人體生物醫學研究國際道德指南

國際醫學科學組織委員會 2002 年

International Ethical Guidelines for Biomedical Research Involving Human Subjects

Council for International Organizations of Medical Sciences (CIOMS)

Guideline 1: Ethical justification and scientific validity of biomedical research involving human beings

The ethical justification of biomedical research involving human subjects is the prospect of discovering new ways of benefiting people's health. Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to, the subjects of that research and are morally acceptable within the communities in which the research is carried out. Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit, investigators and sponsors must ensure that proposed studies involving human subjects conform to generally accepted scientific principles and are based on adequate knowledge of the pertinent scientific literature.

指南 1：人體生物醫學研究倫理之合理性與科學性

人體生物醫學研究倫理之合理性在於希望發現有益人類健康之新方法。僅於研究實施中尊重、保護及公平對待受試者，且符合研究實施所在社會之道德規範時，該研究始具有倫理學上之合理性。此外，將受試者暴露於風險而無可能受益之非科學研究是不道德的。因此研究者與贊助者必須確保所提交涉及人體受試者之研究，能符合公認的科學原理，並具充分相關科學文獻為依據。

Guideline 2: Ethical review committees

All proposals to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees. The review committees must be independent of the research team, and any direct financial or other material benefit they may derive from the research should not be contingent on the outcome of their review. The investigator must obtain their approval or clearance before undertaking the research. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study.

指南 2：倫理審查委員會

所有涉及人類受試者之研究計畫，均應提交給一或以上之科學及倫理審查委員會審查其科學價值及倫理可接受度。審查委員會必須獨立於研究團隊之外，其審查結果不應視研究中可能得到之任何直接財務或物質上利益而定。研究者必須於研究開始前獲得批准或許可。倫理審查委員會應於研究過程中，視需要進一步進行審查，包括監督研究進度。

Guideline 3: Ethical review of externally sponsored research

An external sponsoring organization and individual investigators should submit the research protocol for ethical and scientific review in the country of the sponsoring organization, and the ethical standards applied should be no less stringent than they would be for research carried out in that country. The health authorities of the host country, as well as a national or local ethical review committee, should ensure that the proposed research is responsive to the health needs and priorities of the host country and meets the requisite ethical standards.

指南 3：國外機構所贊助之研究倫理審查

國外申辦組織及個人研究者，應向申辦組織所在國提交研究計畫進行倫理及科學審查，倫理評估標準應與研究實施所在國同樣嚴格。所在國之衛生管理部門及其國家或地方倫理審查委員會應確認研究計畫係針對所在國健康需要及優先原則，並符合必要的倫理標準。

Guideline 4: Individual informed consent

For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.

指南 4：個人之知情同意

所有人體生物醫學研究，研究者必須獲得受試者自願為之知情同意，若於個人無法給予知情同意之情況下，必須依據現行法律取得其法定代理人的許可。免除知情同意應被認為是不尋常且為例外，於任何情況下均應經倫理審查委員會批准。

Guideline 5: Obtaining informed consent: Essential information for prospective research subjects

Before requesting an individual's consent to participate in research, the investigator must provide the following information, in language or another form of communication that the individual can understand:

1. that the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary;
2. that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled;
3. the purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care;
4. for controlled trials, an explanation of features of the research design (e.g. randomization, double-blinding),

指南 5：獲取知情同意：前瞻性研究受試者必須知曉之資訊

於要求個人同意參加研究前，研究者必須以其能理解之語言或其他溝通形式提供以下資訊：

1. 個人是受邀參加研究，認為個人適合參加該研究之理由，及參加應是基於自願的；
2. 個人可自由拒絕參加，並可於任何時候自由地退出研究而不會受到懲罰，亦不會喪失其應得利益；
3. 研究目的，研究者及受試者要進行之研究過程，及說明該研究不同於常規醫療之處；
4. 就受控制之對照試驗，要說明研究設計之特點(例如隨機化、雙

and that the subject will not be told of the assigned treatment until the study has been completed and the blind has been broken;

5. the expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;
6. whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount;
7. that, after completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status;
8. that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure);
9. any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner;
10. the direct benefits, if any, expected to result to subjects from participating in the research;
11. the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge;
12. whether, when and how any products or interventions proven by the research to be safe and effective will be made available to subjects after they have completed their participation in the research, and whether they will be expected to pay for them;
13. any currently available alternative interventions or courses of treatment;
14. the provisions that will be made to ensure respect for the privacy of subjects and for the confidentiality of records in which subjects are identified;
15. the limits, legal or other, to the investigators' ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality;
16. policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in

