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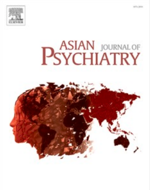

New standards, new vision: Directing modern medical research as per the 2024 revised Declaration of Helsinki

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ABSTRACT

The revised Declaration of Helsinki marks a more informed, inclusive and recognized pathway to clinical research in the contemporary medical field. As clinicians, educators, researchers, administrators or a member of the healthcare community, it becomes our most important responsibility to become more aware and start the adaption of this revised codes. Adhering to these standards is essential not only for fostering public trust but also for upholding the integrity and credibility of medical research. This adherence underscores a commitment to protecting participant welfare and advancing health outcomes that are both ethical and scientifically robust. This opinion paper explores the "what" and "why" of these new standards, urging healthcare professionals, to critically engage with and adopt these revised ethical guidelines. By doing so, the healthcare community can enhance patient safety, promote equity in research participation, and ensure a more ethically sound foundation for scientific advancement. Additionally, one of the four foundational underpinnings of permissible biomedical research enshrined in the Nuremberg code - that of the necessity of potential societal value unprocurable by other means - needs to be re-emphasized in view of the rampant challenges of wasteful medical research. Awareness of research ethics among all involved in healthcare policy and practice is essential.

1. Introduction

In the wake of the World Medical Association's recent release of the 2024 revision of the Declaration of Helsinki, the research community finds itself facing not only an update in ethical guidelines but a bold call to action (World Medical Association, 2024). This revised declaration demands that medical research uphold principles that are far from mere formalities—emphasizing participant dignity, a commitment to equitable practices, and unwavering scientific integrity. This 2024 update carries global significance. With an emphasis on inclusivity, transparency, and the contextualization of consent, the declaration speaks directly to the challenges of conducting research in diverse settings, where cultural and societal dynamics are both complex and rapidly evolving. It's a standard that goes beyond borders, encouraging all researchers to adopt a human-centered approach that respects the individuality and rights of participants. The Declaration's revision serves as more than a regulatory milestone; it's a timely reminder of the responsibility researchers carry in fostering trust and integrity within their work. It challenges us to reflect deeply on our ethical practices, to ensure that scientific progress and the well-being of participants remain intrinsically linked in every study conducted around the world.

2. Expanding horizons

At its core, the 2024 revision of the Declaration of Helsinki dramatically broadens ethical responsibilities in medical research. Moving beyond a physician-centric focus, the Declaration now establishes an inclusive framework that extends to all involved parties: researchers, teams, organizations, and institutions (Bibbins-Domingo et al., 2024). This shift highlights that the ethical obligations of research transcend specific professions, calling on every stakeholder to actively uphold the rights, dignity, and welfare of participants. Researchers are

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no longer viewed as the sole bearers of ethical responsibility; instead, every individual and entity engaged in the research process is charged with a shared duty to maintain transparency, fairness, and respect in their interactions with participants.

By embracing this broader, collective approach, the Declaration aims to embed ethical integrity within the entire structure of research practice. Institutions, for instance, are encouraged to foster environments where ethical standards guide all levels of operation, from research planning to post-study evaluation. This revised Declaration emphasizes that organizations must go beyond merely supporting researchers, implementing active oversight mechanisms that integrate ethical values throughout their systems. In this way, the 2024 Declaration not only reaffirms the commitment to participant welfare but also reshapes the very fabric of medical research, ensuring that ethical responsibility is woven into every layer of the research ecosystem.

3. From subjects to partners

The decision to replace the term "subjects" with "participants" in the 2024 revision of the Declaration of Helsinki marks a pivotal shift in how we approach the ethics of medical research. This change reflects a deeper respect for individual agency, moving away from viewing people as mere data points toward recognizing them as active contributors to the research process (Bloom, 2024). By framing research as a partnership, this language honors each person's role, reinforcing the idea that participants are informed collaborators whose autonomy and dignity are integral to scientific progress. This shift not only elevates the status of individuals within research but also calls on researchers to be mindful of their responsibility toward those who make their studies possible.

