WMA INTERNATIONAL CODE OF MEDICAL ETHICS

Adopted by the 3rd General Assembly of the World Medical Association, London, England, October 1949
Revised by the 22nd World Medical Assembly, Sydney, Australia, August 1968,
the 35th World Medical Assembly, Venice, Italy, October 1983,
the 57th WMA General Assembly, Pilanesberg, South Africa, October 2006
and by the 73rd WMA General Assembly, Berlin, Germany, October 2022

PREAMBLE

The World Medical Association (WMA) has developed the International Code of Medical Ethics as a canon of ethical principles for the members of the medical profession worldwide. In concordance with the WMA Declaration of Geneva: The Physician's Pledge and the WMA's entire body of policies, it defines and elucidates the professional duties of physicians towards their patients, other physicians and health professionals, themselves, and society as a whole.

The physician must be aware of applicable national ethical, legal, and regulatory norms and standards, as well as relevant international norms and standards.

Such norms and standards must not reduce the physician's commitment to the ethical principles set forth in this Code.

The International Code of Medical Ethics should be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs. Consistent with the mandate of the WMA, the Code is addressed to physicians. The WMA encourages others who are involved in healthcare to adopt these ethical principles.

GENERAL PRINCIPLES

1. The primary duty of the physician is to promote the health and well-being of individual patients by providing competent, timely, and compassionate care in accordance with good medical practice and professionalism.

The physician also has a responsibility to contribute to the health and well-being of the populations the physician serves and society as a whole, including future generations.

The physician must provide care with the utmost respect for human life and dignity, and for the autonomy and rights of the patient.

2. The physician must practise medicine fairly and justly and provide care based on the patient's health needs without bias or engaging in discriminatory conduct on the basis of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, culture, sexual orientation, social standing, or any other factor.

3. The physician must strive to use health care resources in a way that optimally benefits the patient, in keeping with fair, just, and prudent stewardship of the shared resources with which the physician is entrusted.

4. The physician must practise with conscience, honesty, integrity, and accountability, while always exercising independent professional judgement and maintaining the highest standards of professional conduct.

5. Physicians must not allow their individual professional judgement to be influenced by the possibility of benefit to themselves or their institution. The physician must recognise and avoid real or potential conflicts of interest. Where such conflicts are unavoidable, they must be declared in advance and properly managed.

6. Physicians must take responsibility for their individual medical decisions and must not alter their sound professional medical judgements on the basis of instructions contrary to medical considerations.

7. When medically appropriate, the physician must collaborate with other physicians and health professionals who are involved in the care of the patient or who are qualified to assess or recommend care options. This communication must respect patient confidentiality and be confined to necessary information.

8. When providing professional certification, the physician must only certify what the physician has personally verified.

9. The physician should provide help in medical emergencies, while considering the physician's own safety and competence, and the availability of other viable options for care.

10. The physician must never participate in or facilitate acts of torture, or other cruel, inhuman, or degrading practices and punishments.

11. The physician must engage in continuous learning throughout professional life in order to maintain and develop professional knowledge and skills.

12. The physician should strive to practise medicine in ways that are environmentally sustainable with a view to minimising environmental health risks to current and future generations.

Duties to the patient

13. In providing medical care, the physician must respect the dignity, autonomy, and rights of the patient. The physician must respect the patient's right to freely accept or refuse care in keeping with the patient's values and preferences.

14. The physician must commit to the primacy of patient health and well-being and must offer care in the patient's best interests. In doing so, the physician must strive to prevent or minimise harm for the patient and seek a positive balance between the intended benefit to the patient and any potential harm.

15. The physician must respect the patient's right to be informed in every phase of the care process. The physician must obtain the patient's voluntary informed consent prior to any medical care provided, ensuring that the patient receives and understands the information needed to make an independent, informed decision about the proposed care. The physician must respect the patient's decision to withhold or withdraw consent at any time and for any reason.

16. When a patient has substantially limited, underdeveloped, impaired, or fluctuating decision-making capacity, the physician must involve the patient as much as possible in medical decisions. In addition, the physician must work with the patient's trusted representative, if available, to make decisions in keeping with the patient's preferences, when those are known or can reasonably be inferred. When the patient's preferences cannot be determined, the physician must make decisions in the patient's best interests. All decisions must be made in keeping with the principles set forth in this Code.

