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-2009 IRB-Regulations of Operation-2009	文件名稱 Title	簡易審查管理程序書 SOP for Expedited 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，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. Pages	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	9	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.”	20150119
C	10	1. 修改 5.1 流程圖之相關表單。 1. Forms related to Flowchart 5.1 were revised. 2. 修改 5.3.2 計畫案編碼。 2. Protocol numbers were revised in item 5.3.2. 3. 新增 5.6.13 其他審查應注意事項及修改部分名詞：5.6.13.1-7。 3. Item 5.6.13 “Other guidelines for protocol review” was added, and some of the terms in items 5.6.13.1-7 were revised. 4. 修改附件 6.16 表單名稱（原人體試驗研究計畫許可書）及內文。 4. The title of the form and content of item 6.16 (Certificate of Approval) were revised.	20150923

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D	10	1. 原「人體試驗委員會」更名為「第一/二人體研究倫理審查委員會」。 1. The original “Human Research Committee” was renamed “The First/Second IRB Committees.” 2. 原「審查意見表」改為「簡易審查案件審查重點注意事項檢核表」，並增修附件 6.10-6.15。 2. The original “Reviewers’ Comments Form” was replaced by “IRB Expedited Review Checklist, and Appendices 6.10-6.15 were revised. 3. 文字校正。 3. Typos were fixed. 4. 修改院外專家為專家。 4. The term “external expert” was replaced by “expert consultant.” 5. 修改 5.5.2 副主任委員擔任審查委員之遴選作業說明。 5. The procedure of selecting the Vice Chair to be a reviewer was revised in item 5.5.2. 6. 修正計畫主持人補件時間說明：5.6.9、5.6.10。 6. The explanation about the time limit for the PI to submit missing or supplementary documents was revised in items 5.6.9 and 5.6.10. 7. 修改 5.6.11 審查次數。 7. The number of reviews was revised in 5.6.11. 8. 修改 5.6.12：新增未依委員審查意見回覆或修改之作	20160318

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		業。 8. Item 5.6.12 was revised: The procedure was added for handling cases in which the PI does not respond to the reviewers' comments or does not revise the protocol according to the comments. 9. 修改 5.7.2.1 確保修改是否完整之權責人員。 9. The responsible personnel for ensuring if revisions of protocol are complete in item 5.7.2.1 was revised. 10. 刪除原附件 6.5 PTMS 系統文件、6.17 公文，並加註說明。 10. The original Appendix 6.5 "PTMS Documents" and Appendix 6.17 "Official Correspondence" were deleted, and explanation was added.	
E	10	1. 新增參考文件 3.5 及 3.6。 1. Items 3.5 and 3.6 were added in References. 2. 修改 5.1 流程圖「判定符合簡易審」及 5.4 之權責：執行秘書(兼任委員時)。 2. Item 5.1 "Flow Chart" was revised regarding "Eligible for Expedited Review," and item 5.4 was revised regarding "Responsible Personnel: Executive Secretary (as Reviewer)." 3. 修改 5.1 流程圖「遴選審查委員」及 5.5.1 之權責：刪除（副）主任委員。 3. "Selection of Reviewers" was revised in item 5.1 "Flow Chart" and "(Vice) Chair" was deleted from	20170709

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		“Responsible Personnel” in item 5.5.1. 4. 修改 5.2.1 簡易審查案件應備之文件：刪除影本。 4. “Photocopies” was deleted from the required documents for protocol submissions for expedited review in item 5.2.1. 5. 修改 5.3.3 合作機構：刪除中山附醫及彰化基督教醫院。 5. Item 5.3.3 Collaborative Institutions was revised: “Chung Shan Medical University Hospital” and “Chang Hua Christian Hospital” were deleted. 6. 刪除原 5.5.2（副）主任委員擔任審查委員時批示說明。 6. The explanation on the approval of the (Vice) Chair serving as a reviewer was deleted in the original item 5.5.2. 7. 修改 5.5.2 審查期限：原 7 個日曆天。 7. The deadline for review in item 5.5.2: The original “7 calendar days” was revised. 8. 刪除原 5.5.4 影本送審及存檔之流程。 8. The procedure for submitting photocopies for review and archiving was deleted in the original item 5.5.4. 9. 新增 5.6.4 研究計畫的風險和潛在利益評估說明。 9. The explanation on the risk/benefit assessment of the protocol was added in item 5.6.4. 10. 修改 5.6.8 審查結果或意見不一致時，請計畫主持人	

