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the risk and burden Page 6/31

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Biomedical laboratory is full of risks. Risk
could be biological, chemical, radioactive,
mechanical, physical, fire and. electrical.

All possible risks need to be identified,

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points after it. The following example

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quotes specific sentences from Sigmund Simonsen ' s book, Acceptable Risk in Biomedical Research: Original direct quotation: “ The principle of human primacy has been criticised as being vague and ill-founded or redundant in bioethical literature.

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Omitting Words from a Direct Quotation
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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

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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 ...

A framework for risk-benefit evaluations in

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Determining whether a research risk meets or exceeds a regulatory standard of risk acceptability is difficult. Recently a framework called the systematic evaluation of research risks (SERR) has been proposed as a method of comparing research risks with predetermined

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standards of acceptability. SERR purports to offer a systematic and largely determinate (definite) way to compare risks and say whether a specific research risk falls below or above an acknowledged standard of acceptable risk.

Is there an objective way to compare

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A key concept in these clauses is the degree of risk acceptable for children involved in research. While it is generally agreed that children require particular attention because of their vulnerability, there is also increasing concern that children in general should not be

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disadvantaged by lack of knowledge due to
reduced research activity.

Ethics and medical research in children
The Council of Europe and the U.K.
Medical Research Council appear to
endorse this approach, stipulating that
research is acceptable when “ it is to be

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expected that [the research] will result, at the most, in a very slight and temporary negative impact on the health of the person concerned. ” 12, 13 Because this approach blocks research that poses any chance, no matter how low, of serious injury, it has the potential to block a good deal of pediatric research.

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A STANDARD FOR ASSESSING THE
RISKS OF PEDIATRIC RESEARCH ...

Most restrictions on the risks that participants are exposed to in biomedical research are soft paternalism. Limitations on the risks faced by children or cognitively impaired adults, mentioned

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above, would be soft paternalism, because these participants may have compromised decision-making abilities.

Limits on Risks for Healthy Volunteers in
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