

CALIFORNIA
BIRTH DEFECTS
MONITORING
PROGRAM

SCIENTIFIC

FOUNDATIONS

SERIES

CONFIDENTIALITY REQUIREMENTS & PROCEDURES

FEBRUARY 2000

CONFIDENTIALITY REQUIREMENTS & PROCEDURES

The California Birth Defects Monitoring Program collects and analyzes data on children with birth defects as part of its mission:

- *to find birth defects causes, risk and preventive factors*
- *to address public concerns about birth defects and the environment.*

To do this vital research, California statutes grant access to medical records in health facilities (Appendix A, Section 103830). Statutes also charge the Program to maintain confidentiality of all records with identifying information (Appendix A, Section 103850).

We believe individuals have a fundamental right to the confidentiality of their medical information. All data is carefully guarded and is used solely to study birth defects. Extensive precautions ensure confidential information will not be used or abused in ways that might directly or indirectly harm the individuals involved.

The Chief Operating Officer is ultimately responsible for developing and implementing these policies and procedures to uphold our ethical and legal obligation to safeguard confidentiality. These procedures are reviewed and updated periodically.

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It is the responsibility of every employee to protect the confidentiality of the records the Program possesses. This is not only a moral obligation, it is a legal one.

EMPLOYEE SECURITY

California Birth Defects Monitoring Program employees understand and respect the confidential nature of medical and other information. To safeguard confidentiality:

- New employees sign a confidentiality agreement (Appendix B). The Employee Handbook stresses its importance.
- Employees receive thorough training in confidentiality-protecting procedures, supplemented by written instruction. Trainers emphasize the importance of strictly following these procedures.
- Supervisors monitor employees to ensure they are following proper confidentiality routines.
- Staff review confidentiality procedures annually.
- Management ensures that when employees leave the Program, all confidential materials and files have been returned.
- Former employees remain under obligation to protect the confidentiality of all data and documents.
- Deliberately violating the confidentiality agreement is grounds for immediate dismissal.

DATA COLLECTION PROCEDURES

State law grants the Program access to medical records in hospitals and outpatient clinics which regularly diagnose or treat children with birth defects, or provide genetic counseling or prenatal diagnostic services (Appendix A).

Data collection staff visit these facilities to gather information about children with birth defects. They log names of children with potentially reportable conditions and/or names of women who are known to have given birth to these children. Staff then review their medical records and record information onto abstract forms and/or laptop computers. At appropriate times, data is purged from the employee's laptop and all logs are shredded.

Because data collection staff work out of their homes and travel to many facilities, special procedures protect the safety of this information. Employees are required to:

- Carry all paper records, computers and computer disks from one location to another in locked briefcases.
- Display external tags on their briefcases and portable computers saying, "If found, please

return to: California Birth Defects Monitoring Program" with the proper office address.

- Conceal locked briefcases and portable computers in their vehicles' trunks if they must temporarily store confidential information while in the field. They must store locked briefcases and portable computers in their homes or hotel rooms overnight.
- Hand carry locked briefcases when traveling by airplane.
- Store all paper records and computer disks in locked metal cabinets in their homes.
- Personally photocopy records, when necessary, rather than using duplicating services.
- Mail all paper containing data and all computerized disks in sealed and taped envelopes stamped "Confidential."
- Shred paper containing confidential information before disposing of it.

The Data Collection Manager ensures that data collection staff follow these regulations. The Program reviews, modifies, and implements new confidentiality procedures as necessary.

Extensive computer security measures control access to confidential information.

COMPUTER SECURITY

Medical information is entered into a computerized database in the Program's main office. Access to the database or other computer files is through a tightly controlled computer network.

- The Network Administrator is responsible for network security and controls access to confidential data.
- To gain entry into the network, employees must correctly type their personal ID and password. Access to the confidential database is granted only to those staff who require it.
- The Network Administrator grants access to the confidential database only to those staff members whose supervisors authorize access. The network bars all others from accessing these files.
- Identifying information is removed from the analytic database and stored in a separate file. Only staff familiar with the database design can link the 2 files.
- Offsite staff with telephone access to the main computer must correctly provide multiple passwords. The computer automatically records the user's identity and the time and length of connection.
- The confidential database cannot be accessed from the Internet.

- Electronic transmission of confidential data is encrypted.
- Files with confidential data are on California's Health and Welfare Data Center mainframe computer. This computer system is protected by the Resource Allocation Control Facility (RACF) software package. An RACF Coordinator controls access and maintains a list of authorized users and passwords.

STORAGE & DISPOSAL OF MATERIALS

Employees take special precautions to safely store and dispose of confidential materials. They are required to:

- Store all paper records, computer disks, and tapes in locked file cabinets at night.
- Shred discarded records daily.
- Store nightly back-up copies of network computer files in a locked area.
- Erase hard disk drives of obsolete computers before discarding.

BUILDING SECURITY

All California Birth Defects Monitoring Program offices follow specific confidentiality-protecting routines:

- Each office has a designated person responsible for building security.
- Offices are not open to the public. Access is controlled by a receptionist and/or locked doors.
- An employee escorts visitors in the office at all times. Non-employees must sign in/out at the front desk and/or wear badges while in the building.
- A security alarm system protects each office after hours.

Because data entry and analysis occurs primarily in the main office, this site has additional procedures in effect.

Parents can participate in research studies confident that personal information will be protected.

The Program conducts case-control interview studies involving parents of children with birth defects (cases) and parents of healthy children (controls). Participation is entirely voluntary – our high response rate indicates parents want to assist these research efforts. Special guidelines for the studies safeguard confidentiality and protect families’ privacy.

- The California Health and Human Services Agency, Committee for the Protection of Human Subjects approves study proposals that protect the privacy and safety of participants and maintain the confidentiality of data.

