# 美國_1979年貝爾蒙報告
# 保護人體實驗標的之倫理原則及方針

## **The Belmont Report**, 1979
Ethical Principles and Guidelines for the protection of human subjects of research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
April 18, 1979

保護生物醫學及行為學研究人體實驗標的之全國委員會報告，
1979 年 4 月 18 日


**SUMMARY:**

On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.

By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of

**概要**

1974 年 7 月 12 日國家科學研究法(出版編號 93348)完成立法，其成立保護參加生物醫學及行為學研究人體實驗標的之全國委員會。委員會主要任務之一即是為涉及人體實驗標的之生物醫學及行為學研究確定基本倫理原則，制定方針以監督有關科學研究依照前述原則進行。於執行以上任務時，委員會另需考慮：(i)生物醫學及行為學研究與所認可之常規醫療行為間之分界，(ii)對危險及利益標準之評估於決定涉及人體實驗標的科學研究之適當性中之作用，(iii)選擇參與科學研究之人體實驗標的之準則，及(iv)各種情況下知情同意之性質及定義。

貝爾蒙報告總結委員會審議後所確定之基本倫理原則。其為 1976 年 2 月於 Smithsonian 協會貝爾蒙會議中心舉行 4 天會議之產物及 4 年來委員會每月審議之結果。其是對基本倫理原則及方針之說明，用於協助解決涉及人體實驗標的之科學研究所產生之倫理問題。

透過由聯邦註冊出版及所提供單行本，部長意使科學家、單位評審會成員及政府雇員容易獲得此

Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfillingthis part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

份報告。兩冊附錄包括協助委員會完成此一任務之專家所完成之長篇報告，由政府印刷辦公室文件主管處出售(華盛頓，哥倫比亞特區，20402)，出版號為 DHEW No.(OS)780013 及 78-0014.

貝爾蒙報告與委員會其他報告不同，其未向衛生教育福利部長推薦具體行政措施。然其建議將報告整體採用，作為該部政策執行之建議。

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## Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes(1) intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their

## 保護人體實驗標的之倫理原則及方針

科學研究對社會具實質效益，然同時也造成一些倫理問題。特別是二次世界大戰期間生物醫學實驗中虐待人體實驗標的之披露引起公眾對此問題之注意。在紐倫堡審判戰犯期間所起草之紐倫堡法則是用來衡量集中營戰俘身上進行生物醫學實驗之醫生及科學家之標準。該法則成為後來許多法則之原型，以確保涉及人體實驗標的科學研究之倫理性。

該法則由許多規定所組成，有些為一般原則，有些很具體，用於

work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

指導科學研究工作者及審查人員。前述法則不適合於複雜情形；有時甚至互相矛盾，且常常難以理解或應用。因此，更周延的倫理原則將可為具體規則之制定、評論及解釋提供基礎。

該報告確定三項與人體標的有關之原則或總體觀點。其他原則亦可能相關，然該三個原則所涉及之廣泛且具概括性之論述，應有助於科學家、實驗標的、評審人員及感興趣之公眾理解有關涉及人體科學研究中倫理方面之問題。這些原則無法完全解決某一具體倫理問題，然其目的係為解決因涉及人體科學研究所引起之倫理問題提供一架構及指導。

該報告包括科學研究與醫療行為之區別，對三基本倫理原則之討論，及有關該原則之應用。

## Part A: Boundaries Between Practice & Research

## 第 A 部份：醫療行為及科學研究之區別

### A. Boundaries Between Practice and Research

### A.醫療行為與科學研究之區別

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called ”experimental” when the terms ”experimental” and ”research” are not carefully defined.

