subchapter 1	approved by the commissioner. The commissioner shall ensure that treatment services are available to all identified individuals…The commissioner may also require testing of newborn infants for other preventable biochemical disorders if reliable and efficient testing techniques are available. If the commissioner determines that an additional test shall be required, 90 days prior to requiring the test he shall advise the President of the Senate, Speaker of the General Assembly and chairmen of the standing reference committees on Revenue, Finance and Appropriations and Institutions, Health and Welfare of his determination. ***The commissioner shall provide a program of reviewing and following up on positive cases*** in order that measures may be taken to prevent mental retardation or other permanent disabilities. Information on newborn infants and their families compiled pursuant to this section may be used by the department and agencies designated by the commissioner for the purposes of carrying out this act, but otherwise the information shall be confidential and not divulged or made public so as to disclose	testing on the grounds that it would conflict with their religious tenets or practices. **26:2-111.1**. **Option of additional screening for disorders in infants required; cost.** …**(2)**A health care provider shall give an infant's parent or guardian a hard copy of the	**(a)** A health care provider who provides care to an expectant parent or to a newborn infant shall, as applicable with respect to the expectant parent or the parent of the newborn (hereinafter both referred to as the "parent"): **1.** Provide the Notice to the parent; **2.** Provide the parent with a reasonable opportunity to read the Notice; **3.** Make reasonable efforts to ensure that the parent understands the information provided in the		

		the identity of any person to which it relates, except as provided by law... *[emphasis added]* **§ 8:18-1.4. Responsibilities of the chief executive officer** …**22.** Cause the development and implementation of written policies and procedures, to be reviewed by the Department and revised as required, for the timely processing of supplemental newborn screening specimen collection test kits in accordance with directions contained in the kits if a parent timely provides such a kit to the health care facility of which the chief executive officer is in charge. **1.** At minimum, the policies and procedures required pursuant to (a)22 above shall address memorializing the time and date of receipt of test kits from parents, obtaining parents' informed consent to the collection of specimens in accordance with the instructions in the test kit, and ensuring that appropriate personnel execute or arrange for the execution of such forms and collect or arrange for the collection of such specimens, and	information prepared pursuant to paragraph (1) of this subsection and provide the parent or guardian with a reasonable opportunity to read the information when giving the parent or guardian the option of consenting to the performance of testing pursuant to subsection a. of this section. **§ 8:18-1.12. Exemption from testing** **(a)** This subchapter shall not apply in the	Notice; **4.** Obtain the signature of the parent on the Acknowledgment; **5.** Retain the executed Acknowledgemen t in the patient's medical record; and **6.** Permit the parent to keep the Notice.		

		otherwise take such steps that are within the health care facility's ability as may be required by a qualified laboratory to assist in and enable the performance of supplemental newborn screening in accordance with instructions accompanying a test kit, subject to applicable standards of care depending upon the particular health situations of newborns from whom supplemental screening specimens are to be collected.	case of any infant or child whose parent or guardian objects to the testing on the grounds that testing would conflict with his or her religious tenets or practices.			
		§ 8:18-1.10. Responsibilities of the Follow-up Program (a) The Follow-up Program shall: **1.** Make every reasonable effort to follow abnormal test results to case disposition as specified in the Follow-up Program Procedures Manual; **2.** Assist families of children with abnormal test results to access health care as necessary; **3.** Identify and maintain contact with medical consultants (neurologists,	**(b)** In case of refusal to test pursuant to (a) above, the chief executive officer or responsible physician or birth attendant or home health agency shall assure that documentation of refusal to test			

		endocrinologists, geneticists, hematologists) for each disease tested; **4.** Identify treatment resources to families and assure that they are receiving care; **5.** Provide educational support for activities carried out under this rule; and **6.** In conjunction with the testing laboratory: **i.** Monitor compliance with this subchapter; **ii.** Identify problems in compliance and assist in their remediation; **iii.** Prepare and distribute an annual report, to include outcome data, descriptive statistics, program evaluation and recommendations.	becomes part of the infant's permanent medical record. **(c)** The chief executive officer or responsible physician or birth attendant or home health agency shall assure that a copy of documentation of refusal to test is forwarded to the testing laboratory. **26:2-111.1 Option of additional screening for disorders in infants required; cost.** **1. a.** A health care provider shall give an infant's parent or guardian the option of			

			consenting to the performance of testing by qualified laboratories for disorders in infants for which testing is not required pursuant to P.L.1977, c.321 (C.26:2-110 et seq.), on a form and in a manner prescribed by the Commissioner of Health and Senior Services. …			

NEW MEXICO

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
NM	STATUTE: NMSA Chapter 24 Article 5 NMAC	**24-1-6. Tests required for newborn infants.** **A.** The department shall adopt screening tests for the detection of congenital diseases that shall be given to every newborn infant,	**24-1-6. A.** … after being informed of the reasons for the tests, the parents or guardians of the newborn child may	**GENETIC INFORMATION PRIVACY ACT** **24-21-3 Genetic analysis prohibited without informed**	NO	YES

	Title 7, Chapter 30, Part 6	except that, after being informed of the reasons for the tests, the parents or guardians of the newborn child may waive the requirements for the tests in writing. The screening tests shall include at a minimum:… **C.** In determining which other congenital diseases to screen for, the secretary shall consider the recommendations of the New Mexico pediatrics society of the American academy of pediatrics. **D.** The department shall institute and carry on such laboratory services or may contract with another agency or entity to provide such services as are necessary to detect the presence of congenital diseases. **E.** The department shall, as necessary, carry on an educational program among physicians, hospitals, public health nurses and the public	waive the requirements for the tests in writing… **7.30.6.9 WAIVER: A.** Pursuant to Section 24-1-6 NMSA 1978, parents or guardians may waive the requirements for the tests in writing. **B.** The department will provide the hospital with forms for waiver. No waiver for newborn screening shall be signed before the parents have been provided with both written and oral explanations by the infant's physician so that they may make	**consent; exceptions** **A.** ***Except as provided in Subsection C*** of this section, no person shall obtain genetic information or samples for genetic analysis from a person without first obtaining informed and written consent from the person or the person's authorized representative. **B.** ***Except as provided in Subsection C*** of this section, genetic analysis of a person or collection, retention, transmission or use of genetic information without the informed and written consent of the person or the person's authorized representative is prohibited.		

		concerning congenital diseases. **F.** The department shall require that all hospitals or institutions having facilities for childbirth perform or have performed screening tests for congenital diseases on all newborn infants except if the parents or guardians of a child object to the tests in writing. **7.30.6.7 DEFINITIONS:** **A. "Phenylketonuria" (PKU)** is a metabolic disorder caused by a genetic defect in which the body cannot use the amino acid phenylalanine properly. Incidence of PKU is approximately 1 in 11,000 - 15,000 births. Untreated PKU causes nerve and brain cell damage which results in mental retardation. Under medical management, a special diet can	an informed decision. The decision will be acknowledged by signature of the parents or guardian on the form provided by the department. The document of waiver shall be placed in the child's hospital medical record. **GENETIC INFORMATION PRIVACY ACT** **24-21-5. Rights of retention** … **D.** Nothing in Paragraph (3) or (4) of Subsection B of Section 5 [24-21-5 NMSA 1978] of the Genetic Information Privacy Act	***C. A person's DNA, genetic information or the results of genetic analysis may be obtained, retained, transmitted or used <u>without the person's written and informed consent</u> pursuant to federal or state law or regulations only:*** **(1)** to identify a person in the course of a criminal investigation by a law enforcement agency; **(2)** if the person has been convicted of a felony for purposes of maintaining a DNA database for law enforcement purposes; **(3)** to identify deceased persons;		

		minimize the effects of PKU. **B. "Other congenital diseases"** are those diseases, in addition to PKU, for which testing is required as a result of recommendation by the New Mexico pediatric society and adoption by the department. They are as follows: **(1)** primary hypothyroidism, approximate incidence 1/4,000 births; **(2)** galactosemia, approximate incidence 1/30,000 to 62,000 births; **(3)** ***any other congenital disease or condition*** for which testing may hereafter be required, on the basis of a formal recommendation made to the department by the New Mexico pediatric society and adopted by the department. … *[emphasis added]* **7.30.6.8 RESPONSIBILITY FOR TESTING:**	authorizes retention of a person's genetic information or samples for genetic analysis ***if the person, his authorized representative or guardian, or the parent or guardian of a minor child, objects on the basis of religious tenets or practices.*** *[emphasis added]*	**(4)** to establish parental identity; ***(5) to screen newborns;*** **(6)** if the DNA, genetic information or results of genetic analysis are not identified with the person or person's family members; **(7)** by a court for determination of damage awards pursuant to the Genetic Information Privacy Act [24-21-1 NMSA 1978]; ***(8) by medical repositories or registries;*** ***(9) for the purpose of medical or scientific research and education, including retention of gene products, genetic information or genetic analysis*** if the identity of the person or person's family members is not disclosed; or		

		A. Every newborn infant shall receive tests on two blood samples. The first blood sample shall be obtained, as late as possible, before the infant is discharged from the hospital, but not later than 96 hours after delivery. The second blood sample shall be obtained between the 8th and 15th day after birth. **B.** Every hospital shall take a first blood sample from each infant born in such hospital. Optimally, the infant shall have been receiving breast milk or formula for at least forty-eight hours before the blood sample is collected. If the blood specimen is collected before the forty-eight-hour period, the exact number of hours the infant has been on breast milk or formula		**(10)** for the purpose of emergency medical treatment consistent with applicable law. *[all emphases added]* …**E.** ***Nothing in Paragraph (5),*** (6), (8), (9) or (10) of Subsection C of Section 3 [24-21-3 NMSA 1978] of the Genetic Information Privacy Act authorizes obtaining, retaining, transmitting or using a person's DNA, genetic information or the results of genetic analysis if the person,		

		must be noted on the collection form. … **F.** Collection forms purchased from the department shall be completed for each blood sample. Each specimen shall be forwarded and en route to the address indicated on the collection form within 24 hours of the time that the sample is taken. … **I.** ***All results will be reported to the hospital and physician for placement in the child's medical record.*** *[emphasis added]* **J.** In the event of positive or questionable screening test results, the department will immediately contact and inform the physician of the need for further testing. The physician will be responsible for contacting and informing the parents of the need for further testing. ---------- "Children's Medical Services		his authorized representative or guardian, or the parent or guardian of a minor child, ***objects on the basis of religious tenets or practices****. [emphasis added]* **24-21-5. Rights of retention**….**B.** A person's genetic information or samples for genetic analysis shall be destroyed promptly upon the specific request by that person or that person's authorized representative unless: …**(3)** retention is authorized under a research protocol approved by an institution review board pursuant to federal law or a medical registry or repository authorized by state or federal law; or **(4)** the genetic information or samples for genetic analysis have been obtained pursuant		