盲)，於研究完成或破盲以前，受試者不會被告知所分配之治療方法；

5. 預期個人參加研究所需的持續時間(包括到研究中心隨訪的次數及持續時間，及參加研究之總時間)，試驗提前中止或個人提前退出試驗之可能性；
6. 是否有金錢或其他形式物質作為個人參加研究的酬謝，如有，說明種類及數量；
7. 一般於研究完成後，受試者將會被告知研究之發現，每位受試者將被告知與其自身健康狀態有關之任何發現；
8. 受試者有權利於提出要求時獲得其資料，即使這些資料未直接的臨床用途(然倫理審查委員會已批准暫時或永久地不公開資料除外，於此種情況下受試者應被告知，且向其說明不公開資料理由)；
9. 與參與研究有關，給個人(或他人)帶來任何可預見之風險、疼痛、不適，或不便，包括給受試者配偶或伴侶之健康或幸福帶來之風險；
10. 受試者參加研究任何預期之直接受益；
11. 研究對社區或整體社會之預期效益，或對科學知識之貢獻；
12. 受試者於參加完成研究後，其能否、何時、如何得到被研究證明為安全及有效藥品或干預方法，其是否要為此支付款項；
13. 任何現有、可替代之干預措施或治療措施；
14. 將用於保證尊敬受試者隱私、可識別受試者身份記錄之機密性規定；
15. 研究者保護機密能力受到法律及其他規定之限制，及洩露機密之可能後果；
16. 利用遺傳試驗結果及家族遺傳資料之政策，及在無受試者同意

place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives or to others (e.g., insurance companies or employers) without the consent of the subject;

17. the sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research;
18. the possible research uses, direct or secondary, of the subject's medical records and of biological specimens taken in the course of clinical care;
19. whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed;
20. whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products;
21. whether the investigator is serving only as an investigator or as both investigator and the subject's physician;
22. the extent of the investigator's responsibility to provide medical services to the participant;
23. that treatment will be provided free of charge for specified types of research-related injury or for complications associated with the research, the nature and duration of such care, the name of the organization or individual that will provide the treatment, and whether there is any uncertainty regarding funding of such treatment;
24. in what way, and by what organization, the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury (or, when indicated, that there are no plans to provide such compensation);
25. whether or not, in the country in which the prospective subject is invited to participate in research, the right to compensation is legally guaranteed;
26. that an ethical review committee has approved or cleared the research protocol.

情況下，防止將受試者之遺傳試驗結果披露給直系親屬或其他人(如保險公司或雇主)之適當預防措施；

17. 研究的贊助者、研究者所隸屬機構，研究資金之性質及來源；
18. 可能進行之研究直接或二次利用受試者之病歷記錄及臨床診療過程中獲取之生物標本；
19. 研究結束時是否計畫將研究中收集之生物標本予以銷毀，如非，關於其貯存之細節(地點、如何儲存、儲存多久及最後之置)及將來可能之利用，及受試者有權做出有關將來使用、拒絕儲存及讓其銷毀之決定；
20. 是否會從生物標本中開發出商業產品，研究參加者是否會從此類產品之開發中獲得金錢或其他收益；
21. 研究者是僅作為研究者，抑或既為研究者，又為受試者之醫生；
22. 研究者為研究參加者提供醫療服務之職責範圍；
23. 與研究有關之具體類型之損害或併發症將提供之免費治療，該治療之性質及持續時間，提供治療之組織或個人名稱，及關於該治療之資金是否存在任何不確定因素；
24. 因此類損害所引起之殘疾或死亡，受試者或受試者家屬或受扶養人將以何種方式？透過哪一組織取得賠償(或指明未提供此類賠償計畫)；
25. 受邀參加研究之可能受試標的所在國對獲賠償權利是否有法律上之保障；
26. 倫理審查委員會已批准或許可該研究計畫。

Guideline 6: Obtaining informed consent: Obligations of sponsors and investigators

指南 6：獲取知情同意：贊助者與研究者的職責

Sponsors and investigators have a duty to:

- refrain from unjustified deception, undue influence, or intimidation;
- seek consent only after ascertaining that the prospective subject has adequate understanding of the relevant facts and of the consequences of participation and has had sufficient opportunity to consider whether to participate;
- as a general rule, obtain from each prospective subject a signed form as evidence of informed consent—investigators should justify any exceptions to this general rule and obtain the approval of the ethical review committee;
- renew the informed consent of each subject if there are significant changes in the conditions or procedures of the research or if new information becomes available that could affect the willingness of subjects to continue to participate; and,
- renew the informed consent of each subject in long-term studies at pre-determined intervals, even if there are no changes in the design or objectives of the research.

