



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	6.2	檔案名稱 File name	會議程序與紀錄及通訊記錄 IRB Meeting and Minutes Communication records		
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1. 目的 Purpose

為提供人委會各類會議程序進行、議事管理之依據，做為本會會議議程之製作、案件審查、議程、會議紀錄、審查決議及開會通知單之寄送等相關作業規範。

To provide relevant operational regulations for the conductance of the meeting agenda and the foundation of meeting management for the KMUH IRB to prepare and conduct case review, meeting agenda, meeting minutes, meeting resolutions and send meeting notifications.

2. 適用範圍 Scope

適用於人委會定期審查、行政與緊急會議議程之行政程序，包含會前準備、會議進行中及會後事宜等三個階段的程序與會議/通訊紀錄。

It is applicable for the IRB to regularly review the administrative procedures of the administrative and emergency meeting agenda, including the procedures and meeting/communication minutes at pre-meeting preparation, during the meeting and after the meeting.

3. 參考文件 References

3.1 人體試驗管理辦法 (2016年4月)

Regulations on Human Trials (April 2016)

3.2 藥品優良臨床試驗準則 (2014年10月)

Guidelines of Good Clinical Practice (October 2014)

3.3 藥物樣品贈品管理辦法 (2003年7月)

Regulations Governing Medicinal Samples and Gifts (July 2003)

3.4 人體研究倫理審查委員會組織及運作管理辦法 (2012年8月)

The Organization and Operational Regulations for the Institutional Review



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Board (August 2012)

3.5 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

3.6 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

4. 名詞定義 Terminology

4.1 審查會議：定期召開審查會議，評估研究計畫是否合乎研究倫理及科學要求。

Review meeting: It is convened regularly to evaluate whether the study has met research ethics and scientific requirements.

4.2 行政會議：定期召開行政會議，檢討與處理人委會各類行政作業程序。

Administrative meeting: Which is convened regularly to discuss and handle various administrative operations of the IRB.

4.3 法定人數：人委會審查會議應有半數以上之委員出席始得開會，若出席委員均為單一性別時，不得進行會議。出席委員應包括機構外之非具生物醫學科學背景委員一人以上、審查查驗登記案時至少有一名執業醫師、至少一位委員足以代表研究受試者之觀點審查案件。

Quorum: The review meeting can only be convened after the number of the attendance is more than half of the number of the members. If the attending members are all the same gender, the meeting cannot be continued. The attendance of at least one non-medical non-affiliated member is required. For reviewing studies for registration, the attendance of at least one practitioner is required. The attendance of at least one member, whose identity is sufficient to represent the subjects' point of view while reviewing the study, is also



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required.

4.4 會議紀錄：人委會審查會議的正式紀錄，包括議程所列事件的討論、決議及各項表決的結果。所審查計畫案的表決紀錄採不記名方式，註明核准、修正後複審、修正後重新送審和不核准的票數及理由。

Meeting minutes: The official record of the IRB review meeting, including the discussion of all listed events, resolutions and the results of the votes. The vote for study review is anonymous, and the vote results shall indicate the votes and reasons for “approved”, “secondary review after amendment”, “resubmission after amendment” and “not approved”, respectively.

4.5 多數票決：議案需在達法定人數之會議中投票，表決過半贊成，才能通過。

Majority vote: The case shall be voted after the number of the attendance has reached quorum, and the case can be approved if more than half vote for “agree”.

5.作業內容 Scope of operation

5.1 流程 Process

程序 Procedure	權責 Rights and responsibilities	相關文件 Related documents
會前準備 Pre-preparation	行政人員 Administrative staff	會議議程/審查資料 Meeting agenda/Review files
會議進行 Meeting is ongoing	主任委員/委員 Committee director/Committee member	錄音檔 Voice recording files
會議決議/投票表決 Meeting resolutions/Vote results	無利益衝突之委員/執行秘書/ 行政人員 Member without conflict of interest/Administrative staff	投票單 Ballot



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會後紀錄整理 Summary after the meeting	行政人員 Administrative staff	會議紀錄 Meeting minutes
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5.2 職責 Responsibilities

5.2.1 主任委員：擔任會議主席，負責主持會議及核准紀錄。

Committee director: The leader of the meeting who is responsible for leading the meeting and approves the minutes.

5.2.2 委員會委員：決議計畫案是否符合受試者權益保護。

IRB members: To decide whether the study has achieved the protection of subject's rights.

5.2.3 執行秘書：確認會議議程及會議紀錄品質與正確性。

Executive secretary: Confirm the meeting agenda and the quality as well as accuracy of the meeting minutes.

