倫理審查工作之監督與評鑑
生物醫學研究審查倫理委員會操作指南之補充指導原則

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Surveying and Evaluating Ethical Review Practices
a complementary guideline to the Operational Guidelines for Ethics Committees That Review Biomedical Research

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1. OBJECTIVE

The purpose of this Guideline is to contribute to an international framework for surveying and evaluating ethical review practices. Ethical review provides essential guidance on research proposals and helps to ensure the protection of participants. The assurance of research protections for individuals and communities requires the establishment of standards for ethical review and the evaluation of the performance of ethical review systems, including the functioning of ECs.

More recently there is growing national and international interest in ensuring that ethical review achieves the highest standards with regard to the protection of individuals and communities. Some countries and regions are in the process of determining methods for evaluating the performance and quality of ECs. In particular, accreditation systems for ECs based on an evaluation of their constitution, Standard Operating Procedures (SOPs), and practices are under development in several countries. This Guideline provides a common reference point for appreciating good ethical review practices and promoting transparency in the work of ECs.

ECs have a public responsibility whose fulfilment requires good practices for ethical review as well as the ongoing education of their members. As part of good practices, there should be a system of quality assurance for surveying and evaluating the performance of ethical review systems. This involves the development by ECs of internal quality assurance mechanisms, such as self-assessment checklists, designed for self-appraisal. Further measures include independent external evaluations of EC practices designed to advise, educate, and improve the ethical review process.

1. 目的

本指南旨在協助構建一監督及評鑑倫理審查工作之國際架構。倫理審查為研究計畫提供基本指導，並有助於確保受試者獲得保護。為確保受試者及其所代表群體於研究中獲得保護，必須制定倫理審查及倫理審查體系(包括倫理委員會權能)運作之評鑑標準。

近年來，國際及各國越來越注重確保倫理審查於保護受試者及其所代表群體方面能達到最高標準。有些國家及地區正在制定評鑑倫理委員會運作與品質之方法。特別是某些國家依據倫理委員會之章程、標準操作規則及工作，正建立倫理委員會認證體系。本指南為正確評鑑倫理審查管理規範及促進倫理委員會工作之透明度提供通用之衡量標準。

倫理委員會為履行其公眾職責，要求倫理審查具備規範管理並對其成員進行繼續教育。作為倫理委員會規範管理的一部分，應有一監督與評鑑倫理審查體系運作之品質保證體系。此包括由倫理委員會制定之內部品質保證機制，如用於自我評鑑之自我評鑑清單。其他措施包括：倫理委員會工作獨立的外部評鑑標準，用於建議、培訓及改善倫理審查過程。

2. THE ROLE OF AN EC

ECs have been established to provide ethical advice to researchers in order to assist decision-making on the adequacy of proposed research projects regarding the protection of potential and actual human participants. In order to fulfil this role it is essential that ECs are constituted and perform according to four principles for ethical review: independence, competence, pluralism, and transparency.

The *Declaration of Helsinki,* Good Clinical Practice Guidelines, and other international and national instruments require the ethical review of research prior to its commencement. These instruments also require ECs to perform regular follow-ups to research projects for which they have provided a positive decision. In their decision-making, ECs must be independent of the sponsor, the investigator, and any undue influence.

ECs must be appropriately constituted and adopt written SOPs in order to achieve independence and quality in decision-making.

2. 倫理委員會之功能

成立倫理委員會係為研究者提供倫理建議，以協助確認研究計畫是否充分保護可能與實際之人類受試者。為履行此一職責，倫理委員會之組成與其運作必須依循倫理審查之四項原則：獨立、有效、多元及透明。

赫爾辛基宣言、藥品臨床試驗管理規範及其他國際與國內法律文件要求於研究開始前進行倫理審查。這些法律文件另要求倫理委員會對其已批准之研究計畫進行定期追蹤審查。倫理委員會之決定必須獨立於贊助者、研究者之外，並避免任何不當影響。

倫理委員會之組成必須適當，並採用書面標準操作規則，以確保其決定之獨立性與品質。

3. The Purpose of Surveying and Evaluating ECs

The purpose of surveying and evaluating ethical review practices is to assist ECs in reviewing their practices and appraising performance while also providing a means to assure the public that the ethical review of research proposals is carried out according to established standards. The survey should establish the basis for an independent evaluation that provides relevant information to parties having a legitimate interest in the appropriate functioning of an EC, as defined within the framework of national legislation or mutually agreed to by the surveying entity and the EC. An independent evaluation should provide an opportunity for an EC to receive advice on its constitution and operation.

