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-2001 IRB-Regulations of Operation- 2001	文件名稱 Title	第一/二人體研究倫理審查委員會會議管理程序書 SOP for IRB Board Meetings
訂定單位 Composed by	第一/二人體研究倫理審查委員會 The First/Second IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □Confidential □Highly Confidential
適用單位 Applied to	□全院 □**All units in the hospital** ■其他，請註明：第一/二人體研究倫理審查委員會 ■**Other (Please specify): The First/Second IRB Committees**		

版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
A	11	新訂。Newly composed.	20140519
B	10	更改文件名稱。由人體試驗委員會標準作業程序 5.4 版轉換成此版本。 The name of the document was revised. This version was converted from “Version 5.4 of the Standard Operating Procedure of the Human Research Committee.”	20141125
C	10	1. 原「人體試驗委員會」更名為「第一/二人體研究倫理審查委員會」。 1. The original “Human Research Committee” was renamed “The First/Second IRB Committees” 2. 修改 5.4.7.1：補充會議電子檔案儲存管理方式。 2. Amended item 5.4.7.1: Added guidelines for the management and retention of electronic files of IRB meetings.	20160318

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適用單位 Applied to	□全院 □**All units in the hospital** ■其他，請註明：第一/二人體研究倫理審查委員會 ■**Other (Please specify): The First/Second IRB Committees**		

版次 Version	頁數 No. Pages	文件修訂摘要 **Summary of Revisions of the Document**	實施日期 Date of Implementation
D	10	1. 修改 4.2.2 延長研究計畫效期為「執行許可書」。 1. Amended item 4.2.2: Replaced “Extension of Research Period” with “Certificate of Approval.” 2. 修改 4.2.4：新增要求計畫主持人及繳交追蹤審查報告 2. Amended item 4.2.4: Added the requirement for the PI to submit continuing review reports. 3. 修改 5.2.2 會議場地及預約方式：刪除臨床技能中心。 3. Amended guidelines for reserving the venue for IRB meetings in Item 5.2.2: Deleted “Clinical Skills Center.” 4. 修改 5.4.2.2 開會資料分送委員之時間。 4. Amended Item 5.6.4: Deleted “Submit a photocopy to superiors.” 5. 修改 5.4.6.1 計畫主持人回覆一般審查案之審查意見時間。 5. Amended the time limit for the PI to respond to full board review comments in item 5.4.6.1.	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
D	10	6. 修改 5.4.7.2 增加試驗暫停案類別：新增 h.核備通過或提案討論之試驗暫停的審查。 6. Amended item 5.4.7.2 Types of Suspensions of Protocols: Added “h. Review of Approved or Proposed Suspensions of Protocols.” 7. 修改 5.6.4：刪除影本上陳。 7. Amended Item 5.6.4: Deleted “Submit photocopies.” 8. 修改 5.8 紀錄保存：刪除原 5.投票統計結果之保存規定。 8. Amended item 5.8 Records Retention: Deleted “5. Guidelines for the record keeping of voting results.”	20170709
E	10	1. 修正 5.3.1「會議法定出席人數」為「須達法定半數以上的出席人數」(即出席委員超過全體委員總數之半數以上，出席委員至少含 1 位不同性別之委員、院外委員、非醫療委員，同 1 位委員得代表多個身分別)。 1. Amended item 5.3.1: “The quorum of the meeting” was replaced by “The quorum should be half of the membership plus one (i.e. the members present should be more than half of the total number of members. Among all members present, both genders should be represented. At least one member present should be non-TCVGH-affiliated. At least one member present should be from a non-medical background. One member may represent various identity groups).”	20180529

