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-2006 IRB-Regulations of Operation- 2006	文件名稱 Title	計畫書送審管理程序書 SOP of Managing Protocol Submissions
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	9	新訂。Newly composed.	20140519
B	6	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	7	1.修改 5.1 流程圖：新增「彙整審查意見」步驟，並新增 5.6.3 諮詢及輔導之流程；修改相關文件。 1. Revised item 5.1 Flow Chart; added ‘Compilation of Reviewers’ Comments’ and item 5.6.3 Procedure for Advice and Guidance; revised relevant documents. 2.新增 5.5.6 審查委員應就研究計畫的風險和潛在利益做評估等內文。 2. Added item 5.5.6 Reviewers shall evaluate the hazards and potential benefits of the protocol.	20150923
D	7	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「審查意見表」改為「案件審查重點注意事項檢核表」：5.1、5.5.2、5.5.5、5.5.6、5.7。 2. Replaced “Review Comment Form” with “IRB Review Checklist”: 5.1, 5.5.2, 5.5.5, 5.5.6, 5.7. 3.原「一般審查送審文件清單」、「簡易審查送審文件清單」改為「新案審查送審文件清單」：5.3.1.1、5.7 紀錄保存、附件 6.1。 3. Replaced “Full Board Review Protocol Submission Checklist” and “Expedited Review Protocol Submission Checklist” with “New Protocol Submission Checklist” in item 5.3.1.1; revised 5.7 Records Retention and Appendix 6.1. 4.新增 5.4.2 遴選副主任委員擔任審查委員之作業方式。 4. Added the procedure of selecting the Vice Chair as a reviewer in item 5.4.2. 5.文字校正。 5. Fixed typos.	20160318

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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
D	7	6.抽換附件 6.2 開會通知、原「免審案送審清單」改為「人體研究/計畫免審申請書」、刪除原附件 6.3「簡易審查送審清單」、原「申請計畫結案送件核對表」改為「結案送件核對表」。 6. Revised Appendix 6.2 Meeting Notice; replaced "Exempt Review Protocol Submission Checklist" with "Exempt Review Application Form;" deleted Appendix 6.3 "Expedited Review Protocol Submission Checklist;" replaced "Application of Protocol Closure Report Checklist" with "Protocol Closure Report Checklist."	20160318
E	8	1.修改 3.1、3.2、3.6 參考文件版本。 1. Revised the versions of references 3.1, 3.2 and 3.6. 2.修改 5.1 流程圖相關文件。 2. Revised relevant documents in item 5.1 Flow Chart. 3.修改 5.2.2 各類計畫案應備文件：一般及簡易審查計畫刪除影本 2 份、修正計畫及追蹤審查報告計畫新增 PTMS 系統申請案則為正本一份說明。 3. Revised item 5.2.2 documents required for protocols of all categories; deleted "required two photocopies" under "Protocol submissions for full board review and expedited review;" added "One hard copy of original documents in the case of PTMS application" under submissions of protocol amendments and continuing review reports. 4.修改 5.4.1 判定審查方式：增列「執行秘書依照標準初步建議是否符合簡易審查要件，由（副）主任委員判定（若執行秘書兼任委員，則可直接進行判定）」，同步修正 5.1 流程圖之權責。 4. Revised item 5.4.1 Review Category Evaluation; added "The Executive Secretary shall make a primary recommendation as to whether the protocol qualifies for expedited review for the Chair or Vice Chair to approve (if the Executive Secretary is also an IRB member, she/he may make the decision directly);" meanwhile, revised the responsible personnel in item 5.1 Flow Chart.	20170709

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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	8	5.刪除原 5.4.2 主任委員及副主任委員擔任審查委員說明。 5. Deleted the explanation about the Chair and the Vice Chair serving as reviewers in the original item 5.4.2. 6.修改 5.4.2：刪除副主任委員遴選審查委員之文字。 6. Revised item 5.4.2; deleted the part about the Vice Chair selecting reviewers. 7.修改 5.5：刪除執行秘書、副主任判定審查方式之文字。 7. Revised item 5.5: Deleted “Review Category shall be judged by the Executive Secretary and the Vice Chair.” 8.修改 5.5.3 審查期限：原 7 個日曆天改為 6 個。 8. Revised item 5.5.3 Review time limit: Replaced “seven” calendar days with “six.” 9.修改 5.5.4 重新遴選委員之權責人員。 9. Revised the personnel responsible for the reselection of IRB members in item 5.5.4. 10. 調整 5.6 紀錄保存及 6.附件之表單名稱及順序一致，同步修改 5.6.2、5.6.3 附件編號。 10. Adjusted the order of items in item 5.6 Records Retention and Appendix 6 to be consistent; meanwhile, revised the appendix number in item 5.6.2 and item 5.6.3. 11.抽換附件 6.1-6.10。 11. Replaced Appendices 6.1 to 6.10.	20170709

