SUBCHAPTER 47C – BIRTH DEFECTS MONITORING PROGRAM

SECTION .0100 - MONITORING PROGRAM

10A NCAC 47C .0101 GENERAL

(a) This Section implements G.S. 130A, Article 5, Part 7 entitled Birth Defects. The legislation establishes a Birth Defects Monitoring Program within the State Center for Health Statistics. The purpose of the monitoring program is to compile, tabulate and publish information related to the incidence and prevention of birth defects.

(b) The Birth Defects Monitoring Program is administered by the State Center for Health Statistics, Department of Health and Human Services.

History Note: *Authority G.S. 130A-131.17;*
Eff. August 1, 2000;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47C .0102 DEFINITIONS

The following definitions shall apply throughout this Section:

(1) "Abstract" refers to a document or documents containing information obtained from a patient's medical record.

(2) "Birth Defect" means any physical, functional or chemical abnormality present at birth that is of possible genetic or prenatal origin.

(3) "Case-Finding" is the process used to identify potential cases for inclusion in the central registry of the Birth Defects Monitoring Program. Potential cases may be ascertained through review of medical records, disease indices, logs, vital records, hospital discharge summaries, and other sources.

(4) "Central Registry" is the database of birth defect cases obtained through the surveillance activities of the Birth Defects Monitoring Program.

(5) "Confidential Information" is any information that could be used to reveal, either directly or indirectly, the identity of a patient with a birth defect.

(6) "Department" is the NC Department of Health and Human Services.

(7) "Director" is the Director of the State Center for Health Statistics (SCHS).

(8) "ICD-9-CM" means the International Classification of Diseases, 9th Revision, Clinical Modification, Volumes 1 and 2, US Department of Health and Human Services, US Government Printing Office, Washington, DC.

(9) "Institutional Review Board" means a committee for the protection of human subjects which is approved by the US Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations.

(10) "Licensed Medical Facility" means general acute care hospitals and ambulatory surgical facilities licensed by the Department of Human Resources pursuant to G.S. 131E-77, which regularly provide services for the diagnosis and treatment of birth defects, genetic counseling, or prenatal diagnostic services.

(11) "Monitoring Program" means the Birth Defects Monitoring Program (BDMP) established within the Department.

(12) "Program Director" is the individual directly responsible for oversight and operation of the Birth Defects Monitoring Program.

(13) "Program Staff" means employees of the State Center for Health Statistics or persons providing services to SCHS under written contract who are authorized by the director to collect and have access to information from the monitoring program.

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10A NCAC 47C .0103 BIRTH DEFECTS ADVISORY COMMITTEE

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Expired Eff. January 1, 2016 pursuant to G.S. 150B-21.3A.

10A NCAC 47C .0104 SURVEILLANCE OF BIRTH DEFECTS; CENTRAL REGISTRY

(a) The monitoring program shall operate statewide.

(b) In order for information on a child to be included in the monitoring program's central registry, the following conditions must be met:

(1) The state of birth or the mother's state of residence at the time of birth must have been in North Carolina; and

(2) The child must have a birth defect or other specified perinatal condition that can adversely affect his or her health and development.

(c) The central registry shall include birth defects occurring in a fetal death, miscarriage, or pregnancy termination.

(d) The coding scheme used by the monitoring program to classify birth defects shall be based on a medically recognized system, such as ICD-9-CM or the CDC/BPA system used by the Centers for Disease Control and Prevention in the Metropolitan Atlanta Congenital Defects Program, as described in the report titled "Metropolitan Atlanta Congenital Defects Program Procedure Manual," dated June, 1993.

(e) The program director shall, in consultation with the birth defects advisory committee, develop a list of specific birth defects to be monitored. In developing this list consideration shall be given to the following:

(1) The medical and public health significance of the condition, including potential preventability;

(2) The feasibility of obtaining reasonably complete and reliable diagnostic information on the condition from the data sources available to the monitoring program; and

(3) The consistency with birth defects data collected and reported by the Centers for Disease Control and Prevention and by other state-based birth defects surveillance programs.

(f) The monitoring program may utilize for case ascertainment any data source routinely collected by or available to the State Center for Health Statistics, such as vital records, hospital discharge information, and Health Services Information System files.

(g) The monitoring program may, upon request, review and abstract information on a diagnosed or suspected birth defect from any medical record in a licensed medical facility. When obtaining such information the following conditions shall apply:

(1) The administrator, director, or person in charge of a licensed medical facility shall designate one staff member as the contact person for the monitoring program. That staff member will coordinate scheduled visits by program staff to review disease indices, labor and delivery logs, or other case-finding data sources. That person will also be responsible for arranging visits by program staff for medical records review;

(2) Monitoring program staff and the contact person shall establish a general schedule of case-finding and record review visits. This schedule shall take into account the capabilities of the medical facility in responding to requests, as well as the expected needs and workload of the monitoring program;

(3) Procedures for record management and the use of copiers and other equipment at the medical facility shall be agreed upon with each facility. Monitoring program staff shall abide by these procedures at all times; and

(4) The medical records and other original materials provided by the medical facility shall not be removed from that facility. All information, either on paper or in electronic form, which is removed from the medical facility shall be transported by secure means at all times. Abstracts, printouts, notes, and other information will be carried in locked briefcases.

