

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.*