In recent years ECs along with health ministries and regulatory authorities have taken measures to improve the process of ethical review. In some instances these measures have included independent reviews and evaluations of ECs as a means to improve practices and achieve more confident results. There has also been an interest on the part of researchers and sponsors to have more information regarding the functioning of ECs.

3. 監督與評鑑倫理委員會目的

監督與評鑑倫理審查工作之目的在於協助倫理委員會檢查與評鑑其運作，同時另提供一方式向公眾確保研究計畫之倫理審查係依照公認標準進行。監督為獨立評鑑奠定基礎，該獨立評鑑向倫理委員會權能範圍內具合法權益之各方提供相關資訊。倫理委員會適當職責由國家法律所界定或由監督機構與倫理委員會雙方商定。獨立評鑑應向倫理委員會提供有關其章程及運作之建議。

近年來，倫理委員會隨同衛生部門及行政管理部門一起已採取措施改善倫理審查之過程。例如，這些措施包括對倫理委員會之獨立審查與評鑑，作為改善其運作與獲得更可靠結論之一種手段。研究者與贊助者亦有興趣獲得更多有關倫理委員會權責之訊息。

At present only a few countries have a legal or regulatory framework for assisting in the evaluation of ECs, while the framework for the inspection of clinical trials is well established in some countries. This Guideline suggests a cooperative and educative model for surveying and evaluating the work of ECs, being concerned less with 'enforcement' of standards and more with 'learning' from the review of practices.

雖然有些國家建立起很好的臨床試驗監督機制，然目前僅有少數國家建立有助於評鑑倫理委員會之法律或行政規定。本指南對監督及評鑑倫理委員會工作建議採用合作及培訓模式，更著重在審查實踐中"學習"而非規範性之"強制"。

4. The Approach to Surveying and Evaluating Ethical Review

4.監督與評鑑倫理審查之方法

A predefined framework should be established for surveying and evaluating ethical review practices. Such a framework may be established by national health or regulatory authorities, or it may be agreed upon in cooperation with national, regional, or international associations. The framework should define the responsible entities for surveying and evaluating ECs as well as the circumstances and frequency of the reviews. Where no predefined framework exists, ECs should be able to avail themselves of surveillance and/or evaluative processes or other quality assurance mechanisms.

監督與評鑑倫理審查工作應有一預先確定之計畫。該計畫可由國家衛生或行政管理部門釐定，或由國家、地區或國際性協會合作達成。該計畫應規定負責監督與評鑑倫理委員會之機構，及於何情況下進行檢視及檢視之頻率。如無預先確定之監督與評鑑計畫，倫理委員會應利用自身監督及評鑑程序或其他品質保證機制。

Open and frank communication should characterise the surveying and evaluative procedures, with both the independent surveyor and the EC providing a supportive structure. Independent surveyors should be bound by a confidentiality agreement prior to the commencement of the review procedures.

監督與評鑑過程之特點應為公開與坦誠之交流，獨立監督人員與倫理委員會應相互支援。獨立監督人員於檢視程序開始前應簽定一份保密協定。

5.SOPs for Surveying and Evaluating Ethical Review

5. 監督與評鑑倫理審查之標準作業程序

SOPs for surveying and evaluating ethical review practices should be developed in advance of the activities taking place. These SOPs should provide detailed guidance on the requirements for assigning independent surveyors, as well as procedures related to conflict of interest and confidentiality, the development of survey plans, the documents to be reviewed, and the writing of the evaluative report and its distribution. The SOPs should be based on the predefined framework for surveying and evaluating ethical review systems and/or the actual practices of specific ECs. These SOPs should be flexible, where necessary, in order to meet the needs of specific systems and their ECs while permitting comprehensives reviews.

