# WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
## Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008

**WMA Declaration of Helsinki Working Group**
**Draft revised text for public consultation, 15 April – 15 June 2013**

**Annotated version**

| | | **Comentários** |
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| | **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.<br><br>The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs. | Anterior parágrafo 1. Sem alterações. |
| 2 | ~~Although~~ **Consistent with the mandate of the WMA,** the Declaration is addressed primarily to physicians~~.~~**.** **T**~~t~~he WMA encourages other participants in medical research involving human subjects to adopt these principles. | Anterior parágrafo 2.<br>Clarificação da razão pela qual a Declaração é primariamente dirigida aos médicos. |
| | **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." | Anterior parágrafo 4. Sem alterações. |
| 4 | It is the duty of the physician to promote and safeguard the health **and well-being** of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty. | Anterior parágrafo 3.<br><br>Alargamento do dever dos médicos. |
| 5 | Medical progress is based on research that ultimately must include studies involving human subjects. | Anterior parágrafo 5 separado em duas partes, sendo esta a primeira parte. A segunda parte está no parágrafo 13. |

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| 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 current **proven** interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality. | Anterior parágrafo 7.<br>Alteração feita com vista à consistência terminológica do documento. |
| 7 | Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. | Anterior parágrafo 9, dividido em duas partes, sendo esta a primeira parte. A segunda parte do antigo parágrafo 9 está, agora, no parágrafo 19. |
| 8 | In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests. | Anterior parágrafo 6.<br>Reconhece-se a existência de uma inconsistência interna no documento. Este parágrafo tem, assim, uma patente intenção programática. |
| 9 | It is the duty of physicians who participate 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. | A primeira frase é o anterior parágrafo 11.<br><br>A última frase é retirada da última parte do anterior parágrafo 16. A primeira parte do anterior parágrafo 16 é agora o parágrafo 12. |
| 10 | Physicians ~~should~~ **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. | Anterior parágrafo 10.<br><br>"Deveriam" foi alterado para "têm de" por forma a reforçar a obrigação do médico nos seus deveres. |
| 11 | Appropriate caution must be exercised in the conduct of medical research that may harm the environment. | Anterior parágrafo 13. Sem alterações. |
| 12 | Medical research involving human subjects must be conducted only by individuals with the appropriate 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. | Introduzido o termo "educação" na primeira parte do anterior parágrafo 16.<br><br>A segunda parte do anterior parágrafo 16 passou para o parágrafo 9. |
| 13 | Populations that are underrepresented in medical research should be provided appropriate access to participation in research. | Do anterior parágrafo 5, segunda frase. Sem alterações. A primeira parte do anterior parágrafo 5 é agora o novo parágrafo 5. |
| 14 | The physician may combine medical research with medical care only to the extent that the research 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. | Anterior parágrafo 31. Sem alterações. |

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| 15 | **Adequate compensation and treatment for subjects who are harmed as a result of participating in the research must be ensured.** | Novo parágrafo. Reflete-se, agora, a obrigação de assegurar que indivíduos que sejam prejudicados receberão compensação e tratamento. |
| | **Risks, Burdens and Benefits** | |
| 16 | In medical practice and in medical research, most interventions involve risks and burdens.<br><br>Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects. | A redação proposta combina dois anteriores parágrafos (os antigos parágrafos 8 e 21). Sem alterações. |
| 17 | Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.<br><br>**Measures to minimise the risks must be implemented. The risks must always be monitored by the researcher throughout the trial.** | Anterior parágrafo 18. Sem alterações.<br><br>A segunda parte é nova. Aborda a questão da minimização do risco e monitorização durante o ensaio. |
| 18 | Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results. | Anterior parágrafo 20. Sem alterações. |
| | **Vulnerable Populations** | |
| 19 | Some research populations are particularly vulnerable and ~~need special protection~~ **have an increased likelihood of incurring additional and greater harm.** These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence. **All vulnerable groups need specifically considered protection.** | Corresponde à segunda parte do anterior parágrafo 9. Primeira parte do anterior parágrafo 9 faz agora parte do parágrafo 7. |
| 20 | Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community **and the research cannot be carried out in a non-vulnerable population. In addition,** ~~and if there is a reasonable likelihood that~~ this population or community **should** stand~~s~~ to benefit from the **knowledge, practices or interventions that result from the** ~~results of the research.~~<br><br>**Consideration should also be given to ensuring that the community receives a fair level of additional benefits.** | Anterior parágrafo 17.<br><br>Articula benefício justo e abordagens a benefícios razoáveis. Integra vários princípios importantes respeitantes às populações vulneráveis. |
| | **Scientific Requirements and Research Protocols** | |

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| 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. | Anterior parágrafo 12. Sem alterações. |
| 22 | The design and performance of each research study involving human subjects must be clearly described in a research protocol. **The research protocol should discuss and justify the chosen study design.**<br><br>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, other potential conflicts of interest, incentives for subjects and **information regarding** provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol ~~should~~ **must** describe arrangements for post-study access by study subjects to interventions identified as beneficial in the to study ~~or access other appropriate care or benefits.~~ | Anterior parágrafo 14.<br><br>Esclarecimento editorial.<br><br>Esclarece a obrigação de incluir esta informação no protocolo do ensaio. |
| | **Research Ethics Committees** | |
| 23 | The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must **be transparent in its functioning, must** be independent of the researcher, the sponsor and anyother 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.<br>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 change to the protocol may be made without consideration and approval by the committee. **At the end of the study, the investigators must submit a final report to the committee containing a summary of the study's findings and conclusions.** | Anterior parágrafo 15.<br><br>Adita a questão da transparência das Comissões de Ética.<br><br>A questão da qualificação das Comissões de Ética e dos seus membros é agora abordada.<br><br>Clarifica o que deverá ocorrer no final do ensaio. |
| | **Privacy and Confidentiality** | |
| 24 | Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity. | Anterior parágrafo 23. Sem alterações. |
| | **Informed Consent** | |

