世界衛生組織
生物醫學研究審查倫理委員會操作指南
2000年2月21日日內瓦

World Health Organization

Operational Guidelines for Ethics Committees That Review Biomedical Research

21 February 2000 Geneva

PREFACE

The ethical and scientific standards for carrying out biomedical research on human subjects have been developed and established in international guidelines, including the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the WHO and ICH Guidelines for Good Clinical Practice. Compliance with these guidelines helps to ensure that the dignity, rights, safety, and well-being of research participants are promoted and that the results of the investigations are credible.

All international guidelines require the ethical and scientific review of biomedical research alongside informed consent and the appropriate protection of those unable to consent as essential measures to protect the individual person and the communities who participate in research. For the purposes of these Guidelines, biomedical research includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, medical records, and biological samples, as well as epidemiological, social, and psychological investigations.

These Guidelines are intended to facilitate and support ethical review in all countries around the world. They are based on a close examination of the requirements for ethical review as established in international guidelines, as well as on an evaluation of existing practices of ethical review in countries around the world. They do not, however, purport to replace the need for national and local guidelines for the ethical review of biomedical research, nor do they intend to supersede national laws and regulations.

The majority of biomedical research has been predominantly motivated by concern for the benefit of already privileged communities. This is reflected by the fact that the WHO

前言

有關針對人體進行生物醫學研究試驗之倫理及科學標準於某些國際指南已被制定及確立，包括赫爾辛基宣言、國際醫學科學組織委員會之人體生物醫學研究國際倫理指南及世界衛生組織及人用藥物註冊技術要求國際協調會議對藥品臨床試驗管理規範之指南。遵循前述指南有助使受試者尊嚴、權利、安全及福利及研究結果之可信性獲得保障。

所有國際指南除要求知情同意及對無法同意者予以適當保護外，另要求對生物醫學研究進行倫理及科學審查，以作為保護參加研究之個人及社區之必要措施。從前述指南目的觀之，生物醫學研究包括對藥品、醫療儀器、醫學放射及影像、外科手術、病歷及生物標本及流行病學、社會及心理學之研究。

WHO 指南目的在促進並支援世界各國之倫理審查。其基於對國際指南已確立之倫理審查要求之嚴格評價及基於對世界各國現有倫理審查實踐之評價，然其無意取代各國及各地區對生物醫學研究之倫理審查要求，亦無意取代各國法律及規定。

大多數生物醫學研究主要考慮某些特殊群體之利益。WHO 估計對醫學研究及開發之 90%資源僅用

estimates that 90% of the resources devoted to research and development on medical problems are applied to diseases causing less than 10% of the present global suffering. The establishment of international guidelines that assist in strengthening the capacity for the ethical review of biomedical research in all countries contributes to redressing this imbalance.

於造成目前不到全球危害 10%之疾病上。已頒佈之國際指南有助於加強各國生物醫學研究之倫理審查能力，並為調整前述不平衡而作出貢獻。

1. OBJECTIVE

The objective of these Guidelines is to contribute to the development of quality and consistency in the ethical review of biomedical research. The Guidelines are intended to complement existing laws, regulations, and practices, and to serve as a basis upon which ethics committees (ECs) can develop their own specific written procedures for their functions in biomedical research. In this regard, the Guidelines establish an international standard for ensuring quality in ethical review. The Guidelines should be used by national and local bodies in developing, evaluating, and progressively refining standard operating procedures for the ethical review of biomedical research.

1. 目的

指南目的係為提高生物醫學研究倫理審查品質及其一致性。指南旨在補充現有法律、法規及慣例，並於此基礎下，各國倫理委員會能制定其各自之書面程序，以發揮其在生物醫學研究之功能。於此方面，指南確立保證倫理審查品質之國際標準。指南應被各國及各地區用來制訂、評估及不斷地修訂對生物醫學研究倫理審查標準操作程序。

2. THE ROLE OF AN EC

The purpose of an EC in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants. A cardinal principle of research involving human participants is 'respect for the dignity of persons'. The goals of research, while important, should never be permitted to override the health, well-being, and care of research participants. ECs should also take into consideration the principle of justice. Justice requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture, and ethnic considerations.

ECs should provide independent, competent, and timely review of the ethics of proposed studies. In their composition, procedures, and decision-making, ECs need to have independence from political, institutional, professional, and market influences. They need similarly to demonstrate competence and efficiency in their work.

ECs are responsible for carrying out the review of proposed research before the commencement of the research. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision.

