



Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Participants



Full paragraph-by-paragraph comparison indicating changes in version 19 October 2024
compared with the most previous version of 19 October 2013

Prepared by Francis P. Crawley, GCPA & SIDCER
Leuven, Belgium; fpc@gcpalliance.org

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Introduction

This full paragraph-by-paragraph comparison of the recently released Declaration of Helsinki (DoH) ([DoH version October 19, 2024](#)) with the most previous [DoH version of 19 October 2013](#) is intended as a service to the international bioethics and medical research communities to assist in identifying the changes recently introduced by the World Medical Association (WMA). A brief preliminary commentary is added to each paragraph as a point of reflection on some of the changes to assist the reader in situating the context and considerations to which the changes may give rise.

This version 4.0 revises the preliminary commentary in the table below (Part A, pages 1-35). Following the table a Part B (pages 37 to 39) was added in version 3.0 to summarize some points of revision found in the 2024 version of the DoH.

A. Full paragraph-by-paragraph comparison

Paragraph 2013 version	Paragraph 2024 version	Wording changes	Preliminary commentary
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	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 term ‘subjects’ is replaced by ‘participants’. This is also the case in the title and throughout the entire 2024 version of the Declaration of Helsinki (DoH).	The change from ‘subjects’ to ‘participants’ reflects a more contemporary approach introduced in common usage 25 years ago. The intent is to highlight the need for respect and recognition of the autonomy of research subjects/participants. The change is reflected in the new title of the Declaration of Helsinki (DoH) and throughout this 2024 revision. This phrase ‘including research on identifiable human material and data’ introduced in the Declaration of Helsinki in the 2000 version is unfortunate and leads to significant confusions (see the utter confusion in

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each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.	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.	A comma is added after the word 'whole'.	paragraph 9). It is inappropriate to consider research on 'human material and data' (identifiable or not) to be understood as having the same standards as that of research on living human persons with their absolute dignity, conscience, and consciousness. Further, where or not 'human material' (an ill-chosen term) or 'data' is identifiable or not is not always what is determinative for research on that material or data.
General Principals			
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.	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.	Significant rewriting. Addition of the clause 'as these principles are fundamental to respect for and protection of all research participants, including both patients and healthy volunteers.'	There is an ongoing attempt by the WMA since 2000 to assert that the DoH should be upheld by those outside its remit. Reference to a 'mandate of the WMA' was invoked by the 2013 leadership of the WMA (largely the same leadership as today). Such a mandate was never provided to the WMA: a mandate did not and does not exist. This extension of the DoH's remit/mandate began with the 2008 version where the following sentence was added 'Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.' The term 'encourage' is quite different from the claims of a 'mandate' or 'should' (with repeated emphasis). The addition of 'should be upheld by all individuals, teams, and organizations' indicates the first attempt by the WMA to introduce research integrity into the DoH (see below in paragraph 12 as well). It is a further attempt to

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			<p>extend a mandate/remit the WMA does not possess to ‘teams and organizations’.</p> <p>One wonders if the added clause indeed adds anything. It may actually only further limit the intended meaning.</p>
The 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).	The purpose of medical research involving human participants is to understand the causes, development, and effects of diseases, and to improve preventive, diagnostic, and therapeutic interventions . This ultimately contributes to advancing public health and well-being.	The deletion of ‘(methods, procedures and treatments)’ indicates correctly that these terms were ill-chosen previously.	<p>The introduction of the following sentence appears to suggest that the DoH should be seen not just for individuals (or groups) but also for public health: ‘This ultimately contributes to advancing public health and well-being.’ This appears to be a forced addition and out of place with the rest of the paragraph.</p> <p>The term ‘well-being’ appears inappropriate in a sentence discussing public health.</p>
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.”	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	<p>The addition of ‘well-being’ in the statement from the Declaration of Geneva.</p> <p>Revision of the quotation from the WMA International Code of Medical Ethics.</p>	<p>This revision brings the DoH in line with the WMA’s Declaration of Geneva: The Physician’s Pledge’, as revised in 2017 and the WMA’s International Code of Medical Ethics, as revised in 2022.</p>

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	in the patient's best interest."		
In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.	The health, rights, and well-being of the individual research participant must always take precedence over the interests of science and society.	The paragraph is rewritten. 'Health' and 'rights' are added.	'always' has been added. One wonders if this was needed and might not complicate interpretations. 'of science and society' have now replaced 'all other interests'. When this paragraph was added to the 2000 version, it then read: 'of science and society'.
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.	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.	Unchanged	This paragraph is what has become of the original first paragraph of the DoH in 1964 : 'It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfilment of this mission.' This remains the core statement from which all others (should) flow. With the addition of the word 'dignity' paragraph 6 of the 2024 version would no longer be needed. Note here only 'physicians' are referred to and not 'other researchers'. This shows an inconsistency in the 2024 (and previous) versions that reflects the WMA's inability to reconcile the limitations of its remit with its wider ambitions.
5. Medical progress is based on research that ultimately must include studies involving human subjects.	5. Medical progress is based on research that ultimately must include human participants.	Addition of the sentence: 'Even well-proven interventions should be evaluated	The first sentence is unchanged. However, this sentence is ambiguous and not always applicable. Not all progress in medicine relies on research that includes human participants. This is the case now and in the past. Indeed, the very next paragraph (paragraph 5) indicates this.

