Update of the Declaration of Helsinki
2024

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The World Medical Association (WMA) has developed the Declaration of Helsinki (DoH) as a statement of ethical principles for medical research with human participants, including research that uses human material or identifiable data. The DoH was adopted in 1964 and has been amended seven times, most recently at the October 2024 General Assembly in Helsinki, Finland. The current version (2024) is the only official one, all previous versions have been superseded and should not be used or quoted, except for historical purposes.

Changes from the previous version:

- Replacement of the term "subject" with that of "participant", with the aim of highlighting the need for respect and recognition of the autonomy of the research participants and avoiding sex and gender bias in language.
- In recognition of the interdisciplinary nature of medical research, the text was also amended so that in addition to physicians, all individuals, teams, and organizations involved in medical research, both in patients and healthy volunteers, are also considered.
- Point 6 addresses distributive and global justice, and calls on researchers to carefully consider how the benefits, risks, and burdens of research are distributed. It is mentioned that researchers should allow potential participants, recruited participants, and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in the understanding and dissemination of the results.
- Point 7 adds that the main purpose of medical research with human participants is to generate knowledge, but that these objectives should never take precedence over the rights and interests of the person participating in the research.
- The new point 8 highlights that while public health emergencies may require urgency and innovation, ethical principles must be fully respected in such circumstances.
- Point 12 emphasizes that scientific integrity is essential in conducting medical research with human participants. The individuals, teams and organisations involved should never commit misconduct in the investigation.
- The new text of paragraphs 19 and 20 recognises that vulnerability can be contextual and dynamic and can be experienced at different levels. It stresses the increased risk that those who experience vulnerability will be harmed or harmed and special protections are required. Fair and responsible inclusion is sought after weighing the harms of both inclusion and exclusion and providing appropriate support and protection.
- Points 20 and 28 maintain specific protections aimed at participants in special situations of vulnerability, and those who lack the capacity to give free and informed consent.
- The content of the research protocol is detailed in point 22. The protocol should refer to the ethical considerations involved and should indicate how the principles set forth in this Declaration have been considered. The protocol should include information on the objectives, methods, expected benefits and potential risks and burdens, qualifications of the investigator, sources of funding, any potential conflicts of interest, provisions to protect privacy and confidentiality, incentives for participants, provisions to treat and/or compensate participants who suffer harm as a result of participation, and any other relevant aspect of the investigation. In clinical trials, the protocol should also describe any stipulations after the trial is conducted.

- Point 23 highlights that research ethics committees must have independence and authority to resist undue influence from the researcher, sponsor or others. In addition, it notes that the committee has the right to monitor, recommend changes, withdraw approval, and suspend ongoing research. When monitoring is required, the investigator has the obligation to provide information to the committee and/or the competent entity for data and safety monitoring, especially about any serious adverse events.
- Item 32 addresses the consent requirements for the inclusion of samples and data of participants in biobanks and databases. Protection is sought against foreseeable or unforeseeable secondary uses, and against commercial or political misuses.
- Paragraph 34 emphasizes the need to establish stipulations to provide all participants who need an intervention that has been identified as beneficial or reasonably safe in the trial, either by themselves or through the health care system or governments.
- Item 37, on unproven interventions, recognizes situations in which unproven interventions are used in an attempt to alleviate suffering, but these interventions should never be carried out to circumvent the protections of research participants set out in this Statement.
- Other changes highlight the need to consider environmental sustainability and avoid wasting research.

Important note for all staff involved in clinical research:
All biomedical research must be conducted in accordance with the Declaration of Helsinki, so it is essential to know the updated version in its entirety.
You can find the full version at the following link:
https://www.wma.net/es/policies-post/declaracion-de-helsinki-de-la-amm-principios-eticos-para-las-investigaciones-medicas-en-seres-humanos/