應在檢查前制定監督與評鑑倫理審查工作的標準作業程序。標準作業程序針對獨立監督人員之任命、與利益衝突及保密有關之程序、擬定監督計畫、審查文件，及書面評鑑報告及其發佈要求提供詳細指導。標準作業程序應基於預先確定之監督與評鑑倫理審查體系之計畫及特定倫理委員會之實際運作。必要時，為滿足特定倫理審查體系及其倫理委員會之需求，又能進行全面審查，標準作業程序應具靈活性。

6. Assigning Independent Surveyors

Independent surveyors should be appropriately trained and quali fied for carrying out the review of ethical review practices. The assignment of an independent surveyor or surveying entity should be based on qualifications expressed in SOPs for a regional, national, local, or specific ethical review system.

Independent surveyors should have experience in working with quality evaluation, preferably within ethical review systems. They should also have demonstrated communication skills and preferably experience in education. Independent surveyors should be thoroughly familiar with the requirements, practices, and needs of ECs, and they should be knowledgeable of the legislative and regulatory framework in which the EC to be reviewed is working.

6.獨立監督人員之任命

獨立監督人員應經過適當培訓，以具備進行倫理審查工作之評鑑資格。任命獨立監督人員或監督機構應符合地區、國家、地方或特定倫理審查體系標準作業程序所規定之資格。

獨立監督人員應有品質評鑑之工作經驗，特別是在倫理審查體系內之工作經驗。其另應具有溝通技巧，特別是培訓經驗。獨立監督人員應該非常精通倫理委員會之要求、操作與需要，其應通曉被監督之倫理委員會所處工作環境下之法律與行政管理。

7. Conflict of Interest

The independence of the surveyor is an essential guarantee for the validity of the survey and evaluation findings. Any real or potential conflict of interest on the part of an (candidate) independent surveyor should be declared prior to the review activity to both the entity responsible for assigning the independent surveyor and the EC. A conflict of interest on the part of an independent surveyor may include financial, research, and/or professional involvement on the part of the independent surveyor with institutions or persons submitting applications to the EC or direct involvement of the independent surveyor with the EC. Where substantial conflict of interest is determined, the assignment of the independent surveyor should not take place or be withdrawn.

7. 利益衝突

監督人員之獨立性是監督與評鑑結果有效性之基本保證。(候選的)獨立監督人員存在有任何實際的或可能的利益衝突時，應於檢查活動開始前向負責任命獨立監督人員之機構及倫理委員會提出聲明。就獨立監督人員而言，利益衝突可能包括財務上、研究上，或專業上，涉及獨立監督人員與向倫理委員會提交申請之機構或個人，或獨立監督人員與倫理委員會間之直接利益衝突。如確定存在實質利益衝突，即不應任命該獨立監督人員或應撤銷其任命。

8. Confidentiality in The Survey and Evaluation Processes

The survey and evaluation processes should be designed to guarantee the full confidentiality of patients/research participants, community, and research design and data. The independent surveyor should sign a confidentiality agreement prior to the initiation of any survey-related activities that bars the disclosure of information considered confidential to patients/research participants, communities, researchers, sponsors, or the EC

8. 監督與評鑑過程中之保密

監督與評鑑過程應能充分確保保守患者/研究受試者、受試群體、研究設計與資料之機密。獨立監督人員應於任何與監督有關活動開始前簽訂一保密協定，以防止洩露有關患者/研究受試者、受試群體、研究者、贊助者，或倫理委員會自身所認定

itself. Correspondence and information related to the survey and evaluation processes, including the final report, should not contain confidential information. In addition, the findings as well as the final report should be available only to those parties defined in advance by the entity responsible for conducting the survey and evaluation or otherwise mutually agreed to by the independent surveyor and the EC.