5.2.4 行政人員：負責製作會議議程與記錄，得視實際需要透過電話或當面討論，凡涉及人委會的申請案和作業程序時，均應有書面紀錄。

Administrative staff: Responsible for preparing meeting agenda and meeting minutes. For the applications and SOPs involving the IRB, the Administrative staff may discuss through telephone or face-to-face, but written records are all required.

5.3 細則 Rules

5.3.1 審查會前準備工作 Pre-preparation for review meeting

5.3.1.1 徵詢院外委員及主任委員意見後訂定每月開會日期，並公告於人委會網頁，必要時由執行秘書安排加開會議。

The monthly meeting schedule is set after consulting the opinions of the committee director and the non-affiliated members. And then the



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schedule will be announced on the IRB website. Additional meeting may be arranged by the executive secretary if necessary.

5.3.1.2 行政人員於會議前確認會議準備資料，並完成會議議程/紀錄表(附件一)。

The Administrative staff shall confirm the meeting materials and complete the Meeting Agenda/Minute Form (Attachment 1).

5.3.1.3 開會日期一週前以電子郵件通知相關人員。

E-mail relevant personnel one week before the meeting date.

5.3.1.4 行政人員至少於開會前7個工作日，將會議議程及申請案件相關資料，送交與會委員，確保給予委員充分時間預先審閱相關會議資料。

The Administrative staff shall send the meeting agenda and application-related materials to the reviewer at least 7 working days before the meeting to ensure that the reviewers have sufficient time to preview meeting-related materials.

5.3.1.5 電子化審查作業以 e-mail 方式通知委員審查，並提供個別委員線上密碼，供委員在會前至 PTMS 系統審查。

For electronic review process, the IRB will notify the reviewers to conduct review through e-mail and provide a set of online password for reviewers to log in to the PTMS system for review before the meeting.

5.3.2 審查會議進行中 The meeting is ongoing

5.3.2.1 委員出席

The attendance of the member



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A. 審查會議應有半數以上委員出席。

At least half of the member shall attend the meeting.

B. 出席委員應包括機構外之非醫療委員 1 人以上。

Among the attendee, there shall be at least one nonmedical member.

C. 出席委員均為單一性別時，不得進行會議。

If all attendance is the same gender, the meeting cannot be continued.

D. 審查查驗登記案時至少有一名執業醫師。

At least one practitioner's attendance is required for reviewing studies for registration.

E. 至少一位委員足以代表研究受試者之觀點審查案件。

At least one member's identity is sufficient to represent the subjects to review the study.

F. 若為委員參與之計畫案，依利益迴避原則執行。

If the reviewer is involved in the study being reviewed, he/she shall comply with the avoidance principles of conflict of interest.

G. 若出席委員不符法定人數時，得由替代委員出席。

If the number of attendee does not reach the quorum, the attendee of alternative members may be required.

5.3.2.2 列席人員 Attendee

A. 人委會審查之一般審查計畫案之計畫主持人應列席會議，若該案件計畫主持人未克出席，得請共同、協同主持人列席報告。

For reviewing regular studies, the PI shall attend the IRB meeting.



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If the PI cannot attend the meeting due to certain reasons, the co-or sub-investigator shall attend the meeting to report.

B. 基因相關與特殊族群及易受傷害族群計畫案得視需要列席報告。

For gene-related studies or studies involve special and vulnerable population, the attendance of the PI may or may not be required depending on the necessity.

C. 若計畫案受試者為特殊族群及易受傷害族群，必要時得邀請非委員之其他專門領域專家或特殊身份之研究對象（受試者）代表參與審查會議或提供審查意見。

If the subjects or special or vulnerable population, the non-member experts in other professional filed or the representative of subjects with special identity (subject) may be invited to attend the meeting or provide review comments.

D. 發生於本院之嚴重不良事件（SAE）由嚴重不良事件(SAE)初審專家判斷該計畫主持人是否須列席報告，若計畫主持人未克出席，得請共同、協同主持人列席報告。

For studies have in-hospital SAE, the attendance of the PI shall be decided by the SAE initial review experts. If the PI cannot attend the meeting due to certain reasons, the attendance of the co-or sub-investigator is required.

5.3.2.3 審查會議流程

The process of review meeting



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A. 會議開始由主任委員確認出席人數已達法定人數，並宣讀利益迴避原則，提醒各委員及出席者會議之規範。若主任委員因故無法出席會議，得由副主任委員代為主持會議。主任委員/副主任委員因故無法出席或需中途離席，得指派委員代為主持會議。但出席委員須達法定人數，始得進行會議。

At the beginning, the committee director will confirm the number of attendance has reached the quorum, and then the committee director will read the conflict of interest avoidance rules to remind all members and attendance of the meeting regulations. If the committee director cannot attend the meeting due to certain reasons, the vice committee director will lead the meeting on behalf of the committee director. If the committee director/vice committee director cannot attend the meeting due to certain reasons or required to leave in the middle of the meeting, he/she may appoint a member to lead the meeting. However, the meeting can only begin if the quorum has achieved.

