



Decision Tree for Inclusion of Children in Human Subjects Research

Human Subjects involved (even if exempted under 45 CFR 46)?

YES

Inclusion policy applies despite exemption

NO

Inclusion policy does not apply

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)**

YES

ABSENT
No Information

NO

ACCEPTABLE

C1A, C2A, C3A, or C4A
Describe: inclusion plan, rationale for any age range exclusions, suitability of team and facilities for dealing with children, plans for meaningful analysis of differential effect. State why this is scientifically acceptable.

UNACCEPTABLE
Contact
Scientific Review Administrator

UNACCEPTABLE
C1U, C2U, C3U, or C4U
Negative impact on score
Describe inclusion plan, rationale for any age range exclusions, suitability of team and facilities for dealing with children, plans for meaningful analysis of differential effect. State why this is scientifically unacceptable.