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The Revised Declaration of Helsinki: cosmetic changes do not protect participants in poor countries

*Social justice is an essential element of ethics.*¹ For that reason, the revised Declaration of Helsinki² needs to be clearer and stronger to protect vulnerable people who participate in international medical research, especially regarding the global search for human participants in low- and middle-income countries.³ The new Declaration tried to be clear about distributive justice¹ in Paragraph 20. However, Malik and Foster¹ brilliantly remind us that *the requirement to be responsive to the 'health needs or priorities' rather than 'health needs and priorities' may compromise the responsiveness principle.*¹ We also agree that Paragraph 34 (post-trial provisions) is drafted rather strangely: *it may be that its eccentricities will frustrate some of its good intentions.*

Nevertheless, there are other problematic paragraphs, such as Paragraph 15 (about compensation), which is not clear about who will decide what kind of compensation and treatments are appropriate for people who are harmed as a result of participating in multinational research, in low- and middle-income countries. The problematic Paragraph 33 asserts that placebos, no intervention or any intervention less effective than the best-proven one may be used when the patients who receive them *will not be subjected to additional risks of serious or irreversible harm as a result of not receiving the best-proven intervention.*² Is 'the best-proven intervention' available locally or worldwide? Also, the insertion of the phrase 'less effective than the best proven' allows

comparisons of interventions used in low- and middle-income countries: double standards in medical research.⁴ Further, the revised Declaration² excluded the division between therapeutic and non-therapeutic research, which implies the patients' vulnerability increases when enrolled as just test participants and not as patients.⁴

While the Declaration does not adopt the highest ethical standards to protect human participants in low- and middle-income countries, abuse and exploitation will be facilitated; risks will be outsourced to low and middle-income countries and benefits will be little distributed among them.

References

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