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	Even well-proven interventions should be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.	continually through research for their safety, effectiveness, efficiency, accessibility, and quality.'	<p>Importantly, what is lacking in this DoH revision is significant reflection on the role of data and digital tools in medical research within the evolving digital landscape. This is hard to comprehend in 2024. The DoH has not stayed abreast with significant and profound changes in medical research.</p> <p>The added sentence is part of paragraph 6 in the 2013 version: '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.'</p> <p>Note that 'must' has been replaced with 'should'. 'Must' was stronger and more appropriate.</p> <p>'for' should be replaced with 'into'</p>
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			<p>This second sentence has been absorbed into paragraph 5 of the 2024 version above.</p> <p>The first sentence has been absorbed into paragraph 7 of the 2024 version below.</p>

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proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.			
7. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights.	<p>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.</p> <p>Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed.</p> <p>Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers</p>	This paragraph is significantly revised in its meaning with the addition of new sentences.	<p>The WMA should have better reflected on this paragraph. All research populations are vulnerable. What is of importance is identifying the specific vulnerabilities involved in each research population for each research protocol.</p> <p>There is no need to differentiate between ‘physician’ and ‘researcher’. Indeed, the responsibility falls on all parties involved in the research, according to their specific roles and responsibilities [the underlying framework of Good Clinical Practice (GCP)].</p> <p>The last sentence is inappropriately placed. This is true for all research, not just research involving ‘vulnerable populations’.</p> <p>The word ‘Since’ should be replaced with ‘Because’ (time is not what is to be indicated here).</p> <p>There is a sense of ongoing colonialism and paternalism in these added sentences. It is unfortunate that these sentences were not better considered in today’s global context of medical research.</p>

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	<p>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.</p> <p>Medical research is subject to ethical standards that promote respect for all human participants and protect their health and rights. Some research populations are vulnerable and require special protection. The responsibility for the protection of research participants must always rest with the physician or researcher, and never with the participants, even when they have provided consent.</p>		

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<p>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).</p> <p>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.</p>	<p>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.</p> <p>These purposes can never take precedence over the rights and interests of individual research participants.</p>	<p>Addition of ‘to generate knowledge’.</p> <p>Addition of ‘and ultimately to advance individual and public health.’</p>	<p>‘to generate knowledge to understand the causes, . . . should be revised as ‘to generate knowledge regarding the causes’.</p> <p>The 2013 version was better written here.</p> <p>The following is a welcomed addition: ‘and ultimately to advance individual and public health.’</p> <p>For the last sentence, ‘and communities’ could have been added after ‘individual research participants’. The WMA failed to properly consider the relationship between individuals and communities/populations in the 2024 version (as well as in previous versions).</p>
	<p>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.</p>	<p>This is a new paragraph in the 2024 version.</p>	<p>This is the first time ‘public health emergencies’ are addressed in any of the DoH versions.</p> <p>Considering the role played by the WMA and its leadership during the Covid-19 pandemic, much more reflection is required on the role of physicians and their organizations during pandemics regarding medical research and the upholding of the DoH.</p>
<p>9. It is the duty of physicians who are</p>	<p>9. It is the duty of physicians who are</p>	<p>The ‘right to self-determination’ has</p>	<p>This is a strange and even non-sensical paragraph in both the 2013 and the 2024 versions: ‘to protect the life, health,</p>

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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.	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.	been replaced with 'autonomy'. 'health care professionals' has been replaced with 'researchers'	dignity . . . of personal information' makes no sense whatsoever. Again, this is a result of the unfortunate inclusion of the phrase 'including research on identifiable human material and data' in the 2000 version of the DoH and the failure of the WMA to remove this confusion in subsequent revisions and to properly address this in the Declaration of Taipei, revised in 2016 . 'physicians or other researchers' shows again the confusion around the WMA's remit (or lack of respect by the WMA for its remit). 'researchers' would suffice. More appropriately to the WMA, the DoH should be addressed to 'physicians as researchers or otherwise engaged with medical research'.
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	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	Significant revisions. Also specified is both 'where the research originated' and 'where is to be conducted'.	Again, the WMA wants to extend the DoH beyond its remit (see the comment above). 'where the research originated and where it is to be performed' is a strange turn of phrase and does not reflect how medical research is generally carried out today. Again, it hints at an ongoing disposition of colonialism and paternalism by physicians (the WMA) in research. More appropriate would have been to state 'in the locations of the included researchers and participants'. The WMA seems to suggest here that only applicable national and international norms and regulations need to be considered. No reference is given to local, national, or

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subjects set forth in this Declaration.	ethical, legal, or regulatory requirement should reduce or eliminate any of the protections for research participants set forth in this Declaration.		<p>regional norms and regulations, what often are of equal or greater importance.</p> <p>The term ‘consider’ here appears inappropriate. The WMA’s failure to require the upholding of other regulatory ethical, legal, and standards – while wanting to impose those of the WMA on everyone as required – gives pause for concern.</p> <p>Incredibly the WMA suggests that it is above the law and that its pronouncements – however appropriate, inappropriate, or confused – recognizes no higher body than itself as the sole rule maker and determiner for what is legally acceptable or not. A private organization where voting is determined within the organization on how much member organizations pay (tiered-voting rights), which regularly accepts money from the pharmaceutical industry, sets itself above democracy and the laws of nations. And, in doing so, it requires all of its member organizations and their members (individual physicians). This is itself unethical and disrespectful of its members and those its presumes to include in its private decisions.</p>
11. Medical research should be conducted in a manner that minimizes possible harm to the environment.	11. Medical research should be designed and conducted in a manner that avoids or minimizes harm to the environment and strives for environmental sustainability.	<p>Addition of ‘designed’.</p> <p>Addition of ‘avoids or’.</p> <p>Addition of ‘and strives for’.</p>	

