Appendizes

Appendix A: Synopse

Tabelle A1: Systematische Synopse der englischen Fassungen der Versionen 2013 und 2024 der DvH. Die roten, durchgestrichenen Passagen in der Spalte Version 2013 wurden in der Version 2024 ersetzt bzw. entfernt. Ersetzte und neue Passagen werden in der Spalte Version 2024 in grün hervorgehoben.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
Preamble			
1	The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human ~~subjects~~, including research on identifiable human material and 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.	„subjects" wird zu „participants". Fokus auf Teilnahme und Freiwilligkeit in der Terminologie.
2	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	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.	Die Version 2024 betont die ethisch-normative Bedeutung für Forscher*innen, die keine Ärzte sind, stärker. Aus einem „encourage" (deutsch „ermutigen") sich an die Empfehlungen zu halten wird ein normatives „should" (deutsch „sollen").
General Principles			
3	The Declaration of Geneva of the WMA binds the physician with the words, ~~"The health 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."~~	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."	Angepasst an Updates der referenzierten Deklarationen / Codes.
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.	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.	Keine Änderung.
5	Medical progress is based on research that ultimately must include ~~studies involving human subjects.~~	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.	Zweiter Absatz stammt aus Artikel6 von 2013.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
6	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.~~	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.	Artikel 6 & 7 wurden im Vergleich zu 2013 getauscht. Ergänzung zu Artikel7 von 2013: (1) Kontext struktureller Ungleichheit soll fokussiert werden hinsichtlich der Verteilung von Belastungen und Nutzen. (2) Teilhabe von Teilnehmer*innen und ihren Gemeinschaften in die Forschung.
7	Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.	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.	Ergänzung zu Artikel6 von 2013: (1) Nachgelagerte Auswirkungen von Forschungsfortschritten sollten der individuellen und öffentlichen Gesundheit zugutekommen. (2) (Guter) Zweck von Forschung überschreibt niemals die Rechte der Teilnehmer*innen (zuvor Artikel 8, 2013).
8	~~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.~~	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.	Neuer Artikel, betont dass selbst in Notfallsituationen im Bereich der öffentlichen Gesundheit die ethischen Prinzipien dieser Deklaration gültig bleiben. Der Artikel aus 2013 findet sich bereits in Artikel 7 von 2024 wieder und ist somit mit gültig.
9	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 ~~subjects~~ must always rest with the physician or ~~other health care professionals~~ and never with the research ~~subjects~~, 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, 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.	(1) Die Version 2024 nutzt den Begriff „Autonomy" (deutsch: „Autonomie") im Gegensatz zu „right to self-determination" (deutsch "Recht auf Selbstbestimmung"). Bei „Autonomie" handelt es sich um ein Konzept, dass die tatsächliche Fähigkeit der Selbstbestimmung beschreibt, statt sich auf das Recht zu beschränken. Das Recht auf Selbstbestimmung ist eine nicht-hinreichende Bedingung für die Autonomie. (2) Die Version 2024 erweitert die Verantwortung für den Schutz von Teilnehmer*innen von „health care professionals" auf alle Forscher*innen.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
10	Physicians must consider the ethical, legal and regulatory norms and standards for research involving human ~~subjects~~ 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 research ~~subjects~~ set forth in this Declaration.	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.	(1) Die Version 2024 erweitert die Verantwortung dieses Artikels von Ärzt*innen auf alle Forscher*innen. (2) Die Version 2024 erweitert den Scope der zu betrachtenden ethischen, legalen und regulatorischen Normen auf alle beteiligte Staaten statt nur auf die Staaten der jeweiligen Verantwortlichen. In bestimmten multinationalen Kontexten war dieser Artikelbereits rechtlich geregelt (siehe EU-Recht), nicht jedoch global und insbesondere nicht innerhalb dieses Ethikkodexes. Ein mögliches Argument könnte die Auslagerung von Forschung in weniger regulierte Staaten sein, um Sicherheitsvorkehrungen zu umgehen. Dieses Vorgehen ist aus der Pharmazrie bekannt und steht stark unter Kritik.
11	Medical research should be conducted in a manner that minimises possible harm to the environment.	Medical research should be designed and conducted in a manner that avoids or minimizes harm to the environment and strives for environmental sustainability.	(1) Die Version 2024 ergänzt die Minimierung von Umweltschäden durch das Streben nach ökologischer Nachhaltigkeit und betont, dass dies bereits im Design bedacht werden muss. Eine subtile, aber wichtige Ergänzung, da die Minimierung von Schäden für die Umwelt nicht ausreicht, um ökologische Nachhaltigkeit zu erreichen.
12	Medical research involving human ~~subjects~~ 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 health care professional.~~	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.	(1) In der Version 2024 wurde die Forschungsüberwachung durch potenziell alle Forscher*innen ergänzt, statt sich auf medizinisches Fachpersonal zu beschränken. (2) Der Artikelwurde gegenüber 2013 durch eine Betonung wissenschaftlicher Integrität ergänzt. So soll die ethisch-normative Komponente wissenschaftlicher Integrität insbesondere bei der Forschung am Menschen explizit gemacht werden. Besonders in der medizinischen Forschung hat „misconduct" potenziell erhebliche Konsequenzen, die primär zu (vermeidbaren) Schäden an Teilnehmer*innen, aber auch nachgelagert zu Schäden in der Gesundheitsversorgung führen können.
13	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.	Keine Anpassung.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
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 study will not adversely affect the health of the patients who serve as research ~~subjects~~.	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.	s.o.
15	Appropriate compensation and treatment for ~~subjects~~ who are harmed as a result of participating in research must be ensured.	Appropriate compensation and treatment for participants who are harmed as a result of participating in research must be ensured.	s.o.
Risks, Burdens, and Benefits			
16	In medical practice and in medical research, most interventions involve risks and burdens. Medical research involving human ~~subjects~~ may only be conducted if the importance of the objective outweighs the risks and burdens to the research ~~subjects~~.	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.	s.o.
17	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 benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.	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.	Der Zweite Absatz von Artikel17 wurde in der Version 2024 um Belastungen erweitert. Es wird somit betont, dass nicht nur Risiken, also potenzielle Schäden, sondern auch definitive Belastungen für Teilnehmer*innen reduziert werden sollten.
18	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 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 study.	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.	Erweiterung des Scopes und der Verantwortlichkeit (s.o.).

