2008年世界醫學會有關涉及人體醫學研究倫理原則之赫爾辛基宣言[1]

World Medical Association DECLARATION OF HELSINKI

Ethical Principles for Medical Research Involving Human Subjects

A. INTRODUCTION	**A.引言**
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. 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.	1.世界醫學會制定赫爾辛基宣言，做為進行人體研究時之倫理指導原則。人體研究包括可辨識人體組織或資料的研究。本宣言應以整體來看，本宣言的每一段在應用時應同時考量其他有關段落的內容。
2.Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.	2.雖然本宣言主要對象是醫師，世界醫學會也鼓勵其他研究人員，在進行人體研究時遵循本宣言。
3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.	3.醫師之職責在促進及維護人類(包括參與研究者)之健康，其專業知識及良知應奉獻於此一使命。
4.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.”	4.世界醫學會之日內瓦宣言中，規範醫師必須以“病人之福祉為首要之考量”，而國際醫療倫理規章亦宣示“提供醫療照護時，醫師應保障病人之最大利益。”
5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.	5.醫學之進步奠基於科學研究，而此研究終究必須仰賴以人為受試者。未能參與人體研究之族群應給予適當的機會參與研究。
6.In medical research involving human subjects, the well-being of the individual research subject must take	6.在進行有關人體之醫學研究時，應將受試者之利益置於任何其他

[1]中譯文資料來源：中央研究院醫學研究倫理委員會網站，網址http://irb.sinica.edu.tw/regulation.htm

precedence over all other interests.

利益之上。

7. 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 interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7.進行人體研究之首要目的，在於了解疾病之成因、及其發展過程和影響；並改善各種預防、診斷及治療之方法。即便對目前已知之最佳治療，也應不斷地經由研究來評估其安全性、有效性、有用性，可近性及其品質。

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

8.在醫療行為及人體研究中，大多數的治療程序都涉及一定的危險與身體之負擔。

9.Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

9.人體研究之倫理標準，應以尊重生命，維護人類之健康及利益為依歸。對於特別之弱勢受試族群必須有特別之保護。如無法自行同意或拒絕研究者、或可能在受脅迫下同意的人。

10.Physicians should 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.醫師應考量該國及國際上與人體研究有關之倫理、法律、相關法規及作業標準。任何國家之倫理、法律、相關法規及作業標準，皆不應減損或忽視本宣言對受試者所宣示之保障。

B. Principles For All Medical Research

B.醫學研究之基本原則

11. 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.

11.醫學研究中，醫師之職責是在於保障受試者之生命、健康、尊嚴、品格、自決、隱私及個人資料之保密。

12.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.

12.涉及人體之醫學研究，必須依循普遍接受之科學原則，並奠基於對科學文獻之徹底瞭解，相關資訊之掌握，及適當的研究數據及動物實驗之結果。實驗動物之福祉也應予以尊重。

13. Appropriate caution must be exercised in the conduct of

13.對於可能影響環境之研究都必

medical research that may harm the environment.

須謹慎進行。

14.The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.

14.在研究計畫書中，有關人體研究的每一個步驟，皆應清楚陳述其研究設計與執行內容。試驗計畫書需檢附相關倫理考量的聲明，並應符合本宣言所揭櫫之原則。.此研究計畫書中必須說明經費來源、贊助者、相關機構、其他潛在利益衝突、對受試者的誘因，及發生研究傷害時，受試者可獲得的治療及/或補償。計畫書中應說明研究結束後，若結果顯示新治療方法有效時，受試者如何繼續接受此新治療方法或其他的治療方式。

15.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 independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.

15.研究計畫書必須先由研究倫理委員會考量、評論、指導及核准後，方可進行研究。此委員會，必須獨立於研究者、贊助者、或任何其他不當影響力之外。此委員會應考慮該國及國際上與人體研究有關之倫理、法律、相關法規及作業標準。任何國家之倫理、法律、相關法規及作業標準，皆不應減損或忽視本宣言對受試者所宣示之保障。委員會應有權監測進行中的試驗。研究人員有責任向委員會提供監測資訊，特別是任何嚴重不良事件。計畫書之任何變更應經此委員會考量及核准後，方可進行變更。

16.Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

16.人體研究須由受過適當科學訓練及認證的人員執行。在病人及健康自願者身上進行之研究，需在合格醫師或醫療人員的監督下進行。對於人體試驗所產生的責任歸屬，皆由參與研究之醫師或醫療人員負責；即使事前已徵得該受試者之同意，該受試者亦不需負任何責任。

17.Medical research involving a disadvantaged or vulnerable

17.在弱勢受試者或族群進行之人

population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

體研究，僅有當此研究符合其首要健康需求，並可合理預測這些人員或族群可由研究結果中獲益時，方屬適當。

18. 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.

18.任何人體研究，事前須審慎評估對受試者或其族群可能的風險與負擔，相對於其可能帶來之預期益處。

19.Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

19.所有臨床試驗需在納入第一位受試者前，須登記在可供大眾取得的資料庫中。

20.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.