為機密之資訊。與監督及評鑑過程有關之信函與資料，包括總結報告不應含有機密資訊。此外，僅負責監督與評鑑機構事先規定之有關方面，或獨立監督人員及倫理委員會商定之其他方面始可獲知檢查結果及總結報告。

9. Working Documents

An independent surveyor should review the standards, regulations, guidelines, constitution, SOPs, and/or project specific requirements applicable to an EC. In addition, the working documents of an EC may be reviewed, including meeting minutes and official correspondence.

9. 作業文件

獨立監督人員應審查倫理委員會所適用之標準、規則、指南、章程、標準作業程序和計畫之具體要求。此外，另可能審查倫理委員會之作業文件，包括會議記錄與正式往返信函。

10. Survey Plan

A survey plan should be designed for each review activity, taking into consideration the reason for the review. The survey plan should be drafted by the independent surveyor and communicated in advance to the EC for agreement. The plan should be designed in accordance with an SOP for surveying and evaluating ethical review practices.

The survey plan should include the following:

10.1 identification and location of the independent surveyor;

10.2 identification and location of the EC, as well as the persons responsible for representing the EC during the survey and evaluation;

10.3 identification of the persons to be interviewed by the independent surveyor;

10.4 reason for the survey and evaluation;

10.5 objectives and scope of the survey and evaluation;

10.6 expected time and duration for each major survey and evaluation activity;

10.7 date(s) and location of the survey and evaluation;

10.8 schedule and purpose of meeting(s) to be held between the independent surveyor and the EC;

10.9 language in which the survey and evaluation is to be conducted and any arrangements for translation;

10.10 confidentiality requirements and confidentiality statements;

10.11 identification of reference documents to be used by the

10. 監督計畫

每次檢查活動應制定監督計畫，考慮檢查之理由。獨立監督人員應起草監督計畫，並事先與倫理委員會協商達成一致。計畫應符合監督與評鑑倫理審查工作之標準作業程序。

監督計畫應包括以下內容：

10.1 獨立監督人員之身份與所在地;

10.2 倫理委員會及監督與評鑑期間倫理委員會代表之身份與所在地；

10.3 獨立監督人員準備訪談人員之身份；

10.4 監督與評鑑之理由；

10.5 監督與評鑑之目的與範圍；

10.6 每項主要監督與評鑑活動之預期時間與持續時間；

10.7 監督與評鑑之日期與場所；

10.8 獨立監督人員與倫理委員會間舉行會議之時間表與會議議題；

10.9 監督與評鑑過程所使用之語言，翻譯安排；

10.10 保密要求與保密聲明；

10.11 確定獨立監督人員所需使用的

independent surveyor (for example, the applicable standards, regulations, guidelines, SOPs);

10.12 documents of the EC to be reviewed (for example, constitution, SOPs, minutes of meetings, relevant correspondence);

10.13 distribution of the report, if applicable;

10.14 foreseen follow-up actions to the survey and evaluation;

10.15 expected date of the survey and evaluation completion.

參考文件(例如現行標準、規定、指南、標準作業程序)；

10.12 準備檢查之倫理委員會文件(例如章程、標準作業程序、會議記錄、有關信函)；

10.13 報告之分發，如適用時；

10.14 監督與評鑑中預計之追蹤監督；

10.15 監督與評鑑預期之完成日期。

11.The Conduct of A Survey and Evaluation

The survey and evaluation of an EC should be conducted according to a mutually agreed survey plan that includes the following:

11.1 Opening Meeting

The survey and evaluation begins with an opening meeting between the independent surveyor and the representative(s) of the EC. These representatives should be appointed in accordance with the SOPs of the EC or determined by the chairperson of the EC. It is expected that an officer (for example, chairperson, assistant chairperson, or secretary) will be present at the opening meeting.

The objectives of the Opening Meeting include the following:

11.1.1 review of the purpose and scope of the survey and evaluation;

11.1.2 review of the survey plan;

11.1.3 discussion of the documents to be reviewed;

11.1.4 discussion of the current practices of the EC;

11.1.5 discussion of any considerations relating to laws, regulatory requirements, or guidelines affecting EC practices;

11.1.6 clarification of arrangements for contacting the representatives of the EC during the survey and evaluation;

11.1.7 confirmation of the time and date for the closing meeting.

