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-2013 IRB-Regulations of Operation-2013	文件名稱 **Title**	結案審查管理程序書 **SOP for Study Closure**
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	21	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	6	1. 修改 5.2.1 結案報告文件數量。 1. The number of documents for the closing report was modified in item 5.2.1. 2. 將原 5.3.1 受試者簽署同意書之試驗檢附資料的說明段移至 5.2.2.5。 2. The details regarding required documents for protocols that include ICFs were moved from item 5.3.1 to item 5.2.2.5. 3. 新增 5.3.1 承辦人員核對送審文件之內文。 3. Item 5.3.1 was added: The staff member should verify that the content of the submitted documents is complete. 4. 修改 5.4.標題（原遴選審查委員）及 5.4.1、5.4.2 遴選委員之內文；新增 5.4.3 新案審查及監督管理程序；並修改 5.1 流程圖之步驟及相關文件。 4. The title of item 5.4 was revised (the original was “selection of reviewers”); the content regarding selection of reviewers in items 5.4.1 and 5.4.2 were revised; the procedure and relevant documents in item 5.1 Flow Chart were revised. 5. 新 5.5.3 審查發現偏離、危及受試者生命安全或其他違反試驗倫理情形之處理方式。 5. Item 5.5.3 was added regarding actions taken when reviewers discover protocol deviation incidents or other incidents that affect the subjects’ safety or violate clinical research ethics.	20150923

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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
C	6	6. 修改 5.6.2 若審查結果為「同意結案」者之處理流程。 6. Item 5.6.2 was revised regarding the follow-up procedure of the review decision of “approval of study closure.” 7. 修改附件 6.8 表單名稱(原人體研究/試驗計畫結案通知)，並修改內文。 7. The title of the form in item 6.8 was revised (the original was “Approval of Human Research/Clinical Trial Study Closure”), and the content was revised accordingly.	20150923
D	6	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. 修改 5.2.2：申請人簽章改為簽名。 2. Item 5.2.2 was revised: “Signature/stamp of the applicant” was replaced by “signature of the applicant.” 3. 原「審查意見表」改為「結案案件審查重點注意事項檢核表」：5.1、5.5.1、5.9、附件 6.4。 3. The original “Reviewers’ Comments Form” was replaced by “IRB Review Checklist for Study Closure,” and items 5.1, 5.5.1, 5.9 and Appendix 6.4 were revised accordingly. 4. 修改 5.6.2 審查結果：原「同意結案」改為「同意結案，提大會進行追認/核備」。 4. Item 5.6.2 was revised regarding review decisions: “Study closure approved” was replaced by “study closure approved and sent to the full board for confirmation/recordation.”	20160318