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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
F	8	1.修改參考文件 3.4 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) 1. Updated reference 3.4 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).” 2.修改附件 6.1、6.2、6.4、6.5、6.7。 2. Revised Appendices 6.1, 6.2, 6.4, 6.5, and 6.7.	20181026
G	18	1. 因應 IRB 無紙化送審作業，修改與「書面資料」相關之內容。 1. Process related to hardcopies was revised to comply with the new IRB policy of paperless submission. 2. 修改 5.2.2 各類計畫案之應備文件。 2. Required documents for protocols in item 5.2.2 were revised. 3. 刪除 5.4.1「應於計畫文件蓋上收文戳章，填上收件日期後」文句。 3. Deleted item 5.4.1 “The staff members should stamp submitted documents and fill in the date. 4. 新增 5.5.7 審查委員於審查時，應考量公平正義之原則，評估研究計畫是否公平的選擇受試者，考量研究對象納入與排除條件之合理性。 4. Added item 5.5.7 The reviewers should judge whether the subjects are selected fairly and whether the terms of exclusion are reasonable based on the principle of justice and fairness.	20190527

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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
G	18	5.新增 5.5.8 審查委員審查受試者知情同意之程序。 5. Added item 5.5.8 The procedure of reviewing the Informed Consent Form. 6. 新增 5.5.9 審查委員審查受試者招募之程序。 6. Added item 5.5.9 The procedure of reviewing recruiting subjects. 7. 修改 6.部份附件。 7. Revised 6. Appendices.	20190527
H	19	1.依據 AAHRPP 國際認證委員之建議進行增修。 1.The following modifications were made according to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) reviewers. 2.新增 5.5.10 項內容。 2.Added item 5.5.10 contents. 3.抽換附件 6.1、6.5、6.6。 3.Appendices 6.1, 6.5 and 6.6 were replaced.	20191018

臺中榮民總醫院
2023.08.10
參考文件

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Taichung Veterans General Hospital

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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
I	19	1. 修改參考文件 3.2 為「藥品優良臨床試驗作業準則」109 年 08 月 28 日衛生福利部部授食字第 1091407788 號令修正。 1. Updated reference 3.2 into ""Regulations for Good Clinical Practice" amended on August 28 2020, pursuant to Ministry of Health and Welfare Bu-Shou-Shi-Zi No. 1091407788." 2. 修改參考文件 3.6 為中華民國 109 年 01 月 15 日總統華總一義字第 10900003861 號令修正公布「醫療法」。 2. Updated reference 3.6 into "Medical Care Act, amended and promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10900003861 dated 15 January 2020." 3. 修正 5.3.7.2 之「臨床試驗受試者名單」為「受試者清單與收案狀況描述表」。 3. Replaced "List of Subjects and Description of Enrollment" with "Name List of Clinical Trial Subjects". 4. 新增 5.5.8.12 項內容。 4. Added item 5.5.8.12 contents. 5. 抽換附件 6.1、6.2、6.3、6.4、6.5、6.6、6.7、6.8、6.9、6.10。 5. Appendices 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, and 6.10 were replaced.	20210528
J	19	1. 修改 5.5.3 審查期限：原 6 個日曆天改為 6 個工作天。 1. Revised item 5.5.3 Review time limit: Replaced "six calendar days" with "six work days."	20211209
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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
K	19	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. 新增參考文件 3.7 ~ 3.9。 2. Items 3.7-3.9 were added in References. 3. 依據 AAHRPP 國際認證之建議新增 5.2.3。 3. According to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) was added Items 5.2.3. 4. 修改 5.3.1.2：原 5 個日曆天改為 5 個工作天。 4. Revised item 5.3.1.2: Replaced “five calendar days” with “5 work days.” 5. 修改 5.5.9.2 項內容。 5. Revised item 5.5.9.2. 6. 抽換附件 6.1~6.7 及 6.10、6.11。 6. Appendices 6.1 ~6.7 and 6.10, 6.11 were replaced.	20230717

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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-2006 IRB-Regulations of Operation- 2006	文件名稱 Title	計畫書送審管理程序書 SOP of Managing Protocol Submissions

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

為促使本院人體研究計畫送審之管理有一明確之規範，以確保人體研究計畫均能符合各項法規規定，特制訂本程序書。

1. Purpose

The purpose of this SOP is to provide standard regulations to manage the review of human research protocols at TCVGH to ensure the lawfulness of the research.

2.適用範圍

凡本院如下各類人體研究計畫之審核項目管理均適用本程序書。

2. Scope

This SOP applies to managing review items of all human research protocols of the following categories at TCVGH.

