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-2010 IRB-Regulations of Operation-2010	文件名稱 Title	一般審查管理程序書 SOP for Full Board Review
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，並請註明填寫：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	11	新訂。Newly composed.	20140519
B	12	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	12	1. 修改 5.1 流程圖之相關文件。 1. The list of relevant documents was revised in item 5.1 Flow Chart. 2. 修改許可書名詞為「人體研究/試驗計畫許可書」。 2. The title of the approval document was revised to “Certificate of Approval.”	20150923
D	13	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 5.4.2 副主任委員擔任審查委員之遴選作業說明。 2. The procedure of selecting the Vice Chair to be a reviewer was revised in item 5.4.2. 3. 文字校正。 3. Typos were fixed. 4. 原「審查意見表」改為「一般審查案件審查重點注意事項檢核表」，並增修附件 6.4-6.9。 4. The original “Reviewers’ Comments Form” was replaced by “IRB Full Board Review Checklist, and Appendices 6.4-6.9 were revised.	20160318

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D	13	5. 將獨立專家修改為專家。 5. The term “independent expert” was replaced by “expert consultant.” 6. 修正計畫主持人補件時間說明：5.7.6.11.b、c。 6. The explanation about the due date for the PI to submit missing or supplementary documents was revised in items 5.7.6.11.b and c. 7. 刪除原附件 6.2 PTMS 系統文件、6.10 公文，並加註說明。 7. The original Appendix 6.2 “PTMS Documents” and Appendix 6.10 “Official Correspondence” were deleted, and explanation was added.	20160318
E	13	1. 修改參考文件 3.1「藥品優良臨床試驗準則」版本，新增 3.3 人體試驗管理辦法。 1. The version of reference 3.1 “Regulations for Good Clinical Practice” was updated, and 3.3 “Regulations on Human Trials” was added. 2. 修改 5.1 流程圖「遴選審查委員」權責為執行秘書，同步修改 5.4.1。 2. The flow chart in 5.1 was revised: The responsible personnel for “Selection of Reviewers” was changed into Executive Secretary. Item 5.4.1 was revised accordingly. 3. 修改 5.2.1.1 一般審查新案應備之文件份數：刪除影本。 3. The number of copies of the required documents for a protocol submission was revised in item 5.2.1.1: The word “photocopies” was deleted. 4. 原 5.4.2（副）主任委員擔任審查委員批示，移至 5.9.3。 4. Item 5.4.2 regarding the signature approval of the (Vice) Chair serving as a reviewer was moved to item 5.9.3.	20170709

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E	13	5. 修改 5.4.4 委員審查天數為 6 個日曆天：原 7 個日曆天。 5. Item 5.4.4 was revised: The original “7 calendar days” was replaced by “6 calendar days” regarding the review period. 6. 修改 5.5.1 不適合審查之說明及再遴選其他適合的審查委員之權責。 6. Item 5.5.1 was revised regarding the explanation on the disqualification of a reviewer and re-selection of reviewers. 7. 修改 5.5.6.4.b 備詢改為說明。 7. The phrase “to answer questions” was replaced by “to provide an explanation” in item 5.5.6.4.b. 8. 修改 5.5.7.5 國中生改為國三生所能瞭解的程度。 8. Item 5.5.7.5 was revised: The phrase “the reading ability of a middle school student” was replaced by “the reading ability of a ninth-grader.” 9. 修改 5.6.1.3 未於限期回覆之計畫案視為撤案之說明。 9. Item 5.6.1.3 was revised regarding the explanation about a protocol being withdrawn from IRB consideration in the case of the PI not responding to reviewers’ comments before the due date. 10. 修改 5.6.2 補正及修訂審查計畫送件至秘書處之期限。 10. Item 5.6.2 was revised regarding the due date of the submission of supplementary documents to the Secretariat by the PI.	20170709

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		11. 修改 5.7.2：新增承辦人員將審查期間之計畫案增加文件，排入下次會期之議程。 11. A new sentence was added in item 5.7.2: “The staff member should place the PI’s supplementary documents on the agenda of the next scheduled IRB board meeting.” 12. 修改 5.7.3 開會資料分送委員之期限。 12. The schedule of distributing meeting materials to IRB members was revised in Item 5.7.3. 13. 修改 5.7.4 主持人蒞會報告改為出席大會說明。 13. Item 5.7.4 was revised: “The PI should give a report in the IRB board meeting.” was replaced by “The PI should attend the IRB board meeting to present/clarify the protocol.” 14. 修改 5.7.6.1：刪除審查委員決定主持人是否出席備詢及提出審查意見。 14. The following sentence was deleted in item 5.7.6.1: “The reviewer should determine whether the PI should attend the IRB boarding meeting to answer questions and give comments.” 15. 刪除 5.7.6.2 由原審查委員報告綜合審查意見。 15. A sentence was deleted in item 5.7.6.2: “The original reviewer should give a report on the overall review comments.” 16. 修改 5.7.6.4：增列邀請主持人前來大會說明。 16. A sentence was added in item 5.7.6.4: “The PI may be invited to present/clarify the protocol in the IRB	

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		board meeting." 17. 刪除原 5.7.6.5 與會委員針對計畫案提出問題與建議。 17. A sentence was deleted in item 5.7.6.5: "The attending members may ask questions and give comments about the protocol." 18. 修改 5.7.6.5 主席統一提問說明。 18. A sentence was deleted in item 5.7.6.5: "The chair of the IRB board meeting shall be responsible for asking the PI questions on behalf of the IRB board." 19. 修改 5.7.6.7 人體試驗管理辦法版本。 19. The version of "Regulations on Human Trials" was updated in item 5.7.6.7. 20. 修改原編號 5.7.6.11.a 及 b 開立「人體研究/試驗計畫許可書」蓋簽名章或親自簽名之權責人員。 20. The numbers of items 5.7.6.11 a & b were updated regarding the responsible personnel for signing on the Certificate of Approval. 21. 修改 5.9.2「許可書」迄始日改為起始日。 21. The wording of the "validity period" of the Certificate of Approval was modified in item 5.9.2. 22. 抽換附件 6.1、6.3 及 6.12。 22. Appendices 6.1, 6.3, and 6.12 were replaced.	

