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-2021 IRB-Regulations of Operation-2021	文件名稱 Title	人體研究/試驗計畫暫停或終止管理程序書 SOP for Protocol Suspension or Termination
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	5	新訂。Newly composed.	20140519
B	5	由人體試驗委員會標準作業程序 5.4 版轉換成此版本。 This version was converted from “Version 5.4 of the SOP of the Human Research Committee.”	20150119
C	5	1. 修改 5.2.3 計畫主持人應提供資料及內文敘述。 1. Item 5.2.3 was revised regarding required documents from the PI and description of the documents. 2. 修改 5.3.1 送審文件必備文件類別。 2. Categories of required documents for submission were revised in item 5.3.1. 3. 新增 5.3.2 受理申請之內文。 3. Item 5.3.2 was revised regarding the acceptance of submission. 4. 修改 5.4 標題，並修改 5.1 流程圖步驟、相關文件。 4. The title of item 5.4 was revised; the process and the list of relevant documents were revised in item 5.1 Flow Chart. 5. 新增 5.4.3 新案審查及監督之內文。 5. Item 5.4.3 was added regarding review and monitoring of new submissions. 6. 新增附件 6.5 案件流程表。 6. Appendix 6.5 Protocol Review Routing Form was added.	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. 修正 5.1 流程圖並新增 5.8 申請「計畫暫停」之人體研究/試驗計畫重新開始執行之處理流程。 2. Item 5.1 Flow Chart was revised; item 5.8 was added regarding the procedure for processing requests to re-open suspended protocols.	20160318

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D	6	3.修正 5.1 流程圖並新增 5.8 申請「計畫暫停」之人體研究/試驗計畫重新開始執行之處理流程。 3. Item 5.1 Flow Chart was revised; item 5.8 was added regarding the procedure for processing requests to re-open suspended protocols. 4.原 6.3「計畫暫停/終止審查意見表」改為「案件審查重點注意事項檢核表」，同步修正內文及紀錄保存規定。 4. The original item 6.3 “Protocol Suspension/Termination Review Comments Form” was replaced by “IRB Review Checklist”; regulations regarding records retention were revised accordingly. 5.文字校正。 5. Typos were fixed. 6.修改 5.6.2 審查結果為「同意暫停/終止，提大會進行追認/核備後存查」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 protocol suspension/termination; send to the full board for confirmation.” 7.修改 5.6.3 審查結果為「請主持人回覆」者之處理流程。 7. Item 5.6.3 was revised regarding the follow-up procedure of the review decision of “request the PI to respond.” 8.修改 5.6.4 審查結果為「提大會討論」者之處理流程。 8. Item 5.6.4 was revised regarding the follow-up procedure of the review decision of “send to the full board for discussion.” 9.新增 5.6.5。 9. Item 5.6.5 was added.	20160318

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E	6	1. 修改參考文件 3.1「藥品優良臨床試驗準則」之版本。 1. The version of reference 3.1 “Regulations for Good Clinical Practice” was updated. 2. 修正 5.1 流程圖「決定審查方式及遴選審查委員」權責為執行秘書(兼任委員時)。 2. The responsible personnel for “determination of review category and selection of reviewers” was revised in item 5.1 Flow Chart: Executive Secretary (as Reviewer). 3. 修正 5.2.3.4 計畫主持人應提供受試者同意書及受試者勾選項目之規定：新增電子檔。 3. Item 5.2.3.4 was revised regarding the requirement of submitting pages with checklists for the subjects to fill in on the ICF: “Electronic files” was added. 4. 修正 5.4.1 原審查委員無法審查時，審查委員指派方式。 4. Item 5.4.1 was revised regarding assigning other reviewers when the original reviewers are not available. 5. 新增 5.5.3 計畫案之審查類型區分為一般審查及簡易審查及 5.5.3.1.a-c、5.5.3.2.a-c 之審查及排入會期說明。 5. Item 5.5.3 was added regarding the review categories of full board review and expedited review; explanation was added in items 5.5.3.1.a-c and 5.5.3.2.a-c regarding review and placing a protocol on the agenda for the IRB board meeting.	20170709

