CHAPTER 47 - INFORMATION SERVICES

SUBCHAPTER 47A - STATE CENTER FOR HEALTH STATISTICS

10A NCAC 47A .0101 CHARGES

Upon request, the State Center for Health Statistics (SCHS) will undertake special computer runs for data not in a published form. The SCHS may charge the requestor for the cost of the computer run, including staff and support time.

History Note: *Authority G.S. 12-3.1(c); 130A-5(3);*
Eff. December 1, 1980;
Transferred and Recodified from 10 NCAC 5C .0007 Eff. April 4, 1990;
Amended Eff. August 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47A .0102 RELEASE OF MEDICAL RECORDS FOR RESEARCH PURPOSES

(a) A person may request the State Center for Health Statistics to release for bona fide research purposes medical records of individual patients which identify the individual described in the record. The request shall be in writing and shall contain the following information:

(1) name of organization requesting the data;
(2) names of principal investigators;
(3) name of project;
(4) purpose of project;
(5) if the project is being conducted for a governmental agency, the name of the agency and a contact person within the agency;
(6) description of proposed use of the data, including protocols for contacting patients, relatives, service providers, etc.;
(7) description of measures to protect the security of the data;
(8) an assurance that the data will not be used for purposes other than those described in the protocol;
(9) an assurance that the data will be properly disposed of upon completion of the project; and
(10) an assurance that the results of the project will be provided to the State Center for Health Statistics.

(b) The Director of the State Center for Health Statistics shall grant or deny the request for release of medical records within 15 days after receipt of the information described in Paragraph (a) of this Rule. The decision will be in writing and will be based upon the following:

(1) do the objectives of the project require patient identifying data;
(2) can the objective of the project be reached with the use of the data;
(3) does the objective of the project have a reasonable chance to answer a legitimate research question;
(4) will the project jeopardize the ability of the State Center for Health Statistics to collect data in the future;
(5) will the project place the patient in jeopardy; and
(6) is the patient's right to privacy adequately protected.

(c) If a request for release of medical records is denied, the applicant may appeal the decision in writing to:

State Health Director
1915 Mail Service Center, Raleigh, North Carolina 27699-1915
Raleigh, North Carolina, 27602-2091.

Appeals shall be conducted in accordance with G.S. 130A-24(a) and 10A NCAC 01.

History Note: *Authority G.S. 130A-374;*
Eff. January 1, 1985;
Transferred and Recodified from 10 NCAC 5C .0008 Eff. April 4, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

SUBCHAPTER 47B - CANCER REGISTRY

SECTION .0100 – CANCER REGISTRY

10A NCAC 47B .0101 GENERAL

(a) The purpose of the central cancer registry is to receive and to compile, tabulate, and preserve statistical, clinical, and other reports and records relating to the incidence, treatment and cure of cancer, and to provide assistance and consultation for public health work. The statistical reports and records, and the assistance rendered to health care facilities, health planning agencies and research facilities are intended to improve cancer treatment, extend the life of the cancer patient, identify high risk groups or areas of the state and attempt to lower the morbidity and mortality of cancer in North Carolina.

(b) The central cancer registry is administered by State Center for Health Statistics, Division of Public Health, North Carolina Department of Health and Human Services, 1908 Mail Service Center, Raleigh, North Carolina 27699-1908.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
Eff. January 1, 1982;
Amended Eff. July 1, 1985;
Transferred and Recodified from 10 NCAC 8A .0801 Eff. April 4, 1990;
Amended Eff. April 1, 2001; December 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47B .0102 DEFINITIONS

The following definitions shall apply throughout this Section:

(1) "Abstract" refers to a document or documents, including electronic documents and files, containing information drawn from a cancer patient's medical record.
(2) "Cancer registrar" is a registrar who abstracts information from the medical records of cancer patients.
(3) "Death match" refers to the procedure of comparing registry cases with death certificate information, for confirmation of the reported death of any cancer patient, to determine if the cancer constituted the cause of death, and for identification of cases missed in routine reporting procedures.
(4) "Definitive treatment" refers to all methods of treatment intended to modify or control the cancer including no treatment, palliative care, and follow-up care.
(5) "Follow-up information" is information on the post-treatment status of a cancer patient whose abstract was submitted to the registry previously.
(6) "Identifying information" is any portion of any abstract that might reveal the personal identity of a cancer patient.
(7) "Morphologic information" refers to pathology, cytology, tumor markers, or laboratory tests that identify cell types of malignant neoplasms.
(8) "Palliative treatment" refers to treatment that is not intended to effect a cure, but the treatment procedure is expected to improve "quality of life" by temporarily relieving distressing symptoms.
(9) "Participating facility" is a health care facility that submits abstracts to the registry.
(10) "Pathology report" is the written report generated by a pathologist, stating the diagnostic interpretation of tissue samples or cellular material examined by the pathologist.
(11) "Personnel" means persons who are employees of the Department of Health and Human Services, or who are persons who provide services to the central cancer registry through a written contract.
(12) "Positive pathology report" is a pathology report confirming the presence of cancer.
(13) "Registrar" is an employee of a health care facility who prepares abstracts of medical records.
(14) "Registry" is the central cancer registry. The registry is administratively assigned to the State Center for Health Statistics, Department of Health and Human Services.
(15) "Statistical report" refers to a report generated by the registry for informational or educational purposes. A statistical report contains aggregated data and does not contain identifying information.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*

Eff. January 1, 1982;
Amended Eff. October 1, 1983;
Transferred and Recodified from 10 NCAC 8A .0802 Eff. April 4, 1990;
Amended Eff. April 1, 2001; December 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47B .0103 CONFIDENTIALITY

(a) The clinical records of individual patients submitted to the registry shall be confidential and shall not be public records open to inspection. Only personnel authorized by the director of the State Center for Health Statistics and other individuals authorized by the director of the State Center for Health Statistics or his/her designee pursuant to Paragraph (c) of this Rule shall have access to the records.

(b) The information contained in the clinical records of individual patients submitted to the registry may be transferred to computer-compatible means of data entry. Only personnel authorized by the director of the State Center for Health Statistics to use computers, terminals, programs, data files, and other computer hardware or software involved in maintaining patient information shall have access to them.

(c) Clinical information in possession of the registry may be disclosed in the following circumstances when authorized by the director of the State Center for Health Statistics or his/her designee:

(1) A patient shall have access to review or obtain copies of his/her records;
(2) Information may be disclosed in response to a valid court order;
(3) Information may be disclosed as provided in Rule .0106 of this Section;
(4) Information contained in death certificates on file with the division (but not actual copies of death certificates) may be released to a participating facility when the facility requests a death match for confirmation of the reported or suspected deaths of cancer patients treated at that facility. Death match information released by the registry shall include only that information contained in the death certificates.

(d) The State Center for Health Statistics may release statistical information and data based on client information so long as no information identifying individual patients is released.

(e) Photocopying or other reproduction of any clinical records or reports containing identifying information, except as may be required in the conduct of the official business of the registry, is prohibited.

(f) Any legible documents other than the original abstracts, such as computer printouts or photocopies of any documents containing identifying information, shall also be considered confidential material while in active use, and shall be destroyed immediately upon termination of their use by the registry.

(g) Original copies of reports and abstracts, and follow-up information received thereunto, shall be retained for 5 years by the registry.