贊助者及研究者有義務：

- 避免使用不當欺騙手段，施加不當影響或恐嚇；
- 僅於確定可能受試標的充分瞭解參加研究有關實情及後果，且有充分機會考慮是否參加之後，才能徵求其同意；
- 作為一般規則，應獲取每一受試者之簽名作為知情同意之證據---針對本規則之任何例外，研究者應有正當理由並獲得倫理審查委員會之批准；
- 如研究條件或程序發生顯著變化，或取得可能影響受試者繼續參加研究意願之新資訊，應重新獲取每位受試者之知情同意；
- 針對長期研究項目，即使該研究之設計或目標未變化，亦應依照事先確定之時間間隔，重新獲取每位受試者之知情同意。

Guideline 7: Inducement to participate

Subjects may be reimbursed for lost earnings, travel costs and other expenses incurred in taking part in a study; they may also receive free medical services. Subjects, particularly those who receive no direct benefit from research, may also be paid or otherwise compensated for inconvenience and time spent. The payments should not be so large, however, or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgement (“undue inducement”). All payments, reimbursements and medical services provided to research subjects must have been approved by an ethical review committee.

指南 7：受試者之招募

受試者於參加某項研究所發生之收入損失、旅費及其他開支應獲得補償；其另可獲得免費醫療照護。受試者，特別是那些無法從研究中直接受益之受試者，亦應參加研究而造成之不便及所耗費時間而被支付報酬或取得其他補償。然報酬不應過大或所提供之醫療服務不應過多，否則形同誘使受試者非基於其自己之最佳判斷同意參加研究("過度勸誘")。所有提供給受試者之報酬、補償及醫療服務均應獲得倫理審查委員會之批准。

Guideline 8: Benefits and risks of study participation

For all biomedical research involving human subjects, the investigator must ensure that potential benefits and risks are

指南 8：參加研究之利益及風險

就所有人體生物醫學研究，研究者必須保證潛在效益及風險能獲得合

reasonably balanced and risks are minimized.

- Interventions or procedures that hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual subject must be justified by the expectation that they will be at least as advantageous to the individual subject, in the light of foreseeable risks and benefits, as any available alternative. Risks of such “beneficial” interventions or procedures must be justified in relation to expected benefits to the individual subject.
- Risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual must be justified in relation to the expected benefits to society (generalizable knowledge). The risks presented by such interventions must be reasonable in relation to the importance of the knowledge to be gained.

理平衡，且將風險最小化。

- 應提供受試者最直接診斷、治療或預防干預措施或治療過程之合理性在於：從可預見風險及效益角度，與任何可得到之替代方法相較至少是同樣有利的。此"效益"干預措施或治療過程之風險相對於受試者預期效益而言必須是合理的。
- 對受試者無直接診斷、治療、或預防干預措施之風險，相對於社會之預期效益(概括知識)而言必須是合理的。此干預措施之風險相對於將要獲得知識之重要性而言，必須是合理的。

Guideline 9: Special limitations on risk when research involves individuals who are not capable of giving informed consent

When there is ethical and scientific justification to conduct research with individuals incapable of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual subject should be no more likely and not greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when an ethical review committee has approved them.

指南 9：研究中涉及不能給予知情同意之受試者，有關風險之特殊限制

當存在倫理及科學合理性，對無法給予知情同意之個人實施研究時，對受試者無直接效益願景之研究，干預措施之風險應不能比對其常規體格檢查或心理檢查之風險更大。如有一非常重要之科學或醫學理論，並取得倫理審查委員會之批准，輕微或較小地超過前述風險是可獲允許的。

Guideline 10: Research in populations and communities with limited resources

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:

- the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and
- any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

指南 10：於資源有限之群體及社會之研究

於開始針對某一資源受限之群體或社會進行研究前，贊助者及研究者必須盡一切努力保證：

- 研究是針對實施研究所在地之群體或社會之健康需要及其優先需求性；
- 任何干預措施或開發之產品，或所獲得之知識，均會為該群體或社會之利益而被合理地使用。

Guideline 11: Choice of control in clinical trials

As a general rule, research subjects in the control group of a trial of a diagnostic, therapeutic or preventive intervention should receive an established effective intervention. In some circumstances it may be be ethically acceptable to use an alternative comparator, such as placebo or “no treatment”. Placebo may be used:

- when there is no established effective intervention;
- when withholding an established effective intervention would expose subjects to, at most, temporary discomfort or delay in relief of symptoms;
- when use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not add any risk of serious or irreversible harm to the subjects.