For the most part, the term ”practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. (2) By contrast, the term ”research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed,

區分生物醫學及行為學研究與一般認可之醫療行為是很重要的，如此才能決定應審查哪些行為以保護科學研究標的。科學研究及醫療行為間之區別很模糊，因二者可能同時發生(例如評估治療之科學研究)，也因為如無詳細針對對“實驗”及“科學研究”下定義，明顯偏離一般醫療行為常被稱作“實驗”。

“醫療行為”大多係指為增進病人或顧客健康所採取有一定成功希望之措施。醫療行為之目的係為個人提供診斷，預防性治療及治療。相反地，“科學研究”係指為測試某種假設而採取之行動，以便獲得結論以發展或增長某概括性知識(例如理論、原則及對某關係之敘述)。科學研究一般有一計畫

for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

包括目標及達到目標所需之步驟。

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is ”experimental,” in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.

某醫生偏離正規醫療行為準則，創新本身並不構成科學研究。某一新的，未被測試過或不同的“實驗”操作並不自然歸屬於科學研究。然而，全新之操作應於早期就成為正式科學研究之目標，以便確定其是否安全有效。因此，要求將主要醫療創新併入正式科學研究課題為醫療行為委員會(例如)之職責。

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

於科學研究係用於評估某治療安全性及有效性時，科學研究及醫療行為可同時進行。至於前述行為是否需要審查不應有所混淆；一般原則是：如行為中有任何科學研究成分，則該行為即應受審查，以保護人體實驗之標的。

## Part B: Basic Ethical Principles

## 第 B 部分：基本倫理原則

## B. Basic Ethical Principles

## B.基本倫理原則

The expression ”basic ethical principles” refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

“基本倫理原則”係指即對許多特殊倫理規則及人之行為評價基本觀點之總體性判斷。於我們所在文化傳統所廣泛接受之原則中，有三個原則與涉及人體標的之科學研究具特別關聯：尊重個人，善行及公平平等原則。

### 1. Respect for Persons

### 1.尊重個人

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

尊重個人包含至少二個倫理守則：第一、個人享有自治權；第二、保護喪失自治能力之人。尊重個人原則因此區分為二要求：承認自治權及保護喪失自治能力之個人。

An autonomous person is an individual capable of deliberation

一具自治能力之人能深思熟慮個

about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

人目標並朝該目標努力。尊重自治權係尊重具自治能之個人之意見及選擇。只要其未對他人造成危害，即不能妨礙其作為。對有自治能力之個人之不尊重係指否定該個人深思熟慮後之看法，剝奪其依其想法為行為之自由，及毫無理由地留置對其做決定有用之資訊。

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

然而，並非所有人均能自我決定。某人之自決能力隨其成長而成熟，有些人會因疾病、精神殘疾或自由受限處境而全部或部分喪失此能力。尊重未成熟及無能力之人需要在其尚未成熟或被剝奪能力時對其進行保護。

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

有些人需要多方面保護，甚至可能不讓其參加對其有害之活動；有些人除確保其能自由參加活動並讓其瞭解可能發生之意外幾乎無需任何其他保護。提供保護程度應取決於傷害機率及好處之可能性。應定期審視有關某人是否喪失自治能之鑑定，此應隨不同場合而變。對大多數涉及人體標的之科學研究而言，對個人尊重表現在標的自願參加計畫且對該計畫有一定程度的瞭解。然於有些情況下這一原則之應用並非如此明顯。以囚犯為標的之科學研究即是一好的例子。一方面出於尊重個人原則應讓囚犯自願參加研究，但另一方面在監獄條件下囚犯儘管不願意可能會被強迫參加科學研究活動。對個人尊重要求保護囚犯，此便提出讓囚犯“自願”參加還是“保護”他們之難題。於多數困難情況下，對個人尊重常是從尊重個人原則出發平衡對抗雙方之要求。

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to ”volunteer” or to ”protect” them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

## 2. Beneficence.

## 2.善行

Persons are treated in an ethical manner not only by respecting

對待他人是否符合倫理要求不僅

their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term ”beneficence” is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The Hippocratic maxim ”do no harm” has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients ”according to their best judgment.” Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A

在於尊重其決定及保護其免遭傷害，尚應盡力確保其健康。此做法歸類為善行原則。“善行”係指超出義務之仁慈或博愛行為。此報告提到善行時之語氣相當強硬的：其代表一義務。此二規則是對善行行為之補充說明：(1)不傷害；(2)儘量增加可能好處，減少潛在害處。

