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-2007 IRB-Regulations of Operation-2007	文件名稱 Title	新案審查管理程序書 SOP for New Protocol Review
訂定單位 Composed by	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：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	5	新訂。 Newly composed.	20140519
B	7	由人體試驗委員會標準作業程序 5.4 版轉換成此版本。 This version was converted from “Version 5.4 of the SOP of the Human Research Committee.”	20141125
C	8	1.新增 5.5.11 其他審查應注意事項。 1. Added item 5.5.11 Other review key points 2.修改附件 6.11 許可書名詞，同步修改 5.1、5.6。 2. Revised the terms in Appendix 6.11 Certificate of Approval, and revised item 5.1 and item 5.6 accordingly.	20150922
D	9	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「新案案件審查重點注意事項檢核表」：5.1、5.5.1.4、5.5.12、5.6、6.7。 2. The original “Reviewers’ Comments Form” was changed into “IRB Review Checklist” in items 5.1, 5.5.1.4, 5.5.12, 5.6, and 6.7. 3.文字校正。 3. Fixed typos. 4.修正 4.2 c-IRB 審查時間。 4. Corrected the IRB review time period in item 4.2 c-IRB.	20160318

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D	9	5.修改 5.4.2.2「全民健康保險資料庫研究計畫送審申請書」檢附文件。 5. Revised the required attachments for “Protocol Submission of Research Using National Health Insurance Research Database” in item 5.4.2.2. 6.修改院外專家為專家：5.1、5.4、5.5.4。 6. Changed the term “external expert” to “expert consultant” in items 5.1, 5.4, and 5.5.4. 7.修改修正計畫主持人補件時間說明：5.5.9、5.5.10。 7. Revised the explanation of the time limit for the PI to submit missing documents for a protocol submission in items 5.5.9 and 5.5.10. 8.刪除原附件 6.4 PTMS 系統文件、6.12 公文並加註說明。 8. Deleted the original Appendix 6.4 “PTMS Documents” and Appendix 6.12 “Official Correspondence” and added a note of explanation. 9.新增 6.6-6.12 各類案件審查重點注意事項檢核表。 9. Added the IRB Review Checklists for all categories of submissions in items 6.6 to 6.12.	20160318
E	9	1.更新參考文件 3.1 版本，新增 3.3- 3.6。 1. Updated the version of reference 3.1. Added items 3.3 to 3.6. 2.修改 5.1 流程圖「安排各項審查」之權責：新增專家。 2. Revised the responsible personnel for “Managing Review of Protocols” in 5.1 Flow Chart: Added “expert consultants.”	20170709

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版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
E	9	3.修改 5.4 一般審查及簡易審查案件應備文件：刪除影本。 3. Revised the required documents for protocol submissions for full board review and expedited review in item 5.4: Deleted “photocopies.” 4.修改 5.5.3：增列「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）」，同步修改 5.1 流程圖「審查方式確認」之權責。 4. Revised item 5.5.3: Added “The Executive Secretary shall make a primary recommendation as to whether the protocol qualifies for expedited review for the Chair or Vice Chair to approve (if the Executive Secretary is also an IRB member, she/he may make the decision directly)” and revised “Evaluation of Review Category” in 5.1 Flow Chart accordingly. 5.修改 5.5.4、5.5.5：「PTMS 系統」自動寄發電子郵件。 5. Revised items 5.5.4 and 5.5.5: “PTMS will be used to send automatic E-mail.” 6.刪除原附件 6.5 送審函，同步修改 5.6 紀錄保存文件及 5.1 流程圖之相關文件；抽換附件 6.1、6.4、6.13-15。 6. Deleted the original Appendix 6.5 “Letter of Submission for Review” and revised the list of relevant documents in item 5.6 Records Retention and item 5.1 Flow Chart accordingly. Replaced Appendices 6.1, 6.4, 6.13, 6.14, and 6.15.	20170709