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D	6	5. 文字校正。 5. Typos were fixed. 6. 修正 5.6.5：計畫主持人回覆審查意見之相關規定。 6. Item 5.6.5 was revised regarding the procedure for the PI to respond to reviewers' comments. 7. 新增 5.7.3 大會投票結果為「不核准」之相關規定。 7. Item 5.7.3 was added regarding the full board voting result of "disapproved." 8. 刪除原附件 6.2 PTMS 結案申請書，並加註說明。 8. The original Appendix 6.2 "PTMS Study Closure Application Form" was deleted, and a note was added.	20160318
E	7	1. 修改 5.1 流程圖「決定審查方式及遴選審查委員」權責。 1. The responsible personnel was revised regarding "Determination of Review Category and Selection of Reviewers" in 5.1 Flow Chart. 2. 新增 5.2.2.6 受試者同意書及受試者勾選項目電子檔或影本之相關規定。 2. Item 5.2.2.6 was added regarding the requirement of submitting electronic file or photocopy of the ICFs and pages with checklists for the subjects to fill in on the ICFs. 3. 新增 5.2.5 執行許可書過期且超過 3 年未繳交追蹤審查報告案件之處理說明。 3. Item 5.2.5 was added regarding the procedure of handling a protocol for which the Certificate of Approval has expired and no continuing review report has been submitted for the last three years.	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	7	4. 修改 5.4.1 遴選審查委員之權責：刪除（副）主任委員。 Item 5.4.1 was revised regarding the responsible personnel for selecting reviewers: “(Vice) Chair” was deleted. 4. 修改 5.5.1：刪除若有意見，得以另紙繕寫審查意見。 5. The following sentence was deleted from item 5.5.1: Further review comments (if any) may be written on a separate piece of paper. 6. 新增 5.5.4 計畫案之審查類型、5.5.4.1 一般審查及 5.5.4.2 簡易審查及入會排程說明。 6. Item 5.5.4 was added regarding the review category of the protocol; item 5.5.4.1 was added regarding full board review; item 5.5.4.2 was added regarding expedited review and procedure of placing a protocol on the agenda for the board meeting. 7. 修改新增 5.6.1 轉交審查委員意見之方式：新增電子檔。 7. The way of sending reviewers’ comments was revised in item 5.6.1: “Electronic file” was added. 8. 抽換附件 6.1、6.2、6.5、6.6、6.7、6.8；新增附件 6.9「審查委員遴選表」及 5.10 紀錄保存文件。 8. Appendices 6.1, 6.2, 6.5, 6.6, 6.7 and 6.8 were replaced; appendix 6.9 “Reviewers Selection Form” was added; item 5.10 “Records Retention” was added.	20170709

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F	15	1. 增加 5.2.2.6 說明內容【若為 PTMS 申請案則僅需上傳電子檔至系統即可，無需印出紙本；若非 PTMS 申請案則需檢附並分裝於另一份資料夾，審查完成後則將分裝文件退還。】 1. The following was added to item 5.2.2.6: For PTMS applications, only electronic files are required to be submitted by uploading to the system. There is no need to print out paper copies. For non-PTMS applications, hard copies of submission documents should be included in a separate binder. The binder will be returned to the PI after the review is completed. 2. 增加 5.2.2.6 文句：受試者同意書第 1 頁受試者資訊。 2. Item 5.2.2.6 “the Informed Consent Form Page1: subject’s information” was added. 3. 修改 5.2.2.5 表單名稱。 3. The wording of the title of item 5.2.2.5 was revised. 4. 增加 5.3.3 若計畫主持人尚無法提供成果報告，請務必檢附說明。 4. Item 5.3.3 was added: If the PI is unable to submit a final report of the research results, an explanation has to be provided. 5. 增加 5.4.3 衛生福利部函文發文日期「民國 103 年 07 月 28 日」。 5. The issuance date of the letter from the Ministry of Health and Welfare “28 July 2014” was added in item 5.4.3. 6. 新增 5.7.3 會議投票結果「核准」案件，若是會議結果仍有建議，承辦人員需先提供審查結果請計畫主持人回覆審查意見，計畫主持人回覆文件由承辦人員陳送（副）主任委員/執行秘書核可後，承辦人員才可以開立「人體研究/試驗計畫結案通知」。	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
F	15	6. Item 5.7.3 was added: If the voting result on a protocol is “approved” and suggestions have been given on the protocol, the staff member should notify the PI of the review result and ask the PI to respond to reviewers’ comments. After the PI’s response has been compiled and submitted by the staff member to the (Vice) Chair/Executive Secretary and approved by the (Vice) Chair/Executive Secretary, the staff member may issue the “Approval of Human Research/Clinical Trial Study Closure.” 7. 新增 5.7.4 若投票結果為「修正後核准」，計畫主持人補件（回覆審查意見）天數為 7 個日曆天，若超過 14 個日曆天則逕行撤案；於回覆期限到期前，申請人有特殊理由，得書面申請延長回覆期限 14 個日曆天，以一次為原則。超過回覆期限且擬書面申請延長回覆期限之案件，將先陳送執行秘書、（副）主任委員批示是否同意受理。承辦人員陳送（副）主任委員/執行秘書核可後，承辦人員才可以開立「人體研究/試驗計畫結案通知」。 7. Item 5.7.4 was added: “If the voting result is “approved after revision,” the PI should submit supplementary documents (or respond to reviewers’ comments) within 7 calendar days. The protocol will be withdrawn from IRB consideration if the PI does not respond within 14 calendar days. Before the due day, the PI may request extension of up to 14 calendar days under special circumstances. The PI may request for extension only once. If the PI intends to request for extension after the deadline for requesting for extension is past, the case should be submitted to the Executive Secretary and the (Vice) Chair for approval. The staff member will issue the Approval of Human Research/Clinical Trial Study Closure after the case has been submitted to and approved by the (Vice) Chair/Executive Secretary.	20190527 臺中榮民總醫院 2023.08.10 參考文件

