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-人員管理-2001 IRB- Personnel Management-2001	文件名稱 Title	第一/二人體研究倫理審查委員會組織章程 The Organizational Charter of the First/Second IRB Committees
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，並請註明：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	2	新訂。 Newly composed.	20140519
B	2	1. 更改文件名稱。 1. The title of the document was revised. 2. 由人體試驗委員會標準作業程序 5.4 版轉換成此版本。 2. This version was converted from “Version 5.4 of the Standard Operating Procedure of the Human Research Committee.”	20141125
C	2	新增第 5 項：獎勵。 Added Item 5: Award.	20150923
D	2	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. 原「醫療機構人體試驗委員會組織及作業基準」更改為「人體研究倫理審查委員會組織及運作管理辦法」。 2. The original “Basic Code Governing the Organization and Operation of Human Research Committee of Medical Care Institutions” was changed to “Regulations for Organization and Operation of IRB Committees.”	20160318

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E	2	1. 修改宗旨，以符合最新人體研究或試驗之法規。 1. Item 1: Purpose was amended in this document to comply with the latest regulations on human research or trials. 2. 配合人體研究法第 7 條及臺中市衛生局醫院督導考核性別友善就醫環境，落實檢視醫院各委員會，「任一性別不得低於三分之一」之要求，修改 2.1。 2. Item 2.1 was amended to comply with the requirement that any committee in a hospital should be represented by both genders, with at least one-third of members from either gender, as specified in Article 7 of the Human Subjects Research Act and in accordance with the monitoring guidelines of Taichung City Health Bureau about gender-friendly medical environments in hospitals.	20170709
F	2	1. 修改 2.2 委員任期為「每兩年一任，連聘得連任」。 1. Item 2.2 was revised to be ”an IRB member's term of office is 2 years and can be renewed upon reappointment. “ 2. 依據人事室建議，2.2 增述「聘期中如因委員異動或新聘委員，本委員會適時辦理，增聘委員之任期自發聘日起至該任期結束為止。」 2. The following statement was added in Item 2.2 based on the Personnel Office’s suggestion: “When a member is changed or a new member is added during a term of office, the new member’s term starts when the appointment is offered, and ends the same as all members.”	20180605

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G	4	依據 FERCAP 國際訪視之建議，增述 2.4「第一及第二人體研究倫理審查委員會建立獨立之審查機制，以保障受試者之權益與福祉，並提升審查效率。」 Following the suggestions made by site-visit reviewers of FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific), item 2.4 was added: “An independent review mechanism is set up by the First/Second IRB Review Committees in order to protect the rights and welfare of clinical trial subjects and to improve review efficiency.”	20181026
H	5	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.新增 2.5：「負責營業發展（例如籌募研究經費）之主管不可擔任人體研究倫理委員會委員及人體研究倫理委員會日常運作等職務。」 2. Added Item 2.5: The head of the business (such as fundraising for research) cannot be a member of the IRB and performs the day-to-day operations of the IRB. 3.新增 5：「評核」之作業方式。修改原 5 之標號為 6。 3. Added Item 5: "Evaluation" procedures of operation. The original item number 5 was changed to 6.	20191018

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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
I	5	1. 修改 5.1 及 5.2 之「評核」程序。 1. Revised Item 5.1 & 5.2: "Evaluation" procedures of operation.	20210528

臺中榮民總醫院
2021.06.10
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		

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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-人員管理-2001 IRB -Personnel Management-2001	文件名稱 Title	第一/二人體研究倫理審查委員會組織章程 The Organizational Charter of "The First/Second IRB Committees

會辦單位 Processing Unit	審查意見 Review Comments	會辦單位主管 Head of Processing Unit

臺中榮民總醫院
2021.06.10
參考文件

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※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.宗旨

遵守世界衛生組織最新版之赫爾辛基宣言、衛生福利部人體研究或試驗等相關法規及醫學研究之最新倫理標準，加強醫療或研究等相關人員之研究倫理教育，以保障病患、受試者及所有參與研究人員的權利及義務，以提升醫學研究水準。

1. Purpose

Complied with the latest version of Helsinki Declaration of the World Health Organization, relevant regulations on human subject research or clinical trials issued by the Ministry of Health and Welfare, and the latest ethical standards for medical research, the purpose of the Institutional Review Board (IRB) of Taichung Veterans General Hospital (TCVGH) is to strengthen research ethics education for medical or research personnel in order to protect the rights and responsibilities of patients, subjects and all research participants and improve the overall quality of medical research.

2.組織

2. Organization

2.1 本院設有第一及第二人體研究倫理審查委員會，各委員會委員人數 11~21 位，並依人體研究法第 7 條：「審查會應置委員五人以上，包含法律專家及其他社會公正人士；研究機構以外人士應達五分之二以上；任一性別不得低於三分之一」條文之要求選派或遴選。

2.1 The IRB of TCVGH has two committees: The First and the Second IRB Committees. Each committee has 11 to 21 members, designated or selected according to Article 7 of the Human Subjects Research Act: "The IRB shall consist of five or more members, including a legal expert and other impartial citizens; more than two-fifths of all members shall not be affiliated with the research entity; and the number of the representatives of each gender shall not be less than 1/3 of

the total members."

