



Policy Statement Regarding Enrollment of Children in Research in Nigeria (PS2.1016)

1. NHREC issues policy guidelines from time to time to address emerging issues in research ethics or existing ones that require further clarification.
2. The ethical issue(s) of concern in this note relates to the enrolment of children in research studies. This is an interim note to guide researchers until the complete guidance on research with children is issued by NHREC.

Policy statement

A. General comments

A.1 For the purposes of this note, a child is anyone younger than 18 years as defined in section 29(4) of the 1999 Constitution of the Federal Republic of Nigeria.

B. Consent Requirements

B.1 Enrollment of children below the age of 12 years requires consent of both parents or the parent that has primary responsibility for the child at the time of research or the legal guardian;

B.2 For children between 12 and less than 18 years, the child must give assent while the relevant parent as described in B.1 above, and appropriate to each specific research scenario gives consent.

B.3 Emancipated minors (in case of children younger than 18 years) can give consent in their cognizance.

B.4 Where a study proposes to include emancipated minors as participants, the rationale for declaring the child as 'emancipated' must be justified in the research protocol and reviewed by the Institutional Health Research Ethics Committee.

B.5 In all instances researchers must specify how the informed consent will be documented including verbal consent.

B.6 Waiver of parental consent may be granted where researcher is able to provide satisfactory justification that the proposed study a) poses no more than minimal risk; b) holds out potential to benefit the children being involved in the study; c) the study objectives could not otherwise be achieved where parents have to be consented.



C. Type of Review

C.1 Children are considered a vulnerable group in research because their intellectual and emotional capacities are limited and therefore, they are considered legally 'incompetent' to give valid informed consent.

C.2 As a vulnerable group, it is standard best practice in research ethics that children are provided additional protection to minimize or eliminate any potential for their vulnerability to be unduly exploited.

C.3 In view of C.1 and C.2 above, research involving children may only be subjected to full committee review.