2.1 一般審查計畫案

2.1 Protocols for Full Board Review

2.2 簡易審查計畫案

2.2 Protocols for Expedited Review

2.3 免審計畫案

2.3 Protocols for Exempt Review

2.4 修正計畫案

2.4 Protocol Amendments

2.5 追蹤審查報告

2.5 Continuing Review Reports

2.6 暫停/終止報告

2.6 Protocol Suspension/Termination Reports

2.7 結案報告

2.7 Protocol Closure Reports

2.8 其他應審查事項

2.8 Other items needing review

3.參考文件

3. References

3.1「人體試驗管理辦法」105 年 4 月 14 日衛生福利部衛部醫字第 1051662154 號令修正

3.1 “Regulations on Human Trials” amended on April 14, 2016,pursuant to Ministry of Health and Welfare Wei-Bu-Yi-Zi No. 1051662154.

3.2「藥品優良臨床試驗作業準則」109 年 08 月 28 日衛生福利部部授食字第 1091407788 號令修正

3.2 “Regulations for Good Clinical Practice” amended on August 28 2020, pursuant to Ministry of Health and Welfare Bu-Shou-Shi-Zi No. 1091407788.

3.3「人體研究法」總統華總一義字第 10000291401 號令制定公布全文 26 條，民國 100 年 12 月 28 日施行

3.3 “Human Subjects Research Act,”26 articles in total, stipulated and promulgated pursuant to Zong-Tung Hua-Zong-Yi-Yi-Zi No. 10000291401; effective since December 28, 2011.

3.4「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)

3.4 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).

3.5「得免取得研究對象同意之人體研究案件範圍」衛署醫字第 1010265083 號，2012

3.5 “The Scope for Human Trials Applicable to Subject Consent Waiver” pursuant to Wei-Shu-Yi-Zi No. 1010265083, 2012.

3.6 中華民國 109 年 01 月 15 日總統華總一義字第 10900003861 號令修正公布「醫療法」。

3.6 Medical Care Act, amended and promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10900003861 dated 15 January 2020

3.7 110 年 12 月 14 日衛部醫字第 1101668486 號函公告「新醫療技術人體試驗案—審查標準作業程序」

3.7 "The Human Trials of New Medical Technology - Review Standard Operating Procedures" announced by Ministry of Health and Welfare on 14 December 2021, pursuant to Wei-Bu-Yi-Zi No. 1101668486.

3.8 109 年 01 月 15 日總統華總一義字第 10900004021 號令制定公布「醫療器材管理法」，全文共 85 條。

3.8 Medical Devices Act, promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10900004021 dated 15 January 2020.

3.9 110 年 04 月 09 日衛生福利部衛授食字第 1101601721 號令訂定發布「醫療器材優良臨床試驗管理辦法」，全文共 72 條。

3.9 Regulations on Good Clinical Practice for Medical Devices, promulgated as per the Ministry of Health and Welfare Wei-Shou-Shi-Zi No. 1101601721 dated 09 April 2021.

4.名詞定義

4. Definition

4.1 PTMS 系統：臨床試驗線上審查系統(Protocol Tracking &Management System，簡稱 PTMS)。

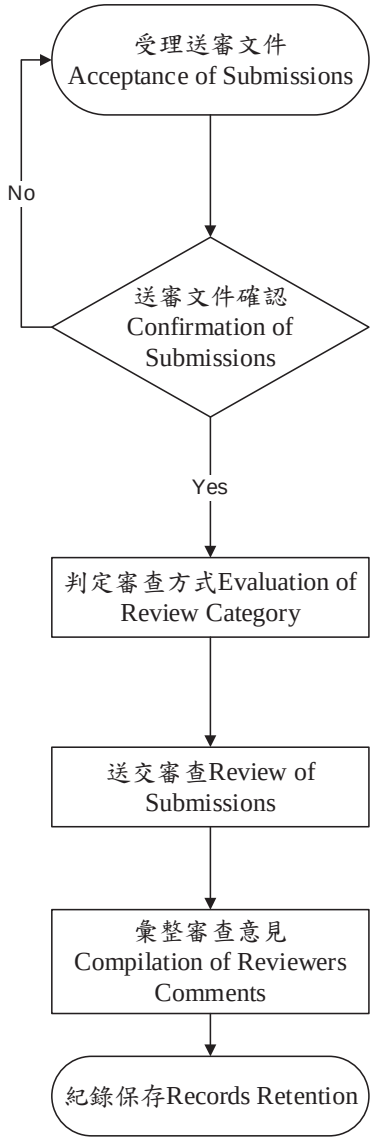
4.1 PTMS: Protocol Tracking & Management System.

