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.

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.