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Editorial: The 2024 Revision of the Declaration of Helsinki and its Continued Role as a Code of Ethics to Guide Medical Research

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Abstract This year, 2024, marks the 60th anniversary of the Declaration of Helsinki, with the latest revision adopted by the World Medical Association (WMA) in October 2024. The 2024 Declaration of Helsinki is a statement document of ethical principles for research involving humans, human data, and human cells and tissues. Revising the 2013 Declaration of Helsinki document was undertaken over more than two years with international collaboration to enhance the inclusivity of medical research, protect the rights of research study participants, and address contemporary research challenges such as global health emergencies and data privacy. The revised Declaration document does not replace the roles of the Institutional Review Board and the local Ethics Committee in reviewing and approving all research study protocols but continues to provide ethical guidance for the individuals who support, review, and conduct medical research. This editorial highlights the timely revisions in the 2024 Declaration of Helsinki and the importance of updating and maintaining an international consensus for a code of ethics that guides medical research.

Keywords: **Medical Research • Ethics • Declaration of Helsinki • Editorial**

On October 19, 2024, the World Medical Association (WMA) announced the adoption of the 2024 Revision of the Declaration of Helsinki, a statement document of ethical principles for research involving humans, human data, and human cells and tissues [1]. The revision process was undertaken over more than two years with international collaboration to enhance the inclusivity of medical research, protect the rights of research study participants, and address contemporary research challenges such as global health emergencies and data privacy [1]. The revised Declaration document updates the previous 2013 Declaration of Helsinki in several ways [1,2]. **Table 1** summarizes the fundamental changes and updates to the content of the 2024 Declaration of Helsinki [1].

The WMA was established in 1947 in response to concerns regarding the ethics of medical and research practices during and after World War II [3]. Since 1947, the WMA has provided a platform for developing and maintaining a global consensus on medical ethics [3]. In 1964, the WMA adopted the first Declaration of Helsinki to establish ethical principles for medical research involving humans [3]. However, although the first Declaration document was driven by international laws that include the Nuremberg Code, the Declaration of Helsinki has never been an official legal document, and the WMA has no legal authority or procedures [4]. However, for more than six decades, the Declaration of Helsinki has been the most recognized and influential international code of ethics guiding medical research [4]. Although the Declaration of Helsinki includes unchanged fundamental ethical principles, the document has been revised several times as medical research has progressed [3].

The history of the WMA and the history of research regulation has focused on protecting individual study participants [3,5]. However, similar ethical frameworks that guide medical interventions in clinical practice still need to be developed [5]. The Declaration of Helsinki guides the protection of participants in trials of experimental or new or previously untested interventions [3]. However, for clinical research of lower risk, such as comparative efficacy studies, guidance may be misaligned, as research participants are highly protected but patients in clinical practice may be under-protected [5,6]. Ethical oversight for clinical trials and the patients who participate in clinical trials, as well as regulatory practice, requires consideration of study design, patient risk, and the requirements of participant research consent [5,7].

Several authors have commented on the main revisions to the 2024 Declaration document and the implications of these revisions [1,5,8,9]. An important addition to the Declaration document is guidance on the appreciation of global ethical challenges that require responsible inclusivity in research with appropriate safeguards, particularly for underrepresented and marginalized groups (**Table 1**) [1,8]. The roles of research Ethics Committees in the approval, monitoring, and implementation

Table 1. Summary of key revisions to the 2024 Declaration of Helsinki [1].

Revision to the Declaration document	Description of the revision
Terminology	The term ‘participants’ has replaced ‘subjects’ throughout the Declaration document, and gender-neutral language has been adopted to respect individuals involved in research
Research inclusivity	The Declaration document now addresses all individuals, teams, and organizations involved in medical research, including physicians, as an acknowledgment of the interdisciplinary nature of modern research studies and the ethical requirements of all research participants
Engagement of study participants	The new Declaration document emphasizes meaningful engagement with research study participants before, during, and after the study has been undertaken
Recognition of participant vulnerability	Researchers are advised to consider the long-term and global benefits, risks, and safety of research studies and the fair and responsible inclusion of vulnerable populations who require adequate support. Vulnerable individuals include those who may be unable to provide consent
Participant data and biobanking	Paragraph 32 of the Declaration document has been rewritten to address informed consent requirements for collecting, storing, and secondary use of data and biological materials. Situations are recognized where obtaining consent for unforeseen secondary research may not be possible, and in these cases, an Ethics Committee review and approval are required
Governance of Biobanks and Health Databases (Declaration of Taipei)	The revised Declaration document cross-references the WMA Declaration of Taipei [16], which provides guidelines on the governance of biobanks and health databases, including data collected for multiple and indefinite use
Public health emergencies	A new paragraph has been added to the Declaration document that mandates that ethical principles must be upheld even during public health emergencies
Unproven or non-evidence-based interventions	Revisions to the new Declaration document clarify that unproven interventions to alleviate pain or suffering must not bypass ethical safety measures or evade evaluation by controlled clinical trials
Study design and environmental sustainability	The new Declaration document strengthens environmental sustainability commitments, and highlights the importance of rigorous study design to prevent wasteful research methods
The role of Ethics Committees	The new Declaration document recommends that sufficient resources be available to ensure the independence of research Ethics Committees to oversee research practices
Participant language, preferences and values, and consent	Study participant language, values, and preferences should be considered when they give consent or when consent is obtained from a legally authorized representative on their behalf

