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COMMENTARY

2024 Revision of Declaration of Helsinki: policy perspectives from India

J RAAJASIRI IYENGAR, ROLI MATHUR

Abstract

The 2024 Declaration of Helsinki (DoH) marks a significant milestone in medical research ethics, addressing contemporary challenges and emphasising global ethical issues. In India, the 2017 Indian Council of Medical Research (ICMR) National Ethical Guidelines, align well with the 2024 DoH principles, particularly in safeguarding vulnerable populations and promoting ethical review processes. However, there is scope to work on further harmonisation and better implementation, such as registering all medical research, empowering ethics committees, and ensuring equitable access and inclusion. This perspective highlights the strengths and limitations of the ICMR guidelines in light of the 2024 DoH, aiming to foster a research environment that upholds ethical integrity, inclusivity, and the well-being of all participants.

Keywords: *2024 Declaration of Helsinki, ICMR National Ethical Guidelines, research ethics, bioethics*

Introduction

The 2024 revision of the Declaration of Helsinki (DoH) [1] marks a significant milestone in medical research ethics, addressing contemporary challenges while reinforcing the fundamental principles of respect for persons, beneficence, and justice in medical research involving human participants. Building on the principles established in previous versions, the updated Declaration reflects a growing appreciation of global ethical issues, emphasising the importance of fair and responsible inclusivity in research — including marginalised and underrepresented groups — as well as for research conducted in resource-limited settings. It also highlights contemporary issues such as research equity, global justice, data privacy, and the ethical implications of emerging technologies, such as artificial intelligence.

In 2017, the Indian Council of Medical Research (ICMR) published the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" (2017 ICMR guidelines) [2], which offer a thorough ethical framework for the country, and aligns considerably with the revised 2024 DoH. An analysis of the ICMR guidelines in light of the 2024 DoH would help bridge the gap between global ethical standards and national implementation. This would

also help in understanding how the provisions of the 2017 ICMR guidelines align with the updated DoH provisions. The sections of the guidelines that effectively mirror the Declaration's principles, as well as those that could benefit from further refinement to better protect human research participants and promote ethical research practices, are reflected upon below.

Key highlights

The 2024 DoH's shift in nomenclature from "subjects" to "participants" is a significant step as it duly recognises individuals as active contributors to the research process rather than passive objects of study, by acknowledging their dignity, value and contribution in clinical research. This shift aligns with the ICMR's long-standing commitment to respecting research participants, as evident in the "Ethical Guidelines for Biomedical Research on Human Participants" published by ICMR in 2006 [3] and in the 2017 revision [2]. The change in nomenclature marks an acknowledgement of a more respectful approach toward research "participants" rather than "subjects", "making them partners in research," as stated by Jack Resneck, former president of the American Medical Association and lead of the working group for the 2024 revision of the DoH [4]. While strengthening safeguards for vulnerable persons, the 2024 DoH further calls for the involvement of patients in setting research priorities, representing a fundamental shift towards people-centricity. This evolution in ethical thinking is likely to prompt other international and national agencies to reconsider and align terminology with the 2024 DoH. Specifically, this may apply to the Indian Good Clinical Practice (GCP) guidelines [5] and the New Drugs and Clinical Trials Rules (NDCT), 2019 [6]. This terminology is consistent with several international guidelines including the 2016 International Ethical Guidelines for Health-Related Research Involving Humans by the Council for International Organizations of Medical Sciences (CIOMS) [7].

The scope of the DoH has now expanded beyond physicians to include all stakeholders involved in medical research, which covers both medical as well as non-medical researchers engaged in the conduct of biomedical and health research. Bierer reiterates this in her viewpoint on the 2024 DoH by stating that "it extends the responsibilities of physicians to other researchers" [8]. The 2017 ICMR guidelines specify that they, "must be followed by all stakeholders including institutions, ethics committees (ECs), researchers and sponsors/ funding agencies", as stated in the handbook published in 2018 [9]. This shows clear alignment with the scope of the 2024 DoH.