17. In emergencies, where the patient is not able to participate in decision making and no representative is readily available, the physician may initiate an intervention without prior informed consent in the best interests of the patient and with respect for the patient's preferences, where known.

18. If the patient regains decision-making capacity, the physician must obtain informed consent for further intervention.

19. The physician should be considerate of and communicate with others, where available, who are close to the patient, in keeping with the patient's preferences and best interests and with due regard for patient confidentiality.

20. If any aspect of caring for the patient is beyond the capacity of a physician, the physician must consult with or refer the patient to another appropriately qualified physician or health professional who has the necessary capacity.

21. The physician must ensure accurate and timely medical documentation.

22. The physician must respect the patient's privacy and confidentiality, even after the patient has died. A physician may disclose confidential information if the patient provides voluntary informed consent or, in

exceptional cases, when disclosure is necessary to safeguard a significant and overriding ethical obligation to which all other possible solutions have been exhausted, even when the patient does not or cannot consent to it. This disclosure must be limited to the minimal necessary information, recipients, and duration.

23. If a physician is acting on behalf of or reporting to any third parties with respect to the care of a patient, the physician must inform the patient accordingly at the outset and, where appropriate, during the course of any interactions. The physician must disclose to the patient the nature and extent of those commitments and must obtain consent for the interaction.

24. The physician must refrain from intrusive or otherwise inappropriate advertising and marketing and ensure that all information used by the physician in advertising and marketing is factual and not misleading.

25. The physician must not allow commercial, financial, or other conflicting interests to affect the physician's professional judgement.

26. When providing medical care remotely, the physician must ensure that this form of communication is medically justifiable and that the necessary medical care is provided. The physician must also inform the patient about the benefits and limitations of receiving medical care remotely, obtain the patient's consent, and ensure that patient confidentiality is upheld. Wherever medically appropriate, the physician must aim to provide care to the patient through direct, personal contact.

27. The physician must maintain appropriate professional boundaries. The physician must never engage in abusive, exploitative, or other inappropriate relationships or behaviour with a patient and must not engage in a sexual relationship with a current patient.

28. In order to provide care of the highest standards, physicians must attend to their own health, well-being, and abilities. This includes seeking appropriate care to ensure that they are able to practise safely.

29. This Code represents the physician's ethical duties. However, on some issues there are profound moral dilemmas concerning which physicians and patients may hold deeply considered but conflicting conscientious beliefs.

The physician has an ethical obligation to minimise disruption to patient care. Physician conscientious objection to provision of any lawful medical interventions may only be exercised if the individual patient is not harmed or discriminated against and if the patient's health is not endangered.

The physician must immediately and respectfully inform the patient of this objection and of the patient's right to consult another qualified physician and provide sufficient information to enable the patient to initiate such a consultation in a timely manner.

Duties to other physicians, health professionals, students, and other personnel

30. The physician must engage with other physicians, health professionals and other personnel in a respectful and collaborative manner without bias, harassment, or discriminatory conduct. The physician must also ensure that ethical principles are upheld when working in teams.

31. The physician should respect colleagues' patient-physician relationships and not intervene unless requested by either party or needed to protect the patient from harm. This should not prevent the physician from recommending alternative courses of action considered to be in the patient's best interests.

32. The physician should report to the appropriate authorities conditions or circumstances which impede the physician or other health professionals from providing care of the highest standards or from upholding the principles of this Code. This includes any form of abuse or violence against physicians and other health personnel, inappropriate working conditions, or other circumstances that produce excessive and sustained levels of stress.

33. The physician must accord due respect to teachers and students.

Duties to society

34. The physician must support fair and equitable provision of health care. This includes addressing inequities in health and care, the determinants of those inequities, as well as violations of the rights of both patients and health professionals.

35. Physicians play an important role in matters relating to health, health education, and health literacy. In fulfilling this responsibility, physicians must be prudent in discussing new discoveries, technologies, or treatments in non-professional, public settings, including social media, and should ensure that their own statements are scientifically accurate and understandable.

Physicians must indicate if their own opinions are contrary to evidence-based scientific information.

36. The physician must support sound medical scientific research in keeping with the WMA Declaration of Helsinki and the WMA Declaration of Taipei.

