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Evolving ethos of medical research: A retrospective analysis of the declaration of Helsinki (1964-2024)

Jovan Yi Jun Liau, Vishal G Shelat

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Abstract

The World Medical Association's Declaration of Helsinki (DoH) serves as a key document of ethical guidance advocating principles of medical research involving human participants. Since its inception in 1964, the DoH has undergone several revisions, reflecting a dynamic evolution in our understanding of research ethics, spurred by gaps identified within the document, harms discovered, challenges identified during ongoing research activities, scientific advancements and societal shifts in values. The DoH addresses a challenge and a conflict that may arise between two key aspects of medical research: On one hand, the fundamental obligation of physicians to do no harm, and on the other, the essential need to ensure the efficacy and safety of medical interventions by testing them on human research participants or healthy volunteers. With each revision, increasing emphasis is given to distributive justice and beneficence and not only to patient autonomy. Despite being a comprehensive and concise document, occasional criticism is reported, such as with regards to the impracticability of obtaining informed consent amongst other challenges. This essay will examine the key changes across the DoH's iterations, highlighting the progressive strengthening of participant protection and the evolving relationship between research, societal benefit, and individual rights.

Key Words: Ethics; Declaration of Helsinki; World medical association; Medical research; Informed consent

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Core Tip: The current 2024 revision of the Declaration of Helsinki (DoH) marks the 11th version of the DoH since its inception in 1964. Throughout the past 60 years, many notable controversies in medical ethics have arisen, such as the Tuskegee syphilis study and the harvesting of the HeLa cell line. Following these incidents, iterations of the DoH have increasingly emphasized distributive justice and beneficence, rather than focusing solely on patient autonomy. This essay will examine the key changes across the DoH's iterations, highlighting the progressive strengthening of participant protection and the evolving relationship between research, societal benefit, and individual rights.

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INTRODUCTION

Medical research is a vital component of clinical medicine and serves as a cornerstone for driving advances in the cure and control of diseases. Throughout history, humanity has engaged in human experimentation. Notably, in 1796, Edward Jenner observed that milkmaids who had cowpox appeared to be immune to smallpox, prompting him to conduct a controversial experiment. He inoculated 8-year-old son of his gardener, James Phipps, with cowpox pus and then deliberately exposed him to smallpox to test immunity. This groundbreaking work laid the foundation for modern vaccination practices and ultimately contributed to the control of smallpox. Lack of informed consent, vulnerability, and severe risk of intentional harm make Jenner's experiment unethical by current standards. But Jenner received numerous accolades and gifts from King Charles III, Napoleon, empress of Russia, was given GBP 30000 by the parliament for his contributions towards public health and conferred an honorary Doctor of Medicine degree by the University of Oxford. About 150 years later, public trust was fractured in revelation of horrific ethical failures of physicians during World War II. The Declaration of Helsinki (DoH) was set up to reaffirm the norms of medical research and practice that must apply to all doctors and to prevent breaches of ethical conduct among physicians in the future, but most importantly, to reestablish patient trust for physicians[1]. The principles in DoH were largely adopted from the Nuremberg Code[2]. The DoH is a living core document that stands as a cornerstone of ethical guidance advocating principles of medical research involving human participants. Since its inception in 1964, the DoH has undergone several revisions (Figure 1), reflecting a dynamic evolution in our understanding of research ethics, spurred by gaps identified within the document, harms discovered, challenges identified during ongoing research activities, scientific advancements and societal shifts in values. The DoH addresses a challenge and a conflict that may arise between two key aspects of medical research: On one hand, the fundamental obligation of physicians to do no harm, and on the other, the essential need to ensure the efficacy and safety of medical interventions by testing them on human research participants (for therapeutic research) or healthy volunteers (for non-therapeutic research). The DoH attempts to set the balance right. The DoH was written and is written by physicians. So, it's firstly and foremost, a moral obligation for physicians, although the world medical association (WMA) has always invited other healthcare professionals and researchers to adopt these principles. With each revision, increasing emphasis is given to distributive justice and beneficence and not only to patient autonomy. This essay will examine the key changes across the DoH's iterations, highlighting the progressive strengthening of participant protection and the evolving relationship between individual rights, scientific research, and societal benefit.