This shift in terminology aligns with broader ethical commitments to transparency, inclusivity, and mutual respect. Recognizing participants as valued contributors emphasizes the importance of trust and accountability in research, underscoring that each interaction with participants must be rooted in ethical practices that respect their autonomy and humanity. This change encapsulates a modern vision for research that is ethically aligned with values of inclusivity and participant empowerment, strengthening the foundation of ethical accountability in research.

4. Commitment to autonomy and community engagement

Next, the change to "free and informed consent" (previously, "informed consent") in the Declaration redefines the ethical core of research participation. Here, "free" captures the right of individuals to make choices unfettered by influence or coercion, emphasizing that true consent involves both understanding and voluntary choice. This adjustment reflects a deep respect for individual autonomy, ensuring that participants retain control over their involvement from beginning to end. Also significant is the call for community consultation, which brings a refreshing layer of inclusivity to the research framework. By encouraging local populations to actively shape and engage with the ethical aspects of studies, the Declaration respects cultural and societal differences, making research both more relevant and trustworthy. This approach builds a genuine partnership between researchers and the communities involved, creating an environment where research is not just conducted on individuals but rather with them, honoring their values, insights, and rights.

The 2024 Declaration of Helsinki further introduces a strengthened framework for informed consent, particularly for biobanking and data use, highlighting a commitment to participant autonomy in the age of data-driven research. By requiring explicit consent for the collection, storage, and secondary use of biological materials, the Declaration acknowledges the sensitive nature of digital and genetic data. This emphasis on transparency ensures that participants maintain control over how their data may be used in the future, cultivating a foundation of trust between researchers and communities. It represents a thoughtful adaptation to the evolving landscape of medical research, where the handling of data must be as ethically robust as the research itself.

5. Dynamics of vulnerability & inclusivity

The updated Declaration of Helsinki also brings a nuanced view of vulnerability, recognizing it as a flexible and situational condition rather than a fixed status. This shift is crucial, as it moves beyond seeing certain populations as permanently vulnerable and instead considers the varied, dynamic contexts that may increase vulnerability in specific situations. By doing so, the Declaration advocates for a balanced approach, one that prioritizes both the protection of vulnerable individuals and their fair inclusion in research.

The emphasis on inclusivity and global justice reflects an ethical commitment to extend research opportunities to groups that have often been overlooked or excluded. This balanced framework aims to correct historic inequities by offering fair access while applying adequate safeguards. In recognizing the diversity of vulnerabilities, the Declaration reinforces that ethical research requires sensitivity to both the specific risks and potential benefits to each individual and group involved. This thoughtful inclusivity represents a commitment to reducing health disparities and fostering a research environment where historically marginalized groups are respected, valued, and empowered.

6. Ethical evolution: flexibility, continuity, and privacy

Building on this foundation, the Declaration addresses the issue of comparator standards with greater flexibility, particularly in low-resource settings. While advocating for "best proven" comparators, it recognizes that these may not always be available in all regions, allowing for adaptable standards that still uphold participant safety and ethical integrity. This change speaks to the Declaration's awareness of global health disparities, emphasizing the importance of local decision-making in contexts where resources are limited. It is an important acknowledgment that ethical research must be both rigorous and responsive to the needs of diverse communities (Kurihara et al., 2024).

Furthermore, the revised Declaration extends its ethical considerations to post-trial access to treatments, underscoring the importance of continuity of care beyond the duration of a study. This is particularly critical in underserved regions, where long-term access to beneficial treatments can be challenging. By encouraging sustained benefits for participants, this provision reinforces the idea that ethical responsibility does not end when the study concludes. It calls upon researchers and sponsors to consider the broader impact of their work, ensuring that participants' contributions are honored in a meaningful and lasting way.

The Declaration introduces requirements for ethical oversight in research involving stored data and biospecimens, addressing the risks of re-identification and the ethical need for re-consent. This approach respects participants' privacy and autonomy, balancing the potential for public health advancements with individual rights. It reflects the Declaration's sensitivity to the ethical challenges inherent in secondary data use, promoting a research environment where participants' original consent is respected even as new research opportunities arise.