指南 11：臨床試驗中對照之選擇

一般而言，診斷、治療或預防性干預試驗中對照組之受試者，應得到公認有效之干預。某些情況下，使用一替代對照，例如安慰劑或"不治療"，於倫理學上是可被接受的。安慰劑可用於：

- 於無公認有效之干預時；
- 如不採取公認有效之干預，至多使受試者感到暫時不適或延遲症狀緩解時；
- 於採用一公認有效之干預作為對照，將會產生科學上不可靠結果，而使用安慰劑不會增加受試者任何嚴重的或不可避免損害之風險。

Guideline 12: Equitable distribution of burdens and benefits in the selection of groups of subjects in research

Groups or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. The exclusion of groups or communities that might benefit from study participation must be justified.

指南 12：於研究中受試者群體選擇時負擔及利益之公平分配

應通過公平分配研究負擔及利益之方式，選擇受邀成為研究受試者之群體。排除可能受益於參加研究之群體必須是合理的。

Guideline 13: Research involving vulnerable persons

Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

指南 13：涉及弱勢群體之研究

邀請弱勢個人作為受試者需要有特殊理由，如選擇這些弱勢個人，必須切實履行保護其權利及健康之措施。

Guideline 14: Research involving children

Before undertaking research involving children, the investigator must ensure that:

- the research might not equally well be carried out with adults;

指南 14：涉及兒童之研究

於進行涉及兒童之研究前，研究者必須確保：

- 以成人為受試標的，研究不能同樣有效地進行；

- the purpose of the research is to obtain knowledge relevant to the health needs of children;
- a parent or legal representative of each child has given permission;
- the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and,
- a child's refusal to participate or continue in the research will be respected.

- 研究目的係為獲得與兒童健康有關所需之知識；
- 每位兒童之父母或法定代理人已賦予許可；
- 已獲得每位兒童於其能力範圍內所賦予之協議(同意)；
- 兒童拒絕參加或拒絕繼續參加研究亦應獲得尊重。

Guideline 15: Research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent

指南 15：因受試者智力或行為障礙而未給予充分知情同意之研究

Before undertaking research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent, the investigator must ensure that:

- such persons will not be subjects of research that might equally well be carried out on persons whose capacity to give adequately informed consent is not impaired;
- the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioural disorders;
- the consent of each subject has been obtained to the extent of that person's capabilities, and a prospective subject's refusal to participate in research is always respected, unless, in exceptional circumstances, there is no reasonable medical alternative and local law permits overriding the objection; and,
- in cases where prospective subjects lack capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with applicable law.

因受試者智力或行為障礙而無法提供充分知情同意之研究展開前，研究者必須保證：

- 於知情同意能力未受損之人體能同樣有效地進行研究，前述群體即不能成為受試者；
- 研究的目的是為取得有關智力或行為障礙者特有之健康需求之知識；
- 已獲得與每位受試者能力程度相應之同意，可能受試標的拒絕參加研究應始終予以尊重，除非於特殊情況下，無合理醫療替代方法，且當地法律允許不去考慮前述拒絕；
- 如可能之受試標的無能力同意，應獲得家庭負責成員或符合現行法律之法定代理人之許可。

Guideline 16: Women as research subjects

指南 16：婦女作為受試者

Investigators, sponsors or ethical review committees should not exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study should not, in itself, be used as a reason for precluding or limiting participation. However, a thorough discussion of risks to the pregnant woman and to her fetus is a prerequisite for the woman's ability to make a rational decision to enrol in a clinical study. In this discussion, if

研究者、贊助者或倫理審查委員會不應排除育齡期婦女參加生物醫學研究。研究期間有懷孕之可能，其本身不能作為排除或限制參加研究之理由。然而，詳盡討論對孕婦及胎兒之風險，是婦女做出參加臨床研究理性決定之先決條件。此一討論包括如懷孕，參加研究可能危害

participation in the research might be hazardous to a fetus or a woman if she becomes pregnant, the sponsors/ investigators should guarantee the prospective subject a pregnancy test and access to effective contraceptive methods before the research commences. Where such access is not possible, for legal or religious reasons, investigators should not recruit for such possibly hazardous research women who might become pregnant.