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版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
F	9	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. Revised reference 3.2 to “Regulations for Organization and Operation of IRB Committees (Ministry of Health and Welfare, promulgated 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. 計畫主持人須依據實際情形提交「利益衝突聲明」(Conflict of Interest, COI)，以便委員審閱是否符合規範。 2. Principal investigators shall submit Statements of Conflict of Interest for reviewers to see if all regulations are followed. 3. 修改原 5.5.12.7 標號為 5.5.12.8。 3. Changed the original item number 5.5.12.7 to 5.5.12.8. 4. 抽換附件 6.1、6.5 ~ 11、6.14。 4. Replaced Appendices 6.1, 6.5 to 6.11, and 6.14.	20181026
G	17	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.刪除原 5.5.1 內容。 2. Deleted item 5.5.1. 3.修改 5.5 之子項目編號。 3. Revised code number of sub-items of 5.5.	20190527

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版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
G	17	4. 新增 5.5.12 按「醫療法」第 78 條規定：「為提高國內醫療技術水準或預防疾病上之需要，教學醫院經擬定計畫，報請中央主管機關核准，或經中央主管機關委託者，得施行人體試驗」。故凡判定為人體試驗之計畫案，均須同時經衛生福利部審查通過後方可執行。 4. Added 5.5.12 According to Article 78, Medical Care Act: "For the purpose of improving the level of medical care or prevention of disease in the country, teaching hospitals may conduct human research after formulating a plan and obtaining approval from the central competent authority, or upon entrustment of the central competent authority." Therefore all protocols considered to be human research are required to obtain approval from the Ministry of Health and Welfare before implementation. 5. 抽換附件 6.1。 5. Replaced Appendix 6.1.	20190527
H	18	1. 新增 5.5.11.9：給受試者的報酬金額、方式與時程，不可對受試者造成脅迫或不當利誘的影響。 1. Added 5.5.11.9: The amount, payment method and schedule of the reward provided to the subject must not be intimidating or improperly enticing for the subject. 2. 新增 5.5.11.10：給受試者的報酬必須隨著研究的進行分段給付，不可於完成全部研究之後才給付。 2. Added 5.5.11.10: The reward provided to the subject must be paid by stage during the research rather than paid after the research completion. 3. 新增 5.5.11.11：如受試者主動或被動退出研究案，仍應按比例給予報酬。 3. Added 5.5.11.11: If the participant subject actively or passively withdraws from the research, he/she should still be rewarded on a pro rata basis.	20191018

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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 First/Second IRB Committees		

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H	18	4. 新增 5.5.11.12：完成所有研究程序而支付之報酬或補償金，必須為合理金額，且不得過高，以致不當影響原本要退出之受試者的意願。 4. Added 5.5.11.12: The reward or compensation paid after the research procedure completion must be reasonable rather than excessively high to avoid the inappropriate impact on the willingness of the subject. 5.新增 5.5.11.13：人體研究倫理審查委員會不允許試驗委託者提供任何形式之轉介費（金錢或實物），或作為加速受試者的招募的酬勞。 5. Added 5.5.11.13: IRB does not allow the sponsor to provide the referral fee in any forms (money or gifts) as the reward for accelerating the recruitment of the subject. 6.抽換附件 6.1。 6. Appendix 6.1 was replaced.	20191018
I	18	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. 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」。 2. 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." 3. 原「臺中榮民總醫院第一/二人體研究倫理審查委員會案件審查重點注意事項檢核表」修改為「PTMS 案件審查重點注意事項檢核表」。 3. The original "IRB Review Checklist" was replaced by "PTMS Review Checklist."	20210528

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I	18	4. 修改 5.4.2.2 內容。 4. Revised item 5.4.2.2. 5. 修改 5.5.8 之計畫主持人回覆期限為 28 個日曆天。 5. Revised the PI's reply period to 28 calendar days in item 5.5.8. 6. 刪除 5.5.8 及 5.5.9 之申請展延說明文字。 6. Deleted the description of the extension in item 5.5.8 and item 5.5.9. 7. 抽換附件 6.1、6.4~ 6.13、6.15。 7. Appendices 6.1, 6.4 - 6.13, 6.15 were replaced.	20210528
J	21	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 3.7 ~ 3.11。 3. Items 3.7-3.11 were added in References. 4. 新增名詞定義 4.3 ~ 4.5。 4. Items 4.3-4.5 were added in Definitions. 5. 本會編號增加 C 項：第三人體研究倫理審查委員會。 5. IRB number was added the term of C: The Third IRB Committee. 6. 依據 AAHRPP 國際認證之建議新增 5.5.11.14 及 5.5.11.15。 6. According to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) was added Items 5.5.11.14 and Items 5.5.11.15. 7. 新增 5.5.11.16 新醫療技術計畫審查應注意事項。 7. Added Items 5.5.11.16: “Considerations for review of New Medical Technology.”	20230717