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F	28	1. 修改參考文件 3.2 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. Reference 3.2 was replaced by “Regulations for Organization and Operation of IRB Committees. Promulgated by Ministry of Health and Welfare 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. 合併 5.2.1.3 和 5.3.1 內容。 2. Combined item 5.2.1.3 and item 5.3.1. 3. 修改 5.4.1 為「由第一/二人體研究倫理審查委員會執行秘書評估計畫性質為一般審查案件，並依據案件屬性、委員專長(如法律背景)等指派委員審查」。 3. Item 5.4.1 was revised: “The Executive Secretary should conduct a preliminary review to determine if the protocol should be sent to the full board for review. The Executive Secretary should then assign reviewers to review the protocol based on the expertise of the reviewers (such as the legal background) and the content of the protocol.” 4. 刪除 5.4.5「(審查委員專用)」之文句。 4. The phrase “(for reviewers only)” was deleted in item 5.4.5. 5. 增加 5.7.6.6 於大會審查中，委員應對於易受傷害族群之保護進行充分討論，並給予適當建議。若為介入性研究，則應針對如何降低受試者參與之風險、受試者所獲得之利益是否高於最小風險、在研究過程中可能產生之利益是否適當等議題進行討論。	20190527

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F	28	5. The following sentence was added in item 5.7.6.6: “During the full board review in an IRB board meeting, members should thoroughly discuss the protection of vulnerable subjects and provide appropriate suggestions regarding protocols involving vulnerable subjects.” Regarding invasive research, the members should discuss issues related to how to reduce risks posed to the subjects, whether the benefits presented to the subjects are more than the minimal risks in research, and whether the benefits incurred by the research are appropriate. 6. 修改原 5.7.6.6 ~ 5.7.6.10 之標號。 6. Item numbers were revised from 5.7.6.6 to 5.7.6.10. 7. 修改 5.7.6.9 之投票方式。 7. The voting method in item 5.7.6.9 was revised. 8. 修改 5.7.6.11 第 a 點：「會議投票結果雖為『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/試驗計畫許可書』，並蓋上（副）主任委員簽名章或請（副）主任委員親自簽名。」。 8. Item 5.7.6.11 a. was revised: “If the voting result of the board meeting on a protocol 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 Certificate of Approval with the stamp or signature of the (Vice) Chair.”	20190527

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F	28	9. 修改 5.7.6.11 第 b 點部份文句為「計畫主持人檢送審查回覆意見及更正附件」。 9. A sentence was revised in item 5.7.6.11 b.: "The PI should submit their response to comments and provide supplementary or revised documents if needed." 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. 11. 抽換附件 6.1、6.3 ~ 6.8、6.10。 11. Appendices 6.1, 6.3 - 6.8, and 6.10 were replaced.	20190527
G	28	1.抽換附件 6.1。 1. Appendix 6.1 was replaced.	20191018
H	28	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. 原「臺中榮民總醫院第一/二人體研究倫理審查委員會一般審查案件審查重點注意事項檢核表」修改為「PTMS 一般審查案件審查重點注意事項檢核表」。 2. The original "IRB Review Checklist for Full Board Review" was replaced by "PTMS Review Checklist for Full Board Review." 3. 依據 AAHRPP 國際認證委員之建議，新增 5.7.6.11 項內容。 3. Item 5.7.6.11 was added according to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) reviewers.	20210528

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H	28	4. 修改原 5.7.6.11 標號為 5.7.6.12。 4. Changed the original item number 5.7.6.11 to 5.7.6.12. 5. 修改 5.7.6.12.b 及 5.7.6.12.c 之計畫主持人回覆期限為 28 個日曆天，並刪除申請展延之說明文字。 5. Revised the PI's reply period to 28 calendar days in item 5.7.6.12.b and item 5.7.6.12.c, and deleted the description of the extension. 6. 抽換附件 6.1~ 6.9、6.11、6.12。 6. Appendices 6.1 - 6.9, 6.11 and 6.12 were replaced.	20210528
I	28	1. 修改 5.4.4 審查期限：原 6 個日曆天改為 6 個工作天。 1. Revised item 5.4.4 Review time limit: Replaced “six calendar days” with “six work days.”	20211209
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J	28	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. 本會編號增加 C 項：第三人體研究倫理審查委員會。 2. IRB number was added the term of C: The Third IRB Committee. 3. 刪除 5.4.5。 3. Item 5.4.5 was deleted. 4. 修改 5.6.2：原 5 個日曆天改為 5 個工作天。 4. Revised item 5.6.2: Replaced “5 calendar days” with “5 work days.” 5. 修改 5.7.3：原 4 個日曆天改為 3 個工作天。 5. Revised item 5.6.2: Replaced “4 calendar days” with “3 work days.” 6. 修改 5.8.1：原 14 天改為 14 個工作天。 6. Revised item 5.8.1: Replaced “14 days” with “14 work days.” 7. 抽換附件 6.1、6.3 ~ 6.12。 7. Appendices 6.1, 6.3 - 6.12 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

文件編號 Document Number	IRB-本會-工作常規-2010 IRB-Regulations of Operation-2010	文件名稱 Title	一般審查管理程序書 SOP for Full Board Review

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

為促使一般審查計畫案的審查管理原則有一明確之規範，以確保案件之申請遵循相關法規，且維持及提昇人體研究倫理審查委員會專業審查品質，特制訂本程序書。

1. Purpose

The purpose of this SOP is to provide specific guidelines for full board review in order to ensure that (1) the review procedure follows relevant laws and regulations, and (2) the professional quality of IRB review is maintained.

2.適用範圍

凡本管理程序書應用在任何經判定不可經簡易審查或免審程序之人體相關研究計畫案之審查管理均適用本程序書。

2. Scope

This SOP applies to the management of the review of protocols not eligible for expedited or exempt review.