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E	6	6. 刪除原 5.6.2、5.6.2.1 審查結果為「同意暫停/終止，提大會進行追認/核備後存查」者，無須回覆、原 5.6.3「請主持人回覆」、原 5.6.4「提大會討論」之說明。 6. The following original items were deleted: Items 5.6.2 and 5.6.2.1 - The PI does not need to respond if the review result is “protocol suspension/termination approved; send to the full board for confirmation/recordation”; item 5.6.3 - The PI should be requested to respond; item 5.6.4 - explanation regarding the review result of “send to the full board for discussion.” 7. 修改 5.6.1 轉交計畫主持人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 6.1-6.5。 8. Appendices 6.1 to 6.5 were replaced.	20170709

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F	15	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 5.2.3.4 文句：受試者同意書第 1 頁受試者資訊。 2. In Item 5.2.3.4 “the Informed Consent Form Page1: subject’s information” was added. 3. 增加 5.2.3.4 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。】 3. 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.	20190527

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F	15	4. 修改 5.2.3.5 表單名稱。 4. The wording of the title of item 5.2.3.5 was revised. 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. 修改 5.5.3.2 第 c 點其委員的審查結果若為「同意暫停/終止，提大會進行追認/核備後存查」且不需計畫主持人回覆之計畫，則承辦人員直接提至大會追認。 6. Item 5.5.3.2-c was revised regarding the follow-up procedure of the review decision of “protocol suspension/termination; send to the full board for confirmation/recordation” without the requirement of the PI to respond. The staff member should directly send the protocol suspension/termination to the IRB board meeting for confirmation. 7. 新增 5.7.1：經討論後，若無任何委員有異議，則予以核備。 7. Item 5.7.1 was added: Protocol suspension/termination is approved when all members come to a consensus to approve it after discussion. 8. 新增 5.7.2：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。 8. Item 5.7.2 was added: 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. After the PI has responded, the staff member should send the response to the (Vice) Chair/Executive Secretary for approval.	20190527

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F	15	9. 新增 5.7.3：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。若是同意受理，承辦人員再陳送（副）主任委員/執行秘書核可。 9. Item 5.7.3 was added: 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 14 days, the protocol should be withdrawn from IRB consideration. Before the due date, the PI may request for extension of up to 14 calendar days with an acceptable excuse. The PI may not request for extension more than one time. 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. If the case is approved to be processed, the staff member should submit the case to the (Vice) Chair/Executive Secretary for approval. 10. 新增 5.7.4：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。 10. Item 5.7.4 was added: 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).	20190527
F	15	11. 抽換附件 6.1、6.2、6.5。 11. Appendices 6.1, 6.2, and 6.5 were replaced.	20190527

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G	15	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. 抽換附件 6.1 2. Appendix 6.1 was replaced.	20191018
H	14	1. 修改參考文件 3.1 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 3.1 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. 新增表單名稱：「PTMS 暫停/終止報告審查意見表」。 2. Document title was added: "PTMS Review Checklist for Protocol Suspension or Termination." 3. 修改 5.1「人體研究/試驗計畫暫停或終止管理流程圖」之相關文件敘述。 3. Revised the contents for "Relevant Documents" in item 5.1 "Flow Chart of Protocol Suspension or Termination." 4. 修改 5.3.1 文件名稱。 4. The wording of the title of item 5.3.1 was revised. 5. 修改 5.5.3.1 一般審查之審查結果。 5. Revised the review decision of Full Board Review in item 5.5.3.1. 6. 修改 5.5.3.2 簡易審查之審查結果。 6. Revised the review decision of Expedited Review in item 5.5.3.2. 7. 修改 5.6.3 及 5.7.3 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。 7. Item 5.6.3 and 5.7.3 were revised the PI's reply period to 28 calendar days, and deleted the description of the extension.	20210528

