



# 高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.5	檔案名稱 File name	審查委員會委員及行政人員之教育訓練 Educational Training		
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## 1. 目的 Purpose

本標準作業程序在規範人體試驗審查委員會（以下簡稱人委會）委員及工作人員所需之研究倫理相關教育訓練課程或研討會的最低要求，以掌握人體研究最新的法規及倫理資訊，提升委員審查、監督及工作人員行政能力。

This standard operating procedure is intended to govern the minimum requirement of research ethics education training courses or seminars attendance for the committee members of the Institutional Review Board (IRB) and staff members, ensuring that the members are up to date on the latest legislatures and ethical information related to human research, and to improve the capacity for review, supervision and administrative work.

## 2. 適用範圍 Scope

本標準作業程序適用於本院人委會委員及工作人員。

This SOP is applicable for the members of the IRB and staff members.

## 3. 參考文件 References

### 3.1 藥品優良臨床試驗準則（2010年7月）

Regulations for Good Clinical Practice (July 2010)

### 3.2 醫療機構人體試驗委員會組織及作業基準（2003年11月）

Organizational and Operational Guidelines on Institutional Review Board in Medical Institutions (November 2003)

### 3.3 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

## 4. 名詞定義 Terminology

### 4.1 新聘人員：前二年未擔任本會相同職務執行相關業務者。

New personnel: individuals who have not been appointed to the same duty



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positions within the IRB for the past 2 years.

4.2資深人員：連續擔任本會相同職務執行相關業務達二年以上者。

Senior personnel: individuals who have remained in the same position within the IRB for more than 2 years.

## 5.作業內容 Scope of operation

### 5.1流程 Process

程序 Procedure	權責 Rights and responsibilities	相關文件 Related documents
檢核委員、工作人員教育訓練時數 Verifying the training hours of the committee members and staff members	執行秘書/工作人員 Executive secretary/Staff member	教育訓練紀錄表 Education training record
安排教育訓練課程 Schedule education training courses	執行秘書 Executive secretary	--
協助報名本院舉辦的教育訓練課程 Assist in registering for the education training courses held in the KMUH	工作人員 Staff member	--
彙整委員、工作人員教育訓練時數證明 Compiling training hour certificates for committee members and staff members	工作人員 Staff member	教育訓練紀錄表/ 訓練時數證明文件 Education training record/Training hour certificate
保存受訓紀錄與資料 Maintaining training record and information	工作人員 Staff member	--



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## 5.2 職責 Responsibilities

5.2.1 執行秘書：由教育訓練組於每年 10 月檢核委員、工作人員教育訓練時數並安排教育訓練課程。

Executive secretary: examine the education training hours of the committee member and staff in October of each year by the education training section, and schedules necessary education training courses.

5.2.2 工作人員：行政人員/專任助理/全職工讀生於每年 10 月協同執行秘書檢核委員、工作人員教育訓練時數。並協助委員報名本院舉辦的教育訓練課程。課程結束後彙整委員、工作人員教育訓練時數證明，並保存相關資料。

Staff member: the administrative staff/assistant/full-time student assist the executive secretary to examine the training hours of committee members and staff in October of each year, and assist the committee members in registering of the education training courses. After the courses have ended, the staff assist in compiling the certificate of training hours for the committee member and staff, and maintain related information.

## 5.3 作業流程 Operation procedure

5.3.1 行政人員每年 10 月彙整新進委員並協助執行秘書檢核所有委員/行政人員/專任助理/全職工讀生教育訓練時數證明。

The administrative staff compiles a list of new committee members in the October of each year and assist the executive secretary in examining the educational training hour certificates of all committee members/administrative staff/assistant/full-time students.



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## 5.3.2 訓練內容

### Content of training

#### 5.3.2.1 新聘委員接受完整訓練後才得進行計畫審查。

New committee members may conduct protocol review after completing education training

A. 人委會委員工作職責及工作說明，包括人體試驗審議會之發展背景、審議會組織架構、審議會之運作、審查流程、國內法規條文、基礎審查訓練課程、執行偏差案例報告等。

Description of responsibilities and tasks of the IRB, including the development background of the IRB, organizational structure, procedures of IRB operation and protocol review, domestic and foreign legislatures, basic review training courses, and case reports of protocol deviations.

B. 計畫案審查相關教育訓練主題，包括「赫爾辛基宣言」、「人體研究法」、「藥品優良臨床試驗準則」、「醫療機構人體試驗委員會組織及作業基準」、倫理議題、法律議題、人委會標準作業程序等相關法規。

Education training subjects for protocol review include “Helsinki Declaration”, “Human Subject Research Act”, “Regulations for Good Clinical Practice”, “Organizational and operational guidelines on institutional review board in medical institutions”, ethical issues, legal issues, and legislatures related to SOPs of IRB.

C. 觀摩至少 1 次審查會議，由資深委員帶領觀摩審查計畫案，包括召開審查會議前，計畫案之審查重點、審查注意事項，與召



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開會議報告審查意見注意事項等。新聘委員於觀摩審查會議階段無投票權。資深委員提供經驗分享與諮詢服務。

To observe at least one review meeting, which is lead by a senior committee member, and observe the procedures of protocol review, including key points for protocol review, important matters, and reporting of comments during review meetings. New committee members have no voting rights during observation of the review meeting. Senior committee members also provide experience sharing and offer consultation service.