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「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)

3.2 Regulations for Organization and Operation of IRB Committees. Ministry of Health and Welfare, promulgated in 2012. (Articles 2, 3, 6, 7 amended in 2018 pursuant to Wei-Bu-Yi-Zi No. 1071661626)

3.3「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

3.3 Regulations on Human Trials (Ministry of Health and Welfare, amended on 14 April 2015, pursuant to Wei-Bu-Yi-Zi No. 1051662154)

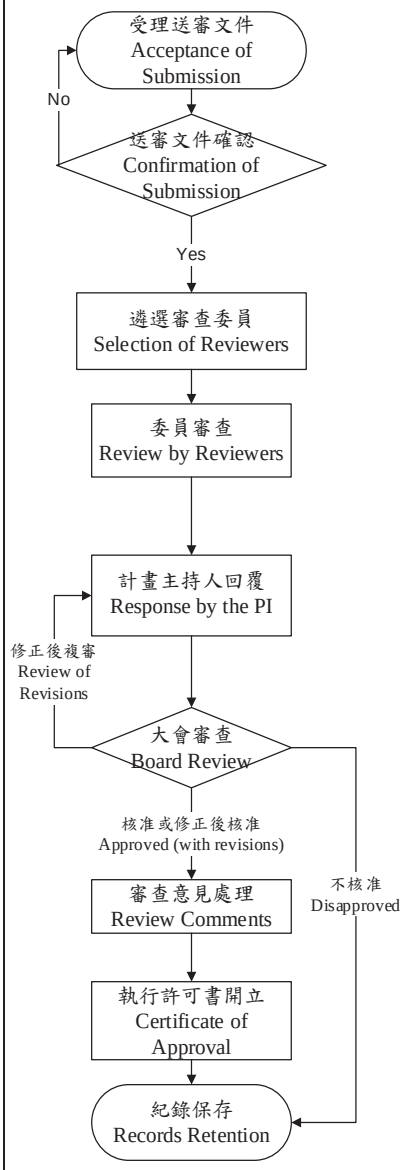
4.名詞定義

4. Definitions

無。

None.

5.作業內容
5. Procedure
5.1 一般審查管理流程圖
5.1 Flow Chart of Full Board Review

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	承辦人員 Staff Members 承辦人員 Staff Members 執行秘書 Executive Secretary 審查委員 Reviewers 審查委員/承辦人員 Reviewers/ Staff Members 承辦人員/出席委員 Staff Members/ Attendees 承辦人員/執行秘書/（副）主任委員 Staff Members/Executive Secretary/(Vice) Chair 承辦人員/執行秘書/（副）主任委員 Staff Members/ Executive Secretary/(Vice) Chair 承辦人員 Staff Members	一般審查申請案文件/臨床試驗線上審查系統 Full Board Review Protocols/PTMS 新案審查送審文件清單/人體試驗研究計畫程序審查說明 New Protocol Submission Checklist/ Statement of Procedure for IRB Review 審查文件/審查委員遴選表 Submission Documents/ Reviewers Selection Form PTMS 一般審查案件審查重點注意事項檢核表 PTMS Review Checklist for Full Board Review 臺中榮民總醫院人體研究倫理審查委員會審查意見回覆表 Taichung Veterans General Hospital Institutional Review Board Form of Response to IRB Reviewers' Comments 大會審查結果意見表 Review Comments 大會審查結果意見表 Review Comments 人體研究/試驗計畫許可書/公文 Certificate of Approval/ Official Correspondence 一般審查計畫案/人體研究/試驗計畫許可書/公文 Protocols for Full Board Review/Certificate of Approval/ Official Correspondence

5.2 受理送審文件

5.2 Acceptance of Submissions

5.2.1 由人體研究倫理審查委員會新案承辦人員依據公告之「人體研究倫理審查委員會收案時間」分別受理申請計畫案。(若為本院主審之 c-IRB 審查機制或類似程序之計畫則不在此限，以最接近之人體研究倫理審查委員會會期進行分派。)

5.2.1 Staff members should accept protocol submissions in accordance with the announced “Submission Timeline of Protocols for IRB Review.” (Exception: Protocols submitted for c-IRB led by TCVGH may not follow the above-mentioned timeline. They should be submitted to the earliest session of IRB board meeting for review.)

5.2.1.1 新案承辦人員至本院的「臨床試驗線上審查系統」(Protocol Tracking & Management System：以下簡稱 PTMS)確認是否申請案由計畫主持人"送出"後，進入行政審查程序之狀態。

5.2.1.1The staff member should confirm if the PI has submitted the protocol on the PTMS (Protocol Tracking & Management System) of TCVGH, and if the protocol submission has entered the phase of administrative review.

5.2.1.2 依「新案審查送審文件清單」，檢視計畫主持人準備之文件。

5.2.1.2 The staff member should review the documents, according to the “New Protocol Submission Checklist.”

5.3 送審文件確認

5.3 Confirmation of Submissions

5.3.1 承辦人員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。行政審查

程序通過後，承辦人員負責受理申請案件，並於本會管理系統建檔新計畫案編號及相關內容，以便日後進行審查進度追蹤。

5.3.1 Staff members should check the completeness and accuracy of all submitted documents. Upon finding any missing or mistaken item, the staff member sends a notice via the PTMS to the PI and returns 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 determination. Upon completion of the administrative review of a protocol submission, the staff member shall create an electronic folder in the IRB protocol management system with a new IRB number and relevant information in order to follow up on the progress of review.

5.3.2 行政審查確認後，應依照如下規範，給予計畫案本會編號，並建立專屬計畫檔案及資料夾。

5.3.2 Upon completion of the administrative review of a protocol submission, the staff member shall assign the protocol with an IRB number and set up a designated folder for all relevant files of the protocol.