5.作業內容

5. Procedure

5.1 計畫書送審管理流程圖

5.1 Flow Chart of Managing Protocol Submissions

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	計畫主持人/承辦人員 PI/Staff Members	各類計畫案相關文件/人體研究倫理審查委員會審查費收費表 Relevant Documents of All Submissions/IRB Review Fee Schedule
	承辦人員 Staff Members	各類送審文件清單/開會通知/各類申請書/案件流程表/資料排列順序表/修正案送件核對表/追蹤審查報告核對表/計畫暫停/終止報告表內之檢送資料核對表/結案送件核對表/臨床試驗受試者名單/管理資料庫 Submission Checklists of All Categories/Meeting Notice/Application Forms of All Categories/Protocol Review Routing Form/List of Organized Documents/Protocol Amendments Checklist/Continuing Review Report Checklist/Protocol Suspension or Termination Report/Protocol Closure Report Checklist/Name List of Clinical Trial Subjects/Management Database
	執行秘書（若兼任委員時）/（副）主任委員 Executive Secretary (if also an IRB member)/(Vice) Chair	送審文件/審查委員遴選表/ PTMS 系統/電子郵件/依各審查程序之相關審查表單 Submitted Documents/Reviewers Selection Form/PTMS/Email/Relevant review forms according to the SOP
	承辦人員/審查委員/諮詢專家 Staff Members/ Reviewers/ Expert Consultants	人體研究倫理審查委員會案件審查重點注意事項檢核表/人體研究倫理審查委員會審查意見回覆表 IRB Review Checklists/Form of Response to IRB Reviewers' Comments
	各業務承辦人員 Staff Members	撤案申請書/受試者權益保護與研究倫理相關諮詢與輔導紀錄表 Protocol Withdrawal Application Form/Record of Guidance on Human Subject Protection and Research Ethics
	各業務承辦人員 Staff Members	

5.2 受理送審文件

人體研究倫理審查委員會業務承辦人員於接獲各類審查案件時，應參照如下規範受理送審文件。

5.2 Acceptance of Submissions

When receiving submissions of all categories, IRB staff members shall process them by following the guidelines below.

5.2.1 參照本院「人體研究倫理審查委員會審查費收費表」，完成繳費程序。

5.2.1 Confirm completion of payment pursuant to the “IRB Review Fee Schedule” of TCVGH.

5.2.2 各類計畫案之應備文件

5.2.2 Confirm receipt of documents required for submissions of all categories

計畫案類別 Submission Category	應備文件 Required Documents
一般審查計畫案 Protocol for Full Board Review	電子檔案 Electronic files
簡易審查計畫案 Protocol for Expedited Review	電子檔案 Electronic files
免審查計畫案 Protocol for Exempt Review	正本一份書面審查資料及電子檔案 One original documents and electronic files
修正計畫案 Protocol Amendments	電子檔案（非 PTMS 系統申請案則為正本一份、影本一份之書面審查資料及電子檔案） Electronic files (one hard copy of original and duplicate documents if applied not on PTMS)
追蹤審查報告 Continuing Review Report	電子檔案（非 PTMS 系統申請案則為正本一份、影本一份之書面審查資料及電子檔案） Electronic files (one hard copy of original and duplicate documents if applied not on PTMS)
暫停/終止報告 Protocol Suspension/Termination Report	電子檔案（非 PTMS 系統申請案則為正本一份之書面審查資料及電子檔案） Electronic files (one hard copy of original documents if applied not on PTMS)
結案報告 Protocol Closure Report	電子檔案（非 PTMS 系統申請案則為正本一份之書面審查資料及電子檔案） Electronic files (one hard copy of original documents if applied not on PTMS)
其他應審查事項	電子檔案（非 PTMS 系統申請案則為正本一份、影本一

Others items needing review	份之書面審查資料及電子檔案） Electronic files (one hard copy of original and duplicate documents if applied not on PTMS)

5.2.3 如遇特殊情況如疫情或天災等情形，審查方式有所變動時，文件檔案需保存完整。

5.2.3 In case of extraordinary circumstances such as the pandemic or natural disasters, when the review method is changed, the documents must be kept intact.

5.3 送審文件確認

業務承辦人須依據「各類送審文件清單」確認文件是否備齊，且確實檢查版本的正確性及文件的完整性。核對後若發現文件有疏漏或錯誤，以 PTMS 系統通知計畫主持人並退回所有送審文件，退回送審文件以一次為限，若計畫主持人有不同意見，則逕送委員審查。

5.3 Confirmation of Submissions

Staff members shall confirm if all needed documents are submitted, and check the correctness of the documents according to the submission checklists of all categories. Upon finding any missing or mistaken item, staff members shall send a PTMS notice to the principal investigator (PI) and return all submitted documents to the PI. Any incomplete submission may only be returned once. If the PI disagrees, the case shall be sent to an IRB member for judgment.

5.3.1 一般審查計畫案

5.3.1 Protocols for full board review

5.3.1.1 業務承辦人員依「新案審查送審文件清單」(請參考附件 6.1）確認文件是否備齊。

5.3.1.1 Staff members shall confirm if all documents are submitted according to the “New Protocol Submission Checklist” (see Appendix 6.1).

