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-2015 IRB-Regulations of Operation-2015	文件名稱 Title	實地訪查管理程序書 SOP for Monitoring Visits
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，並請註明填寫：人體研究倫理審查委員會 ■ **Others (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	11	新訂。Newly composed.	20140519
B	5	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	5	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. 修正 5.2.1 實地訪查的研究計畫檔案之規定。 2. Item 5.2.1 was revised regarding regulations about files of protocols for monitoring visits. 3. 修正5.5.2.1實地訪查總結報告提供給計畫主持人進行回覆天數相關規定。 3. Item 5.5.2.1 was revised regarding the regulation about the time limit for the PI to respond to comments given in the monitoring visit report.	20160318
D	10	1. 內文審查改為審查。 1. “Review of the content” was replaced by “review.” 2. 修改 1.目的：新增 2 項法規。 2. Two regulations were added in item 1. Purpose. 3. 修改參考文件 3.1 人體試驗管理辦法之版本。 3. The version of “Regulations on Human Trials” was updated in reference item 3.1. 4. 修改 5.1 流程圖「實地訪查前作業」之權責，並修改 5.3.1.3 指派訪查委員之權責。 4. Responsible personnel for “pre-visit preparation” was revised in 5.1 Flow Chart; responsible personnel for assigning monitors was revised in item 5.3.1.3.	20170709

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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
D	10	5. 新增附件 6.3 實地訪查審查委員勾選表，並新增 5.8 紀錄保存文件。 5. Item 6.3 Monitors Selection Form was added to the list of appendices; the form also was added to item 5.8 Records Retention.	20170709
E	9	1.修改 5.5.1 為「訪查代表彙整審查意見後，應在 6 個日曆天內完成實地訪查總結報告」。 1. Revised item 5.5.1: “The representative of monitors should compile the reviewers’ comments and complete the Monitoring Visit Report within 6 calendar days.” 2.刪除 5.5.2.1「計畫主持人未收到本會許可書前不得執行計畫」之文句。 2. Deleted item 5.5.2.1: “The PI must not implement the research before receiving the Certificate of Project Extension from TCVGH IRB.”	20190527
F	9	1. 修改「藥品優良臨床試驗準則」中文名稱為「藥品優良臨床試驗作業準則」。 1. Revised the Chinese name of "Regulations for Good Clinical Practice". 2. 修改 5.5.2.1 之計畫主持人回覆期限為 28 個日曆天，並刪除申請展延說明文字。 2. Item 5.5.2.1 was revised the PI's reply period to 28 calendar days, and deleted the description of the extension. 3. 文字校正。 3. Fixed typos.	20210528

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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	9	4. 抽換附件 6.3。 4. Replaced Appendix 6.3.	20210528
G	9	1. 修改 5.5.1 審查期限：原 6 個日曆天改為 6 個工作天。 1. Revised item 5.5.1 Review time limit: Replaced “6 calendar days” with “6 work days.”	20211209
H	9	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. 5.2 增加實地訪查條件。 2. Item 5.2: Added the conditions of Monitoring Visit. 3. 抽換附件 6.1、6.2。 4. Appendices 6.1, 6.2 were replaced.	20230717

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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。

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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-2015 IRB-Regulations of Operation-2015	文件名稱 Title	實地訪查管理程序書 SOP for Monitoring Visits

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.	

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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

本管理程序書之目的是在提供何時及如何進行實地訪查的流程，以監測經其審查通過之計畫案執行狀況及遵守「人體研究法」、「醫療法」、「人體試驗管理辦法」及「藥品優良臨床試驗作業準則」等相關法規。

1. Purpose

The purpose of this SOP is to describe the process for when and how to prepare and conduct monitoring visits to monitor the implementation of an approved protocol and to ensure that the research implementation complies with Human Subjects Research Act, Medical Care Act, Regulations on Human Trial, Regulations for Good Clinical Practice, and other relevant laws and regulations.

2.適用範圍

本管理程序書適用於實地訪查及監測審查通過計畫之研究執行場所及執行方式。

2. Scope

This SOP applies to the monitoring visits to research sites and the monitoring process of research implementation of IRB approved protocols.

3.參考文件

3. References

3.1 人體試驗管理辦法：衛生福利部衛部醫字第 1051662154 號令修正發布，2016

3.1 Regulations on Human Trials, amended and promulgated by the Ministry of Health and Welfare, pursuant to Wei-Bu-Yi-Zi No. 1051662154, 2016.

3.2 人體研究法：總統華總一義字第 10000291401 號令，2011

3.2 Human Subjects Research Act, promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10000291401, 2011

4.名詞定義

4. Definitions

4.1 訪查委員與訪查代表

人體研究倫理審查委員會對審核通過之試驗案進行實地訪查時，會委派一至三位委員或專家。（副）主任委員應指定其中一位為訪查代表，負責完成書面之實地訪查紀錄表，並於大會中將結果向全體委員報告。

4.1 Monitors and Representative of Monitors

The IRB may appoint one to three members or expert consultants as monitors to conduct a monitoring visit to the study site of an approved protocol. The (Vice) Chair should assign one of the monitors as the representative of monitors, who should be responsible for completing the Monitoring Visit Report Form and presenting the review results to all IRB members in a board meeting.

