

Children and Minors

1. Does the research have an identifiable prospect of direct benefit to the individual child participant? Can that benefit be achieved through alternative means?
2. Does the research have an identifiable prospect of risk to the individual child participant? What safeguards are proposed to minimize these risks? When procedures involving greater than minimal risk to children are anticipated, are convincing scientific and ethical justifications given?
3. Is the inclusion of normal volunteers justified?
4. Do studies involving placebo controls place the child at greater risk by withholding from selected subjects potentially therapeutic research drugs or interventions?
5. When possible, have appropriate studies been conducted on animals and adults first? Will older children be enrolled before younger ones?
6. What is the age of majority in the state? Can a child consent to medical care for certain conditions, and, if so, at what age? What legal limits are there on the right of parents to consent on behalf of their children?
7. Is permission of both parents necessary? Under what conditions may one of the parents be considered "not reasonably available?"
8. Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?
9. Are mechanisms in place to ensure that children are involved as research subjects in ways that do not undermine their dignity as young persons? Are provisions made that show respect for the developing rights of children, such as: (a) obtaining their assent, and, where appropriate, honoring their dissent; and (b) protecting their need for privacy and the confidentiality of information regarding them?
10. Are there special problems that call for the presence of a monitor or advocate during consent procedures?
11. Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?
12. Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?
13. If conditions present in children have implications for other family members' health statuses, are appropriate mechanisms proposed for dealing with the larger family unit (*e.g.*, genetic risks or HIV infection)?
14. Should parents be required to be present during the conduct of the research? (Are proposed subjects to be very young? Are the procedures involved painful? Must subjects stay overnight in the hospital when they otherwise would not have to?)