		(CMS) Newborn Screening program provides programmatic follow-up of all children diagnosed on newborn screening to age 21" – *NM Dept. of Health website, 8/25/08.*		to Subsection C of Section 3 of the Genetic Information Privacy Act. … **D.** Nothing in Paragraph (3) or (4) of Subsection B of Section 5 [24-21-5 NMSA 1978] of the Genetic Information Privacy Act authorizes retention of a person's genetic information or samples for genetic analysis if the person, his authorized representative or guardian, or the parent		

				or guardian of a minor child, ***objects on the basis of religious tenets or practices.*** *[emphasis added]*		

NEW YORK

State	Statute/ Rule	Language Specific to Genetic Testing & Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
NY	STATUTE: Public Health Law, Article 25, §2500-G, Title 1	**§ 2500. Maternal and child health; duties of commissioner. 1.** The commissioner shall act in an advisory and supervisory capacity, in matters pertaining to the	**§ 2500-a.** …**(b)** The provisions of this section shall not apply in the case of any infant or	**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	NO	YES

	Civil Rights Law, Article 7, § 79-l 10 NYCRR 69-6.1	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 are or shall hereafter be made available. **§ 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	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 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	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		

		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 such other diseases and conditions as may from time to time be designated by the commissioner in accordance with rules or regulations prescribed by the commissioner. Testing, the recording of the results of such tests, tracking, follow-up reviews and educational activities shall be performed at such times and in such manner as may be prescribed by the commissioner…	parent is informed of the purpose and need for newborn screening, and given newborn screening educational materials provided by the testing laboratory.	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.		

				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]*		
		Section 69-1.3.Responsibilities of the chief executive officer… **(b)** 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		**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		

		processing specimens, 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		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…. **(e) Written informed consent for use of stored human tissue for general research purposes shall consist of written**		

		and test result for hepatitis B surface antigen (HBs Ag); **(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		**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 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		

		laboratory shall: **(a)** record requested diagnoses and case follow-up information submitted by health care providers and specialty care centers; **(b)** maintain tracking records on identified cases; and **(c)** provide educational activities and materials.		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... *[emphasis added]*		

NORTH CAROLINA

State	Statute/ Rule	Language Specific to Database	Exemption	Research Authority	Consent Required?	Dissent Allowed?
NC	STATUTE: NCGS Chapter 130A, Article 5 Part 1, and Article 15	**§130A□125. Screening of newborns for metabolic and other hereditary and congenital disorders.** **(a)** The Department shall establish and	**§130A-125** … **(b)** The Commission shall adopt rules necessary to implement the Newborn Screening Program. The rules	*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	NO	YES

	(Center for Health Statistics) 10A NCAC 42H.0314	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. **(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	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 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 SPECIMENSS FOR SCREENING OF NEWBORNS.**	**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]* "The North Carolina Birth Defects Monitoring Program (NCBDMP) operates under the statutory authority (G.S. 130A-131.17) of the State Center for Health Statistics. North Carolina Department of Health and Human Services." *From the North Carolina State Center for Health Statistics website:* <u>Special Projects within the Birth Defects Monitoring Program:</u> "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		

		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….	**(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.	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		

			10A NCAC 43H.0314 SUBMISSION OF BLOOD SPEIMENS FOR SCREENING OF NEWBORNS …**(b)** Notwithstanding Paragraph **(a)** of this Rule, parents or guardians may object to screening in accordance with G.S. 130A−125(b).	**(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]*		

NORTH DAKOTA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
ND	STATUTE: NDCC Title 25, Chpt 25-17 RULE:	**25-17-03. Treatment for positive diagnosis - Registry of cases.** The state department of health shall: **1.** Follow up with	**25-17-04. Testing and reporting requirements.** The physician attending a	**23-01-03.1. Newborn metabolic and genetic disease screening tests.** The health council may authorize the use of newborn metabolic and genetic disease screening tests, as provided for in chapter 25-17, for research purposes. The council	NO	YES

	Chapter 33-06-16	attending physicians cases with positive tests for metabolic diseases in order to determine the exact diagnosis. **2.** Refer every diagnosed case of a metabolic disease to a qualified health care provider for necessary treatment. **3.** Maintain a registry of cases of metabolic and genetic diseases… **25-17-00.1. Definitions.**...**3.** "Metabolic disease" and "genetic disease" means a disease as designated by rule of the state health council for which early identification and timely intervention will lead to a significant reduction in mortality, morbidity, and	newborn child, or the birth attendant in the case of an out-of-hospital birth, shall provide the parents with written information regarding the nature of the proposed testing and then cause that newborn child to be subjected to testing for metabolic and genetic diseases, in the manner prescribed by the state department of health. A physician attending a patient with a metabolic disease or genetic disease, or both, shall report the case to the state	shall adopt rules to ensure that the results are used for legitimate research purposes and to ensure that the confidentiality of the newborns and their families is protected. **23-01-15. Research studies confidential - Penalty.** **1.** All information, records of interviews, written reports, statements, notes, memoranda, or other data procured by the state department of health, in connection with studies conducted by the state department of health, or carried on by the department jointly with other persons, agencies, or organizations, or procured by such other persons, agencies, or organizations, for the purpose of reducing the morbidity or mortality from any cause		

		associated disabilities. *State Title V Block Grant Narrative, State: ND Application Year: 2007*: "**Birth certificate and newborn screening files have been linked since 1996.** This linkage has helped identify the characteristics of infants not screened as well as assess the	department of health. The testing requirements of this section do not apply if the parents of a newborn child object to the testing.	or condition of health is confidential and must be used solely for the purposes of medical or scientific research. **33-06-16-05. Research and testing materials.** Information and testing materials generated by the newborn screening program under North Dakota Century Code chapter 25-17 are strictly confidential information subject to North Dakota Century Code chapter 23-01.3 and section 23-01-15. **1.** Access to information or testing materials may be obtained only as follows: …**c.** Information and testing materials may be disclosed to a person engaged in a bona fide research project concerning medical, psychological, or sociological issues provided all of the following conditions are met: … **2.** Retention and destruction of information and testing materials. **a.** Information and testing materials provided to the university of North Dakota school of medicine and health sciences ***may be retained indefinitely or destroyed according to this subsection.*** *[emphasis added]* **b.** Information and testing materials may be destroyed by any available means that preserves individual confidentiality and, for the testing materials, complies with any applicable standards for destruction of		

		characteristics of women who breastfeed at hospital discharge. Data linkages are a primary focus of the 2007-2011 SSDI grant.//2007//"		human blood samples. **c.** Information and testing materials may be destroyed based upon the following schedule: **(1)** Information and testing materials created less than ten years before the present date may be destroyed only with the state health officer's prior written approval. **(2)** After ten years, information and testing materials may be destroyed without prior approval.		

OHIO

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
OH	STATUTE: ORC Title 37, Chapter 3701 ORC Title 1, Chapter 101	**3701.501 Newborns screened for genetic, endocrine, and metabolic disorders.** **(A)(1)** Except as provided in division (A)(2) of this section, all newborn children shall be screened for the presence of the genetic, endocrine, and metabolic disorders	**3701.501 A**…**(2)** Division (A)(1) of this section does not apply if the parents of the child object thereto on the grounds that the screening conflicts	**3701.501.** ...**(C)(2)** The newborn screening advisory council shall evaluate genetic, metabolic, and endocrine disorders to assist the director in determining which disorders should be included in the screenings	NO	YES

	OAC Title 37, Chapter 3701	specified in rules, adopted pursuant to this section. **Chapter 3701-55-02**…**(B)** All hospitals and freestanding birthing centers that are required by this chapter to cause specimens to be collected for newborn screening for genetic, endocrine, or metabolic disorders shall: **(3)** Develop a written protocol for tracking newborn screening. The protocol must include a requirement that the name of the physician attending the child after birth or a designee be placed on the specimen slip sent with the initial specimen to the Ohio department of health public health laboratory. **3701-55-03 Public health laboratory responsibilities.** The bureau of public health laboratories shall provide screening for the presence of genetic, endocrine, or	with their religious tenets and practices. **3701-55-04 Notification prior to screening.** **(A)** Prior to collecting the blood specimen for screening, the person designated in the applicable provision of this rule shall give each newborn child's parent, legal guardian, or legal	required under this section. In determining whether a disorder should be included, the council shall consider all of the following: **(a)** The disorder's incidence, mortality, and morbidity; **(b)** Whether the disorder causes disability if diagnosis, treatment, and early intervention are delayed; **(c)** The potential for successful treatment of the disorder; **(d)** The expected benefits to children and society in relation to the risks and costs associated with screening for the disorder; **(e)** Whether a screening for the disorder can be conducted without taking an additional blood sample or specimen		

		metabolic disorders in newborn children. In providing this screening, the bureau shall do all of the following: **(D)** Keep all newborn screening specimens and the demographic forms associated with each specimen for not less than two years from the date of the bureau's initial receipt of each specimen; **(E)** Keep electronic raw test data and any electronic images of reports and/or letters created for each specimen for not less than two years from the date of the bureau's initial receipt of each specimen; **(F)** Maintain electronically the screening results, demographic information, and case management information for each properly collected and submitted specimen received by the bureau for not less	custodian, notice of the screening to be conducted by providing printed information describing the newborn genetic, endocrine and metabolic screening program. … **3701-55-09 Religious exception.** **(A)** The provisions of this chapter requiring screening of newborn children do not apply if the parents of the child object thereto on the grounds that such screening conflicts with their religious	**3701-55-10 Supplemental studies.** The director may conduct supplemental studies of the initial blood specimen collected pursuant to rule 3701-55-05 of the Administrative Code for the purpose of determining whether additional genetic, endocrine, or metabolic screening is necessary. The results of such		

		than twenty one years; … **101.38 Cystic fibrosis legislative task force.** …**(B)** There is hereby created the Ohio cystic fibrosis legislative task force to study and make recommendations on issues pertaining to the care and treatment of individuals with cystic fibrosis. The task force shall study and make recommendations on the following issues: **(2)** Screening of newborn children for the presence of genetic disorders, as required under section 3701.501 of the Revised Code;…	tenets and practices. **(B)** Refusal to consent to the newborn screening must be documented on forms provided by the Ohio department of health or must meet the minimum warning requirements set forth on the Ohio department of	supplemental studies will assist in determining whether additional screening can help detect other genetic, endocrine or metabolic disorders that cause disability if undiagnosed and untreated and are treatable. No additional blood samples or specimens shall be required to conduct a supplemental study or screening.		

			health forms. A copy of the refusal form shall be sent to the Ohio department of health.			

