

## California

### Birth Defects Surveillance System

State	Statute/ Rule	Language Specific to Surveillance System	Data Sharing	Research Authority	Consent Required?	Dissent Allowed?
CA	<p>STATUTES: Health and Safety Code Sections:</p> <p>103825 – 103855 (birth defects)</p> <p>124975 – 124996 (Hereditary Disorders Act)</p> <p>125005 (newborn Screening)</p>	<p><b>103825.</b> The Legislature hereby finds and declares that birth defects, stillbirths, and miscarriages represent problems of public health importance about which too little is known; that these conditions lead to severe mental anguish on the part of parents and relatives and frequently to high medical care costs; and that a system to obtain more information about these conditions could result in development of preventive measures to decrease their incidence in the future. Therefore, it is the intent of the Legislature in enacting this section to accomplish all of the following:</p>	<p><b>103850.</b> ... (c) All research proposed to be conducted by persons other than program staff, using confidential information in the system, shall first be reviewed and approved by the director and the State Committee for the Protection of Human Subjects. Satisfaction of the terms of the director's rules for data access shall be deemed to establish a valid scientific interest for purposes of</p>	<p><b>103840.</b> The director shall use the information collected pursuant to Section 103830 and information available from other reporting systems and health providers to conduct studies to investigate the causes of birth defects, stillbirths, and miscarriages and to determine and evaluate measures designed to prevent their occurrence. The department's investigation of poor reproductive outcomes shall not be limited to geographic, temporal, or occupational associations, but may include investigation of past exposures.</p>	<b>NO</b>	NO

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	<p>NO RULE FOUND, however: <b>“California Research-Ready Biobank”</b> is on the 2010 CA Dept of Public Health’s Rulemaking Calendar: <a href="http://bit.ly/R4NZ8J">http://bit.ly/R4NZ8J</a></p>	<p><b>(a)</b> To maintain an ongoing program of birth defects monitoring statewide. "Birth defect" as used in this chapter means any medical problem of organ structure, function, or chemistry of possible genetic or prenatal origin.  <b>(b)</b> To provide information on the incidence, prevalence, and trends of birth defects, stillbirths, and miscarriages.  <b>(c)</b> To provide information to determine whether environmental hazards are associated with birth defects, stillbirths, and miscarriages.  <b>(d)</b> To provide information as to other possible causes of birth defects, stillbirths, and miscarriages.  <b>(e)</b> To develop prevention strategies for reducing the incidence of birth defects, stillbirths, and miscarriages.  <b>(f)</b> To conduct interview studies about the causes of <b>birth defects</b>. . [emphasis added]</p>	<p>subdivision (a), entitling the researcher to review records collected pursuant to Section 103830 and to contact case subjects and controls. Before confidential information is disclosed pursuant to this section to any other person, agency, or organization, the requesting entity shall demonstrate to the department that the entity has established the procedures and ability to maintain the confidentiality of the information.</p>	<p><b>103850. (a)</b>...Access to confidential information shall be limited to authorized program staff, and persons with a valid scientific interest, who meet qualifications as determined by the director, who are engaged in demographic, epidemiological or other similar studies related to health.  <b>125002. (a)</b> 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.</p>		
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		<p><b>(g)</b> To affirm the authority of the state department to contract with a qualified entity to operate the birth defects monitoring program statewide.</p> <p><b>103830.</b> The director shall maintain a system for the collection of information, necessary to accomplish the purposes of this chapter. The director shall require health facilities, with 15 days' notice, to make available to authorized program staff the medical records of children suspected or diagnosed as having birth defects, including the medical records of their mothers. In addition, health facilities shall make available the medical records of mothers suspected or diagnosed with stillbirths or miscarriages and other records of persons who may serve as controls for interview studies about the causes of birth defects...</p>	<p><b>(d)</b> Notwithstanding any other provision of law, any disclosure authorized by this section shall include only the information necessary for the stated purpose of the requested disclosure, and shall be made only upon written agreement that the information will be kept confidential, used for the approved purpose, and not be further disclosed.</p>	<p><b>(b)</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:</p> <p><b>(1)</b> Research to identify risk factors for children's and women's diseases.</p> <p><b>(2)</b> Research to develop and evaluate screening tests.</p> <p><b>(3)</b> Research to develop and evaluate prevention strategies.</p> <p><b>(4)</b> Research to develop and evaluate treatments.</p> <p><b>(c)</b> Before any pregnancy blood samples are released for research purposes, all of the following conditions must be met:</p>		
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		<p><b>103835.</b> The birth defects monitoring program shall operate statewide...</p> <p><b>103855.</b> The department may enter into a contract for the establishment and implementation of the birth defects monitoring program. The contract shall include provisions requiring full compliance with all the requirements of this chapter. The term of the contract may be in excess of one year, but no longer than three years. Funds shall be allocated in accordance with the state Budget Act. Funds withheld from the contractor at the conclusion of a fiscal year until specified tasks are completed shall be released promptly on proof of substantial completion, and shall not be offset against any funding for the subsequent fiscal year.</p>	<p><b>(e)</b> The furnishing of confidential information to the department or its authorized representative in accordance with this section shall not expose any person, agency, or entity furnishing the information to liability, and shall not be considered a waiver of any privilege or a violation of a confidential relationship.</p>	<p><b>(1)</b> 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><b>(2)</b> Protocol review for scientific merit by the department or another entity authorized by the department.</p> <p><b>(3)</b> Protocol review by the State Committee for the Protection of Human Subjects.</p> <p><b>(d)</b> 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 department, the storage, analysis and sharing of pregnancy blood samples for research purposes shall be done in compliance with Section 103850, pertaining to confidentiality of information.</p>		
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		<p><b>124977.</b>  <b>(b)...</b>(7) The Birth Defects Monitoring Program Fund is hereby created as a special fund in the State Treasury. Fee revenues collected pursuant to paragraph (4) shall be deposited into the fund and shall be available upon appropriation by the Legislature to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program. Notwithstanding Section 16305.7 of the Government Code, interest earned on funds in the Birth Defects Monitoring Program Fund shall be deposited as revenue into the fund to support the Birth Defects Monitoring Program.</p>		<p><b>(e)</b> The department shall adopt regulations specifying the protocols and conditions under which blood samples will be released for research purposes...  <b>(f)</b> Until such time that regulations are adopted by the department pursuant to subdivision (e), the Genetic Disease Screening Program and the Birth Defect Monitoring Program shall release blood samples to only those researchers who meet the requirements of this section, including . . .</p>		
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