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		environmental sustainability’.	
<p>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.</p>	<p>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.</p> <p>Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in research misconduct.</p>	<p>‘or other health care professional’ replaced with ‘or other researcher’.</p> <p>Addition of the sentence: ‘Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in research misconduct.’</p>	<p>The addition of the sentence on ‘scientific integrity’ should have been better considered. This sentence would be better placed in paragraph 2 above. It would have helped clarify the new addition to paragraph 2 while also helping to construct a better sentence than the one presented here.</p>
<p>13. Groups that are underrepresented in medical research should be provided</p>	<p>13. Groups that are underrepresented in medical research should be provided</p>	No changes.	<p>‘provided appropriate access’ is better written ‘provided with appropriate access’</p>

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appropriate access to participation in research.	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 study will not adversely affect the health of the patients who serve as research subjects.	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.	No changes	This paragraph is addressed only to physicians. However, it could equally apply to other healthcare workers. Why when the WMA goes outside its remit throughout the DoH does it then limit this paragraph to physicians.
15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.	15. Appropriate compensation and treatment for participants who are harmed as a result of participating in research must be ensured.	No significant change.	‘as a result of participating in’ was better written ‘as a result of their participation in’ Included here should have been ‘as a result of their participation in research or taking experimental medication’. Why did the WMA leave out the latter?
Risks, Burdens, and Benefits			
16. In medical practice and in medical research, most interventions involve risks	16. In medical practice and in medical research, most interventions involve risks	No significant changes.	This is the only place in the DoH where ‘medical practice’ is introduced. It appears out of place and inappropriate.

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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.	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 .		Further, it undermines the difference between ‘medical practice’ and ‘medical research’.
<p>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.</p> <p>Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.</p>	<p>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.</p> <p>Measures to minimize the risks and burdens must be implemented. The risks and burdens must be continuously monitored, assessed, and documented by the researcher.</p>	<p>No significant changes.</p> <p>One change from British to American spelling.</p>	<p>The ‘importance of the objective’ is vague. It does not align with other requirements of the DoH. This appears to allow for research that may violate dignity and rights based on objectives.</p> <p>Unfortunately, this paragraph leaves out other important conditions to be met.</p> <p>This paragraph was better deleted or more fully thought through.</p> <p>Medical research is seldom ‘continuously monitored’. This is also seldom required. Usually medical research is ‘continually monitored’.</p>

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<p>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.</p> <p>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.</p>	<p>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.</p> <p>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.</p>	<p>Addition of ‘and other researchers’.</p> <p>Addition of ‘and burdens’.</p>	<p>The addition of ‘and other burdens’ indicates just how limited this paragraph is for justifying research on human participants.</p> <p>The indication that ‘when there is conclusive proof of definitive outcomes’ would suggest that there is no continuation or modification of the research and it should be stopped immediately, unless (and this is important) the continuation of the research is to the benefit of those in the research.</p> <p>More importantly, ‘definite outcomes’ are rarely (if ever) reasons for stopping medical research. Most often, it is because the study is no long in scientific equipoise. Equipoise, however, is a concept the WMA has failed to understand and this failure leads to many of the shortcomings in the DoH, including in the 2024 version.</p>
<p>19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.</p> <p>All vulnerable groups and individuals should receive</p>	<p>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</p>	<p>Considerably rewritten.</p> <p>‘communities’ have been added to ‘groups and individuals’</p>	<p>In this paragraph, and in others, ‘groups and communities’ would have been better expressed as ‘specific research populations’.</p> <p>Importantly (and correctly), rather than seeing ‘individuals, groups, or communities as themselves vulnerable, they as seen as being ‘in situations of vulnerability’. See also paragraph 20 below.</p>

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specifically considered protection.	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.		<p>What the DoH fails to understand throughout is the specific vulnerability of human dignity and to take this into account separately from the vulnerability of situations.</p> <p>What is stated here is valid for all medical research and all populations that might benefit from a specific medical intervention in an experimental/research state.</p> <p>There is much more that comes into consideration here than ‘harms’. This paragraph appears inadequate and ill-considered for what it might hope to achieve.</p>
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 nonvulnerable group. In addition, this group should stand to benefit from the knowledge, practices or	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	<p>Substantially rewritten.</p> <p>‘vulnerable group’ replaced with ‘individual, groups, or communities in situations of particular vulnerability’</p>	<p>Paragraph 20 should clearly precede paragraph 19. However, paragraphs 20 and 19 should have been combined.</p> <p>A greater understanding of vulnerabilities in medical research would be needed to clarify these paragraphs individually or combined.</p>

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interventions that result from the research.	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 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	addition of ‘must have a scientifically sound and rigorous design and execution that are likely to produce reliable, valid, and valuable knowledge and avoid research waste’	‘of the scientific literature’ should be rewritten as ‘of the appropriate scientific literature’ ‘The welfare of animals’ should be rewritten as ‘The welfare of the animals’ ‘and avoid research waste’ appears oddly appended here

