10A NCAC 28A .0306 CONSENT TO PARTICIPATE IN RESEARCH

(a) The State Facility Director shall assure that all clients who participate in research, except minimal risk research, elect to do so after having received a full explanation of the purpose, potential benefits and risks of participation.

(b) Informed written consent shall be obtained from the client or legally responsible person for each new research project. Whenever a client is adjudicated incompetent and is a ward of the state, or whenever a client adjudicated incompetent or a minor client objects to participation in a research project, the client shall not participate in the research project. Consent shall be documented in the client record and shall include:

(1) client or legally responsible person's signature and date;
(2) brief description of the research project;
(3) length of consent, which shall not exceed six months without renewal;
(4) notification that consent may be withdrawn at any time without penalty;
(5) explanation of any potential risks and plans to reduce or address such risks;
(6) signature and title of the investigator and date;
(7) disclosure of any established alternative procedures that would probably achieve similar therapeutic goals as those anticipated through the research; and
(8) a provision that the client or legally responsible person will be given notification of any significant changes in the research procedures which directly affect the client.

History Note: *Authority G.S. 122C-51; 122C-57; 131E-67; 143B-147;*
Eff. October 1, 1984;
Amended Eff. July 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 24, 2017.