碼別 Digit	第一碼 1st digit	第二碼 2nd digit	第三、四碼 3rd & 4th digits	第五至七碼 5th to 7th digits	第八碼 8th digit
代表意義 meaning	案件性質 Type of protocol	審查程序 Review category	新案受理年份 Year of the new protocol submission	流水號 Serial number	人體研究倫理審查委員會編號 IRB Numbers
代碼意義 Meaning of the digit	J：JIRB 案件 J: JIRB S：有合作廠商 S: Collaboration with a company C：院內自行研究 C: Research within	F：一般審 F: Full Board Review G：簡易審改為一般審 G: Category Change from Expedited to Full Board	西元年 Year	001 至 999 001 to 999	A：第一人體研究倫理審查委員會 A: The First IRB Committee B：第二人體研究倫理審查委員會 B: The Second IRB Committee

	TCVGH N：國衛院案件 N: Research from the National Health Research Institutes (NHRI)	Review C：承接其他合法審查會通過之研究計畫 C: Contracted protocols approved by another legal IRB			C：第三人體研究倫理審查委員會 C: The Third IRB Committee

5.3.3 承辦人員依「新案審查送審文件清單」確認文件備齊後，依「PTMS 操作手冊」進行審查作業。

5.3.3 After the staff member has confirmed that a protocol submission is complete and accurate, then the review of the protocol may be processed according to the instructions in the PTMS handbook.

5.3.4 已完成行政審查程序之計畫，得視經費贊助單位要求，開立「人體試驗研究計畫程序審查說明」，證明本案申請人已將文件至本院人體研究倫理審查委員會進入行政審查程序。

5.3.4 After the IRB Secretariat has received complete and accurate protocol submission from the PI, a “Statement of IRB Review Process” may be issued upon request by the research sponsor to prove that the protocol is under review by TCVGH-IRB.

5.4 遴選審查委員

5.4 Selection of Reviewers

5.4.1 由人體研究倫理審查委員會執行秘書評估計畫性質為一般審查案件，並依據案件屬性、委員專長(如法律背景)等指派委員審查。

5.4.1 The Executive Secretary should conduct a preliminary review to determine if the protocol should be sent to the full board for review. The Executive Secretary should then assign reviewers to review the protocol based on the expertise of the reviewers (such as the legal background) and the content of the protocol.

5.4.2 經判定為一般審查之新申請計畫案，由二位委員負責審查，一位為生物醫學科學領域委員，另一位為非生物醫學科學領域委員。當計畫案涉及新臨床藥物/新醫療器材/新醫療技術時，得邀請一位具有相關專長之專家協助審查。

5.4.2 New protocols under full board review should be reviewed by two reviewers--one with a biomedical science background and the other a non-biomedical science background. If the protocol involves any new clinical drug/new medical device/new medical technology, an expert consultant with a relevant background may be invited to review the protocol.

5.4.3 承辦人員準備「PTMS 一般審查案件審查重點注意事項檢核表」。

5.4.3 The staff member should prepare the PTMS Review Checklist for Full Board Review.

5.4.4 填寫審查期限，為期 6 個工作天。

5.4.4 The staff member should fill in the review due date, which should be within 6 work days.

5.5 委員審查

5.5 Review

5.5.1 分案後，審查委員若覺得有利益衝突、專長不符或其他不適合審查的情況，可將計畫案退回給承辦人員，由執行秘書再遴選其他適合的審查委員。

5.5.1 After a protocol is assigned to a reviewer, if the reviewer considers that there is potential conflict of interest or any conditions that make it inappropriate for the reviewer to conduct the review, including a mismatch between the reviewer's expertise and the content of the protocol, the reviewer may return the protocol to the staff member. The Executive Secretary should then assign the protocol to another more suitable reviewer.

5.5.2 被指派之審查委員應於期限內完成每次的審查程序，並將審查意見擲回承辦人員

5.5.2 The reviewer should complete the review within the due date and submit comments to the staff member.

5.5.3 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。

5.5.3The name of the reviewer should be kept confidential. Any potential interference or pressure related to the review of the protocol should be prevented.

5.5.4 審查委員必須以公平而客觀的立場進行審查。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。

5.5.4 The reviewer should conduct the review fairly and objectively. If the reviewer encounters any interference of pressure, he/she should report the incident to the (Vice) Chair. The IRB has the responsibility to eliminate the interference or pressure.

5.5.5 審查委員依審查意見表進行審查程序。

5.5.5 The reviewers should proceed with the review in accordance with the items on the “Form of IRB Reviewers’ Comments.”

5.5.6 綜合審查意見及建議：

5.5.6 Reviewers’ Comments and Suggestions:

5.5.6.1 審查意見必須詳盡，審查委員應依審查意見表之各項逐一填寫審查結果。

5.5.6.1 The reviewer’s comments should be detailed and thorough. The reviewer should fill in the comments according to each item on the Form of IRB Review Comments.

5.5.6.2 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。

5.5.6.2 The reviewer should provide appropriate comments or suggestions on each relevant issue and should avoid inconsistencies in the comments or suggestions.

5.5.6.3 受試者同意書內容評估需是否淺顯易懂。

5.5.6.3 The understandability of the content of the ICF should be evaluated.

5.5.6.4 審查結果：

a.將審查結果分別勾選於「推薦」、「須做修正」欄位。

b.為一般審查之計畫案，審查委員應勾選主持人是否需列席審查會議報告，出席說明之案件得以風險性較高之案件（如：phase Ⅰ、phase Ⅱ…等）或其他經審查委員、（副）主任委員認為計畫主持人須出席說明之計畫案；另計畫主持人亦得要求出席說明。

c.建議追蹤審查頻率：一年一次、六個月一次、三個月一次，（按「人體試驗管理辦法」第 9 條規定：審查會對其審查通過之人體試驗應每年至少查核一次。建議：除較高風險之研究，如 Phase Ⅰ及 Phase Ⅱ…等研究外，追蹤審查頻率以一年一次為宜）。

5.5.6.4 Review Determination:

A. The reviewer should check either “Recommended for approval” or “Revisions required” in the review determination check box.

