臺中榮民總醫院
Taichung Veterans General Hospital

管制文件訂修廢紀錄表
Record of Composition and Revisions of Controlled Documents

文件編號 Document Number	IRB-本會-工作常規-2020 IRB-Regulations of Operation-2020	文件名稱 Title	檔案維護管理程序書 Sop for Document Management
訂定單位 Composed by	人體研究倫理審查委員會 The IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □Confidential □Highly Confidential
適用單位 Applied to	□全院 □All units in the hospital ■其他，並請註明：人體研究倫理審查委員會 ■Other (Please specify): The IRB Committees		

版次 Version	頁數 No. Page	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
A	5	新訂。Newly composed.	20140519
B	5	由人體試驗委員會標準作業程序 5.4 版轉換成此版本。This version was converted from “Version 5.4 of the Standard Operating Procedure of the Human Research Committee.”	20150119
C	5	原「人體試驗委員會」更名為「第一/二人體研究倫理審查委員會」。The original “Human Research Committee” was renamed “The First/Second IRB Committees.”	20160318
D	5	修改參考文件 3.2「人體試驗管理辦法」版本。The version of “Regulations on Human Trials” was updated in reference item 3.2.	20170709
D	10	依本院規定，於 2019 年 05 月 17 日重新審視本文件，內容無須修改。According to the regulations by TCVGH, this document was reviewed again on 17 May 2019 and no revision was needed.	20170709
E	10	修改參考文件 3.1 為「藥品優良臨床試驗作業準則」(109 年 08 月 28 日修正)。Updated reference 3.1 into “the Regulations for Good Clinical Practice (amended on 28 August 2020).”	20210528
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版次 Version	頁數 No. Page	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
F	10	1. 原「第一/二人體研究倫理審查委員會」修改為「人體研究倫理審查委員會」。 1. The original “The First/Second IRB Committees” was renamed “The IRB Committees.” 2. 抽換附件 6.1、6.2、6.3。 2. Appendices 6.1, 6.2, 6.3 were replaced.	20230717

臺中榮民總醫院 2023.08.10 參考文件

訂修廢 Composed/Revised/Deleted	審核 Reviewed	核准 Approved

本文件已經權責主管正式核准，
核章紀錄之正本儲放於 SOP 管理中心

臺 中 榮 民 總 醫 院
Taichung Veterans General Hospital

管制文件訂修廢會審單
Review Form of Composition and Revisions of Controlled Documents

文件編號 Document Number	IRB-本會-工作常規-2020 IRB-Regulations of Operation-2020	文件名稱 Title	檔案維護管理程序書 Sop for Document Management

會辦單位 Processing Unit	審查意見 Review Comments	會辦單位主管 Head of Processing Unit
	無跨部科會審需求。 There is no need for review by other departments or divisions.	

臺中榮民總醫院
2023.08.10
參考文件

※請各會辦單位主管惠賜審查意見後核章，必要時得直接與訂定單位協商。

※**The head of each processing unit is advised to provide comments before signing/stamping to approve. If needed, it is recommended that the head of each processing unit discuss with the unit that made the SOP.**

1.目的

本管理程序書為管理、傳送及維護已由人體研究倫理審查委員會審查通過的計畫檔案及相關文件。對於如何安全保密地存放、調閱、影印以及相關文件銷毀提供指引。

1. Purpose

The purpose of this SOP is to provide guidelines for managing, distributing, and maintaining documents related to protocols approved by the IRB. The SOP also gives instructions for document retention, viewing and copying, and for destruction of copies.

2.適用範圍

本管理程序書適用於所有由人體研究倫理審查委員會辦公室所維護之計畫檔案及相關文件。

2. Scope

This SOP applies to all protocol records and related documents retained and maintained by the IRB.

3.參考文件

3. References

3.1「藥品優良臨床試驗作業準則」(109 年 08 月 28 日修正)(第 29 條規定：「人體試驗委員會應保存書面作業程序、委員名單、委員職業及聯繫名單、送審文件、會議紀錄、信件、及其他臨床試驗相關資料至試驗結束後三年，且可供主管機關隨時調閱。」)

3.1 According to Article 29 of the Regulations for Good Clinical Practice (amended on 28 August 2020), “The Ethics Committee should retain written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, correspondence and any other relevant records for a period of at least 3 years after completion of the trial and make them available upon request

from the Competent Authority."

3.2「人體試驗管理辦法」（民國 105 年 04 月 14 日衛生福利部衛部醫字第 1051662154 號令修正發布）第 10 條規定：「審查會應將人體試驗計畫、會議紀錄、查核紀錄等相關文件，保存至人體試驗完成後至少三年」。

3.2 According to Article 10 of the Regulations on Human Trials (amended on 14 April 2016 and promulgated by the Ministry of Health and Welfare, pursuant to Wei-Bu-Yi-Zi No. 1051662154), "The Review Board shall preserve the relevant documentation, such as Human Trial proposal, meeting minutes, or audit records for at least three(3) years after the completion of Human Trial."

