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A global ethics charter to protect healthy volunteers

During the COVID-19 pandemic, thousands of healthy individuals volunteered to contribute to research, potentially consenting to put their health at risk to accelerate the search for effective drugs and vaccines.¹ Tens of thousands of healthy volunteers are also involved in hundreds of clinical trials every year, all around the globe, without public attention or fanfare.² However, three key features typically make healthy volunteers' participation in interventional clinical trials different from that of patients' involvement. First, volunteers cannot expect direct medical benefit from participating and, therefore, have a different benefit-risk balance. Second, volunteers participate in studies with rules that might impinge on their wellbeing. Third, the prospect of financial compensation, usually the decisive factor in agreeing to participate, exposes volunteers to the risk of being exploited. Internationally accepted reference texts aimed at protecting human research participants have primarily been developed for patients,³ leaving ethical and regulatory gaps in the protection of healthy volunteers.

In 2022, the ethics committee of the French medical research agency (INSERM) launched VolREthics, an international initiative to identify good practices to protect healthy volunteers in research.⁴ This initiative resulted in the recent launch of the Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials, which has been subjected to a robust public consultation process.⁵ The charter's goal is, foremost, to build global awareness of the unique characteristics of interventional studies involving healthy volunteers. In most countries, the absence of specific regulations

tailored to clinical trials involving healthy volunteers exposes such individuals to the risk of for-profit companies exploiting existing social and economic inequalities to fill studies with healthy volunteers who need a source of income. Without advocacy organisations representing their interests, healthy volunteers have little or no voice to demand better conditions or advocate for change. The charter highlights the urgent need for better representation of healthy volunteers throughout the research process. The charter further calls on responsible authorities to ensure their legal frameworks and other regulatory measures protect healthy volunteers in each country's context. Global adoption of the charters' 15 principles is crucial to avoid disparities in standards within and across countries that could lead to the misuse of populations in lower-income settings.

Healthy people are involved in many different research fields. The motivations to participate, the risks and benefits to which people are exposed, and the ethical issues related to multiple types of research are too diverse and evolving to be addressed in a single document. It is hoped that the momentum created by the publication of this ethics charter will encourage debates about and initiatives around the involvement of healthy participants in research more broadly and on ways to ensure adherence globally to the best scientific and ethical standards.

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