37. The physician should avoid acting in such a way as to weaken public trust in the medical profession. To maintain that trust, individual physicians must hold themselves and fellow physicians to the highest standards of professional conduct and be prepared to report behaviour that conflicts with the principles of this Code to the appropriate authorities.

38. The physician should share medical knowledge and expertise for the benefit of patients and the advancement of health care, as well as public and global health.

Duties as a member of the medical profession

39. The physician should follow, protect, and promote the ethical principles of this Code. The physician should help prevent national or international ethical, legal, organisational, or regulatory requirements that undermine any of the duties set forth in this Code.

40. The physician should support fellow physicians in upholding the responsibilities set out in this Code and take measures to protect them from undue influence, abuse, exploitation, violence, or oppression.

Croatian translation

Portuguese translation

WMA DECLARATION OF GENEVA

Adopted by the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948
and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968
and the 35th World Medical Assembly, Venice, Italy, October 1983
and the 46th WMA General Assembly, Stockholm, Sweden, September 1994
and editorially revised by the 170th WMA Council Session, Divonne-les-Bains, France, May 2005
and the 173rd WMA Council Session, Divonne-les-Bains, France, May 2006
and amended by the 68th WMA General Assembly, Chicago, United States, October 2017

The Physician's Pledge

AS A MEMBER OF THE MEDICAL PROFESSION:

I SOLEMNLY PLEDGE to dedicate my life to the service of humanity;

THE HEALTH AND WELL-BEING OF MY PATIENT will be my first consideration;

I WILL RESPECT the autonomy and dignity of my patient;

I WILL MAINTAIN the utmost respect for human life;

I WILL NOT PERMIT considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient;

I WILL RESPECT the secrets that are confided in me, even after the patient has died;

I WILL PRACTISE my profession with conscience and dignity and in accordance with good medical practice;

I WILL FOSTER the honour and noble traditions of the medical profession;

I WILL GIVE to my teachers, colleagues, and students the respect and gratitude that is their due;

I WILL SHARE my medical knowledge for the benefit of the patient and the advancement of healthcare;

I WILL ATTEND TO my own health, well-being, and abilities in order to provide care of the highest standard;

I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat;

I MAKE THESE PROMISES solemnly, freely, and upon my honour.

VIEWPOINT

AI IN MEDICINE

The Revised Declaration of Helsinki—Considerations for the Future of Artificial Intelligence in Health and Medical Research

James A. Shaw, PT, PhD

Editor's Note page 30

Multimedia

Related article page 71

The Declaration of Helsinki (DoH) is a statement of principles intended to guide the ethical conduct of health and medical research on a global scale, developed and endorsed by the World Medical Association first in 1964. Inspired by the demand that medical research with human participants be conducted to the highest ethical standards in the wake of Nazi war crimes, the DoH looks beyond the prevention of egregious harms to the promotion of ethical science more generally.[1] The DoH has been amended to reflect the dynamic nature of both ethics and science on 9 occasions since 1964 (including notes of clarification), with a 10th amendment published in 2024.[2] In the 11 years between the prior amendment in 2013 and the most recent 2024 amendment, medical science has also evolved in important ways. In this Viewpoint, I highlight some important updates to the DoH and comment on its relevance in the context of the growing influence of artificial intelligence (AI) in health and medical science.

The renewed declaration has made important changes, but the contexts of health and medical science are also changing rapidly. Despite the hype and lack of clarity that often accompany the discussions of AI as a class of technologies, AI applications have also shown promise for a range of health care tasks.[3] Furthermore, AI technologies hold potential to enhance the conduct of research in a variety of ways, ranging from accelerating drug discovery to enhancing the efficiency of clinical trials.[4] These documented advances, along with massive financial investments, have led to a widespread interest in using AI techniques across health and medical science. Three issues should inform the implementation of and future revisions to the DoH, and other forms of research ethics guidance, on AI in health and medical science.

Getting Ethical Data Governance Right

First, the implementation of the DoH must confront the realities of jurisdictional data governance regimes. The DoH states in paragraph 10 that researchers must "consider the ethical, legal and regulatory norms and standards for research" where the research originated or is performed. However, when it comes to the governance of existing health-related datasets, norms diverge in substantial ways across jurisdictions internationally. Which entities should have access to health-related data—and under which circumstances—continues to be an issue inflected by social, cultural, and policy realities. For example, the European Union implemented the General Data Protection Regulation in 2016, but the US still lacks federal legislation on data protection, and regulation is becoming splintered across individual states.[5] There are a number of divergent positions on the matter of protecting privacy vs sharing data in the name of solidarity,[6] each needing to navigate complex social and legal expectations in specific jurisdictions. Although the global dialogue in which the DoH is embedded is hugely important on these matters, and the Declaration of Taipei that specifically addresses the issue of ethics and big data is an essential contribution, these statements have yet to catalyze a shared vision on the governance of health-related data that supports public goods.