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
	~~Vulnerable Groups and Individuals~~	**Individual, Group, and Community Vulnerability**	Der Term „vulnerable group“ bezieht sich allgemein auf Gruppen, die eher dazu neigen, irregeführt, misshandelt oder auf andere Weise ausgenutzt zu werden. Dieses Konzept wurde unter anderem dafür kritisiert, ganze Gruppen verallgemeinert als vulnerabel darzustellen, anstatt auf bestimmte Vulnerabilitäten in bestimmten Situationen hinzuweisen [1]. Die DvH in der Version 2024 scheint auf die Debatte um dieses Konzept zu reagieren, da von Vulnerabilitäten und „situations of vulnerability“ gesprochen wird.
19	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.	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.	Wichtige Ergänzung in Version 2024: Die Exklusion wegen Vulnerabilität birgt Risiken durch Unterrepräsentation oder durch spezielle medizinische Bedürfnisse. Daraus folgende Schäden und Ungleichheiten müssen in Betracht gezogen werden. Vulnerabilität als Begriff wird präziser verwendet.
20	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.	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.	s.o.
Scientific Requirements and Research Protocols			
21	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.	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.	Die Version 2024 ergänzt Artikel21 um Nachhaltigkeitsaspekte. So soll nur Forschung am Menschen stattfinden, welche erfolgsversprechend ist und Abfall reduziert.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
22	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 ~~subjectsand 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.	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.	Die Version 2024 aktualisiert die Anforderungen an Forschungsprotokolle, indem sie eine umfassendere Beschreibung der Forschung verlangt. Alle medizinischen Forschungsstudien, die Menschen betreffen, müssen klar beschrieben und gerechtfertigt werden. Der Protokollinhalt umfasst nun wichtige Elemente wie Ziele, Methoden, erwartete Vorteile sowie potenzielle Risiken und Belastungen. Zudem wird die Qualifikation des Forschers erwähnt. Sponsoren werden nicht mehr explizit aufgeführt: Wenn der Sponsor gleichzeitig die Studie finanziert, dann ist er durch die Angabe der „source of funding“ implizit genannt. Wenn jedoch die Finanzierung über Dritte erfolgt (z. B. durch ein öffentliches Förderprogramm), ohne dass der Sponsor direkt genannt wird, ist der Sponsor nicht automatisch ersichtlich. Außerdem wird der Schutz von Privatsphäre und Vertraulichkeit angesprochen, was für den Umgang mit Teilnehmendendaten relevant ist.
Research Ethics Committees			
23	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.~~ 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	The protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the research. 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.	(1) Die Version 2024 betont die Unabhängigkeit der Ethikkommissionen auch durch die Betonung hinreichender Ressourcen und ausreichender Qualifikation. (2) Der Fokus der Ethikkommissionen wurde von „laws and regulations" auf „ethical, legal, and regulatory norms" erweitert. (3) Es wird verlangt, dass Ethikkommissionen aller an internationaler Forschung beteiligten Staaten das Forschungsvorhaben billigen. (4) Die geforderten Rechte der Ethikkommissionen wurden erweitert um die Möglichkeit, laufender Forschung die Billigung zu entziehen und laufende Forschung zu suspendieren.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
	committee containing a summary of the ~~study's~~ findings and conclusions.	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 ~~subjects~~ and the confidentiality of their personal information.	Every precaution must be taken to protect the privacy of research participants and the confidentiality of their personal information.	s.o.
~~Informed Consent~~		**Free and Informed Consent**	
25	Participation by individuals capable of giving informed consent ~~as subjects~~ in medical research must be voluntary. Although it may be 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 agree~~s~~.	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.	Die ethische Bedeutung von freiem und informiertem Einverständnis wird eingeführt. Es wird sprachlich besser präzisiert.