(h) The director of the State Center for Health Statistics shall make known to all individuals with access to patient information submitted to the registry the privileged and confidential nature of such information.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
Eff. January 1, 1982;
Amended Eff. October 1, 1982;
Transferred and Recodified from 10 NCAC 8A .0803 Eff. April 4, 1990;
Amended Eff. April 1, 2001; December 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47B .0104 REPORTING OF CANCER

(a) Health care facilities and providers shall submit a complete abstract for each cancer case that is screened, diagnosed, treated, or followed by its staff and that was initially diagnosed with cancer subsequent to May 7, 1999. A complete abstract is defined as one that adheres to the standards and definitions of the North American Association of Central Cancer Registries (NAACCR), the World Health Organization (WHO), the American College of Surgeons Commission on Cancer (COC), and the National Cancer Institute Surveillance, Epidemiology, and End Results Program (SEER). These standards and definitions are delineated in the following publications: the NAACCR *Standards for Cancer Registries,* the WHO *International Classification of Diseases for Oncology;* the COC *Standards of the Commission on Cancer, Volume II, Registry Operations and Data Standards (ROADS);* and the SEER Coding Manuals. Subsequent amendments and editions of these publications are included. NAACCR

documents are free of charge and may be obtained from the North American Association of Central Cancer Registries, 2121 West White Oaks Drive, Springfield, Illinois 62704. The *International Classification of Diseases for Oncology* may be purchased for twenty-seven dollars ($27.00) from WHO Publications Center USA, 49 Sheridan Avenue, New York, NY 12210. The *ROADS* publication may be purchased for twenty dollars ($20.00) from ACS Publications Fulfillment Section, Box 92425, Chicago, IL 60675-2425. SEER publications are free of charge and may be obtained from the National Cancer Institute, Publications Ordering Service, P.O. Box 24128, Baltimore, MD 21227.

(b) A health care provider or facility may delegate the tasks of reporting cancer cases to office or hospital staff, but the provider or facility shall not delegate the legal responsibility for the reporting of cancer to others.

(c) A report of cancer shall be submitted to the registry by health care facilities and providers by one of the following methods:

(1) by submission of an electronic file containing the information required in Paragraph (a) of this Rule;

(2) for pathology laboratories, by submission of a positive electronic pathology report containing the information required in Paragraph (a) of this Rule; or

(3) facilities or providers that have fewer than 30 reportable cases per year may submit photocopies of the medical record sufficient to complete a full abstract of the case.

(d) The following documents shall not constitute a report of cancer:

(1) a death certificate; and

(2) a request for authorization submitted to the Cancer program requesting third party reimbursement for treatment of cancer, although a positive pathology report is required by 10 NCAC 8A .0408(f).

(e) Reports shall be forwarded to the following address: Central Cancer Registry, State Center for Health Statistics, 1908 Mail Service Center, Raleigh, North Carolina 27699-1908.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
Eff. January 1, 1982;
Amended Eff. October 1, 1984; October 1, 1982;
Transferred and Recodified from 10 NCAC 8A .0804 Eff. April 4, 1990;
Amended Eff. April 1, 2001; December 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47B .0105 COOPERATION OF THE CENTRAL CANCER REGISTRY WITH HEALTH FACILITIES

(a) Any health care facility that is staffed and equipped for the diagnosis, treatment or follow-up care of cancer patients may participate with the registry in the exchange of information regarding the referral, treatment, maintenance or cure of cancer.

(b) The registry shall cooperate and consult with participating health care facilities and providers to the end that cancer registries in such facilities may provide the most accurate data available and may otherwise operate in the best interest of the cancer patients being treated therein. The registry will provide:

(1) Quality control reports to assure that computerized data utilized for statistical information and data compilation are correct;

(2) The most accurate and effective treatment, survival and comparative information available;

(3) Educational information available from registry, morbidity and mortality statistics upon request of a professional staff;

(4) Assistance to health care facilities by providing appropriate data and consultation to help the facilities meet the requirements for accreditation as a cancer treatment center, and to assist in the maintenance of such accreditation;

(5) Confirmation of the reported or presumed deaths (including such causes of deaths) of cancer patients to assist health care facilities to more accurately assess patient survival and to conduct more efficient long-term follow-up of cancer patients;

(6) Other information for the purpose of follow-up of a patient. This information is limited to the name of another facility or physician providing services to the patient, the date of last contact with the patient, and the vital status.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*

Eff. January 1, 1982;
Amended Eff. October 1, 1983; October 1, 1982;
Transferred and Recodified from 10 NCAC 8A .0805 Eff. April 4, 1990;
Amended Eff. April 1, 2001; December 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47B .0106 RELEASE OF CENTRAL CANCER REGISTRY DATA FOR RESEARCH

(a) The registry may release statistical data to any person or agency for the following purposes:

(1) medical research or education;
(2) epidemiological studies;
(3) health education;
(4) health planning or administration;
(5) required statistical reports; and
(6) other statistical reports by written request for research, information or education.

