

Ethics of peds countermeasure research discussed

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(HealthDay)—Pediatric research on medical countermeasures should present no more than minimal risk to participants, and should follow a specific framework if there is a minor increase over minimal risk, according to a perspective piece published online March 19 in the *New England Journal of Medicine*.

Amy Gutmann, Ph.D., from the Presidential Commission for the Study of <u>Bioethical Issues</u> in Washington, D.C., discusses the ethical considerations pertaining to pediatric research on medical countermeasures designed for use in response to chemical, biologic, radiologic, or nuclear attacks.



Gutmann notes that pre-event research can be considered ethical if it presents no more than minimal risk to participants and poses no significant threat to the child's health or well-being. A minor increase over minimal risk is only acceptable if research is likely to yield generalizable knowledge about participants' specific condition or under exceptional circumstances. A framework for ethical considerations of research includes specific circumstances; for example, that the research is of vital importance for addressing a serious problem. A rigorous set of five categories of conditions was developed to ensure that research adheres to 'sound ethical principles.' In addition, informed <u>parental</u> <u>permission</u> and developmentally appropriate assent by children are necessary. Different ethical and <u>regulatory standards</u> apply to post-event research which directly benefits participants, but should be limited to minimal risk if possible.

"Sound science must always respect our <u>ethical obligations</u> to protect children from unnecessary risks," Gutmann writes. "Medical countermeasure research warrants an ongoing national conversation to ensure an unwavering commitment to safeguard all children both from unacceptable risks in research and through research promoting their health and well-being."

More information: Full Text

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