Does the new EU Regulation on clinical trials adequately protect vulnerable research participants?

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Vulnerable research participants deserve special protection because of their increased risks of being wronged. Yet, paradoxically, the conduct of trials involving vulnerable groups is sometimes inescapable to develop safe and efficient therapies suitable to these groups. The key question is therefore how to protect vulnerable research participants from harm and exploitation without excluding the populations they belong to from the benefits of research. The European Union faced this challenge in April 2014 when adopting the new Regulation on clinical trials, which will replace the currently applicable 2001 Clinical Trials Directive in 2016. In order to assess the protection of vulnerable persons in the new Regulation, this paper makes four suggestions: first, the need to adopt a risk-based approach to vulnerability in biomedical research; second, to better distinguish between decisional vulnerabilities and health-related vulnerabilities; third, to emphasise the need to preserve the freedom of consent of subjects with decisional vulnerability, who are more susceptible to undue influence; and finally to assert the need of actively promoting specific clinical trials involving people with physical or psychological vulnerabilities. In conclusion, this paper claims that the protection of vulnerable subjects still needs to be improved in the new EU Regulation.
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