2. 倫理委員會之功能

倫理委員會審查生物醫學研究之目的係為保護所有實際或可能受試者之尊嚴、權利、安全及福利。涉及人類受試者研究之主要原則為"尊重人的尊嚴"，研究的目的雖然重要，然絕不能超越受試者之健康、福利及保健。倫理委員會應考慮公正原則。公正要求研究利益及負擔在社會所有團體及階層中之公平分配，同時考慮年齡、性別、經濟狀況、文化及種族等問題。

倫理委員會應對研究項目之倫理學進行獨立、稱職及及時的審查。倫理委員會之組成、運作及決議應不受政治、機構、職業及市場之影響。同樣地，其應於自己工作中證明其工作能力及效率。

倫理委員會負責研究開始前對研究項目進行審查。同時另應對已通過審查、正在進行之研究計畫實施定期倫理評價。

ECs are responsible for acting in the full interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

倫理委員會有義務依據可能受試者及有關社區之整體利益行事，同時應考慮研究人員利益及需求，並對有關行政機構及現行法律要求保持應有之尊重。

3. Establishing A System Of Ethical Review

Countries, institutions, and communities should strive to develop ECs and ethical review systems that ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical research. States should promote, as appropriate, the establishment of ECs at the national, institutional, and local levels that are independent, multi-disciplinary, multi-sectorial, and pluralistic in nature. ECs require administrative and financial support.

Procedures need to be established for relating various levels of review in order to ensure consistency and facilitate cooperation. Mechanism for cooperation and communication need to be developed between national committees and institutional and local committees. These mechanisms should ensure clear and efficient communication. They should also promote the development of ethical review within a country as well as the ongoing education of members of ethics committees. In addition, procedures need to be established for the review of biomedical research protocols carried out at more than one site in a country or in more than one country. A network of ethical review should be established at the regional, national, and local levels that ensures the highest competence in biomedical review while also guaranteeing input from all levels of the community.

3. 倫理審查系統之建立

國家、機構及社會團體應努力建立倫理委員會及倫理審查系統，以最大限度地保護受試者並為生物醫學研究於科學及倫理方面能達到的最高品質做出貢獻。政府應適當地促進國家、機構及地方建立獨立、多學科、多部門、成員為兼職之倫理委員會。倫理委員會需要行政上及財政上之支持。

需要建立各級倫理審查相互聯繫之程序，以保證審查之一致性並促進合作。國家、機構及地方委員會間應建立合作及交流機制，以保證暢通、有效地交流，促進國內倫理審查發展及倫理委員會成員之持續教育。此外，對某國內多地點或多個國家進行之生物醫學研究計畫，另應建立審查程序。應建立區域、國家及地方多層次之倫理審查網絡，以保證發揮生物醫學審查之最大作用，同時亦保證接受社會各方面之意見。

4. CONSTITUTING AN EC

ECs should be constituted to ensure the competent review and evaluation of all ethical aspects of the research projects they receive and to ensure that their tasks can be executed free from bias and influence that could affect their independence.

ECs should be multidisciplinary and multi-sectorial in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community.

4. 倫理委員會之組成

倫理委員會的組成應保證其有能力對申請研究項目之所有倫理問題進行審查及評價，並保證能在無偏頗及影響其獨立性之情況下進行工作。

倫理委員會組成應由多學科及多部門的，包括相關科學技術專長，均衡年齡及性別分佈，另必須有代表社區利益之非專業人士參加。

ECs should be established in accordance with the applicable laws and regulations of the country and in accordance with the values and principles of the communities they serve.

ECs should establish publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties of the EC, membership requirements, the terms of appointment, the conditions of appointment, the offices, the structure of the secretariat, internal procedures, and the quorum requirements. ECs should act in accordance with their written operating procedures.

It may be helpful to summarize the activities of the EC in a regular (annual) report.

倫理委員會之設立應符合國家現行法律規定，並符合其所服務社會之價值觀念及原則。

倫理委員會應建立公開之標準操作程序，並說明倫理委員會之主管部門、倫理委員會功能及職責、成員資格要求、任期、任職條件、辦公室、秘書處結構、內部程序及法定開會人數要求。倫理委員會應依既定操作程序為工作。

以定期(年度)報告形式總結倫理委員會之工作是有益的。

4.1 Membership Requirements

4.1 成員資格要求

Clear procedures for identifying or recruiting potential EC members should be established. A statement should be drawn up of the requirements for candidacy that includes an outline of the duties and responsibilities of EC members.

Membership requirements should be established that include the following:

4.1.1 the name or description of the party responsible for making appointments;

4.1.2 the procedure for selecting members, including the method for appointing a member (e.g., by consensus, by majority vote, by direct appointment);

4.1.3 conflicts of interest should be avoided when making appointments, but where unavoidable there should be transparency with regard to such interests.

A rotation system for membership should be considered that allows for continuity, the development and maintenance of expertise within the EC, and the regular input of fresh ideas and approaches.