B. 執行秘書報告上次會議執行情況。

The executive secretary will report the implementation status of the last meeting.

C. 會議依議程順序進行，但主席得視實際情況調整。審查委員若涉及利益衝突，於該案討論前需離席迴避。

The meeting will be run by following the procedures, but the committee director may modify the procedures depending on actual situations. If the reviewer has conflict of interest against the



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study, he/she shall leave the meeting before the case is sent for discussion.

- D.視實際情況需要，委員/諮詢專家得以視訊方式參與會議討論。以視訊方式參與會議討論之委員須簽署視訊會議保密切結書，並確保視訊須於非開放性空間進行，且於會議進行中不可有其他人在場。

If necessary, the reviewers/consultant experts may participate in the meeting through conference call. Members who use conference call shall sign the confidentiality agreement regarding to guarantee the conference call is not in a public space, and no other attendance is allowed during the meeting.

- E.特殊案件可邀請受試者(團體)代表，提供諮詢意見或列席會議參與討論。

For special cases, subject (group) representatives may be invited to provide consultation, comments or even attend the meeting for discussion.

- F.主席有權裁決是否允許來賓觀摩會議議程，來賓需簽署保密協議書(附件二)。

The committee director has the rights to decide whether the visitors could observe the meeting process. The visitors shall sign a Confidentiality Agreement (Attachment 2).

- G.個別研究計畫討論過程中，審查委員應參考初審審查意見表，針對計畫案研究設計提出審查意見。主席須主動詢問非醫療委員之意見。討論結束後，主席總結討論意見並依議定的方式，



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請出席委員表決(附件三)。

During the discussion of individual studies, the reviewer shall take the initial review comment form as references and provide review comments for the study. The committee director shall actively inquiry the comments of the nonmedical members. After discussion, the committee director shall summarize the review comments and ask the attendant members to vote based on the designated approach (Attachment 3).

H.一般審查案、基因相關與特殊族群及易受傷害族群研究計畫之新案表決方式採不記名投票，投票結果分為：「核准(須依審查意見修正)」、「修正後複審」、「修正後重新送審」、「不核准」。人委會對決議「不核准」之計畫案須說明理由。計畫主持人對於「不核准」之決議得申請覆議一次。

For regular cases, gene-related studies and studies involving special and vulnerable population, the vote shall be anonymous. The vote results could be “approved (amendment is required based on the review comments)”, “secondary review after amendment”, “resubmission after amendment”, and “not approved”. The IRB shall describe the reasons for deciding “not approved”. The PI may apply for appeal once regarding the resolution of “not approved”.

I.表決結果票數相同時，則於再次討論後，重新表決，以超過出席總人數半數為有效票；若再為同票時，採下列從嚴原則：(1) 投票結果為『核准』及『修正後複審』之票數相同時，以『修正後複審』為最後之決議。(2) 投票結果為『修正後重新送審』



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及『不核准』之票數相同時，以『不核准』為最後之決議。

If the votes are tied, the members will vote again after the secondary discussion. Effective votes are determined as the votes more than half of the attendance. If the votes are tied again, the following rules shall be followed whichever is stricter: (1) If the votes for “approved” and the votes for “secondary review after amendment” are tied, “secondary review after amendment” shall be the final resolution; (2) If the votes for “resubmission after amendment” and the votes for “not approved” are tied, “not approved” shall be the final resolution.

J.主席宣布票數統計結果，並確認討論議案之紀錄。

The committee director will announce the statistic results of the votes and confirm the meeting minutes.

K.臨時動議：人委會委員或執行秘書得針對申請案或相關議題提出臨時動議，經附議後採共識決。

Extempore motion: The IRB or executive secretary may propose an extempore motion for the application or relevant topics. The decision will be made as a consensus after the motion has been seconded.

L.會議全程應錄音，並由行政人員記錄會議報告事項、討論重點、決議及特殊事件。

Voice recording is required during the entire meeting, and the Administrative staff shall record the reports, discussion key points, resolutions and special events.



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5.3.3 審查會後事宜 Matters after the review

5.3.3.1 會議紀錄之製作

The preparation of meeting minutes

A. 行政人員參照會議議程/紀錄表(附件一)撰寫會議紀錄，並於會議結束後7個工作日內製作完成。

The Administrative staff will prepare the meeting minutes based on the Meeting Agenda/Minute (Attachment 1) and complete the minutes within 7 working days after the meeting is finished.

B. 執行秘書核對會議紀錄的正確性及完整性。

The executive secretary shall verify the accuracy and completeness of the meeting minutes.

