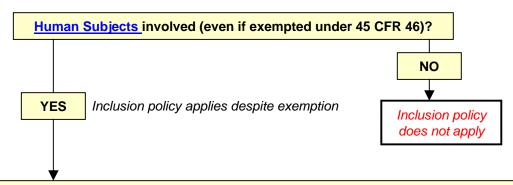


Decision Tree for Inclusion of Children in Human Subjects Research



What is the representation of children and adults? Is representation of children acceptable?

- 1. Both children and adults are included in scientifically appropriate numbers and with appropriate age ranges for children? (Code C1: both adults and children)
- 2. Only children are included? (Code C2: children only)
- 3. All or some age ranges of children are excluded because one of the following exceptions applies?
 - The research topic is irrelevant to children
 - Laws or regulations bar inclusion of children in the research
 - The data already exists or is being obtained for children (must document); duplicative studies are unnecessary
 - A separate, age-specific study in children is preferable (e.g., conditions are rare in children vs. adults; most eligible subjects already enrolled in nationwide study; study design issues preclude applying hypotheses/interventions to both groups in parallel fashion)
 - Existing data in adults is insufficient to judge risks in children
 - Proposal is to obtain follow-up data on a prior adult study which enrolled no children
 - Other special cases acceptable to the review group and Institute Director.
 (Code C3: adults only; or may be Code C1: both adults and children, though participation of children is limited)
- 4. Representation of children in specimens or datasets cannot be accurately determined **and** this does not compromise the scientific objectives? (Code C4: children representation unknown)

