

## **10A NCAC 26C .0202    PROTOCOL**

Before any investigation is launched involving the Division's clients, their records, or a mental health program's records, a written protocol of the planned study shall be submitted to the chief executive offices of the institution or area program. The protocol shall contain the following:

- (1) identification of project and investigator;
- (2) abstract, containing a short description;
- (3) statement of objectives and rationale;
- (4) description of methodology, including projected number of people and time involved;
- (5) measures taken to protect subjects' interests, including, if necessary, informed consent;
- (6) statement of interests of involved mental health programs; and
- (7) plans for dissemination and disposition of findings.

*History Note:*    *Authority G.S. 143B-147;*  
*Eff. February 1, 1976;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1,*  
*2018.*