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E	10	2. 增加 5.5.11.4 說明文字：即出席委員超過全體委員總數之半數以上，出席委員至少含 1 位不同性別之委員、院外委員、非醫療委員，同 1 位委員得代表多個身分別。 2. Explanation was added to item 5.5.11.4: The members present should be more than half of the total number of members. Among all members present, both genders should be represented. At least one member present should be non-TCVGH-affiliated. At least one member present should be from a non-medical background. A member may represent more than one identity groups.	20180529
F	23	1. 更新參考文件 3.1 資訊。 1. Updated the information regarding Reference 3.1. 2. 修改 4.2.3 承辦人員會定期提醒計畫主持人繳交此報告。 2. Revised item 4.2.3: staff members shall regularly remind PI to submit the report. 3. 修改 5.4.2.2 開會資料送達方式。 3. Revised item 5.4.2.2: the way meeting documents are delivered. 4. 修改 5.4.7.1 開會資料電子檔案存放方式。 4. Revised item 5.4.7.1: the way meeting documents are stored.	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
F	23	5. 修改 5.4.7.2 會議中進行討論、核備及追認之計畫案類型。 5. Amended item 5.4.7.2: The categories of protocols under IRB discussion, review, or confirmation of approval. 6. 修改及新增 5.4.7.3 大會議程項目。 6. Amended and added item 5.4.7.3 meeting agenda. 7. 修改 5.5.1 為「委員及承辦人員出席會議時，應於『簽名單』簽到。會議結束時或中途離席應簽退，簽到及簽退應註明時間。」 7. Revised item 5.5.1 as follows: “The reviewers and staff members should sign in with date and time when attending the meeting, and sign out with date and time when the meeting is over or when leaving.” 8. 新增 5.5.9 一般計畫案說明文字：「含新案、修正案、追蹤審查、院內不良反應通報、試驗偏離/背離、結案、計畫暫停或終止」。 8. The following was added in item 5.5.9 Full Board Review Protocols: “including new protocols, protocol amendment, continuing review, serious adverse event reporting within TCVGH, protocol deviation/violation, study closure, protocol suspension or termination.”	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
F	23	9. 修改 5.5.11.1 為一般審查案(含新案、修正案、追蹤審查、院內不良反應通報、試驗偏離/背離、結案、計畫暫停或終止)。 9. Amended item 5.5.11.1: Full Board Review Protocols (including new protocols, protocol amendment, continuing review, serious adverse event reporting within TCVGH, protocol deviation/violation, study closure, protocol suspension or termination). 10. 修改 5.5.11.4「非醫療委員」為「非生物醫學科學背景委員」。 10. Revised item 5.5.11.4: change “a member from a non-medical background” to “a member from a non-biomedical science background.” 11. 修改 5.5.11.6 之投票方式。 11. Revised item 5.5.11.6: the way to vote. 12. 抽換附件 6.1、6.2、6.4。 12. Replaced Appendices 6.1, 6.2, 6.4.	20190527
G	23	1. 依據 AAHRPP 國際認證委員之建議進行增修。 1. The following modifications were made according to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) reviewers. 2. 修改 5.4.2.2「院內 SAE」為「院內嚴重不良事件(僅通報 SUSAR)」。 2. Revised item 5.4.2.2: change “SAE within TCVGH” to “reports of SAE (only SUSAR is reported) within TCVGH.” 3. 修改 5.4.7.2.a-n 部分名詞。 3. Some of the terms in items 5.4.7.2.a-n were revised. 4. 修改 5.5.1 為「委員及承辦人員出席會議時，應於「簽名單」簽到。會議結束時或中途離席應簽退，簽到及簽退應註明時間及中途離席之原因。」	20210528

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適用單位 Applied to	□全院 □All units in the hospital ■其他，請註明：第一/二人體研究倫理審查委員會 ■Other (Please specify): The First/Second IRB Committees		

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G	23	4. Revised item 5.5.1: "The reviewers and staff members should sign in with date and time when attending the meeting, and sign out with date and time when the meeting is over or when leaving early with reasons written in the sign-out sheet." 5. 修改 5.5.9 及 5.5.11.1 之「院內不良反應」為「院內嚴重不良事件」。 5. Revised item 5.5.9 & 5.5.11.1: change "serious adverse reaction" to "serious adverse event (SAE)." 6. 抽換附件 6.1、6.2、6.4。 6. Replaced Appendices 6.1, 6.2, 6.4.	20210528
H	23	1. 增加 5.2.2 說明文字：「若因特殊情況如疫情等因素，得以視訊方式召開會議」。 1. Explanation was added to item 5.2.2: "If due to extraordinary circumstances such as the pandemic, the video conference can be held." 2. 修改 5.4.6.3 文句。 2. Revised item 5.4.6.3. 3. 抽換附件 6.2、6.4。 3. Replaced Appendices 6.2, 6.4.	20211209

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2021.12.23
參考文件

訂修廢 Composed/Revised/Deleted	審核 Reviewed	核准 Approved
	本文件已經權責主管正式核准，核章紀錄之正本儲放於 SOP 管理中心	

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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-2001 IRB-Regulations of Operation-2001	文件名稱 Title	第一/二人體試驗委員會會議管理程序書 SOP for IRB Board Meetings

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.	

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2021.12.23
參考文件

※請各會辦單位主管惠賜審查意見後核章，必要時得直接與訂定單位協商。

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

1. 目的

1. Purpose

為促使第一/第二人體研究倫理審查委員會之會議管理有一明確之規範，以確保人員召開各項會議，能夠透過討論有具體明確的紀錄並追蹤各項議題，特制訂本程序書。

The purpose of this SOP is to provide clear guidelines for the management of meeting procedures of the First/Second IRB Committees, and to ensure that participating members of all IRB meetings have access to detailed records of the meetings and can follow up on the issues discussed in the meetings.

2. 適用範圍

2. Scope

凡第一/第二人體研究倫理審查委員會人員舉辦相關會議之管理均適用本程序書。

This SOP applies to all meetings held by the personnel of the First/Second IRB Committees.

3. 參考文件

3. References

3.1「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，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)

3.1 Regulations for Organization and Operation of IRB Committees, promulgated by the Ministry of Health and Welfare, pursuant to Wei-Shu-Yi-Zi No. 1010265129, 2012 (Articles 2, 3, 6, 7 amended in 2018, pursuant to Wei-Bu-Yi-Zi No. 1071661626, by the Ministry of Health and Welfare).

