CALIFORNIA

Birth Defects Surveillance System

State	Statute/Rule	Language Specific to Surveillance System	Data Sharing	Research Authority	Consent Required?	Dissent Allowed?
CA	STATUTES: Health and Safety Code Sections: 103825 – 103855 (birth defects) 124975 – 124996 (Hereditary Disorders Act) 125005 (newborn Screening) NO RULE FOUND, however: **"California Research-Ready Biobank"** is on the 2010 CA Dept of Public Health's Rulemaking Calendar: http://bit.ly/R4NZ8J	**103825.** 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: **(a)** 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)** To provide information on the incidence, prevalence, and trends of birth defects, stillbirths, and miscarriages. **(c)** To provide information to determine whether environmental hazards are associated with birth defects, stillbirths, and miscarriages. **(d)** To provide information as to other possible causes of birth defects, stillbirths, and miscarriages. **(e)** To develop prevention strategies for reducing the incidence of birth defects, stillbirths, and miscarriages. **(f)** To conduct interview studies about the causes of ***birth defects***. . *[emphasis added]* **(g)** To affirm the authority of the state department to contract with a qualified entity to operate the birth defects monitoring program statewide.	**103850.** … **(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 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. **(d)** 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	**103840.** 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. **103850. (a)**…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. **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**	NO

		103830. 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… **103835.** The birth defects monitoring program shall operate statewide… **103855.** 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. **124977. (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.	that the information will be kept confidential, used for the approved purpose, and not be further disclosed. **(e)** 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.	**(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. **(c)** Before any pregnancy blood samples are released for research purposes, all of the following conditions must be met: **(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. **(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 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. **(e)** The department shall adopt regulations specifying the protocols and conditions under which blood samples will be released for research purposes… **(f)** 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 . . .		

Cancer Surveillance System

State	Statute/Rule	Language Specific to Surveillance System	Data Sharing	Research Authority	Consent Required?
CA	STATUTE: Health and Safety Code Section 103875-103885 RULE: California Code of Regulations, Title 17, §2593 -	**Section 103875. (a)** The department shall conduct a program of epidemiological assessments of the incidence of cancer. The program shall encompass all areas of the state for which cancer incidence data are available. The program shall include the monitoring of cancers associated with suspected carcinogens encountered by the general public both in occupational locations and in the environment generally. **103885. (a)** The director shall establish a statewide system for the collection of information determining the incidence of cancer, using population-based cancer registries modeled after the Cancer Surveillance Program of Orange County. As of the effective date of this section the director shall begin phasing in the statewide cancer reporting system…By July 1, 1990, the statewide cancer reporting system shall be fully operational… **(c)** The director shall designate cancer as a disease required to be reported in the state or any demographic parts of the state in which cancer information is collected under this section. All cancers diagnosed or treated in the reporting area shall thereafter be reported to the representative of the department authorized to compile the cancer data, or any individual, agency, or organization designated to cooperate with that representative. **§2593 Neoplasm, Cancer. (a)** Definitions. …**(3)** Regional cancer registry means the organization authorized to receive and collect cancer data for a designated area of the state an which maintains the system by which the collected information is reported to the Department…**(13)** Modeled after the Cancer Surveillanc3 Program of Orange County means a population-based registry that collects treatment data, has a phased implementation, collects follow-up data, has a community advisory component and receives data in a machine-readable format from cancer reporting facilities…	**103885.** …**(f)** All physicians and surgeons, hospitals, outpatient clinics, nursing homes and all other facilities, individuals or agencies providing diagnostic or treatment services to patients with cancer shall grant to the department or the authorized representative access to all records that would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or ***medical status of any identified cancer patient*** … **(g)(4)**The department and any regional cancer registry designated by the department may enter into agreements to furnish confidential information to other states' cancer registries, federal cancer control agencies, local health officers, or health researchers… *[emphasis added]* **103885.** …**(g)(6)** 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 information to liability, and shall not be considered a waiver of any privilege or a violation of a confidential relationship. **§2593**. …**(b)(18)** Cancer reporting facilities and physicians shall employ a mechanism to ensure that their patients are informed that cancer has been designated a reportable disease and that the facility will report each patient with cancer to the Department as required by law. Patient information sheets for this purpose will be supplied to physicians by the Department.	**103885.** …**(g)(3)** Persons with a valid scientific interest who are engaged in demographic, epidemiological, or other similar studies related to health who meet qualifications as determined by the department, and who agree, in writing, to maintain confidentiality, may be authorized access to confidential information. **(4)** The department and any regional cancer registry designated by the department may enter into agreements to furnish confidential information to other states' cancer registries, federal cancer control agencies, local health officers, or health researchers for the purposes of determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect. Before confidential information is disclosed to those agencies, officers, researchers, or out-of-state registries, the requesting entity shall agree in writing to maintain the confidentiality of the information, and in the case of researchers, shall also do both of the following: **(A)** Obtain approval of their committee for the protection of human subjects established in accordance with Part 46 (commencing with Section 46.101) of Title 45 of the Code of Federal Regulations…	NO