4.2 實地訪查

人體研究倫理審查委員會之代表至研究單位現場訪查，評估計畫主持人及計畫執行情況之行動。

4.2. Monitoring Visit

The representatives from the IRB may conduct monitoring visits to the study site to evaluate the PI’s implementation of the research.

5.作業內容

5. Procedure

5.1 實地訪查管理流程圖

5.1 Flow Chart of Monitoring Visits

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
選擇計畫 Selection of Protocols	大會決議/（副）主任委員/執行秘書 IRB Resolutions/(Vice)Chair/ Executive Secretary	研究計畫檔案 Files of protocols
實地訪查前準備 Pre-Visit Preparation	承辦人員/執行秘書/訪查委員/計畫主持人（計畫連絡人） Staff/Executive Secretary/ Monitors/PI (contact person)	實地訪查紀錄表/計畫書 Monitoring Visit Log/ Protocol
實地訪查 Monitoring Visit	訪查委員 Monitors	受試者同意書/實地訪查紀錄表/實地訪查總結報告 ICF/Monitoring Visit Log/ Monitoring Visit Report
實地訪查後作業 Post-Visit Follow-Up	承辦人員/計畫主持人 Staff Members/PI	實地訪查總結報告 Monitoring Visit Report
大會討論 Board Meeting（核備 Approval）	委員 IRB Members	實地訪查總結報告 Monitoring Visit Report
執行決議事項 Follow-Up on Resolutions	承辦人員/計畫主持人 Staff Members/PI	
紀錄保存 Records Retention	承辦人員 Staff Members	

5.2 選擇計畫

5.2 Selection of Protocols

得依以下標準選擇需接受實地訪查的「研究計畫檔案」。

The following criteria may be considered when selecting protocols for monitoring visits:

5.2.1 計畫主持人自行發起研究之人體研究/試驗案(風險較高)。

5.2.1 Principal Investigator Initiated study/trial (High risk).

5.2.2 早期臨床試驗案

5.2.2 Early phase clinical trial.

5.2.3 經審查委員提大會討論之案件。

5.2.3 Protocols sent by reviewers for IRB full board discussion.

5.2.4 有違規紀錄、或經檢舉或有試驗偏差、或與受試者保護有相關疑義，經大會決議或主任委員裁示實地訪查之案件。

5.2.4 The IRB Chair or IRB full board may determine that a monitoring visit should be conducted to the research of a study in which incidents of protocol deviation or violation have occurred or other misconduct has been reported, or have doubts related to the protection of subjects.

5.2.5 有嚴重不良反應事件之通報，經大會決議實地訪查之案件。

5.2.5 By the IRB full board resolution, a monitoring visit may be conducted to the research site of a study in which a serious adverse event has been reported.

5.2.6 逾時繳交追蹤審查報告或結案報告，經大會決議實地訪查之案件。

5.2.6 By the IRB full board resolution, a monitoring visit may be conducted to the research site of a study for which a continuing review report or closing report was submitted later than the due date.

5.2.7 其他（如經大會決議或主任委員裁示實地訪查之案件）。

5.2.7 Other (Monitoring visits may be conducted to the study site

of any research by IRB full board resolution or by the decision of the IRB Chair.)

5.3 實地訪查前作業

5.3 Pre-Visit Preparation

5.3.1 承辦人員進行準備

5.3.1 Preparation by IRB staff

5.3.1.1 訪查前聯絡計畫主持人協調適合的訪查時間，並隨後以公文通知該計畫案主持人及單位實地訪查的時間。

5.3.1.1 The staff member should contact the PI to coordinate the appropriate time for the monitoring visit. After the time has been decided, the staff member should notify the PI and the research site.

5.3.1.2 請計畫主持人事先填妥主持人自評部份之「實地訪查紀錄表」，並儘速送回承辦人員處。

5.3.1.2 The staff member should ask the PI to complete the section of self-evaluation on the Monitoring Visit Log and return the form to the staff member before the monitoring visit.

5.3.1.3 由執行秘書依利益迴避原則與專長，指定一至三位委員（至少一位為生物醫學科學背景委員）或專家，生物醫學科學背景委員擔任訪查代表，由承辦人員安排訪查行程。

5.3.1.3 The Executive Secretary should assign one to three members (at least one with a biomedical science background) or expert consultants as monitors, based on their expertise and following the conflict of interest policy. The representative of the reviewers should have a biomedical science background. The staff member is responsible for scheduling and arranging the monitoring visit.

5.3.1.4 檢查計畫主持人繳交之「實地訪查紀錄表」後，將之交付訪查委員。

5.3.1.4 The staff member should conduct an initial review of the Monitoring Visit Log sent by the PI and submit it to the monitors.