4.名詞定義

4. Definitions

4.1 檔案文件

4.1 Documents

檔案文件包括但不限於下列各項，可以是任何形式，如列印或書寫的紙本、影印本、電子郵件、傳真、影音紀錄檔案或電子文件檔等。

Documents may include but are not limited to the following items, and may be in any format: printed or written copies, photocopies, e-mail, fax, video or audio recordings, electronic files, etc.

4.1.1 計畫書及相關文件（如個案報告表、受試者同意書、日誌表、科學性文件、報告、紀錄、專家意見或審查評論）。

4.1.1 Protocols and related files (e.g. case reports, ICF, daily journal, scientific documents, reports, records, comments by expert consultants or reviewers).

4.1.2人體研究倫理審查委員會文件（標準化文件、會議記錄、建

議及決議）。

4.1.2 Documents related to the IRB Committees (standardized documents, meetings minutes, recommendations and resolutions).

5. 作業內容

5. Procedure

5.1 檔案維護管理流程圖

5.1 Flow Chart of Document Management

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
受理各類計畫及檔案 Acceptance of applications and documents	承辦人員 Staff Members	計畫清冊/IRB 專案管理系統/PTMS 系統 List of protocols/IRB project management system/PTMS system
重複文件歸還 Return of duplicate documents	承辦人員 Staff Members	重複文件 Duplicate documents
檔案儲存及防護 Document retention and maintenance	承辦人員 Staff Members	檔案室人員進出管制表 Personnel control record for IRB Archive
檔案借閱及影印 Request for viewing or copying documents	承辦人員 Staff Members	文件調閱表/文件影印申請表 Application for documents/Application for copying documents
過期檔案銷毀 Destruction of expired documents	承辦人員 Staff Members	銷毀清冊 List of destroyed documents
紀錄保存 Records retention	承辦人員 Staff Members	

5.2 受理各類計畫及檔案

5.2 Acceptance of applications and documents

承辦人員於受理各類計畫及檔案後，應依據各項審查管理程序書之規定，檢查其完整性，確認無誤後將相關資料登錄於各類「計畫清冊」、「IRB 專案管理系統」、「PTMS 系統」等。

The staff member should verify that submitted documents are complete and accurate when receiving applications. If the applications are confirmed to be complete and accurate, the staff member should then record the documents in relevant list of protocols, IRB project management system, or PTMS system.

5.2.1 新計畫。

5.2.1 New protocol.

5.2.2 審查中計畫。

5.2.2 Protocol under review.

5.2.3 執行中計畫。

5.2.3 Study in progress.

5.2.4 已結案之計畫。

5.2.4 Closed study

5.2.5 各類行政文件，如委員會會議紀錄、委員名單...等。

5.2.5 Administrative documents, e.g. IRB meeting minutes, list of IRB members….

5.3 重複文件歸還

5.3 Return of duplicate documents

承辦人員於接受各類計畫及檔案時，若發現重複文件，退回計畫主持人。

If the staff member discovers duplicate documents when reviewing applications and submitted documents, the

duplicates should be returned to the PI.

5.4 檔案儲存及防護

5.4 Document retention and maintenance

承辦人員應參照如下之規範，進行檔案儲存及防護。

The staff member should retain and maintain documents following the guidelines below.

5.4.1 將其他相關行政文件置入合適的檔案櫃保管儲存。

5.4.1 Related administrative documents should be stored in appropriate file cabinets.

5.4.2 檔案室應進行必要之門禁管制，嚴禁工作人員以外之人員進出，工作人員進出時須填寫「檔案室人員進出管制表」。

5.4.2 Access to the archive should be monitored and controlled. No personnel should be allowed to enter the IRB Archive except staff members. Staff members should fill in the form of “Personnel Control Record for IRB Archive” while entering or exiting the IRB Archive.

5.4.3 檔案室應設置適當之消防設施。

5.4.3 The Archive should be equipped with a fire detection and fire protection system.

5.4.4 若為電子檔，則應由系統設定當資料有異動時系統自動備份至雲端資料庫，並設定帳號密碼以進行管制。

5.4.4 Electronic files should be set to back up automatically in a cloud database every time a file is modified. Accounts and passwords should be set to control access to the files.

