



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	4.1	檔案名稱 File name	計畫主持人資格及研究團隊之倫理教育訓練 The qualification of the principal investigator and the ethical training of the research team		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

1. 目的 Purpose

提供研究團隊成員所需相關研究倫理的訓練要求，符合最新的法規及倫理資訊，作為申請研究計畫的必要條件。

Provide the research team member with ethics-required training to meet the most updated laws and provisions and ethical information as the prerequisite of submitting study protocols.

2. 適用範圍 Scope

本標準作業程序適用於申請本院研究倫理審查之計畫案研究團隊成員中可能接觸研究對象本人或其資料檢體之研究人員，包括主持人、共同主持人、協同主持人、研究護理師、研究助理、研究生及研究相關人員等。

This SOP is applicable to the research personnel of the research team applying for the KMUHIRB review and who may contact the subjects or the data/specimens, including the PI, sub-investigator, co-investigator, research nurse, research assistant, research student and research-related personnel.

3. 參考文件 References

3.1 人體試驗管理辦法 (2016年4月)

Regulations on Human Trials (April 2016)

3.2 藥品優良臨床試驗準則 (2014年10月)

Guidelines of Good Clinical Practice (October 2014)

3.3 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

3.4 International Conference on Harmonization, Guidance on Good Clinical



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Practice (ICH GCP) 2006

4.名詞定義：無

Terminology : NA

5.作業內容 Scope of operation

5.1 流程圖 Flowchart

程序 Procedure	權責 Rights and responsibilities	相關文件 Related documents
受理計畫案 Receive study applications	行政秘書 Administrative secretary	計畫案相關文件 Study-related files
申請計畫案時確認研究團隊相關教育訓練證明 The certificate of educational training of the research team shall be confirmed during applying for studies	行政秘書 Administrative secretary	個人訓練時數統計表及教育訓練證明文件 The summary table of personal training hours and the certificate of educational training
期中報告補交研究團隊相關教育訓練證明 The certificate of educational training of the research team shall be supplied during interim report	行政秘書 Administrative secretary	個人訓練時數統計表及教育訓練證明文件 The summary table of personal training hours and the certificate of educational training

5.2 職責 Responsibilities

5.2.1 行政秘書：於新案申請及期中報告繳交時確認個人訓練時數統計表(附件一)及教育訓練證明文件。

The administrative secretary: will confirm The Summary Table of



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Personal Training Hours (Attachment 1) and the certificate of educational training during new applications.

5.2.2 執行秘書：於實地訪視時確認個人訓練時數統計表(附件一)及教育訓練證明文件。

The executive secretary: will confirm The Summary Table of Personal Training Hours (Attachment 1) and the certificate of educational training during site visit.

5.2.3 研究團隊 Research Team

5.2.3.1 依據衛福部 98 年 12 月 14 日公告「人體試驗管理辦法」臨床試驗主持人資格條件如下：

According to the announcement “Regulations on Human Trials” promulgated by MOHW dated December 14, 2009, the criteria for being a PI of a clinical trial shall be as follows:

A. 領有執業執照並從事臨床醫療五年以上之醫師、牙醫師或中醫師。

The physician, dentist or Chinese Medicine physician with practice license and has clinically practiced for at least 5 years.

B. 最近六年曾受人體試驗相關訓練三十小時以上；於體細胞或基因治療人體試驗之主持人，另加五小時以上之有關訓練。

The person who has received human study-related training at least 30 hours in the past 6 years; for the PI of human studies involving



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somatic cells or gene therapy, he/she must have received additional 5 hours of relevant training.

C.最近六年研習醫學倫理相關課程九小時以上。

The person who has received at least 9 hours of medical ethics-related training in the past 6 years.

D.曾受醫師懲戒處分，或因違反人體試驗相關規定，受停業一個月以上或廢止執業執照處分者，不得擔任主持人。

The person who ever received medical sanctions such as suspension of practice for more than 1 month or the practice license has been revoked due to the violation against human study-related regulations, is not eligible for being a PI.