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	appropriate, animal experimentation. The welfare of animals used for research must be respected.		
<p>22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.</p> <p>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</p>	<p>22. The design and performance of all medical research involving human participants must be clearly described and justified in a research protocol.</p> <p>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</p>	<p>Considerable revision.</p> <p>‘sources of funding’ replaces ‘funding’</p> <p>‘methods, anticipated benefits and potential risks and burdens, qualifications of the researcher’ are added</p> <p>‘any potential conflicts of interest’ replaces ‘conflict of interest’</p> <p>‘provisions to protect privacy and confidentiality’ is added</p>	<p>Clearly this paragraph is influenced by the requirements for protocols in clinical trials (as becomes evident in the last paragraph and in later paragraphs here in the 2024 version). Not all medical research is designed or conducted in the same way as clinical trials. Much of what is suggested here (and elsewhere in the DoH) is confusing or simply inappropriate for other forms of medical research. This lack of a broad and inclusive view of medical research undermines the DoH.</p> <p>‘sources of funding’ replacing ‘funding’ suggests that the WMA does not consider it of importance or relevance that research participants are informed of the size of the funding (for example, the size of a payment to a researcher per participant enrolled).</p> <p>The listing has been extended but is still very much incomplete as the ‘and any other relevant aspects of the research suggests’. This is not a good way to write a guidance document.</p> <p>The revision of ‘appropriate arrangements for post-trial provisions’ to ‘any post-trial provisions’ seems to indicate that the rule maker wants to weaken the previous requirement and provide certain researchers or researcher organizations with less of a burden for their research. This</p>

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a consequence of participation in the research study. In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.	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.	‘and any other relevant aspects of the research’ is added ‘any post-trial provisions’ replaces ‘appropriate arrangements for post-trial provisions’	may be appropriate (it may also not be appropriate), but then why does the WMA have this privilege as a private organization while not allowing the same for lawmakers or official public bodies? It is not only in clinical trials where participants may want access to the interventions being studied.
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	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	Substantial changes and additions.	This revision is extremely poorly considered and presented. Not all ethics committees that review medical research are designed as ‘research ethics committees’. The use of this term reflects a certain understanding in a limited number of countries. ‘to resist undue influence from the researcher, the sponsor, or others’ appears curious. Why is there no mention of the ‘institution of the researcher or the funder’? ‘The committee must have sufficient familiarity with local circumstances and context’ is an absurd requirement. Ethics committees do (necessarily) know the local situation of where the research is carried out. This is true

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<p>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.</p> <p>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</p>	<p>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.</p> <p>When collaborative research is performed</p>		<p>for research reviewed carried out in a country outside of the one reviewing it and it is true also for many ethics committee even for research being carried out in their own country.</p> <p>‘[must] include at least one member of the general public’. Every member of every ethics committee is a member of the general public. What could possibly be meant by this requirement?</p> <p>‘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’ Again, no consideration for local, provincial, state, or regional ethical, legal, and regulatory norms and standards.</p> <p>And, again, ‘take into consideration’ for all others, but for the WMA the rules of their private institution surpass those of public authorities, lawmakers, and government agencies.</p> <p>The use of the terms ‘sponsoring and host countries’ is antiquated, vague, and inappropriate for medical research as it is today carried out. Again, it reflects a colonial and paternalistic approach from the WMA.</p> <p>‘the right to monitor’ ‘Rights’ are legal instruments. They can only be conferred by lawmakers, not by private institutions. More importantly, not all countries want or allow their ethics committees to monitor the research they review. And this for good reason.</p>

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summary of the study's findings and conclusions.	<p>internationally, the research protocol must be approved by research ethics committees in both the sponsoring and host countries.</p> <p>The committee must have the right to monitor, recommend changes to, withdraw approval for, and suspend ongoing research.</p> <p>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</p>		<p>Encouraging ethics committees to monitor medical research will eventually undermine ethics committees and lead to conflicts of interest and conflicts between parties that cannot be resolved. This requirement ('right') is ill considered.</p> <p>This entire paragraph indicates a poor understanding of the role of ethics committees and the ethical review requirements and process. It should not be used as a guide for the ethical review of medical research.</p>

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	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.	24. Every precaution must be taken to protect the privacy of research participants and the confidentiality of their personal information.	No significant change.	In paragraphs 19, 22, and 26, privacy and confidentiality are already adequately covered. Nothing is added here. This paragraph should have been deleted.
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 agrees.	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	Addition of the first sentence: ‘Free and informed consent is an essential component of respect for individual autonomy.’	‘Although it may be appropriate to consult family members or community representatives,’ It appears strange that ‘physicians or other healthcare professionals’ is not included in this clause, especially considering that this document comes from physicians. In medical research, would not invited participants very often want to first consult their physician? ‘freely agree’ is not the same as ‘freely consent’ Further, there is no consent if it is not freely given. This paragraph is not well considered.

