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-2003 IRB-Personnel Management-2003	文件名稱 Title	人體研究倫理審查委員會人員職掌 Responsibilities of IRB Members and Staff
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，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. Pages	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	4	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	4	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 1.1 主任委員任命方式。 2. Amended the appointment procedure of Chair in Item 1.1. 3. 修改各類人員職掌：簽署保密及利益迴避聲明書。 3. Amended duties and responsibilities of all personnel: Signing statements of confidentiality and conflict of interest. 4. 「人體試驗」改為「人體研究/試驗」。 4. “Human clinical trials” was changed to “Human research/clinical trials.” 5. 修改 6.6：原「藥品不良反應」改為「非預期嚴重藥物不良反應」。 5. Amended 6.6: "Adverse drug reaction" was changed to "unexpected serious adverse drug reaction.”	20160318

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-2003 IRB-Personnel Management-2003	文件名稱 Title	人體研究倫理審查委員會人員職掌 Responsibilities of IRB Members and Staff
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，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. Pages	文件修訂摘要 Summary of Revisions of the document	實施日期 Date of Implementation
D	4	1. 修正 1.1：「互相兼任」改為「得由一人兼任」。 1. Amended Item 1.1: “Shared appointment” was changed to “The same person can be appointed as the Chair of both committees.” 2. 刪除主任委員及副主任委員簽署並遵守人體研究/試驗相關之保密及利益迴避聲明書之條文：原 1.10 原 2.8。 2. Deleted Items 1.10 and 2.8 concerning the obligations of the Chair and Vice Chair to sign statements of confidentiality and conflict of interest and to observe relevant regulations. 3. 修正 1.11：新增擔任標準化文件修訂小組召集人。 3. Amended 1.11: Added “The Chair serves as the Coordinator of Document Revision and Standardization Group.” 4. 增刪副主任委員職掌：新增 2.3 為主任委員職務代理人；刪除原 2.4 指派審查委員/獨立專家，及原 2.7 職務代理人；修正 2.5 擔任召集人改為得代理主任委員擔任。 4. Amendments to the duties and responsibilities of the Vice Chair: Added Item 2.3: The Vice Chair is the deputy of the Chair; deleted Item 2.4: Appoints Reviewers/Independent Experts; deleted Item 2.7: Serves as deputy; replaced “Serves as the Coordinator” with “May serve as the Coordinator on behalf of the Chair” in Item 2.5. 5. 修正 3.委員職掌為「委員義務及職責」，及修正 3.6 人體研究/試驗相關講習訓練時數規定。 5. Amendments to Section 3: Replaced “Duties of Committee Members” with “Duties and Responsibilities of Committee Members;” amended the regulation about the hours of training received on human research/clinical trials in Item 3.6. 6. 修正 4.獨立專家職掌為「獨立專家義務及職責」，及修正 4.2 接受講習訓練之頻次，刪除「每年」。 6. Amendments to Section 4: Replaced “Duties of Expert Consultants” to “Duties and Responsibilities of Independent Expert Consultants;” amended the frequency of receiving training in Item 4.2 by deleting “every year.” 7. 修正 5.執行祕書職掌：修正 5.5 建議審查委員及獨立諮詢專家名單，改為「指派新案或監督管理案件之審查委員或獨立專家」；刪除在（副）主任委員授權下之職掌：原 5.8 指派審查委員審查、原 5.9 審查低風險的修正案、追蹤及結案審查、原 5.10 審查試驗偏離事件報告。 7. Amendments to Section 5 “Duties and Responsibilities of Executive Secretary”: Replace “The Executive Secretary recommends Reviewers and Independent Expert Consultants.” with “The Executive Secretary appoints Committee Members or Independent Expert Consultants to review or monitor new research protocols or ongoing research.” in Item 5.5; deleted the following items related to duties authorized by the (Vice) Chair—Item 5.8 “The Executive Secretary appoints IRB members to review cases,” Item 5.9 “The Executive Secretary reviews low-risk cases of protocol amendments, continuing review and project closure,” and Item 5.10 “The Executive Secretary reviews reports of protocol deviation.”	20170709