of medical research have been highlighted (**Table 1**) [1,8,9]. The revised Declaration document has developed beyond its traditional focus on individual research participants to emphasize community engagement and global responsibility for ethics, avoid waste, and reduce the ecological impact of the research study (**Table 1**) [1,9].

Access to patient health data and biobanks has rapidly developed since the 2013 Declaration document, and the roles of machine learning or artificial intelligence (AI) in medical research have begun to be realized [10]. Each year, the number of medical research studies that include the applications of artificial intelligence (AI) in medical research, including studies with patients and patient data, continues to rise [10]. AI is now used in clinical drug development, drug target selection, and patient selection to accelerate clinical trials [11,12]. There are concerns regarding ethical issues, including patient confidentiality and the lack of evidence-based clinical guidelines that require support from clinical trial data using AI [10,13,14]. In September 2020, the CONSORT-A1 extension guidelines were developed with 14 additional reporting items [14]. However, ethical guidance has yet to keep pace with medical research that involves human and AI interactions [14]. There is an increasing need for ethical data governance and improved clarity regarding current and future applications, ethical considerations, and potential risks of AI in medical research (**Table 1**) [1,13]. The WMA will continue to revise the Declaration of Helsinki document to improve human health through medical research [1,15]. Data-driven research is expected to increase, which means that consent, the rights of study participants, and risk minimization will require ethical guidance [1,15].

Conclusions

The Declaration of Helsinki has provided an international code of ethics to guide medical research for over six decades. The revised Declaration document does not replace the roles of the Institutional Review Board and the local Ethics Committee in reviewing and approving all research study protocols but continues to provide ethical guidance for the individuals who support, review, and conduct medical research.

References:

1. World Medical Association. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human participants. JAMA. 2024; doi: 10.1001/jama.2024.21972. Epub ahead of print
2. World Medical Association. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. JAMA. 2013;310(20): 2191-94
3. World Medical Association. History: The Story of the WMA. Available from: https://www.wma.net/who-we-are/history/
4. Sprumont D, Girardin S, Lemmens T. The Helsinki Declaration and the law: An international and comparative analysis. In: Frewer A, Schmidt U, eds. History and Theory of Human Experimentation: The Declaration of Helsinki and Modern Medical Ethics. Franz Steiner Verlag; 2007
5. Wise J. Helsinki Declaration: Rights of study participants are put at the heart of latest update. BMJ. 2024;387:q2357
6. 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. 2024; doi: 10.1001/jama.2024.21902. Epub ahead of print
7. Kass NE, Faden RR, Angus DC, Morain SR. Making the ethical oversight of all clinical trials fit for purpose. JAMA. 2024; doi: 10.1001/jama.2024.0269. Epub ahead of print
8. Bierer BE. Declaration of Helsinki – revisions for the 21st century. JAMA. 2024; doi: 10.1001/jama.2024.22281. Epub ahead of print
9. Reis AA, Upshur R, Moodley K. Future-proofing research ethics – key revisions of the Declaration of Helsinki 2024. JAMA. 2024; doi: 10.1001/jama.2024.22254. Epub ahead of print
10. Chustecki M. Benefits and risks of AI in health care: Narrative review. Interact J Med Res. 2024;13:e53616
11. Jin Q, Wang Z, Floudas CS, et al. Matching patients to clinical trials with large language models. Nat Commun. 2024;15(1):9074
12. Hutson M. How AI is being used to accelerate clinical trials. Nature. 2024;627(8003):S2-S5
13. Shaw JA. The revised Declaration of Helsinki-considerations for the future of Artificial Intelligence in health and medical research. JAMA. 2024; doi: 10.1001/jama.2024.22074. Epub ahead of print
14. Parums DV. Editorial: Artificial Intelligence (AI) in clinical medicine and the 2020 CONSORT-AI Study Guidelines. Med Sci Monit. 2021;27:e933675
15. Kurihara C, Kerpel-Fronius S, Becker S, et al. Declaration of Helsinki: Ethical norm in pursuit of common global goals. Front Med (Lausanne). 2024;11:1360653
16. World Medical Association. Declaration of Taipei. Research on Health Databases, Big Data and Biobanks. Available from: https://www.wma.net/what-we-do/medical-ethics/declaration-of-taipei/