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	research unless they freely agree.		
<p>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</p>	<p>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.</p> <p>The potential participant must be informed of the</p>	<p>Significantly revised.</p> <p>‘in plain language’ has been added</p> <p>The following has also been added: ‘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.’</p>	<p>Again, this DoH 2024 version provides too much and too little detail. The DoH seems incapable of remaining with principles and wanders repeatedly into incomplete and confusing rulemaking.</p> <p>In this already incomplete and inadequately expressed listing, one wonders why the WMA decided to remove ‘institutional affiliations of the researcher’. So much for transparency in consent.</p> <p>Again, stating that consent must be ‘freely given’ indicates a lack of understanding of the very essence of consent.</p> <p>The following sentence is completely confused and incapable of clear interpretation: ‘If the consent cannot be expressed on paper or electronically, then on written consent must be formally witnessed and documented.’ Should it be that the suggestion here is that for a research participant who cannot provide themselves written or electronic consent, then the consent provided must be written consent. If this is what was intended, then this too is absurd in 2024.</p>

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<p>as well as to the methods used to deliver the information.</p> <p>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.</p> <p>All medical research subjects should be given the option of being informed about the general outcome and results of the study.</p>	<p>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.</p> <p>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, then on written consent must be formally witnessed and documented.</p>	<p>'study' has been replaced by 'research'</p> <p>'and communication' has been added</p> <p>'institutional affiliations of the researcher' of the researcher has been deleted</p> <p>'documented . . . electronically' has been added.</p>	

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	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.	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.	The term ‘research study’ has been replaced with the term ‘research’. The word ‘completely’ has been removed.	Again, the WMA is intent on extending beyond its remit adding ‘or other researcher’. Does the WMA not understand that in every physician/patient relationship there is a dependent relationship, including when the patient is him/herself a physician? All relationships between a medical researcher and a research participant create a condition of dependency and, thus, vulnerability. This is at the core of medical research, and it is the essential reason for informed consent and ethics review in all medical research. It is impossible for consent to take place under duress. A situation of duress makes consent impossible. Here the term ‘appropriately qualified individual’ is used. It is a vague term and does not show agreement with ‘physician or other researcher’ as used throughout this 2024 version. The entire paragraph is written in the singular regarding the participant and the physician or other researcher, yet the pronoun ‘them’ is used. To whom does ‘them’ refer?

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<p>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.</p>	<p>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.</p> <p>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.</p>	<p>Considerable revision.</p> <p>A single change in spelling from British English to American English.</p> <p>‘free and’ has been added</p> <p>‘considering preferences and values expressed by the potential participant’ has been added.</p> <p>‘that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject’ has been removed.</p> <p>‘Those persons incapable of giving free and informed consent are in situations of</p>	<p>Again ‘free’ adds nothing to consent. Consent is, by definition, freely given. Adding ‘free’ only suggests (wrongly) that consent could be given ‘under duress’ (as above) or through coercion.</p> <p>This is a strange selection of considerations for those who cannot consent: ‘considering preferences and values expressed by the potential participant’. No reference to their decisions, wishes, or beliefs.</p> <p>Why does the WMA want to suggest that it is acceptable to include those who are incapable of giving consent in research when it has no benefit for them (or their health-related population – this has been deleted) and yet the research entails ‘minimal risk and minimal burden’.</p>

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		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' has been added.	
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.	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	'or other qualified individual' has been added. A single spelling change from British English to American English. 'considering any preferences and values expressed by the potential participant' added	Comments as above. 'give assent' should be 'assent' 'must seek that assent' should be 'must seek assent' One expects that if 'the potential participant's dissent should be respected' then that person will not be included in the research. This is likely not what is intended, but this is what is stated.

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	any preferences and values expressed by the potential participant. The potential participant's dissent should be respected.	as in the above paragraph 28.	
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	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	‘or other qualified individual’ added. ‘free and informed’ added to ‘consent’. ‘or, if they regain capacity to give consent, from the participant’ has been added.	‘research group’ should be replaced with ‘research population(s)’ Again, a plural pronoun ‘they’ has been used to represent a singular subject ‘participant’. ‘have been stated in the research protocol and the research has been approved by a research ethics committee’ This adds nothing to this paragraph as this is the case for all medical research as has been made clear in paragraphs 22 and 23 above. This entire paragraph is not needed. It has been said above. Paragraphs 28, 29, and 30 should be consolidated into a single short paragraph focused on principles.

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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.	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 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. 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.	'or other researcher' added. 'research' replaces 'study' (twice) 'or provision of the standard of care' added	'the research' in the first sentence should be changed to 'research'. The use of the term 'patient' here instead of 'participant' is not consistent. Even as a patient, individuals participate in research as a 'research participant', not as a 'patient'. The distinction is fundamental, and it is hoped that physicians would understand this. This shift to 'patients' also does not agree with the introduction into this paragraph of 'or other researcher'. The term 'patient' aligns with the term 'physician', not with the term 'researcher'. 'or provision of the standard of care' is not the first consideration for a patient refusing to participate in

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			research. It is not necessarily the ‘standard of care’ that is most appropriate for a specific patient. The standard of care may be appropriate for a particular patient, but it may also just as likely be inappropriate. This is an individual patient-by-patient decision that a physician is required to make outside of the research context.
<p>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.</p>	<p>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</p>	<p>Revised significantly.</p> <p>The term ‘human material’ is now here (only) replaced with ‘biological material’</p>	<p>The 2013 version specifies ‘identifiable human material or data’.</p> <p>‘Physicians or other qualified individuals must obtain free and informed consent from research participants’. This is incorrect. It is generally not the physicians or researchers that ‘seek’ or ‘obtain’ the consent of individuals to use their biological material or data. Consent for biological material or data is obtained in a wide array of situations and through many different actors and methods.</p> <p>The term ‘biological material’ is introduced in this paragraph. It does not align with the term ‘human material’ used in paragraph 1 of this 2024 version of the DoH.</p> <p>‘identifiable or re-identifiable data’ makes no sense.</p> <p>It is unclear why questions of biological material and data are handled in the DoH and not left to the WMA’s Declaration of Taipei. This only adds confusion and undermines both documents.</p> <p>‘A research ethics committee must approve the establishment and monitor ongoing use of such databases and biobanks.’ This sentence has no place in this</p>