Low AI Literacy

Second, the implementation of the DoH must acknowledge variability in AI literacy both within and between jurisdictions. A survey published in 2024 on knowledge and perceptions of AI in 21 countries found discrepancies between respondents' relatively high confidence in their knowledge of AI and their relatively low knowledge of specific outputs of AI, such as deepfakes.[7] Furthermore, it is widely acknowledged that limited expertise in AI is a challenge for institutional review boards and research ethics committees around the world, interfering with their abilities to make informed decisions about research involving AI.[8] The implementation of the DoH, and the Declaration of Taipei on which it relies for guidance on research with large datasets, will depend in profound ways on whether and how the public and professionals adequately understand AI and its uses in health care.

Lack of Clarity on Present and Future AI Harms

Third, the implementation of the DoH will need to acknowledge the lack of clarity around present and future harms of health-related AI. Setting aside dialogue regarding hypothetical doomsday scenarios and existential threats, the actual present-day harms that may accrue, especially to communities already structurally marginalized as a consequence of these technologies, remain poorly understood. Beyond some well-known examples in health care,[9] researchers are beginning to identify "hidden" harms of AI development and deployment that should also be considered in discussions regarding the ethics of health and medical research involving AI.[10] For example, the DoH does not explicitly encourage researchers to avoid conflicts of interest, but in a field in which industry is immensely powerful and well-resourced, such conflicts are salient to the ethics of medical research. The implications of the potential conflicts of interest regarding these entanglements in the development and deployment of AI in health are only just

emerging, and the harms may evolve along with the technology over time. These are, and will grow as, important challenges facing the application of the DoH to issues related to AI in health and medical science.

When implemented well, the DoH has potential to affect health and medical science involving AI in positive ways. However, declarations are only as good as the capacity and commitment of people and institutions who use them. The capacity to meaningfully adopt the principles of the DoH in the era of AI requires creativity, foresight, and the resources necessary to keep abreast of progress in the field and the rapidly evolving knowledge of ethical issues that accompany these advances.

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WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013
and by the 75th WMA General Assembly, Helsinki, Finland, October 2024

PREAMBLE

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human participants, including research using identifiable human material or data.

   The Declaration is intended to be read as a whole, and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. While the Declaration is adopted by physicians, the WMA holds that these principles should be upheld by all individuals, teams, and organizations involved in medical research, as these principles are fundamental to respect for and protection of all research participants, including both patients and healthy volunteers.

GENERAL PRINCIPLES

3. The WMA Declaration of Geneva binds the physician with the words, “The health and well-being of my patient will be my first consideration,” and the WMA International Code of Medical Ethics declares “The physician must commit to the primacy of patient health and well-being and must offer care in the patient’s best interest.”

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician’s knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include participants.

Even well-proven interventions should be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.

6. Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights.

   Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed.

   Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results.

7. The primary purpose of medical research involving human participants is to generate knowledge to understand the causes, development and effects of diseases; improve preventive, diagnostic and therapeutic interventions; and ultimately to advance individual and public health.

   These purposes can never take precedence over the rights and interests of individual research participants.

8. While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, autonomy, privacy, and confidentiality of personal information of research participants. The responsibility for the protection of research participants must always rest with physicians or other researchers and never with the research participants, even though they have given consent.

10. Physicians and other researchers must consider the ethical, legal and regulatory norms and standards for research involving human participants in the country or countries in which the research originated and where it is to be performed, as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research participants set forth in this Declaration.

11. Medical research should be designed and conducted in a manner that avoids or minimizes harm to the environment and strives for environmental sustainability.

12. Medical research involving human participants must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Such research requires the supervision of a competent and appropriately qualified physician or other researcher.

    Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in research misconduct.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research will not adversely affect the health of the patients who serve as research participants.

15. Appropriate compensation and treatment for participants who are harmed as a result of participating in research must be ensured.

