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-2011 IRB-Regulations of Operation-2011	文件名稱 Title	追蹤審查管理程序書 SOP for Continuing Review
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	8	新訂。Newly composed.	20140519
B	7	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	8	1.修改 5.4 項目標題（原為遴選審查委員），並修改 5.1 流程圖步驟名稱及相關文件。 1. The title of item 5.4 was revised (the original was "selection of reviewers"), and the procedure and relevant documents in item 5.1 Flow Chart were revised accordingly. 2.新增 5.2.5 追蹤審查報告為有委託者計畫者，其審查費用之說明。 2. Explanation about review fees was added in item 5.2.5 regarding continuing reports of contracted research projects. 3.修改 5.3.1 僅需繳交新收案之受試者同意書簽名頁及受試者勾選頁影本之類別及繳交全部受試者清單之類別。 3. The following was revised in item 5.3.1: The categories of (1) requiring only photocopies of the pages of ICF with subjects' signatures and the pages with checklists for the subjects to fill out, and (2) requiring the complete list of subjects. 4.修改 5.4.2 可先給予核發「人體研究/試驗計畫追蹤審查許可書」之條件。 4. The following was revised in item 5.4.2: The criteria for issuing the Certificate of Project Extension. 5.修改 5.4.3「新案」監督管理之程序。 5. The procedure of monitoring new protocols was revised in item 5.4.3. 6.新增 5.5.4 審查結果為「同意繼續進行，提大會進行核備」之處理程序。 6. Item 5.5.4 was added regarding the follow-up procedure of the review result of "project extension approved and sent to the full board for confirmation."	20150923

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C	8	7.修改 5.6.2 審查結果為「同意繼續進行，提大會進行核備」計畫主持人回覆程序。 7. Item 5.6.2 was revised regarding the follow-up procedure of the PI's response if the review result is "project extension approved and sent to the full board for confirmation." 8.修改 5.6.5：新增計畫主持人未收到本會許可書前不得執行計畫之說明。 8. The following was added to item 5.6.5: The PI must not implement the research before receiving the Certificate of Project Extension from TCVGH IRB. 9.新增 5.8.5 原計畫依新案送審時分類及處理流程。 9. Item 5.8.5 was added regarding the procedure of determining the review process based on the review category of the initial review of the protocol. 10.修改附件 6.9 表單名稱（原人體試驗研究計畫追蹤審查許可書），並修改 5.9 紀錄保存名稱。 10. The wording of the title of Appendix 6.9 was revised (the original title being "Certificate of Clinical Trial Project Extension"), and the title of the document in item 5.9 Records Retention was revised accordingly.	20150923

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D	8	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「追蹤審查意見表」改為「追蹤審查報告案件審查重點注意事項檢核表」，並修改 5.1、5.5.1。 2. The original “Reviewers’ Comments Form for Continuing Review” was replaced by “IRB Continuing Review Checklist, and Appendixes 5.1, 5.5.1 were revised. 3.修改 5.1 流程圖「送審文件確認」：新增審查費收據。 3. Item 5.1 Flow Chart “Confirmation of Submission Documents” was revised: “Review fee payment receipt” was added. 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. Item 5.4.2 was added regarding the procedure of selecting the Vice Chair to be a reviewer. 5.修正 5.6.5 審查意見通知計畫主持人回覆期限之說明。 5. Item 5.6.5 was revised regarding the time limit for the PI to respond to reviewers’ comments. 6.新增 5.7.2 大會投票結果為「不核准」之說明。 6. Item 5.7.2 was added regarding the full board voting result of “disapproval.” 7.修正 5.8.4 提出追蹤審查之期限及繳交結案報告規定。 7. Item 5.8.4 was revised regarding the time limit for submitting continuing review applications and guideline for submitting closing reports. 8.刪除原附件 6.3 PTMS 追蹤/持續審查申請書，加註說明。 8. The original Appendix 6.3 “PTMS Continuing Review Application Form” was deleted and a note was added.	20160318