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H	14	8. 修改原 5.8.2.標號為 5.8.3。 8. Changed the original item number 5.8.2. to 5.8.3. 9. 修改原 5.8.3.標號為 5.8.2。 9. Changed the original item number 5.8.3. to 5.8.2. 10. 修正 5.8.2 為「承辦人員將文件陳送執行祕書、(副)主任委員批核，而後排入最近一次大會進行討論/核備。」 10. Revised item 5.8.2 to be “The staff member should submit the documents to the Executive Secretary and (Vice) Chair for confirmation, and should be scheduled in the earliest session of IRB board meeting for discussion/confirmation.” 11. 增加附件 6 說明內容：【「PTMS 暫停/終止報告審查意見表」、「公文」為線上系統輸入，無版本誤用之虞，故不列入附件管理。】 11. The following was added to Appendices 6: “PTMS Review Checklist for Protocol Suspension/Termination” 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. 12. 抽換附件 6.1、6.2、6.4。 12. Appendices 6.1, 6.2 and 6.4 were replaced.	20210528
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I	14	1. 更改文件名稱。 1. The title of the document was revised. 2. 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」。 2. The original “The First/Second IRB Committees” was renamed “The IRB Committees”. 3. 新增參考文件 3.2。 3. Items 3.2 was added in References. 4. 刪除原 5.2.3.2 內容。 4. Deleted item 5.2.2.3. 5. 修改 5.3.1 項內容。 5. Revised item 5.3.1. 6. 依據 AAHRPP 國際認證之建議新增 5.5.4。 6. According to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) was added Items 5.5.4. 7. 抽換附件 6.1、6.3、6.4、6.5。 7. Appendices 6.1, 6.3, 6.4 and 6.5 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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※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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臺中榮民總醫院
Taichung Veterans General Hospital

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

文件編號 Document Number	IRB-本會-工作常規-2021 IRB -Regulations of Operation-2021	文件名稱 Title	人體研究/試驗計畫暫停或終止管理程序書 SOP for Protocol Suspension or Termination

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

本管理程序書主要說明承辦人員處理計畫暫停/終止時的行政流程。

1. Purpose

The purpose of this SOP is to describe the administrative procedure for the IRB staff to process protocol suspension / termination.

2.適用範圍

本管理程序書適用所有在完成期限前即被要求暫停或終止的計畫案。

2. Scope

This SOP applies to all protocols which are requested to be suspended or terminated before the study has been completed.

3.參考文件

3. References

3.1「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。

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

3.2「醫療器材優良臨床試驗管理辦法」110 年 04 月 09 日衛生福利部衛授食字第 1101601721 號令訂定公告。

3.2 “Regulations on Good Clinical Practice for Medical Devices” promulgated on 09 April 2021 by the Ministry of Health and Welfare, pursuant to Wei-Shou-Shi-Zi No. 1101601721.

4.名詞定義

4. Definitions

4.1 計畫暫停（Suspension）：在人體研究倫理審查委員會執行許可書有效期限內暫時停止執行計畫。

4.1 Protocol Suspension: Temporary cessation of research activities within the IRB approval period of the protocol.

4.2 計畫終止（Termination）：當計畫的安全性或效益有疑慮或有風險增加時，主管機關、人體研究倫理審查委員會、資料與安全監測委員會提出要求、或試驗委託者、計畫主持人於計畫完成前決定停止執行。

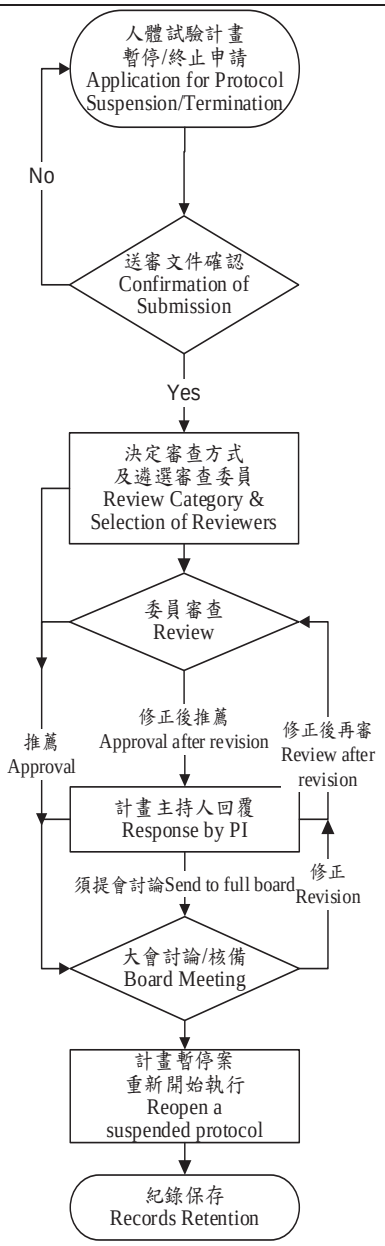
4.2 Protocol Termination: When there is a concern about the safety or effectiveness of a trial or when there is an increased risk presented to the subjects, permanent cessation of all research activities may be requested or initiated by the competent authority, the IRB, the Data and Safety Monitoring Board (DSMB), the sponsor of the trial, or the PI, before the completion of the study.

