Synopse der aktuellen Version der Declaration of Helsinki im Vergleich zur Version von 2013

DoH 2024	DoH 2013	Chapter
PREAMBLE		
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.	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.	1
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.	Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.	2
GENERAL PRINCIPLES		
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."**	The Declaration of Geneva of the WMA binds the physician with the words, "The health and well-being of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care.	3
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.	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.	4
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.**	Medical progress is based on research that ultimately must include studies involving human subjects.	5

DoH 2024	DoH 2013	Chapter
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.**	The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.	6
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.**	Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights	7
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.	While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.	8
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.	It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. 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.	9
Physicians **and other researchers** must consider the ethical, legal and regulatory norms and standards for research involving human	Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in the country or	10

DoH 2024	DoH 2013	Chapter
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.	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 subjects set forth in this Declaration.	
Medical research should be **designed and** conducted in a manner that **avoids or** minimizes harm to the environment **and strives for environmental sustainability**.	Medical research should be conducted in a manner that minimizes possible harm to the environment.	11
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.**	Medical research involving human participants must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other researcher.	12
Groups that are underrepresented in medical research should be provided appropriate access to participation in research.	Groups that are underrepresented in medical research should be provided appropriate access to participation in research.	13
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**.	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 subjects.	14
Appropriate compensation and treatment for **participants** who are harmed as a result of participating in research must be ensured.	Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.	15
RISKS, BURDENS, AND BENEFITS		
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**.	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 subjects.	16
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	All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable	17

DoH 2024	DoH 2013	Chapter
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.	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.	
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.	Physicians may not be involved in a research study involving human subjects unless they are confident that the risks 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 must assess whether to continue, modify or immediately stop the research.	18
INDIVIDUAL, GROUP, AND COMMUNITY VULNERABILITY	VULNERABLE GROUPS AND INDIVIDUALS	
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.	Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.	19
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**	Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.	20

DoH 2024	DoH 2013	Chapter
vulnerable group or community, or when excluding them would perpetuate or exacerbate their disparities.		
SCIENTIFC REQUIREMENTS AND RESEARCH PROTOCOLS		
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.	Medical research involving human subjects 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.	21
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.	The design and performance of each research study involving human subjects 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 funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.	22
RESEARCH ETHICS COMMITTEES		
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**	The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified.	23

DoH 2024	DoH 2013	Chapter
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.	It must take into consideration the laws and regulations 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 subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information 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 study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.	
PRIVACY AND CONFIDENTIALITY		
Every precaution must be taken to protect the privacy of research **participants** and the confidentiality of their personal information.	Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.	24
FREE AND INFORMED CONSENT	INFORMED CONSENT	
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	Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be	25

DoH 2024	DoH 2013	Chapter
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**.	appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.	
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.	In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed. All medical research subjects should be given the option of being informed about the general outcome and results of the study.	26
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	When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an	27

DoH 2024	DoH 2013	Chapter
sought by an appropriately qualified individual who is independent of this relationship.	appropriately qualified individual who is completely independent of this relationship.	
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.	For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.	28
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.	When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.	29
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.	Research involving subjects 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 must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee.	30

DoH 2024	DoH 2013	Chapter
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.**	Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.	
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.**	The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.	31
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.**	For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.	32
USE OF PLACEBO		
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	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: -Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or -Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no	33

DoH 2024	DoH 2013	Chapter
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.	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		
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.	In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.	34
RESEARCH REGISTRATION, PUBLICATION, AND DISSEMINATION OF RESULTS	RESEARCH REGISTRATION AND PUBLICATION AND DISSEMINATION OF RESULTS	
Medical research involving human **participants** must be registered in a publicly accessible database before recruitment of the first **participant**.	Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.	35
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.	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 subjects and are accountable for the 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.	36
UNPROVEN INTERVENTIONS IN CLINICAL PRACTICE		
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	In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven	37

DoH 2024	DoH 2013	Chapter
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.	intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.	