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E	9	1.修改流程圖「決定審查方式及遴選審查委員」之權責為執行秘書(兼任委員時)。 1. The responsible personnel for "determination of review category and selection of reviewers" was revised in the Flow Chart: Executive Secretary (as Reviewer). 2.修改 5.2.1：增列 PTMS 申請案準備文件說明。 2. Item 5.2.1 was revised: Details about required documents for PTMS applications were added. 3.修改 5.2.3 通知計畫主持人方式：電子郵件改為由 PTMS 系統自動寄發電子郵件。 3. Item 5.2.3 was revised regarding the way of notifying the PI: "Via E-mail" was replaced by "Automatic E-mail notifications will be sent out from PTMS." 4.原 5.2.4.6 受試者同意書及受試者勾選項目頁面影本移至 5.2.4.8，並增列 PTMS 申請案及非 PTMS 申請案檢附文件說明。 4. The original item 5.2.4.6 was changed into 5.2.4.8 regarding photocopies of ICF pages containing checklists for the subjects to fill out. Details about required documents for PTMS and non-PTMS applications were added. 5.修改 5.4.1 圈選委員之權責：刪除（副）主任委員。 5. Responsible personnel for selecting reviewers was revised in item 5.4.1: "(Vice) Chair" was deleted. 6.修改 5.5.1：刪除「若有意見，得以另紙繕寫(打)審查意見」之字句。 6. The following sentence was deleted from item 5.5.1: Further review comments (if any) may be written on a separate piece of paper. 7.修正 5.5.3：原試驗案執行時間太長改為「試驗案執行期間」；原經審查委員要求改為「得」經審查委員要求。 7. Item 5.5.3 was revised: "The duration of the trial was too long" was replaced by "the duration of the trial;" the original "by request of the reviewer" was replaced by "may be requested by the reviewer."	20170709

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E	9	8.修改 5.5.4 依追蹤審查案件審查的類型區分為一般審查結果及簡易審查結果，新增 5.5.4.1.b-c 排入會期說明、及新增 5.5.5.1.a-c 簡易審查及排入會期說明。 8. Item 5.5.4 was revised: Continuing review may be conducted by full board review process or by expedited review process. Items 5.5.4.1 b-c were added regarding the details about placing the applications on the agenda for IRB meetings. Items 5.5.5.1 a-c were added regarding the expedited review process and details about placing the applications on the agenda for IRB meetings. 9.修改 5.6.1 審查意見轉交計畫主持人方式：新增電子檔。 9. The way of notifying the PI of the reviewers' comments was revised in item 5.6.1: "Electronic file" was added. 10.刪除原 5.6.2、5.6.2.1 審查結果「同意繼續進行，提大會進行核備」、5.6.3「須再補充說明」與 5.6.4「提大會討論」之內容。 10. The following phrases were deleted: "Project extension approved and sent to the full board for confirmation" from the original item 5.6.2 and item 5.6.2.1; "additional explanation required" from item 5.6.3; and "sent to the full board for discussion" from item 5.6.4. 11.新增 5.8.5.1 於開立人體研究/試驗計畫追蹤審查許可書時，若（副）主任委員擔任審查委員批示說明。 11. Item 5.8.5.1 was added regarding the issuance of the Certificate of Project Extension approved by the (Vice) Chair serving as a reviewer. 12.修改抽換附件 6.2、6.3、6.6、6.7、6.8、6.9、及新增 6.10「審查委員遴選表」並新增 5.9 紀錄保存文件。 12. Appendices 6.2, 6.3, 6.6, 6.7, 6.8, and 6.9 were replaced. Appendix 6.10 "Reviewers Selection Form" was added. Item 5.9 "Records Retention" was added.	20170709