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		出席大會備詢，改為得請其說明。 10. Item 5.6.8 was revised: If reviewers disagree on their review decisions, the PI may be invited to present/clarify the protocol in the IRB board meeting (The original stated that the PI should attend the board meeting to answer questions). 11. 修改 5.6.11 審查結果為「修正後再審」，計畫主持人必須列席大會說明備詢，改為審查委員、(副) 主任委員判定計畫主持人是否出席大會說明。 11. Item 5.6.11 was revised regarding the review decision of "further review after revisions": The original sentence "The PI should attend the IRB board meeting to explain the protocol or answer questions" was replaced by "The reviewer or the (Vice) Chair decides whether the PI should attend the IRB board meeting to present/clarify the protocol." 12. 刪除原 5.9.2「人體研究/試驗計畫許可書」迄始日日期說明。新增 5.9.2 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。 12. The explanation on the validity period of the Certificate of Approval was deleted in the original item 5.9.2. Item 5.9.2 was added: "If the Vice Chair serves as a reviewer, the protocol approval should be signed by the Chair, and vice versa." 13. 刪除原附件 6.5 送審函，同步修改 5.1 流程圖之相關	

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		文件、內文附件編號及 5.11 紀錄保存文件；抽換附件 6.1、6.2、6.7、6.8、6.16-18。 13. The original Appendix 6.5 “Letter of Submission for Review” was deleted and the following items were revised accordingly: 5.1 “Relevant documents” in the flow chart, the number codes of the appendixes, and 5.11 “Record retention documents.” Appendices 6.1, 6.2, 6.7, 6.8, 6.16-18 were replaced.	
F	22	1. 修改參考文件 3.2 為「International Conference on Harmonization of Good Clinical Practice Guidelines (ICH GCP) 2016」。 1. Reference 3.2 was revised: “International Conference on Harmonization of Good Clinical Practice Guidelines (ICH GCP) 2016.” 2. 更新參考文件 3.3 為 2011 年。 2. The year of reference 3.3 was updated to 2011. 3. 修改參考文件 3.6「中華民國 106 年 5 月 10 日總統華總一義字第 10600056441 號令修正公布「醫療法」第 8、70、78、79、79-1、79-2、80、98、105 條條文。 3. Reference 3.6 was revised: “Articles 8, 70, 78, 79, 79-1, 79-2, 80, 98, and 105 of Medical Care Act, amended and promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10600056441 dated 10 May 2017.”	20190527

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		4. 合併 5.2.1.3 和 5.3.1 內容。 4. Combined item 5.2.1.3 and item 5.3.1. 5. 修改 5.3.5 文句。 5. The wording in item 5.3.5 was modified. 6. 修改 5.5.1 為「所有案件均由二位委員負責審查，一位為生物醫學科學背景委員，另一位為非生物醫學科學背景委員。承辦人員送交執行秘書，由執行秘書依據案件屬性、委員專長(如法律背景)等指派委員審查」。 6. Item 5.5.1 was revised: All protocols shall be reviewed by two reviewers--one with a biomedical science background and the other a non-biomedical science background. After the staff member reports to the executive secretary with a protocol submission, the executive secretary should assign reviewers to review the protocol based on the nature of the protocol and the reviewers' backgrounds and expertise (such as the legal background). 7. 修改 5.6.4 審查委員應就研究計畫的風險和潛在利益做評估（依據「案件審查重點注意事項檢核表」之風險、利益衝突評估）。 7. Item 5.6.4 was revised: Reviewers should assess the risks and potential benefits of the protocol (according to the risk/benefit assessment guidelines in "IRB Review Checklist").	

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		8. 因應 IRB 無紙化送審作業，修改與「書面資料」相關之內容。 8. Process related to hardcopies was revised to comply with the new IRB policy of paperless submission. 9. 抽換附件 6.1、6.2、6.5、6.9 ~ 6.14、6.16。 9. Appendices 6.1, 6.2, 6.5, 6.9-6.14, 6.16 were replaced.	
G	22	1. 抽換附件 6.1。 1. Appendix 6.1 was replaced.	20191018
H	21	1. 修改參考文件 3.6 為中華民國 109 年 01 月 15 日總統華總一義字第 10900003861 號令修正公布「醫療法」。 1. Updated reference 3.6 into “Medical Care Act, amended and promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10900003861 dated 15 January 2020.” 2. 原「臺中榮民總醫院第一/二人體研究倫理審查委員會簡易審查案件審查重點注意事項檢核表」修改為「PTMS 簡易審查案件審查重點注意事項檢核表」。 2. The original “IRB Review Checklist for Expedited Review” was replaced by “PTMS Review Checklist for Expedited Review.” 3. 修改 5.6.10 之計畫主持人回覆期限為 28 個日曆天。 3. Revised the PI's reply period to 28 calendar days in item 5.6.10.	20210528

