赫尔辛基宣言中英文对照版（2013 年版）
WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

《赫尔辛基宣言》全称《世界医学协会赫尔辛基宣言》，该宣言制定了涉及人体对象医学研究的道德原则， 是一份包括以人作为受试对象的生物医学研究的伦理原则和限制条件，也是关于人体试验的第二个国际文件，比《纽伦堡法典》更加全面、具体和完善。

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the:

赫尔辛基宣言在第 18 届世界医学协会联合大会(赫尔辛基，芬兰，1964 年 6 月)采用，并在下列联合大会中进行了修订：

29th WMA General Assembly, Tokyo, Japan, October 1975

第 29 届世界医学协会联合大会，东京，日本，1975 年 10 月

35th WMA General Assembly, Venice, Italy, October 1983

第 35 届世界医学协会联合大会，威尼斯，意大利，1983 年 10 月

41st WMA General Assembly, Hong Kong, September 1989

第 41 届世界医学协会联合大会，香港，1989 年 9 月

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

第 48 届世界医学协会联合大会，西索莫塞特(Somerset West)，南非，1996 年 10 月

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

第 52 届世界医学协会联合大会，爱丁堡，苏格兰，2000 年 10 月

53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)

第 53 届世界医学协会联合大会，华盛顿，美国，2002 年

55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)

第 55 届世界医学协会联合大会，东京，日本，2004 年

59th WMA General Assembly, Seoul, Republic of Korea, October 2008

第 59 届世界医学协会联合大会，首尔，韩国，2008 年 10 月

64th WMA General Assembly, Fortaleza, Brazil, October 2013

第 64 届世界医学会联合大会，巴西福塔雷萨，2013 年 10 月

Preamble

前言

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.

1、世界医学会(WMA)制定《赫尔辛基宣言》，是作为关于涉及人类受试者的医学研究，包括对可确定的人体材料和数据的研究，有关伦理原则的一项声明。

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.

《宣言》应整体阅读，其每一段落应在顾及所有其他相关段落的情况下方可运用。

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、与世界医学会的授权一致，《宣言》主要针对医生。但世界医学会鼓励其他参与涉及人类受试者的医学研究的人员采纳这些原则。

General Principles

一般原则

3. The Declaration of Geneva of the WMA binds the physician with the words,

3、世界医学会的《日内瓦宣言》用下列词语约束医生:

“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.”

“我患者的健康是我最首先要考虑的。”《国际医学伦理标准》宣告:“医生在提供医护时应从患者的最佳利益出发。”

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、促进和保护患者的健康，包括那些参与医学研究的患者，是医生的责任。医生的知识和良心应奉献于实现这一责任的过程。

5. Medical progress is based on research that ultimately must include studies involving human subjects.

5、医学的进步是以研究为基础的，这些研究必然包含了涉及人类受试者的研究。

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

6、涉及人类受试者的医学研究，其基本目的是了解疾病的起因、发展和影响，并改进预防、诊断和治疗干预措施(方法、操作和治疗)。即使对当前最佳干预措施也必须通过研究，不断对其安全性、效果、效率、可及性和质量进行评估。

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

7、医学研究应符合的伦理标准是，促进并确保对所有人类受试者的尊重，并保护他们的健康

和权利。

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.

8、若医学研究的根本目的是为产生新的知识，则此目的不能凌驾于受试者个体的权利和利益之上。

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

9、参与医学研究的医生有责任保护受试者的生命、健康、尊严、公正、自主决定权、隐私和个人信息。保护受试者的责任必须由医生或其他卫生保健专业人员承担，决不能由受试者本人承担，即使他们给予同意的承诺。

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

10、医生在开展涉及人类受试者的研究时，必须考虑本国伦理、法律、法规所制定的规范和标准，以及适用的国际规范和标准。本《宣言》所阐述的任何一项受试者保护条款，都不能在国内或国际伦理、法律、法规所制定的规范和标准中被削减或删除。

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

11、医学研究应在尽量减少环境损害的情况下进行。

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.

