

Investigators who have conflicts of interest should make these known to volunteers in the consent form. A conflict of interest exists when an investigator has financial or personal relationships that inappropriately influence his/her actions or judgment (35).

Considerations for Studies Involving Children and Infants

Children are not empowered to grant informed consent until they have reached the legal age of majority, or have been deemed emancipated. The degree of involvement of a child in the decision to participate in a vaccine trial depends on his/her intellectual capacity and stage of development. Assent to participate usually should be obtained from children with an intellectual age of seven years. In trials involving children, a parent or guardian assumes responsibility for the child, and grants consent by proxy. This places an increased responsibility on the sponsor, the investigator, and the IRB to assure that risk is minimized, the study is fully understood by the parent, and that there is no coercion to participate. It is essential that the parent understand that participation is entirely voluntary, and that the parent may withdraw the child from the study at any time. An investigator who also serves as the child's primary care physician has the additional burden to assure that the parent does not feel compelled to enroll the child to please the physician.

Remuneration for participation is a more sensitive issue in trials involving children than adults. Rewards must be only a token of appreciation, and not of a magnitude to induce parents to enroll the child into the study. Generally acceptable compensation includes a small savings bond, free routine vaccinations, or payment for costs incurred by the trial, such as travel.

SUMMARY

Vaccine testing enters the twenty-first century using methods based on sound epidemiological and ethical principles by which the safety and efficacy of future vaccines will be established. Although vaccine development may be an empirical science, the methodological framework for clinical testing to determine safety and efficacy has been largely codified. Precedents have been set for the study of vaccines containing recombinant DNA and for methods to study the transmissibility of live vaccines. We anticipate that clinical vaccine testing will continue to be a productive and exciting area of clinical research as vaccines against infectious diseases, such as malaria, tuberculosis, HIV, and agents of bioterror, are developed.

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