Guiding Principles for Protecting Children in and through Pediatric Clinical Research

1. Children and their health needs are an important research priority.
2. Children's rights must be respected within the clinical research context.
3. Children should only be enrolled in research that follows ethical principles.
4. Children should only be enrolled in research that has scientific and social value related to the health of children or diseases that originate in childhood.
5. National health authorities should regulate pediatric clinical research in accordance with internationally accepted ethical principles.
6. Pediatric studies of medical products should only be done in countries where there is a plan to market the product after completion of development.
7. Pediatric research often requires multi-site and multi-national trials. Regulations across jurisdictions should be aligned.
8. The global burden of pediatric disease should inform, but not limit, pediatric product development and research.
9. Evidence of potential for clinical benefit to the enrolled children must justify the risks of participation.

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The extent of data necessary to begin a pediatric trial depends in part on the urgency of the medical need and the degree to which that need is unmet.

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Children should not be placed at a significant disadvantage by being enrolled in a clinical trial as compared with available alternatives outside the trial.

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Risks of the research must be distinguished from the risks of the condition or disease that rendered the child eligible for participation.

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There are limits on the research-specific risks and burdens to which children can be exposed in the absence of the possibility of direct benefit to the individual participant.

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The burdens of research participation should be minimized.

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The costs of research participation should be minimized.

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Children are entitled to have a voice in making decisions to the extent their capacity allows throughout the research process.

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A child's assent should be sought, and withdrawal of assent respected, unless the research offers a potential benefit not available outside of the research.

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Investigators and sponsors have responsibilities to the child who has participated in research after the research has ended.

MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD