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-2012 IRB-Regulations of Operation-2012	文件名稱 Title	修正案審查管理程序書 SOP for Protocol Amendments
訂定單位 Composed by	人體研究倫理審查委員會 The IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □Confidential □Highly Confidential
適用單位 Applied to	□全院 □**All units in the hospital** ■其他，請註明：人體研究倫理審查委員會 ■**Other (Please specify): The IRB Committees**		

版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
A	8	新訂。Newly composed.	20140519
B	8	由人體試驗委員會標準作業程序 5.4 版轉換成此版本。 This version was converted from “Version 5.4 of the Standard Operating Procedure of the Human Research Committee.”	20141125
C	8	1.修改 5.1 流程圖之相關文件。 1. The list of relevant documents was revised in item 5.1 Flow Chart. 2.新增 5.2.3.4.a-c 對照表相關內容。 2. New content was added to the comparison table in item 5.2.3.4 a-c. 3.新增 5.2.8 計畫主持人手冊及個案報告表更新繳費及審查之處理方式。 3. The payment method and review process were updated in the investigator’s brochure and case report form in item 5.2.8. 4.修改 5.4 標題（原決定修正風險），並修改 5.1 流程圖之步驟及相關文件。 4. The title of item 5.4 was revised (the original was “the decided amendment of risk”), and the list of relevant documents was revised in item 5.1 Flow Chart. 5.修改 5.4.3.10 計畫主持人手冊及個案報告表更新收費及許可書處理方式。 5. The payment method and procedure of issuing the Certificate of Approval were updated in the investigator’s brochure and case report form in item 5.4.3.10. 6.新增 5.6.5 審查結果為「同意修正，提大會追認/核備」且不需回覆之計畫之處理方式。 6. Item 5.6.5 was added regarding the procedure of the review decision being “amendments approved and sent to the full board for confirmation” without requiring the PI’s response.	20150923

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C	8	7.修改 5.7.2 若審查結果為「同意修正，於大會追認/核備」之程序。 7. Item 5.7.2 was revised regarding the procedure of the review determination being “amendments approved and sent to the full board for confirmation.” 8.修改 5.7.4：刪除審查結果為「同意修正，必須提大會複審」之項目。 8. The following was deleted from item 5.7.4: The review determination of “amendments approved and sent to the full board for further review.” 9.修改 5.7.5：刪除微幅修正及重大修正案件回覆內容。 9. The following was deleted from item 5.7.5: The response regarding protocols of minor amendments and major amendments. 10.修改附件 6.7 表單名稱：原「人體試驗研究計畫修正案許可書」改為「人體研究/試驗計畫修正案許可書」。 10. The document title in Appendix 6.7 was revised: The Certificate of “Amendment of Clinical Research” was replaced by “Amendment of Clinical Trial.” 11.新增附件 6.8「承接其他合法審查會通過之研究計畫修正案」送審清單。 11. Appendix 6.8 was added: Submission Checklist of “Contracted Research Project Approved by Another Legal IRB”	20150923
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「修正案案件審查重點注意事項檢核表」，並修改 5.1、5.5.3、5.10、附件 6.4。 2. The original “Reviewers’ Comments Form” was replaced by “IRB Review Checklist for Protocol Amendment,” and items 5.1, 5.5.3, 5.10 and Appendix 6.4 were revised.	20160318

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D	9	3.文字校正。 3. Typos were fixed. 4.新增 5.4.3.13 計畫為競爭型收案人數規定。 4. Item 5.4.3.13 was added regarding regulations on the number of subjects if the research involves competitive enrollment. 5.新增 5.5.2 遴選副主任委員擔任審查委員之作業方式。 5. Item 5.5.2 was added regarding the procedure of selecting the Vice Chair to be a reviewer. 6.修改 5.7.5 申請延長回覆期限之規定。 6. The regulation on the time limit of extension for submitting response was revised in item 5.7.5. 7.新增 5.7.6 c-IRB 案件申請延長回覆規定。 7. Item 5.7.6 was added regarding the regulation on the time limit of extension for submitting response in the case of c-IRB protocol review. 8.修改 5.9.1：刪除歸還送審文件及修正許可書之效期。 8. The following was deleted in item 5.9.1: The return of submitted documents and the validity of the Certificate of Amendment of Clinical Trial. 9.刪除原附件 6.2 PTMS 變更案申請書，並加註說明。 9. The original Appendix 6.2 “PTMS Documents” was deleted, and explanation was added.	20160318

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E	9	1.修改 5.1 流程圖「決定審查方式」之權責。 1. The responsible personnel was revised regarding "Determination of Review Category" in 5.1 Flow Chart. 2.修改 5.2.1 修正案準備文件：附註舊案須準備及新增採 PTMS 系統申請案之說明。 2. The list of required documents for protocol amendments was revised in item 5.2.1: Explanation was added regarding the preparation for submission of a previously approved protocol and regarding the application through PTMS. 3.修改 5.2.5：增列研究成員需提供顯著財務利益暨非財務關係申報表。 3. Item 5.2.5 was revised: The research members are required to submit statements of disclosure of significant financial and non-financial conflicts of interest. 4.刪除原 5.2.8 計畫主持人手冊及個案報告表更新需開立許可書之流程。 4. The original item 5.2.8 was deleted regarding the requirement of re-issuing the Certificate of Approval if the investigator's brochure or the case report form was updated. 5.修改 5.4.3.10 主持人手冊(IB)及個案報告表(CRF)更新免收審查費之類別說明。 5. Item 5.4.3.10 was revised regarding the explanation on waiving review fees for updating investigator's brochure and case report form.	20170709