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F	15	8. 修改原 5.7.3 之標號為 5.7.5。 8. The original item number 5.7.3 was changed to 5.7.5. 9. 抽換附件 6.1、6.4、6.7。 9. Appendices 6.1, 6.4 and 6.7 were replaced. 10. 因應 IRB 無紙化送審作業，修改與「書面資料」相關之內容。 10. Process related to hardcopies was revised to comply with the new IRB policy of paperless submission.	20190527
G	14	1. 新增表單名稱：「PTMS 結案報告審查意見表」。 1. Document title was added: “PTMS Review Checklist for Closing Report.” 2. 修改 5.5.4.1 一般審查之審查結果。 2. Revised the review decision of Full Board Review in item 5.5.4.1. 3. 修改 5.5.4.2 簡易審查之審查結果。 3. Revised the review decision of Expedited Review in item 5.5.4.2. 4. 修改 5.6.3 及 5.7.4 之計畫主持人回覆期限為 28 個日曆天，並刪除申請展延說明文字。 4. Item 5.6.3 and 5.7.4 were revised the PI's reply period to 28 calendar days, and deleted the description of the extension. 5. 抽換附件 6.1、6.3、6.6、6.9。 5. Appendices 6.1, 6.3, 6.6 and 6.9 were replaced.	20210528

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G	14	6. 抽換附件 6.1、6.3、6.6、6.9。 6. Appendices 6.1, 6.3, 6.6 and 6.9 were replaced.	20210528
H	14	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. 刪除原 5.2.2.3 內容。 2. Deleted item 5.2.2.3. 3. 抽換附件 6.1、6.2、6.5 ~ 6.8。 3. Appendices 6.1, 6.2, 6.5-6.8 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

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

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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.	

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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

為提供先前通過審查之計畫案，其結案報告之繳交、追蹤和審查作業可依循之規範，特訂定本管理程序書。

1. Purpose

The purpose of this SOP is to describe the procedure for the submission of closing reports and the review and monitoring of study closure of approved protocols.

2.適用範圍

適用於試驗計畫執行許可書到期，且未申請延長試驗執行期限，該計畫主持人需如期繳交結案報告之計畫。

2. Scope

This SOP applies to the protocols for which the approval period has expired and an extension application has not been submitted. For these protocols, the PIs should submit closing reports before the due date.

3.參考文件

無。

3. References

None.