OKLAHOMA

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
OK	STATUTE: OSC, Title 63, Chapter 1, Article 5. OSC, Title 36, Chapter	**§63-1-533. Phenylketonuria, related inborn metabolic disorders and other genetic or biochemical disorders – Educational and newborn screening programs.** A. The State Board of Health shall provide, pursuant to the	**63-1-534. Tests.** …provided that the provisions of this section shall not apply to any infant whose parents object thereto on the grounds that such	**OAC 310:550-3-1. Testing of newborns** **(a)** All newborns in Oklahoma shall be tested by a Certified Newborn Screening Laboratory for phenylketonuria,	NO	YES

	3, Article 6. RULE: OAC Title 310, Chapter 550	provisions of Section 1-534 of this title as technologies and funds become available, an intensive educational and newborn screening program among physicians, hospitals, public health nurses, and the public concerning phenylketonuria, related inborn metabolic disorders, and other genetic or biochemical disorders for which: **1.** Newborn screening will provide early treatment and management opportunities that might not be available without screening; and **2.** Treatment and management will prevent mental retardation and/or reduce infant morbidity and mortality. … **63-1-534. Tests.** The State Board of Health shall make such rules and regulations pertaining to such tests as accepted medical practice shall	examination conflicts with their religious tenets and practices. **OAC 310:550-3-1. Testing of newborns** **(a)** …a parent or guardian may refuse screening of their newborn on the grounds that such examination conflicts with their religious tenets and practices	congenital hypothyroidism, galactosemia, sickle cell diseases, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD) and after October 1, 2007, ***upon completion of validation studies*** and establishment of short-term follow-up services, infants shall be screened for biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, and organic acid disorders detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of		

		indicate, and ***is authorized to make such testing mandatory if sufficient evidence exists that the public has been negligent in accepting such practice*** and if the Board considers it in the public interest to do so.		Health… *[emphasis added]* **OAC 310:550-19-1. Physician Reporting** …**(c)** These reports shall be confidential and may be utilized only for the purpose of ensuring service delivery, program administration, data analysis, and evaluation.		
		The State Board of Health is hereby authorized to set up laboratory facilities and use existing facilities for the performance of examinations and tests for the detection of these diseases and make a reasonable charge therefore; provided, however, that no child shall be denied such laboratory work or tests because of the inability of its parents or guardian to pay therefore. Provided, further, that the State Board of Health	**(b)** A parent or guardian who refuses the newborn screening blood test of their newborn on the grounds that such examination conflicts with their religious tenets and practices shall also indicate in writing this refusal utilizing the Newborn Screening Program Parent Refusal Form	**36-3614.4. Disclosure of genetic research studies. A.** This section shall be known and may be cited as the "genetic Research Studies Nondisclosure Act." **B.** … "genetic research study or studies" shall mean those genetic research studies approved by an institutional review board… **E.** All stored tissues, including blood, that arise		

		may approve other laboratories for the performance of such tests***; provided that the provisions of this section shall not apply to any infant whose parents object thereto on the grounds that such examination conflicts with their religious tenets and practices.*** *[emphasis added]* **OAC 310:550-1-1. Purpose** Under 63 O.S., Sections 1-533 and 1-534 the following rules and regulations are established concerning the screening of all infants born in Oklahoma… **OAC 310:550-19-1. Physician Reporting** **a)** If confirmatory or follow-up testing is not performed by the Newborn Screening Laboratory or through a contract laboratory designated by the Newborn Screening Program, the infant's	as illustrated in Appendix C of this Chapter. This signed refusal form shall be placed in the newborn's medical record with a copy sent to the Newborn Screening Program Coordinator.	from surgery, other diagnostic or therapeutic steps, or autopsy may be disclosed for genetic or other research studies if informed consent has been obtained. ***Informed consent may be included in a section of the consent for treatment, admission to a hospital or clinic, or permission for an autopsy and no other consent shall be required***. *[emphasis added]* **F.** It shall be permissible to publish or otherwise use the results of genetic research studies for research or educational purposes if no individual subject is identified. ***If specific informed consent*** from the individual has been obtained, the individual may be identified. (eff. Nov. 1, 1999) *[emphasis added]*		

		physician must report to the Newborn Screening Program Coordinator the results within 7 days after the completion of the medical evaluation, using the Department's Newborn Screening Report Form as illustrated in Appendix B of this Chapter. A copy of the confirmatory test results must accompany the report form...				

OREGON

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
OR	STATUTE: ORS Title 36, Chapter 433 RULE: OAR	**433.285 Policy to control metabolic diseases; testing; fees; exemptions; waiver of fees; rules. (1)** It hereby is declared to be a matter of public	**433.285 (3)** The testing required by subsection (1) of this section shall not be required if the infant is being reared as an adherent to a religion the teachings of which are opposed	*Unclear.* **Oregon Genetic Privacy LAW:** **192.535 Informed consent for obtaining genetic information. (1)** A person may not obtain genetic information from an individual, or	NO	YES

	Chapter 333	policy of the State of Oregon that in the interest of public health and the prevention of mental retardation, every infant, shall be given tests approved by the Oregon Health Authority for the detection of the disease of phenylketonuria and other metabolic diseases. **(2)** The authority by rule shall specify the diseases for which infants shall be tested under subsection (1) of this section, the appropriate time following delivery for collecting specimens, the manner in which the specimens are to be submitted, the persons responsible for submitting the	to such testing. The person responsible for submitting specimens under the rules of the authority shall be responsible for submitting a statement signed by the infant's parent that the infant is being so reared. The department by rule shall prescribe the form of the statement. **333-024-0235 Religious Exemption from Testing (1)** A religious exemption from testing for Metabolic Diseases may be claimed if the infant is being reared as an adherent to in a religion the teachings of which are opposed to such testing. **(2)(a)** In the event a religious exemption is claimed from the	from an individual's DNA sample, without first obtaining informed consent of the individual or the individual's representative, <u>except:</u> … **(b)** For anonymous research or coded research conducted under conditions described in ORS 192.537 (2), after notification pursuant to ORS 192.538 or pursuant to ORS 192.547 (7)(b); … **(d)** As permitted by rules of the Health Authority for newborn screening procedures; **192.537 Individual's rights in genetic information; retention of information; destruction of information.** …**(2)(a)** A person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research only if the individual: **(A)** Has granted informed consent for the specific anonymous research or coded research project; **(B)** Has granted consent for genetic research generally;		

		specimens, the methods of testing and the manner of payment of the fees…	requirements for testing for Metabolic Diseases, the person otherwise responsible for submitting the specimen for testing shall be responsible for submitting a completed statement to the state public health laboratory signed by the infant's parent using the following language:	**(C)** Was notified in accordance with ORS 192.538 that the individual's biological specimen or clinical individually identifiable health information may be used for anonymous research or coded research and the individual did not, at the time of notification, request that the biological specimen or clinical individually identifiable health information not be used for anonymous research or coded research; or		
		(5) The authority by rule shall prescribe the procedure to be followed in cases where initial testing for metabolic diseases is administered too early to detect these diseases, where the sample submitted for testing is improperly collected and where a sample shows an abnormal result.	STATEMENT OF RELIGIOUS EXEMPTION The undersigned parent of_____ states that this child is exempt from testing for detection of METABOLIC DISEASES in that the child is being reared as an adherent to a religion the teachings of which are opposed to such testing.	**(D)** Was not notified, due to emergency circumstances, in accordance with ORS 192.538 that the individual's biological specimen or clinical individually identifiable health information may be used for anonymous research or coded research and the individual died before receiving the notice. **192.538 Notice by health care provider regarding anonymous or coded research. (1)** A health care provider that is a covered entity as defined in ORS 192.519 (2)(c) and that obtains an individual's biological specimen or clinical		

		The authority, within the limits of funds available from fees collected under this section, shall institute a pilot program for ***follow-up on abnormal test results***. **433.295 Report of cases required; forms to be furnished. (1)** All physicians, public health nurses and the administrators of hospitals shall report the discovery of ***cases of phenylketonuria*** to the Oregon Health Authority.		individually identifiable health information shall notify the individual that the biological specimen or clinical individually identifiable health information may be disclosed or retained by the provider for anonymous research or coded research….**(3)** The notice must contain a place where the individual may mark the individual's request that the specimen or information not be disclosed or retained for anonymous research or coded research before returning the notice to the health care provider. **Oregon Genetic Privacy RULE:** **333-025-0140 Informed Consent Procedures** (**1)** Unless exempted by ORS 192.535(1)(a)-(f), all persons collecting genetic information must conform to standards of informed consent… **333-025-0155 Retention for the Purpose of Newborn Screening Procedures** Oregon Health Authority may retain the blood samples of newborns collected for the control of metabolic diseases, as provided in ORS 433.285, for up to		

				one year.		

