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-2024 IRB-Regulations of Operation-2024	文件名稱 Title	多中心研究計畫管理程序書 **SOP for Management in Multicenter Studies**
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 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	3	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	3	1. 原「人體試驗委員會」更名為「第一/二人體研究倫理審查委員會」。 1. The original “Human Research Committee” was renamed “The First/Second IRB Committees” 2. 修改 5.1 流程圖之相關文件。 2. The list of relevant documents was revised in item 5.1 Flow Chart.	20160318
C	3	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 July 2017 and no revision was needed.	20160318
D	8	1. 修改本管理程序書之標題為「多中心研究計畫管理程序書」。 1. Revised the title to be “SOP for Management in Multicenter Studies”. 2. 新增 5.2 多中心研究計畫之職責。 2. Added responsibilities of multi-center studies in item 5.2. 3. 新增 5.3 多中心研究計畫之審查。 3. Added review process of multi-center studies in item 5.3. 4. 原標號 5.2 修改為 5.4、5.3 修改為 5.5、5.4 修改為 5.6、5.5 修改為 5.7 及 5.6 修改為 5.8。 4. Changed item numbers 5.2-5.6 to 5.4-5.8.	20190527

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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
D	8	依本院規定，於 2021 年 03 月 25 日重新審視本文件，內容無須修訂。 Complied with the regulations of TCVGH, this document was to be re-examined on 25 March, 2021, and the content did not need to be revised.	20190527
E	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”. 2. 抽換附件 6.1。 2. Replaced Appendix 6.1.	20230420

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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。
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※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-2024 IRB-Regulations of Operation-2024	文件名稱 Title	多中心研究計畫管理程序書 SOP for Management in Multicenter Studies

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

為促使本院人體研究倫理審查委員會多中心研究計畫審查及溝通管道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 the review and coordination of TCVGH-IRB multicenter studies.

2.適用範圍

2. Scope

凡本院人體研究倫理審查委員會審查或追認通過之多中心研究計畫案有關的審查、溝通、聯繫之管理均適用本管理程序書。

This SOP applies to the review, communication and management of multicenter studies reviewed and approved by TCVGH-IRB or confirmed by TCVGH-IRB after having been approved by another IRB.

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 多中心研究計畫相關溝通管理流程圖

5.1 Flow Chart for Communication in Multicenter Studies

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
發現案件疑慮 Discovery of issues or concerns ↓ 溝通聯絡及記錄 Communication log ↓ 提大會報告討論 IRB board meeting discussion ↓ 執行後續行政作業 Follow-up administrative procedure ↓ 紀錄保存 Records retention	大會決議/（副）主任委員指示 Meeting Resolutions/ Instructions by the (Vice) Chair 承辦人員或本會委員 Staff or IRB Members 執行秘書/（副）主任委員 Executive Secretary/ (Vice) Chair 承辦人員 Staff Members 承辦人員 Staff Members	多中心研究計畫申請資料 Submission Documents of Multicenter Study Protocol 多中心研究計畫相關溝通紀錄表 Communication Log for Multicenter Studies

5.2 多中心研究計畫之職責

5.2 Responsibilities of Multicenter Studies

5.2.1 計畫主持人：

5.2.1 Principal Investigator:

除了一般計畫主持人應盡之職責外，依計畫之性質，需額外注意：

In addition to the standard duties, depending on the nature of the study, additional special attention is required:

5.2.1.1 跨國研究計畫：

5.2.1.1 Transnational research studies:

a.對於國外受試者應提供與國內受試者相同程度之保護。

a. For foreign subjects, the protection provided should be the same as subjects in Taiwan.

b.執行研究應符合當地國之法令規定及尊重其社會文化背景。

b. The study should be conducted in accordance with the regulations of respective countries and proper respect given in compliance with their social and cultural backgrounds.

5.2.1.2 多機構合作臨床試驗計畫：

5.2.1.2 Multicenter Studies:

a.確保參與研究之其他機構及研究者遵守計畫書及相關倫理規範與法律規定。

a. Ensure that other institutions and researchers involved in the study comply with the protocol and related ethical and legal regulations.

b.試驗進行前，應以書面記載試驗主持人及其他參與之試驗主持人之責任分配及協調方式。

b. Before the start of study, the assignment of respective responsibilities, and coordination among principal

investigators/institutes should be determined in writing.

c.應加強各參與機構間有關該試驗受試者保護方面訊息(包括：對受試者或他人造成風險之非預期問題、期中分析結果、計畫書變更等)之交流。

c. Communication should be strengthened among joint investigators regarding the protection of study subjects (including unanticipated problems with risks on subjects or other persons), interim results of study, changes to the protocol etc.

5.2.2 人體研究倫理審查委員會

5.2.2 Institutional Review Board

與審查一般研究計畫之職責相同，且需額外注意：

The Committee's responsibilities are the same as those in reviewing ordinary research applications, it should also pay attention to the following conditions:

5.2.2.1 跨國研究計畫：

5.2.2.1 Transnational research studies:

a.考量國外研究機構選擇之合理性。

a. Consider the rationale for choosing the foreign participating institutes.

b.考量當地國之法令規定及社會文化背景，確保國內外之受試者接受到相等程度的保護。

b. Consider respective countries' laws/regulations, social and cultural backgrounds and ensure that subjects at home and abroad receive the same protection.

5.2.2.2 多機構合作臨床試驗計畫：應考量參與研究各機構之受試者是否受到相同程度的保護。

5.2.2.2 Multicenter Studies: should consider whether all subjects participating in the study are protected to the same extent.