B. Regarding protocols for full board review, the reviewer should determine whether the PI should attend the IRB board meeting to present the protocol. The PI may be required to attend the board meeting if the protocol presents higher risk (such as phase I, phase II, etc.) or if the reviewer or the (Vice) Chair considers it necessary. The PI may also request to attend the

board meeting to present or clarify the protocol.

C. The continuing review frequency should be determined: Once a year, once every six months, or once every three months. (In accordance with Article 9 of Regulations on Human Trials, an IRB must review previously approved research at least once a year.) Therefore, it is recommended that, except for higher risk clinical trials such as Phase I or Phase II, the continuing review frequency should be once a year.)

5.5.7 其他審查應注意事項

委員審查計畫案時，除依審查意見表逐項審查之外，有一些特定情況須特別注意：

5.5.7 Other Guidelines for Review

When the reviewer reviews a protocol, in addition to following each item on the IRB Review Checklist, he/she shall pay special attention to the following aspects:

5.5.7.1 計畫設計有對照組或超過（含）二組受試者時，應考量其公平性，並注意是否對受試者有完整的保護。

5.5.7.1 If the research design involves a control group or two or more groups of trial subjects, special attention shall be given to the protection of subjects and the fairness of the trial.

5.5.7.2 計畫書應載明發生何種情況會暫停或終止試驗之進行，且應有暫停或終止試驗時維護受試者安全與權益的處置方式。

5.5.7.2 The protocol shall specify in which conditions the trial would be suspended or terminated, and how the trial subjects' rights and safety would be protected in the case of trial suspension or termination.

5.5.7.3 對計畫之受試者（含易受傷害族群）應評估其參與試驗可能造成的危險是否在可接受的程度之內。應注意是否

適當的保護其權益與福祉。亦應注意知情同意之程序、簽署同意書方式、受試者同意書取得程序是否合理。適當保護決定能力有欠缺之受試者，評估受試者參與研究計畫所獲得之補助是否恰當。及確認研究團隊於研究計畫執行結束後，是否能夠確實執行受試者隱私及可辨識資料機密之保護措施。

5.5.7.3 The protocol shall detail the risk assessment of the clinical trial for the trial subjects (including vulnerable subjects), and specify whether the risk would be acceptable. Special attention shall be given to whether the trial subjects' rights and benefits would be well protected. The procedure for obtaining signed Informed Consent Forms shall be reasonable and appropriate. Trial subjects with limited capacity shall be well protected, and the compensation for trial subjects participating in the research shall be appropriate. When the research is concluded, the research members shall continue to protect the privacy of trial subjects and keep all classified information confidential.

5.5.7.4 依醫療法第 79 條規定，接受試驗者以有意思能力之成年人為限。但顯有益於特定人口群或特殊疾病罹患者健康權益之試驗，不在此限。

5.5.7.4 According to Article 79 of "Medical Care Act," "the subjects of human research must be adults with disposing capacity. The preceding provision however does not apply to human research that is apparently beneficial to the health of specific population or patients with a special disease."

5.5.7.5 受試者同意書內容，應盡量口語化，不應超過一般國三生所能瞭解的程度。

a.受試者同意書應告知此為試驗，非常規治療必須的程

序。且應告知受試者可以在完全自主的情況下決定是否願意參加。

b.對於 7 歲至 12 歲之受試者，得要求計畫主持人另外撰寫「兒童版受試者說明書」送審，受試者說明書內容宜為國小生所能瞭解的程度。

5.5.7.5 The wording of the Informed Consent Form (ICF) shall be colloquial and shall be understandable to a person with the reading level of an average ninth grader.

a. The ICF shall specify that the clinical trial is not a necessary procedure in a standard medical treatment. It shall also state that the participation in the trial is completely voluntary and up to the trial subjects to decide whether to participate or not.

b. For research involving subjects between 7 and 12 of age, the PI may be required to compose the “Informed Consent Form and Instructions for Children” and submit the form for IRB review. The content of the form shall be understandable to a person with the reading ability of an average primary school student.

5.5.7.6 若計畫為在急診室或必須在緊急情況下進行，應詳細評估取得受試者簽署同意書之流程是否恰當。

5.5.7.6 If the research is conducted in the emergency room or in an emergency situation, the protocol shall provide details to ensure that the procedure of obtaining signed ICF is appropriate.

5.5.7.7 研究結果之報告或發表，雖非委員會之職責，但主持人應於計畫書中陳述會尊重並保護受試者之隱私。

5.5.7.7 The PI shall state in the protocol that the trial subjects’ privacy will be protected and respected when the research results are announced or published, even though it is not the responsibility of the IRB to regulate the publication of the results.

5.5.8 視需要得依程序徵詢專家意見。

5.5.8 An expert consultant may be invited to provide comments if needed in compliance with the SOP.

5.5.9「免取得研究對象同意」之範圍，須依照 2012 年 07 月 05 日衛生福利部衛署醫字第 1010265083 號函公告之「得免取得研究對象同意之人體研究案件範圍」辦理。

5.5.9 The scope of waiving informed consent should comply with "The Scope of Waiving Informed Consent for IRB Review" announced by Ministry of Health and Welfare on 5 July 2012, pursuant to Wei-Shu-Yi-Zi No. 1010265083.

5.5.10 審查委員應就研究計畫的風險和潛在利益做評估。

5.5.10 The reviewer should assess the risks and potential benefits of the research.

5.6 計畫主持人回覆

5.6 The PI's Response to Reviewers' Comments:

5.6.1 通知審查意見

5.6.1 Notification of the Reviewers' Comments

5.6.1.1 完成初審程序承辦人員彙整審查意見(含院外諮詢專家意見）送交計畫主持人，須隱去審查委員姓名，通知計畫主持人於規定期限內回覆審查意見。

5.6.1.1 The staff member should compile reviewers' comments (including comments from expert consultants) after the primary review has been completed and notify the PI of the comments. The identity of the reviewers should not be disclosed to the PI. The PI should be informed of the due date of responding to reviewers' comments.