11.2 Review of Documentation

The independent surveyor is required to review the constitution and SOPs of an EC. The independent surveyor may also need to consider other working documents of an EC, such as the application form, decision form, specific procedures for reviewing certain kinds of protocols, evaluation forms for reviewing applications, and minutes of meetings. The documents

11. 監督與評鑑之實施

倫理委員會之監督與評鑑應依照雙方所協商之監督計畫實施，包括以下內容：

11.1 首次會議

監督與評鑑開始於獨立監督人員與倫理委員會代表(們)之首次會議。該代表們應依據倫理委員會之標準作業程序予以選定或由倫理委員會主席決定。應請一名行政人員(如主席、副主席、或秘書)出席首次會議。

首次會議議題包括以下內容：

11.1.1 審議監督與評鑑之目的及範圍；

11.1.2 審議監督計畫；

11.1.3 討論準備審查之文件；

11.1.4 討論倫理委員會之現行工作；

11.1.5 討論影響倫理委員會工作之有關法律、行政管理要求或指導原則等事項；

11.1.6 說明監督與評鑑期間與倫理委員會代表們聯繫之安排；

11.1.7 確認閉幕會議之時間及日期。

11.2 文件審查

獨立監督人員必須審查倫理委員會之章程及標準作業程序。獨立監督人員可能另必須審查倫理委員會之其他工作文件，如申請表、決議表、某種計畫之具體審查程式、審查申請之評鑑表及會議記錄。審查之文

to be reviewed may include the following information:

11.2.1 Documents Referring to the Establishment of the EC

11.2.1.1 the authority under which the EC was established;

11.2.1.2 a statement from the EC indicating the relevant laws, regulatory requirements, as well as appropriate national and international guidelines according to which it operates;

11.2.2 Documents Referring to the Membership of the EC

11.2.2.1 the membership requirements;

11.2.2.2 the terms and procedure for the appointment of members of the EC;

11.2.2.3 the conditions of appointment;

11.2.2.4 a listing of current and previous members of the EC;

11.2.2.5 the curriculum vitae of current and past members of the EC;

11.2.2.6 a description of the requirements for holding EC offices (for example, chairperson, secretary);

11.2.2.7 a description of the responsibilities and duties of the offices of the EC;

11.2.2.8 the quorum requirements;

11.2.3 Documents Referring to Applications Made to the EC

11.2.3.1 the published guidelines for submission of applications for the review by the EC;

11.2.3.2 the required documentation to be included in the application;

11.2.3.3 the registration procedure for applications;

11.2.3.4 the maintenance of records for communications regarding the application;

11.2.3.5 the review procedure timelines;

11.2.4 Documents Referring to Review Procedures of the EC

11.2.4.1 the meeting procedures;

11.2.4.2 the provisions and conditions for expedited EC review and decision;

11.2.4.3 the elements of the review of the application;

11.2.4.4 the decision-making procedure;

11.2.4.5 the procedure for communicating a decision;

11.2.4.6 the follow-up review;

11.2.4.7 the documentation and archiving procedures;

11.2.5 Documents Referring to Actions Taken by the EC

11.2.5.1 the materials submitted by applicants;