Risks, Burdens, and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

    Medical research involving human participants may only be conducted if the importance of the objective outweighs the risks and burdens to the research participants.

17. All medical research involving human participants must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

    Measures to minimize the risks and burdens must be implemented. The risks and burdens must be continuously monitored, assessed, and documented by the researcher.

18. Physicians and other researchers may not engage in research involving human participants unless they are confident that the risks and burdens have been adequately assessed and can be satisfactorily managed.

    When the risks and burdens are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians and other researchers must assess whether to continue, modify or immediately stop the research.

Individual, Group, and Community Vulnerability

19. Some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm. When such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion. In order to be fairly and responsibly included in research, they should receive specifically considered support and protections.

20. Medical research with individuals, groups, or communities in situations of particular vulnerability is only justified if it is responsive to their health needs and priorities and the individual, group, or community stands to benefit from the resulting knowledge, practices, or interventions. Researchers should only include those in situations of particular vulnerability when the research cannot be carried out in a less vulnerable group or community, or when excluding them would perpetuate or exacerbate their disparities.

Scientific Requirements and Research Protocols

21. 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. The research must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation.

    The welfare of animals used for research must be respected.

22. The design and performance of all medical research involving human participants must be clearly described and justified in a research protocol.

    The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding aims, methods, anticipated benefits and potential risks and burdens, qualifications of the researcher, sources of

funding, any potential conflicts of interest, provisions to protect privacy and confidentiality, incentives for participants, provisions for treating and/or compensating participants who are harmed as a consequence of participation, and any other relevant aspects of the research.

In clinical trials, the protocol must also describe any post-trial provisions.

Research Ethics Committees

23. The protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the research begins. This committee must be transparent in its functioning and must have the independence and authority to resist undue influence from the researcher, the sponsor, or others. The committee must have sufficient resources to fulfill its duties, and its members and staff must collectively have adequate education, training, qualifications, and diversity to effectively evaluate each type of research it reviews.

    The committee must have sufficient familiarity with local circumstances and context, and include at least one member of the general public. It must take into consideration the ethical, legal, and regulatory norms and standards of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research participants set forth in this Declaration.

    When collaborative research is performed internationally, the research protocol must be approved by research ethics committees in both the sponsoring and host countries.

    The committee must have the right to monitor, recommend changes to, withdraw approval for, and suspend ongoing research. Where monitoring is required, the researcher must provide information to the committee and/or competent data and safety monitoring entity, especially about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the research, the researchers must submit a final report to the committee containing a summary of the findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research participants and the confidentiality of their personal information.

Free and Informed Consent

25. Free and informed consent is an essential component of respect for individual autonomy. Participation by individuals capable of giving informed consent in medical research must be voluntary. Although it may be appropriate to consult family members or community representatives, individuals capable of giving informed consent may not be enrolled in research unless they freely agree.

26. In medical research involving human participants capable of giving informed consent, each potential participant must be adequately informed in plain language of the aims, methods, anticipated benefits and potential risks and burdens, qualifications of the researcher, sources of funding, any potential conflicts of interest, provisions to protect privacy and confidentiality, incentives for participants, provisions for treating and/or compensating participants who are harmed as a consequence of participation, and any other relevant aspects of the research.

    The potential participant must be informed of the right to refuse to participate in the research or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information and communication needs of individual potential participants as well as to the methods used to deliver the information.

    After ensuring that the potential participant has understood the information, the physician or another

qualified individual must then seek the potential participant's freely given informed consent, formally documented on paper or electronically. If the consent cannot be expressed on paper or electronically, the non-written consent must be formally witnessed and documented.

All medical research participants should be given the option of being informed about the general outcome and results of the research.

27. 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.

28. In medical research involving human participants incapable of giving free and informed consent, the physician or other qualified individual must seek informed consent from the legally authorized representative, considering preferences and values expressed by the potential participant.

    Those persons incapable of giving free and informed consent are in situations of particular vulnerability and are entitled to the corresponding safeguards. In addition to receiving the protections for the particularly vulnerable, those incapable of giving consent must only be included if the research is likely to either personally benefit them or if it entails only minimal risk and minimal burden.

29. When a potential research participant who is incapable of giving free and informed consent is able to give assent to decisions about participation in research, the physician or other qualified individual must seek that assent in addition to the consent of the legally authorized representative, considering any preferences and values expressed by the potential participant. The potential participant's dissent should be respected.