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F	9	1.增加 5.3.1 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 5.3.1: 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 5.4.4 衛生福利部函文發文日期為「民國 103 年 07 月 28 日」。 2. The issue date of the letter from the Ministry of Health and Welfare “28 July 2014” was added in item 5.4.4. 3.新增 5.7.2 ~ 5.7.4 詳述會議投票結果之後續處理流程。另，原 5.7.2 順延調整為 5.7.5，並修改其內容描述。 3. Item 5.7.2 ~ item 5.7.4 were added detailing the follow-up procedures on the voting results. In addition, the original item 5.7.2 changed to item 5.7.5, and its contents modified accordingly. 4.新增 5.7.6：若投票結果為「其他」，承辦人員將大會決議通知計畫主持人，依大會附帶決議（如：計畫暫緩執行、實地訪查等）辦理。 4. Item 5.7.6 was added: If the voting result is “other,” then the staff member should notify the PI of the resolution. The follow-up procedure should comply with the resolution of the board meeting (e.g. Protocol suspension, or on-site monitoring visit). 5.抽換附件 6.1、6.8。 5. Appendices 6.1 and 6.8 were replaced.	20181026

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G	20	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. 增加 5.3.1 文句：受試者同意書第 1 頁受試者資訊。 2. Item 5.7.6 was added the Informed Consent Form Page1: subject information. 3. 修改附件 6.5 表單名稱。 3. The wording of the title of Appendix 6.5 was revised	20190527
H	21	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 5.2.4.9：計畫主持人、共同/協同主持人及研究人員之臨床試驗及醫學倫理相關訓練課程證明影本。 2. Added Item 5.2.4.9: Copies of training certificates on clinical trials and medical ethics received by PI, CO-I, Sub-I and research members. 3. 新增 5.3.3：若是所提供之訓練課程證明不符合規定，須待補齊文件後方進入審查程序。 3. Added Item 5.3.3: If the training certificates provided to the Investigators do not meet the official requirements, the proper documentation shall be collected before application to the IRB Committee for review is accepted.	20191018

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H	21	4. 修改原 5.3.3 之標號為 5.3.4。 4. The original item number 5.3.3 was changed to 5.3.4. 5. 抽換附件 6.1、6.2。 6. Appendices 6.1 and 6.2 were replaced.	20191018
I	20	1. 新增表單名稱:「PTMS 追蹤審查報告案件審查重點注意事項檢核表」。 1. Document title was added: “PTMS Continuing Review Checklist.” 2. 5.2.4.9 增加了利益衝突課程證明。 2. Added Item 5.2.4.9: Training certificates on Conflicts of Interest. 3. 新增 5.2.4.10：PTMS 系統之顯著利益線上申報表/顯著財務利益暨非財務關係申報說明及申報表。 3. Added Item 5.2.4.10: PTMS Statement of Significant Financial Interest/Statement of Significant Financial Interest and Other Relationships. 4. 修改 5.5.4.1 一般審查之審查結果。 4. Revised the review decision of Full Board Review in item 5.5.4.1. 5. 修改 5.5.5.1 簡易審查之審查結果。 5. Revised the review decision of Expedited Review in item 5.5.5.1.	20210528

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I	20	6. 修改 5.6.3、5.7.3、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。 6. Item 5.6.3, 5.7.3 and 5.7.4 were revised the PI's reply period to 28 calendar days, and deleted the description of the extension. 7. 抽換附件 6.2、6.4、6.7、6.9、6.10。 7. Appendices 6.2, 6.4, 6.7, 6.9 and 6.10 were replaced.	20210528

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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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.	

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

1. Purpose

本管理程序書在規範第一/二人體研究倫理審查委員會對於通過審查之計畫案於進行期間之追蹤審查作業。

追蹤審查的目的，是在監督計畫案的執行過程是否符合原審查通過之計畫內容，以確保受試者的權利和福祉。

The purpose of this SOP is to manage IRB continuing review of approved protocols. The purpose of continuing review is to monitor the implementation of the research to ensure that the procedure complies with the protocol approved by the IRB and to ensure the rights and welfare of the research subjects.

2.適用範圍

2. Scope

2.1 追蹤審查適用於所有委員會發給執行許可且仍在執行效期內之計畫案，追蹤審查之頻率，視計畫之風險與受試者可能面臨之危險程度而定，由初審的二位主審委員建議後，經大會討論決議，但每年不可少於一次。

2.1 The scope of continuing review applies to all IRB approved protocols within the validity period specified on the Certificate of Approval. The continuing review frequency is decided based on the level of risk that the study presents to the subjects. The two initial reviewers should propose the continuing review frequency to the full board for discussion and resolution. Continuing review frequency should be at least once per year.