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| 25 | Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees. | Anterior parágrafo 22. Sem alterações.<br><br>Comentário da OM: A redação deste parágrafo carece, em nosso entender, de uma adenda que se articula com a questão suscitada no parágrafo 33. Com efeito, nos ensaios em que esteja envolvido o uso de placebo, releva de forma determinante o reforço da informação a fornecer para as diferentes situações. O consentimento só pode ser obtido com uma informação especificada sobre as distintas implicações que cada grupo de participantes possa ter. Por outro lado, não se encontra nos parágrafos sobre consentimento informado do texto em apreço qualquer referência explícita à especificidade da informação do consentimento no uso do placebo. Para que os participantes aceitem efetivamente os níveis de risco envolvidos num ensaio a informação e a garantia da sua compreensão são prioridades absolutas.<br><br>Propõe-se, assim, a seguinte adenda ao texto: When the research involves the use of a placebo or other control different from the best proven current intervention, potential subjects must be informed of the implications for participants assigned to each of the different study arms, including the risks of not receiving a known effective intervention. |
| 26 | In medical research involving competent human subjects, 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-trial access** and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed. | Anterior parágrafo 24. |
| 27 | When seeking informed consent for participation in a research study the physician should 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 should be sought by an appropriately qualified individual who is completely independent of this relationship. | Anterior parágrafo 26. Sem alterações. |

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| 28 | For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized 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 population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden. | Anterior parágrafo 27. Sem alterações. |
| 29 | When a potential research subject who is deemed incompetent 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 authorized representative. The potential subject's dissent should be respected. | Anterior parágrafo 28. Sem alterações. |
| 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 population. In such circumstances the physician should seek informed consent from the legally authorized 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 should be obtained as soon as possible from the subject or a legally authorized representative. | Anterior parágrafo 29. Sem alterações. |
| 31 | The physician must fully inform the patient which aspects of the 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 interfere with the patient-physician relationship. | Anterior parágrafo 34. Sem alterações. |
| 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 normally seek consent for ~~the~~ **its** ~~collection,~~ analysis, storage and/or reuse. There may be **exceptional** situations where consent would be impossible or **impracticable** ~~impractical~~ to obtain for threat to the the such research or would pose avalidity of research. In such situations the research may be done only after consideration and approval of a research ethics committee. | Anterior parágrafo 25. |
| | **Use of Placebo** | |

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| 33 | The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best ~~current~~ proven intervention**(s),** except in the following circumstances:<br><br>The use of placebo~~,~~ or no ~~treatment~~ **intervention** is acceptable in studies where no current proven intervention exists; or<br>Where for compelling and scientifically sound methodological reasons the use of **any intervention less effective than the best proven one,** placebo **or no treatment** 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 treatment will not be subject to ~~any~~ **additional** risk**s** of serious or irreversible harm **as a result of not receiving the best proven intervention.**<br><br>Extreme care must be taken to avoid abuse of this option. | Anterior parágrafo 32.<br><br>Comentário: Entendemos que, no sentido de proteger os participantes nos ensaios clínicos, os critérios para o uso do placebo devem ser claramente reforçados e explicitados. Com efeito, é muito difícil aceitar o uso de placebos quando existem terapias alternativas que já demonstraram ser úteis. Deste modo, defendemos que só é possível a utilização do placebo quando se verifiquem critérios muito restritos que visam assegurar que os riscos para a saúde, vida e bem estar dos participantes no ensaio são equivalentes entre os diversos grupos intervenientes.<br><br>Propõe-se, assim, a seguinte alteração:<br><br>Where for compelling and scientifically sound methodological reasons the use of **any intervention less effective than the best proven one,** placebo **or no treatment** 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 treatment will not be substantially more likely than those in the active-treatment group to die; to have irreversible morbidity or disability; to suffer reversible but serious harm; or to experience severe discomfort as a result of not receiving the best proven intervention. |
| | **Post-Trial Access** | |
| 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 study. This information should also be disclosed to participants during the informed consent process. All study participants should be informed about the outcome of the study.**<br><br>~~At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.~~ | Anterior parágrafo 33.<br>Clarifica e reforça as questões relacionadas com o acesso pós-ensaio. |
| | **Trial Registration and Publication of Results** | |
| 35 | Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject. | Anterior parágrafo 19. Sem alterações. |

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| 36 | **Researchers,** ~~A~~**a**uthors, **sponsors,** editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors 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. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication. | Anterior parágrafo 30.<br><br>Acrescenta os investigadores e os patrocinadores a todos aqueles que têm obrigações éticas. |
| | **Unproven Interventions** | |
| 37 | In the treatment of a**n individual** patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. ~~Where possible, t~~**T**his intervention should **subsequently** be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available. | Anterior parágrafo 35.<br><br>As modificações propostas pretendem clarificar os objetivos deste parágrafo.<br><br>Reforça os requisitos para tornar a intervenção objeto de ensaio subsequente. |