THE GENESIS OF THE DECLARATION OF HELSINKI (1964)

The 1964 version established a relatively simple framework with five basic principles. It emphasized the physician's duty to safeguard the health of the people and introduced the crucial concept of prioritizing the patient's well-being over scientific advancement. The primary obligation of the physician is to the patient, and DoH makes a reference to both Declaration of Geneva as well as International Code of Medical Ethics. DoH acknowledges a physician's duty to promote and safeguard the health, well-being, and rights of patients, including those who are involved in medical research. It reaffirms that while the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research participants. Jerry Menikoff highlights the conflict of interest with inherent tension between prioritizing individual patient well-being (clinical practice) and scientific research [3]. However, this tension is not an ethical failure, but a challenge addressed by DoH that weigh competing (not conflicting) interests by recommending principles and processes to ensure participant safety and ethical research conduct. The 1964 version was narrow in its scope to include clinical research on subjects. Over the various revisions, the scope is broadened to include medical research, including research on identifiable human material and data and the human subjects are accorded agency and dignity by rephrasing as participants. Measures such as disclosing conflicts of interest, establishing independent oversight, free and informed consent, funding transparency, and meaningful engagement serve to maintain patient and public trust to participate in research. Furthermore, the language regarding informed consent was less explicit and it was detailed in subsequent versions. The document lacked the nuanced considerations for vulnerable populations and did not address the potential for structural inequities to influence the distribution of risks and benefits.

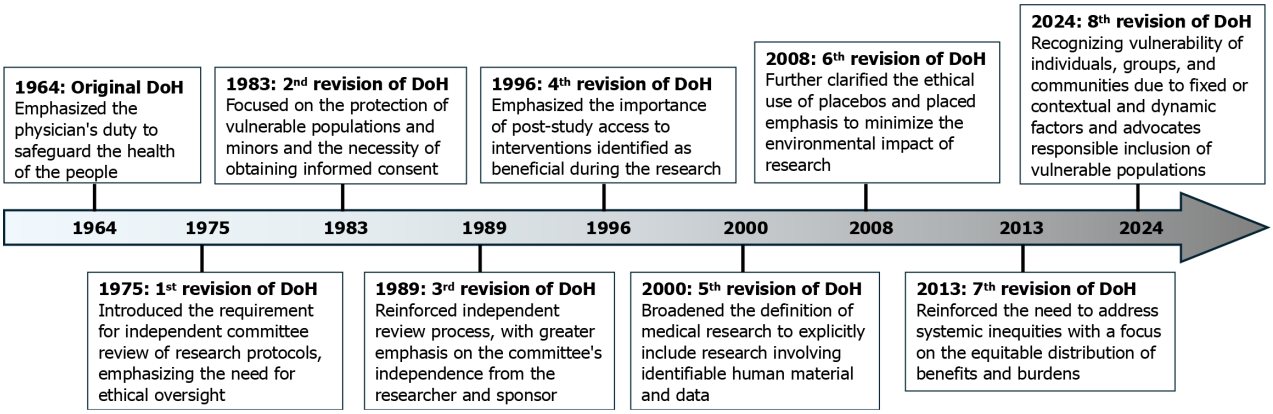


Figure 1 Timeline of the declaration of Helsinki document versions. DoH: Declaration of Helsinki.

The role of independent ethical review was absent, empowering physician with responsibility and professional judgment. This reflected the prevailing medical ethos of the era, *i.e.* physician paternalism.