5.6.1.2 承辦人員將依審查委員之審查結果，進行主持人是否須列席大會的通知程序。

5.6.1.2 The staff member should inform the PI whether the PI is requested to attend the IRB board meeting according to the reviewer's determination.

5.6.1.3 主持人未於限期內回覆之計畫案，若未以書面說明理由，得視為撤案（仍須繳交審查費）。主持人得填寫撤案申請書或由承辦人員提報大會逕行撤案，其後若欲進行應以新案重新送審。

5.6.1.3 If the PI does not respond to reviewers' comments before the due date and if he/she does not provide an explanation in writing, then the protocol should be withdrawn from IRB consideration (and the PI still needs to pay the review fee).The PI shall then fill out and submit the "Protocol Withdrawal Application Form," or the protocol may be withdrawn by the staff member and reported to the IRB board meeting. The PI may submit the protocol again as a new protocol for future IRB review.

5.6.2 補正及修訂審查計畫

承辦人員彙整計畫修改文件（加註版本及日期）後排進最近一次大會進行複審（所有修改文件至少於大會前 5 個工作天完成送件至秘書處）。

5.6.2 Revisions of Protocol

The staff member should compile revised documents of a protocol (specifying the version and the date) and place the revised protocol on the agenda for the next scheduled IRB board meeting for secondary review (all revisions should be submitted to the Secretariat at least 5 work days before the board meeting).

5.6.3 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。

5.6.3 The PI should apply for protocol withdrawal if they decide not to proceed with the research project before the review process is completed. Application for protocol withdrawal should be reviewed and approved by the IRB Chair, Vice Chair, and Executive Secretary, and it should be sent to the IRB board meeting for recordation.

5.7 大會審查

5.7 IRB Board Meeting

5.7.1 主任委員、副主任委員、執行秘書和審查委員負責判定所申請之計畫案不可經簡易審查程序核准通過。

5.7.1 The Chair, Vice Chair, Executive Secretary, and reviewers are responsible for determining that a protocol should go through the full board review (and not eligible for expedited review).

5.7.2 承辦人員有職責追蹤審查期間之計畫案，將已經過審查程序且主持人完成回覆審查意見修改或增加文件，排入下次會期之議程。

5.7.2 The staff member is responsible for following up on the progress of the review of a protocol. After compiling submitted revisions or supplementary documents from the PI for a protocol previously reviewed, the staff member should place the protocol on the agenda for the next scheduled IRB board meeting for further review.

5.7.3 提案至大會的審查案之相關資料，應於大會召開前3 個工作天提供給委員，以確實給充分的時間進行預先審閱。

5.7.3 All relevant documents regarding protocols submitted to the full board for review should be sent to the IRB members at least 3 work days before the board meeting for the members to have adequate time to review the documents.

5.7.4 主持人得出席大會說明計畫目的、評估資料及試驗方法等，

並回覆委員所提的問題。

5.7.4 The PI may attend the board meeting to present the protocol and clarify the research purpose, analysis of data, or trial methodology, and to respond to questions by the IRB members.

5.7.5 當審查的計畫案有易受傷害族群【為未成年人、受刑人、原住民、孕婦、身心障礙、精神病患、或其他缺乏自主能力或自願性受到限制者（例如經濟貧困、教育不足、醫療緊急狀況沒有充分時間思考者、或無法治癒的致命性疾病者等）】參與此計畫，得邀請相關人員（如：病友會工作人員或病友代表...等）擔任受試者代表，參與大會之相關案件審查或提供諮詢意見。會前應簽署並遵守人體試驗相關之隱私及保密協定，並遵守利益衝突迴避原則。會中有發言權，但無投票權。

5.7.5 If the research involves vulnerable subjects such as children, prisoners, indigenous people, pregnant women, persons with physical or mental disabilities, persons with cognitive impairment, or other persons with limited decision-making capacity (due to lack of financial resources, lack of education, emergency situations in which the subjects do not have adequate time to think, or terminal illness), relevant personnel (such as staff of the patients association or patient advocates) may be invited to attend the board meeting as advocates of trial subjects to review the protocol or give suggestions. The advocate should sign the statement of confidentiality and conflict of interest and follow relevant regulations. The advocates are non-voting attendees who have the right to speak in the IRB board meeting.

5.7.6 委員討論

5.7.6 Discussion by Reviewers

5.7.6.1 原審查委員須於大會中報告該審查申請案及審查意見。

5.7.6.1 The primary reviewer of a protocol should give a report on the protocol and the review comments in the board meeting.

5.7.6.2 若原審查委員因故無法出席，得由執行秘書/副主任委員/主任委員擇一代為報告。

5.7.6.2 If the primary reviewer is unable to attend the meeting, the IRB Executive Secretary, Vice Chair or Chair may give a report on behalf of the reviewer.

5.7.6.3 審查程序開始時，原審查委員簡短報告該申請案之摘要內容及審查意見。審查意見之報告建議遵循審查意見表，內容應含計畫設計與執行、潛在受試者招募、受試者之照護、受試者知情同意、隱私與保密、獨立數據監測計畫、綜合審查意見及建議與審查結果。

5.7.6.3 When the review process begins, the primary reviewer should give a brief summary of the protocol and reviewers' comments. The report on the reviewers' comments should follow the format of the review form, which includes items such as protocol design and implementation, recruitment of potential subjects, subjects protection, informed consent of subjects, privacy and confidentiality, data safety monitoring plan, overall comments and suggestions, and review determination.

5.7.6.4 原審查委員報告之後，所有與會委員均有責任針對計畫案積極提出問題與建議，於會議中提出討論。若原審查委員未勾選主持人需出席，但大會認為有必要，得邀請主持人前來大會說明。

5.7.6.4 After the reviewer's report, all members in attendance have the responsibilities to actively make comments or suggestions, and ask questions about the protocol. Even if the primary reviewer has not requested the PI to attend the board meeting, the PI may still be invited

to present/clarify the protocol in a board meeting if considered necessary by the full board.