4.名詞定義

無。

4. Definitions

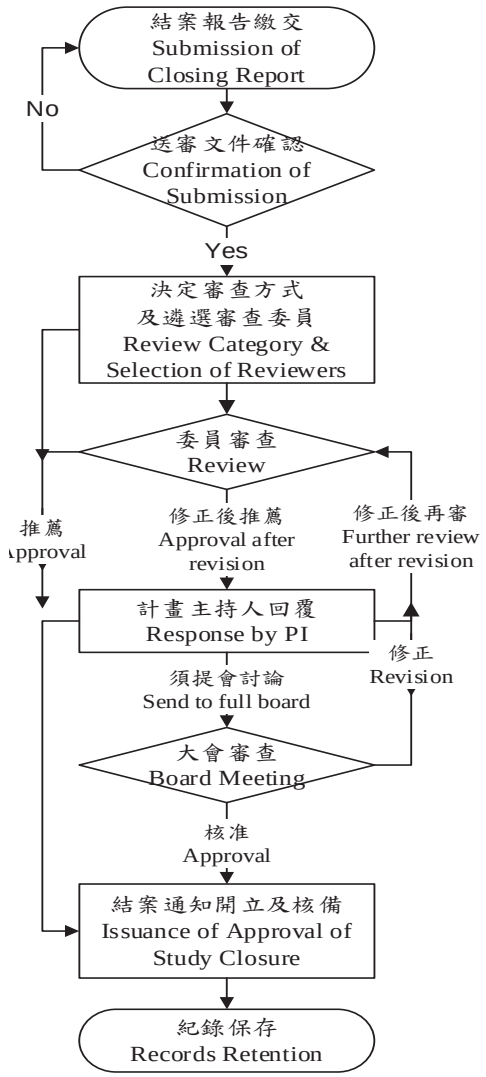
None.

5.作業內容

5. Procedure

5.1 計畫結案審查管理流程圖

5.1 Flow Chart of Study Closure Review

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	計畫主持人 Principal Investigator 承辦人員 Staff Members 執行祕書/（副）主任委員 Executive Secretary/ (Vice) Chair 審查委員 Reviewers 計畫主持人 Principal Investigator 委員 Reviewers 承辦人員/執行祕書/（副）主任委員 Staff Members/ Executive Secretary/(Vice) Chair 承辦人員 Staff Members	計畫結案報告相關表單 Relevant forms for closing reports 結案報告/案件流程表 Closing reports/Protocol Review Routing Form 送審文件 Submission documents 結案資料/PTMS 結案報告審查意見表 Study closure documents/ PTMS Review Checklist for Closing Report 人體研究倫理審查委員會審查意見回覆表 Form of Response to IRB Reviewers' Comments 會議紀錄 Meeting Minutes 公文/人體研究/試驗計畫結案通知 Official Correspondence/ Approval of Clinical Trial Study Closure

5.2 結案報告繳交

5.2 Submission of Closing Report

5.2.1 計畫主持人準備結案報告文件。

5.2.1 The PI should submit the closing report.

5.2.2 計畫主持人備妥所須結案報告資料如下：

5.2.2 The PI should submit the closing report along with the following documents:

5.2.2.1 結案送件核對表。

5.2.2.1 Study Closure Submission Checklist

5.2.2.2 結案報告表/ PTMS 結案申請書（申請人需簽名，如有成果報告請附上）。

5.2.2.2 Closing Report Form/PTMS Study Closure Application Form (The PI should sign on the form. Submit the final report with research results if applicable.)

5.2.2.3 受試者清單與收案狀況描述表。

5.2.2.3 List of Subjects and Description of Subject Enrollment.

5.2.2.4 嚴重不良事件通報紀錄表(僅通報 SUSAR)。

5.2.2.4 Serious Adverse Event Report Form (only SUSAR is reported)

5.2.2.5「受試者同意書」及受試者勾選項目頁面電子檔或影本【每一新版應附一份完整的「受試者同意書」影本，其他附受試者同意書第 1 頁受試者資訊、簽名頁及有受試者勾選項目頁面之影本即可(影印「受試者同意書」時，需要受試者勾選項目的內容都要影印）。「受試者同意書」總份數低於（含）30 份之計畫案，須全數繳交「受試者簽署同意書」送本會審查；若「受試者同意書」總份數大於 30 份之計畫案，依受試者清單之「同意書」簽署日期等距比例（受試者總數除以 30）抽出，以 30 份為限。第二年開始之追蹤審查案僅需繳交新收案或新簽署之「受試者同意書」第 1 頁受試者資訊、簽名頁及

受試者勾選頁影本；若是未納入新個案且未有新簽署之「受試者同意書」，僅需繳交全部「受試者清單」即可】。【若為PTMS申請案則僅需上傳電子檔至系統即可，無需印出紙本；若非PTMS申請案則需檢附並分裝於另一份資料夾，審查完成後則將分裝文件退還。】