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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 First/Second IRB Committees		

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J	21	8. 新增 5.5.11.17 新醫療器材計畫審查應注意事項。 8. Added Items 5.5.11.17: “Considerations for review of New Medical Device.” 9. 抽換附件 6.1、6.5~ 6.15。 9. Appendices 6.1, 6.5 - 6.15 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

※管制文件不得擅自塗改及做記號並禁止影印。
※本文件以 KM 系統為最新版本，紙本發行需經 SOP 管理中心核章，嚴禁自行列印。
※Changing, marking, or copying controlled documents without permission is prohibited.
※The latest version of this document in the Knowledge Management System (KMS) takes precedence. Distribution of hard copies of this document must be approved and stamped by the SOP Administrative Center. Copying without permission is strictly prohibited.

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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
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

為促使新案初次申請計畫案審查的受理流程有一明確之規範，以確保案件之申請遵循相關法規，且維持及提昇人體試驗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 the review of new protocols 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新案審查程序之管理均適用本程序書。

2. Scope

This SOP applies to the management of review of all new protocols.

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, pursuant to Wei-Shu-Yi-Zi No. 1010265129; articles 2, 3, 6, 7 amended in 2018 pursuant to Wei-Bu-Yi-Zi No. 1071661626)

3.3「人體研究法」總統華總一義字第 10000291401 號令制定公布全文 26 條，民國 100 年 12 月 28 日施行

3.3 Human Subjects Research Act, promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 100002914011 dated 28 December 2011

3.4 101 年 07 月 05 日衛署醫字第 1010265098 號函公告「倫理審查委員會得簡易程序審查之人體研究案件範圍」

3.4 "The Scope of Expedited Categories for IRB Review" announced by Ministry of Health and Welfare on 5 July 2012, pursuant to Wei-Shu-Yi-Zi No. 1010265098

3.5 101 年 07 月 05 日衛署醫字第 1010265075 號函公告「得免倫理審查委員會審查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. 1010265075

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

3.7 110 年 12 月 14 日衛部醫字第 1101668486 號函公告「新醫療技術人體試驗案—審查標準作業程序」

3.7 "The Human Trials of New Medical Technology - Review Standard Operating Procedures" announced by Ministry of Health and Welfare on 14 December 2021, pursuant to Wei-Bu-Yi-Zi No. 1101668486.

3.8 109 年 01 月 15 日總統華總一義字第 10900004021 號令制定公布「醫療器材管理法」，全文共 85 條。

3.8 Medical Devices Act, promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10900004021 dated 15 January 2020.

3.9 110 年 04 月 26 日衛生福利部衛授食字第 1101603292 號令訂定發布「醫療器材管理法施行細則」，全文共 34 條。

3.9 Enforcement Rules of Medical Devices Act, promulgated as per the Ministry of Health and Welfare Wei-Shou-Shi-Zi No. 1101603292 dated 26 April 2021.

3.10 110 年 04 月 09 日衛生福利部衛授食字第 1101601721 號令訂定發布「醫療器材優良臨床試驗管理辦法」，全文共 72 條。

3.10 Regulations on Good Clinical Practice for Medical Devices, promulgated as per the Ministry of Health and Welfare Wei-Shou-Shi-Zi No. 1101601721 dated 09 April 2021.

3.11 110 年 04 月 27 日衛授食字第 1101603684 號函公告「無顯著風險之醫療器材臨床試驗態樣」。

3.11 "Conditions of Clinical Trials for Medical Devices with Non-Significant Risk" announced by Ministry of Health and Welfare on 27 April 2021, pursuant to Wei-Shou-Shi-Zi No. 1101603684.