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E	9	6.修改 5.5.1 圈選審查委員之權責：刪除（副）主任委員。 6. Item 5.5.1 was revised regarding the responsible personnel for selecting reviewers: “(Vice) Chair” was deleted. 7.修改 5.5.3 修正計畫行政審查：刪除不需開立繳費單。 7. The following sentence was deleted in Item 5.5.3 regarding the administrative review of protocol amendments: A payment slip does not need to be issued. 8.修改 5.6.1：刪除若有意見，得以另紙繕寫審查意見。 8. The following sentence was deleted from item 5.6.1: Further review comments (if any) may be written on a separate piece of paper. 9.修改 5.6.2：刪除轉交回覆意見請審查委員再次評核。 9. The following sentence was deleted from item 5.6.2: The response to reviewers’ comments should be sent to reviewers for evaluation. 10.新增 5.6.5 計畫案之審查類型、5.6.5.1.b-c 一般審查入會排程說明；新增簡易審查 5.6.5.2.a 須再補充說明、b 提大會討論、c 同意修正，排入會期說明。 10. The following items were added: 5.6.5 Protocol review categories, 5.6.5.1 b-c Procedure of scheduling full board review. The following items were added in 5.6.5.2 Expedited review: a. further explanation required, b. submit to IRB board meeting for discussion, c. amendment approved; the amendment will be presented in an IRB board meeting. 11.修改 5.7 轉交審查委員意見之方式：新增電子檔。 11. The way of sending reviewers’ comments was revised in item 5.7: “Electronic file” was added.	20170709

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E	9	12.刪除原 5.7.2 審查結果為「同意修正，於大會追認/核備」、原 5.7.2.1 排入大會說明、原 5.7.3「須再補充說明」、原 5.7.4「提大會討論」之說明。 12. The following original items were deleted: 5.7.2 - the review result of “amendments approved; the protocol will be confirmed/recorded in an IRB board meeting;” 5.7.2.1 - the protocol amendments will be scheduled to be presented in an IRB board meeting; 5.7.3 further explanation required; and 5.7.4 the protocol amendments will be submitted to the IRB board meeting for discussion. 13.新增 5.9.2（副）主任委員擔任審查委員批示說明。 13. Item 5.9.2 was added regarding the explanation on the approval of the (Vice) Chair serving as a reviewer. 14.修改 5.9.5：刪除重大修正案件，應依一般審查辦理。 14. The following sentence was deleted from item 5.9.5: Significant changes to a protocol should be submitted to the full board for review. 15.修改 5.9.6：刪除新案送審為『簡易審查』開立「人體研究/試驗計畫修正案許可書」之說明。 15. The following was deleted from item 5.9.6: the explanation regarding the issuance of Certificate of Protocol Amendment for expedited review protocols. 16.刪除原附件 6.5-6.9 修正案案件審查重點注意事項檢核表(含適用屬孕婦或胎兒、未成年人、生存力不明的新生兒、受拘禁人、無法存活的新生兒之研究)；抽換附件 6.1-2、6.6-7、6.9；新增附件 6.9 審查委員遴選表。 16. The original appendices 6.5 to 6.9 were deleted: IRB Review Checklists (for research involving pregnant women or fetuses, children, neonates with uncertain viability, prisoners, or nonviable neonates). Appendices 6.1, 6.2, 6.6, 6.7, and 6.9 were replaced. Appendix 6.9 “Reviewers Selection Form” was added.	20170709

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F	20	1.修改 5.2.3.4.b：對照表的呈現方式，除了主持人手冊以外，皆以上述規定辦理。 1. Item 5.2.3.4.b was revised: The presentation of the comparison Table, except for the Investigator's Brochure, is handled in accordance with the above provisions. 2.修改 5.2.3.4.c 為主持人手冊。 2. Item 5.2.3.4.c was revised the Investigator's Brochure. 3.增加 5.4.2 衛生福利部函文發文日期為「民國 103 年 07 月 28 日」。 3. The issuance date of the letter from the Ministry of Health and Welfare "28 July 2014" was added in item 5.4.2. 4.新增 5.8.2：會議投票結果為「核准」案件，由承辦人員陳送（副）主任委員/執行秘書核可後，開立「人體研究/試驗計畫修正案許可書」。 4. Item 5.8.2 was added: If the IRB full board voting result on the protocol amendments is "approval," then the staff member should submit the case to the (Vice) Chair/Executive Secretary for confirmation and issue the Certificate of Protocol Amendment. 5.新增 5.8.3：若投票結果為「修正後核准」，計畫主持人補件（回覆審查意見）天數為 7 個日曆天，若超過 14 個日曆天則逕行撤案；於回覆期限到期前，申請人有特殊理由，得書面申請延長回覆期限 14 個日曆天，以一次為原則。超過回覆期限且擬書面申請延長回覆期限之案件，將先陳送執行秘書、（副）主任委員批示是否同意受理。若是同意受理，承辦人員陳送（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/試驗計畫修正案許可書」。	20190527