應建立篩選及招募倫理委員會成員之明確程序，應擬訂候選人資格之規定，包括倫理委員會成員義務及職責要點。應建立包括以下各點之成員資格要求：

4.1.1 負責任命機構之名稱；

4.1.2 成員選擇程序，包括任命成員之方法(如一致同意、多數表決通過、直接任命)；

4.1.3 任命時應避免利益衝突，如無法避免，有關該利益應予透明；

成員輪調制應考慮保證倫理委員會成員之連續性、專業知識發展及維持，並不斷吸收新觀點及方法。

4.2 Terms of Appointment

4.2 任期

Terms of appointment should be established that include the following:

4.2.1 the duration of an appointment,

4.2.2 the policy for the renewal of an appointment,

4.2.3 the disqualification procedure,

4.2.4 the resignation procedure,

4.2.5 the replacement procedure.

應確定任期，包括下列幾點：

4.2.1 任職期限；

4.2.2 連任規定；

4.2.3 取消資格之程序；

4.2.4 辭職程序；

4.2.5 替換程序。

4.3 Conditions of Appointment

4.3 任命之條件

A statement of the conditions of appointment should be drawn up that includes the following:

4.3.1 a member should be willing to publicize his/her full name, profession, and affiliation;

4.3.2 all reimbursement for work and expenses, if any, within or related to an EC should be recorded and made available to the public upon request;

4.3.3 a member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters; in addition, all EC administrative staff should sign a similar confidentiality agreement.

任命條件之陳述包括下列各點：

4.3.1 成員應同意公開其完整姓名、職業及隸屬關係；

4.3.2 倫理委員會內部及有關工作報酬及其他開支應予以記錄，並能應要求公佈於眾；

4.3.3 成員應簽署一有關會議審議、申請、受試者資訊及相關事宜之保密協議；倫理委員會所有行政工作人員亦應簽署類似保密協定。

4.4 Offices

ECs should establish clearly defined offices for the good functioning of ethical review. A statement is required of the officers within the EC (e.g., chairperson, secretary), the requirements for holding each office, the terms and conditions of each office, and the duties and responsibilities of each office (e.g., agenda, minutes, notification of decisions). Clear procedures for selecting or appointing officers should be established.

In addition to the EC officers, an EC should have adequate support staff for carrying out its responsibilities.

4.4 辦公室

為能更佳地進行倫理審查，倫理委員會應設立有明確職責之辦公室。倫理委員會內部行政人員(如主席、秘書)、設立每一辦公室之必備條件、辦公室名稱及地位、辦公室職責及義務(如：會議日程，會議記錄，決議通告)應予以說明。應設立選擇或任命行政人員之明確程序。除倫理委員會行政人員外，倫理委員會應有足夠輔助人員以行使職責。

4.5 Quorum Requirements

ECs should establish specific quorum requirements for reviewing and deciding on an application. These requirements should include:

4.5.1 the minimum number of members required to compose a quorum (e.g., more than half the members);

4.5.2 the professional qualifications requirements (e.g., physician, lawyer, statistician, paramedical, layperson) and the distribution of those requirements over the quorum; no quorum should consist entirely of members of one profession or one gender; a quorum should include at least one member whose primary area of expertise is in a non-scientific area, and at least one member who is independent of the institution/research site.

4.5 法定人數規定

倫理委員會應確定審查及批准某申請所需法定人數之明確規定。該要求包括：

4.5.1 構成法定人數所需之最少開會人數(例如超過半數成員)；

4.5.2 專業資格要求(例如醫生、律師、統計人員、醫療輔助人員、非專業人士)，及法定人數中專業資格分佈之要求；法定人數中不能完全由某一專業或某一性別之人組成；法定人數中至少應有一成員之主要技術專長為非科學領域，並至少有一成員獨立於機構/研究場所。

4.6 Independent Consultants

4.6 獨立顧問

ECs may call upon, or establish a standing list of, independent consultants who may provide special expertise to the EC on proposed research protocols. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, or they may be representatives of communities, patients, or special interest groups. Terms of reference for independent consultants should be established.

倫理委員會可聘請或委任常任獨立顧問，其可就所提議之研究計畫向倫理委員會提供專門意見。該顧問可為倫理或法律方面、特定疾病或方法學之專家，亦可為社區、病人或特定利益團體代表。應規定獨立顧問之授權範圍。

4.7 Education for EC Members

4.7 倫理委員會成員之教育

EC members have a need for initial and continued education regarding the ethics and science of biomedical research. The conditions of appointment should state the provisions available for EC members to receive introductory training in the work of an EC as well as ongoing opportunities for enhancing their capacity for ethical review. These conditions should also include the requirements or expectations regarding the initial and continuing education of EC members. This education may be linked to co-operative arrangements with other ECs in the area, the country, and the region, as well as other opportunities for the initial and continued training of EC members.