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	<p>ethics committee must approve the establishment and monitor ongoing use of such databases and biobanks.</p> <p>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.</p>		<p>paragraph or document. ‘such databases and biobanks’ makes no sense as no databases or biobanks are previously mentioned.</p> <p>‘monitor ongoing use’ should be written as ‘monitor the ongoing use’ (grammar)</p> <p>In 2013, research without consent on human materials or data was to be considered only in ‘exceptional situations’. The term ‘exceptional situations’ has been removed.</p> <p>In general, the WMA has failed to consider developments in ‘health data spaces’ and more contemporary concerns regarding the use of human biological materials and data in medical research. This paragraph ignores existing practices and regulations, including the US Common Rule. (And then sets itself above these practices and laws.)</p> <p>By directly referring to ‘requirements set forth in the WMA Declaration of Taipei’ here, the WMA also wants to establish the Declaration of Taipei as being above/beyond the law, beyond democratic and rule by government principals.</p>
Use of Placebos			
33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in	33. The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in	<p>‘Where’ is replaced by ‘If’ (twice)</p> <p>‘less effective than the best proven one’ is replaced by</p>	Since the introduction of the term ‘placebo’ in 1996, the WMA has failed to provide a scientifically sound or ethically founded resolution to the question of the role and appropriate use of placebos in clinical trials.

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<p>the following circumstances:</p> <p>Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or</p> <p>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.</p> <p>Extreme care must be taken to avoid abuse of this option.</p>	<p>the following circumstances:</p> <p>If no proven intervention exists, the use of placebo, or no intervention, is acceptable; or</p> <p>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.</p> <p>Extreme care must be taken to avoid abuse of this option.</p>	<p>‘other than the best proven one(s)’</p>	<p>There is no significant change in the 2024 version, restating that use is permitted when there is no proven intervention or when there are compelling sound methodological scientific reasons. Note that the first exception is already part of the second. Thus, only ‘compelling scientific sound methodological reasons’ is the standard proposed. And, indeed, ‘sound methodological’ does not add to ‘compelling scientific reasons’. Clearly the WMA is not clear itself about what it is putting forth.</p> <p>This paragraph does not improve the confusion the WMA has brought to this topic because of its own failure to understand the fundamental role of controls in clinical trials.</p> <p>This failure in understanding the scientific method also leads to a failure in the understanding of the role of clinical trials in medicine and society as a whole.</p> <p>The long discussion around the use of terms like ‘standard of care’ and ‘best proven intervention’ neglect both the specific patient’s or research participant’s interest and the requirements of sound medical research involving human participants.</p> <p>The position expressed here in this 2024 revision (if indeed one can call this a position), hardly reflects anything near a consensus or even an allaying of the confusion the WMA introduced itself.</p> <p>This statement appears entirely inappropriate: ‘Extreme care must be taken to avoid abuse of this option.’ This</p>

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Paragraph 2013 version	Paragraph 2024 version	Wording changes	Preliminary commentary
			suggests that the WMA is proposing a requirement that is easily abused – perhaps because the requirement is itself not clearly understood and articulated.
<p>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.</p>	<p>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.</p>	<p>‘should make provisions’ has been replaced by ‘must be arranged’</p> <p>‘clinical trial, sponsors, researchers and host country governments’ has been replaced with ‘sponsors and researchers to be provided by themselves, healthcare systems, or governments’</p> <p>‘Exceptions to this requirement must be approved by a research ethics committee.’</p>	<p>One wonders how well the WMA understands clinical trials and the value of their outcomes. Individual clinical trials seldom, if ever, on their own bring outcomes that demonstrate ‘an intervention [is] identified as beneficial and reasonably safe’. Further, delivering experimental interventions to research participants (or other populations) prior to regulatory approval would not only be in many cases seen as reckless and unlawful, but would also potentially bring (former) research participants into high-risk situations.</p> <p>The WMA should also consider that the outcomes of clinical trials are rarely known within a short time of the ending of a clinical trial.</p> <p>Somehow the WMA now asserts that a research ethics committee can approve ‘exceptions to this requirement’ (solely a WMA requirement), but nowhere else can a research ethics committee approve exceptions to the rulemaking of the WMA. Clearly, if the subject of this paragraph was well understood and the principle well articulated, no exception would be needed.</p>

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Research Registration and Publication and Dissemination of Results			
<p>35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.</p>	<p>35. Medical research involving human participants must be registered in a publicly accessible database before recruitment of the first participant.</p>	<p>‘study’ replaced by ‘medical research’</p>	<p>The registration of a study is a requirement for clinical trials that is now widely accepted. However, medical research involves many more kinds of studies and methodologies than those of clinical trials. There is no widely accepted practice of registering on ‘publicly acceptable database’ surveys, interviews, focused discussions, and many other methodologies of medical research. Has the WMA consulted with the full breadth of medical researchers prior to introducing this requirement on its own?</p>
<p>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</p>	<p>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</p>	<p>‘timeliness’ has been added ‘inconclusive results’ has been added</p>	<p>This paragraph is vague and lacks precision and clarity.</p> <p>Why have regulators and regulatory bodies not been included in this obligation to report the information they receive?</p> <p>The WMA here intends now to not only bind the entire medical research field (including researchers and their institutions) to this ‘declaration’ without mandate and beyond its remit, but also ‘authors, editors, and publishers’.</p> <p>Do ‘researchers, authors, sponsors, editors, and publishers all’ feel confident that this document, this 2024 version of the DoH, from a private organization provides sufficient scientific and ethical clarity that they should impose it upon</p>