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F	20	5. Item 5.8.3 was added: If the voting result is “approval after revision,” the PI should submit supplementary documents (or respond to reviewers’ comments) within 7 calendar days. If the PI does not respond within 14 days, the protocol should be withdrawn from IRB consideration. Before the due date, the PI may request for extension of up to 14 calendar days with an acceptable excuse. The PI may not request for extension more than one time. If the PI intends to request for extension after the deadline for requesting for extension is past, the case shall be submitted to the Executive Secretary and the (Vice) Chair to determine whether it should be processed. If the case is determined to be processed, the staff member will issue the Certificate of Protocol Amendment after submitting the case to the (Vice) Chair/Executive Secretary for approval. 6.新增 5.8.4：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，最遲不能超過 14 個日曆天，若超過 14 個日曆天則逕行撤案；於回覆期限到期前，申請人有特殊理由，得書面申請延長回覆期限 14 個日曆天，以一次為原則。超過回覆期限且擬書面申請延長回覆期限之案件，將先陳送執行秘書、(副）主任委員批示是否同意受理】內回覆審查意見，承辦人員彙整資料後排入最近一次大會議程討論，若有其他需求，依大會之決議辦理。 6. Item 5.8.4 was added: If the voting result is “further review after revision,” the PI should respond to the reviewers’ comments before the due date (the PI should try to respond within 7 days and no later than 14 days. If the PI does not respond within 14 days, the protocol should be withdrawn from IRB consideration. Before the due date, the PI may request for extension of up to 14 calendar days. The PI may not request for extension more than one time.	20190527

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F	20	If the PI intends to request for extension after the deadline is past, the case shall be submitted to the Executive Secretary and the (Vice) Chair for approval). Once the staff member has received and compiled the response and supplementary documents from the PI, the case should be placed on the agenda for the next scheduled IRB board meeting for discussion. The board meeting will determine how to process any other additional requests by the PI. 7.因應 IRB 無紙化送審作業，修改與「書面資料」相關之內容。 7. Process related to hardcopies was revised to comply with the new IRB policy of paperless submission. 8.修改原 5.8.2 之標號為 5.8.5。 8. The original item number 5.8.2 was changed to 5.8.5. 9.抽換附件 6.1、6.4、6.6、6.8。 9. Appendices 6.1, 6.4, 6.6, and 6.8 were replaced.	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	20	1. 修改 5.2.3.4.b：對照表的呈現方式，除了計畫主持人手冊及個案報告表以外，皆以上述規定辦理。 1. Item 5.2.3.4.b was revised: The presentation of the comparison Table, except for the Investigator's Brochure and Case Report Form, is handled in accordance with the above provisions. 2. 2.修改 5.2.3.4.c：主持人手冊及個案報告表的對照表：①維持原呈現方式的規定、②可提供以中文撰寫的變更內容及變更理由(如：summary of changes / rationale of changes)。 2. Item 5.2.3.4.c was revised: The comparison Table of the Investigator's Brochure and Case Report Form: (1) keep the original method of presentation; (2) provide a summary of changes and the rationale for changes in Chinese.	20191018
H	19	1. 新增表單名稱：「PTMS 修正案案件審查重點注意事項檢核表」。 1. Document title was added: "PTMS Review Checklist for Protocol Amendment." 2. 修改 5.4.3 行政變更項目部份文字，以至與財團法人醫藥品查驗中心(CDE)公告的 c-IRB 行政變更項目一致。 2. Revised the part of the administrative change in item 5.4.3, in order to be consistent with the c-IRB's administrative change which was announced by Center for Drug Evaluation(CDE). 3. 修改 5.6.5.1 一般審查之審查結果。 3. Revised the review decision of Full Board Review in item 5.6.5.1.	20210528

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-2012 IRB-Regulations of Operation-2012	文件名稱 Title	修正案審查管理程序書 SOP for Protocol Amendments
訂定單位 Composed by	人體研究倫理審查委員會 The IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □Confidential □Highly Confidential
適用單位 Applied to	□全院 □**All units in the hospital** ■其他，請註明：人體研究倫理審查委員會 ■**Other (Please specify): The IRB Committees**		

版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
H	19	4. 修改 5.6.5.2 簡易審查之審查結果。 4. Revised the review decision of Expedited Review in item 5.6.5.2. 5. 修改 5.7.3、5.8.3、5.8.4 之計畫主持人回覆期限為 28 個日曆天，並刪除申請展延說明文字。 5. Item 5.7.3, 5.8.3 and 5.8.4 were revised the PI's reply period to 28 calendar days, and deleted the description of the extension. 6. 刪除 5.7.4 之申請展延說明文字。 6. Deleted the description of the extension in item 5.7.4. 7. 抽換附件 6.1、6.5、6.7、6.8 及 6.9。 7. Appendices 6.1, 6.5, 6.7, 6.8 and 6.9 were replaced.	20210528
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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-2012 IRB-Regulations of Operation-2012	文件名稱 Title	修正案審查管理程序書 SOP for Protocol Amendments
訂定單位 Composed by	人體研究倫理審查委員會 The IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □Confidential □Highly Confidential
適用單位 Applied to	□全院 □All units in the hospital ■其他，請註明：人體研究倫理審查委員會 ■Other (Please specify): The IRB Committees		

