

## Protecting people who participate in research

*CITI Training Study Guide*  
**Research Involving Children**

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## Research Involving Children - Special Rules Set Forth by DHHS

Subpart D of the federal Department of Health and Human Services regulations, "**Additional DHHS Provisions for Children Involved as Subjects in Research**" defines categories of research with children that an IRB may approve.

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## Definitions

- "Children" generally are persons under the age of 18.
  - For some purposes, NIH regards youth up to the age of 21 as "children."
- "Assent" means a child's agreement to participate in research.
  - Since not all children are capable of assent, the IRB must decide when assent is an absolute requirement.

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**Three Categories of Allowable Research**

1. 45 CFR 46.404:  
Research involving no greater than minimal risk, which means:  
“the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

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**Three Categories of Allowable Research**

1. Research involving no greater than minimal risk, examples:
  - Blood tests
  - Urine collections
  - Chest x-rays
  - Psychological tests
  - Classroom observations

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**Three Categories of Allowable Research**

2. 45 CFR 46.405:  
Research that poses greater than minimal risk, but also offers direct benefits to the child participant.  
Example: a new antibiotic that requires fewer doses for simple ear infection. Potential benefits are reduced cost, increased likelihood of completing the course of treatment, and reduced likelihood of diarrhea.

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**Three Categories of Allowable Research**

- 3. 45 CFR 46.406:  
Research that poses greater than minimal risk, and does NOT offer direct benefits to the child participant, but is likely to provide vital information about the child's disease or condition.

Additional requirements apply (next slide).

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**Three Categories of Allowable Research**

- 3. 45 CFR 46.406,  
Additional requirements:
  - Procedure poses no significant threat to the child's health or well being;
  - Risks are similar to those the child faces due to their medical condition ("commensurability").

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**Exception**

45 CFR 46.407 allows the DHHS Secretary and a panel of experts to approve research that will assist in understanding, preventing or alleviating a serious problem affecting children's health and welfare.

This research must be conducted according to sound ethical principles.

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### **Who Provides Consent?**

Under 45 CFR 46.408 some studies may require just one parent's permission and others will require both parents' permission.

- For Categories #1 and #2, the IRB may allow permission of just one parent.
- For Category #3, permission must be obtained from both parents (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child).
- Children's assent (if feasible) is always required.

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### **Wards of the State**

Under 45 CFR 46.409 the law specifically protects orphans or foster children.

- Wards of the State may be included in research that falls into Categories #1 or #2.
  - Under Category #3, wards may be enrolled only:
    - if the research relates to their status as wards; or
    - if the research is conducted in settings where the majority of children involved as subjects are not wards.
- Also:
- each child must have an advocate appointed by the IRB who is not associated with either the research or the guardian organization.

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### **Concern for Research Needed for Children**

- The National Institutes of Health require that children be included in all research unless there are scientific or ethical reasons not to include them.
- Why?
  - Example: Excluding children from research may result in drugs that are only available to, or appropriate for, adults.

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