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-2025 IRB-Regulations of Operation-2025	文件名稱 Title	非機構內之研究計畫審查管理程序書 SOP for Reviewing Non-TCVGH Research Protocols
訂定單位 Composed by	人體研究倫理審查委員會 The IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □Confidential □Highly Confidential
適用單位 Applied to	□全院 □**All units in the hospital** ■其他，並請註明：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. Page	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
A	4	新訂。Newly composed.	20140519
B	4	由人體試驗委員會標準作業程序 5.4 版轉換成此版本。 This version was converted from “Version 5.4 of the SOP of the Human Research Committee.”	20150119
C	4	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.文句修訂。 2. Minor changes in the wording. 3.刪除附件 6.1-6.6。 3. Appendices 6.1 to 6.6 were deleted.	20160318
C	4	依本院規定，於 2017 年 7 月 3 日重新審視本文件，內容無須修訂。 According to the regulations by TCVGH, this document was reviewed again on 3 August 2018 and no revision was needed.	20160318
C	8	依本院規定，於 2019 年 05 月 17 日重新審視本文件，內容無須修訂。 According to the regulations by TCVGH, this document was reviewed again on 17 May 2019 and no revision was needed.	20160318
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版次 Version	頁數 No. Page	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
C	8	依本院規定，於 2021 年 04 月 07 日重新審視本文件，內容無須修訂。 According to the regulations by TCVGH, this document was reviewed again on 07 April 2021 and no revision was needed.	20160318
D	8	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”.	20230420
E	8	1. 修改 5.1「非機構內之研究計畫審查管理流程圖」。 1. Revised “Flow Chart of Reviewing Non-TCVGH Research Protocols” in item 5.1. 2. 修改 5.5.1.2 及 5.5.1.3 之「秘書處」為「承辦人員」。 2. The “IRB Secretariat” was revised the “staff member” in item 5.5.1.2 and 5.5.1.3 3. 5.5.2.2 增加「非預期問題」。 3. Item 5.5.2.2 was added “unexpected problems.” 4. 修改 5.6 紀錄保存。 4. Item 5.6 Records Retention was revised.	20250513

訂修廢 Composed/Revised/Deleted	審核 Reviewed	核准 Approved

臺中榮民總醫院 2025.07.04 參考文件

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.**

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-2025 IRB-Regulations of Operation-2025	文件名稱 Title	非機構內之研究計畫審查管理程序書 SOP for Reviewing Non-TCVGH Research Protocols

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
2025.07.04
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

為促使本院人體研究倫理審查委員會受理非機構內研究計畫審查之管理有一明確之規範，特制訂本管理程序書。

1. Purpose

The purpose of this SOP is to provide guidelines for processing and reviewing protocols submitted from non-TCVGH principal investigators.

2.適用範圍

凡本院人體研究倫理審查委員會受理非機構內研究計畫審查之管理均適用本管理程序書。

2. Scope

This SOP applies to the review of all protocols unaffiliated to TCVGH.

3.參考文件

3. References

3.1「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 日自公布日施行。

3.1 Human Subjects Research Act, promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10000291401 dated 28 December 2011.

4.名詞定義

4. Definitions

4.1 非機構內之研究計畫(non-institutional research)：由其他機構委託本委員會審查，且沒有臺中榮民總醫院同仁參與之所有人體研究/試驗計畫案。

4.1 Non-TCVGH research: Research conducted outside TCVGH and submitted by another institution to be reviewed by TCVGH-IRB. No TCVGH personnel is involved in the research.

4.2 人體研究：人體研究法第 4 條：「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。」

4.2. Human subjects research: 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.作業內容

5. Procedure

5.1 非機構內之研究計畫審查管理流程圖

5.1 Flow Chart of Reviewing Non-TCVGH Research Protocols

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
受理非機構內案件 Acceptance of submissions from non-TCVGH research centers	承辦人員 Staff Members	各類計畫案相關文件 Protocol-related Documents
No / 行政審查 Administrative review	承辦人員 Staff Members	各類申請書/案件流程表/資料排列順序表 Application Forms/ Protocol Review Routing Form/ List of Organized Documents
Yes / 審查 IRB Review	審查委員/承辦人員 Reviewers/ Staff Members	依各審查程序之相關審查表單 Relevant Review Forms
執行後續行政作業 Follow-up administrative procedure	承辦人員/執行秘書/（副）主任委員 Executive Secretary/ (Vice) Chair Staff Members	臺中榮民總醫院人體研究倫理審查委員會審查意見回覆表 Taichung Veterans General Hospital Institutional Review Board Form of Response to IRB Reviewers' Comments
紀錄保存 Records retention	各業務承辦人員 Staff Members	計畫案/人體試驗研究計畫許可書 Protocol/Certificate of Approval

5.2 受理非機構內案件(non-institutional research)

5.2 Acceptance of Submissions from Non-TCVGH Research Centers

當其他機構未設立人體研究倫理審查委員會(IRB)，且執行之研究計畫無臺中榮民總醫院同仁共同參與，該機構得委託本會協助審查。

If a research center does not have an IRB and no TCVGH personnel is involved in the study, the research center may send the study protocol to TCVGH-IRB for review.

5.3 行政審查

5.3 Administrative Review

其他機構委託本會審查人體研究計畫案時，應注意下列行政審查項目：

The following guidelines should be followed during the initial administrative review of a non-TVCVGH research protocol:

5.3.1 確認該委託機構是否與本院簽署正式契約書。

5.3.1 The IRB staff should verify if research center sending the protocol for review has signed an official agreement with TCVGH.