26	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-	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	Die Version 2024 ergänzt Artikel 26 um zusätzliche Informationen, die im Sinne des informierten Einverständnisses bereitzustellen sind. Die Aktualisierung betont erstmals, dass potenzielle Teilnehmer*innen in **einfacher Sprache** über die Ziele, Methoden, erwarteten Vorteile sowie mögliche Risiken und Belastungen informiert werden müssen. Außerdem werden Aspekte wie die „Qualifikationen des Forschers" und „Maßnahmen zum Schutz der Privatsphäre" hinzugefügt. Zudem wird auf Anreize für Teilnehmer*innen eingegangen.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
	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.	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 ~~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 appropriately qualified individual who is completely independent of this relationship.	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.	s.o.
28	~~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.~~	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.	(1) Die Version 2024 präzisiert diesen Artikelsprachlich. (2) Die Version 2024 betont, dass bei stellvertretendem informierten Einverständnis durch Angehörige / Vormund / etc., die Interessen und Präferenzen der potenziellen Teilnehmer*innen in Betracht gezogen werden müssen. (3) Die Kriterien für die Teilnahme wurden angepasst. Persönliche Vorteile oder Vorteile der repräsentierten Gruppe sind nicht mehr Voraussetzung, falls Risiken und Belastungen minimal sind. (4) Die Vulnerabilität der Betroffenen wird angesprochen. Die Exklusion dieser Gruppe wird weniger streng, was ggfs. in den zuvor angesprochenen Argumenten gegen die Exklusion von Teilnehmer*innen mit Vulnerabilität begründet ist.
29	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.	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.	s.o.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
30	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. Consent to remain in the research must be obtained as soon as possible from the ~~subject or a legally authorised representative.~~	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.	Die Version 2024 präzisiert sprachlich.
31	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.	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.	Dieser Artikelfordert, dass das Verweigern des Einverständnisses keine negativen Folgen für potenzielle Teilnehmer*innen haben darf. Die Version 2024 betont, dass das Verweigern des informierten Einverständnisses nicht zur Folge haben darf, dass der „standard of care" nicht erbracht wird.
32	~~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 consideration and approval of a research ethics committee.	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.	Die Neuformulierung in der Version 2024 lässt mehr Spielraum für Broad-Consent Ansätze in der Datenerhebung und referenziert die Declaration of Taipei mit Bezug auf die Data-Governance.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
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: • ~~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 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.	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.	Die Version 2024 präzisiert sprachlich.
Post-Trial Provisions			
34	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.~~	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.	Die Version 2024 präzisiert sprachlich. Es wird eingeführt, dass Ausnahmen von dieser Anforderung durch Ethikkommissionen gebilligt werden können.
Research Registration, Publication, and Dissemination of Results			
35	~~Every~~ research study involving human ~~subjects~~ must be registered in a publicly accessible database before recruitment of the first ~~subject~~.	Medical research involving human participants must be registered in a publicly accessible database before recruitment of the first participant.	In Version 2024 wird „Every research“ zu „Medical research“, um besser dem Scope dieser Deklaration zu entsprechen.