30. Research involving participants who are physically or mentally incapable of giving consent (for example, unconscious patients) may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician or other qualified individual must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the research may proceed without informed consent provided that the specific reasons for involving participants with a condition that renders them unable to give informed consent have been stated in the research protocol and the research has been approved by a research ethics committee.

    Free and informed consent to remain in the research must be obtained as soon as possible from a legally authorized representative or, if they regain capacity to give consent, from the participant.

31. The physician or other researcher must fully inform potential participants which aspects of their care are related to the research. The refusal of a patient to participate in research or the patient's decision to withdraw from research must never adversely affect the patient-physician relationship or provision of the standard of care.

32. Physicians or other qualified individuals must obtain free and informed consent from research participants for the collection, processing, storage, and foreseeable secondary use of biological material and identifiable or re-identifiable data. Any collection and storage of data or biological material from research participants for multiple and indefinite uses should be consistent with requirements set forth in the WMA Declaration of Taipei, including the rights of individuals and the principles of governance. A research ethics committee must approve the establishment and monitor ongoing use of such databases and biobanks.

    Where consent is impossible or impracticable to obtain, secondary research on stored data or biological material may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

    - If no proven intervention exists, the use of placebo, or no intervention, is acceptable; or
    - If for compelling and scientifically sound methodological reasons the use of any intervention other than the best proven one(s), the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention; and the participants who receive any intervention other than the best proven one(s), placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

    Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, post-trial provisions must be arranged by sponsors and researchers to be provided by themselves, healthcare systems, or governments for all participants who still need an intervention identified as beneficial and reasonably safe in the trial. Exceptions to this requirement must be approved by a research ethics committee. Specific information about post-trial provisions must be disclosed to participants as part of informed consent.

Research Registration, Publication, and Dissemination of Results

35. Medical research involving human participants must be registered in a publicly accessible database before recruitment of the first participant.

36. Researchers, authors, sponsors, editors, and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human participants and are accountable for the timeliness, completeness, and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations, and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. When an unproven intervention is utilized in an attempt to restore health or alleviate suffering for an individual patient because approved options are inadequate or ineffective and enrollment in a clinical trial is not possible, it should subsequently be made the object of research designed to evaluate safety and efficacy. Physicians participating in such interventions must first seek expert advice, weigh possible risks, burdens, and benefits, and obtain informed consent. They must also record and share data when appropriate and avoid compromising clinical trials. These interventions must never be undertaken to circumvent the protections for research participants set forth in this Declaration.

WMA DECLARATION OF TOKYO – GUIDELINES FOR PHYSICIANS CONCERNING TORTURE AND OTHER CRUEL, INHUMAN OR DEGRADING TREATMENT OR PUNISHMENT IN RELATION TO DETENTION AND IMPRISONMENT

Adopted by the 29th World Medical Assembly, Tokyo, Japan, October 1975
Editorially revised by the 170th WMA Council Session, Divonne-les-Bains, France, May 2005
and the 173rd WMA Council Session, Divonne-les-Bains, France, May 2006
and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016

PREAMBLE

It is the privilege of the physician to practise medicine in the service of humanity, to preserve and restore bodily and mental health without distinction as to persons, and to comfort and to ease the suffering of his or her patients. The utmost respect for human life is to be maintained even under threat, and no use is to be made of any medical knowledge contrary to the laws of humanity.

For the purpose of this Declaration, torture is defined as the deliberate, systematic or wanton infliction of physical or mental suffering by one or more persons acting alone or on the orders of any authority, to force another person to yield information, to make a confession, or for any other reason.

DECLARATION

1. The physician shall not countenance, condone or participate in the practice of torture or other forms of cruel, inhuman or degrading procedures, whatever the offense of which the victim of such procedures is suspected, accused or guilty, and whatever the victim's beliefs or motives, and in all situations, including armed conflict and civil strife.

2. The physician shall not provide any premises, instruments, substances or knowledge to facilitate the practice of torture or other forms of cruel, inhuman or degrading treatment or to diminish the ability of the victim to resist such treatment.

3. When providing medical assistance to detainees or prisoners who are, or who could later be, under interrogation, physicians should be particularly careful to ensure the confidentiality of all personal medical information. A breach of the Geneva Conventions shall in any case be reported by the physician to relevant authorities.