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		4. 刪除 5.6.10 及 5.6.11 之申請展延說明文字。 4. Deleted the description of the extension in item 5.6.10 and item 5.6.11. 5. 刪除原附件 6.2「承接其他合法審查會通過之研究計畫」送審清單。 5. The original Appendix 6.2 “Submission Checklist of Contracted Research Project Approved by Another Legal IRB” was deleted. 6. 抽換附件 6.1、6.5 ~ 6.14、6.16、6.17。 6. Appendices 6.1, 6.5 - 6.14, 6.16 and 6.17 were replaced.	
I	21	1. 修改 5.5.2 審查期限：原 6 個日曆天改為 6 個工作天。 1. Revised item 5.5.2 Review time limit: Replaced “six calendar days” with “six work days.”	20211209

臺中榮民總醫院 2021.12.23 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

臺中榮民總醫院
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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
2021.12.23
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 discusses with the unit that made the SOP.

1.目的

1. Purpose

此管理程序書提供評估計畫案是否符合簡易審查的要件及審查管理原則。

The purpose of this SOP is to provide guidance for evaluating whether a protocol is qualified for expedited review and for managing the procedure of expedited review.

2.適用範圍

2. Scope

此管理程序書適用於：

This SOP applies to:

2.1 受試者風險較低的計畫案審查。

2.1 The review of protocols which present low risks to subjects.

2.2 承接其他合法審查會通過案件。

2.2 The review of contracted protocols previously approved by another legal IRB.

3.參考文件

3. References

3.1 Code of Federal Regulation (CFR) 21.

3.2 International Conference on Harmonization of Good Clinical Practice Guidelines (ICH GCP), 2016.

3.3 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.

3.4「人體研究法」子法規「倫理審查委員會得簡易程序審查之人體研究案件範圍」之第 9 條：「審查會承接其他合法審查會通過之研究計畫，得以簡易審查程序追認之。」

3.4 According to Article 9 of “The Scope of Expedited Categories for IRB Review” under Human Subjects Research Act,

contracted research projects previously approved by another legal IRB may go through the expedited review procedure for IRB approval.

3.5 2012 年 07 月 05 日衛生福利部衛署醫字第 1010265083 號函公告之「免取得研究對象同意之人體研究案件範圍」

3.5 "The Scope of Exemption Categories for IRB Review" announced by Ministry of Health and Welfare on 5 July 2012, pursuant to Wei-Shu-Yi-Zi No. 1010265083.

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

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

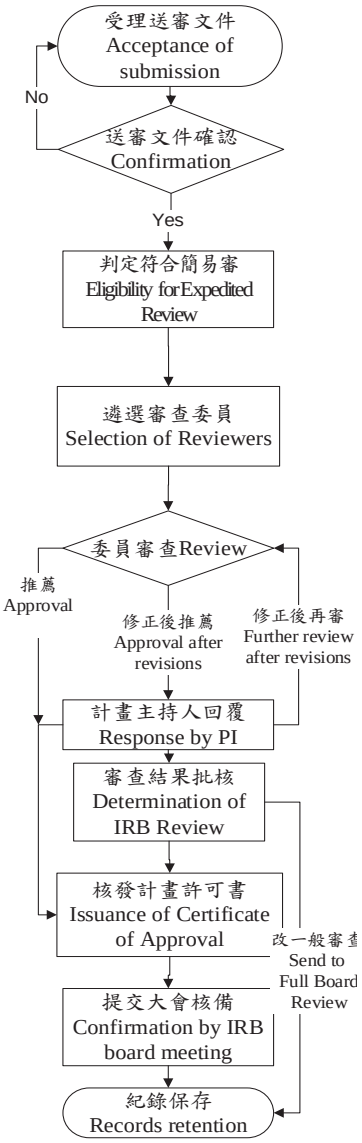
4.名詞定義

4. Definitions

無。

None.

