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-2019 IRB-Regulations of Operation-2019	文件名稱 Title	受試者申訴管理程序書 SOP for Handling Subject Complaints
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	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	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 4.1 名詞定義用詞：原臨床試驗改為人體研究/試驗。 2. Item 4.1 was revised: The original “clinical trial” was replaced by “human research/clinical trial.” 3. 修改 5.1 流程圖之相關文件。 3. The list of relevant documents was revised in item 5.1 Flow Chart.	20160318
D	3	修改 5.3.1「申訴記錄表」送（副）主任委員修辭：新增批示 2 字。 Item 5.3.1 was revised: “Review and approval” was added to the sentence “The subject complaint form should be submitted to the (Vice) Chair for review and approval.”	20170709
E	6	1.修改 5.4.1（副）主任委員得指派委員或承辦人員進行協調處理或調查。 1. Item 5.4.1 was revised: “The (Vice) Chair may assign an IRB member or staff member to conduct an investigation or intervention.” 2. 修改5.4.4承辦人得在收到申訴請求日起之14個日曆天內回覆申訴者初步處理進度。 2. Item 5.4.4 was revised: “The staff member may inform the complainant of the initial handling progress within 14 calendar days after receiving the complaint or request.”	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
E	6	3.新增 5.6.2 計畫主持人在收到 IRB 之通知後，應在 7 個日曆天內給予書面回覆，最遲不能超過 14 個日曆天。 3. Item 5.6.2 was added: "The PI should provide a response within 7 calendar days after receiving the IRB's notice, no later than 14 calendar days." 4.新增 5.6.3 承辦人得於大會結束後 14 天內，通知申訴者或計畫主持人之最終處理決議。 4. Item 5.6.3 was added: "The staff member should inform the complainant or PI of the final handling decision within 14 calendar days after a decision is done at the IRB board meeting." 5.新增 5.6.4 申訴者或計畫主持人對於最終決議存在不同意見時，可於 7 個日曆天內提出申訴申請，申訴以一次為限。 5. Item 5.6.4 was added: "Where there is a disagreeing on the final decision made at the review meeting, the appeal should be filed within 7 calendar days by the complainant or PI, and the appeal would be limited to one time." 6.修改附件 6.1。 6. Appendix 6.1 was replaced.	20190527
E	6	依本院規定，於 2021 年 03 月 25 日重新審視本文件，內容無須修訂。 Complied with the regulations of TCVGH, this document was to be re-examined on 25 March, 2021, and the content did not need to be revised.	20190527
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臺中榮民總醫院 2023.08.10 參考文件

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Record of Composition and Revisions of Controlled Documents

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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	7	1. 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」。 1. The original “The First/Second IRB Committees” was renamed “The IRB Committees”. 2. 修改 1.「目的」之內容。 2. Item 1 “Purpose” was revised. 3. 修改附件 6.1。 3. Appendix 6.1 was replaced.	20230420

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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。
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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-工作常規-2019 IRB-Regulations of Operation-2019	文件名稱 Title	受試者申訴管理程序書 SOP for Handling Subject Complaints

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.	

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。

※**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

人體研究倫理審查委員會的任務在保護受試者的權利與福祉，審查通過的受試者同意書中都會有『如果您在試驗/研究過程中對試驗/研究工作性質產生疑問，對身為患者之權利有意見或懷疑因參與研究而受害時，您可與臺中榮民總醫院之相關單位聯絡獲得諮詢』的字句，且有聯絡電話與電子信箱的資訊。本管理程序書主要是提供當受試者對其權益有疑慮而申訴時的處理原則，必要時本會將積極介入、協調，以協助受試者爭取應有之權益。

1. Purpose

It is the responsibility of the IRB Committees to protect the rights and welfare of research subjects. On each approved ICF, the following passage should be included: "If you have doubts about the nature of the clinical trial/research during the clinical trial/research process, have opinions on the rights of a patient, or suspect that you have been victimized by participating in the research, you can contact the relevant units of Taichung Veterans General Hospital for consultation" Contact information including telephone number, and e-mail should also be included. The purpose of this SOP is to provide guidance for handling complaints by research subjects who have concerns about their rights. The IRB, if necessary, will intervene and assist the subjects to protect their rights.

2.適用範圍

本管理程序書適用於所有受試者對其自身權益或福祉有疑慮而提出申訴之案件。

2. Scope

This SOP applies to all cases of complaints by research subjects who have concerns about their rights or welfare.

3.參考文件

無。

3. References

None.

4.名詞定義

4. Definitions

4.1 受試者權益

參與人體研究/試驗之受試者，其個人尊嚴及所有家庭成員的權益，必須以自由、正義及和平為基礎予以保護，其人權應被法律規範所保護。

4.1 Subjects' Rights

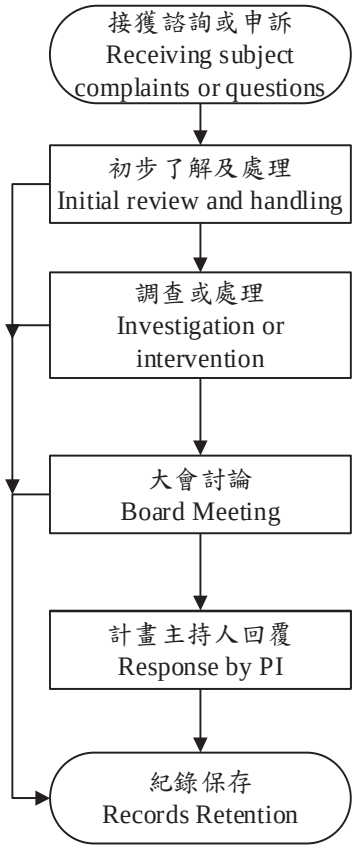
The human rights and dignity of human research/clinical trial subjects and their family members should be protected by laws and regulations on the foundation of freedom, justice, and peace.