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-2003 IRB-Personnel Management-2003	文件名稱 Title	人體研究倫理審查委員會人員職掌 Responsibilities of IRB Members and Staff
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，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. Pages	文件修訂摘要 Summary of Revisions of the document	實施日期 Date of Implementation
E	5	1. 增加 3.8「委員辭職、解聘、替補之程序」。 1. Added item 3.8 “Resignation, Termination, and Replacement of IRB Members.” 2. 增加 6 承辦人員之任期說明：「承辦人員無任期之限制，若主任委員/副主任委員評估該員不適任，得重新指派其他符合條件之人員取代，但不得同時更換超過一名，以免影響業務之運作。」 2. Added the explanation about the term of appointment of staff members in item 6: “A staff member may be appointed for an indefinite term. If the Chair/Vice Chair considers a staff member incapable of continuing with the job, another qualified individual may be appointed to replace the staff member. However, no more than one staff member shall be replaced at one time in order not to affect the operation and functions of the IRB.”	20180529
F	5	1. 依據 FERCAP 國際訪視之建議，修改本管理程序書名稱為「IRB-本會-人員管理-2003 第一/二人體研究倫理審查委員會人員職掌」。 1. Following the suggestions made by site-visit reviewers of FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific), the title of this SOP was renamed “IRB- Personnel Management- 2003: Responsibilities of IRB Members and Staff.” 2. 內文格式調整。 2. The format of the document was adjusted.	20181026

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-2003 IRB-Personnel Management-2003	文件名稱 Title	人體研究倫理審查委員會人員職掌 Responsibilities of IRB Members and Staff
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，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. Pages	文件修訂摘要 Summary of Revisions of the document	實施日期 Date of Implementation
G	12	1. 新增 9.「紀錄保存」。 1. “9. Record retention” was added. 2. 新增 10.「附件」。 2. “10. Appendices.” was added.	20190527
H	12	1. 「獨立專家」修改為「專家」。 1. “Independent expert consultants” was changed to “expert consultants”. 2. 修改 3.8.2 為「委員有下列情形之一者應予解聘」。 2. Revised item 3.8.2 to be “IRB membership will be terminated if one or more of the following situations occurs.” 3. 抽換附件 10.1、10.2。 3. Appendices 10.1 & 10.2 were replaced.	20210528
		本欄空白，接續下頁。 Blank. Continued on next page.	

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-2003 IRB-Personnel Management-2003	文件名稱 Title	人體研究倫理審查委員會人員職掌 Responsibilities of IRB Members and Staff
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，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. Pages	文件修訂摘要 Summary of Revisions of the document	實施日期 Date of Implementation
I	12	1. 更改文件名稱。 1. The title of the document was revised. 2. 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」。 2. The original “The First/Second IRB Committees” was renamed “The IRB Committees”. 3. 增加「第三人體研究倫理審查委員會」名詞。 3. Add the term of the “Third IRB Committees”. 4. 修改主任委員職掌。 4. The Duties and Responsibilities of the Chair were revised. 5. 增加 5「人體研究倫理審查行政中心主任職掌」。 5. “5. Duties and Responsibilities of the Director of the Administrative Center for Human Research Ethics Review” were added. 6. 修改原 5 標號為 6。 6. Changed the original item number 5 to 6. 7. 修改原 6 標號為 7。 7. Changed the original item number 6 to 7. 8. 修改原 7 標號為 8。 8. Changed the original item number 7 to 8. 9. 修改原 8 標號為 9。 9. Changed the original item number 8 to 9. 10. 修改原 9 標號為 10。 10. Changed the original item number 9 to 10. 11. 修改原 10 標號為 11。 11. Changed the original item number 10 to 11. 12. 修改 8.5：「修訂後之標準化文件須經第一、第二及第三人體研究倫理審查委員會大會追認核備，由人體研究倫理審查行政中心主任簽署核可後送至品質管理中心進行後續管理程序。」	20230717

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-2003 IRB-Personnel Management-2003	文件名稱 Title	人體研究倫理審查委員會人員職掌 Responsibilities of IRB Members and Staff
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，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. Pages	文件修訂摘要 Summary of Revisions of the document	實施日期 Date of Implementation
I	12	12. Revised item 8.5: "The revised standardized documents shall be reviewed by the First, Second and Third IRB Committees and approved at the IRB board meeting. Signed and approved by the Director of the Administrative Center for Human Research Ethics Review, the revised documents shall then be submitted to the Quality Management Center for follow-up management procedures." 13. 抽換附件 11.1、11.2、11.3。 13. Appendices 11.1, 11.2 and 11.3 were replaced.	20230717

臺中榮民總醫院 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。

※Changing, marking, or copying controlled documents without permission is prohibited.