倫理委員會成員需要有關生物醫學研究倫理道德及科學方面之最初培訓及繼續教育。任命條件應規定倫理委員會成員接受倫理委員會工作之最初培訓及繼續培訓之機會，以提高其倫理審查能力。任命條件中另應包括最初培訓及繼續教育之要求及預期目標。該教育可與同地區、國家及領域內之其他倫理委員會合作安排，及與針對倫理委員會成員最初及繼續教育之其他機會相互聯繫。

5 SUBMITTING AN APPLICATION

5. 提交申請

ECs are responsible for establishing well-defined requirements for submitting an application for review of a biomedical research project. These requirements should be readily available to prospective applicants.

倫理委員會負責對提交生物醫學研究計畫審查之申請規定詳細要求。申請者應可很容易地取得前述要求。

5.1 Application

5.1 申請

An application for review of the ethics of proposed biomedical research should be submitted by a qualified researcher responsible for the ethical and scientific conduct of the research.

生物醫學研究倫理審查之申請，應由對該研究之倫理及科學行為負責且具資格之研究人員提交之。

5.2 Application Requirements

5.2 申請要件

The requirements for the submission of a research project for ethical review should be clearly described in an application procedure. These requirements should include the following:

研究計畫申請倫理審查要件應於申請程序中予以明確說明。其要件包括下列事項：

5.2.1 the name(s) and address(es) of the EC secretariat or member(s) to whom the application material is to be

5.2.1 受理申請資料之倫理委員會秘書或委員姓名、地址；

submitted;

5.2.2 the application form(s);

5.2.3 the format for submission;

5.2.4 the documentation (see 5.3);

5.2.5 the language(s) in which (core) documents are to be submitted;

5.2.6 the number of copies to be submitted;

5.2.7 the deadlines for submission of the application in relation to review dates;

5.2.8 the means by which applications will be acknowledged, including the communication of the incompleteness of an application;

5.2.9 the expected time for notification of the decision following review;

5.2.10 the time frame to be followed in cases where the EC requests supplementary information or changes to documents from the applicant;

5.2.11 the fee structure, if any, for reviewing an application;

5.2.12 the application procedure for amendments to the protocol, the recruitment material, the potential research participant information, or the informed consent form.

5.2.2 申請表格；

5.2.3 提交格式；

5.2.4 文件(見 5.3 文件)；

5.2.5 準備提交(核心)文件中所使用之語言；

5.2.6 提交之副本份數；

5.2.7 與審查日期有關之提交申請截止日期；

5.2.8 收到申請之告知方式，包括申請不完整之告知方式；

5.2.9 審查後通知決議之預期時間；

5.2.10 倫理委員會要求申請人補充資料或修改資料之期限；

5.2.11 審查某項申請所需之費用結構(如有)；

5.2.12 修正、補充資料、可能的受試者訊息、或知情同意書之申請程序。

5.3 Documentation

5.3 文件

All documentation required for a thorough and complete review of the ethics of proposed research should be submitted by the applicant. This may include, but is not limited to,

5.3.1 signed and dated application form;

5.3.2 the protocol of the proposed research (clearly identified and dated), together with supporting documents and annexes;

5.3.3 a summary (as far as possible in non-technical language), synopsis, or diagrammatic representation ('flowchart') of the protocol;

5.3.4 a description (usually included in the protocol) of the ethical considerations involved in the research;

5.3.5 case report forms, diary cards, and other questionnaires intended for research participants;

5.3.6 when the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g., recent investigator's brochure, published data, a summary of

申請者應提供對所提交研究進行全面完整之倫理審查所需之全部資料。包括(但不限於)下列內容：

5.3.1 簽名並註明日期之申請表；

5.3.2 所提交之研究計畫(明確標註並註明日期)及相關佐證資料及附件；

5.3.3 摘要(盡可能使用非技術性語言)、大綱或流程圖；

5.3.4 針對研究所涉及倫理方面之描述(通常包括於計畫中)；

5.3.5 病例報告表、受試者日記卡及其他問卷；

5.3.6 如研究涉及某研究產品時(如正在研究中之藥品及醫療儀器)，有關該產品之所有安全性、藥理學、製藥及毒理學資料摘要，以及對該產品迄今之臨床經驗總結(如最近之研究者手冊，公開發表之資

the product's characteristics);

5.3.7 investigator(s)'s curriculum vitae (updated, signed, and dated);

5.3.8 material to be used (including advertisements) for the recruitment of potential research participants;

5.3.9 a description of the process used to obtain and document consent;

5.3.10 written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;

5.3.11 informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;

5.3.12 a statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants;

5.3.13 a description of the arrangements for indemnity, if applicable;

5.3.14 a description of the arrangements for insurance coverage for research participants, if applicable;

5.3.15 a statement of agreement to comply with ethical principles set out in relevant guidelines;

5.3.16 all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.