THE 1975 REVISION: A PIVOTAL SHIFT TOWARDS INFORMED CONSENT

The 1975 revision, drafted by three Scandanavian doctors, marked a significant leap forward with emphasis on the independent review of research protocols, prioritizing the well-being of research participants above the interests of science, and enhancing requirements for informed consent[4]. This change was a direct response to previous unethical practices. This was following the media coverage of the disreputable Tuskegee syphilis study conducted from 1932 to 1972, where African American men participating in the study were not informed about their syphilis diagnosis, and were not treated even when penicillin became standard of care in 1947. 399 men with syphilis and 201 uninfected males were enrolled into the study believing that they would receive treatment for any diagnosed illnesses. Several of these men were subjected to lumbar punctures under the impression that it was therapeutic and suffered complications[5]. Eventually, 28 men died of syphilis, and another 100 dying of related complications[6]. Similarly, the Willowbrook state school study took place between 1956 to 1972, and involved the intentional infection of children with developmental disabilities with hepatitis by feeding them with hepatitis virus titrated from stool samples[7]. This was done to study the progression of the disease and investigate the possibility of developing a hepatitis vaccine[8]. Subsequent studies then determined that these individuals were infected with hepatitis A and B, with several inoculated individuals developing jaundice as a result[9]. Exploitation of vulnerable groups, lack of informed consent, and disregard for disproportionate risk of harm render this comparable to Jenner's experiment. No longer a mere mention, informed consent became a central tenet, demanding that participants receive comprehensive information regarding the study's purpose, procedures, risks, and potential benefits, enabling them to make a truly autonomous decision about participation. The revision also explicitly addressed the need for ethical considerations regarding environmental protection and the treatment of animals used in research, while stipulating that the DoH itself should be subject to ongoing review. Aside from echoing patient autonomy, the 1975 version also underscored the importance of independent ethical review, laying the foundation for institutional review boards (IRBs) or Ethics Committees to oversee research protocols, providing an external check on research integrity and protecting participant rights. These independent ethics committees are entrusted with maintaining checks and balances on researchers' pursuits, as they stand to benefit from the research through enhanced professional and personal reputations, improved career prospects, and increased remuneration. This revision implicitly acknowledged the need for more robust protections of vulnerable populations, though it lacked explicit guidelines for these specific groups. Table 1 provides a summary of key highlights of each DoH version.

FURTHER REFINEMENTS (1983-1996): STRENGTHENING PROTECTIONS AND CLARITY

The 1983, 1989, and 1996 revisions built upon the 1975 foundation, refining existing principles and enhancing clarity. In 1983 there were fairly minor changes to the text of the DoH[10]. For example, the word 'doctor(s)' was changed to 'physician(s)', the Latin phrase a forteriori was changed to 'especially'. In addition, there was rewording of quote from the International Code of Medical Ethics and consent for minors. In the 1989 version, the independent review process was reinforced, with greater emphasis on the committee's independence from the researcher and sponsor. The focus on protecting the integrity of participants and ensuring their privacy became more explicit, addressing concerns about potential coercion and undue influence. The first time the DoH refers to any specific type of research methodology, *i.e.* the placebo-controlled trial, was its 1996 version. While the 1964 version briefly mentioned vulnerable populations, the subsequent revisions gradually refined the guidelines for their protection. For example, the AIDS Clinical Trials Group published trial results on the usage of zidovudine in the 1994s in Africa. These trials in Africa were highly controversial,

