

Declaration of Helsinki Should Be Strengthened

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The Declaration of Helsinki places the interests of individual patients who participate in experiments above the interests of society. A key provision requires that all patients in medical experiments, even those in a comparison group, receive the best available treatment. In 2000 the World Medical Association was debating a revision to the Declaration. Critics of the Declaration, including the US Food and Drug Administration, have been trying to weaken it to give scientists and regulators greater latitude than the Declaration allows. But that latitude comes at the cost of loosening the protection of patients who serve as research subjects. In this paper, Michels and I offered several suggestions to revise the Declaration in order to strengthen the protection of patients who participate in medical experiments.

1. The Declaration should clarify that even small exceptions to the principle that the interests of patients prevail over the interests of science and society would be damaging, opening a hole in the dike that would ultimately cripple the authority of the Declaration.
2. The Declaration should state that no investigator or regulatory official has the right to decide how much sacrifice, in terms of risk or discomfort, a patient should endure in the name of science.
3. Equipoise is a state of genuine uncertainty regarding which of two or more treatments is preferable. We proposed that Declaration should state that equipoise is an essential ingredient of an ethical human experiment.
4. The Declaration should emphasize that informed consent should be obtained using language readily comprehensible to patients, even uneducated patients, and it should describe all treatment options that would be available if the patient declines to participate.
5. The Declaration should clarify that the standard for judging whether those in a comparison group receive "best available" care should be universal, not local, so that trials that are unethical in one community or country are considered ethical in other communities or countries.
6. The Declaration should require that the design of all medical experiments be opened to public scrutiny.

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