2.2主任委員由院長自院內資深專科醫師選派擔任，另設副主任委員，由主任委員自委員中選派。主任委員、副主任委員為當然委員，其餘委員由主任委員或全體委員推薦、或由公開方式遴聘之，經大會核備後，由主任委員聘任，並將相關名單報請中央衛生主管機關備查，每兩年一任，依「人體研究倫理審查委員會組織及運作管理辦法」辦理。聘期中如因委員異動或新聘委員，本委員會適時辦理，增聘委員之任期自發聘日起至該任期結束為止。

2.2 The IRB Chair is appointed by the Superintendent of TCVGH from among senior medical specialists of TCVGH. The IRB Vice Chair is appointed by the IRB Chair from among IRB members. The Chair and Vice Chair are ex-officio members of the IRB. The remaining members are selected either by recommendations made by the Chair or other members, or by open elections. After the selection is approved in the IRB board meeting, the members shall be appointed by the Chair. The list of all IRB members shall then be submitted to the central competent health authority for recordation. IRB members are appointed to a term of two years. The above appointment procedure complies with the "Regulations for Organization and Operation of IRB Committees." When a member is changed or a new member is added during a term of office, the new member's term starts when the appointment is offered, and ends the same as all members.

2.3 第一及第二人體研究倫理審查委員會各設秘書處，秘書處設執行秘書及承辦人員若干人，由主任委員依人事進用程序公開徵選，執行秘書得為委員。第一及第二人體研究倫理審查委員業務得由秘書處人員互相支援。

2.3 A secretariat is set up within each of the First and Second IRB Committees. The secretariat of each committee has an executive secretary and several staff members, selected publicly by the IRB Chair in accordance with personnel employment procedures. The executive secretary can be an IRB committee member. The staff in each committee

secretariat of the First and Second IRB Committees may share duties and responsibilities across the two committees.

2.4 第一及第二人體研究倫理審查委員會建立獨立之審查機制，以保障受試者之權益與福祉，並提升審查效率。

2.4 An independent review mechanism is set up by the First/Second IRB Review Committees in order to protect the rights and welfare of clinical trial subjects and to improve review efficiency.

2.5 負責營業發展（例如籌募研究經費）之主管不可擔任人體研究倫理委員會委員及人體研究倫理委員會日常運作等職務。

2.5 The head of business development (such as fundraising for research) cannot be a member of the IRB and performs the day-to-day operations of the IRB.

3.任務

3. Mission

3.1 關於本院人體研究政策與規章之制定。

3.1 Compose human research policies and regulations in TCVGH.

3.2 促進本院醫療人員研究倫理教育。

3.2 Promote research ethics education for medical personnel in TCVGH.

3.3 關於受試者權益之審核與保護。

3.3 Review and protect the rights of clinical trial participants.

3.4 審核人體研究計畫書及其成果。

3.4 Review human research protocols and research findings.

3.5 追蹤審查進行中之試驗，必要時可決議暫停/終止計畫。

3.5 Monitor ongoing trials and suspend or terminate trials if necessary.

3.6 監測嚴重不良反應事件報告並建議適當的處理措施。

3.6 Monitor reports of serious adverse events and recommend

appropriate measures.

3.7 依相關法令之規定，保存相關資料及會議紀錄。

3.7 Keep records of documents and meeting minutes in accordance with relevant laws and regulations.

4.會期

4. Session

4.1 按實際需求定期開會，會議應有法定人數。

4.1 Regular meetings are held according to actual needs, and the meeting should have a quorum.

4.2 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，主任委員/副主任委員得依實際情況，召開臨時會議。

4.2 When there is a problem or an emergency that threatens the life safety of a clinical trial subject, the Chair or Vice Chair may hold an ad hoc meeting according to the actual situation.

5.評核

5. Evaluation

5.1主任委員就副主任委員、委員之出席率、審查品質、接受教育訓練情形等進行評核，每年評核一次。秘書處將於每年底統計各項評核資料，由主任委員進行評核，並做為聘任之依據。主任委員由院長填寫主任委員評核表，評核結果須包括回饋及建議事項，以書面交付主任委員，並做為聘任之依據。

5.1 The Chair conducts evaluation of the Vice Chair/IRB Members on meeting attendance rate, quality of review, etc. The Secretariat will tally all evaluation data in the end of the year and send for evaluation by the Chair, who will use the data as basis for re-appointment. The Chair is assessed in a similar way by the Superintendent. The assessment results will be returned in writing, with feedback and suggestions, to the Chair and used as the basis for extending the appointment.

5.2主任委員就秘書處(執行秘書、承辦人員)之工作表現、合作協調、

學習態度、接受教育訓練情形等進行評核，每年評核一次。執行秘書由主任委員評核，承辦人員由執行秘書及主任委員評核。

5.2 The Chair evaluates once a year, the performance of the Secretariat (the Executive Secretary, staff members), in terms of abilities to cooperate and coordinate, their learning attitude, and reception of education and training. The Executive Secretary is assessed by the Chair. The staff members are assessed by the Executive Secretary and the Chair.

6.獎勵

本委員會之秘書處將記錄院內審查委員及承辦人員於第一/二人體研究倫理審查委員之優良事績（如：通過衛生福利部/財團法人醫院評鑑暨醫療品質策進會查核、FERCAP 國際認證...等），簽請專案酌予敘獎，並陳請院部長官核准，移請考績委員會審議辦理。

6. Award

The secretariat of the committee will record the excellent performance of the in-house review committee members and the staff members of the First/Second IRB Committee (e.g. passing the review of Ministry of Health /Legal Foundation of Hospital Evaluation & Medical Quality Policy Promotion Committee, receiving FERCAP International Certification, etc.), and submit applications of awards for the above-mentioned personnel based on their performances. The applications of awards should be approved by higher ranked directors and the Superintendent of TCVGH and referred to the Performance Appraisal Committee for review and processing.