Hippocratic 格言“不傷害”長期以來一直是醫療倫理之基本原則。Claude Bernard 將其延伸於科學研究領域，主張不管有多大好處亦不應傷害個人。然而，即使是躲避傷害也應瞭解什麼是有害的；於獲取此資訊過程中會有被傷害之危險。另外，Hippocratic 誓言要求醫生“依據自己最佳判斷”為病人造福，而瞭解何者會帶來好處也會給人帶來危險。關鍵在於決定何時既使有危險也應追尋好處，何時又因危險性而放棄追尋好處。

善行之執行不僅牽涉到個別科學研究工作者亦涉及整個社會，因其將二者與具體科學研究計畫及整個科學研究領域串連在一起。就具體計畫而言，科學研究工作者及所屬單位成員必須事先籌畫以便最大限度地增加好處，減低研究可能帶來之危險。就科學研究總體觀之，人們必須認清因知識進步及醫學、心理治療及社會發展所帶來較長期之好處及危險。

善行原則於研究人體實驗標的許多領域均具有相當明確的作用。有關兒童之研究即為明例。有效地治療兒科疾病促進其健康發展為有關兒童研究所帶來之好處，即使個別實驗標的並未受益。有些以前被認可之常規處理經仔細檢查後證明是具危險性的，科學研究可避免這些常規所造成之傷害。然善行原則所具備之作用往往區分不易。具一定風險而又不

difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

能給兒童帶來直接好處之研究就存有倫理難題。有人主張不能進行此類研究，另些人則覺得此種限制會排除許多將來能為兒童造福之可能研究。如同所有難題，不同情形下對善行原則之執行可導致不同選擇。

**3. Justice.**

**3.公正**

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of ”fairness in distribution” or ”what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

誰應享受科學研究成果所帶來的好處？誰應承擔科學研究之責任？此為一平等公正問題，亦即平等分配或應不應該的問題。無故拒絕應受益者或過度施加責任會導致不公平。執行公正原則之另一方式是平等對待平等雙方。然此句話需要解釋。誰是誰不是平等的一方？怎麼證明不平等？幾乎所有審查人員均以經驗、年齡、免職、勝任、功績及職位為標準用以決定不同待遇。此必須說明哪些方面應平等對待。有幾條公認且合理配置責任及利益之原則。每一原則依據須配置之責任及利益所涉及之相關特性。這些原則是(1)每人平分、(2)依據個人需要、(3)依據各人努力、(4)依據每人對社會之貢獻，及(5)依據每人之功績。

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this

公正問題長期以來與社會實踐有關，例如處罰、徵稅及政治表述。這些問題直到最近才與科學研究連結起來，然於最早對進行人體實驗倫理觀之反思中已對這些問題有所預示。例如於在 19 世紀及 20 世紀初，實驗標的大多是貧窮病人，而醫療改進帶來的好處卻大都由富有的私人病人享受。後來，納粹集中營對囚犯強行進行的實驗因其極度不公平而遭譴責。美國本世紀 40 年代對社會地

country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

位低下的鄉下黑人男子進行Tuskegee梅毒實驗，以研究此一非侷限於農村窮黑人之疾病未經治療之過程。為不中斷該計畫之進行，該實驗標的被剝奪早就廣泛使用之有效治療。

在此一歷史背景下，人們看到公正觀念與人體研究之相關性。例如應仔細檢查對實驗標的之選擇，以確定是否某些階層(例如福利病人，特別種族或少數民族、被隔離人員)出於同研究計畫無直接關係之原因而被有系統地選出。這些原因可包括其易得性，被損害地位，或可被隨意擺佈性。最後，當由公共基金贊助之科學研究導致醫療器械及操作之發展，公正原則要求不能將這些好處只給那些有支付能力之人，這些研究也不應過度使用那些不可能享受科學研究成果好處之團體。

