

The declaration of helsinki and recent updates on medical research

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Editorial

The final 2024 revision of the Declaration of Helsinki provides stronger approaches to transparency, fairness, and equity in clinical research, while providing greater protection for vulnerable populations.

Since 1964, through seven revisions, the World Medical Association's Declaration of Helsinki has remained an important statement of ethical principles guiding medical research involving human participants. It is consulted by ethics committees, funders, researchers, and research participants.

The main changes in the latest update of the Declaration of Helsinki (2024) were; in addition to the revision of the words and expressions used (such as using "participant" instead of "subject"), the following emphases:

- I. The Declaration's call for all individuals, teams and organizations involved in the entire research process, not just physicians;
- II. In extraordinary circumstances such as epidemics, such as the COVID-19 outbreak, the rules set out in the declaration are also valid in extraordinary circumstances in order to maintain trust, against the discourse that research should be conducted very "fast" from research design to publication stage and the perception that rules can be relaxed in extraordinary circumstances,
- III. The fundamental purpose of conducting scientific research is to improve public health,
- IV. Considering that researchers conduct scientific research in a world where inequalities are widespread, they have the obligation to consider how benefits, burdens and risks are distributed to which parties,
- V. Ethics committee members and staff must have the qualifications, education and diversity to effectively evaluate all types of research,
- VI. The rules set out in the WMA Taipei Declaration are valid in the face of increasing risks as all types of personal data collected during the research process increase.

The Declaration of Helsinki remains relevant and continues to strongly influence health research.

The Declaration now reflects best practices and existing frameworks such as the SAN Code of Research Ethics and the TRUST Code for Fair Research Partnerships, which the Declaration supports. They should require the recruitment of a patient, public, or community advisory board before research begins, commitment to co-design, and the ability to pivot based on community feedback.

Meaningful participation is especially important in resource-limited settings, including low- and middle-income countries, where exploitation risks are particularly high. The Declaration acknowledges "structural inequalities" for the first time and includes

a new requirement for dual research ethics committee approval "in both sponsoring and host countries." The Declaration should help ensure that researchers in low- and middle-income countries are true partners; that data, samples, and knowledge remain in (and benefit) the host country; and that research is collaborative rather than extractive.

Similarly, the revised Declaration requires "rigorous design" to prevent "research waste," interpreted as well-powered studies that can demonstrate safety and efficacy, to avoid repeating the fiasco that resulted in over 500,000 people being exposed to potential risks by participating in poorly designed clinical trials during the COVID-19 pandemic.

Clinical trials aim to test the safety and efficacy of therapies, but they also provide an opportunity to access new, potentially life-saving treatments for life-threatening diseases such as cancer. The placebo control arm, a cornerstone of medical research in the twentieth century, has become increasingly problematic in the twenty-first century.

The current Declaration now encourages the use of the "best-evidenced intervention" instead of placebo, but advancing technology now allows for the interpretation of trial data using synthetic control arms, AI-generated digital twins, or real-world data to ensure that the As Journal Editors, we can and should insist that inclusive health research is a prerequisite for publication. But by the time a paper reaches our desk, the research has already been done—fairly or not. The power of the Declaration lies in the impact it has on the research process at the point it is approved by a research ethics committee. So, to bring together the principles of community engagement and global justice in inclusive health research, the Current Declaration is a powerful tool for enacting this change.

Traditional measures and approaches to various health issues must also be updated to meet our rapidly changing world

Today's research is tomorrow's health care...

No regulatory system can function properly unless professionals are aware of their ethical responsibilities.¹⁻³

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Conflict of interest

The author declares there is no conflict of interest.

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