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Essentially all guidelines and regulations require that biomedical research studies have an acceptable risk-benefit profile. However, these documents offer little concrete guidance for implementing this requirement and determining when it is satisfied. As a result, those charged with risk-benefit evaluations currently assess the risk-benefit profile of biomedical research studies in unsystematic ways, raising concern that some research participants are not being protected from excessive ...

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All clinical research involves a degree of risk. This risk may be acceptable as long as appropriate preclinical safety studies have been conducted and sufficient effort is made to ensure that the informed consent process is rigorous, with particular attention given to the communication of risks to prospective subjects.

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Author information: (1)Institute of Biomedical Ethics, University of Zurich. Essentially all guidelines and regulations require that biomedical research studies have an acceptable risk-benefit profile. However, these documents offer little concrete guidance for implementing this requirement and determining when it is satisfied. As a result, those charged with risk-benefit evaluations currently assess the risk-benefit profile of biomedical research studies in unsystematic ways, raising concern ...

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Across these studies, 545 undergraduate students took part in a

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