20.除非醫師已充份評估並有自信能充分掌控研究可能產生的風險，否則不應從事人體研究。一旦發現研究的風險高過其潛在利益，或已可得到正面或有益之結論時，醫師應立即停止此研究。

21.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.

21.唯有在研究目的之重要性超過受試者可能遭受的風險時，人體研究才可進行。

22.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.

22.一般人參與人體研究必須是志願參加。雖然有時需要諮詢家人或社區領袖的意見，一般人須是在自由意志下同意方可參與人體研究。

23.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.

23.應採取一切之預防措施，以保護受試者之隱私，維護其個人資料的機密性，並將此研究對其身心及社會地位之影響降到最低。

24. 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, and any other

24.在一般人的人體研究中，每一個可能的受試者，必須被告知該研究的目的、方法、經費來源、任何可能的利益衝突、研究人員所屬機構、該研究可預見的益處，及可能伴隨的危險與不適。受試

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.

者也應被告知其擁有的權利，包括可拒絕參與研究，或可隨時撤回同意而不受報復。需特別注意需滿足受試者對特定資訊的需求，及告知的方法。在確知受試者已充分瞭解以上資訊後，醫師或適當合格之人員應取得受試者於自由意志下簽署之受試者同意書，此受試同意書以書面行之為佳。若受試者同意書無法以書面方式行之，則非書面之同意必須經過正式地紀錄與見證。

25.For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

25.當使用可辨識之人體組織或資料進行研究時，通常醫師必須取得同意後，方可收集、分析、儲存和/或再利用。在不可能或無法取得同意之情況，或取得同意後將造成研究無效時，此種研究需經研究倫理委員會審議和批准後，方可在免除同意書之情況下進行。

26.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.

26.醫師在取得受試同意書時，應特別注意受試者是否對醫師有依賴關係，或受試者是否在脅迫下同意。在此情況下，此受試同意書應由一位充分瞭解此研究，但獨立於此醫病關係外之合格人員取得。

27.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.

27.若潛在受試者無行為能力時，研究人員必須取得法定代理人之同意。但唯有在研究本身有其促進上述族群健康之必要性，而研究又無法於具行為能力之受試者身上施行，且將研究本身之風險和負擔極低時，方可進行研究。

28.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

28.若潛在受試者被視為無行為能力，但能表達同意參加研究之決定時，醫師除了應取得該受試者法定代理人之同意外，亦必須取

representative. The potential subject's dissent should be respected.

得其贊同。應該尊重潛在受試者不贊同的意見。

29. 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.

29. 在身心狀況無法表達同意之受試者(如神智不清者)進行的研究，只有當此無法表達同意之身心狀況是參與研究必須有之的條件時才可進行。此時醫師應取得該受試者法定代理人之同意。若無法定代理人而研究無法延遲時，可在未取得同意下進行。但對於此種在無法簽署受試同意書之受試者的研究，研究人員應於計畫書中，陳述其研究之具體理由，且須先經研究倫理委員會核准。但仍並應儘速從受試者本人，或其法定代理人處，取得繼續參與此研究之同意書。

30. Authors, 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.

30. 作者、主編及出版者對於研究成果之發表皆負道德責任。作者有責任公開人體研究之結果並保證資料的完整和正確性。應遵守公認之報告倫理之準則。正面與負面及無結論的研究結果都應發表，或可公開取得。經費來源、所屬組織或研究中任何可能之利益衝突皆應公布於出版資料中。不該發表不合乎此宣言之研究報告。

C. Additional Principles For Medical Research Combined With Medical Care

丙.兼顧醫療照護的醫學研究之附加原則

31. 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.

31. 醫師可以結合醫學研究與醫療照護，但此情況僅止於此研究有潛在的預防、診斷或治療的價值。且醫師有充足的理由相信參與研究不會對其病人的健康有不良的影響。

32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
    - The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
    - Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

32.一個新醫療方法的好處、風險、負擔、及效果，應與目前已知最佳的治療方法比較，除非符合以下狀況：
- 對於尚無證實有效治療方式的狀況，可使用安慰劑或不予治療。
- 因為說服力及科學方法的因素，必需使用安慰劑以確認治療之有效及安全性時，必須確認接受安慰劑或不予治療的病人不會有嚴重或不可逆傷害的危險。使用此原則時要特別小心避免濫用。

33 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.

33.研究結束後，每一個參與研究的病人，都應被告知研究結果，且得以分享研究成果，例如可接受經此研究證實為有效或其他合宜的治療方法或好處。

34.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.

34.醫師應全盤告知病人，那些醫療照護與研究有關。病人的拒絕參與研究或中途退出，絕對不應影響醫病關係。

35.In the treatment of a 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, this intervention should 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.

35.在治療病人的過程中，若無有效的治療方法，醫師在諮詢過專家，且取得病人或其法定代理人之同意書後，倘若醫師判斷有希望挽救生命，重建健康或減輕痛苦，得採用未經證實之治療方法。這些治療方法，在可能的情況下，應被當作研究目標，來評估其安全性及有效性。應將所有新的資訊紀錄下來，並適時公布。