料及產品特性摘要)；

5.3.7 研究人員之履歷(最新並簽名及註明日期)；

5.3.8 用於招募受試者之資料(包括廣告)；

5.3.9 獲得並證明知情同意過程之敘述；

5.3.10 使用受試者能理解之語言(必要時使用其他語言)，向其提供書面及其他形式之研究資訊(明確標註並註明日期)；

5.3.11 使用受試者能理解之語言(必要時使用其他語言)製作之知情同意書(明確標註並註明日期)；

5.3.12 向受試者提供因其參與研究而給予之任何補償(包括費用及獲得醫療保健)之說明；

5.3.13 對損害賠償安排之說明(如適用)；

5.3.14 對受試者的保險計畫安排之說明(如適用)；

5.3.15 同意遵循相關指南規定之倫理原則聲明；

5.3.16 所有之前其他倫理委員會或管理機構(無論是否於同一地點或其他地點)對所提交研究之重要決議(包括否定結論或修改計畫)及對計畫作修改之說明。應提供之前否定結論之理由。

6. REVIEW

All properly submitted applications should be reviewed in a timely fashion and according to an established review procedure.

6. 審查

所有正確遞交之申請應及時並依照既定審查程序進行審查。

6.1 Meeting Requirements

ECs should meet regularly on scheduled dates that are announced in advance. The meeting requirements should include the following:

6.1.1 meetings should be planned in accordance with the needs

6.1 議事要求

倫理委員會應依事先宣佈之預定日期定時舉行會議。會議要求如下：

6.1.1 依據工作負荷安排會議；

of the workload;

6.1.2 EC members should be given enough time in advance of the meeting to review the relevant documents;

6.1.3 meetings should be minuted; there should be an approval procedure for the minutes;

6.1.4 the applicant, sponsor, and/or investigator may be invited to present the proposal or elaborate on specific issues;

6.1.5 independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements.

6.1.2 召開會議前，倫理委員會成員應有足夠時間審查相關資料；

6.1.3 會議應予以記錄；應有批准會議記錄之程序；

6.1.4 申請者、申辦者及(或)研究人員可應邀陳述計畫或就某特定問題進行詳細說明；

6.1.5 依據有效之保密協定，獨立顧問可應邀與會或提供書面意見。

6.2 Elements of the Review

6.2 審查之要件

The primary task of an EC lies in the review of research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. ECs need to take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations. The following should be considered, as applicable:

倫理委員會的主要任務在於審查研究計畫及其佐證文件，應特別注意簽署知情同意書之過程、文件、計畫之適當性及可行性。倫理委員會應考慮先前科學審查(如有)，以及現行法律及法規之要求。於適用時，可考慮以下各點：

6.2.1 Scientific Design and Conduct of the Study

6.2.1.1 the appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants;

6.2.1.2the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;

6.2.1.3 the justification for the use of control arms;

6.2.1.4criteria for prematurely withdrawing research participants;

6.2.1.5 criteria for suspending or terminating the research as a whole;

6.2.1.6 the adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring board (DSMB);

6.2.1.7 the adequacy of the site, including the supporting staff, available facilities, and emergency procedures;

6.2.1.8 the manner in which the results of the research will be reported and published;

6.2.2 Recruitment of Research Participants

6.2.2.1 the characteristics of the population from which the

6.2.1 研究之科學設計及實施

6.2.1.1 與研究目的有關研究設計之合理性、統計方法(包括樣本計算)及使用最少受試者人數獲得可靠結論之可能性；

6.2.1.2 權衡受試者及相關群體之預期利益與預計危險及不便是否合理；

6.2.1.3 應用對照組之理由；

6.2.1.4 受試者提前退出之標準；

6.2.1.5 暫停或終止整個研究之標準；

6.2.1.6 對研究實施過程之監測及審查之適當規定，包括成立資料安全監督委員會；

6.2.1.7 合適場地，包括輔助人員、可用設施及應急措施；

6.2.1.8 報告及出版研究結果方式。

6.2.2 招募受試者

6.2.2.1 受試者之人群特徵(包括性

research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity);

別、年齡、文化程度、文化背景、經濟狀況及種族)；

6.2.2.2 the means by which initial contact and recruitment is to be conducted;

6.2.2.2 初次接觸及招募受試者準備採取之方式；

6.2.2.3 the means by which full information is to be conveyed to potential research participants or their representatives;

6.2.2.3 將所有資訊傳達給可能受試者或其代表人之方式；

6.2.2.4 inclusion criteria for research participants;

6.2.2.4 受試者之納入標準；

6.2.2.5 exclusion criteria for research participants;

6.2.2.5 受試者之排除標準；

6.2.3 Care and Protection of Research Participants

6.2.3 受試者之醫療及保護

6.2.3.1 the suitability of the investigator(s)'s qualifications and experience for the proposed study;

6.2.3.1 對所提交之研究，研究人員資格及經驗之適當性；

6.2.3.2 any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action;

6.2.3.2 因研究目的而撤銷或不給予標準治療之設計及採取此類設計之理由；

6.2.3.3 the medical care to be provided to research participants during and after the course of the research;