※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-人員管理-2003 IRB-Personnel Management-2003	文件名稱 Title	人體研究倫理審查委員會人員職掌 Responsibilities of IRB Members and Staff

會辦單位 Processing Unit	審查意見 Review Comments	會辦單位主管 Head of Processing Unit
	無跨單位會辦之需求。 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。

※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.主任委員職掌

1. Duties and Responsibilities of the Chair

1.1 第一/第二/第三研究倫理審查委員會主任委員得由院長任命，得由一人兼任。

1.1 The Chair of the First/Second/Third IRB Committees shall be appointed by the Superintendent. The same person can be appointed as the Chair of both committees.

1.2 為第一/二/第三人體研究倫理審查委員會委員。

1.2 The Chair serves as a member of the First/Second/Third IRB Committees.

1.3 對外代表第一/二/第三人體研究倫理審查委員會。

1.3 The Chair represents the First/Second/Third IRB Committees.

1.4 核定第一/二/第三人體研究倫理審查委員會委員/諮詢專家/受試者代表名單。

1.4 The Chair approves the list of IRB Members/ Expert Consultants/Advocates of Research Subjects.

1.5 邀請諮詢專家對計畫案提供專家之意見。

1.5 The Chair invites expert consultants to provide expert advice on protocols.

1.6 邀請受試者代表對計畫案提供意見。

1.6 The Chair invites advocates of research subjects to provide comments on protocols.

1.7 簽署各項公文和證明書。

1.7 The Chair signs official documents and certificates.

1.8 主持第一/二/第三人體研究倫理審查委員會大會，核定會議記錄。

1.8 The Chair conducts board meetings of the First/Second/Third IRB Committees and approves meeting minutes.

1.9 職務代理人為副主任委員。

1.9 The deputy of the Chair should be the Vice Chair.

1.10 擔任第一/二/第三人體研究倫理審查委員會標準化文件修訂小組召集人並指派成員。

1.10 The Chair serves as the Coordinator of Document Revision and Standardization Group.

2.副主任委員職掌

2. Duties and Responsibilities of the Vice Chair

2.1 第一/二/三人體研究倫理審查委員會各設一位副主任委員

2.1 Each of the First, Second and Third IRB Committees has a Vice Chair.

2.2 為人體研究倫理審查委員會委員。

2.2 The Vice Chair serves as an IRB member.

2.3 為主任委員職務代理人。

2.3 The Vice Chair is the deputy of the Chair.

2.4 督導人體研究倫理審查委員會行政事務。

2.4 The Vice Chair supervises the administrative affairs of the IRB.

2.5 得代理主任委員擔任標準化文件修訂小組召集人。

2.5 The Vice Chair may act on behalf of the Chair as the Coordinator of Document Revision and Standardization Group.

2.6 處理主任委員指派之相關事項。

2.6 The Vice Chair completes relevant tasks assigned by the Chair.

3.委員義務及職責

3. Duties and Responsibilities of IRB Members

3.1 負責審查送審計畫及標準化文件修訂。

3.1 IRB members are responsible for reviewing protocols and revising standardized documents.

3.2 參加人體研究倫理審查委員會各項相關會議。

3.2 IRB members should attend relevant IRB meetings.

3.3 得在人體研究倫理審查委員會會議投票表決送審之計畫案和提案。

3.3 IRB members may vote on protocols and motions at IRB meetings.

3.4 任期內不得累計無故缺席三次以上或超過應出席次數三分之一以上。

3.4 IRB members should not be absent without excuse from three or more meetings or from more than one-third of required meetings during a term of appointment.

3.5 協助主任委員/副主任委員交付之相關業務。

3.5 IRB members shall complete relevant tasks assigned by the Chair.

3.6 每年應依規定接受足夠時數之人體研究/試驗相關講習訓練。

3.6 IRB members shall receive enough hours of training on human research/clinical trials every year.

3.7 簽署並遵守人體研究/試驗相關之保密及利益迴避聲明書，並遵守利益迴避原則。

3.7 IRB members shall sign statements of confidentiality and conflict of interest related to human research/clinical trials, abide by relevant regulations, and follow the principle of avoidance of conflict of interest.