5.3.1.2 一般審查之案件，若於開大會前 5 個工作天，完成初審審查程序並依委員審查結果完成回覆意見，均可排進該

次大會，進行複審討論。

5.3.1.2 A protocol for full board review may be scheduled in the agenda of an IRB board meeting if the preliminary review was completed and the PI responded to reviewers' comments at least 5 work days before the scheduled board meeting.

5.3.1.3 承辦人員依「開會通知單」確認文件是否備齊。

5.3.1.3 Staff members shall confirm if all documents are submitted pursuant to "Meeting Notice".

5.3.2 簡易審查計畫案

5.3.2 Protocols for expedited review

5.3.2.1 業務承辦人員依「新案審查送審文件清單」確認文件是否備齊。

5.3.2.1 Staff members shall confirm if all documents are submitted pursuant to "New Protocol Submission Checklist".

5.3.3 免審查計畫案

業務承辦人員依「人體研究/計畫免審申請書」確認文件是否備齊。

5.3.3 Protocols for exempt review

Staff members shall confirm if all documents are submitted following the checklist on the "Exempt Review Application Form".

5.3.4 修正計畫案

5.3.4 Protocol amendments

5.3.4.1 業務承辦人員依「修正案送件核對表」確認文件是否備齊。

5.3.4.1 Staff members shall confirm if all documents are submitted pursuant to "Protocol Amendments Checklist".

5.3.4.2 修正前後對照表應含修正前後所有不同處之比較。

5.3.4.2 All amendments shall be included in the comparison table.

5.3.4.3 文件更改處必須以底線、粗體或色筆標示。

5.3.4.3 All amendments shall be underlined, boldfaced or highlighted.

5.3.5 追蹤審查報告

業務承辦人員依「追蹤審查報告核對表」確認文件是否備齊。

5.3.5 Continuing review reports

Staff members shall confirm if all documents are submitted pursuant to “Continuing Review Report Checklist”.

5.3.6 暫停/終止報告

業務承辦人員依「計畫暫停/終止報告表」內之檢送資料核對表確認文件是否備齊。

5.3.6 Protocol suspension/termination reports

Staff members shall confirm if all documents are submitted pursuant to “Protocol Suspension/Termination Report”.

5.3.7 結案報告

5.3.7 Protocol closure reports

5.3.7.1 業務承辦人員依「結案送件核對表」確認文件是否備齊。

5.3.7.1 Staff members shall confirm if all documents are submitted according to the “Protocol Closure Report Checklist”.

5.3.7.2 試驗性質為「醫療法」第 8 條認定於人體施行新醫療技術、新藥品、新醫療器材及學名藥生體可用率、生體相等性之試驗研究，病歷依法須永久保存。請準備二份「受試者清單與收案狀況描述表」，一份送交病歷室，一份由人體研究倫理審查委員會存檔備查。

5.3.7.2 If the nature of the trial conforms with the “experimental research of new medical technology, new medicament, new medical implement, or the bioavailability and bioequivalence of generic drugs on humans” stipulated in Article 8 of Medical Care Act,

medical records shall be preserved indefinitely pursuant to laws. Two copies of "List of Subjects and Description of Enrollment" shall be submitted—one for the Section of Medical Records, and the other for the IRB Archive.

5.3.7.3 若為非藥物試驗者，部份表格項目可註明「不適用」。

5.3.7.3 For non-drug clinical trials, some entries on the forms may be specified as "Not applicable."

5.3.8 初次送審新案時，依各審查管理程序書所訂之編號原則，給予正式編號，並記錄於「送審資料」各類文件之「本會編號欄」。

5.3.8 Each new submission shall be given a number according to the principles of assigning numbers stipulated in the SOPs. The number shall be recorded in the column of "IRB Number" on all forms related to the submission.

5.3.9 各類送審計畫經行政審查完成後，應將該送審計畫之名稱記錄於「管理資料庫」。

5.3.9 Upon completion of the administrative review of protocols of all categories, staff members shall record the title of each submission in "Management Database."

5.4 判定審查方式

5.4 Evaluation of Review Category

5.4.1 業務承辦人員依各類審查程序確認「送審文件」資料完整後，送交執行秘書。執行秘書依照標準初步建議是否符合簡易審查要件，由（副）主任委員判定（若執行秘書兼任委員，則可直接進行判定），並視需要遴選審查委員，登錄於「審查委員遴選表」。

5.4.1 After confirming all required documents are submitted pursuant to the SOPs of all categories of submission, staff members send them to the Executive Secretary. The Executive Secretary shall make a primary recommendation as to whether the protocol qualifies for expedited review for the Chair or Vice Chair to approve (if

the Executive Secretary is also an IRB member, she/he may make the decision directly), and in case needed, select reviewers and fill in the “Reviewers Selection Form.”