5.作業內容
5. Procedure
5.1 簡易審查管理流程圖
5.1 Flow Chart of Expedited 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(兼任委員時)/(副)主任委員 Executive Secretary (as an IRB member)/ (Vice) Chair 執行秘書 Executive Secretary 審查委員 Reviewers 計畫主持人/執行秘書/(副)主任委員 PI/Executive Secretary/(Vice) Chair 執行秘書/(副)主任委員 Executive Secretary/(Vice) Chair 承辦人員 Staff Members 承辦人員/出席委員 Staff Members/ Attendees 承辦人員 Staff Members	送審文件/簡易審查計畫相關表單 Submitted Documents/Relevant Forms of Expedited Review 簡易審查計畫相關表單/人體試驗研究計畫程序審查說明 Relevant Forms of Expedited Review/ Statement of Procedure for IRB Review 審查類型評估表 Review Category Evaluation Form 審查委員遴選表 Reviewers Selection Form PTMS 簡易審查案件審查重點注意事項檢核表/第一、二人體研究倫理審查委員會審查意見回覆表 PTMS Expedited Review Checklist/Form of Response to IRB Reviewers' Comments 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 送審計畫文件 Submitted Documents 人體研究/試驗計畫許可書/公文 Certificate of Approval/Official Correspondence 會議紀錄 Meeting Minutes 簡易審查計畫案/人體研究/試驗計畫許可書/公文 Protocols for Expedited Review/Human Research/Certificate of Approval/Official Correspondence

5.2 受理送審文件

5.2 Acceptance of Submissions

5.2.1 由第一/二人體研究倫理審查委員會新案承辦人員依據公告之「第一/二人體研究倫理審查委員會收案時間」分別受理申請計畫案。

5.2.1 Staff members should accept protocol submissions in accordance with the announced “Submission Timeline of Protocols for IRB 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。

5.2.1.1 The staff member should confirm if the PI has submitted the protocol on 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」（請參考附件 6.1），檢視計畫主持人準備之文件。

5.2.1.2 The staff member should review the documents submitted according to the “New Protocol Submission Checklist” (please refer to Appendix 6.1).

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 to the PI and returns all submitted documents to the PI via the PTMS. 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 of the digit	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 Meanings of letter codes	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 TCVGH	E：簡易審 E: Expedited review G：簡易審改為一般審 G: Category Change from Expedited to Full Board Review C：承接其他	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

	N：國衛院案件 N: Research from the National Health Research Institutes (NHRI)	合法審查會通過之研究計畫 C: Protocols previously approved by another legal IRB			

5.3.3 依「人體研究法」之子法規「倫理審查委員會得簡易程序審查之人體研究案件範圍」得以簡易審查程序追認經 c-IRB、臺北榮民總醫院、高雄榮民總醫院、三軍總醫院及其他與本院簽訂合作備忘錄之機構（簡稱「合作機構」）審查通過的研究計畫。

5.3.3 In accordance with Article 9 of “The Scope of Expedited Categories for IRB Review” under Human Subjects Research Act, research protocols may go through the expedited review procedure for IRB approval if they have been previously approved by c-IRB or the IRB of Taipei Veterans General Hospital, Kaohsiung Veterans General Hospital, or Tri-Service General Hospital, or by the IRB of other partner institutions which have signed an MOU with TCVGH.

5.3.4 文件齊全後，依「PTMS 操作手冊」進行審查作業。

5.3.4 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.

5.3.5 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送至本院第一/二人體研究倫理審查委員會進入審查程序。

5.3.5 After the IRB Secretariat has received complete and accurate protocol submission from the PI, and upon

completion of the administrative review of a protocol submission, 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.

5.3.6 為避免廠商規避利益迴避申報，由本院人員擔任計畫主持人，自己卻退居協同計畫主持人，應要求所有計畫主持人（包括計畫主持人、共同計畫主持人及協同計畫主持人）皆應填計畫主持人「利益迴避聲明書」。

5.3.6 All investigators (including the Principal Investigator, Co-Investigator, and Sub-Investigator) should fill out and sign a “Statement of Conflict of Interest” to prevent the case in which a company-sponsored protocol lists the actual PI as Sub-I and lists a TCVGH-affiliated investigator as the PI to avoid disclosing conflict of interest.