12、涉及人类受试者的医学研究必须由受过适当伦理和科学培训，且具备资质的人员来开展。对患者或健康志愿者的研究要求由一名能胜任的并具备资质的医生或卫生保健专业人员负责监督管理。

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

13、应为那些在医学研究中没有被充分代表的群体提供适当的机会，使他们能够参与到研究之中。

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、当医生将医学研究与临床医疗相结合时，只可让其患者作为研究受试者参加那些于潜在预防、诊断或治疗价值而言是公正的，并有充分理由相信参与研究不会对患者健康带来负面影响的研究。

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

15、必须确保因参与研究而受伤害的受试者得到适当的补偿和治疗。

Risks, Burdens and Benefits

风险、负担和获益

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

16、在医学实践和医学研究中，绝大多数干预措施具有风险，并有可能造成负担。

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

只有在研究目的的重要性高于受试者的风险和负担的情况下，涉及人类受试者的医学研究才可以开展。

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.

17、所有涉及人类受试者的医学研究项目在开展前，必须认真评估该研究对个人和群体造成的可预见的风险和负担，并比较该研究为他们或其他受影响的个人或群体带来的可预见的益处。

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

必须考量如何将风险最小化。研究者必须对风险进行持续监控、评估和记录。

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.

18、只有在确认对研究相关风险已做过充分的评估并能进行令人满意的管理时，医生才可以参与到涉及人类受试者的医学研究之中。

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.

当发现研究的风险大于潜在的获益，或已有决定性的证据证明研究已获得明确的结果时，医生必须评估是继续、修改还是立即结束研究。

Vulnerable Groups and Individuals

弱势的群体和个人

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

19、有些群体和个人特别脆弱，更容易受到胁迫或者额外的伤害。

All vulnerable groups and individuals should receive specifically considered protection.

所有弱势的群体和个人都需要得到特别的保护。

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

20、仅当研究是出于弱势人群的健康需求或卫生工作需要，同时又无法在非弱势人群中开展时，涉及这些弱势人群的医学研究才是正当的。此外，应该保证这些人群从研究结果，包括知识、实践和干预中获益。

Scientific Requirements and Research Protocols

科学要求和研究方案

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.

21、涉及人类受试者的医学研究必须符合普遍认可的科学原则，这应基于对科学文献、其他相关信息、足够的实验和适宜的动物研究信息的充分了解。实验动物的福利应给予尊重。

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

22、每个涉及人类受试者的研究项目的设计和操作都必须在研究方案中有明确的描述。

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

研究方案应包括与方案相关的伦理考量的表述，应表明本《宣言》中的原则是如何得到体现的。研究方案应包括有关资金来源、申办方、隶属机构、潜在利益冲突、对受试者的诱导，以及对因参与研究而造成的伤害所提供的治疗和/或补偿条款等。

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

临床试验中，研究方案还必须描述试验后如何给予适当的安排。

Research Ethics Committees

研究伦理委员会

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

23、研究开始前，研究方案必须提交给相关研究伦理委员会进行考量、评估、指导和批准。该委员会必须透明运作，必须独立于研究者、申办方及其他任何不当影响之外，并且必须有正式资质。该委员会必须考虑到本国或研究项目开展各国的法律、法规，以及适用的国际规范和标准，但是本《宣言》为受试者所制定的保护条款决不允许被削减或删除。

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

该委员会必须有权监督研究的开展，研究者必须向其提供监督的信息，特别是关于严重不良事件的信息。未经该委员会的审查和批准，不可对研究方案进行修改。研究结束后，研究者必须向委员会提交结题报告，包括对研究发现和结论的总结。

Privacy and Confidentiality

隐私和保密

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

24、必须采取一切措施保护受试者的隐私并对个人信息进行保密。

Informed Consent

知情同意

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、个人以受试者身份参与医学研究必须是自愿的。尽管与家人或社区负责人进行商议可能是恰当的，但是除非有知情同意能力的个人自由地表达同意，不然他/她不能被招募进入研究项目。

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

26、涉及人类受试者的医学研究，每位潜在受试者必须得到足够的信息，包括研究目的、方法、资金来源、任何可能的利益冲突、研究者组织隶属、预期获益和潜在风险、研究可能造成的不适等任何与研究相关的信息。受试者必须被告知其拥有拒绝参加研究的权利，以及在任何时候收回同意退出研究而不被报复的权利。特别应注意为受试者个人提供他们所需要的具体信息，以及提供信息的方法。

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.

在确保受试者理解相关信息后，医生或其他合适的、有资质的人应该设法获得受试者自由表达的知情同意，最好以书面形式。如果同意不能以书面形式表达，那么非书面的同意必须进行正式记录并有证明人在场。

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

必须向所有医学研究的受试者提供获得研究预计结果相关信息的选择权。

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、如果潜在受试者与医生有依赖关系，或有被迫表示同意的可能，在设法获得其参与研究项目的知情同意时，医生必须特别谨慎。在这种情况下，知情同意必须由一位合适的、有资质的、且完全独立于这种关系之外的人来获取。

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.