5.4.2 業務承辦人員於執行秘書遴選審查委員後，以「PTMS 系統」或電子郵件通知審查委員。

5.4.2 After the Executive Secretary has selected reviewers, staff members shall notify the reviewers via PTMS or via E-mail.

5.5 送交審查

業務承辦人員應依照各項「計畫審查管理程序書」之規定，將資料送交委員審查。

5.5 Review of Submissions

Staff members shall send protocol documents to reviewers pursuant to the regulations in the “SOP for Managing Protocol Submissions.”

5.5.1 審查委員的姓名必須保密，避免任何可能與審查計畫有關之干擾與壓力。

5.5.1 The names of reviewers shall be confidential to avoid any potential interference or pressure related to the protocol under review.

5.5.2 承辦人員準備「案件審查重點注意事項檢核表」。

5.5.2 Staff members shall prepare the IRB Review Checklists.

5.5.3 填寫審查期限，為期 6 個工作天。

5.5.3 Staff members shall fill in the review time limit, which shall be 6 work days.

5.5.4 分案後，審查委員若覺得有利益衝突或專長不適合的情況，可將計畫案退回給承辦人，由執行秘書再遴選其他適合的審查委員。

5.5.4 If an assigned reviewer discovers any potential conflict of interest, or if the reviewer’s expertise does not match the content of the protocol, the reviewer may return the protocol to the staff member, and the Executive Secretary shall select another reviewer more suitable for the task.

5.5.5 審查委員必須以公平而客觀的立場進行審查，審查意見必須詳盡，並依「案件審查重點注意事項檢核表」逐項填寫審查結果。如遇任何可能之干擾或壓力，應立即向（副）主任委員陳述。委員會有責任排除其干擾或壓力。

5.5.5 Reviewers shall conduct the review with fairness and objectivity. Reviewers' comments shall be written in detail according to each item in the IRB Review Checklists. In the case of any possible interference or pressure, reviewers shall report the incident immediately to the Chair or Vice Chair. The IRB is responsible for eliminating any interference or pressure.

5.5.6 審查委員應就研究計畫的風險和潛在利益做評估（依據「案件審查重點注意事項檢核表」之風險、利益評估）。

5.5.6 Reviewers shall evaluate the hazards and potential benefits of the protocol (pursuant to the evaluation of hazards and benefits in the IRB Review Checklists).

5.5.7 審查委員於審查時，應考量公平正義之原則，評估研究計畫是否公平的選擇受試者，考量研究對象納入與排除條件之合理性。

5.5.7 The reviewers should judge whether the subjects are selected fairly and whether the terms of exclusion are reasonable based on the principle of justice and fairness.

5.5.8 審查委員審查受試者知情同意之程序：

5.5.8 The procedure of reviewing the Informed Consent Form:

5.5.8.1 審查委員於審查時，審查受試者同意書之內容及取得程序。受試者同意書須包括所有受試者於參與實驗前應被告知並須了解將參與之臨床試驗之相關訊息。審查委員須確認受試者是否能於斟酌參與試驗之所有因素後，自願參與試驗。

5.5.8.1 Reviewers shall evaluate contents in the Informed Consent Form, and the procedures in obtaining the subject signatures. The Informed Consent Form must provide all information each subject needs to know

prior to enrolling in the study. Reviewers shall confirm that each subject is free to participate in the study voluntarily after considering all factors involved.

5.5.8.2 審查委員於審查時，應注意臨床試驗進行前，試驗主持人或其指定之人員，是否能給予受試者、法定代理人或有同意權之人充分時間與機會，以詢問臨床試驗之細節，取得受試者自願給予之受試者同意書。

5.5.8.2 Reviewers should pay attention to whether the principal investigator or the designated personnel can give subjects, their legal representatives or those with the right to have sufficient time and opportunity to inquire on details of the study beforehand. The Informed Consent Form must be obtained from the subject under voluntary conditions.

5.5.8.3 審查委員於審查時，應注意試驗主持人或由其指定之人員，是否能充分告知受試者臨床試驗進行之資訊、受試者同意書之內容及所有由本會所核准與臨床試驗相關之書面意見，並使用口語化及非專業性之語言，使受試者充分瞭解後親筆簽名，並載明日期。

5.5.8.3 Reviewers should pay attention to confirm the principal investigator or the designated personnel is able to provide each subject all necessary information in full on the study, explain contents of the Informed Consent Form and provide all written opinions related to the study approved by IRB. A colloquial and non-professional language should be used to enable subjects to fully understand the contents before signing and dating the consent form at the end.

5.5.8.4 審查委員於審查時，須確認計畫主持人可依法(醫療法、人體研究法、人體試驗管理辦法及 GCP 等)完成知情同意之取得。

5.5.8.4 Reviewers shall confirm that the principal investigator completes the Informed Consent Form in accordance with law (Medical Care Act, Human Subjects Research

Act, Regulations on Human Trials, GCP, etc).

