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-2003 IRB-Regulations of Operation-2003	文件名稱 Title	標準化文件制修審頒管理程序書 SOP for Creating and Updating Standardized Documents
訂定單位 Composed by	第一/二人體研究倫理審查委員會 The First/Second 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：第一/二人體研究倫理審查委員會 ■**Other (Please specify): The First/Second 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	4	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 SOP of the Human Research Committee.”	20141125
C	4	1.修改 5.1 流程圖之相關文件。 1.The list of relevant documents was revised in item 5.1 Flow Chart. 2.修改 5.4 審核：新增 5.4.2 特殊狀況文件審核程序。 2.Item 5.4 Review was revised: Item 5.4.2 “Procedure for reviewing documents for special circumstances” was added.	20150922
D	4	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. 修 4.2 改標準化文件修訂小組組成。 2. The composition of the Document Revision and Standardization Group was revised in item 4.2.	20160318
E	4	1. 修改 4.1：ISO 9002 改為 ISO 9001。 1. Item 4.1 was revised: “ISO 9002” was replaced by “ISO 9001.” 2. 修改 5.2.2 標準化文件修訂小組成員須具備教育訓練主題：新增「審查會之標準作業程序」。 2. Item 5.2.2 was revised regarding training topics for the members of Document Revision and Standardization Group: The topic of “IRB Standard Operating Procedures” was added.	20170709

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訂定單位 Composed by	第一/二人體研究倫理審查委員會 The First/Second 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：第一/二人體研究倫理審查委員會 ■Other (Please specify): The First/Second 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
E	4	3. 因標準化文件改為線上申請，予修改 5.3.2、刪除原附件 6.1，及新增附件說明。 3. Standardized document applications became completely online, so item 5.3.2 was revised, the original appendix 6.1 was deleted, and a new note about appendices was added.	20170709
F	7	1. 修改參考文件 3.1 為 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011. 1. Reference 3.1 was changed to “World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.” 2. 更新參考文件 3.2 為 2016 年。 2. The year of reference 3.2 was updated to 2016.	20190527
F	7	依本院規定，於 2021 年 04 月 07 日重新審視本文件，內容無須修訂。 According to the regulations by TCVGH, this document was reviewed again on 07 April 2021 and no revision was needed.	20190527

臺中榮民總醫院 2021.06.10 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。
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※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.

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-2003 IRB-Regulations of Operation-2003	文件名稱 Title	標準化文件制修審頒管理程序書 SOP for Creating and Updating Standardized Documents

會辦單位 Processing Unit	審查意見 Review Comments	會辦單位主管 Head of Processing Unit

臺中榮民總醫院
2021.06.10
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

界定第一/二人體研究倫理審查委員會管理程序書的制定、修訂、審訂和頒佈。內容將提供清楚並符合世界衛生組織倫理審查操作指引，以供第一/二人體研究倫理審查委員會執行相關活動時之依據，特制訂本管理程序書。

1. Purpose

The purpose of this SOP is to manage the composition, revision, review, and promulgation of the IRB Standard Operating Procedures, which shall provide clear guidelines for IRB operation in compliance with the WHO ethical standards and procedures for research with human beings.

2.適用範圍

涵蓋第一/二人體研究倫理審查委員會標準化文件的制定、修訂、審訂和頒佈之管理均適用本管理程序書。

2. Scope

This SOP applies to the composition, revision, review, and promulgation of all standardized documents of the First/Second IRB Committees.

3.參考文件

3. References

3.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.

3.2 ICH E6: GCP 2016.

4.名詞定義

4. Definitions

4.1 標準化文件(ISO Document)：原為「標準作業程序」(SOP)，轉換為 ISO 9001 版本後，改稱為「標準化文件」。機構為確保某一

任務的執行能夠標準化，將所有作業方式或行動以一個固定的格式詳細地撰寫成指引；標準化文件及其相關表單的目的都是為了簡化執行作業，使作業維持優良的標準。

4.1 Standardized Document (ISO Document): The original SOP was converted to the ISO 9001 version and is now called “standardized document” or “ISO document.” To ensure the standardization of the execution of a task in an organization, all procedures or actions are written down as guidelines in a standard format. Standardization of documents and related forms can simplify the process of operation and maintain high standards for the quality of the operation.

4.2 標準化文件修訂小組：由（副）主任委員、執行秘書、委員及承辦人員所組成的一個小組，負責第一/二人體研究倫理審查委員會標準化文件的制定、修訂和審訂。

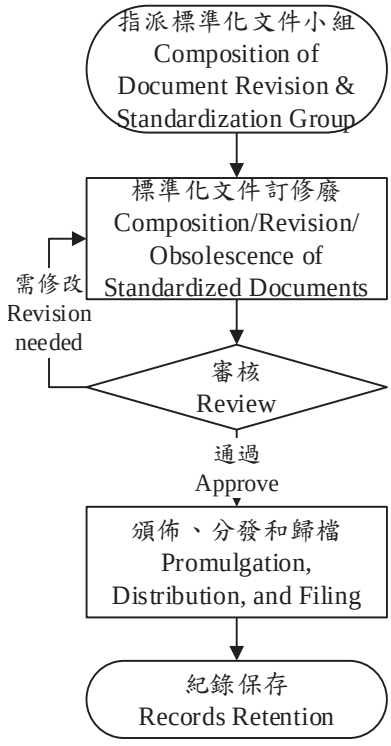
4.2 Document Revision and Standardization Group: Document Revision and Standardization Group is composed of the (Vice) Chair, Executive Secretary, IRB members, and staff members. The group is responsible for the composition, revision, and review of IRB standardized documents.