3.2 胡世雄、李育如、余志明(2011)。國際專案管理知識體中範疇管理之綜合研析。全球管理與經濟，第七卷第一期，14-31 頁。

3.2 Hu, Shr-Shiung; Li, Yu-Ru; Yu, Chih-Ming. (2011). On a Comprehensive Research and Analysis for the Scope Management in the Project Management Body of Knowledge, Journal of Global Management and Economics, Vol. 7, No. 1, 14-31.

4. 名詞定義

4. Definitions

4.1 大會

4.1 Board Meeting

由祕書處各承辦人、委員會委員、計畫主持人、列席報告人所組成的例行性一般審查會議。

Board meetings are regular review meetings attended by staff members of the IRB Secretariat, IRB members, principal investigators, and invited guests.

4.2 追蹤審查

4.2 Continuing Review

4.2.1 一年型計畫之計畫主持人於人體試驗研究計畫許可書核發日起一年內繳交追蹤審查報告或結案報告。

4.2.1 Principal investigators of one-year research projects should submit continuing review reports or closing reports within one year after the issuance of the Certificate of Approval.

4.2.2 多年型計畫之計畫主持人須於人體試驗研究計畫許可書到期前繳交追蹤審查報告，以延長研究計畫執行許可書之效期。

4.2.2 Principal investigators of multi-year research projects should submit continuing review reports before the approved research period ends in order for the Certificate of Approval to have an extended effect.

4.2.3 承辦人員會定期提醒計畫主持人繳交此報告。

4.2.3 Staff members should remind PIs to submit the above-mentioned report(s) by sending written notifications regularly to the PIs.

4.2.4 委員會得酌情要求計畫主持人，繳交更頻繁的追蹤審查報告次數。

4.2.4 The IRB may request the PI to submit continuing review reports more frequently depending on the situation.

5. 作業內容

5. Procedure

5.1 第一/二人體研究倫理審查委員會會議管理流程圖

5.1 Flow Chart of IRB Meeting Procedures

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
訂定會議時間 Meeting schedule	各業務承辦人 Staff Members	預定會議行程表 Tentative Meeting Schedule
收集資料 Meeting documents	各業務承辦人 Staff Members	開會通知單 Meeting Notice
會議前準備 Pre-meeting preparation	各業務承辦人 Staff Members	會議議程 Agenda
召開會議 Meeting procedure	各業務承辦人 Staff Members	會議簽到、退記錄表/投票統計結果 Sign-In & Sign-Out Sheets/Voting Results
製作會議紀錄 Meeting minutes	各業務承辦人 Staff Members	會議紀錄 Minutes
決議事項分辦 Follow up on resolutions	各業務承辦人 Staff Members	簽稿會核單 Review Comments and Approval Form
紀錄保存 Records retention	各業務承辦人 Staff Members	

5.2 訂定會議時間

5.2 Meeting Schedule

5.2.1 第一/二人體研究倫理審查委員會負責及參與之各項相關會議召開時間，由各承辦人詢問及協調各會議主席時間後訂定，現行之會議召開頻率規定如下列。

5.2.1 The schedule of IRB meetings should be determined by coordination between staff members and the chairs of the meetings. The frequency of regular meetings is listed below:

會議名稱 Name of Meeting	舉行時間 Schedule	會議主席 Chair of the Meeting	出席人員 Attending Members
第一/二人體研究倫理審查委員會大會 IRB Board Meeting	每月 Once a month	主任委員 IRB Chair	第一/二人體研究倫理審查委員會委員、祕書處承辦人、計畫主持人、報告列席人 IRB members, staff members of the Secretariat, principal investigators, invited guests

5.2.2 會議承辦人員於會議時間確定後，應參考如下規範，預先借用場地及設備。若因特殊情況如疫情等因素，得以視訊方式召開會議。

5.2.2 After the meeting schedule is determined, the staff member in charge should reserve the venue and equipment following the guidelines below. If due to extraordinary circumstances such as the pandemic, the video conference can be held.

場地/設備 Venue/Equipment	預約方式 Reservation Method
醫學研究部 308 會議室 Meeting Room 308 in the Department of Medical Research	直接將會議使用時間登記於「308 室使用時間登記簿」 Reserve by signing on the “Booking Calendar of Meeting Room 308.”
內科部各討論室 Discussion Rooms in the	直接將會議使用時間登記於會議室之「會議使用時間登記表」

場地/設備 Venue/Equipment	預約方式 Reservation Method
Department of Internal Medicine	Reserve by signing on the “Booking Calendar of Discussion Rooms.”
行政大樓七樓會議室 Meeting Room on the 7th floor of the Administration Building	應至本院員工入口網站「設備借用預約」登記 Reserve on the TCVGH online system for booking venue/equipment by logging into the staff account.
本院其他會場 Other venues in TCVGH	應至本院員工入口網站「設備借用預約」登記，再依規定填寫「會場借用申請單」送予醫學教學組會場管理負責人 Reserve on the TCVGH online system for booking venue/equipment by logging into the staff account, and then submit the Venue Reservation Application Form to the staff in charge of managing meeting venues in the Department of Medical Education.
資訊室 IT Office	通知安裝「筆記型電腦」時間及數量 Notify IT staff of the number of laptop computers needed and the time of the meeting.
預約需視訊設備 Reserve video conferencing equipment if needed.	除依上述方式完成借用後，另於會議前與會場管理負責人預約進行「視訊」測試之時間。 After the reservation is made, IRB staff should make an appointment with the staff in charge of managing the meeting venue to test the video conferencing equipment before the meeting.