11.2.5.2 the correspondence regarding applications, decisions,

件可能包括以下內容：

11.2.1 有關倫理委員會組織之文件

11.2.1.1 倫理委員會所隸屬之部門；

11.2.1.2 倫理委員會之聲明，陳述其運作所依據之有關法律、行政管理要求，及適當之國內、國際指導原則。

11.2.2 關於倫理委員會成員資格之文件

11.2.2.1 成員資格要求；

11.2.2.2 任命倫理委員會成員之條件與程序；

11.2.2.3 任命之方式；

11.2.2.4 倫理委員會現任及先前之成員名單；

11.2.2.5 倫理委員會現任與先前之成員簡歷；

11.2.2.6 說明設立倫理委員會辦公室必備條件(例如主席、秘書)；

11.2.2.7 說明倫理委員會辦公室之職責與義務；

11.2.2.8 法定開會人數要求。

11.2.3 倫理委員會審查申請之文件

11.2.3.1 向倫理委員會提交審查申請之公開作業指南；

11.2.3.2 申請中應包含之文件；

11.2.3.3 申請之登記程序；

11.2.3.4 與申請有關之聯繫記錄；

11.2.3.5 審查程序之時間安排。

11.2.4 倫理委員會審查程序之文件

11.2.4.1 會議議程；

11.2.4..2 有關倫理委員會加快審查與決議之規定及條件；

11.2.4.3 對申請進行審查之要素；

11.2.4.4 決議程序；

11.2.4.5 決議送達之程序；

11.2.4.6 追蹤審查；

11.2.4.7 文件管理與歸檔之程序。

11.2.5 倫理委員會運作文件

11.2.5.1 申請者提交之資料；

11.2.5.2 與申請、決議及追蹤審查有

and follow-ups;

11.2.5.3 the record of incomes and expenses of the EC;

11.2.5.4 the agenda of EC meetings;

11.2.5.5 the minutes of EC meetings;

11.2.5.6 the decisions and advice provided to applicants;

11.2.5.7 interim and annual reports during follow-up;

11.2.5.8 notifications of completion or premature study suspensions/ terminations;

11.2.5.9 final summaries or reports of studies;

11.2.5.10 regular (annual) reports of the EC.

The independent surveyor should also review the manner in which documents are filed and stored, including previous versions of the EC constitution and/or SOPs.

11.3 Survey Observations

All survey findings should be documented. Following the survey, the independent surveyor should review the findings and present an evaluation. The independent surveyor should ensure that these findings are documented in a clear and concise manner, without disclosing any patient/participant, researcher, sponsor, and EC information of a confidential nature. The findings should be, where possible, supported by objective evidence and reference made to the relevant requirements. The evaluation based on the findings should assist the EC in improving its working procedures.

11.4 Closing Meeting

At the conclusion of the survey and evaluation, a meeting should be held with the independent surveyor and EC to review the findings and clarify any misunderstandings. The meeting should be of a mutually supportive nature.

11.5 The Report

The report should reflect the findings and evaluation of the independent surveyor. It should be dated and signed by the independent surveyor and contain, at the minimum, the following items:

11.5.1 identification of the independent surveyor;

11.5.2 identification of the EC and the representative(s) of the EC;

11.5.3 objectives and scope of the survey and evaluation;

11.5.4 survey plan;

11.5.5 identification of the facilities, persons interviewed, and the

關之往來信函；

11.2.5.3 倫理委員會之收支記錄；

11.2.5.4 倫理委員會會議之議程；

11.2.5.5 倫理委員會之會議記錄；

11.2.5.6 決定及給申請者之建議；

11.2.5.7 追蹤審查之期中與年度報告；

11.2.5.8 完成或提前中止研究(暫停/中止)之通知；

11.2.5.9 研究總結報告及摘要；

11.2.5.10 倫理委員會之定期(年度)報告。

獨立監督人員另應審查文件歸檔與存檔之方式，包括倫理委員會章程或標準作業程序先前的版本。

11.3 觀察資料的監督

所有監督結果應記錄成文。監督後，獨立監督人員應分析監督結果，遞交評鑑報告。獨立監督人員應確保監督結果以清晰簡明方式記錄成文，且未洩露任何患者/受試者、研究者、贊助者與倫理委員會之機密資料。於可能時，監督結果應具客觀證據之支持，並參考有關要求。基於監督結果之評鑑應能幫助倫理委員會改善其工作程序。

11.4 閉幕會議

監督與評鑑結束時，應舉行由獨立監督人員與倫理委員會參加之會議，以回顧其監督結果，並澄清任何誤會。該會議應具有相互支持之性質。

11.5 報告

報告應反映獨立監督人員之監督結果與評鑑。報告應註明日期並由獨立監督人員簽名，並至少包含下列項目：

11.5.1 獨立監督人員之身份；

11.5.2 倫理委員會及其代表(們)之身份；

11.5.3 監督與評鑑目的與範圍；

11.5.4 監督計畫；

11.5.5 所訪視機構、人員以及審查文

documents reviewed;

11.5.6 findings of the survey;

11.5.7 the independent surveyor's evaluation based on the findings;

11.5.8 observations and recommendations for corrective actions or areas of suggested revisions in practice;

11.5.9 report distribution list;

11.5.10 signature and date of the independent surveyor.

