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.