5.作業內容

5. Procedure

5.1 人體研究/試驗計畫暫停或終止管理流程圖

5.1 Flow Chart of Protocol Suspension or Termination

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	主管機關/人體研究倫理審查委員會/試驗相關人員 The competent authority/IRB/ Research personnel 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 IRB Members 廠商/承辦人員 Company/Staff Members 承辦人員 Staff Members	計畫暫停/終止報告表相關表單 Relevant forms for Protocol Suspension or Termination Report 送審文件/案件流程表 Submitted Documents/ Protocol Review Routing Form 送審文件/審查委員遴選表 Submitted Documents/ Reviewers Selection Form PTMS 暫停/終止報告審查意見表 PTMS Review Checklist for Protocol Suspension or Termination 審查意見回覆表 Form of Response to Reviewers' Comments 會議紀錄 Meeting Minutes 公文/人體研究/試驗計畫 Official Correspondence/Clinical Study Protocol

5.2 人體研究/試驗計畫暫停/終止申請

5.2 Application for Protocol Suspension or Termination

5.2.1 資料與安全監測委員會、計畫主持人、試驗委託者以 PTMS 系統提出計畫暫停/終止之申請【新案非為 PTMS 申請案者，以書面提出申請】。

5.2.1 Protocol suspension or termination may be requested on PTMS by DSMB (the Data and Safety Monitoring Board), the PI, or the sponsor of the trial. (If the protocol was previously approved, submit one original copy.)

5.2.2 主管機關或人體研究倫理審查委員會大會提出計畫暫停/終止的建議。

5.2.2 Protocol suspension or termination may be recommended by the competent authority or the IRB full board.

5.2.2.1 承辦人員通知計畫主持人提出計畫暫停/終止的相關文件。

5.2.2.1 The staff member should notify the PI to submit document related to protocol suspension/termination.

5.2.3 計畫主持人應提供資料包括：

5.2.3 The PI is required to submit the following documents:

5.2.3.1 計畫暫停/終止報告表。

5.2.3.1 Protocol Suspension/Termination Report Form.

5.2.3.2 受試者清單與收案狀況描述表。

5.2.3.2 List of Subjects and Description of Subject Enrollment.

5.2.3.3「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。】

5.2.3.3 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.

5.2.3.4 嚴重不良事件通報紀錄表(僅通報 SUSAR)。

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

5.2.3.5 其他。

5.2.3.5 Others

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「計畫暫停/終止報告表」外，應檢附必備文件【受試者清單與收案狀況描述表、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 "Protocol Suspension/Termination Report Form," other required documents need to be included 【List of Subjects and Description of Subject Enrollment, and Serious Adverse Event Report Form (only SUSAR is reported)】.

5.3.2 非 PTMS 申請案，資料齊全後，承辦人員於文件中放入「案件流程表」，並受理申請辦理。若為 PTMS 申請案，資料齊全後，承辦人員於 PTMS 系統受理申請及辦理。

5.3.2 For non-PTMS applications, the staff member should place the Protocol Review Routing Form with the documents and process the application. If the suspension or termination is submitted on PTMS, the staff member should accept the application and process it on PTMS.

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 對於本院未納入任何受試者之計畫，得經執行祕書、(副)主任委員審閱同意後提大會追認後核備。

5.4.2 If the protocol has not enrolled any subject within TCVGH, the protocol suspension/termination may be approved by the Executive Secretary or (Vice) Chair and confirmed in a convened 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 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。若有意見，得於「PTMS 暫停/終止報告審查意見表」繕寫(打)審查意見。

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. Further review comments (if any) may be written on “PTMS Review Checklist for Protocol Suspension /Termination”.

5.5.2 可於必要時召開臨時會議討論此一「計畫暫停/終止建議案」，並依臨時會議之決議處理。

5.5.2 An extraordinary IRB board meeting may be called to discuss a recommendation for protocol suspension/termination. Follow-up actions should be taken according to the resolution of the extraordinary meeting.

5.5.3 計畫案之審查類型區分為一般審查及簡易審查。

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

5.5.3.1 一般審查

5.5.3.1 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 suspension/termination 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」但需計畫主持人回覆之計畫，則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 review decision is “approved to be placed on the agenda for the next scheduled meeting for confirmation,” then the protocol suspension/termination should be placed on the agenda for the next scheduled 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 “send 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 suspension/termination on the agenda for the next scheduled IRB meeting for discussion.