5.2.2.5 A photocopy or electronic file of the pages with the subjects' signatures and checklists on the ICF. For each new version of the ICF, submit a photocopy of the complete ICF. For the other ICFs of the same version, only photocopies of the pages with the subject's information, signatures and checklists need to be submitted (photocopies of all of the items for the subjects to fill out on the checklist should be submitted). If the protocol has fewer than 30 ICFs, all of the ICFs should be submitted to the IRB for review. If the protocol has more than 30 ICFs, then up to 30 ICFs should be submitted. An approximately equal number of ICFs should be selected from each date that the ICFs were signed For continuing review applications of second-year research, if new subjects are recruited and new ICFs are signed, submit photocopies of the pages of ICF with the subject's information, signatures and the pages with checklists for the subjects to fill out. If no new subjects are recruited, then only a list of all subjects needs to be submitted. For PTMS applications, only electronic files are required to be submitted by uploading to the system. There is no need to print out paper copies. 【 For non-PTMS applications, hard copies of submission documents should be included in a separate binder. The binder will be returned to the PI after the review is completed.】

5.2.2.6 其他。

5.2.2.6 Others.

5.2.3 若計畫主持人未於許可書到期前提出效期展延之申請，應於

許可書到期後三個月內繳交「結案報告」，否則（副）主任委員有權決定暫不受理其新案申請。

5.2.3 If the PI has not applied for a continuing review before the Certificate of Approval expires, the PI should submit a closing report within three months after the Certificate of Approval expires. Otherwise, the (Vice) Chair may determine that new protocol submissions from the PI will not be accepted by the IRB.

5.2.4 送本會審查之計畫案，許可書之有效期限過期六個月後，未送「結案報告」予本會審查之計畫主持人，暫不受理新案審查，俟其結案報告繳交後，始受理新案審查。

5.2.4 If the PI does not submit the closing report within six months after the Certificate of Approval expires, then any new protocol submission from the PI will not be accepted by the IRB until a closing report is submitted.

5.2.5 執行許可書過期且超過 3 年未繳交追蹤審查報告之案件，承辦人員得提大會報告，依大會決議處理後續相關事宜（如實地訪查、行政結案並建議主持人接受教育訓練...等決議）。

5.2.5 If the PI does not submit a continuing review report within three years after the Certificate of Approval expires, the staff member may place the protocol on the agenda for the IRB board meeting. The IRB board meeting will make a resolution on follow-up actions (such as conducting a monitoring visit or administrative closure of the study, suggesting the PI to receive training, or other actions).

5.3 送審文件確認

5.3 Confirmation of Submissions

5.3.1 承辦人員核對「送審文件」，除計畫結案報告表/ PTMS 結案申請書外，應檢附必備文件【本會執行許可書/追蹤審查許可書/修正案同意函影本、受試者清單、嚴重不良事件通報紀錄表(僅通報 SUSAR)】。

5.3.1 The staff member should verify that the submitted documents are complete. In addition to the Closing

Report Form/PTMS Study Closure Application Form, other required documents need to be included 【photocopy of Certificate of Approval/Certificate of Project Extension/Certificate of Protocol Amendment issued by TCVGH-IRB, List of Research Subjects, and Serious Adverse Event Report Form (only SUSAR is reported)】.

5.3.2 資料齊全後，承辦人員受理申請辦理。

5.3.2 After compiling the submission documents, the staff member process the application.

5.3.3 若計畫主持人尚無法提供成果報告，請務必檢附說明。

5.3.3 If the PI is unable to submit a final report of the research results, an explanation has to be provided.

5.4 決定審查方式及遴選審查委員

5.4 Decision on Review Category and Selection of Reviewers

5.4.1 原則上送原審查委員審查，若原審查委員已非現任委員或其他特殊情況，則由執行秘書指派一位委員代為審查。

5.4.1 The submission should be reviewed by the original reviewer of the protocol. If the original reviewer does not serve as an IRB member or under other special circumstances, the Executive Secretary may assign another member to review the submission.