PENNSYLVANIA

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
PA	STATUTE: P.S. Title 35 Chapter 3, Section 623 RULE: PA CODE Title 28, Chapter 28	**§ 623. Newborn Child Screening and Follow-up Program (a)** In order to assist health care providers to determine whether treatment or other services are necessary to avert mental retardation, permanent disabilities or death, the department, with the approval of the Newborn Screening and Follow-up Technical Advisory Committee, shall establish a program providing for:	**§ 623. Section 3**. …**(c)** No screening test shall be performed if a parent or guardian dissents on the ground that the test conflicts with a religious belief or practice.	**§ 28.5. Confidentiality. (a)** A health care provider, testing laboratory, the Department or any other entity involved in the newborn screening program may not release any identifying information relating	NO	YES

		(1) The screening tests of newborn children for the following diseases: **(i)** Phenylketonuria (PKU). **(ii)** Maple syrup urine disease (MSUD). **(iii)** Sickle-cell disease (hemoglobinopathies). **(iv)** Galactosemia. **(v)** Congenital adrenal hyperplasia (CAH). **(vi)** Primary congenital hypothyroidism.		to any newborn child screened in the newborn screening program to anyone other than a parent or guardian of the newborn child or the health care provider for the newborn child designated by a parent or the guardian except as follows:		
		(2) Follow-up services relating to case management, referrals, confirmatory testing, assessment and diagnosis of newborn children with abnormal, inconclusive or unacceptable screening test results for the following diseases… **(b.1)** All laboratories performing the screening tests for newborn children shall report the results to the department for follow-up activities. **(d)** The department…shall establish, by periodic publication in the Pennsylvania Bulletin, changes	**§ 28.11. Informing the parent or guardian.** Prior to specimen collection, the health care provider shall provide the pregnant woman, prior to the infant's birth, or the mother or guardian, after the infant's birth, with a pamphlet supplied by the Department to explain the nature of the newborn screening blood tests for the diseases in	**(1)** As may be necessary to provide services to the newborn child. **(2)** With the consent of the newborn child's parent or guardian. **(3)** With the child's consent when the child is 18 years of age or older, has graduated from high school, has married or has been pregnant. **(b)** Only the		

		to the lists under subsection (a)(1) and (2) of those diseases for which newborn children shall be screened and laboratory screening results reported. **(f)** Test results for genetic diseases listed in this section and any diseases subsequently added by the department under subsection (d) shall be subject to the confidentiality provision of the "Disease Prevention and Control Law of 1955." **§521.15 Confidentiality of reports and records** [Disease Prevention and Control Law of 1955] State and local health authorities may not disclose reports of diseases, any records maintained as a result of any action taken in consequence of such reports, or any other records maintained pursuant to this act or any regulations, to any person who is not a member of the department or of a local board or department of health, except where necessary to carry out the purposes of this act. State and local health authorities may permit the use of data contained in disease reports and	§28.2 (relating to newborn diseases listed). **§ 28.12. Religious objections. (a)** A health care provider may not collect or cause to be collected, a specimen from a newborn child if the parent or guardian of the newborn child objects on the ground that the specimen collection conflicts with religious beliefs or practices held by the parent or guardian.	Department will have the authority to release or authorize the release of nonidentifying information concerning the newborn screening program. *From* "Pennsylvania Screening Services for NEW BORN BABIES," PA Dept. of Health brochure,(no date, accessed online 1/4/09): "By Pennsylvania law, your baby's blood filter paper test cannot be used for scientific research by any laboratory without your signed permission."		

		other records, maintained pursuant to this act, or any regulation, for research purposes, subject to strict supervision by the health authorities to insure that the use of the reports and records is limited to the specific research purposes.		"Pennsylvania and Nebraska require written consent from parents for any medical research use of these blood spots…" –*" Informing the Debate, Stored Blood Spots," Leonard M. Fleck et. al, Michigan State University 2008*		
		§ 28.41 Recordkeeping requirements. A health care provider offering maternity and newborn services shall collect and forward data semiannually to the Department on the number of patients for whom specimens for newborn disease testing have been collected and the number of patients for whom the specimens have not been collected, together with the reason in each instance for the failure to collect.	**(b)** If the parent or guardian of the newborn child objects to the collection of the specimen for screening on the ground that the specimen collection conflicts with religious beliefs or practices held by the parent or guardian, the health care provider shall ensure that the recorded objection of the parent or guardian is			

Updated September 2013. 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.

			entered into the medical record of the newborn child. The entry shall include a written statement of the objection signed by the parent or guardian.			

RHODE ISLAND

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
RI	STATUTE: RGL Title 23, Chapter 23-13 RGL Title 5, Chapter 5-37	**§ 23-13-14 Newborn screening program. – (a)** The physician attending a newborn child shall cause that child to be subject to newborn screening tests for metabolic, endocrine, and hemoglobinopathy disorders, and other conditions for which there is a medical benefit to the early detection and treatment of the disorder, and an assessment for developmental risk. The department of health shall make rules and regulations pertaining to screenings,	**§ 23-13-14 (a)**…The provisions of this section shall not apply if the parents of the child object to the tests on the grounds that those tests conflict with their religious tenets and practices. **R23-13 Section 2.0**	**§ 5-37.3-1 Short Title** This chapter may be cited as the "Confidentiality of Health Care Information Act." **§ 5-37.3-4—Limitations on and permitted disclosures.** **(a)** Except as provided in subsection **(b)** of this section or as specifically provided by	NO	YES

	RULE: R23-13 (METAB & HRG)	diagnostic, and treatment services as accepted medical practice shall indicate….	**Newborn Metabolic, Endocrine and Hemoglobinopathy Screening Program.**	the law, a patient's confidential health care information shall not be released or transferred without the written consent of the patient or his or her authorized representative, on a consent form meeting the requirements of subsection (d) of this section.		
		… **(b)** In addition, the department of health is authorized to establish by rule and regulation a reasonable fee structure for the newborn screening and disease control program, which includes but is not limited to screening, diagnostic, and treatment services. The program shall be a covered benefit and be reimbursable by all health insurers, as defined in § 27-38.2-2(1), providing health insurance coverage in Rhode Island except for supplemental policies which only provide coverage for specific diseases, hospital indemnity Medicare supplements, or other supplemental policies. The department of human services shall pay for the program where the patient is eligible for medical	**2.1** The physician and/or midwife attending a newborn child shall cause said child to be subject to screening tests for the conditions listed below. Provided, however, if parents of a newborn child object thereto, on the grounds that such tests conflict with their religious tenets and practices pursuant to section 23-13-14 of the Act, such tests shall not	***(b) No consent for release or transfer of confidential health care information shall be required in the following situations:*** …**(3)** To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, program evaluations, actuarial, insurance underwriting, or similar studies; provided, that personnel shall not identify, directly or indirectly, any individual patient in any report of that research, audit, or		

		assistance under the provisions of chapter 8 of title 40. The charges for the program shall be borne by the hospitals or other health-care facilities where births occur in the absence of a third-party payor. Nothing in this section shall preclude the hospital or health care facility from billing the patient directly. **R23-13 Section 1.0 Definitions. 1.6** "Newborn disease" means conditions that have their origin in mutational events that alter the genetic constitution of an individual and/or disrupts normal functions through some other disease mechanism. …**1.9** "The Programs", as used herein, means the Rhode Island Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program. **Section 2.0 Newborn Metabolic, Endocrine and Hemoglobinopathy Screening Program.** …**2.2** The Department shall provide	be performed.	evaluation, or otherwise disclose patient identities in any manner;… **(9)** To public health authorities in order to carry out their functions as described in this title and titles 21 and 23, and rules promulgated under those titles. These functions include, but are not restricted to, investigations into the causes of disease, the control of public health hazards, enforcement of sanitary laws, investigation of reportable diseases, certification and licensure of health professionals and facilities, review of health care such as that required by the federal government		

		specimen collection testing kits to health care facilities where births are known to occur and to physicians and midwives attending newborns in locations other than health care facilities. The specimen collection testing kits shall contain instructions for the collection and submission of specimens to the laboratory contracted by the Department. **2.3** Laboratories performing newborn **disease** screening tests shall be approved by the Director to perform the tests cited in section 2.1 and as required herein. **2.3.1** All reports of newborn disease screening tests performed by a laboratory shall be submitted to the attending physician and the Department and shall include actual value and reference ranges used for each disorder.		and other governmental agencies;		

SOUTH CAROLINA

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
SC	STATUTE: SCCL, Title 44, Chapter 37 RULE: Chapter 61-80, Sections A to I, and Appendices	**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	**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,..	**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	NO	YES

	A to C	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.		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.		
		(B) Information obtained as a result of the tests 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. **(C)** A blood sample obtained pursuant to this section is confidential and may be released only as the parent or legal	**(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 the child if eighteen years of age or older, requests return of the blood sample on a form provided by the	**61-80. Section F – Storage of Specimen …**3. 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.		

		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.	department.			
		(D)(1) Unless otherwise directed pursuant to this subsection, a blood sample obtained pursuant to this section must be 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	…**(E)(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.	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		

		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: **(a)** return a blood sample in its entirety and any test results not less than two years after the date of testing; **(b)** destroy a blood sample in a scientifically acceptable manner not less than two years after the date of the testing; or **(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.	**61-80 Section D - Collection of Specimen.** …2…c. 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 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	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		

		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 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.	procedure specified in the Official Departmental Instructions. **61-80 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	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 of that individual or a person legally authorized to consent on behalf of the individual, except that genetic information may be disclosed without consent:		

		(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. 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	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.	***…(6) as specifically authorized or required by a state or federal statute.*** *[emphasis added]* **Section 38-93-50.** Informed consent required for genetic test; exceptions. It is unlawful to perform a genetic test 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		

		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….Section 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 collected and submitted to the Laboratory. **61-80. Section F-Storage of Specimen**	**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 request that my child not be tested by blood spot screening in order to detect silent, deadly metabolic diseases and hemoglobinopathies. I	received a specimen referral from the individual's treating physician or another clinical 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]* **61-80. Neonatal Screening For Inborn Metabolic Errors and Hemoglobinopathies….** **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		

		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.	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).	SC CODE ANN. Section 44-37-30 AT -20 DEGREES CENTIGRADE AND MAY BE RELEASED ONLY FOR CONFIDENTIAL, ANONYMOUS SCIENTIFIC STUDY.		
		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	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	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.		