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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.	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.		themselves to be wholly and without exception followed?
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 authorised 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	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	Substantially revised. 'made publicly available' has been removed. The following has been added: 'Physicians participating in such interventions must first seek expert advice, weigh possible risks, burdens, and benefits, and obtain	This paragraph appears inappropriate here in a document that presumes to address 'medical research'. The provision of an 'unproven' (or 'experimental') interventions outside of a research protocol (thus, as a treatment and not part of research) is not research. Physicians should understand the difference between clinical care and research. It is not the case that every unproven treatment given to an individual patient should necessarily then be made the object of a clinical trial. Once again, and in closing, the WMA finds a need to assert the importance it gives to its DoH. One would think that in these cases, the research participant would prefer the full protection of

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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.	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.	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.'	ethics, human rights, and the law (and not just 'consideration' for what lies outside the DoH). After closely considering this 2024 revision of the DoH does the scientific community find a sufficiently well-considered, ethically and scientifically robust supported by a well-written and clearly presented standard that should be imposed outside of the private organization and its members who have arrived at this outcome?
Copyright			
Disclaimer: ©2013World Medical Association, Inc. All Rights Reserved. All intellectual property rights in the Declaration of Helsinki are vested in the World Medical Association. The WMA has granted JAMA exclusive rights to publish the English-language version of the	Disclaimer: ©2024 World Medical Association. All Rights Reserved. All intellectual property rights in the Declaration of Helsinki are vested in the World Medical Association. The WMA has granted JAMA exclusive rights to publish the English-language version of the	'Inc.' has been removed from the name of the World Medical Association (WMA). Same claim to 'all intellectual property rights'. Same granting of exclusive rights to	Why has 'Inc.' been removed in the 2024 version of the DoH, which is part of the legal designation of the World Medical Association, an association incorporated in the state of Delaware in the United States since 1984? Since 1974 the WMA has been located in Ferney-Voltaire in France. Prior to that between 1954 and 1984 the WMA was incorporated in New York. The WMA was founded in 1947 in Paris with 27 members and moved in 1948 to New York City. Between 1947 and 1954 it was not a legal entity.

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Declaration through December 31, 2013.	Declaration through December 31, 2024.	publish to the <i>Journal of the American Medical Association</i> (JAMA), the official journal of the American Medical Association (AMA).	When claiming that the DoH principles should be upheld by every person engaged in medical research globally, why does the WMA the DoH? Versions prior to 2013 claimed no such copyright. How is it that this is even needed? And, if the WMA has significant reason to copyright the could have been done through a Creative Commons or similar procedure. According to the JAMA copyright, if I am an African physician and I ask only to e-mail a copy of the 2024 DoH, I receive this response: ‘Thank you for your request to republish AMA copyrighted journal content. Unfortunately, the publisher does not grant permission for the reproduction of full-text articles in the type of project you are proposing. Please contact the AMA's Reprint Sales Office directly for more information about ordering full-text article content.’ See here . So all of the people who contributed hours of their time to comment on the DoH, who spent their own money to go to 2.5 years of meetings, now are not allowed to (or need to pay?) the AMA (not the WMA) to e-mail the DoH. Hardly a document in the global domain. Hardly ethical. (Significantly, this 2024 DoH revision was led by the President of the AMA.)
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B. A summary of the key revision points found in the 2024 version of the Declaration of Helsinki

Below are nine key points briefly summarizing some of the major changes in the 2024 revision of the Declaration of Helsinki (DoH).

1. **Expanded claim of authority:** The 2024 revision continues an ongoing attempt by the WMA since 2013 to extend the DoH beyond just physicians to all researchers, research teams, institutions, authors, editors, and publishers involved in medical research. While the WMA may seek to see a more cohesive and universally applicable ethical framework across all types of medical research participants, it should be aware of the limitations of its remit. The WMA's attempt to expand its remit, invoke a mandate, did not bode well for the DoH since 2013. The 1964 version of the DoH contained the following statement: 'The World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world.' In 2006 this statement had to evolve to read as follows: 'the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world.' No attempt was made by the WMA to impose its ruling beyond physicians. (However, one should note that not all physicians or organizations of physicians were or are members of the WMA. The WMA has always tended to go beyond its remit and even those included in its consultation.) Between 1964 and 2006, the principles were considered by the WMA in the DoH as 'recommendations' and 'a guide to physicians'. In 2013 the terms 'recommendations' and 'a guide to physicians' disappear and are replaced with 'encouraged' in 2013 and 'should' in 2024. This may limit the DoH's original intent and cause confusion about the WMA's role in setting ethical standards beyond physicians. In ethics it is always better to claim less, rather than more. Most importantly, each institution should be mindful of its role and place in society, respecting that of others.
2. **From principles to rulemaking:** The DoH still claims today in its title to be a presentation of 'ethical principles'. The first version of the DoH in 1964 indeed made a serious attempt to provide only principles. Since 1975 the WMA has entered into the business of expanding from 'principles' to 'procedures' or 'rulemaking'. Each version increases the length of explanations, often explanations that do more to engender confusion than clarity, and where few principles are discernible. The word count has risen from 572 words to 2889 words. Today the DoH fails both as a statement of principles and as a guideline.
3. **Terminology shift:** The 2024 version replaces the term 'subjects' with 'participants', now hailed in 2024 as a significant shift toward greater respect and acknowledgment of autonomy. The first version of the [DoH in 1964](#) designated what are now termed 'subjects'/'participants' as 'human beings'. Has the DoH really improved its view on those who are the subjects of human experimentation? Does this shift in terminology represent any serious improvement in 'patient rights' ('rights' being a term that the WMA has not the authority to either dispute or impose as this is a legal term that applies in the context of law or institutions with a legitimate mandate to make law).
4. **Public health:** The 2024 version addresses the need for research to address public health and well-being, which extends the previous focus of the DoH on individuals (with some reference to 'groups'). This reflects the growing importance of public health research, especially