Table 1 1964-2024 versions of declaration of Helsinki with key points

Month, year	City, country	WMA general assembly	Remarks
June, 1964	Helsinki, Finland	18th	First version of the guiding principles of clinical research by international collaboration mentions 'freely given consent' from patient
October, 1975	Tokyo, Japan	29th	(1) Clinical research changed to biomedical research; (2) Patient – changed to human subjects; (3) Consent – changed to informed consent with mention of written consent; (4) Introduced concept of doctor-patient relationship; (5) Strengthened protection of vulnerable populations; (6) Oversight of specially appointed independent committee (concept of Institutional Review Boards); and (7) Guidance on publication of research
October, 1983	Venice, Italy	35th	(1) Doctor – changed to physician; (2) Minor assent/consent emphasis if applicable; and (3) Subjects termed as volunteers for non-therapeutic research
September, 1989	Hong Kong	41st	(1) The independent committee should have impartial oversight to minimize conflict of interest; and (2) The independent committee should be free from the influence of both the researcher and the sponsor
October, 1996	Somerset West, RSA	48th	(1) Emphasis on the wellbeing of the patient/subject; (2) The responsibility extends beyond obtaining informed consent, including monitoring for safety and welfare; (3) Adds a clarification - use of placebos is acceptable in studies only when there is no proven diagnostic or therapeutic method; and (4) Reinforces the need for extra caution when obtaining informed consent in vulnerable populations
October, 2000	Edinburgh, Scotland	52nd	(1) Replaced 'biomedical' with 'medical' and explicitly includes research on identifiable human material and data; (2) Highlights the challenges of obtaining consent from individuals who may be under duress or coercion; (3) The role and responsibilities of independent ethics committees are expanded; (4) Adds the condition that the research should only be done if the population involved will directly benefit from the research findings; and (5) In publication, stresses the necessity of transparency by including information on funding, sponsors, and potential conflicts of interest
October, 2002	Washington DC, United States	53rd	(1) Clarification of placebo use - a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under specific circumstances
October, 2004	Tokyo, Japan	55th	(1) Clarification on post-trial access - Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review
October, 2008	Seoul, Republic of Korea	59th	(1) Regarding vulnerable populations, it reiterates that research is only justified when it directly addresses their health needs and there's a reasonable likelihood of benefit; (2) Enhances the authority and responsibilities of ethics committees; (3) Mandates that all clinical trials must be registered in a publicly accessible database before the enrolment of the first participant. This improves transparency; and (4) Re-emphasizes the importance of publishing both positive and negative findings and reporting conflicts of interest in research publications
October, 2013	Fortaleza, Brazil	64th	(1) Emphasizes the importance of transparency and public access to research data; (2) Explicitly states that the research ethics committees must have the authority to monitor ongoing studies and ensure that the researchers provide timely and complete information, especially regarding serious adverse events; (3) Biobanks included alongside identifiable human material and data; and (4) Compensation must be provided to research participants who are harmed as a result of participating in a study
October, 2024	Helsinki, Finland	75th	(1) Broadened accountability for all individuals, teams, and organizations; (2) "Subject" replaced by "participant" for autonomy and engagement; (3) Inclusion of healthy volunteers as participants; (4) "Informed consent" changed to "free and informed consent"; (5) Emphasis on community consultation and engagement; (6) Emphasizes meaningful engagement with participants and their communities before, during, and after the study; (7) Essential to uphold principles during public health emergencies; (8) Promoting environmental sustainability; and (9) Substantial changes in vulnerability section

as the control groups were given a placebo drug despite availability of effective drugs that prevent vertical transmission of human immunodeficiency virus[11]. This incremental development reflects a growing awareness of the potential for exploitation of vulnerable populations and a greater recognition of the need for proactive measures to prevent harm. Figure 2 summarises the structural details of the various DoH versions. It is evident that the document has ballooned to four time its original word count.

THE 2000 DECLARATION: AN INCLUSIVE APPROACH

The 2000 declaration represented a watershed moment with only three of the 32 paragraphs unchanged and eight new paragraphs added. The introduction of this version recognizes the conflict between advancing medical practice through research (by challenging existing methods) and ethical obligation to protect research participants from exploitation, particularly vulnerable populations. The previous versions dichotomized research into therapeutic and nontherapeutic, but the 2000 version broadened the definition of medical research to explicitly include research involving identifiable human material and data[12]. The revision of DoH was driven by overall scientific trends and multiple incidents during the time, one being the HeLa cell line controversy, in which Henrietta Lacks' tumor cells were harvested and propagated

