

# Declaration of Helsinki: Comparison of the 2024 Version and the 2013 Version

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## Dear Editor,

Since it was first published at the 18th meeting of the World Medical Association (WMA) in 1964, the Declaration of Helsinki (DoH) has been revised nine times, including the 2013 revision, and has been updated to the latest version with the 2024 revision (1, 2). For this revision, the WMA and its members spanned 30 months, rigorous processes, and several meetings in different regions (3). The revisions include terminological changes, additional phrases, and significant rewriting.

## Key Revisions

- The foremost and most remarkable change is in the title of the declaration. In the 2013 version, the term “subject,” which referred to the people who participated in the research, is replaced with the term “participant” in the 2024 version (1, 2). Compared to the 2013 version, the new term reflects a modern and ethical approach that emphasizes respect for the autonomy and rights of individuals (4). This revision exists throughout the 2024 version of DoH.
- The phrase “ultimately to advance individual and public health” in paragraph seven, which did not exist in the 2013 version, has been added to emphasize that clinical research is not only research for the treatment of diseases (1, 2). The purpose of research is to serve to advance the health of individuals and societies.
- The issue of ethical violations, which emerged more frequently with the COVID-19 pandemic, was scrutinized by adding a new paragraph to the 2024 version. The new paragraph clearly states that the urgent need for new knowledge and interventions in public health emergencies should be implemented without compromising the principle of compliance with ethical principles (2). Although this update is appropriate and necessary, when looking back at historical abuses, this paragraph is considered as too late for a 60-year period.

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- In the 2013 version, the phrase used to refer to participants, “he or she,” has been replaced with the term that does not specify any gender, “they,” paragraph 25 in the 2024 version. When we look back at the first version of the DoH published in 1964, only the male gender was addressed with the term “his” when referring to the physician (1, 2, 5).
- Paragraph 26 in the 2024 version remarks on the requirement to use plain language to ensure that participants understand the research while obtaining their consent (2). Failure to adequately understand the risks, burdens, and benefits of the research may cause participants to withdraw from the research at the following stages and jeopardize its completion. Therefore, it is important to emphasize the use of plain language in the 2024 version.
- Paragraph 37 in the 2024 version addresses clinical trials with substantial changes and mentions the vulnerability of the interventions to abuse by adding the sentence, “These interventions must never be undertaken to circumvent the protections for research participants set forth in this Declaration.” (2).
- In the DoH, except for three paragraphs, all other paragraphs have been revised at various levels. With the revision, the rights of participants and respect for these rights are at the forefront. In addition, fairer and stricter ethical principles have been set in accordance with the times. The 2024 revision has drawn a general roadmap for these purposes.

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## REFERENCES

- 1 WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects [Internet]. Ferney-Voltaire: World Medical Association (WMA); October 2013 [cited November 3, 2024]. Available from: <https://www.wma.net/wp-content/uploads/2024/10/DoH-Oct2013.pdf>
- 2 WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – 2024 [Internet]. Ferney-Voltaire: World Medical Association (WMA); October 2024. [cited November 3, 2024]. <https://www.wma.net/policies-post/wma-declaration-of-helsinki/>
- 3 Resneck JS Jr. Revisions to the Declaration of Helsinki on its 60th anniversary: a modernized set of ethical principles to promote and ensure respect for participants in a rapidly innovating medical research ecosystem. *JAMA*. 2025;333(1):15-7. [CrossRef]
- 4 Crawley FP. Declaration of Helsinki: Full paragraph-by-paragraph comparison indicating changes in version 19 October 2024 compared with the most previous version of 19 October 2013. In: Zenodo; October 27, 2024. [CrossRef]
- 5 Declaration of Helsinki: Recommendations Guiding Doctors in Clinical Research – 1964 Version [Internet]. Ferney-Voltaire: World Medical Association (WMA); June 1964 [cited November 3, 2024]. <https://www.wma.net/wp-content/uploads/2018/07/DoH-Jun1964.pdf>