5.4.2 未收案之結案報告可由執行祕書、(副)主任委員同意後，得依行政程序先給予核發「人體研究/試驗計畫結案通知」及公文並於大會追認。

5.4.2 The closing report of a protocol which has not recruited subjects may be approved by the Executive Secretary and the (Vice) Chair to be issued the “Approval of Study Closure” with an official notice by the administrative procedure, which will be confirmed in the IRB board meeting.

5.4.3「新案」若經一般審查程序，後續之監督管理(即追蹤審查、修正案、結案...等)，亦同為一般審查程序為之(民國 103

年 07 月 28 日衛生福利部衛部醫字第 1030120703 號函）。反之，若經簡易審查程序，則後續監督管理，得採行簡易審查程序。

5.4.3 If the protocol was sent to the full board for review as a new protocol, all of the follow-up monitoring (including continuing review, protocol amendment, study closure, etc.) should be sent to the full board for review as well (in compliance with the regulation issued by the Ministry of Health and Welfare on 28 July 2014, pursuant to Wei-Bu-Yi-Zi No. 1030120703). If the protocol was reviewed by the expedited review process as a new protocol, then the follow-up monitoring may be conducted by the expedited review process.

5.5 委員審查

5.5 Review

5.5.1 承辦人員將齊全之「結案資料」送委員審查。委員應依照試驗之基本倫理原則進行審查，確定試驗之執行均符合應有程序與對受試者之保護。

5.5.1 The staff member should compile submitted study closure documents and submit them to IRB members for review. The reviewer should conduct the review according to the basic ethics principles of clinical trials and ensure that the implementation of the trial has complied with required procedures and has protected the rights of the research subjects.

5.5.2 研究計畫執行結束後，委員應確認研究團隊確實執行受試者隱私及可辨識資料機密之保護措施。

5.5.2 The reviewer should evaluate if the PI and research personnel have protected the privacy of the subjects and kept identifiable data confidential even after a research project has been completed.

5.5.3 審查發現偏離、危及受試者生命安全或其他違反試驗倫理情形，須立即處理者，可請（副）主任委員召開臨時會議；非

緊急情況，可要求計畫主持人於下一次大會時到場說明，必要時安排實地訪查。

5.5.3 If the reviewer discovers any protocol deviation incident that endangers the subjects' safety, or any other violation against trial ethics that requires immediate action, then the reviewer may ask the (Vice) Chair to call an emergency IRB meeting. If the incident is not urgent, then the PI may be required to attend the next scheduled IRB meeting to give explanation. An on-site monitoring visit may also be arranged if needed.

5.5.4 計畫案之審查類型為一般審查及簡易審查。

5.5.4 The review category of the protocol may be full board or expedited review.

5.5.4.1 一般審查

5.5.4.1 Full Board Review

a.若審查結果為「建議通過」且不需回覆之計畫，則直接排入最近一次大會議程核備。

a. If the review decision is "recommended" and no response is required, then the protocol should be placed on the agenda for the next scheduled board meeting for confirmation.

b.其委員審查的結果為「建議修正或提供進一步說明」，計畫主持人應於限期內回覆審查意見，承辦人員彙整資料後將該案件呈送入會批示單予執行祕書、（副）主任委員審核，若審核的結果為「同意排入最近一次的大會核備」，則直接排入最近一次大會議核備。

b. If the review decision is "recommended for revision or provided further explanation" and response from the PI is required, then the PI should respond to the reviewers' comments by the due date. The staff member should compile relevant documents and submit them to the Executive Secretary and the (Vice) Chair for approval. If the result is "approved to be

placed on the agenda for the next scheduled IRB board meeting for confirmation," then the protocol should be placed on the agenda for the next scheduled IRB board meeting for confirmation.

c.其委員審查的結果為「建議不通過(提會討論)」，計畫主持人應於限期內回覆審查意見，承辦人員彙整資料後排入最近一次大會議程討論。

c. If the review decision is "sent to the full board for discussion," then the PI should respond to the reviewers' comments by the due date. The staff member should compile relevant documents and place the protocol on the agenda for the next scheduled IRB board meeting for discussion.