## Part C: Applications

## 第 C 部分：應用

### C. Applications

### C.應用

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

總則適用於科學研究行為時應考慮以下要求：知情同意、對危險好處之評估，及實驗標的之選擇。

### 1. Informed Consent.

### 1.知情同意

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

尊重個人原則要求依據實驗標的之能力提供讓其選擇是否參與某實驗之機會。此機會應於符合知情同意標準後提供之。

知情同意之重要性是無庸置疑的，然對知情同意之性質及可能性尚有爭論。無論如何，公認的同意過程應包括三要素：資訊、理解及自願。

### Information.

### 資訊

Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

大多數科學研究準則均制定具體的公開規範，以使實驗標的瞭解足夠情況。這些規範大多包括：實驗操作過程、目的、潛在危險及預計好處、其他類似操作(當涉及治療時)，及聲明實驗標的有提出問題之機會且可於任何時候退出實驗。有些人亦提出另一些規範，包括標的如何挑選、實驗負責人等。

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of ”the reasonable volunteer” should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

然而，一簡單項目名單並無法代表提供多少及提供哪方面資訊之標準。一經常被醫學實踐所採用之標準(即由該領域或當地醫務工作者所提供之一般性資料)是不適當的，因僅有於欠缺一般理解時才會導致科學研究。另一目前在治療失誤法中很流行之標準則要求醫務人員公開大眾希望瞭解有關決定治療計畫之資訊。此一標準看來亦不夠充分，因自願參加之實驗標的可能比病人找醫生看病更想知道其將無償承擔之風險。或許我們應設立一“合理自願者”標準：資訊範圍及性質應是在知道操作過程對其治療既無必要且也許人們尚未完全理解該操作之情況下，實驗參加者能決定其是否希望參加實驗以增進知識及理解。即使預計有直接好處，實驗標的應清楚地意識到風險大小及參加實驗之自願性。

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the

告知標的實驗某些方面可能會削減實驗有效性會導致特殊同意問題之產生。於多數情況下，只需向標的指出其是被邀請來參加實驗，實驗中有些部分得等到實驗結束才能公開。所有涉及不完全公開之科學研究僅於以下條款清楚之情況下方屬正當：(1)不完全公開對達到科學研究的目標是必須的，(2)對實驗標的無隱藏性危險，及(3)有一於適當時能讓實驗標的瞭解科學研究性質及結果之合理計畫。絕對不能為想取得標

purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

的之合作而隱瞞潛在危險性，應予以實驗標的所提出有關實驗問題並如實回答。公開於某些情況下會毀壞或使實驗失效，而於某些情況下則只是給研究者帶來不便，應謹慎區分此二種情況。

**Comprehension.**

The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

**理解**

傳達資訊方式方法與資訊本身同樣重要。比如混亂且迅速之傳達會給他人很少的思考時間，或縮減別人提問之機會，都可能負面地影響實驗標的作出選擇之能力。

因為實驗標的之理解力是智力、合理性、成熟性及語言的組合，應依據實驗標的之能力來決定傳達資訊之方式。科學研究工作者應保證讓實驗標的理解所傳達之資訊。保證全面提供有關潛在危險之資料及保證實驗標的對危險性已有充分理解是科學研究工作者之責任。危險性增加時，科學研究工作者之責任即隨之增加。有時有必要針對實驗標的之理解程度進行口試或筆試。

Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

當實驗標的之理解力受嚴重限制時，可能需要制定某些特殊規定，例如未成年人或精神殘疾情況。應依據每類無能力之實驗標的(例如嬰兒及兒童、精神病患、臨終病人及昏迷病人)之自身情況而對其進行考慮。然而，即使對這些人，出於尊重原則而無論其是否最終會參加實驗均應給予其適當的選擇機會。除非研究需要為這些人提供絕無僅有之治療，否則應尊重其不參加實驗之決定。個人尊重原則亦要求取得其他人之同意，以保護這些實驗標的免遭傷害。如此這些人就受到尊重，不僅是透過對其意願之承認，且是利用第三方保護其免遭傷害。