5.3 收集資料

5.3 Meeting Documents

第一/二人體研究倫理審查委員會大會將由負責之承辦人員於會議前 10 日發出「開會通知單」，並彙整相關資料及製作會議議程（含簽名單及附件），會議內容應包含如下資料：

The staff member in charge of organizing an IRB board meeting should send out the meeting notice at least ten days before the date of the meeting, and compile relevant

documents and meeting agenda (including a sign-in sheet and appendices). Meeting documents should include the following information:

5.3.1 須達法定半數以上的出席人數（即出席委員超過全體委員總數之半數以上，出席委員至少含 1 位不同性別之委員、院外委員、非生物醫學科學背景委員，委員，同 1 位委員得代表多個身分別）

5.3.1 The quorum should be half of the membership plus one (i.e. the members present should be more than half of the total number of members. Among all members present, both genders should be represented. At least one member present should be non-TCVGH-affiliated. At least one member present should be from a non-biomedical science background. A member may represent more than one identity groups).

5.3.2 前次會議決議事項之執行情形追蹤紀錄

5.3.2 Resolutions from the last meeting and the record of follow-up on previous resolutions.

5.3.3 工作報告

5.3.3 Work reports.

5.3.4 審查案件及提案討論之案由及說明

5.3.4 Protocols for review, motions and rationales.

5.3.5 其他會議所需附件資料

5.3.5 Other relevant documents and appendices.

5.4 會議前準備

5.4 Pre-meeting Preparation

5.4.1 由負責之承辦人員準備該場次會議資料、簽名單、出席費領據，並確認會議場地各項設備之功能（電腦、單槍投影機、麥克風、錄音器材、簽到筆、延長線、座位牌、計時器、叫人鈴、相機、椅子、電池、午餐、咖啡/茶水…等），並提醒

與會人員準時出席。

5.4.1 The staff member in charge should prepare the meeting documents, a sign-in sheet, and receipts of stipends for attendees, and make sure that all equipment in the venue functions normally (staff member's tasks include checking computers, projector, microphones, recording equipment, pens for signing in, extension cords, name cards on assigned seats, timer, bell, cameras, chairs, batteries, and preparing lunch, coffee or tea for the attendees). The staff member should also remind participating members to attend the meeting on time.

5.4.2 第一/二人體研究倫理審查委員會於召開每月例行性的審查大會，請依照以下規範執行。

5.4.2 The monthly IRB board meetings should be convened following the guidelines:

5.4.2.1 在會期前 10 個日曆天，依據年度既定會議行程表以電子郵件方式通知本會全體委員出席，信中告知開會日期、時間及地點，收到開會通知的委員請提早安排出席會議時間。如委員無法參加，請回信或致電承辦人告知請假理由，委員盡量不要當天臨時請假，會議須達法定半數以上的出席率。

5.4.2.1 At least ten calendar days before a scheduled meeting, the staff member in charge should notify all members by email of the time, date, and location of the meeting, and remind members to mark their calendars to attend the meeting. If a member is unable to attend a scheduled meeting, they shall notify the staff member in charge by email or by phone and explain the reason why they are unable to attend the meeting. Members should avoid asking for leave on the same day that the meeting is scheduled to take place. The quorum should be half of the number of all members plus one.

5.4.2.2 於大會前 4 個日曆天，承辦人員將開會資料，包括：一般

審查案、修正案、追蹤審查報告、結案報告、試驗偏離、院內嚴重不良事件(僅通報 SUSAR)、非預期問題等相關提會討論之審查資料以及會議議程存放於加密雲端硬碟中，並提供委員雲端硬碟之連結網址，祕書處應確保給予委員充分時間預先審閱相關會議資料。

5.4.2.2 At least four calendar days before a scheduled meeting, the staff member should give each member a link to read encrypted meeting documents stored in an cloud drive, which include primary review comments of full board review protocols, amended protocols (if any), continuing review reports, closing reports, incidents of protocol deviation, reports of SAE (only SUSAR is reported) within TCVGH, unanticipated problems, and meeting agenda. The Secretariat should ensure that members are given adequate time to review relevant meeting documents.

5.4.2.3 遇有特殊案件討論時，視需要邀請受試者(團體)代表列席。

5.4.2.3 If a meeting involves discussion on special cases, advocate(s) of trial subjects (groups) may be invited to attend the meeting.