The 2024 revision of the Declaration incorporates contemporary ethical considerations, such as minimising research waste by avoiding poorly designed studies. Point 21 emphasises this by stating, "Medical research involving human participants must have a scientifically sound and rigorous design and execution that are likely to produce reliable, valid, and valuable knowledge and avoid research waste", thus upholding the ethical imperative to generate reliable research outcomes. The 2017 ICMR guidelines address this in Section 3 on "Responsible Conduct of Research" stating, "Implementation of poorly designed research wastes resources and should be avoided." Further, poorly designed studies with smaller-than-optimal sample size and low statistical power (as evidenced during the Covid-19 pandemic) do not clearly answer the research question, and on the other hand studies with larger-than-optimal sample sizes may put larger numbers of people at risk of exposure. Both scenarios are unacceptable, as they lead to research waste. Hence, determining optimal sample sizes by appropriate statistical methods is important to ensure adequate statistical power and meaningful study results.

"Meaningful" community engagement has been encouraged in the sixth general principle of the 2024 DoH. The use of the word "meaningful" is significant as this clarifies that research must be aligned with community needs. This is addressed in point 2.10.4 in the 2017 ICMR guidelines, which states, "Community engagement does not replace individual informed consent. It ensures that the community's health needs and expectations are addressed, informed consent is appropriate, and access to research benefits are provided through research that is designed and implemented in the best interests of science and the community." Such community engagement that truly makes a positive difference to the communities and public at large will help foster public trust. Further, the guidelines emphasise the need to effectively engage with and involve communities in the research design, implementation, and in the understanding and dissemination of results. This promotes the "co-design" approach and makes research truly participatory. It is time to initiate discussions around "people-centric participatory approaches" so that peoples' views are represented not only in biomedical and health research but also in ethics review. The emphasis on community engagement [10], particularly for research conducted among disadvantaged groups, is consistent in both the ICMR guidelines and the Declaration's call for meaningful interaction with participants and communities throughout the research process.

Point 23 of the Declaration empowers the autonomy of local ethics committees by stating that they must have the "independence and authority to resist undue influence from the researcher, sponsor, or others". Additionally, the ethics committee (EC) must have the "right to monitor, recommend changes to, withdraw approval for, and suspend ongoing research." EC approval has been mandated for any amendment to research protocols. The ICMR guidelines also include guidance on protected time for ECs, budget allocation for EC offices and necessary infrastructure and further provisions for common review of multicentre research. Point 4.0.2 of the 2017 ICMR guidelines, reinforces the need for institutional support for ethics committees by stating that, "the institution is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and protected time for the Member

Secretary to run the EC functions." In India, for ECs to be functional, they must be registered with the relevant regulatory authority, namely Department of Health Research (DHR) for ethics committees that review biomedical and health research, and additionally with the Central Drugs Standards and Control Organisation (CDSCO) for those reviewing clinical trials. All ECs in India must therefore be registered on the NAITIK [11] and/or SUGAM portals [12]. This DoH revision also seeks to empower ECs by emphasising the need for them to have adequate resources and training to effectively review research protocols. Both the 2024 DoH and the 2017 ICMR guidelines underscore the necessity for thorough ethics review processes, continuous monitoring, and adherence to established standards. The ICMR guidelines specify that ECs must evaluate scientific soundness and ethical considerations, ensuring that proposed research meets both criteria before approval. Along with the registration of clinical trials, the registration of ECs is also mandated in India. ECs reviewing clinical trials also have the provision to voluntarily seek accreditation from the National Accreditation Board of Hospitals (NABH) [13] to be duly recognised for their quality benchmarks. The 2017 ICMR guidelines also includes provisions for study monitoring, which aligns well with the 2024 DOH's requirements for monitoring of research.

The Declaration's new emphasis on environmental sustainability (11th general principle) and ethical data governance [14], continued as set forth in the World Medical Association Declaration of Taipei, represents a forward-thinking approach, ensuring that research practices adapt to rapidly evolving technological and environmental landscapes. This is reflected in the 2017 ICMR guidelines under the *"Principle of Environmental Protection",* which holds researchers accountable for ensuring the protection of the environment and resources at all stages of research.

The ICMR guidelines outline circumstances under which placebos may be used (Box 7.4), aligning with the criteria in Point 33 of the Declaration, which provides strict conditions for placebo use, specifically, when no proven intervention exists, or when withholding standard treatment would not cause serious harm. This ensures that participants are not deprived of effective therapies.