版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
I	19	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. 修改 5.4.2 文句為「已退出 c-IRB 審查機制之案件，則回歸一般審查程序辦理。」 2. Item 5.4.2 was revised: The protocol that has exited the mechanism of c-IRB review will return to the full board review process. 3. 5.9.3 修改許可書核發方式。 3. Item 5.4.2 was revised the way of issuing the Certificate of Protocol Amendment. 4. 刪除 5.9.5 及 5.9.6。 4. Item 5.9.5 & Item 5.9.6 were deleted. 5. 抽換附件 6.1、6.2、6.4 ~ 6.8。 5. Appendices 6.1, 6.2, 6.4-6.8 were replaced.	20230717
J	19	1. 修改 5.4.1 審查方式。 1. Revised the Review Category in item 5.4.1. 2. 抽換附件 6.1、6.8。 2. Appendices 6.1, 6.8 were replaced.	20250910

訂修廢 Composed/Revised/Deleted	審核 Reviewed	核准 Approved

※管制文件不得擅自塗改及做記號並禁止影印。

※本文件以 KMS 系統為最新版本，紙本發佈需經 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.

臺中榮民總醫院
Taichung Veterans General Hospital

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

文件編號 Document Number	IRB-本會-工作常規-2012 IRB-Regulations of Operation-2012	文件名稱 Title	修正案審查管理程序書 SOP for Protocol Amendments

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.	

※請各會辦單位主管惠賜審查意見後核章，必要時得直接與訂定單位協商。

※**The head of each processing unit is advised to provide comments before signing/stamping to approve. If needed, it is recommended that the head of each processing unit discuss with the unit that made the SOP.**

1.目的

1. Purpose

此管理程序書的目的是在描述人體研究倫理審查委員會如何處理及審查計畫修正案。

The purpose of this SOP is to manage the IRB review of protocol amendments.

2.適用範圍

2. Scope

本管理程序書是針對人體研究倫理審查委員會已通過但又提出修正申請之研究計畫案。修正案需經由人體研究倫理審查委員會審查及通過後才能再度開始執行。

This SOP applies to amendment applications of protocols approved by the IRB. Protocol amendments must be reviewed and approved by the IRB before implementation.

3.參考文件

無。

3.References

None.

4.名詞定義

無。

4.Definitions

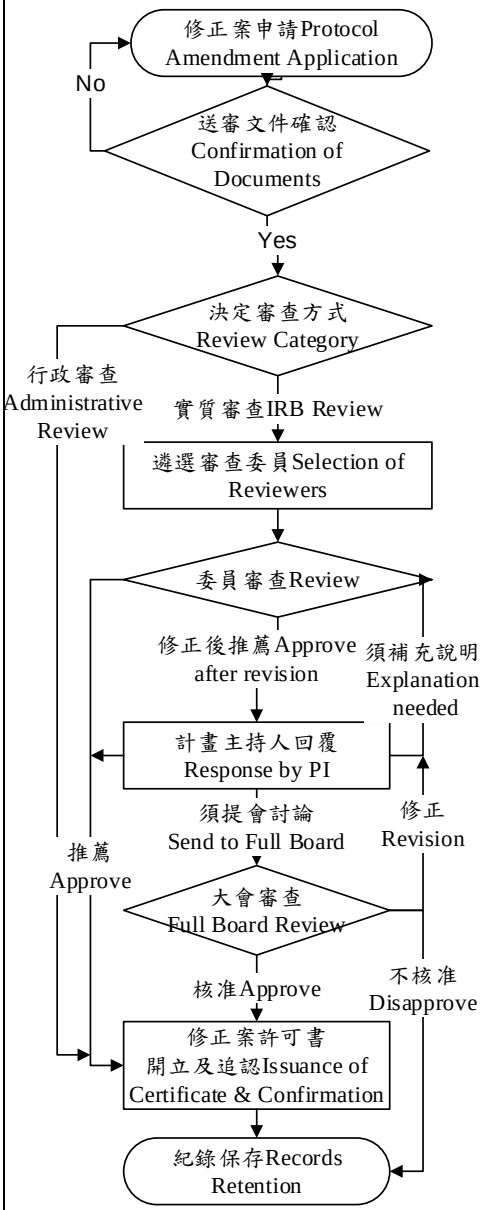
None.

5.作業內容

5. Procedure

5.1 修正案審查管理流程圖

5.1 Flow Chart of Protocol Amendment Review

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	計畫主持人 Principal Investigator: 承辦人員 Staff Members 執行秘書/（副）主任委員 Executive Secretary /(Vice) Chair 執行秘書/（副）主任委員 Executive Secretary/(Vice) Chair 審查委員 Reviewers 計畫主持人 Principal Investigator 委員/承辦人員/執行秘書/（副）主任委員 Members/Staff/Executive Secretary/(Vice) Chair 承辦人員 Staff Members 承辦人員 Staff Members	修正案申請相關表單 Protocol Amendment Application Form 送審文件/審查費收據/案件流程表 Submission documents/Review fee payment receipt/Protocol Review Routing Form 送審文件 Submission documents 送審文件 Submission documents PTMS 修正案案件審查重點注意事項檢核表 PTMS Review Checklist for Protocol Amendment 人體研究倫理審查委員會審查意見回覆表 Form of Response to IRB Reviewers' Comments 會議紀錄 Meeting Minutes 人體研究/試驗計畫修正案許可書 Certificate of Protocol Amendment

5.2 修正案申請

5.2 Protocol Amendment Application

5.2.1 計畫主持人準備修正案文件（舊案須準備正本 1 份及影印本 1 份共 2 份）。

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

5.2.2 若送審文件之「許可書」有效期限已經過期，須先送追蹤審查報告，俟追蹤審查報告通過後，方可受理修正案。

5.2.2 If the Certificate of Approval of the protocol has expired, a continuing review report must be submitted and approved before the application for protocol amendment will be accepted and processed.