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in

選定之第三人應為那些最能理解無能力實驗標的情形且代表其切

that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

身利益之人。代表對象之授權人應有機會觀察實驗進行，以便出於對標的切身利益之考慮而讓標的退出實驗。

**Voluntariness.**

An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

**自願**

一份自願參加實驗之協議構成一有效的同意。知情同意此一要素要求毫無強迫及過分影響。強迫係指某人為讓對方屈服而對其蓄意進行恐嚇。相反地，過分影響係指為使對方屈服而採用過度且未經授權、不當或不合適之獎賞或表示之方式。此外，當實驗標的處於特別脆弱情況時，一般情況下可行之誘惑亦可能變成過分影響。

當具權威或具影響地位之人--尤其是涉及可能制裁時，主張對某實驗標的採取行動時，往往對周圍之人會產生過分壓力。然而，此一影響因素以連續整體形式存在時，不太可能地能精確地區分合理勸說及過分影響之界限。過分影響包括行動，例如透過近親控制影響力來控制某人之選擇及威脅撤銷某人應享有之健康服務。

**2. Assessment of Risks and Benefits.**

**2.對風險及好處之評估**

The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

對風險及好處之評估要求一系列詳細斟酌過之資料，包括有時採用其他辦法以獲取實驗所帶來之好處。因此，評估既代表一機會又為一收集有關研究計畫全面系統資訊之責任。對研究者而言，此為一檢查有關研究計畫是否合理設計之方式。對審查委員會而言，此為一判定是否會給實驗標的帶來潛在危險正當與否之方法。對未來實驗標的而言，評估將有助於其作出是否參與實驗之決定。

**The Nature and Scope of Risks and Benefits.**

The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons.

The term ”risk” refers to a possibility that harm may occur. However, when expressions such as ”small risk” or ”high risk” are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term ”benefit” is used in the research context to refer to something of positive value related to health or welfare. Unlike, ”risk,” ”benefit” is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

**風險及好處之性質及範圍**

要求科學研究之合理性建立於一有利風險及好處評估基礎上，其與善行原則相似，正如要求獲取知情同意主要來自尊重個人原則一樣。

“風險”乙詞係指傷害產生之可能性。然而，“小風險”或“大風險”則通常係指(模糊地)體驗傷害之機率及傷害預估的嚴重程度。

科學研究之“好處”係指對健康及福利有益之事項。與“風險”不同，“好處”並非在指可能性。風險與好處之可能性相對應，好處則是與傷害而非傷害可能性對應。因此，所謂風險/好處評估是與潛在傷害之大小及可能性及預期之好處有關。需要考慮多種可能帶來之傷害及好處。比如精神傷害、身體傷害、法律傷害、社會及經濟傷害及相應之好處。對實驗標的而言最可能帶來之傷害為精神與身體所遭受之痛苦及損害，然亦不能忽視其他種類之傷害。

科學研究帶來的風險及好處可影響對象本人、其家庭及社會(或社會特別對象團體)。先前規則及聯邦規定要求給實驗標的帶來之預期好處及給社會帶來之知識進步超過潛在危險。於平衡這些不同因素時，直接影響實驗標的之潛在危險及好處一般將作為具決定性之作用。另外，於對象之權利受保護前提下，實驗標的以外之利益有時足以彌補科學研究所帶來之風險。善行原則要求我們保護標的免遭傷害，並注意雖有可能從科學研究成果得到彌補之許多利益之喪失。

**The Systematic Assessment of Risks and Benefits.**

It is commonly said that benefits and risks must be ”balanced” and shown to be ”in a favorable ratio.” The metaphorical

**有系統地對風險及好處為評估**

通常認為好處及風險必須“平衡”並顯示“有利比率”。此比喻性的

character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: (i) Brutal or inhumane treatment of human subjects is never morally justified. (ii) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. (iii) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation). (iv) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. (v) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