5.3 多中心研究計畫之審查：

5.3 Review of Multicenter Studies:

本會於進行審查時需考慮以下各點：

IRB should address the following issues in the review:

5.3.1 選擇國內外合作機構與研究者之合理性。

5.3.1 How reasonable it is to choose the local and foreign investigators/institutes for the joint study.

5.3.2 計畫內容是否合乎國內文化與法律規範的要求。

5.3.2 Whether the contents of the study protocol fit in with the cultural and legal norms of the participating countries.

5.3.3 試驗執行之前，是否針對各不同執行單位之主持人進行相關的訓練，或審查各執行單位之主持人是否具有符合該國法令之計畫主持人資格，以確保試驗的一致性。

5.3.3 Before the start of study, whether supervisors of the participating units are properly trained, or whether the moderators of the execution units are sufficiently qualified in accordance with the respective country's laws and regulations to ensure the consistent execution of the study protocol.

5.3.4 針對研究計畫的風險，規劃適宜的資料與安全數據監測計畫(Date Safety and Monitoring Plan, DSMP)或成立資料與安全數據監測委員會(Date Safety and Monitoring Board, DSMB)，以確保受試者之安全。

5.3.4 Install the appropriate Data Safety Monitoring Program (DSMP) or the Data Safety and Monitoring Board (DSMB) to ensure safety and protect subjects from risks.

5.3.5 是否有其他人體試驗委員會不同意此計畫之執行。

5.3.5 Whether there are any other IRBs objects to the study protocol.

5.3.6 研究計畫之受試者抱怨、違規及造成危險之非預期問題之處理辦法合理性。

5.3.6 Whether measures are reasonable to handle complaints of

participating subjects, legal violations of study, and unanticipated problems that cause hazards.

5.3.7 取得受試者知情同意過程之合理性。

5.3.7 Whether the subject informed consent forms are properly obtained.

5.3.8 有關受試者保護之相關管理資訊是否合宜。

5.3.8 Whether information about subject protection is properly managed.

5.3.9 是否設有專責之協調中心或協調人員，來負責各機構主持人間充分的協調與合作。

5.3.9 Whether a dedicated coordinating center or coordinator is assigned to manage the joint study.

5.4 發現案件疑慮

5.4 Discovery of Issues or Concerns

5.4.1 多中心研究計畫申請資料中提及相關之研究機構係指國內各大醫學中心、教學醫院、大學院校系所及相關之學會、協會或學術機構。

5.4.1 Issues or concerns may be raised by any research center listed in the submission documents of a multicenter study protocol. The research centers involved may include domestic medical centers, teaching hospitals, relevant university departments or schools, relevant associations or academic institutions.

5.4.2 當多中心研究計畫審查、計畫執行及監督、嚴重不良反應、追蹤審查/執行效期之展延、計畫修正發現偏離時或其他試驗中心傳來相關訊息時，需進行多中心研究計畫之溝通。

5.4.2 Communication for a multicenter study should take place when issues or concerns are raised during the process of protocol review, research implementation and monitoring, protocol amendment, continuing review or research extension, or when a serious adverse event or an incident

of protocol deviation occurs.

5.5 溝通聯絡及記錄

5.5 Communication Log

5.5.1 溝通方式為正式書函、電話、傳真及電子郵件。

5.5.1 Communication among research centers involved in a multicenter study should be done by official written correspondence, telephone, fax, or e-mail.

5.5.2 溝通內容不得涉及個人隱私，並應作成記錄，以便作為後續追蹤之依據。

5.5.2 The content of communication should not invade personal privacy. All communication should be logged for future monitoring and follow-up.

5.5.3 記錄內容應包括通訊日期/時間、研究計畫本會編號、計畫書編號、計畫名稱、本院計畫主持人姓名、相關試驗中心聯絡人姓名、聯絡方式、聯絡地址（電話/電子郵件）、通訊內容摘要、記錄人姓名。

5.5.3 The communication log should include the following items: Date and time of communication, TCVGH-IRB number, protocol number, protocol title, PI from TCVGH, contact persons from involved trial centers and their contact methods (address, telephone number, e-mail address), summary of communication, and the person writing the log.

5.6 提大會報告討論

5.6 IRB Board Meeting Discussion

必要時提大會上報告，由大會討論並作成決議。

If necessary, the communication log may be presented in an IRB board meeting for discussion and resolution.

5.7 執行後續行政作業

5.7 Follow-Up Administrative Procedure

經大會決議或（副）主任委員指示，承辦人員或本會委員得與相

關試驗中心之 IRB 進行溝通，必要時得回覆原詢問試驗中心之 IRB。

Based on the resolution from the IRB meeting or instructions by the (Vice) Chair, the staff member or an IRB member may contact the IRB of another research center involved in the study for further communication. If needed, TCVGH-IRB should respond to inquiries made by the IRB of another involved trial center.

5.8 紀錄保存

5.8 Records Retention

5.8.1 紀錄完成後正本歸檔於該研究計畫檔案，視需要備份於其他相關檔案。

5.8.1 The original copy of the communication log should be filed in the same folder where the protocol documents are kept. Photocopies may be made and filed in other folders based on actual needs.

5.8.2 相關人員應依據如下規定，妥善保存各項紀錄。

5.8.2 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	多中心研究計畫相關溝通紀錄表 Communication Log for Multicenter Studies	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. Appendix

6.1 多中心研究計畫相關溝通紀錄表

6.1 Communication Log for Multicenter Studies