赫爾辛基宣言（Declaration of Helsinki） 2000 年版

引言 INTRODUCTION A. INTRODUCTION

1. 世界醫學會制定赫爾辛基宣言，作為醫師及醫學研究人員在人體試驗時之倫理指導原則。而所謂人體試驗之對象即包涵任何可辨識之人體組織或資料。
The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human aterial or identifiable data.

2. 醫師之職責在促進及維護人類之健康，其專業知識及良知應奉獻於此一使命。
It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

3. 世界醫學會之日內瓦宣言中，規範醫師必須以“病患之福祉為首要之考量”，而國際醫療倫理規章（International Code of Medical Ethics）亦宣示“在實施任何可能危及病患身心之醫療措施時，醫師應以病患之福祉為唯一之考慮。”
The Declaration of Geneva of the World Medical （Declaration of Geneva） Association 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 only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

4. 醫學之進步奠基於科學研究，而此研究終究必須有部份仰賴以人為受試驗者。
Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

5. 在進行有關人體試驗之醫學研究時，應將受試驗者之利益置於科學及社會利益之上。
In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

6. 進行人體醫學實驗之首要目的，在於改進各種預防、診斷及治療之方法，及增進對於疾病成因之瞭解。對於目前已知最有效之預防、診斷及治療之方法，也應不斷地以研究來檢證其效果，效率，可行性，及品質。
The primary purpose of medical research involving human subjects is to improve

prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.)

7. 在當前的醫療行為及醫學研究中，大多數的預防、診斷及治療程序都涉及一定的危險與醫療責任。
In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

8. 醫學研究之倫理標準，應以尊重生命，維護人類之健康及利益為依歸。對於較易受傷之受測族群必須特別加以保護。經濟弱勢及醫療資源匱乏之族群的特別需求也應加以關注。對於無法自行同意或拒絕研究的人、對於可能在脅迫下行使同意的人、對於那些無法因研究而親身受惠的人、及那些同時接受研究和醫療照護的人，也應特別關注。
Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

9. 試驗主持人應注意該國與人體試驗有關之倫理、法律、及主管機關相關規定及適用的國際法規。任何國家之倫理、法律、條例之制定，皆不應減損或忽視本宣言對受試驗者所宣示之保障。
Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

醫學研究之基本原則
BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. 醫學研究中，醫師之職責是在於保障受試驗者之生命、健康、個人隱私及尊嚴。
It is the duty of the physician in medical research to protect the life, health, privacy,

and dignity of the human subject.

11. 任何涉及人體試驗之醫學研究，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。
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 on adequate laboratory and, where appropriate, animal experimentation.

12. 對於可能影響環境之研究都必須謹慎進行，而實驗動物之福祉也應予以尊重。
Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

13. 在實驗計劃中，有關人體試驗的每一個實驗步驟，皆應清楚陳述其實驗之設計與執行。此試驗計畫書必須交由一特別任命之倫理審查委員會，加以考查、評判及指導，如果適當，才予以核准。此倫理審查委員會，必須獨立於研究者、資助者、或任何其他不當影響力之外。此獨立委員會應遵守該研究實驗所在國的法律及規定。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實驗監測資訊，特別是任何嚴重不良事件。研究人員應向委員會提供資訊以供審查，包括研究經費、試驗委託者、所屬機構，及其潛在的利益衝突，和受試者參與實驗之誘因。
The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

14. 試驗計畫書需檢附相關倫理考量的聲明，並得符合本宣言所揭櫫之原則。
The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in

this Declaration.

15. 凡涉及人體試驗的醫學研究，皆須由受過科學訓練的合格人員執行，並由合格臨床醫療人員的監督下進行。對於人體試驗所產生的責任歸屬，皆由合格的醫療人員負責；即使事前已徵得該受試驗者之同意，該受試驗者亦不需負任何責任。
Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

16. 任何有關人體試驗的醫療研究計劃，事前須審慎評估可能的風險、責任、以及對受試驗者或其他人的可能益處。此種評估亦應涵括參與研究的健康志願者。所有研究的設計皆應開放供大眾取得。
Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

17. 除非醫師已充份評估可能產生的風險，並自信能充分地掌控實驗，否則應避免從事有關人體試驗的研究計劃。一旦發現實驗的風險高過其潛在的利益；或已可得到正面或有益之結論時，醫師即應停止其研究計劃。
Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. 唯有在研究目的之重要性大於受試驗者可能身受的風險時，有關人體試驗的醫學研究才可以進行。當該受試驗者為健康的志願者時，尤需重視此原則。
18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

19. 唯有被研究的族群可能從醫學研究成果中獲益時，此醫學研究才有其執行之價值。
Medical research is only justified if there is a reasonable likelihood that the

populations in which the research is carried out stand to benefit from the results of the research.