5.4 判定符合簡易審

5.4 Determination on the Eligibility for Expedited Review

由第一/二人體研究倫理審查委員會之執行秘書依照標準初步建議是否符合簡易審查要件，由（副）主任委員判定。若執行秘書兼任委員，則可直接進行判定（請參考附件 6.2、6.3 及 6.6）。

The IRB Executive Secretary should conduct a preliminary review of the protocol according to relevant guidelines to recommend to the (Vice) Chair whether the protocol is eligible for expedited review. The (Vice) Chair will determine whether the protocol is eligible for expedited review. If the Executive Secretary also serves as an IRB member, then the Executive Secretary can determine whether the protocol is eligible for expedited review (please refer to Appendices 6.2, 6.3 & 6.6).

5.5 遴選審查委員

5.5 Selection of Reviewers

5.5.1 所有案件均由二位委員負責審查，一位為生物醫學科學背景委員，另一位為非生物醫學科學背景委員。承辦人員送交執行秘書，由執行秘書依據案件屬性、委員專長(如法律背景)等指派委員審查。

5.5.1 All protocols shall be reviewed by two reviewers--one with a biomedical science background and the other a non-biomedical science background. After the staff member reports to the executive secretary with a protocol submission, the executive secretary should assign reviewers to review the protocol based on the nature of the protocol and the reviewers' backgrounds and expertise (such as the legal background).

5.5.2 填寫審查期限，為期6 個工作天。

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

5.6 委員審查

5.6 Review

5.6.1 承辦人員將審查案送交審查委員。

5.6.1 The staff member should submit the protocol to the assigned reviewers.

5.6.2 審查委員依「PTMS 簡易審查案件審查重點注意事項檢核表」進行審查。

5.6.2 The reviewers should review the protocol according to the PTMS Review Checklist for Expedited Review.

5.6.3 審查以書面評論方式進行。

5.6.3 Review comments should be given in writing.

5.6.4 審查委員應就研究計畫的風險和潛在利益做評估（依據「案件風險與利益評估檢核表」之風險、利益衝突評估）。

5.6.4 Reviewers should assess the risks and potential benefits of the protocol (according to the risk/benefit assessment guidelines in “IRB Risk and Benefit Assessment Checklist”).

5.6.5 審查委員預期對受試者的風險可能高於最低風險時，得建議改為以一般審查方式進行。

5.6.5 If the reviewers consider that the protocol presents more than minimal risk to subjects, they may determine that the protocol should be sent to the full board for review.

5.6.6「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「免取得研究對象同意之人體研究案件範圍」辦理。

5.6.6 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.

5.6.7 審查委員得依研究計畫之風險高低於「臺中榮民總醫院第一/二人體研究倫理審查委員會簡易審查案件風險與利益評估檢核表」中勾選追蹤審查頻率。一般標準是以「一年一次」為主，若有特殊風險之考量，審查委員可提高追蹤審查頻率為「六個月、三個月一次或其他（視情況而定）」。

5.6.7 The reviewers should check the frequency of continuing review on “IRB Risk and Benefit Assessment Checklist for Expedited Review” based on the level of risk posed by the research. The regular frequency is once per year. If the reviewers consider that the protocol presents more risk than usual, then the frequency of continuing review may be once every six months, or once every three months, or other (depending on the situation).

5.6.8 審查結果或意見不一致時：

5.6.8 When the reviewers are not in agreement:

審查委員間之審查意見或審查結果不一致時，只要任一位審查委員建議改為一般審查，即從嚴認定，改以一般審查流程，

提交大會討論，得請計畫主持人出席大會說明。
If one of the reviewers determines that the protocol should be sent to the full board for review, then the protocol should be submitted for full board review. The PI may be invited to present the protocol in the IRB board meeting.

5.6.9 主任委員、副主任委員或執行秘書於簡易審查整個流程中，若發現該研究計畫並不符合簡易審查之要件（與初步判定之結果有出入時），得將簡易審查改為一般審查，依一般審查流程進行。

5.6.9 During the review process, if the IRB Chair, Vice Chair, or Executive Secretary finds that the protocol does not meet the requirements for expedited review (even if the preliminary review has determined that the protocol is eligible for expedited review), then the protocol may be sent to the full board for review.

5.6.10 承辦人員彙整審查結果，以不揭露審查委員姓名的方式通知計畫主持人，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。

5.6.10 After the staff member has compiled the review comments by reviewers, the PI should be notified of the comments without disclosing the identity of the reviewers. The due date for the PI to respond to reviewers' comments or to submit supplementary materials should be within 7 calendar days. If the PI does not respond within 28 calendar days, the protocol will be withdrawn from IRB consideration.

