

possibilities as "an inflection point in how platforms can be more socially responsible".<sup>1</sup> Yet, TikTok profits from the problems that WHO wants to solve and poses an obstacle to understanding and addressing them. TikTok is also likely to gain indirect influence at the agency during a time of intensive efforts to develop regulations related to digital infrastructures.

Like other social media platforms, TikTok is designed to sustain user engagement. All engagement, including exposure to misinformation, is profitable for social media platforms, whose business models rely on advertising revenue and data capitalism. The collaboration overlooks this profit model, the potential geopolitical and public relations benefits for TikTok amid multiple lawsuits, and a potential ban in the USA. The announcement underscores larger, unresolved questions about WHO collaborations with digital platforms and the ethics and regulatory frameworks that should guide them.

TikTok is designed so that the longer a user engages with a TikTok, the more advertisements and similar content they are shown. For some users, this can lead to repeated harmful exposure to misinformation and disinformation. TikTok's restricted transparency and strict data access controls stymie research on these issues. Researchers must apply for permission to access data and face strict conditions; this includes agreeing to give TikTok access to manuscript copies before publication, disclosing the intent of their research before receiving data access, and consenting to TikTok audits of researchers' tools at any time without notice.<sup>3</sup>

There is no doubt that public health relies on digital platforms to inform the public. But the terms under which institutions do this are exceptionally important. As purveyors of complex digital infrastructures for information spread, platforms cannot be treated as neutral. Platforms promote specific

types of information—including misinformation and advertising content—through their algorithms, discovery systems, brand partnerships, and support for influencers. Users, researchers, and policy makers have very little information about these corporate choices. WHO's collaboration endorses TikTok without demanding transparency or accountability about its information practices.

As WHO continues work on the commercial determinants of health,<sup>4</sup> this case shows the need for stronger and more nuanced guidelines on engagement with commercial actors, especially in emerging industries. The Framework of Engagement with Non-State Actors<sup>5</sup> is especially challenging in this situation. Some industries like tobacco are banned from engagement with WHO, but digital platforms provide the digital infrastructures necessary for public health and directly and indirectly contribute to health harms. This paradoxical relationship highlights the need for more careful, nuanced, and transparent approaches to engagement.

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## Declaration of Helsinki's missed opportunity for healthy volunteer trials

For the first time since 1964, the revised Declaration of Helsinki provides an ethical framework for medical research and explicitly states that its provisions apply to all research participants, "whether patients or healthy volunteers".<sup>1</sup> This statement is important since, alongside patients, healthy people participating in biomedical research greatly contribute to advancing science. Globally, every year, thousands of healthy volunteers participate in clinical trials that include phase 1 first-in-human studies and studies that fulfil other research and regulatory needs that cannot be addressed by patients alone. As previously communicated,<sup>2</sup> ethical issues in interventional research differ greatly between patients and healthy volunteers, because volunteers, unlike patients, cannot derive any direct medical benefits from their participation, are primarily motivated to participate by financial compensation, and must adhere to much stricter study conditions than most patients.

Although we applaud the Declaration of Helsinki for clarifying that similar ethical standards must apply to all research participants, a single mention of healthy volunteers does not go far enough, in our opinion. Indeed, although several paragraphs guide ethical issues related to patients, such as integration of medical care with research, none address healthy volunteers. Healthy volunteer trials deserve specific guidance, given that the risk–benefit balance differs when trials involve healthy people instead of patients. Additionally, no mention is

made of the need to mitigate risks of exploitation when healthy volunteers receive financial compensation for their participation, a crucial feature that differentiates them from patients. Finally, the revised Declaration of Helsinki states: "Medical research with some particularly vulnerable individuals, groups, or communities is only justified if it is responsive to their health needs or priorities; they stand to benefit from the resulting knowledge, practices, or interventions." Such a statement ignores the sociofinancial vulnerabilities experienced by many volunteers who, by definition, have no specific health needs or priorities and thus do not stand to derive any benefit other than financial gains from their participation.<sup>3,4</sup>

The Declaration of Helsinki is a fundamental text for medical research. Although we wish its revision process resulted in specific provisions for healthy volunteers, we appreciate that its broad principles must apply to all medical research fields in a fast-changing world in which new and complex ethical issues continuously arise. Unlike patients, whose voices are increasingly heard in care and research, healthy volunteers are largely invisible in public fora. In an attempt to change this, in 2024, we released the first *Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials*,<sup>5</sup> which we propose as a complement to the revised Declaration of Helsinki to better protect this specific group of participants in human research.

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## AI ethics in medical research: the 2024 Declaration of Helsinki

The recent update to the World Medical Association's Declaration of Helsinki,<sup>1</sup> adopted at the 75th World Medical Association General Assembly in October, 2024, signals yet another milestone in the ongoing effort to safeguard ethical standards in medical research involving human participants. As with previous revisions, this update aims to reflect contemporary challenges, but it raises questions about the extent of its novelty and efficacy in addressing the evolving landscape of medical research.

On reviewing the latest changes, some aspects of the Declaration have undergone noteworthy improvements. The inclusion of environmental sustainability in medical research (article 11) is a progressive step, acknowledging the growing concern for the environmental impact of scientific pursuits. Moreover, enhanced emphasis on the inclusion of underrepresented groups (article 13) and the focus on minimising disparities by weighing the risks of inclusion versus exclusion in research (article 19) are commendable advancements towards equity. Another substantial addition is the call for meaningful engagement with communities and participants throughout the research process (article 6). This engagement reinforces

the ethical obligation to involve participants in decision making, enhancing the collaborative nature of medical research. However, although these advancements are positive, the 2024 revision does not radically transform the Declaration.

Many of the core ethical principles remain unchanged from previous iterations, whereas some essential areas still require further development. For example, despite the growing prominence of artificial intelligence (AI) and digital health in research,<sup>2</sup> the Declaration remains largely silent on the unique ethical challenges posed by these technologies. Additionally, although post-trial provisions (article 34) have been reinforced, their practical implementation remains an area of concern. Without a robust mechanism for enforcing these provisions globally, vulnerable populations might still be left unprotected in regions with weaker regulatory frameworks.

Finally, although the 2024 revision of the Declaration of Helsinki offers incremental improvements, it does not constitute a radical overhaul. The ethical challenges of modern medical research, particularly in the digital era, necessitate continued updates and increased specificity to remain relevant and protective of all participants. Will the current version of the Declaration adequately address the ethical complexities introduced by AI in research? Unfortunately, no. The absence of detailed guidance on AI, including issues of data privacy, algorithmic bias, and the role of machine learning in clinical decision making, suggests that more robust updates are necessary to fully confront these emerging ethical dilemmas.

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