5.5.8.5 審查委員於審查時，須評估計畫主持人於研究計畫執行期間，是否能確保研究對象及時得到與其權利、安全與福祉相關之最新資訊。若具有重要之新資訊可能影響研究對象之同意時，應修訂受試者同意書內容及提供研究對象書面資料，並應立即告知研究對象。

5.5.8.5 Reviewers should assess whether the principal investigator has the ability to ensure that the recruited subjects receive timely and up-to-date information related to their rights, safety and well-being throughout the course of study. In the case that important new information arises that may affect the consent of subjects, the Informed Consent Form should be revised and the written information be provided to subjects with immediate oral disclosure.

5.5.8.6 審查委員於審查時，須要求計畫主持人於研究期間，建立研究對象之詢問或投訴並予以回應之機制。

5.5.8.6 Reviewers should demand the principal investigator to establish a mechanism for responding to inquiries or complaints from the subjects during the study period.

5.5.8.7 審查委員於審查時，須審視受試者同意書及提供受試者之任何其他書面資料，不得有任何會造成受試者、法定代理人或有同意權之人放棄其法定權利，或免除試驗主持人、試驗機構、試驗委託者或其代理商責任之記載。

5.5.8.7 Reviewers should examine the Informed Consent Form to ensure it provides all necessary written information to the subjects, and in no case that any subject, legal representative or person with the right to consent to waive their legal rights or to be exempted from signing the Informed Consent Form. In no case that the legal responsibility of the Principal Investigator, the Organization, the Sponsor, the Contract Research Organization be waived.

5.5.8.8 用以治療或處置緊急病況之人體試驗，預期無法預先取

得受試者、法定代理人或有同意權之人同意，試驗計畫書中須詳列緊急事件處理程序，經審查同意，得於取得受試者、法定代理人或有同意權之人書面同意前，先進行試驗。但若能取得受試者、法定代理人或有同意權之人書面同意時，應立即為之。

5.5.8.8 In the case that human trials need to be used to treat emergency conditions when informed consent cannot be obtained beforehand from the subjects, legal representative or person with the right to consent, an emergency plan must be detailed in the study protocol and be approved by the IRB Committee. However, if written consent of the subjects, legal representative or person with the right to consent can be obtained, that should be done as soon as possible prior to the start of study.

5.5.8.9 當研究者可能接觸沒有同意能力的成年人，IRB 將評估：

5.5.8.9 When the principal investigator may be in contact with adults who are unable to give consent, the IRB should evaluate whether:

5.5.8.9.1 所提出的計畫是否能夠評估受試者表達同意的能力。

5.5.8.9.1 The proposed study protocol is sufficient to assess the capacity of subjects to give consent.

5.5.8.9.2 受試者的同意是否必要，而且是否可滿足計畫所需。

5.5.8.9.2 The consent of subjects is necessary, and the consent is sufficient for the study.

5.5.8.10 簽署受試者同意書應為必要。若事先合理預期無法取得知情同意，或取得知情同意會增加受試者風險，需由主持人提出申請，送請審查委員進行審查。

5.5.8.10 Signing the Informed Consent Form is a necessary prerequisite for the study. If the informed consent is

not reasonably expected to be obtained, or if the informed consent increases the risk of the subjects, the principal investigator must submit an application to the IRB Committees for approval of this situation.

5.5.8.11 審查委員須依照研究風險之高低，評估研究計畫是否得免除知情同意之程序，並依 101 年 07 月 05 日衛生福利部(前衛生署)衛署醫字第 1010265083 號公告訂定之「得免取得研究對象同意之人體研究案件範圍」，判定是否得以免除知情同意之取得。

5.5.8.11 Reviewers should determine if the research protocol can or cannot be exempt from the informed consent procedures based on the risk level of the study according to the announcement by the Ministry of Health and Welfare (formerly known as the Department of Health) on July 5, 2012, pursuant to Wei-Shu-Yi-Zi No. 1010265083.

5.5.8.12 審查委員依據計畫審查是否涉及決定能力缺乏之受試者，並要求計畫主持人應提出相關具體的保護措施；且依照受試對象、案件、時間、地點與生理、心理、社會及經驗、隱私等影響層面，進行評估並追蹤。

5.5.8.12 The reviewers examines whether participants with lack of deciding ability are involved according to the protocol, and requires the principal investigator to propose relevant specific protective measures. The reviewers should also evaluate and track in accordance with the participants, cases, time, location, and physical, psychological, social and experience, privacy and other impacts.

