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-2004 IRB-Regulations of Operation- 2004	文件名稱 **Title**	保密協議書及利益迴避聲明書管理程序書 SOP for Confidentiality and Conflict of Interest Statement
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，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. Pages	文件修訂摘要 **Summary of Revisions of the Document**	實施日期 Date of Implementation
A	6	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.”	20141125
C	5	1. 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」。 1. The original “Human Research Committee” was renamed “The First/Second IRB Committees” 2. 原「獨立專家」更名為「專家」。 2. The original “independent expert” was replaced by “expert consultant.”	20160318
D	5	1. 更新 3.1 藥品優良臨床試驗準則版本。 1 Updated the version of item 3.1 “Regulations for Good Clinical Practice.” 2. 修改 5.2 聲明書項目：新增 5.2.9 計畫研究團隊成員「利益迴避」及「保密」聲明書。 2 Revised an item under 5.2 Composition of Statement Forms – Added “Conflict and Confidentiality Statement by Research Personnel.” 3. 新增附件 6.7 計畫主持人利益迴避聲明書、6.8 研究成員保密聲明書、6.9 計畫研究團隊成員「利益迴避」及「保密」聲明書，同步新增 5.6 紀錄保存規定。 3 Added “Appendix 6.7 – Conflict of Interest Statement by the Principal Investigator,” “Appendix 6.8 – Confidentiality Statement by Research Personnel,” “Appendix 6.9 – Conflict of Interest and Confidentiality Statement by Research Personnel,” and added “5.6 Records Retention.”	20170709

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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
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版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
E	9	修改參考文件 3.1 為「人體研究倫理審查委員會組織及運作管理辦法」。行政院衛生福利部衛署醫字第 1010265129 號令，2012。(衛生福利部衛部醫字第 1071661626 號令修正第 2、3、6、7 條條文，2018) Updated reference 3.1 into “Regulations for Organization and Operation of IRB Committees (Ministry of Health and Welfare, promulgated in 2012 pursuant to Wei-Shu-Yi-Zi No. 1010265129; articles 2, 3, 6, 7 amended in 2018 pursuant to Wei-Bu-Yi-Zi No. 1071661626).”	20181026
F	9	1. 修改參考文件 3.2 為「藥品優良臨床試驗作業準則」（衛生福利部部授食字第 1091407874 號）。 1. Updated reference 3.2 into “Regulations for Good Clinical Practice (Ministry of Health and Welfare, Pursuant to Bu-Shou-Shi-Zi No. 1091407874).” 2. 抽換附件 6.2、6.7。 2. Replaced Appendices 6.2, 6.7.	20201117
G	9	1. 依 2020 年 ISO 9001:2015 國際驗證稽核建議進行修正。 1. The following modifications were made according to the recommendations of ISO 9001:2015 (International Organization for Standardization) in 2020. 2. 抽換附件 6.7、6.8、6.9。 2. Replaced Appendices 6.7, 6.8, 6.9.	20210528
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適用單位 Applied to	□全院 □**All units in the hospital** ■其他，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. Pages	文件修訂摘要 **Summary of Revisions of the Document**	實施日期 Date of Implementation
H	9	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 ~ 6.6。 2. Replaced Appendices 6.1 - 6.6.	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	

※管制文件不得擅自塗改及做記號並禁止影印。
※本文件以 KM 系統為最新版本，紙本發行需經 SOP 管理中心核章，嚴禁自行列印。
※Changing, marking, or copying controlled documents without permission is prohibited.
※The latest version of this document in the Knowledge Management System (KMS) takes precedence. Distribution of hard copies of this document must be approved and stamped by the SOP Administrative Center. Copying without permission is strictly prohibited.

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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-2004 IRB-Regulations of Operation- 2004	文件名稱 Title	保密協議書及利益迴避聲明書管理程序書 SOP for Confidentiality and Conflict of Interest Statement

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

此管理程序書的目的為提供保密及利益迴避聲明書的使用表格，確認有誰應該閱讀、了解、接受、牢記並簽署。本管理程序書同時提供簽署的細節，及如何保存相關文件。

1. Purpose

The purpose of this SOP is to provide forms for the statement of confidentiality and conflicts of interest, and to define who shall read, understand, accept, and remember the conditions stated on the forms, and who shall sign them. This SOP also provides detailed guidelines for document signing and records retention.