C. 主席簽署核准會議紀錄及審查決議。

The committee director will sign and approve the meeting minutes and review the resolutions.

D. 主任委員審閱後，送交受試者保護中心及行政室核備。

After being reviewed by the committee director, the minutes will be sent to the CHSP and administrative office for reference.

5.3.3.2 工作人員應於會議結束後10個工作日內，將會議結果通知申請人。

The staffs shall notify the meeting results to the application within 10 working days after the meeting is finished.

5.4 行政會議 Administrative meeting

5.4.1 定期召開之行政會議，由主任委員、副主任委員、執行秘書及行政人員出席，必要時得視情況加開緊急會議。



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The administrative meeting is convened regularly, and the attendance of the committee director, vice committee director, executive secretary and Administrative staff is required. Emergency meeting may be convened if necessary.

5.4.2 會議討論事項 Meeting discussion matters

5.4.2.1 人委會相關業務溝通協調。

To communicate and coordinate IRB-related businesses

5.4.2.2 臨時發生必須裁決之行政業務。

The administrative businesses occur accidentally and require ruling.

5.4.2.3 研究計畫案之倫理申訴案件。

Ethical complaints about studies.

5.4.2.4 人委會評鑑相關事宜。

IRB accreditation-related matters.

5.4.2.5 人委會參訪相關事宜。

IRB visiting-related matters.

5.4.2.6 三分之一委員連署要求召開之議題。

One third of the members have submitted a petition to decide the topic of the meeting.

5.4.2.7 其他需人委會全體人員出席討論之事項。

Other matters that require full attendance of the IRB to discuss.

5.4.3 行政會議流程 The process of administrative meeting

5.4.3.1 主任委員確定會議時間，行政人員於會期前至少 2 個工作日，以電子郵件寄發開會通知單、議程及其他相關資料。

The committee director will confirm the meeting time, and the



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Administrative staff shall post meeting notice, agenda and other related materials through e-mail at least 2 working days prior to the date of the meeting.

5.4.3.2 與會人員針對行政議題提出意見說明，採共識決。

The attendance will propose comments and descriptions about the administrative topics. The decision will be made as a consensus.

5.4.3.3 與會人員針對其他相關行政議題提出臨時動議，經附議後採共識決。

The attendance will propose extempore motion about the administrative topics. The decision will be made as a consensus after the motion has been seconded.

5.4.3.4 行政人員撰寫會議紀錄，並於會議結束後3個工作日內製作完成。

The Administrative staff will prepare the meeting minutes and complete the minutes within 3 working days after the meeting is finished.

5.4.3.5 執行秘書核對會議紀錄的正確性及完整性。

The executive secretary shall verify the accuracy and completeness of the meeting minutes.

5.4.3.6 主任委員核定會議紀錄及決議後，陳行政室備查。

The committee director shall review and approve meeting minutes and send to the administrative office for reface after making decisions.

5.5 文件歸檔 File archiving



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5.5.1 人委會行政人員應妥善保存會議紀錄，包括會議議程、會議簽到單、會議審查意見格式表(附件四)、會議審查結果統計格式表(附件五)及所有來往文件。

The Administrative staff of the IRB shall preserve the meeting minutes properly, including the meeting agenda, meeting sign-in list, Meeting Review Comments Form (Attachment 4), Meeting Review Results Statistic Form (Attachment 5) and all communication files.

5.5.2 人委會保留已簽署核准之審查決議文件，正本存於行政室歸檔，副本副知受試者保護中心。

The IRB shall retain signed and approved resolution files, archive the original file in the administrative office and carbon copy the copies to the CHSP.

5.5.3 會議紀錄可提供調閱及網站下載瀏覽。

Meeting minutes are available for review and downloaded from the website.

6.附件 Attachment

6.1 附件一 (KMUH/IRB/AF/6.2-01/11.0) 會議議程/紀錄表

Attachment 1 (KMUH/IRB/AF/6.2-01/11.0) Meeting Agenda/Minutes

6.2 附件二 (KMUH/IRB/AF/6.2-02/11.0) 參訪人員-保密協議書

Attachment 2 (KMUH/IRB/AF/6.2-02/11.0) Visitors - Confidentiality Agreement

6.3 附件三 (KMUH/IRB/AF/6.2-03/11.0) 投票單

Attachment 3 (KMUH/IRB/AF/6.2-03/11.0) Ballot

6.4 附件四 (KMUH/IRB/AF/6.2-04/11.0) 會議審查意見格式表



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Attachment 4 (KMUH/IRB/AF/6.2-04/11.0) IRB Review Comment Form

6.5 附件五 (KMUH/IRB/AF/6.2-05/11.0) 會議審查結果統計格式表

Attachment 5 (KMUH/IRB/AF/6.2-05/11.0) Meeting Results Statistic Form