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	STATUTES: Health and Safety Code Sections: 12500 – 125002 124975 – 124996 (Heriditary 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 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 facilities or contract with any laboratory that it deems qualified to conduct tests required under this section. However, notwithstanding	**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. **§ 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.	**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. **(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: **(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.	NO	YES

		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 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. ***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]*	**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. **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: …**(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]*	**(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]*		

Vaccination Surveillance System

State	Statute/ Rule	Language Specific to Surveillance System	Exemption	Data Sharing	Consent Required?	Dissent Allowed?
CA	STATUTE: Health & Safety Code Division 105, Part 2, Chapter 2.5 NO RULE FOUND	**DISCLOSURE OF IMMUNIZATION STATUS. Section 120440**. …**(c)** …unless a refusal to permit record sharing is made pursuant to subdivision (e), health care providers, and other agencies, including, but not limited to, schools, child care facilities, service providers for the California Special Supplemental Food Program for Women, Infants, and Children (WIC), health care plans, foster care agencies, and county welfare departments, ***may disclose the information set forth in paragraphs (1) to (9)***, inclusive, from the patient's medical record, or the client's record, to local health departments operating countywide or regional immunization information and reminder systems and the State Department of Health Services. *[emphasis added]* The following information shall be subject to this subdivision: **(1)** The name of the patient or client and names of the parents or guardians of the patient or client. **(2)** Date of birth of the patient or client. **(3)** Types and dates of immunizations received by the patient or client. **(4)** Manufacturer and lot number for each immunization received. **(5)** Adverse reaction to immunizations received. **(6)** Other nonmedical information necessary to establish the patient's or client's unique identity and record. **(7)** Current address and telephone number of the patient or client and the parents or guardians of the patient or client. **(8)** Patient's or client's gender. **(9)** Patient's or client's place of birth.	**Section 120440**. …**(e)** A patient or a patient's parent or guardian may refuse to permit record sharing. The health care provider administering immunization and any other agency possessing any patient or client information listed in subdivision (c), if planning to provide patient or client information to an immunization system, as described in subdivision (b), shall inform the patient or client, or the parent or guardian of the patient or client, of the following:… …**(4)** The patient or client, or the parent or guardian of the patient or client, may refuse to allow this information to be shared in the manner described, or to receive immunization reminder notifications at any time, or both. After refusal, the patient's or client's physician **may maintain access** to this information for the purposes of patient care or protecting the public health. After refusal, the local health department and the State Department of Health Services ***may maintain access*** to this information for the purpose of protecting the public health pursuant to Sections 100325, 120140, and 120175, as well as Sections 2500 to 2643.20, inclusive, of Title 17 of the California Code of Regulations.	**Section 120440.** …**(l)** Subject to any other provisions of state and federal law or regulation that limit the disclosure of health information and protect the privacy and confidentiality of personal information, local health departments and the State Department of Health Services may share the information listed in subdivision (c) with a state, local health departments, health care providers, immunization information systems, or any representative of an entity designated by federal or state law or regulation to receive this information. The State Department of Health Services may enter into written agreements to exchange confidential immunization information with other states for the purposes of patient care, protecting the public health, entrance into school, child care and other institutions requiring immunization prior to entry, and the other purposes described in subdivision (d). The written agreement shall provide that the state that receives confidential immunization information must maintain its confidentiality and may only use it for purposes of patient care, protecting the public health, entrance into school, child care and other institutions requiring immunization prior to entry, and the other purposes described in subdivision (d). Information may not be shared pursuant to this subdivision if a patient or client, or parent or guardian of a patient or client, refuses to allow the sharing of immunization information pursuant to subdivision (e).	NO	YES – but state health dept. will continue to have access. (Sec. 120440 (e)(4)