- The Program identifies cases through routine data collection (discussed on page 3). We identify controls from birth certificates or hospital records.
 - We mail an introductory letter explaining the study and requesting participation. Parents are asked to respond by mail or telephone.
 - A highly trained interviewer asks a series of structured questions and records parents' replies. All responses are confidential.
- Some studies involve taking biologic samples (such as blood or cheek cells) from parents and infants. Research staff assign laboratory results a study number and store them separately from participants' names.
 - Researchers do not reveal any identifying information when they report study findings.

Program information is designed for improving public health, and is not available for other purposes.

PUBLISHED REPORTS

The California Birth Defects Monitoring Program reports findings to researchers, health care professionals, public health officials, and the general public in scientific journals, Program publications, and the news media.

- The Chief Operating Officer or his designee reviews data prior to public release, ensuring confidentiality is maintained.
- Data is reported in summary form, most commonly as rates.
- The Program does not report rates based on less than 5 cases when the anonymity of the individuals involved would be compromised.

SCIENTIFIC COLLABORATION

Qualified researchers can request access to confidential information for scientific purposes according to rules outlined in the California Birth Defects Monitoring Program's *Scientific Collaboration Protocol*. Research must be approved by the State Committee for the Protection of Human Subjects. Collaborators must sign a written confidentiality agreement – violation is subject to a civil penalty of \$500.

OTHER REQUESTS FOR DATA

Health professionals and the public have questions about birth defects occurrence. The Program responds with rates and other non-confidential information.

The Program **DOES NOT RELEASE:**

- Names, addresses or other identifying information.
- Data regarding individual physicians.
- Birth defects rates by hospital. Hospitals can receive information on their own facilities by request.
- Information to insurance companies or employers.

FUTURE ACCESS

Amendment of state law is required to change the regulations for accessing data or releasing confidential information. The legislative process is conducted under public scrutiny which helps protect against potential abuses.

**CHAPTER 1 BIRTH DEFECTS
MONITORING PROGRAM****§ 103825. Legislative findings and
declaration**

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 division 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.

(g) To affirm the authority of the state department to contract with a qualified entity to operate the birth defects monitoring program statewide.

§ 103830. Collection of information; system establishment; medical records

The director shall maintain a system for the collection of information, necessary to accomplish the purposes of this division. 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. If it is necessary to photocopy records made available under this section, copying expenses shall be paid by the state department.

“Health facilities” as used in this section means general acute care hospitals, and physician-owned or operated clinics, as defined in Section 1200,

which regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services.

§ 103835. Scope of program; assessment of resources

The birth defects monitoring program shall operate statewide. It is the intent of the Legislature that the adequacy of program resources shall be assessed annually, and that the annual assessment shall include a consideration of at least all the following factors:

- (a) The numbers of births in the state.
- (b) The scope of program activities.
- (c) Any urgent situation requiring extraordinary commitment of present or planned program staff or resources.

§ 103840. Investigative studies

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.

§ 103845. Advisory committee; membership

The director shall appoint an advisory committee to advise on the implementation of this division. Each of the disciplines of epidemiology, hospital administration, biostatistics, maternal and child health and public health shall be represented on the committee. At least one of the members shall be a representative of the manufacturing industry.

§ 103850. Confidentiality of information; research; review and approval; civil penalty

(a) All information collected and analyzed pursuant to this division shall be confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purposes provided in this division. Access to the 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, and who agree, in writing, to maintain confidentiality.

(b) The state department shall maintain an accurate record of all persons who are given access to the information in the system. The record shall include: the name of the persons authorizing access; name, title, and organizational affiliation of persons given access; dates of access; and the specific

purpose for which information is to be used. The record of access shall be open to public inspection during normal operating hours of the state department.

(c) All research proposed to be conducted by persons other than program staff, using the 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.

(d) Whenever program staff, pursuing program objectives, deems it necessary to contact case subjects and controls, program staff shall submit a protocol describing the research to the director and to the State Committee for the Protection of Human Subjects. Once a protocol is approved by that committee, program staff shall be deemed to have established a bona fide research purpose, and shall be entitled to complete the approved project and contact case subjects and controls without securing any additional approvals or waivers from any entity.

(e) Nothing in this section shall prohibit the publishing by the state department of statistical complications relating to birth defects, stillbirth, or miscarriage which do not in any way identify

individual cases or individual sources of information.

(f) Any person who, in violation of a written agreement to maintain confidentiality, discloses any information provided pursuant to this section, or who uses information provided pursuant to this section in a manner other than as approved pursuant to this section may be denied further access to any confidential information maintained by the state department. That person shall also be subject to a civil penalty of five hundred dollars (\$500). The penalty provided in this section shall not be construed as restricting any remedy, provisional or otherwise, provided by law for the benefit of the state department or any person.

§ 103855. Contract for establishment and implementation of program

The state 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 division. 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.

I recognize and accept

- The necessity of maintaining the confidentiality of all data and documents collected and processed by the California Birth Defects Monitoring Program.
- The importance of my part in assuring the right of privacy of persons and institutions cooperating in this project.
- The Department of Health Services is obliged by law to maintain confidentiality.

Therefore, I will not divulge any confidential information to anyone except another member of the California Birth Defects Monitoring Program staff or the original reporting source.

When I am no longer an employee of the Program, I agree to remain under obligation to protect the confidentiality of all data and documents.

I have read the confidentiality procedures document and recognize that any deliberate violation of confidentiality will result in immediate dismissal.

Signature _____

Title _____

Date _____

Human Resources _____

Date _____



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The California Birth Defects Monitoring Program –
a public health program devoted to finding causes of birth defects –
is funded through the California Department of Health Services
and jointly operated with the March of Dimes Birth Defects Foundation.

www.cbtmp.org