4.名詞定義

4. Definitions

4.1 JIRB：聯合人體試驗委員會(Joint Institutional Review Board)。

4.1 JIRB: Joint Institutional Review Board

4.2 c-IRB：為衛生福利部規劃之審查機制。由衛生福利部補助之「卓越臨床試驗與研究計畫」項下之多家醫學中心輪流擔任國內外多中心藥品臨床試驗之 IRB 主審中心，每案 IRB 審查時間，主審醫院以 20 個工作天為原則（不含計畫主持人補件），副審醫院以 10 個工作天為原則（含計畫主持人補件）。

4.2 c-IRB: C-IRB refers to the review mechanism established by the Ministry of Health and Welfare. The medical centers awarded "Excellent Clinical Trial Research Project" grants by the Ministry of Health and Welfare will take turns running the central IRB of domestic/international multicenter clinical trials. The IRB review time period for each protocol shall be: (1) 20

days for the primary reviewing medical center (not including the time for the PI to submit missing documents); (2) 10 days for the secondary reviewing medical center (including the time for the PI to submit missing documents).

4.3 新醫療技術：指醫療處置之安全性或效能，尚未經醫學證實或經證實而該處置在國內之施行能力尚待證實之醫療技術。

4.3 New Medical Technology: New medical technology refers to medical technology whose safety or efficacy of medical treatment has not been medically proven or proven and the ability of the treatment to be performed in the country has yet to be proven.

4.4 新醫療器材：醫療法施行細則第 2 條以新原理、新結構、新材料或新材料組合所製造，其醫療之安全性或效能尚未經醫學證實之醫療器材。

4.4 New Medical Devices: Article 2 of the Enforcement Rules of Medical Care Act refers to medical devices that are manufactured with new principles, new structures, new materials, or combinations of new materials, and whose medical safety or efficacy has not yet been medically proven.

4.5 無顯著風險醫療器材：沒有顯在風險的試驗醫療器材。

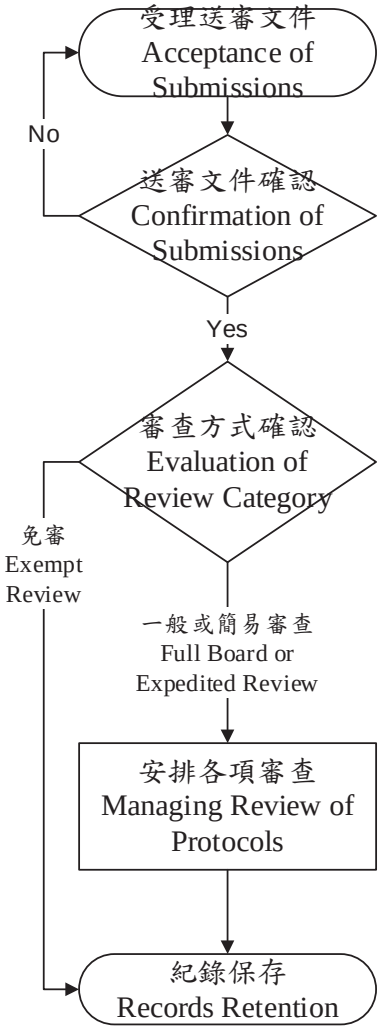
4.5 Nonsignificant Risk Medical Device: Experimental medical devices with Nonsignificant Risk.

5.作業內容

5. Procedure

5.1 新案審查管理流程圖

5.1 Flow Chart of New Protocol 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 (if also an IRB member)/ (Vice) Chair 執行秘書/承辦人員/審查委員/專家 Executive Secretary/ Staff Members/ Reviewers/ Expert Consultants 承辦人員 Staff Members	計畫書送審管理程序書/人體研究法/醫療法/各類送審相關文件 SOP of Managing Protocol Submissions/Human Subjects Research Act//Medical Care Act/Relevant Documents of All Submissions 送審文件/案件流程表/資料排列順序表 Submission Documents/Protocol Review Routing Form/List of Organized Documents 計畫送審申請書/審查委員遴選表/PTMS 案件審查重點注意事項檢核表 Protocol Application Form/Reviewers Selection Form/PTMS Review Checklists 送審案件資料/審查委員遴選表/PTMS 系統/電子郵件/人體研究倫理審查委員會審查意見回覆表/修正文件/計畫書側背/檔案資料記錄 Documents of Protocol Submissions/Reviewers Selection Form/PTMS/Email/ Form of Response to IRB Reviewers' Comments/Revised Documents/Protocol Binder Spine Insert/Record of Documents 人體研究/試驗計畫許可書/公文 Certificate of Approval/ Official Correspondence

5.2 受理送審文件

5.2 Acceptance of Submissions

業務承辦人員應依照「計畫書送審管理程序書」之規定，參考如下說明，受理新案送審文件。

When receiving submissions of new protocols, IRB staff members shall process them by following the SOP of Managing Protocol Submissions and the regulations below.