5.2.3 計畫主持人提出的文件，應包括計畫修正案現存及先前通過的文件：

5.2.3 The PI should submit the following documents, which must include current protocol amendment documents and previously approved documents:

5.2.3.1 計畫修正案申請表/PTMS 變更案申請書（申請人需簽章）。

5.2.3.1 Protocol Amendment Application Form/PTMS Protocol Amendment Application Form (Signed by PI)

5.2.3.2 陳述/描述修正內容，說明修正原因。

5.2.3.2 A summary of proposed changes in the research and the rationale for the changes

5.2.3.3 提供計畫及相關文件之修正版本。

5.2.3.3 Revised documents related to the protocol.

5.2.3.4 提出核對原始計畫間差異之修正前後對照表，文件更改處必須畫線或標示。

a.新增文件也請檢附修正前後對照表。

b.對照表的呈現方式，除了計畫主持人手冊及個案報告表以外，皆以上述規定辦理。

c.主持人手冊及個案報告表的對照表：①維持原呈現方式的規定、②可提供以中文撰寫的變更內容及變更理由(如：summary of changes / rationale of changes)。

5.2.3.4 A comparison table of the original protocol and the proposed modified protocol with the changes highlighted or underlined should be provided.

a. Comparison tables showing revisions of additional documents should be submitted.

b. The presentation of the comparison Table, except for the Investigator's Brochure and Case Report Form, is handled in accordance with the above provisions.

c. The comparison Table of the Investigator's Brochure and Case Report Form: (1) keep the original method of presentation; (2) provide a summary of changes and the rationale for changes in Chinese.

5.2.3.5 修正計畫書需要註明版本及日期。

5.2.3.5 The version and date of the modified protocol should be specified.

5.2.4 修正案性質若為有委託者計畫，每次申請需繳交修正案審查費，未繳費者不受理申請文件。

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

5.2.5 新增加共（協）同計畫主持人需提供共（協）同計畫主持人之「個人簡歷」、「訓練證明」、「計畫主持人利益迴避聲明書」、「研究成員保密聲明書」及「顯著財務利益暨非財務關係申報表」。【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）皆應填報利益迴避聲明書。】

5.2.5 If a co-investigator or sub-investigator is added to the research personnel, the following documents of the co-investigator or sub-investigator should be submitted: CV, training certificate, conflict of interest statement, confidentiality statement, and statement of significant financial / non-financial relationship. 【All investigators (including principal investigator, co-investigator, and sub-investigator) should fill out and sign a “Conflict of Interest Statement” 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.

5.2.6 新增加研究場所需提供「研究場所同意書」。

5.2.6 If a new research site is added in the protocol, the “Research Site Authorization Statement” must be submitted.

5.2.7 計畫主持人自退休生效之日起，即不能再為計畫主持人，計畫主持人應於事先提出計畫修正案，更改計畫主持人。

5.2.7 If the PI retires, he/she should not continue to be the PI of the study. The PI should apply for protocol amendments in advance to change the PI of the protocol.

5.3 送審文件確認

5.3 Confirmation of Submissions

承辦人員依收到的文件循「計畫書送審管理」及「保密協議書及利益迴避聲明書」之管理程序書辦理及編號，若是第一次計畫修正案，則在原本會 IRB 編號後加上「#1」，第二次計畫修正案則為「#2」，以此類推。

The staff member should process the application and give it a number according to the SOP for protocol submission and the SOP for confidentiality and conflict of interest statements. If it is the first revised version of the proposal, the document continues to use the original IRB assigned number, with "#1" added for the first amendment, and "#2" added for the the

second amendment, and so on to indicate the revised versions.

5.4 決定審查方式

5.4 Evaluation of Review Category

5.4.1 審查方式以該計畫之原來負責初審委員為優先，如遇特殊狀況得請（副）主任委員重新遴選審查委員。若為「行政審查」修正之案件，則送請執行秘書進行判定。

5.4.1 The review category would be reviewed by the original reviewers of the protocol. Under special circumstances, the (Vice) Chair is assigned the new reviewers. For the administrative review of a protocol amendment, the determination would be made by the Executive Secretary.

5.4.2「新案」若經一般程序審查，後續之監督管理（即追蹤審查、修正案、結案...等），亦同為一般程序審查為之（民國 103 年 07 月 28 日衛生福利部衛部醫字第 1030120703 號函）。「新案」若是簡易程序審查，後續之監督管理（即追蹤審查、修正案、結案...等），亦同為簡易程序審查。（已退出 c-IRB 審查機制之案件，則回歸一般審查程序辦理。）

5.4.2 If the protocol is sent to the full board for review as a new protocol, all of the follow-up monitoring (including continuing review, protocol amendment, protocol closure, etc.) should be sent to the full board for review as well (in compliance with the letter issued by the Ministry of Health and Welfare on 28 July 2014, pursuant to Wei-Bu-Yi-Zi No. 1030120703). If the protocol qualifies for expedited review as a new protocol, all of the follow-up monitoring (including continuing review, protocol amendment, protocol closure, etc.) should go through expedited review procedure as well. (The protocol that has exited the mechanism of c-IRB review will return to the full board review process.)