5.5.3.2 簡易審查

5.5.3.2 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 further 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 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，則承辦人員直接提至大會追認。

c. If the review decision is “recommended for approval” and no response from the PI is required, then the staff member should directly submit the protocol suspension/termination to the IRB board meeting for confirmation.

5.5.4 當計畫被要求暫停或終止時，委員會必須考慮以下措施：

5.5.4 When the study is requested to suspend or terminate, IRB shall consider the following measures:

5.5.4.1 對目前參與之受試者採取保護措施，以維護其權利與福祉(例如在獨立監測下繼續執行試驗等)

5.5.4.1 Exercising protective measures to current subjects to ensure their rights and welfare (for example, continue study under independent monitoring).

5.5.4.2 是否對退出之受試者安排醫療處置以維護其權利與福祉(例如安排適當之醫療照護、轉介給其他研究者等)。

5.5.4.2 Whether or not to arrange medical management for withdrawn subjects to ensure their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another investigator, and

continuation in the research under independent monitoring).

5.5.4.3 通知目前參與試驗之受試者此暫停或終止試驗之決定。

5.5.4.3 Inform current subjects of the study of the decision of study suspension or termination.

5.5.4.4 有任何不良事件或結果要通報本會。

5.5.4.4 Any adverse events or outcome shall be reported to IRB.

5.6 計畫主持人回覆

5.6 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陳送執行祕書、(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 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 大會討論/核備

5.7 IRB Board Meeting Discussion/Confirmation

5.7.1 經討論後，若無任何委員有異議，則予以核備。

5.7.1 Protocol suspension or termination is approved and recorded when all members come to a consensus to approve it after discussion.

5.7.2 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。

5.7.2 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. The PI’s response to comments should be submitted by the staff member to the (Vice) Chair/Executive Secretary for approval.

5.7.3 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。

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 days, the protocol should be withdrawn from IRB consideration.

5.7.4 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。

5.7.4 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 申請「計畫暫停」之人體研究/試驗計畫重新開始執行

5.8 Request to Reopen a Suspended Protocol

5.8.1 廠商以「公文」之方式，通知本會該「人體研究/試驗計畫」將重新開始執行。

5.8.1 The company that sponsors the trial may request to reopen a suspended protocol by sending an official request letter to the IRB.

5.8.2 承辦人員將文件陳送執行祕書、(副）主任委員批核，而後排入最近一次大會進行討論/核備。

5.8.2 The staff member should submit the documents to the Executive Secretary and (Vice) Chair for confirmation, and should be scheduled in the earliest session of IRB board meeting for discussion/confirmation.

5.8.3 若非照原計畫書執行人體研究/試驗，需送「修正案」進行計畫變更。

5.8.3 If the clinical trial is not implemented as designed in the original protocol, then an application for protocol amendment should be submitted to the IRB.

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	計畫暫停/終止報告表 Protocol Suspension/Termination Report	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
2	計畫暫停/終止審查委員遴選表 Protocol Suspension/Termination 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
3	臺中榮民總醫院人體研究倫理審查委員會暫停/終止報告案件審查重點注意事項檢核表 / PTMS 暫停/終止	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed

	報告審查意見表 TCVGH-IRB Review Checklist for Protocol Suspension/Termination / PTMS Review Checklist for Protocol Suspension/Termination		
4	試驗暫停/終止報告審查意見回覆表 Form of Response to Reviewers' Comments on Protocol Suspension/Termination	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
5	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

6.附件

6. Appendices

「PTMS 暫停/終止報告審查意見表」、「公文」為線上系統輸入，無版本誤用之虞，故不列入附件管理。

"PTMS Review Checklist for Protocol Suspension/Termination" 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 計畫暫停/終止報告表

6.1 Protocol Suspension/Termination Report

6.2 計畫暫停/終止審查委員遴選表

6.2 Protocol Suspension/Termination Reviewers Selection Form

6.3 臺中榮民總醫院人體研究倫理審查委員會暫停/終止報告案件審查重點注意事項檢核表

6.3 TCVGH-IRB Review Checklist for Protocol Suspension/Termination

6.4 試驗暫停/終止報告審查意見回覆表

6.4 Form of Response to Reviewers' Comments on Protocol Suspension/Termination

6.5 案件流程表

6.5 Protocol Review Routing Form