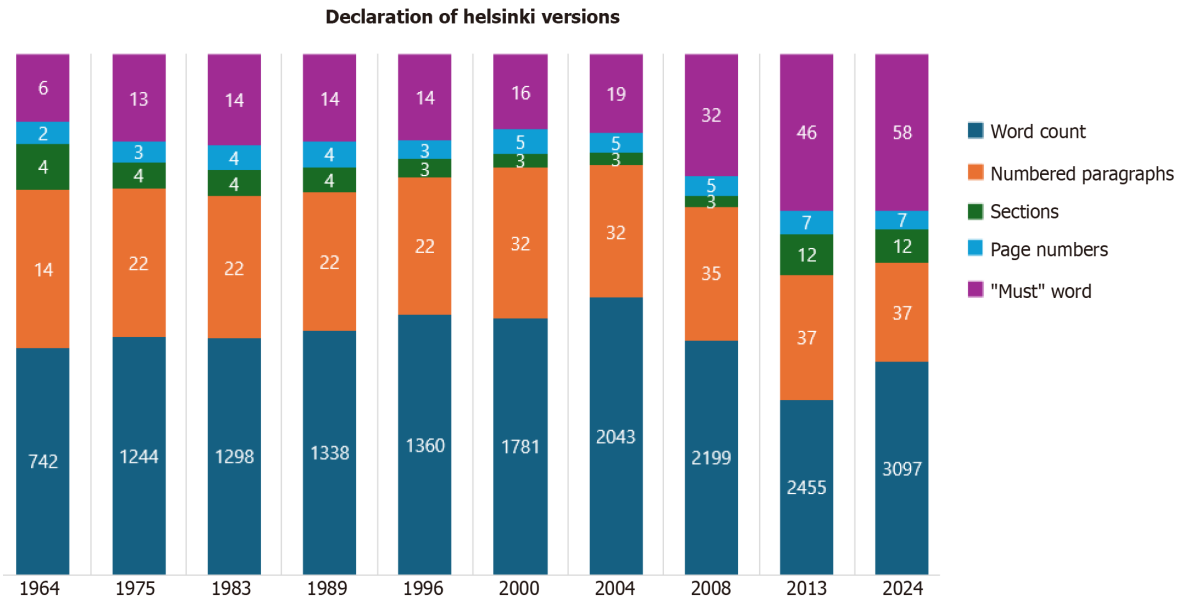


Figure 2 Structural details of the declaration of Helsinki document versions by years. Word count was generated using https://www.montereylanguages.com/pdf-word-count-online-free-tool.html (Accessed on January 7, 2025).

without her or her family's consent for the usage of biomedical research[13]. As the HeLa cells provided to researchers were readily identifiable, Henrietta Lacks' genetic information could be disclosed. In addition to the lack of informed consent, Lacks' family were not informed regarding the use of these cells in medical research for decades, and received no compensation as a result[14]. This episode highlighted the importance of taking informed consent from individuals, including human biospecimens such as cells or genomes.

In addition to the above changes, this revision reworded 'biomedical research' to 'medical research' and strengthened the emphasis on equitable access to participation in research, acknowledging that historically marginalized communities were often underrepresented. Another aspect of the revision includes a significant clarification and expansion of the placebo cause, stating that researchers should offer the best-known therapy available instead of a placebo, with the exception being when no proven or effective treatment exists. However, Tollman *et al*[15] argued that the placebo clause may inadvertently hinder research in resource-constrained settings due to the demands it places on already weak healthcare systems. While this may hold true, it is crucial to prioritize patient welfare, as providing the best-known therapy not only upholds research integrity but also ensures that participants receive optimal care. The principles governing informed consent were further refined, with more specific considerations for vulnerable populations and those lacking capacity for autonomous decision-making. The concept of proxy consent was further developed. This marked a significant shift towards a more inclusive and equitable approach, aiming to address existing societal disparities and promote fairness in research participation. However, the concept of Gillick competency has not been acknowledged in DoH and Hilda Bastian has considered this as a "step backwards for people who are legally 'incompetent' to make their own decisions (including those under 18years old) but who are in fact capable of doing so"[15]. While the declaration may be viewed as restrictive, it is essential to ensure that the protection of vulnerable populations, including those deemed legally incompetent, is prioritized to prevent harm and safeguard their rights within the research process. As WMA is not prescriptive document, within the governance of local ethical and regulatory framework, research may be conducted in legally incompetent persons. Lastly, the WMA has set strict tone to global institutions that rich populations should not exploit poor populations: "...research should not be carried out in countries in development just because it is cheaper and the laws are more lax"[16].