2.2 計畫主持人需依規定於期限內提出追蹤報告送本院第一/二人體研究倫理審查委員會審查。

2.2 The PI should submit the continuing review report to TCVGH IRB before the due date.

3.參考文件

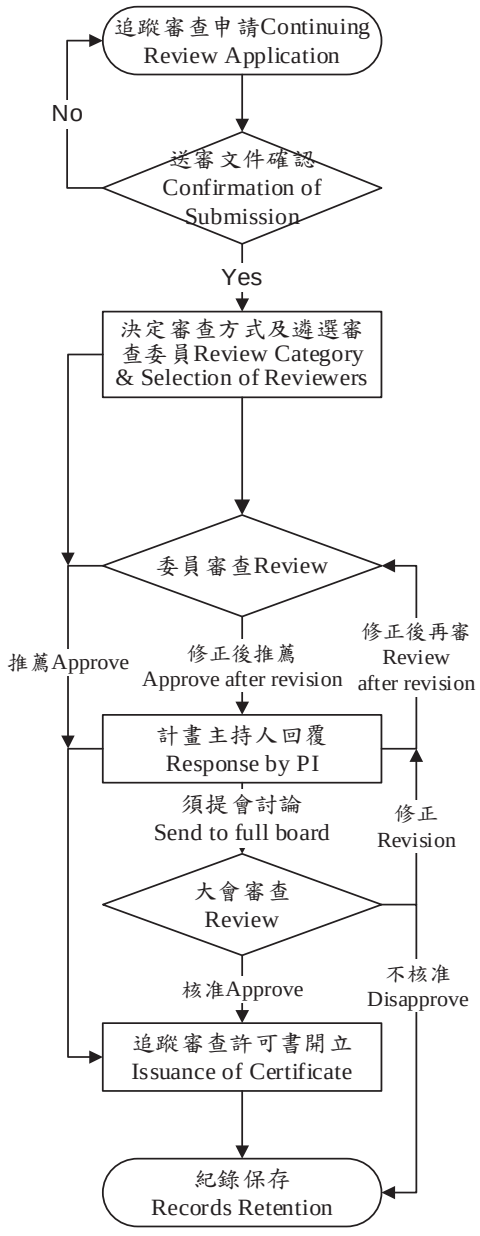
無。

3. References
None.

4.名詞定義
無。

4. Definitions
None.

5.作業內容
5. Procedure
5.1 追蹤審查管理流程圖
5.1 Flow Chart of Continuing 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 執行秘書/（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/執行秘書/（副）主任委員 Staff/Executive Secretary/(Vice) Chair 承辦人員 Staff Members	送審文件/研究計畫追蹤審查通知書/追蹤審查報告相關表單 Submission documents/Notification of continuing review/Forms relevant to continuing review report 送審文件/審查費收據/案件流程表 Submission documents/Review fee payment receipt/Protocol Review Routing Form 送審文件/追蹤審查案/審查委員遴選表 Submission Documents/Continuing review applications/ Reviewers Selection Form PTMS追蹤審查報告案件審查重點注意事項檢核表 PTMS Continuing Review Checklist 第一/二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/試驗計畫追蹤審查許可書 Official Correspondence/ Certificate of Project Extension

5.2 追蹤審查報告申請

5.2 Continuing Review Application

5.2.1 計畫主持人準備追蹤審查文件（舊案須準備正本 1 份及影印本 1 份，共 2 份）。

5.2.1 The PI should submit the continuing review application documents. (If the protocol was previously approved, submit one original copy and one photocopy.)

5.2.2 計畫主持人有責任依原審查要求的追蹤審查期間主動繳交追蹤審查報告（一年一次、六個月一次、三個月一次或其他）或於執行許可書到期前二個月將所須資料送至委員會，以進行追蹤審查或執行效期之展延作業。

5.2.2 It is the responsibility of the PI to voluntarily submit a continuing review report to the IRB according to the required frequency determined in the initial IRB review (once per year, once every six months, once every three months, or other) or two months before the Certificate of Approval expires, in order for the continuing review to be conducted or for the research to be extended.