5.4.3 承辦人員得依以下修正項目進行行政審查，直接送交執行秘書/（副）主任委員審閱通過後，請（副）主任委員覆核。

5.4.3 The staff member may conduct an administrative review of

a protocol amendment application of any of the items listed below. Once a protocol amendment passes the administrative review, the staff member should submit the amendment to the Executive Secretary/(Vice) Chair for approval, and to the (Vice) Chair for confirmation of the approval.

5.4.3.1 增加或變更計畫主持人/試驗共（協）同計畫主持人/研究人員、計畫主持人或試驗/研究人員之職稱、所屬單位。

5.4.3.1 The addition or change of PI/Co-I/Sub-I/researchers, PI/research personnel's title, or affiliation.

5.4.3.2 增加或變更試驗執行機構。

5.4.3.2 The addition or change of the institution that implements the research.

5.4.3.3 變更試驗單位(公司)。

5.4.3.3 The change of the research sponsor (company).

5.4.3.4 僅變更受試者同意書中聯絡人資訊（如：研究護士異動、更換電話）。

5.4.3.4 The change of the information of the contact person (such as the change of research nurses, telephone numbers).

5.4.3.5 其他與試驗相關人員資訊異動。

5.4.3.5 The change of the information of other research-related personnel.

5.4.3.6 實驗室地址異動。

5.4.3.6 The change of the address of the research site.

5.4.3.7 計畫書/同意書相關文件僅做格式調整或錯別字勘誤修正（如：誤字）。

5.4.3.7 The adjustment of the format and corrections of typographical errors (including incorrect wording) in the protocol/ICF or other relevant documents.

5.4.3.8 個案報告表格式調整。

5.4.3.8 The adjustment of the format of the case report form.

5.4.3.9 僅修正版本編號或頁碼，不改變文件內容。

5.4.3.9 Modification of the version number or page numbers without changing the content of the document.

5.4.3.10 不改變既有風險利益與影響受試者權益之主持人手冊(IB)及個案報告表(CRF)更新。

5.4.3.10 An update of the Investigator's Brochure (IB) or the Case Report Form (CRF) without changing the risk/benefit ratio or the impact on the subjects' rights.

5.4.3.11 展延試驗期限。

5.4.3.11 An extension of study period.

5.4.3.12 修改原因為本院核准後，至衛生福利部申請核准時，發生衛生福利部要求修改之情況，計畫主持人或試驗委託廠商得依衛生福利部審查意見修改計畫書、受試者同意書，公文副本及相關修改內容應送人體研究倫理審查委員會核備。

5.4.3.12 A protocol approved by TCVGH was requested by the Ministry of Health and Welfare to be modified. The PI or the clinical trial sponsor may modify the protocol and/or the ICF according to the review comments by the Ministry of Health and Welfare. A photocopy of the official correspondence and documents containing relevant modifications should be submitted to TCVGH-IRB for confirmation and recordation.

5.4.3.13 若該計畫為競爭型收案，在全球總人數不變下，變更本院收案人數。

5.4.3.13 If the study involves competitive enrollment, the number of enrolled participants in TCVGH will be changed, while the global total number of participants will not be changed.

5.4.3.14 其他經（副）主任委員確認為行政變更者

5.4.3.14 Other administrative changes confirmed by the (Vice) Chair.

5.4.4 執行秘書/（副）主任委員判定重大修正的標準包括但不僅限於下列各項，需送大會複審。

5.4.4 Major changes to the protocol as determined by the Executive Secretary/(Vice) Chair must be submitted to the full board for review. Major changes include but are not limited to:

5.4.4.1 任何納入/排除條件的改變。

5.4.4.1 Changes to the inclusion and exclusion criteria for research participants.

5.4.4.2 受試者數目有意義的改變。

5.4.4.2 Significant change to the number of research participants.

5.4.4.3 若為簡易審查通過案，但修正內容已超過簡易審查範圍核對表之條件及其他經認定為重大修正之狀況。

5.4.4.3 The proposed changes to an expedited review protocol are beyond the scope of the expedited review checklist, or if major changes are proposed.

5.4.4.4 影響受試者權益（包括風險與利益的改變）。

5.4.4.4 The rights of the subjects are affected (including changes of the risk-benefit ratio).

5.4.4.5 其他經審查委員認為有疑慮之案件。

5.4.4.5 Other protocols that reviewers have concerns about.

5.5 遴選審查委員

5.5 Selection of Reviewers

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

5.5.1 The staff member should submit the application

documents to the Executive Secretary. The Executive Secretary should then assign one or two reviewers, preferably the original reviewers of the protocol. New reviewers may be assigned under special circumstances.

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

5.5.2 If the Vice Chair serves as a reviewer, the protocol approval should be signed by the Chair, and vice versa. Under special circumstances, the Executive Secretary may be authorized to sign the approval.

5.5.3 若執行秘書/（副）主任委員決定此計畫之修正之狀況為行政審查，行政審查案件不需附「PTMS 修正案案件審查重點注意事項檢核表」。

5.5.3 If the Executive Secretary/(Vice) Chair determines that the protocol amendment qualifies for an administrative review, then the review does not need to include the PTMS Review Checklist for Protocol Amendment.