CLARIFICATIONS AND ENHANCEMENTS (2002-2004): PRECISION AND POST-TRIAL ACCESS

The 2002 and 2004 versions were primarily focused on clarifying existing guidelines. In 2002, a note of clarification was added by the WMA saying that placebo control may be ethically acceptable even if proven therapy is available if two conditions are met: (1) If there are compelling and scientifically sound methodological reasons; or (2) If patients would not be subject to any risk of serious or irreversible harm. Back then, these two conditions were linked with an 'or'. A few years later in 2008, this note of clarification was removed and this wording was then changed and put into the main document. The two conditions were linked with an 'and' instead of an 'or'. Furthermore, the phrase 'extreme care must be taken to avoid the abuse of this option' was added in 2008, which serves to add additional protection for study participants. The 2004 version also emphasized the importance of planning for post-trial access to any benefits identified during the study. These refinements reflect a continuous effort to ensure study participants receive appropriate timely access to medical care.

THE 2008 DECLARATION: BROADER SOCIETAL CONTEXT AND SUSTAINABILITY

The 2008 Declaration introduced even more significant changes, emphasizing the importance of considering the broader societal context of medical research. It explicitly called for researchers to consider the ethical, legal, and regulatory norms in their countries and internationally, while stressing that national regulations should not diminish the protections for research participants. The 2008 version also placed emphasis to minimize the environmental impact of research.

THE 2013 DECLARATION: PARTICIPANT-CENTRIC APPROACH AND SYSTEMIC INEQUITIES

The 2013 Declaration further strengthened the participant-centric approach, explicitly stating that the well-being of the individual research participant must take precedence over all other interests. The "responsiveness principle" mandates that studies address local health needs, fairly select participants, and ultimately benefit the community through improvements in healthcare, economic activity, and research capacity building[17]. It reinforced the role of research ethics committees (RECs) in the oversight of research, granting them greater autonomy and emphasizing their responsibility to monitor ongoing studies. The 2013 version also reinforced the need to address systemic inequities with a focus on the equitable distribution of benefits and burdens.

THE 2024 DECLARATION: A COMMITMENT TO EQUITY AND TRANSPARENCY

The 2024 Declaration represents the most recent iteration that fruited following a two year inclusive process of regional and topical meetings (Table 2) by the working group of members from 19 countries, formed in April 2022. This was followed by two phases of general public feedback and comment gathering and is an incremental evolution rather than revolution. The 2024 version changed the preamble to include participants rather than subjects to respect rights and agency. The latest version also advocates that principles should be upheld by all individuals, teams, and organizations involved in medical research. It emphasizes the importance of 'free and informed consent' so research participants can make decisions free from undue influence[18]. In addition, protection of vulnerable populations, avoiding research waste, and the role of RECs, also introduces several significant shifts. The 2024 version mentions recognizing vulnerability of individuals, groups, and communities due to fixed or contextual and dynamic factors. It advocates responsible inclusion of vulnerable populations by not depriving them from the important benefits of participation in research. It emphasizes meaningful engagement with participants and their communities, advocating for their input at all stages of research, from design to dissemination. It directly addresses the problem of structural inequities, calling for conscious effort to avoid perpetuating or exacerbating social inequalities. The 2024 version advocates for resourceful and independent ethics committee with diversity of members who has received necessary education, qualifications, and training. It places a heavy emphasis on transparency, particularly in data sharing and publishing results, and on ensuring post-trial access to any benefits arising from the research (Figure 3). This version reflects a deeper understanding of how societal factors can influence the ethical conduct of research and a strong commitment to creating a more equitable and just research environment.

CONCLUSION

Critical analysis and future directions

The DoH despite being a comprehensive and concise guiding document, occasional criticism is reported. Dal-Ré[19] has reported that DoH guidelines fall short of certain situations where it is impracticable to obtain informed consent, such as in emergency medicine. The Council for International Organizations of Medical Sciences (CIOMS) is an organization that works with the World Health Organization to develop ethical guidelines for health-related research involving humans. These guidelines are widely used and often serve as a reference point for national regulations and research ethics committees worldwide, especially Australia, Canada, and United States. According to CIOMS, a REC may approve a modification or waiver of informed consent to research if: (1) The research would not be feasible or practicable to carry out without the waiver or modification; (2) The research has important social value; and (3) The research poses no more than minimal risks to participants. The 2024 DoH version does not mention the three conditions and empowers the local RECs, *i.e.* DoH is not prescriptive and it is consistent with its intent and purpose of providing broad guiding principles that has to be applied and interpreted by research teams under institutional governance framework.