胎兒或她本人，贊助者、研究者應以妊娠試驗確認可能受試標的並未受孕，並在研究開始前採取有效避孕方法。如因法律或宗教原因而無法如此為之，研究者不應招募可能懷孕之婦女進行可能有此類風險之研究。

Guideline 17: Pregnant women as research participants

指南 17：孕婦作為受試者

Pregnant women should be presumed to be eligible for participation in biomedical research. Investigators and ethical review committees should ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring, and to their fertility. Research in this population should be performed only if it is relevant to the particular health needs of a pregnant woman or her fetus, or to the health needs of pregnant women in general, and, when appropriate, if it is supported by reliable evidence from animal experiments, particularly as to risks of teratogenicity and mutagenicity.

應假定孕婦有資格參加生物醫學研究。研究者及倫理審查委員會應確保已懷孕之可能受試標的被充分告知有關她們自身、其身孕、胎兒及其後代、及其生育力風險及效益。僅於針對孕婦或其胎兒特有之健康需要、或孕婦總體健康需要，且於合適時，有來自動物實驗、尤其是關於導致畸形及導致突變風險之可靠證據予以支持，才能於該群體中進行研究。

Guideline 18:Safeguarding confidentiality

指南 18：機密保全

The investigator must establish secure safeguards of the confidentiality of subjects' research data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.

研究者應採取安全措施，保護受試者研究資料之機密。受試者應被告知研究者保全機密之能力受到法律及其他規定之拘束，及機密洩露之可能後果。

Guideline 19: Right of injured subjects to treatment and compensation

指南 19：受害受試者獲得治療及賠償之權利

Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In the case of death as a result of their participation, their dependants are entitled to compensation. Subjects must not be asked to waive the right to compensation.

受試者因參加研究而受到傷害，研究者應保證其有權獲得對該傷害之免費醫療及經濟或其他補償，作為對於所造成之任何損傷、殘疾或障礙之公正賠償。如因參加研究而死亡，其受扶養人有權獲得賠償。受試者決不能被要求放棄獲得賠償之權利。

Guideline 20: Strengthening capacity for ethical and scientific review and biomedical research

Many countries lack the capacity to assess or ensure the scientific quality or ethical acceptability of biomedical research proposed or carried out in their jurisdictions. In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible in such countries contribute effectively to national or local capacity to design and conduct biomedical research, and to provide scientific and ethical review and monitoring of such research. Capacity-building may include, but is not limited to, the following activities:

- establishing and strengthening independent and competent ethical review processes/committees
- strengthening research capacity
- developing technologies appropriate to health-care and biomedical research
- training of research and health-care staff
- educating the community from which research subjects will be drawn.

指南 20：加強倫理及科學審查能力及生物醫學研究之能力

許多國家沒有能力審查或確保在其管轄範圍內所提交或進行之生物醫學研究之科學性或倫理可接受性。於國外機構發起之合作研究，贊助者及研究者於倫理上有義務保證，於這些國家由其負責之生物醫學研究項目將對該國或地方之生物醫學研究之設計及實施能力發生有效的促進功能，並為該類研究提供科學及倫理審查及監督。能力培養包括，但不限於以下工作：

- 建立及強化獨立、具能力之倫理學審查過程及委員會
- 加強研究能力
- 發展適用於衛生保健及生物醫學研究之技術
- 培訓研究及衛生保健人員
- 對從中篩選受試者之群體進行教育。

Guideline 21: Ethical obligation of external sponsors to provide health-care services

External sponsors are ethically obliged to ensure the availability of:

- health-care services that are essential to the safe conduct of the research;
- treatment for subjects who suffer injury as a consequence of research interventions; and,
- services that are a necessary part of the commitment of a sponsor to make a beneficial intervention or product developed as a result of the research reasonably available to the population or community concerned.

指南 21：國外贊助者提供健康醫療服務之倫理義務

國外贊助者於倫理上有義務確保：

- 安全地進行研究所需之衛生保健服務；
- 治療因研究干預措施而受到損害之受試者；
- 贊助者承諾之一，必須使作為研究成果有益干預措施或產品合理地用於有關群體或社會所為之服務。