6.2.3.3 於研究過程中及研究後，為受試者提供之醫療保健；

6.2.3.4 the adequacy of medical supervision and psycho-social support for the research participants;

6.2.3.4 對受試者提供之醫療監督及心理社會支持是否完備；

6.2.3.5 steps to be taken if research participants voluntarily withdraw during the course of the research;

6.2.3.5 如研究過程中受試者自願退出時將採取之措施；

6.2.3.6 the criteria for extended access to, the emergency use of, and/or the compassionate use of study products;

6.2.3.6 延長使用、緊急使用、和或出於同情而使用研究產品之標準；

6.2.3.7 the arrangements, if appropriate, for informing the research participant's general practitioner (family doctor), including procedures for seeking the participant's consent to do so;

6.2.3.7 於必要時，向受試者之一般醫生(家庭醫生)提供資訊之安排，包括取得受試者對該做法同意之程序；

6.2.3.8 a description of any plans to make the study product available to the research participants following the research;

6.2.3.8 研究結束後，受試者可獲得研究產品計畫之說明；

6.2.3.9 a description of any financial costs to research participants;

6.2.3.9 對受試者任何費用支出之說明；

6.2.3.10 the rewards and compensations for research participants (including money, services, and/or gifts);

6.2.3.10 對受試者之獎勵與補償(包括金錢、服務、和或禮物)；

6.2.3.11 the provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research;

6.2.3.11 因參與研究造成受試者損傷/殘疾/死亡之補償或治療之規定；

6.2.3.12 the insurance and indemnity arrangements;

6.2.3.12 保險及損害賠償安排；

6.2.4 Protection of Research Participant Confidentiality

6.2.4 受試者隱私之保護

6.2.4.1 a description of the persons who will have access to personal data of the research participants, including medical records and biological samples;

6.2.4.1 針對可接觸受試者個人資料(包括醫療記錄、生物學標本)人員規定之敘述；

6.2.4.2 the measures taken to ensure the confidentiality and security of personal information concerning research participants;

6.2.4.2 保證有關受試者個人資料之保密及安全措施。

6.2.5 Informed Consent Process

6.2.5 知情同意之過程

6.2.5.1 a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent;

6.2.5.2 the adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s);

6.2.5.3 clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals;

6.2.5.4 assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety, and well-being);

6.2.5.5 the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project;

6.2.6 Community Considerations

6.2.6.1 the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn;

6.2.6.2 the steps taken to consult with the concerned communities during the course of designing the research;

6.2.6.3 the influence of the community on the consent of individuals;

6.2.6.4 proposed community consultation during the course of the research;

6.2.6.5 the extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs;

6.2.6.6 a description of the availability and affordability of any successful study product to the concerned communities following the research;

6.2.6.7 the manner in which the results of the research will be made available to the research participants and the concerned communities.

6.2.5.1 獲得知情同意過程之詳細描述，包括確認取得知情同意之負責之人；

6.2.5.2 給予受試者或其法定代理人之書面及口頭資料之充分性、完整性及可理解性；

6.2.5.3 試圖將不能表達知情同意者納入試驗之充分理由，及為這些人等參加試驗而取得同意或授權之詳細敘述；

6.2.5.4 保證受試者於研究過程中可得到與其參加試驗相關有用之訊息(包括其權利、安全及福利)；

6.2.5.5 於研究過程中聽取並答覆受試者或其代表人之疑問及意見之規定。

6.2.6 社區考慮

6.2.6.1 對從當地社區及有關社區中選取受試者，及研究之影響與關聯；

6.2.6.2 研究設計階段所採取向有關社區諮詢之步驟；

6.2.6.3 社區對個人同意之影響；

6.2.6.4 研究過程中所提議之社區諮詢；

6.2.6.5 研究對增強當地能力之貢獻程度，例如增強當地醫療保健、研究、及對公共衛生需求之應對能力；

6.2.6.6 研究結束後，有關社區就成功的研究產品之可取得性及可負擔性；

6.2.6.7 受試者及有關社區獲得研究結果之方式。

6.3 Expedited Review

ECs should establish procedures for the expedited review of research proposals. These procedures should specify the following:

6.3 加速審查

倫理委員會應建立對研究計畫加速審查之程序。這些程序應詳細說明下列各點：

6.3.1 the nature of the applications, amendments, and other considerations that will be eligible for expedited review;

6.3.2 the quorum requirement(s) for expedited review;

6.3.3 the status of decisions (e.g., subject to confirmation by full EC or not).