5.4.6 準備審查計畫書

5.4.6 Preparation of Protocols for Review

5.4.6.1 承辦人員檢核進行審查中之新案，依委員審查結果，若有須回覆初審委員意見者，依序通知計畫計畫主持人於期限內回覆審查意見，並排入大會一般審查案件名單。計畫主持人須於會期前 5 個日曆天送至祕書處，以利與會委員於大會進行討論並投票決議。

5.4.6.1 The staff member should check the status of ongoing review of new protocols. Based on the reviewers' comments, if there is a need for the PI to respond to comments by primary reviewers, the staff member should notify the PI to respond within a deadline. The reviewers' comments and the PI's response should be

placed on the agenda for the meeting. The PI should submit their response to the Secretariat at least five calendar days before the scheduled meeting to facilitate members' discussion and voting at the meeting.

5.4.6.2 承辦人員確認資料是否備齊，若有缺漏，應請申請人補齊資料。

5.4.6.2 The staff member should verify that all needed documents are prepared for the meeting. If there is a missing document, the staff member shall contact the PI to submit it.

5.4.6.3 為因應施行電子審查措施，請計畫主持人提供已排入大會之一般審查申請案件之完整審查資料電子檔案給承辦人員。

5.4.6.3 To comply with the policy of digitalizing the review process at TCVGH, the PI should submit the electronic files with the complete protocol submission documents to the staff member in advance.

5.4.7 製作會議議程

5.4.7 Meeting Agenda

5.4.7.1 第一/二人體研究倫理審查委員會秘書處將提供每位委員一個雲端硬碟之連結網址，裡面存入會議議程及相關提會討論案之審查資料完整電子檔案（檔案以壓縮檔並設有密碼），不提供會議議程紙本文件，改以電子檔案供委員在會議前審閱以及會中以投影方式報告。

5.4.7.1 The IRB Secretariat should provide each member with a link connecting with zipped and encrypted files stored in a cloud drive of the meeting agenda and complete protocol submissions for full board review. Hard copies of the meeting agenda will not be distributed. Rather, members should review the agenda electronically in advance. The agenda should also be projected to a screen during the

meeting.

5.4.7.2 依計畫案性質和狀況於會議中進行討論、核備及追認，主要分為以下幾類：

5.4.7.2 Protocols submitted for IRB discussion, review, or confirmation of approval are classified into the following categories based on the nature and status of the protocols:

a.提會討論之一般審查案。

a. Review of full board protocols.

b.追認審查通過之簡易審查案。

b. Confirmation of approval of expedited protocols.

c.追認審查通過之免審案件。

c. Confirmation of approval of exempt protocols.

d.追認、核備通過及提案討論之修正案。

d. Confirmation and recordation of approval, review or discussion of protocol amendment.

e.追認、核備通過及提案討論之追蹤審查報告。

e. Confirmation and recordation of approval, review or discussion of continuing review report of approved protocols.

f.核備通過或提案討論之院內嚴重不良事件(僅通報SUSAR)通報。

f. Confirmation and recordation or discussion of reports of SAE (only SUSAR is reported) within TCVGH.

g.核備通過或提案討論之院內非預期問題通報案。

g. Confirmation and recordation or discussion of reports of unanticipated problem within TCVGH.

h.核備通過或提案討論之試驗偏離/背離(不遵從事件)的處理。

h. Confirmation and recordation or discussion of the handling of protocol deviation/Violation (Non-compliance).

i.追認、核備通過及提案討論之結案報告。

i. Confirmation and recordation of approval, review or discussion of closing reports.

j.追認、核備通過及提案討論之試驗終止案。

j. Confirmation and recordation of approval, review or discussion of protocol termination.

k.追認、核備通過及提案討論之試驗暫停案。

k. Confirmation and recordation of approval, review or discussion of protocol suspension.

l.追認、核備通過及提案討論之其他事項通報案。

l. Confirmation and recordation of approval, review or discussion of other reports.

m.追認通過「撤案」之申請。

m. Confirmation of approval of protocol withdrawal.

n.備查計畫案之新案公文、修正案公文、結案/終止公文，包含：衛生福利部、藥廠等往來公文。

n. Confirmation of administrative correspondence documents related to new protocols, protocol amendments, and protocol closure/termination, including correspondence to and from the Ministry of Health and Welfare and pharmaceutical companies.

5.4.7.3 大會議程包含：

5.4.7.3 The meeting agenda shall include:

a.報告工作事項。

a. Work reports

b.前期會議記錄。

b. Minutes of the last meeting

c.計畫案之討論表決、審查核備。

c. Review of, voting on, and approval of protocols.

d.實地訪查。

d. Monitoring visits.

e.提案討論。

e. Motions.

f.臨時動議。

f. Other business.

g.主席結論。

g. The chair's concluding remarks.

h.附錄(包含追認案、衛生主管機關公文備查等)。

h. Appendices (including confirmation of approval documents, official correspondence from the Ministry of Health and Welfare, etc.)

5.5 召開會議

5.5. Meeting Procedure

5.5.1 委員及承辦人員出席會議時，應於「簽名單」簽到。會議結束時或中途離席應簽退，簽到及簽退應註明時間及中途離席之原因。

5.5.1 The reviewers and staff members should sign in with date and time when attending the meeting, and sign out with date and time when the meeting is over or when leaving early with reasons written in the sign-out sheet.