5.6.11 c-IRB 案件回覆意見以 3 個工作天為原則。

5.6.11 In the case of c-IRB protocol submission, the due date for the PI to respond to comments should be within 3 work days.

5.6.12 若審查結果為「修正後再審」，俟計畫主持人回覆審查意見後，送委員評核。委員審查以兩次為限，若委員再審審查結果仍為「修正後再審」，則逕送大會以一般審查方式進行

討論，審查委員、(副）主任委員判定計畫主持人是否出席大會說明。另，計畫主持人需補繳一般審查費用之差額。

5.6.12 If the review decision is “further review after revisions,” then the protocol should be submitted for further review after the PI has responded to reviewers’ comments. Further review should be limited to one time. If the further review decision is still “further review after revisions,” then the protocol should be sent to the full board for discussion. The reviewer and the (Vice) Chair should determine whether the PI should attend the board meeting to give a presentation. In addition, the PI should pay the difference between expedited and full board review according to the IRB Review Fee Schedule.

5.6.13 若審查結果為「修正後推薦」，俟計畫主持人回覆審查意見後，送執行秘書、(副）主任委員審核後發「人體研究/試驗計畫許可書」。若計畫主持人未依委員審查意見回覆或修改，逕送大會討論（計畫主持人需補繳審查費差額)。

5.6.13 If the review decision is “recommended for approval after revisions,” after the PI has responded to reviewers’ comments and the response to comments has been reviewed and approved by the Executive Secretary and the (Vice) Chair, a Certificate of Approval will be issued. In the case that the PI does not respond to the reviewers’ comments or revise the protocol according to the reviewers’ comments, then the protocol should be submitted to the IRB board meeting for discussion (and the PI should pay the outstanding review fee according to the IRB Review Fee Schedule).

5.6.14 試驗受試者以易受傷害族群【如：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)】應特別注意是否有個人或族群歧視之潛在可能。

5.6.14 Reviewers should pay special attention to potential

discrimination against any individual or group 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 a lack of financial resources, education, or due to terminal diseases or emergency situations in which the subjects do not have adequate time to think).

5.6.15 其他審查應注意事項

5.6.15 Additional Guidelines for Review

委員審查計畫案時，除依「PTMS 簡易審查案件審查重點注意事項檢核表」逐項審查之外，有一些特定情況須特別注意：

Reviewers should review a protocol by checking each item listed in the “PTMS Review Checklist for Expedited Review” and following the additional guidelines:

5.6.15.1 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。

5.6.15.1 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.

5.6.15.2 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。

5.6.15.2 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.

5.6.15.3 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。

5.6.15.3 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.

5.6.15.4 依醫療法第 79 條規定，接受試驗者以有意識能力之成年人為限。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。

5.6.15.4 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."

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

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。

5.6.15.5 The wording of the Informed Consent Form shall be colloquial and understandable to a person with the reading ability of an average middle school student.

a. The Informed Consent Form 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.

5.6.15.6 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。

5.6.15.6 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 Informed Consent Forms is appropriate.

5.6.15.7 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。

5.6.15.7 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.

5.7 計畫主持人回覆

5.7 The PI's Response to Reviewers' Comments:

5.7.1 通知審查意見

5.7.1 Notification of the Reviewers' Comments

5.7.1.1 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。

5.7.1.1 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.

5.7.1.2 計畫主持人未於限期內回覆之計畫案，得視為撤案（仍須繳交審查費），計畫主持人得填寫「撤案申請書」（請參考附件 6.16）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。

5.7.1.2 If the PI does not respond before the due date, the protocol will be withdrawn from IRB consideration (the PI still needs to pay the review fee). The PI shall then fill out and submit the "Protocol Withdrawal Application Form" (please refer to Appendix 6.16), 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.

5.7.2 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，請原審查委員進行再審，或由執行秘書、（副）主任委員確保修改是否完整，提供再審意見。

5.7.2 Revisions of Protocol

The staff member should compile the revised protocol and

supplementary materials (specifying version and date), and submit them to the original reviewers, the Executive Secretary, or the (Vice) Chair for further review to ensure that the revisions are accurate and complete. The reviewers who conduct this further review should provide comments.