6.3.1 符合加速審查之申請、修改及其他需要考慮事項之類型；

6.3.2 加速審查之法定開會人數要求；

6.3.3 決議權(如是否需全體倫理委員會成員確認)。

7. DECISION-MAKING

In making decisions on applications for the ethical review of biomedical research, an EC should take the following into consideration:

7.1 a member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes;

7.2 a decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of EC staff;

7.3 decisions should only be made at meetings where a quorum (as stipulated in the EC's written operating procedures) is present;

7.4 the documents required for a full review of the application should be complete and the relevant elements mentioned above (see 6.2) should be considered before a decision is made;

7.5 only members who participate in the review should participate in the decision;

7.6 there should be a predefined method for arriving at a decision (e.g., by consensus, by vote); it is recommended that decisions be arrived at through consensus, where possible; when a consensus appears unlikely, it is recommended that the EC vote;

7.7 advice that is non-binding may be appended to the decision;

7.8 in cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified;

7.9 a negative decision on an application should be supported by clearly stated reasons.

7. 倫理審查之決議

於生物醫學研究倫理審查申請進行決議時，倫理委員會應考慮下列各點：

7.1 如存在利益衝突，該成員應退出該會議有關申請審查決議之程序；該利益衝突應於審查前向主席說明，並在會議摘要中予以記錄；

7.2 僅於有充分時間進行審查討論，除倫理委員會成員及工作人員以外之其他人員(如研究人員、申辦者代表、獨立顧問)離場之情況下，始可為決議；

7.3 僅於達法定開會人數(符合倫理委員會書面操作程序規定)時，會議始可為決議；

7.4 對申請進行詳細審查所要求之文件應準備齊全，且於作決議前應考慮上面所提到之有關要件(見 6.2 審查之要件)；

7.5 僅參與審查人員始可參與決議；

7.6 應依事先確定之方法為決議(如一致同意或投票表決)；建議於可能情況下，以一致同意方式為決議；若無法達成一致同意，建議倫理委員會投票表決；

7.7 非正式的建議可作為決議之附件；

7.8 如為附條件之決議，則應提出修改之明確建議，及對申請重新審查程序之詳細說明；

7.9 就申請之否定性決議，應明確陳述理由予以證明。

8. COMMUNICATING A DECISION

A decision should be communicated in writing to the applicant according to EC procedures, preferably within two weeks' time of the meeting at which the decision was made. The communication of the decision should include, but is not limited to, the following:

8.1 the exact title of the research proposal reviewed;

8.2 the clear identification of the protocol of the proposed research or amendment, date and version number (if applicable). on which the decision is based;

8.3 the names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential research participant information sheet/material and informed consent form;

8.4 the name and title of the applicant;

8.5 the name of the site(s);

8.6 the date and place of the decision;

8.7 the name of the EC taking the decision;

8.8 a clear statement of the decision reached;

8.9 any advice by the EC;

8.10 in the case of a conditional decision, any requirements by the EC, including suggestions for revision and the procedure for having the application re-reviewed;

8.11 in the case of a positive decision, a statement of the responsibilities of the applicant; for example, confirmation of the acceptance of any requirements imposed by the EC; submission of progress report(s); the need to notify the EC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study); the need to notify the EC in the case of amendments to the recruitment material, the potential research participant information, or the informed consent form; the need to report serious and unexpected adverse events related to the conduct of the study; the need to report unforeseen circumstances, the termination of the study, or significant decisions by other ECs; the information the EC expects to receive in order to perform ongoing review; the final summary or final report;

8.12 the schedule/plan of ongoing review by the EC;

8.13 in the case of a negative decision, clearly stated reason(s) for the negative decision;

8.14 signature (dated) of the chairperson (or other authorized

8. 決議之送達

決議應以書面方式，依倫理委員會相關程序送達給申請者，最好於作出決議之會議後二週內。決議應包括(但不限於)下列內容：

8.1 所審查研究計畫之準確標題；

8.2 明確標註決議所依據、所提交之研究計畫或其修改稿、日期及版本號(如有)；

8.3 審查資料之名稱、及(如有)專門識別號(版本號/日期)，包括受試者資訊表/材料及知情同意書；

8.4 申請人姓名及頭銜；

8.5 研究場所名稱；

8.6 決議日期及地點；

8.7 做出決議之倫理委員會名稱；

8.8 所達成決議之明確闡述；

8.9 倫理委員會之任何建議；

8.10 如為附條件決議，倫理委員會之任何要求，包括修改建議及對申請重新審查之程序；

8.11 如為肯定性決議，則應具一項申請者責任聲明：如確認接受論理委員會所提出之任何要求；提交進度報告；進行計畫修改時應通知倫理委員會(如僅涉及研究後勤及行政管理方面修改除外)；若對招募材料、可能受試者資訊、或知情同意書進行修改時應通知倫理委員會；應報告與研究有關嚴重及意外之不良事件；應報告無法預料之情況、終止研究或其他倫理委員會之重要決議；為針對正在進行之研究審查，倫理委員會需要取得之資料；最後總結或報告；

8.12 倫理委員會對正進行之研究審查時間表/計畫；

8.13 如為否定性決議，明確說明作出否定性決議之理由；

8.14 倫理委員會主席(或其他被授

person) of the EC.

