



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-2018 IRB-Regulations of Operation-2018	文件名稱 Title	臨時會議管理程序書 SOP for Extraordinary IRB 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	<input checked="" type="checkbox"/> 普通 <input type="checkbox"/> 密件 <input type="checkbox"/> 極機密 <input checked="" type="checkbox"/> Unclassified <input type="checkbox"/> Confidential <input type="checkbox"/> Highly Confidential
適用單位 Applied to	<input type="checkbox"/> 全院 <input type="checkbox"/> All units in the hospital <input checked="" type="checkbox"/> 其他，請註明：第一/二人體研究倫理審查委員會 <input checked="" type="checkbox"/> 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	6	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	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」。 The original "Human Research Committee" was renamed "The First/Second IRB Committees"	20160318
D	4	修改 4.1.2 修辭：新增議案進行「討論」2 字。 The wording of item 4.1.2 was revised: "Discussion" was added to the sentence regarding a new motion on the meeting agenda.	20170709
E	6	1. 修改 5.4.2 之投票方式。 1. The voting method in item 5.4.2 was revised. 2. 抽換附件 6.1。 2. Appendix 6.1 was replaced.	20190527
F	6	1. 文字校正。 1. Typos were fixed. 2. 抽換附件 6.1。 2. Appendix 6.1 was replaced.	20210528
G	6	1. 抽換附件 6.1。 1. Appendix 6.1 was replaced.	20211209

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



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

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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。

※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.



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1. 目的

1. Purpose

本管理程序書訂定的目的為確立臨時會議召開的行政流程，包括審查方式和案件決議的程序。

The purpose of this SOP is to provide guidelines for the administrative procedures of extraordinary IRB meetings, which include the review procedure and the process of making a resolution on a protocol.

2. 適用範圍

2. Scope

2.1 本管理程序書適用於第一/二人體研究倫理審查委員會臨時召開之會議。

2.1 This SOP applies to extraordinary IRB meetings held by the First/Second IRB Committees.

2.2 主要是審查當發生危及臨床試驗受試者生命安全之議題或突發事件時，臨時召開之會議。

2.2 An extraordinary IRB meeting is convened in order to review an urgent issue or incident that threatens the safety of the subjects.

3. 參考文件

3. References

無。

None.

4. 名詞定義

4. Definitions

4.1 臨時會議

4.1 Extraordinary IRB Meeting

4.1.1 除了定期舉行的第一/二人體研究倫理審查委員會大會外，視實際情況需要而臨時召開之會議。





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4.1.1 The extraordinary IRB meeting is an ad hoc meeting that is convened outside the schedule of regular IRB board meetings.

4.1.2 需達法定人數方得召開會議及就議案進行討論及投票表決。

4.1.2 A quorum has to be present for the meeting to be called to order and for the motions to be discussed and voted on.





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5.作業內容

5. Procedure

5.1 臨時會議管理流程圖

5.1 Flow Chart of the Extraordinary IRB Meeting

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2021.12.23
參考文件

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Document
	(副)主任委員/執行秘書/委員/承辦人員 (Vice) Chair/Executive Secretary/IRB Members/Staff (副)主任委員/執行秘書/委員/承辦人員 (Vice) Chair/Executive Secretary/IRB Members/Staff (副)主任委員/執行秘書/委員/承辦人員 (Vice) Chair/Executive Secretary/IRB Members/Staff 承辦人員/研究相關人員 Staff/Research personnel 承辦人員 Staff Members	會議資料/ 會議簽到單 Meeting documents/ Meeting sign-in sheet 會議決議 Meeting resolutions 會議紀錄 Meeting minutes



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5.2 接獲臨時會議通知

5.2 Calling an Extraordinary IRB Meeting

5.2.1 主任委員召開臨時會議之情況：

5.2.1 In one of the following situations, the IRB Chair may call an extraordinary IRB meeting:

5.2.1.1 危害公共福祉、國家經濟之突發事件。

5.2.1.1 An urgent incident occurred that had a negative impact on public welfare or national economy.

5.2.1.2 發生非預期嚴重不良反應事件。

5.2.1.2 An unexpected serious adverse event occurred.

5.2.1.3 發生攸關受試者死亡的事件。

5.2.1.3 A subject died due to participating in the study.

5.2.1.4 其它。

5.2.1.4 Others.

5.2.2 聯絡相關出席委員，並通知會議之召開時間及地點。

5.2.2 The staff member should contact IRB members who should attend the meeting, and inform them of the time and the location of the meeting.

5.2.2.1 會議至少必須有半數以上之委員出席，其中至少須有一名生物醫學科學背景委員、一位非生物醫學科學背景委員、院外人員及不同性別之委員代表出席。

5.2.2.1 The members present should be more than half of the total number of members. At least one member present should be with a biomedical science background. At least one member present should be without a biomedical science background. At least one member present should be non-TCVGH-affiliated. Attending members should include both men and women.





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- 5.2.2.2 視實際情況可邀請相關議題之專家（為委員或非委員）出席。
- 5.2.2.2 Expert consultants (IRB members or non-IRB members) may be invited to attend the meeting based on actual needs.
- 5.2.2.3 必要時，可請計畫主持人或相關人員列席說明。
- 5.2.2.3 If needed, the PI or relevant personnel may be invited to attend the meeting as guests and give presentations.
- 5.3 臨時會議會前準備
- 5.3 Pre-meeting Preparation
- 承辦人員準備文件如下：
- The staff member should prepare the following documents:
- 5.3.1 準備會議資料分送給各出席委員。
- 5.3.1 Prepare meeting documents and distribute them to the attending members.
- 5.3.2 準備會議簽到單。
- 5.3.2 Prepare a sign-in sheet for the meeting.
- 5.4 會議討論
- 5.4 Meeting
- 5.4.1 承辦人員確定出席委員已達法定人數。
- 5.4.1 The staff member should confirm that a quorum is present before the meeting is called to order.
- 5.4.2 出席委員和專家應就召開臨時會議之議題討論，並做出決議。結果之表決，以「多數決方式」為原則。
- 5.4.2 Attending members and expert consultants should discuss the issues on the agenda of the extraordinary meeting and make resolutions. Voting outcome is based on the principle of "Majority rule".





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5.5 執行決議事項

5.5 Follow-Up on Resolutions

承辦人員依照會議決議及密等，製作成「會議紀錄」，並通知主持人及相關人員/單位。

The staff member should write meeting minutes based on the resolutions and levels of classification, and notify the PI and relevant personnel/units.

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	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.附件

6. Appendix

6.1 會議紀錄

6.1 Meeting Minutes