The ICMR guidelines align well with the DoH's requirement to describe post-trial provisions in the protocol (Point 22). They also emphasise the importance of post-trial access and benefit sharing, and how the provisions must be planned right at the inception of research, and worked out through *a priori* arrangements. As part of the general ethical principle of "Distributive Justice", the 2017 ICMR guidelines, in Point 2.4.4, state that, "plans for direct or indirect benefit sharing in all types of research with participants, donors of biological materials or data should be included in the study, especially if there is a potential for commercialization. This should be decided *a priori* in consultation with the stakeholders and reviewed by the EC." The DoH further requires ECs to review post-trial provisions, which must be planned prospectively, and any exceptions must be approved by the relevant EC.

The 2017 ICMR guidelines, in a dedicated Section 3.8 on collaborative research, encourage "free flow of knowledge and capacity at bilateral/multilateral levels." The DoH states that in case of international collaborative research, the EC approvals must be taken in both the sponsoring and the host country (Point 23). This is a much-needed update to bring the global community together and have a common understanding about the importance of local ethics review. While the Indian guidelines already include this requirement, implementation remains incomplete unless the foreign investigator agrees to comply with it. This change in the DoH is expected to improve compliance, as it will promote global acceptance of the much-needed clause to recognise local cultural values and respect local ethics committees.

Point 19 in the DoH emphasises the need to carefully weigh the harms of inclusion against the harms of exclusion, particularly for vulnerable persons or groups, clearly putting forth that their protection should not come at the cost of excluding them from research, which would further exacerbate existing health disparities. The ICMR guidelines partially align with this provision by acknowledging the right to inclusion of vulnerable groups, ensuring that the benefits of the research are fairly and equitably distributed. Specifically, the guidelines mention, "Vulnerable groups may be recruited after proper justification is provided". However, in the forthcoming revisions of the guidelines, there is an opportunity to mention the harms of exclusion for the vulnerable groups. The DoH goes a step further to address "situations of vulnerability", which can be fixed, contextual or dynamic (*dynamic vulnerability*), clearly indicating that the status of vulnerability may change with time or contexts. Researchers need to acknowledge this is in the protocol and plan monitoring/evaluation mechanisms accordingly. The ICMR guidelines indirectly touch upon this by stating, "Risks are non-measurable and dynamic in nature and therefore might be misconstrued as no/minimum risk research", in the context of social and behavioural science studies. Provisions in the ICMR guidelines for safeguarding marginalised groups include safeguards against situational vulnerability (stated as individuals whose "voluntariness or understanding is compromised due to their situational conditions").

The DoH uses the term "free and informed consent" throughout, prioritising participant autonomy in informed consent. As stated in point 26, it reinforces the need for informed consent documents to be in simple language, disclosing funding source(s), potential conflicts of interest and planned privacy measures. Further, the participants must be informed about the qualifications of researchers, provisions in the protocol to protect privacy and confidentiality, provisions for treatment, management and compensation; and in case of those incapable of providing consent, provisions to seek consent later upon regaining capacity, where applicable. Point 26 clarifies participants' choice to be informed or not informed about study results, by

stating that "all medical research participants should be given the option of being informed about the general outcome and results of the research". The DoH's focus on independent informed consent for participants in dependent relationships marks a key enhancement to ethical guidelines. Specifically, point 27 states, "When seeking informed consent for participation in research the physician or other researcher must be particularly cautious if the potential participant is in a dependent relationship with them or may consent under duress. In such situations, the informed consent must be sought by an appropriately qualified individual who is independent of this relationship." This clearly addresses potential coercion in dependent relationships, strengthening protections for vulnerable populations, thus promoting autonomous decision-making, and enhancing research integrity by mitigating biased participation. This has also been addressed in the ICMR guidelines in a dedicated section on vulnerability, point 6.2.6, which states, "As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period."

Additionally, point 26 of the DoH introduces guidance for seeking electronic consent which acknowledges the need for digital transformation in documenting informed consent. The 2017 ICMR guidelines had discussed the same and it was further reiterated in ICMR's Covid-19 guidelines, 2019 [15]. While section 5 of the ICMR guidelines focused on "Informed Consent Process" much in alignment with the Declaration's provisions on "free and informed consent", there is an opportunity to harmonise terminology and include clearer provisions on sharing study outcomes with participants.