28、如果潜在受试者不具备知情同意的能力，医生必须从其法定代理人处设法征得知情同意。这些不具备知情同意能力的受试者决不能被纳入到对他们没有获益可能的研究之中，除非研究的目的是为了促进该受试者所代表人群的健康，同时研究又不能由具备知情同意能力的人员代替参与，并且研究只可能使受试者承受最小风险和最小负担。

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、当一个被认为不具备知情同意能力的潜在受试者能够表达是否参与研究的决定时，医生在设法征得其法定代理人的同意之外，还必须征询受试者本人的这种表达。受试者的异议应得到尊重。

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

30、当研究涉及身体或精神上不具备知情同意能力的受试者时(比如无意识的患者)，只有在阻碍知情同意的身体或精神状况正是研究目标人群的一个必要特点的情况下，研究方可开展。在这种情况下，医生必须设法征得法定代理人的知情同意。如果缺少此类代理人，并且研究不能

被延误，那么该研究在没有获得知情同意的情况下仍可开展，前提是参与研究的受试者无法给予知情同意的具体原因已在研究方案中被描述，并且该研究已获得伦理委员会批准。即便如此，仍应尽早从受试者或其法定代理人那里获得继续参与研究的同意意见。

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 patientphysician relationship.

31、医生必须完全地告知患者在医疗护理中与研究项目有关的部分。患者拒绝参与研究或中途退出研究的决定，绝不能妨碍患者与医生之间的关系。

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.

32、对于使用可辨识的人体材料或数据的医学研究，通常情况下医生必须设法征得对收集、分析、存放和/或再使用这些材料或数据的同意。有些情况下，同意可能难以或无法获得，或者为得到同意可能会对研究的有效性造成威胁。在这些情况下，研究只有在得到一个伦理委员会的审查和批准后方可进行。

Use of Placebo

安慰剂使用

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

33、一种新干预措施的获益、风险、负担和有效性，必须与已被证明的最佳干预措施进行对照试验，除非在下列情况下：

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

在缺乏已被证明有效的干预措施的情况下，在研究中使用安慰剂或无干预处理是可以接受的;或者

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

有强有力的、科学合理的方法论支持的理由相信，使用任何比现有最佳干预低效的干预措施、或使用安慰剂、或无干预处理对于确定一种干预措施的有效性和安全性是必要的

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.

并且接受任何比现有最佳干预低效的干预措施、或使用安慰剂、或无干预处理的患者，不会因未接受已被证明的最佳干预措施而遭受额外的、严重或不可逆伤害的风险。

Extreme care must be taken to avoid abuse of this option

要特别注意，对这种选择必须极其谨慎以避免滥用。

Post-Trial Provisions

试验后规定

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.

34、在临床试验开展前，申办方、研究者和主办国政府应制定试验后规定，以照顾所有参加试验，并仍需要获得在试验中确定有益的干预措施的受试者。此信息必须在知情同意过程中向受试者公开。

Research Registration and Publication and Dissemination of Results

研究的注册、出版和结果发布

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

35、每项涉及人类受试者的研究在招募第一个受试者之前，必须在可公开访问的数据库进行登记。

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

36、研究者、作者、申办方、编辑和出版者对于研究成果的出版和发布都有伦理义务。研究者有责任公开他们涉及人类受试者的研究结果，并对其报告的完整性和准确性负责。他们的报告应遵守被广泛认可的伦理指南。负面的、不确定的结果必须和积极的结果一起发表，或通过其他途径使公众知晓。资金来源、机构隶属和利益冲突必须在出版物上公布。不遵守本《宣言》原则的研究报告不应被接受发表。

Unproven Interventions in Clinical Practice

临床实践中未经证明的干预措施

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 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.

37、对个体的患者进行治疗时，如果被证明有效的干预措施不存在或其它已知干预措施无效，医生在征得专家意见并得到患者或其法定代理人的知情同意后，可以使用尚未被证明有效的干预措施，前提是根据医生的判断这种干预措施有希望挽救生命、重建健康或减少痛苦。随后，应将这种干预措施作为研究对象，并对评估其安全性和有效性进行设计。在任何情况下，新信息都必须被记录，并在适当的时候公之于众。