Are research participants safe enough?

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Every year, millions of patients worldwide participate in randomized clinical trials hoping to benefit from an experimental treatment or potentially help someone else with the same condition.

However, rules and regulations are becoming a menace to academic clinical trials where resources are limited and risks may be much less than those associated with new experimental drugs.

"There is no question that research participants need protection," write Paul Hébert, Editor-in-Chief, *CMAJ*, and coauthors. "But regulations have grown so burdensome that they are overwhelming the very things they are meant to support and safeguard. Consequently, clinical research has been substantially decreased among industrialized countries."

International bodies, regulatory authorities, the academic community and major granting agencies need to work together to develop and adopt proper, study-specific standards instead of having ineffective monitoring of all clinical research.

The authors conclude that without significant changes, our academic research enterprise and eventually even commercial trials will be immobilized by increasing bureaucracy and spiraling costs.

More information: www.cmaj.ca/cgi/doi/10.1503/cmaj100404