3.8 委員辭職、解聘、替補之程序

3.8 Resignation, Termination, and Replacement of IRB Members:

3.8.1 委員於任期中得以書面方式向主任委員提出辭呈，經主任委員核定後，報請衛生福利部核備。

3.8.1 IRB members may submit resignation to the Chair in writing during a term of service. Once approved by the Chair, the resignation shall be submitted to the Ministry of Health and Welfare for recordation.

3.8.2 委員有下列情形之一者應予解聘：

3.8.2 IRB membership will be terminated if one or more of the following situations occurs:

3.8.2.1 任期內累計無故缺席三次以上或超過應出席次數三分之一以上。

3.8.2.1 Unexcused absence of a member from three or more meetings, or from more than one-third of the required meetings, during a term of appointment.

3.8.2.2 負責審查案件，因可歸責事由致會議延期，累計三次以上。

3.8.2.2 Three or more incidents of a member being responsible for reviewing protocols and causing delay of board meetings due to unexcused reasons.

3.8.2.3 嚴重違反利益迴避原則。

3.8.2.3 Serious violation of the principle of avoidance of conflict of interest.

3.8.3 委員出缺時，主任委員或全體委員推薦、或由公開方式遴聘，經主任委員同意或大會開會通過，報請衛生福利部核備。

3.8.3 When there is an IRB member vacancy, the candidate for the vacancy may be recommended by the Chair or all other IRB members, or selected through open elections. Once approved by the Chair or by the IRB board meeting,

the name of the new IRB member shall be reported to the Ministry of Health and Welfare for recordation.

4.專家義務及職責

4. Duties and Responsibilities of Expert Consultants

4.1 負責審查計畫。

4.1 The expert consultants are responsible for reviewing protocols.

4.2 應接受人體研究/試驗相關之講習訓練。

4.2 The expert consultants shall receive training on human research/clinical trials.

4.3 簽署並遵守人體研究/試驗相關之保密及利益迴避聲明書，並遵守利益衝突迴避原則。

4.3 The expert consultants shall sign statements of confidentiality and conflict of interest related to human research/clinical trials, abide by relevant regulations, and follow the principle of avoidance of conflict of interest.

4.4 任期內所有有關津貼應加以記錄，必要時得以公開。

4.4 All relevant stipends within the term of appointment shall be recorded, and the record shall be made public if necessary.

4.5 專家可為病人或病友會代表或醫藥、統計、社會科學、法律、倫理、宗教等不同領域之專家。

4.5 The expert consultants may be advocates of patients, advocates of associations of patients, or experts from different fields including medicine, statistics, social science, law, ethics, religion, and others.

4.6 專家參與大會時有發言權，無投票權。

4.6 The expert consultants are non-voting attending members at IRB board meetings and have the right to voice opinions at meetings.

5.人體研究倫理審查中心行政主任職掌

5. Duties and Responsibilities of the Director of the Administrative Center for Human Research Ethics Review

5.1 得為人體研究倫理審查委員會委員。

5.1 The Director may be an IRB member.

5.2 協調各IRB會務之運作。

5.2 The Director Coordinates the operation of various IRB affairs.

5.3 負責綜理中心日常業務與協調相關作業。

5.3 The Director manages the daily business of the Center and coordinates related operations.

5.4 主持中心工作小組會議。

5.4.The Director conducts the working group meeting of the Center.

6.執行祕書職掌

6. Duties and Responsibilities of the Executive Secretary

6.1 得為人體研究倫理審查委員會委員。

6.1 The executive secretary may be an IRB member.

6.2 經主任委員授權後得代理行使（副）主任委員之職責。

6.2 The executive secretary may act as the deputy of the (Vice) Chair if authorized by the Chair.

6.3 至少須每兩年檢視標準化文件，並視需要提出修正建議。

6.3 The executive secretary shall review standardized documents at least once every two years and make suggestions of amendments based on needs.

6.4 隨時就法律與倫理規範提出對現行作業流程的修正建議。

6.4 The executive secretary shall promptly propose amendments to current operational procedures in accordance with proper legal and ethical practices.