Art.	Version 2013	Version 2024	Kommentare / Erklärungen
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 ~~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.	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.	s.o.
Unproven Interventions in Clinical Practice			
37	~~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 11uthorized representative, may use an unproven 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.~~	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.	Die Version 2024 präzisiert sprachlich. Die Bedeutung der ethischen Prinzipien der DvH werden betont. Es wird ergänzt, dass „unproven interventions in clinical practice“ nicht als Methode verwendet werden sollen, um diese Prinzipien zu umgehen.

Appendix B: Nürnberger Kodex

Tabelle B1: Grundsätze des Nürnberger Kodex (1947) [2] *(Übersetzung:* [3]*). Der Nürnberger Kodex wurde seitdem zu allgemeinen Kodizes der medizinischen Ethik erweitert und beeinflusst weiterhin moderne forschungsethische Rahmenwerke weltweit. Die Deklaration von Helsinki basiert auf den ursprünglichen Grundsätzen des Nürnberger Kodex als Ergebnis des Nürnberger Ärzteprozesses von 1946/1947, in dem Ärzte wegen „Kriegsverbrechen" und „Verbrechen gegen die Menschlichkeit" während der Nazi-Diktatur angeklagt und in einigen Fällen auch verurteilt wurden* [4], [5]*.*

Die zehn Grundsätze des Nürnberger Kodex (1947)	
1	Die freiwillige Zustimmung der Versuchsperson ist unbedingt erforderlich. Das heißt, dass die betreffende Person im juristischen Sinne fähig sein muss, ihre Einwilligung zu geben; dass sie in der Lage sein muss, unbeeinflusst durch Gewalt, Betrug, List, Druck, Vortäuschung oder irgendeine andere Form der Überredung oder des Zwanges, von ihrem Urteilsvermögen Gebrauch zu machen; dass sie das betreffende Gebiet in seinen Einzelheiten hinreichend kennen und verstehen muss, um eine verständige und informierte Entscheidung treffen zu können. Diese letzte Bedingung macht es notwendig, dass der Versuchsperson vor der Einholung ihrer Zustimmung das Wesen, die Länge und der Zweck des Versuches klargemacht werden; sowie die Methode und die Mittel, welche angewendet werden sollen, alle Unannehmlichkeiten und Gefahren, welche mit Fug zu erwarten sind, und die Folgen für ihre Gesundheit oder ihre Person, welche sich aus der Teilnahme ergeben mögen. Die Pflicht und Verantwortlichkeit, den Wert der Zustimmung festzustellen, obliegt jedem, der den Versuch anordnet, leitet oder ihn durchführt. Dies ist eine persönliche Pflicht und Verantwortlichkeit, welche nicht straflos an andere weitergegeben werden kann.
2	Der Versuch muss so gestaltet sein, dass fruchtbare Ergebnisse für das Wohl der Gesellschaft zu erwarten sind, welche nicht durch andere Forschungsmittel oder Methoden zu erlangen sind. Er darf seiner Natur nach nicht willkürlich oder überflüssig sein.
3	Der Versuch ist so zu planen und auf Ergebnissen von Tierversuchen und naturkundlichem Wissen über die Krankheit oder das Forschungsproblem aufzubauen, dass die zu erwartenden Ergebnisse die Durchführung des Versuchs rechtfertigen werden.
4	Der Versuch ist so auszuführen, dass alles unnötige körperliche und seelische Leiden und Schädigungen vermieden werden.
5	Kein Versuch darf durchgeführt werden, wenn von vornherein mit Fug angenommen werden kann, dass es zum Tod oder einem dauernden Schaden führen wird, höchstens jene Versuche ausgenommen, bei welchen der Versuchsleiter gleichzeitig als Versuchsperson dient.
6	Die Gefährdung darf niemals über jene Grenzen hinausgehen, die durch die humanitäre Bedeutung des zu lösenden Problems vorgegeben sind.
7	Es ist für ausreichende Vorbereitung und geeignete Vorrichtungen Sorge zu tragen, um die Versuchsperson auch vor der geringsten Möglichkeit von Verletzung, bleibendem Schaden oder Tod zu schützen.
8	Der Versuch darf nur von wissenschaftlich qualifizierten Personen durchgeführt werden. Größte Geschicklichkeit und Vorsicht sind auf allen Stufen des Versuchs von denjenigen zu verlangen, die den Versuch leiten oder durchführen.
9	Während des Versuches muss der Versuchsperson freigestellt bleiben, den Versuch zu beenden, wenn sie körperlich oder psychisch einen Punkt erreicht hat, an dem ihr seine Fortsetzung unmöglich erscheint.
10	Im Verlauf des Versuchs muss der Versuchsleiter jederzeit darauf vorbereitet sein, den Versuch abzubrechen, wenn er auf Grund des von ihm verlangten guten Glaubens, seiner besonderen Erfahrung und seines sorgfältigen Urteils vermuten muss, dass eine Fortsetzung des Versuches eine Verletzung, eine bleibende Schädigung oder den Tod der Versuchsperson zur Folge haben könnte.

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