7. Towards sustainable science

The 2024 revision of the Declaration of Helsinki introduces a critical focus on environmental sustainability within medical research, recognizing the need to align scientific practices with global sustainability goals. By advocating for reduced research waste and careful consideration of environmental impacts throughout the research process, the Declaration emphasizes that responsible science extends beyond ethical treatment of participants to include stewardship of the planet. This call for sustainability encourages researchers to think broadly about their work, ensuring that scientific advancement does not come at an undue environmental cost (Reis et al., 2024).

Incorporating sustainability into its ethical guidelines, the Declaration champions a holistic view of research integrity. It underscores that the long-term welfare of both research participants and the environment are integral to ethical science. This forward-looking approach reflects a broader commitment to public health, urging researchers to reflect on the lasting impacts of their work. By embedding environmental responsibility into its core values, the Declaration not only supports immediate scientific progress but also promotes a legacy of sustainable, ethical research practices for future generations.

8. What is still missing

The origins of our modern principles of permissible biomedical research can be traced back to the Nuremberg code formulated in 1949 as part of the Nuremberg Military Tribunal's decision in the case of the United States vs Karl Brandt et al. (Schuster, 1997). This ten-point statement delimiting permissible biomedical research can be summarized as "human experimentation is justified only if its results can benefit society and is carried out in accord with basic principles that satisfy fundamental moral, ethical, and legal concepts". Over its evolution over the past 75 years in the form of the Belmont report (Adashi et al., 2018) and multiple iterations of the Helsinki declaration (most recently in 2024, World Medical Association., 2024), several elements have been amplified and better defined. One fundamental principle, however, receives no attention in these enunciations- that of the necessity of clear potential societal benefit for any biomedical research to be justified. The second clause of the Nuremberg code states "the experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature". The absence of this core value from current articulations of standards of permissible biomedical research is particularly concerning in view of the increasing and rampant waste in current medical research, with estimates of 85–90 percent of all such research being a wasted effort (Altman, 1994; Chalmers et al., 2014; Rosengaard et al., 2024), with challenges reflected in psychiatry (Tandon, 2023a). Several factors contribute to such wasteful, and therefore unethical, research: poorly articulated and/or relevant research questions, design flaws, non-publication or inadequate reporting of results, failure to consider or discuss previous relevant research, falsification and fabrication in reported research, etc. National and institutional mechanisms to monitor and enforce proper research practice pay little or no attention to this principle, assuming that bodies that fund research are responsible for this piece. As a result, this necessary principle receives little consideration. Not only does increasing waste in biomedical research have pernicious scientific and public health implications, it is unethical. This problem of wasteful medical research has additionally been fueled by the proliferation of predatory journals and challenges and the changing environment of medical publishing (Tandon, 2023b). The need for good and necessary science in the interest of societal benefit is an absolutely essential ingredient of any justifiable human experimentation and needs to be formally reincorporated in medical research ethics codes (Lancet, The REWARD statement, 2024).

9. Looking to the future

Looking ahead, the 2024 Declaration of Helsinki inspires a new era of ethical research, urging us to move beyond mere compliance toward a deeper commitment to participant respect, inclusivity, and global responsibility. It challenges researchers to embrace scientific progress that values transparency, fairness, and shared benefit—ensuring that each study reflects both ethical integrity and a profound respect for human dignity. With these principles, the Declaration lays a path forward where innovation is grounded in trust and accountability, fostering research that benefits all communities in a meaningful and sustainable way. Additionally, reincorporation of the need for clear potential societal benefit as a foundational ethical principle for permissible biomedical research is required.

CRediT authorship contribution statement

Russell Franco D'Souza: Methodology, Writing – original draft, Writing – review & editing. **Krishna Mohan Surapaneni:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Declaration of Competing Interest

All the authors declare that, there is No Conflict of Interest associated with this study.

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