

1949年 紐倫堡守則

The Nuremberg Code_1949

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problems under study that the anticipated results will justify the performance of the experiment.
 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve as subjects.
 6. The degree of risk to be taken should never exceed that
1. 以人體為試驗對象時，事先徵得參與試驗者的自願同意，乃絕對必要的條件。亦即，參與試驗者必須具有行使同意權的法律權利，必須是處在沒有任何強迫、利誘、詐欺、虛偽、哄騙，或其他隱藏形式的強制、威脅，而能夠自由運用其選擇的情況下作決定；尚須參與試驗者對於所涉及的主題內容，具有充分的認識與理解，使其能做明智的選擇。對查明同意書品質的義務與責任在於每一位發起、主導或參與實驗的人，這是一種個人的義務與責任，是不可以委任給其他不受懲罰的人。要達到後者須在參與試驗者確定決定之前，讓參與試驗者了解實驗的本質、期間、目的、實驗的方法、可預期遭遇的不便與困難，對參與試驗者或其它因參與試驗而相關的人其健康的影響。
 2. 實驗必須對社會有所助益的豐碩結果，且此一結果無法從其他實驗的方法獲得，而且本質上不是任意而是必要的。
 3. 實驗的設計必須是依據動物實驗的結果及對疾病自然病程的認知或其他研究中的問題，以使所預期的結果能讓實驗的執行有正當性。
 4. 實驗必須避免所有對身體與心理上產生不必要的痛苦與傷害。
 5. 如果有較優先的理由相信實驗會發生死亡或傷殘，則實驗不能執行，或許除非參與實驗的醫師當做試驗對象。
 6. 實驗的危險性程度，絕不可超過

- determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
 10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe in the exercise of the good faith, superior skill and careful judgement required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.
- 以人道主義立場來判定的實驗本身重要性。
7. 需提供適當的準備及充分的設施，以避免將來對參與試驗者產生可能的傷害、傷殘或死亡。
 8. 實驗只能由合格的科學家來執行，在實驗的所有階段中，操作者必須具備最高程度的技巧與關懷。
 9. 在實驗期間，接受試驗者應該有自主意願去終止實驗，假如其生理上或心理上的狀況，已無法再接受試驗。
 10. 在實驗的過程中，負責的科學家必需準備在任何階段可終止實驗，若他以必須具備的充分信心、高超技術與細心判斷，相信如果實驗繼續下去有可能導致接受試驗者傷害、傷殘或死亡。