5.2.1 按「人體研究法」第 4 條第 1 項：「人體研究：指從事取得、調查、分析、運用人體檢體或個人之生物行為、生理、心理、遺傳、醫學等有關資訊之研究」。

5.2.1 According to Article 4, Paragraph 1 of Human Subjects Research Act, “Human subject research (hereinafter “research”): refers to research that involves obtaining, investigating, analyzing, or using human specimens or an individual person’s biological behavior, physiological, psychological, genetic or medical information.”

5.2.2 按「人體研究法」第 5 條規定：「研究計畫主持人實施研究前，應擬定計畫，經倫理審查委員會審查通過，始得為之。」；違反者將依該法第 22 條相關規定處理。

5.2.2 According to Article 5 of Human Subjects Research Act, “Prior to conducting research, the principal investigator shall submit the research protocol for review and approval by the Institutional Review Board (hereinafter “IRB”).” Violators of Article 5 will be penalized according to Article 22.

5.2.3 按「醫療法」第 8 條規定：「本法所稱人體試驗，係指醫療機構依醫學理論於人體施行新醫療技術、新藥品、新醫療器材及學名藥生體可用率、生體相等性之試驗研究。人體試驗之施行應尊重接受試驗者之自主意願，並保障其健康權益與隱私權。」

5.2.3 According to Article 8 of the Medical Care Act, “The term ‘human trial’ as used in the Act shall refer to experimental

research of new medical technology, new medicament, new medical implement, or the bioavailability and bioequivalence of generic drugs conducted by medical care institutions on humans based on medical theory. In conducting a human trial, the medical care institution shall respect the voluntary intent of the trial subjects and protect their right to health and privacy."

5.3 送審文件確認

5.3 Confirmation of Submissions

業務承辦人員應依照如下之規範，進行送審文件確認。

Staff members shall follow the guidelines and confirm the correctness of submitted documents.

5.3.1 依照送審清單所列之項目逐項審查，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。

5.3.1 Staff members shall check if all needed documents are submitted according to the submission checklist. Upon finding any missing or mistaken item, staff members shall send a PTMS notice to the principal investigator (PI) and return 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 judgment.

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 protocol submissions, staff members shall assign each submission with an IRB number following the guidelines below and set up a designated folder for all files of the protocol.

碼別 Digit	第一碼 1st	第二碼 2nd	第三、四碼 3rd & 4th	第五至七碼 5th to 7th	第八碼 8th
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	流水號 Serial number	人體研究倫理審查委員會編號

			submission		IRB Committee
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 N：國衛院案件 N: Research from the National Health Research Institutes (NHRI)	F：一般審 F: Full board review E：簡易審 E: Expedited review W：免審 W: Exempt review G：簡易審改為一般審 G: Category changed from expedited to full board review C：承接其他合法審查會通過之研究計畫 C: Contracted protocol approved by another legal IRB	西元年 Last two digits of the 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 C：第三人體研究倫理審查委員會 C: The Third IRB Committee

5.4 審查方式確認

5.4 Evaluation of Review Category

委員應參照如下規範，進行審查方式之確認。

IRB members shall evaluate and decide the review category of each protocol according to the guidelines below.

5.4.1 一般審查案件申請案

5.4.1 Full Board Review Protocols

適用於不可經簡易審查及免審程序，計畫主持人需依「新案送審文件清單」準備文件。

Protocols not qualified for expedited or exempt review are categorized as full board review protocols. Principal investigators shall prepare the documents according to the “New Protocol Submission Checklist” (refer to Appendix 6.1).

5.4.2 簡易審查案件申請案

5.4.2 Expedited Review Protocols

5.4.2.1 申請範圍依 101 年 07 月 05 日衛署醫字第 1010265098

號函公告「倫理審查委員會得簡易程序審查之人體研究案件範圍」訂定。

5.4.2.1 The research categories for expedited review are defined in “The Scope of Expedited Categories for IRB Review” announced by Ministry of Health and Welfare on 5 July 2012, pursuant to Wei-Shu-Yi-Zi No. 1010265098.