Currently, India requires only clinical trials to be registered on a publicly accessible database, as stated in point 7.1.10 of the ICMR guidelines. However, point 35 of the DoH mandates that information of all medical research must be freely accessible to the public, "Medical research involving human participants must be registered in a publicly accessible database before recruitment of the first participant." This mandate has elevated the requirements for upholding transparency and accountability by necessitating registration of all medical research before the recruitment of the first study participant. The ICMR guidelines recommend this, but do not mandate the requirement for medical research though it is mandatory to register clinical trials prospectively as per NDCT Rules, 2019. Adopting this requirement would increase the accountability of all types of medical research and ensure that results — including negative or inconclusive outcomes — are made available for public scrutiny. If this is to be implemented, platforms such as the Clinical Trial Registry of India (CTRI) [16] would need major revamping exercises. To enable registration of all biomedical and health research, the ICMR suggested this in their 2017 ethical guidelines and reiterated it in their 2019 ethical guidelines for Covid-19. But this remains theoretical due to various implementation challenges.

Point 7 of the DoH places a greater emphasis on research benefitting both individuals and public health. Point 16 requires researchers not to engage in proposed research, unless they are confident that the foreseeable benefits outweigh the foreseeable risks, and also document any harm or discomfort arising from research, as stated, "Medical research involving human participants may only be conducted if the importance of the objective outweighs the risks and burdens to the research participants." It reaffirms the need for high standards, research integrity and fair distribution of risks and benefits. The 2017 ICMR guidelines go a step further by including a dedicated sub-section on benefit-risk assessment (Section 2.1). They also emphasise the importance of conducting meaningful research with a social value as reiterated in Table 4.3, in section 4 focused on ethical review procedures which states, "The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value". The Guidelines mandate that in public health research proposals "societal benefits outweigh individual harm", and state in point 2.1.1 that "the researcher, sponsor and EC should attempt to maximize benefits and minimize risks to participants so that risks are balanced to lead to potential benefits at individual, societal and/or community levels", aligning with point 18 of the DoH.

As a commitment to evolving ethical requirements related to the use of biological material and identifiable data, point 32 of the DoH discusses the process of consent for the foreseeable secondary use of biological samples where participants can consent to multiple and indefinite uses. However, an ethics committee must approve and monitor the use of biobanks/ databases. Section 11 of the ICMR guidelines discusses biobanking and the use of datasets. Aligning with the DoH's October 2013 revision, the ICMR guidelines state that "for secondary or extended uses of stored samples/dataset, one of the preliminary considerations for ECs must be to identify the circumstances under which the research requires re-use of collected identifiable biological material to generate the data or utilize the pre-existing identifiable dataset. This must also include review of the informed consent obtained originally to see if re-consent is warranted. There may be situations where consent would be impossible or impracticable to obtain for such research, in which case the research may be done only after independent evaluation by an EC." ICMR has gone a step further in the "MoHFW-ICMR Joint Guidelines for Ethical Use of Leftover De-identified/ Anonymous Samples for Commercial Purpose" which addresses the ethical use of leftover, irreversibly de-identified or pooled samples, that are non-identifiable and initially collected for clinical care (non-research purposes) to develop commercial products or technologies [17].

The 6th and 15th general principles of the DoH state that medical research must ensure respect for all participants and protect their health and rights, and ensure appropriate compensation and treatment for participants harmed as a result of their participation in research. In India, there are already clear timelines for reporting serious adverse events (SAEs) in clinical research and stringent regulatory requirements when it comes to compensation for research-related harm [18]. There is a definitive compensation formula to determine the quantum of compensation, which is commensurate with the level of research-related harm/discomfort. Furthermore, establishing clear budgets and insurance at the outset is encouraged. The ICMR guidelines require research protocols to detail the proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after the research period. Additionally, point 4.11.5 of the ICMR guidelines prioritise participant safety and dignity by requiring that "compensation must be given for research-related injuries if applicable, as determined by the EC and as per applicable regulatory requirements".