4. As stated in WMA Resolution on the Responsibility of Physicians in the Documentation and Denunciation of Acts of Torture or Cruel or Inhuman or Degrading Treatment and as an exception to professional confidentiality, physicians have the ethical obligation to report abuses, where possible with the subject's consent, but in certain circumstances where the victim is unable to express him/herself freely, without explicit consent.

5. The physician shall not use nor allow to be used, as far as he or she can, medical knowledge or skills, or health information specific to individuals, to facilitate or otherwise aid any interrogation, legal or illegal, of those individuals.

6. The physician shall not be present during any procedure during which torture or any other forms of cruel, inhuman or degrading treatment is used or threatened.

7. A physician must have complete clinical independence in deciding upon the care of a person for whom he or she is medically responsible. The physician's fundamental role is to alleviate the distress of his or her fellow human beings, and no motive, whether personal, collective or political, shall prevail against this higher purpose.

8. Where a prisoner refuses nourishment and is considered by the physician as capable of forming an unimpaired and rational judgment concerning the consequences of such a voluntary refusal of nourishment, he or she shall not be fed artificially, as stated in WMA Declaration of Malta on Hunger Strikers. The decision as to the capacity of the prisoner to form such a judgment should be confirmed by at least one other independent physician. The consequences of the refusal of nourishment shall be explained by the physician to the prisoner.

9. Recalling the Declaration of Hamburg concerning Support for Medical Doctors Refusing to Participate in, or to Condone, the Use of Torture or Other Forms of Cruel, Inhuman or Degrading Treatment, the World Medical Association supports, and encourages the international community, the National Medical Associations and fellow physicians to support, the physician and his or her family in the face of threats or reprisals resulting from a refusal to condone the use of torture or other forms of cruel, inhuman or degrading treatment.

10. The World Medical Association calls on National Medical Associations to encourage physicians to continue their professional development training and education in human rights.

WMA DECLARATION OF TAIPEI ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS

Adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002
and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016

PREAMBLE

1. The Declaration of Helsinki lays down ethical principles for medical research involving human subjects, including the importance of protecting the dignity, autonomy, privacy and confidentiality of research subjects, and obtaining informed consent for using identifiable human biological material and data.

2. In health care provision, health information is gathered by physicians or other members of the medical team to record health care events and to aid physicians in the on-going care of their patient.

3. This Declaration is intended to cover the collection, storage and use of identifiable data and biological material beyond the individual care of patients. In concordance with the Declaration of Helsinki, it provides additional ethical principles for their use in Health Databases and Biobanks.

This Declaration should be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

4. A Health Database is a system for collecting, organizing and storing health information. A Biobank is a collection of biological material and associated data. Biological material refers to a sample obtained from an individual human being, living or deceased, which can provide biological information, including genetic information, about that individual. Health Databases and Biobanks are both collections on individuals and population, and both give rise to the similar concerns about dignity, autonomy, privacy, confidentiality and discrimination.

5. Research using Health Databases and Biobanks can often significantly accelerate the improvement in the understanding of health, diseases, and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions. Health research represents a common good that is in the interest of individual patients, as well as the population and the society.

6. Physicians must consider the ethical, legal and regulatory norms and standards for Health Database and Biobanks in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for individuals and population set forth in this Declaration.

When authorized by a national law adopted through a democratic process in respect of human rights, other procedures could be adopted to protect the dignity, autonomy and privacy of the individuals. Such procedures are only acceptable when strict rules on data protection are implemented.

7. Consistent with the mandate of WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in using data or biological material in Health Databases and Biobanks to adopt these principles.

ETHICAL PRINCIPLES

8. Research and other Health Databases and Biobanks related activities should contribute to the benefit of society, in particular public health objectives.

9. Respecting the dignity, autonomy, privacy and confidentiality of individuals, physicians have specific obligations, both ethical and legal, as stewards protecting information provided by their patients. The rights to autonomy, privacy and confidentiality also entitle individuals to exercise control over the use of their personal data and biological material.

10. Confidentiality is essential for maintaining trust and integrity in Health Databases and Biobanks. Knowing that their privacy will be respected gives patients and donors the confidence to share sensitive personal data. Their privacy is protected by the duty of confidentiality of all who are involved in handling data and biological material.