5.4.2.2「全民健康保險資料庫研究計畫送審申請書」內容：(1) 中文摘要；(2) 本會中文人體研究/試驗計畫書及預算表；(3) 計畫主持人、共同計畫主持人、協同計畫主持人之利益迴避聲明書及研究成員保密聲明書；(4) 顯著財務利益暨非財務關係申報說明及申報表；(5) 計畫主持人、共同計畫主持人、協同計畫主持人及研究人員之最新履歷資料；計畫主持人、共同計畫主持人檢附三年內 6 小時以上、協同計畫主持人及研究成員檢附近三年內有相關訓練證明即可(廠商提供之人體試驗相關教育訓練證明無法接受)；(6) 每位研究團隊成員須接受 1 小時以上之利益衝突管理之教育訓練。

5.4.2.2 The “Protocol Application Form for Research Using National Health Insurance Research Database” includes the following content: (1) Abstract in Chinese, (2) Human Research/Clinical Trial Proposal and Budget Form, (3) Statements of Conflict of Interest by the Principal Investigator (PI), Co-Investigator (Co-I), and Sub-Investigator (Sub-I), and Confidentiality Statement by Research Members, (4) Statement of Significant Financial Interest and Other Relationships, (5) Updated CVs of the PI, Co-I, and Sub-I; proof of 6 or more hours of human research training received by the PI within the past three years, and proof of human research training received by the Co-I and Sub-I within the past three years. (Proof of training provided by companies will not be accepted.) (6) Each research personnel must receive at least 1 hour of educational

training on conflicts of interest.

5.4.3 免審案件

5.4.3 Exempt Review Protocols

申請範圍依 101 年 07 月 05 日衛署醫字第 1010265075 號函公告「得免倫理審查委員會審查之人體研究案件範圍」訂定，「計畫送審申請書」正本一份。

The research categories for exempt review are defined in “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. 1010265075. An original copy of the “Protocol Application Form” shall be submitted.

5.5 安排各項審查

5.5 Managing Review of Protocols

5.5.1 專案檔案管理，進行新案編號、電腦建檔及記錄各階段的時間流程。

5.5.1 Project management, assignment of IRB numbers, creating electronic files and recording the timeline of each step.

5.5.2 承辦人員於受理計畫後送交執行秘書分案。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），並視需要遴選審查委員。

5.5.2 After the staff members acknowledge receipt of a new review application, the Executive Secretary shall make a primary recommendation as to whether the protocol qualifies for expedited review for the (Vice) Chair to approve (if the Executive Secretary is also an IRB member, she/he may make the decision directly). The Executive Secretary shall then select reviewers.

5.5.3 已批示之新案計畫，「PTMS 系統」自動寄發電子郵件通知審查委員或專家進行審查。

5.5.3 PTMS will be used to send automatic E-mail messages to notify reviewers or expert consultants to review new protocol submissions.

5.5.4 記錄審查委員回來時間及彙集製作「審查委員意見回覆表」，以「PTMS 系統」自動寄發電子郵件通知計畫主持人。

5.5.4 Staff members shall record the time of receiving comments from each reviewer, compile comments and create the "Form of Response to IRB Reviewers' Comments." PTMS will be used to send automatic E-mail to notify the PI.

5.5.5 檢查送審委員申請案是否逾期。

5.5.5 Staff members shall check if a protocol submitted for review has passed the deadline.

5.5.6 確認審查委員之審查期限，並 E-mail 提醒審查委員。

5.5.6 Staff members shall check the review deadline and remind reviewers via E-mail.

5.5.7 檢查送交計畫主持人之審查意見是否逾期。

5.5.7 Staff members shall check if the reviewers' comments sent to the PI has past the deadline.

5.5.8 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。

5.5.8 The time period for re-submission of documents (or response to reviewers' comments) by the PI shall be within 7 calendar days. If the re-submission or response has passed 28 calendar days, the protocol shall be withdrawn.

5.5.9 c-IRB 案件以 3 個工作天為原則。

5.5.9 In the case of c-IRB protocol submission, the time period for re-submission of documents or response to reviewers' comments shall be 3 work days.