5.2.3.2 主持人、協同主持人、研究護士/助理之相關教育訓練時數規範，請依人委會公告為主。

For the regulations for educational training hours of the PI, co-investigator, research nurse/assistant, please comply with the announcement promulgated by the IRB.

5.2.3.3 主持人資格須符合下列之一

The PI must meet one of the following criteria

A.為高雄醫學大學、附設醫院或其所屬機構聘僱之教、職、員工(不含研究助理)及博士後研究員，或由本院借調至其他機構，且於本院仍有執行業務行為者，方可擔任計畫主持人。

The faculty, staff, employee (not including research assistant) and



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postdoctoral fellow of KMU, KMUH or its subsidiary institutes, or the person who had been temporarily transferred from KMU(H) to other institutes but still has practice in KMU(H), is eligible for being a PI.

B. 多中心計畫案，須由高雄醫學大學、附設醫院或其所屬機構聘僱之教、職、員工(不含研究助理)及博士後研究員，或由本院借調至其他機構，且於本院仍有執行業務行為者擔任計畫主持人。

It's a multicenter study, which requires a PI that is the faculty, staff, employee (not including research assistant) and postdoctoral fellow of KMU, KMUH or its subsidiary institutes, or the person who had been temporarily transferred from KMU(H) to other institutes but still has practice in KMU(H).

C. 委託代審之其他機構人體研究案，須以合約機構所聘僱之員工為計畫主持人。

It's a human study commissioned by other institutes and thus the PI shall be the staff employed by the Contract Research Organization (CRO).

E. 本院以外且非簽約之機構人員，經院方行文同意得擔任計畫主持人者。

The person affiliate institutes other than KMUH or person who



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does not have contract with KMUH, but has been approved for being the PI by KMUH with written approvals.

5.3 細則 Rules

5.3.1 行政秘書於新案申時確認個人訓練時數統計表(附件一)及教育訓練證明文件。

The administrative secretary will confirm The Summary Table of Personal Training Hours (Attachment 1) and the certificate of educational training during new applications.

5.3.2 教育訓練不符合規定者，須待補齊文件後方進入審查程序。

For those educational training courses fail to meet the regulations, the review procedures will proceed after all required documents have been supplied completely.

5.3.3 執行秘書於實地訪視時確認人體試驗/研究相關教育訓練紀錄表及教育訓練證明文件符合規定。

The executive secretary will confirm whether the human study/research-related educational training record and the documents of certificate of educational training have met the regulations during site visit.

5.3.4 教育訓練證明文件不符合規定者，提交行政會議討論，嚴重違規者得呈報審查會議表決，中止其研究計畫之執行。

For those who do not have qualified educational training certificate, the cases will be submitted to the administrative meeting for discussion.



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Those who seriously violate the regulations shall be reported to the review meeting for voting whether the study implementation shall be discontinued.

- 5.3.5 行政秘書於期中報告繳交時再度確認人體試驗/研究相關教育訓練紀錄表及教育訓練證明文件符合規定。

The administrative secretary will confirm again whether the human study/research-related educational training record and the documents of certificate of educational training have met the regulations during the interim report.

- 5.3.6 教育訓練證明文件不符合規定者，提交行政會議討論，嚴重違規者得呈報審查會議表決，中止其研究計畫之執行。

For those who do not have qualified educational training certificate, the cases will be submitted to the administrative meeting for discussion. Those who seriously violate the regulations shall be reported to the review meeting for voting whether the study implementation shall be discontinued.

- 5.3.7 受訓相關證明存檔於計畫案相關檔案資料中。

The training certificates are stored in study-related files.

6.附件 Attachment

- 6.1 附件一(KMUH/IRB/AF/4.1-01/11.0) 個人訓練時數統計表

Attachment 1 (KMUH/IRB/AF/4.1-01/11.0) The Summary Table of Personal Training Hours