5.作業內容

5. Procedure

5.1 受試者諮詢/申訴管理流程圖

5.1 Flow Chart for Handling Subject Complaints or Questions

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	承辦人員/委員/執行秘書/（副）主任委員 Staff Members/Executive Secretary/(Vice) Chair 承辦人員/執行秘書/（副）主任委員 Staff Members/Executive Secretary/(Vice) Chair 承辦人員/委員/執行秘書/（副）主任委員 Staff Members/Executive Secretary/(Vice) Chair 委員 Members 計畫主持人 Principal Investigator 承辦人員 Staff Members	諮詢/申訴紀錄表 Subject Consultation/ Complaint Form 諮詢/申訴記錄表 Subject Consultation/ Complaint Form 諮詢/申訴記錄表 Subject Consultation/ Complaint Form

5.2 接獲諮詢或申訴

5.2 Receiving subject complaints or questions

5.2.1（副）主任委員、執行秘書、委員或承辦人員均可受理臨床試驗受試者之諮詢或申訴。

5.2.1 Questions or complaints raised by clinical trial subjects may be handled by the (Vice) Chair, Executive Secretary, IRB members, or staff members.

5.2.2 承辦人員將此諮詢/申訴事件記錄於「諮詢/申訴記錄表」中，並作初步處理。

5.2.2 The IRB staff member is responsible for initial review and handling of the subject complaint and record it in the Subject Consultation/Complaint Form.

5.3 初步了解及處理

5.3 Initial review and handling

5.3.1 承辦人員將「諮詢/申訴記錄表」交執行秘書處理後，送（副）主任委員批示。

5.3.1 The staff member should submit the Subject Consultation/Complaint Form to the Executive Secretary for initial handling. The Executive Secretary should then submit the case to the (Vice) Chair for review and determination.

5.3.2（副）主任委員須：

5.3.2 The (Vice) Chair should:

5.3.2.1 確認與受試者溝通的情況。

5.3.2.1 review the status of communication between the subject and the IRB office or research personnel.

5.3.2.2 請受試者提供後續資料。

5.3.2.2 ask the subject to provide follow-up information.

5.3.2.3 視需要提出建議。

5.3.2.3 give recommendations based on needs.

5.4 調查或處理

5.4 Investigation or intervention

5.4.1（副）主任委員得指派委員或承辦人員進行協調處理或調查。

5.4.1 The (Vice) Chair may assign an IRB member or staff member to conduct an investigation or intervention.

5.4.2 在諮詢/申訴紀錄表中記錄所有的資訊及行動，包括後續追蹤。

5.4.2 All relevant information and actions taken should be recorded on the Subject Consultation/Complaint Form, including follow-up monitoring.

5.4.3 在「紀錄表」上簽名並註明日期和時間。

5.4.3 The Subject Consultation/Complaint Form should be signed and dated by the IRB member or staff member.

5.4.4 承辦人得在收到申訴請求日起之 14 個日曆天內回覆申訴者初步處理進度。

5.4.4 The staff member may inform the complainant of the initial handling progress within 14 calendar days after receiving the complaint or request.

5.5 大會討論

5.5 IRB Board Meeting Discussion

若為嚴重影響受試者權益之申訴，將提大會討論並依大會決議辦理。

A subject complaint determined by the IRB to have major impact on the subject's rights should be placed on the agenda for the IRB board meeting for discussion and resolution.

5.6 計畫主持人回覆

5.6 The PI's Response

5.6.1 將會議決議以書面通知計畫主持人，並請計畫主持人提出說

明。

5.6.1 The PI should be notified by writing of the IRB board meeting resolution regarding a subject complaint. The PI should be required to provide an explanation.

5.6.2 計畫主持人在收到 IRB 之通知後，應在 7 個日曆天內給予書面回覆，最遲不能超過 14 個日曆天。

5.6.2 The PI should provide a response within 7 calendar days after receiving the IRB's notice, no later than 14 calendar days.

5.6.3 承辦人得於大會結束後 14 天內，通知申訴者或計畫主持人之最終處理決議。

5.6.3 The staff member should inform the complainant or PI of the final handling decision within 14 calendar days after a decision is done at the IRB board meeting.

5.6.4 申訴者或計畫主持人對於最終決議存在不同意見時，可於 7 個日曆天內提出申訴申請，申訴以一次為限。

5.6.4 Where there is a disagreeing on the final decision made at the review meeting, the appeal should be filed within 7 calendar days by the complainant or PI, and the appeal would be limited to one time.

5.7 紀錄保存

5.7 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	諮詢/申訴紀錄表 Subject Consultation/Complaint Form	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed

6.附件

6. Appendix

6.1諮詢/申訴紀錄表

6.1 Subject Consultation/Complaint Form