5.6 委員審查

5.6 Review

5.6.1 委員應依照試驗之基本倫理原則進行審查，確定試驗之執行均符合應有程序與對受試者之保護。

5.6.1 The reviewer should conduct the review according to the basic ethics principles of clinical trials and ensure that the implementation of the trial complies with required procedures and protects the rights of the research subjects.

5.6.2 審查委員評估「修正案」或「受試者同意書」是否影響受試者安全及權益，由承辦人員將匿名之審查意見交計畫主持人，並限期回覆。

5.6.2 The reviewer should evaluate if the modified protocol or ICF will affect the safety and rights of the research subjects. The staff member should send the anonymous reviewers'

comments to the PI and request the PI to respond within a limited time period.

5.6.3「計畫主持人手冊」若有重要資訊更新，有影響受試者安全及權益之虞，委員審查時需判定是否修改「受試者同意書」。

5.6.3 If important information is updated in the Investigator's Brochure which might affect the safely and rights of the research subjects, the reviewer should determine if the ICF should be modified.

5.6.4 審查委員若有疑慮，則提報大會討論。

5.6.4 Any concerns of the reviewers should be submitted to the IRB board meeting for discussion.

5.6.5 計畫案之審查類型為一般審查及簡易審查。

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

5.6.5.1 一般審查

a.若審查結果為「建議通過」且不需回覆之計畫，則直接排入最近一次大會議程核備。

b.其委員審查的結果為「建議修正或提供進一步說明」，計畫主持人應於限期內回覆審查意見，承辦人員彙整資料後將該案件呈送入會批示單予執行秘書、（副）主任委員審核，若審核的結果為「同意排入最近一次的大會核備」，則直接排入最近一次大會議核備。

c.其委員審查的結果為「建議不通過(提會討論)」，計畫主持人應於限期內回覆審查意見，承辦人員彙整資料後排入最近一次大會議程討論。

5.6.5.1 Full Board Review

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

b. If the review decision is "recommended for revision or

provided further explanation" and response from the PI is required, then the PI should respond to the reviewers' comments by the due date. The staff member should compile relevant documents and submit them to the Executive Secretary and the (Vice) Chair for approval. If the result is "approved to be placed on the agenda for the next scheduled IRB board meeting for confirmation," then the case should be placed on the agenda for the next scheduled board meeting for confirmation.

c. If the review decision is "sent to the full board for discussion," then the PI should respond to the reviewers' comments by the due date. The staff member should compile relevant documents and place the case on the agenda for the next scheduled board meeting for discussion.

5.6.5.2 簡易審查

a.其委員的審查結果若為「建議修正或提供進一步說明」，計畫主持人應於限期內回覆審查意見及檢送更正附件。若審查意見註明「修正後再審」，承辦人員再將計畫主持人之回覆意見轉請審查委員再次評核。

b.其委員的審查結果若為「不符合簡易審查，改送一般審查」，計畫主持人應於限期內回覆審查意見，承辦人員彙整資料後排入最近一次大會議程討論。

c.其委員的審查結果若為「通過」且不需計畫主持人回覆之計畫，則承辦人員應先將該案件陳送執行秘書、(副)主任委員審核後核發許可書並提至大會追認。

5.6.5.2 Expedited Review

a. If the review decision is "recommended for revision or provided further explanation," then the PI should respond to the reviewers' comments and submit relevant revised documents. If the review decision is "further review after revisions," the response and

supplementary documents from the PI should be sent to the reviewers for evaluation.

b. If the review decision is "not meet the requirements for expedited review and sent to the full board for discussion," then the PI should respond to the reviewers' comments by the due date. The staff member should compile relevant documents and place the case on the agenda for the next scheduled board meeting for discussion.

c. If the review decision is "recommended for approval" and no response from the PI is required, then the staff member should submit the case to the Executive Secretary and the (Vice) Chair for approval. Once the case is approved, a Certificate of Protocol Amendment should be issued, and the amendment should be submitted to the board meeting for confirmation.

5.7 計畫主持人回覆

5.7 The PI's Response to Reviewers' Comments

5.7.1 當審查委員有意見時，承辦人員應隱去審查者姓名並將意見內容以電子檔交計畫主持人「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」，請其回覆。

5.7.1 If the reviewer has comments, the staff member should remove the reviewer's name before sending the comments to the PI. The comments should be sent to PI in an electronic file. The Form of Response to IRB Reviewers' Comments should be included for the PI to give response to the comments.

5.7.2 須回覆委員審查意見之案件，計畫主持人於限期內回覆審查意見後，承辦人員應先將該回覆呈送執行秘書、(副) 主任委員審核，以確認是否可排入最近一次會期核備或需提至大會討論。

5.7.2 If the review requires the PI to submit response to the reviewers' comments, then the PI should give response by

the due date. The staff member should submit the response to the Executive Secretary and the (Vice) Chair for evaluation to decide if the case should be placed on the agenda for the next scheduled board meeting for confirmation or discussion.

5.7.3 審查意見通知計畫主持人後需於 7 個日曆天回覆，若超過 28 個日曆天仍未回覆則逕行撤案。

5.7.3 The PI should submit the response to reviewers' comments within 7 calendar days after having received the comments. If the PI does not respond within 28 calendar days, then the protocol will be withdrawn from IRB consideration.