2.適用範圍

此管理程序書包含與人體研究倫理審查委員會保密和利益迴避有關的資訊和作業流程。

2. Scope

This SOP contains information and operating procedures for topics related to confidentiality and conflicts of interest for the IRB Committees.

3.參考文件

3. References

3.1「人體研究倫理審查委員會組織及運作管理辦法」。行政院衛生福利部衛署醫字第 1010265129 號令，2012。(衛生福利部衛部醫字第 1071661626 號令修正第 2、3、6、7 條條文，2018)

3.1 Regulations for Organization and Operation of IRB Committees (Ministry of Health and Welfare, promulgated in 2012 pursuant to Wei-Shu-Yi-Zi No. 1010265129; articles 2, 3, 6, 7 amended in 2018 pursuant to Wei-Bu-Yi-Zi No. 1071661626)

3.2「藥品優良臨床試驗作業準則」（衛生福利部部授食字第 1091407874 號）

3.2 Regulations for Good Clinical Practice (Ministry of Health and Welfare, Pursuant to Bu-Shou-Shi-Zi No. 1091407874)

4.名詞定義

4. Definitions

4.1 保密性：非經授權不得任意公佈之資訊。

4.1 Confidentiality: Distribution of information without permission is prohibited.

4.2 保密性聲明

4.2 Confidentiality Statement

4.2.1 有時稱為秘密或不公開協議。

4.2.1 Confidentiality Statement is also referred to as Agreement of Privacy or Agreement of Non-disclosure.

4.2.2 這協議是設計用來保護計畫有關之秘密、資訊和專業，使其他人不致於濫用。

4.2.2 This agreement is designed to protect the privacy, the information and the expertise in a research project to prevent misuse by others.

4.2.3 在保密資料保護下，任何類型的資訊都可被保密。

4.2.3 Under the protection of the policy of confidentiality, any type of information can be kept secret.

4.2.4 大部分的保密協議都有排除範圍。在保密協議接受排除範圍是很重要的。

4.2.4 Most agreements of privacy allow exceptions. It is important to accept exceptions in an agreement of privacy.

4.2.5 協議必須建立在某段期間內，在此段期間內將維持資料的保密性。

4.2.5 Agreements shall be effective during a certain period of time. Within the specified period of time, information shall be kept confidential.

4.3 利益迴避

4.3 Avoidance of Conflict of Interest

4.3.1 委員不得因公務上有關經費、文獻發表等利益，而影響其獨立審查與作業之公正性。

4.3.1 IRB members should not allow any interest incurred by work-related funding or publication of documents to affect their impartiality in independent review and other related work.

4.3.2 當一個人有私人利益存在時，將影響他（或她）公務上責任的客觀性。

4.3.2 When personal interests are involved, an individual's objectivity regarding work- related responsibilities will be affected.

4.3.3 這個定義有三個關鍵要素：財產利益、公務責任和專業利益。

4.3.3 The definition of this term contains three key elements: financial interest, work- related responsibility, and professional interest.

