



# 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	2.7	檔案名稱 File name	複審案 Secondary Review		
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## 1.目的 Purpose

提供人委會處理及審查研究計畫案之複審案的依據。

To provide evidence for IRB to handle and review study protocol secondary review.

## 2. 適用範圍 Scope

適用所有人委會審查會議決議為“修正後複審”，須修正或補充書面說明之研究計畫案。

The file is applicable to all study protocols that require amendments or written supplements after the IRB has decided as “Secondary review after amendments” through the review meeting.

## 3.參考文件 References

### 3.1 人體研究法(2011年12月)

Human Subjects Research Act (December 2011)

### 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 醫療器材管理辦法(2015年)

Regulations on Medical Devices (2015)

### 3.4 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000

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

## 4.名詞定義 Terminology

4.1 複審案：人委會會議審查決議為“修正後複審”，經計畫主持人依據審查意見修正及回覆後，提出複審的研究計畫案。



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Secondary review: refers to the amended and responded study protocol submitted by the Principal Investigator that is based on the review comments after the IRB has decided as “Secondary review after amendments” through the review meeting.

## 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
送交申請資料 Submit the application	計畫主持人 Principal Investigator	複審申請表及修正後資料 Secondary review application form and amended files
確認送審文件 Check whether submitted files completely	行政人員 Administrative staff	依送審文件清單 Checklist of files for review
審查 Review	審查委員/專家 Reviewer/Expert	送審資料 Files for review
審查會議 Review Meeting	人委會 IRB	議程資料 Meeting agenda
通知審查結果 Inform review results	行政人員 Administrative staff	會議紀錄、通知文件 Meeting minutes, Notification
歸檔 Archiving	行政人員 Administrative staff	相關資料 Relevant documents



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## 5.2 職責Responsibilities

5.2.1 計畫主持人：回覆委員審查意見並提供文件修正說明，於修改處標記，提供審查委員核對。

Principal Investigator (PI): shall respond to review comments, provide amendment descriptions, and highlight amended parts for reviewers to verify.

5.2.2 行政人員：受理、核對複審案申請資料，送原審查委員審查，並負責將審查意見彙整通知申請人/計畫主持人，文件歸檔。

Administrative staff: responsible for receiving and verifying applications for secondary review, submit to the original review committee for review, summarizing review comments and inform the applicant/PI, and archiving files.

5.2.3 審查委員/專家：被指定的審查委員/專家應於5個工作日內完成審查程序，並將審查意見送回。

Reviewers and review experts: will complete review procedures and send back the review comments within 5 working days.

## 5.3 流程 Process

5.3.1 計畫主持人填寫複審案申請表（附件一），填寫複審案審查意見回覆表（附件二）回覆委員審查意見，連同修正資料，提出申請。

The PI shall fill in a Secondary Review Application Form (Attachment 1), fill in a Secondary Review Comments Response Form (Attachment 2), and submit applications along with amended files.



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5.3.2 行政人員受理並核對複審案申請資料，確認申請文件齊全後，由主任委員指派委員審查。若執行秘書曾任醫療委員，主任委員得授權執行秘書分派案件。

The administrative staff shall receive and verify the application files for secondary review. After confirming the required files are prepared completely, the committee director will point designated reviewers for review. If the executive secretary were a medical member, the committee director may authorize the secretary to assign review cases.

5.3.3 審查委員/專家複審案審查重點：

Key review items of the reviewers/experts:

A. 對先前審查意見是否逐項回答及修正

Has the PI responded to previous review comments point-by-point and amend accordingly?

B. 修正內容是否符合審查意見

Have the amendments met the review comments?

5.3.4 審查委員/專家填寫複審審查意見表（附件三），並勾選 核准 修正

後複審 提會討論。審查結果若為「修正後複審」，計畫主持人需依

審查意見修正至審查核准，才入審查會討論；審查結果若為「提會討論

」，需勾選是否邀請諮詢專家或受試者(團體)代表列席或提供書面諮



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詢意見。

Reviewers/Experts shall fill in review comments form (Attachment 3) and select one of the followings: Approved Secondary review after amendment Submit to the Meeting for discussion. If the review results show “Secondary review after amendment”, the PI will attend the IRB Meeting after the protocol amendment based on review comment are approved by the IRB. If the review results are “Submit to the meeting for discussion”, the PI shall decide whether to invite experts or subject (groups) representatives to attend the meeting, or provide written consultations/comments instead.

5.3.5 行政人員彙整審查意見，排入原委員會議審議。

The administrative staff will summarize the review comments and schedule the amendments for review by the original IRB Committee.

