10A NCAC 27G .0210 RESEARCH REVIEW BOARD

(a) For purposes of this Rule, "research" means inquiry involving a trial or special observation made under conditions determined by the investigator to confirm or disprove a hypothesis, or to explicate some principle or effect. The term "research" as used here means research which is not standard or conventional; involves a trial or special observation which would place the subject at risk for injury (physical, psychological or social injury), or increase the chance of disclosure of treatment; utilizes elements or steps not ordinarily employed by qualified professionals treating similar disorders of this population; or is a type of procedure that serves the purpose of the research only and does not include treatment designed primarily to benefit the individual.

(b) Prior to the initiation of any research activity in a facility which involves clients or client records, it shall be reviewed and approved by a research review board recognized by the facility in which the proposed research is to be conducted.

(c) The Board shall consist of at least three members, the majority of whom are not directly associated with the research proposal which is under consideration.

(d) Each proposed research project shall be presented to the research review board as a written protocol including, at least, the following information:

(1) name of the project and the principal investigator;

(2) statement of objectives (hypothesis) and rationale; and

(3) description of the methodology, including informed consent if necessary.

(e) The board shall assure that informed, written consent is obtained from each client, or each legally responsible person if the client is a minor or incompetent adult, in each research project, to include:

(1) documentation that the client has been informed of any potential dangers that may exist and that he understands the conditions of participation; and

(2) notice of the client's right to terminate participation at any time without prejudicing the treatment he is receiving.

A copy of the dated, signed consent form shall be kept on file in the client record by the facility.

(f) Each approved research project shall be reviewed by the research review board at least annually. Modifications in the research protocol shall be reviewed and approved in advance by the research review board.

(g) Minutes of each research board meeting shall be maintained.

History Note: *Authority G.S. 122C-26; 122C-52; 143B-147;*
Eff. May 1, 1996;
Recodified from 10 NCAC 14V .0208 to 10 NCAC 14V .0210 Eff. January 3, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20, 2019.