



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

妥善管理計畫案及人委會會議等相關文件的歸檔與存放方式(包含存檔、調閱/複印、保密機制)，以利稽核或查核時調閱，及提供人委會銷毀相關文件之依據。

To properly manage the archive and retention of studies and IRB-related materials (including storage, review/copy, confidentiality mechanisms) to facilitate review during audit or inspection, and provide the IRB the foundations of destroying relevant files.

2.範圍 Scope

本標準作業程序適用於所有由人委會審查過的研究計畫檔案(含執行中之研究計畫檔案及非活動之研究計畫檔案)及會議記錄等相關文件。

This SOP is applicable to all study files (including the active and non-active study files) and meeting minutes that have been approved by the IRB.

3.參考文件：References:

3.1 藥品優良臨床試驗準則 (2014年10月)

Guidelines of Good Clinical Practice (October 2014)

3.2 人體試驗管理辦法(2016年4月)

Regulations on Human Trials (April 2016)

3.3 人體研究倫理審查委員會組織及運作管理辦法 (2012年8月)

The Organization and Operational Regulations for Governing the Institutional Review Board (August 2012)

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



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

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

3.6 AAHRPP Domain II.5.A

4. 名詞定義 Terminology

4.1 執行中之研究計畫檔案：已通過正在執行的研究之計畫書、支持性文件和報告。

Ongoing study files: The protocol, supportive files and reports that is currently under implementation.

4.2 非活動之研究計畫：目前已未在進行之研究計畫案，包含結案、終止、或撤案。

Non-active study protocol: The studies that are not currently under implementation, including case close, termination or withdrawal.

4.3 行政文件：包括人委會會議正式紀錄、標準作業程序，及如標準作業程序所述之歷史檔案及主要檔案等文件。

Administrative files: Including IRB official meeting minutes, SOPs and the historical files and master files described in the SOPs.

4.4 往來公文：包括人委會發出之臨床試驗同意證明書、修正計畫同意書、期中報告同意證明書、決議函及相關機關發出之公文等。

Official letters: Including the certificate of approval for clinical trial issued by the IRB, approval for amendments, approval for interim report, resolution letter and official letters issued by relevant agencies.

4.5 異地備援：資料分開兩地存放並且即時運轉提供服務，以防一地的設備發生運轉問題，另一地建置的設備可以立即接手取代繼續運轉。

Backup in different places: The data shall be stored in two different places and



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

uploaded promptly for services. In case the equipment in one place is not functional, the equipment in another place can take over right away and maintain the functions.

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 document
確認研究計畫檔案的完整 Verify the completeness of the study files	行政人員 Administrative staff	清單 List
檔案歸檔/調閱/複印 File archiving/review/copy	申請人/行政人員 Applicant/Administrative staff	文件、影本申請表、資料庫進出登記表 Files, copy application form and database entry log
文件銷毀 Destroy files	行政人員 Administrative staff	文件 Document

5.2.職責 Responsibilities

5.2.1 行政人員：

Administrative staff:

5.2.1.1 根據文件清單確認檔案完整。

Verify the completeness of the files based on the file list.

5.2.1.2 將計畫案資料歸檔至資料庫。

Archive the studies materials into the database.

5.2.1.3 收到文件調閱/影本申請時，提供相關資料。

Provide relevant information when receiving the requests of reviewing/copying files.



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

5.2.1.4 保管期限終了時，列出計畫案銷毀清單，依規定進行銷毀。

Make a list of protocols for destroy and perform destruction procedures in accordance with the regulation at the end of the retention period.

5.2.1.5 依法規進行檔案保密。Perform confidentiality by law.

5.3 流程 Process

5.3.1 確認檔案完整

Verify the completeness of the files

5.3.2 檔案歸檔

Archive files

5.3.2.1 依文件清單排列順序整理計畫案相關資料，包括：

Organize the study-related materials in the order of the checklist, including:

A. 原始申請資料及研究期間收到的任何新增資料。

The original application materials and any new addition materials received during the study.

B. 科學審查及倫理審查之相關文件(如委員審查意見表、專業諮詢報告表、受試者(團體)代表諮詢意見表)。

Scientific review and ethical review of relevant files (e.g. reviewer review comment form, professional consultation report, subject (group) representative consultation/comment form).

C. 同意臨床試驗證明書或其他 IRB 與主持人通聯記錄。

The certificate of approval for clinical trials or the communication record between other IRBs and the PI.



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

D.被核准的文件(計畫書、主持人手冊、受試者同意書、宣傳資料...等)。

The approved files (protocol, investigator brochure, subject ICF, promotion materials, etc.)

E.安全性報告(含嚴重不良反應報告、未預期事件報告、試驗偏差報告...等)。

Safety reports (including serious ADR, UP report, study deviation report, etc.)

F.變更文件。

Amendments.

