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The revised declaration of Helsinki: Time for ethical review committees to revise their guidelines

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Journal of American Medical Association (JAMA) published a series of articles on "2024 Revised Declaration of Helsinki" in its online edition on October 21, 2024 [1]. The World Medical Association (WMA) in 1964 endorsed the first version of the Declaration of Helsinki (DoH). The 10th amendment was published in 2024 after 11 years of the 9th amendment done in 2013. DoH is a statement of principles envisioned to guide the ethical conduct of healthcare and medical research worldwide [2]. The 2024 DoH comprises 37 paragraphs [3] as shown in table 1.

The 2024 DoH puts more emphasis on the role and responsibilities of researchers and academic institutions concentrating on research ethics, honesty and rigorous design. The new paragraph on scientific integrity and research misconduct seems to be obligatory. It mainly focuses on retracted studies, plagiarism, AI, and unreproducible results. [4] All research studies involving human "subjects" should be approved by research ethics committees of institutions involved as documented in the 1975 version of the DoH. Since then, research ethics committees (RECs) or institutional review boards (IRBs) have been created in almost all countries of the globe and principles for their optimal practices have been issued. The updated paragraph 23 in the 2024 DoH stresses on the availability of adequate resources and approval of research proposals in both the sponsoring and host countries keeping limited fund and staff institutional guarantee in mind [4].

Table 1: Paragraphs of 2024 DoH [3]

Paragraph No	Heading
No. 1-2	"Preamble"
No. 3-15	"General Principles"
No. 16-18	"Risks, Burdens and Benefits"
No. 19-20	"Individual, Group and Community Vulnerability"
No. 21-22	"Scientific Requirements and Research Protocols"
No. 23	"Ethics and Research Committee"
No. 24	"Privacy and Confidentiality"
No. 25-32	"Free and Informed Consent"
No. 33	"Use of Placebo"
No. 34	"Post-Trial Provisions"
No. 35-36	"Research Registration and Publication and Dissemination of Results"
No. 37	"Unproven Interventions in Clinical Practice"

The 2024 DoH also places greater emphasis on involvement of patients, ensuring privacy of data, and global fairness, parity and equity. Patients are considered as "partner" not subjects. This edition of DoH emphasizes transparency and shared decision-making process among researchers and participants too [5]. The addition in paragraph 21 "medical research involving human participants must have a scientifically sound and rigorous design" as to avoid research waste underpins the obligations of researchers. The vulnerability concept in this DoH has been expanded to involve communities, with emphasis put on engagement of community. Paragraph 37 "Unproven Interventions in Clinical Practice" has also been extended by adding that clinicians must avoid compromising clinical trials [4]. Paragraph 32 on informed consent is completely rewritten in this DoH [6].

Over the last one-decade, medical science has evolved very rapidly with the fast-growing impact of artificial intelligence (AI). AI technologies have great potential to enrich the conduct of research in different aspects, stretching from fast-tracking discovery of drugs and to improving the efficacy of clinical trials. The 2024 DoH has made important changes, but the contexts of healthcare and medical science have also been changing rapidly, so constant review and revision is required on ethical guidelines related to AI in research [2].

After the COVID pandemic, the World Health Organization (WHO) Regional Office for South-East Asia, research ethics review committee (SEARO-ERC) developed standard operating procedures (SOPs) for the Research Ethics Review Committee of the region. These SOPs have been published in April 2022. Six countries of South Asia i.e. Bangladesh, Bhutan, India, Maldives, Nepal, and Sri Lanka are members of the SEARO region. These SOPs are based on the 2013 DoH (9th amendment of DoH). Certainly, what is revised in 2024 DoH has yet not been incorporated in IRB or ERC of six countries of South Asia, especially the AI related aspects [7]. The Drug Regulatory Authority of Pakistan published the second edition of "Guidelines to Conduct Clinical Research in

Pakistan" the effective date of which is March 14, 2024. It mentions the Institutional Review Committee (IRC)/ Independent Ethics Committee (IEC)/ Ethics Review Committee (ERC) / Institutional Review Board (IRB) but does not mention anything about AI and DoH [8].

There is revision of certain paragraphs, update of some of the existing paragraphs and new additions in 2024 DoH. In the light of these changes and keeping the importance of AI in the field of research and national perspectives of bioethics in mind, related institutes in South Asian countries must review and revise their ethical review committee (ERC) or institutional review board (IRB) guidelines instantly. The research proposals/protocols which are scientifically and ethically sound following IRB or ERC guidelines must get approval without difficulty and delay.

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