5.2.3 承辦人員於原審查委員要求的追蹤審查期間，或執行「許可書」到期日前二個月通知計畫主持人（PTMS 系統將自動寄發電子郵件），請計畫主持人依計畫執行進度，決定送審所須文件。

5.2.3 The staff member should notify the PI to submit required documents for continuing review according to the continuing review frequency required by the initial reviewers or two months before the Certificate of Approval expires. (An automatic email notice is sent out from the PTMS.)

5.2.3.1 若計畫可於執行許可書到期日前完成，則計畫主持人可於計畫完成後三個月內直接繳交「結案報告表」與相關文件資料。

5.2.3.1 If the research will be completed before the Certificate

of Approval expires, then the PI may submit a closing report and relevant documents within three months after the research is completed without submitting a continuing review report.

5.2.3.2 若計畫無法於執行許可書到期日前完成，則計畫主持人須於收到本會通知後 14 個工作天內繳交追蹤審查報告表與相關文件資料。經審查通過後，依原審查委員要求的追蹤審查頻率（一年一次、六個月一次、三個月一次或其他）延長研究計畫效期。

5.2.3.2 If the research is not able to be completed before the Certificate of Approval expires, then the PI should submit a continuing review report and relevant documents within 14 work days after receiving a notice from TCVGH IRB. Once the continuing review report is approved by IRB review, the research project may be extended according to the continuing review frequency determined by the initial reviewers (once a year, once every six months, once every three months, or other).

5.2.4 確定無法於執行許可書到期日前完成計畫之計畫主持人，應辦理展延執行許可期限之申請手續，填妥追蹤審查報告表，送委員會承辦人員，並備妥所須附件資料如下：

5.2.4 If the research will not be completed before the Certificate of Approval expires, the PI should apply for project extension by filling out the continuing review report form and submitting it along with the following documents to the IRB staff:

5.2.4.1 追蹤審查報告核對表

5.2.4.1 Continuing Review Report Checklist

5.2.4.2 追蹤審查報告表/ PTMS 追蹤/持續審查申請書（申請人需簽章）。

5.2.4.2 Continuing Review Report Form/PTMS Continuing Review Application Form (signed by PI)

5.2.4.3 本會執行許可書影本。

5.2.4.3 Photocopy of the Certificate of Approval issued by TCVGH IRB.

5.2.4.4 本會修正案許可書影本。

5.2.4.4 Photocopy of the Certificate of Protocol Amendment issued by TCVGH IRB.

5.2.4.5 受試者清單與收案狀況描述表。

5.2.4.5 List of Subjects and Description of Enrollment.

5.2.4.6 嚴重不良事件通報紀錄表(僅通報 SUSAR)。

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

5.2.4.7 其他（若計畫案為免除受試者同意書的臨床資料收集案件，但一年內並沒有做完，提出追蹤審查申請，須另提供資料收集進度說明）。

5.2.4.7 Other (If the research involves collecting clinical data and qualifies for the waiver of informed consent, but is not completed within a year, then the PI should submit a continuing review application and a statement describing the progress of data collection.)

5.2.4.8「受試者同意書」簽名頁及受試者勾選頁影本（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）。

5.2.4.8 Photocopies of the ICF pages with the subjects' signatures and checklists filled out by the subjects (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 should be included in a separate binder. The binder will be returned to the PI after the review is completed).

5.2.4.9 計畫主持人、共同/協同主持人及研究人員之臨床試驗及醫學倫理及利益衝突等相關訓練課程證明影本。

5.2.4.9 Copies of training certificates on clinical trials, medical ethics and Conflicts of Interest received by PI, CO-I, Sub-I and research members.

5.2.4.10 PTMS系統之顯著利益線上申報表/顯著財務利益暨非財務關係申報說明及申報表。

5.2.4.10 PTMS Statement of Significant Financial Interest/Statement of Significant Financial Interest and Other Relationships.