		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…	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			

			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, which may result to my child as the result of my refusal of blood spot screening. Parent: _____ Date: _____ Witness: _____			

SOUTH DAKOTA

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
SD	STATUTE: SDCL, Chapter 34-24, Sections 34-24-17 – 34-24-25 Medical /Genetic Research	**34-24-17. Screening of newborn infants for metabolic disease.** All infants born in the State of South Dakota shall be screened for metabolic disease. This screening shall be as prescribed by	**44:19:02:05. Responsibilities of parents.** The parents, guardian, or custodian of each infant is responsible for having blood tests for metabolic disorders performed within the first 48 hours of an infant's life. If a parent, guardian, or custodian refuses to have a	**34-14-4. Immunity from liability for furnishing information to research agencies.** The furnishing of information described in § 34-14-1 in the course of a research project to the Department of Health, South Dakota State Medical Association, or allied	NO	YES

	Law: SDCL Chapter 34-14 RULE: SDAR, Article 44-19	the State Department of Health.	newborn tested for metabolic disorders, despite having been notified of the need for testing, the parent, guardian, or custodian shall sign a written statement regarding the refusal.	medical societies or their authorized representatives, shall not subject any person, hospital, sanitarium, nursing, or rest home or any such agency to any action for damages or other relief.		
		34-24-18. Phenylketonuria, hypothyroidism, and galactosemia testing in newborn. The tests for detecting metabolic disorders of the newborn infant, as prescribed by the Department of Health, shall include, but not be limited to, the testing for excessive phenylalanine in the serum of the newborn, for hypothyroidism and for elevated blood	**44:19:02:06. Responsibilities of hospitals, physicians, and other health professionals.** The attending physician, other health professional, hospital, or public health facility shall notify the parents, guardian, or custodian of each infant of the responsibility and need to have the newborn screening tests performed. The attending physician or other health professional shall place all newborn screening test results in the	**34-14-22. Informed consent required prior to predictive genetic testing--Minimum requirements of written, informed consent.** No person may order or perform a predictive genetic test without first obtaining the written, informed consent of the person to be tested. For purposes of this section, written, informed consent consists of a signed writing executed by the person to be tested or the legally authorized		

		galactose in the newborn. **34-24-22. Testing for other metabolic diseases.** When tests for detecting a metabolic disease other than phenylketonuria, hypothyroidism, and galactosemia are perfected, the Department of Health may require that tests for the syndrome or syndromes be made and reported to the health department.	newborn patient's record. If a parent, guardian, or custodian refuses to have the newborn tested, the attending physician, other health professional, hospital, or public health facility shall obtain a written signed statement from the parent, guardian, or custodian of the infant regarding the refusal and place it in the newborn patient's record, notify the department within 24 hours of the refusal at 1-800-738-2301, and send a copy of the signed refusal to the department. If a parent, guardian, or custodian refuses to sign the statement, the attending physician, other health professional, hospital, or public health facility shall document such refusal, place it in the newborn patient's record, and send a copy of such documentation to the department.	representative of the person to be tested that includes, at a minimum, all of the following: **(1)** The nature and purpose of the predictive genetic test; **(2)** The effectiveness and limitations of the predictive genetic test; **(3)** The implications of taking the predictive genetic test, including, the medical risks and benefits; **(4)** ***The future uses of the sample taken*** from the person tested in order to conduct the predictive genetic test and the information obtained from the predictive genetic test; **(5)** The meaning of the predictive genetic test results and the procedure for providing notice of the results to the person tested; and		

				(6) A listing of who will have access to the sample taken from the person tested in order to conduct the predictive genetic test and the information obtained from the predictive genetic test, and the person's right to confidential treatment of the sample and the information. *[emphasis added]*		
		34-24-23. Reports to department on metabolic disease tests--Forms. Results of such tests for metabolic disorders in infants, as prescribed by the Department of Health, shall be sent to the department on forms to be prescribed and furnished by the department to all physicians, public health nurses, and hospitals.		***FROM SD Newborn Screening Brochure: (Revised 11-10)*** **"What happens to my baby's blood sample after the lab tests it?** "The newborn screening laborator will destroy your baby's blood sample once it is no longer needed for testing. It will not be used for any purpose other than newborn screening. If you have questions about how your baby's blood sample is		

				handled, call the South Dakota Newborn Screening Program at (605) 773-3361." **NOTE:** The brochure says, "All newborns in South Dakota are required by law to have a blood test shortly after birth…" but does not tell parents that the law allows them to refuse.		
		34-24-24. Follow-up on children with metabolic disease. It shall be the responsibility of the Department of Health ***to follow the development of all children carrying the syndrome of any metabolic disease*** to ensure that those persons responsible for the care of the child are fully informed of accepted medical procedures				

		for the detection, prevention, and treatment of such condition. *[emphasis added]*				

TENNESSEE

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
TN	STATUTE: T.C., Title 68, Chapter 5 Part 4 and Part 5 (genetic testing) Sections 68-1-801 – 68-5-404	**68-5-401. Testing required – Public policy. (a) (1)** The general assembly declares that, as a matter of public policy of this state and in the interest of public health, every newborn infant shall be tested for phenylketonuria, hypothyroidism, galactosemia and other metabolic/genetic defects that would result in intellectual disability or physical dysfunction as determined by the department, through rules and	**68-5-403. Exemptions for religious beliefs.** Nothing in this part shall be construed to require the testing of or medical treatment for the minor child of any person who files with the department a signed, written statement that such tests or medical treatment conflict with the	**68-5-504. Functions of program — Duties of department.**… **(b)** The department shall: …	NO	YES

Updated September 2013. 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.

	RULE: TAR, Chapter 1200-15-1-.01 - .07	regulations duly promulgated in accordance with the provisions of the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, and that the people of this state shall be extensively informed as to the nature and effects of such defects. **68-5-404. Failure to have child tested — Misdemeanor.** Any person violating the provisions of this part or parts of this chapter or the rules promulgated pursuant thereto, relative to testing of newborn infants, commits a Class C misdemeanor. **68-5-502. Establishment of genetics program.** **(a)** The department shall establish a statewide genetics program to ensure the availability of genetic services to citizens of the state who need them for the prevention and treatment of mental retardation or other physical dysfunction.	person's religious tenets and practices, affirmed under penalties of perjury. **1200-15-1-.01. Tests.** **(1)** Exemptions for religious beliefs. Nothing in this part shall be construed to require the testing of or medical treatment for the minor child of any person who shall file with the Department of Health a signed, written statement that such tests or medical treatment conflict with such person's religious tenets and practices, affirmed under penalties of perjury pursuant to	**(9)** Develop a reporting system to allow data to be collected and stored and to facilitate the compilation of statistical information on causes, methods of treatment and prevention of genetic disorders and birth defects. The system shall be in accordance with laws and		

		(b) The program shall include comprehensive genetic services programs***, including genetic and metabolic screening programs***, genetic counseling services, and other related services that will aid in the prevention and treatment of particular genetic disorders and birth defects or related conditions as determined by the department... *[emphasis added]*	T.C.A. 68-5-403. The newborn screening refusal form provided by the State should be completed and retained in the medical record for the period of time defined by the hospital or provider policy.	rules of the department governing confidentiality of information;…		
		68-5-504. Functions of program — Duties of department.… **(b)** The department shall: **1) Develop** and administer statewide genetic and metabolic screening programs to prevent, detect and assure follow-up for birth defects and genetic disorders. The screening programs shall include testing for phenylketonuria and hypothyroidism as provided by part 4 of this chapter, testing for sickle cell disease and other hemoglobinopathies and other testing programs as the department shall deem appropriate for the preventive treatment of intellectual disability or physical dysfunction, as publicly noted through rules and regulations…	**(2)** Failure to have a child tested for the genetic/metabolic disorders is a Class C misdemeanor. Reporting of hearing screening is not to be construed as mandatory testing, therefore, failure to have a child tested for hearing loss will not be considered a misdemeanor…			

TEXAS

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
TX	STATUTE: T.S., Chapter 33. Sections 33.001 – 33.037 RULE: T.A.C. Title 25, Part 1,	**Sec. 33.002. DETECTION AND TREATMENT PROGRAM ESTABLISHED. (a)** The department shall carry out a program to combat morbidity, including mental retardation, and mortality in persons who have phenylketonuria, other heritable diseases, or hypothyroidism. **(b)** The board shall adopt rules	**Sec. 33.012. EXEMPTION**. **(a)** Screening tests may not be administered to a newborn child whose parents, managing conservator, or guardian objects on the ground that the tests conflict with	**Sec. 33.002. DETECTION AND TREATMENT PROGRAM ESTABLISHED …(c)** The department shall establish and maintain a laboratory to: **(1)** conduct experiments, projects, and other activities necessary to develop screening or diagnostic tests for the early detection of	NO	YES

	Chapter 37, Subchapter D, Rules 37.51 – 37.65	necessary to carry out the program, including a rule specifying other heritable diseases covered by this chapter. **Sec. 33.011. TEST REQUIREMENT**. **(a)** The physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician shall subject the child to screening tests approved by the department for phenylketonuria, other heritable diseases, hypothyroidism, and other disorders for which screening is required by the department. **Sec. 33.015. REPORTS;**	the religious tenets or practices of an organized church of which they are adherents. **(b)** If a parent, managing conservator, or guardian objects to the screening tests, the physician or the person attending the newborn child that is not attended by a physician shall ensure that the objection of the parent, managing conservator, or guardian is entered into the medical record of the child.	phenylketonuria, other heritable diseases, and hypothyroidism; **(2)** develop ways and means or discover methods to be used to prevent or treat phenylketonuria, other heritable diseases, and hypothyroidism; and **(3)** serve other purposes considered necessary by the department to carry out the program. **Sec. 33.018 Confidentiality** (a) In this section…(5) ***"Public health purpose***" means a purpose that relates to caner, a birth defect, an infectious disease, a chronic disease, environmental exposure, or newborn screening…. **(a-1)** Reports, records, and information obtained or developed by the department		