6.5 指派新案或監督管理案件之審查委員或專家。

6.5 The executive secretary appoints IRB members or expert consultants to review or monitor new research protocols or ongoing research.

6.6 與計畫主持人溝通及初步處理受試者之詢查或抱怨。

6.6 The executive secretary communicates with principal investigators (PIs) to discuss about and respond to inquiries or complaints made by research/trial subjects in the initial stage of handling such inquiries or complaints.

6.7 在（副）主任委員授權下負責判定送審計畫是否符合簡易審查適用範圍。

6.7 Authorized by the (Vice) Chair, the executive secretary may be responsible for judging whether submitted protocols qualify for expedited review.

6.8 處理（副）主任委員指派之相關事項。

6.8 The executive secretary shall complete relevant tasks assigned by the (Vice) Chair.

6.9 職務代理人為(副)主任委員，或由(副)主任委員授權資深委員代理。

6.9 The deputy of the executive secretary shall be the (Vice) Chair or a senior IRB member authorized by the (Vice) Chair.

6.10 簽署並遵守人體研究/試驗相關之保密及利益迴避聲明書，並遵守利益迴避原則。

6.10 The executive secretary shall sign statements of confidentiality and conflict of interest related to human research/clinical trials, abide by relevant regulations, and follow the principle of avoidance of conflict of interest.

7.組員(承辦人員)職掌

組員為執行人體研究倫理審查委員會行政工作之人員，由中心主任指派並核發聘用證明。組員無任期之限制，若中心主任評估該員不適任，得重新指派其他符合條件之人員取代，但不得同時更換超過一名，以免影響業務之運作。其職掌如下：

7. Duties and Responsibilities of Staff Members

Staff members are administrative staff of the IRB. Staff members are appointed by the Director of the Center. The Director issues employment contracts to the staff members. A staff member may be appointed for an indefinite term. If the Director considers a staff member incapable of continuing with the job, another qualified individual may be appointed to replace the staff member. However, no more than one staff member shall be replaced at one time in order not to affect the operation and functions of the IRB. The duties and responsibilities of staff members are listed below:

7.1 受理申請文件。

7.1 Staff members accept and handle documents of submissions.

7.2 送審文件之程序審查。

7.2 Staff members conduct initial procedural review of submissions.

7.3 協助與計畫主持人溝通及初步處理受試者之查詢或抱怨。

7.3 Staff members facilitate the communication with principal investigators (PIs) to discuss about and respond to inquiries or complaints made by research/trial subjects in the initial stage of handling such inquiries or complaints.

7.4 依據「人體研究倫理審查委員會管理程序書」開立計畫執行同意書、程序審查說明書、追蹤審查許可書和結案證明書等文件。

7.4 In accordance with TCVGH-IRB Standard Operating Procedures, staff members issue IRB documents such as Certificate of Approval, Manual for Procedural Reviews, Certificate of Project Extension, and Approval of Study Closure.

7.5 協助不定期查核和監督通過之人體研究/試驗計畫。

7.5 Staff members facilitate continuing review of human research/clinical trial protocols approved by the IRB.

7.6 協助處理非預期嚴重藥物不良反應的通報。

7.6 Staff members handle reports of unexpected serious adverse

reaction.

7.7 追蹤計畫審查之時效。

7.7 Staff members keep track of the progress of the review of protocols.

7.8 保管存放相關文件及人體研究倫理審查委員會審查計畫之檔案。

7.9 Staff members keep and maintain IRB related files and documents.

7.9 承辦衛生主管機關所有來函之公文。

7.9 Staff members process all official letters, notices, and memorandums issued by health authorities.

7.10 承辦人體研究/試驗相關訓練課程。

7.10 Staff members organize training courses on human research/clinical trials.

7.11 提供人體研究/試驗相關諮詢和網站資料維護。

7.11 Staff members provide consultations and maintain a website about human research/clinical trials.

7.12 負責人體研究倫理審查委員會大會之行政作業，包括議程及大會紀錄，並將主任委員核定之會議紀錄呈送院長陳閱。

7.12 Staff members are responsible for administrative work related to IRB meetings, including preparing meeting agendas and minutes and submitting the minutes approved by the IRB Chair to the Superintendent of TCVGH.