5.2.5 追蹤審查報告性質若為有委託者計畫，每次申請需繳交追蹤審查報告審查費，未繳費者不受理申請文件。

5.2.5 If the protocol is a contracted study, then the review fee must be paid for each application of continuing review. Applications will not be accepted or processed until the payment is made.

5.3 送審文件確認

5.3 Confirmation of Submission

5.3.1 審查時為須受試者簽署同意書之試驗，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。】

5.3.1 If the initial IRB review determined that ICF is required for the research, then the application should include a complete photocopy of each new version of the 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.】

5.3.2 承辦人員核對送審文件，除追蹤審查報告表外，應有受試者清單。若試驗期間曾發生嚴重不良事件，應附通報紀錄。

5.3.2 When checking the submission documents, the staff member should make sure that a list of subjects has been submitted along with the continuing review report form. If serious adverse events happened during the study, a record of relevant reports should also be submitted.

5.3.3 若是所提供之訓練課程證明不符合規定，須待補齊文件後方進入審查程序。

5.3.3 If the training certificates provided to the Investigators do

not meet the official requirements, the proper documentation shall be collected before application to the IRB Committee for review is accepted.

5.3.4 資料齊全後，承辦人員受理申請辦理及編號。若是第一次計畫追蹤審查報告案，則在原本會 IRB 編號後加上「-1」，第二次計畫則為「-2」，以此類推。

5.3.4 After compiling the submission documents, the staff member should give the application a number and process the application. The number given to the first continuing review report application should be “-1” followed by the original IRB number. The number given to the second continuing review report application should be “-2” followed by the original IRB number. The same rule goes with the third and the fourth, etc.

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 承辦人員將完整之送審文件送執行秘書，圈選一或兩名委員審查，委員之選擇以該計畫原來負責初審之委員為優先。如遇特殊狀況得重新圈選委員審查。

5.4.1 The staff member should submit the application documents to the Executive Secretary. The Executive Secretary should then assign one or two reviewers, preferably the original reviewers of the protocol. Under special circumstances, new reviewers may be assigned.

5.4.2 副主任委員擔任審查委員時，其案件應由主任委員批示，反之，亦同。若因故無法遴選，則授權執行秘書進行批示。

5.4.2 If the Vice Chair serves as a reviewer, the selection of reviewers should be approved by the Chair, and vice versa. If the (Vice) Chair is unable to sign the approval, then the Executive Secretary will be authorized to approve the selection of reviewers.

5.4.3 計畫主持人於試驗期間因經費或材料或其他因素導致未開始收案，且無任何受試者需要評估安全性，其追蹤審查申請可

由執行秘書或（副）主任委員同意後，得依行政程序先給予核發「人體研究/試驗計畫追蹤審查許可書」及公文，並於大會追認後核備。

5.4.3 In the case that the PI has not recruited subjects due to lack of funding, materials, or other reasons, and no subjects have enrolled that would require any assessment of safety, the continuing review application may be approved by the Executive Secretary or (Vice) Chair and the Certificate of Project Extension and an official letter may be issued complied with the administrative procedure. The application and approval will then be confirmed later in an IRB board meeting.

5.4.4「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。

5.4.4 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, protocol closure, etc.) should be sent to the full board for review as well (in compliance with the letter 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 should be conducted by the expedited review process.

5.5 委員審查

5.5 Review

5.5.1 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 reviewer should conduct the review according to the basic ethics principles of clinical trials and ensure that the

implementation of the trial complies with required procedures and protects the rights of the research subjects.

5.5.2 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）主任委員召開緊急會議；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。

5.5.2 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.

5.5.3 試驗案執行期間，若因國內法規修正而影響受試者權益，得經審查委員要求請計畫主持人提出計畫修正案。

5.5.3 During the trial period, if the subjects' rights are affected due to any modification of national regulations, then the reviewer may require the PI to submit a protocol amendment application.

5.5.4 依計畫案之審查類型區分為一般審查結果及簡易審查結果。

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

5.5.4.1 一般審查

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。

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陳送入會批示單予執行秘書、（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。

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。

5.5.4.1 Full Board Review

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

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 application should be placed on the agenda for the next scheduled board meeting for confirmation.