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considering global health crises like the COVID-19 pandemic, the Ebola epidemic, and Mpox. While medical research has traditionally focused on individual patient outcomes, this addition broadens the framework to include the societal implications of research findings. The reference to public health acknowledges the collective responsibility to ensure that medical research contributes to the overall well-being of populations. It also suggests that research must balance individual interests with broader societal benefits, a concept that has become critical as global health challenges demand more cooperative and holistic solutions.

5. **Public health emergencies:** For the first time, the 2024 version includes guidelines on handling research during public health emergencies, highlighting the importance of upholding ethical standards even in times of crisis. This addition likely stems from the ethical challenges encountered during the COVID-19 pandemic, where the urgency of research at times appears to conflict with ethical best practices. By explicitly addressing these scenarios, the DoH stresses that public health emergencies do not justify compromising ethical principles. It suggests that while expediency is necessary in crises, participant rights and safety must remain a priority. Moreover, the inclusion of this provision reflects a recognition that emergency situations are likely to become more frequent, necessitating clear ethical guidelines to navigate these complex scenarios responsibly. The addition may be inadequate as it fails to fully address the ethical challenges that arise when the urgency of public health emergencies conflicts with ethics.
6. **Research integrity:** The introduction of research integrity and transparency is a response to growing concerns about unethical practices in medical research. The DoH emphasizes the importance of ensuring that research is conducted ethically from start to finish, safeguarding participants' rights while promoting transparency in research design and reporting. This is particularly important given the increasing complexity of clinical trials and the greater reliance on digital and data-driven research methods. The added emphasis on ensuring transparency in funding, conflicts of interest, and data use reflects broader trends in ethical governance, aimed at reducing the risk of bias and improving the credibility of research outcomes. This also signals the WMA's commitment to keeping pace with evolving standards of Good Clinical Practice (GCP) and scientific integrity in a rapidly changing research environment.
7. **Informed consent:** The 2024 revision increases the discussion on 'free and informed consent', reinforcing the autonomy of participants and ensuring that they are fully aware of their role in research. This is intended to assist participants in making educated decisions, particularly in vulnerable populations. The WMA here address concerns about coercion or exploitation in medical research. Additionally, the document emphasizes that informed consent must be adapted to the specific needs of each participant, indicating a shift toward more personalized consent processes. This ensures that participants' decisions are respected at every stage of research and that they remain fully informed, even in complex or high-risk studies. Although the DoH now uses the term 'electronically' for consent, it fails to consider the evolving complexities of consent in the digital age.
8. **Use of placebos:** The 2024 version addresses again the question of the use of placebos [in clinical trials]. There is no significant change, restating that use is no proven intervention or when there are compelling scientific reasons. The inclusion of phrases like 'extreme care must be taken to avoid abuse of this option' appears to indicate that this DoH principle (?) prone to misuse, perhaps precisely because it is an

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incorrect understanding of the methodology of controlled trials while also reflecting the WMA's failure to resolve the ethical debate around placebo-controlled trials.

9. **Post-trial provisions:** The 2024 version requires ensuring post-trial provisions for participants who may benefit from the research interventions. The attempt to require such post-trial responsibilities fails to understand the role of individual clinical trials in medical research. This requirement may also have an adverse effect on the participation of certain populations in clinical research where meeting this requirement would not be achievable and where an ethics committee was not willing to make an exception.
10. **Environmental considerations:** The 2024 version introduces a requirement for medical research to minimize environmental harm and strive for sustainability. This reflects growing awareness of the environmental impact of medical research. The inclusion of environmental considerations aligns with the global movement toward sustainability in all sectors, acknowledging that medical research cannot be isolated from these broader concerns. This change also signals a shift in how research ethics are conceptualized, expanding beyond human and animal welfare to include environmental stewardship. The DoH does not provide any mechanism for evaluating or enforcing environmental standards in research, making this addition more aspirational than actionable. The inclusion of environmental sustainability appears more like a superficial acknowledgment of a growing concern rather than a fully integrated ethical principle.

While there appears to be near universal praise for this two-and-a-half-year revision process and its outcome, a closer reading of the 2024 version of the DoH suggests that the most significant controversies around the 2013 version (placebo and post-trial access) are fundamentally unchanged. The more 'clarification' added on issues around consent, vulnerability, and research ethics committees, the more confusion has been introduced and the less applicable the DoH has become. The attempt of the WMA to expand its remit/mandate beyond its member organizations and their membership is fundamentally wrong and unethical. Significantly, the DoH has lost its focus on principles and transformed itself into an incomplete guideline that cannot be fully followed and in places should not be followed.