## 5.3.2.2 新進工作人員

New staff members

A.本會所有相關職務之工作職責及工作說明、人委會標準作業程序。

Description of the duties and responsibilities of all job positions within the IRB, and the standard operating procedures of the IRB.

B.教育訓練主題，包括「赫爾辛基宣言」、「人體研究法」、「藥品優良臨床試驗準則」、「醫療機構人體試驗委員會組織及作業基準」、倫理議題、法律議題、人委會標準作業程序等相關法規。

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C. 資訊管理系統與行政作業流程。

Procedures for information management system and administrative operation.

5.3.3 行政人員確認並彙整委員/行政人員/專任助理/全職工讀生不足的教育訓練時數。

The administrative staff verifies and compiles the insufficient education training hours of the committee member/administrative staff/assistant/full-time student.

5.3.3.1 委員每年需接受至少 6 小時的受試者保護或研究倫理之相關在職教育訓練課程。

Committee members should attend at least 6 hours of subject protection or research ethics related in-job education training courses per year.

5.3.3.2 工作人員每年需接受至少 6 小時的受試者保護或研究倫理之相關在職教育訓練課程。

Staff members should attend at least 6 hours of subject protection or research ethics related in-job education training courses per year.

5.3.4 執行秘書安排教育訓練課程每年至少 6 小時。行政人員協助籌備暨舉辦教育訓練課程，包括「赫爾辛基宣言」、「人體研究法」、「藥品優良臨床試驗準則」、「醫療機構人體試驗委員會組織及作業基準」、倫理議題、法律議題、人委會標準作業程序等國內與國際相關法令與規範、以及科學、技術、環境、健康及安全等方面發展的相關議題。

The executive secretary should schedule at least 6 hours of education training courses per year; the administrative staff should assist in



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organizing and preparing education training courses on the following topics: domestic and international legislatures such as the “Helsinki Declaration”, “Human Subject Research Act”, “Regulations for Good Clinical Practice”, “Organizational and operational guidelines on institutional review board in medical institutions”, ethical issues, legal issues, SOPs of IRB and domestic and foreign related legislation, or topics related to development of science, technology, environment, health and safety.

5.3.5 行政人員協助委員/行政人員/專任助理/全職工讀生報名本院舉辦的教育訓練課程。

The administrative staff assist the committee member/administrative staff/assistant/full-time student in registering to the education training courses held in the hospital.

5.3.5.1 行政人員不定期在網站、電子信件及其他傳播管道提供研究倫理相關的教育訓練課程、研討會等訊息，並通知人委會委員和工作人員。

The administrative staff will infrequently update information about the research ethics education training courses and seminars via website, e-mails and other communication channels, and will notify the IRB members and staff members.

5.3.5.2 行政人員統一協助報名本院舉辦的教育訓練課程，並依院內規章會議進修辦法與差旅費申請辦法進行申請。

The administrative staff will assist in the registration of the education training courses in the hospital, and will assist in the application for



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travel subsidies according to the hospital regulations on continuous training.

5.3.6 教育訓練課程結束後，行政人員彙整委員、工作人員教育訓練時數證明，並保存受訓紀錄與資料

After the education training courses, the administrative staff will compile the certificates for training hours of the committee members and staff members, and keep a record of the training.

5.3.6.1 行政人員彙整委員/行政人員/專任助理/全職工讀生教育訓練時數證明並掃描、存檔。

The administrative staff compiles the training hour certificates of the committee member/administrative staff/assistant/full-time student, and keep a scanned copy on file.

5.3.6.2 行政人員定期統計分析工作人員教育訓練時數，提醒委員及工作人員須完成教育訓練。

The administrative staff will regularly analyze the training hours of the staff member, and to remind committee and staff members on completion of required education training.

5.3.6.3 未完成教育訓練者，由主任委員協助瞭解原因，並評估其適任性，視需要重新聘任。

The committee director will inquire the reasons for those who have not completed education training, and to evaluate their suitability as committee member. When necessary, the committee director may re-appoint another new members.





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5.3.6.4 受訓相關證明交由人委會工作人員存檔並登錄於受訓紀錄表(附件)。

The certificates of education training are filed and registered in the training record by the staff members of the IRB (Attachment).

### 5.3.7. 未符合教育訓練要求之處理

#### Procedure for failed requirement of education training

5.3.7.1 委員：在每年進行委員評核時，若未符合訓練時數要求，將不再續聘。

Committee members: if the training hours are not met during the annual committee member performance evaluation, the member will not be re-appointed.

5.3.7.2 行政人員：在每年進行評核時，若未符合訓練時數要求，將不能執行人委會日常運作業務，並作為考績評核依據之一。

Administrative staff: if the training hours are not met during the annual performance evaluation, the staff may not continue with the daily operation of the IRB, and will be noted in the record for performance evaluation.

## 6. 附件 Attachment

6.1 附件一 (KMUH/IRB/AF/1.5-01/11.0)第\_\_人體試驗審查委員會參加受試者保護或研究倫理之相關教育訓練紀錄表。

Attachment 1 (KMUH/IRB/AF/1.5-01/11.0) Institutional Review Board \_\_\_\_  
Record of Participating in Education Training on Subject Protection or Research Ethics