5.5.2 由該會議負責之承辦人員負責議程及相關資料頌讀，再由會議主席進行主持。經與會者充分討論達成共識後，由會議主席宣讀會議之決議。

5.5.2 The meeting should be conducted by the chair of the meeting. Agenda items and related information should be read aloud by the staff member in charge of arranging the meeting. For discussion items, after the attendees have fully discussed each item and come to a consensus, the chair should announce the resolution.

5.5.3 若有拍照需求時，業務承辦人應於會前指派專人，於會議過程中擇適當時機拍照。

5.5.3 If there is a need for photo taking, the staff member should assign a photographer in advance to take photos at appropriate times during the meeting.

5.5.4 來賓觀摩會議

5.5.4 Inviting Guests

主任委員有權裁決是否允許來賓觀摩會議，來賓得包括觀察員、訪查人員或評鑑委員，並需簽署保密協議書。
The IRB Chair has the right to determine whether guests are allowed to attend and observe a meeting or not. Guests may include observers, auditors or outside reviewers. Guests should be required to sign agreements of confidentiality.

5.5.5 若為召開例行性審查大會，會議開始時應請委員遵守利益迴避原則。
5.5.5 At the beginning of a regular IRB board meeting, members should be asked to comply with the conflict of interest policy.

5.5.6 承辦人員報告
5.5.6 Staff Member's Report
承辦人員報告前次會議之提案與決議及本次會議議程。
The staff member gives a report on the motions and resolutions from the last meeting and the agenda for the current meeting.

5.5.7 會議討論及決議事項
5.5.7 Discussion and Resolutions of Agenda Items
承辦人員應記錄會議討論及各項決議事項。
The staff member should record the discussion and resolutions of all agenda items.

5.5.8 會議進行之調整
5.5.8 Adjustment of the Meeting Procedure
會議依議程進行，但主任委員得視實際情況調整。
Meetings should be conducted according to the agenda, but the Chair may make adjustments if necessary.

5.5.9 一般計畫案(含新案、修正案、追蹤審查、院內嚴重不良事件通報、非預期問題、試驗偏離/背離、結案、計畫暫停或終止)之審查程序（如有利益衝突之委員應於離席後始進行報告、討論與表決）。
5.5.9 Review of Full Board Protocols (including new protocols, protocol amendment, continuing review, serious adverse

event reporting within TCVGH, unanticipated problems, protocol deviation/violation, study closure, protocol suspension or termination) (Members with conflict of interest should excuse themselves from the meeting room before any report, discussion or voting about the protocol begins.)

5.5.10 審查委員報告

5.5.10 Reviewer's Report

5.5.10.1 審查程序開始時，主審委員簡短報告該申請案之摘要內容及審查意見。審查意見之報告應遵循審查意見表，內容含計畫設計與執行、潛在受試者招募、受試者之照護、受試者知情同意、隱私與保密、數據安全監測計畫、綜合審查意見及建議與審查結果等。

5.5.10.1 When the review process begins, the primary reviewer should give a brief report on the summary of the protocol and the reviewer's comments. The report on the reviewer's comments should follow the format of the review form, which includes items such as protocol design and implementation, recruitment of potential subjects, subjects protection, informed consent of subjects, privacy and confidentiality, data safety monitoring plan, overall comments and suggestions, and review decision.

5.5.10.2 若原審查委員因故無法出席，得由執行祕書/副主任委員/主任委員擇一代為報告。

5.5.10.2 If the original reviewer is unable to attend the meeting, the IRB Executive Secretary, Vice Chair or Chair may give the report on behalf of the reviewer.

5.5.10.3 審查委員報告之後，所有與會委員均有責任針對計畫案積極提出問題與建議。

5.5.10.3 After the reviewer's report, all members in attendance have the responsibilities to actively make comments, give suggestions, and ask questions about the protocol.

5.5.10.4 主席應注意與會委員是否均發言且已充分表達意見，尤

其是非生物醫學科學背景委員。

5.5.10.4 The Chair should pay attention to the participation of all members in attendance and notice whether or not they have spoken or fully expressed their opinions, especially members who are non- biomedical science practitioners

5.5.10.5 主席應主動邀請受試者（團體）代表發言表達意見。

5.5.10.5 The Chair should actively invite advocate(s) of trial subjects (groups) to speak and express their opinions during the meeting.