4.3.4 利益迴避會發生在：

4.3.4 Avoidance of Conflict of Interest may occur in the following situations:

4.3.4.1 個人利益與其對醫院的專業義務分歧時。

4.3.4.1 When individuals' personal interests diverge from their professional responsibilities at TCVGH.

4.3.4.2 超然獨立的觀察員合理地懷疑專業行為或決定時。

4.3.4.2 When a well-informed independent observer has reasonable doubts about professional behavior or decisions.

4.3.4.3 迴避視情況而定，不是針對個人行為。

4.3.4.3 A conflict of interest depends on the situation, and not the character or actions of the individual.

4.3.5 潛在的利益迴避必須公開並個別處理。

4.3.5 Potential conflicts of interest must be disclosed and addressed case by case.

5.作業內容

5. Procedure

5.1 保密協議書及利益迴避聲明書管理流程圖

5.1 Flow Chart of Managing Confidentiality and Conflict of Interest Statement

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
編修聲明書 Composition of Statement Forms	標準化文件修訂小組委員/相關人員 Document Revision and Standardization Group Members/Relevant Personnel	各類聲明書 Statement Forms
審核 Review No	人體研究倫理審查委員會 The IRB Committees	保密/利益迴避聲明書 Confidentiality/Conflict of Interest Statement
Yes 發生聲明書簽署需求 Occurrence of the need to sign a statement	委員/專家/受試者代表/相關人員 IRB Members/Expert Consultants/ Advocates of Research Subjects/Relevant Personnel	保密/利益迴避聲明書 Confidentiality/Conflict of Interest Statement
聲明書簽署 Signing a statement		
紀錄保存 Records Retention	承辦人員 Staff Members	保密/利益迴避聲明書 Confidentiality/Conflict of Interest Statement

5.2 編修聲明書

依各業務需求，人體研究倫理審查委員會需製作下列「聲明書」:

5.2 Composition of Statement Forms

Based on the needs in different situations, IRB shall compose the following statement forms:

5.2.1 保密聲明書（適用委員與專家）

5.2.1 Confidentiality Statement (by IRB Members or Expert Consultants)

5.2.2 利益迴避聲明書（適用委員與專家）

5.2.2 Conflict of Interest Statement (by IRB Members or Expert Consultants)

5.2.3 保密聲明書（適用承辦人員）

5.2.3 Confidentiality Statement (by Staff Members)

5.2.4 利益迴避聲明書（適用承辦人員）

5.2.4 Conflict of Interest Statement (by Staff Members)

5.2.5 保密/利益迴避聲明書（適用委員與專家以外人員）

5.2.5 Confidentiality/Conflict of Interest Statement (by Individuals other than IRB Members and Expert Consultants)

5.2.6 保密聲明書（適用借閱委員會檔案資料人員）

5.2.6 Confidentiality Statement (by Individuals viewing IRB documents)

5.2.7 計畫主持人利益迴避聲明書

5.2.7 Conflict of Interest Statement by the Principal Investigator

5.2.8 研究成員保密聲明書

5.2.8 Confidentiality Statement by Research Personnel

5.2.9 計畫研究團隊成員「利益迴避」及「保密」聲明書

5.2.9 Conflict of Interest and Confidentiality Statement by

Research Personnel

5.3 審核

經編修完成之「聲明書」須經大會核備後方能公告。

5.3 Review

The statement forms shall be approved at an IRB board meeting before they are announced.

5.4 發生聲明書簽署需求

5.4 Occurrence of the Need to Sign a Statement

5.4.1 為了保護受試者的權利，在開始審核計畫案之前，新聘任的委員、專家、受試者代表及相關人員等皆有責任去閱讀、了解、接受和簽署「保密/利益迴避聲明書」。

5.4.2 To protect the rights of research subjects, new IRB members, expert consultants, advocates of research subjects, and other relevant personnel are obliged to read, understand, and accept the conditions and sign on the Confidentiality/Conflict of Interest Statement forms before reviewing protocols.

5.4.2「聲明書」改版後須重新簽署。

5.4.2 Statement forms shall be signed again after revisions.

5.5 聲明書簽署

5.5 Signing a Statement

5.5.1 承辦人員應提供新聘任的委員、專家及承辦人員「保密/利益迴避聲明書」，提供受試者代表、觀察員、借閱委員會檔案資料等人員「保密聲明書」。

5.5.1 Staff members shall provide new IRB members, expert consultant and staff members with the relevant forms of Confidentiality/Conflict of Interest Statement. Staff members shall provide advocates of research subjects, observers, and other individuals viewing IRB documents with the relevant forms of Confidentiality Statement.

5.5.2 接獲聲明書應仔細閱讀後簽署，需在簽名處填寫姓名、服務

機構（若無則可免填）和簽署日期。

5.5.2 After receiving a statement form, an individual shall read it carefully, sign and date it, and fill in information about their affiliation (if any).

5.5.3 若有不清楚處，可洽詢承辦人員，要求其解釋或說明文件的內容。

5.5.3 If an individual is unclear about any part of the statement, she/he may contact staff members for detailed explanation about the content of the statement.