In fact, one of the key features of DoH is that it is not a detailed rulebook! The revised versions have more uncontroversial principles and guidelines and less controversial aspects. The absence of globally recognized ethical standards for forensic research using human cadavers and remains has garnered traction for application of DoH principles responsible practice by forensic scientists[20]. Similarly, Ashall *et al*[21] has highlighted the potential of adapting the ethical principles outlined in the DoH to create an internationally agreed best practice in clinical veterinary research.

While the 2024 Declaration commendably broadens its scope, controversy and debate are inevitable as the declaration takes on complex ethical issues with inherent conflicts[22]. Significant omissions remain. The lack of explicit guidance on embryo research, particularly given evolving understandings of personhood[23], alongside the superficial treatment of animal research (limiting itself to a general statement on welfare and neglecting the 3Rs principle), reveal crucial gaps as

Table 2 Regional and topical meetings convened for 2024 revision

City	Topic
Tel Aviv	Implications of big data, machine learning, artificial intelligence
Sao Paulo	Ethical considerations on use of placebo
Copenhagen	Emerging trial designs
Tokyo	Research during public health emergencies/pandemics
Vatican	Research in resource-poor settings, global justice
Johannesburg	Community inclusiveness, post-trial access, vulnerability
Munich	Specific and particularly vulnerable groups
Washington DC	Final consolidation

Adapted from: https://www.youtube.com/watch?v=hvcQ1hj_Xqs&t=2796s (Accessed on January 6, 2025).



Figure 3 Key elements of the declaration of Helsinki.

animals are fellow creatures with dignity, and animal deaths do matter morally[24,25]. Further, the Declaration's narrow focus on medical research overlooks the ethical challenges inherent in non-medical health research, including studies on social determinants of health and genetic research, where the heritable nature of data raises unique concerns about individual autonomy and broader societal impact. Expanding the scope to encompass all health research with human participants, as suggested by Saenz *et al*[26], would enhance its relevance and impact, particularly in low- and middle-income countries. The growing interconnectedness of data and potential privacy issues necessitate attention to cybersecurity. The next iteration of the DoH may need to explicitly address the evolving role of data security and responsible data sharing. Furthermore, the Declaration's emphasis on autonomy presents significant challenges for high-risk research, such as that conducted in intensive care units, where surrogate consent is often compromised[27]. The variability of REC standards may exacerbate these issues. Last but not least, the DoH will have to consider ethical implications of artificial intelligence, health economics, and scientific publishing.

In the work of senior author as a researcher, research mentor, and chairperson of Institutional Animal Care and Use Committee, he has found the DoH to be an invaluable guide in designing research protocols, training researchers, and conducting ethical reviews. Its emphasis on participant autonomy, transparency, and equity has significantly influenced his approach to obtaining informed consent, minimizing risks, and ensuring equitable benefit sharing. The continuous evolution of the DoH in response to emerging societal trends and scientific advances remains an inherent strength of DoH.

In conclusion, DoH is the first amongst the equals in medical research ethics considerations[28]. From a relatively basic framework focused primarily on physician responsibility, the DoH has evolved into a comprehensive document that places the well-being and rights of research participants at its core. The increasing emphasis on free and informed

consent, protection of vulnerable populations, transparency, and equity reflects a commitment to ethical research practices that prioritize both scientific progress and social justice. The revised document does not replace the roles of the IRBs in reviewing and approving all research study protocols[29]. Though, the influence and relevance of DoH has been questioned due to availability of other ethical guidelines and codes of practices, the ongoing revisions demonstrate a commitment to adapt to the ever-changing medical research landscape ensuring that scientific progress remains ethically sound and socially responsible[30].

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