		RECORD KEEPING. **(a)** Each physician, health authority, or other individual who has the information of a confirmed case of a disorder for which a screening test is required that has been detected by a mechanism other than identification through a screening of a specimen by the department's diagnostic laboratory shall report the confirmed case to the department. **(b)** The department may collect data to derive incidence and prevalence rates of disorders covered by this chapter from the information on the specimen form submitted to the department for screening determinations. **(c)** The department shall maintain a roster of children born in this state who have been diagnosed as having one of the disorders for which the screening tests are required. **(d)** ***The department may cooperate with other states in the***	The parent, managing conservator, or guardian shall sign the entry. **Sec. 33.013. LIMITATION ON LIABILITY**. A physician, technician, or other person administering the screening tests required by this chapter is not liable or responsible because of the failure or refusal of a parent, managing conservator, or guardian to consent to the tests for	under this chapter are confidential and are not subject to disclosure under Chapter 552, Government Code, are not subject to subpoena, and may not otherwise be released or made public ***except as*** provided by this section. **(b)** Notwithstanding other law, reports, records, and information obtained or developed by the department under this chapter ***may be disclosed…*** *(*5) to public health programs of the department for ***public health research purposes***, provided that the disclosure is approved… **(6)** for purposes relating to review or quality assurance of the department's newborn screening… **(7)** for purposes related to obtaining or maintaining		

		development of a national roster of individuals who have been diagnosed as having one of the disorders for which the screening tests are required if: **(1)** participation in the national roster encourages systematic follow-up in the participating states; **(2)** incidence and prevalence information is made available to participating newborn screening programs in other states; and **(3)** each participating newborn screening program subscribes to an agreement to protect the identity and diagnosis of the individuals whose names are included in the national roster. *[emphasis added]* **RULE §37.58 Follow-up and Record Keeping on Abnormal Screens** **(a)** The department shall maintain an active system of follow-up for suspected cases of each disorder for which screens are required. **(b)** Health authorities, public health	which this chapter provides. **RULE §37.54. Exemption from Screens** A newborn may not be screened if the parent, managing conservator, or guardian objects to the screens because the screens conflict with the religious tenets or practices of the parent, managing conservator, or guardian.	federal certification, including related quality assurance, for the department's laboratory… **(8)** for purposes relating to improvement of the department's newborn screening under this chapter or the department's newborn screening program services under Subchapter C… **(f)** In accordance with this section, the commissioner or the commissioner's designee: **(1)** may approve disclosure of reports, records, or information obtained or developed under this chapter only for a ***public health purpose;*** and **(2)** may not approve disclosure of reports, records, or information obtained or developed under this chapter for purposes related to forensic science or health insurance underwriting. …		

		departments, public health districts, and the department's health service regions may provide follow-up and other needed assistance for individuals at risk from the disorders for which screens are required as requested by the department… **(e)** Physicians or health care practitioners shall report to the department all confirmed cases of the disorders for which required screens are performed that have been detected by other mechanisms… **(g)** The department may follow up with a confirmed case through periodic data collection from the physician or health care practitioner or parent, managing conservator, or guardian. **(h)** The department shall maintain a registry of children born in Texas who have been diagnosed as having one of the disorders for which screens are required.				

UTAH

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
UT	STATUTE: U.C., Title 26, Chapter 10 RULE: R398-1	**26-10-6. Testing of newborn infants.** **(1)** Except in the case where parents object on the grounds that they are members of a specified, well-recognized religious organization whose teachings are contrary to the tests required by this section,	**26-10-6. Testing of newborn infants. (1)** Except in the case where parents object on the grounds that they are	**R398-1-15. Blood Spots.** **(1)** Blood spots become the property of the Department. **(2)** The Department includes in parent education materials information about the Department's policy on the retention and use of residual newborn blood spots.	NO	YES

Updated September 2013. 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.

		each newborn infant shall be tested for: **(a)** phenylketonuria (PKU); **(b)** other metabolic diseases which may result in mental retardation or brain damage and for which: **(i)** a preventive measure or treatment is available; and **(ii)** there exists a reliable laboratory diagnostic test method; and…	members of a specified, well-recognized religious organization whose teachings are contrary to the tests required by this section, each newborn infant shall be tested for:…	**(3)** The Department may use residual blood spots for newborn screening quality assessment activities. **(4)** The Department may release blood spots for research upon the following:		
		(c) (i) beginning July 1, 1998, for an infant born in a hospital with 100 or more live births annually, hearing loss; and **(ii)** beginning July 1, 1999, for an infant born in a setting other than a hospital with 100 or more live births annually, hearing loss. **(2)** In accordance with Section 26-1-6, the department may charge fees for: **(a)** materials supplied by the department to conduct tests required under Subsection **(1)**;	**R398-1-11. Testing Refusal.** A parent or legal guardian may refuse to allow the required testing for religious reasons only. The medical home/ practitioner or institution shall file in the newborn's record documentation of refusal,	**(a)** The person proposing to conduct the research applies in writing to the Department for approval to perform the research. The application shall include a written protocol for the proposed research, the person's professional qualifications to perform the proposed research, and other information if needed and requested by the Department. When appropriate, the proposal will then be submitted to the Department's Internal Review Board for approval. **(b)** The Department shall de-identify blood spots it releases unless it obtains		

		(b) tests required under Subsection (1) conducted by the department; **(c)** laboratory analyses by the department of tests conducted under Subsection (1); and **(d)** the administrative cost of follow-up contacts with the parents or guardians of tested infants. **R398-1. Newborn Screening.** **R398-1-12. Access to Medical Records.** **(1)** The Department shall have access to the medical records of a newborn in order to identify medical home/practitioner, reason appropriate specimen was not collected, or to collect missing demographic information. **(2)** The institution shall enter the Newborn Screening form number, also known as the Birth Record Number, into the Vital Records database and the Newborn Hearing Screening	reason, education of family about the disorders, and signed waiver by both parents or legal guardian. The practitioner or institution shall submit a copy of the refusal to the Utah Department of Health, Newborn Screening Program, P.O. Box 144710, Salt Lake City, UT 84114-4710.	informed consent of a parent or guardian to release identifiable samples. **(c)** All research must be first approved by the Department's Internal Review Board. **R398-1-16. Retention of Blood Spots.** **(1)** The Department retains blood spots for a minimum of 90 days. **(2)** Prior to disposal, the Department shall de-identify and autoclave the blood spots. **26-25-1. Authority to provide data on treatment and condition of persons to designated agencies -- Immunity from liability. (1)** Any person, health facility, or other organization may, without incurring liability, provide the following		

		database. **R398-1-13.Noncompliance by Parent or Legal Guardian.** If the medical home/practitioner or institution has information that leads it to believe that the parent or legal guardian is not complying with this rule, the medical home/practitioner or institution shall report such noncompliance as medical neglect to the Department. **R398-1-17. Reporting of Disorders.** If a diagnosis is made for one of the disorders screened by the Department that was not identified by the Department, the medical home/practitioner shall report it to the Department.		information to the persons and entities described in Subsection (2): **(a)** information as determined by the state registrar of vital records appointed under Title 26, Chapter 2, Utah Vital Statistics Act; **(b)** interviews; **(c)** reports; **(d)** statements; **(e)** memoranda; **(f)** familial information; and **(g)** other data relating to the condition and treatment of any person. **(2)** The information described in Subsection (1) may be provided to: **(a)** the department and local health departments; **(b)** the Division of Substance Abuse and Mental Health within the Department of Human Services; **(c)** scientific and health care research organizations affiliated with institutions of higher education; **(d)** the Utah Medical Association or any of its allied medical societies; **(e)** peer review committees; **(f)** professional review organizations; **(g)** professional societies and associations; and **(h)** any health facility's in-house staff		

				committee for the uses described in Subsection (3). **(3)** The information described in Subsection (1) may be provided for the following purposes: **(a)** study and advancing medical research, with the purpose of reducing the incidence of disease, morbidity, or mortality; or **(b)** the evaluation and improvement of hospital and health care rendered by hospitals, health facilities, or health care providers.		

VERMONT

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?

Updated September 2013. 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.

VT	STATUTE: Title 18, Chapter 3, Section 115 (Chronic Disease) Title 18, Chapter 217, Section 9332 RULE: CVR 13-140-057	**Newborn Screening Regulations Website:** "These regulations are made under the Department of Health's statutory responsibility and authority to develop an early case-finding program, in cooperation with the medical profession, concerning chronic diseases." *http://healthvermont.gov/regs/newborn_screening_reg.aspx* **§ 115. Chronic diseases; study; program** **(a)** The department of health may, in the discretion of the commissioner, accept for treatment children suffering from chronic diseases such as cystic fibrosis and severe hemophilia. **(b)** The state board of health is authorized to: **(1)** Study the prevalence of chronic disease, **(2)** Make such morbidity studies as may be necessary to evaluate the over-all problem of chronic disease, ***(3) Develop an early case-finding program, in cooperation with the medical profession***, **(4)** Develop and carry on an educational program as to the causes, prevention and	**CVR 13-140-057 III** **B.** Screening tests shall be performed on newborn infants, except that after being informed of the reasons for the tests, the parents, guardians, or custodians may refuse in writing to have the tests performed. The written objection shall be sent to the Vermont Department of Health, Vermont Newborn Screening Program.	**Chapter 217 § 9332. Genetic testing; limitations…(b)** A person may be required to undergo genetic testing in connection with insurance subject to the limitations imposed under section 9334 of this title or if otherwise required by law for the following reasons: … **(2)** To determine the presence of ***metabolic disorders in a newborn*** by testing conducted pursuant to newborn screening and protocols. … **…(d)** Except for the provisions of subsection (b) of this section, no genetic testing shall be performed on any individual or body parts of any individual nor	NO	YES

		alleviation of chronic disease, **(5)** Integrate this program with that of the state rehabilitation center where possible, by seeking the early referral of persons with chronic disease, who are capable of being rehabilitated… *[emphasis added]* **§ 9332. Genetic testing; limitations** **…(b)** A person may be required to undergo genetic testing in connection with insurance subject to the limitations imposed under section 9334 of this title or if otherwise required by law for the following reasons: … **(2)** To determine the presence of metabolic disorders in a newborn by testing conducted pursuant to newborn screening and protocols. … **(c)** Samples collected pursuant to subdivisions (1), (2)**,** (3) or (4) of subsection (b) of this section or collected voluntarily pursuant to an agreement shall not be utilized for any purpose in		shall any bodily materials be released for purposes of genetic testing without the prior written authorization and informed consent of the individual to be tested ***except for medical research*** where the identity of the subject is unknown or, if the research shall be conducted with anonymized medical information where individual identifiers are encrypted or encoded and the identity of the individual is not disclosed, or if the identity of the individual is known, where standards of protection are equal to those contained in regulations promulgated by the federal Office for Protection from Research Risk (OPRR). *[all emphasis added]*		

		connection with the state DNA data bank, the state DNA database and CODIS unless specifically authorized by subchapter 4 of chapter 113 of Title 20. **CVR 13-140-057 I**. Authority and Purpose. These regulations are made under the Department of Health's statutory responsibility and authority to develop an early case-finding program, in cooperation with the medical profession, concerning chronic diseases. II. DEFINITIONS Newborn Screening Program: The Vermont Department of Health's program to assure that infants born in the state are				

		tested for certain metabolic diseases for which early identification and treatment will prevent mental retardation and/or death, and, for those affected, to assure timely initiation of treatment services. Newborn Screening Test: A laboratory procedure capable of detecting the possible presence of one of the diseases specified in section III.A. Screening: The presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly.				