(h) Physicians and other persons involved in the diagnosis, care, and treatment of birth defects may report information on a diagnosed birth defect to the monitoring program. Physicians and other persons who submit a case report or other information to the monitoring program shall be immune from civil or criminal liability that might otherwise be incurred or imposed for releasing this information based upon invasion of privacy or breach of physician-patient confidentiality.

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10A NCAC 47C .0105 CONFIDENTIALITY

(a) Access to patient-level information collected by the monitoring program shall be limited to program staff authorized by the doctor.

(b) All program staff shall be required to sign an agreement to actively protect the confidentiality of patient information collected through the monitoring program.

(c) All identifying or potentially identifying information collected by the monitoring program, including abstracts, case reports, computer printouts, notes and other material shall be stored in locked offices or in locked file cabinets at all times.

(d) Central registry files stored in electronic format shall be maintained in a password-protected local area computer network. Only authorized program staff shall have access to this information. Access to the data is controlled by the network administrator. Back up data files shall be maintained at the State Computer Center. This computer system is protected by the Resource Allocation Control Facility (RACF) system.

(e) A publicly accessible data file containing limited patient-level information from the central registry may be made available. This file may contain the following data items only: county of residence, county of birth, year of birth, sex of infant, race of infant, age of mother, and birth defect diagnoses. All other patient information contained in the central registry shall be considered confidential and not open to public inspection, except as specified in Paragraph (f) of this Rule.

(f) Confidential information maintained in the central registry may be disclosed in the following circumstances, when authorized by the Director:

(1) A patient shall have access to review or obtain copies of his/her own records; or

(2) Information may be disclosed as provided in Rule .0106 of this Section.

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10A NCAC 47C .0106 RELEASE OF MONITORING PROGRAM INFORMATION FOR RESEARCH

(a) Individuals other than authorized program staff requesting access to confidential monitoring program information for research purposes must establish a valid scientific interest in order to obtain this information. An application requesting access to monitoring program information must contain a research protocol and be submitted to the Director. The protocol shall contain the following information:

(1) The name and qualifications of the principal investigator, professional staff, and every person who will review, analyze, or access the data;

(2) The purpose of the research;

(3) The research design and statistical methods to be used to analyze the data;

(4) The proposed benefits to be derived from such research and the potential risk to human subjects; and

(5) The plans and procedures to maintain the confidentiality of information provided by the monitoring program.

(b) The criteria to establish a valid scientific interest shall include the following:

(1) The key investigators shall have significant training and experience in biomedical research as demonstrated by a history of prior research and publication of results in peer-reviewed journals. For bona fide student proposals and research carried out for educational purposes, faculty committee members should possess these qualifications;

(2) The purpose of the research shall be clearly stated, and the hypotheses under investigation shall be scientifically compelling, as judged by the importance of the question relative to the fields of epidemiology, medicine, or public health;

(3) The research design shall be scientifically sound with respect to exposure measurement, assessment and control of other relevant risk factors, and statistical power. Statistical techniques to be used in the analysis shall be clearly described and appropriately applied;

(4) The benefits of the proposed research, and the potential risk to individuals whose identity may be disclosed or who are involved as study participants must be clearly stated;

(5) Plans of how the investigators propose to maintain the confidentiality and integrity of the information provided by the monitoring program shall be clearly detailed and must adequately protect the security of the data;

(6) The hypothesis or topic to be studied must not already be under investigation; and

(7) If the investigator intends to contact individuals whose names were provided by the monitoring program, the protocol must contain strong methodologic support for the need for such contact.

(c) Before any data are released, the investigator will be required to submit to the Director a signed written statement guaranteeing the following:

(1) The investigator has received written approval of the research protocol from an Institutional Review Board;

(2) The investigator shall not allow any person other than those identified in the protocol to access, use, or otherwise review the data supplied by the monitoring program;

(3) There shall be no deviation from the protocol without explicit advance review and approval by the Director and the Institutional Review Board;

(4) Information obtained in the course of activities undertaken or supported using the data from the monitoring program shall not be used for any purpose other than the exact purpose for which it was supplied; and

(5) Any confidential or potentially identifying information supplied by the monitoring program which is copied or otherwise transferred shall be destroyed upon completion of the study unless otherwise stated in the research protocol.

(d) Upon completion of the study, the investigator shall submit one copy of the completed research paper or abstract to the Director.

History Note: *Authority G.S. 130A-131;*
Eff. August 1, 2000;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.