5.5.4.2 簡易審查

5.5.4.2 Expedited Review

a.其委員的審查結果若為「建議修正或提供進一步說明」，計畫主持人應於限期內回覆審查意見及檢送更正附件，若審查意見註明「修正後再審」，承辦人員再將計畫主持人之回覆意見轉請審查委員再次評核。

a. If the review decision is "recommended for revision or provided further explanation," then the PI should respond to the reviewers' comments and submit relevant revised documents. If the review decision is "further review after revisions," the response and supplementary documents from the PI should be sent to the reviewers for evaluation.

b.其委員的審查結果若為「不符合簡易審查，改送一般審查」，計畫主持人應於限期內回覆審查意見，承辦人員彙整資料後排入最近一次大會議程討論。

b. If the review decision is "not meet the requirements for expedited review and sent to the full board for discussion," then the PI should respond to the reviewers' comments by the due date. The staff

member should compile relevant documents and place the protocol on the agenda for the next scheduled IRB board meeting for discussion.

c.其委員的審查結果若為「通過」且不需計畫主持人回覆之計畫，則承辦人員應先將該案件呈送執行祕書、(副)主任委員審核後核發許可書並提至大會追認。

c. If the review decision is “recommended for approval” and no response from the PI is required, then the staff member should submit the application to the Executive Secretary and the (Vice) Chair for approval. Once study closure is approved, an Approval of Study Closure should be issued, and the study closure approval should be submitted to the board meeting for confirmation.

5.6 計畫主持人回覆

5.6 The PI’s Response to Reviewers’ Comments

5.6.1 當審查委員有意見時，承辦人員應隱去審查者姓名並將意見內容以電子檔交送計畫主持人，請其回覆。

5.6.1 If the reviewer has comments, the staff member should remove the reviewer’s name before sending the comments to the PI for response. The comments should be sent in an electronic file.

5.6.2.須回覆委員審查意見之案件，計畫主持人於限期內回覆審查意見後，承辦人員應先將該回覆呈送執行祕書、(副)主任委員審核，以確認是否可排入最近一次會期核備或需提至大會討論。

5.6.2 If the review requires the PI to submit response to reviewers’ comments, then the PI should give response by the due date. The staff member should submit the response to the Executive Secretary and the (Vice) Chair for evaluation to decide if the response should be placed on the agenda for the next scheduled IRB board meeting for discussion.

5.6.3 審查意見通知計畫主持人後需於 7 個日曆天回覆，若超過 28 個日曆天仍未回覆則逕行撤案。

5.6.3 The PI should respond to reviewers' comments within 7 calendar days. If the PI does not respond within 28 days, the protocol should be withdrawn from IRB consideration.

5.7 大會審查

5.7 IRB Board Meeting

5.7.1 委員應審慎地討論及審查「結案報告」。

5.7.1 IRB members should thoroughly discuss and review closing reports.

5.7.2 經討論後，若無任何委員有異議，則予以核備。

5.7.2 Study closure is approved when all members come to a consensus to approve it after discussion.

5.7.3 會議投票結果「核准」案件，若是會議結果仍有建議，承辦人員需先提供審查結果請計畫主持人回覆審查意見，計畫主持人回覆文件由承辦人員陳送（副）主任委員/執行秘書核可後，承辦人員才可以開立「人體研究/試驗計畫結案通知」。

5.7.3 If the voting result of the board meeting is 'approval' with further comments, then the staff member should notify the PI of the comments from the board meeting and request the PI to respond to the comments. After the PI's response to comments has been received and approved by the (Vice) Chair/Executive Secretary, then the staff member may issue the Approval of Study Closure.