7.13 簽署並遵守人體研究/試驗相關保密及利益迴避聲明書，以保障會議內容、申請案件、受試者資訊等相關事宜的機密性與隱私權。

7.13 Staff members shall sign statements of confidentiality and conflict of interest and follow relevant IRB regulations to protect the confidentiality and privacy of the content of meetings, protocols, and personal information of research/trial subjects.

8.人體研究倫理審查委員會標準化文件修訂小組職掌

8. Duties of the IRB Document Revision and Standardization Group

8.1 由（副）主任委員擔任召集人。

8.1 The (Vice) Chair serves as the Coordinator.

8.2 開會時由召集人或由召集人指派資深委員一名擔任主席。

8.2 Meetings are chaired by the Coordinator or a senior member appointed by the Coordinator.

8.3 指派至少 5~9 名第一/二/三人體研究倫理審查委員會委員參與。

8.3 The group has 5 to 9 members appointed from among IRB members.

8.4 負責人體研究倫理審查委員會標準化文件的制定、審訂和修訂。

8.4 Members are responsible for composing, reviewing, and revising IRB standardized documents.

8.5 修訂後之標準化文件須經第一、第二及第三人體研究倫理審查委員會大會追認核備，由人體研究倫理審查行政中心主任簽署核可後送至品質管理中心進行後續管理程序。

8.5 The revised standardized documents shall be reviewed by the First, Second and Third IRB Committees and approved at the IRB board meeting. Signed and approved by the Director of the Administrative Center for Human Research Ethics Review, the revised documents shall then be submitted to the Quality Management Center for follow-up management procedures.

9.受試者代表職掌

9. Duties of Advocates of Human Research/Clinical Trial Subjects

9.1 代表「易受傷害族群」

9.1 Advocates of subjects represent vulnerable subjects.

9.1.1 未成年人

9.1.1 Children

9.1.2 受刑人

9.1.2 Prisoners

9.1.3 原住民

9.1.3 Indigenous people

9.1.4 孕婦

9.1.4 Pregnant women

9.1.5 身心障礙

9.1.5 Persons with physical or mental disabilities

9.1.6 精神病患

9.1.6 Persons with psychiatric disorders

9.1.7 其他缺乏自主能力或自願性受到限制者（例如：經濟貧困、教育不足、醫療緊急狀況沒有充分時間思考者、或無法治癒的致命性疾病者等）。

9.1.7 Other persons with limited decision-making capacity or restricted autonomy (e.g. economically disadvantaged, undereducated, being in a medical emergency and lacking adequate time to think, or terminally ill.)

9.2 得受邀參與大會之相關案件審查或提供諮詢意見，會中有發言權，但無投票權。

9.2 Advocates of subjects may be invited to attend IRB board meetings to review relevant protocols or offer suggestions. Advocates of subjects are non-voting members in attendance at IRB meetings and have the rights to voice opinions at meetings.

10.紀錄保存

相關人員應依據如下規定，妥善保存各項紀錄。

10. Record retention

Relevant personnel should keep all records safely following the guidelines below.

編號 Document Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	人體研究倫理審查委員會主任委員評核表 Taichung Veterans General Hospital IRB Chair Evaluation Checklist	IRB 辦公室 IRB Office	任期結束後至少 3 年 At least 3 years after the appointment is over
2	人體研究倫理審查委員會委員評核表 Taichung Veterans General Hospital IRB Member Evaluation Checklist	IRB 辦公室 IRB Office	任期結束後至少 3 年 At least 3 years after the appointment is over
3	人體研究倫理審查行政中心組員評核表 Staff Evaluation Checklist of the Administrative Center for Human Research Ethics Review	IRB 辦公室 IRB Office	任期結束後至少 3 年 At least 3 years after the appointment is over

11.附件。

11. Appendices

11.1 人體研究倫理審查委員會主任委員評核表

11.1 Taichung Veterans General Hospital IRB Chair Evaluation Checklist

11.2 人體研究倫理審查委員會委員評核表

11.2 Taichung Veterans General Hospital IRB Member Evaluation Checklist

11.3 人體研究倫理審查行政中心組員評核表

11.3 Staff Evaluation Checklist of the Administrative Center for Human Research Ethics Review