

OPINION PAPER

Declaration of Helsinki 2024: Advances and Persistent Setbacks From a Latin American and Caribbean Bioethical Perspective

The World Medical Association adopted a new version of the Declaration of Helsinki (DoH) at its 75th General Assembly in October 2024 (1). While the revision introduced some positive changes regarding the human rights of research participants, significant setbacks remain. These concerns were highlighted during public consultations by Redbioética, a non-profit interdisciplinary network of bioethics experts established in 2003 with the support of UNESCO, where it submitted recommendations (2) based on UNESCO's Universal Declaration on Bioethics and Human Rights (UDBHR) (3).

Among the advances in the 2024 DoH is the extension of ethical principles beyond physicians to encompass research teams and organizations, thereby broadening ethical accountability (4). In addition, the recognition of “various structural inequities” in health research and the emphasis on engaging participants and communities at every stage promote equity and social justice. The concept of vulnerability has also been refined to reflect its dynamic, contextual, and social dimensions (4). However, these advances are tempered by persistent ethical concerns.

The Covid-19 pandemic underscored the importance of maintaining rigorous ethical standards during emergencies, particularly for unproven interventions. The 2024 DoH includes important advances, such as requiring unproven interventions to comply with ethical safeguards, yet it lacks several of Redbioética's proposed measures, including mandatory ethics review, continuous safety monitoring, and compulsory reporting of observational studies in unregulated settings. The absence of these provisions weakens oversight, jeopardizes the balance of benefits and harms, and puts the safety of participants at risk.

One of the persistent issues in the 2024 DoH remains the flexibility regarding the use of placebos — or no treatment — in clinical trials. Their use is permitted in “methodologically justified” circumstances, provided that patients “will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention” (1). However, the interpretation of this provision remains unclear, which continues to raise ethical concerns about double standards in international medical research (5). The changes introduced in the placebo paragraph of the DoH (2013), which continue in the 2024 ver-

sion, “were presumably introduced to allow comparisons of interventions used in resource-poor countries, to compare existing interventions with new ones” [...] (6). We advocate for stricter guidelines, and believe that the use of placebo should be limited to situations where there is no proven, effective, and safe comparator treatment (2,4). This position is based on the principles of respect for human dignity and human rights, and affirms that the protection of research participants must always prevail (3).

Another critical issue is post-trial access to treatments that have proven to be safe and effective. While the 2024 DoH recognizes this need, it does not provide a clear framework for implementation, leaving a significant gap. It is concerning that the 2024 DoH leaves decisions on post-trial access to research ethics committees, potentially weakening protections, particularly in countries with less robust ethical oversight systems. Redbioética has called for stronger commitments from sponsors to ensure that research participants, especially in low- and middle-income countries (LMICs), have access to these interventions once studies are completed (2,4), in line with the UDBHR's “benefit-sharing” principle (3).

It is important to note that the Uruguayan Medical Association submitted motions against the paragraphs on placebo use and post-trial access at the 75th WMA General Assembly in October 2024. Despite limited support, the German and Dutch Medical Associations defended the original proposal to avoid hindering “necessary research” (7). The Uruguayan motions were rejected.

Redbioética expresses its concern about the 2024 DoH version and joins efforts to broaden its impact (2,4), urging states to adopt standards that go beyond those in the current version and are more closely aligned with the UDBHR and the highest level of participant protection.

*The views expressed are solely those of the signatories and do not necessarily reflect the positions of UNESCO, and are therefore not binding on the organization.

References

1. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for Medical research involving Human participants. JAMA 2025;333:71–74. <https://doi.org/10.1001/jama.2024.21972>.

2. Redbioética UNESCO para América Latina y el Caribe. Posición de Redbioética sobre la Declaración de Helsinki 2024. <https://doi.org/10.5281/zenodo.14017430> (Accessed April 3, 2025).
3. United Nations Educational, Scientific and Cultural Organization (UNESCO). Universal Declaration on Bioethics and Human Rights. Paris: UNESCO; 2005 <https://unesdoc.unesco.org/ark:/48223/pf0000142825> Accessed April 3, 2025.
4. Helsinki statement from an independent stakeholders' Group to expand the impact of the 2024 revision of the WMA Declaration of Helsinki. Clin Eval 2024;52. http://cont.o.oo7.jp/52pop/HelsinkiStatement_18Oct24_final.pdf Accessed April 3, 2025.
5. Hellmann F, Verdi M, Schlemper BR Jr, Caponi S. 50th anniversary of the Declaration of Helsinki: the double standard was introduced. Arch Med Res 2014;45:600–601. doi:10.1016/j.arcmed.2014.10.005.
6. Macklin R. Double standards in multinational research. In: Porto D, Schlemper BR, Martins GZ, Cunha T, Hellmann F, editors. Bioética: saúde, pesquisa, educação. Brasília: CFM/SBB; 2014. p. 59–75.
7. Kurihara C, Matsuyama K, Baroutsou V. World Medical Association's declaration of Helsinki, 2024 revision: celebrating the 60th anniversary, at Helsinki. Clin Eval 2025;52. http://cont.o.oo7.jp/52pop/52pop_contents_e.html Accessed April 3, 2025.

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