(b) A researcher may request the release of medical records from the registry by the submission of a written research proposal. This request must adhere to the requirements pertaining to release of medical records by the State Center for Health Statistics as defined by 10A NCAC 47A .0102.

(c) The medical records or reports of the individual patients may be disclosed to research staff for the purpose of medical research, provided that the registry has determined that:

(1) disclosure of this information is deemed necessary to accomplish the purposes of the research;
(2) the research warrants the risk to individual patients of the potential disclosure of their medical records; and
(3) adequate safeguards to protect the medical records or identifying information are established or maintained.

(d) The registry shall provide regular reports of research activity and data released to the cancer committee of the North Carolina Medical Society. Where there exists the potential for direct patient contact, the registry shall consult with the chairman of the Committee on Cancer of the North Carolina Medical Society before determining to release information for research as provided in Paragraphs (b) and(c) of this Rule. The registry shall forward the research proposal to the chairman for review. The chairman may forward the proposal to any or all members of the committee for comment.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
Eff. January 1, 1982;
Amended Eff. October 1, 1983;
Transferred and Recodified from 10 NCAC 8A .0806 Eff. April 4, 1990;
Amended Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47B .0107 RESERVED FOR FUTURE CODIFICATION

10A NCAC 47B .0108 ASSISTANCE AND CONSULTATION FOR PUBLIC HEALTH WORK

(a) The registry shall provide assistance and consultation for public health work.

(b) The registry shall accept requests for assistance and consultation for any agency, facility or organization actively engaged in the effort to reduce the incidence of cancer, whether through direct service to or the education of cancer patients and their families, the public, or the health care professions.

(c) The registry may accept requests from students requesting assistance with research projects in accordance with the provisions of Rule .0106 of this Subchapter and the availability of staff time and resources.

History Note: *Authority G.S. 130A-205;*
Eff. January 1, 1982;
Transferred and Recodified from 10 NCAC 8A .0808 Eff. April 4, 1990;
Amended Eff April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

10A NCAC 47B .0109 FAILURE TO REPORT

(a) The registry shall monitor the reporting of health care facilities and providers on a quarterly basis. If a health care facility or provider has failed to report at least 90 percent of its cases within six months of diagnosis, the registry shall notify the facility or provider in writing of that fact within 30 days and the facility or provider shall be given another 30 days, or up to 60 days for good cause shown, to fulfill its reporting requirement.

(b) If a facility or provider is out of compliance for two consecutive quarters and is not demonstrating progress toward becoming compliant, then the State Health Director shall direct the registry to collect the data and shall direct the facility or provider to reimburse the registry for all actual costs expended in order to obtain the data up to one hundred dollars ($100.00) per case abstracted. The amount of the reimbursement shall include both travel expenses and the full cost of personnel time.

(c) Facilities or providers may request the director of the registry for abstracting assistance at no cost to them. The decision as to what assistance will be provided shall be based on the following:

(1) Size of the facility;
(2) Consistency of non-compliance;
(3) Staffing of the registry;
(4) Duration of needed assistance. The registry shall not provide long term abstracting assistance to any facility that has greater than 100 cases per year;
(5) The potential for compromising the registry's data quality; and
(6) Plans of the facility to reach compliance.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 20, 2015.

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.

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 .0103 BIRTH DEFECTS ADVISORY COMMITTEE

History Note: *Authority G.S. 130A-131.17;*
Eff. August 1, 2000;
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.

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 .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.

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 .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.