5.5.10.6 試驗計畫主持人報告

5.5.10.6 Principal Investigator's Report

a.試驗計畫主持人進入會場後針對申請案的任何問題提出答覆，並就計畫目的、評估資料及試驗方法等提出報告。

a. The PI should respond to questions raised during the meeting about the protocol and give a report on the objective, assessment and methodology of the protocol.

b.得允許計畫管理者、試驗委託者等列席參與申請案相關部分的會議議程。

b. Protocol manager or sponsor of a clinical trial may be allowed to attend and participate in the part of a meeting related to the protocol.

c.若審查委員判定計畫主持人需列席說明，計畫主持人或共(協)同計畫主持人須出席大會說明計畫案。若計畫主持人或共(協)同計畫主持人無法出席，可請審查委員進行報告及委員討論後直接給予大會意見，或該計畫案順延至下次會期審查。若審查委員審查結果為「推薦」，而計畫主持人或共(協)同計畫主持人因故無法出席時，大會得對該案進行討論與表決。

c. If judged necessary by the reviewer, the principal investigator or co-investigator of a protocol will be required to attend the meeting to present the protocol. If the PI or Co-I is unable to attend the meeting, the

reviewer can give the report and make the final comment after discussion with board members or the review of the protocol be tabled to the next meeting. If the previous review result of the protocol was “recommended for approval” but the PI or Co-PI is unable to attend the meeting, then the meeting members may discuss and vote on the protocol.

d.兩名審查委員於初審時均判定此案計畫主持人不需列席說明時，承辦人員會在會前告知計畫主持人。

d. If both reviewers in the primary review determined that the PI is not required to attend the meeting to present the protocol, then the staff member should inform the PI before the scheduled meeting.

e.若初審時委員判定計畫主持人不需列席說明，計畫主持人亦得要求出席報告。會議中如為增進審查效率，主席得視狀況臨時邀請試驗計畫主持人蒞會說明。

e. If in the primary review, the reviewers determined that the PI does not need to attend the meeting to give a presentation, the PI may still request to attend the meeting and present the protocol. In order for the review to be efficient during the meeting, the Chair may ask the PI to attend the meeting and present without prior notice.

f.計畫主持人出席會議討論時，因有非生物醫學科學背景委員在場，請計畫主持人報告計畫時，盡量勿使用醫療專業術語表達。

f. In the presence of members who are not bio-medical science practitioners, the PI should avoid using medical jargons when presenting the protocol during the meeting.

5.5.10.7 全體出席委員進行討論後，透過電子表決器匿名投票。

5.5.10.7 After discussion, all attending members should vote on the protocol anonymously on an electronic voting device.

5.5.11 投票表決

5.5.11 Voting

5.5.11.1 一般審查案(含新案、修正案、追蹤審查、院內嚴重不良事件通報、非預期問題、試驗偏離/背離、結案、計畫暫停或終止)。

5.5.11.1 Full Board Review Protocols (including new protocols, protocol amendment, continuing review, adverse event reporting within TCVGH, unanticipated problems, protocol deviation/violation, study closure, protocol suspension or termination).

5.5.11.2 只有與計畫主持人及試驗委託者無利益衝突之委員有投票權。未全程參與審查案討論之委員，無投票權。

5.5.11.2 Members have the right to vote only if they have no conflict of interest with the PI or the sponsor of the clinical trial. Members who do not attend the whole discussion of the protocol in the meeting cannot vote.

5.5.11.3 投票表決需在利益衝突的委員和計畫相關人員均離席後方可舉行。

5.5.11.3 Voting should take place only after all personnel with conflicts of interest have left the meeting room.

5.5.11.4 主席需確認每個案件可投票的委員人數是否達到法定投票人數(Quorum)（即出席委員超過全體委員總數之半數以上，出席委員至少含 1 位不同性別之委員、院外委員、非生物醫學科學背景委員，同 1 位委員得代表多個身分別）。

5.5.11.4 The Chair should make sure that a quorum is reached for voting for each motion. (The members present should be more than half of the total number of members. Among all members present, both genders should be represented. At least one member present should be non-TCVGH-affiliated. At least one member present should be from a non-biomedical science background. A member may represent more than one identity groups.)

5.5.11.5 委員會審查案件，非經討論，不得逕行決定。決定前，

主席宜主動詢問院外及非生物醫學科學背景委員委員之意見。

5.5.11.5 The resolution on a protocol should not be made without discussion. Before a resolution is made, the Chair should actively ask non-TCVGH-affiliated members and non-biomedical science background members to voice their opinions.

5.5.11.6 投票表決前應先確定可投票委員人數已達法定人數，投票結果以「多數決方式」為原則，如投票結果有重大歧異（如：表決結果票數相近等），主席得裁示經討論後重新投票。應紀錄包括核准、修正後核准、修正後複審、不核准和棄權等各項票數。

5.5.11.6 Before voting on the approval of the study application, the number of voting members present should be counted and it has to reached the quorum. Voting outcome is based on the principle of "Majority rule". If there is a major discrepancy in the voting result, the Chair may ask the attending members to vote again. The record of the voting results should include the number of votes for “approval,” “approval after revision,” “further review after revisions,” “disapproval,” and “abstention,” respectively.

5.5.11.7 投票結果有兩項以上票數相同時，將請委員重新投票。

5.5.11.7 If two of the voting options get the same number of votes, all members should vote again.

5.5.11.8 主席應於大會中宣讀投票結果及修正內容，並確認新案的追蹤審查頻率。

5.5.11.8 During the meeting, the Chair should announce the voting results and the revisions required for the protocol, and confirm the continuing review frequency for new protocols.

5.5.12 臨時動議

5.5.12 Other Business

5.5.12.1 委員得針對相關議題提出臨時動議。

5.5.12.1 Members may propose relevant extempore motions

in other business.