5.3.2 未與本院簽訂研究合作協議之機構，需由計畫主持人所屬機構正式來函以個案申請，經（副）主任委員評估是否受理。

5.3.2 If the research center has not signed any agreement with TCVGH, the PI's affiliated research center should make an official request by writing to apply for TCVGH-IRB review of the protocol. The IRB (Vice) Chair should evaluate the application and decide whether to accept the application or not.

5.3.3（副）主任委員同意受理並確認已完成繳費程序後，進入審查流程。

5.3.3 Once the IRB (Vice) Chair has agreed to accept the review application and has verified that payment has been made, the IRB review process will be initiated.

5.4 審查

5.4 IRB Review

除依照各項管理程序書之規範執行，委員審查其他機構委託之人體研究計畫時，應注意下列項目。

In addition to following the guidelines described in the other IRB SOPs, the following items should also be verified during the IRB review of non-TCVGH research protocols:

5.4.1 主持人是否接受足夠之教育訓練時數，主持人是否有能力在該機構或其他地點執行試驗。

5.4.1 The PI has received enough hours of relevant training and is capable of conducting the trial in the affiliated research center or other research sites.

5.4.2 其餘所有審查、追蹤、監督與管理之程序，原則與本院執行之人體研究計畫案相同。

5.4.2 All procedures including initial review, continuing review, monitoring and protocol management should follow the same procedures for the review and management of TCVGH research protocols.

5.5 執行後續行政作業

5.5. Follow-Up Administrative Procedure

5.5.1 非機構內研究案件之聯絡往返資料：

5.5.1 Correspondence related to the review of non-TCVGH research protocols should be done by the following procedures:

5.5.1.1 主持人及其所屬機構之研究計畫相關資訊，應主動告知本會，特別是會影響試驗受試者利益及風險評估之重要安全性資訊。

5.5.1.1 The PI and affiliated research center should notify TCVGH-IRB of all information related to the research protocol, especially important safety information which may affect the subjects' benefit-risk assessment.

5.5.1.2承辦人員應將主持人及其所屬機構繳交之試驗相關重要資訊，儘快送交本會（副）主任委員審核。

5.5.1.2 All important research information submitted by the PI and affiliated research center should be sent immediately by the staff member to the IRB (Vice) Chair for review.

5.5.1.3承辦人員依據各項繳交文件之相關作業程序規定時程，儘快回覆該計畫主持人；若（副）主任委員或執行秘書認為係重大議題，基於時效性，應同步知會主持人所屬機構【電話、電子郵件或公文（系統文件不列入附件）】，並提報大會討論。

5.5.1.3 The staff member should respond to the PI promptly according to the regulated timeline for processing each submitted document. If the protocol involves major issues which the (Vice) Chair or Executive Secretary considers urgent, the PI's affiliated research center should be notified immediately (by telephone, e-mail, or official correspondence), and the protocol should be placed on the agenda for the IRB board meeting for discussion.

5.5.2 研究執行狀況之定期檢視

5.5.2 Regular monitoring of research implementation

5.5.2.1 非機構內研究監督管理頻率與方式，依據風險等級，由本會議定之。

5.5.2.1 The monitoring frequency and procedure of non-TCVGH research will be decided by TCVGH-IRB based on the degree of risk.

5.5.2.2 嚴重不良反應事件或未預期嚴重藥品不良反應(SUSAR)（特別是其它中心發生之經評估為確定相關/很可能相關／可能相關 --- 具合理相關性 Reasonable Possibility、非預期或超過預期之SAE）、非預期問題、影響利益與風險評估之重要資訊，依據相關管理程序書評估辦理。

5.5.2.2 The management of serious adverse events (SAE) or incidents of suspected unexpected serious adverse reaction (SUSAR) should follow relevant TCVGH-IRB SOPs, especially unexpected incidents of SAE assessed by other research centers to be “certain,” “probable” or “possible” in the assessment of causality, unexpected problems, and the handling of important information which may affect the subject’s benefit-risk assessment should also follow relevant TCVGH-IRB SOPs.

5.5.2.3 試驗主持人應定期繳交試驗之追蹤審查/結案報告。

5.5.2.3 The PI should submit the continuing report/closing report on time.

5.5.2.4 實地訪查依據 ISO「實地訪查管理程序書」辦理。

5.5.2.4 Monitoring visits to the research site should follow the ISO SOP for Monitoring Visits.

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 guideline below.

編號 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	各類計畫案相關文件 Protocol-related Documents	PTMS系統 PTMS	試驗結束後 3 年 At least 3 years after the trial is closed
2	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
4	相關審查表單 Relevant Review Forms	PTMS系統 PTMS	試驗結束後 3 年 At least 3 years after the trial is closed
5	人體試驗研究計畫許可書 Certificate of Approval	PTMS系統 PTMS	試驗結束後 3 年 At least 3 years after the trial is closed

6.附件

6. Appendices

「各類計畫案相關文件」、「案件流程表」、「相關審查表單」、「人體試驗研究計畫許可書」等附件，參照各類計畫管理程序書，不再重覆列入附件。

Appendices including protocol documents, Protocol Review Process Routing Form, relevant review forms, and Certificate of Approval are the same as in other TCVGH-IRB SOPs, so they are not listed here.