5.5 檔案借閱及影印

5.5 Request for viewing or copying documents

5.5.1 檔案借閱

5.5.1 Request for viewing documents

5.5.1.1 委員、審查委員、計畫主持人若有借閱檔案之需求時，應填寫「文件調閱表」，且僅限於調閱其研究計畫之相關資料，經（副）主任委員核准後，方可調閱。

5.5.1.1 IRB members, reviewers, or PI may request to view IRB documents if needed by filling in the “Application for Viewing Documents.” Only documents related to relevant protocols may be requested for viewing after the approval of the (Vice) Chair.

5.5.1.2 承辦人員應依據「文件調閱表」所列之文件，找出須調閱文件之儲存位置，取出調閱文件，並於「文件調閱表」上簽名和簽註日期。

5.5.1.2 The staff member should find the storage location and retrieve the documents listed on the “Application for Viewing Documents,” and sign and date the “Application for Viewing Documents.”

5.5.1.3 承辦人員應要求調閱人於本委員會辦公室內查閱，並不得用任何方式自行複製，閱畢後須將調閱文件完整歸還承辦人員。

5.5.1.3 The staff member should require the person requesting to view the documents to view the documents in the IRB Office. No photocopies or duplicates should be made in any format during the viewing. The documents should be returned to the staff member after viewing.

5.5.1.4 歸檔之承辦人員將調閱文件歸回檔案櫃後，應在文件調閱表上簽名和簽註日期，並將該檔案櫃上鎖。

5.5.1.4 After the documents are returned to the staff member, the staff member should put the documents back to the original file cabinets, sign and date the “Application for Viewing Documents,” and lock the file cabinets.

5.5.1.5 若有其他特殊調閱需求時，須以專案專簽經主任委員核

示辦理。

5.5.1.5 If a special request is made to view documents, the request should be processed on a case-by-case basis following the instructions of the Chair.

5.5.2 檔案影印

5.5.2 Request for copying documents

5.5.2.1 文件的影印本，包括初稿和後續修正的版本，均視為機密而不得公開。

5.5.2.1 Photocopies of documents, including first drafts and follow-up amended versions, should be handled as classified documents and should not be disclosed to the public.

5.5.2.2 計畫主持人若有影印文件之需求時，應填寫「文件影印申請表」，且僅限於其研究計畫之相關資料，經（副）主任委員核准後，方可影印。

5.5.2.2 The PI may request to copy documents if needed. An “Application for Copying Documents” should be filled in and submitted. Only documents related to the study conducted by the PI may be requested to be copied with the approval of the (Vice) Chair.

5.5.2.3 承辦人員應依據「文件影印申請表」所列之文件，找出須影印文件之儲存位置，取出文件，並於「文件影印申請表」上簽名和簽註日期。

5.5.2.3 The staff member should find the storage location and retrieve the documents listed on the “Application for Copying Documents,” and sign and date the “Application for Copying Documents.”

5.5.2.4 經（副）主任委員指定之審查委員有權要求影印本。

5.5.2.4 Reviewers assigned by the (Vice) Chair may request copies of documents.

5.5.2.5 承辦人員有權進行影印。

5.5.2.5 The staff members are authorized to photocopy documents.

5.5.2.6 若有其他特殊影印需求時，須以專案專簽經主任委員核示辦理。

5.5.2.6 If a special request is made to photocopy documents, the request should be processed on a case-by-case basis following the instructions of the Chair.

5.5.3 承辦人員應將申請人之「文件調閱表」及「文件影印申請表」影印一份放置於其所查閱文件之檔案資料夾中，以瞭解該檔案被借閱及影印情形。

5.5.3 The staff member should make a photocopy of the “Application for Viewing Documents” and the “Application for Copying Documents” and place the photocopy in the folder of each requested document in order to keep a record of the documents being viewed or copied.

5.6 過期檔案銷毀

5.6 Destruction of expired documents

對於超過保管年限之文件，承辦人員得提出過期文件銷毀申請作業，經奉核後執行銷毀。

The staff member may propose to destroy documents which have passed the time limit for records retention. The expired documents may be destroyed after being approved by the staff member’s supervisor.

5.7 紀錄保存

5.7 Records Retention

相關人員應依據如下規定，妥善保存各項紀錄。

Relevant personnel should keep all records carefully following the guidelines below.

編號 No.	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	檔案室人員進出管制表 Personnel Control Record for IRB Archive	IRB 檔案室 IRB Archive	3 年 3 years
2	文件調閱表 Application for Viewing Documents	IRB 辦公室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
3	文件影印申請表 Application for Copying Documents	IRB 辦公室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed

6.附件

6. Appendices

6.1 檔案室人員進出管制表

6.1 Personnel Control Record for IRB Archive

6.2 文件調閱表

6.2 Application for Viewing Documents

6.3 文件影印申請表

6.3 Application for Copying Documents