

California

Newborn Genetic Testing and Surveillance System

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)	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 <i>establish a genetic disease unit</i> 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	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

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	<p>RULE: CA Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 9, Group 3, Article 2 §6501 – 6507.1</p>	<p>responsibility of designating tests and regulations to be used in executing this program. <i>[emphasis added]</i> 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</p>	<p>§ 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.</p>	<p>(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. <i>[emphasis added]</i></p>		
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		<p>the standards and principles specified in Section 124980.</p> <p>The department may provide laboratory testing 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</p>	<p>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.</p> <p>124975. The Legislature hereby finds and declares that: ...</p> <p>(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.</p>	<p>(c) Before any pregnancy blood samples are released for research purposes, all of the following conditions must be met:</p> <p>(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.</p> <p>(2) Protocol review for scientific merit by the department or another entity authorized by the department.</p> <p>(3) Protocol review by the State Committee for the Protection of Human Subjects.</p>		
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		<p>provide laboratory testing services pursuant to this section and shall perform laboratory services, including, but not limited to, quality control, confirmatory, and emergency testing, necessary to ensure the objectives of this program... <i>[emphasis added]</i></p> <p>...(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.</p>	<p>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: ...</p> <p>(f) No testing, <i>except initial screening for phenylketonuria (PKU) and other diseases that may be added to the newborn screening program, shall require mandatory participation</i>, 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</p>	<p>(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. <i>[emphasis added]</i></p>		
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		<p><i>These experts shall be designated agents of the state with respect to their assignments.</i> 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. <i>[emphasis added]</i></p>	<p>where necessary to determine eligibility for further programs of diagnoses of or therapy for hereditary conditions. <i>[emphasis added]</i> ...</p> <p><i>(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]</i></p>			
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