5.7.6.5 全體委員皆可提出審查意見，但研究相關人員在場時，由主席統一提問。

5.7.6.5 All members may give comments on a protocol in the board meeting. However, if research personnel are present, the Chair should ask questions on behalf of the members.

5.7.6.6 於大會審查中，委員應對於易受傷害族群之保護進行充分討論，並給予適當建議。若為介入性研究，則應針對如何降低受試者參與之風險、受試者所獲得之利益是否高於最小風險、在研究過程中可能產生之利益是否適當等議題進行討論。

5.7.6.6 During the full board review in an IRB board meeting, members should thoroughly discuss the protection of vulnerable subjects and provide appropriate suggestions regarding protocols involving vulnerable subjects. Regarding invasive research, the members should discuss issues related to how to reduce risks posed to the subjects, whether the benefits presented to the subjects are more than in research involving minimal risks, and whether the benefits incurred by the research are appropriate.

5.7.6.7 出席委員投票依「人體試驗管理辦法（2009.12.14 衛署醫字第 0980263557 號公告）」第八條以及人體研究倫理審查委員會組織及運作管理辦法等規定辦理，審查人員有下列情形之一者，應即迴避：

a. 為人體試驗計畫之主持人、協同主持人或委託人。

b. 與主持人有配偶、四親等內之血親或三親等內之姻親或曾有此關係。

c. 與人體試驗計畫委託廠商有聘僱關係。

d.有具體事實，足認有偏頗之虞。

e.其他經審查會認有利益迴避之必要者。

5.7.6.7 Attending members should vote on a protocol in compliance with Article 8 of the Regulations on Human Trials (promulgated by the Ministry of Health and Welfare on 14 December 2009, pursuant to Wei-Shu-Yi-Zi No. 0980263557) and other regulations regarding IRB management and procedures. A review board member shall immediately recuse himself/herself in any of the following circumstances:

a. serving as the principal investigator, co-investigator, or sponsor of the trial;

b. being, currently or in the past, the spouse, blood relative of four degrees or closer, or relative by marriage of three degrees or closer of the principal investigator;

c. being in an employment relationship with the sponsor of the trial;

d. having the potential of being biased in any way due to substantial evidence;

e. being in other situations where the recusal of the review board member is deemed necessary by the Review Board.

5.7.6.8 投票表決需在有利益衝突的委員和計畫相關人員均離席後方可舉行。

5.7.6.8 Voting shall take place only after all personnel with conflicts of interest have left the meeting room.

5.7.6.9 投票表決前應先確定可投票委員人數已達法定人數，投票結果以「多數決方式」為原則，如投票結果有重大歧異（如：表決結果票數相近等），主席得裁示經討論後重新投票。

5.7.6.9 Before voting on the approval of the study application, the number of voting members present should be counted and it has to reached the quorum. Voting outcome is based on the principle of "Majority rule". If there is a major discrepancy in the voting result, the Chair may ask the attending members to vote again.

5.7.6.10 委員會審查案件，非經討論不得逕行表決。表決前，主席宜主動詢問「非生物醫學科學背景委員」與「院外機構委員」是否仍有其他意見。委員個別意見非經大會討論不得列為會議紀錄。

5.7.6.10The resolution on a protocol shall not be made without discussion. Before voting, the Chair should ask “members without biomedical science backgrounds” and “non-TCVGH-affiliated members” whether they have other comments. Opinions from individual members should not be included in the minutes unless they have been discussed in the board meeting.

5.7.6.11 一般審查案件於大會討論後，若請計畫主持人進行實質上修正或釐清者(例如要求修正可能影響受試者風險程度之試驗方法、納入條件或其他資訊等)，大會結果應為「修正後複審」，需再提至下一次會議討論。

5.7.6.11 After discussed in IRB board meeting, if the protocol is required to be clarified or made substantive change(s) (for example, it is requested clarifications about procedures and inclusion criteria or additional information that could affect the degree of risk to participants), the voting result should be “further review by the convened IRB after revisions.

5.7.6.12 會議結果表決決定時，應紀錄其核准、修正後核准、修正後複審、不核准和棄權之票數。

a.會議投票結果雖為「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/試驗計畫許可書」，並蓋上（副）主任委員簽名章或請（副）主任委員親自簽名。

b.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。計畫主持人檢送審查回覆意見及更正附件（若要加入新的文件，請於取得「許可書」後再送修正案），經承辦人員陳送（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/試驗計畫許可書」，並蓋上（副）主任委員簽名章或請（副）主任委員親自簽名，發給計畫主持人「人體研究/試驗計畫許可書」。

c.若投票結果為「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，若超過 28 個日曆天仍未回覆則逕行撤案】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，並請主持人出席會議說明及溝通；若有其他需求，依大會之決議辦理。

d.若投票結果為「不核准」，大會之會議紀錄須有明確之理由，承辦人員將大會決議通知計畫主持人，計畫主持人不得進行本研究，但得修正後再以新案程序重新送審。計畫主持人欲對於『不核准』之大會決議提出申訴，須於 7 個工作天內提出申訴申請(含相關修正後文件），經執行秘書/副主任委員/主任委員同意後，排入最近一次會期進行討論，申訴以一次為限。

5.7.6.12 The record of the voting results shall include number of votes for “approval,” “approval after revisions,” “further review after revisions,” “disapproval,” and “abstention.”

a. If the voting result of the board meeting on a protocol

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 Certificate of Approval with the stamp or signature of the (Vice) Chair.

b. If the voting result is “approval after revisions,” 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. The PI should submit the Form of Response to Reviewers’ Comments and revised documents (if the PI intends to add new documents to the protocol, he/she should apply for Protocol Amendment after receiving the Certificate of Approval). After the staff member has received the submission, the staff member should send the PI’s response and revisions to the (Vice) Chair/Executive Secretary for approval. Once the response and revisions are approved, the staff member may issue a Certificate of Approval with the signature or stamp of the (Vice) Chair to the PI.