字詞表明作出精確判斷之困難度。僅於極少情況下可用定量方法來仔細檢查實驗計畫。然應儘量提倡對風險及好處進行系統及有規律分析之主張。此一理想要求決定實驗合理性之人歸納整理有關實驗之全部資訊並對之作出徹底之評估，且有系統地考慮其他選擇方案。此過程能使對實驗之評估更為嚴格及精確，亦能使審查委員與科學研究工作者之間的交流少受錯誤解釋、錯誤情報及具衝突判斷之影響。因此，應該先決定實驗假設之有效性；然後再盡可能清楚地區分風險性質、可能性及大小。確定風險之方法應明瞭清楚，特別是當無其他選擇而只能使用諸如小或輕微風險之模糊分類。另外亦應依據已知事實或其他可用之研究以確定科學研究工作者對傷害可能性或好處之評估是否合理。

最後，評估科學研究合理性時應考慮以下幾點：(i)野蠻或非人性對待實驗參加者於倫理上是絕對不被允許的。(ii)風險應減少到對達到科學研究目標所需程度。應確定是否有必要使用人體實驗標的。風險也許無法消除，但可透過注意選用其他途徑而減少。(iii)當科學研究帶有很大嚴重傷害之風險時，審查委員會應特別注意風險之合理性(側重對實驗標的可能帶來好處—或在少數一些情況下側重參加實驗之明顯自願性)。(iv)當科學研究涉及易受傷害之某一群人時，應證明利用這些人之適當性。作判斷時應考慮以下變數，包括風險之性質及程度，所涉及之特定人群情況，及預計帶來之好處之性質及程度。(v)相應風險及好處必須於知情同意過程之文件及程序中予以詳細列明出。

**3. Selection of Subjects.**

**3.實驗標的之選擇**

Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

正如同意表達尊重個人原則，對風險/好處之評估表達善行原則，對選擇標的之公平程序及結果之倫理要求代表平等公正原則。

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only ”undesirable” persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

平等公正於二層次上與實驗標的之選擇有關：社會及個人。對個人之平等公正要求科學研究工作者在選擇實驗標的時應顯示其公平：因此其不能只對某些其喜歡之病人進行能帶來潛在好處之實驗，或只選“不受歡迎的”人進行有風險之實驗。對社會之平等公正要求區分哪些種類之實驗標的應該或不應該參加任何一項特定之實驗，這一區分應依據該種類成員承受負擔之能力及對已有負擔之人們再施加壓力之適當性而進行。因此，可將其視為社會正義，因於進行實驗標的種類之選擇時有一優先順序(比如成人先於兒童)，某些種類之潛在實驗標的(例如被隔離之精神病患者或囚犯)僅於特定情況下才能參與實驗。

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

即使科學研究工作者公平地選出每一實驗標的並於實驗過程中公平地對待他們，選擇實驗時仍會出現不公正。不公正源自社會固有的社會、種族、性別及文化之偏見。因此，即使每一科學研究工作者公平地對待其實驗標的，即使機構審查委員會儘量確保該機構公平挑選實驗標的，不公平之社會傾向依然可能會在科學研究好處及負擔之總體配置上表現出來。雖然每一機構或科學研究工作者可能無法解決此一廣見於社會之問題，其於挑選實驗標的時卻可考慮標的之平等分佈。

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to

某些人群，特別是那些被隔離者，已於很多方面因其疾病及環境而承受負擔。若所進行之科學研究只會有風險而不包含治療因素，僅於科學研究不直接與參加

accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

者之特殊情況有關，即應先請另外那些承受較輕負擔之人來承受科學研究所造成之可能傷害。另外，儘管公共科學研究基金可能常常與公共健康保健基金涵蓋面相似，如處更優越地位之人群更有可能享受科學研究帶來之好處，讓那些依靠公共健康保健之人群作為首選實驗標的就顯得不公平。

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

一不公正之特殊案例涉及易受傷害之實驗標的。某些團體，像少數民族、經濟地位低下、病重、被隔離，由於其所處場所對實驗而言為現成可利用，就會被不斷地挑選為實驗標的。鑑於其依賴他人之狀況及其自由同意之能力常遭約束，應對其進行保護，避免其出於人們行政上之方便或由於其病情或社會經濟情況易受擺佈而參加實驗。