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 application on the agenda for the next scheduled IRB board meeting for discussion.

5.5.5.1 簡易審查

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。

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。

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陳送執行秘書、(副)主任委員審核後核發許可書並提至大會追認。

5.5.5.1 Expedited Review

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. 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 application on the agenda for the next scheduled IRB board meeting for discussion.

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 the application is approved, a Certificate of Project Extension should be issued, and the approval should be sent to the IRB 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送交計畫主持人，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陳送執行秘書、(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 calendar days, the protocol should be withdrawn from IRB consideration.

5.7 大會審查

5.7 IRB Board Meeting

5.7.1 委員審查期間，如懷疑知情同意過程未落實，或認為可能因安全性疑慮影響受試者，可建議提案至大會討論，由大會決議。

5.7.1 During the review process, if the reviewer has concerns about the execution of informed consent or about the safety of the subjects, the reviewer may make a motion to the IRB board meeting for discussion and resolution.

5.7.2 會議投票結果為「核准」案件，由承辦人員陳送（副）主任委員/執行秘書核可後，開立「人體研究/試驗計畫追蹤審查許可書」。

5.7.2 If the IRB full board voting result is "approval," then the staff member should issue the Certificate of Project Extension with the approval of the (Vice) Chair/Executive

Secretary.

5.7.3 投票結果若為「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。

5.7.3 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 calendar days, the protocol should be withdrawn from IRB consideration.

5.7.4 投票結果若為「修正後複審」，計畫主持人應於限期【儘量於 7 個日曆天內回覆，最遲不能超過28個日曆天，若超過28個日曆天則逕行撤案】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，若有其他需求，依大會之決議辦理。

5.7.4 If the voting result is “further review after revision,” the PI should respond to the reviewers’ comments before the due date. (The PI should try to respond within 7 calendar days and no later than 28 calendar days. If the PI does not respond within 28 calendar days, the protocol should be withdrawn from IRB consideration.) The staff member should compile relevant documents and place the request on the agenda for the next IRB board meeting for discussion. Any other outstanding requests should be handled according to the resolutions made in the board meeting.

5.7.5 若是投票結果為「不核准」，承辦人員將大會決議通知計畫主持人，計畫主持人不得繼續進行本研究，計畫必須終止或結案。

5.7.5 If the voting result is “disapproval,” the staff member should notify the PI of the resolution. The PI may not proceed with the research. The research must be terminated or closed.

5.7.6 若投票結果為「其他」，承辦人員將大會決議通知計畫主持

人，依大會附帶決議（如：計畫暫緩執行、實地訪查等）辦理。

5.7.6 If the voting result is “other,” then the staff member should notify the PI of the resolution. The follow-up procedure should comply with the resolution of the board meeting (e.g. Protocol suspension, or on-site monitoring visit).

5.8 人體研究/試驗計畫追蹤審查許可書開立

5.8 Issuance of the Certificate of Project Extension

5.8.1 經委員審查同意/大會核備之追蹤審查案，陳送（副）主任委員覆核同意後，即開立「人體研究/試驗計畫追蹤審查許可書」。

5.8.1 If a continuing review report application is approved by the reviewers and confirmed by the IRB board meeting, then a Certificate of Project Extension will be issued with the approval of the (Vice) Chair.

5.8.2 由承辦人員開立「人體研究/試驗計畫追蹤審查許可書」，呈主任委員簽章後，以公文方式發予計畫主持人保存。

5.8.2 The staff member should issue the Certificate of Project Extension and submit it to the Chair for approval stamp/signature. Then the Certificate of Project Extension should be sent to the PI via official correspondence.