5.作業內容

5. Procedure

5.1 標準化文件制修審頒管理流程圖

5.1 Flow Chart of Composing/Revising/Reviewing Standardized Documents

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	主任委員/ 副主任委員 Chair/Vice Chair	
	主任委員/副主任委員/執行秘書 Chair/Vice Chair/Executive Secretary	標準化文件申請表/ 標準化文件 Standardized Document Application Form/ Standardized Document
	第一/二人體研究倫理審查委員會 The First/Second IRB Committees	標準化文件/ 修訂小組會議紀錄 Standardized Document/ Meeting Minutes of the Document Revision and Standardization Group
	品質管理中心 Center for Quality Management	標準化文件 Standardized Documents
	品質管理中心 Center for Quality Management	

5.2 指派標準化文件修訂小組

5.2 Composition of the Document Revision and Standardization Group

5.2.1 由第一/二人體研究倫理審查委員會主任委員自第一/二人體研究倫理審查委員會中指派至少 5 ~ 9 名委員組成標準化文件修訂小組，由（副）主任委員擔任召集人，開會時由召集人或由召集人指派資深委員一名擔任主席。

5.2.1 The IRB Chair should assign at least 5 to 9 IRB members to be in the Document Revision and Standardization Group. The coordinator of the group should be the (Vice) Chair. A group meeting should be chaired by the coordinator or a senior member assigned by the coordinator.

5.2.2 標準化文件修訂小組成員須具備人體研究、倫理法律、審查會之標準作業程序等相關教育訓練，並不定期接受相關教育訓練。

5.2.2 All members of the Document Revision and Standardization Group should have received training related to human research, law and regulations on research ethics, and the IRB Standard Operating Procedures. Group members should receive relevant training periodically.

5.3 標準化文件訂修廢

5.3 Composition/Revision/Deletion of Standardized Documents

5.3.1 標準化文件得依實務運作需求，訂定新標準化文件。

5.3.1 New standardized documents may be composed based on practical operational needs.

5.3.2 委員、執行秘書或承辦人員察知標準化文件有修訂/廢止需求時，經（副）主任委員同意後，應以「標準化文件申請表」向品質管理中心提出申請。

5.3.2 When there is a need to revise a standardized document

or to make it obsolete, an IRB member, the Executive Secretary, or a staff member may submit a “Standardized Document Application Form” to the Center for Quality Management, with the approval of the (Vice) Chair.

5.3.3 標準化文件之訂定/修改，由祕書處準備相關資料。

5.3.3 The Secretariat should prepare relevant information for the composition or revision of a standardized document.

5.3.4 召開標準化文件修訂小組會議進行內容討論與修訂/廢止。

5.3.4 A meeting is convened by the Document Revision and Standardization Group to discuss the revision or deletion of a standardized document.

5.3.5 執行秘書至少須每兩年檢視標準作業程序，並記錄檢視的日期。

5.3.5 The Executive Secretary should review the IRB standard operating procedures at least once every two years and record the date of each review.

5.4 審核

5.4 Review

5.4.1 訂修廢後之標準化文件須經第一/二人體研究倫理審查委員會大會審議核備，由主任委員簽署核可後送至品質管理中心進行後續管理程序。

5.4.1 After a standardized document is composed, revised, or deleted, the IRB board meeting should review and confirm the document. The document should then be submitted to the Center for Quality Management for follow-up procedure after the IRB Chair has signed off the IRB board meeting confirmation.

5.4.2 如遇特殊狀況，為維護委員會實務運作之時效，得由主任委員簽署核可後送至品質管理中心進行後續管理程序，再提第一/二人體研究倫理審查委員會大會追認後核備。

5.4.2 To maintain the efficiency of the IRB operation, under special circumstances, the IRB Chair may sign to approve the composition/revision/deletion of the standardized document and submit it to the Center for Quality Management for follow-up procedure before it is confirmed in an IRB board meeting.

5.5 頒佈、分發和歸檔

5.5 Promulgation, Distribution, and Filing

5.5.1 核准之標準化文件自品質管理中心頒佈日起生效。

5.5.1 An approved standardized document is in effect on the day of its promulgation by the Center for Quality Management.

5.5.2 核准之標準化文件，承辦人員得向品質管理中心申請「參考文件」，分發給各委員並公告於本會網站。

5.5.2 The staff member may submit an application to the Center for Quality Management to distribute an approved standardized document to IRB members and announce it on the IRB website.

5.6 紀錄保存

5.6 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 guideline below.

編號 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	標準化文件參考文件 Documents related to the standardized documents	IRB 辦公室 IRB Office	截至該版本廢止時 Until the version is deleted

6.附件

6. Appendix

「標準化文件申請表」為線上輸入，無版本誤用之虞，故不列入附件管理。

“Standardized Document Application Form” is generated from the online system, preventing the usage of the wrong version; therefore, the document is not listed as an appendix.