c. If the voting result is “further review after revisions,” the PI should respond to the reviewers’ comments before the due date (the PI should try to respond within 7 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 the PI’s response and relevant documents and place the protocol on the agenda of the next scheduled IRB board meeting for discussion. The PI should be invited to present and clarify the protocol. Other requirements may be

requested according to resolutions by the IRB board meeting.

d. If the voting result is “disapproval,” specific reasons for disapproval should be recorded in the minutes. The staff member should notify the PI of the resolution. The PI may not proceed with the research, but the PI may submit the protocol as a new protocol for future review after revision. If the PI intends to appeal against the IRB resolution of disapproving the protocol, the appeal should be filed within 7 work days (relevant revised documents should be included). After the filing for an appeal is approved by the Executive Secretary/(Vice) Chair, the case should be placed on the agenda for the next scheduled IRB board meeting for discussion. The PI may not file more than one appeal on a protocol.

5.8 審查意見處理

5.8 Review Comments

5.8.1 承辦人員於會議結束後 14個工作天內，以PTMS系統通知申請人會議結果與審查意見。

5.8.1 The staff member should notify the PI via the PTMS of the resolution of the IRB board meeting and the review comments within 14 work days after the board meeting.

5.8.2 計畫主持人回覆大會審查意見，(副）主任委員/執行秘書得請原審查委員進行複審，提供複審意見。

5.8.2 The (Vice) Chair/Executive Secretary may invite the original primary reviewer to conduct further review of the PI's response and give comments.

5.9 執行許可書開立

5.9 Issuance of the Certificate of Approval

5.9.1「人體研究/試驗計畫許可書」將依大會決議之追蹤審查頻率（一年一次、六個月一次、三個月一次或其他）開立研究計

畫有效期間。

5.9.1 The validity period of the Certificate of Approval should be determined in accordance with the continuing frequency (once a year, once every six months, once every three months, or other) decided` by the IRB board meeting.

5.9.2「人體研究/試驗計畫許可書」之有效期間，起始日為承辦人員開立之日期。

5.9.2 The start date of the validity period of the Certificate of Approval should be the date on which the staff member issues the certificate.

5.9.3 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。

5.9.3 If the Vice Chair serves as a reviewer, the protocol approval should be signed by the Chair, and vice versa.

5.9.4 若試驗團隊相關成員為本會現任委員，在審查討論過程需遵守利率迴避原則，秘書處得配合申請人要求開立證明文件，表示該委員未參與本案核准之相關過程，包含未參與該次會議或投票。

5.9.4 If a research member of a protocol is also an IRB member, then the member should not be involved in any IRB discussion or review related to the protocol, in accordance with the conflict of interest policy. By request of the member, the Secretariat should issue a statement to prove that the member has not been involved in the review process of the protocol, including attending related meetings or voting.

5.9.5 未經初審委員初審或大會複審之文件，須於收到許可書後，再送修正案修改文件。

5.9.5 If the PI intends to submit supplementary documents not required by the primary reviewer or by the IRB full board further review, then the PI should apply for Protocol

Amendment after receiving the Certificate of Approval.

5.10 紀錄保存

5.10 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 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 At least 3 years after the trial is closed
2	PTMS 新案申請書 PTMS New Protocol Application Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
3	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
4	人體研究倫理審查委員會一般審查案件風險與利益評估檢核表 IRB Risk and Benefit Assessment Checklist for Full Board Review	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人體研究/試驗案件納入易受傷害族群申請表 IRB Vulnerable Subjects Application Form for Research	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
6	得免取得研究對象同意之人體研究案件申請表 Application for Waiver of Informed Consent	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
7	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	撤案申請書 Checklist and Application Form of Protocol Withdrawal	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
10	人體研究/試驗計畫許可書 Certificate of Approval	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the

編號 Document Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
			trial is closed
11	公文 Official Correspondence	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 新案申請書」、「PTMS 一般審查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。

6. Appendices

"PTMS New Protocol Application Form", "PTMS Review Checklist for Full Board Review" and "Official Correspondence" are generated in the online system and would not have the problem of the wrong version being used; therefore, these three items are not listed in the appendices.

6.1 新案審查送審文件清單

6.1 New Protocol Submission Checklist

6.2 審查委員遴選表

6.2 Reviewers Selection Form

6.3 人體研究倫理審查委員會一般審查案件風險與利益評估檢核表

6.3 IRB Risk and Benefit Assessment Checklist for Full Board Review

6.4 人體研究倫理審查委員會人體研究/試驗案件納入易受傷害族群申請表-適用屬孕婦或胎兒之研究

6.4 IRB Vulnerable Subjects Application Form for Research Involving Pregnant Women or Fetuses

6.5 人體研究倫理審查委員會人體研究/試驗案件納入易受傷害族群申請表-適用屬未成年人之研究

6.5 IRB Vulnerable Subjects Application Form for Research

Involving Children

6.6 人體研究倫理審查委員會人體研究/試驗案件納入易受傷害族群申請表-適用屬生存力不明的新生兒之研究

6.6 IRB Vulnerable Subjects Application Form for Research Involving Neonates of Uncertain Viability

6.7 人體研究倫理審查委員會人體研究/試驗案件納入易受傷害族群申請表-適用屬受拘禁人之研究

6.7 IRB Vulnerable Subjects Application Form for Research Involving Prisoners

6.8 人體研究倫理審查委員會人體研究/試驗案件納入易受傷害族群申請表-適用屬無法存活的新生兒之研究

6.8 IRB Vulnerable Subjects Application Form for Research Involving Nonviable Neonates

6.9 人體研究倫理審查委員會審查意見回覆表

6.9 Form of Response to IRB Reviewers' Comments

6.10 案件流程表

6.10 Protocol Review Routing Form

6.11 撤案申請書

6.11 Protocol Withdrawal Application Form

6.12 人體研究/試驗計畫許可書

6.12 Certificate of Approval