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Protecting Children Participating in Research

Since India is expected to develop into an international hub for clinical research, the editorial on ethics of research in children has not come a day sooner(1). The Ethics committees (EC) and Institutional Review Boards (IRB) have the onerous responsibility to ensure that children, who constitute a vulnerable population, are not used as a commodity in clinical research in absence of explicit national guidelines for pediatric research and in the milieu of abject poverty.

It is the responsibility of EC/IRB to take care that the participation is without coercion or inducement. The American Academy of Pediatrics expects that, assent is obtained from children over the age of 7 years in pediatric practice(2). There have been arguments favoring a much higher cut-off age of 14 years for pediatric research trials(3). Several guidelines state that assent should be obtained where children have sufficient understanding and intelligence to understand what is proposed(4) and that this ability could be determined taking into consideration the

child's age, maturity and psychological state. Most parents act in the best interests of their children on most occasions. However, given the magnitude of poverty prevalent in the country, it is possible that amount provided as compensation for participation could act as inducement and influence parental judgment regarding enrolling the child. EC/IRB should formulate local guidelines concerning these issues, share their expertise and collaborate with each other and form a consortium so that national guidelines concerning pediatric research could be evolved.

Obtaining assent from the child and permission from parents is not equivalent to obtaining consent from an adult participant. Hence, EC/IRB have additional responsibilities while dealing with these studies by probing the potential risks and benefits of a trial in children and adolescents. EC/IRB could seek assistance from persons with experience of dealing with sick children so as to develop specific expertise in evaluating pediatric trials. They should also monitor the process of obtaining assent to ensure that developmentally appropriate information is being provided to children before requesting their assent, that their dissent is respected and that

their participation is entirely voluntary. Going beyond their usual role, the EC/IRB should also take up the mantle of an educator, informing researchers about the ethical standards to be followed while conducting pediatric trials. Only with such affirmative actions would the EC/IRB be able to fulfill their mandated role of safeguarding the interests of children and adolescents participating in research trials.

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Malnutrition and Anemia in Tribal Pediatric Population of Purnia District (Bihar)

Malnutrition and anemia form major public health problems among the school age children, particularly in the developing countries(1). In India too, the problems of malnutrition and anemia exist in a greater dimension among the young children(2,3). The children of tribal communities, due to their low socio-economic status and social isolation, become highly vulnerable in this regard. We presently report a study of the prevalence of malnutrition and anemia among randomly selected 180 oraoon, 150 santhal and 100 munda children of 6-9 yr age group from among the tribal habitats of Purnia district of Bihar.

Anthropometric measurements *viz.*, height, weight, mid-arm circumference, chest circumference and head circumference of the selected children, comprising of both sexes, were recorded employing standard techniques. Blood hemoglobin levels of the children were estimated by cyanmethemoglobin method. On the basis of anthropometric measurements, the children were grouped under different grades of malnutrition by following Gomez classification. On the basis of blood hemoglobin levels, the children were grouped under different grades of anemia by adopting the criteria suggested by WHO(4).

It was observed that only 27.5% of tribal children belong to normal grade of nutrition. A major chunk of 37.5% fall in grade I, whereas, 8.4% are highly malnourished falling into grade III. Race wise, the severity of malnutrition is with mundas, where only 7%