Both the independent surveyor and the EC should retain a copy of the report for the same time period for which the EC stores essential records.

11.6 Addressing the Independent Surveyor's Findings and Evaluation

The EC is responsible for determining, initiating, and completing the actions required to address the findings and evaluation as presented in the report. These actions and a time period for their accomplishment should, if appropriate, be communicated to the independent surveyor within a reasonable time period following the receipt of the report.

11.7 Follow-up

A follow-up survey and evaluation may be appropriate. A survey plan should be prepared by the independent surveyor for the follow-up review and agreed to by the EC. The EC is responsible for determining, initiating, and completing the actions required to address the findings and evaluation as presented in the follow-up report.

11.8 Final Report

The independent surveyor should present a final report containing the final set of findings and an overall evaluation supported, where possible, by objective evidence. The final report should be communicated to the entity under which the survey and evaluation takes place, the EC, and others as defined within the framework of national law or as mutually agreed by the surveying entity and the EC.

GLOSSARY

The definitions provided within this glossary apply to terms as they are used in these Guidelines. The terms may have different meanings in other contexts.

件之標識；

11.5.6 監督結果；

11.5.7 獨立監督人員基於監督結果作出之評鑑；

11.5.8 與實際工作之改進措施或需修訂部分有關之觀察資料與建議；

11.5.9 報告發送清單；

11.5.10 獨立監督人員簽名與日期。

獨立監督人員與倫理委員會均應保留同一時期之報告，倫理委員會保存記錄要點。

11.6 獨立監督人員監督結果與評鑑之處理

報告中所提出之監督結果與評鑑所需之處理，由倫理委員會負責判定、啟動與完成。倫理委員會於收到報告後之一合理期間內，於可能時，應將這些處理措施與完成之期限告知獨立監督人員。

11.7 追蹤監督

有可能需要進行追蹤監督與評鑑。獨立監督人員應準備一份追蹤監督計畫，並獲得倫理委員會的認可。追蹤監督報告中所提出之監督結果與評鑑所需之處理，由倫理委員會負責判定、啟動與完成。

11.8 總結報告

獨立監督人員應提交一份包含監督最終的全部結果及綜合評鑑之總結報告，於可能時，應援附客觀證據。總結報告應提交給展開監督與評鑑之機構，及由國家法律所界定或由監督機構與倫理委員會雙方商定之其他團體。

術語表

本術語表所提供之定義用於本指南使用之術語。這些術語於其他情況可能有不同的含義。

Community
A community is a group of people understood as having a certain identity due to the sharing of common interests or to a shared proximity. A community may be identified as a group of people living in the same village, town, or country and thus, sharing geographical proximity. A community may be otherwise identified as a group of people sharing a common set of values, a common set of interests, or a common disease.

社區
社區可被理解為因具有共同利益或近似性而具有某種特徵之一群人。社區可看作為生活於同一村莊、市鎮或國家等，具有地理近似性之一群人。另外社區亦可看作為具有共同價值觀、共同利益或患有同一疾病之一群人。

Confidentiality Agreement
An agreement signed by the independent surveyor prior to the initiation of a survey or any survey-related activities that bars the independent surveyor, the survey and evaluation process, and the report from the disclosure of any patient/participant, researcher, sponsor, and EC information of a confidential nature.

保密協定
於進行審查或審查相關活動前，由獨立審查者簽署之協定，以防止獨立審查者、審查及評鑑過程、及有關病人/參加者、研究者、贊助者及倫理委員會之機密資訊報告之洩漏。

Conflict of Interest
A conflict of interest arises when an independent surveyor holds any real or potential financial, research, and/or professional interests that may affect the validity of the survey findings and evaluation.