5.7.3 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。

5.7.3 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.

5.8 審查結果批核

最後獲得審查委員「推薦」進行之計畫案，由承辦人員請計畫主持人回覆審查意見或再確認後，送執行秘書、(副）主任委員審核。

5.8 Determination of IRB Review

Once a protocol is recommended for approval by reviewers, the staff member should notify the PI of the decision and to respond to reviewers' comments if necessary. The protocol should then be sent to the Executive Secretary and the (Vice) Chair for confirmation.

5.9 核發人體研究/試驗計畫許可書

5.9 The Issuance of the Certificate of Approval

5.9.1 計畫經執行秘書、(副）主任委員審核通過後核發公文及「人體研究/試驗計畫許可書」。

5.9.1 Once a protocol is confirmed by the Executive Secretary and the (Vice) Chair for approval, an official letter of notification and the Certificate of Approval should be

issued.

5.9.2 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。

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

5.9.3 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，秘書處請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。

5.9.3 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.

5.10 提交大會追認後核備

5.10 Confirmation by the IRB Board Meeting

5.10.1 由第一/二人體研究倫理審查委員會承辦人員排入最近一次大會，予以追認後核備。

5.10.1 The protocol approval should be scheduled in the earliest session of IRB board meeting for confirmation and recordation.

5.10.2 大會追認後核備通過後，由承辦人員繼續處理相關行政事宜。

5.10.2 After the protocol approval has been confirmed by the IRB board meeting, the staff member should follow up on administrative work related to the protocol.

5.11 紀錄保存

5.11 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:

編號 No.	紀錄名稱 Title 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	「承接其他合法審查會通過之研究計畫」送審清單 Submission Checklist of "Contracted Research Project Approved by Another Legal IRB"	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
3	臨床研究簡易審查範圍核對表(A) Expedited Review Checklist (A)	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
4	臨床研究簡易審查範圍核對表(B) Expedited Review Checklist (B)	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
5	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
6	免除或改變受試者同意書 Waiver or Alteration of ICF	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
7	全民健康保險資料庫研究計畫送審申請書 Protocol Submission Application of Research Using National Health Insurance Research Database	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
8	審查類型評估表 Review Category Evaluation Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
9	審查委員遴選表 Reviewers Selection Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
10	第一/二人體研究倫理審查委員會簡易審查案件風險與利益評估檢核表 IRB Risk and Benefit Assessment Checklist for Expedited Review	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed

編號 No.	紀錄名稱 Title of Document	保存地點 Retention Location	保存期限 Retention Period
11	第一/二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
12	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
13	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
14	撤案申請書 Protocol Withdrawal Application Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
15	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 trial is closed
16	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

6. Appendices

「PTMS 新案申請書」、「PTMS 簡易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。

"PTMS New Protocol Application Form", "PTMS Review Checklist for Expedited 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 臨床研究簡易審查範圍核對表(A)

6.2 Expedited Review Checklist (A)

6.3 臨床研究簡易審查範圍核對表(B)

6.3 Expedited Review Checklist (B)

6.4 免除或改變受試者同意書

6.4 Waiver or Alteration of ICF

6.5 全民健康保險資料庫研究計畫送審申請書

6.5 Protocol Submission Application of Research Using National Health Insurance Research Database

6.6 審查類型評估表

6.6 Review Category Evaluation Form

6.7 審查委員遴選表

6.7 Reviewers Selection Form

6.8 第一/二人體研究倫理審查委員會簡易審查案件風險與利益評估檢核表

6.8 IRB Risk and Benefit Assessment Checklist for Expedited Review

6.9 第一/二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

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

6.10 第一/二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

6.10 IRB Vulnerable Subjects Application Form for Research Involving Children

6.11 第一/二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

6.11 IRB Vulnerable Subjects Application Form for Research

Involving Neonates of Uncertain Viability

6.12 第一/二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

6.12 IRB Vulnerable Subjects Application Form for Research Involving Prisoners

6.13 第一/二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

6.13 IRB Vulnerable Subjects Application Form for Research Involving Nonviable Neonates

6.14 第一/二人體研究倫理審查委員會審查意見回覆表

6.14 Form of Response to IRB Reviewers' Comments

6.15 案件流程表

6.15 Protocol Review Routing Form

6.16 撤案申請書

6.16 Protocol Withdrawal Application Form

6.17 人體研究/試驗計畫許可書

6.17 Certificate of Approval