Section 12 of the ICMR Guidelines, titled "Research during Humanitarian Emergencies and Disasters" specifically focuses on public health emergencies, aligning with the DoH's eighth general principle that recognises the need to uphold ethical standards even in urgent situations requiring new knowledge and interventions. This ensures that ethical safeguards are not compromised during emergencies, and participant rights are upheld regardless of the research context.

Conclusion

The 2017 ICMR guidelines align substantially with the 2024 DoH, particularly in harmonised terminology and scope, and their commitment to empowering ethics committees, promoting meaningful community engagement and international collaborations, ethical use of biological samples, compensation for research-related injury, post-trial access and environmental sustainability. This synergy strengthens research practices while encouraging a participant-centred approach and promoting meaningful biomedical and health research. Moving forward, researchers, ethics committees, institutions, sponsors, regulatory bodies and policymakers should embrace the updated ethical framework presented by the 2024 DoH and actively engage in ongoing ethical dialogue. Collective efforts could accelerate the creation of a global research environment that prioritises ethical integrity, inclusivity, and the well-being of all participants, ultimately leading to meaningful advancements in biomedical research that benefit society as a whole.

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COMMENTARY

The use of "tortured phrases" in science communication

JANMEJAYA SAMAL

Abstract

A recent publication in an Indian journal stated that "Charak is known as the dad of Ayurveda (or) the dad of Ayurvedic medication." Such inappropriate terms used in science communication are called "tortured phrases". The use of such phrases could suggest deeper issues in science communication, such as concealment of plagiarism and fraudulent research facilitated by paper mills. Non-expert writers and AI tools are being used in the mass production of research articles in paper mills that report fabricated data, graphs and tables mimicking legitimate research papers. Although efforts are being made to detect tortured phrases, poor editorial review allows the publication of articles with tortured phrases in reputed journals. This compromises scientific integrity and leads to wastage of resources. Proper screening, rejection of inappropriate language and transparency in the editorial process can help to curb this unethical practice.

Keywords: *duplicate publication, ghost author, paper mill, plagiarism, tortured phrases*

The term "tortured phrases" refers to inappropriate phrases used instead of established scientific ones, as in the case of Charaka being called the "dad of Ayurveda" instead of the "father of Ayurveda" [1]. These could be language errors arising from unfamiliarity with the English language, and can be corrected if warranted by the value of the content. However, one frequently comes across the repeated use of such awkward non-standard terms in academic papers. While this is most commonly seen among early career researchers, who may not be well-versed in specialised scientific terminology [2], research articles containing multiple "tortured phrases" may indicate the use of templates from reputed journals being scrambled to escape plagiarism detection. These may not be detected due to flaws in oversight in the affected journals [3]. An online platform, Problematic Paper Screener (https://www.irit.fr/~Guillaume.Cabanac/problematic-paper-screener), leverages human assessment and automatic machine detection to flag problematic published articles using such strange terms [4], which could be products of "paper mills".

"Paper mills" involve the mass production of research papers [5], by using software to produce papers, or employing writers who are not experts in the given field of research. Many such paper mills are able to counterfeit layout and design and produce exact micrographs, photographs, graphs, and numerical datasets to write fake research papers [6]. Generative artificial intelligence (AI) makes it difficult to detect such frauds. Many reputed publishing houses such as Springer, Taylor & Francis, Wiley, and the Public Library of Science have fallen prey to paper mills [7]. Despite the difficulties, experienced researchers can detect plagiarism using specific methods and scrutinising the duplication of graphics, out-of-context and meaningless texts, questionable peer review processes and similarities in grammatical structure [8-10].

The repercussions

The idea that a fraudulent paper, using reverse translation software, can be published without being noticed by the editor, reviewer, or publisher raises serious doubts about the quality of editorial review, and about the ownership and management of the research publication business. More importantly, the publication of fraudulent research affects the scientific integrity of research [11]. A genuine researcher may be taken in by such fraudulent research and cite it, muddying the waters further.

Such bogus papers, even after retraction, can still be found through searches on Google. These practices pose a real threat to the academic community and are detrimental to healthcare research. This is a breach of the trust of editors and reviewers of journals besides leading to a complete waste of limited resources [12].

What can be done

To improve the quality of health research and communication, stricter ethical and screening guidelines are required. These guidelines should include an extra screening mechanism for "tortured phrases" and the rejection of articles that use imprecise language [13]. According to