20. 受試驗者必須是志願參加，並充份瞭解研究內容，才得以參與該項研究計劃。
The subjects must be volunteers and informed participants in the research project.

21. 受試驗者保護其本人身心健全與完整性的權利必須加以尊重。研究人員應採取一切之預防措施，尊重受試驗者之個人隱私，維護其個人資料的私密，並將此研究對其身心健全及人格造成之傷害降到最低。
The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

22. 在任何人體試驗中，每一個可能的受試驗者，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。受試驗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。在確知受試驗者已充分瞭解以上訊息後，醫師應取得受試驗者於自由意志下簽署之受試同意書，此受試同意書以書面行之為佳。若受試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。
In any research on human beings, 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. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. 醫師在取得受試同意書時，應特別注意受試驗者是否對醫師有依賴關係，或受試驗者是否在脅迫下行使同意。在此情況下，此受試同意書應由一位充分瞭解全盤研究，但沒有參與研究，並完全與彼無關係的醫師取得。
When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is

completely independent of this relationship.

24. 若受試驗者無法律上之行為能力，或生理或心智上無同意能力，或無法律上行為能力之未成年者，研究人員必須取得符合適用法令之法定代理人受試同意書。除非研究本身有其促進上述族群健康之必要性，而研究又無法於法律上具行為能力之人員上施行，否則此研究不應包涵此類族群。
For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

25. 當一個被視為無法律行為能力之受試驗者，例如未成年之孩童，對參與研究的決定有表達同意之能力時，研究人員除了應取得該受試驗者之同意外，亦必須取得其法定代理人之同意。
When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

26. 當無法從個人取得同意，包括代理人同意或預先同意時，此項對於個人之研究不應進行；除非阻止其簽署受試同意書的個人特殊身心狀況，正是此受試驗者族群的必然特徵。對於此種在無法簽署受試同意書之受試驗者上的研究，研究人員應於試驗計畫書中，陳述其研究之具體原因，以供審查委員會之考量而核准。試驗計畫書中應表明，會儘速從本人，或合法授權之代理人處，取得繼續參與此研究之同意。
Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the xperimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27. 作者及出版者皆負道德責任。研究人員在發表研究成果時，即有責任保持其結果的正確性。正面與負面的研究結果都應發表，或可公開取得。研究人員之經費來源，其所屬組織，或研究中任何可能之利益爭議皆應公佈於出版之中。凡

不合乎此宣言之原則的實驗報告，皆不該被接受發表。
Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

兼顧醫療照護的醫學研究之附加原則
ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. 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。當醫學研究結合醫療照護時，另有額外的準則來保護這些同為病患和研究對象的人。
The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29. 一個新醫療方法的益處、危險性、責任、及其效果，應與目前已知最佳的預防、診斷與治療方法對照檢驗。而對於尚無有效預防、診斷與治療方式之研究，不排除使用安慰劑或不予治療來檢驗其療效。
The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.

30. 研究結束後，每一個參與研究的病患，都應得到保證其可以接受經此研究證實為最佳的預防、診斷和治療的方法。
At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

31. 醫師應全盤告知病患，那些方面的醫療照護與研究有關。病患的拒絕參與研究，絕對不應影響醫病關係。
The physician should fully inform the patient which aspects of the care are related to

the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship. patient-physician relationship.

32. 在治療病患的過程中，若無有效的預防，診斷和治療的方法，醫師在取得病患之受試同意書後，得以自由採用其判斷下有希望挽救生命，重建健康或減輕痛苦的任何未經證實或新的預防，診斷及治療方法。這些方法，在可能的情況下，應被當作研究的目標，來評估其安全性及有效性。在各種情況下，應將新的消息資訊紀錄，適當時並發表，並應遵守此份宣言的其他相關準則。
In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.