利益衝突
於獨立審查者擁有任何真實或潛在可能影響審查發現及評鑑有效性之財務、研究或專業利益，即具有利益衝突。

Constitution
A document establishing the authority under which an EC is established, the mandate and remit of an EC, and general provisions for its activities. The term 'constitution' may be replaced at times by other terms, such as 'terms of reference'.

章程
為確定職權之文件，據此建立倫理委員會，確定倫理委員會之設立及任免權利，及有關倫理委員會運作之一般規定。“章程”乙詞可用其他術語代替，如“職權範圍”。

Decision
The response (positive, conditional, or negative) by an EC to an applicant following the review of an application.

決議
倫理委員會對申請進行審查後給予申請人之答復(包括肯定性、附條件性，否定性)。

Evaluation
The assessment by an independent surveyor of the strong and weak points of an EC's practices based on the findings of a survey.

評鑑
根據調查結果，獨立監督人員對倫理委員會工作之優點及不足之評鑑。

Findings
The findings of a survey based on the purpose of the survey and the materials reviewed by the independent surveyor. The findings should refer to specific observations made by the independent surveyor and be supported by objective evidence. Findings express the independent surveyor's conclusions

調查結果
依據監督目的及獨立監督人員審查之資料所作出之監督報告。調查結果應該涉及獨立監督人員之特定觀察，並具有客觀證據予以佐證。調查報告敘述獨立監督人員依據相關

regarding specific procedures or systems reviewed according to the relevant requirements. The findings are the basis for the independent surveyor's evaluation of the ethical review practices of an EC.

要求對特定過程或體系進行審查得出之結論。

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of research participants are protected.

良好臨床實踐(GCP)

有關臨床試驗之設計、實施、執行、監察、稽查、記錄、分析及報告的標準，以確保資料及報告結果為準確可信，研究受試者的權利、安全及隱私獲得保障。

Independent Surveyor

The person(s) responsible for carrying out the survey and evaluation of an EC.

獨立監督人員

負責對倫理委員會進行監督及評鑑之人員。

Report

A written evaluation by the independent surveyor of the results of the survey and evaluation. The report may take the form of an 'initial report', 'follow-up report', or 'final report'. In all cases the report should not disclose any patient/participant, researcher, sponsor, and/or EC information of a confidential nature.

報告

獨立監督人員對監督及評鑑結果之書面評鑑。報告可分為“初步報告”，“追蹤報告”或“總結報告”。在所有情況下，報告均不得公開病人/受試者、研究者、贊助者或倫理委員會之機密資訊。

Research Participant

An individual who participates in a research project, either as the direct recipient of an intervention (for example, study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated.

研究受試者

參加某項生物醫學研究之個人，其可以是受干預之直接接受者(如試驗產品或侵入性干預)，或是對照干預接受者或觀察標的。該個人可以是某自願參加研究之健康人，或其身體狀況與開展研究無關之自願者，或其身體狀況與使用研究產品或與研究問題有關之人(通常是病人)，或接受調查之人。

Sponsor

An individual, company, institution, or organisation that takes responsibility for the initiation, management, and / or financing of a research project.

贊助者

負責研究計畫之啟動、管理及資助之個人、公司、機構或組織。

Standard Operating Procedures (SOPs)

Detailed, written instructions to achieve uniformity in the performance of a specific function.

標準作業程序(SOPs)

為保持特定活動實施取得一致性之詳細書面說明。

Survey

The activity of reviewing ethical review practices, usually

監督

對倫理審查工作之審查行為，通常

those of a specific EC, in order to analyse and evaluate those practices with a view toward quality improvement and transparency.

是審查特定倫理委員會之審查工作，其目的是為分析及評鑑倫理委員會之審查工作，以提高工作品質及工作之透明度。

Survey Plan

A plan setting out the specific practices, resources, activities, and timelines relevant to a particular survey and evaluation.

監督計畫

規定特定監督及評鑑相關實施、資源、活動及時間軸之計畫。