VIRGINIA

State	Statute/Rule	Language Specific to Genetic	Exemption	Research	Consent	Dissent

		Testing and Surveillance System		Authority	Required?	Allowed?
VA	STATUTE: C.V., Title 32.1, Chapter 2 RULE: V.A.C., Title 12, Agency 5, Chapters 71 and 191	**§ 32.1-65. Certain newborn screening required**. In order to prevent mental retardation and permanent disability or death, every infant who is born in the Commonwealth shall be subjected to screening tests for various disorders consistent with, but not necessarily identical to, the uniform condition panel recommended by the American College of Medical Genetics in its report, Newborn Screening: Toward a Uniform Screening Panel and System, that was produced for the U.S. Department of Health and Human Services. Further, upon the issuance of guidance for states' newborn screening programs by the federal Department of Health and Human Services, every infant who is born in the Commonwealth shall be screened for a panel of disorders consistent with, but not necessarily identical to, the federal guidance document. **§ 32.1-66. Commissioner to notify physicians; reports to Commissioner.** Whenever a newborn screening test result indicates suspicion of any	**§ 32.1-65.** …Any infant whose parent or guardian objects thereto on the grounds that such tests conflict with his religious practices or tenets shall not be required to receive such screening tests. **12VAC5-71-40. Religious exemption from newborn dried-blood-spot screening requirements.** Refusal	**§ 32.1-67.1. Confidentiality of records; prohibition of discrimination.** The results of the newborn screening services conducted pursuant to this article may be used for research and collective statistical purposes. No publication of information, biomedical research, or medical data shall be made that identifies any infant having a heritable or genetic disorder. All medical records maintained as part of newborn screening services shall be confidential and shall be accessible	NO	YES

		condition pursuant to § 32.1-65, the Commissioner shall notify forthwith the attending physician and shall perform or provide for additional testing required to confirm or disprove the diagnosis. All physicians, certified nurse midwives, public health nurses, or any nurse receiving such test result, and administrators of hospitals in the Commonwealth, shall report the discovery of all cases of any condition for which newborn screening is conducted pursuant to § 32.1-65 to the Commissioner for infants and children ***up to two years of age.*** *[emphasis added]* **12VAC5-71-10. Definitions.** The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:	by the infant's parent or guardian to consent to the collection and submission of a newborn dried-blood-spot screening specimen because the test conflicts with his religious practices or tenets shall be documented in the medical record and communicated to the department. **12VAC5-71-50. Responsibilities of the physician or midwife.** For every live birth in the Commonwealth, the	only to the Board, the Commissioner, or his agents. **§32.1-69. Records confidential; disclosure of results of screening.** The		

		"Dried-blood-spot specimen" means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper. "Heritable disorders and genetic diseases" means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration. "Infant" means a child less than 12 months of age. "Population-based" means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation. "Virginia Newborn Screening System" means a coordinated and comprehensive group of services, including education, screening, follow up, diagnosis, treatment and	physician or midwife in charge of the infant's care after delivery shall cause the initial collection and submission of a newborn dried-blood-spot screening specimen for testing of those heritable disorders and genetic diseases listed in 12VAC5-71-30 D and ***in accordance with 12VAC5-71-70 or 12VAC5-71-80.*** *[emphasis added; NOTE: no mention of being in accordance with the 12VAC5-71-40 exemption]* **12VAC5-71-90. Responsibilities of the chief executive officer.** The chief executive officer shall assure that	results of any particular screening program shall be sent to the physician of the person tested, if known, and either to the parents when the person screened is under the age of eighteen or to the person if he is eighteen years of age or over. The results of a screening program may be used for research and collective statistical purposes. Except as hereinabove provided, all records maintained as part of any screening program shall be strictly confidential and shall be accessible only to the Board, the Commissioner or his agents or to		

		management, and program evaluation, managed by the department's Virginia Newborn Screening Services and Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia. **12VAC5-71-30. Core panel of heritable disorders and genetic diseases.** …**D.** Infants under six months of age who are born in Virginia shall be screened in accordance with the provisions set forth in this chapter for the following heritable disorders and genetic diseases, which are identified through newborn dried-blood-spot screening tests:… **12VAC5-71-100. Responsibilities of the testing laboratory providing newborn dried-blood-spot screening tests.** **A.** Newborn dried-blood-spot	the hospital providing birthing services develops and implements policies and procedures to make certain that the following steps take place: **1.** Collection of newborn dried-blood-spot screening specimens shall occur after 24 hours of birth, and collection and submission of the specimens shall meet the standards required by the testing laboratory; **2.** Notification of the newborn's physician of record or designee shall occur within one business day in the	the local health director who is conducting the screening program except by explicit permission of the person who has been screened if such person is eighteen years of age or over or of such person's parent or guardian if he is under age eighteen.		

		screening tests shall be performed by the Division of Consolidated Laboratory Services or other laboratory the department has contracted with to provide this service in accordance §32.1-65 of the Code of Virginia. **B.** The testing laboratory shall maintain accreditation under the Clinical Laboratory Improvement Amendments as defined in 42 CFR Part 493. … …**E.** The testing laboratory shall provide the department's newborn screening services with the newborn dried-blood-spot screening test data that are necessary to carry out follow-up services. … …**H.** The testing laboratory shall maintain an information management system capable of electronic data exchange between the laboratory and the department's	event that the infant is discharged before the newborn dried-blood-spot screening specimen has been collected; **3.** Communication of the newborn dried-blood-spot screening test results to the newborn's physician of record or designee shall occur so that test results may become part of the infant's medical record on file with the physician; **4.** Information relative to newborn screening dried-blood-spot results and treatment shall be recorded in the patient's medical record, and retention of the information shall comply with applicable medical record retention requirements; and **5.** Training of staff on newborn dried-blood-			

		newborn screening services.	spot screening specimen collection and submission and parental notification shall be implemented in a way that ensures an adequately trained and knowledgeable workforce is maintained for implementing specimen collection and submission and parental notification according to standards required by the testing laboratory and guidance from the department. ***[NOTE: nothing about option to refuse]***			

WASHINGTON

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
WA	STATUTE: RCW Title 70 Chapter 70.83, RULE: Chapter 246-65-WAC	**RCW 70.83.010□Declaration of policy and purpose.** It is hereby declared to be the policy of the state of Washington to make every effort to detect as early as feasible and to prevent where possible phenylketonuria and other preventable heritable disorders leading to developmental disabilities or physical defects. **70.83.023 Specialty clinics – Defined disorders – Fee for infant screening.** The department has the authority to	**70.83.020 Screening tests of newborn infants.** It shall be the duty of the department of health to require screening tests of all newborn infants before they are discharged from the hospital for the detection of phenylketonuria and other heritable or metabolic disorders leading to intellectual disabilities or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices.	**246-650-050 Privacy and security of screening specimen/information forms. …** …**(4)** Release: Dried blood spot samples and specimen information may only be released when required by state or federal law or under the following conditions: **(a)** A sample from a specimen and copies of associated information (patient information and testing results, if requested) may be released to: … **(ii)** A researcher with the written, informed consent of the patient or their patient's legal representative as part of	NO	YES

		collect a fee of three dollars and fifty cents from the parents or other responsible party of each infant screened for congenital disorders as defined by the state board of health under RCW 70.83.020 to fund specialty clinics that provide treatment services for those with the defined disorders. The fee may also be used to support organizations conducting community outreach, education, and adult support related to sickle cell disease. The fee may be collected through the facility where a screening specimen is obtained. **246-650-050 Privacy and security of screening specimen/information forms.** The specimen/information form	**246-650-020 Performance of screening tests.** **(1)** Hospitals providing birth and delivery services or neonatal care to infants shall: **(a)** Inform parents or responsible parties, by providing a departmental information pamphlet or by other means, of: **(i)** The purpose of screening newborns for congenital disorders, **(ii)** Disorders of concern as listed in WAC 246-650-020(2), **(iii)** The requirement for newborn screening, and	a research project that has been reviewed and approved by the DOH/DSHS human subjects research review board and the secretary or designee of the department of health… **(b)** Anonymous samples may be released if the department determines that the intended use has significant potential health benefit and that each of the following criteria have been met: **(i)** The investigation design is adequate to assure anonymity will be preserved. **(ii)** All newborn screening tests have been completed and the status of the infant is resolved. **(iii)** At least one fully adequate spot will remain after the anonymous sample has been taken.		

		submitted to the department pursuant to WAC 246-650-020 ***becomes the property of the state of Washington*** upon receipt by the Washington state public health laboratory. The department shall protect the privacy of newborns and their families and assure that all specimen/ information forms submitted for screening are protected from inappropriate use or access. *[emphasis added]* **(1)** Storage: The specimen/information forms shall be kept at ambient temperature in secured storage to preserve their confidentiality and prevent access by unauthorized persons. **(2)** Retention/destruction: The specimen/information form shall be retained until the child is twenty-one years old in	**(iv)** The legal right of parents or responsible parties to refuse testing because of religious tenets or practices as specified in RCW 70.83.020, and **(v)** The specimen storage, retention and access requirements specified in WAC 246-650-050…	**(iv)** Sufficient resources (personnel) are available for extracting the samples. **(v)** The DOH/DSHS human subjects research review board has reviewed and approved the investigation. ***This requirement may be waived by the department for a very small (i.e., less than 100 sample) pilot study*** where the intent is to evaluate a testing tool, as opposed to an evaluation where the intent is to measure some characteristic of a population. *[emphasis added]*		

		accordance with the requirements for hospitals specified in RCW 70.41.190. After this time the form will be destroyed. EXCEPTION FOR PARENTAL REQUEST: Upon request of a parent or guardian (or a patient who is over the age of eighteen years), the department will destroy the specimen/ information form only after all required screening tests have been performed and if the patient's screening/clinical status related to these tests is not in question. **(3)** Access: Access to stored specimen/ information forms shall be restricted to department employees and those contractors				

		or others approved by the department as necessary to meet specific program needs. Access is contingent upon compliance with all applicable federal and state laws, regulations, and policies safeguarding the privacy and confidentiality of medical information. The department shall assure that those granted access understand the confidentiality requirements and have a signed confidentiality agreement on file. … …**(5)** Notification: The department shall notify parents of the specimen storage, retention/ destruction and access requirements through the department's newborn screening informational pamphlet.				