5.3.6 審查會議審議結果得為下列之決定：

The review results of the review meeting will be as follows:

- A. 【核准】：主持人依審查會議意見修改，交由原審委員/專家確認依審查意見修正後，經行政人員確認相關文件版本無誤後，製作人體研究新案/變更案/期中報告同意證明書(附件四)送交主任委員簽名，於10個工作日內完成。

[Approved]: The PI shall amend the protocol based on the review



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comments, submit the amended files to the original reviewers/experts for reviewing whether the amendments have been made following the review comments. After the administrative staff have confirmed that the amendment files are all correct, a Certificate of Approval for New Application/Amendment/Interim Report (Attachment 4) will be established and sent to the Committee director for his/her signature within 10 working days.

- B. 【修正後複審】：行政人員應於會議結束後7個工作日內，將會議審議結果，以新案/變更案/期中報告審議結果通知表(附件五)通知申請人/計畫主持人及試驗委託者。主持人依審查會意見修改，以複審案方式送審，交由原審委員/專家複審後，須等待入會決議，同意後核發同意證明書。

[Secondary review after amendment]: The administrative staff must inform the applicant/PI and Sponsor about the IRB Meeting results using a New Application/Amendment/Interim Report Review Results Notification Form (Attachment 5) within 7 working days after the completion of the meeting. The PI will amend the application based on the review comments and submit the amended files for secondary review. After the original reviewers/experts have conducted secondary review, the PI shall wait for IRB resolutions. The Certificate of Approval will be issued after the amendments have been approved.



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C. **【修正後重新送審】**：行政人員應於會議結束後7個工作日內，將會議審議結果，以新案/變更案/期中報告審議結果通知表(附件五)通知申請人/計畫主持人及試驗委託者。主持人依審查會意見修改後，須於下次審查會議再次列席。

[Resubmission after amendment]: The administrative staff must inform the applicant/PI and Sponsor about the IRB Meeting results using a New Application/Amendment/Interim Report Review Results Notification Form (Attachment 5) within 7 working days after the completion of the meeting. The PI shall attend the next meeting again after amending the application based on the review comments.

D. **【不核准】**：不予通過。行政人員應於會議結束後7個工作日內，將會議審議結果，以新案/變更案/期中報告審議結果通知表(附件五)通知申請人/計畫主持人及試驗委託者，並詳細說明不核准理由。計畫主持人如需申覆，應於14個工作日內以書面資料提出。若未於期限內提出申覆，則依原審議結果辦理。

[Not approved]: Not approved. The administrative staff must inform the applicant/PI and Sponsor about the IRB Meeting results using a New Application/Amendment/Interim Report Review Results Notification Form (Attachment 5) within 7 working days after the completion of the meeting. The reasons of not approval shall also be





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detailed. If the PI needs to reapply, he/she should submit an application in writing within 14 working days. If the PI fails to reapply within time limit, following the original resolutions will process subsequent matters.

- 5.3.7 複審案修正資料未於3個月內回覆，本會將逕予撤案。撤案後，計畫主持人須以新案方式重新送審。查驗登記計畫案依衛福部規定，研究計劃案經人委會審查通過後，須函送一份至衛福部審核。

If the PI fails to submit amended documents for secondary review within 3 months, the IRB will reject the application directly. After being rejected, the PI must submit the case as a new application for review. Studies for registration shall be in accordance with regulations established by Ministry of Health and Welfare. In addition, the PI is required to submit a copy to Ministry of Health and Welfare for review after the study protocol has been reviewed and approved by the IRB.

- 5.4 文件歸檔依標準作業程序（SOP 6.1）規定辦理。

Document archiving shall be in accordance with the SOP 6.1.

## 6.附件 Attachment

- 6.1 附件一(KMUH/IRB/AF/2.7-01/11.0)複審案申請表

Attachment 1 (KMUH/IRB/AF/2.7-01/11.0) Secondary Review Application Form





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6.2 附件二(KMUH/IRB/AF/2.7-02/11.0)複審案審查意見回覆表

Attachment 2 (KMUH/IRB/AF/2.7-02/11.0) Secondary Review Comments Response Form

6.3 附件三(KMUH/IRB/AF/2.7-03/11.0)複審審查意見表

Attachment 3 (KMUH/IRB/AF/2.7-03/11.0) Secondary Review Comment Form

6.4 附件四(KMUH/IRB/AF/2.7-04/11.0) 人體研究新案/變更案/期中報告同意證明書

Attachment 4 (KMUH/IRB/AF/2.7-04/11.0) Certificate of Approval of New Protocol/Protocol Change/Interim Report of Human Subject Research

6.5 附件五(KMUH/IRB/AF/2.7-05/11.0)新案/變更案/期中報告複審審查結果通知表

Attachment 5 (KMUH/IRB/AF/2.7-05/11.0) Secondary Review Results Notification Form of New Application/Amendment/Interim Report