G.期中報告(含資料安全監測報告、重大的新發現...等)

Interim reports (including data safety monitoring report, significant findings, etc.)

H.結案報告/暫停或終止/撤案。

Case close/suspension or termination/withdrawal.

5.3.2.2 線上申請案件資料另異地備援，存放於指定硬碟

The online application materials shall be backup in another place and stored in a designated hard drive.

5.3.2.3 執行中與非活動之研究計畫檔案，需分開存放管理。

The files of active and non-active study files shall be retained and managed separately.

5.3.2.4 紙本資料依人委會編號排序，鎖置於檔案櫃中。

The written materials will be locked in the file closet in the order of IRB No.



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

5.3.2.5 查驗登記計畫案應保存所有試驗相關文件，至試驗藥品於我國核准上市後至少二年。

All study-related documents for registration shall be retained for at least 2 years after the investigational drug has been approved for listing in Taiwan.

5.3.2.6 非活動計畫案的相關文件資料，在人體研究完成後依法規保存至少三年，以便稽核/查核委員調閱。

Relevant non-active study files shall be retained for at least 3 years after the completion of the human study for the auditor/inspector to review.

5.3.2.7 會議簽到單、審查意見統計表、會議通知、會議紀錄等紙本檔案十年後可銷毀；電子檔永久保存。

Written files such as meeting sign-in list, review comments statistic form, meeting notice, meeting minutes could be destroyed after 10 years. The electronic files shall be stored permanently.

5.3.3 檔案調閱/複印

File review/copy

5.3.3.1 會議紀錄摘要公告於人委會網站上

The summary of meeting minutes will be published on the IRB website.

5.3.3.2 計畫主持人/稽核人員/查核人員需要調閱/複印計畫案相關資料時，須填寫檔案調閱/複印表(附件一)申請，依規定繳費後，向人委會領取資料。

If the PI/auditor/inspector requires reviewing/copying study-related



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

materials, it is required to submit an application for File Review/Copy (Attachment 1), pay the fees and then claim the materials from the IRB.

5.3.3.3 行政人員複印文件後，文件影本需蓋人委會戳章，以確保該文件經由人委會所出具。

The administrative staff will copy the documents. The copies shall be affixed with IRB stamps to ensure the authenticity of the document (issued by the IRB).

5.3.3.4 調閱之相關資料閱畢後，連同調閱表交由行政人員歸檔。

After reviewing required materials, the files along with the checklist shall be returned to the administrative staff for archiving.

5.3.3.5 文件歸還時調閱者及行政人員皆需簽名並註明日期。

The reviewer and administrative staff shall both sign and date the form when returning the materials.

5.4 文件保密：依人委會標準作業程序(SOP 1.4)進行計畫案相關資料保密。文件的影本亦視為機密而不得公開。

File confidentiality: The confidentiality procedures of the protocol shall be in accordance with the IRB SOP 1.4. The copies of the files are also considered as confidential and thus any information breach is prohibited.

5.5 文件銷毀 File destruction

5.5.1 歷年 SOP 版本，各保留 1 本，新版出刊後一年舊版可銷毀。

The SOPs from each year will retain one copy, respectively. The old version can be destroyed 1 year after the publication of new versions.



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

5.5.2 當次評鑑資料於下次評鑑通過後方可銷毀，惟簡報檔永久保存。

The materials for accreditation this time can be destroyed after the approval of next accreditation. However, power point files shall be retained permanently.

5.5.3 銷毀程序

Procedures of destruction

5.5.3.1 行政人員整理後，由第二位行政人員再次確認銷毀文件清單。

After the summery of the 1st administrative staff the 2nd administrative staff will verify the list of destruction again.

5.5.3.2 執行秘書與總幹事確認銷毀文件後簽名，並經主任委員覆核簽名後封箱。

The executive secretary and director general will sign on the paper after verifying the files for destruction, and the committee director will sign on the paper and seal the box after double verification.

5.5.3.3 行政人員交由本院合作廠商代為銷毀。

The administrative staff will send the files to the KMUH contract companies for destruction.

5.5.3.4 送出銷毀後行政人員於清單上簽名，留存銷毀紀錄。

After sending for destruction, the administrative staff shall sign on the list and retain destruction records.

6.附件 Attachment

6.1 附件一 (KMUH/IRB/AF/6.1-01/11.0) 檔案調閱/複印表

Attachment 1 (KMUH/IRB/AF/6.1-01/11.0) File Review/Copy

6.2 附件二 (KMUH/IRB/AF/6.1-02/11.0) 文件銷毀目錄



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	6.1	檔案名稱 File name	計劃檔案之管理及文件銷毀 Maintenance of the Study Files and Destroying Expired Documents Procedure		
生效日期 Effective 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

Attachment 2 (KMUH/IRB/AF/6.1-02/11.0) Table of Contents of File
Destruction