WEST VIRGINIA

State	Statute/Rule	Language Specific to Genetic	Exemption	Research Authority	Consent	Dissent

		Testing and Surveillance System			Required?	Allowed?
WV	STATUTE W.V.C Chapter 16, Articles 22 and 40 RULE: CSR, Title 64, Series 91	**§16-22-2. Program to combat intellectual disability or other severe health hazards; rules; facilities for making tests.** The State Bureau of Public Health is hereby authorized to establish and carry out a program designed to combat intellectual disability or other severe health hazards in our state's population due to phenylketonuria, galactosemia, hypothyroidism, and certain other diseases specified by the State Public Health Commissioner, and may adopt reasonable rules and regulations necessary to carry out such a program. The Bureau of Public Health shall establish and maintain facilities at its state hygienic laboratory for testing specimens for the detection of phenylketonuria, galactosemia, hypothyroidism, and certain other diseases specified by the State Public Health Commissioner. Tests shall be made by such laboratory of specimens upon request by physicians, hospital medical personnel and other individuals attending newborn infants. The State Bureau of Public Health is	NONE	**§16-40-3. Purposes of [Statewide Birth Defects Information] system.** The birth defects information system may be used for all of the following purposes: **(1)** To identify and describe congenital anomalies, stillbirths and abnormal conditions of newborns; **(2)** To detect trends and epidemics in congenital anomalies, stillbirths and abnormal conditions of newborns; **(3)** To quantify morbidity and mortality of congenital anomalies and abnormal conditions of newborns; ***(4) To stimulate epidemiological research regarding congenital anomalies, stillbirths and abnormal conditions of***	NO	NO

		authorized to establish additional laboratories throughout the state to perform . . . **§16-22-3. Tests for diseases specified by the State Public Health Commissioner; reports; assistance to afflicted children; Public Health Commissioner to propose rules.** (…**(b)** A positive result on any test specified in subsection (a) of this section, or a positive result for any other diseases specified by the Bureau for Public Health, shall be promptly reported to the Bureau for Public Health by the director of the laboratory performing such test. **§16-22-4. Penalties for violating provisions of article.** Any person violating the provisions of this article shall be guilty of a misdemeanor, and, upon conviction		***newborns;*** **(5)** To identify risk factors for congenital anomalies, stillbirths and abnormal conditions of newborns; **(6)** To facilitate intervention in and prevention of congenital anomalies, stillbirths and abnormal conditions of newborns; **(7)** To facilitate access to treatment for congenital anomalies and abnormal conditions of newborns; **(8)** To inform and educate the public about congenital anomalies, stillbirths and abnormal conditions of newborns.		

		thereof, shall be fined not less than twenty-five nor more than fifty dollars. Violation of each such provision shall be considered a separate offense. **§64-91-5. When Screening is Required.** 5.1. W. Va. Code §16-22-3 requires that all infants born in the state be screened for detection and control of diseases in newborn children as listed in sections 4 and 6 of this rule.				

WISCONSIN

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?

Updated September 2013. 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.

WI	STATUTE: W.S.A., Chapter 253 RULE: W.A.C., Chapter HFS 115	**253.13 Tests for congenital disorders.** **253.13(1) Blood tests.** The attending physician or nurse licensed under s. 441.15 shall cause every infant born in each hospital or maternity home, prior to its discharge therefrom, to be subjected to blood tests for congenital and metabolic disorders, as specified in rules promulgated by the department. If the infant is born elsewhere than in a hospital or maternity home, the attending physician, nurse licensed under s. 441.15 or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to these blood tests. **(1m) URINE TESTS.** The department may establish a urine test program to test infants for causes of congenital disorders. The state laboratory of hygiene board may establish the methods of obtaining	**253.13** …(**3) Exceptions.** This section shall not apply if the parents or legal guardian of the child object thereto on the grounds that the test conflicts with their religious tenets and practices. No tests may be performed under sub. (1) or (1m) unless the parents or legal guardian are fully informed of the purposes of testing under this section and have been given reasonable opportunity to object as authorized in this subsection or in sub. (1m) to such tests. ***[NOTE: Nothing***	**HFS 115.05 Laboratory tests.** …**(2)** ADDITIONAL TESTS FOR RESEARCH AND EVALUATION PURPOSES. The state department may direct the state laboratory to perform other tests on specimens for research and evaluation purposes related to congenital and metabolic disorders or laboratory procedures. In directing that additional testing be performed, the department shall ensure that all applicable laws relating to protection of human subjects of research are observed.	NO	YES

		urine specimens and testing such specimens, and may develop materials for use in the tests. No person may be required to participate in programs developed under this subsection. **(2) TESTS: DIAGNOSTIC DIETARY AND FOLLOW_UP COUNSELING PROGRAM; FEES**. The department shall contract with the state laboratory of hygiene to perform the tests specified under this section and to furnish materials for use in the tests... **(4) CONFIDENTIALITY OF TESTS AND RELATED INFORMATION**. The state laboratory of hygiene shall provide the test results to the physician, who shall advise the parents or legal guardian of	***was found in the Rule about informing parents about or allowing this exception]***			

		the results. No information obtained under this section from the parents or guardian or from specimens from the infant may be disclosed except for use in statistical data compiled by the department without reference to the identity of any individual and except as provided in s. 146.82(2). The state laboratory of hygiene board shall provide to the department the names and addresses of parents of infants who have positive test results. **(5) RELATED SERVICES.** The department shall …refer families of children who suffer form congenital disorders to available health services programs and shall coordinate the provision of these programs… **HFS 115.01 Authority and purpose.** This chapter is promulgated under the authority of §§ 253.13(1) and 227.11 (2), Stats., to specify the congenital and metabolic disorders for which newborn infants are to be screened by				

		means of a sample of blood taken from an infant shortly after birth and tests performed on that sample by the state laboratory of hygiene. **HFS 115.04 Congenital and metabolic disorders.** Blood samples taken from newborns as required under s. 253.13 (1) Stats., shall be tested by the state laboratory… **HFS 115.05 Laboratory tests. (1)** PROCEDURES. The state laboratory shall establish procedures, with the approval of the department, for obtaining blood specimens for the testing required under s. 253.13(1), Stats., and this chapter, performing tests and reporting results of tests performed to the infant's physician and the department as required under s. 253.13(4), Stats. **HFS 115.06 Criteria for adding or deleting conditions.** In determining which disorders are to be added or deleted from s. HFS 115.04, the department shall seek the advice and guidance of medical consultants, staff				

		of the state laboratory and other persons who have expertise and experience in dealing with congenital and metabolic disorders. Criteria to be considered in adding or deleting disorders shall include all of the following :…**(6)** The expected benefits to children ***and society*** in relation to the risks and costs associated with testing for the specific condition. *[emphasis added*]				

WYOMING

State	Statute/ Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?

WY	STATUTE: W.S.A. Title 35, Chapter 1, Article 1 W.S.A. Title 35, Chapter 4, Article 8 RULE: W.C.R. 6959, Chapter 1, Sections 1-8	**35-4-801. Screening required for detection of metabolic diseases and hearing defects in newborn children; conduct of screening; exceptions; fees.** **(a)** Every child born in the state of Wyoming, within three (3) to five (5) days for full term children and five (5) to eight (8) days for premature children following birth unless a different time period is medically indicated, shall be given medical examinations for detection of remedial inborn errors of metabolism major hearing defects and any other metabolic or genetic diseases pursuant to subsection (b) of this section. The screening shall be conducted in accordance with accepted medical practices and in the manner prescribed by the state department of health. **(b)** The specific tests to be done shall be determined by a committee consisting of the following: **(i)** The state health officer in the department of health; **(ii)** The president of the Wyoming state medical society;	**35-4-801.** …**(c)** Informed ***consent*** of parents shall be obtained and if any parent or guardian of a child ***objects to*** a mandatory examination the child is exempt from subsection (a) of this section… *[emphasis added]* **WCR 6959. Chapter 1, Section 5: Consent for Screening.** Consent for screening can be from natural parents, either custodial parent, a sole guardian, single	NO LAW FOUND	YES, but NO: WY law uses the word "consent" but also uses "objects to" which is "dissent." Current DOH practice appears to be opt-out (dissent), not opt-in (consent).	YES

		(iii) A member designated by the Wyoming state pediatric society; **(iv)** A member designated by the Wyoming obstetric/gynecological society. …**(d)** Following consultation with the committee described in subsection (b) of this section, the department of health may provide by rule and regulation for the assessment of a fee, payable to the department, to cover the reasonable cost of the screenings required by this section. Fees collected pursuant to this subsection shall be deposited into a separate account and are continuously appropriated to the department of health for purposes of the newborn screening program required by this section.	parent having custody, prospective adoptive parents or parent of whom the child's custody has been released. No test shall be performed until the written ***consent*** of the natural parents, the custodial parent, the guardian, or the adoptive parents is obtained. If any parent or guardian ***objects to*** the mandatory testing for a child, then the objection shall be in written form and the child exempt from such testing. *[emphasis added]*			
		WCR 6959, Chapter 1, Section 4. Definitions. …Specific genetic and metabolic tests to be done in Wyoming as by the committee designated in W.S. 35-4-801, Section (b), are as follows:…**(g)** ***Any other genetic metabolic disease*** for which testing may	**[DOH PRACTICE]:** *From "News from the Wyoming Department of Health" press release, June 30, 2006:* "Under Wyoming law,			

		hereinafter be required on the basis of action taken by the designated committee. *[emphasis added]*	newborns are initially screened between 24-48 hours after birth unless parents sign a waiver **opting out** of the program." *[emphasis added]*			