5.3.2 訪查委員進行準備

5.3.2 Preparation by Monitors

5.3.2.1 詳閱「實地訪查紀錄表」。

5.3.2.1 The monitor should read the Monitoring Visit Log carefully.

5.3.2.2 得借閱擬進行實地訪查之「計畫書」。

5.3.2.2 The monitor may review the protocol of the study conducted on the research site.

5.3.3 計畫主持人或計畫連絡人進行準備

5.3.3 Preparation by the PI or the Protocol Contact Person

5.3.3.1 填妥實地訪查紀錄表自評部份。

5.3.3.1 The PI or the protocol contact person should complete the section of self-evaluation on the Monitoring Visit Log.

5.3.3.2 預先準備受試者病歷及訪查場地。

5.3.3.2 The PI or the protocol contact person should prepare the medical records of the trial subjects and set up the research site for the visit.

5.3.3.3 準備相關資料備查。

5.3.3.3 The PI or the protocol contact person should prepare all relevant documents for review.

5.4 實地訪查

5.4 Monitoring Visit

5.4.1 訪查委員應攜帶計畫主持人已填妥之「實地訪查紀錄表」。

5.4.1 The monitors should bring the Monitoring Visit Log completed by the PI.

5.4.2 訪查委員「實地訪查紀錄表」逐項審查，如：

5.4.2 The monitors should check each item listed on the Monitoring Visit Log, including:

5.4.2.1 檢視已簽署之「受試者同意書」，以確認使用核定版本。

5.4.2.1 Reviewing the signed Informed Consent Form (ICF) and verifying that the version signed is the IRB approved version of ICF.

5.4.2.2 檢查「受試者同意書」中受試者的簽名與日期。

5.4.2.2 Checking the signatures and dates signed by the subjects on the ICFs.

5.4.2.3 隨機抽查「受試者檔案」，以確定計畫依原核准計畫書內容執行。

5.4.2.3 Selecting subjects' files randomly for review to ensure that the research implementation has followed the approved protocol.

5.4.2.4 得觀察「受試者同意書」的簽署過程。

5.4.2.4 Observing the process of the signing of ICF.

5.4.2.5 觀察執行單位、場所及其他必要設備的情況。

5.4.2.5 Observing the operation of the research implementing unit, research site, and other needed equipment.

5.4.2.6 給予受訪單位意見，計畫主持人得立即回覆。

5.4.2.6 Giving comments to the visited site and requesting the PI to respond promptly.

5.5 實地訪查後作業

5.5 Post-Visit Follow-Up

5.5.1 訪查代表

訪查代表彙整審查意見後，應在 6 個工作天內完成「實地訪查總結報告」。

5.5.1 Representative of Monitors

The representative of monitors should compile the

reviewers' comments and complete the Monitoring Visit Report within 6 work days.

5.5.2 承辦人員

5.5.2 IRB Staff

5.5.2.1 將實地訪查總結報告提供給計畫主持人進行回覆，計畫主持人補件（回覆審查意見）天數為 7 個日曆天回覆，若超過 28 個日曆天仍未回覆則逕行撤案。

5.5.2.1 The staff member should send the Monitoring Visit Report to the PI for the PI to respond to reviewers' comments. The PI should submit supplementary documents (or response to reviewers' comments) within 7 calendar days. If the PI does not respond within 28 days, the protocol will be withdrawn from IRB consideration.

5.5.2.2 等計畫主持人回覆後，提至最近一次會期進行報告，並將相關資料歸入「實地訪查檔案夾」。

5.5.2.2 After the PI has submitted response to reviewers' comments, the staff member should place the submission on the agenda for the next IRB board meeting. Relevant documents should be filed in the Monitoring Visit Portfolio.

5.6 大會討論

5.6 IRB Board Meeting Discussion

5.6.1 承辦人員將報告列入大會議程。

5.6.1 The staff member should place the Monitoring Visit Report on the agenda for the IRB board meeting.

5.6.2 訪查代表將實地訪查結果向全體委員報告。

5.6.2 The representative of monitors should give a report on the monitoring visit results to all IRB members during the board meeting.

5.7 執行決議事項

5.7 Follow-Up on Resolutions of Agenda Items

依大會討論後之決議辦理後續相關事宜。

Follow-up actions should be taken according to the IRB full board resolutions.

5.8 紀錄保存

5.8 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 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	實地訪查紀錄表 Monitoring Visit Log	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
2	實地訪查總結報告 Monitoring Visit Report	IRB 辦公室 IRB Office	試驗結束後 3 年 At least 3 years after the trial is closed
3	實地訪查審查委員勾選表 Monitors Selection 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. Appendices

6.1 實地訪查紀錄表

6.1 Monitoring Visit Log

6.2 實地訪查總結報告

6.2 Monitoring Visit Report

6.3 實地訪查審查委員勾選表

6.3 Monitors Selection Form