5.5.4 承辦人員將簽署後之聲明書陳（副）主任委員核章。

5.5.4 Staff members shall submit signed statements to the IRB Chair or Vice Chair for stamp of approval.

5.5.5 審查委員遇有下列情形之一者，應即迴避，不得參加審查：

5.5.5 In case of any one of the following situations, IRB members shall recuse themselves from the review:

5.5.5.1 為人體試驗計畫之主持人、協同主持人或委託人。

5.5.5.1 You are the principal investigator, co-investigator, or sponsor of the clinical study.

5.5.5.2 與主持人有配偶、四親等內之血親或三親等內之姻親或曾有此關係。

5.5.5.2 You are or were the principal investigator’s spouse, lineal/collateral relative within fourth degree of relationship, or relative by marriage within third degree of relationship.

5.5.5.3 與人體試驗計畫委託廠商有聘僱關係。

5.5.5.3 You have an employment relationship with the sponsor of the clinical study.

5.5.5.4 有具體事實，足認有偏頗之虞。

5.5.5.4 There is substantial evidence that you may be biased in any way.

5.5.5.5 其他經審查會認有利益迴避之必要者。

5.5.5.5 Other situations in which the IRB committee considers there is potential conflict of interest.

5.6 紀錄保存

5.6 Records Retention

5.6.1 承辦人員將前項「聲明書」保存於特定的檔案夾。

5.6.1 Staff members shall keep the above-mentioned statements in designated folders.

5.6.2 相關人員應依據如下規定，妥善保存各項紀錄。

5.6.2 Relevant personnel shall keep all records carefully following the guidelines below.

編號 Document Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	保密聲明書（適用委員與專家） Confidentiality Statement (by IRB Members or Expert Consultants)	IRB 辦公室 IRB Office	15 年 15 years
2	利益迴避聲明書（適用委員與專家） Conflict of Interest Statement (by IRB Members or Expert Consultants)	IRB 辦公室 IRB Office	15 年 15 years
3	保密聲明書（適用承辦人員） Confidentiality Statement (by Staff Members)	IRB 辦公室 IRB Office	15 年 15 years
4	利益迴避聲明書（適用承辦人員） Conflict of Interest Statement (by Staff Members)	IRB 辦公室 IRB Office	15 年 15 years
5	保密及利益迴避聲明書（適用委員與專家以外人員） Confidentiality and Conflict of Interest Statement (by Individuals other than IRB Members and Expert Consultants)	IRB 辦公室 IRB Office	15 年 15 years
6	保密聲明書（適用借閱委員會檔案資料人員） Confidentiality Statement (by Individuals viewing IRB documents)	IRB 辦公室 IRB Office	15 年 15 years
7	計畫主持人利益迴避聲明書 Conflict of Interest Statement by the Principal Investigator	IRB 辦公室 IRB Office	15 年 15 years
8	研究成員保密聲明書	IRB 辦公室	15 年

	Confidentiality Statement by Research Personnel	IRB Office	15 years
9	計畫研究團隊成員「利益迴避」及「保密」聲明書 Conflict of Interest and Confidentiality Statement by Research Personnel	IRB 辦公室 IRB Office	15 年 15 years

6.附件

6. Appendices

6.1 保密聲明書（適用委員與專家）

6.1 Confidentiality Statement (by IRB Members or Expert Consultants)

6.2 利益迴避聲明書（適用委員與專家）

6.2 Conflict of Interest Statement (by IRB Members or Expert Consultants)

6.3 保密聲明書（適用承辦人員）

6.3 Confidentiality Statement (by Staff Members)

6.4 利益迴避聲明書（適用承辦人員）

6.4 Conflict of Interest Statement (by Staff Members)

6.5 保密及利益迴避聲明書（適用委員與專家以外人員）

6.5 Confidentiality and Conflict of Interest Statement (by Individuals other than IRB Members and Expert Consultants)

6.6 保密聲明書（適用借閱委員會檔案資料人員）

6.6 Confidentiality Statement (by Individuals viewing IRB documents)

6.7 計畫主持人利益迴避聲明書

6.7 Conflict of Interest Statement by the Principal Investigator

6.8 研究成員保密聲明書

6.8 Confidentiality Statement by Research Personnel

6.9 計畫研究團隊成員「利益迴避」及「保密」聲明書

6.9 Conflict of Interest and Confidentiality Statement by Research Personnel