5.8.3 請計畫主持人依據規定在計畫到期前提出追蹤審查申請，即使在失效最後一天申請，只是因為審查時間，而有空窗期的產生，秘書處仍受理處理，並於審查同意後，以銜接之前同意函核准的日期開立「人體研究/試驗計畫追蹤審查許可書」，不會造成有中斷執行效期產生。

5.8.3 The PI should submit a continuing review application according to the IRB requirements. Even if the PI submits the application on the last effective date of the Certificate of Approval, the IRB Secretariat should still accept and process the application. If the Certificate of Approval

expires during the review process, once the continuing review application is approved, the start date of the Certificate of Project Extension should be expiry date of the Certificate of Approval for the continuation of the research project.

5.8.4 計畫主持人應於許可書到期前提出追蹤審查申請，若未提出申請者應於許可書到期後三個月內繳交「結案報告」，若許可書有效期限過期六個月後，仍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。

5.8.4 The PI should submit a continuing review application before the Certificate of Approval expires. If the PI does not submit the application, then a closing report should be submitted within three months after the expiry date of the Certificate of Approval. If the PI does not submit a closing report within six months after the expiry date, then any new protocol submission application from the PI will not be accepted by the IRB until a closing report is submitted.

5.8.5 若原計畫於新案送審時為『一般審查』，則承辦人員彙整資料並排入最近一次大會議程，會後再開立「人體研究/試驗計畫追蹤審查許可書」；若原計畫於新案送審時為『簡易審查』，則可先開立「人體研究/試驗計畫追蹤審查許可書」後於大會進行追認後核備。

5.8.5 If the protocol was initially approved by full board review, then the staff member should compile relevant documents and place the application on the agenda for the next scheduled IRB board meeting. After the application is approved by the full board, the Certificate of Project Extension should be issued. If the protocol was initially approved by expedited review process, then the Certificate of Project Extension may be issued first and confirmed in an IRB board meeting later.

5.8.5.1 開立「人體研究/試驗計畫追蹤審查許可書」時，若副主任委員擔任審查委員時，其案件應由主任委員批示，反

之，亦同。

5.8.5.1 If the Vice Chair serves as a reviewer, the Certificate of Project Extension should be signed by the Chair, and vice versa.

5.9 紀錄保存

5.9 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 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	研究計畫追蹤審查通知書 Notification of Continuing Review	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
2	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 At least 3 years after the trial is closed
3	追蹤審查報告表/ PTMS 追蹤/持續審查申請書 Continuing Review Report Form/PTMS Continuing Review Application Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
4	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
5	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

編號 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
6	第一/二人體研究倫理審查委員會追蹤審查報告案件審查重點注意事項檢核表/PTMS追蹤審查報告案件審查重點注意事項檢核表 IRB Continuing Review Checklist /PTMS Continuing Review Checklist	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
7	第一/二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
8	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
9	人體研究/試驗計畫追蹤審查許可書 Certificate of Project Extension	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
10	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

6. Appendices

「PTMS追蹤/持續審查申請書」、「PTMS追蹤審查報告案件審查重點注意事項檢核表」、「公文」為線上系統輸入，無版本誤用之虞，故不列入附件管理。

"PTMS Continuing Review Application Form", "PTMS Continuing Review Checklist" and "Official Correspondence" are generated from the online system, preventing the usage of the wrong version; therefore, these three items are not listed in the appendices.

6.1 研究計畫追蹤審查通知書

6.1 Notification of Continuing Review

6.2 追蹤審查報告核對表
6.2 Continuing Review Report Checklist
6.3 追蹤審查報告表
6.3 Continuing Review Report Form
6.4 受試者清單與收案狀況描述表
6.4 List of Subjects and Description of Enrollment
6.5 嚴重不良事件通報紀錄表(僅通報 SUSAR)
6.5 Serious Adverse Event Report Form (only SUSAR is reported)
6.6 第一/二人體研究倫理審查委員會追蹤審查報告案件審查重點注意事項檢核表
6.6 IRB Continuing Review Checklist
6.7 第一/二人體研究倫理審查委員會審查意見回覆表
6.7 Form of Response to IRB Reviewers' Comments
6.8 案件流程表
6.8 Protocol Review Routing Form
6.9 人體研究/試驗計畫追蹤審查許可書
6.9 Certificate of Project Extension
6.10 審查委員遴選表
6.10 Reviewers Selection Form