5.5.10 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」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。

5.5.10 If the PI does not respond within the deadline, the protocol will be withdrawn (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 withdrawal may be submitted by the staff members to the IRB board meeting. If the PI intends to submit the protocol again, it shall be submitted as a new protocol.

5.5.11 其他審查應注意事項

5.5.11 Other Review Key Points

委員審查計畫案時，除依「PTMS 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：

When IRB members review a protocol, in addition to following the PTMS Review Checklists, they shall pay special attention to the following aspects:

5.5.11.1 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。

5.5.11.1 If the research design involves a control group or two or more groups of trial subjects, special attention shall be given to whether the trial subjects would be well protected and whether the research would be conducted with fairness.

5.5.11.2 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。

5.5.11.2 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.

5.5.11.3 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。

5.5.11.3 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. When the research is concluded, the research members shall continue to protect the privacy of trial subjects and keep all classified information confidential.

5.5.11.4 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。

5.5.11.4 According to Article 79 of the 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."

5.5.11.5 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。

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

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。

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.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。

b. For research involving subjects between ages 7 and 12, 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.

5.5.11.6 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。

5.5.11.6 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.

5.5.11.7 計畫主持人須依據實際情形提交「利益衝突聲明」(Conflict of Interest, COI)，以便委員審閱是否符合規範。

5.5.11.7 The PI shall submit Statements of Conflict of Interest (COI) for the reviewers to see if all regulations are followed.

5.5.11.8 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。

5.5.11.8 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.

5.5.11.9 給受試者的報酬金額、方式與時程，不可對受試者造成脅迫或不當利誘的影響。

5.5.11.9 The amount, payment method and schedule of the reward provided to the subject must not be intimidating or improperly enticing for the subject.

5.5.11.10 給受試者的報酬必須隨著研究的進行分段給付，不可於完成全部研究之後才給付。

5.5.11.10 The reward provided to the subject must be paid by stage during the research rather than paid after the research completion.

5.5.11.11 如受試者主動或被動退出研究案，仍應按比例給予報酬。

5.5.11.11 If the participant subject actively or passively withdraws from the research, he/she should still be rewarded on a pro rata basis.

5.5.11.12 完成所有研究程序而支付之報酬或補償金，必須為合理金額，且不得過高，以致不當影響原本要退出之受試者的意願。

5.5.11.12 The reward or compensation paid after the research procedure completion must be reasonable rather than excessively high to avoid the inappropriate impact on the willingness of the subject.

5.5.11.13 人體研究倫理審查委員會不允許試驗委託者提供任何形式之轉介費（金錢或實物），或作為加速受試者的招募的酬勞。

5.5.11.13 IRB does not allow the sponsor to provide the

referral fee in any forms (money or gifts) as the reward for accelerating the recruitment of the subject.

5.5.11.14 若受試者有轉介醫師且經受試者同意，計畫主持人應通知其轉介醫師。

5.5.11.14 The investigator should inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

5.5.11.15 儘管受試者沒有義務說明提前退出臨床試驗的理由，但計畫主持人應在尊重受試者之權利及意願之條件下，盡量確認其退出試驗之原因。

5.5.11.15 Although a subject is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the investigator makes a reasonable effort to ascertain the reason, while fully respecting the subject's rights and will.

5.5.11.16 新醫療技術計畫審查應注意事項：

5.5.11.16 Considerations for review of New Medical Technology:

a.計畫主持人及研究人員資格(學經歷、專業)之適當性。

a. Appropriateness of the qualifications (study experience, major) of the Principal Investigator and researchers

b.試驗所需設備、設施、及處理緊急狀況之能力（是否使用輻射性物品）。

b. Equipment, facilities, and emergency handling capabilities required for clinical trials (whether radioactive materials are used).

c.試驗期間，時間和人力是否足以執行與完成試驗。

c. Whether the time and manpower are sufficient to

conduct and complete the trial during the clinical trial.

d.研究設計是否合理—選擇對照組之合理性。

d. Whether the study design is reasonable - the rationality of choosing a control group.

e.研究假設是否明確？

e. Are the research hypotheses clear?

f.樣本數計算是否合宜？

f. Is the sample size calculation appropriate?

g.使用的醫療器材是否有顯著風險(第二等級：中風險性、第三等級：高風險性)或無顯著風險(第一等級：低風險性)。

g. Whether the medical device used has Significant Risk (Class II: Medium risk, Class III: High risk) or NonSignificant Risk (Class I : Low risk).

h.是否考慮到盡可能使用已有的檢驗或檢查的資料，而不新增加受試者風險與不適。

h. Whether it is considered to use the data of the existing test or examination as much as possible without adding new risks and discomfort to the subjects.

i.研究步驟及執行過程，有考量降低受試者的風險。

i. During the research steps and execution, consideration is given to reducing the risk to the subjects.