11. The collection, storage and use of data and biological material from individuals capable of giving consent must be voluntary. If the data and biological material are collected for a given research project, the specific, free and informed consent of the participants must be obtained in accordance with the Declaration of Helsinki.

12. If the data or biological material are collected and stored in a Health Database or a Biobank for multiple and indefinite uses, consent is only valid if the concerned individuals have been adequately informed about:

- The purpose of the Health Database or Biobank;
- The risks and burdens associated with collection, storage and use of data and material;
- The nature of the data or material to be collected;
- The procedures for return of results including incidental findings;
- The rules of access to the Health Database or Biobank;
- How privacy is protected;
- The governance arrangements as stipulated in paragraph 21;
- That in case the data and material are made non-identifiable the individual may not be able to know what is done with their data/material and that they will not have the option of withdrawing their consent;
- Their fundamental rights and safeguards established in this Declaration; and
- When applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or third countries.

13. In addition to the requirements set forth in the Declaration of Helsinki, when persons who were not able to consent, whose data and biological materials have been stored for future research, attain or regain the capacity to consent, reasonable efforts should be made to seek the consent of those persons for continued storage and research use of their data and biological materials.

14. Individuals have the right to request for and be provided with information about their data and its use as well as to request corrections of mistakes or omissions. Health Databases and Biobanks should adopt adequate measures to inform the concerned individuals about their activities.

15. Individuals have the right, at any time and without reprisal, to alter their consent or to ask for their identifiable data to be withdrawn from the Health Database and their biological material to be withdrawn from a Biobank. This applies to future use of the data and biological materials.

16. In the event of a clearly identified, serious and immediate threat where anonymous data will not suffice, the requirements for consent may be waived to protect the health of the population. An independent ethics committee should confirm that each exceptional case is justifiable.

17. The interests and rights of the communities concerned, in particular when vulnerable, must be protected, especially in terms of benefit sharing.

18. Special considerations should be given to the possible exploitation of intellectual property. Protections for ownership of materials, rights and privileges must be considered and contractually defined before collecting and sharing the material. Intellectual property issues should be addressed in a policy, which covers the rights of all stakeholders and communicated in a transparent manner.

19. An independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes. In addition the ethics committee must approve use of data and biological material and check whether the consent given at the time of collection is sufficient for the planned use or if other measures have to be taken to protect the donor. The committee must have the right to monitor on-going activities. Other ethical review mechanisms that are in accordance to par 6 can be established.

GOVERNANCE

20. In order to foster trustworthiness, Health Databases and Biobanks must be governed by internal and external mechanisms based on the following principles:

- Protection of individuals: Governance should be designed so the rights of individuals prevail over the interests of other stakeholders and science;
- Transparency: any relevant information on Health Databases and Biobanks must be made available to the public;
- Participation and inclusion: Custodians of Health Databases and Biobanks must consult and engage with individuals and their communities.
- Accountability: Custodians of Health Databases and Biobanks must be accessible and responsive to all stakeholders.

21. Governance arrangements must include the following elements:

- The purpose of the Health Database or Biobank;
- The nature of health data and biological material that will be contained in the Health Database or Biobank;
- Arrangements for the length of time for which the data or material will be stored;
- Arrangements for regulations of the disposal and destruction of data or material;
- Arrangement for how the data and material will be documented and traceable in accordance with the consent of the concerned persons;
- Arrangement for how the data and material will be dealt with in the event of change of ownership or closure;
- Arrangement for obtaining appropriate consent or other legal basis for data or material collection;
- Arrangements for protecting dignity, autonomy, privacy and preventing discrimination;
- Criteria and procedures concerning the access to and the sharing of the health data or biological material including the systematic use of Material Transfer Agreement (MTA) when necessary;
- The person or persons who are responsible for the governance;
- The security measures to prevent unauthorized access or inappropriate sharing;
- The procedures for re-contacting participants where relevant;
- The procedures for receiving and addressing enquiries and complaints.

22. Those professionals contributing to or working with Health Databases and Biobanks must comply with the appropriate governance arrangements.

23. Health Databases and Biobanks must be operated under the responsibility of an appropriately qualified professional assuring compliance with this Declaration.

24. The WMA urges relevant authorities to formulate policies and law that protect health data and biological material on the basis of the principles set forth in this document.