

10A NCAC 26D .1302 RESEARCH REVIEW BOARD

- (a) Research that involves a client shall be reviewed and approved by a research review board established by the Department.
- (b) The research review board shall approve, require modification, or disapprove proposed research projects subject to the approval of the Department.
- (c) Individuals who are not directly associated with research projects under consideration shall comprise a majority of the review board.
- (d) Each proposed research project shall be presented to a research review board as a written protocol containing the following information:
 - (1) identification of the project and the investigator;
 - (2) abstract, containing a short description of the project;
 - (3) statement of objectives and rationale; and
 - (4) description of methodology, including informed consent if necessary.
- (e) Prior to the initiation of each research project, a research review board shall:
 - (1) conduct an initial review of the project;
 - (2) state the frequency with which it will review the project after it has been initiated; and
 - (3) hold a review prior to any major changes being made in research procedures.
- (f) Written minutes of each research board's meeting shall be maintained and contain documentation that:
 - (1) risks to the client were minimal and reasonable for the benefits to be accrued;
 - (2) client participation was voluntary;
 - (3) unnecessary intrusion on the client was eliminated;
 - (4) informed consent was obtained; and
 - (5) compliance with confidentiality requirements as contained in Rule .0704 of these Rules.

*History Note: Authority G.S. 148-19(d);
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.*