5.7.4 c-IRB 案件回覆意見以 3 個工作天為原則。

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

5.8 大會審查

5.8 IRB Board Meeting

5.8.1 修正下列項目者，可評估提大會討論

5.8.1 The following modifications may be determined to be sent to the board meeting for discussion.

5.8.1.1 新增或刪除治療。

5.8.1.1 Addition or deletion of a treatment.

5.8.1.2 新增或刪除檢查項目。

5.8.1.2 Addition or deletion of an examination.

5.8.1.3 使用之藥物劑量有意義的減少及增加。

5.8.1.3 A significant decrease or increase of drug dosage used in the study.

5.8.1.4 研究設計及進行方法的改變。

5.8.1.4 Changes in research design or implementation.

5.8.1.5 用藥方法的改變，例如口服改成靜脈注射。

5.8.1.5 Changes in how the drug enters the subject's body, e.g. from oral dosage to intravenous injection.

5.8.1.6 納入/排除條件的改變。

5.8.1.6 Changes in inclusion/exclusion criteria.

5.8.1.7 受試者數目有意義的改變。

5.8.1.7 A significant change in the number of research participants.

5.8.2 會議投票結果為「核准」案件，由承辦人員陳送（副）主任委員/執行秘書核可後，開立「人體研究/試驗計畫修正案許可書」。

5.8.2 If the IRB full board voting result on the protocol amendments is "approval," then the staff member should submit the case to the (Vice) Chair/Executive Secretary for confirmation and issue the Certificate of Protocol Amendment.

5.8.3 會議投票結果若為「修正後核准」，計畫主持人補件（回覆審查意見）天數為 7 個日曆天，若超過 28 個日曆天仍未回覆則逕行撤案。

5.8.3 If the voting result is "approval after revision," the PI should submit supplementary documents (or respond to reviewers' comments) within 7 calendar days. If the PI does not respond within 28 calendar days, the protocol should be withdrawn from IRB consideration.

5.8.4 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，最遲不能超過 28 個日曆天，若超過 28 個日曆天則逕行撤案】內回覆審查意見，承辦人員彙整資料後排入最近一次大會議程討論，若有其他需求，依大會之決議辦理。

5.8.4 If the voting result is "further review after revision," the PI should respond to the reviewers' comments before the due date. (The PI should try to respond within 7 days and no

later than 28 calendar days. If the PI does not respond within 28 calendar days, the protocol should be withdrawn from IRB consideration.) The staff member should compile relevant documents and place the application on the agenda for the next scheduled board meeting for discussion. Any other outstanding requests should be handled in accordance with the decisions made in the IRB board meeting.

5.8.5 若大會投票結果為「不核准」，承辦人員將大會決議通知計畫主持人，該修正案之相關文件不得使用。

5.8.5 If the voting result in the board meeting is “disapproval,” then the staff member should inform the PI of the result. The documents submitted for the application of protocol amendment must not be used in the research.

5.9 修正案許可書開立及追認

5.9 Issuance of the Certificate of Protocol Amendment

5.9.1 修正案審查同意後，承辦人員陳送執行秘書、(副）主任委員覆核同意核發「人體研究/試驗計畫修正案許可書」。

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 Protocol Amendment 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 由承辦人員開立「人體研究/試驗計畫修正案許可書」一份，陳主任委員簽章後發予計畫主持人保存。

5.9.3 The staff member should issue the Certificate of Protocol Amendment and submit it to the Chair for approval stamp/signature. Then the Certificate of Protocol Amendment should be sent to the PI.

5.9.4 修正案與追蹤審查同時申請者，須俟通過追蹤審查後，方可送（副）主任委員審核。

5.9.4 If the PI applies for protocol amendment and continuing review simultaneously, the continuing review must be approved before the protocol amendment is sent to the (Vice) Chair for review and 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 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	修正案送件核對表 Protocol Amendment 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	修正案申請表/PTMS 變更案申請書 Protocol Amendment Application Form/PTMS Protocol Amendment 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	修正前後對照表 Comparison Table of Proposed Changes	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修正案案件審查重點注意事項檢核表/PTMS 修正案案件審查重點注意事項檢核表 IRB Review Checklist for Protocol Amendment/PTMS Review Checklist for Protocol Amendment	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
6	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
7	人體研究/試驗計畫修正案許可書 Certificate of Protocol Amendment	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed

編號 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
8	審查委員遴選表 Reviewers Selection Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed

6.附件

6. Appendices

「PTMS 變更案申請書」、「PTMS 修正案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，故不列附件管理。
"PTMS New Protocol Application Form", "PTMS Review Checklist for Protocol Amendment" 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 修正案送件核對表

6.1 Protocol Amendment Submission Checklist

6.2 修正案申請表

6.2 Protocol Amendment Application Form

6.3 修正前後對照表

6.3 Comparison Table of Proposed Changes

6.4 人體研究倫理審查委員會修正案案件審查重點注意事項檢核表

6.4 Protocol Amendments Review Checklist

6.5 人體研究倫理審查委員會審查意見回覆表

6.5 Form of Response to IRB Reviewers' Comments

6.6 案件流程表

6.6 Protocol Review Routing Form

6.7 人體研究/試驗計畫修正案許可書

6.7 Certificate of Protocol Amendment

6.8「承接其他合法審查會通過之研究計畫修正案」送審清單

6.8 Submission Checklist of "Contracted Research Project

Approved by Another Legal IRB”

6.9 審查委員遴選表

6.9 Reviewers Selection Form