權人)之簽名(日期)。

9 FOLLOW-UP

ECs should establish a follow-up procedure for following the progress of all studies for which a positive decision has been reached, from the time the decision was taken until the termination of the research. The ongoing lines of communication between the EC and the applicant should be clearly specified. The follow-up procedure should take the following into consideration:

9.1 the quorum requirements, the review procedure, and the communication procedure for follow-up reviews, which may vary from the requirements and procedures for the initial decision on an application;

9.2 the follow-up review intervals should be determined by the nature and the events of research projects, though each protocol should undergo a follow-up review at least once a year;

9.3 the following instances or events require the follow-up review of a study:

a. any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study;

b. serious and unexpected adverse events related to the conduct of the study or study product, and the response taken by investigators, sponsors, and regulatory agencies;

c. any event or new information that may affect the benefit/risk ratio of the study;

9.4 a decision of a follow-up review should be issued and communicated to the applicant, indicating a modification, suspension, or termination of the EC's original decision or confirmation that the decision is still valid;

9.5 in the case of the premature suspension/termination of a study, the applicant should notify the EC of the reasons for suspension/termination; a summary of results obtained in a study prematurely suspended/terminated should be communicated to the EC;

9.6 ECs should receive notification from the applicant at the time of the completion of a study;

9.7 ECs should receive a copy of the final summary or final report of a study.

9. 追蹤審查

倫理委員會應建立追蹤審查程序，追蹤所有作出批准決議之研究進展，從作出決議開始直到研究終止。應指定倫理委員會及申請者間之聯繫管道。追蹤審查程序應考慮以下各點：

9.1 法定開會人數要求、審查程序、及追蹤審查之聯繫程序，其可能與對申請所作最初審查之要求及程序有所不同；

9.2 雖然研究方案每年應至少進行一次追蹤審查，然追蹤審查之間隔應由研究計畫之性質及事件為決議；

9.3 以下情況與事件要求應對研究進行追蹤審查：

a.計畫之任何修改，其可能影響受試者權利、安全及(或)福利或影響研究之實施；

b.與研究實施及研究產品有關、嚴重及意外之不良事件，及研究者、申辦者及管理機構所採取之措施；

c.可能影響研究受益/風險比之任何事件或新資訊；

9.4 追蹤審查之決議應公佈並送達給申請者，指出對倫理委員會最初決議之更改、暫停或終止，或確認原決議仍然有效；

9.5 於研究提前暫停/終止之情況下，申請者應通知倫理委員會暫停/終止之原因；提前暫停/終止之研究所取得結果之總結應送交倫理委員會；

9.6 研究結束後，申請者應通知倫理委員會；

9.7 研究之最後總結或報告副本應遞交倫理委員會。

10. DOCUMENTATION AND ARCHIVING

All documentation and communication of an EC should be dated, filed, and archived according to written procedures. A statement is required defining the access and retrieval procedure (including authorized persons) for the various documents, files, and archives.

It is recommended that documents be archived for a minimum period of 3 years following the completion of a study.

Documents that should be filed and archived include, but are not limited to,

10.1 the constitution, written standard operating procedures of the EC, and regular (annual) reports;

10.2 the curriculum vitae of all EC members;

10.3 a record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;

10.4 the published guidelines for submission established by the EC;

10.5 the agenda of the EC meetings;

10.6 the minutes of the EC meetings;

10.7 one copy of all materials submitted by an applicant;

10.8 the correspondence by EC members with applicants or concerned parties regarding application, decision, and follow-up;

10.9 a copy of the decision and any advice or requirements sent to an applicant;

10.10 all written documentation received during the follow-up;

10.11 the notification of the completion, premature suspension, or premature termination of a study;

10.12 the final summary or final report of the study.

10. 文件及檔案

倫理委員會之所有文件及往來信件，依書面程序應註明日期、予以建檔並存檔。應說明有關文件、資料及檔案之存取及返回程序(包括授權者)。

建議文件存檔至少到研究結束後 3 年。

應建立文檔並存檔之文件包括(但不限於)：

10.1 倫理委員會之組成、書面標準操作規則，及常規(年度)報告；

10.2 所有倫理委員會成員之履歷；

10.3 倫理委員會全部收支記錄，包括對秘書處及倫理委員會成員之津貼及補償；

10.4 倫理委員會制定、公佈之申請指南；

10.5 倫理委員會之會議日程；

10.6 倫理委員會之會議記錄；

10.7 申請者所提交之所有資料之副本一份；

10.8 倫理委員會成員與申請者或有關人員就申請、決議及追蹤審查問題之往來信件；

10.9 送達給申請者之決議、建議或要求之副本；

10.10 追蹤審查期間所收到之所有書面資料；

10.11 研究完成、提前暫停或提前終止之通知；

10.12 研究最後總結或報告。