5.5.9 審查委員審查受試者招募之程序：

5.5.9 The procedure of reviewing recruiting subjects:

5.5.9.1 審查委員審查受試者招募的各種資料，包括平面廣告與多媒體，受試者收到的報酬、方式與時程，以確保招募方式的公平。

5.5.9.1 Reviewers should examine the various materials used in recruiting subjects, including print advertisements, multimedia materials, rewards, methods, and schedules received by potential subjects to ensure fairness in recruitment.

5.5.9.2 審查委員須審視受試者招募廣告之適當性，並確認招募廣告中無強調受試者將可獲得免費醫療。

5.5.9.2 Reviewers should evaluate the appropriateness of the advertisements for subject recruitment, and ensure that no emphasis is made in the advertisement regarding free medical treatment for the subjects.

5.5.10 若是審查過程中涉及社區成員參與研究，為了加強 IRB 審查社區參與性研究的能力，可採用以下方式：

5.5.10 In the case when community members shall participate in the research project during the review process, in order to strengthen the IRB's ability to review the the research involving community participation, the following methods can be used:

5.5.10.1 納入具有社區參與性研究專業知識之委員或專家。

5.5.10.1 Inclusion of IRB members with expertise in community based participatory research.

5.5.10.2 提供委員社區參與式研究的教育訓練

5.5.10.2 Education of IRB members in community based participatory research.

5.5.10.3 分享 IRB 對於此類型研究之經驗。

5.5.10.3 Sharing IRB experience with this type of research.

5.6 彙整審查意見及建議

5.6 Compilation of Reviewers' Comments

5.6.1 審查委員對每個相關議題應有適當的建議或意見，但應避免有前後不一致之建議或意見。

5.6.1 Reviewers shall provide comments or opinions pertinent to

every relevant issue and shall avoid inconsistent comments or opinions.

5.6.2 若在審查通過以前，計畫主持人決定不執行該計畫者，須提出「撤案申請」。經主任委員、副主任委員、執行秘書審閱同意後提大會核備。

5.6.2 If the PI decides not to execute the research before the protocol is approved, she/he shall submit a “Checklist and Application Form of Protocol Withdrawal”. After being reviewed and approved by the Chair, the Vice Chair and the Executive Secretary, the protocol withdrawal shall be reported to the IRB board meeting for confirmation.

5.6.3 當研究人員或與該研究計畫相關其他人員對「受試者權益保護」與「研究倫理」相關議題有疑義時，得向本會提出「諮詢」或「輔導」，受理人應填具「受試者權益保護與研究倫理相關諮詢與輔導紀錄表」，於「諮詢」或「輔導」結束後，送（副）主任委員批示。

5.6.3 It researchers and other protocol-related staff have questions or concerns related to issues about human subject protection and research ethics, they may request advice or guidance from the IRB. Staff members shall fill in the “Record of Guidance on Human Subject Protection and Research Ethics”, and send it to the Chair or the Vice Chair for approval after having provided advice or guidance.

5.7 紀錄保存

相關人員應依據如下規定，妥善保存各項紀錄。

5.7 Records Retention

Relevant personnel should keep all records safely 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	新案審查送審文件清單 New Protocol Submission Checklist	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed

2	開會通知 Meeting Notice	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed
3	人體研究計畫免審案送審清單 Exempt Review Application Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed
4	修正案送件核對表 Protocol Amendments Checklist	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed
5	追蹤審查報告核對表 Continuing Review Report Checklist	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed
6	計畫暫停/終止報告表 Protocol Suspension/Termination Report	IRB 檔案室 IRB Archives	試驗結束後 3 年 3 years after the trial is closed
7	結案送件核對表 Protocol Closure Report Checklist	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed
8	審查類型評估表 Review Category Evaluation Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed
9	審查委員遴選表 Reviewers Selection Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed
10	撤案申請書 Protocol Withdrawal Application Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed
11	受試者權益保護與研究倫理相關諮詢與輔導紀錄表 Record of Guidance on Human Subject Protection and Research Ethics	IRB 檔案室 IRB Archive	試驗結束後 3 年 3 years after the trial is closed

6.附件

6. Appendices

6.1 新案審查送審文件清單

6.1 New Protocol Submission Checklist

6.2 開會通知單

6.2 Meeting Notice

6.3 人體研究計畫免審申請書

6.3 Exempt Review Application Form

6.4 修正案送件核對表

6.4 Protocol Amendments Checklist

6.5 追蹤審查報告核對表

6.5 Continuing Review Report Checklist

6.6 計畫暫停/終止報告表

6.6 Protocol Suspension/Termination Report

6.7 結案送件核對表

6.7 Protocol Closure Report Checklist

6.8 審查類型評估表

6.8 Review Category Evaluation Form

6.9 審查委員遴選表

6.9 Reviewers Selection Form

6.10 撤案申請書

6.10 Protocol Withdrawal Application Form

6.11 受試者權益保護與研究倫理相關諮詢與輔導紀錄表

6.11 Record of Guidance on Human Subject Protection and Research Ethics