5.7.4 若投票結果為「修正後核准」，計畫主持人補件（回覆審查意見）天數為 7 個日曆天，若超過 28 個日曆天仍未回覆則逕行撤案。承辦人員陳送（副）主任委員/執行秘書核可後，承辦人員才可以開立「人體研究/試驗計畫結案通知」。

5.7.4 If the voting result is "approval after revision," the PI should submit supplementary documents (or respond to reviewers' comments) within 7 calendar days. If the PI does not respond within 28 days, the protocol should be

withdrawn from IRB consideration. The staff member will issue the Approval of Clinical Trial Study Closure after the case has been submitted to and approved by the (Vice) Chair/Executive Secretary.

5.7.5 若大會投票結果為「不核准」，則依大會附帶決議（如：實地訪查等）辦理後續相關事宜。

5.7.5 If the voting result is “disapproval,” then the staff member should notify the PI of the resolution. Follow-up actions may be taken according to the board meeting resolution (e.g. conducting an on-site monitoring visit).

5.8 結案通知開立及核備

5.8 Issuance of Approval of Study Closure

結案報告審查同意後，承辦人員陳送執行祕書、（副）主任委員覆核同意核發「人體研究/試驗計畫結案通知」。

Once the closing report of an expedited review protocol has been reviewed and approved, the staff member may issue the Approval of Study Closure with the confirmation of the Executive Secretary and (Vice) Chair.

5.9 經會議決議同意結案者，承辦人員可開立「人體研究/試驗計畫結案通知」。

5.9 Once the study closure of a full board review protocol has been approved by the IRB board meeting resolution, the staff member may issue the Approval of Study Closure.

5.10 紀錄保存

相關人員應依據如下規定，妥善保存各項紀錄。

5.10 Records Retention

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

編號 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	結案送件核對表 Study Closure Submission Checklist	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
2	結案報告表/ PTMS 結案申請書	IRB 檔案室	試驗結束後 3 年

編號 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
	Closing Report Form/PTMS Study Closure Application Form	IRB Archive	At least 3 years after the trial is closed
3	受試者清單與收案狀況描述表 List of Subjects and Description of Enrollment	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
4	嚴重不良事件通報紀錄表(僅通報 SUSAR) Serious Adverse Event Report Form (only SUSAR is reported)	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
5	人體研究倫理審查委員會結案報告案件審查重點注意事項檢核表/PTMS 結案報告審查意見表 IRB Review Checklist for Closing Report/PTMS Review Checklist for Closing Report	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
6	人體研究倫理審查委員會審查意見回覆表 Form of Response to IRB Reviewers' Comments	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
7	案件流程表 Protocol Review Routing Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
8	人體研究/試驗計畫結案通知 Approval of Study Closure	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 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 At least 3 years after the trial is closed

6.附件

「PTMS 結案申請書」、「PTMS 結案報告審查意見表」、「公文」為線上系統輸入，無版本誤用之虞，故不列入附件管理。

6. Appendices

"PTMS Study Closure Application Form", "PTMS Review Checklist for Closing Report" and "Official Correspondence" are generated from the online system, preventing the usage of the wrong version; therefore, the documents are not listed as an appendix.

6.1 結案送件核對表
6.1 Study Closure Submission Checklist
6.2 結案報告表
6.2 Closing Report Form
6.3 受試者清單與收案狀況描述表
6.3 List of Subjects and Description of Enrollment
6.4 嚴重不良事件通報紀錄表(僅通報 SUSAR)
6.4 Serious Adverse Event Report Form (only SUSAR is reported)
6.5 人體研究倫理審查委員會結案報告案件審查重點注意事項檢核表
6.5 IRB Review Checklist for Closing Report
6.6 第一/二人體研究倫理審查委員會審查意見回覆表
6.6 Form of Response to IRB Reviewers' Comments
6.7 案件流程表
6.7 Protocol Review Routing Form
6.8 人體研究/試驗計畫結案通知
6.8 Approval of Study Closure
6.9 審查委員遴選表
6.9 Reviewers Selection Form