5.5.11.17 新醫療器材計畫審查應注意事項：

5.5.11.17 Considerations for review of New Medical Device:

a.計畫主持人及研究人員資格(學經歷、專業)之適當性。

a. Appropriateness of the qualifications (study experience, major) of the Principal Investigator and

researchers

b.使用該醫療器材所衍生的傷害性，並對受試者是否有顯著風險(第二等級：中風險性、第三等級：高風險性)或無顯著風險(第一等級：低風險性)。

b. The harmfulness derived from the use of the medical device, and whether there is Significant Risk to the subjects (Class II: Medium risk, Class III: High risk) or Nonsignificant Risk (Class I: Low risk) .

c.醫療器材本身的安全性也應列入考量，如有疑問可向相關機構諮詢。

c. The safety of the medical device itself should also be taken into consideration, and if the IRB has any doubts, they can consult the relevant organizations.

5.5.12 按「醫療法」第 78 條規定：「為提高國內醫療技術水準或預防疾病上之需要，教學醫院經擬定計畫，報請中央主管機關核准，或經中央主管機關委託者，得施行人體試驗」。故凡判定為人體試驗之計畫案，均須同時經衛生福利部審查通過後方可執行。

5.5.12 Article 78, Medical Care Act: “For the purpose of improving the level of medical care or prevention of disease in the country, teaching hospitals may conduct human research after formulating a plan and obtaining approval from the central competent authority, or upon entrustment of the central competent authority.” Therefore all protocols considered to be human research are required to obtain approval from the Ministry of Health and Welfare before implementation.

5.6 紀錄保存

5.6 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.

臺中榮民總醫院 2023.08.10 參考文件

編號 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 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
2	臨床研究簡易審查範圍核對表(A) Expedited Review Checklist (A)	IRB 辦公室 IRB Office	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(B) Expedited Review Checklist (B)	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
4	PTMS 新案申請書 PTMS New Protocol Application Form	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
5	審查委員遴選表 Reviewers Selection Form	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
6	人體研究倫理審查委員會案件風險與利益評估檢核表 IRB Risk and Benefit Assessment Checklist	IRB 辦公室 IRB Office	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 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
8	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 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
9	撤案申請書 Protocol Withdrawal Application Form	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
10	案件流程表 Protocol Review Routing Form	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
11	人體研究/試驗計畫許可書 Certificate of Approval	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
12	公文 Official Correspondence	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed

6.附件

6. Appendices

「PTMS 系統文件」、「PTMS 案件審查重點注意事項檢核表」、「公文」為線上系統輸出，無版本誤用之虞；故不列入附件管理。

"PTMS Documents" "PTMS Review Checklist" and "Official Correspondence" are generated from the online system, preventing the usage of the wrong version; therefore, the above two items are not listed in the management of 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 審查委員遴選表

6.4 Reviewers Selection Form

6.5 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

6.5 IRB Risk and Benefit Assessment Checklist for Full Board Review

6.6 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

6.6 IRB Risk and Benefit Assessment Checklist for Expedited Review

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-適用屬孕婦或胎兒之研究

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

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-適用屬未成年人之研究

6.8 IRB Vulnerable Subjects Application Form for Research

Involving Children

6.9 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

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

6.10 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

6.10 IRB Vulnerable Subjects Application Form for Research Involving Prisoners

6.11 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

6.11 IRB Vulnerable Subjects Application Form for Research Involving Nonviable Neonates

6.12 人體研究倫理審查委員會審查意見回覆表

6.12 Form of Response to IRB Reviewers' Comments

6.13 撤案申請書

6.13 Protocol Withdrawal Application Form

6.14 案件流程表

6.14 Protocol Review Routing Form

6.15 人體研究/試驗計畫許可書

6.15 Certificate of Approval