5.5.12.2 臨時動議經附議後可提付表決。

5.5.12.2 If an extempore motion is seconded, then the motion may be voted on.

5.5.12.3 當超過半數與會委員投贊成票時，通過臨時動議決議。

5.5.12.3 An extempore motion passes when more than half of the attending members vote in favor of the motion.

5.5.13 會議結束前，主席應做總結，並宣佈散會。

5.5.13 Before the end of the meeting, the Chair should give concluding remarks and announce the adjournment of the meeting.

5.6 製作會議紀錄

5.6 Meeting Minutes

5.6.1 會議由承辦人員負責記錄，承辦人可聽取錄音設備以確實正確記錄，先以電子郵件方式將記錄初稿提供全體委員審閱，經主任委員核准後於下次大會時進行核備。

5.6.1 The staff member in charge of organizing the meeting should be the recording secretary of the meeting and write meeting minutes. The staff member may listen to audio recording of the meeting while writing the minutes in order to ensure that accurate record of the meeting is kept. The draft of the minutes should be sent to all attending members by email for review. After the IRB Chair confirms the minutes, the minutes should be voted on for approval in the next scheduled meeting.

5.6.2 若為召開例行性的審查大會，承辦人應於大會結束後 14 天內，並將大會決議通知計畫主持人，以利計畫主持人回覆大會審查意見。

5.6.2 If the meeting is a regular review meeting, the staff member should inform the PI of the resolution made in the meeting about the protocol within 14 days after the meeting so that the PI may respond to reviewers' comments promptly.

5.6.3 錄音檔保存至少至大會結束後 3 年，需承辦人員密碼方能存取。

5.6.3 The audio recording of the meeting should be kept for at least three years after the meeting. The file of the audio recording should be protected by a password set by the staff member.

5.6.4 經副主任委員/主任委員批核之會議紀錄，將上陳院長陳閱。

5.6.4 Meeting minutes approved by the IRB Chair or Vice Chair should be submitted to the Superintendent of TCVGH for review.

5.7 決議事項分辦

5.7 Follow-up on Resolutions

5.7.1 會議紀錄歸檔

5.7.1 Record Keeping of Meeting Minutes

應將會議紀錄正本及已簽署核准之審查決議文件歸檔。

Meeting minutes and documents of approved review resolutions should be filed and kept in record.

5.7.2 分送會議紀錄與審查決議

5.7.2 Distribution of Meeting Minutes and Review Resolutions.

5.7.2.1 以電子郵件方式將已核備之會議記錄寄送全體委員，委員應予保密。

5.7.2.1 Approved minutes should be sent to all members by email. Members should keep the minutes confidential.

5.7.2.2 配合人體試驗管理辦法第六條規定有關「公開」方式規定，將核准之會議紀錄內容公開公布於本會網頁，內容包含一般審查件數、計畫主持人及會議投票結果，以表示對審查過程之資訊的透明化。

5.7.2.2 To comply with the regulation regarding disclosure of information in Article 6 of the Regulations on Human Trials, the content of approved meeting minutes should be announced on the IRB website. The content disclosed to the public includes number of reviewed protocols, names of principal investigators,

and voting results. The disclosure of the information shows the transparency of information about the review procedures.

5.8 紀錄保存

5.8 Records Retention

5.8.1 大會承辦人員應將大會會議紀錄網路版上傳至本會網頁公告。

5.8.1 Staff members should upload the public version of the meeting minutes to the IRB website.

5.8.2 會議承辦人員應依會議之規定，妥善保存各項相關紀錄。

5.8.2 Staff members should keep all records carefully following the regulations about meeting procedures.

5.8.3 承辦人員應依據檔案管理之標準文件程序妥善保存會議紀錄核定本。

5.8.3 Staff members should follow the SOP on Records Retention to keep the approved meeting minutes.

編號 No.	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	開會通知單 Meeting Notice	IRB 辦公室 IRB Office	會議結束後至少 3 年 At least 3 years after the meeting is over
2	會議議程 Meeting Agenda	IRB 辦公室 IRB Office	會議結束後至少 3 年 At least 3 years after the meeting is over
3	簽文（含簽名單、會議紀錄、附件） Meeting Documents (including sign-in/sign-out sheets, minutes, appendices)	IRB 辦公室 IRB Office	會議結束後至少 3 年 At least 3 years after the meeting is over
4	錄音檔 Files of audio recording	IRB 辦公室 IRB Office	會議結束後至少 3 年 At least 3 years after the meeting is over
5	會議紀錄 Meeting Minutes	IRB 辦公室 IRB Office	會議結束後至少 3 年 At least 3 years after the meeting is over
6	大會審查結果意見表 Review Comments	IRB 辦公室 IRB Office	會議結束後至少 3 年 At least 3 years after the meeting is over

6.附件

6. Appendices

6.1 開會通知單

6.1 Meeting Notice

6.2 會議議程

6.2 Meeting Agenda

6.3 簽文

6.3 Request for Approval of Meeting Resolutions

6.4 紀錄撰寫格式

6.4 Meeting Minutes Templates