

## **Ethical Issues in Research Involving Infants**

Douglas S. Diekema, MD, MPH\*, †the future health of infants and children is dependent on the performance of clinical research in which infants participate. Achieving a proper balance between this social good and the obligation to protect infants who participate in research is a significant challenge. As investigators design and implement research protocols, they should be aware of the ethical and legal requirements that govern research with infants. For research to satisfy ethical and legal requirements it must be scientifically sound and significant, subject Selection must be fair, approaching families for enrollment must avoid pressure, the risks to participants cannot be excessive and must be minimized, risks must be justified by the benefits of the research, valid and voluntary informed consent must be obtained, enrolled subjects must be respected, and the protocol must have obtained approval of an independent ethical review board.

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**KEYWORDS** research ethics, human subject research, infants, neonates, research, ethics,

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